Plain Language Statement

Main study

Faculty of Medical, Dental and Health Sciences

UNIVERSITY OF BIRMINGHAM

THE UNIVERSITY OF MELBOURNE

Valuing the benefits and risks associated with treating low risk breast conditions

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Introduction

You are invited to participate in this PhD student research project which aims to investigate how women value the different treatments for low risk breast conditions. This is because you have either been referred through the Breast Cancer Network Australia or because you have responded to an advertisement. This plain language summary tells you about the research project. It explains what is involved to help you to decide if you want to take part.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about. Before deciding whether to take part, you might want to talk it through with a relative, friend or your local health worker. You will be given a copy of this plain language summary to keep.

Your participation is this research voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time without needing to give a reason.

What is the purpose of this research project?

The reason this project is being undertaken is that we want to know more about how women value the benefits and risks associated with breast screening programs. In particular, we are interested in seeing how women make choices between the different treatments for low risk breast conditions that have been picked up by routine screening mammograms (x-rays of the breast).

This is because many women do not know about the range of treatments available for low risk breast conditions. We want to help women make better informed choices by exploring how they think the imaginary treatment of a breast cancer might impact upon their quality of life.

We will measure your preferences by asking you to choose between imaginary scenarios relating to treatments for low risk pre-cancers (sometimes referred to as low risk '**ductal carcinoma in situ' or 'DCIS**'). These scenarios might describe having surgery (where either the affected part or the entire breast is removed), radiotherapy or monitoring of the abnormal area with a yearly mammogram.

Why is this research important?

It is not known how women would feel about monitoring low risk breast cancers compared to undergoing invasive surgery. We expect different women will think differently about the type of treatment they would prefer.

We are keen to know *your* individual view so that we can better plan breast treatment services and reduce the harm of unnecessary harmful treatments for DCIS. By finding out how women prefer to manage screen detected breast cancers, the research findings may be used to justify changes to the way low risk cancers are screened and treated.

What will I be asked to do?

You will be invited to attend a face-to-face interview with the research student at the University of Melbourne or a local venue suitable for you. During the interview, you will be asked to complete a short questionnaire asking about your preferences for a number of different treatments for DCIS. The questionnaire will take around 60 minutes to complete and you will have the opportunity to ask the research student any questions at any time during the interview. The questionnaire will have been tested by doctors, patients and women at the University of Melbourne beforehand to make sure the questions are easy enough to understand and answer.

When you arrive we will remind you about the details of the project and ask you to sign a consent form stating that you are happy to take part. You will be asked to make choices between different treatments for DCIS and to answer some basic questions about yourself.

The questionnaire is split into three sections:

1) A rating scale exercise
You will be asked to rate each of the treatments on a scale from 0 to 100.

2) A gambling exercise
We will ask you to choose between different treatments by varying the benefits and risks in each of the descriptions, one at a time.

3) A few questions about yourself
Finally we will ask you a few questions about yourself, simply to help with the analysis.

1 • **Introduction to the questionnaire**
2 • **Rating scale**
3 • **Gamble exercise**
3 • **A few basic questions about yourself to help the analysis**

What are the possible benefits?

This is your opportunity to share your views with breast cancer researchers. We think it is important that women's preferences for treatments are included in the decision making process when it comes to planning breast cancer services. Although there may be no clear immediate benefits to you from your participation, we hope that the results of this project can be used to improve local breast cancer services in Victoria in the future by contributing to the literature. The values obtained from this study will be used to inform an economic evaluation of breast cancer screening and treatment and may be used to justify changes to the way breast cancer resources are allocated in Australia.

Your responses will be used to inform a PhD thesis at the University of Melbourne. The results may be presented at scientific conferences, to policy makers at local breast cancer meetings or the public through the media (e.g. in newspaper articles). The main findings may also be published in scientific journals.

What are the possible risks?

Sometimes talking about cancer can be a sensitive or upsetting topic. We will not ask you to talk about your own experiences and you will be free to withdraw from the study at any time, without needing to give a reason. We can direct you to breast cancer support services if you have any further concerns or questions about breast cancer screening or treatment services in the area.

Do I have to take part?

No. Participation is completely voluntary. If you don't wish to take part, you don't have to do so. If you do decide to take part and later change your mind, you are free to withdraw (quit) at any time. If you decide to leave the project, the researchers would like to keep the information about you that has been collected. This is to help them make sure that the results of the research can be measured properly. If you don't want them to do this, you must tell them before you withdraw from the study. Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with the researchers.

Will I hear about the results of this project?

A plain language summary of the general findings of this research project will be made available to all participants via email or post, if they have provided consent to receive any further communication from the research team. Please leave your contact details if you are interested in hearing about the results of the project. It is expected that the results will be made available following the completion of the PhD thesis and publication of the results in scientific journals in late 2018.

What will happen to information about me?

All information will be kept entirely confidential. We will not be publishing any personal details and data will be stored securely on password protected servers or under lock-and-key at the University of Melbourne.

All information collected in the questionnaire is anonymised. The results from the questionnaire will be grouped and presented as averages so that no personal information is published. Any data collected in the interview or questionnaire will be destroyed after five years following publication as per University of Melbourne data management and ethics guidelines.

In accordance with the relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers if you would like to access your information.

Who is funding this project?

The study is funded as part of a joint PhD programme between the Universities of Melbourne (Australia) and Birmingham (UK) to try and improve breast cancer screening and treatment services worldwide. The PhD student is supervised by a team of experienced doctors and University of Melbourne researchers to make sure the research is of the highest quality.

Where can I get further information?

If you would like more information about the project, please contact the researchers;

Hannah Bromley (doctoral research student),
Email: hbromley@student.unimelb.edu.au Melbourne School of Population & Global Health, University of Melbourne, 207 Bouverie Street, Parkville, Melbourne, VIC 3053.

Who can I contact if I have any concerns about the project?

This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: HumanEthics-complaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.

Where can I get more information if I have questions about breast cancer?

There are some excellent resources available if you have any further questions or concerns relating to breast cancer or screening services as a result of participating in this project:

Breast Cancer Network Australia:
An excellent resource talking more about breast screening, breast cancer and women's health and well-being. Website: https://www.bcna.org.au. Telephone: 1800 789 209

BreastScreen Victoria
A resource specifically listing the benefits and risks associated with breast screening programs. The team are happy to provide advice about local breast screening services. Website: https://www.breastscreen.org.au Telephone: 13 20 50.

Lifepool
A source of information about your participation in the Lifepool research cohort. Website: http://www.lifepool.org/ Telephone: 1800 198 082.

Cancer Council Victoria
A resource dedicated to local cancer facilities and service in Victoria. Website: http://www.cancervic.org.au/ Telephone: 13 11 20

The Royal Women's Hospital
A summary of the local cancer resources available in the Melbourne Metropolitan area and guidelines on local breast cancer screening and treatment policies. Website: https://www.thewomens.org.au/patients-visitors/clinics-and-services/womens-cancers/breast-cancer/ Telephone: 03 8345 3561.