

MAGENTA

Managed Activity Graded Exercise iN Teenagers and pre-Adolescents

Information leaflet for young people 12-17 years

We would like to invite you to take part in a research study exploring the effectiveness and cost-effectiveness of Graded Exercise Therapy (GET) compared to Activity Management for Chronic Fatigue Syndrome or Myalgic encephalopathy (CFS/ME) in young people

Before you decide whether you would like to take part, it is important for you to understand *why* the study is being done and *what* it will involve. The leaflet is divided in to two parts. Part 1 tells you about the study and what will happen if you choose to take part. Part 2 gives details about how the study will be run.

Please read this leaflet carefully. You can talk about it with your family, friends, doctor, or us.

Ask us if there is anything you don't understand or if you want more information.

Take time to decide whether or not you want to join in.

Thank you for reading this!

PART 1

Why are we doing this study?

We want to test whether a treatment that we use for CFS/ME called "Graded Exercise Therapy" is effective and value for money. We want to compare this with "Activity Management" which we also use for CFS/ME.

We think we are not very good at knowing which children with CFS/ME are worried, sad or unhappy. We are trying to improve this by doing a proper assessment of mood and seeing which questionnaires can help us identify young people with mood problems.

Why have I been asked to take part?

You have been asked to take part in this study because you are aged between 8 and 17 years and have a diagnosis of CFS/ME from the CFS/ME specialist unit.

If you are not able to attend your CFS/ME hospital appointments (e.g. you cannot leave the house), or any of the appointments required for the research study, we do not feel you should take part.

Do I have to take part?

You do not have to take part in this study. If you agree to meet the research nurse, they will explain more about the study. This will not commit you to taking part.

If you think that you might not want to take part in any of the activities or treatments in this you should not enter the study.

We hope that up to 222 young people and their parents/carers will take part in this study but it is up to you to decide whether or not you would like to take part.

If I agree to take part can I change my mind?

Yes. If you decide you would like to take part but change your mind later, we will continue to follow you up like we do other young people who are not part of the study unless you tell us you don't want us to.

You can leave the study at any point and if you would like us to, we will take out the information collected about you at any point before we carry out data analysis.

If you leave the study at any time, this will not affect the standard of specialist medical care you will receive.

What will I be asked to do if I take part?

First stage:

If you would like to hear more about the study, the doctor will ask a research nurse to arrange a time to talk to you. You can do this in the clinic or on the telephone. The research nurse will explain the study to you and your parents/carers, and answer any questions you may have. This discussion will be audio-recorded with your permission and will last about 30 minutes, but you can talk for longer if you have more questions. The research nurse might ask you about how you felt when the doctor asked you to take part in this study.

If you want to take part in the study, you will be asked to fill in an assent or consent form to show us that you agree. You can do this at home and post it to us, (we will provide a stamped addressed envelope) or you can email it to the research nurse, or fill in a consent form on-line.

If you take part in this study, we need to make sure that those in both groups are matched. This is the only way we can compare the groups and make sure the study is fair. You will therefore be given either Activity Management or Graded Exercise Therapy at random. Half of those taking part in the study will have Activity Management and half will have Graded Exercise Therapy. Your chance of getting either group is 50%. These are both treatments we currently use in our service and lots of children have already tried them.

Second stage:

In the second stage you of the study you will have treatment for your CFS/ME. **Both** groups will be seen in the specialist service and you will get lots of advice about how to improve your sleep and you will get treatment for your symptoms. We will probably see you 8-12 times in clinic.

We will ask your parents to complete a questionnaire when you first join the study. You and you parents will also be asked to complete a questionnaire on-line at 6 months and at 12months.

A researcher will also make contact with you to arrange a time to talk with you and your parents (separately or together, you can decide). You can be interviewed using Skype or face to face in clinic. The interview will involve asking questions about your mood and activities that change mood in young people. For example, whether you drink alcohol or take drugs. This information might be helpful to your clinician who looks after you. You can decide whether they know or not. For most people, this discussion will take less than an hour. We will not continue if you get tired. You can take breaks if you need them.

We will ask you to wear an accelerometer to measure exercise at 3 times: at the beginning and 3 and 6 months later. This is a small box that you will wear on a band around your hips. Lots of young people have used these to measure exercise. We may ask you to record when you wear it and when you take it off.

In addition you will get either Activity Management or Graded Exercise Therapy.

Activity Management

If you are in this group you will have a detailed assessment of the activity you do. This includes thinking activity such as school work, homework, time on the computer and screens, reading and hobbies that require concentration and physical activity such as walking or PE. We call

this high energy activity. We will ask you to record your activity on paper or our iPhone app "ActiveME". We will then help you find your "baseline" activity which is the average amount of activity that you can do each day. When you have found your baseline activity, we will help you increase this by 10-20% each week. This is called activity management.

Graded Exercise Therapy

If you are in this group you will receive a detailed physical assessment including how far you can walk in 2 minutes and how many times you can move from sitting to standing in one minute. This will help us set a safe exercise programme. You will be asked about the exercise you do each day and will be helped to find your exercise baseline. The baseline is the average amount of exercise you do each day. It will be less than you do on a good day. When you have found your baseline, we will ask you to slowly increase your exercise. When you are able to do 30 minutes each day, we will increase the intensity of your exercise. You will be asked to record exercise using either charts or the iPhone app ActiveME. You will not be asked to record other activities, only your exercise. To make sure you do not over do your exercise, we will ask you to use a heart rate monitor.

What is the difference between Activity Management and Graded Exercise Therapy?

