Author's response to reviews

Title: Comparing exercise interventions to increase persistence with physical exercise and sporting activity among people with hypertension or high normal blood pressure: protocol for a randomised trial

Authors:

Chris Fife-Schaw (c.fife-schaw@surrey.ac.uk)
Simon de Lusignan (s.lusignan@surrey.ac.uk)
Joe Wainwright (j.wainwright@surrey.ac.uk)
Hannah Sprake (h.sprake@surrey.ac.uk)
Suzannah Laver (suzannah.laver@surreycc.gov.uk)
Victoria Heald (victoria.heald@surreycc.gov.uk)
Julian Orton (julian.orton@gp-h81091.nhs.uk)
Matt Prescott (matt@isostasy.co.uk)
Helen Carr (hfcarr@doctors.org.uk)
Mark O'Niell (mark.oneill@gp-h81091.nhs.uk)

Version: 3 Date: 16 April 2014

Author's response to reviews: see over
Dear Profs Altman, Furberg and Grimshaw

Re: Comparing exercise interventions to increase persistence with physical exercise and sporting activity among people with hypertension or high normal blood pressure: protocol for a cluster randomised trial.

We have uploaded a revised version of the above manuscript and have used ‘track changes’ as requested which should make it clear where we have responded to the editorial requests. Specific responses to Prof Wizner’s report were dealt with as follows (item numbers refer to Prof Wizner’s points):

We would prefer not to remove the reference to persistence from the title of the paper as it is a central element of the trial. A major issue in the field is that activity levels are known to increase in the short term after an exercise programme but the changes are not sustained in the longer term which is the ultimate goal of these interventions.

1 and 2) The project is focussed on people whose GPs regard them as being likely to benefit from an exercise programme. We have added “as recorded on their GP records and is regarded by their GP as someone who would benefit from attending an exercise programme” to clarify this in the inclusion criteria. We have also added the definition of high normal blood pressure (prehypertension) to the inclusion criteria. The BP readings used to identify potential participants are those that are on the GP records and will have been taken by the GP or surgery staff – they are not patient-assessed home recordings.

3) The Qrisk2 calculator is intended for use irrespective of a diagnosis of heart disease or stroke. It is not being used as a formal part of the recruitment process which is why it is not referred to in the inclusion and exclusion criteria. As above, and as the trial is attempting to compare the new interventions against existing referral practice, we are selecting patients on the basis of clinical opinion about the benefit of exercise for the patient.

4) We have specified the BP monitors used and indicated that these measurements will be taken by GP surgery staff and/or trained exercise professionals. We are not in a position to...
impose a consistent location for the follow-up BP measurements as GP surgeries have differing working practices and resources to take these measurements. Those that cannot be taken by the surgery staff will be taken by the research team.

5) It is not the intention of this trial to monitor all aspects of patients’ behaviours relevant to hypertension. We will however assess behaviours such as smoking and drinking and, for those in the web arms of the trial we will have information on click through to related self-help web resources.

6) While the exercise referral specialists will know about all of a patient’s medications we do not have ethical clearance to record anything other than whether they are taking medication for hypertension. We will know what medication they are taking but will not be able to know sure whether they are complying with the prescription regimen.

7) We have added some clarification about the exercise activities which makes it clear that these are tailored to the individual by trained referral practitioners. These people hold NHS recognised qualifications specifically for GP referral exercise programmes. The GPs, at the point of referral, do not know which arm of the study Ps will be allocated to and so do not make specific recommendations about which activities are completed.

8) Within the sports arm patients have an individually tailored programme designed for them which not only gives some flexibility over activity types but also the level of intensity of those activities. Although such analyses would be interesting were the intensities held constant we will only be able to assess the degree to which patients enjoyed the different activities on offer.

9) We have indicated that the SF36, AUDIT and Fagerstrom tests are administered at baseline and at 12-month follow-up.

The SPOGO website is explained as being an online sports and physical activities database.

We hope that these amendments and comments are helpful to you.

Yours sincerely,

Chris Fife-Schaw