MAGENTA

Managed Activity Graded Exercise iN Teenagers and pre-Adolescents

Information leaflet for parents/carers

We would like to invite your child 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 aged 8 to 17 years.

Before you decide whether you would like your child 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 to your child if you choose for them 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 compare a treatment that we use regularly for children with CFS/ME called "Graded Exercise Therapy (GET)" with another treatment called "Activity Management". We want to see if GET is effective and value for money.

We think we need to improve our assessment of mood disorders in young people with CFS/ME. 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 has my child been asked to take part?

Your child has been asked to take part in this study because they are aged between 8 and 17 years and have a diagnosis of CFS/ME from the CFS/ME specialist unit. If you feel that your child is will not able to attend hospital appointments because they cannot leave the house this would mean they should not take part. If you would not want your child to take part or receive one of the treatments in this study, you should not allow your child to enter the study.

Does my child have to take part and can I change my mind?

Your child does not have to take part in this study. If you and your child agree to meet the research nurse who will explain more about the study, this will not commit your child to taking part in the study.

If you decide you would like your child to take part but change your mind later, we will continue to follow your child 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 withdraw your child from the study at any point.
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 your child to take part. If you decide you

would not like you child to take part or decide to withdraw your child at any time, this will not affect the standard of specialist medical care your child will receive.

What would we ask you and your child to do?

First stage:

A clinician at your specialist CFS/ME centre will invite you and your child to take part in this study. They will briefly describe the study and give you an information pack. If you would like r further information, the clinician will give your contact details to a research nurse who will arrange a time to discuss the study with you and your child at the CFS/ME centre or on the telephone.

The research nurse will explain the study 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 may ask you and your child about how you felt when the clinician asked you to take part in this study.

If you and your child agree to take part in the study, you will be asked to fill in a consent form to confirm this. You can do this at home and post it or email it to us, or give it to the research nurse or fill in the form on line.

If you child takes part in the study, we need to make sure that both groups are matched as this is the only way we can compare groups and make sure the study is fair. You child will be randomly allocated (in other words, by chance) to one of two groups: either Activity Management or Graded Exercise Therapy. As this study is trying to find out whether we can compare both groups, it will not be possible for you to choose the group for your child.

Second stage:

In the second stage of the study your child will have treatment for their CFS/ME. Children in both groups will be seen regularly in the specialist service and receive assessment and treatment for symptoms and sleep. We think they will probably be seen 8-12 times but you will be able to decide how often and for how long.
We will ask you to complete a questionnaire when your child first joins the study. You and you child 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 child (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 child's mood and activities that change mood in young people. For example, whether children drink alcohol or take drugs. This information might be helpful to the clinician who looks after your child. You can decide whether they know or not. For most people, this discussion will take less than an hour. We will not continue if your child gets tired. You can take breaks if you need them.

Children in both groups will be asked to wear an accelerometer. This is a small box that they will wear on a band around their hips. Lots of young people have used these to measure exercise. We may ask your child to record when they wear it and when they take it off.

In addition, your child will get either Activity Management or Graded Exercise Therapy

Activity Management

If your child is in this group they will have a detailed assessment of the total activity they do each day. This will mainly be thinking activity such as school work, homework, time on the computer and screens, reading and hobbies that require concentration. It will also include the amount of time spent doing physical activity such as walking or PE but we will not ask for any detail of exercise or for this to be recorded separately. We call all of this "high energy activity".

We will ask your child to record this on paper or our iPhone app “ActiveME”. We will then help them find their “baseline” activity which is the average amount of activity that they do each day. When your child has found their baseline, we will help them increase their activity by 10-20% each week.

Graded Exercise Therapy

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

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

Activity Management will work on the total amount of activity done each day. This is mainly thinking activities. It does not provide specific advice about exercise include a physical assessment or heart rate monitoring. Graded Exercise Therapy provides specific advice about exercise with a physical assessment and uses heart rate monitoring.

Are there any disadvantages to my child taking part in this study?

You and your child will need to spend time talking to a clinician for about 10 minutes and a research nurse for about 30 minutes to understand about the study.

If you take part, you will complete a questionnaire when your child first joins the study. You and your child will also need to complete questionnaires at 6 months and 12 months after starting the study. We ask all children to complete these questionnaires. We will also ask you to complete questionnaires so we can measure the cost of treatment. These questionnaires will take you about 20 minutes.

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

Treatments for CFS/ME don’t help everybody and you may find the treatment your child has been offered does not help them. This could be true for both treatments. Young people with CFS/ME can get worse with any intervention offered and we do not know how likely this is. If your child does not get better with the treatment, they can have the other treatment after 6 months if they want it.

Will my child 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 of these two treatments.

What are the benefits of my child taking part in this study?

Your child may benefit from the treatment they receive, but we cannot guarantee this. Some children with CFS/ME like to know that they are helping other children in the future. Your child may also learn about research.

What will happen when the study stops?

After the study stops, your child will continue to have specialist medical care if they still need it. Your child will also continue to receive follow up questionnaires, like the young people who did not take part in the study.

Research can take quite a long time but if you give us your email address we will write to you and let you know what we find out when we finish the study if you are interested.

PART 2

If you are considering your child taking part in this study, please read the additional information below before deciding.

Consent

We have to be absolutely certain that you are happy for your child to join in this study, so if you say you are, we will ask you to sign our consent form. We will also ask you to sign a consent form if your child is aged between 8 -15 and we discuss the study with them. Even if you do sign the forms on behalf of your child, you will be free to withdraw your child at any point. Just tell us if this is the case. Whether or not you wish your child to participate, your child will continue to receive the same care from the clinical team.

Your privacy and data protection

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

We will only use a research code to identify your child on data. No name or personal information will be on the questionnaires we send out to you or your child. 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.

Quotes from conversations will be used when results are published but the names of the people quoted will not be used so no one will know who was speaking. We would like to keep anonymised data and quotes collected during the study so that the University of Bristol's School of Social and Community Medicine can use it for research and teaching purposes now, and in the future. We will ask you to tell us if you are happy for us to them in this way.

If you tell us something that makes us worried about yours or your child's 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 the necessary police checks to make sure they are safe to work with children and young people.

Who will know that my child is taking part in the study?

We think your child's GP should know that they are taking part in this study because they need to know what happens to your child. We will write to their GP to tell them which treatment they will be receiving in the study.

What will happen to the results of the study?

This study will test how effective Graded Exercise Therapy is compared to Activity Management. It will also tell us if it is good value for money or not.

What if new information becomes available?

If new information becomes available, we will tell you about it and discuss with you 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 governments 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 Dr Esther Crawley or any member of the clinical team. Dr Crawley's contact details can be found at the end of this leaflet.

In the event that something does go wrong and your child is harmed during the research and this is due to someone being careless then you may be able to take legal action to get repayment from the hospital but in this case you may need to pay a lawyer to help you. You can also use the normal National Health Service system for complaints: Patient Advice and Liaison services (PALS) 01225 473424.

Will I need to pay for my child 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.

Contact / further information:

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

Address:

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