

Participant information sheet

[sample of electronic information sheet content]

Home Goals

We would like to invite you to take part in our research study. Before you decide whether you would like to join in, it is really important that you understand what the study is about, why the study is being done and what it would involve for you. So please read and think about this information carefully. Also talk to your family, friends, teachers or nurses about it if you want to. You can ask us for more information at any point.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

If something isn't clear or you have more questions you can ask your parents/guardians to contact us and we can discuss it with you and your parents/guardians. Thank you for reading this.

Part 1:

Why are we doing this research?

We know that mental health problems, such as depression and anxiety are common among young people, and this has been made even worse by COVID-19. We also know that young people are encouraged to engage in at least one hour of physical activity a day, and this has been shown to improve our mood and feelings of anxiety. However, it is very hard to complete physical activity at the moment because we are all at home, and PE classes are easily missed. We wanted to create groups for young people to be able to access information on common mental health problems, why they occur and how they can be reduced, and at the same time introduce simple physical activity which will be run by a professional from a local sports team (such as Scunthorpe United and Bradford City). All of this will be done online, and you will be asked not to have your camera on so no one can see you. This also means you don't have to travel anywhere to access the material.

Who can take part?

Anyone aged 11-17 (we will accept you if you turn 18 in the trial period, but not before the trial starts) who may benefit from low level intervention can take part.

You cannot take part if you:

- Are already receiving psychological therapy (such as counselling, or you are seeing a psychologist, or psychiatrist)
- Are diagnosed with a condition (such as Autism Spectrum Disorder, learning disabilities, severe depression)
- Are experiencing thoughts of killing yourself
- Have no access to electronic devices
- Are 18 at the time of recruiting
- Have taken part in Home Goals or Safety Nets before

Why have I been invited to take part?

You have been invited because one of your teachers, school nurses, a professional at CAMHS, or your parents or guardians thought you may find it helpful to go to these groups, or you may even have thought it would be good to take part.

Do I have to take part?

No, you don't. It is your choice whether you want to take part and you can always change your mind at any time, without having to tell us why.

What will happen to me if I take part?

IRAS:

You will be asked via email to complete a short electronic questionnaire which will ask you about your age, gender, which school you go to, and other things about you. You will then be asked about your mood, your anxiety, and finally how often you exercise. After you complete these questionnaires, you will be sent instructions via email to tell you how to log onto your online sessions, what day and what time you need to log on. You will also be sent a group number and a code that you use instead of your name so no one knows who you are when you log on to the session online (via video-conferencing software such as Microsoft Teams, or Zoom). This study is known as 'stepped wedge', this means that there will be two groups that attend the group sessions. Both will receive exactly the same information, but one group will start as soon as recruitment has finished, and the other will start after the first group finishes. There is no advantage to being in either group. If you are in group 1 you will start your online sessions straight away, for 6 weeks. If you are in group 2, you will start your online sessions after group 1 have finished, so you will wait for 6 weeks. For your 6 weeks, you will log on for 1 hour once a week. During these sessions you will be taught about common negative feelings, why we feel like we do, and how we can control them. We will also have a period of physical activity which will be taken by a member of your local sports club (Scunthorpe United or Bradford City FC). You will be asked to complete the questionnaires about your mood, anxiety and physical activity after the first group has finished, after the second group have finished, and also 6 months later.

Will taking part in the study help me?

We hope it will yes. You will start to understand why we feel sad and anxious, and that it's normal to feel these sometimes. You will also learn ways to control these feelings, whether that be mentally, or physically, through exercise or breathing techniques. Of course, we cannot guarantee these feelings will improve, the reason for the study is to test the material and physical activity to see whether it does reduce sad feelings and anxiety.

What do I do if I don't want to take part anymore?

Just tell your parents, guardian, or the people carrying out the research that you don't want to take part anymore. You don't have to give any reason. It is your choice.

Who should I ask if I have further questions?

If you have any questions, please talk to your parents/guardians first. You can also contact the research team in Doncaster: Dr Vikki Laker by telephone on 07970 049942 or email rdash.groundedresearch@nhs.net.

Thank you for reading so far, if you are still interested please carry on reading below.

Part 2:

What happens when the research project stops?

We will collect all the information together and the result of the study will be written up so that people can read about it but they won't know that you are in the study.

Will information collected in the study be kept confidential?

All the information collected from participants will be entirely anonymised. This means that no one will know that the data we collect belongs to you. To complete the first questionnaire we will ask for your email address. This is to ensure we are able to contact you during the study (e.g., sending email reminders). Once you have completed the consent form we will email you a code, which cannot identify you. You will then use this code to identify yourself throughout the rest of the study (i.e., to log in to the online sessions, and to complete the final set of questionnaires), so that your data is completely anonymous. The Research team will keep a record of your email address and associated code, so if you forget your code you can contact us to confirm it. Your email address will be used to invite you to the online sessions. Your email address will then be deleted when the study has completed.

If we become worried that you may harm yourself or others, or if you tell us that you or someone else is being abused, we will have to break our confidentiality agreement. We will tell you we are going to do this, and we will still do it even if you do not agree, but we would like to get your consent first. Confidentiality will be broken by either referral to your GP or by calling 999 depending on how serious and urgent we feel your needs are. Your parent/guardians will also be informed if it is appropriate to do so.

Who is organising and funding the project?

This study is led by cooperation between Rotherham Doncaster and South Humber NHS Foundation Trust, the University of Sheffield. The study is being paid for by Rotherham Doncaster and South Humber NHS Foundation Trust and the charities: Yorkshire Sport and Active Humber.

Monetary incentives for participation

Participants will be entered into a prize draw to win a £20 and a £50 Amazon voucher.

To be included in the prize draw for the £20 Amazon voucher you need to attend at least four of the online groups, and have completed the three online questionnaires up to the end of the intervention (i.e., at the beginning, after group 1 has finished and after group 2 has finished).

To be included in the prize draw for the £50 Amazon voucher you need to attend at least four of online groups, and have completed all four online questionnaires phases (i.e., at the beginning, after group 1 has finished, after group 2 has finished and six months later).

To fit with the University of Sheffield's policy for the ethical use of incentives in research, the prize winners will receive their electronic voucher code via email and you will be asked to return a signed receipt via email, which includes your name and email address. We have to do this to make sure we follow the rules of the University of Sheffield. The prize winner's names and email addresses will be saved in a secure University network drive, which can only be seen by members of the research team. Your contact details will be kept at the University for 12 months after the groups have finished.

Does the study have ethical approval?

Before any research goes ahead, it has to be checked by a group of people called a Research Ethics Committee. They make sure the research is fair. This study has received ethical approval by The Review Ethics Committee was: South West - Frenchay Research Ethics Committee and was approved by the NHS Health Research Authority.

What if something goes wrong?

If there is a problem you should talk to your parents or guardians first, or any of the researchers.

Contact details for enquiries

Email: rdash.groundedresearch@nhs.net

IRAS:

Chief investigator: Dr Victoria Laker (Victoria.laker@nhs.net)
Grounded Research Team, Almond Tree Court, Tickhill Road Hospital, Balby, Doncaster, DN4 8QP

To participate please complete the electronic consent form using the following link:
[web-link]

Thank you for taking the time to consider participating in this study.