
From: Corporate [mailto:Corporate@headoffice.mrc.ac.uk]
Sent: 21 December 2015 09:55
To: 'Susan'
Subject: RE: breast screening age-extension trial

Dear Professor Bewley,

Thank you for your enquiry. I will provide you with some background information on the MRC's link to this trial and will then answer your questions in turn.

The nationwide cluster-randomised trial of extending the NHS breast screening age range in England is funded mainly by Public Health England (PHE). The Trial co-ordinating centre is located in the Cancer Epidemiology Unit (CEU) in the Nuffield Department of Population Health which receives no direct support from the MRC for the trial.

The MRC provides support to the Clinical Trial Service Unit & Epidemiological Studies Unit (CTSU), in partnership with Cancer Research UK (CRUK) and the British Heart Foundation (BHF). Professor Sir Richard Peto is one of the Co-Directors of the CTSU and is also a co-investigator on the trial that you are enquiring about. Whilst the MRC is listed as a co-funder of the trial, the MRC support is only through core support for Professor Peto's research programme at the CTSU. The CTSU does not contribute any money to the conduct of the trial, but does allow Professor Peto time to be involved in the trial. Therefore the only support that the MRC provides to this trial is through Professor Peto's time. Although Professor Peto would generally acknowledge MRC support in describing his academic activities, they do not always have a direct funding link to the MRC. As such, the MRC does not routinely review or monitor such activities. As is the case for all MRC Units, the overall strategy and scientific direction of the CTSU is reviewed every 5 years via a Quinquennial Review (QQR) and funding support is renewed based on the outcome of the review. The last QQR of the CTSU was conducted jointly between CRUK, BHF and MRC in 2013.

a) *What were the MRC review and governance processes when this trial started?*

You will see from the information that I have provided above that the MRC's review and governance processes are not applicable in this situation. However, information on the QQR process that all MRC funded units and institutes undertake can be found at:

<http://www.mrc.ac.uk/documents/pdf/summary-of-mrc-unit-and-institute-quinquennial-reviews/>.

b) *Would you have expected such an RCT to satisfy ICH-GCP?*

The MRC is not able to comment on this specific trial, however we would expect all medical research to comply with the relevant regulations.

c) *As a cofounder, how was the MRC informed, involved with, and satisfied by, (a) the initial peer review process of protocol v1, and (b) the change of research question to protocol v3?*

As described above, the MRC only provides core support for the CTSU, which includes Professor Peto's programme. As such the MRC was not involved with initial peer review and has not required notification of, or consultation on changes to protocols.

d) *How much funding have you supplied and will continue to supply?*

As described above, the MRC only provides core support for the CTSU, which includes Professor Peto's programme.

I hope that this information provides clarity on the MRC's involvement with this trial.

Yours sincerely,

Tiffany

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From: Susan [<mailto:sbewley@doctors.org.uk>]

Sent: 02 November 2015 12:18

To: 'john.savill@headoffice.mrc.ac.uk'

Cc: 'Linda.Willmott@headoffice.mrc.ac.uk'; 'corporate@headoffice.mrc.ac.uk.'

Subject: breast screening age-extension trial

Dear Sir John Saville

I understand that the MRC is a funder of the nationwide cluster-randomised trial of extending the NHS breast screening age range in England, <http://www.isrctn.com/ISRCTN33292440> a cluster RCT without explicit consent running since 2009 and which has undergone major revision in the light of the 2012 Marmot report finding of equipoise and our submissions.

Healthwatch-UK (a charity "for science and integrity in medicine") has concerns about the science and ethics – all detailed on its website starting with <http://www.healthwatch-uk.org/news/44-concerns-over-age-extension-trial-of-mammography-screening-part-1.html>. You will see that it took an FOI request to obtain a copy of the initial protocol v1 and there are grave scientific concerns about its credibility.

I would be very grateful to understand the MRCs role in supporting this trial:

- a) What were the MRC review and governance processes when this trial started?
- b) Would you have expected such an RCT to satisfy ICH-GCP?
- c) As a cofounder, how was the MRC informed, involved with, and satisfied by, (a) the initial peer review process of protocol v1, and (b) the change of research question to protocol v3?
- d) How much funding have you supplied and will continue to supply?

With best wishes

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