ISRCTN66452702 https://doi.org/10.1186/ISRCTN66452702

Evaluating an exercise intervention to treat depression in young people

Submission date
27/03/2020

Recruitment status
No longer recruiting

Registration date
09/04/2020

Overall study status
Completed

Last Edited
24/06/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression in young people is a serious problem that can lead to lifelong poor mental health and stigma. Depression is reported in around 20% of under 18s, and over half continue to be depressed into adulthood. Problems include difficulties at home and school, maintaining friendships and taking part in social activities, including exercise. Young people with depression often delay seeking psychological support. Antidepressants can help, but they have negative side effects. Research shows that adults with depression benefit from exercise, but it is not known whether exercise is helpful for young people who are depressed. The aim of this study is to find out whether exercise is an effective treatment for young people with depression and whether it is good value for money for the NHS.

Who can participate?
Young people, aged 13-17, diagnosed with depression, from Child & Adolescent Mental Health Services (CAMHS) and GP practices.

What does the study involve?
The young people will continue to receive their usual health care and will be allocated randomly to one of three groups:
1. High-intensity exercise, through vigorous activities (e.g. football, dance)
2. Low-intensity exercise, through moderate activities (e.g. walking football/netball)
3. A control group of social non-exercise based activities (playing games, watching films)
Participants will attend two 60-minute sessions per week for 12 weeks. All groups will receive behaviour change education and support. Sessions will be delivered by Registered Exercise Professionals (REPs) supported by Mental Health Support Workers (MHSWs) at local sports and community centres. Researchers will collect information from participants at the start, and at 14 and 26 weeks. This will include questionnaires on depression, quality of life, self-esteem, service use, session attendance and changes in physical activity. The researchers will ask some participants, parents/carers, REPs and MHSWs about their experience in the study.

What are the possible benefits and risks of participating?
Taking part in the groups may lead to an improvement in low mood or depression. It is hoped that the information from this phase of the study will help to determine if a larger trial is

possible. In the long-term, this might show that the READY exercise groups are helpful for young people with depression. This may mean that young people can be offered an exercise group as an alternative to drug treatment or talk therapy for treating depression. It's difficult for some people to discuss personal things. If participants get upset whilst taking part, the researchers will stay with them until they feel better and make sure they know where to go for support if they need it. The exercises are safe for most young people, but they should not take part if they have been told by a doctor not to exercise. With any exercise programme there is a small risk of minor injuries e.g. pulled muscles or sprains. More serious injuries that can be associated with exercising e.g. fractures or ligament damage, are very rare.

Where is the study run from?
The study is sponsored by the University of Hertfordshire and will be run at three sites in Norfolk, Hertfordshire and Bedfordshire in collaboration with Active Sports Partnerships (UK)

When is the study starting and how long is it expected to run for?
June 2016 to August 2022

Who is funding the study?
NIHR Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?
1. Dr Daksha Trivedi
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2. Dr David Wellsted
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Study website
https://readytrial.co.uk/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
276093

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 44795, IRAS 276093

Study information

Scientific Title
The clinical and cost-effectiveness of an exercise intervention for depression in adolescents: a phased, multi-site randomised controlled trial

Acronym
READY

Study objectives
The aim of this feasibility study is to ascertain whether a full-scale definitive study is feasible.
The objectives are to:
1. Finalise the development of the intervention and control, including the Education Component (with Behaviour Change Techniques)
2. Finalise the development of intervention training programmes for staff
3. Examine the feasibility of delivering the intervention across three sites (Hertfordshire, Norfolk and Bedfordshire)
4. Establish the potential adherence and engagement to the intervention by young people
5. Establish potential reach and representativeness
6. Examine the feasibility of delivering a randomised trial at scale
The findings will be used to refine the intervention and study delivery for a full-scale trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/04/2020, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)20 7104 8096; cambsandherts.rec@hra.nhs.uk), REC ref: 20/EE/0047

Study design
Randomised; Both; Design type: Treatment, Psychological & Behavioural, Qualitative

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 the contact details to request a patient information sheet

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

Interventions
The young people will continue to receive their usual health care. Those suitable for exercise will be allocated randomly to one of three groups:
1. High-intensity exercise, through vigorous activities (e.g. football, dance)

2. Low-intensity exercise, through moderate activities (e.g. walking football/netball)
3. A control of social non-exercise based activities (playing games, watching films)

Participants will attend two 60-minute sessions per week for 12 weeks. All groups will receive behaviour change education and support. Sessions will be delivered by Registered Exercise Professionals (REPs) supported by Mental Health Support Workers (MHSWs) at local sports and community centres. Researchers will collect information from participants at the start, and at 14 and 26 weeks. This will include questionnaires on depression, quality of life, self-esteem, service use, session attendance and changes in physical activity. We will ask some participants, parents /carers, REPs and MHSWs about their experience in the study.

