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# Specialist Medical Intervention & Lightning Evaluation: Comparing specialist medical care with specialist medical care plus the Lightning Process for Chronic Fatigue Syndrome or Myalgic Encephalopathy (CFS/ME)

**Submission date**
07/06/2012

**Recruitment status**
No longer recruiting

**Registration date**
31/07/2012

**Overall study status**
Completed

**Last Edited**
12/03/2018

**Condition category**
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

## Plain English summary of protocol

Background and study aims

Chronic fatigue syndrome (CFS)/myalgic encephalomyelitis (ME) is relatively common in teenagers and can be serious. Over half of teenagers with CFS/ME are bed bound at some stage and on average, they miss one year of school. Little is known about how to treat CFS/ME and even though over 250 teenagers a year use the Lightning Process as an intervention for CFS/ME, no studies have investigated whether it is either effective or safe.

Specialist Medical Care is the current treatment teenagers normally receive if they have CFS/ME. They are offered either activity management, Cognitive Behavioural Therapy (CBT), graded exercise or a mixture of all three depending on their goals and needs. The timing and number of the sessions varies but on average, most teenagers have a follow-up phone call 2 weeks after assessment followed by three or four follow-up sessions, spread out over 3 to 6 months usually at 6-weekly intervals. Sessions are normally run as family-based sessions with a member of the Bath Specialist CFS/ME team (physiotherapist, psychologist or occupational therapist).

The Lightning Process is based on the idea that the body and mind work together to affect your health. It is a training programme, run as a course on three consecutive days (for 3 hours 45 minutes a day) in a group with up to five other young people aged between 12 and 18 years old. The course is run by a Lightning Process Practitioner. Lightning Process Practitioners are trained in Neuro Linguistic Programming (NLP), life coaching, clinical hypnotherapy and the Lightning Process  they are not medically trained. The course is run as a mixture of group and individual discussions with theory and practical sessions each day. In the theory session, teenagers learn about stress and its physical effects, how the mind and body interact and how thought processes can be helpful and unhelpful. In the practical session, teenagers identify goals they wish to achieve (for example, standing for longer) and are given different ways to think about and prepare for this. They then have the chance to practise this on the course with the Lightning Process practitioner there to support them. A parent can attend and a researcher may be present to watch the session. Teenagers are given up to 30 minutes homework each day so they

can continue to practise the skills they have learnt using a goal they identified on the course. This aim of this study is to investigate whether adding the Lightning Process to specialist medical care is effective or cost effective. We have already shown that it is feasible to recruit children into this study.

Who can participate?
Children with CFS/ME aged 12  18 years old.

What does the study involve?
Children will be randomly allocated to receive either specialist medical care or specialist medical care plus the Lightning Process.
Specialist Medical Treatment: children and their families are offered a variety of treatments centred around graded activity and involves a follow-up phone call at 2 weeks followed by family-based rehabilitation consultations at approximately 6 weeks (1 hour), 3 months (1 hour), and 4.5 months (1 hour). Children who have high levels of anxiety are offered three individual sessions of CBT every 2 weeks over a 6-week period. Other interventions such as Graded Exercise Therapy (GET) are available for children and young people if needed.
Specialist Medical Treatment plus the Lightning Process: In addition to the specialist medical care detailed above, young people and their parents will be asked to read the information about the Lightning Process on the website or using information sheets. If the young person is well enough, they will be asked to read a book about the Lightning Process. If they are unable to read the book, they will be asked to listen to an audio book. Children/young people and their parents will be asked to complete an assessment form (which will take about 10 minutes) where they are asked to identify their goals and describe what they learnt from reading the book. After this they will have a telephone call with a Lightning Process practitioner (LPP) (usually about 20 minutes). This is used to check that the young person and their parents are happy about attending the course, checks the goals identified by the young person and is an opportunity for the young person and their parents to ask further questions. If the young person and their family are happy to continue, the young person will be given a date to attend a course.
The course is three sessions on three consecutive days. Each session is 3 hours 45 minutes long. Group sessions include four to five young people between 12  18 years of age who live within the region covered by the CFS/ME service. During the group, children and young people will have a theory session and a practical session.
The LPP will then arrange two follow-up phone calls with the young person and parents within 2 weeks of the course and then about 6-8 weeks later.

What are the possible benefits and risks of participating?
There are no specific benefits for children participating in this study. We do not think there are any side effects of the interventions but because the Lightning Process has not been tested before, we will be monitoring all interventions and closely following up all young people who take part. Those taking part will need to complete questionnaires 3 months after the intervention as well as the normal time points (6 months and annually). They will also need to complete two more questionnaires at each time point which we think will take about 5 minutes to complete. Some parents of children who receive Specialist Medical Care and the Lightning Process have told us that they find the two approaches, and the language used in them, are different. If this is a problem for children and young people, we will offer support.

Where is the study run from?
The study is run by Dr Esther Crawley who leads the Bath paediatric specialist CFS/ME clinical service at the Royal National Hospital for Rheumatic Diseases. The research is being done by Dr

Crawleys research team at the University of Bristol. The Bath paediatric specialist CFS/ME clinical service runs clinics throughout Somerset, Bath and North East Somerset, Wiltshire and Gloucester and children are recruited from all clinics.

When is the study starting and how long is it expected to run for?
The study started as a feasibility study (to see if a study was possible) in October 2010. We have now shown that it is possible to run the study and are planning to convert the study to a randomised trial. We anticipate that this will start in September and will run for a further 8 months.

