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Early intervention for depression and anxiety in 16-18 year olds: a multi-centre trial of self-referral psychological stress workshop programmes in schools

Submission date
28/05/2020

Recruitment status
No longer recruiting

Registration date
02/06/2020

Overall study status
Completed

Last Edited
02/09/2024

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
Poor mental health in young people is increasing, with clear evidence of mounting psychiatric problems. However, less than a quarter of young people with mental health problems can access services, meaning there is an urgent need for easily accessible and effective mental health resources. Common barriers include the limited provision of services, reluctance of adolescents to seek professional help as well as a fear of stigmatisation.

Young people's mental health is a major government priority, with current policy advocating the development of effective education based mental health care to prevent the escalation of mental health problems, improve access and reduce service waiting times. However, existing school-delivered programmes for depression and anxiety only have modest effects. These programmes are also mainly focused on younger children.

With these factors in mind, we have developed an accessible and non-stigmatising workshop program for older students. This award-winning programme, named DISCOVER, is a brief group workshop programme for 16 - 18-year-olds that was developed in collaboration with a Teenage Advisory Group (TAG) of 16 - 18-year-olds. DISCOVER aims to improve engagement, offer effective treatment, and maintain participants' motivation and improvement to reduce relapse. The DISCOVER workshop is delivered in a group setting, to around 12 - 15 young people, over one school day. The workshop includes videos, discussions, and the chance to learn and practice techniques designed to improve and maintain mental wellbeing. The workshop material is organised into eight short (20 minute) sections and particular attention is paid to personal, relationship and academic worries typical for 16 - 18-year-olds. Specific methods taught include (i) Behavioural methods e.g. time management, sleep hygiene and maintaining motivation (ii) Cognitive methods e.g. learning to challenge negative thoughts and (iii) mindfulness e.g. meditation exercises. Following the workshop, to maintain progress and adherence, participants

receive a DISCOVER workbook and access to a workshop-specific DISCOVER app to remind them of the methods. Participants also receive three 'follow-up' phone calls from the workshop leader to discuss how they are progressing with their personal goals.

We would like to understand whether this workshop is more effective at improving students' mental health than the normal care they receive at school. Specifically, this clinical trial aims to answer the research question of whether the DISCOVER workshop is a clinically effective and cost-effective intervention in schools that reduces symptoms of depression in 16-18-year-olds at 3 and 6 months after the intervention.

The results of this trial will tell us whether DISCOVER is a suitable programme to take forward as a school-based mental health provision. It is very possible that DISCOVER could be a highly effective and popular component in frontline education-based mental health care as advocated by government health and education policy. We see DISCOVER fitting in very well with the current education-based mental health care aims of the government. Therefore, this trial is essential to inform the Department of Health about the effectiveness of this potentially very important intervention for 16 - 18-year-olds.

Who can participate?
The DISCOVER workshop is designed for sixth form/college students between 16 and 18 who are experiencing, or have experienced, stress or low mood problems recently. We hope this program will be helpful for as many people as possible from this group, however we are still assessing how effective it can be. It is not so suitable for young people who have very severe problems or who do not understand spoken and written English.

What does the study involve?
The study involves the comparison of two different intervention groups; the active intervention (the DISCOVER workshop) and a control intervention (normal school care). Each of the 60 schools will be randomly assigned to one of these two groups. Half of the schools (30) will receive the DISCOVER workshop and the other half (30) of schools will receive their normal care. We will assess participants' mood, stress levels and wellbeing before the intervention and at several points afterwards, in both the workshop and control groups. Following trial completion of all participants, we will then analyse this data to evaluate whether the workshop was more beneficial than the normal care students receive.

What are the possible benefits and risks of participating?
If you receive the workshop, it could help you handle stressful situations in a more helpful way, making it easier to tackle everyday problems. The DISCOVER workshop leaders will offer advice and help during the workshop and at the follow up session. However, the decision may be that your school/college will not be receiving the workshops. In which case, you will receive the normal help available from the school/college (e.g. access to websites, school counsellor). This will be helpful for us to know how students get on without receiving any extra help.

Participation does not have any likely risks associated with it. Sometimes, when we ask young people questions about their feelings, it can be mildly upsetting, but there will always be someone available for them to talk to and to provide any help needed.

Where is the study run from?
King's College London (UK). The study will be taking place in 4 sites; London, Bath, Manchester, and Northampton (London is the lead centre for the study). It will involve a total of 60 schools and 900 sixth form students.

When is the study starting and how long is it expected to run for?
January 2020 to April 2024

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

Who is the main contact?
Dr Stephen Lisk, stephen.lisk@kcl.ac.uk
Dr June Brown, june.brown@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Stephen Lisk

Contact details
King's College London
16 De Crespigny Park
Camberwell
London
United Kingdom
SE5 8AF
+44 (0)20 784 80715
stephen.lisk@kcl.ac.uk

Type(s)
Public

Contact name
Dr June Brown

Contact details
King's College London
16 De Crespigny Park
Camberwell
London
United Kingdom
SE5 8AF
+44 (0)20 78485004
june.brown@kcl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
NIHR127951

Study information

Scientific Title
Brief Educational workshops in Secondary Schools Trial: a multi-centre cluster randomised controlled trial of self-referral psychological stress workshops in schools for depression and anxiety in 16-18 year-olds.

Acronym
BESST

Study objectives
Current study hypothesis as of 22/07/2021:
1. Compared to those receiving a control intervention, participants receiving the DISCOVER workshop intervention will show greater reduction in symptoms of depression at 3 and 6 months
2. Compared to those receiving a control intervention, participants receiving the DISCOVER workshop intervention will show greater reduction in symptoms of anxiety at 3 and 6 months post-intervention
3. Compared to those receiving a control intervention, participants receiving the DISCOVER workshop intervention will show greater improvement in wellbeing at 3 and 6 months post-intervention
4. Cost-effectiveness of DISCOVER will be comparable to the control treatment in terms of quality adjusted life years (QALYs) at 3 and 6 months post-intervention?
5. The intervention will be considered acceptable by young people
6. What are the contextual (e.g. school) and process (e.g. workshop publicity) factors that influence implementation and clinical effectiveness?
7. Compared to those receiving a control intervention, participants receiving the DISCOVER workshop intervention will show greater improvement in sleep quality at 3 and 6 months post-intervention
8. Compared to those receiving a control intervention, participants receiving the DISCOVER workshop intervention will show greater improvement in resilience at 3 and 6 months post-intervention

Previous study hypothesis:
1. Compared to those receiving a control intervention, participants receiving the DISCOVER workshop intervention will show greater reduction in symptoms of depression at 3 and 6 months
2. Compared to those receiving a control intervention, participants receiving the DISCOVER workshop intervention will show greater reduction in symptoms of anxiety at 3 and 6 months post-intervention
3. Compared to those receiving a control intervention, participants receiving the DISCOVER workshop intervention will show greater improvement in wellbeing at 3 and 6 months post-intervention
4. Cost-effectiveness of DISCOVER will be comparable to the control treatment in terms of quality adjusted life years (QALYs) at 3 and 6 months post-intervention?
5. The intervention will be considered acceptable by young people
6. What are the contextual (e.g. school) and process (e.g. workshop publicity) factors that influence implementation and clinical effectiveness?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/10/2020, King's College London Research Ethics Committee (Waterloo Campus, 57 Waterloo Road London, SE1 8WA, UK; rec@kcl.ac.uk)

Study design
Two-arm blinded (researchers, analyst) multi-centre cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
Participants in the intervention arm will receive a one-day, school-based mental health programme called the DISCOVER workshop, administered by trained NHS practitioners. Participants in the control arm will receive normal school provision and will be offered a brief leaflet signposting them to relevant local and web-based mental health resources.
Using an online randomisation system set up by the Kings Clinical Trials Unit (CTU), schools will be randomly assigned to the intervention or control arm (1:1 allocation ratio) after students have consented and baseline data has been collected.

Intervention Type
Behavioural

Primary outcome(s)
Symptoms of depression, measured using the Mood and Feelings Questionnaire (MFQ), collected at baseline, and 3 and 6 months post-intervention

Key secondary outcome(s))
Current secondary outcome measures as of 22/07/2021:
1. Symptoms of anxiety, measured using the Revised Child Anxiety and Depression Scale (RCADS), collected at baseline, and 3 and 6 months post-intervention
2. Wellbeing, measured using the Warwick Edinburgh Mental Wellbeing scale (WEMWBS), collected at baseline, and 3 and 6 months post-intervention
3. Cost-effectiveness, measured using the Child and Adolescent Service Use Schedule (CA-SUS), collected at baseline and 3 and 6 months post-intervention
4. Quality of life, measured using the EQ-5D-3L (a self-report measure of health-related quality of life, used to calculate quality-adjusted life years (QALYs) suitable for economic evaluation), collected at baseline, and 3 and 6 months post-intervention
5. Participant satisfaction, measured using the the Client Satisfaction Questionnaire, collected immediately post-intervention, and 3 and 6 months post-intervention
6. A qualitative process evaluation, designed to (a) examine the contextual and process factors that either support or obstruct the implementation of the intervention, (b) examine the

experience of participants and workshop facilitators and (c) assess whether and how the contextual (e.g. school regime and environment) and process factors (e.g. publicity, component parts of the workshop) identified through this work influence the intermediary outcomes (e.g. engagement, intervention fidelity, adherence to intervention protocol) as well as the primary and secondary outcomes assessed in the trial. The qualitative process evaluation will be conducted in 8 intervention schools (following completing of follow-up measures), using semi-structured interviews (with n=16 students, n=8 workshop facilitators) and focus groups with school staff (n=8).
7. Sleep quality, measured using the Sleep Condition Indicator (SCI), collected at baseline, and 3 and 6 months post-intervention.
8. Resilience, measured using the Child and Youth Resilience Measure 12 (CYRM-12), collected at baseline, and 3 and 6 months post-intervention.

