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

Submission date 03/08/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered
		[X] Protocol
Registration date 04/08/2016	**Overall study status** Completed	[X] Statistical analysis plan
		[X] Results
Last Edited 10/06/2025	**Condition category** Nervous System Diseases	☐ Individual participant data

Plain English summary of protocol

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

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May 2016 to October 2021

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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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Prof. Esther Crawley

Contact information

Type(s)
Scientific

Contact name
Prof Esther Crawley

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Additional identifiers

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 objectives
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
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(s)
Disability measured using the Physical Function Scale (SF-36-PFS) at 6 months after randomisation

Key secondary outcome(s))
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)

Completion date
12/01/2022

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 years

Upper age limit
17 years

Sex
All

Total final enrolment
314

Key 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)

Date of first enrolment
01/11/2016

Date of final enrolment
11/11/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
United Kingdom
BA1 1RL

Sponsor information

Organisation
University of Bristol (UK)

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Results article	pilot phase results	12/08/2020	17/08/2020	Yes	No
Results article		31/10/2024	04/11/2024	Yes	No
Protocol article	protocol	22/02/2018	23/12/2019	Yes	No
Protocol article	protocol update	19/12/2019	23/12/2019	Yes	No
HRA research summary			28/06/2023	No	No
Other unpublished results			10/06/2025	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	version 1	06/10/2021	08/11/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes