

LETTERS

BREAST CANCER SCREENING TRIAL

Time to halt an out of control trial with ineffective oversight

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Detailed scientific and ethical concerns have repeatedly been raised about the less than robust mammography screening age extension trial.¹⁻³ The chief investigator is not medically or scientifically qualified, encourages contamination, ignores questions or obfuscates, and both runs the national programme and chairs the (non-independent) trial steering committee.

The eight page study protocol,⁴ produced only after repeated freedom of information requests, contains two references and has no statistical analysis plan. The most important outcomes of all cause mortality and morbidity (mastectomy) are not mentioned. The independent Marmot review expressed equipoise about benefits and harms and noted that the impact of breast screening outside the ages of 50-69 is very uncertain.⁵ The pilot found harm with a doubling of recalls yet much lower confirmed diagnoses at younger ages. However, neither investigation resulted in a revision of the protocol.

The governance and oversight are opaque. The original research ethics committee did not contain a statistician. The current one has twice rejected proposed substantial amendments and expressed concerns about consent, but nevertheless countenances continuing cluster randomisation and inadequate information. Women aged 47-50 and 70-73, who receive the same "new improved" national leaflet, are not fully informed about the harms of overdiagnosis. Thus, recruits cannot realise that it is uncertain whether breast screening works at their age or that research participation may carry risks. There is no assurance that they even realise that they are in a randomised trial.

The age extension trial may be the largest ever human experiment. Lack of a proper research question and competence, inherent bias, and under-informed women have resulted in improper science and an unethical trial. We call for the age extension trial to be halted and for an independent review.

Competing interests: CR is a founding member of HealthWatch-UK (a charity "for science and integrity in medicine") of which SB, LR, JI, and JM are current trustees. MP was diagnosed through breast screening. SB's interests can be found at www.whopaysthisdoctor.org/doctor/58. All other authors declare no conflicts of interest.

Full response at: www.bmj.com/content/349/bmj.g5105/rr/762657.

- 1 McCartney M. A trial to extend breast cancer screening may be unethical. *BMJ* 2014;349:g5105. (12 August.)
- 2 Blennerhassett MAJ et al. Rapid responses to "An independent review is under way," 17 October and 1 November 2012. *thebmj.com* 2012. www.bmj.com/content/343/bmj.d6843/rapid-responses.
- 3 HealthWatch. Concerns over age extension trial of mammography screening. 2014. www.healthwatch-uk.org/concerns-over-age-extension-trial-of-mammography-screening/.
- 4 Evaluation of the net effects of extending the age range for breast screening in the NHS breast screening programme in England from 50-70 years to 47-73 years. Protocol. 2009. www.healthwatch-uk.org/wp-content/uploads/2014/07/Protocol-Age-Extension-26.11.09.pdf.
- 5 Independent UK Panel on Breast Cancer Screening. The benefits and harms of breast cancer screening. Independent breast screening review. 2012:70. www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/breast-screening-report.pdf.

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