

YOUNG PERSON PARTICIPANT INFORMATION SUMMARY SHEET

The READY Trial

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

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- You are being invited to take part in a research study
 - Before you decide whether to do so, it's important you understand the research and what will happen if you take part
 - Please take your time reading the information and feel free to discuss with others
 - If anything is not clear or you would like more information, please do ask!
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Why is the research being done?

We're exploring the best way to organise and deliver the study so that young people will want to take part in a larger study and continue to want to take part in the group activities.

The study aims to answer the following questions:

- Does exercise of a high, or a low intensity help 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 the intensity of the exercise matter?

Why have I been invited and if I agree what will I be doing?

You have been invited to take part because you have sought help for low mood/depression.

If you agree to take part, you will be asked to attend one of three groups:

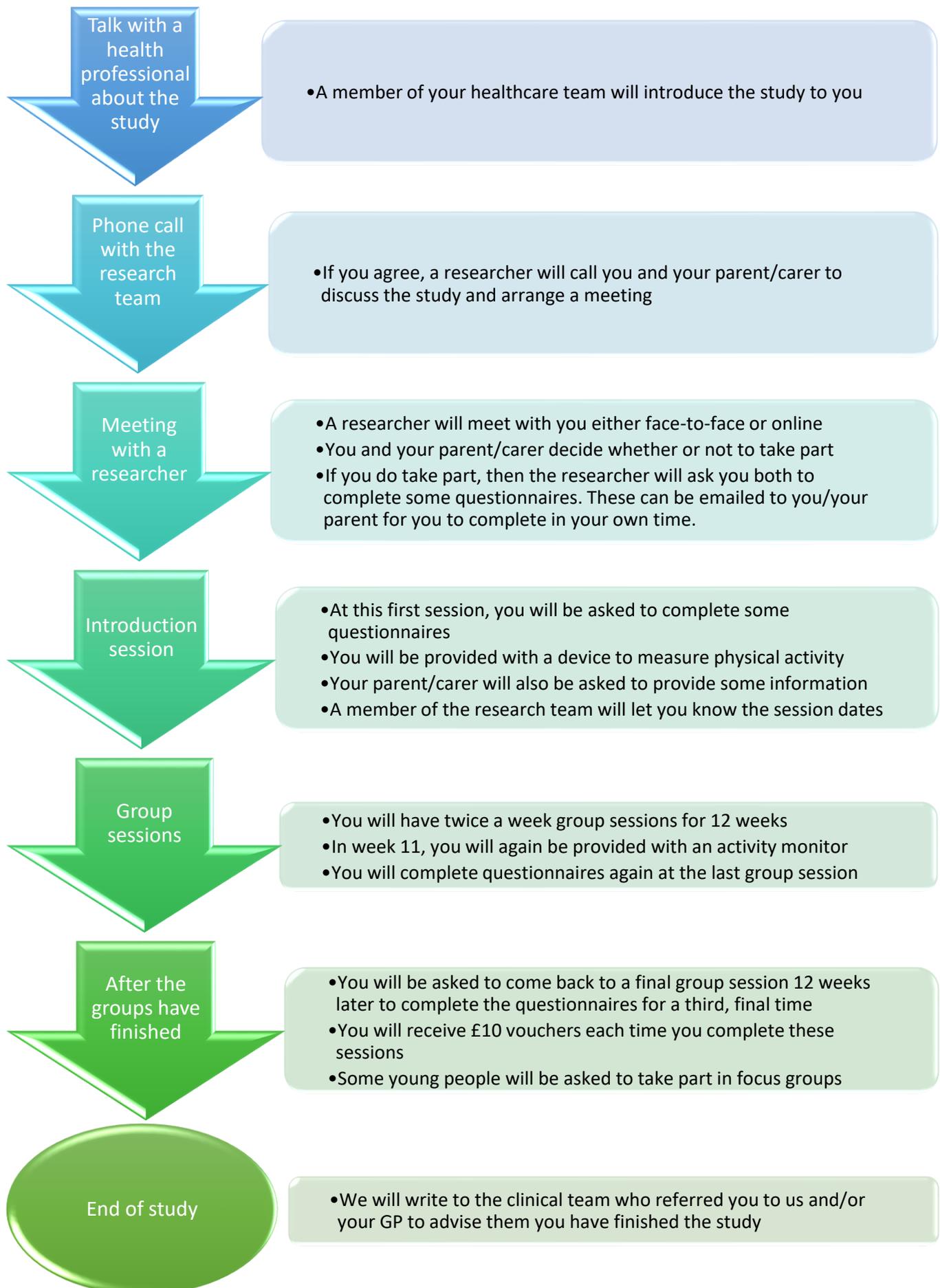
High intensity physical exercise (e.g. basketball, football, circuit training to music, boxing drills)

Low intensity physical exercise (e.g. walking sport such as football and netball).

The social control (e.g. board and computer-based games, and group discussions)

- If you decide to join the study, you will be asked to answer some questionnaires
- If you are eligible, you will then be invited to an introductory session where you will meet other young people in the study and the professionals delivering the sessions
- At this session you will be asked to answer questionnaires and be provided with a physical activity monitor
 - You will be required to complete the same questionnaires 14 and 26 weeks later
- Parents/carers will be asked to complete some questionnaires at the same time point

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.



YOUNG PERSON PARTICIPANT INFORMATION SHEET – DETAILED VERSION

Why is the research being done?

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?

Do I have to take part?

No! It is completely up to you whether you want to take part in this study.

What will happen if I, and/or my parent/carer, don't want to take part?

If your parent/carer decides that they do not wish to take part in the study, you will not be able to participate but this will not affect the standard of care your family receives.

You can stop taking part whenever you want without having to explain why.

If I would like to take part, what will I have to do?

Providing consent

- You will be asked if it's okay to pass on your contact details to the research team and if it is, a researcher, or a member of the central study team, will call you to arrange a meeting with you and your parent/carer.
- At the meeting, the researcher, or a member of the central study team will talk you and your parent/carer through the study and answer any questions.
- If you want to take part, you will be asked to provide consent (over 16) or assent (under 16) either at this meeting or after you've had time to think.
- An information sheet will also be provided to your parent/carer, who will be asked to provide separate consent and to provide consent on your behalf if you are under 16.
- If you decide to take part, you will be involved for around six months.

Step 1: Checking the study is right for you

- You will be asked to complete questionnaires on depression, wellbeing and physical activity. These can be emailed to you/your parent for you to complete in your own time. Your parent/carer will also be asked to complete a wellbeing assessment and some of the questionnaires, depending on your age. 
- These questionnaires will help assess whether you are eligible to join the study.
- If you are not eligible to join the study, we will let you know the reasons why and let your clinical team/GP know.
- If you are eligible you will be allocated randomly to either a group of **high-intensity exercise**, **low-intensity exercise** or a **social group**.
- The groups may be single sex but it is more likely that they will include a mix of young people i.e. boys and girls. Whilst we will collect if you have a preference for single sex versus mixed groups prior to treatment group allocation, we cannot guarantee that this can be offered.
- You will be contacted by a member of the research team or central study team letting you know which group you are in and details of the sessions.
- You will continue to receive usual care (healthy lifestyle advice, encouraging physical activity, psychotherapy and, or drug therapy as needed), from the NHS.

Step 2: Introductory Session

At your first group session you will:



- Meet other members of the group, and the team who will be running the groups.
- Learn about how the sessions will work
- Be given a physical activity monitor to wear on your wrist for one week.
- Be asked to answer a few questionnaires on the tablets provided or on your phones by scanning a QR code or following the link in an email.

High
Intensity
physical
exercise

Low
Intensity
physical
exercise

The social
group

- 15-min healthy living session
- 10-min warm up
- High intensity exercise e.g. basketball, football, dance or boxing drills
- 5-min cool down
- Heart monitors will be used at week 4 & 8 \pm 1 week to tailor each person's maximum intensity

- 15-min healthy living session
- 5-min warm up
- Low intensity exercise e.g. table tennis, yoga, tai chi, walking football, gymnastics
- 5-min cool down
- Heart monitors will be used at week 4 & 8 \pm 1 week

- 15-min healthy living session
- 45 minutes of social non-exercise activities e.g. board and computer-based games, group discussions

Step 3: Study Group sessions



- Groups of up to 10 young people will run during school terms twice a week for 12-weeks
- In the 11th week you will be given the activity monitor to wear until your final session
- Exercise sessions will be delivered by Registered Exercise Professionals with additional training in mental health, with a support worker who has experience of working in mental health. You will receive one of the below three interventions
- You will be encouraged to keep exercising between sessions, and after the study ends
- Your intervention sessions may be observed by members of the research team

Step 4: After the sessions have finished

- You will be asked to fill out the same questionnaires you completed in the introductory session
- Your GP and/or referring clinical service will be told you have completed the sessions
- 12 weeks later you'll be invited to attend a final group session where you'll complete the same questionnaires as before
- You will receive **£10 in vouchers** for each of the two follow up sessions and be invited to take part in focus groups
- Your GP and/or clinical service will be told you have finished the study.



What will happen to the results of the research study?

- Results will be published in sports science, psychology, and health journals and will be presented at meetings. Any publications or reports will not identify you.
- 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, let one of the researchers know and we will send any publications describing the results of this research to you.
- We plan to hold events to disseminate the research at the UH and/or with local or national support groups.





Are there any risks?

- It's difficult for some people to discuss personal things. If you get upset whilst taking part, we will stay with you until you feel better and make sure you know where to go for support if you need it.
- The exercises you may do are safe for most young people, but you should not take part if you 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.



Are there any benefits?

- Taking part in the groups may benefit you and lead to an improvement in your low mood or depression.
- We hope the information from this phase of the study helps us 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.



How will you use my information?

- **The University of Hertfordshire (UH)** is the sponsor and will be looking after your information and using it properly
- **[Local NHS organisation]** will keep identifiable information about you confidential. This information will only be used as needed, to contact you and/or your parent/carer about the study and make sure relevant information is recorded for your care, and to oversee the study quality.
- Some personally 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). Your email address will also be stored on this database to send questionnaires and e-consent forms to you to complete remotely.
- Your 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 decide to leave the study, we will keep the information about you that we have already been given but we will use the minimum personally identifiable information possible.
- Certain individuals from UH, NCTU, **[local NHS Trust]** and regulatory organisations may look at your medical and 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 you are invited and take part in the focus groups, we may use direct quote(s), but these will be anonymised. If you are selected to take part in the focus group a third party transcription company with a confidentiality agreement in place will complete the audio transcriptions.
- Only the research team will have access to files and hard copy questionnaires that might identify you and your family. Personal data will be destroyed within 6 months of the study end-date. Anonymised data will be kept securely for up to ten years after completion of the full trial and then shredded and disposed of.
- We will use the data collected to support future research and share with other researchers but no personal data (e.g. names) will be shared and all data will be anonymised.
- Please visit www.hra.nhs.uk/information-about-patients if you would like more information.



Who has checked 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?



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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:



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