

CFS/NHS/PAEDIATRICS - Specialist help for ME.

SMILE Specialist Medical Intervention & Lightning Evaluation

Feasibility randomised controlled trial for Chronic Fatigue Syndrome/ME

INFORMATION LEAFLET FOR PARENTS

We would like to invite you to take part in a research study which will tell us whether it is possible to study specialist medical care compared to specialist medical care plus the Lightning Process as interventions for Chronic Fatigue Syndrome or Myalgic encephalopathy (CFS/ME) in children.

Before you decide to take part it is important for you to understand *why* the study is being done and *what* it will involve. Please read this leaflet carefully. You can talk about it with your family, friends, doctor, or us if you want to. We would like to go through this information with you and we think this will take about 20 to 30 minutes. The leaflet is divided in to two parts. Part 1 tells you about the study and what will happen to you and your child if you take part. Part 2 give details about the conduct of the study.

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 this study?

- We want to find out whether young people will take part in a study comparing specialist medical care with or without the Lightning Process.
- We also want to find out about the differences between the Lightning Process and specialist medical care and your views them.
- We will study the cost of the illness to families and measure the cost of treatment.
- We know that the questionnaires we are using don't always suit children and young people with CFS/ME so we are going to use this study to understand more about what your child thinks about the questionnaires we use.

What is Specialist Medical Care?

Specialist Medical Care is the current treatment children normally receive if they have CFS/ME. After their assessment, they will have a follow up phone call at 2 weeks followed by individual sessions with a member of the Bath Specialist CFS/ME team. This could be a physiotherapist, psychologist or occupational therapist depending on your child's goals and where you would like to receive follow up. They will be offered either activity management, cognitive behavioural therapy (CBT), graded exercise or a mixture of all three depending on the goals and needs of your child. The timing and number of the sessions depends on your child's needs but on average, most young people have three or four follow up sessions, spread out over 3 to 6 months, usually at 6 weeks and then every 6 weeks.

What is the Lightning Process?

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 who is trained and licensed to run the course. The courses will be held somewhere near you, either in a clinic or hospital, or in a hotel or community hall.

There are regular breaks throughout the course and a mixture of group and individual discussions. The daily seminars will include a theory session and a practical session. In the theory session, children learn about stress, how the mind-body interacts and how thought processes can be helpful and unhelpful. In the practical session children and young people identify goals they wish to achieve (for example, standing for longer) and are given alternative ways to think about and prepare for this. They then have the opportunity 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 observe the session. Young people are given up to 30 minutes homework each day so they can continue to practise the skills they have learnt using a goal identified by the young person on the course.

Why has my child been asked to take part?

Your child has been asked if they want to take part because they are between 12 and 18 years of age, have CFS/ME and have attended an assessment at the Bath Specialist CFS/ME service.

We do not think your child should take part if they are severely affected (cannot leave the house) or if they do not speak English. Your child should not take part if there is one intervention they do not want to do, for example, if they don't feel comfortable working in groups.

Does my child have to take part?

Your child does not have to take part in this study. If you agree to meet the researcher who will ask you about your views about the interventions or the nurse who will explain more about the study, this will not commit you to taking part in the study.

If you decide to take part but withdraw later, we will continue to follow up your child as if they were not in the study unless you tell us you don't want us to. Your child can withdraw at any point in the study. Your child can withdraw their information collected at interview at any point in the study before analysis.

We hope that up to 90 young people and their parents will take part in this study but it is up to you and your child to decide whether or not to take part. If you decide not to take part or decide to withdraw at any time, this will not affect the standard of specialist medical care you would normally receive.

What are we asking you to do.

First stage: If you agree to take part in this study, a researcher may arrange a time to interview you in the next two weeks and during the study (on no more than three occasions) at a place and time that is convenient for you. This is to find out what you know about the

Lightning Process and about your experience of each type of intervention. The interviews will be audio-recorded with your permission and will last between 20 minutes to an hour. Your child will be interviewed at one of these time points for approximately 20 minutes.

If you and your child agree to proceed, a research nurse will arrange to visit you at a location of your choice, to discuss the two different intervention options and explain more about the study. If you are willing to take part, your child will be randomly allocated to one of two intervention groups: either specialist medical care or specialist medical care plus the Lightning Process. As this study is trying to find out whether we can compare both groups, it will not be possible for you to choose the group for your child. The group that your child will be part of will be determined by computer at random (in other words, by chance).

Second stage: In the second stage you child will be part of group 1 (which is Specialist Medical Care) or group 2 (which is Specialist Medical Care plus the Lightning Process)

Group 1: Specialist Medical Care

If your child is in group 1, they will receive specialist medical care. While your child is in this intervention arm, we will ask them not to access the Lightning Process outside the study.

Group 2: Specialist Medical Care plus the Lightning Process

If your child is in group 2, they will receive specialist medical care and the Lightning Process intervention. In addition to the specialist medical care described above, young people in this group will be asked to read the "Introduction to the Lightning Process" book (140 pages) or listen to the audio book before they attend the lightning process course. You will be asked to read or listen to the Lightning Process book as well. Your child will then complete an assessment form asking about what goals they have set themselves and what they learnt from reading the book/listening to the audio book.

After this, the Lightning Process Practitioner will phone and talk to you and your child to check that having found out more about what is going to happen they are still happy with attending the course. They will discuss your child's goals with both of you and the content of the book you have read. This is an opportunity for you or your child to ask questions, and find out more about the Lightning Process. You and your child may feel you need more time to discuss the Lightning Process with the Lightning Process Practitioner and you can arrange more telephone calls if you want to.

If you and your child are happy to attend a Lightning Process course, your child will be booked on to the Lightning Process course which will run 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 who are also involved in the study. After the Lightning Process course, you will have two follow up phone calls at 2 and 4 weeks at a time that is convenient for you. This will be in addition to the specialist medical follow up sessions as above. You and your child can cancel follow up sessions at any stage, if you feel you do not need or want them.

Group 1 and Group 2

The intervention sessions will be audio-recorded and for approximately half the interventions, the researcher will also observe the session.

Children in both groups (and those who do not take part) will receive questionnaires by post at 6 weeks, 6 months and a year to check how they are doing. Each pack of questionnaires takes about ten minutes to complete. If your child takes part in this study, they will receive two more questionnaires at each time point than children who do not take part in the study, which will take an extra five minutes (or so) to complete. These questionnaires are to help us understand more about which questionnaires we should use and to find out more about the

cost of treatment and the cost of the illness. If your child takes part in this study, they will also receive questionnaires at 3 months (in addition to 6 weeks, 6 months and annually).

We will also contact your child's school at assessment and at each of these follow up time points to find out how much school they are attending.

If your child takes part in the study, we will also ask you to fill in three questionnaires at the start and two at follow-up, so we can understand more about the cost of this illness to your family and the cost of treatment. We estimate that these questionnaires will take you less than 10 minutes to complete.

Are there any disadvantages of taking part in this study?

You may need to spend time talking to us on three different occasions. We think this will take about 20 minutes each time but may take longer (no more than an hour). You will need to spend 20 minutes talking to the research nurse about the study. Your child may be interviewed as well but only at one time point and for no more than 20 minutes. If your child takes part, they will need to complete questionnaires at 3 months after the interventions as well as the normal time points (6 weeks, 6 months and annually). They will also need to complete two more questionnaires at each time point that we think will take about 5 minutes (or so) to complete.

You will need to complete three more questionnaires at the start and two questionnaires at follow up. This will take 10 to 20 minutes each time.

Your child may not find the intervention arm they have been offered helps them. This could be true for both interventions.

Are there any side effects of the interventions?

We do not think there are any side effects of the interventions but because the Lightning Process has not been evaluated before, we will be monitoring all interventions and closely following up all young people who take part.

Benefits of joining in

There are no specific benefits for you or your child taking part in this study although some parents may find it helpful to talk to others about their experiences. If we understand more about the interventions, taking part in this study may help other children and young people with CFS/ME in the future.

What happens when the research study stops?

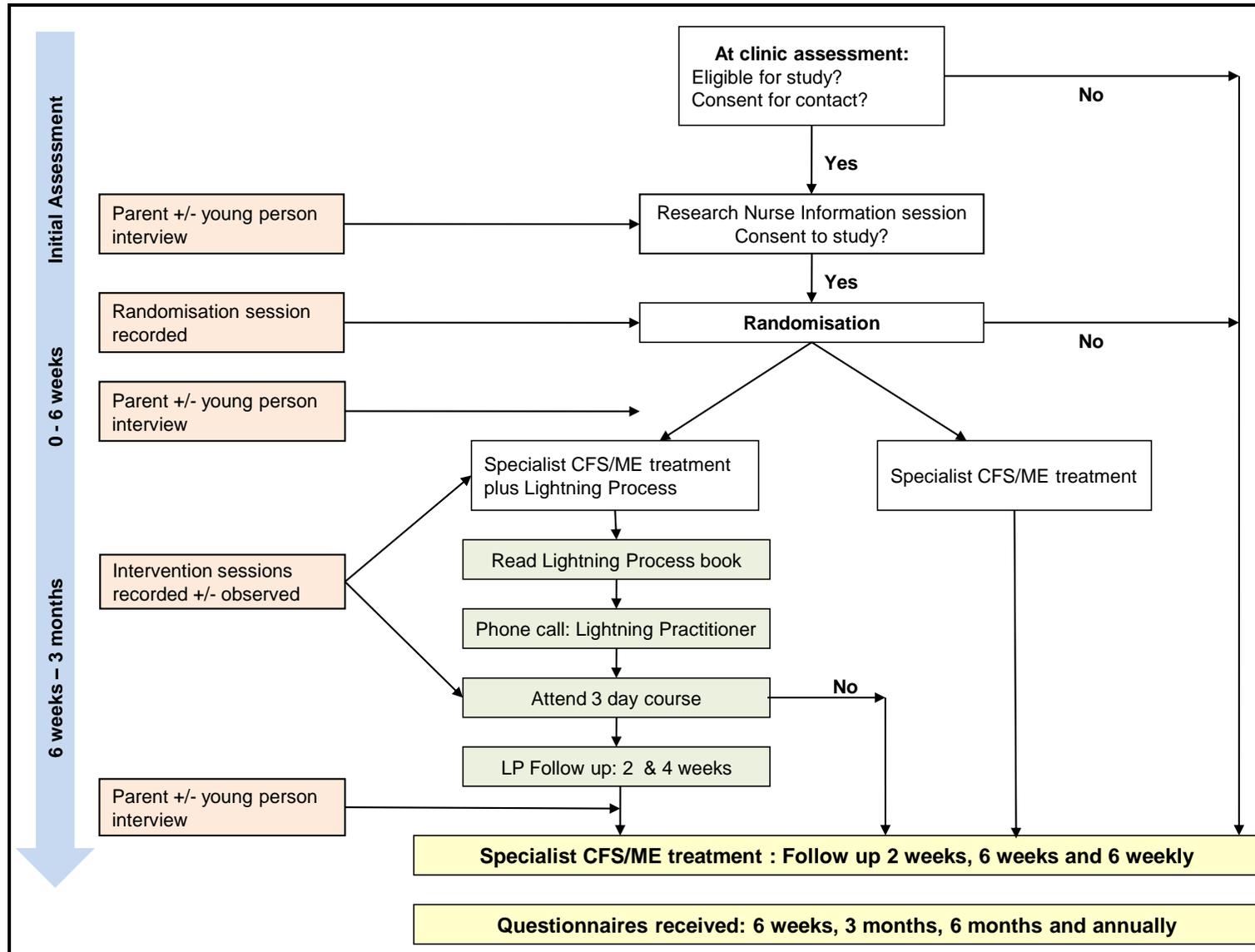
After the study stops, your child will continue to access specialist medical care if they still need it. They will also continue to receive follow up questionnaires like the young people who did not take part in the study.

What if there is a problem?

We will try and deal with any problem you or your child has during this study. Detailed information is given in part 2.

Will my details be kept private?

Yes. Your privacy is important to us and all your details will be handled in confidence. The details are included in part 2.



SMILE: Protocol Flow Chart

If the information in Part 1 has interested you and you are considering taking part in this study, please read the additional information in Part 2 before making any decision.

What if new information becomes available?

If new information becomes available, we will tell you about it and discuss whether you and your child want to continue in the study. If the study stops for any reason, we will tell you and your child and arrange continuing care for your child.

What will happen if I don't want to carry on with the study?

Your child can withdraw from the study at any point and this will not affect the care that we give them. We will keep the information that we have collected up to the point of withdrawal but this is completely anonymous and nobody will know it is your child. Your child will continue to receive the follow up questionnaires that other young people receive who are not part of the study but you can tell us if you do not want to complete this as well and we will stop sending them to your child.

What should I do if I have a problem with this study?

If you have any problems with this study, please speak to Dr Esther Crawley (01225 465941. esther.crawley@bristol.ac.uk) or any member of the clinical team that you know. You would be able to complain to the NHS in the usual way if you were not happy with the study by contacting the Patient Advice and Liaison services (PALS) 01225 473424.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the RNHRD, but you may have to pay your legal costs. The normal National Health Service complaints mechanism will still be available to you (if appropriate).

Does everybody involved in the study have the appropriate police checks?

Yes

Your privacy

It is very important that all the information you and your child give us is completely private. We will write down the things that you and your child say from the audio-recording and take out any details linking the recording to you or your child so that nobody will know that it was you. We may use small bits of what you say when we report the study, but your quotes will be anonymised and nobody will know it was you. The recording will be encrypted and password protected (so nobody else can listen to it) before it is stored on a secure university server. The copy of what you said in the interview (the transcript) will be linked to you and your child via a code. All personal details or lists that could identify you will be kept secure in locked cabinets in locked offices or password protected on secure NHS computers.

All questionnaires that you fill out are anonymised before they are given to you. We will give you a 13 digit identification code that will be on the top of the questionnaires. A list of names and corresponding identification numbers are kept separately and securely on a password protected NHS server.

As with any child being seen in clinic, if we have concerns over your child's welfare, we may have to break confidentiality. In some cases, we may have to discuss your child with another professional such as a social worker or child protection officer.

Data protection

All data is completely anonymised and is kept on secure encrypted password protected University Servers.

Consent

We have to be absolutely certain that you are happy to join in this study, so if you say you are, we will ask you and your child to sign our consent form. We will also ask you to sign a consent form if we interview you, to check you are still happy. Even if you do sign the consent forms, you and your child will be free to withdraw at any point. Just tell us if this is the case. Whether or not you wish to participate, your child will continue to receive the same care from the clinical team.

Who will know I am taking part in the study?

We think your GP should know about the interventions your child receives and we will ask your permission to let your GP know.

What will happen to the results of the study?

This study will give us information about how much families use health services and will tell us more about which questionnaires we should use. We aim to publish these results in journals to help other health professionals. If it is possible to recruit young people into this study, we will use the results to plan for a larger study to look at whether the Lightning Process is helpful or not.

Who is organising and funding the study?

This research is organised by Dr Esther Crawley who is the Clinical Lead for the Bath specialist CFS/ME service at the RNHRD and leads the Paediatric CFS/ME Research team at the University of Bristol. Dr Crawley is working with a group of researchers at the University of Bristol who are helping her with this study. The study is funded by the Linbury Trust and The Ashden Trust.

Will I need to pay to be part of this study?

No

Ethical Approval

The study has been approved by the South West 2 Research Ethics Committee. It has also been checked and approved by the RNHRD research committee.

Contact / Further Information:

Dr Esther Crawley - Paediatric Consultant and Clinical Lead of the Paediatric CFS/ME Service. Specialist CFS/ME Service for Children and Young People, Royal National Hospital for Rheumatic Diseases NHS Foundation Trust, Upper Borough Walls, Bath, BA1 1RL, Tel: 01225 465941. esther.crawley@bristol.ac.uk

Or if you want to talk to somebody independent please contact Jane Carter, Research and Development Manager, Royal National Hospital for Rheumatic Diseases NHS Foundation Trust, Upper Borough Walls, Bath, BA1 1RL, Tel: 01225 465941

THANK YOU for taking the time to read this leaflet