

How effective is FITNET-NHS for children and young adults with CFS/ME

Information Leaflet for Parents/Carers

We would like to invite you and your child to take part in a research study which will tell us how effective FITNET-NHS (online cognitive behavioural therapy) is compared to Activity Management for Chronic Fatigue Syndrome or Myalgic Encephalopathy (CFS/ME) in young people.

Before you decide whether you would like your child to take part, it is important for you and your child to understand *why* the study is being done and *what* it will involve. The leaflet is divided into two parts. Part 1 tells you about the study and what will happen to you and 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 the study?

We want to test whether a treatment called 'FITNET-NHS', which delivers cognitive behavioural therapy (CBT) for CFS/ME at home via the internet, is effective and value for money. CBT focuses on cognitive behavioural strategies to identify, challenge and change cognitive (thinking) processes. We want to compare this with another treatment for CFS/ME called Activity Management which will be delivered via video call (e.g. Skype).

In the first part of the study, we want to know whether young people will take part in the study and whether young people think FITNET-NHS and Activity Management are acceptable treatments.

In the second part of the study, we want to see how effective FITNET-NHS and Activity Management are at treating young people with CFS/ME and measure the costs of each treatment.

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 11 and 17 years, have a diagnosis of CFS/ME and do not have a local specialist CFS/ME service.

If you feel that either you or your child will not be able to read and understand the study materials or have no phone or internet/video call (e.g. Skype) access this would mean they should not take part.

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 speak to the research nurse who will explain more about the study, this will not commit your child to taking part in the study.

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.

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

What would we ask you and your child to do?

Before the treatment:

If you would like further information about the study, the research team will arrange a time to discuss the study with you and your child over the telephone. The research team will explain the study and answer any questions you may have. This discussion will be audio-recorded with your permission and will last about **45 minutes** but you can talk for longer if you have more questions. The research team may ask you and your child about how you felt when you were asked if you wanted 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 an on-line consent form to confirm this.

If your child takes part in the study, we need to make sure that both groups are as similar as possible. This is the only way we can compare groups and make sure the study is fair. Your child will be allocated to either Activity Management or FITNET-NHS by a process of randomisation (in other words, by chance). Half of those taking part in the study will receive Activity Management and half will receive FITNET-NHS, so your child will have a 50% chance of getting either treatment. As this study is trying to compare both treatments it will not be possible for you to choose which treatment you would like for your child. Both treatments have been used before.

During the treatment:

Your child will receive treatment for their CFS/ME at home via the internet. Children in **both** groups will receive an assessment, treatment and advice from members of Bath Specialist CFS/ME Service about how to improve symptoms and sleep. You and your child will need to complete questionnaires at baseline, 3 months, 6 months and 12 months which will take you about **20 minutes** each time.

We want to find out more about what you and your child think about this study. A researcher may ask to speak with you and/or your child over the phone to find out what you think about the study or the treatments. With your permission we would like to audio-record these discussions. This may last around 30 minutes. It is up to you and your child if you want to do this or not.

In addition, your child will get either Activity Management or FITNET-NHS.

Activity Management

If your child is in this group they will receive up to six video (e.g. Skype) calls with a therapist. For the initial assessment appointment, 90 minutes is allocated, which allows plenty of time to explain the treatment and answer any questions which arise. There is flexibility with the length of the appointment and it may only take 45 -60 minutes, depending on the needs of you and your child. During this first video (e.g. Skype) call, they will have a detailed assessment of the total activity they do each day. 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 them to record their activity 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 can do each day. When they have found their baseline activity, we will provide follow up video (e.g. Skype) calls to help them increase this by 10-20% each week. Each follow up call usually takes around **60 minutes**. This is called Activity Management.

FITNET-NHS

If your child is in this group both you and they will be asked to work through 19 interactive treatment chapters on-line. Each chapter will take about **60 minutes** to complete. These chapters are based on cognitive behavioural therapy (CBT) treatment specifically developed for children with CFS/ME. Chapters focus on what CBT is and how it works, ‘helpful thoughts’ and ‘shifting attention away from fatigue’ to teach you and your child to think differently and problem solving to help your child build up physical, mental (including school) and social activities. It also helps develop treatment goals and discusses the role of the family in the treatment process. Your child will be asked to read through the chapters, answer questions and complete diaries online. Parents’ sections explore and address parents’ beliefs and behaviours towards their child with CFS/ME focussing on their role as carers. The therapist works with parents and children separately and provide weekly e-consultations (emails) with children and parents to review homework and support behaviour change. Researchers will look at the messages you and your child send to the therapist and the messages they send to you to help us to understand how to best use online treatment in the future, but only if you consent to this.

What is the difference between the two treatments?

Both treatments will: give advice on sleep and building up physical, thinking and school activities, have one-to-one contact with a therapist and give advice based on your child’s individual symptoms, activity levels and goals.

In Activity Management, you and your child will talk to a therapist over Skype. In FITNET, you and your child will talk to a therapist over emails and complete treatment chapters online. FITNET also includes chapters focusing on CBT, helpful thoughts and shifting attention away from fatigue.

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

You and your child will initially need to spend time talking to the research team for about **10 minutes** so we can understand if you are interested in hearing more about the study. If you and your child are potentially interested in taking part, you and your child will need to arrange a time to talk on the phone to the research team to hear more about the study. This will take about **45 minutes**.