Who is funding the study?
The study is funded by the Linbury Trust and the Ashden Trust

Who is the main contact?
Dr Esther Crawley
esther.crawley@bristol.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Esther Crawley

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# Additional identifiers

### Protocol serial number
Version 9 June 2012

# Study information

### Scientific Title
Comparing specialist medical care with specialist medical care plus the Lightning Process for Chronic Fatigue Syndrome or Myalgic Encephalopathy (CFS/ME) - a randomised controlled trial

### Acronym
SMILE

## Study objectives
Adding the Lightning Process to specialist medical treatment will not change the effectiveness or cost effectiveness of treatment.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
South West 2 Local Research Ethics Committee, 8th September 2010, ref: 10/H0206/32. Amendement approved on 31/05/2011

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Chronic Fatigue Syndrome / Myalgic Encephalopathy (CFS/ME)

## Interventions
Specialist Medical Treatment: children and their families are offered a variety of treatment options that are recommended in NICE guidelines. Typically this is centred around graded activity and involves a follow up phone call at 2 weeks followed by family based rehabilitation consultations at approximately 6 weeks (1 hour), 3 months (1 hour), and 4.5 months (1 hour). The number and timing of the sessions are agreed with the child and family and varies depending on the needs and goals of the child. Children who have high levels of anxiety are offered 3 individual sessions of Cognitive behavioral therapy (CBT) every 2 weeks over a 6 week period. Other interventions such as Graded Exercise Therapy (GET) are available for children and young people if needed.

Specialist Medical Treatment plus the Lightning Process: In addition to the specialist Medical Care detailed above, young people and their parents will be asked to read the information about the Lightning Process on the website or using information sheets. If the young person is well enough, they will be asked to read a book about the Lightning Process. If they are unable to read the book, they will be asked to listen to an audio book. Children/young people and their parents will be asked to complete an assessment form (which will take about 10 minutes) where they are asked to identify their goals and describe what they learnt from reading the book. After this they will have a telephone call with a Lightning Process practitioner (LPP) (usually approximately 20 minutes). This is used to check that the young person and their parents are happy about attending the course, checks the goals identified by the young person and is an opportunity for the young person and their parents to ask further questions. If the young person and their family are happy to continue, the young person will be given a date to attend a course.

The course is 3 sessions on 3 consecutive days. Each session is 3 hours 45 minutes long. Group sessions include 4 to 5 young people between 12  18 years of age who live within the region covered by the CFS/ME service. During the group, children and young people will have a theory session and a practical session.

The theory session will include taught elements on the stress response, how the mind-body interacts and how thought processes can be helpful and negative. The language used by young people will be discussed and in some cases challenged. Young people will be encouraged to think about what they may be able to take responsibility for and change. The taught sessions are followed by a group discussion.

The practical session is used to put some of the skills learnt into practise. Young people identify a goal they wish to achieve (such as standing for longer) and are then given alternative ways to think about and prepare for this. This involves using different cognitive (thinking) strategies before and during the goal is attempted. Young people are also asked to identify a goal in which they can practise the strategies in the afternoon or evening. This goal will usually be short but could be an activity that is up to 30 minutes long.

The LPP will then arrange two follow up phone calls with the young person and parents within 2 weeks of the course and then approximately 6 to 8 weeks later.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
Current primary outcome measures as of 12/03/2018:
1. SF 36 physical function short form at 6 months

Previous primary outcome measures:
1. Chalder Fatigue Scale at 6 months
2. SF 36 physical function short form at 6 months

### Key secondary outcome(s))
Current secondary outcome measures as of 12/03/2018:
1. Chalder Fatigue scale and SF-36 physical function short term at 6 months and 12 months
2. School attendance (6 months and 12 months)
3. Health resource use
4. Parental loss of earnings
5. Anxiety and depression (6 months and 12 months)

Previous secondary outcome measures:
1. Chalder Fatigue scale and SF-36 physical function short term (12 months)
2. School attendance (6 months and 12 months)
3. Health resource use
4. Parental loss of earnings
5. Anxiety and depression (6 months and 12 months)

### Completion date
31/03/2013

## Eligibility

### Key inclusion criteria
Children will be included if they have CFS/ME and are between 12 and 18 years old

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. They are too severely affected to attend hospital appointments (defined as children and young people that do not regularly leave their house)
2. If they or their parents have insufficient English to either understand the Patient Information Sheet (PIS) and consent form to take part in the Lightning Process or take part in the interviews

### Date of first enrolment
01/08/2012

### Date of final enrolment
31/03/2013

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Center of Child and Adolescent Health**
Bristol
United Kingdom
BS8 2BN

## Sponsor information

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

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

# Funder(s)

**Funder type**
Charity

**Funder Name**
The Linbury Trust (UK)

**Funder Name**
The Ashden Trust (UK)

# Results and Publications

**Individual participant data (IPD) sharing plan**
Given the nature of this dataset, access is controlled. Requests are referred to the University of Bristol Data Access Committee for approval before data can be released under an appropriate data access agreement. For details on how to access data, see the repository record at http://dx.doi.org/10.5523/bris.1myzti8qnv48g2sxtx6h5nice7.

**IPD sharing plan summary**
Stored in repository

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 05/12/2013 | | Yes | No |
| Results article | results | 01/12/2015 | | Yes | No |
| Results article | results | 01/02/2018 | | Yes | No |
| Protocol article | protocol | 26/12/2013 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |