

The impact of treatment-focused genetic testing in patients newly diagnosed with breast cancer



The Research Officer will discuss this study with you and any queries you may have. If you would like to know more about this study at any stage, please do not hesitate to contact her on freecall number 1800 814 403.

Treatment-focused genetic testing

You are invited to participate in a research study comparing different methods of informing women about treatment-focused genetic testing (TFGT)*. As part of this study, you will be offered the opportunity to have TFGT. The research is part of an Australia-wide study, which is being co-ordinated by the Prince of Wales Hospital, Sydney.

Before you decide whether or not you want to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the study is to determine the most patient-friendly way of delivering information about TFGT. It is important to know this because TFGT may be offered more routinely in the future because the results can sometimes influence treatment, including the type of surgery a woman chooses to have. If TFGT does become more common, the information gained from this study will help health professionals to best meet women's information needs at a very difficult time for them.

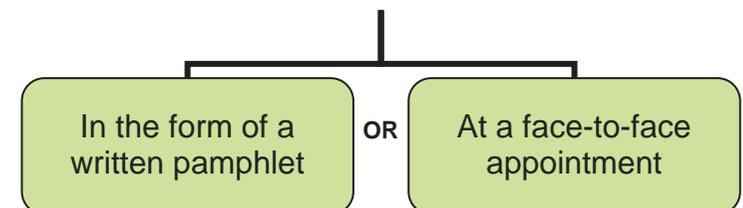
WHY HAVE I BEEN INVITED TO ENTER THE STUDY?

You have been invited to participate in this study because you have been diagnosed with breast cancer **before the age of 50** AND you **Either**:

- have a strong family history of breast and/or ovarian cancer; **OR**,
- have **at least one** of the following features: (i) cancer in both breasts, **AND/OR** (ii) Ashkenazi Jewish ancestry, **AND/OR** (iii) a particular tumour type.

WHAT WILL HAPPEN IN THE STUDY?

If you agree to participate in this study, you will be asked to complete a total of 4 questionnaires over a 12 month period. Each questionnaire will take about 10-15 minutes to complete, all of which may be completed on-line if you prefer. First, you will be asked to complete the 1st questionnaire. One of our research officers will then phone you to tell you whether you will receive the information about TFGT in one of two ways: written form **OR** face-to-face. Participants will not be able to choose their method of information delivery.



IF YOU ARE ALLOCATED TO GROUP 1 (PAMPHLET):

If you are allocated to receive the information about TFGT in written form, the pamphlet will be mailed to you, along with the 2nd questionnaire. After you have read the information and if you decide to have TFGT, we will ask you to sign a 'Consent form for Genetic Testing' and to attend a local pathology lab, your hospital pathology lab or your GP to have blood taken. A genetic counsellor will then phone you to arrange for you to attend the Familial Cancer Clinic (FCC) at your treating hospital to receive your test results in person, and to discuss them in detail with a genetic specialist. The test results will take between 2 and 4 weeks.

IF YOU ARE ALLOCATED TO GROUP 2 (APPOINTMENT WITH FCC):

If you are allocated to receive the information about TFGT at an appointment, a staff member from the FCC located at your treating hospital will phone you to arrange an appointment, and the 2nd questionnaire will be mailed to you. After receiving the information at the FCC appointment, if you decide you want genetic testing, you will be asked to sign a 'Consent form for Genetic Testing'. The FCC will arrange for you to have blood taken at the pathology lab located at your treating hospital. The FCC will also schedule a follow-up appointment for you to receive your results in person, and to discuss them in detail with the genetic specialist. The test results will take between 2 and 4 weeks.

For both groups, TFGT is optional: you can decline genetic testing at any stage and we can still gain very helpful information from your experience.

For both groups, the researchers would also like to seek your permission to access your medical records (including your pathology and genetic test results) in order to obtain information relevant to the study. The 3rd questionnaire will be completed about 5 weeks after your enrolment in the study and the fourth about 12 months later.

ARE THERE RISKS TO ME IN TAKING PART IN THIS STUDY?

- If you decide to have TFGT, a small amount of blood will be drawn. Any time you have blood taken there is a small risk of bruising.
- If you decide to have TFGT, there is some inconvenience involved in having to attend the FCC and/or a pathology lab or GP to have blood drawn.
- It is also possible that thinking about TFGT and its implications may cause some worry or distress. If you decide to have TFGT, you will have the opportunity to discuss your test result in detail, including your concerns with a genetics specialist at your FCC. If you require further support at any time during the study, you can contact Kaaren Watts on freecall no 1800 814 403 and she will provide you with details of an appropriate and confidential support service.

Treatment-focused genetic testing (TFGT)
involves looking for alterations in genes that
can cause breast cancer

WILL I BENEFIT FROM THE STUDY?

Participants will have access to TFGT which is not yet widely available in publicly funded services. This study may help you and your surgeon with decision-making about your breast surgery. The information gained from this study may also help women newly diagnosed with breast cancer in the future. However, some participants may not directly benefit. There is no financial compensation for taking part in the study.

DO I HAVE A CHOICE?

Participation in this study is completely voluntary. It is up to you whether or not you participate. **If you decide not to participate:** (a) it will not affect the treatment you receive now or in the future, or your relationship with the staff caring for you, and (b) you can still talk to your surgeon about whether you should see a genetics specialist outside the study. The genetics team may offer genetic testing depending on your family history. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Any identifiable information collected about you in connection with this study will remain confidential and disclosed only with your permission, except as required by law. Only the researchers directly associated with the research will have access to your details and the information you have provided. All information will be held securely in locked filing cabinets and password-protected computers.

WILL TAKING PART IN THIS STUDY COST ME ANYTHING?

Participation in this study will not cost you anything, other than the personal transport costs and your time in attending an FCC and a pathology lab (if required). If you elect to have TFGT, it will be provided to you free of charge. In the unlikely event that you are charged for blood collection, please keep the receipt and we will reimburse you.

WHAT WILL HAPPEN AT THE END OF THE STUDY AND WITH THE STUDY RESULTS?

At the end of the study, the research data will be filed confidentially for a minimum of seven years and for five years after publication of the final paper arising from this research, as is standard practice for scientific research. After this period, all irrelevant material will be disposed of by shredding, and computer-generated data will be erased. We plan to publish and discuss the results in peer-reviewed scientific journals and at scientific meetings. In any publication or presentation, information will be provided in such a way that you cannot be identified.

WHO SHOULD I CONTACT IF I HAVE A COMPLAINT ABOUT THE STUDY?

This study has been approved by the Human Research Ethics Committee in your area health service. Please refer to the site specific Participant Information Pamphlet provided to you at enrolment for contact information.