

FAST MRI: Diagnostic Yield study for Average Mammographic screening Density

Stage 1 Information Leaflet

Finding breast cancers early saves lives.

We know that the earlier a breast cancer is diagnosed the better the outcomes for that patient. Mammograms (a type of breast x-ray) have been used for many years to check for breast cancers but may not always find cancers early enough to be helpful. We would like to try out a new method of MRI, called “FAST MRI”.

It is like the MRI scans you may have heard of or experienced, but takes much less time, about 3-5 minutes, which would make it suitable to offer to many more people.

What is the FAST MRI DYAMOND study? (“DYAMOND” for short)

DYAMOND will test if a FAST MRI scan can detect cancers not seen on mammogram, in women with average density breasts.

1000 women will be invited for a FAST MRI if:

- they are aged around 50-52,
- their mammogram is clear
- their breast density is “average” (a computer measures this from mammogram images)

Why have I been given this leaflet?

You have been given this leaflet because we think you might be able to help us with this research. We would like to invite you to take part in Stage 1 of the study, which uses your mammogram images to measure your breast density. If we find that you are in the 40% of women with “average” breast density, then we will contact you again to invite you to join Stage 2 of the study and have a FAST MRI scan.

Who can take part?

Women with “average” breast density and a clear mammogram may be able to have a FAST MRI. To find this out, we are first inviting women to Stage 1 of the DYAMOND study.

If you agree to take part in Stage 1, we will send your mammogram to the DYAMOND team at the Royal Surrey NHS Foundation Trust so that they can measure your breast density. We won't send your mammogram to be measured for 10 working days after we receive your consent. This is in case you change your mind about participating. If you do, please let us know.

The results will then be sent to Warwick Clinical Trials Unit, to be stored.

If your mammogram is measured as anything other than average breast density, you will be looked after by the screening service, and you won't be able to take part in this study. This is because we are only inviting people with “average” breast density to have a FAST MRI.

If your mammogram measurement is in the “average” breast density group, we will look at your mammogram screening results to check if the screening service says you need any further investigations. This is because in this study, we are only inviting people with clear mammograms to have a FAST MRI.

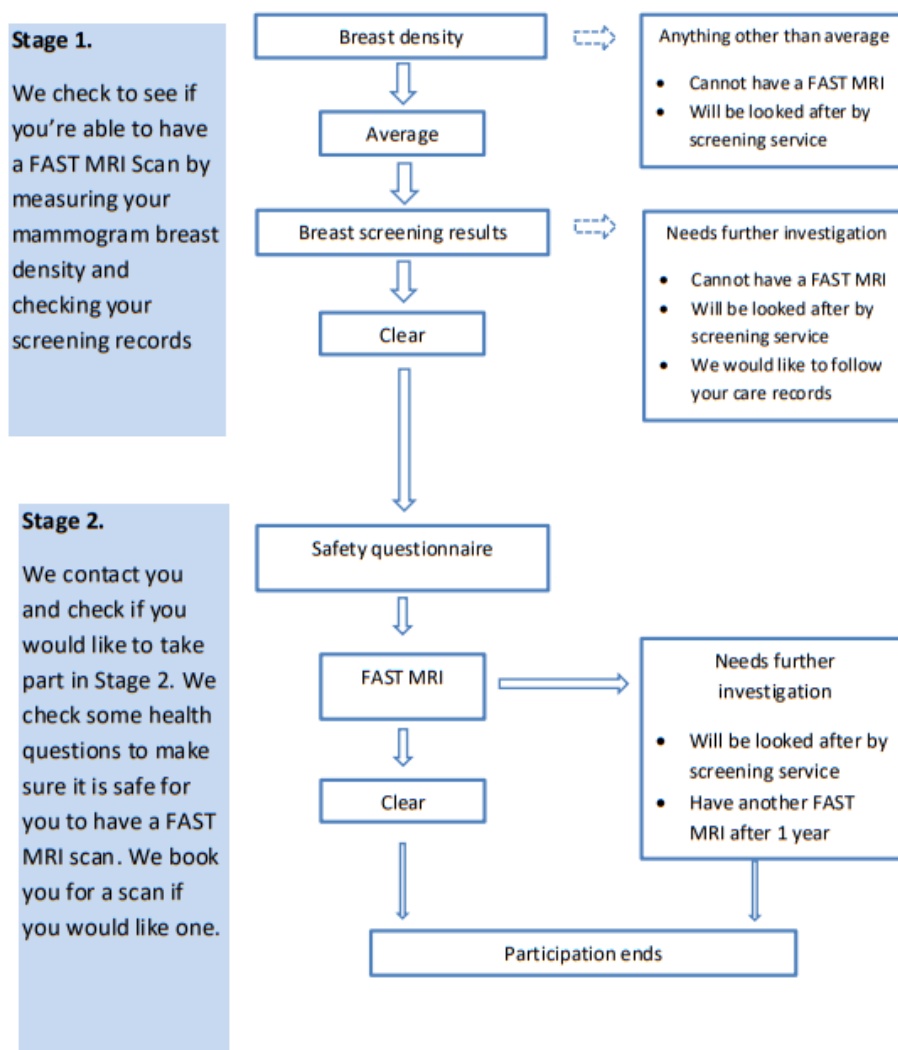
If you do need some further investigations, the screening service will contact you directly. You won't be able to have the FAST MRI scan as part of this study. Instead, with your consent, we would like to access your screening and medical records to discover the outcome of your investigations. We will do this for up to 3 years after your first mammogram.

If the screening service says your mammogram needs no further investigations and you are in the average breast density group, we will send you information and an invitation to take part in Stage 2 of the study.

Agreeing to take part in Stage 1 does not mean you will automatically have a FAST MRI scan. If the Stage 1 density grading shows you are eligible to take part in Stage 2, you will be invited and can then decide whether to take part or not. The picture below may help explain what would happen.

Stage 2 of the FAST MRI DYAMOND study involves having the FAST MRI scan.

A member of the research team will contact you to give you the information about Stage 2. They will discuss the study with you. If you can have the scan and would like to, they will book you a scan appointment. The scan itself takes just 3-5 minutes, but the whole appointment would last up to 45 minutes. Scans are provided at [local].



Do I have to take part?

No, it's up to you to decide whether to take part. If you do not want a FAST MRI scan or know you cannot have one, then you can let us know you don't want to take part. Whether or not you choose to take part, be reassured that your clinical care will not be affected. You will still be offered your routine screening mammograms every 3 years until you turn 71.



To see a short film that might help you decide if you'd like to take part in the FAST MRI DYAMOND Study follow this link: [XXXX](#) or scan this QR code: [XXX](#)



You can also find out more about the main study and about other FAST MRI research, including the potential benefits and risks to taking part in the FAST MRI DYAMOND study at the study website: [XXXXX](#)

Further information about the FAST MRI DYAMOND study

In this study we will use information from you and from your medical records. We will only use information that we need for the research study. We will let very few DYAMOND team members know your name or contact details, and only if they really need it for this study. This includes research staff at Royal Surrey Hospital who are providing the Consent Form website. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data for up to 5 years after the study closes, in case we need to check it and for future research (if you have given us permission). We will make sure no-one can work out who you are from the reports we write. Please contact us on the details below for more information about this.

This study is run by Dr Lyn Jones (Consultant Radiologist) at the FAST MRI Programme Team at North Bristol NHS Trust and [Dr XX XXX at local NHS Trust.](#)

Thank you for taking the time to read this leaflet.

Get in touch!

Your local DYAMOND Research team **at xxx Trust; local email address, phone number, named HCP**

The DYAMOND Central Research team (at North Bristol NHS Trust): 0117 414 7014 or email FASTMRI@nbt.nhs.uk

What are your options?



You can complete a paper consent form now. Please complete the form and place it in the **[local]**. Or follow this link **[xxx]** or scan **this QR code** to complete it online.



If you'd like more time to decide, that's fine: a Research Nurse will contact you in a couple of days to talk through your options.



If you feel this is not right for you, you can let us know, either by writing your name and date of birth in the box below and placing it in the **[local]**. Or follow this link **[yyy]** or scan this **QR code** to let us know online.

If we do not hear from you, we may still contact you to check that you received the information we sent you, but you can simply tell us that you do not want to take part in the study.

I do NOT want to take part in this study.

My name is: _____

My date of birth is: ___ / ___ / _____