Upright Radiotherapy, improving patient positioning systems for accurate and comfortable treatments.

Participant Information Sheet

We invite you to take part in a research study

Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. You are free to decide whether or not to take part in this study.

Ask us if there is anything that is not clear or if you would like more information.

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1. Why are we doing this study?

Approximately one third of cancer patients in the UK will have radiotherapy as part of their cancer treatment. Currently, patients are treated lying on their back while machinery is rotated around them. As the machine rotates, it delivers a beam of radiation from different directions.

This study is a partnership between researchers from Leo Cancer Care and Sheffield Hallam University. Leo Cancer Care is a young British company. Working with experts that specialise in human centred design of equipment, Leo Cancer Care have developed a new, flexible patient positioning system that slowly spins a seated patient to:

1. Try to improve the benefits achieved from radiotherapy, by positioning the patient differently.

2. Reduce the cost of radiotherapy by removing the need for large and expensive equipment moving around the patient and instead move the patient slowly to the same effect.

3. Empower patients by allowing them to see and be more aware of what is
The purpose of this study is to help researchers to improve upright radiotherapy patient positioning on the Leo Cancer Care upright chair (Eve) for patients diagnosed with breast, prostate and lung cancer.

2. What do we plan to do in this study?

We plan to include 8 people in the study who meet the criteria in section 3 below. If you give consent to join this study, you will be invited to attend for one full day visit at Sheffield Hallam University. In the morning we would like to hear about your experience of having radiotherapy lying on your back. To help you think about what your experience was like we will ask you to make some notes on a diagram that will be shared with you before the face-to-face event. In the afternoon we will invite you to sit in the Leo Cancer Care chair for 10 minutes, after which we will assess your comfort. We will explore various arm/body positions and how these might be supported, for example using arm rests. This will help the Leo Cancer Care team to make the experience more comfortable, if the treatment positions are used for future patients.

Morning event

In the morning of the full day event, we will ask you to talk through the notes you have made with others in a group. We aim to have between 8 and 10 people attend the session. You would not be required to disclose anything specific about your radiotherapy that you did not feel comfortable sharing in a group situation. Others in the group will have had the same cancer diagnosis as you.

Afternoon event

During the afternoon you will be asked to sit in the special Leo Cancer Care chair with your arms in different positions, the picture below gives an example of one of the positions you may be asked to try.
To understand how the experience of sitting up for treatment might differ from the experience of lying down for treatment we will ask you to wear a small head mounted camera called a GoPro as you try the Leo Cancer Care chair.

In the afternoon session we will ask you to stay still on the chair for as long as you feel able to do so, up to a maximum of 10 minutes. We would like to take camera photos to monitor your stability on the chair during this time. We will also ask you to complete a short questionnaire about how comfortable you felt while sitting on the chair. As an optional activity, we may ask you to A) take a deep breath in through your nose and hold it for around 20 seconds or as long as you feel able to, and B) we will ask you to try holding a special mouthpiece sometimes used for radiotherapy where a patient is asked to hold their breath. We would like to understand how comfortable these activities are in the upright treatment position.

3. Why am I being asked to take part?

You are being asked to take part because you meet our criteria, which are:

- You are over 18 years of age.
- You have had previous radiotherapy for either breast cancer, prostate cancer, or lung cancer.
- You can raise and lower yourself from a seated position easily.
- You have no known mobility issues, back or joint problems (please discuss this with us if you are unsure about this).

4. What will I need to do if I take part?

The table below lists the things you will be asked to do and how long we think each activity will take.

<table>
<thead>
<tr>
<th>Procedure or questionnaire</th>
<th>When will I complete this?</th>
<th>Why do I need to complete this?</th>
<th>How long will this take?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A questionnaire about your personal details, area where you live, age, ethnicity and gender if you are willing to share these.</td>
<td>Before the face-to-face event.</td>
<td>We need to make sure we have a variety of participants in our sample to reflect the wider population of people that would eventually be treated using the upright chair.</td>
<td>Approximately 10mins</td>
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<tr>
<td>Sign a consent form to participate in the study.</td>
<td>Before the face-to-face event.</td>
<td>We need your written consent to include you in the study.</td>
<td>This should take no longer than 20 mins depending on whether you have</td>
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<tr>
<td>Activity</td>
<td>Time/Event</td>
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<td>------------------------------------------------------------------------</td>
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<tr>
<td>Make notes on a diagram that we will provide on the different stages of radiotherapy from planning to treatment and then the immediate period after treatment.</td>
<td>Before the face-to-face event. We would like to understand what your experience was like at different stages of radiotherapy. Approximately 30 - 40 minutes.</td>
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<tr>
<td>Participate in a discussion about the experience of radiotherapy</td>
<td>At the face-to-face event. We would like to understand what your experience was like at different stages of radiotherapy. 2 hours</td>
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<td>Position yourself on the Leo Cancer Care chair wearing your own clothes</td>
<td>At the face-to-face event. This will enable us to review how to use accessories to improve comfort or positioning 20 minutes (10 minutes staying still on the chair)</td>
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<tr>
<td>Complete a questionnaire on comfort in the chair</td>
<td>At the face-to-face event. We would like to understand how you felt sitting in the chair. 15 minutes</td>
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<tr>
<td>Voluntary participation in a round table discussion about different supports for patients’ arms while on the chair.</td>
<td>At the face-to-face event. This will allow us to review comfort for future patients. Approximately 1.5 hours</td>
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<tr>
<td><strong>Total time for the face-to-face visit</strong></td>
<td>A full day</td>
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<td>Review of the themes identified from the workshops</td>
<td>After the face-to-face event via email. We would like to check that we have interpreted the comments at the workshop correctly. Approximately 30 minutes</td>
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<tr>
<td><strong>Total time involved in the study</strong></td>
<td>1 full day event in person and 1.5 hours involvement at home before and after the face to face event.</td>
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5. **What are the possible benefits of taking part?**

The main benefit is the opportunity to make future radiotherapy for breast, prostate or lung cancer easier and cheaper to deliver, while providing more dignity and accuracy for future cancer patients. However, we can also offer participants a multi-shop gift voucher to the value of £25 plus travel expenses (expenses to be agreed in advance of the face-to-face event). Hot drinks and light refreshments will be available at the face-to-face event.

6. **Are there any disadvantages or risks of taking part?**

When asked to think back on your experience of radiotherapy it is possible you may remember situations that make you feel sad. During the face-to-face event we will keep checking in with you to make sure you feel ok.
You will be asked to sit in the special Leo Cancer Care chair for 10 minutes with your arms in a certain position- if you have any shoulder injuries or restricted movement in your upper limbs then please inform the research team.

The main disadvantage for participants is the time commitment to participate.

**Further supporting information**

All information recorded about you during the study will remain confidential. No individual will be identifiable in any report or publication about the study.

We will give each participant a unique code that will be assigned to each completed questionnaire, any personal details you provide us with and any comments you make in the workshop.

By taking part in this study, you consent to non-identifiable comments or camera images (faces will be blocked out/removed from the images) to be used as illustrations in academic publications, and for the purpose of ongoing data analyses. All data will be stored securely on password protected Sheffield Hallam University secure storage systems (backed up daily on a secure server), in compliance with the Data Protection Act.

You are free to withdraw from the study at any time without giving a reason. If you choose to withdraw before the face-to-face event your data will be removed from the study database. If you choose to withdraw after the face-to-face event, we will hold the anonymised data collected at the event.

The data you provide will be used to guide the positioning of future cancer patients referred for upright radiotherapy. Non-identifiable data from the focus groups will be made available to other researchers for the purposes of improving care of future patients. If you would like to see a copy of the results of this study, please let the research team know and we will forward a summary of the outcomes of this study to you.

If you have any further questions about this study, you can contact Dr Tracy Underwood on (tracy.underwood@leocancercare.com, 07902105415) or Dr Janet Ulman at Sheffield Hallam University on janet.ulman@shu.ac.uk before Friday 3rd March.

**Legal basis for research for studies.**
Sheffield Hallam University undertakes research as part of its function for the community under its legal status. Data protection allows us to use personal data for research with appropriate safeguards in place under the legal basis of public tasks that are in the public interest. A full statement of your rights can be found at: www.shu.ac.uk/about-this-website/privacy-policy/privacy-notices/privacy-notice-for-research. However, all University research is reviewed to ensure that participants are treated appropriately, and their rights respected. This study was approved by UREC with Converis number ER AA29549574. Further information at: www.shu.ac.uk/research/excellence/ethics-and-integrity
What should I do if I wish to complain about this study?

In the first instance you can contact the lead researcher Dr Tracy Underwood at Leo Cancer Care on (tracy.underwood@leocancercare.com, 07902105415). Or Professor Heidi Probst at Sheffield Hallam University on h.probst@shu.ac.uk.

Alternatively, you can contact the ethics lead for Sheffield Hallam University, Dr Mayur Ranchordas on hscmr@exchange.shu.ac.uk.

<table>
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<tr>
<th>You should contact the Data Protection Officer if:</th>
<th>You should contact the Head of Research Ethics if:</th>
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<tbody>
<tr>
<td>● you have a query about how your data is used by the University</td>
<td>● you have concerns with how the research was undertaken or how you were treated</td>
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<tr>
<td>● you would like to report a data security breach (e.g. if you think your personal data has been lost or disclosed inappropriately)</td>
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<tr>
<td>● you would like to complain about how the University has used your personal data</td>
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</tr>
</tbody>
</table>

DPO@shu.ac.uk

ethicssupport@shu.ac.uk

Postal address: Sheffield Hallam University, Howard Street, Sheffield S1 1WBT Telephone: 0114 225 5555