Activity Management will mainly be working on activities that take up most of the day like school work. It does not focus on exercise or include a physical assessment or heart rate monitoring. Graded Exercise Therapy gives detailed advice about exercise with an assessment of your exercise and uses a heart rate monitor. Graded Exercise Therapy will not ask you to monitor other activities such as school work.

Are there any disadvantages to taking part in this study?

You will need to spend time talking to a doctor for about 10 minutes so we can understand if you are interested in the study. You and your parents/carers will need to arrange a time to meet or talk (on the phone) to a research nurse about the study. This will take about 30 minutes.

If you take part, your parents/carers will need to complete questionnaires when you first join the study. You and your parents will also be asked to complete questionnaires at 6 months and 12 months. We ask all young people to complete these questionnaires. These questionnaires will take you about 20 minutes.

You will also be asked to meet with a researcher to complete an interview about your mood. For most people, this discussion will take less than an hour. You can take breaks when needed.

You may not find the treatment you are offered helps you. Young people with CFS/ME can get worse even with the treatment offered and we do not know how many will get worse (or better) with either Activity Management or Graded Exercise Therapy. This is why we are doing a study. If you do not find the treatment helps you, you can have the other treatment after 6 months.

Will I experience any side effects from taking part in this study?

We have used both treatments in our service and we are not aware of side effects. Studies in adults have also not shown that there are any side effects from these treatments.

What are the benefits of taking part in this study?

You may feel better from the treatment you are undergoing, but we cannot say this for certain. You may learn something about how a research trial works. Some young people with CFS/ME like to know that they are helping others with CFS/ME in the future.

What will happen when the study stops?

After the study stops, you will continue to access specialist medical care if you still need it. You will also continue to receive follow up questionnaires, like the young people who did not take

part in the study. If you want to know the study results, let us know and we can send them to you.

PART 2

If you are still interested in taking part in the study, please read the information below before making your decision.

Assent and consent

We have to be absolutely certain that you are happy to join this study. We will ask you to sign an assent form (if you are 12-15 years old) or consent form (if you are 16-17 years old). We will also ask you to sign one of these forms if we record treatment sessions or discussions. Even if you do sign the forms, you will be free to stop the recording or leave the study at any point. Just tell us if this is the case. Whether or not you wish to take part, you will continue to receive the same care from the clinical team.

What will happen to the information you collect about me?

It is very important that all the information you give us is completely private. The conversations that you say we can record will be encrypted and password protected (so no-one else can listen to them). They will be stored on a secure University of Bristol server.

We only use a research code to identify you. No name or personal information will be on the questionnaires we send you. All personal details that could identify you will be kept secure in locked cabinets in locked offices or password protected on secure NHS or University of Bristol computers.

We may use some of the things you say when we write about the study but we will take your name and any other information off so no one will know who was speaking.

We would also like to keep the things you say so that other researchers can use it for research and teaching now, and in the future. We will check you are happy for us to use the things you say in this way.

If you tell us something that makes us worried about your safety, we may have to discuss this with somebody else as we need to be sure you are safe. This means, what you say would not be kept completely private. We would do the same if you told us something in clinic.

Does everybody involved in the study have the right police checks?

Yes. All those working in the study have had police checks to make sure they are safe to work with children and young people.

Who will know that I am taking part in the study?

We think your GP should know that you are taking part in this so we will write to your GP to tell them which treatment you will be receiving in the study.

What will happen to the results of the study?

This study will give us information about how effective Graded Exercise Therapy and Activity Management are. We aim to publish these results in journals to help other people treating young people with CFS/ME.

What if new information becomes available whilst I am in the study?

If new information becomes available, we will tell you about it and discuss whether you want to continue in the study.

Who is organising and funding the study?

This research is organised by Dr Esther Crawley who leads the Bath specialist CFS/ME service and the CFS/ME Research team at the University of Bristol.

The study is funded by the government's research fund - the National Institute of Health Research (NIHR) and is sponsored by The Royal United Hospitals (RUH) Bath NHS Foundation Trust. This research is organised by Dr Esther Crawley who leads the Bath specialist CFS/ME service and the CFS/ME Research team at the University of Bristol.

The study is funded by the government's research fund -the National Institute of Health Research (NIHR) and is sponsored by The Royal United Hospitals (RUH) Bath NHS Foundation Trust.

What should I do if I have a problem with this study?

If you have any problems with this study, please speak to your parents/carers, Dr Esther Crawley, or any member of the clinical team that you know. Dr Crawley's contact information can be found at the end of this information.

You can also complain to the NHS in the usual way through the Patient Advice and Liaison services (PALS) 01225 473424.

Will I need to pay to be part of this study?

No.

Ethical approval

Ethical approval means that this study is safe to carry out on young people. The study has been approved by the National Research Ethics Service Committee South West – Frenchay REC.

Who can I contact for further information?

Dr Esther Crawley - Paediatric Consultant and Clinical Lead of the Paediatric CFS/ME Service:

Address: Specialist CFS/ME Service for Children and Young People, [Children's Centre, Royal United Hospital, Combe Park, Bath, BA1 3NG](#)

Tel: 01225 465941

Email: esther.crawley@bristol.ac.uk Or if you want to talk to somebody independent please contact Jane Carter, Research Manager Development:

Address: Royal United Hospitals Bath NHS Foundation Trust, Combe Park, Bath, BA1 3NG

Tel: 01225 465941

Email: jane.carter14@nhs.net

THANK YOU for taking the time to read this leaflet!