Intervention Type
Behavioural

Primary outcome measure
As a feasibility study, there is no primary outcome. For the future main trial, the primary outcome will be depression measured using the Child Depression Inventory (2nd Edition) score, most likely at 4 months from baseline. For the feasibility study, the outcomes are listed as follows:
1. Referral rate recorded as the number of people referred for screening via any route by the end of recruitment
2. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by the end of recruitment
3. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of follow-up at 26 weeks post randomisation
4. Attendance rate at the intervention sessions as a proportion of the total number of sessions by 12 weeks
5. Heart rate as measured using a heart rate monitor at each exercise session up to 12 weeks
6. Physical activity measured using an accelerometer as proportion of time active at baseline, 14 weeks and 26 weeks post randomisation
7. Adherence to the intervention protocol as captured by the intervention logs and rated against the adherence checklist by members of the study team at weekly intervention sessions up to 12 weeks and at 14 and 26 weeks post randomisation
8. Proportion of missing data will be reported as the percentage of recorded outcomes against those expected after account for withdrawal for each outcome separately at the end of follow-up at 26 weeks post randomisation
9. Adverse event rate recorded as the frequency, type (injury or clinical progression of depression) and severity of event by treatment arm at the end of follow-up at 26 weeks post randomisation
10. Estimate of resource use as measured through observation and study-specific questionnaire at the end of the follow-up at 26 weeks post randomisation
11. Reach and representativeness measured by the proportions of patients who are screened for participation and are randomised in comparison to the characteristics of local populations by the end of recruitment

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/06/2016

Completion date
24/08/2022

Eligibility

Key inclusion criteria
In order to be as inclusive as possible, any young person meeting the inclusion criteria for low mood or depression should be considered for the study. Low mood or depression does not need to be the primary diagnosis and comorbid conditions that do not preclude exercise should not be a barrier to inclusion.

1. Help-seeking adolescents aged 13-17 years with a CDI 2 score between 17 and 36, inclusive (mild to moderate symptoms)
2. Current treatment with antidepressants or other drug, or psychological therapy is allowed
3. Young person understands their role in the trial and is able to complete trial activities
4. Young person consent to participate, with consent from parent/carer for under 16s and consent of parent/carer to provide data
5. Parent/carer/guardian also taking part in the study
6. Young person and parent/carer is able to complete the questionnaires in English
7. Young person able to get to the site where the intervention will be held

Participant type(s)
Patient

Age group
Child

Lower age limit
13 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
Planned Sample Size: 81; UK Sample Size: 81

Total final enrolment
15

Key exclusion criteria
1. Considered unsuitable by the clinician screening for eligibility
2. Current treatment, or co-morbid conditions present contraindications to engaging in RCT or exercise
3. Active psychosis, significant substance abuse, self-harm, or suicidal ideation presenting significant risk (assessed as part of the DAWBA)

Date of first enrolment

06/10/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Norfolk and Suffolk NHS Foundation Trust
Hellesdon Hospital
Drayton High Road
Norwich
United Kingdom
NR6 5BE

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
99 Waverley Road
St Albans
United Kingdom
AL3 5TL

Study participating centre
NIHR CRN: Eastern
-
United Kingdom
NR1 1QQ

Study participating centre
NIHR CRN: North Thames
-
United Kingdom
W1T 7HA

Study participating centre

East London NHS Foundation Trust
CAMHS Dunstable
Beech Close Resource Centre
Beech Close
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United Kingdom
LU6 3SD

Sponsor information

Organisation
University of Hertfordshire

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Sponsor type
University/education

Website
http://www.herts.ac.uk/

ROR
https://ror.org/0267vjk41

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 17/78/10

Results and Publications

Publication and dissemination plan
The main study findings will be published in a peer-reviewed, open-access journal within one year of the end of the trial.

Intention to publish date
31/10/2023

Individual participant data (IPD) sharing plan
Anonymised data (CSV file format) will be stored in the University of Hertfordshire Research Archive which is publicly available. The data will be available at the end of the study as defined in the protocol. Consent will have been obtained for data purposes. There are no ethical or legal restrictions. Requests for access to the data can be emailed to the scientific contacts.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1.0	16/01/2020	09/04/2020	No	No
Protocol file	version 3.0	27/05/2021	02/12/2022	No	No
Statistical Analysis Plan	version 1.0	12/07/2022	05/12/2022	No	No
HRA research summary			28/06/2023	No	No
Basic results			17/10/2023	No	No
Protocol article		04/01/2021	24/06/2025	Yes	No