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Breast screening age extension trial for women who are younger than 50 or older than 70

Why have you been sent this leaflet?

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

This leaflet tells you about a research study* taking place across England that is looking at the potential risks and benefits of extending breast screening to women who are 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 50 or older than 70 at the end of this year, we are inviting you for screening as part of this trial. Please read about the trial on the other side of this sheet.

* Nationwide cluster-randomised trial of extending the NHS breast screening age range in England

Original ethical approval: Ref 10/H0710/9; ongoing ethical approval confirmed in 2014.

Why do we need a trial?

While we know a lot about the effects breast screening has on 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 potential 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 mid-2014 there were already 1.5 million women in the trial and eventually it is likely to involve several million. It will take until at least the mid-2020s to get reliable information like that for women aged 50-70 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 for all women.

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, those women 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. The enclosed brochure 'NHS breast screening, Helping you decide' describes the screening process and discusses the risks and benefits of screening for women aged 50 to 70 years. However, the numbers given in the brochure (on pages 6-8 and page 11) do not apply to women who are younger than 50 or older than 70. For example, the diagram on page 7 of the brochure, which shows what typically happens when 100 women aged between 50 and 70 are screened, is based on information that has been collected on large numbers of women over many years.

Equivalent information for women younger than 50 or older than 70 is not reliably known. The brochure says that each time 100 women have breast screening, about 4 women need more tests and 1 woman is diagnosed with cancer. It could be that more or less than 4 women need more tests and that more or less than a hundred women need to be screened to diagnose 1 woman with cancer. Similarly, the brochure says on page 11 that screening saves about 1 life from breast cancer for every 200 women who are screened. As this means accepting all 7 of their 3-yearly screening invitations, the gain per single screening visit at ages 50 to 70 is on average about 1 in 1400. For a single extra screening visit just before 50 or just after 70 the extra gain might be somewhat higher or lower than a 1 in 1400 chance of avoiding death from breast cancer.

If you take part in the trial your screening records will be linked, using information such as your name and date of birth, to any other NHS screening records and any hospital admission or cancer records. This will allow us 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 agree to take part?

If you don't want to accept this invitation, then please ignore it. 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. Almost all areas in England are taking part in the trial, except for a small number unable to do so for organisational reasons. Please ask your GP for details, if you want to.

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

On the NHS Cancer Screening Programmes website at **www.cancerscreening.nhs.uk**

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