PARENT/CARER INFORMATION SHEET SUMMARY SHEET

The READY Trial

Feasibility of a Randomised controlled trial of Energetic Activity for Depression in Young people

- You and your child are being invited to take part in a research study
- Before you decide whether to do so, it is important you understand the research being done and what your involvement will include.
- Please take the time to read the following information carefully and discuss it with others if you wish
- We have also provided an information sheet for your child
- Do not hesitate to ask us anything that is not clear or for any further information you would like to help you make your decision
- Please do take your time to decide whether you and your child wish to take part

What is the purpose of the research?

In this study, we are trying to find out whether it is possible to undertake a very large study. We are exploring the best way to organise and deliver the study so that young people will want to take part in the large study and will continue to want to take part in the group activities. If this small study works well, we will be able to move on to the large one.

The aim of this study is to address the following questions:

- Does exercise of a high, or a low intensity help to improve the mood of young people with low mood or depression, or does a social group work just as well?
- Are the exercise groups good value for money?
- Do young people continue to attend the exercise groups enough to benefit from the exercise, and does it matter whether the exercise is high or low intensity?

What will happen if my child and I participate?

Young people who have sought help for feeling low or depressed will be given the opportunity to take part in a twice-weekly group. If the young person agrees to take part, they will be asked to attend one of three groups which will be randomly assigned:

1. **High intensity physical exercise** (e.g. basketball, football, circuit training to music, boxing drills)
2. **Low intensity physical exercise** (e.g. walking sport such as football and netball)
3. **The social control** (e.g. board and computer-based games, and group discussions)

- You and your child will be asked to complete some questionnaires after providing consent to join the study.
- If your child is eligible, they will be invited to an introductory session where they will meet the other young people in the study and the professionals delivering the sessions. At this session your child will be asked to complete questionnaires and be provided with equipment to measure their activity levels.
- Your child will attend twice weekly group sessions for 12 weeks during term time
- They will be required to complete the same questionnaires 14 and 26 weeks later
- You will be asked to complete questionnaires at the same time points.

We hope that you will consider taking part in this research. If you'd like to know more, please read on for a detailed overview of the project.

Discuss the study with a health professional	•A member of your child's healthcare team will introduce the study to them
Phone call with the research team	•If they agree, a researcher will call you both to discuss the study and arrange a meeting
Meeting with a researcher	•A researcher will meet with you either face-to-face or online •You both decide whether or not to take part •If you do take part, then the researcher will ask you both to complete some screening measures. These can be emailed to you/your child for you to complete in your own time.
Introduction Session	•A member of the research team will advise you of the dates of sessions •During this first session, your child will be asked to complete some questionnaires. •Your child will be provided with a device to measure physical activity (accelerometer) •You will also be asked to provide some information
Groups	•Your child will have twice weekly group sessions for 12 weeks •In week 11, they will again be provided with an activity monitor
After the Groups have finished	•Your child will complete questionnaires again at the last group session. •They will be asked to come back to a final group session 12 weeks later to complete the same set of questionnaires. •Your child will receive £10 vouchers each time they complete these sessions. •Some children will be asked to take part in focus groups.
End of study	•We will write to the clinical team who referred your child to the study and/or your child's GP to advise them they have finsihed the study.

PARENT/CARER INFORMATION SHEET – DETAILED VERSION

What is the purpose of this study?

The aim of this study is to address the following questions:

- Does exercise of a high, or a low intensity help to improve the mood of young people with low mood or depression, or does a social group work just as well?
- Are the exercise groups good value for money?
- Do young people continue to attend the exercise groups enough to benefit from the exercise, and does it matter whether the exercise is high or low intensity?

Why have I, and my child, been invited?

You have been invited to take part because your child has sought help for their low mood/depression.

Do I, and my child, have to take part?

It is completely up to you whether you, and your child if they are under 16, take part in this study. If you, along with your child, decide to take part you will be given this information sheet to keep. If your child is under 16 they will be asked to provide assent and you will be asked to provide consent on their behalf. If your child is over 16 they are able to provide their own consent. In both cases we also will ask you to provide your consent for your participation in the study. There is also an information sheet that will be provided to your child, who will be asked to provide separate consent form. If your child is under 16 you will be asked to provide consent on their behalf, too.

What will happen to me and my child if I do not take part?

a) If you decide that you (and your child if they are under 16) do not wish to take part in the study, your child will not be able to participate. Deciding not to take part will not affect the standard of care your family receives in any way.
b) If you have agreed to pass your, and your child's, contact details to the research team and then decide not to take part, the research team will destroy records of your identifiable information (e.g. your name, your child's name and your contact details).

How long will my, and my child's, part in the study take?

If you and your child decide to take part in this study, you and your child will be involved in it for approximately six months.

Providing consent

If you and your child agree, then your details will be passed to the research team. A researcher will call you and your child to arrange a time to meet you both. This meeting will take place either face-to-face or remotely and will take approximately two hours.

The researcher will use this information sheet to discuss the study with you and if you and your child would like to take part, you will complete a consent form (paper or online). You and your child do not have to decide at this meeting. You can both take some time to think about and discuss it.

The researcher will also discuss the study with your child and whether they would like to take part in the study, using the information sheet provided to them. This can happen at the same meeting but can be arranged to take place separately. They will be asked to complete a consent form (paper or online). If they are under 16 years of age, we will ask them to provide assent and for you to provide consent on their behalf by completing a separate consent form.

What will happen to me and my child if we take part?

Step 2. Introductory session

The first session will be an introductory one where your child will meet the other members of the group and the team running the groups. They will also learn about the format of the sessions and additional requirements of the study. Your child will be given an accelerometer, measuring physical activity, to wear on their wrist and provided with instructions on how to use it.

Your child will be asked to complete the following questionnaires either using the tablets provided or using their phones by scanning a QR code or following a link emailed to them:

- Child Depression Inventory (this is being repeated in case things have changed).
- Positive and Negative Affect Schedule (PANAS), which will look at how they perceive emotions (5 minutes)
- New General Self-Efficacy scale measuring how much they think they can achieve their goals (5 minutes)
- Multidimensional scale of perceived Social Support (MSPSS) (5-10 minutes)
- A six-question measure looking at the young person's Capability (Physical and Psychological), Opportunity (Social and Physical), and Motivation (Reflective and Automatic) to be regularly active (less than 5 minutes)
- EQ-5D-5L, to measure their quality of life (5 minutes)
- The Modified Client Service Receipt Inventory (CSRI) designed to measure how many times your child has accessed health and social services. if your child is unable to fully answer the CSRI, you will be asked to help with this.

Either at this visit or remotely *you* will be asked to complete the Burden Scale for Family Caregivers.

Step 3. Study Group Sessions

A week after the first session, your child will return the accelerometers and the sessions will begin.

What will the group sessions be?
Your child will attend one of the groups, chosen by chance. Groups will run during school terms, as far as possible, at accessible venues and convenient times.

All three groups will be delivered in supervised small groups of up to 10 young people, at local community venues or online if circumstances dictate, twice a week over 12 weeks. The people delivering the intervention will be Registered Exercise Professionals (REP) with additional training in mental health, with a support worker with experience of working in mental health (MHSW). Your child's intervention session(s) may be observed by a member of the research team to see what the intervention looks like in practice.

For the first 15 minutes of each of the groups, there will be a Healthy Living session focusing on promoting and maintaining healthy behaviour. There are three main objectives of the Healthy Living sessions:

- to help ensure the young people attend the sessions and engage with the intervention
- to encourage the young people doing physical activity outside of the intervention
- to encourage physical activity as a habit that continues after the intervention is completed

What are the interventions?

1. **High intensity physical exercise:**
    - 15-minute healthy living session
    - 10-minute warm up
    - Alternating training session e.g. basketball, football, dance or boxing drills
    - 5-min whole body cool down
    - Heart rate monitors will be used at week 4 & 8 ± 1 week to tailor each person's maximum intensity.
2. **Low intensity physical exercise:**
    - 15-minute healthy living session
    - 5-minute warm up
    - Alternating low intensity training sessions e.g. table tennis, yoga, tai chi, walking football, gymnastics. The overall exercise session will be longer (to make sure they are using the same amount of energy as the high intensity group).
    - 5-min cool down.
3. **The social group:**
    - 15-minute healthy living sessions
    - 45-minutes of social non-exercise activities e.g. board and computer-based games, and group discussions, with the exact activities agreed upon by the group.

Young people in all three groups will be encouraged to engage in appropriate intensity activities between sessions, and after the intervention ends to keep on exercising.

Step 4. After the sessions have finished.

The activity monitor will again be provided to the young people in the 11th week, so they can be returned in the final session.

In the final session, your child will once again be asked to complete the following measures either using the tablets provided or using their phones by scanning a QR code or following a link emailed to them:

- Child Depression Inventory 2nd edition (CDI-2)
- Positive and Negative Affect Schedule (PANAS)
- New General Self-Efficacy scale
- Multidimensional scale of perceived Social Support (MSPSS)
- COM-B measure
- EQ-5D-5L
- Modified client service receipt inventory (CSRI)

You will be asked to help complete any gaps in the CSRI and to repeat the Burden Scale for Family Caregivers.

At this point, your child's GP and/or the referring clinical service will be advised that your child has completed the group sessions.

Twelve weeks later, your child will be invited to attend a final group session. At this session the final set of measurements (as outlined above) will be completed.

Your child will receive £10 in vouchers for each of the two follow up sessions.

We will also invite some young people to take part in focus groups. Focus groups are a way of us finding out what young people thought about taking part in the study, and their views on the intervention. We will re-contact you with more information about the focus groups if your child is selected to take part, and you can decide whether to take part in this phase of the study.

What will happen if I, or my child, don't want to carry on with the study?

Agreeing to join the study does not mean that you or your child must complete it. You and/or your child are free to withdraw at any stage without giving a reason. A decision to withdraw at any time, or a decision not to take part at all, will not affect any treatment/care that you or your child may receive.

If you or your child decide you do not want to take part anymore, please contact the Clinical Trial Manager using the contact details at the end of this leaflet.

What are the possible disadvantages, risks or side effects of taking part?

Your child will be asked about how they are feeling using questionnaires that are routinely used for this purpose. Some people can find talking about personal things difficult or upsetting. If you or your child gets upset whilst taking part in the research, we will stay with you or your child until you feel better and make sure you and your child know where to go for support if you or your child need it later on.

The exercises your child may do are safe for most young people, but they should not take part if they have been told by a doctor that they should not exercise. With any programme of exercise

there is a small risk of minor injuries such as pulled muscles or sprains. More serious injuries that can be associated with exercising, such as fractures or ligament damage, are very rare.

What are the possible benefits of taking part?

Taking part in the groups may benefit your child and lead to an improvement in their low mood or depression.

We hope that the information we get from this phase of the study will help us determine if a larger randomised controlled trial is feasible, and 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 as an alternative treatment for depression.

How will my taking part in this study be kept confidential?

The University of Hertfordshire (UH) is the sponsor for this study based in England. We will be using information from you and your child and your child's medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your, and your child's, information and using it properly.

Your, and your child's, rights to access, change or move your information are limited as we need to manage your information in specific ways for the research to be reliable and accurate. If you and your child withdraw from the study, we will keep the information about you and your child that we have already obtained. To safeguard your rights and that of your child we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients

[Insert Local NHS organisation] will keep your, and your child's name, age and your child's NHS number confidential. This information will only be used as needed, to contact you and/or your child about the study and to make sure relevant information is recorded for your care, and to oversee the study quality.

