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# MAGENTA: Managed activity graded exercise in teenagers and pre-adolescents

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 03/09/2015 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [X] Statistical analysis plan |
| 03/09/2015 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 04/03/2024 | Nervous System Diseases | |

## Plain English summary of protocol

Background and study aims
Chronic fatigue syndrome (CFS), also known as myalgic encephalomyelitis (ME), is a condition which causes persistent exhaustion, which is not relieved by sleep or rest. It is relatively common in children and can be very disabling, seriously affecting their education, family and social life. In the UK, national guidance (NICE) recommends that children suffering from CFS/ME should be offered graded exercise therapy (GET), cognitive behavioural therapy (CBT) or activity management (AM), all of which teach people ways of coping with their condition day-to-day. GET has been shown to be very helpful in adults suffering from CFS/ME; however there are very few studies which look at how effective it is in children, and whether it is an economical treatment option. The aim of this study is to find out how successful and cost-effective GET is compared to AM for the treatment of CFS/ME in children.

Who can participate?
Children between 8 and 17 years old who have been diagnosed with CFS/ME.

What does the study involve?
Participants are randomly allocated into two groups. Children in group one are given AM, and those in group two are given GET. The children and their parents are then interviewed in order to judge how well the treatment is working.

What are the possible benefits and risks of participating?
Participants will not benefit directly from taking part in the study although it may prove enjoyable contributing to the research. There are no risks of participating in the study.

Where is the study run from?
Centre for Child & Adolescent Health, University of Bristol (UK)

When is the study starting and how long is it expected to run for?
September 2015 to March 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Chris Metcalfe, chris.metcalfe@bristol.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Mr Chris Metcalfe

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
176764

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
CPMS 19035

# Study information

### Scientific Title
A randomised controlled trial investigating the effectiveness and cost effectiveness of graded exercise therapy compared to activity management for paediatric CFS/ME

### Acronym
MAGENTA

### Study objectives
Current hypothesis as of 27/03/2017:
Feasibility trial:
It is feasible and acceptable to conduct a trial investigating the effectiveness and cost-

effectiveness of graded exercise therapy compared to activity management for the treatment of CFS/ME in children.

Full trial:
The aim of this study is to
1. Estimate the effectiveness of Graded Exercise Therapy compared to Activity Management for paediatric CFS/ME
2. Estimate the cost effectiveness of Graded Exercise Therapy and Activity Management

Previous hypothesis:
It is feasible and acceptable to conduct a trial investigating the effectiveness and cost-effectiveness of graded exercise therapy compared to activity management for the treatment of CFS/ME in children.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
NRES Committee South West - Frenchay, 03/07/2015, ref: 15/SW/0124

Favourable ethical opinion to amend from feasibility to full trial: NRES Committee South West - Frenchay, 06/03/2017, ref: 15/SW/0124

## Study design
Current study design as of 27/03/2017:
Feasibility trial:
Multi-centre randomized controlled feasibility trial

Full trial:
Multi-centre randomized controlled trial

Previous study design:
Randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Topic: Children; Subtopic: All Diagnoses; Disease: All Diseases

## Interventions
Current intervention as of 27/03/2018:
Feasibility trial and full trial:
Children are randomly allocated into two groups:

Group 1: Activity management (AM) will be delivered by CFS/ME specialists that are not physiotherapists (occupational therapists, nurses, psychologists). Therapists will receive guidance on the Mandatory, Prohibited and Flexible components. Activity management aims to

convert a “boom-bust” pattern of activity (lots one day and little the next) to a baseline with the same daily amount. For children/teenagers with CFS/ME these are almost entirely cognitive activities: school, school work, reading.

Group 2: Graded Exercise Therapy (GET) will be delivered by referral to a GET-trained specialist CFS/ME physiotherapist who will receive guidance on the Mandatory, Prohibited and Flexible components. Children will be offered advice that is focused on exercise with detailed assessment of current physical activity, advice about exercise and a programme including timed daily exercise. Children will be asked to record the amount of exercise and taught to use a heart rate monitor with target heart rates.

Participants will be asked to complete follow up at baseline, 6 and 12 months.

Previous intervention:
Children are randomly allocated into two groups:

Group 1: Activity management (AM) will be delivered by CFS/ME specialists that are not physiotherapists (occupational therapists, nurses, psychologists). Therapists will receive guidance on the Mandatory, Prohibited and Flexible components. Activity management aims to convert a “boom-bust” pattern of activity (lots one day and little the next) to a baseline with the same daily amount. For children/teenagers with CFS/ME these are almost entirely cognitive activities: school, school work, reading.

Group 2: Graded Exercise Therapy (GET) will be delivered by referral to a GET-trained specialist CFS/ME physiotherapist who will receive guidance on the Mandatory, Prohibited and Flexible components. Children will be offered advice that is focused on exercise with detailed assessment of current physical activity, advice about exercise and a programme including timed daily exercise. Children will be asked to record the amount of exercise and taught to use a heart rate monitor with target heart rates.

## Intervention Type
Behavioural

## Primary outcome(s)
Current primary outcome measures as of 27/03/2018:
Feasibility trial:
Feasibility and acceptability of investigating GET in a randomised controlled trial measured after 1 year.

Full trial:
Physical function is measured with the 36-Item Short Form Health Survey (SF36, physical function sub scale), collected at the 6 month time point.

Previous primary outcome measures:
Feasibility and acceptability of investigating GET in a randomised controlled trial measured after 1 year.

## Key secondary outcome(s))
Current secondary outcome measures as of 27/03/2018 (prior to this date there were no secondary outcome measures):
Feasibility trial:
No secondary outcome measures.

Full trial:
1. School attendance is measured as percentage attendance of expected sessions
2. Fatigue is measured using the Chalder Fatigue score
3. Pain is measured using the visual analogue scale
4. Depression and anxiety are measured using the Spence Children's Anxiety Scale (SCAS) and the Hospital Anxiety and Depression Scale (HADS, if they are 12-17 years old)
5. Health related quality of life is measured using the EQ-5D-Y

All of the above outcomes will be measured via child self-completed questionnaires at baseline, 6 and 12 months as well as a measure of physical function the SF36-PFS at 12 months.

### Completion date
23/06/2019

## Eligibility

### Key inclusion criteria
1. Diagnosis of chronic fatigue syndrome or myalgic encephalomyelitis (made using NICE guidance)
2. Aged between 8 and 17 years inclusive

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
8 years

### Upper age limit
17 years

### Sex
All

### Total final enrolment
237

### Key exclusion criteria
1. Too severely affected to attend hospital appointments (and require a domiciliary assessment)
2. Referred for CBT at their first clinical assessment
3. Unable to attend follow up appointments

### Date of first enrolment
10/09/2015

**Date of final enrolment**
23/03/2018

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Royal United Hospital**
Combe Park
Bath
United Kingdom
BA1 3NG

**Study participating centre**
**Newcastle upon Tyne NHS Foundation Trust (feasiblity trial only)**
Children and young people
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

# Sponsor information

**Organisation**
Royal National Hospital for Rheumatic Disease (UK)

**ROR**
https://ror.org/05va5gy74

# Funder(s)

**Funder type**
Government

**Funder Name**

National Institute for Health Research

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan
The study participants provided consent to their data being retained and used by the University of Bristol for present and future research and teaching purposes. Individual study data cannot be released to research groups outside of the University of Bristol.

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 02/05/2019 | 18/06/2019 | Yes | No |
| Results article | | 19/12/2019 | 10/10/2023 | Yes | No |
| Results article | Primary results | 02/03/2024 | 04/03/2024 | Yes | No |
| Protocol article | protocol | 04/07/2016 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Statistical Analysis Plan | version 1.0 | 30/10/2019 | 04/01/2024 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |