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Evaluating school-based psychological interventions for low mood in adolescence

Submission date
02/09/2023

Recruitment status
Recruiting

Registration date
11/09/2023

Overall study status
Ongoing

Last Edited
07/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and aims

Depression is one of the most common mental health conditions worldwide. The symptoms of depression can vary greatly from person to person but generally include low mood, problems with sleeping and/or loss of interest in life. If a person experiences depression during adolescence, it can impact the rest of their life. Adolescent depression is often associated with mental health and social difficulties that often continue into adulthood, including higher social dysfunction, poorer academic performance, more physically ill health complaints and more complete suicides. With young people, schools and practitioners, the study team have developed a new psychological intervention, IMAGINE (Integrating Memories and Generating New Experiences). Previous research has demonstrated IMAGINE is possible and acceptable to deliver in schools and shows promising signs of reducing depression. This study aims to evaluate in a bigger trial whether, in young people aged 16-18 years old, IMAGINE reduces symptoms of depression relative to an active control intervention (non-directive support). The study will take place in several secondary schools and sixth-form colleges in the UK.

Who can participate?

Young people aged between 16 to 18 years old who are showing signs of depression

What does the study involve?

Young people will be randomly allocated to receive one of two psychological programmes. Both programmes involve meeting with a researcher for three to four, ninety-minute sessions, each one week apart. Participants are also asked to complete four assessments over a six-month period. The assessments include completing some questionnaires, the researcher asking some questions and a task that asks about memories. Each assessment will take an hour to complete.

What are the possible benefits and risks of participating?

Benefits to taking part include: receiving a programme that aims to reduce low mood and improve self-esteem, being part of a study that will help us develop interventions for low mood and low self-esteem, and participants being reimbursed for their time for each assessment they complete.

Risks to taking part include: that it can sometimes be upsetting when young people are asked questions about their thoughts, feelings and behaviour either in the assessments or during the programmes. Usually, young people tell us that if they do find it upsetting this feeling only lasts for a short period of time and there will always be someone available for participants to talk to and to help. Asking these questions also helps us to know whether participants need additional help, e.g., from a GP.

Where is the study run from?
The assessments and programme will take place across secondary schools and colleges. The research is based at King's College London (UK).

When is the study starting and how long is it expected to run for?
February 2023 to August 2026

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

Who is the main contact?
Dr Victoria Pile, victoria.pile@kcl.ac.uk (UK)

Contact information

Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
334147

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 334147, CPMS 58469

Study information

Scientific Title
Harnessing mental imagery in a brief school-based intervention for adolescent depression: A phase IIB randomised controlled trial

Acronym
INDIGO-RCT

Study objectives
To evaluate whether, in young people aged 16-18 (P), a brief imagery-based intervention (I: IMAGINE; 4 face-to-face sessions) reduces symptoms of depression (O) relative to non-directive support (C: NDS; 4 face-to-face sessions) at 8 weeks following randomisation (T).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/08/2023, Health Faculties (Purple) Research Ethics Subcommittee (Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London, SE1 9NH, United Kingdom; +44 (0) 2078484020; rec@kcl.ac.uk), ref: RESCM-23/24-36782

Study design
Multi-school assessor-blind parallel-group randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Treatment, Efficacy

Health condition(s) or problem(s) studied
Adolescent depression

Interventions
This study is a multi-school, assessor-blind, parallel-group, randomized, controlled trial in adolescents in England comparing two psychological interventions. Both interventions consist of individual sessions with young people. The two psychological interventions: Integrating Memories and Generating New Experiences (IMAGINE) and an active control condition (non-directive support; NDS) are assigned with a 1:1 allocation ratio. Following the baseline visit, eligible participants will be randomised using an online Kings Clinical Trials Unit (KCTU) randomisation system.

IMAGINE: Imagery-based psychological intervention, consisting of 3-4 (45 to 90 minutes) sessions. IMAGINE will follow a treatment manual and will be accompanied by a therapy workbook. The intervention will combine (A) imagery protocols to reduce the distress associated with negative images and build positive future images and (B) Memory Specificity Training to increase specificity and access to memories.

Control: NDS consisting of 3-4 (45 to 90 minutes) sessions delivered by the therapy team. This intervention is designed to control for factors that, other than active components of therapy, could contribute to change such as the passage of time and non-specific aspects of therapy (e.g., speaking to an empathic therapist). NDS is designed to be matched for contact time and frequency of sessions. NDS is based on the principles of non-directive supportive therapy. NDS will follow a treatment guide.