Previous secondary outcome measures:
1. Symptoms of anxiety, measured using the Revised Child Anxiety and Depression Scale (RCADS), collected at baseline, and 3 and 6 months post-intervention
2. Wellbeing, measured using the Warwick Edinburgh Mental Wellbeing scale (WEMWBS), collected at baseline, and 3 and 6 months post-intervention
3. Cost-effectiveness, measured using the Child and Adolescent Service Use Schedule (CA-SUS), collected at baseline and 3 and 6 months post-intervention
4. Quality of life, measured using the EQ-5D-3L (a self-report measure of health-related quality of life, used to calculate quality-adjusted life years (QALYs) suitable for economic evaluation), collected at baseline, and 3 and 6 months post-intervention
5. Participant satisfaction, measured using the the Client Satisfaction Questionnaire, collected immediately post-intervention, and 3 and 6 months post-intervention
6. A qualitative process evaluation, designed to (a) examine the contextual and process factors that either support or obstruct the implementation of the intervention, (b) examine the experience of participants and workshop facilitators and (c) assess whether and how the contextual (e.g. school regime and environment) and process factors (e.g. publicity, component parts of the workshop) identified through this work influence the intermediary outcomes (e.g. engagement, intervention fidelity, adherence to intervention protocol) as well as the primary and secondary outcomes assessed in the trial. The qualitative process evaluation will be conducted in 8 intervention schools (following completing of follow-up measures), using semi-structured interviews (with n=16 students, n=8 workshop facilitators) and focus groups with school staff (n=8).

Completion date
01/04/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 01/09/2023:
1. Aged between 16 - 18 years
2. Enrolled at one of the schools taking part in the trial, with planned attendance until the end of the summer term
3. Sufficient English to provide valid informed consent and complete assessments
4. Be seeking help for stress (with or without teacher encouragement)
5. Able to attend and take part in the workshop

School/college inclusion criteria:
1. Secondary school with 6th form or dedicated 6th form college
2. State-funded
3. Sufficient resources available to host trial

Previous participant inclusion criteria as of 22/07/2021 to 01/09/2023:
1. Aged between 16 - 18 years
2. Enrolled at one of the schools taking part in the trial, with planned attendance until the end of the summer term
3. Sufficient English to provide valid informed consent and complete assessments
4. Be seeking help for stress (with or without teacher encouragement)
5. Able to attend and take part in the workshop

School/college inclusion criteria:
1. Secondary school with 6th form or dedicated 6th form college
2. State-funded
3. Mixed gender
4. Sufficient resources available to host trial

Previous participant inclusion criteria:
1. Aged between 16 - 18 years
2. Enrolled at one of the schools taking part in the trial, with planned attendance until the end of the summer term
3. Sufficient English to provide valid informed consent and complete assessments
4. Be seeking help for stress (with or without teacher encouragement)
5. Able to attend and take part in the workshop

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
18 years

Sex
All

Total final enrolment
900

Key exclusion criteria
Current participant exclusion criteria as of 01/09/2023:
1. Identified as actively suicidal (through risk assessment)

2. Current involvement with Child and Adolescent Mental Health Services (reviving psychological therapy for anxiety or depression)
3. Severe learning difficulties or psychosis

School/college exclusion criteria:
1. Further education college
2. Privately funded school/college
3. 6th form/College student population <70

Previous participant exclusion criteria as of 27/09/2022 to 01/09/2023:
1. Identified as actively suicidal (through risk assessment)
2. Current involvement with Child and Adolescent Mental Health Services
3. Severe learning difficulties or psychosis

School/college exclusion criteria:
1. Further education college
2. Single-gender school/college
3. Privately funded school/college
4. 6th form/College student population <70

Previous participant exclusion criteria as of 22/07/2021:
1. Identified as actively suicidal (through risk assessment)
2. Current involvement with Child and Adolescent Mental Health Services
3. Current involvement with school counselling
4. Severe learning difficulties or psychosis

School/college exclusion criteria:
1. Further education college
2. Single-gender school/college
3. Privately funded school/college
4. 6th form/College student population <70

Previous participant exclusion criteria:
1. Identified as actively suicidal (through risk assessment)
2. Current involvement with Child and Adolescent Mental Health Services
3. Current involvement with school counselling
4. Severe learning difficulties or psychosis

Date of first enrolment
01/09/2021

Date of final enrolment
01/12/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
Institute of Psychiatry, Psychology and Neuroscience (IoPPN)
16 De Crespigny Park
Camberwell
London
United Kingdom
SE5 8AF

Study participating centre
The University of Manchester
Oxford Rd
Manchester
United Kingdom
M13 9PL

Study participating centre
University of Bath
Claverton Down
Bath
United Kingdom
BA2 7AY

Study participating centre
University of Northampton
Waterside Campus,
University Drive
Northampton
United Kingdom
NN1 5PH

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

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

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/05/2024	07/05/2024	Yes	No
Results article	Clinical effectiveness and cost-effectiveness	13/05/2024	20/05/2024	Yes	No
Protocol article		09/11/2022	11/11/2022	Yes	No
Other publications	Secondary analysis	29/08/2024	02/09/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes