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A psychological programme to improve low mood in adolescence

Submission date
03/04/2017

Recruitment status
No longer recruiting

Registration date
04/04/2017

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study 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 eating, and 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 physical ill health complaints and more completed suicides. The aim of this study is to assess the possibility of running a trial of a brief talking therapy in schools for adolescents with symptoms of depression. The study will take place in several secondary schools and sixth form colleges in the UK.

Who can participate?
Adolescents aged 16-18 who are showing signs of depression.

What does the study involve?
Participants are randomly allocated to one of two groups, who each receive a different type of talking therapy. Those in the first group receive an 'imagery-based cognitive behavioural intervention' and those in the second group receive 'non-directive supportive therapy'. Both therapies involve three to four face to face sessions, lasting for up to 90 minutes. Participants in both groups are asked to complete three assessments: one before therapy, one after therapy and one three months later. Each assessment takes around an hour to complete.

What are the possible benefits and risks of participating?
Both talking therapies are likely to have some benefit as both aim to reduce low mood and improve self-esteem. There are no known risks of taking part in the study.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
April 2015 to May 2019

Who is funding the study?
1. Health Education England (UK)
2. National Institute for Health Research (UK)

Who is the main contact?
Dr Victoria Pile (public)
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A brief early intervention for adolescent depression that targets emotional memories: a feasibility randomised controlled trial

Acronym
IMAGINE

Study objectives
The aim of this study is to establish the practicality and acceptability of implementing a new early intervention for adolescent depression that targets emotional memories, within a school setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Psychiatry, Nursing and Midwifery Research Ethics Subcommittee of the College Research Ethics Committee (CREC) at Kings College London, 21/10/2016, ref: HR-16/17-3548

Study design
Intreventional feasibility randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Depression

Interventions
Eligible participants will be randomised by the Kings Clinical Trials Unit (KCTU). Participants will be randomised using block randomisation via a web interface. Randomly varying block sizes will reduce the predictability of the sequence. There will be two arms and allocation will be 1:1.

Both interventions will be delivered via individual therapy sessions and consist of three to four sessions, delivered by a clinical psychologist. Sessions will last up to a maximum of 90 minutes, with the possibility of young people taking breaks during the session if needed.

'Imagery-based cognitive behavioural intervention' (ICBI): The intervention will combine components of (A) imagery rescripting 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. ICBI will follow a treatment manual and will be accompanied by a therapy workbook.

'Non-directive supportive therapy' (NDST): NDST will involve planned delivery of individual sessions with an empathic, concerned professional for emotional support and discussion of

participant-initiated options for addressing problems. 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). NDST will follow treatment guidelines.

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcome:
Feasibility and acceptability of the intervention is assessed by recording numbers of eligible participants, recruitment rate, retention rate outcome measure completion rate, data completeness, incidence of unexpected adverse events, data on adherence/compliance, and feedback questionnaires.

Secondary outcome measures
Principal clinical outcome
Depression is measured using the Mood and Feelings Questionnaire (MFQ; long version) pre-therapy, post-therapy and 3-month follow-up. (The short version of the MFQ will also be administered at each intervention session.)

Other measures
1. Anxiety is measured using the Screen for Child Anxiety Related Disorders pre-therapy, post-therapy and 3-month follow-up
2. Symptoms of post-traumatic stress are measured using the Revised Impact of Event Scale: child version pre-therapy, post-therapy and 3-month follow-up
3. Response style is measured using the Children's Response Style Questionnaire pre-therapy, post-therapy and 3-month follow-up
4. Self-esteem is measured using the Rosenberg Self-Esteem Scale pre-therapy, post-therapy and 3-month follow-up
5. Self-Concept Clarity is measured using the Self-Concept Clarity scale pre-therapy, post-therapy and 3-month follow-up
6. Mental Imagery for future events is measured using the Prospective Imagery Task pre-therapy, post-therapy and 3-month follow-up
7. Memory specificity is measured using the Autobiographical Memory Task pre-therapy, post-therapy and 3-month follow-up
8. Daily mood is measured for seven days using daily mood ratings pre-therapy and post-therapy
9. Emotional response (subjective ratings and heart rate variability) to autobiographical memories is measured using a positive memory recall task pre-therapy and post-therapy

Overall study start date
01/04/2015

Completion date
31/05/2019

Eligibility

Key inclusion criteria
1. Aged 16-18
2. Informed consent

3. Willing and able to engage in psychological therapy and complete assessments
4. Scoring above clinical cut-off on Mood and Feelings Questionnaire (MFQ clinical cut-off ≥ 20).

Participant type(s)
Patient

Age group
Child

Lower age limit
16 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
56

Total final enrolment
56

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. Unable to give informed consent
4. Factors contra-indicating imagery rescripting, e.g. high levels of current risk
5. Currently receiving therapy
6. Experiencing psychotic symptoms or depressed in the postnatal period (participants with comorbid physical illness or non-psychotic disorders such as anxiety will not be excluded)

Date of first enrolment
10/04/2017

Date of final enrolment
31/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
Institute of Psychiatry, Psychology and Neuroscience

London
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SE5 8AF

Sponsor information

Organisation
King's College London

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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Health Education England

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
1. Planned publication of trial protocol
2. Planned publication of outcomes to peer-reviewed journal within a year from end of trial.
3. Dissemination via conferences and to NHS services at a local level

Intention to publish date
31/05/2020

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 Pile (victoria.pile@kcl.ac.uk)

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2018		Yes	No
Results article		01/08/2021	08/06/2021	Yes	No
Other publications		16/11/2021	07/06/2023	Yes	No
Other publications		23/08/2021	07/06/2023	Yes	No