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Skills for adolescent wellbeing

Submission date
14/03/2023

Recruitment status
Recruiting

Registration date
15/03/2023

Overall study status
Ongoing

Last Edited
11/11/2025

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 study aims
Depression is common in young people. It is impairing and can have a long-term impact. Finding ways to prevent depression from developing in young people is important. Studies have found that a type of talking therapy - Cognitive Behavioural Therapy (CBT) - which involves learning skills like how to solve problems and how to think in a balanced, less negative way, can help to reduce depression in young people. This type of talking therapy may work particularly well for young people who have a higher-than-average chance of developing depression (e.g. for young people whose parent(s) have a history of depression, those who have experienced depression before themselves, or have mild depressive symptoms).
This study aims to test whether an online group CBT program helps to prevent depression in young people who are at increased risk of developing depression. It also aims to understand how the CBT program works, and what young people and their parents think of it. As there is evidence to suggest that the presence of depression in parents may reduce the effectiveness of CBT programs for depression in young people, this study will also involve optimizing the treatment of parents who are depressed at the start of the study.

Who can participate?
We are inviting young people aged 13-19 years old and their parents to take part. In order to take part we are asking that young people:
• have been diagnosed with depression before, OR currently have mild symptoms of depression (but are not depressed)
• live with a parent who has been diagnosed with depression recently or in the past, who is also willing to take part in the study
• have access to the internet and have a valid email address.

What does the study involve?
Parents and young people who are interested in taking part in the study will first complete screening questions with a researcher, including questions about depression symptoms, to check they are eligible to take part in the study.
For those that are eligible to take part, where the parent has high levels of depression symptoms at the screening stage, the parent will undergo a 12-week period of depression treatment optimization with a study psychiatrist. At the end of the treatment optimization, the parent and young person will be entered into the study. For those that are eligible to take part, where the parent does not have high levels of depression symptoms at the screening stage, the

parent and young person will be entered straight into the study.
On entering the study, baseline assessments (questionnaires and interviews) will be completed with parent and young person. Following these assessments the young person will be allocated randomly to receive either i) a group psychological intervention designed for the prevention of adolescent depression plus treatment as usual (TAU), OR ii) treatment as usual (TAU).
Young people allocated to the psychological intervention group will join an online group of 6-8 young people plus a facilitator. The group will meet via video call, for up to 1.5 hours per week over 8 weeks, followed by 3 continuation sessions held monthly. During online group sessions young people will learn new skills by taking part in group Cognitive Behavioural Therapy (CBT). Young people in this psychological intervention group will also be free to continue any existing treatment and begin new treatments outside the study, alongside the trial intervention.
Young people allocated to the treatment as usual group (TAU) will not receive the group psychological intervention, but they will be able to continue with any treatment that they already receive and will be free to begin new treatment outside the study.
All parents and all young people participating will be asked to complete questionnaires and meet with researchers to answer questions over a 9-month follow-up period. In addition to this, some parents who took part in the parent depression treatment optimisation, and some of the young people who took part in the psychological intervention group will be asked to talk to researchers separately about their experience of taking part.

What are the possible benefits and risks of participating?
Possible benefits: Research participants will have the chance to increase understanding of depression, and the ways to prevent it from developing in young people. This might help to improve the care of other young people in the future.
Young people and parents involved in the study may also directly benefit from taking part. The young people who are allocated to the group therapy intervention will be taught problem solving skills, how to cope with stress and how to reduce unrealistic negative thinking, with the aim of preventing them from developing depression in the future. Parents who are depressed at the screening stage of the trial will undergo treatment optimisation, with the aim of reducing their depression symptoms.
Possible risks: Some people may find it difficult to discuss certain things such as their mood and how they are feeling. For those who feel they need support whilst taking part in the study, our study team will be available for them to talk to and discuss whether it would be helpful to talk to someone else, such as their family doctor.

