

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

Information Leaflet for Young People Aged 16-17 Years

We would like to invite you 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 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 into two parts.

Part 1 tells you about the study and what will happen to you 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 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, like you, 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 have I been asked to take part?

You have been asked to take part in this study because you 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 are not able to attend telephone or online consultations required for the research study (e.g. you don't have a phone line or internet/video call (e.g. Skype) access at home), you will not be able to take part.

Do I have to take part?

You do not have to take part in this study. If you agree to speak to the research team, 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 treatments, you should not enter the study.

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 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 medical care you will receive.

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

Before the treatment:

If you would like to hear more about the study, the research team will arrange a time to talk to you over the telephone. The research team will explain the study to you and your parents/carers, and answer any questions you may have. With your permission, this discussion will be audio-recorded and will last about **45 minutes**, but you can talk for longer if you have more questions. The research team might ask you about how you felt when you were asked if you wanted to take part in this study.

If you want to take part in the study, you will be asked to fill in an on-line consent form to show us that you agree.

If you take part in this study, we need to make sure that participants in both groups areas similar as possible. This is the only way we can compare the groups and make sure the study is fair. You will therefore be allocated to either Activity Management or FITNET-NHS by a process of randomisation. Half of those taking part in the study will receive Activity Management and half will receive FITNET-NHS, so you will have a 50% chance of getting either treatment. Both treatments have been used before.

During the treatment:

You will receive treatment for your CFS/ME at home via the internet. **Both** groups will get lots of advice from members of Bath Specialist CFS/ME Service about how to improve your sleep and you will get treatment for your symptoms. You and your parents/carers 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 think about this study. A researcher may ask to speak with you and your parents/carers over the phone to find out what you think about the study or the treatments. This discussion will be audio-recorded with your permission. This may last around 30 minutes. It is up to you if you want to do this or not.

In addition you will get either Activity Management or FITNET-NHS.

Activity Management

If you are in this group you 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 this first appointment and it may only take 45 -60 minutes, depending on your needs. During this first video (e.g. Skype) call, 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 provide follow up video (e.g. Skype) calls to help you increase this by 10-20% each week. Each follow up call usually takes around **60 minutes**. This is called Activity Management.

FITNET-NHS

If you are in this group both you and your parents will be asked to work through 19 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'. The treatment teaches you and your parent(s) to think differently and problem solving to help you 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. You will be asked to read through the chapters, answer questions and complete diaries online. Your parents will also have to work through sections separately in which they will explore their beliefs and behaviours towards your CFS/ME and focus on their role as carers. The therapist will work with you and your parents and provide weekly e-consultations (emails) to review homework and support you. Researchers may look at the messages you 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 individual symptoms, activity levels and goals.

In Activity Management, you and your parent(s) will talk to a therapist over Skype. In FITNET, you and your parent(s) 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 taking part in this study?

You 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 are potentially interested in taking part, you and your parents/carers 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 take part, you will have to spend time completing the treatment. For Activity Management this will be up to **90 minutes (usually between 45-60 minutes)** for the initial assessment and **60 minutes** for each follow up call. For FITNET-NHS you will spend approximately **60 minutes** on each on-line chapter. We think your parents will spend about **10 - 15 minutes** on each chapter.

If you take part, you and your parents/carers will need to complete questionnaires at baseline, 3 months, 6 months and 12 months. We ask all young people to complete these questionnaires. These questionnaires will take you about **20 minutes** each time.

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 FITNET-NHS. This is why we are doing a study.

Will I 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 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 can continue to have medical care from your local team if you still need it. 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 this study, please read the information below before making your decision.

Consent

We have to be certain that you are happy to join this study, so we will ask you to sign a consent form. We will also ask you to sign one of these forms if you are happy for us to record discussions with you. Once you have signed the forms, you will still be free to stop the recording or leave the study at any point. Just tell us know 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.

Will you access my 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 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 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 organisation. 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.

All you need to do is agree to us accessing your health records on the consent form and we will do the rest. We will regularly request copies of your records from the relevant organisations to look at additional information that may have been added.

You can choose not to agree to us accessing your medical records without it affecting your 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 you get from the NHS.

What will happen to the information you collect about me?

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

We will 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 may also use some of the things you say in messages sent to your therapist (if you consent to this) but we will also make sure that no one will know who was writing the message.

We would also like to keep the things you say so that other researchers can use it anonymously 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 or the safety of those around you, we may have to discuss this with somebody else. This means, what you say would not be kept completely private if we were 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 I feel unwell during the study?

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

If you do 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 local care providers and try to inform you of other services which may help you. The CFS/ME research team may not be able to reply to your queries immediately (e.g. if you send 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 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 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?

Your GP should know that you are taking part in this study so we will write to them 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 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 compared with each other at helping young people with CFS/ME and how much the treatments cost.

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 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 your parents/carers, Professor Esther Crawley, or any member of the clinical team that you know. Professor Crawley’s contact information can be found at the end of this information leaflet.

You can also complain to the NHS in the usual way through the Patient Advice and Liaison Services (PALS) on 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 South West – Frenchay Research Ethics Committee.

Who can I contact for 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