Participant information sheet - Parents

[sample of electronic information sheet content]

Home Goals

We would like to invite your child/a child you care for, to take part in our research study. Before you decide we would like you to understand why the research is being done and what it will involve.

Please feel free to talk to others about the study, and you can ask us for more information at any point.

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

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

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you want your child to take part.

Part 1 – to give you first thoughts about the project

What is the purpose of the study?

Mental health problems in adolescents are common, and specialist services such as the Child and Adolescent Mental Health Services (CAMHS) services have been established to address this issue. Demand for CAMHS services are at an all-time high and referrals have increased by over a quarter in five years. Another issue is that, once children and young people have been assessed, half will wait more than 18 weeks to start treatment and over 3% wait over 12 months. This is especially true thanks to the COVID-19 pandemic which has added extra stress and strain to our child and adolescent population.

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 people's 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).

This project aims to create groups for adolescents to improve their mental and emotional wellbeing, without a referral into CAMHS, and therefore the long wait for treatment.

Who can take part?

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

They cannot take part if they:

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

Why has my child been chosen?
They have been invited because someone thought they may benefit from the sessions, or someone your child knows, or your child themselves may even have thought it would be good for them to take part. Other people who may think they would benefit from these sessions include, their teachers, school nurses, or a professional from the CAMHS team.

Do they have to take part?
No. It is up to you and your child (wherever possible) to decide to join the study. Participation is voluntary. If you agree to take part, we will then ask you to complete a consent form. If your child is able to understand the research and is happy to take part, they will be asked to complete a consent form if they want to. Your child can withdraw from the study at any time without any negative consequences, and they do not have to give a reason. If they wish to withdraw from the research, please use the contact details at the end of this form.

What will happen to my child if we agree take part?
Your child will be asked via email to complete a short electronic questionnaire which will ask them about their age, gender, which school they go to, and other demographic information which is relevant to the study. They will then be asked about their mood, anxiety, and finally how often they exercise. After they complete these questionnaires, they will be sent instructions via email to tell them how to log online for their session, what day and what time they need to log on. They will also be sent a group number and a code that they use instead of their name so no one knows who they are when they log on to the session online (via video conferencing software such as Microsoft Teams or Zoom). This study is what is known as a 'stepped wedge' trial. This means that there are two groups that are involved in the study. Both groups will receive exactly the same information and intervention, but one group will start the intervention as soon as recruitment has finished. The second group will start once the first group has finished. The young people will be randomly assigned and it makes no difference which group your child is assigned to. If your child has been assigned into Group 1, they will start their online sessions immediately. If they have been assigned to Group 2, they will start their online sessions after Group 1 has finished (i.e., in 6 weeks). The allocation into these groups is random and will be done by an independent member of staff at the university. For 6 weeks, they will log online for 1 hour once a week. During these sessions they will be taught about common negative feelings, why they feel like they do, and how they can control them. There 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). Your child will be asked to complete the questionnaires about their mood, anxiety and physical activity at the end of the study too.

What are the possible disadvantages and risks of taking part?
Your child is giving up time to complete this study, the sessions will run after school time and this may be seen as a burden. However, we do not expect that taking part in the study would have any disadvantages or risks, given that the tasks and materials are all designed to help your child to cope and understand their negative emotions. However, if your child does feel uncomfortable or upset by any aspects of this study, you can contact the research team who can offer support and advice. The research team can also link participants in with locally available emotional support services if necessary.

If the research team becomes concerned about the welfare of a participant, or any abuse of the participants, or someone else is disclosed, we will have to break confidentiality. We will discuss this with your child initially, but we may have to break confidentiality without their consent if we feel it is appropriate. Confidentiality will be broken by either a referral to the GP or emergency services, depending on the severity and urgency, we will also inform yourselves if this occurs and it is appropriate to do so.

What are the possible benefits of taking part?
Your child will hopefully start to understand why they feel sad and anxious, and that it's normal to feel these sometimes. They 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.

This research also allows access to psychological intervention without a referral into CAMHS and the long wait associated with that.

What happens when the research study 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 your child was in the study.

What if there is a problem?

Any complaint you might have will be addressed about the research. The detailed information on this is given in Part 2.

Will my child's taking part in the research project be kept confidential?

Yes. We will follow ethical and legal practice and all information about your child will be handled in confidence. The details are included in Part 2.

Contact for further information

Name: Dr Victoria Laker
Designation: Post-Doctoral Research Associate and Chief Investigator for this study
Hospital/Department: Grounded Research, Tickhill Road Hospital, Balby
Telephone: 07970 049942
Email rdash.groundedresearch@nhs.net.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2 - more detail – information you need to know if you still want your child to take part.

What will happen if my child doesn't want to carry on with the research?

If your child withdraws from the study, we will destroy your child's identifiable data forms if you wish, but we will need to use the data collected up to their withdrawal.

What if there is a problem?

Complaints

If you have a concern about any aspect of this study, you should speak to the research team who will do their best to answer your questions.

Name: Dr Victoria Laker
Designation: Post-Doctoral Research Associate and Chief Investigator for this study
Hospital/Department: Grounded Research, Tickhill Road Hospital, Balby
Telephone: 07970 049942
Email rdash.groundedresearch@nhs.net.

If you remain unhappy and wish to complain formally, you can do this through the normal hospital complaints procedure and contact the following person:

Patient Advice & Liaison
PALs telephone: 0800 015
Email: rdash.pals@nhs.net.

Will participation and 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 your child. To complete the first questionnaire we will ask for you or your child's email address. This is to ensure we are able to contact them during the study (e.g., sending email reminders). Once they have completed the consent form we will email you/them a code, which cannot identify your child. They will then use this code to identify themselves throughout the rest of the study (i.e., to log in to Zoom, and to complete the final set of questionnaires), so that their data is completely anonymous. The research team will keep a record of their/your email address and associated code, so if your child forgets their code they can contact us to confirm it. Your/their email address will be used to invite your child to the online sessions. Your/their email address will then be deleted when the study has been completed.

Information will be kept strictly confidential and will only be accessible to members of the research team. This gives participants the assurance that no sensitive information (e.g., their feelings of anxiety) will be available to anyone else. In certain circumstances (e.g., disclosure of suicidal thoughts, or risk to self and/or others) confidentiality will have to be broken, but we will do all we can to discuss this with your child before disclosing the information to the appropriate authorities.

The final study dataset will be stored in a secure University network drive, only accessible to members of the research team, which is located behind The University of Sheffield Firewall. This will ensure the security and adequate storage of research data, consistent with NHS and academic codes of information governance and data protection. All analyses will be carried out at a University site, and data will be held in a restricted-access drive. The study dataset will be archived at the University for possible use in the future.

What will happen to the results of this study?

When the study has finished we will present out findings using a variety of forms of communication, including:

- Scientific journal publications
- Newsletters you can have access to if you want to
- NHS Trust conferences, strategic meetings
- Mental health conferences in the UK and abroad

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 £20 prize draw your child should have attended at least four of the online sessions and have completed the three online questionnaires up to the end of the intervention phase (i.e., at the beginning, after group 1 has finished and after group 2 has finished).

To be included in the £50 prize draw your child should have attended at least four of the online sessions and have completed the all four online questionnaires (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 they will be asked to return a signed receipt via email, which includes their name and email address, which is essential for auditing purposes and for legal reasons. The prize winners names and email addresses will be stored in a secure University network drive, only accessible to members of the research team. This will ensure the security and adequate storage of research data, consistent with NHS and academic codes of information governance and data protection. The contact details will be held at the University for 12 months after the conclusion of the study, this is for audit purposes.

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.

Legal statement under the General Data Protection Regulation (GDPR)

How will we use information about you?

RDaSH will need to use information from you for this research project. This information will include your name and email. The research team will use this information strictly for the purpose of contacting you via email during the study period. The information that is collected as part of your participation in the study will be fully anonymised, and linked to a participant ID number instead of your name or email. RDaSH will keep all information about you safe and secure in a password protected network drive, which is only accessible to a restricted number of research team members who are in charge of data collection. Once the team has finished the study, we will keep fully anonymous data so we can work out the results. We will write our reports in a way that nobody will know that you took part in the study. The anonymous data you provide will possibly be used in future studies too, and by other authorised researchers.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- The anonymised dataset from this study will possibly be used in future studies too, and by other authorised researchers. It will not be possible for researchers using the dataset to identify you and any future research will have appropriate approvals in place.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- by asking one of the research team

- by sending an email to rdash.groundedresearch@nhs.net
- by sending an email to the RDaSH Trust Data Protection Officer at rdash.dpo@nhs.net
- by going to the RDaSH Information Governance webpage at IG Compliance
- by going to the HRA website; www.hra.nhs.uk/information-about-patients/

Contact details for enquiries
Name: Dr Victoria Laker
Telephone: 07970 049942
Email rdash.groundedresearch@nhs.net.

If you and your child decide to take part in this study, please follow the link below to access the consent forms

Thank you for taking the time to read this information sheet.

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