



Secondary intention wound healing following excision of keratinocyte cancers on the lower leg (HEALS2)

Participant Information Sheet (PIS) for interviews

Dear <<insert name>>,

We would like to invite you to consider taking part in an interview to understand your views and feelings about using compression therapy (firm bandages, stockings or socks applied to the lower leg). Before you decide whether you would like to take part we would like to explain why you have been invited, what taking part will involve and how we will use the information collected about you. Please read this information carefully and discuss with others if you like.

Why am I being invited?

We are getting in touch as you are taking part in the HEALS2 trial and at the point of joining the study indicated you would be happy to receive further information about taking part in an interview.

You don't have to take part, your participation in an interview is voluntary and you may change your mind at any time. If you decide to take part, a researcher will go through a consent form with you during a telephone or video call.

What are we trying to find out?

As part of the HEALS2 trial you used compression therapy after your surgery, and we would like to understand patients' experiences of the treatment in their own words.

Who is taking part?

We are inviting people who have taken part in the HEALS2 trial and were randomised to compression therapy. We would still like to speak to you, even if you have not used the therapy at all, only used it for a short time or part of the time or have stopped using it.

What will taking part involve?

If you agree to take part, we will arrange a date and time for the interview convenient to you. The interview will take place as a phone call or a video call. Before the interview starts

the researcher will complete a consent form with you which will take approximately 10 minutes.

The interview will last about 15 minutes and we will ask your permission for this to be recorded. If you are on a video call only your voice will be recorded.

The recordings will be transcribed (written out in full), but this will not include any details which identify you.

What are the risks and benefits?

There are no specific benefits to taking part, although we hope that you will find it beneficial to share your views on this topic. We don't expect there to be any drawbacks to taking part, apart from the small amount of time required.

What if I change my mind?

You can stop taking part in the interviews at any time and without giving a reason. In the very unlikely event, you feel upset at any stage in the interview, please discuss this with the researcher.

How will my information be used?

We will need to use information from you for this research project. This information will include your name and contact details. People will use this information to do the research. People who do not need to know who you are, will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure at the University of Leeds Clinical Trials Research Unit (CTRU). The recording device will be encrypted. The recording of your interview will be saved using a study ID and transferred securely to the University of Leeds Clinical Trials Research Unit (CTRU). The recording of your interview will be removed from the recording device once the University of Leeds CTRU has received it.

The transcription agency will have a confidentiality agreement with us. The recording of your interview will be deleted once the transcription has been completed.

Your name and contact details will be shared with the researcher who will complete the interview with you. They will be based at either St George's Hospital London or NHS Greater Glasgow & Clyde. They must follow our rules about keeping your information safe. Once the interview has been completed all of the information will be sent to the CTRU, no information about you will be stored in these locations.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We may include a quotation of something you said in our report, but we will make sure that any information which would identify you is removed.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have and use it in the analysis. You can choose to withdraw any data you provided up until they have been transcribed and analysed.

Where can you find out more about how your information is used?

You can find out more about how we use your information at <https://ctr.leeds.ac.uk/ctr-comprehensive-privacy-guide/>. If you have any concerns you can contact the University of Leeds Data Protection Officer at DPO@leeds.ac.uk, +44 (0)113 343 7641 or at University of Leeds, Room 11.72 EC Stoner Building, Leeds, LS2 9JT.

How to contact us

If you need to contact us about the study, you can either email us at: HEALS2-Patients@leeds.ac.uk

or

Telephone one of the researchers <<insert number>>

Thank you for taking the time to read this information sheet.