Author's response to reviews

Title:'On Your Feet to Earn Your Seat': update to randomised controlled trial protocol

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Author's response to reviews:

Dear editors,

Thank you for your positive feedback on our manuscript. We have made the changes suggested, and an additional change, as described below. We hope the paper may now be suitable for publication in Trials.

Best wishes
Benjamin Gardner
With and on behalf of all co-authors

RESPONSES TO REVIEWER COMMENTS

1. Please include the date of registration with your trial registration number at the end of your Abstract.

OUR RESPONSE:

We have done this as requested. Note however that, for the original version of the protocol that was previously published in Trials, we were asked to do the same, but the registration date was removed by the BMC proofing team, as it does not appear to be journal style to include this information in the abstract.

2. Please include the names of all ethical bodies that approved your study in the various centers involved. If you do not wish to list them all in the methods
section, please include the list with the Acknowledgements section or as an additional file and refer to this in the methods section.

OUR RESPONSE:

In England and Wales, ethical approval is provided by a single ethics committee, of which there are many, spread out across the country, but which can provide approval for work taking place anywhere in England and Wales. Hence, in line with NHS ethics procedures, ethical approval for the original proposal, and all amendments made necessary by the addition of new sites, was provided by one Research Ethics Committee. Governance approval is however needed from Clinical Research Networks (CRNs), within which sits the local site at which the work will take place. We have therefore added the name of the NHS Research Ethics Committee (Bromley), and listed the CRNs that provided governance approval for each site, as follows:

“The changes detailed in this update have been approved as a series of Substantial and Non-Substantial Amendments by the Bromley NHS Research Ethics Committee (reference 13/LO/1549). Site-specific local governance approvals were provided by North Thames Clinical Research Network (CRN; London sites), East Midlands CRN (Lincs site), and Kent, Surrey and Sussex CRN (Surrey and Kent sites). The independent project steering committee was notified of all changes and no objections were raised.”

We have added the ‘CRN’ acronym to the Abbreviations section.

3. Please revise the statement of consent, so that it clearly states that written informed consent will be obtained from all participants prior to enrollment in the study.

OUR RESPONSE:

We have added the following sentence to the ‘study setting’ section:

“Participants at all sites provided written informed consent prior to enrolment in the study.”

ADDITIONAL CHANGE:

We realised we had not provided details of which equipment we bought for the non-London sites, and which we could not afford. We have added the following information to the ‘Study procedures’ section:

“Non-London sites were provided, on request, with blood pressure monitors and stopwatches, to collect objective functioning data, and digital recorders to capture
interview data. There were however insufficient project funds to provide hand
dynamometers, for grip strength measurement, to non-London sites."

Additionally, we now mention dynamometers and grip-strength in the following
sentence within the ‘Analysis plan’ section:

“Exploratory analyses of changes in physical activity, habit, wellbeing, physical
health, functioning (secondary outcomes) will proceed as detailed in our original
protocol, with the exception that objective physical activity, sedentary behaviour
and grip-strength data will only be analysed for participants at the London sites,
for whom accelerometry and dynamometer data are available.”

We have added a row into Table 1 that describes the objective health and
wellbeing variables measured at each site: only the London sites measure of grip
strength.