Author's response to reviews

Title: The New Zealand 1986 very low birth weight cohort as young adults: mapping the road ahead. Study protocol

Authors:

Brian A Darlow (brian.darlow@otago.ac.nz)
L John Horwood (john.horwood@otago.ac.nz)
Lianne J Woodward (LJWOODWARD@partners.org)
John M Elliott (john.elliott@otago.ac.nz)
Richard W Troughton (richard.troughton@otago.ac.nz)
Mark J Elder (Mark.Elder@cdhb.health.nz)
Michael J Epton (Michael.Epton@cdhb.health.nz)
Josh D Stanton (Josh.Stanton@cdhb.health.nz)
Maureen P Swanney (Maureen.Swanney@cdhb.health.nz)
Ross Keenan (ross_keenan@clear.net.nz)
Tracy R Melzer (tracymelzer@gmail.com)
Victoria A McKelvey (Victoria.McKelvey@cdhb.health.nz)
Karelia Levin (kjlevin@gmail.com)
Margaret G Meeks (Maggie.Meeks@cdhb.health.nz)
Eric A Espiner (eric.espiner@otago.ac.nz)
Vicky A Cameron (vicky.cameron@otago.ac.nz)
Julia Martin (julia.martin@otago.ac.nz)

Version: 2 Date: 29 June 2015

Author's response to reviews: see over
The Editors
BMC Pediatrics

Re: MS: 6919134401610537
Study protocol
The New Zealand 1986 very low birth weight cohort as young adults: mapping the road ahead.
Study protocol
BMC Pediatrics

Dear Editors.

This manuscript was sent to you on 19th February 2015. In an email dated 29th June you have asked for very minor revisions prior to editorial assessment. In the letter below I have detailed our response to each request.

I trust that this manuscript can now be assessed promptly.

Yours sincerely,

Brian A. Darlow MD FRCP FRACP FRCPCH
Cure Kids Professor of Paediatric Research

1. Please provide sample size calculation.

Answer. Under “Statistical analysis and statistical power” page 19, from line 434 we say “Assuming a minimum of 250 recruits from the VLBW cohort and 100 controls, the study will have 80% power at alpha=.05 to detect differences between groups of .30 SD or greater on continuous outcomes, and ORs in the region of 2.0-3.5 for dichotomous outcomes (depending on the base rate).[59] This suggests the study will have adequate power to detect effect sizes in the small to
As our protocol states, this is a follow-up study of all surviving members of the national cohort of very low birthweight infants born in New Zealand in 1986. 250 recruits is 77% of survivors (line 260, page 12).

2. Date of Trial Registration:
Once you know your trial registration number, please submit a revised version of your manuscript with the number included in the abstract. The last section of the abstract should be Trial Registration: listing the trial registry and the unique identifying number and the date of registration, e.g. Trial registration: Current Controlled Trials ISRCTN73824458. Registered 28 September 2004. Please note that there should be no space between the letters and numbers of the trial registration number.

Answer. We previously gave details of trial registration (in the Abstract, in the correct format – line 85) and have now supplied the date (Registered 1 October 2012).

3. As you may be aware, it is the policy of the journal not to peer review study protocols where ethical and external funding approval have been obtained, as these processes usually involve peer review and as there is little possibility to change a protocol after enrolment begins. Therefore, could you please respond to the following points below and provide the requested responses in your cover letter.

A. Ethical and Funding Approval Documentation
Before we can proceed with your submission, can you please forward copies of all ethical approval and funding approval for our records. These documents should be sent as email attachments to the following email address, BMCSeriesEditorial@biomedcentral.com. Please DO NOT upload these documents as additional files in the submission system. If your documents are not in English, please could you provide translated versions of the relevant parts. These should be endorsed and signed by a contactable person at the institution. Please also include the original documents. Can you please confirm in your cover letter that you have forwarded the requested documentation to BMCSeriesEditorial@biomedcentral.com.

Answer. A letter recording Ethics approval was supplied with our original submission. I can now confirm that this has been sent separately to the email address above.
B. Funding
A study is considered to be externally funded if the authors have been awarded a grant for the study by a major funding body (e.g. governmental funding/award from a charitable foundation). If a study has not received external funding, then the study protocol will be sent for peer-review with a member of our Editorial Board. If a study has received funding/assistance from a commercial organization, this should be clearly stated in the 'competing interests' section of your manuscript, and the study protocol will be sent for peer-review by a member of our Editorial Board. Can you please confirm whether your study protocol has undergone peer-review by the funding body.

Answer. A letter recording that we have received funding for the study from The Health Research Council of New Zealand (Project grant 12/129), the major funding body for clinical research in the country, was supplied with our original submission. Extensive peer review is undertaken during the assessment process and only approximately 10% of applications are funded. I can now confirm that this letter has been sent separately to the email address above.

C. Study status
The protocol must be for a study that is ongoing. An ‘ongoing’ study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at.

Answer. I can confirm that the study is still ongoing. We expect to complete recruitment and assessments by June 2016 and analysis by December 2016

D. Related Articles
Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal. If so, can you please provide a list of the related articles.

Answer. I can confirm that there have been no publications containing results of the study and no manuscripts with results have been submitted.