







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

Submission date 03/08/2016	Recruitment status No longer recruiting	 Prospectively registered
		 Protocol added
Registration date 04/08/2016	Overall study status Completed	 SAP added
		 Results added
Last Edited 18/03/2022	Condition category Nervous System Diseases	 Raw data not yet added
		 Study completed

Plain English Summary

Current plain English summary as of 01/07/2019:

Background and study aims

Children who have Chronic Fatigue Syndrome or myalgic encephalomyelitis (CFS/ME) have fatigue that stops them going to school or doing other activities for more than 3 months. In England, up to 2 in 100 children have CFS/ME and 1% of secondary school children miss a day a week or more because of it. Most children with CFS/ME will recover if they receive specialist treatment, such as Cognitive Behaviour Therapy (CBT) or Activity Management. However, about 90% of children in the UK cannot have treatment because they live too far away from specialist services. For these children, probably only 8% will recover at 6 months. One solution is for these children to receive specialist CBT for CFS/ME using the internet at home. FITNET-NHS provides internet-based CBT for CFS/ME and has been shown to be effective in the Netherlands with 63% of children recovering at 6 months. We cannot use this treatment in the NHS until we know if children find it acceptable, and we know if it is effective and good value for money. We also need to know if FITNET-NHS will work in children with both CFS/ME and mood problems (one third of children with CFS/ME). The aim of this study is to test whether FITNET-NHS, a treatment delivered via the internet, is effective and value for money for children with CFS/ME.

Who can participate?

Children aged 11 to 17 years with CFS/ME who have no local specialist CFS/ME service

What does the study involve?

Participants are randomly allocated to be treated with either Activity Management or FITNET-NHS. Those who get Activity Management receive information on managing activities and sleep. They have six Skype calls (one assessment and five follow-up) with CFS specialist therapists to understand and provide advice on sleep and activity. The specialist therapist hands over care to the local GP or paediatrician but provides support to them with up to three phone calls. Those who get FITNET-NHS (and their parents) are given information and then work through up to 19 interactive CBT modules. Children are asked to do homework (answer questions and complete diaries). CBT-trained therapists make weekly appointments with the children and their parents to review homework and support behaviour change. Disability is assessed at 6 months, and fatigue, pain, quality of life, anxiety and depression are measured at 3, 6, 9 and 12 months, along

with information on how much the NHS and families spend on treatment and whether parents return to work.

What are the possible benefits and risks of participating?

Most children in the UK are unable to access treatment because there is no local specialist service. Children who take part in this study will be offered treatment delivered by specialist CFS/ME therapists in both groups. If FITNET-NHS is effective, it may reduce NHS and wider costs to society, improve school attendance and quality of life, and change attitudes about paediatric CFS/ME being “untreatable” to being “treatable”. There is a small risk that the study may recruit children that do not have CFS/ME but instead have other disorders that present with fatigue. To avoid this we have put in place rigorous tests to ensure that other causes of fatigue are diagnosed and referred for appropriate treatment. If children are recruited with fatigue and other disorders, the treatment approaches offered are sufficiently generic approaches to fatigue, they are likely to benefit to some extent.

Where is the study run from?

Royal United Hospitals Bath NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

May 2016 to January 2022

Who is funding the study?

Health Technology Assessment Programme (UK)

Who is the main contact?

Prof. Esther Crawley

Previous plain English summary as of 09/07/2018:

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the local GP or paediatrician but provides support to them with up to three phone calls. Those who get FITNET-NHS (and their parents) are given information and then work through 19 interactive CBT modules. Children are asked to do homework (answer questions and complete diaries). CBT-trained therapists make weekly appointments with the children and their parents to review homework and support behaviour change. Disability is assessed at 6 months, and fatigue, pain, quality of life, anxiety and depression are measured at 3, 6, 9 and 12 months, along with information on how much the NHS and families spend on treatment and whether parents return to work.

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Where is the study run from?

Royal United Hospitals Bath NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

May 2016 to October 2021

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Prof. Esther Crawley

Previous plain English summary:

Background and study aims

Children who have Chronic Fatigue Syndrome or myalgic encephalomyelitis (CFS/ME) have fatigue that stops them going to school or doing other activities for more than 3 months. In England, up to 2 in 100 children have CFS/ME and 1% of secondary school children miss a day a week or more because of it. Most children with CFS/ME will recover if they receive specialist treatment, such as Cognitive Behaviour Therapy (CBT) or Activity Management. However, about 90% of children in the UK cannot have treatment because they live too far away from specialist services. For these children, probably only 8% will recover at 6 months. One solution is for these children to receive specialist CBT for CFS/ME using the internet at home. FITNET-NHS provides internet-based CBT for CFS/ME and has been shown to be effective in the Netherlands with 63% of children recovering at 6 months. We cannot use this treatment in the NHS until we know if children find it acceptable, and we know if it is effective and good value for money. We also need to know if FITNET-NHS will work in children with both CFS/ME and mood problems (one third of children with CFS/ME). The aim of this study is to test whether FITNET-NHS, a treatment delivered via the internet, is effective and value for money for children with CFS/ME.

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What does the study involve?

Participants are randomly allocated to be treated with either Activity Management or FITNET-NHS. Those who get Activity Management receive information on managing activities and sleep. They have three Skype calls (one assessment and two follow up) with CFS specialist therapists to understand and provide advice on sleep and activity. The specialist therapist hands over care to the local GP or paediatrician but provides support to them with up to three phone calls. Those who get FITNET-NHS (and their parents) are given information and then work through 19 interactive CBT modules. Children are asked to do homework (answer questions and complete diaries). CBT-trained therapists make weekly appointments with the children and their parents to review homework and support behaviour change. Disability is assessed at 6 months, and fatigue, pain, quality of life, anxiety and depression are measured at 3, 6, 9 and 12 months, along with information on how much the NHS and families spend on treatment and whether parents return to work.

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Study website

<http://www.bristol.ac.uk/fitnet-nhs/>

Contact information

Type(s)

Scientific

Contact name

Prof Esther Crawley

ORCID ID

<http://orcid.org/0000-0002-2521-0747>

Contact details

Centre for Academic Child Health
Population Health Sciences
University of Bristol
Bristol
United Kingdom
BS8 1NU
+44 (0)1225 821340
fitnet-nhs@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

HTA 14/192/109

Study information

Scientific Title

Investigating the effectiveness and cost-effectiveness of using FITNET-NHS (Fatigue In Teenagers on the interNET in the NHS) compared to Activity Management to treat paediatric Chronic Fatigue Syndrome (CFS)/Myalgic Encephalomyelitis (ME) in the United Kingdom: a randomised controlled trial (FITNET-NHS)

Acronym

FITNET-NHS

Study hypothesis

FITNET-NHS is more effective and cost-effective than Activity Management for treating paediatric CFS/ME.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/14192109>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Frenchay Research Ethics Committee, 10/10/2016, ref: 16/SW/0268

Study design

Single-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Treatment

Participant information sheet

<http://www.bristol.ac.uk/fitnet-nhs>

Condition

Paediatric CFS/ME

Interventions

Current interventions as of 09/07/2018:

A single-centre randomised controlled trial investigating the effectiveness and cost-effectiveness of using FITNET-NHS (internet delivered cognitive behavioural therapy) compared to Activity Management to treat paediatric Chronic Fatigue Syndrome (CFS)/Myalgic Encephalomyelitis (ME) in the United Kingdom. Participants will be allocated in a 1:1 ratio, minimised by age and gender, to each of the interventions. An internal pilot study has been conducted with continuation of the trial based on achieving defined stop criteria. Integrated qualitative research methods have been used to optimise recruitment and retention.

Activity Management arm (comparator): specialist CFS/ME occupational therapists deliver activity management over a series of video calls to the participants. This includes help with activity management, symptom management, sleep and problem solving.

FITNET-NHS arm (intervention): The FITNET-NHS intervention delivers specialist cognitive behavioural therapy (CBT) for CFS/ME via the internet at home. Participants and their parents work through up to 19 modules and have e-consultations with CBT therapists.

Previous interventions:

A single-centre randomised controlled trial investigating the effectiveness and cost-effectiveness of using FITNET-NHS (internet delivered cognitive behavioural therapy) compared to Activity Management to treat paediatric Chronic Fatigue Syndrome (CFS)/Myalgic Encephalomyelitis (ME) in the United Kingdom. Participants will be allocated in a 1:1 ratio, minimised by age and gender, to each of the interventions. An internal pilot study will be conducted with continuation of the trial based on achieving defined stop criteria. Integrated qualitative research methods will be used to optimise recruitment and retention.

Activity Management arm (comparator): specialist CFS/ME occupational therapists delivery activity management over video call to the participants. This includes help with activity management, symptom management, sleep and problem solving.

FITNET-NHS arm (intervention): The FITNET-NHS intervention delivers specialist cognitive behavioural therapy (CBT) for CFS/ME via the internet at home. Participants and their parents work through 21 modules (Amended on 01/09/2017 to 19 modules) and have e-consultations with CBT therapists.

Intervention Type

Behavioural

Primary outcome measure

Disability measured using the Physical Function Scale (SF-36-PFS) at 6 months after randomisation

Secondary outcome measures

Secondary outcomes are measured at 3, 6 and 12 months unless otherwise specified, and include:

1. SF36-PFS measured at 3 and 12 months after randomisation
2. Fatigue (Chalder scale and Checklist Individual Strength (CIS) fatigue severity subscale)
3. School attendance (self-report school or home tuition)
4. Mood (Revised Children's Anxiety and Depression Scale (RCADS))
5. Pain visual analogue scale
6. Clinical Global Impression Scale
7. Quality of Life (EQ-5D-Y)
8. Parental completed: Healthcare Resource Use questionnaire
9. Parental completed: Work Productivity & Activity Impairment Questionnaire General Health (WPAI:GH)

Overall study start date

01/05/2016

Overall study end date

12/01/2022

Eligibility

Participant inclusion criteria

1. Children aged 11 to 17 years
2. Children with CFS/ME (defined using NICE guidance)
3. Children with no local specialist CFS/ME service

Participant type(s)

Patient

Age group

Child

Lower age limit

11 Years

Upper age limit

17 Years

Sex

Both

Target number of participants

314

Total final enrolment

314

Participant exclusion criteria

1. Children not disabled by fatigue
2. Children whose fatigue is due to another cause
3. Children or parents unable to complete video calls (e.g. Skype) or FITNET-NHS modules (e.g. unable to read FITNET-NHS material, or significant development problems, or limited internet access, unwilling/unable to set up personal email address/video call (e.g. Skype) account)

Recruitment start date

01/11/2016

Recruitment end date

11/11/2020

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Royal United Hospitals Bath NHS Foundation Trust

United Kingdom

BA1 1RL

Sponsor information**Organisation**

University of Bristol (UK)

Sponsor details

Research and Enterprise Development

One Cathedral Square

Bristol

England
United Kingdom
BS1 5DD

Sponsor type
University/education

ROR
<https://ror.org/0524sp257>

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We intend to publish the protocol, the results of the internal pilot and the results of the full trial.

Intention to publish date
30/04/2023

Individual participant data (IPD) sharing plan
Given the nature of this data set, access is controlled. Requests are referred to the University of Bristol Data Access Committee (DAC) for approval before data can be released under an appropriate data access agreement. For details on how to access data please see the data repository search record at <https://data.bris.ac.uk/data/>.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/02/2018	23/12/2019	Yes	No
Protocol article	protocol update	19/12/2019	23/12/2019	Yes	No
Results article	pilot phase results	12/08/2020	17/08/2020	Yes	No
Statistical Analysis Plan	version 1	06/10/2021	08/11/2021	No	No
HRA research summary			28/06/2023	No	No