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An evaluation of a cognitive-behavioural intervention for medical students

Submission date
09/06/2025

Recruitment status
No longer recruiting

Registration date
11/06/2025

Overall study status
Ongoing

Last Edited
21/09/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] 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

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

Primary study design
Interventional

Study design
Randomized controlled parallel groups intervention trial

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.

Removed 21/09/2026:
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
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
232

Key exclusion criteria
Not meeting the participant inclusion criteria

Date of first enrolment
16/06/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

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

Study participating centre
Aston Medical School
Aston University
Birmingham
England
B4 7ET

Study participating centre
Barts and the London School of Medicine and Dentistry
Garrod Building, Turner St
London

England
E1 2AD

Study participating centre
Brighton and Sussex Medical School
94 N - S Rd, Falmer
Brighton
England
BN1 9PX

Study participating centre
Brunel University London
Kingston Lane
Uxbridge
England
UB8 3PH

Study participating centre
Cardiff University
Park PLACE
Cardiff
Wales
CF10 3AT

Study participating centre
City St George's, University of London
Northampton Square
London
England
EC1V 0HB

Study participating centre
Edge Hill Medical School
Edge HIll University, St Helens Rd
Ormskirk
England
L39 4QP

Study participating centre

Imperial College London
Exhibition Rd, South Kensington
London
England
SW7 2AZ

Study participating centre
Kent and Medway Medical School
Pears Building
Canterbury
England
CT2 7FS

Study participating centre
Keele University Medical School
David Weatherall building
University Road
Keele University
Staffordshire
England
ST5 5BG

Study participating centre
King's College London
Strand
London
England
WC2R 2LS

Study participating centre
Lancaster Medical School, Lancaster University
Bailrigg House, Bailrigg
Lancaster
England
LA1 4YE

Study participating centre
Leicester Medical School
George Davies Centre, Lancaster Rd

Leicester
England
LE1 7HA

Study participating centre
Lincoln Medical School
University of Lincoln
Brayford Pool
Lincoln
England
LN6 7TS

Study participating centre
Newcastle University
-
Newcastle upon Tyne
England
NE1 7RU

Study participating centre
University Medical Centre
University of East Anglia
Earlham Road
Norwich
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NR4 7TJ

Study participating centre
Queen Mary University of London
327
Mile End Road
London
England
E1 4NS

Study participating centre
Queen's University of Belfast
University Road
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Northern Ireland
BT7 1NN

Study participating centre
University of Dundee
ScotGEM (University of St Andrews and University of Dundee), Nethergate
Dundee
Scotland
DD1 4HN

Study participating centre
Swansea University Medical School
Institute of Life Science 2, Sketty
Swansea
England
SA2 8QA

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University of Ulster
Cromore Road
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Northern Ireland
BT52 1SA

Study participating centre
University College London
Gower St
London
England
WC1E 6BT

Study participating centre
University of Aberdeen
Regent Walk
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AB24 3FX

Study participating centre
University of Birmingham
-

Birmingham
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B15 2TT

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Senate House
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Bristol
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BS8 1TH

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University of Buckingham
Yeomanry House
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Buckingham
England
MK18 1EG

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University of Cambridge
The Old School
Trinity Lane
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England
CB2 1TN

Study participating centre
University of Central Lancashire
Fylde Rd
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PR1 2HE

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University of Chester
Parkgate Road
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CH1 4BJ

Study participating centre
University of Dundee
Perth Road
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DD1 4HN

Study participating centre
University of Edinburgh
Old College
South Bridge
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Scotland
EH8 9YL

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University of Exeter
Stocker Road
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EX4 4PY

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University of Glasgow
University Avenue
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Scotland
G12 8QQ

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University of Leeds
Woodhouse Lane
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LS2 9JT

Study participating centre

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University Road
Leicester
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LE1 7RH

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Foundation Building, 765 Brownlow Hl
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L69 7ZX

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University of Manchester
Oxford Rd
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England
M13 9PL

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Nottingham
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NG7 2RD

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University of Oxford
University Offices
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England
OX1 2JD

Study participating centre
University of Portsmouth
University House
Portsmouth
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PO1 2UP

Study participating centre
University of Sheffield
Western Bank
Sheffield
England
S10 2TN

Study participating centre
University of Southampton
University Road
Southampton
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SO17 1BJ

Study participating centre
University of St Andrews
College Gate
North Street
St. Andrews
Scotland
KY16 9AJ

Study participating centre
University of Sunderland
Chester Road
Sunderland
England
SR1 3SD

Study participating centre
University of Surrey
Stag Hill Campus
Guildford
England
GU2 7XH

Study participating centre
University of Warwick
University House

Gibbet Hill Road
Coventry
England
CV4 7AL

Study participating centre
University of Worcester
Henwick Grove
Worcester
England
WR2 6AJ

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
Available on request, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol file	version 2.3	15/01/2026	15/06/2026	No	No
Statistical Analysis Plan	version 0.6	16/12/2025	15/06/2026	No	No
Statistical Analysis Plan	version 1		18/09/2026	No	No