If you and your child take part, your child will have to spend time completing the treatment. For Activity Management this will be up to **90 minutes** for the initial assessment and **60 minutes** for each follow up call. For FITNET-NHS your child will spend approximately **60 minutes** on each online chapter. We think each parental chapter will take **10 - 15 minutes**.

If you take part, both you and your child will need to complete questionnaires at baseline, 3 months, 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** each time.

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.

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

We have used Activity Management and face-to face CBT in our service and are not aware of any side effects. A study of on-line CBT treatment for children with CFS/ME has also shown that there were no side effects.

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 can continue to have medical care from their local team if they still need it. 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 certain that you and your child are happy to join in this study, so if you say you are, we will ask you to sign our consent form. We will also discuss the study with your child and ask them to sign an assent form if they are aged between 11 -15 or a consent form if they are aged between 16 –17. We will also ask you and your child to sign one of these forms if you are happy for us to record discussions with you. Even if you do sign the forms on behalf of your child, you will be free to stop the recording or 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.

Will you access my child's health records?

A great deal of information is collected and stored about all of us in our official records. This information gives a detailed picture of many aspects of our life, such as our health and the treatment we get in the NHS. The FITNET-NHS study can use this together with the information you and your child give us to help us understand how well FITNET-NHS works, how much the NHS spends on treatment and whether FITNET-NHS reduces or increases these costs. We will be able to tell whether those taking part in the study get other illnesses and check which treatments they get.

Information can only be released with your/your child's permission. In order to make sure we collect information on the right person we will provide the minimum necessary personal details (such as your name and address) to the organisations holding the information, for example your general practitioner (GP). These will only be used to identify your information. Before the organisations send any information you have authorised back to us, your name and other

details will be removed. None of the information you have told us, will be given to these organisations. In the same way as the answers you give us in the questionnaires, the information from the sources will be kept completely confidential in accordance with the Data Protection Act. This process of bringing together all these different pieces of the jigsaw of our lives is called 'data-linkage'.

Health records include those held by your GP and The Health & Social Care Information Centre. This includes data on Hospital Episode Statistics (e.g. details of visits to your doctor and any treatment you were given; if you have ever been to hospital, why you were there and what happened whilst you were there) and the Mental Health and Learning Disabilities Data Set (e.g. details of treatment you may have received for things like depression and anxiety). When we ask for sensitive information it's because we want to use this information to help us understand why things are the way they are and use this understanding to help people to be healthier.

If your child is aged between 11-15 years of age, all you need to do is agree to us accessing your child's health records on the consent form and we will do the rest. If your child is 16-17 years of age we will ask them whether they are happy for us to access their health records. We will regularly request copies of your child's records from the relevant organisations to look at additional information that may have been added.

You can chose not to agree to us accessing your child's medical records without it affecting your child's involvement in the rest of the study. You are free to tell us to stop at any time without giving a reason. Your decision will not in any way affect the treatment your child gets from the NHS.

Your privacy and data protection

Any information that you give us will be completely private. The conversations that you have given your permission to be recorded will be encrypted and password protected (so that only members of the study team can listen to them). They will then be stored on a secure University of Bristol server.

We will use a research code to identify your child's 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 or your child will be kept secure in locked cabinets in locked offices or password protected on secure NHS or University of Bristol computers.

Quotes from conversations, including from messages sent to the therapist (if you consent to this), 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 or your child 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 and your child are safe. This means, what you say would not be kept completely private if we are sufficiently concerned about you or those around you. We would do the same if you told us something in clinic.

You can find out more about how we use your information at:

<https://www.bristol.ac.uk/ccah/research/childdevelopmentdisability/chronic-fatigue/fitnet-nhs/participantinfo/>

What will happen if my child feels unwell during the study?

If during the course of the study your child starts to feel unwell (e.g. if they feel anxious or depressed, or if they have a fever), you should contact your child's local care providers (e.g. GP or paediatrician). The research team provide specialist treatment for CFS/ME but cannot provide treatment for other problems your child may have.

If your child does contact the CFS/ME research team about other concerns (e.g. feeling anxious or depressed), the research team will do their best to help. If they feel it's appropriate they may pass the information on to your child's local care providers and try to inform your child of other services which may help. The CFS/ME research team may not be able to reply to your child's queries immediately (e.g. if your child sends the research team a message with concerns on a Saturday it may not be picked up until the Monday). This is why you should always contact your local care provider if you or your child have any health-related concerns.

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?

Your child's GP should know that they are taking part in this study so we will write to them to tell them which treatment your child will be receiving in the study.

What will happen to the results of the study?

This study will give us information on whether young people are interested in taking part in a study like this and whether they think the "Activity Management" and "FITNET-NHS" treatments are acceptable. It will also tell us how effective these treatments are at helping young people with CFS/ME and how much the treatments cost.

What if new information becomes available?

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

Who is organising and funding the study?

This research is organised by Professor 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 University of Bristol.

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

If you have any problems with this study, please speak to Professor Esther Crawley or any member of the clinical team. Professor 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 South West – Frenchay Research Ethics Committee.

Contact details and further information

Prof Esther Crawley - Paediatric Consultant/Clinical Lead of the Paediatric CFS/ME Service

Address: Paediatric CFS/ME Service, Children's Centre, Royal United Hospital, Combe Park, Bath, BA1 3NG

Tel: 01225 821340

Email: esther.crawley@bristol.ac.uk

Or if you want to talk to somebody independent please contact:

Jane Carter - Research Lead

Address: RUH 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