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 TEENAGERS

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 (ways to help) for Chronic Fatigue Syndrome or Myalgic encephalopathy (CFS/ME) in teenagers.

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 if you take part. Part 2 gives details about how the study will be run.

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 it is possible to do a study investigating specialist medical care with or without the Lightning Process. To do this, we need to know whether young people will take part.
- We also want to find out more about the differences between the Lightning Process and specialist medical care. We are particularly interested in your views of both interventions.
- As part of this study, we will also try and 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 teenagers with CFS/ME so we are going to use this study to understand more about what you think about the questionnaires we use.

What is Specialist Medical Care?

Specialist Medical Care is the current treatment teenagers normally receive if they have CFS/ME. They normally have a follow up phone call at 2 weeks followed by individual family based sessions with a member of the Bath Specialist CFS/ME team. This could be a physiotherapist, psychologist or occupational therapist depending on your goals and where you would like to receive follow up. You will be offered either activity management, Cognitive Behavioural Therapy (CBT), graded exercise or a mixture of all three depending on your goals and needs. The timing and number of the sessions depends on your needs but on average, most teenagers 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. Lightning Process Practitioners are trained in Neuro Linguistic Programming (NLP), life coaching, clinical hypnotherapy and the Lightning Process – they are not medically trained. The courses will be held somewhere near you, either in a clinic or hospital, or in a hotel or community hall. Where ever it is held, it will be suitable for the course and for young people your age.

There are regular breaks throughout the course and a mixture of group and individual discussions. Each day the course will include a theory session and a practical session. In the theory session, teenagers learn about stress and its physical effects, how the mind-body interacts 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.

Why have I been asked to take part?

You have been asked if you want to take part because you 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 you should take part if you are severely affected (cannot leave the house) or if you do not speak English. You should not take part if there is one intervention you don’t want to do for example, if you aren’t comfortable working in groups.

Do I have to take part?

You do 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 change your mind later, we will continue to follow you up like we do other teenagers who are not part of the study unless you tell us you don’t want us to You can withdraw from the study at any point and if you want us to we will take out the information collected at interview at any point before we carry out data analysis

We hope that up to 90 young people and their parents will take part in this study but it is up to you 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 at a place and time that is convenient for you and your family to find out what you know about the Lightning Process and what your views are about the different types of intervention. The interview will be audio-recorded with your permission and will last for around 20 minutes.

If you (and your parent if you are under 16) agree to proceed, a research nurse will then arrange to visit you at home (or a location of your choice), spend some time with you to discuss the two different interventions and explain more about the study. If you are willing to take part, you will be randomly allocated (in other words, by chance) 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. The group that you will be part of will be determined by computer at random. This is the same as rolling a dice.

Second stage: In the second stage you 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 you are in group 1, you will receive specialist medical care.

Group 2: Specialist Medical Care plus the Lightning Process

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

After this, the Lightning Process Practitioner will phone and talk to you and your parents/guardian to check that having found out more about what is going to happen you are still happy with attending the course. They will discuss your goals and the content of the book you have read with you and your parent/guardian. This is an opportunity for you to ask questions, and find out more about the Lightning Process. If you or your parents need more time to talk to the Lightning Process Practitioner, you can arrange other phone calls with them.

If you are happy to attend the course, you will be booked on to the Lightning Process course which will run on three consecutive days (for 3 hours 45 minutes a day). You will be 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 be offered 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 can cancel follow up sessions at any stage if you feel you do not need or want them.

Group 1 and Group 2

After you know which intervention group you are in, we may interview you (if you haven't already been interviewed) to find out what you felt about the process of randomisation or we may interview you after the intervention to find out what you feel about it and how you found completing study questionnaires. We will only interview you once. Interviews will take approximately 20 minutes and will be held at your home or a location of you and your parents/guardians choice.

We want to find out more about both interventions. The intervention sessions will be audio-recorded and for about half the interventions, the researcher will also observe the session.

Whether you take part in this study or not, you will receive questionnaires by post at 6 months and a year to check how you are doing. Each pack of questionnaires takes about ten minutes to complete. If you take part in this study, you will receive two more questionnaires at each time point, than teenagers who do not take part in the study. 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. They will take you an extra five minutes (or so) to complete. We will also send questionnaires to you at 3 months after the intervention.

We will ask your school with your permission about how much you have been at school when we first see you and at follow up.

Do I have to take part?

You do 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.

We hope that up to 90 young people and their parents will take part in this study but it is up to you 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.

Are there any disadvantages of taking part in this study?

You may need to spend time talking to a researcher for about 20 minutes so we can understand what you think about the study and the sessions either before or after you have them. You will need to spend 20 minutes talking to the research nurse about the study. If you take part, you will need to complete questionnaires at 3 months after the interventions as well as the normal time points (6 months and annually). You will also need to complete 2 more questionnaires at each time point that we think will take about 5 minutes to complete. You may not find the intervention arm you have been offered helps you. This could be true for both interventions. Teenagers with CFS/ME can get worse with any intervention offered. There is no data in teenagers, see tables 1 and 2 for data in adults.

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 is different. If this is a problem for you, we will talk about it with you and offer support.

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 tested 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 in taking part in this study. If we understand more about the interventions, taking part in this study may help other teenagers with CFS/ME in the future.

What happens when the research study stops?

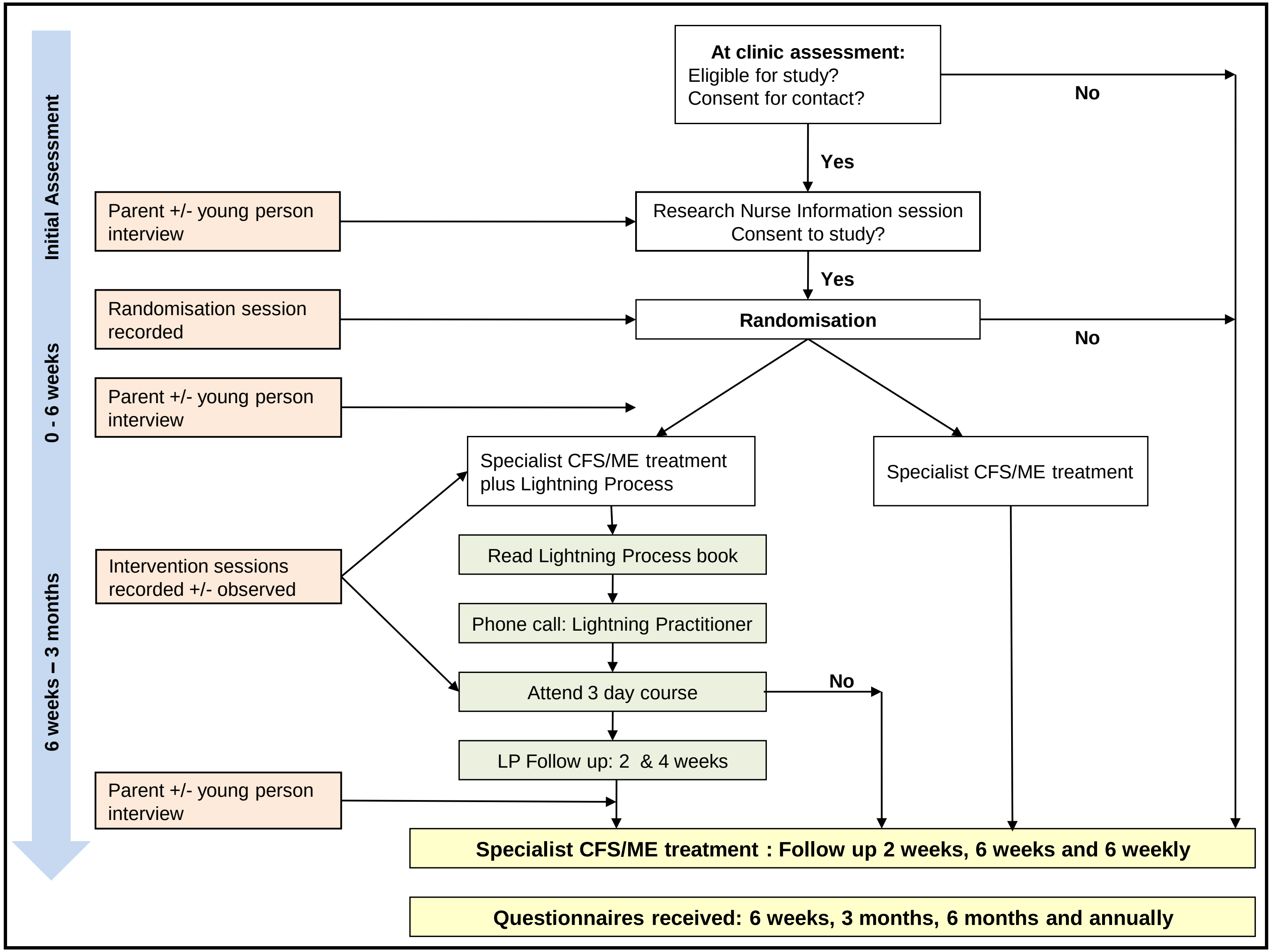
After the study stops, you will continue to access specialist medical care if you still need it. You will also continue to receive follow up questionnaires, like the teenagers who did not take part in the study.

What if there is a problem?

We will try and deal with any problem you have 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?

Sometimes during the course of a research study, new information becomes available about the interventions that are being studied. If this happens, we will tell you about it and discuss with you whether you want to continue in the study.

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

You can withdraw from the study at any point and this will not affect the care that we give you. We will keep the information that we have collected up to the time you leave the study but this is completely private and nobody will know it is you. You will continue to receive the follow up questionnaires that other teenagers receive who are not part of the study but you can tell us if you do not want these and we will stop sending them to you.

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 through 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 being careless then you may be able to take legal action to get repayment from the hospital but your parents may need to pay a lawyer to help you. You can also use the normal National Health Service system for complaints if you want to.

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

Yes. All those working in the study have had the necessary police checks to make sure they are safe to work with children and young people.

Your privacy

It is very important that all the information you give us is completely private. We will write down the things that you say from the audio-recording and take out any details linking the recording to you so that nobody will know that it was you. We may use small bits of what you say when we report the study, but the quotes will be completely anonymised so nobody will know it was you. The recording will be encrypted and password protected (so no-one 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 parents 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.

If you tell us something that makes us worried about your safety, we may have to discuss this with somebody else as we need to be sure you are safe. This means, what you say would not be kept completely private. We would do the same if you told us something in clinic.

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 to sign our consent form. We will also ask you to sign a consent form if we interview you. Even if you do sign the forms, you will be free to withdraw at any point. Just tell us if this is the case. Whether or not you wish to participate, you 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 that you are taking part in this study because they need to know what happens to you 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 young people with CFS/ME use health services and will tell us more about which questionnaires we think we should use. We aim to publish these results in journals to help other people seeing teenagers with CFS/ME. If young people take part in 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.

Table 1. Data taken from Action for ME (AfME) and Association of Young people with ME (AYME) joint report “M.E. 2008: What progress”. 2763 people answered this survey (7% were children and young people)

Intervention	Helpful (%)	No change (%)	Made worse (%)
GET	45	21	34
CBT	50	38	12
Lightning Process	53	31	16

*GET = Graded Exercise Therapy; CBT = Cognitive Behavioural Therapy;

For the full report:

http://www.actionforme.org.uk/Documents/get-informed/Survey%20Summary%20Report%202008.pdf

Also reported in Parliamentary enquiry found here:

http://www.actionforme.org.uk/Documents/get-informed/APPG%20Report%20FINAL.pdf

Table 2. Data taken from 2008 MEA survey of 4217 people (<5% where children and young people)

Answer Options	Response count	Greatly improved	Improved	No change	Slightly Worse	Much worse
GET	906	3.4	18.7	21.4	23.4	33.1
CBT	997	2.8	23.1	54.6	11.6	7.9
LP	101	25.7	18.8	34.7	7.9	12.9

*GET = Graded Exercise Therapy; CBT = Cognitive Behavioural Therapy; LP = Lightning Process

For the full report:

http://www.meassociation.org.uk/wp-content/uploads/2010/09/2010-survey-report-lo-res10.pdf

Also reported in Parliamentary enquiry found here:

http://www.actionforme.org.uk/Documents/get-informed/APPG%20Report%20FINAL.pdf

Contact / Further Information:

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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 ext 210.

THANK YOU for taking the time to read this leaflet