Where is the study run from?
Wolfson Centre for Young People's Mental Health at Cardiff University (UK)

When is the study starting and how long is it expected to run for?
March 2021 to May 2027

Who is funding the study?
The Wolfson Foundation (UK)

Who is the main contact?
Professor Frances Rice, Professor of Developmental Psychopathology, ricef2@cardiff.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Frances Rice

ORCID ID
https://orcid.org/0000-0002-9484-1729

Contact details
Hadyn Ellis Building
Maindy Road
Cardiff
United Kingdom
CF24 4HQ
+44 2920688384
ricef2@cardiff.ac.uk

Type(s)
Scientific

Contact name
Dr Olga Eyre

ORCID ID
https://orcid.org/0000-0003-1944-9679

Contact details
Hadyn Ellis Building
Maindy Road
Cardiff
United Kingdom
CF24 4HQ
+44 2920688452
eyreo2@cardiff.ac.uk

Type(s)
Scientific

Contact name
Dr Victoria Powell

Contact details
Hadyn Ellis Building
Maindy Road
Cardiff
United Kingdom
CF24 4HQ
+44 29 2068 8452
powellv@cardiff.ac.uk

Type(s)
Public

Contact name
Mr Rhys Williams-Thomas

Contact details
Centre for Trials Research
Cardiff University
Cardiff
United Kingdom
CF14 4YS
-
ThomasR95@cardiff.ac.uk

Type(s)
Scientific

Contact name
Dr Jac Airdrie

Contact details
Centre for Trials Research
Cardiff University
Cardiff
United Kingdom
CF14 4YS
-
AirdrieJ@Cardiff.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
305331

Protocol/serial number
SPON1902-22

Central Portfolio Management System (CPMS)
54480

Study information

Scientific Title
A randomised controlled trial of a group Cognitive Behavioural Therapy intervention for young people with parental treatment optimisation: skills for adolescent WELLbeing (SWELL)

Acronym
SWELL

Study objectives
Current study hypothesis as of 22/08/2024:

The group CBT intervention evaluated in this trial will increase the time to depressive disorder in young people aged 13-19 years who are at increased risk for developing depression compared to treatment as usual.
The group CBT intervention will reduce symptoms of mental health problems, depression risk score and time to recovery from depressive episodes, improve functioning and quality of life and increase the number of depression free days, length of wellness intervals and time to depression recurrence more than treatment as usual.

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Previous study hypothesis:

The group CBT intervention evaluated in this trial will increase the time to depressive disorder in young people aged 13-17 years who are at increased risk for developing depression compared to treatment as usual.
The group CBT intervention will reduce symptoms of mental health problems, depression risk score and time to recovery from depressive episodes, improve functioning and quality of life and increase the number of depression free days, length of wellness intervals and time to depression recurrence more than treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/09/2022, Wales REC 5 (Health and Care Research Wales Support Centre, Bangor, CF11 9AB, UK; +44 2922 941106; Wales.REC5@Wales.nhs.uk), ref: 22/WA/0254

Study design
Randomized controlled effectiveness trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of depression in young people at increased risk for depression

Interventions
Current interventions as of 22/08/2024:

Following parental depression treatment optimization for all parents who are depressed at the recruitment/screening stage of the study, and following baseline assessments, young people will be allocated randomly to either receive
1. Intervention plus treatment as usual (TAU), OR
2. TAU.

Young people will be randomised 1:1 via simple permuted block randomisation and the unit of randomisation will be the young person.

Each young person randomised to the intervention plus TAU arm will be assigned to an online therapy group (maximum size: 8 young people) and will receive the psychological intervention. The intervention consists of group therapy sessions delivered in two phases – the acute and continuation phase.

The acute phase consists of eight up to 90-minute sessions delivered online by a trained therapist once a week. The acute phase is followed by 3 continuation sessions, which are held monthly.

The online sessions start by giving an overview of depression and its relationship to stressful situations. They then focus on training young people in cognitive-restructuring skills and in modifying irrational or negative thoughts, as these are hypothesised to contribute to the development and maintenance of depressive disorder. Sessions will also cover problem solving strategies, behavioural activation, relaxation, and assertiveness training. Young people in the intervention group will also be free to continue any existing treatment and begin new treatments outside the study, alongside the trial intervention.

Young people in the TAU arm will not receive the psychological intervention, though they will be able to continue with any treatment that they already receive and will be free to begin new treatment outside the study.

All participants in both the intervention + TAU and the TAU arms will be followed up for 9 months via questionnaires and interviews.

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All participants in both the intervention + TAU and the TAU arms will be followed up for 9 months via questionnaires and interviews.

Intervention Type
Behavioural

Primary outcome(s)
Time to a DSM-5 major depressive episode occurring in the young person during the 9 month follow up period (measured using the young person and parent rated Longitudinal Interview Follow-up Evaluation (LIFE) at 9 months)

Key secondary outcome(s))
1. Number of depression free weeks, length of wellness intervals, time to recovery from depressive episodes and time to recurrence of depressive episodes in the 9-month follow up period assessed with the LIFE
2. Depressive symptoms assessed with the CES-D at 9 months
3. Anxiety symptoms assessed using the Revised Children's Anxiety and Depression scale (RCADS) at 9 months
4. Irritability symptoms assessed using the Affective Reactivity Index (ARI) at 9 months
5. Quality of life assessed using EQ-5D-Y at 9 months
6. Developmental competence assessed using Developmental Competence Scale at 9 months
7. Functional impairment and mental health related impairment assessed using Children's Global assessment Scale (cGAS) at 9 months
8. Individual depression risk score (an individual risk algorithm developed at Cardiff University which assesses 3 year risk of depression)
9. Service use and treatment assessed with the CSRI.

Data on potential mediators will also be collected at baseline, 3 month and 9 month follow-up:
10. Negative self-beliefs assessed with the DAS-C
11. Self-efficacy and problem solving assessed with the GSE
12. Perceived stress assessed with the PSS
13. Behavioural activation assessed with the BADS-SF
14. Interpersonal relationships assessed with the CBQ, CRPBI, and the child disclosure subscale from the parent monitoring measure

Completion date
31/05/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 22/08/2024:

1. Adolescents aged 13-19 years at study entry
2. Experiencing subthreshold depressive symptoms (CES-D score >=16) , and/or has a history of depression according to DSM-5.

3. Living with a parent (biological or non-biological) who has a history of recurrent unipolar depression (at least 1 previous episodes) who is willing and able to engage with a depression treatment plan
4. Both young person and parent have access to the internet via a desktop/laptop/phone/tablet and have a valid email address or mobile phone number
5. Both young person and parent have the ability to complete trial activities as specified in the protocol, e.g., sufficient understanding of English language, absence of learning disability that would impair ability to participate, and for the young person, ability to participate in small group therapy sessions

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Previous inclusion criteria:

1. Adolescents aged 13-17 years at study entry
2. Experiencing subthreshold depressive symptoms (CES-D score >=20) , and/or has a history of depression according to DSM-5.
3. Living with a parent (biological or non-biological) who has a history of recurrent unipolar depression (at least 2 previous episodes) who is willing and able to engage with a depression treatment plan
4. Both young person and parent have access to the internet via a desktop/laptop/phone/tablet and have a valid email address or mobile phone number
5. Both young person and parent have the ability to complete trial activities as specified in the protocol, e.g., sufficient understanding of English language, absence of learning disability that would impair ability to participate, and for the young person, ability to participate in small group therapy sessions

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
13 years

Upper age limit
19 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 22/08/2024:

1. Young person already receiving specialist treatment for depression (e.g. currently on antidepressants, or is currently receiving cognitive behavioural therapy (CBT))
2. Young person has a current diagnosis of depression as given by a doctor or healthcare professional
3. Young person has been told by a doctor or healthcare professional that they have a primary diagnosis of bipolar disorder, schizophrenia, eating disorder or alcohol/drug dependence or have generalized learning difficulties, that the parent judges would prevent them from participating in trial activities
4. Parent has been told by a doctor or healthcare professional that they have a diagnosis of bipolar disorder, schizophrenia or personality disorder
5. Parent is receiving treatment from secondary mental health services (e.g. community mental health team or psychiatrist)
6. Parent or young person are not resident in the UK

Previous exclusion criteria as of 01/03/2024:

1. Young person already receiving specialist treatment for depression (e.g. currently on antidepressants, or has received a full course of cognitive behavioural therapy (CBT) previously)
2. Young person is experiencing a current depression episode at baseline that meets DSM-5 diagnostic criteria (i.e. five or more symptoms including either depressed mood/irritable mood and loss of interest that are present during the same 2-week period and represent a change from previous functioning)
3. Young person has been told by a doctor or healthcare professional that they have a primary diagnosis of bipolar disorder, schizophrenia, eating disorder or alcohol/drug dependence or have generalized learning difficulties, that the parent judges would prevent them from participating in trial activities
4. Parent has been told by a doctor or healthcare professional that they have a diagnosis of bipolar disorder, schizophrenia or personality disorder
5. Parent is receiving treatment from secondary mental health services (e.g. community mental health team or psychiatrist)
6. Parent or young person are not resident in the UK

Previous exclusion criteria:

1. Young person already receiving specialist treatment for depression (e.g. currently on antidepressants, or has received a full course of cognitive behavioural therapy (CBT) previously)
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3. Young person has been told by a doctor or healthcare professional that they have a primary diagnosis of bipolar disorder, schizophrenia, eating disorder or alcohol/drug dependence or have generalized learning difficulties, that the parent judges would prevent them from participating in trial activities
4. Parent has been told by a doctor or healthcare professional that they have a diagnosis of bipolar disorder, schizophrenia, personality disorder or post-traumatic stress disorder

5. Parent is receiving treatment from secondary mental health services (e.g. community mental health team or psychiatrist)
6. Parent or young person are not resident in the UK

Date of first enrolment
21/08/2023

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Wolfson Centre for Young People's Mental Health
Hadyn Ellis Building
Maindy Road
Cardiff
Wales
CF24 4HQ

Study participating centre
Cardiff & Vale University Health Board
Cardigan House
University Hospital of Wales
Heath Park
Cardiff
Wales
CF14 4XW

Study participating centre
Cwm Taf Morgannwg University Health Board
Ynyfmeurig House
Unit 3
Navigation Park

Mountain Ash
Wales
CF45 4SN

Study participating centre
Aneurin Bevan University Lhb, Headquarters - St Cadoc's Hospital, Lodge Road, Caerleon, Newport, Gwent, NP18 3XQ
Headquarters - St Cadoc's Hospital
Lodge Road
Caerleon
Newport
Wales
NP18 3XQ

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Wolfson Foundation

Alternative Name(s)
The Wolfson Foundation, wolfsonfdn

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Current IPD sharing plan as of 05/06/2025:
All trial participants (parents and young people) will be asked for consent for confidential data sharing with other researchers (for young people aged under 16 years this is parental consent and young person assent). Identification numbers will be used to ensure participant data remains de-identified. We will store data and metadata on Cardiff University's curated repository. Currently, this is the Research Portal curated data catalogue (which assigns DOI numbers to datasets), but there are plans to update this to Figshare for Institutions. We will use the appropriate method to share following the publication of the main trial results. A data access committee is not required and the process will be managed by data repository staff with support from the study PI and trial management group. Data access statements will be included in publications and on the study website explaining where data can be accessed and providing the DOI.

Previous IPD sharing plan:
The datasets generated are not expected to be made publicly available. However, the data or information generated as part of this trial may be shared with other researchers in the UK or abroad in the future. The data will not identify the participant by name (pseudoanonymised data), and any future research using this data will be in the interest of public health and care.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/06/2025	20/06/2025	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 5.8	05/03/2025	25/03/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes