

MAGENTA

Managed Activity Graded Exercise in Teenagers and pre-Adolescents



Information leaflet for children aged 8-11 years

We would like to invite you to take part in a research study which will tell us if we can find out whether one type of treatment for CFS/ME works compared to another treatment.

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

Ask us if there is anything you don't understand.

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

Thank you for reading this!

Why have I been asked to take part?

We are asking you to take part because you have CFS/ME and you come to our service.

Do I have to take part?

You do not have to take part in this study. It is up to you. Your parents or your carers can help you decide. You can stop at any time.

If you decide you don't want to take part you can still use the CFS/ME service as usual.

Why are we doing this study?



We want to know which treatment is better – Activity Management or Graded Exercise Therapy for children with CFS/ME.

We want to know if children want to take part in our study and the best way to ask children to take part.

If you decide to take part we will ask you to do either Activity Management or Graded Exercise Therapy.

What will happen if I take part?

Part 1 – finding out about the study

A doctor at your CFS/ME centre will tell you a little bit about the study and invite you to take part. If you are interested in the study, the doctor will ask a nurse to speak with you and your parents/carers to give you more information.



When you speak with the nurse, the nurse will ask if they can record the conversation. You can ask the nurse any questions you have.

When you have heard all of the information and asked any questions, you will be asked if you would like to take part in the study. You can go home and think about it with your parents/carers.

Part 2 – taking part in the study

All children will have treatment for their symptoms such as pain and all children will get help with their sleep. We will ask you to fill out questionnaires (like the ones you filled in already) in 6 months and 12 months time.

We will also ask you to wear something called an “accelerometer”. This is very small and measures your exercise. You only have to wear this for a week at the start, at 3 months and 6 months.

We need the groups to be the same to make the study fair. That means that a computer will decide which treatment you have, a bit like rolling a dice for a game. Your nurse or doctor, or you or your parents cannot decide.



One group is called **Activity Management**. If you are in this group we will mainly be helping you do the same amount of total activities each day. This will mainly be thinking activities like school work, seeing friends, reading and spending time on the computer.

The other group is called **Graded Exercise Therapy**. If you are in this group we will mainly be helping you manage the amount of exercise you do each day.

If you decide that you don't want to take part at any point, that is ok, and you don't have to say why.

What might be hard about taking part?

If you take part you will need to fill out questionnaires like the ones you did in the clinic which might take a little bit of time and effort. We might ask you to talk to a research nurse about the study.

We don't know if the treatment you have will make you feel better. You might feel better or you might feel the same, or you might feel worse.

What are the good things about taking part?

Some children like taking part in research because they know it will help children in the future.

What will happen when the study stops?

After the study stops, you will continue to get the same help from your CFS/ME service if you still need it. Research can take quite a long time to complete, but if you give us an email address we will write to you and let you know what we find out when we finish the study.

What will happen to all of the information about me?

All of the information you tell us will be kept private. Your name will be replaced by a number on the documents we keep about you so that you cannot be identified from them.



We will look at all of the information you and other children have given us and write about it to help other doctors help more children with CFS/ME.

What if there is a problem?

We will try and help with any problems you may have. If you get upset we will make sure someone helps you.

All of the researchers involved in the study have had special checks for working with children.

You, or your parents/carers can talk to Dr Esther Crawley who is organising the study by calling 01225 465 941 or emailing esther.crawley@bristol.ac.uk.

THANK YOU for reading this leaflet!