

Home Goals: A study looking at improving mental and physical health and well-being in young people using short physical activity and psychological education sessions

Submission date 24/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/07/2021	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/03/2025	Condition category Mental and Behavioural Disorders	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Mental health problems are common in adolescents. For the treatment of depressive symptoms, existing literature reports the benefits of psychoeducation-based interventions.

The WHO (2018) recommends that young people engage in at least one hour of moderate physical activity a day. Vigorous physical activity has been shown to be a protective factor against mental health problems in adolescents. Physical activity has a huge potential to enhance our wellbeing. Even a short burst of 10 minutes' brisk walking increases our mental alertness, energy and positive mood.

The combination of physical activity and psychoeducation in treatment of stress and depressive symptoms has shown to be superior than merely exercise alone.

The project aims to create therapy groups for children to improve their mental and emotional wellbeing. Each therapy group runs for one hour after school for six weeks, one half an hour focussing on physical activity (led by a local sports club) and another half an hour focusing on psychoeducation, led by NHS staff (e.g mental health nurse, psychiatrist, psychologist, Psychological Well-being Practitioners). The physical health aspect of the groups encompasses a broad range of physical activities, adapted to try at home. The groups also enable young people to learn about how and why anxiety and depression occur, and how we can learn ways of managing them.

This project is especially crucial given the nature of the COVID-19 pandemic, and ensuring the safety of staff and patients, by allowing the delivery of the interventions over video-conferencing software.

Who can participate?

School children aged 11-18 years who attend a participating school who are at risk of or are suffering from low-level mental health problems.

What does the study involve?

Participants will take part in one of the two 6-week interventions, depending on their group

assignment. The intervention is the same for both groups but undertaken at different time points. Each therapy group runs for one hour after school for 6 weeks, one half an hour focussing on physical activity (led by a local sports club) and another half an hour focusing on psychoeducation, led by NHS staff (e.g., mental health nurse, psychiatrist, psychologist, psychological well-being practitioners). The physical health aspect of the groups encompasses a broad range of physical activities, adapted to try at home. The groups also enable young people to learn about how and why anxiety and depression occur, and how we can learn ways of managing them. This project is especially crucial given the nature of the COVID-19 pandemic, and ensuring the safety of staff and patients, by allowing the delivery of the interventions over video-conferencing software.

What are the possible benefits and risks of participating?

Participants should increase their understanding of negative emotions and why we experience them, and that it is normal to do so. They will then be given tools to help them deal with the negative impact of these emotions. They will be given the opportunity to try out new physical activities which also provides benefits to their physical and mental health. This may also encourage them to continue with physical activity, leading to long-term benefits. Some participants may experience unexpected discomfort during the physical exercise, at which point they will be encouraged to stop. They can withdraw from the study at any time. There is a small chance that children may become distressed during the psychoeducation section, at which time they can leave the session, and they will be signposted on to services that can help them using a support services leaflet. There will be two presents during the session, so if necessary one presenter can speak privately to the distressed participant. Confidentiality will be broken if the participant discloses self-harm or suicidal ideation.

Where is the study run from?

Rotherham Doncaster and South Humber NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

September 2020 to January 2023

Who is funding the study?

1. Active Humber (UK)
2. Yorkshire Sport Foundation (UK)

Who is the main contact?

Dr Victoria Laker

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Contact information

Type(s)

Scientific

Contact name

Dr Victoria Laker

Contact details

Research Governance Manager

Grounded Research Hub

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

HG01 RDaSH 0243

Study information

Scientific Title

Home Goals: a randomised controlled trial to improve mental and physical health and well-being in young people

Acronym

Home Goals

Study objectives

1. Exposure to the intervention will be associated with a significantly lower mean score of depression and anxiety by comparison to a waitlist (delayed intervention) control group
2. After the control group is exposed to the intervention, there will be no significant differences in mean depression and anxiety level between the two groups (immediate intervention group, delayed intervention group)
3. Mean depression and anxiety severity for all participants at the end of the 6-month follow-up period will be significantly lower than baseline severity (prior to intervention), but not significantly different to end-of-treatment severity, indicating maintenance of gains
4. Attitude towards physical exercise will significantly improve following the intervention, and be maintained at the 6-month follow-up period

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/05/2021, South West - Frenchay Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, UK; frenchay.rec@hra.nhs.uk), REC ref: 21/SW/0046

Study design

Pragmatic stepped-wedge open-label randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Mental health

Interventions

Consenting participants will be randomly assigned to two groups by a research assistant using a computerized randomization algorithm (applying a simple 1:1 randomization schedule). Participants will take part in one of the two 6-week interventions, depending on their group assignment.