Identifiable information (e.g. name and date of birth) will be stored on a secure database managed by approved members of the Norwich Clinical Trials Unit (NCTU). Yyours and your child's email address will also be stored on this database to send questionnaires and the e-consent form to you and your child to complete remotely. Certain individuals from UH, NCTU, [local NHS trust] and regulatory organisations may look at your child's medical records and your and your child's research records to check the accuracy of the research study. UH will only receive anonymised data/files and the people who analyse the information will not be able to identify you.

If your child is selected to take part in the focus group a third party transcription company with a confidentiality agreement in place will complete the audio transcriptions.

[Insert Local NHS organisation] will keep identifiable information about you and your child from this study for 10 years.

We follow ethical and legal practices and all information kept about you and your child will be handled in strict confidence. As researchers we are bound by certain confidentiality rules and this means that only in exceptional circumstances, in which you or your child tells us something that

raises serious concerns that you, your child, or someone else is at significant risk from harm, may we pass this information on.

Participant confidentiality will be maintained. Data/files will be anonymised by assigning each person a unique participant code. All participant data, associated files and hard copy questionnaires including any that might identify your child and family, will be accessed only by the research team. Personal data (e.g. names and contact details) will be destroyed within 6 months of the study end-date.

Anonymised data will be kept for up to ten years after the full trial has been completed. After this the papers will be shredded and disposed of. Paper data will be stored in a lockable cabinet at the University of Hertfordshire. Consent forms will be stored in a lockable cabinet separately to other study data. All electronic files will be password-protected and the research data will also have a password-protected system. Data relevant to your child's participation in the research may be requested by regulatory authorities who monitor research activity.

What will happen to the results of the research study?

We will use the data collected to support future research and to share with other researchers. No personal data (e.g. names) will be shared and all data will be anonymised. The results of the study will be published in sports science, psychology, and health journals and will be presented at meetings. Any research publications or reports will not identify you or your child individually. We will send you a summary of the research report within six months of the study's end-date. If you would like a copy of the published research, please let one of the researchers know and we would be delighted to send any publications describing the results of this research to you as and when they become available. We also plan to hold events to disseminate the research at the University of Hertfordshire and/or with local or national support groups.

To find out more about how we use your information, please contact our Data Protection Officer:

Abi Tomlinson
University of Hertfordshire,
College Lane,
Hatfield,
Hertfordshire
AL10 9AB
✉ dataprotection@herts.ac.uk
✆ 01707 285900

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This committee is here to protect your interests. This study has received ethical approval from the East of England - Cambridgeshire and Hertfordshire Research Ethics Committee.

Who can I contact if I have any questions?

If you would like further information or would like to discuss any details personally, please get in touch with the Clinical Trial Manager or one of the Chief Investigators in writing, by phone or by email:

Claire Rourke – Trial Manager
Department of Psychology and Sports Science,
University of Hertfordshire,
College Lane,
Hatfield,
AL10 9AB
01707 284139
c.rourke@herts.ac.uk

Dr Daksha Trivedi – Chief Investigator
Centre for Research in Public Health and Community Care,
University of Hertfordshire,
College Lane,
Hatfield,
AL10 9AB
01707 285990
d.trivedi@herts.ac.uk

Dr David Wellsted – Chief Investigator
Health Research Methods Unit,
Centre for Health Services and Clinical Research,
University of Hertfordshire,
College Lane,
Hatfield,
AL10 9AB
01707 286291
d.m.wellsted@herts.ac.uk

What if there is a problem?

If you would like to speak to an independent advice service, then please contact your local Patient Advice and Liaison Service (PALS):

Address
Address
Post Code
Phone
Email

The sponsors of the study are the University of Hertfordshire and as the sponsor, the University will provide indemnity through its insurance cover. You may also contact the representatives of the sponsors if you have any concerns or complaints:

Professor J M Senior
Pro Vice-Chancellor (Research and International),
University of Hertfordshire
j.m.senior@herts.ac.uk

Thank you very much for reading this information and considering taking part in this study.