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

Study Summary

Why am I being invited?

You have been asked to consider taking part in this study as you have a planned surgery to remove a lesion on your lower leg which will be allowed to heal by secondary intention healing.

What are we trying to find out?

We are trying to find out if compression therapy (a type of bandage or hosiery) will help these wounds heal more quickly.

Who is taking part?

We are aiming for 396 people from over 20 clinics across the UK having this type of surgery to take part.

What will taking part involve?

- You will be in the study for at least 6 months, and maybe up to 12 months
- Your surgery will take place as planned
- Everyone will receive best standard care
- 50% of people will also receive compression therapy
- You will be asked to complete some questionnaires
- We will call you by phone to ask you about your wound
- We will ask you to come into clinic on 2 occasions
- We will ask to take a photo of your wound

What are the risks and benefits?

You will be giving up some of your time to take part.

If you receive compression therapy this can occasionally cause discomfort and mild skin irritation

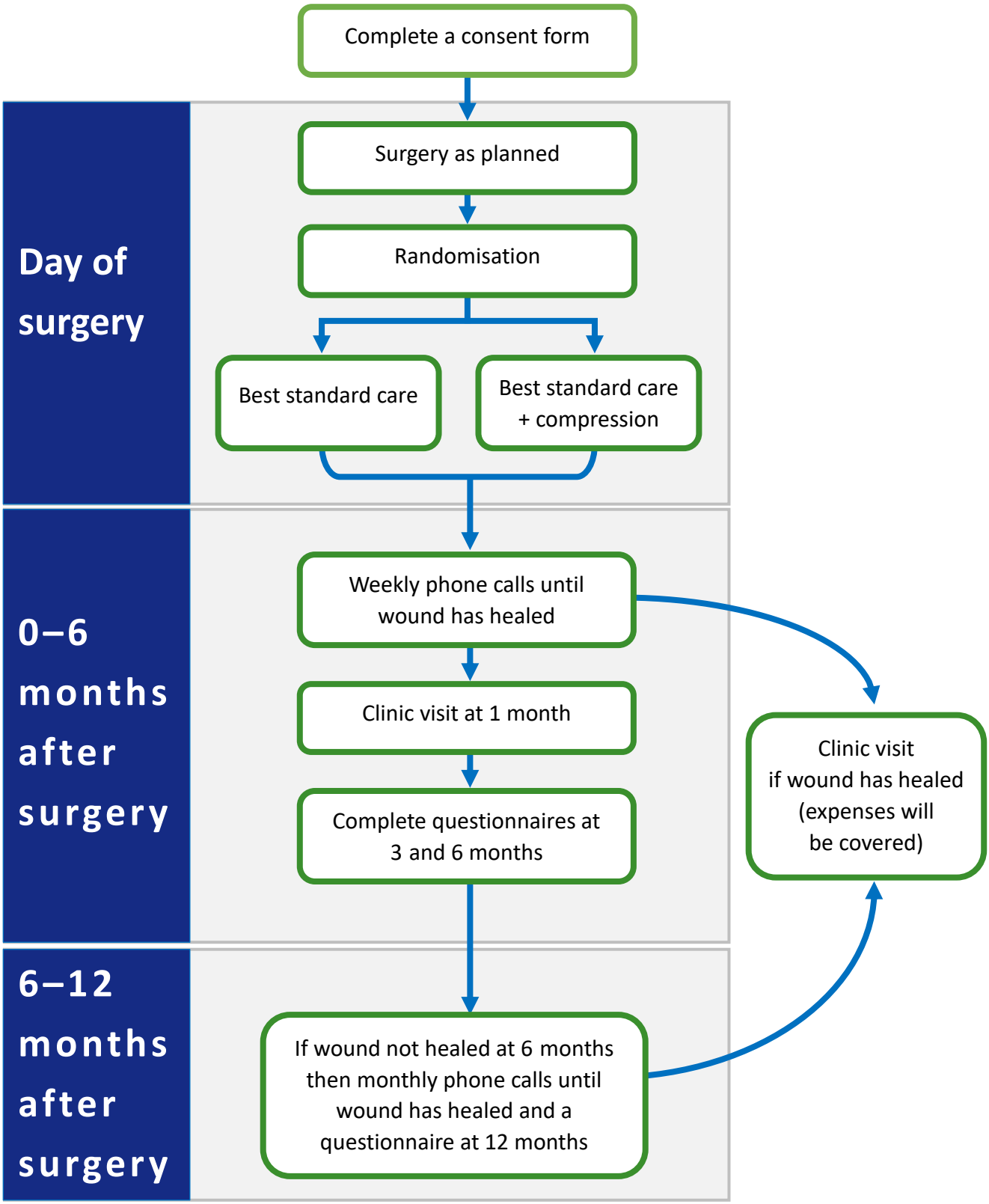
What if I change my mind?

You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. The standard of care you receive will not be affected.

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

A large-print or OpenDyslexic version of this sheet is available on request

The HEALS2 study



FUNDED BY
NIHR | National Institute for Health and Care Research

Contents (Click on the number to go to that topic)

Glossary (important words and names explained)

Keratinocyte cancer (KC):	Cancer can affect different types of skin cells. Depending on what type of cells are involved will affect how you are treated and how serious the cancer can be. KC rarely spreads to any other part of the body although people can have one or more KC lesion. Basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) are types of KC.
Secondary intention wound healing	At the end an operation, a wound can be either closed with the skin edges touching each other and held together e.g. with stitches, staples or glue (primary intention wound healing) or can be allowed to heal naturally, with new skin growing over the wound (secondary intention wound healing). In secondary intention healing, the wound is covered by a dressing to reduce the risk of drying out or infection.
Ankle brachial pressure index (ABPI):	This is a test of the blood supply to your leg. You will need to lay down and rest for a few minutes then the nurse or doctor will take you blood pressure in both your arms. They will also take the blood pressure in your affected leg.

Best standard care (SC):	This is the care everyone will get whether they get allocated the extra therapy or not. It will include regular assessment and dressing of your wound, advice about activity. Where and when you receive this care will depend on local arrangements. It may include visits to the hospital, GP, practice nurse, wound clinic or if you are unable to get out, a community nurse may visit you at home.
Compression therapy (CT):	This can be either bandages or hosiery (stockings or socks). Bandages can be 2, 3, or 4 layers. These will be initially applied to your leg, from the base of your toes to just below your knee. If you are to have bandages, these will always be changed by a healthcare professional. If you are to have hosiery, you may be able to change these yourself. Advice about how to do this will be given.
Clinical Trials Research Unit (CTRU)	The CTRU at the University of Leeds are responsible for running this study. (https://ctru.leeds.ac.uk/).

1. Introduction

We would like to invite you to take part in a research study called "HEALS2". Please take time to read this information carefully, and discuss it with others if you like. Ask us if anything is unclear, or if you would like more information. Once you have read this information, a member of the research team will talk to you about the study again and you can ask any questions you like.

2. Why have I been invited?

You have been asked to consider taking part in this study as you have a lesion on your lower leg which is thought to be a keratinocyte cancer. The surgeon is planning to remove the lesion and the wound will be allowed to heal by secondary intention healing.

You don't have to take part, your participation in HEALS is voluntary and you may withdraw your consent to take part at any time, without giving us a reason.

If you decide to take part, you will be asked to sign a consent form and be given this information sheet to keep.

3. What are we trying to find out?

HEALS2 will try to find out if secondary intention wounds heal more quickly when we use compression therapy after removal of a keratinocyte skin cancer on the lower leg.

4. What is compression therapy?

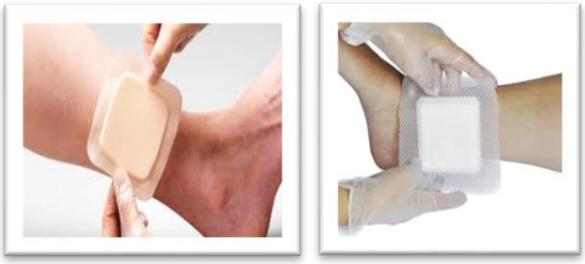
Compression therapy is the use of firm bandages, stockings or socks applied to the lower leg. They are usually applied by a healthcare professional but may be applied by the patient or their carer. It is used in the NHS to treat wounds on the lower leg that are covered with dressings and healing by secondary intention. Examples of compression therapy are shown below:

Compression therapy takes about 5-10 minutes to apply. How frequently the therapy is renewed will depend on the which bandages or hosiery are used and how often your dressings are changed. The choice of type will depend on which ones are available locally, who is going to apply the treatment and your lifestyle.

5. Who is being invited to take part and why?

We are inviting people from hospitals across the UK to take part. We are aiming for 396 patients with planned removal of KC from the lower leg to take part, 198 (50%) of these will receive compression therapy.

6. What will study participation involve?



Your surgery will take place as planned. We will also need to carry out a test of your circulation using an ABPI (or similar assessment) and ask you some questions to make sure this trial is suitable for you. You will also be asked to complete a questionnaire which should take about 5-10 minutes.

All patients will continue to receive current NHS best standard care in line with national and local guidelines. This will usually include wound dressings, advice about skin care and what activities they can carry out, as well as wound checks with a nurse or doctor. Your care will continue as long as you have the wound on your leg.

After your surgery will use a computer to complete a process called randomisation to decide whether you receive compression therapy in addition to best standard care. Randomisation will reduce the risk of bias in the study, will not influence the outcome, allow more accurate conclusions to be drawn and a fair comparison to be made. Neither your doctor nor you will choose which treatment you receive.

There is a very small chance that during your surgery your surgeon decides to close the wound rather than allowing it to heal by secondary intention. If this happens this trial would unfortunately no longer be suitable for you. If this happens your nurse or doctor will let you know what care you will receive for your wound.

If you are chosen to receive compression therapy, this will be applied as soon as possible after your operation and should be continued until your wound has healed.

You will be given a patient identification card (or an electronic version to save to your phone) to have available at every appointment to let the clinical teams know you are part of the study. If you or your healthcare team think your wound has healed, please inform the research team as soon as possible.

Your follow up schedule

- **Weekly phone calls until your wound has healed (or up to 6 months) with a member of the research team** You will be asked some questions about your wound and the treatments you have received. This will take approximately 10 minutes.
- **A clinic visit 1 month after your surgery** Your wound will be assessed by a nurse or doctor and a photo taken. Photographs will only be taken of your wound (this is optional), and you will not be identified from any of the pictures. We will ask you to complete a questionnaire booklet during your visit. This visit will take approximately 5-10 minutes and will take place at the same time you would usually attend the clinic.
- **Complete a questionnaire booklet 3, 6 months (and 12 months if not healed after 6 months) after your surgery** The booklets should take 5-10 minutes to complete. You can choose whether to receive these by post, or email.

- **Monthly phone calls until your wound has healed (up to maximum of 12 months) with a member of the research team** If your wound is not healed after 6 months, you will continue to receive phone calls monthly until your wound has healed (or a maximum of 12 months). Once you have finished taking part in the study, you will continue to be looked after by your GP and any other specialists as before.
- **Review of your clinical records** This will take place at 3 and 6 months after your surgery.
- **A clinic visit when your wound has healed** When you or your healthcare practitioner think your wound has healed, you will be invited to attend the clinic for confirmation. A photograph will be taken. You will be asked to complete a questionnaire booklet.
- **Optional interview for those who received the compression therapy** If you agree to be contacted regarding an interview we will explain what this entails when we contact you.

7. what are the risks and benefits?

What are the potential benefits of taking part in this study?

We want to find out whether the addition of compression therapy will help wounds heal quicker with fewer complications. Participation in this study will help to answer this question and help us to improve the care of patients such as yourself in the future.

You will be closely monitored and supported by the research team in addition to the routine healthcare care you will receive.

What are the potential disadvantages of taking part in this study?

We are asking you to give up some of your time to take part. You will be asked to attend a research appointment 4 weeks after your surgery. However, it is likely that this appointment will be at the same time as your usual clinic appointment You will also be asked to attend the clinic when your wound has healed.

What are the potential risks associated with compression therapy?

If you are randomised to compression therapy there is a slight chance you may experience issues such as:

- Discomfort, particularly when first applied. You may need to take paracetamol or other painkillers you have been prescribed. The pain will lessen as your wound starts to heal.
- Some dryness, rubbing or irritation of your skin under the compression therapy.
- Feeling a little too tight and uncomfortable in bed at night.

What are the potential benefits associated with compression therapy?

Having compression therapy is designed to squeeze your legs and encourage blood to flow back up to your heart, many patients find this supportive and helps relieve aching.

To help us with protecting your safety and the safety of other patients like you, you should always tell your doctor about any health events you have experienced during your time on the study or afterwards (such as having to go to hospital for any reason).

8. What if I change my mind?

You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. However, we would like to know the reason if you are willing to say, because this can be useful when we produce the results of the study.

Before deciding to stop, you should talk to your study doctor or nurse. They can advise you and may be able to deal with any concerns you may have. If you decide to stop taking part at any time, it will not affect the standard of care you receive.

If you decide to stop your study treatment, you will continue to receive best standard care. Trial visits and assessments can still go ahead, if you agree to this.

If during the study your clinical care team determine that you have permanently lost the ability to make your own decisions, no further study intervention will be given. Any information collected up until this point will remain on file and will be included in the analysis.

9. What if something goes wrong?

In the unlikely event that you are injured as a result of the managing organisation (University of Leeds), compensation may be available and you may have to pay your related legal costs. Your hospital where you receive your treatment has a duty of care to you whether or not you agree to participate in the trial and the University of Leeds accepts no liability for negligence on the part of your hospital's employees. If you wish to complain about any aspect of the way you have been treated, please contact your research doctor in the first instance (contact details provided in section 10). Any claims will be subject to UK law and must be brought in the UK.

If you have private medical insurance, you should tell your insurer that you are taking part in research. They will let you know if it affects your policy.

10. How to contact us

If you have any questions about this study, please talk to your doctor at

<<Enter PI, nurse name >>

<< Contact details for site>>

If you have any further questions about your illness or clinical studies, please discuss them with your doctor.

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published various resources to help people learn more about clinical trials. Contact UKCRC: Tel: 0207 395 2271; email: info@ukcrc.org; website www.ukcrc.org. Further information about HEALS2 study is available at http://ctru.leeds.ac.uk/heals2/

And (add ISRCTN number)

11. How will my information be used?

The Clinical Trials Research Unit at University of Leeds (https://ctru.leeds.ac.uk/), who are running this study will need to use information from you and from your medical records for this research project and are responsible for keeping this information secure.

This information will include your

- Initials
- NHS number
- Name and date of birth
- contact details (address, telephone number, email address)

People will use this information to do the research or to check your records to make sure that the research is being done properly. 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.

Photographs

All pictures will be transferred securely to CTRU and will not be stored at the hospital or shared without your permission. The photographs will contain your initials, date of birth and study number only. The research team will check you are happy before each photograph is taken and you may decline to have a photograph taken at any time during follow up.

Your **GP, and the other doctors involved in your healthcare, will be informed** of your participation in this study. This is because they might need to know you took part when they treat you for anything in future.

We may also **need to contact your GP and other doctors** involved in your healthcare if you have not had any trial visits or questionnaires for a while, to check you are still OK to take part in the study.

Your **healthcare records may be looked at by authorised individuals** from the research team, University of Leeds (the study Sponsor), the regulatory authorities or other authorised bodies to check that the study is being carried out correctly. This will only be done in line with your hospital's policies to ensure your records are secure.

To comply with laws and other rules about research, we need to keep your identifiable information until at least 5 years after the study has finished.

We will sometimes need to share your information with people outside the University of Leeds. This is so that we can run the study, keep you and others safe, comply with laws and other rules around research, and support further research in the public interest. We will never sell your information, or pass it on to people who will sell it. Information that we share will never be used to make decisions about future services available to you, such as insurance.

12. What are my choices about how my 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 to make sure the research is still reliable and include it in the study analysis.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital and/or your GP to help ensure the results of the study are valid. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable as it is being done in the public interest. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. We will only do this for worthwhile research projects with all appropriate ethical approvals. If people outside the original study team are involved, they will only receive the minimum information needed for the new project, and they will not receive any clearly identifiable information (such as your name).

13. What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified. You can find out the results of the study on our website http://ctru.leeds.ac.uk/heals2/ or by scanning the code below or the NIHR journals website https://www.journalslibrary.nihr.ac.uk/#/ (this website also has a 'notify me' option).

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Participant ID:	Initials:
Date of Birth:	NHS/CHI/Hospital Number:
ISRCTN <<insert>>	Principal Investigator:

HEALS2 PARTICIPANT CONSENT FORM

Please initial each box

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I understand that even if I withdraw from the above study, the data collected from me will be used in analysing the results of the study and in some cases further information about any unwanted effects of my treatment may need to be collected by the study team. ☐

3. I understand that my healthcare records may be looked at by authorised individuals from the study team, regulatory bodies or Sponsor in order to check that the study is being carried out correctly. ☐

4. I agree to the local research team holding my contact details for purposes of contacting me for follow up phone calls.

5. I understand that if during this study my clinical care team determine that I have lost my ability to make my own decisions, no further study intervention will be given. I understand that information collected up until this point will remain on file and will be included in the analysis. ☐

6. I have provided my preferred method to receive questionnaires and contact details and agree for a copy of this information to be sent to CTRU. ☐

7. I agree to a copy of this Consent Form being sent to the CTRU which includes my full name, date of birth and NHS number. ☐

8. I agree that my GP, or any other doctor treating me, will be notified of my participation in this study. ☐

9. I agree to take part in the study. ☐

The following points are OPTIONAL.

Even if you agree to take part in this study, you do not have to agree to this section

	Please initial	
	Yes	No
1. I agree for photographs of my wound to be taken and sent to the CTRU which will include my initials and date of birth.	☐	☐
2. I agree to allow any information or results arising from this study to be used for healthcare and/or further medical research upon the understanding that my identity will remain anonymous (your name will not be used).	☐	☐
3. I give permission for the photographs taken of my wound to be used for teaching, future research or publications upon the understanding that my identity will remain anonymous.	☐	☐
4. I am happy to be contacted by a member of the research team about taking part in a semi-structured interview. I understand that taking part in this is separate to the main study and is not mandatory.	☐	☐

Patient:

Signature……

Name (block capitals)……

Date……

Investigator:

I have explained the study to the above named patient and they have indicated their willingness to participate.

Signature……

Name (block capitals)……

Date……

(If used)Translator:

Signature……

Name (block capitals)……

Date……

Witness:

I have completed this consent form on behalf of the person named above who has freely given their consent to participate.

Signature……

Name (block capitals)……

Date……

(Paper consent: 1 copy for patient; 1 for the CTRU; 1 held in patient notes, original stored in Investigator Site File)

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14. Appendix: more about how your information will be used

If you still have questions after reading this appendix, or would like more detail about anything, you should look through our **comprehensive guide** to how your information is used. You do not have to read it before taking part in this study, but you might want to look at specific sections if you have particular concerns. It is available at https://ctru.leeds.ac.uk/ctru-comprehensive-privacy-guide/ or you can ask for a printed copy from your study doctor or nurse. This can also be made available in large print or other formats, if you need them. You should read through these sections as much as you would like to.

What information will be collected, and what will it be used for?

If you agree to take part in this study, we will need to collect and use some information about you and your health. We will only use what we need to run the study, to produce the results of the study and to make sure you and other people taking part in the study are safe.

This research is in the public interest, which means our results will be used to improve the healthcare of patients in the future. Because of this, if you agree to take part in the study, we will be able to use information about you, including sensitive information about your health**.**

Specifically, the ways we will use information about you are:

- We will use information from you and your medical notes to run the study, to produce the study results and to confirm it is safe and appropriate for you to join the study. We will also collect information about your health from your study doctor or nurse and your medical notes to help make sure you and others are safe.
- We will collect a copy of your signed consent form so that we can be sure you have agreed to take part in the study.
- We will collect information about you and your health directly from you on study questionnaires. We will use this information to produce the study results.
- Sometimes we need to ask doctors who work with us to give us advice on specific medical situations. To help the doctors do this, we might need to collect copies or scans of parts of your medical notes. These will have any details that could identify you removed before they are sent to us.
- In this study, we need to check that wound healing is being recorded consistently **.** To do this, we want to collect photographs of your wound site (this is optional)**.** These will have any details that could identify you removed before they are sent to us.
- If you join this study, we would like to call you by phone at prespecified time points and send you study questionnaires. To do this, we will need to collect your phone number, email address or address. You can choose which details to provide and we will only use it for the purposes mentioned here.

If you want to find out more about any of these, please refer to the **comprehensive guide** to how your information is used.

Who is collecting my information?

Your information will be collected by the Clinical Trials Research Unit within the Leeds Institute of Clinical Trials Research, University of Leeds. You can find out more about our work at https://ctru.leeds.ac.uk/.

University of Leeds has overall responsibility for what information is collected, how it is collected, and making sure people's information is used securely and correctly. If you want to contact someone within the University about how your information has been or will be used, you can see section 9, below. See the **comprehensive guide** for more about what this means for you.

We will make sure we follow the principles of data protection in everything we do. This means we will keep your information secure, keep it only for as long as we need it, only use the minimum information we need for specific, necessary purposes, and we will be open, transparent and fair with you about how we use your information. You can find out more about how we follow the principles of data protection in the **comprehensive guide.**

Will my information be kept secure?

We will take all necessary measures to ensure that information about you is sent and stored securely by us or by anyone acting on our behalf.

Your study doctor or nurse will enter most of the information needed for the study directly into our secure study database. Your study doctor or nurse will also send us some information by post. This may include your completed consent form, so that we can be sure you have agreed to take part in the study. This will be sent separately to any other study forms.

Sometimes we will also get information about you by email. Emails will never contain your name, only your trial identifying number and sometimes your initials and date of birth.

Finally, some particularly sensitive documents, such as photographs will be sent to us via a 'secure file transfer'. This means information is sent by the internet in a very secure way.

Information stored in our databases or other electronic storage locations is held very securely, in a way that would make it very difficult for any unauthorised people to access it.

Who will see my information in the research team?

We will make sure that the only people at the University of Leeds who can see your information are people who need to run or analyse the study.

Who else will see my information?

There are some specific situations where we need to share information with other people or other organisations. We will always do this carefully and only when it's really necessary. We will avoid sharing information that could identify you whenever possible. We will never sell your information, or pass it on to people who will sell it. We will only share information when it is necessary for the study, necessary to protect your safety or the safety of others, or in the public

interest. Information we share will not be used to make decisions about future services available to you, such as insurance.

We will share your information for the following reasons. You can find out more about these in the **comprehensive guide.**

- To run and analyse parts of the study, we need to share your information with collaborators (such as doctors, statisticians or other experts) outside the University of Leeds.
- To keep you and other people safe, we will need to share some information about health-related events you may have with authorised organisations. None of these organisations will be able to identify you from this information.
- To report to authorised people about the progress of the study, we will need to share some basic information with some authorised organisations, including the Research Ethics Committee that has approved this study. None of these organisations will be able to identify you from this information.
- To allow other researchers to carry out future research in the public interest. We will only share your information for worthwhile research with all appropriate approvals. We will only share your information in such a way that researchers outside the University of Leeds will not be able to identify you. Your information will not be shared if you have explicitly said you did not want this to happen.
- We may also use study information for additional research projects within the University of Leeds. We will only agree to do this for worthwhile projects with all appropriate approvals, and we will not share any clearly identifiable information with researchers outside the original study team.
- Due to storage space limitations, we will store information securely away from the University of Leeds for a period after the main part of the study is over. The archiving companies we use to do this for us will only store your information and will not access it or see your details.

Can I see my information, or ask you to correct it?

