# *Living better with advanced breast cancer (LIBERATE):*

## Feasibility study of a supportive, self-management website for women living with secondary breast cancer

**Randomised controlled trial**

## Participant information sheet

We would like to invite you to take part in a research study that will explore a new interactive website designed to support the needs of women living with secondary breast cancer.

Before you decide whether or not you would like to take part, please read this information sheet to find out why we are carrying out this research and what it would involve for you.

### *Background*

This study is part of the LIBERATE (*'Living better with advanced breast cancer'*) three year PhD project, funded by Breast Cancer Now and supported by Breast Cancer Care. The overall aim of the project is to better understand the needs of women living with secondary breast cancer and to develop and test out an online resource designed to support and address these needs.

Guided by evidence of current online resources supporting patients in the advanced stages of cancer, as well as interviews with secondary breast cancer patients and health and charity professionals, we have now designed a tailored, interactive website. This is made up of a number of features:

- **Holistic health information**: evidence based information on lots of different health and lifestyle topics relevant to secondary breast cancer, brought together in one place.
- **Virtual 'waiting room' of case studies**: a wide variety of cases based on the real life experiences of secondary breast cancer patients, promoting learning through shared experience.
- **Support for others**: a range of information for family, friends, loved ones, colleagues and others affected by the diagnosis of secondary breast cancer, gathered in one place.
- **Signposting support**: a list of websites, resources and support services for women and families coping with secondary breast cancer, alongside guidance on how to search for appropriate support using the internet.
- **Symptom monitoring**: link to an online questionnaire system, developed within our research group, where patients can report on a range of symptoms and issues and receive tailored self-management advice.

We want to explore how we can test out the LIBERATE website in a large scale study by first testing out the procedures in a smaller study. We also want to get an idea of whether or not patients living with secondary breast cancer find the website useful and whether it might positively affect their quality of life and how they manage their cancer.

### *Why have I been invited to take part?*

We are inviting women who are living with secondary breast cancer to take part in this study.

By 'secondary breast cancer', we mean breast cancer which has spread from the breast to another part of the body such as the liver, lungs or bones. This is different to a 'local recurrence', where the breast cancer returns to the breast or surrounding area (e.g. the skin

surrounding the original site or scar, the chest wall or to lymph nodes in the chest, neck or under the breastbone). Specifically, we are recruiting those who receive their care and follow up at St James's University Hospital. We are aiming to recruit approximately 30 patients.

***Do I have to take part?***

No. Taking part is completely voluntary. If you choose not to take part, we will fully respect your decision and this will not affect any of your ongoing care or follow up.

***What happens if I decide to take part?***

You are free to take as much time as you need to decide whether or not you would like to take part in the study. If you do decide to take part, a member of the research team will answer any questions you might have and ask you to sign a consent form. This simply states that you understand what the study involves and have agreed to take part.

We want to compare patients using the LIBERATE website with patients who are not using the website. To allow us to do this, we are carrying out a study called a 'randomised waiting list controlled trial'. This means that half of the patients who agree to take part will be selected at random to use the website immediately (the 'intervention group') and the other half will be randomly selected to **not** use the website during the study period (the 'control group'). This allows us to compare the two groups. The control group will instead be placed on a waiting list and will be able to access the website once the study is finished.

If you are randomly selected to be in the **group receiving immediate access to LIBERATE ('intervention group')**:

- The researcher will provide you with your own 'log-in' details to access the LIBERATE website.
- They will then show you how to use the different parts of the LIBERATE website, including a brief demonstration of how to complete a symptom report when directed to do so from the symptom monitoring section.
- You will be provided with a booklet to take home with you that explains how to use the different features of the LIBERATE website. This will include contact details for the researcher, in case you need to get in touch with any issues or queries.
- You will be free to use the LIBERATE website as little or as often as you would like over a period of **12 weeks**, though you will be asked to complete a symptom monitoring questionnaire at least once a week. We will send you a text or email reminder (whichever you prefer) to complete these. The questionnaire will take approximately 20 minutes to complete. You are able to start a questionnaire and come back to it later (your responses will be saved for up to 24 hours).
- Your doctor and breast cancer nurse will be able to see the results of your symptom monitoring questionnaires in your electronic medical record.
- If you report any severe symptoms, an alert message will pop up on your screen asking you to contact your hospital for medical advice.
- At the start and end of the study, we will ask you to complete paper questionnaires about your quality of life and how you are managing with your cancer. At the start of the study, these can be completed in clinic and handed to the researcher. At the end of the study, we will post some more questionnaires for you to complete at home. We will provide a stamped and addressed envelope for you to send these back to us.
- We will also ask you to tell us how often you contact the hospital or breast cancer nurse (clinical nurse specialist) in between your appointments during the course of the study.

It is important to remember that the LIBERATE website will **not be a replacement** for the usual care and support you receive from the hospital. Throughout the study, you will be advised to **contact the hospital as usual for medical advice** on managing symptoms and side effects, or if you have any worries relating to your cancer or treatment.

If you are randomly selected to be in the **group placed on a waiting list ('control group'):**

- You will receive follow-up and support provided by the hospital and your healthcare team as usual.
- Alongside this, we will ask you to complete paper questionnaires about your quality of life and how you are managing with your cancer at the start of the study (in clinic) and after 12 weeks (we will post these to you at the end of the study and provide a stamped and addressed envelope for you to return them to us).
- We will also ask you to tell us about the number of contacts you have with the hospital or with your breast cancer nurse outside of your appointments during the study period.
- After the study has finished, you will receive training on how to use the LIBERATE website and will be able to access it for 12 weeks.

At the end of the study period (12 weeks), you may be asked if you would like to take part in a brief interview to find out your thoughts on using the LIBERATE website and/or taking part in this research. This is entirely voluntary. It would involve having a short (approximately 30 minutes) informal discussion with one of our researchers, which would be audio-recorded with your permission. This could be held in a private clinic room, at your home or over the telephone depending on your preference and what would be most convenient for you.

***If I choose to take part, will my information be kept confidential?***

Yes. Respecting your confidentiality and keeping your information (data) safe is very important to us. You will be assigned an anonymous study number so that your identity cannot be linked to your contributions. All of the data you provide (questionnaires/interviews) will be anonymised and securely stored within restricted areas of either University of Leeds or Leeds Teaching Hospitals NHS Trust computing systems.

Your consent form will be stored in a locked filing cabinet in the research offices at St James' University Hospital, with access strictly limited to those within the LIBERATE research team.

If you take part in an end of study interview, your audio-recording will be stored in a secure, password protected folder on the University of Leeds computing system. LIBERATE's PhD student, Kathleen Kane, will listen to the recording and write down what you have said (a transcription) whilst removing any information which might identify you. Should time become limited, this may be carried out by a University of Leeds approved transcription company, who work in line with strict confidentiality and data protection practices.

***Who will see my information?***

The information that you provide within questionnaires and (for the 'intervention group') within online symptom monitoring reports will only be seen by members of the LIBERATE research team or by your healthcare professionals. We will also ask for your permission to see details about your treatment and disease within your electronic medical records, through the Patient

Pathway Management (PPM) system. This information will only be viewed and collected with your permission and will be kept strictly confidential.

The only situation where we may need to share information about you with others would be if the researchers had any serious concerns about your health and well-being. In this case, they would have a responsibility to inform an appropriate professional, such as your breast cancer nurse or hospital consultant. Every effort would be made to keep you involved and to discuss our reasoning before doing so.

***What happens to the information I have provided?***

Once the study ends, your personal information (such as name, postal and/or email addresses) will be securely held in locked filing cabinets in the research offices at St James's University Hospital for six months before it is confidentially destroyed. This is in case you get in touch with us with any queries regarding the study and also allows us to send you a summary of what we have found.

The anonymised information you provide within questionnaires and end of study interview will be stored electronically for five years after the end of the study, within a restricted part of the University of Leeds computing system, for use within the PhD project and potentially within other projects in the research group. With your permission, it may also be shared with other researchers for educational and research purposes. It will not be possible to identify you from this information.

***What are the benefits of taking part?***

We hope that using the LIBERATE website will support your needs and help you to manage your cancer.

You will also be helping to further develop the resource and to guide the best way of testing it out on a larger scale.

***What are the disadvantages of taking part?***

There is the possibility that some of the information or resources that you encounter through the LIBERATE website may prove distressing. If this is the case, with your permission, our researchers will be able to inform a member of the clinical team who is involved in your care. We will also be able to signpost you towards sources of support provided by Breast Cancer Care. You may decide that you no longer wish to participate in the study and we will respect and support you in this decision.

***What happens if I decide not to continue with the study?***

If you change your mind about taking part in the study at any point, that is completely acceptable and we will respect your decision. You can withdraw from the study at any time and do not need to give us any reason for doing so. This will not affect any of the care or follow up that you receive.

We will ask if we can keep the information that you have provided so far but this will be your decision. We may also ask if you would be willing to provide some feedback about the study and the LIBERATE website, though this will again be up to you.

***What if I have any concerns about the study?***

If you have any concerns or queries about any aspects of the study, please do not hesitate to contact a member of the research team (contact details provided at the end of this information sheet), who will do their best to answer your questions.

If you are not satisfied with our response, you can make a complaint to an independent professional, Claire Skinner. Claire is the Head of Research Integrity & Governance for Medicine and Health at the University of Leeds and will be able to give you independent advice about any problems you are encountering with the research.

Ms Claire Skinner Tel: 0113 343 4897 Email: governance-ethics@leeds.ac.uk

***What happens next?***

You are welcome to take as much time as you need to consider this information and to decide whether or not you would like to take part in the study. If you would like some more time to consider your decision, we can arrange to speak to you at your next appointment or contact you at a later date.

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

If you have any questions regarding the LIBERATE study, please contact:

Kathleen Kane, PhD Student. Tel: 0113 20 67580 Email: um08k2k@leeds.ac.uk

Dr Fiona Kennedy, Chief Investigator. Tel: 0113 20 68939

Email: f.r.kennedy@leeds.ac.uk

If reading this information or taking part in the LIBERATE study causes you any worry or anxiety, please speak to your doctor, breast cancer nurse or GP. Alternatively, Breast cancer Care offer support through a free helpline and online live chat facility. These services can be accessed via the details below:

**The Breast Cancer Care Helpline**

**0808 800 6000**

Helpline open:

Monday – Friday, 9am-5pm

Late opening Wednesday 9am-7pm

Saturday, 9am-1pm

Information and details on how to register for live chat can be found at:

www.breastcancercare.org.uk/information-support/support-you