Health Research Authority

National Research Ethics Service

NRES Committee London - Bloomsbury
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11th September 2013

Professor Chris Fife-Schaw
Professor of Psychology
University of Surrey
Stag Hill
Guildford
Surrey
GU2 7XH

Dear Professor Fife-Schaw

Study title:	**Guildford Hypertension 2000: A randomised trial of exercise interventions**
REC reference:	**13/LO/1170**
Protocol number:	**130710 GHT2000 Protocol**
IRAS project ID:	**130286**

The Research Ethics Committee reviewed the above application at the meeting held on 04 September 2013. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Dr Ashley Totenhofer, nrescommittee.london-bloomsbury@nhs.net.

Ethical opinion

Ethical issues raised by the Committee in private discussion, together with responses given by the researcher when invited into the meeting

1. The committee noted that patients activity is usually measured using the GPAQ questionnaire but the outcome measure for this study uses the IPAQ questionnaire.

   You stated that the GPAQ is widely used but is not recognised and is just used as a screening tool in this project. You will use the IPAQ at the start and finish of the study and the difference in this is what you will measure.

2. The committee queried how many questionnaires would participants have to complete.

   You stated they would complete the background questionnaires at screening and the IPAQ at each time period.

3. The committee commented that the IPAQ states it is for young and middle-aged people but the study was open to individuals up to seventy-four years old.

   You stated it is validated up to this age.

4. The committee queried why the randomisation letter is sent by the GP rather than by the study team.

   You stated that it is their referral letter so it must come from the GP.

5. The committee queried whether any email addresses would be disclosed to third parties.

   You stated they would not, there is no transfer of data outside the study team.

6. The committee queried who would have access to participant's medical records.

   You stated it would just be the study team; the gym staff would not have access to this.

7. The committee queried whether there would be any payments to participants.

   You stated no, the study just mimics current practice which partially subsidises the cost of the gym.

8. The committee queried whether the advert was a poster and stated they didn't think it would attract many people in a GP surgery.

   You stated it is a card that is given out to patients.

9. The committee queried what the clinical data referred to in the GP letter is.

   You stated it is the data mentioned in section 5.2 of the protocol and consists of heart disease history, cholesterol and blood sugar.

10. The committee asked Professor Fife-Schaw if he had any questions.

    You asked why for future reference the application was given a No Opinion by the Proportionate Review Sub-Committee.

    The committee showed you the letter you should have been sent detailing why it had been referred to a full committee for review.

    You stated you did not think you had ever been sent this.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, **subject to the conditions specified below**.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see

"Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Additional Conditions Specified by the REC

1. Please revise the Participant Information Sheet in the following manner:
    a. Please make it clear that the GPAQ questionnaire will be completed at baseline.
    b. Please make it clear that the IPAQ questionnaire will be completed at each of the timepoints.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*	
Advertisement	2	10 July 2013	
Evidence of insurance or indemnity	Zurich Municipal	06 June 2013	

GP/Consultant Information Sheets	4	11 July 2013	
Investigator CV	Christopher Fife-Schaw	29 May 2013	
Letter from Sponsor	University of Surrey	03 June 2013	
Other: Example Screenshots		10 July 2013	
Other: Letter from Funder	Surrey County Council		
Participant Consent Form	4	11 July 2013	
Participant Information Sheet	4	12 July 2013	
Protocol	12	10 July 2013	
Questionnaire: AUDIT: Self Report	Validated		
Questionnaire: Additional Questions and Non-Validated Measures	4	09 July 2013	
Questionnaire: SF-36	Validated		
Questionnaire: Fagerstrom Test for Nicotine dependence	Validated		
Questionnaire: General Practice Physical Activity Questionnaire	Validated		
Questionnaire: IPAQ	Validated		
REC application	3.5	12 July 2013	
Referees or other scientific critique report	Jane Ogden	13 June 2013	

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

Signed on behalf of:
Reverend James Linthicum
Vice-Chair

Email: nrescommittee.london-bloomsbury@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: Mr Mike Chenery – University of Surrey

Dr Helen Evans - Research Department, Worthing & Southlands Hospitals NHS Trust

NRES Committee London - Bloomsbury

Attendance at Committee meeting on 04 September 2013

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Joe Brierley	Consultant Intensivist	No	Chair
Ms Sally Doganis	Executive Producer and Media Consultant	Yes	
Dr Rashmi Gandhi	Neonatal registrar	No	
Professor Faith Gibson	Clinical Professor of Children and Young People's Cancer Care	Yes	Alternate Vice-Chair
Ms Claire Khalil	Pharmacist	No	
Dr Rachel L Knowles	Clinical Research Fellow	Yes	
Dr Leah Li	Statistician	No	
Dr Vincenzo Libri	Consultant in Clinical Pharmacology	Yes	
Reverend Jim Linthicum	Lay member - Hospital Chaplain	Yes	Vice-Chair
Michelle McPhail	Lecturer in Management Studies	Yes	
Dr Katie Elizabeth Myers Smith	Health Psychologist	No	
Mrs Rosa Pizer	Lay member - Retired Teacher/Volunteer Jewish Chaplain	No	
Mr Roger Selby	Lay member - Retired Solicitor	No	
Ms Nabila Youssouf	Clinical Trials Manager	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Rosie Keal	Observer
Dr Ashley Totenhofer	REC Manager