
L i T E F O R M

End of Study Update 2 to Participant Information Sheet

For patients who started laser therapy after 06July2018

Version Number 1.0 03Sep2019

Dear Participant

We are contacting you because you took part in “**LiTEFORM: Lite Therapy Effectiveness For ORal Mucositis**” study.

There are two important changes that we would like to tell you about.

1. Shorter follow-up period

Fewer people took part in the study in the time given than was originally predicted. This means the study team can write the results sooner than planned. They will use the information that has already been, and is still being, collected from the participants who consented to take part in LiTEFORM.

What does this mean for me?

We have decided to **stop the study** for you after your **4 month follow up visit**. We do not need you to attend any further visits that are no longer necessary.

- If you **have** already been to your 4 month visit, you won't need to go to your final 14 month visit.
- If you **haven't** been to your 4 month visit yet, you should still attend this as scheduled. This will be your last study visit.
- You should still attend all your clinical appointments these are unaffected.

Shortening the follow-up does not mean that your participation is any less important. The information that we have collected is very important and will help us to increase our understanding of low level laser therapy in the treatment of oral mucositis.

Thank you for all your help until this point. We greatly value your participation in the LiTEFORM study.

2. Getting to know your results

During our patient interviews, some participants told us they were interested in finding out which 'group' they had taken part in (active or sham laser).

We are giving you the opportunity to find out this information, if you wish.

To make the study fair, both you and the research team did not know who had the laser light therapy and who had the sham during the study. We will have finished collecting all our information from participants shortly so we will be able to let you know which group were in, but only if you would like to find out. If you were allocated to the sham laser you still received the standard treatment that you would have received if you did not take part in the study. If you have any clinical questions about your ongoing care please speak to your doctor.

If you would like to find out which group you were in you can contact your local research administrator **between** {site to localise with date} - {site to localise with date} using the details below:

Contact name: {site to localise}

Contact phone/ email: {site to localise}

If you **do not** wish to find out then you **don't** have to contact your local team.

Study Results: The results for the whole study will be available in spring/summer 2020 on our website www.liteform.org.uk. Remember these results will not identify you in any way.

We would like to thank you again for participating in the LiTEFORM study.

Yours sincerely,

LiTEFORM trial team.