Usually, when an organisation or a company has information about you, you can ask to have access to that information at any time, or ask them to correct it if it needs correcting. However, this does not apply in the same way to information used for research in the public interest, because allowing people to access or change their information could harm the quality of the research. You therefore cannot ask to access or correct information we have about you. However, most of the information we will collect will also be in your medical notes, which you can get access to if you want to. You should speak to your study doctor and nurse if you would like more information about care you have received.

If you have provided us with contact details for use in the study (**[address, email address, phone number]**) it is important that we find out about any changes to these. Please let your study doctor or nurse know about any changes so that they can let us know. Otherwise, we might lose contact with you or send messages for you to your previous contact details.

How long will my information be stored for?

If you agree to take part in this study, we will need to keep your information for at least 5 years after the end of the study. We need to do this in order to comply with laws and other rules about research, which say it must be possible to check the results of the research for a period of time after it has finished. We will keep your information secure during all this time. For practical reasons, we may ask reputable archiving companies to store information securely on our behalf, away from the University of Leeds. At the end of this period, we will securely destroy your information.

What will happen if I stop taking part in the trial?

If you decide you would like to stop all your study visits for any reason, we will need to keep the information we have about you to make sure the results of the study are reliable.

Usually, when an organisation or a company has information about you, you can ask them to delete it, or not use it for a certain purpose. However, this does not apply in the same way to information used for research, because it would harm the quality of the research if people could delete or remove their information. We also need to comply with laws and other rules about research that say we need to keep all information used in research for a period of time after the research finishes. If you agree to take part in this study, it will therefore not be possible for us to remove or delete your information later on, although you can ask us to collect no further information after a given time.

Some other things you should know about what will happen to your information if you stop taking part:

- If you stop all study visits, you should discuss with your study doctor and nurse. If you still occasionally go to your hospital for routine visits, we would like to hear from your study doctor or nurse about these visits, if they are relevant to this study. This way, you can still contribute to the study and help make the study results more reliable, without giving any more of your time. However, you can tell your study doctor or nurse that you do not want any more information sent to us, and they will make sure your wishes are respected.
- If you stop attending your study visits without telling anyone at your hospital, or you change your contact details or move house and do not tell your hospital, they will lose contact with you. If this happens, we may ask your study doctor or nurse to contact your GP to check if you are OK and still happy to take part in the study.

If you want to know more about what might happen to your information if you stop taking part in the study, including *why* we need to use your information in the ways we do, please see the **comprehensive guide.**

What if I have concerns about how my information is being used?

Your study doctor or nurse should be your first contact for any questions about your participation in this study. If you still have questions that they cannot answer, and which are not answered by any of these documents, you can contact the University of Leeds Data

Protection Officer (the University's main contact for anything to do with how your information is used). You can do this using any of the details below. If you do contact them, please mention the name of this study (HEALS2) and the Clinical Trials Research Unit.

- Email: DPO@leeds.ac.uk
- Telephone number: +44 (0)113 343 7641
- Postal address for data protection issues: University of Leeds, Room 11.72 EC Stoner Building, Leeds, LS2 9JT

If you are not happy with the response to any queries or complaints, or believe your information is being used incorrectly or unlawfully, you should contact the Information Commissioner's Office:

- General website: ico.org.uk
- ICO contact webpage: https://ico.org.uk/global/contact-us
- Telephone number: 0303 123 1113
- Postal address: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Where can I find out more about how my information is used?

You can find out more about how we use your information in the following ways;

- You can find more general information from the NHS about how people's information is used in research at www.hra.nhs.uk/patientdataandresearch. (Please feel free to ask for a printed copy of this if you cannot access this online version.)
- by asking one of the research team

Who has organised, reviewed and funded the research and who will be supervising it?

HEALS2 is has been reviewed and is funded by the National Institute for Health Research's Health Technology Assessment (HTA) Programme and is being organised by the Clinical Trials Research Unit at the University of Leeds . In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This committee exists to protect the safety, rights, wellbeing, and dignity of patients (Ethics ref: 23/YH/0247). This research has also been reviewed by patients and carers.