ISRCTN88636606 https://doi.org/10.1186/ISRCTN88636606

Feasibility trial of open-access psychological workshops in schools

Submission date
14/01/2015

Recruitment status
No longer recruiting

Registration date
15/01/2015

Overall study status
Completed

Last Edited
09/02/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Adolescence is an important time for mental health prevention and treatment, with one in nine adolescents having a mental disorder. However, less than a quarter of young people in the UK are in touch with mental health services. Common obstacles for those who do not seek help range from inconvenient appointment times to fear of stigmatisation. Even if adolescents do reach services, they are unlikely to access cognitive behavioural therapy (CBT) treatment, a proven therapy that helps people to change how they think and behave. CBT workshops have been developed for delivery in schools, targeting anxiety and depression in 16 – 18 year olds. The workshops are based on 'Wellbeing Workshops' for adults, developed by Brown and colleagues. These workshops are delivered in a one-off, day-long group format based on CBT principles and methods. The adult workshops have been successfully delivered in local community settings with evidence suggesting relatively high rates of uptake among traditionally hard-to-reach groups and improvement in depression and anxiety. A recent study has also provided evidence for how possible it is to run CBT workshops in schools for 16-18 year olds and the potential impact of being able to do so. We want to test the possibility of running a full trial of the school-based workshops. We will work in 10 schools to see if we can develop appropriate measures to show how well they work, whether they are acceptable to the children and whether they are value for money. We will also explore whether teachers and students can work with us on a potentially complex research study.

Who can participate?
Young people aged between 16 and 18, attending a recruited school or college in Southwark or Lambeth, who are fluent in English, are able to attend the workshops and would like psychological help for managing emotional difficulties.

What does the study involve?
Schools participating in the trial are randomly allocated into one of two groups, an experimental group or a waitlist group. Between 12-15 children from each school are recruited into the study. Those children that attend one of the schools in the experimental group attend a day-long 'How to Handle Stress' workshop straight away. Those children attending a school in the waitlist group attend the workshop three months later. Assessments are made of all the children in both schools before the study begins. Those children in the experimental group are then interviewed

three months later and asked about their experiences of the workshop, what they got out of it, whether they felt any stigmatisation and what they thought of participating in a research project. Those students in the waitlist attend the same interview three months after they have attended their own workshop. All students are also invited to attend a focus group 6 months later.

What are the possible benefits and risks of participating?
The 'How to Handle Stress' workshops are adapted from the adult 'Wellbeing' workshops, which has been proven to alleviate anxiety and depression. In the pilot study, the workshops for adolescents were found to be an effective intervention, whereby students reported significantly reduced depression and anxiety and were very satisfied with the workshops. The 'How to Handle Stress' workshops are based on theory and principles from cognitive behavioural therapy, which has increasing evidence to support its effectiveness with adolescents for anxiety and depression. The theory and strategies provided aim to provide the 16-18 year olds with the ability to build resilience to stress and build their capacity to resolve problems. There are few risks or burdens anticipated for participants. We work in close partnership with schools in order to allow students day release from classes in order to attend the South London and Maudsley NHS Foundation trust (SLaM) provided workshop intervention. Workshops are not run during exam periods, in order to reduce potentially stressful timetable clashes. It may be that some students with literacy problems find it difficult and potentially stressful to complete the self-report questionnaires throughout the study. A research worker is available in order to assist with the completion of these forms and explain any problematic terms. Students who remain troubled and wish for further mental health support over the course of the research project receive clear and accurate information regarding accessing local services. The research team also make direct referrals to the adolescent mental health teams in Southwark and Lambeth if this help is required. Young people may also experience some stress if they feel stigmatised by expressing an interest in and/or attending the workshops. Several methods have been employed in order to reduce potential stigma. Although the workshop intervention is provided by SLaM and comprises of CBT techniques targeting anxiety and depression, the workshops are entitled 'How to Handle Stress' in order to normalise the experience and the content of the workshop aims to normalise stress. Participants are reassured that what is said in the workshops is kept confidential. Teachers are advised on how to discuss the possibility of enrolling for the workshops with students sensitively. Finally, the open access approach, compared to a targeted approach also helps to avoid students feeling stigmatised, as it avoids only those being assessed as the most distressed being targeted.

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?
October 2014 to June 2016

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

Who is the main contact?
Dr June Brown

Contact information

Type(s)

Scientific

Contact name
Dr June Brown

ORCID ID
http://orcid.org/0000-0002-0479-8166

Contact details
King's College London
London Institute Of Psychiatry
16 De Crespigny Park
London
United Kingdom
SE5 8AF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17964

Study information

Scientific Title
Early Intervention for Depression and Anxiety in 16-18 year olds: a Feasibility Trial of Open-Access Psychological Workshops in Schools

Acronym
DISCOVER

Study objectives
The study aims to examine the feasibility of a cluster randomised clinical trial of open-access cognitive behavioural therapy (CBT) workshops for anxiety and depression for 16-18 year olds versus a waitlist control. The feasibility of such an RCT will be looked at with regards to the following primary and secondary objectives.

Primary objectives:
1. To recruit and randomise 10 schools
2. To assess student attendance rates at initial information meetings
3. To assess participant attendance rates at workshops
4. To assess follow-up rates at 3 and 6 months after intervention
5. To assess the proportion of missing data in each questionnaire (acceptability is less than 10%)

6. To obtain sample size calculations of a full trial using intraclass correlations and variance estimates for clinical outcomes to indicate it is feasible
7. To produce a trial protocol for a definitive trial (provided feasibility study is successful)

Secondary objectives:
1. To explore willingness of teachers to encourage students to enrol at information meetings
2. To explore suitable clinical outcome measures that are sensitive to change with this group
3. To explore acceptability of programme and use of quantitative and qualitative methods to stakeholders (teenagers, teachers)
4. To explore the feasibility of conducting a cost-effectiveness analysis alongside the phase 3 trial by assessing the suitability of data collection instruments and estimating preliminary intervention costs.
5. To assess the accessibility of the workshops by comparing the estimates of the number of students with problems of depression and anxiety eligible for this study with the number of those who do participate
6. To assess the accessibility of the workshops by examining the take-up by hard-to-engage groups such as BME groups and students who have not accessed CAMHS or school counselling
7. To refine the intervention content in light of participant feedback

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/LO/1416; First MREC approval date 18/09/2014

Study design
Randomised; Interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Anxiety, Depression; Disease: Depression, Anxiety

Interventions
A day long workshop titled 'How to Handle Stress'. Materials are organised into short sections and delivered over the course of six hours (with breaks). This includes introductions, ice breakers, an explanation of the CBT model, and the introduction and practice of CBT techniques. Particular attention is given to personal, relationship and academic stresses typical for the age

group. Behavioural methods include techniques such as problem-solving and time management. Cognitive methods include becoming aware of negative thoughts and learning to challenge unhelpful ones. Workshops will be run in a quiet room in schools and will be facilitated by two clinical psychologists and an assistant according to a detailed manual with a fidelity checklist. The workshops aim to provide the students who attend with the theory and strategies to help to build resilience to stress and build their capacity to resolve problems. After the workshop participants will be helped to set personal goals, which will be discussed and progress reviewed in a follow-up phone call with one of the workshop leaders, one week after the workshop.

Intervention Type
Behavioural

Primary outcome measure
The Mood and Feelings Questionnaire (MFQ; Costello & Angold, 1988).; Timepoint(s): T1 (baseline), T3 (3-month follow-up), T5 (6-month follow-up)

Secondary outcome measures
1. The Revised Child Anxiety and Depression Scale (RCADS; Chorpita et al 2000) is a 47-item self-report measure. The child version has been shown to have good construct validity, internal consistency, and test-re-test reliability (T1, T3, T5).
2. The Paediatric Quality of Life Enjoyment and Satisfaction Form (PQ-LES-Q; Endicott et al, 2006) is a 15-item self-report questionnaire. Items are scored on a 1-5 point likert scale. It has been found to have high internal consistency and test-retest reliability (T1, T3, T5).
3. The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS, Tennant et al., 2007) is a measure of mental wellbeing and consists of 14 positively worded items with five response categories. The scale was initially designed to assess mental wellbeing in adults, but a recent report from the WAVES Project, reported on its suitability with secondary school children aged 13 and over (T1, T3, T5).
4. Sociodemographic proforma: Information on date of birth, gender and ethnicity will also be obtained (T1 only).
5. The Client Service Receipt Inventory (CSRI, Beecham and Knapp 2001) is a self-report measure of service use. A short version covering a retrospective 3-month period will be specially developed and adapted for use with this group of students. Participants will be asked to provide information about contacts with general health services, mental health services, charities and education support as well as informal help received from carers and friends (T1 and T3).
6. The EQ-5D (The EuroQol Group 1990) is a self-report measure of health-related quality of life, on five dimensions (mobility, self-care, usual activities, pain / discomfort, anxiety / depression). In addition, participants are asked to rate their current health on a scale from 0-100 (worst to best). The instrument allows for the calculation of quality-adjusted life years (QALYs) (T1 and T3).

Timepoints: T1 (baseline), T3 (3-month follow-up), T5 (6-month follow-up).

Overall study start date
17/10/2014

Completion date
08/06/2016

Eligibility

Key inclusion criteria

Young people aged between 16 and 18, attending a recruited school or college in Southwark or Lambeth, who are fluent in English, are able to attend the workshops and would like psychological help for managing emotional difficulties.
Eligibility criteria:
1. Aged 16 – 18 years old
2. Attending a recruited school or college in Southwark or Lambeth
3. Fluent in English
4. Wanting psychological help for managing emotional difficulties
5. Able to attend the workshop

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 150; UK Sample Size: 150; Description: 120 – 150 (12 – 15 in each of the 10 schools). Five schools are randomly allocated to the experimental condition and five schools are randomly allocated to the control condition.

Total final enrolment
155

Key exclusion criteria
Young people who are identified as being at acute risk of harm to themselves or others, who have severe learning difficulties, are unable to complete the assessment and consent forms and are unable to attend the workshop information meetings.
Exclusion criteria
1. People identified as being at acute risk of harm to themselves or others
2. Severe learning difficulties
3. Unable to complete the assessment and consent forms
4. Unable to attend the workshop information meetings

Date of first enrolment
17/10/2014

Date of final enrolment
08/06/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London Institute Of Psychiatry
16 De Crespigny Park
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London

Sponsor details
Room 1.8
Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 4UL

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/03/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019		Yes	No
Protocol article		12/02/2016	09/02/2023	Yes	No
HRA research summary			28/06/2023	No	No