Participant Information Sheet

Title: The health of adults’ longitudinal observational study (HALO)

You have been invited to take part in this research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish to. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part or not. Should you wish to become involved in this study, please retain a copy of this information sheet for your records.

Thank you for reading this.

Name of Investigators:

Chief investigator: Dr Kim Edwards
Course Director: Sports and Exercise Medicine
Academic Orthopaedics, Trauma and Sports Medicine
University of Nottingham
C Floor, West Block, Queen’s Medical Centre
Nottingham, NG7 2UH

Background

Many health conditions, including cardiovascular disease, type 2 diabetes, cancers and chronic lung disease, mental illness and osteoarthritis, are linked to what are called ‘modifiable risk factors’ which are physical inactivity, obesity, smoking and poor diet. The health burden of these conditions in developed countries is expected to worsen, mainly due to population ageing and continued rises in risk factors. This presents a large challenge to policy makers and researchers alike. One difficulty is the lack of data of sufficient quality, particularly detailed physical activity data, and lack of such data at multiple time points over many years.

What does the study involve?

No intervention is required as part of the study, we simply wish to observe your lifestyle choices and behaviours and how this relates to your health. This study would involve completing an initial online questionnaire (we can post you a hard copy if you prefer), which we anticipate will take approximately 30 minutes to complete.

At the end of the questionnaire we will ask you if we can contact you again about this study. If you consent we will send you the other two initial questionnaires (which also take about 30 minutes to complete). Then (if you wish) we will send a follow-up questionnaire after roughly 12 months, then further questionnaires every 2-5 years. We plan to collect data for at least 15 years. You can withdraw from the study at any time.

Some data to be collected is more onerous, e.g. in terms of the time or cost of collecting the data. Accordingly these data will only be gathered from smaller sub-groups of all participants. If you consent to being contacted again, from time to time we would invite you to participate in these studies. Full details about these studies would be provided at the time. Participation would be entirely optional and would not affect whether you continue to participate in the questionnaire element of the study or not. In short, you could do as much or as little as you wish.
Why have you been chosen?

We are recruiting people from all walks of life. We would like to recruit very active people, very inactive people, and everyone in-between. If you are aged 18 or over, we would like you to complete our questionnaire.

Do you have to take part?

It is up to you to decide whether or not to take part. Your completion of the online questionnaire is considered your consent to be involved in the study.

If you decide to take part you are still free to withdraw at any time and without giving a reason.

What do you have to do?

If you wish to take part, if you are reading this on our website, then the questionnaire will start automatically at the end of this page. If you are reading a paper version, please go to the following link (or contact us for a paper version of the questionnaire):

http://tinyurl.com/haloquestionnaire

If you do not wish to take part, please feel free to close down this window/leave this website/throw away this document.

Please note, as a participant in our study, we would not require any alteration to your lifestyle choices. No change in running participation or any other sporting activity would be expected, nor any change in diet or other lifestyle behaviours. Should you make any changes to your behaviours (e.g. stopping running) in the future, we would hope that you would continue with your involvement in our study as this may provide significant information that is important as part of our analysis.

What are the side effects of any treatment or procedures received when taking part?

There is no intervention within this study, therefore there are no possible side effects.

What are the possible disadvantages and risks of taking part?

Participant data shall be securely protected throughout the study. There is a minimal risk, for example due to unforeseen circumstance or human error, that some data is accessible by someone other than the research authors. Thorough measures shall be put in place by the authors to ensure that the chances of this happening are negligible. All study data will be anonymised and password protected.

What if something goes wrong? Who can you complain to?

In case you have a complaint about your treatment by a member of staff or anything to do with the study, you can initially approach the lead investigator (Dr Kim Edwards), details below.

If this achieves no satisfactory outcome, you should then contact the University of Nottingham Faculty of Medicine and Health Research Ethics Committee Secretary:

Mrs Louise Sabir,
Division of Therapeutics and Molecular Medicine,
D Floor, South Block,
Queens Medical Centre,
Nottingham, NG7 2UH

Telephone 0115 8231063
E-mail louise.sabir@nottingham.ac.uk
The University of Sydney Ethics Committee contact details:

Research Integrity and Ethics Administration
The University of Sydney Level 2
Margaret Telfer Building – K07 Arundel Street
The University of Sydney | NSW | 2006

Email address: ro.humanethics@sydney.edu.au
Phone number: +61 2 8627 8111 / +61 2 9036 9161

In the unlikely event that you suffer injury to yourself or damage to your property as a result in taking part in this research, the University does have an insurance policy to cover harm arising as a result of the defect in the design of the study. In addition, all medical practitioners taking part in the research have personal medical negligence cover (for UK-based work only).

**Will my taking part in this study be kept confidential?**

All information that is collected about you during the course of the research will be kept on a password-protected database and is strictly confidential. Any information about you that leaves the research unit will have your name and address removed so that you cannot be recognised from it.

**What will happen to the results of the research study?**

Results from the study will be published in various sources, including PhD thesis, MSc dissertations, and academic peer reviewed journals. In addition, we hope to present this work at academic conferences internationally. Participants will not be identifiable in any report / publication.

**Who is organising and funding the research?**

This study is sponsored by the University of Nottingham. Academic support from tenured staff within Academic Orthopaedics, Trauma and Sports Medicine in the University of Nottingham, who are associated with the Arthritis Research UK Centre for Sport, Exercise and Osteoarthritis, will support the long term study. RL is funded by the University of Nottingham and Arthritis Research UK through the Arthritis Research UK Centre for Sport, Exercise and Osteoarthritis.

**Who has reviewed the study?**

This study has been reviewed and approved by the University of Nottingham Faculty of Medicine and Health Research Ethics Committee. It has also been agreed with the parkrun Research Board and the University of Sydney Research Ethics Committee.

**Contact for Further Information**

Primary point of contact for general enquiries:

Mr Richard Leech Email: theHALOstudy@nottingham.ac.uk

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