LiTEFORM

To be printed on local headed paper

STAFF INFORMATION SHEET
Version 1.1

Lite **T**herapy **E**ffectiveness **F**or **OR**al **M**ucositis Trial

The **LiTEFORM** Study

Qualitative Study Information

We are delighted that your Trust is taking part in the LiTEFORM trial. This information sheet tells you more about the qualitative work which forms an important part of the LiTEFORM study. As part of this study, we may ask you to help in **one or more** of the following ways:

- If you would take part in a face to face or telephone interview.
- If we can make notes at meetings or training that you are involved in for LiTEFORM.
- If we can audio-record conversations that you have with patients about LiTEFORM.

Before you decide how to respond to these invitations we would like you to understand why we are doing this research and what it would mean for you. Talk to others about the study if you wish and please ask us if there is anything that is not clear.

Thank you for taking time to read this information.

What is LiTEFORM about?

The aim of the LiTEFORM trial is to establish the benefit of delivering Low Level Laser Therapy (LLLT) in the management of oral mucositis (OM) in head and neck irradiation. To do this patients will be randomised 1:1 to receive the standard care for OM and laser therapy, versus standard care for OM and sham laser therapy. Both arms will receive standard care which includes good oral hygiene, hydration and use of analgesia, topical analgesia and coating gels for pain management.

The aims of the LiTEFORM qualitative research are to identify any barriers to recruitment and address them so that we can meet our recruitment targets. We also want to know about patient and staff experiences of LLLT.

Why do patients agree (or disagree) to take part in the LiTEFORM study?

- Do patients have concerns about LLLT treatment or randomisation?
- Could we change how/when we approach patients or the information we give them to make it easier for patients to decide whether to take part?

How could we implement LLLT treatment into routine NHS care?

LLLT treatment is a new intervention in the NHS. Head and neck cancer treatment involves a multidisciplinary team and lots of visits for patients. If the trial shows this intervention “works” we need to know how to make sure that it can “fit” smoothly into the patient pathway. Hearing about the experiences of both staff and patients involved in LiTEFORM is vital for this.

What do we want to find out?

Interviews

- We want to know about your experiences of being involved in the LiTEFORM trial.
- For staff who are involved in recruiting patients to LiTEFORM we want to know how easy it is to approach patients about the study, how patients react to the idea of taking part and what factors affect their willingness to consider the study.
- For staff involved in delivering LLLT to patients we want to know whether there are any challenges in delivering this new intervention in the NHS.

Observations of SIV, LiTEFORM meetings and training in LLLT

- We want to know what your expectations are of the LLLT therapy, and your initial thoughts about how the treatment will fit into the patient care pathway

Audio-recording recruitment consultations

- We want to know about the questions patients have about the study and how they respond when invited to participate.

How is this being done?

We will collect data through:

- Observation of Site Initiation Visits
- Observation of LiTEFORM meetings
- Audio-recording LiTEFORM recruitment conversations with patients
- Observation of training in how to deliver LLLT
- Interviews with staff involved in LiTEFORM
- Interviews with patients invited to take part in LiTEFORM

Why have I been asked to take part?

You have been chosen because you are involved in the LiTEFORM Trial.

Do I have to take part?

No, it is entirely up to you whether you want to be interviewed, observed or audio-recorded. You will not be pressured to do any of these. However previous research has shown that where staff do take part in qualitative research, trials are more able to recruit to target, and produce more useful findings for the NHS. We have designed this study to minimise the demands on staff as much as possible. We will not ask you to do more than two interviews across the four years of the study. Your confidentiality will be protected at all times.

What if I change my mind?

You can withdraw from all or part of this study at any time without giving a reason. We will ask you if we can use any information collected up to your withdrawal for our research. If you do not want us to use your information it will not be used and will be deleted from our file.

What happens next?

We will ask you to complete a consent form. We will ask if you are willing for your conversations with patients about LiTEFORM to be audio-recorded (we will also get consent from patients and any friends or relatives who accompany them to their appointment). We will also ask if you are willing to have notes made about things that you might say at any meetings or training that you are involved in for LiTEFORM (LLLT training, LiTEFORM meetings and site initiation visits). Finally we will ask if we can contact you about an interview.

Interviews
We want to speak to as many people as we can, but we will not be able to speak to everyone involved in LiTEFORM. If we do contact you, a member of the Newcastle University qualitative research team will get in touch to arrange a convenient date and time to do the interview.

- The interview can be face to face (e.g. at your place of work) or over the telephone.
- The interview will last about 20-40 minutes, no longer than an hour (depending on how much you have to say). It will be conducted by an experienced researcher.
- We will ask for your verbal and/or written consent before the interview starts.
- We will ask your permission to audio-record the conversation so that the interviewer can talk to you without having to make too many notes.
- We may ask you for another interview later on in the study. We will not ask you for any more than two interviews.

Observations
These will involve a researcher attending the meeting or training and making notes of any questions that people have about LiTEFORM and LLLT, or issues that are identified with implementing LLLT in the NHS. Occasionally the researcher may ask a question if s/he is not clear about something, but they will take care not to interfere with the smooth running of the meeting. The notes will be written up and anonymised.

Audio-recording LiTEFORM recruitment conversations.
If you are involved with recruiting patients to LiTEFORM, we will ask you to audio-record conversations you have with patients about participating in LiTEFORM. We will provide you with equipment to record these discussions. You will also be asked to gain informed consent from patients and any friends or family present for these recordings.

Will what I tell you be kept confidential?
Anything you say will be held in strict confidence. Every care will be taken to make sure you cannot be identified personally from the information that is used. General feedback on recruitment processes will be given to sites but done in such a way that the confidentiality of individuals is maintained.

- Any recordings of your voice and transcripts will be kept securely at Newcastle University.
- All recordings will be deleted at the end of the study
- Anonymised transcripts will be kept to help with future research..
- You will identified using a participant ID number and all identifiable information removed.
- Information about you will be looked at by people directly involved in the study, as well as by people who are checking it is running as it should.

How will the data be used?
- The conversation will be transcribed and used by the researchers. Your name and any personal details and any other identifying information will be removed from the transcript. We hope to publish the results of the study in medical journals, which may include using quotes from the interviews and recruitment conversations.
- We would like to keep the anonymised transcripts after the study finishes so that we can use the data to help with future research. This may include sharing the transcripts with other researchers who are interested in doing their own analyses of the data. All data will be anonymised before it is made available. There will be no way to identify you or any other people mentioned in your interviews/appointments. Sharing access to data and results from studies is viewed as good practice and many funders and

journals ask for this. Sharing data can encourage new ideas for research. We will not share any recordings – only the anonymised transcripts.
- Results of the study will be available via the LiTEFORM website www.liteform.org.uk

Expenses and payments
If you agree to take part by telephone, we will telephone you so that you do not have to pay for the call. We cannot pay you for taking part.

What are the benefits of me taking part?
Although there will not be a direct benefit to you, you will be helping to give the LiTEFORM study the best possible chance of meeting its recruitment targets and providing useful information for the NHS. The main LiTEFORM trial will help us gather information to learn about the best treatments for patients who are suffering from oral mucositis. We hope we can improve the quality of life patients in the future.

What if there is a problem?
If you are unhappy about any aspect of this study, you should ask to speak to the lead researcher for the interview study, Dr Nikki Rousseau first who will do her best to answer your questions (her contact details are at the end of this information sheet). If you are still not happy after this, then you are free to complain via the NHS complaints processes (please talk to your line manager in the first instance).

Who is organising and funding the research?
Mike Nugent, a Surgeon at City Hospitals Sunderland NHS Foundation Trust is leading the LiTEFORM study. The LITEFORM interview study is being led by Dr Nikki Rousseau who is a health services researcher based at Newcastle University. It is sponsored within the NHS by the Newcastle Upon Tyne Hospitals NHS Foundation Trust and funded by the National Institute for Health Research Health Technology Assessment Programme.

Who has approved the study?
This study has been reviewed and given a favourable opinion by the West Midlands - Solihull Research Ethics Committee. Patients have been involved in deciding how to do LiTEFORM from the start. For example, patients helped us choose the outcome measures for the LiTEFORM trial and design the consent process for audio-recording the LiTEFORM recruitment consultations.

What do I do now?
You will be contacted by a member of the study team. Please let them know whether you would like to take part

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