The intervention is a 6-week, psychoeducation and physical education course consisting of online live psychoeducation sessions and physical activity sessions. The intervention is the same for both groups but undertaken at different time points. The interventions will be delivered using an online approach; weekly online video-conference sessions involving half an hour of psychoeducation and half an hour of physical activity. Both interventions will involve a total of six 1-hour sessions delivered once per week using video-conferencing software that can involve large groups of participants. The study will be carried out in four phases.

Participants will complete an online survey with standardised measures at baseline (prior to starting the interventions), after 6 weeks (after group 1 has finished and prior to group 2 commencing), after 12 weeks (post-treatment) and finally after 6 months (follow-up). All measures will be completed online using an industry-standard survey system that automatically sends email reminders to consenting participants.

Intervention Type

Behavioural

Primary outcome measure

Depression is measured using the Patient Health Questionnaire-adapted for Adolescents (PHQ-A) at baseline, six weeks, 12 weeks and six months after completion of the interventions

Secondary outcome measures

1. Demographic information, including age, gender, ethnicity measured by self-report
2. Anxiety is measured using the Generalized Anxiety Disorder-adapted for Adolescents (GAD-A)

at baseline, six weeks, 12 weeks and six months after completion of the interventions
3. Physical activity is measured using the physical activity section of the Health Behaviour in School-Aged Children (HBSC) at baseline, six weeks, 12 weeks and six months after completion of the interventions

Overall study start date

01/09/2020

Completion date

23/01/2023

Eligibility

Key inclusion criteria

1. Any child aged 11-17 years (the researchers will accept participants who turn 18 in the trial period) who may benefit
2. Children must attend a school within the Rotherham, Doncaster, North Lincolnshire or Bradford locality

Participant type(s)

Other

Age group

Child

Lower age limit

11 Years

Upper age limit

17 Years

Sex

Both

Target number of participants

192

Total final enrolment

57

Key exclusion criteria

1. Adolescents who are already in receipt of psychological therapy
2. Adolescents with a diagnosed condition (such as autism spectrum disorder, learning disabilities, severe depression)
3. Adolescents experiencing suicidal ideation
4. Adolescents with no access to electronic devices
5. Anyone who has participated in either Home Goals or Safety Nets before
6. Anyone who is 18 years old at the time of recruiting (the researchers will accept if they turn 18 over the trial period – but not before the trial starts)

Date of first enrolment

08/06/2021

Date of final enrolment

31/03/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Grounded Research**

Rotherham Doncaster and South Humber NHS Foundation Trust

2 St. Catherine's Close

Tickhill Rd Site

Balby

Doncaster

United Kingdom

DN4 8QP

Study participating centre**Bradford District Care NHS Foundation Trust**

New Mill

Victoria Rd

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Shipley

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Sponsor information

Organisation

Rotherham Doncaster and South Humber NHS Foundation Trust

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.rdash.nhs.uk/>

Funder(s)

Funder type

Charity

Funder Name

Active Humber

Funder Name

Yorkshire Sport Foundation

Results and Publications

Publication and dissemination plan

After the conclusion of data analysis, we plan to disseminate findings about this study using a variety of forms of communication, including:

1. Scientific journal publications
2. Newsletter in lay terminology
3. NHS Trust communications newsletter and email
4. NHS Trust conferences, strategic meetings
5. Mental health conferences in the UK and abroad

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request - victoria.laker@nhs.net. We do not wish to make

the dataset readily available due to the age of the participants. The dataset will be held in a restricted-access drive. The study dataset will be held at the University for a minimum of 5 years after the conclusion of the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2.1	23/04/2021	14/07/2021	No	Yes
Participant information sheet	version v1.1	23/04/2021	14/07/2021	No	Yes
Protocol file	version v2.1	23/04/2021	14/07/2021	No	No
HRA research summary			28/06/2023	No	No
Basic results			03/03/2025	No	No
Statistical Analysis Plan			03/03/2025	No	No
Dataset			07/03/2025	No	No