

BreastScreen SA is trialling new technology to read breast screen images

BreastScreen SA is committed to delivering a caring, high-quality service for South Australian women. We are always looking for ways to improve our service and increase the early detection of breast cancer in South Australia. As part of this, **we are testing new software for reading breast screen images.**

What will change for the trial?

The way we take your images and care for you during your appointment will remain the same. After your appointment, the way your breast screen images are read may change. All images will still be read by a specially trained doctor (radiologist), some images may also be read using new software.

	Current process	Trial process
Booking an appointment	Book online, via telephone or an Aboriginal health service	Same
Having a breast screen	A radiographer takes the images	Same
Reading the breast screen images	The images are read by two specialist doctors (radiologists)	Different - trial participants will be randomly assigned into one of two groups: - Group 1: images read by two specialist doctors (radiologists) - Group 2: images read by one specialist doctor and the new software
Receiving results	Receive results 2-4 weeks after appointment	Same

Why is this trial important?

New technology is already being used in other parts of Australia and internationally to assist in reading breast screen images. The evidence on this software so far suggests it could improve the early detection of breast cancer. Early detection can improve health outcomes for women as cancers are typically smaller and more easily treated. Before we start using this technology in South Australia, we are doing this trial to see if it can help us improve our service and health outcomes.

Taking part in the trial is optional

If you do not wish to participate in the trial, you can opt out right up until your appointment. To opt out, contact BreastScreen SA to say you don't want to take part. If you do not contact us, you will be a trial participant.

You do not need to give a reason for opting out. This will not affect the care you receive during your appointment, or any follow up appointments. You can still have a breast screen and it will be read using the current process. If you have questions, we encourage you to contact us before your appointment. You are also welcome to speak with staff at your appointment.

Thank you for taking the time to read this information and consider participating in the trial. For further questions or to opt out contact BreastScreen SA.



13 20 50



helloBSSA@sa.gov.au



www.breastscreen.sa.gov.au/OptOut

Frequently Asked Questions

What does participating in the trial involve?

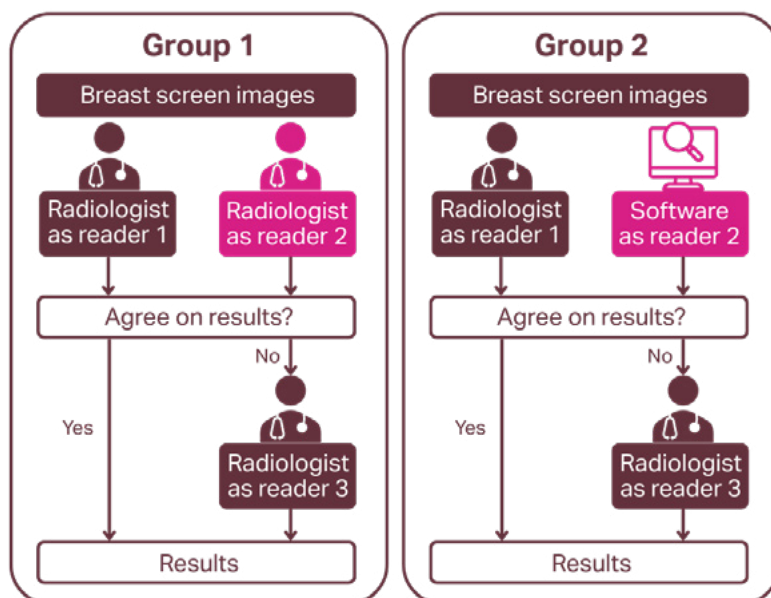
Trial participants will be randomly assigned into one of two groups:

- **Group 1:** Participants in this group will have their images read by two specialist doctors (radiologists)
- **Group 2:** Participants in this group will have their images read by one specialist doctor (radiologist) and by the new software.

Whether you are in Group 1 or Group 2, your images will be read by at least one specialist doctor (radiologist).

If the doctors or the software do not agree on the results, a third specialist doctor (radiologist) will read your images and decide on the outcome.

The researchers will compare the data from these two groups. We want to be confident that having both a doctor and the software read images is just as accurate, or even better, than our current process.



What technology is being trialled?

The technology being used in this trial is software called an AI-reader. It has been developed by an Australian team using artificial intelligence (AI). This means that the software has already read millions of breast screen (mammogram) images to learn to accurately identify areas of possible breast cancer.

Can I choose which group I am in?

No. Trial participants will be randomly assigned to either Group 1 or Group 2. This means you can't choose which group you're in. BreastScreen SA will also not be able to tell you which group you are in. However, you can choose to opt out of the trial.

What are the possible benefits and risks?

A possible benefit of participating in the trial is you may help us to detect more cancers and improve our service for South Australian women.

There are no new or additional risks related to participating in the trial. You may be called back for further tests whether or not you take part in the trial. This does not mean that you have breast cancer, but sometimes more tests are needed to make sure.

Where can I learn more about the trial and technology?

You can learn more about the trial on the BreastScreen SA website: www.breastscreen.sa.gov.au If you have any questions, you can phone 13 20 50 or email HelloBSSA@sa.gov.au

Frequently Asked Questions

Can I withdraw from the trial after my breast screen images are read?

It is important to understand that if you change your mind about participating in the trial, we cannot remove your images from the reading process and your images will not be read again.

However, your data (images and results from your breast screen) can still be withdrawn from the research while the trial is underway. This means the researchers delete your data from the research database and do not use this in analysis and reporting for this trial. BreastScreen SA will still retain your personal information and the reading result of your mammogram in our client database as this is important information that we require to re-invite you to your next breast screen.

You can withdraw your data by calling **13 20 50** or emailing **HelloBSSA@sa.gov.au**

Who are the researchers?

The research is a partnership between BreastScreen SA, BreastScreen Victoria, St Vincent's Institute of Medical Research, St Vincent's Hospital Melbourne, the University of Melbourne, Monash University and Adelaide University. The research is funded by the Australian Government.

Will the research be published?

The research will be published in medical and scientific journals. No participants in the trial will be identified, as all data is anonymised. The research findings will also be available at www.breastscreen.sa.gov.au

Right to your study data

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team that identifies you. You also have the right to request that any information with which you disagree be corrected. Please contact your study team member named at the end of this document if you would like to access your information. Research data will be de-identified for study analysis and stored for 15 years, unless there is a legal requirement for keeping them longer.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. Your participation in this study shall not affect any other right you may have to compensation under common law.

What if I have concerns about the research?

This research is overseen by the Royal Melbourne Hospital Human Research Ethics Committee. If you have any concerns about this research or the way it is being conducted, you can contact them and provide the study name and project number:

Royal Melbourne Hospital Human Research Ethics Committee

HREC Executive Officer: Manager HREC Phone: (03) 9342 8530

Email: research@mh.org.au

Study Name: A Multi-State, Single-Blinded Randomised Controlled Trial to Assess if the Implementation of a Deep Learning Classification Model Improves Mammogram Reading in Breast Cancer Population Screening (BRAIx RCT)

Project Number: 2024.045

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Position: Manager, CALHN Research Services

Telephone: (08) 7117 2209

Email: Health.CALHNResearchMonitoring@sa.gov.au