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An evaluation of a cognitive-behavioural intervention for medical students

Submission date
09/06/2025

Recruitment status
Recruiting

Registration date
11/06/2025

Overall study status
Ongoing

Last Edited
12/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Medical students experience high rates of burnout and mental health distress, with approximately half reporting burnout, one-third experiencing depression, and one-tenth having suicidal thoughts. These issues are exacerbated during clinical placements and contribute to workforce attrition after qualification. Existing interventions are largely generic and show limited effectiveness. Thumos, a cognitive-behavioural therapy (CBT)-based intervention specifically tailored for healthcare professionals and students, addresses the stressful situations intrinsic to medical training and practice. This study will evaluate whether Thumos improves psychological resilience, confidence, burnout, and depression in medical students compared with services as usual (SAU).

Who can participate?
UK medical students in years involving clinical placements (e.g., Y4/Y5) nationally, aged 18 years and over.

What does the study involve?
Participants will be asked to complete a consent form and some baseline questionnaires. Random allocation will occur 1:1 to either the intervention or the control group. The intervention group will be asked to participate in a CBT intervention of two online group workshops and one individual video/phone call. The control group will continue with SAU. A follow-up questionnaire will be sent to all participants at post-intervention, 4 and 9 months. As part of the process evaluation, all participants will be asked to complete an evaluation questionnaire, and a subset of intervention participants will be invited to attend a qualitative interview.

What are the possible benefits and risks of participating?
Potential benefits for intervention arm participants include improved psychological wellbeing through engaging with the CBT intervention: Thumos. Risks are minimal, but for all participants, may include some emotional distress when responding to the questionnaires or discussing personal experiences in the interviews. For intervention arm participants, it is possible that the intervention may not be effective for everyone.

Where is the study run from?
Hull York Medical School, UK. The study will be run remotely using an online video platform.

When is the study starting and how long is it expected to run for?
December 2024 to March 2027

Who is funding the study?
The MPS Foundation, UK

Who is the main contact?
Dr Judith Johnson, University of Manchester, judith.johnson@manchester.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
TMPSF2024001

Study information

Scientific Title
ACTIVATE: A randomised Controlled evaluation of Thumos: a cognitive-behavioural InterVention for medicAl sTudEnts

Acronym
ACTIVATE

Study objectives
Medical students receiving Thumos, a cognitive behavioural intervention, will have improved psychological resilience at 4 month follow up in comparison to medical students receiving services as usual.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/12/2024, University of Manchester Research Ethics Committee 1 (2nd Floor, Christie Building, The University of Manchester, Oxford Road, Manchester, M139PL, United Kingdom; +44 (0)161 306 6000; urec1@manchester.ac.uk), ref: 2024-21589-38791

Study design
Randomized controlled parallel groups intervention trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Improvement of psychological resilience in UK medical students

Interventions
UK medical students in clinical placement years will be randomised 1:1 to receive either Thumos (a CBT intervention of two online group workshops and one individual video/phone call) or Services As Usual (SAU). Assessments will occur at baseline, post-intervention, 4-month, and 9-month follow-up. A mixed-methods process evaluation will assess acceptability and implementation with CBT therapists and medical educators from participating medical schools.

Both control and intervention arm students will be invited to complete process questionnaires; only intervention arm medical students will be invited to take part in qualitative interviews. The study will invite UK medical educators from medical schools with participating students within the intervention arm to qualitative interviews as part of the process evaluation. It will also invite the cognitive behavioural therapists/clinical psychologists delivering the intervention to participate in qualitative interviews as part of the process evaluation.

Added 11/06/2025:
Participants will be randomised using simple 1:1 allocation via the Sealed Envelope platform, which generates the allocation sequence and maintains allocation concealment to ensure investigators remain blinded to treatment assignment. With 220 participants undergoing individual-level randomisation, simple randomisation is expected to achieve adequate balance between treatment arms without the need for blocking or stratification. Any post-randomisation covariate imbalances will be addressed through standard statistical adjustment methods during analysis.

Intervention Type
Behavioural

Primary outcome(s)
Psychological resilience will be measured using the 6-item Brief Resilience Scale (BRS) at baseline, post-intervention, 4- and 9-month follow-up. The primary endpoint is psychological resilience at the 4-month follow-up.

Key secondary outcome(s))
The following secondary outcome measures are assessed at baseline, post-intervention, 4- and 9-month follow-up:
1. Confidence in coping with adverse events measured using the Confidence in Coping with Adverse Events (CCAE) questionnaire
2. Burnout measured using the Oldenburg Burnout Inventory (OLBI)
3. Depression measured using the Patient-Health Questionnaire-9 (PHQ-9)
4. Areas of Quality of Life will be measured using the Recovery of Quality of Life-Utility Index (ReQoL-UI)
5. Self-reported sickness absence measured using two question items. The first question asks about total days lost within the past 4 weeks; the second question asks how many working or studying days specifically were lost within this timeframe.
6. Support access will be measured using four question items. Four question items will be used to assess whether participants are accessing any form of psychological wellbeing service, which type of support they are accessing, when they began accessing this, and when they anticipate they will stop accessing this

Completion date
31/03/2027

Eligibility

Key inclusion criteria
UK medical students in years involving clinical placements (e.g., Y4/Y5) nationally. We will recruit from these groups for the main trial until the recruitment target is reached

Participant type(s)
Health professional, Learner/student

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

Not meeting the participant inclusion criteria

Date of first enrolment
16/06/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hull York Medical School
York Medical School
Siwards Way
Heslington
Hull
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research organisation

Funder Name
The MPS Foundation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be stored in a publicly available repository: University of Manchester research repository - (https://figshare.manchester.ac.uk/)

IPD sharing plan summary

Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes