Clinical trial of an intervention to support medical doctors with occupational burnout

Submission date	Recruitment status	Prospectively registered
24/09/2023	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
28/02/2024	Ongoing	Results
Last Edited	Condition category	[] Individual participant data
09/05/2025	Other	[X] Record updated in last yea

Plain English summary of protocol

Background and study aims

Occupational burnout and associated mental health symptoms are known to affect around 44% of UK doctors. Previous studies show that burnout has a negative impact upon psychological well-being and physical health, as well as being associated with poorer job performance. Burnout is also associated with poorer patient treatment outcomes. The purpose of this study is to assess the effects of a psychological intervention called Mind Management Skills for Life Programme on NHS Doctors' health and wellbeing.

Who can participate?

Doctors working in the English National Health Service.

What does the study involve?

Participating doctors will access an 8-session, internet-enabled, psychological intervention delivered by experienced facilitators using videocall software. Half of the consenting participants will access this intervention immediately, while the other half wait to access the intervention ten weeks later. Participants will complete online surveys at four time-points (baseline, after 10 weeks, after 20 weeks, after 6 months) including measures of occupational burnout, psychological wellbeing, and job satisfaction. We will compare mean levels of severity across all of these measures at multiple timepoints. We expect that there will be no differences between groups at baseline. After group 1 completes the intervention, we expect their measures will indicate better occupational health and wellbeing than group 2 (who did not yet receive the intervention). After group 2 completes the intervention, we expect to find no significant differences in outcome measures, nor do we expect to find significant differences between groups at 6 months' follow-up.

What are the possible benefits and risks of participating?

We expect that participants will experience improvements in occupational burnout, wellbeing and job satisfaction. We do not foresee any risks or adverse effects, based on prior research examining the impact of this intervention.

Where is the study run from?

This study is led by the Psychological Health Observatory, part of the Grounded Research Team at Rotherham Doncaster and South Humber NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for? September 2023 to September 2025

Who is funding the study?

The study has been partly funded by a grant from Health Education England, and partly supported by in-kind funding (specifically to cover the cost of intervention delivery) from Chimp Management Ltd. (UK)

Who is the main contact? rdash.research-gov@nhs.net

Contact information

Type(s)

Principal Investigator

Contact name

Dr Victoria Laker

ORCID ID

http://orcid.org/0000-0002-6009-2440

Contact details

Grounded Research Hub, No 2 St Catherine's Close, Tickhill Road Hospital, Balby Doncaster
United Kingdom
DN4 8QN
+44 (0)3000 212 456
victoria.laker@nhs.net

Type(s)

Scientific

Contact name

Ms Jeannie McKie

Contact details

Rotherham Doncaster and South Humber NHS FT Grounded Research 2 St Catherine's Close Tickhill Road Hospital Doncaster United Kingdom DN4 8QN +44 3000 212 456 rdash.research-gov@nhs.net

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

326365

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 56864. IRAS 326365

Study information

Scientific Title

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

Acronym

CPM Trial 2

Study objectives

Exposure to the "Mind Management Skills for Life Programme" will be associated with significantly lower mean burnout severity by comparison to a waitlist (delayed intervention) control group.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 14/09/2023, South West - Frenchay Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 207 1048106; frenchay. rec@hra.nhs.uk), ref: 23/SW/0075

Study design

Pragmatic delayed intervention randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Occupational burnout

Interventions

Consenting participants will be randomly assigned to one of two groups using an electronic random sequence generator. Participants allocated to group 1 will have immediate access to the Mind Management Skills for Life Programme, which is an eight-session, group-based psychological intervention delivered online (video conference) by trained mentors. The intervention lasts for 10 weeks (4 weekly consecutive sessions, followed by a two-week break, followed by another 4 consecutive weekly sessions). Participants allocated to group 2 are part of a waitlist (no intervention) control group during the first 10 weeks of the study. After week 10, participants in group 2 access the same intervention that was completed by group 1. All study participants will be asked to complete online surveys including primary (occupational burnout) and secondary (job satisfaction, psychological well-being) at four time-points: [1] Baseline; [2] after 10 weeks; [3] after 20 weeks; [4] 6 months after the third measurement point.

Intervention Type

Behavioural

Primary outcome measure

Occupational burnout, measured by the Oldenburg Burnout Inventory (OLBI), at baseline, 10 weeks, 20 weeks, and 6 months follow-up.

Secondary outcome measures

- 1. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS), measured at baseline, 10 weeks, 20 weeks, and 6 months follow-up.
- 2. The Job Discrepancy and Satisfaction Scale (JDSS), measured at baseline, 10 weeks, 20 weeks, and 6 months follow-up.

Overall study start date

14/09/2023

Completion date

25/09/2025

Eligibility

Key inclusion criteria

- 1. GMC registered doctors from any areas of specialty and NHS healthcare services.
- 2. Trainee doctors in medical school, who have already started clinical rotations.
- 3. Working either part-time or full-time in a clinical role.

Participant type(s)

Health professional

Age group

Adult

Lower age limit

18 Years

Upper age limit

99 Years

Sex

Both

Target number of participants

180

Key exclusion criteria

- 1. 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).
- 2. 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).
- 3. Doctors that work in a purely managerial, supervisory or educational role (e.g., not in clinical practice at the time of recruitment).
- 4. Medical students in the early phase of training, who are not yet in clinical practice.

Date of first enrolment

26/09/2023

Date of final enrolment

17/11/2023

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Rotherham Doncaster and South Humber NHS Foundation Trust

Woodfield House Tickhill Road Doncaster United Kingdom DN4 8QN

Sponsor information

Organisation

Rotherham Doncaster and South Humber NHS Foundation Trust

Sponsor details

Grounded Research Hub
No 2 St Catherine's Close
Tickhill Road Hospital, Balby
Doncaster
England
United Kingdom
DN4 8QN
+44 3000 212 456
rdash.research-gov@nhs.net

Sponsor type

Hospital/treatment centre

Website

https://www.rdash.nhs.uk/about-us/grounded-research/

Funder(s)

Funder type

Government

Funder Name

Health Education England

Funder Name

Chimp Management Ltd.

Results and Publications

Publication and dissemination plan

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

Intention to publish date

01/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Victoria Laker, victoria.laker@nhs.net.

IPD sharing plan summary

Available on request