

Patient Information Sheet

LIBERATE: Living Better with Advanced Breast Cancer

Quality of life interview study

We would like to invite you to take part in a study which will involve having a one-off interview to discuss your experiences of living with secondary breast cancer. Before you decide whether or not you would like to take part, please read the information below. This will explain why we are performing this research and what it will involve for you.

Why are we carrying out this study?

This study is part of a PhD project funded by a charity called Breast Cancer Now. We are looking to develop an online tool which will allow patients to report any symptoms or concerns they are experiencing and to access information and advice which is suited to their needs. Through reporting their symptoms, we also hope that this will help patients to have more open discussions with their health professionals and to feel involved in decisions about their care.

We want to make sure that this tool is specifically suited to the needs of women living with secondary breast cancer. It is therefore really important for patients to be involved in its development. There are no right or wrong answers; we are simply looking to better understand the range of issues that women with secondary breast cancer experience. We will also be separately interviewing professionals who are involved in the care and support of secondary breast cancer patients, so that the online tool is informed by a range of perspectives.

Why have I been asked 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 have received care at St James' University Hospital or accessed support through Breast Cancer Haven or Breast Cancer Care. Our aim is to recruit approximately 30 patients.

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Do I have to take part?

No. It is completely your choice as to whether or not you would like to take part and you can take as much time as you need to make this decision. Any decision you do make will be respected; choosing not to take part will not affect the usual standard of care you are receiving. You can take this information sheet away with you to think about your decision and we will arrange to see you again, or to contact you at a later date.

Should you agree to take part and change your mind prior to interview, you are free to withdraw from the study without giving a reason. If you do withdraw, it will not affect any of the care or services you receive. If you take part in the interview and later decide that you do not want us to use any of the information you have provided, you will be able to ask for it to be removed from the study up to two weeks after your interview date. To request to be withdrawn from the study, please contact Kathleen Kane on 011320 67580 or via email at um08k2k@leeds.ac.uk

What will be involved?

If you choose to take part in the study, you will be asked to sign a consent form. This simply states that you understand what the study involves and have agreed to take part. The interview itself will be an informal discussion between yourself and one of our researchers. You will be given the choice as to where you would like the interview to take place e.g. a private clinic room at St James' University Hospital, a private room at Breast Cancer Haven, in your own home or, if you prefer, over the telephone. We want to make sure that it is the most convenient option for you.

When would the interview take place?

Should you decide that you would like to take part in the study, the researcher will contact you to arrange a suitable date, location and time. The interview will last for approximately 30-60 minutes (depending on how much you would like to discuss) and will be audio-recorded. The researcher may also take some brief notes to refer back to.

Will my confidentiality be maintained?

Yes. Your information and the audio-recording of your interview will be stored securely and access will be restricted to those within the research team. You will be assigned an anonymous study number so that your identity cannot be linked to your contributions. As far as possible, your audio-recording will be transcribed by the researcher undertaking this research, Kathleen Kane (PhD student). Should time become limited, this may be carried out

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by a University of Leeds approved transcription company, who work in line with strict confidentiality and data protection practices.

Your consent form and other personal information (such as name, email and postal addresses, to allow us to send you information relating to the study) will be held in locked filing cabinets in the research offices at St James' University Hospital, with access strictly limited to those within the LIBERATE research team.

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 GP or hospital consultant. Every effort would be made to keep you involved and to discuss our reasoning before doing so.

If you are a patient at St James' hospital, we will ask for your permission to look at your medical records to clarify information about the treatment that you received and details of your illness. This information will only be collected following your permission and will be kept strictly confidential.

What happens to the information I have provided?

The information you provide will be used to guide the development of an online supportive resource. 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' 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 anonymous information you provide within the interview itself 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 three-year overall PhD project and to allow an additional two years for research findings to be shared.

Are there any benefits of taking part?

We hope that the information and experiences you share will help us to develop more effective support for women living with secondary breast cancer, both now and in the future. If you are interested, we would be happy to inform you of future research outcomes.

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What happens next?

You are welcome to take as much time as you need to consider this information. 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 you are unhappy or dissatisfied with any aspect of this study, we would ask you to contact a member of the research team via the contact details above, so that we can try to address your concerns and find a solution.

If you are not satisfied with our response, you can make a complaint to an independent professional, Claire Skinner. Claire is the Faculty Head of Research and Innovation Support 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

If reflecting upon your experiences has caused you any worry or anxiety, please speak to your 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:

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