

The AgeX trial

Trial of extending the age range for breast screening to include some women aged under 50 or over 70

Why have you been sent this leaflet?

Women of ages 50 to 70 in the UK are normally invited for breast screening every three years.

This leaflet tells you about a research study taking place across most of England of the risks and benefits of extending breast screening to women slightly younger or older than the usual 50 to 70 age range.

If your age will be 50 to 70 at the end of this year you are not being invited to take part in the trial, but are being offered routine breast screening. You don't need to read this leaflet any further.

If you will be younger than age 50 or older than 70 at the end of this year, we are inviting you for screening as part of this trial. Please read more about the trial in this information sheet.

* Nationwide cluster-randomised trial of extending the breast screening age range in England: the AgeX trial (formerly called the Age Extension Trial, with original ethical approval Ref 10/H0710/9, and ongoing ethical approval confirmed in 2014 and 2016)

Why do we need a trial?

While we know a lot about the effects breast screening has for women aged 50 to 70, there is not enough evidence on the effects for women aged somewhat less than 50 or over 70. This trial will assess the risks of screening (in particular, the chances of being diagnosed and treated for a non-life-threatening cancer) and benefits (in particular, the chances of saving life) for these slightly younger and older women.

The trial began in 2009 and is still recruiting women. By late 2016 there were already three million women in the trial and eventually the trial will be substantially larger. It will, however, take until at least the mid-2020s to get reliable information like that for women aged 50 to 70 years shown in the enclosed brochure 'NHS breast screening, Helping you decide'. The findings will help the UK government decide whether or not to widen the age range for routine breast screening.

What happens if you agree to take part?

In the area where you live, we are randomly selecting half the women aged 47 to 49 and half the women aged 71 to 73 and inviting them for screening. This is done by allocating groups of women (clusters) at random, like tossing a coin, either for the whole group to be invited for screening, or for the whole group not to be invited. A typical cluster might involve a few dozen or a few hundred women who live near each other. So for each separate age range the study can compare over the following years what happens to those women in the clusters invited for screening and those women in the clusters not invited for screening. Any woman who accepts the invitation will be screened in the normal way.

Possible risks and benefits

The enclosed brochure 'NHS breast screening, Helping you decide' describes the screening process and discusses the risks and benefits of screening women at ages 50 to 70 years. Equivalent information for younger or older women is not as reliably known, especially about the long-term benefits that screening is intended to provide.

Before age 50, about 15 out of every 200 women screened will be asked to return for more tests, but on average only about one of them will be found to have breast cancer. So, about 1 in every 200 screens before age 50 is likely to result in a breast cancer being found.

After age 70, only about 7 out of every 200 screens results in the woman being asked to return for more tests, but on average about two of them will be found to have breast cancer. So, about 2 in every 200 screens after age 70 is likely to result in a breast cancer being found.

The brochure says screening prevents about 1 breast cancer death for every 200 women screened regularly from ages 50 to 70. Since UK women are offered 7 screens between age 50 and 70, the number quoted in the brochure is the equivalent of about 1 death prevented per 1400 screens.

For each screen just before 50 or after 70, however, there might well be a somewhat lower or a somewhat higher than 1 in 1400 chance of avoiding death from breast cancer. The trial is designed to give reliable information about what those chances are.

What medical records will be used?

Your screening records will be linked, using information such as your name and date of birth, to routinely collected data held by NHS Digital on hospital admissions and cancer. This will allow researchers to assess the risks and benefits of the extra screening.

Once linked, however, all these records will be made anonymous so the researchers using them will not be able to identify any individuals. A research team at the University of Oxford is organising the trial and analysing the data.

What happens if you don't want to take part?

If you don't want to accept this invitation, then please let your local breast screening unit know that you are unable to attend. If you are aged over 70 at the end of this year you will not be invited again for routine screening as that stops at 70, but you can still ask to be screened if you wish. If you are aged 47 to 49 at the end of this year, you will still be invited for routine screening in about 3 years time.

Women aged 47 to 49 who are not invited or initially decline this invitation but then change their mind can still ask to be screened if they live in an area that is participating in the trial. Most areas in England are taking part in the trial, except for a small number unable to do so for organisational reasons.

For further details see www.AgeX.uk or ask your GP.

Where can you find out more about this trial and about breast screening?

www.gov.uk/topic/population-screening-programmes/breast gives further information about the Breast Screening Programme.

www.AgeX.uk gives further information about the trial, about how trial information is handled or used, and how to opt out, if you wish.

Funded by Public Health England

Public Health England leads the NHS screening programmes

To order more copies of this leaflet visit: www.gov.uk/phe/screening-leaflets