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Is it possible to conduct a study of a positive mental imagery intervention in students with suicidal thinking and/or behaviour?

Submission date
13/12/2021

Recruitment status
No longer recruiting

Registration date
17/12/2021

Overall study status
Completed

Last Edited
27/05/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Suicide is the main cause of death in young people. Many students experience suicidal thoughts. These thoughts can be distressing. They can lead to suicide attempts and worse mental health. University and NHS services typically manage this risk. However, there are few evidence based treatments for targeting suicidal thinking.

We want to evaluate a new talking therapy called the Broad-Minded Affective Coping (BMAC) intervention. It is brief, structured, and easily used by student services. The BMAC asks people to revisit and focus on positive memories and experiences. This may help people to break out of cycles of suicidal thinking. We want to see whether we can do a trial of the BMAC.

Who can participate?
Students aged 18 years or older, with suicidal thoughts.

What does the study involve?
We will recruit 66 students with suicidal thoughts to a clinical trial. We will randomly assign 33 students to receiving risk assessment and signposting. The other 33 students will receive risk assessment and signposting plus the BMAC. We will assess students' suicidal thinking and other difficulties at the start of trial and after eight, 16 and 24 weeks. We will explore whether young people are happy to complete the clinical assessments and the BMAC.
We will interview students and staff as they finish the trial. Staff will also keep detailed notes of their experiences. This will help us to understand how people found the therapy and the trial. The results will improve the BMAC for young people. It will help to plan a larger study. We will work with young people to decide how to best share our findings.

What are the possible benefits and risks of participating?
Although the study asks participants about sensitive information, participants sometimes report taking part in research rewarding.

Where is the study run from?
Greater Manchester Mental Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2021 to October 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Palmier-Claus, j.palmier-claus@lancaster.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
305348

ClinicalTrials.gov number
NCT05296538

Secondary identifying numbers
IRAS 305348, CPMS 51344

Study information

Scientific Title

The Mental Imagery for Suicidality in Students Trial (MISST): A feasibility study.

Acronym
MISST

Study objectives
We aim to conduct a feasibility trial of a six-session BMAC intervention with University students experiencing suicidal thoughts and/or behaviours. Our overall objectives are:
1. To determine whether University students are willing to be randomised to a trial targeting suicidal experiences.
2. To understand whether it is feasible to collect clinical outcome data in this population.
3. To explore whether patients engage with the BMAC intervention.
4. To determine the safety of the intervention and trial procedures.
5. To explore the initial promise of the intervention, in terms of impact upon clinical outcomes.
6. To investigate what aspects of suicidal experiences might be an appropriate primary clinical outcome for a full trial
7. To understand the potential factors affecting (e.g. facilitators and barriers) acceptability and delivery.
8. To gather participant and staff feedback to configure and optimise the intervention and full-scale trial design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/12/2021, London - Bromley Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 207 104 8105; bromley.rec@hra.nhs.uk), ref: 21/LO/0897

Study design
Interventional randomized controlled trial (feasibility study)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Suicidal thinking and/or behaviour

Interventions

We will randomly allocate (1:1 ratio; random block size) participants to either, up to:
- Two sessions of risk assessment and signposting (control) over eight weeks.
- Two sessions of risk assessment and signposting plus six sessions and a booster session of the Broad Minded Affective Coping (BMAC) intervention over eight weeks.

BMAC intervention:
A clinician will ask people to identify, revisit and rehearse positive memories in order to strengthen alternative patterns of thinking that then compete with and reduce repetitive suicidal thoughts. The sessions with typically last one hour and can be delivered face-to-face or remotely via telephone/video calls.

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcomes measured using participant records:
1. Recruitment rates: Ability to randomise 66 participants in an 11-month recruitment window
2. Adherence to treatment: Percentage of participants receiving the minimum dose of therapy (≥2 sessions) within eight-week treatment window
3. Retention to follow-up: Percentage of participants completing the 24-week assessment as potential primary outcome timepoint
4. Suitability of proposed primary outcome: Informed by qualitative workstream plus percentage of participants completing the Beck Scale for Suicidal ideation at all timepoints
5. Safety of trial participation: Monitoring and review of research related serious adverse events (SAEs).

Secondary outcome measures
Measured at baseline, 8, 16 and 24 weeks:
1. Beck Scale for Suicidal Ideation
2. Linehan Suicide-Attempt Self-Injury Interview items
3. Self-injurious Thoughts and Behaviours Interview items
4. General health measured using the Patient Health Questionnaire 9
5. Anxiety measured using the Generalised Anxiety Scale 7
6. Hopelessness measured using Beck Hopelessness Scale
7. Defeat and entrapment measured using Defeat and Entrapment scales
8. Perceived Stress Scale
9. Emotion measured using the Positive and Negative Affect Schedule
10. Perceived Control of Internal States Scale

Overall study start date
25/10/2021

Completion date
24/10/2023

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Accessing full or part time education through a HEI
3. Suicidal ideation and/or behaviours in the past three months, ascertained using the questions

‘have you had any thoughts about ending your life in the past three months?’ and ‘have you attempted to end your life in the past three months?’. Endorsement of either item will confirm eligibility for the trial and progression to full assessment. This approach is consistent with previous trials and is sensitive to detecting suicidal experiences amongst adults

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
66

Key exclusion criteria
1. Active/historical full threshold first episode psychosis or bipolar disorder as identified by the patient or referring service and the MINI diagnostic interview.
2. Known moderate to severe learning disability (IQ:<70).
3. Organic cerebral disease/injury affecting receptive and expressive language comprehension.
4. Non-English speaking to the degree that the participant is unable to answer questions and give written informed consent.
5. Imminent and immediate risk to self or others, operationalised as the presence of active intent or planning to harm oneself or others in the near future (e.g. next month). Where individuals are excluded on this basis, with the person’s consent, the researcher will aim to recontact them and the referrer in approximately one-month’s time (or a time period agreed in collaboration with the individual) to determine if risk has subsided to a point where they are now eligible.

Date of first enrolment
24/02/2022

Date of final enrolment
24/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Prestwich Hospital
Greater Manchester Mental Health NHS Foundation Trust
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

Sponsor details
3rd Floor
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Hathersage Road
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M13 9WL
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researchoffice@gmmh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.gmmh.nhs.uk//

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We will disseminate widely across all stakeholders (clinical, academic, voluntary sector, service users, caregivers), ensuring suitability for diverse audiences in collaboration with PPI committee, and throughout the lifetime of the project. Specific outputs may include:
- Papers in high-impact academic journals.
- Lay summaries on websites, magazines, and leaflets for charities (e.g. McPin) and Universities UK.
- Presentations at academic conferences and general audience events.
- Project-specific website and Twitter feed, including lay summaries.
- A full report for NIHR RfPB
- Two national online dissemination events.
- Newsletters and infographics co-developed with young people with support from a graphic designer.

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
Following publication of the trial results, we will make suitable arrangements for anonymised data to be available from the Research Team, in line with NIHR data sharing guidance. Data available from Jasper Palmier-Claus, J.Palmier-Claus@lancaster.ac.uk, raw data, at least five years, for the purpose of relevant research into suicidality in students at the discretion of the research team, we will be gathering informed consent from participants to this purpose.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/03/2023	20/03/2023	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 1	22/06/2023	06/10/2023	No	No
Other publications	Qualitative study of participants experiences	27/09/2024	27/09/2024	Yes	No

Results article	20/05/2025	27/05/2025	Yes	No