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Participant Information Sheet

Feasibility testing of OurPERSPECTIVE: a co-designed survivorship intervention for women following endometrial cancer treatment

OurPERSPECTIVE Feasibility Study

Chief Investigator: Dr Esther Moss, Associate Professor in Gynaecological Oncology

Introduction

You are being invited to take part in a research study. Before you decide whether or not 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 and discuss it with others if you wish. Please ask any questions you may have.

What is the purpose of the research study?

This study aims to test whether an online survivorship course, called OurPERSPECTIVE, is acceptable and useful for women who have completed treatment for endometrial (womb) cancer. The course runs for 8 weeks and will be led by a gynaecology clinical nurse specialist. Each week covers the common issues women often face after treatment, such as fatigue, bladder and bowel changes, lymphoedema, sleep disturbance, diet and exercise, and fears about the cancer returning. The sessions also provide practical self-management advice and the chance to connect with other women who have had similar experiences.

In addition, this study is designed to assess whether the OurPERSPECTIVE course can be delivered successfully as part of routine cancer survivorship care. We will explore how easy it is for women to take part, how acceptable the session content and format are, and whether the questionnaires, interviews, and group discussions capture what matters most to women following endometrial cancer treatment. The findings from this study will be used to refine the course materials and delivery, and to inform the design of a larger future study, with the longer-term aim of improving survivorship support for women after endometrial cancer.

Overall, this research will help determine whether OurPERSPECTIVE is a suitable, acceptable, and sustainable way to support women following endometrial cancer treatment and to inform future improvements in survivorship care.

Why have I been invited to participate?

You have been invited to take part because you meet the criteria to be included in the study, as identified by your gynaecology team.

Do I have to take part?

No, taking part in this study is voluntary. If you do not wish to take part, this will not affect your ongoing or future care.

What will happen to me if I take part?

If you decide to take part, you will first be asked to sign a consent form. You will then be invited to:

- Complete a questionnaire about your wellbeing and quality of life before the course begins. This questionnaire will take approximately 15 to 20 minutes to complete.
- Join the **OurPERSPECTIVE course**, which runs for 8 weeks. Each week you will take part in an online education session, lasting 1 hour using Microsoft Teams. These sessions will be led by a gynaecology nurse specialist and attended by other women who have completed treatment for endometrial cancer. It is expected that there will be between 8 to 10 women per group. Each week a different topic will be discussed and you will be given a workbook to help you keep notes during the course.
- We will ask you to keep a diary of your experiences on the course and some people after the first few weeks will be asked to take part in a short online or telephone interview to see how they are finding the course.
- Some participants may be invited, after the first few weeks of the course, to take part in a one-to-one interview to help us understand how the course is being experienced. Participants will be selected to reflect a range of ages, backgrounds, and experiences. The interview is optional, will take place online using Microsoft Teams or by telephone, depending on your preference, and will last approximately 30 to 45 minutes. You do not have to take part in an interview to continue in the study.
- At the end of the course you will be asked to complete another questionnaire, taking approximately 15-20 minutes to complete, and invited to take part in a group discussion (focus group) to share your views and feedback about the course. You will also receive more questionnaires (15-20 minutes to complete) at 6 months and 12 months after completing the course to see whether attending the course has had a longer-term impact on you and your cancer survivorship journey

The course sessions will be delivered securely online using Microsoft Teams.

With your permission, the focus group will be recorded so that we can capture your comments accurately. Recordings will be written up (transcribed), anonymised, and securely stored on University of Leicester computers. The recordings will then be deleted.

Will I be reimbursed or receive any payment for participating?

To thank you for your time, you will receive a **£25 shopping voucher** for taking part in the study.

What are the possible benefits of taking part?

Taking part in this study may benefit you by giving you access to reliable information, practical self-management advice on the common challenges following endometrial cancer treatment. It will also give you the chance to meet and share experiences with other women who have recently completed treatment. It will also benefit others in the future, as your feedback will help us improve the survivorship course so that it better supports women after treatment.

What are the possible disadvantages and risks of taking part?

Taking part in this study may sometimes bring back difficult memories of your cancer treatment. Some of the topics we discuss, such as fatigue or fear of the cancer returning, may feel upsetting. If this happens, you are free to pause, take a break, or leave a session at any time. Each session will include a short wellbeing check-in, and the nurse specialist leading the course will be available to provide one-to-one support if needed after the session. The research team can also advise you on sources of further help, and, if appropriate, refer you to psychological support services. Additionally, due to the nature of the intervention, which includes group-based sessions and discussions with other participants, there is a possibility that confidentiality may be compromised. To reduce this risk, participants will be reminded to only share information they feel comfortable discussing in a group setting, and clear ground rules will be agreed at the start of the course to encourage respect for privacy and confidentiality.

What if something goes wrong?

It is very unlikely that you would be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you can contact the team via the research nurses or contact your clinical nurse specialist, who will do their best to answer your concerns.

If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient Advice and Liaison Service (PALS) at:

University of Leicester Patient Advice and Liaison Service (PALS)
Freephone: 0808 178 8337 or Email: uhl-tr.pals@nhs.net

If you would like to speak to someone independent of the research team, please contact the study Sponsor via rgosponsor@le.ac.uk

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

How will we use information about you?

We will need to use information from you and your medical records for this research study.

This information will include your;

- Initials
- NHS number
- Name
- Contact details
- Ethnicity
- Education level and employment
- Medical history
- Age
- Languages that you speak
- Country of birth

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.

The University of Leicester is the Sponsor of this research, and is responsible for looking after your information. We will share your information relating to this project with the following types of organisations;

- Universities
- Regulatory organisations

We will keep all information about you safe and secure by:

- Keeping electronic records on secure password protected servers
- Keeping paper records in secure offices with access limited to members of the research team only
- Collecting the minimum amount of data possible to conduct the research
- Using a code number in place of your name on all research data other than the consent form
- Using secure data transfer methods

International Transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- Work with researchers and cancer specialists in other countries to improve cancer survivorship care

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Universities

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach

How will we use information about you after the study ends?

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 will keep your study data for the minimum period of time required by University Policy (6 years). The data will then be fully anonymised and securely archived or destroyed.

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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital records. If you do not want this to happen, tell us and we will stop
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- 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.

Where can you find out more about how your information is used?
You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- at www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to leicestergcrg@leicester.ac.uk
- by ringing us on 07929838393
- by contacting the University's Data Protection Officer via email on dpo@le.ac.uk

What else will happen to the data I provide?
Your consent form and research data will be collected using the online JISC surveys platform. Information will be downloaded from the platform and saved to servers owned and maintained by UHL NHS Trust and University of Leicester as soon as practically possible and within 3 months after which the data will be deleted from the JISC platform.

Your research data will be entered onto a password protected study database which is owned and maintained by UHL NHS Trust and University of Leicester.

A separate database containing identifiable information for the purpose of contacting participants will be held on the UHL NHS trust server, access will be limited to relevant members of the research team only.

Paper copies of your research data will be stored in a secure office environment at UHL NHS trust for the duration of the research study.

At the end of the study your coded/deidentified research data will be transferred to the University of Leicester for analysis and will be stored on servers owned and maintained by the University of Leicester.

Your medical records and research data may be accessed by authorised individuals from the Sponsor, regulatory authorities, and UHL NHS Trust for monitoring and audit purposes.

Interviews will be audio-recorded using an encrypted recorder or Microsoft Teams, transcribed (written up) by members of the research team.

The recording will be labelled with a unique code in place of your name. The recording will be deleted from the audio recorder/Microsoft Teams as soon as it has been transferred to the University of Leicester secure server. It will be deleted from the server once the recording has been written up and analysed. Any identifying information within the recording will be removed when your interview is written up. Direct quotations from the interviews and focus groups may be used in the study outputs. These quotations will be coded so you will not be identifiable in any way.

If you would like to be informed of the results of the study, please indicate this on your consent form.

Data collected as part of this study may be used, in part or in whole, for the writing of educational projects such as a Master's Degree or a PhD.

The results of this study will be published in medical journal(s) and/or presented at medical conferences and meetings.

Who is organising and funding the research study?

This research is funded by Leicester, Leicestershire and Rutland integrated care Board (LLR ICB)
The research is being coordinated by Dr Esther Moss

Who has reviewed the research study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This study has been reviewed and has been granted a favourable opinion by <insert REC name> Research Ethics Committee. Favourable Opinion means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision.

What should I do if I want to take part?

You will be asked to complete an Informed Consent Form and to opt-in to a variety of research options by placing your initials within the Yes or No box. This will confirm you understand how your data will be processed, protected and reviewed for research purposes.

Contact for Further Information

If you have a question that you wish to direct to members of the research team, please contact:

ourperspective@leicester.ac.uk or 07929838393

We recognise that thinking about the topics covered in this study may be difficult for some people. If you feel affected by taking part in this study, please reach out to your specialist nurse (0116 258 4840) or there are the following support services which are available to you;

Charity	**Type of support and how to access this support**
Macmillan Cancer support	Macmillan provides a free telephone support line with minimal waiting times. Support is offered from trained employees and Macmillan nurses. Waiting times may be slightly longer if you would like to speak to a nurse. Support line phone number: **0808 808 00 00**

	Macmillan also provide an online community where you can anonymously speak to others who have been affected by cancer. You can join this by selecting 'online community' on the Macmillan website: **https://www.macmillan.org.uk/**
Mind Charity	Mind is a charity that provides immediate online support for those who are experiencing poor mental health. This online support can be accessed at: **https://www.mind.org.uk/information-support/**

Thank you for taking the time to read this information and consider taking part in this research.