Intervention Type
Other

Primary outcome(s)
Depressive symptoms measured using the Mood and Feelings Questionnaire (MFQ). The primary endpoint is 8 weeks following randomization. The MFQ will be collected at four-time points: pre-randomisation/baseline, 8, 16 and 24 weeks after randomisation.

Key secondary outcome(s))
Secondary outcomes measures of therapeutic mechanisms:

All measures will be collected at four time points: pre-randomisation/baseline, 8, 16 and 24 weeks after randomisation.
1. Anxiety measured using the anxiety subscales on the Revised Children's Anxiety and Depression scale (RCADS)
2. Self-worth measured using the Harter Self-Perception Scale Self-worth subscale (SPPC)
3. Sleep difficulties measured using the Insomnia Severity Index (ISI)
4. School and social impairment, activity levels and rumination measured using the Behavioural Activation for Depression Scale (BADS)
5. Mental Imagery measured using the Assessing Mental Imagery in Youth (AMI-Y) Questionnaire
6. Distress/post-traumatic stress symptoms to a negative event measured using Child Revised Impact of Event Scale (CRIES)
7. Future imagery vividness measured using Prospective Imagery Task (PIT)

8. Memory specificity measured using Autobiographical Memory Task (AMT)
9. Self-Compassion measured using the Self-Compassion Scale- Short Form (SCS)

Acceptability, Safety and Adherence, Fidelity and Contamination:
1. Recruitment and retention will be recorded in a CONSORT diagram. The number of participants who drop out at each stage of the trial and the reasons for this will be recorded.
2. Acceptability will be measured using a feedback questionnaire (including quantitative and written responses). The feedback questionnaire will also ask questions probing peer-to-peer contamination, the therapeutic relationship and therapist motivation.
3. Risk to self and to/from others (e.g., self-harm; suicidal ideation) is measured in a semi-structured clinical interview at each assessment and monitored throughout. This semi-structured interview will also assess clinical history (e.g. diagnoses, medication). All adverse events will be recorded and reported.
4. The range and average number of sessions completed, total contact time and homework adherence will indicate participant compliance.
5. Adherence and competency (and contamination) will be assessed by an independent psychologist using an Adherence and Competency scale
6. Participant beliefs about the potential effectiveness of the intervention will be measured using The Credibility/Expectancy Questionnaire

Health economics measures:
The assessment of comprehensiveness, feasibility and acceptability include:
1. Child and Adolescent Service Use Schedule (CA-SUS)
2. EuroQol -5D-5L
3. Recovering Quality of Life (ReQoL)
Feasibility and acceptability will be assessed by: (1) numbers agreeing to complete the measures, (2) data completeness, (3) level of explanation required and (4) verbal feedback on preferences between the EQ-5D-5L and the ReQoL.

Demographic information will be assessed using the General Information Questionnaire administered at baseline assessment

Completion date
01/08/2026

Eligibility

Key inclusion criteria
1. Aged 16-18
2. Able to provide Informed consent
3. Willing and able to engage in psychological therapy and complete assessments
4. Scoring above the clinical cut-off on the Mood and Feelings Questionnaire at both screen and baseline assessment (MFQ of 29 items at the screen, clinical cut-off ≥17; MFQ of 33 items at baseline, clinical cut-off ≥20)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
16 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
1. Diagnosis of learning disability or significant head injury, neurological disorder or epilepsy
2. Unable to fluently communicate in spoken English
3. Currently receiving another psychological intervention (including school counselling)
4. Moderate to high levels of risk. This will be verbally assessed by the participant at the first interview and discussed under supervision with the Chief Investigator (VP). This will be based on clinical judgement, but an outline is that Imagery Rescripting is unlikely to be appropriate for young people presenting with current and/or significant self-harm (e.g., which requires medical attention); active suicidal ideation and an active plan to harm themselves and; those presenting with significant risk to others. The clinical decision will be informed by their history of risk.
5. Current diagnosis of bipolar disorder, PTSD or psychosis. This will be stated in the information sheet and verbally assessed by the participant at the first interview
6. Other significant conditions or factors that contraindicate the individual's participation in the trial

Date of first enrolment
14/09/2023

Date of final enrolment
05/07/2026

Locations

Countries of recruitment
United Kingdom

England

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Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Individual participant data (IPD) sharing plan
The primary dataset generated during the current study will be stored in a publicly available repository (e.g. Mendeley data; https://data.mendeley.com/). This will contain no identifiable information.

The type of data stored are questionnaire scores for clinical and cognitive tasks from the 8, 16 and 24-week assessments. The timing for availability is following the publication of the main trial paper. Only pseudonymised data will be shared.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/07/2025	07/07/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes