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**Compression Hosiery to Avoid Post-Thrombotic Syndrome**

**(CHAPS)**

**ISRCTN: 73041168**

**HRA/REC Reference: 19/LO/1585**

**IRAS 263041**

**Sponsor Reference: 19CX5434**

***Acknowledgement***

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***Disclaimer***

*The views expressed in this publication are those of the author(s) and not necessarily those of the MRC, NHS, NIHR or the Department of Health.*

# PATIENT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

*You have been invited to take part in a research study called CHAPS. Before you decide whether to accept, we would like to explain why the research is being carried out and what it will involve.*

*Please read this information carefully, and discuss it with others if you wish. Ask us if anything is unclear, or if you would like more information.*

* *Part 1 tells you the purpose of this study and what will happen to you if you take part.*
* *Part 2 gives you more detailed information about the conduct of the study.*

*Please take your time to decide whether or not you wish to take part.*

**Thank you for reading this information sheet.**

**Part 1**

**What is the purpose of the study?**

Patients with a deep vein thrombosis (DVT) may develop long-term symptoms, e.g. lifelong leg pain, skin changes and occasionally ulceration, known as post-thrombotic syndrome (PTS). This affects about half of people with a history of DVT.

This study aims to show whether the regular use of a compression stocking after DVT in the leg, prevents long-term pain, swelling and ulceration. Currently small trials show varied results and a large trial is required to answer the question.

**Why have I been chosen?**

You have been invited to consider this study because you are a patient who has recently been diagnosed with a deep vein thrombosis, a blood clot in the leg veins. We hope that about 864 people like you from across the UK will take part in this study.

**Do I have to take part?**

No, participation in this study is entirely voluntary. If you do decide to take part you will be given this information sheet to keep. You will be asked to sign a consent form, but you are still free to withdraw at any time and without giving a reason. If you decide not to take part in the study, your doctor will be happy to talk through how he/she will treat you outside of the study. You do not have to give a reason for not taking part and your treatment and care will not be affected in any way.

**Tell me more about the stockings**

Compression stockings have been used safely in the UK for about 50 years. They contain an elastic fibre designed to fit tightly around the legs. These specialist stockings are tighter around the ankle, with the level of compression gradually decreasing up the garment.

The pressure created by the stockings helps blood flow up the leg, allowing blood to flow freely to the heart and not pool in the leg which can result in pain and swelling.

It is important for us to check whether your leg arteries are normal before wearing a stocking, because they can be compromised if they are not. This is performed by your doctor feeling the pulses in your foot. If there is any doubt they will arrange for the blood pressure to be taken around your ankle to check the flow is adequate, before letting you join CHAPS. If there are any problems with this, you will be informed and referred to your local vascular specialist.

**What will happen to me if I take part?**

If you choose to be involved in the research, your participation will last between 6 – 30 months from trial entry depending on whether you are the first or last patient to enter into the trial. The following section tells you more about what will happen on each of your visits

There are no restrictions on your activity when you are taking part in this study. You will continue with any other medical care or treatments, such as taking regular medication, as you would normally do. This will include the standard treatment for DVT, which will be blood thinning tablets for a minimum of 3 months.

**Your first visit**

If you decide to participate in the study, the following steps will be taken at your first visit (often referred to as the screening/baseline visit) which will last 1½ hours:

* You will first be asked to sign the consent form to confirm that you would like to be included (you will be given a copy of this).
* Some information about your medical history and current medical condition will be collected to check that you are able to take part and will include a check of your pulses in your legs.
* You will have your height and weight recorded.

If the research team confirm that you are able to take part in the study, a computer programme will randomly select whether you will receive either ‘standard care’ or ‘standard care plus the compression stocking’. There is an equal chance of either treatment being the one you will receive. Neither your doctor nor you will choose which treatment you receive. In this way, a fair comparison between the two groups can be made.

At this visit you will also be asked to complete two health questionnaires about your quality of life so we can collect information about your health throughout the study. These are called the EQ-5D-5L and the VEINS-QoL Sym questionnaire. You will also be asked to complete a number of questionnaires relating to taking your medication. These are called the MARS, BIPQ, TIQ. In some instances we might send you the health questionnaires by mail or obtain them over the telephone.

Standard care group

Your treatment plan will be the same as per those who decide not to enter the trial and will involve taking blood thinning medication, called anticoagulants, for a minimum of 3 months.

Stocking group

If you have been allocated to the group that will receive the compression stocking, you will receive the standard care as detailed above but you will also be fitted with a tight stocking to wear. This helps push venous blood back up the leg to the heart and theoretically reduce pain and swelling. The stockings are to be worn as much possible but you can take them off to shower or bathe. You can wear socks, slippers, and shoes over the stockings. You can watch a short video about how to put them on and the research nurse will provide a demonstration.

You may also be asked for consent to participate in interviews in which your perspectives of the stockings will be explored in greater detail by a qualitative researcher from University College London

We will ask participants in both groups to fill out a 2 minute electronic questionnaire about their stocking use each month and one about your views of your condition called the BSQ up to 1 year from trial entry. You will log into an electronic database to complete these online but you can also complete these by telephone or a letter in the post instead of email.

All participants will be given a diary to complete whenever you see a doctor or nurse so we can collect the costs associated with your condition.

We will then invite you back to the hospital at 2 weeks (for stocking group patients only), 6 months, 12 months and a final visit (around 18 months) for repeated measures of the above tests in order to answer our research questions.

Further details for each study visit:
 **2 week follow-up**

At 2 weeks if you have received a stocking you will be asked to come in to see your clinic nurse to check that it fits well. This visit will last about ½ hour. We will ask you to fill out the questionnaires relating to your medication (called the TIQ) as well as one which tells us how you are getting on with wearing the stockings regularly (the BSQ).

You will be offered a variety of helpful aids to wearing the stocking including: a weekly text message reminder, a slipper or frame to help put the stocking on and the membership of an anonymous group to put you in contact with others with your condition who can share tips regarding different stockings. In addition, you will be able to watch the short video again about how stockings work and some tips for wearing them.

**6 month follow-up**

At 6 months you will be seen in clinic for a check-up similar to the first session and will last about ½ hour.

An independent researcher will examine your leg for varicose veins, swelling or skin changes. It is important that you do not wear your stocking to this appointment or talk about your stocking to the independent researcher, as we are trying to keep them unaware of the treatment you are receiving, so they are not influenced. Don’t worry we will remind you!

At this time, you will be asked to complete the same quality of life, medication and stocking usage questionnaires that you completed at earlier visits.

We will supply you with a hotline to ring when your stockings lose their elasticity, or if they become damaged. This should be every 6 months.

If you are in the stocking group of the trial, we will ask you to rate how useful the stocking wearing aids are and what your use of the stocking was on average over the last month.

**1 year follow-up**

At 1 year you may be seen in clinic for a session of measurements similar to the first session and will last about ½ hour.

An independent researcher will examine your leg for varicose veins, swelling or skin changes. It is important that you do not wear your stocking to this appointment or talk about your stocking to the independent researcher, as we are trying to keep them unaware of the treatment you are receiving, so they are not influenced. Don’t worry we will remind you!

At this time, you will be asked to complete the same quality of life, medication and stocking usage questionnaires again.

If you are in the stocking group of the trial, we will ask you to rate how useful the stocking wearing aids are and what your use of the stocking was on average over the last month.

**Final follow-up**

At around 18 months you may be invited for a final session of measurements similar to the previous visit which will also last approximately ½ hour and will conclude your study participation.

An independent researcher will examine your leg for varicose veins, swelling or skin changes. It is important that you do not wear your stocking to this appointment or talk about your stocking to the independent researcher, as we are trying to keep them unaware of the treatment you are receiving, so they are not influenced. Don’t worry we will remind you!

At this time, you will be asked to complete the same quality of life, medication and stocking usage questionnaires again.

**What is the standard treatment in the UK?**

If you decide not to take part in the trial, in most hospitals you will be offered the standard care for DVT which involves taking blood thinning medication, for a minimum of 3 months. This is the same as the standard care group receive as part of the trial.

**Are there alternative treatments?**

There is no evidence that other kinds of tight socks, such as flight socks, or lower grade compression stockings have any benefit after deep vein thrombosis.

If you develop an open wound on the leg (leg ulcer) after deep vein thrombosis, you may be asked to wear a compression bandage for wound care, rather than a stocking.

If you develop varicose veins after your deep vein thrombosis, please consult your vascular specialist.

## Unwanted effects of treatment

You should not join the study if you have a known intolerance to, or are already wearing graduated compression stockings.

**Pregnancy**

Pregnant women are permitted to join CHAPS as the study only involves wearing a stocking. We do not specifically need to test for pregnancy for this trial, but please inform us if you become pregnant during the trial.

## How is my condition monitored?

Participating in this study will not significantly affect how your condition is monitored or any other treatment you receive, although you would be reviewed in clinic more regularly than you would be outside the study.

## What are the possible benefits of taking part?

We cannot promise the study will help you but the information gained from the study may help doctors and patients make future decisions as to whether compression stockings offer an additional benefit to patients who are receiving blood thinners and could potentially improve patients’ quality of life.

Those patients who receive a stocking may have a lower risk of long-term pain, swelling and ulceration. They will also have the benefit of peer support via an online Facebook group and receive additional education about deep vein thrombosis. Those patients who are not asked to wear a stocking will still benefit from longer, enhanced follow up after deep vein thrombosis.

Participants in both groups of the trial will be monitored closely for any complications of deep vein thrombosis, so that they can quickly be detected and acted upon. All patients will in addition have the arteries in their legs checked for adequate flow down to the feet.

You will not get paid for participating in this study, but can claim for travel expenses.

## What are the possible disadvantages and risks of taking part?

Whilst compression stockings are used very frequently, all medical procedures carry risks of complications. Possible complications of compression stockings are listed below. These are only the complications which could occur; we are not expecting any of them to happen to you.

Compression stockings:

Side effects of compression stockings are uncommon. Whilst we do not anticipate any specific side effects as a result of taking part in this trial, in rare circumstances, some patients may be allergic to the materials that are contained within the stockings. If this is the case, we will use another product which does not contain that material. Other complications are:

* discomfort
* blistering, or in rare cases, skin abrasion
* restriction of the blood supply to the leg (which is checked before you join CHAPS)

COVID-19

We know that coming to hospital during the current COVID-19 pandemic might cause you some anxiety. COVID infection has to be recognised as a risk however we want to reassure you that the NHS, [SITE PI] and the Research team have your safety in mind.  The Trust has made changes to the hospital to reduce the risks so you will find things different from your previous visits.

Please do not come to hospital if any of the following apply:

* If you feel unwell
* If you have symptoms of COVID or are self-isolating.
* If you have been diagnosed with COVID in the last 14 days or have been in close contact with some who has.

If this is the case then please call [local study team contact details] and we will rearrange your visit for another time.

To mitigate this risk you will be required to wear a mask during your visit, to clean your hands with alcohol gel and to maintain a safe distance from other people.  The Research team and indeed all hospital staff will do the same.  Where necessary, the appropriate Personal Protective Equipment (PPE) will be worn.

**What happens when the research study stops?**

The information from this study will be used to decide if compression stockings offer any additional benefit to patients who are receiving blood thinners. Additionally, the research team will also use the information collected to compare the safety and cost of the two types of treatment. We hope that the result of the study will help patients and doctors to decide whether stockings should be used to prevent PTS in patients coming to hospital with a DVT.

At the end of the trial you will revert to standard care for your condition. There will be a period of around 6 months where the results from CHAPS are analysed, before recommendations are made. During this time you will not be asked to wear a stocking, unless recommended by your vascular specialist.

## Will my taking part be kept confidential?

Yes, it will. If you decide to participate, the information collected about you will be handled strictly in accordance with the consent form that you have signed and also the 2018 Data Protection Act. Please refer to Part 2 for further details.

**This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.**

**Part 2**

**What if relevant new information becomes available?**

Sometimes during the course of a research project, new information becomes available about a treatment that is being studied. If this happens, your research doctor will tell you about it and will discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

If, after one year, the Data Monitoring Committee decide that not enough people are wearing stockings regularly the CHAPS study could be stopped early.

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

You can decide to leave the study at any time. You do not need to give a reason.

If you leave the study before your treatment, then your doctor will discuss with you what type of treatment they will use outside the study. If you decide to leave the study, any data collected up until that time will remain on file and will be included in the final study analysis and follow up information will continue to be collected from your medical records.

If you decide to leave the study and do not wish for any further data to be collected about you, you should inform your clinical care team of this in order that no further follow up information is collected from your medical records. In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived. In this study, data will be archived for a minimum of 10 years after which arrangements for confidential destruction will be made.

**What if something goes wrong?**

A group of independent researchers (called the Data Monitoring Committee) will closely monitor the study. If there are any problems then they will be detected as soon as possible so that the study can be changed or stopped if necessary.

Imperial College London holds insurance policies which apply to this study.  If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault.  This does not affect your legal rights to seek compensation.

If you are harmed due to someone’s negligence, then you may have grounds for legal action.  Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Insert name and contact details).  The normal National Health Service complaints mechanisms are also available to you.  If you are not satisfied with the response, you may contact your local Patient Advice and Liaison Service (PALS) which offers confidential advice, support and information on health-related matters (insert contact details). You may also contactthe Imperial AHSC Joint Research Compliance Office (Room 215, Medical School Building, St. Marys Campus, Norfolk Place, London W2 1PG. Tel: 0207 594 9459).

**Will my taking part in this study be kept confidential?**

Yes, it will. All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.

With your permission, your data will be entered onto a secure database held at the University of Edinburgh, in accordance with the 1998 Data Protection Act. Your relevant medical records may be inspected by authorised individuals from the research team, NHS or Imperial College London (the study Sponsor). They may also be looked at by the relevant regulatory authorities to check that the study is being carried out correctly.

Anonymous data may also be linked with appropriate national databases, including Hospital Episode Statistics (HES), and the National Vascular Database as well as for longer term follow-up in the event the trial is extended.

For those patients in the stocking group of the trial, with your consent, your mobile phone number and email address will be entered into a secure database hosted by the University of Edinburgh who will send you weekly text message reminders. Your e-mail address and number will be kept confidential and deleted at the end of the study. The Health Economist is based at the University of Granada and therefore your de-identified quality of life and healthcare usage data will be transferred there. This will determine the cost and effect on your quality of life that the two treatment groups may have. The company that make the stockings (Medi UK Ltd) will only have access to the anonymised results.

Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep safe identifiable information about you for 10 years after the study has finished. If you are a patient at Imperial College Healthcare NHS Trust, this will be held at Imperial College London. Otherwise, this will be held at your local NHS Trust (as below a copy of your consent form will be kept at Imperial College London).

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the Principal Investigator on [INSERT] or emailing chapstrial@imperial.ac.uk, or consulting the following link: [http://www.imperial.ac.uk/clinical-trials-unit/dataprotection/](http://www.imperial.ac.uk/clinical-trials-unit/dataprotection/%20)

[Trust] will collect information from you and your medical records for this research study in accordance with our instructions.

**TEMPLATE WORDING FOR EXTERNAL SITES – BELOW WORDING IS TO BE USED. DELETE FOR IMPERIAL COLLEGE HEALTHCARE NHS TRUST PATIENTS**

[NHS/other site] will keep your name, NHS number and contact details confidential and will not pass this information to Imperial College London. [NHS/other site] will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Imperial College London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Other than a copy of your consent form, Imperial College London will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

[NHS/ other site] will keep identifiable information about you from this study for x years after the study has finished.

**TEMPLATE WORDING FOR IMPERIAL COLLEGE HEALTHCARE NHS TRUST PAITENTS WHOSE DATA WILL BE ARCHIVED AT IMPERIAL COLLEGE LONDON. PLEASE DELETE THIS WORDING FOR EXTERNAL SITES**

Imperial College Healthcare NHS Trust will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Imperial College London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Imperial College Healthcare NHS Trust site will pass these details to Imperial College London along with the information collected from you and your medical records The only people in Imperial College London who will have access to information that identifies you will be people who need to contact you for the CHAPS study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Imperial College London will keep identifiable information about you from this study for 10 years after the study has finished.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)**.**

Your information could be used for research in any aspect of health or care and could be combined with information about you from other sources held by researchers, the NHS or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

Imperial College London will collect information about you for the CHAPS study via the local research nurses who will not provide any identifying information about you to Imperial College London, except a copy of the consent form you signed when you joined the study. Imperial College London will store a copy of the consent form and the other information you provide will be used to help answer the CHAPS research question.

**Involvement of the General Practitioner (GP) / Family Doctor:**

With your permission, your GP and other doctors involved in your clinical care will be kept informed of your participation in the study, but otherwise all information about you and your treatment will remain confidential. We may contact your GP to obtain information about your health status if we cannot reach you.

**What will happen if I lose mental capacity during the study period?**

This is expected to be a very rare occurrence. If this did occur your doctor or carer will determine whether you should be withdrawn from the study. If you are withdrawn, anyidentifiable data already collected with consent will be retained and may be analysed, but no further data will be collected or any other research procedures carried out on or in relation to you.

**What will happen to the results of the research study?**

When the study is complete, we plan to inform patients of the results of the study by letter, email, newsletter, social media or publication on the trial website. We may ask patients if there are any other methods they would prefer. The results will be presented at conferences and published in a medical journal. No individual participants will be identified.

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

This research has been supported by a National Institute for Health Research, Health Technology Assessment programme grant, which is funded by the National Institute for Health Research. The Sponsor of this study (Imperial College London) will pay your hospital to cover the costs of your participation in this study. You are able to claim the travel costs (e.g. bus / train / tube fare or parking costs and petrol) for your hospital visits. Please speak to the study nurse about how to make this claim. Stockings are supplied free of charge for those patients allocated to this group.

The research is being co-ordinated by Imperial College London, who have overall responsibility for coordination of the study. The research has been reviewed by the National Institute for Health Research, representatives from all of the participating hospitals and organisations, and an independent National Research Ethics Committee, and the Health Research Authority (HRA).

CHAPS is supported by Thrombosis UK the UK charity for patients suffering DVT.

**Contact Details**

If you have any further questions about your treatment, please discuss them with your doctor. You may also find it helpful to contact the research nurse on XXXXXX.

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) has published a booklet entitled ‘Understanding Clinical Trials’. Contact UKCRC: website: <http://www.ukcrc.org/wp-content/uploads/2014/03/iCT_leaflet.pdf>

**THANK YOU FOR READING THIS INFORMATION SHEET**



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| Site ID:  | Initials:  |
| Participant Trial ID: | Principal Investigator Name: |
|  |  |

**Compression Hosiery to Avoid Post-thrombotic Syndrome (CHAPS)**

**IRAS 263041**

 **PATIENT CONSENT FORM** Please initial box

1. I confirm that I have read and understand the information sheet dated 24/02/2021 (Version 4.0) for the above study and have had the opportunity to ask questions which have been answered fully.
2. I understand that my participation is voluntary and that I am free to leave the study at any time without my medical care or legal rights being affected.
3. I understand that relevant sections of my medical records may be looked at by authorised individuals from the research team, from regulatory bodies, from the study Sponsor, or from the NHS Trust in order to check that the study is being carried out correctly. I give permission, provided that strict confidentiality is maintained, for these bodies to have access to my medical records for the above study.
4. I understand that my mobile phone number and email address will be stored until the end of the study securely by the University of Edinburgh and used to send weekly text message reminders to you until your participation on the study ends
5. I understand that my pseudonymised data will be transferred to the University Of Granada for the analysis.
6. I agree to my data being entered onto a secure database held at the University of Edinburgh, in accordance with the Data Protection Act 2018.
7. I agree to my GP, or any other doctor treating me, being notified of my participation in this study. I agree to my GP being involved in the study, including any necessary exchange of information about me between my GP and the research team.
8. If during the study my clinical care team determine that I have lost capacity to provide informed consent, I will be withdrawn from the study and any identifiable data collected with consent would be retained and used in the study.
9. I agree to take part in the CHAPS study.

**Optional consent section (please initial the appropriate box)**

10. I give/do not give consent for information collected about me to be used to support other research in the future, including those outside of the EEA.

 Give consent Do not give consent

11. I give/do not give consent for my data may be linked with appropriate national databases, including Hospital Episode Statistics (HES), and the National Vascular Database as well as for longer term follow-up in the event the trial is extended

 Give consent Do not give consent

12. I give/do not give consent to be contacted in the future with regards to this study, should the study be extended.

 Give consent Do not give consent

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Full Name of Participant |  | Date |  | Signature |
|  |
| Name of Person Taking Consent |  | Date |  | Signature |

(1 copy for participant; 1 copy for the patient’s medical notes, 1 copy for the site file)