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Contact: create.library@canterbury.ac.uk
7.0 APPENDICES

The influence of walking on risk factors associated with metabolic syndrome

Andrew Scott

Department of Sport Science, Tourism and Leisure

Canterbury Christ Church University

Thesis submitted to the University of Kent at Canterbury for the degree of Doctor of Philosophy

December 2008
Appendix A – 24 week walking study

A.1 Research ethics committee proposal

Date: 06/10/2004  
Reference: 04/Q1803/82  
Online Form

**NHS Research Ethics Committee**

**APPLICATION FORM**

This form should be completed by the Chief Investigator, after reading the guidance notes. See Glossary for clarification of different terms in the application form.

<table>
<thead>
<tr>
<th>Short Title and version number: (maximum 70 characters – this will be inserted as header on all forms)</th>
<th>The effect of 30 minutes of accumulative brisk walking on five days of</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of NHS Research Ethics Committee to which application for ethical review is being made:</td>
<td>East Kent Research Ethics Committe</td>
</tr>
<tr>
<td>Project Reference number from above REC:</td>
<td>04/Q1803/82</td>
</tr>
<tr>
<td>Submission Date:</td>
<td>06/10/2004</td>
</tr>
</tbody>
</table>

**PART A: Introduction**

**A1. Title of Research**

<table>
<thead>
<tr>
<th>Full title:</th>
<th>The effect of 30 minutes of accumulative brisk walking on five days of the week upon, metabolic syndrome risk factors and lipid metabolism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key words:</td>
<td>Metabolic Syndrome, brisk walking, lipid metabolism, accumulative physical activity</td>
</tr>
</tbody>
</table>

**A2. Chief Investigator**

<table>
<thead>
<tr>
<th>Title:</th>
<th>Dr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forename/Initials:</td>
<td>Kate</td>
</tr>
<tr>
<td>Surname:</td>
<td>woolf may</td>
</tr>
<tr>
<td>Post:</td>
<td>Research Fellow</td>
</tr>
<tr>
<td>Qualifications:</td>
<td>BSc (Hons), MSc, PhD, BASES accredited researcher &amp; exercise scient</td>
</tr>
<tr>
<td>Organisation:</td>
<td>Canterbury Christ Church University College (CCCUC)</td>
</tr>
<tr>
<td>Address:</td>
<td>North Holmes Road</td>
</tr>
<tr>
<td>Canterbury</td>
<td></td>
</tr>
<tr>
<td>Kent</td>
<td></td>
</tr>
<tr>
<td>Host Code:</td>
<td>U11 1UJ</td>
</tr>
<tr>
<td>E-mail:</td>
<td><a href="mailto:kwa24@cant.ac.uk">kwa24@cant.ac.uk</a> &amp; <a href="mailto:kate@woolf-may.forest.nct.uk">kate@woolf-may.forest.nct.uk</a></td>
</tr>
<tr>
<td>Telephone:</td>
<td>01227 767700 x 3233</td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
</tbody>
</table>

A copy of a current CV, (maximum 2 pages of A4) for the Chief Investigator must be submitted with application

**A3. Proposed Study Dates and Duration**

<table>
<thead>
<tr>
<th>Start Date:</th>
<th>01/10/2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>End Date:</td>
<td>30/09/2006</td>
</tr>
<tr>
<td>Duration:</td>
<td>Months: 0 ; Years: 2</td>
</tr>
</tbody>
</table>
A4. Primary purpose of the research: (Tick as appropriate)

☐ Commercial product development and/or licensing
☐ Publicly funded trial or scientific investigation
☐ Educational qualification
☐ Establishing a database/data storage facility
☐ Other

If Other, give details:
To further contribute toward the knowledge-base of health related physical activity, and the research profile of the college
Department of Sport Science, Tourism and Leisure.

A5. Tick the box if your research:

☐ Involves testing a medicinal product
☐ Involves investigating a medical device
☐ Involves additional radiation above that required for clinical care
☐ Involves using stored samples of human biological material (e.g. blood, tissue)
☐ Involves taking new samples of human biological material
☐ Involves only patient records or data, with no other direct patient contact
☐ Involves prisoners or others in custodial care
☐ Involves adults unable to consent for themselves through physical or mental incapacity
☐ Has the primary aim of being educational (e.g. a student project, or a project or research necessary for a
  postgraduate degree or diploma)

A6. Do you consider that this research falls within the category where there is no need to appoint a Principal
Investigator at each site?

☐ Yes  ☐ No

If Yes, please justify:

Advice can be found in the guidance notes on this topic. Some studies do not require further consideration of site-specific
issues by local research ethics committees, but will still require approval to proceed from the host organisation(s).
A7. What is the principal research question/objective? (Must be in language comprehensible to a lay person.)

Whether the government guidelines for the accumulation of 30 minutes of physical activity on five days of the week is a useful strategy for reducing Metabolic Syndrome risk in abdominally obese individuals, who are at increased risk of Metabolic Syndrome.

A8. What are the secondary research questions/objectives? (If applicable, must be in language comprehensible to a lay person.)

1. Whether the government guidelines for accumulation of 30 minutes of physical activity on five days of the week (for 24 weeks) is effective at increasing lipid metabolism in abdominally obese men.
2. Whether detraining, after 30 minutes of physical activity on five days of the week, for 24 weeks causes a change in risk of Metabolic Syndrome and lipid metabolism.
3. Whether the government guidelines for accumulation of 30 minutes of physical activity on five days of the week (for

A9. What is the scientific justification for the research? What is the background? Why is this an area of importance? (Must be in language comprehensible to a lay person.)

Metabolic syndrome (MIS) is characterised by insulin resistance in the presence of obesity and high levels of abdominal fat, blood glucose, cholesterol and triglycerides; low levels of high-density lipoprotein cholesterol and high blood pressure. It is now extremely common in western societies, and findings from the third NHANES Survey 2 estimate that in the US around 47 million Americans may exhibit this syndrome. Although high levels of moderate intensity physical activity and aerobic fitness are inversely associated with MIS, there is still little research to determine the direct effect of physical activity intervention upon reducing MIS risk. One of the few studies that have been carried out 5, showed that after 20 weeks of aerobic exercise, 30.3% of those with MIS were no longer classified as having the syndrome. Therefore, considering the recent government guidelines for the accumulation of 30 minutes of physical activity throughout the day 1, it is of interest to determine whether such an intervention would be a useful strategy for reducing risk of MIS in a group of abdominally obese men, who are known to be at high risk of MIS. Additionally, since those at risk of MIS tend to have a poor blood lipid profile, it is therefore of further interest to determine whether the government physical activity guidelines have an influence upon lipid metabolism in this group. Furthermore, although epidemiological evidence suggests that accumulation of physical activity can reduce mortality and morbidity rates by around 20–30%, there are still relatively few studies to clearly determine whether a single continuous daily bout of physical activity, when compared to accumulative bouts of similar intensity and total volume, are more effective at reducing risk to health. Therefore, by comparing accumulative bouts to a single daily bout of physical activity, this study may further contribute to determining whether accumulative or continuous physical activity should be advocated. The intervention will be carried out over a period of 24 weeks, and once completed the effect of a further 24 weeks detraining will be investigated, where the subjects will be required to revert to pre-intervention lifestyle. The aim of this is to establish the extent of detraining on any changes as a result of the interventions.

References:

A10. Give a brief synopsis/summary of methods and overview of the planned research, including a brief explanation of the theoretical framework which informs it. It should include a brief description of how prospective research participants and concerned communities (not necessarily geographical) from which they are drawn have been consulted over the design and details of the research.

(Where appropriate a flow chart or diagram should be submitted separately. It should be clear exactly what will happen to the research participant, how many times and in what order).

This section **MUST** be completed in language comprehensible to the lay person. Do **NOT** simply reproduce the protocol.
1. Type of study
The study will be a randomised controlled trial. Subjects will be allocated at random (using computer generated sequences) to either a control group (n=52) or accumulative brisk walking (ABW) (n=52) or single daily bout of brisk walking (SBW) (n=52) group.

2. Study subjects

Recruitment – Volunteers will be recruited via an editorial placed in the local papers and through a poster placed within CCCUC. The aim is to successfully recruit into the study 156 subjects on a rolling programme over a period of 10 months, which is considered to be a realistic target.

Inclusion criteria – Abdominally obese men with a waist circumference of 102 cm (~40 inches) and waist hip ratio equal to 1.0, aged between 40 and 65 years.

Screening – volunteers will be screened for their suitability for the study, through a medical and activity lifestyle screening questionnaire, and with their general practitioners approval to participate. Once cleared, subjects will be further screened from their initial various blood samples, for diabetes.

Exclusion criteria – volunteers will be excluded if:
   a) They are symptomatic of cardiovascular disease
   b) They are diabetic
   c) They smoke tobacco
   d) Their waist circumference is <102 cm (~40 inches) or waist hip ratio of < 1.0
   e) Their general practitioner is unable to provide health clearance for them to participate, and
   f) The subject is unable to understand the nature of the study.

3. Variables of interest
At baseline (pre-intervention), post-intervention and during detraining (for the ABW and SBW subject groups only), the variables of interest will include:
- Measures of waist circumference and waist hip ratio
- Body fat percentage (sum of skin folds)
- A fasted venous blood test to determine insulin, fibrinogen, blood lipids (total cholesterol, high density lipoprotein cholesterol, and low density lipoprotein cholesterol) and markers of lipid metabolism (free fatty acids, cholesterol ester transfer protein, lecithin cholesterol transfer protein)
- Systolic, diastolic and mean arterial blood pressure
- Aerobic fitness (graded submaximal treadmill test)

4. Intervention
Subjects will be randomly allocated to either a group of controls or either of the ABW group (brisk walking in bouts of no less than 5 minutes and no more than 15 minutes) or the SBW (brisk walking in one single daily bout of 30 minutes) groups.

Controls will carry out their usual daily lifestyle. Subjects will be asked to make no dietary or other lifestyle changes. The intervention will be over a period of 24 weeks, where, upon completion the subjects from the walking groups will undergo a further 24 weeks of detraining. Variables of interest will therefore be measured pre- and post-intervention and at 4, 12 and 24 post-intervention. The subjects from the walking groups will keep a diary of their daily physical activity.

5. Sample size
To determine the sample size needed to achieve a statistically significant amount of change in all the variables of interest, standard statistical packages were employed. Power calculations were carried out using the mean and standard deviation from previous studies looking at changes in the variables of interest after exercise intervention. In order to avoid any type 1 errors, subject numbers were decided from the variable that required the greatest number of subjects (CETP; mean difference 0.53; 0.55 ml/l). The results showed that in order to ensure a 99% chance of finding significant differences, at an alpha of 0.05, a total sample size of 156 subjects would be required (controls n=52, ABW n=52 and SBW n=52). These values include an estimated 20% subject drop out.

A11. Will any intervention or procedure, which would normally be considered a part of routine care, be withheld from the research participants?

☐ Yes ☐ No
A12. Will the research participants receive any clinical intervention(s) or procedure(s) including taking samples of human biological material over and above that which would normally be considered a part of routine clinical care?

☐ Yes  ☐ No

<table>
<thead>
<tr>
<th>Additional Intervention</th>
<th>Average number per patient</th>
<th>Average time taken (mins/hours/days)</th>
<th>Details of additional intervention or procedure, who will undertake it, and what training they have received.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venepuncture</td>
<td>5</td>
<td>2 minutes</td>
<td>Trained phlebotomist at OFM/H, Margate</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>45 minutes</td>
<td>Trained exercise physiologists at Canterbury Christ Church University College (CCCU) Sports Science Accredited Laboratory</td>
</tr>
</tbody>
</table>

A13. Will the research participant be subject to any non-clinical research-related intervention(s) or procedure(s)?
(These include interviews, non-clinical observations and use of questionnaires.)

☐ Yes  ☐ No

<table>
<thead>
<tr>
<th>Additional Intervention</th>
<th>Average number per patient</th>
<th>Average time taken (mins/hours/days)</th>
<th>Details of additional intervention or procedure, who will undertake it, and what training they have received.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>120+</td>
<td>30 min/day</td>
<td>Subjects are required to brisk walk for 30 minutes on 5 days of the week for 24 weeks. Controls carry out their usual daily lifestyle</td>
</tr>
</tbody>
</table>

A14. Will individual or group interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study (e.g. during interviews/group discussions, or use of screening tests for drugs)?

☐ Yes  ☐ No

The Information Sheet should make it clear under what circumstances action may be taken.

A15. What is the expected total duration of participation in the study for each participant?

For those selected into the walking groups, 24 weeks walking and 24 training (total 48 weeks). Those selected into the control group 24 weeks.

A16. What are the potential adverse effects, risks or hazards for research participants either from giving or withholding medications, devices, involving radiation, or from other interventions (including non-clinical)?

During any physical activity there is a heightened risk of injury or sudden cardiac death. For those without underlying cardiovascular disease, the risk of sudden cardiac death during physical activity and exercise is minimal. Stuart & Ellerst (Stuart RJ & Ellerst MH National Survey of Exercise Stress Testing Facilities. Chest 77:94–97) observed only 5 incidence per 100,000 maximum aerobic fitness test. Since this study proposes to employ only sub-maximal tests, the risk of sudden cardiac death are even lower. This is further reduced when accompanied by physical activity and health screening questionnaires (American College of Sports Medicine 1995 & 1991Guideline for Exercise Testing and Prescription. Philadelphia: Williams & Wilkins, Chapters 5 & 6).
A17. What is the potential for pain, discomfort, distress, inconvenience or changes to lifestyle for research participants?

This study requires the subjects to exercise at a moderate intensity which should be at a level where the subject becomes 'slightly breathless and slightly sweaty'. Subjects will not be required during any testing or intervention to exercise beyond this level. The subject will be required to be committed to the study, and those that are selected into the intervention groups will follow the government guidelines for 30 minutes of physical activity per day on 5 days of the week. Subjects may experience discomfort during when blood is taken, or when wearing the facemask when collecting expired air during the sub-maximal treadmill walking test.

A18. What is the potential for benefit to research participants?

The benefit to the subjects is that they will undergo a comprehensive assessment of their health and physical fitness. The workers are likely to improve their fitness, which will probably be reversed during detraining.

A19. What is the potential for adverse effects, risks or hazards, pain, discomfort, distress, or inconvenience to the researchers themselves? (if any)

Minimal

A20. How will potential participants in the study be (i) identified, (ii) approached and (iii) recruited?

Give details for cases and controls separately if appropriate.

i. Abdominally obese men with a waist circumference of 102 cm (~ 40 inches) and waist hip ratio of no less than 1.0, aged between 40 and 65 years.

ii & iii. Volunteers will be recruited via an editorial placed the local papers and through a poster placed within CCCUC.

Volunteers will be screened for their suitability for the study, through a medical and activity/lifestyle screening questionnaires, and with their general practitioners approval to participate. Once cleared, subjects will be further screened from their initial venous blood samples, for diabetes.

Exclusion criteria – volunteers will be excluded if:

a) They are symptomatic of cardiovascular disease
b) They are diabetic
c) They smoke tobacco
d) Their waist circumference is < 102 cm (~ 40 inches) or waist hip ratio of < 1.0

e) Their general practitioner is unable to provide health clearance for them to participate, and

f) The subject is unable to understand the nature of the study.

A21. Where research participants will be recruited via advertisement, give specific details.

☐ Not Applicable

Volunteer will be recruited via an editorial placed in the local papers and through a poster placed within CCCUC

If applicable, enclose a copy of the advertisement/radio script/website video for television (with a version number and date).

A22. What are the principal inclusion criteria? (Provide justification)

Inclusion criteria: Abdominally obese men with a waist circumference of 102 cm (~ 40 inches) and waist hip ratio of no less than 1.0, aged between 40 and 65 years.
A23. What are the principal exclusion criteria? (Please justify)

Exclusion criteria – volunteers will be excluded if:

a) They are symptomatic of cardiovascular disease
b) They are diabetic
c) They smoke tobacco
d) Their waist circumference is < 102 cm (~ 40 inches) or waist hip ratio of < 1.0.
e) Their general practitioner is unable to provide health clearance for them to participate, and
f) The subject is unable to understand the nature of the study.

A24. Will the participants be from any of the following groups? (Tick as appropriate)

☐ Children under 16
☐ Adults with learning disabilities
☐ Adults who are unconscious or very severely ill
☐ Adults who have a terminal illness
☐ Adults in emergency situations
☐ Adults with mental illness (particularly if detained under Mental Health Legislation)
☐ Adults suffering from dementia
☐ Prisoners
☐ Young Offenders
☐ Adults in Scotland who are unable to consent for themselves
☐ Healthy Volunteers
☐ Those who could be considered to have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students
☐ Other vulnerable groups

Justify their inclusion.

The subjects of this study will be asymptomatic of cardiovascular disease, and diabetes, yet have an abdominal circumference of at least 40 inches, hence, their inclusion criteria does mean that they are at risk of these diseases. Therefore, although the subjects are termed healthy, this is obviously debatable. However, these subjects are the target population for this study i.e. those at most risk of metabolic syndrome.

A25. Will any research participants be recruited who are involved in existing research or have recently been involved in any research prior to recruitment?

☐ Yes  ☐ No  ☐ Not Known

If Yes, give details and justify their inclusion. If Not Known, what steps will you take to find out?

A26. Will informed consent be obtained from the research participants?

☐ Yes  ☐ No

If Yes, give details of who will take consent and how it will be done. Give details of any particular steps to provide information (in addition to a written information sheet) e.g. videos, interactive material.

If participants are to be recruited from any of the potentially vulnerable groups listed in A24, give details of extra steps taken to assure their protection. Describe the arrangements to be made for obtaining consent from a legal representative.

If consent is not to be obtained, please explain why not.

Prior to any study measures being taken, and before undertaking the exercise intervention, all subjects will be required to
<table>
<thead>
<tr>
<th>Date: 03/10/2004</th>
<th>Reference: 04/Q1803/82</th>
<th>Online Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>complete an informed consent form (see attached). The informed consent form will be sent to each subject by the researchers from CCCUIC, along with an information sheet (see attached).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Copies of the written information and all other explanatory material should accompany this application.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**A27. Will a signed record of consent be obtained?**
- [ ] Yes
- [ ] No

If Yes, attach a copy of the information sheet to be used, with a version number and date.

**A28. How long will the participant have to decide whether to take part in the research?**
After pre-screening and acceptance onto the study, each subject will have two weeks in which to decide whether they wish to participate in the study.

**A29. What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g., translation, use of interpreters etc.)**
There are not the resources to be able to accommodate those who do not adequately understand, for whatever reason, the requirements of the study. Therefore, if a volunteer is unable, for whatever reason, is unable to understand the requirements of the study they shall not be permitted to take part.

**A30. What arrangements are in place to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?**
If any of the measures taken reveal any course for concern with regard to the subjects health, their GP will be informed immediately.

**A31. Does this study have or require approval of the Patient Information Advisory Group (PIAG) or other bodies with a similar remit? (See the guidance notes)**
- [ ] Yes
- [ ] No

**A32a. Will the research participants’ General Practitioner be informed that they are taking part in the study?**
- [ ] Yes
- [ ] No

If Yes, enclose a copy of the information sheet/letter for the GP with a version number and date.

**A32b. Will permission be sought from the research participants to inform their GP before this is done?**
- [ ] Yes
- [ ] No

If No to either question, explain why not.

It should be made clear in the patient information sheet if the research participants’ GP will be informed.
A33. Will individual research participants receive any payments for taking part in this research?

☐ Yes  ☐ No

A34. Will individual research participants receive reimbursement of expenses or any other incentives or benefits for taking part in this research?

☐ Yes  ☐ No

A35. What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants for negligent harm?

Currently an honorary NHS research contract is being drawn up between the researchers at CCCUC. Once this is established, indemnity and compensatory insurance will be in place.

Please forward copies of the relevant documents.

A36. What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants for non-negligent harm?

See A35.

Please forward copies of the relevant documents.

A37. How is it intended the results of the study will be reported and disseminated? (Tick as appropriate)

☐ Peer reviewed scientific journals
☐ Internal report
☐ Conference presentation
☐ Other publication
☐ Submission to regulatory authorities
☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
☐ Written feedback to research participants
☐ Presentation to participants or relevant community groups
☐ Other/none e.g. Cochrane Review, University Library

A38. How will the results of research be made available to research participants and communities from which they are drawn?

Each individual subject will, at the end of the study, be given their own results. Each subject will also be sent an abstract of the overall results of the study, written in layman's terms.
A30. Will the research involve any of the following activities at any stage (including identification of potential research participants)? (Tick as appropriate)

- Examination of medical records by those outside the NHS, or within the NHS by those who would not normally have access
- Electronic transfer by magnetic or optical media, e-mail or computer networks
- Sharing of data with other organisations
- Export of data outside the European Union
- Use of personal addresses, postcodes, fax numbers, e-mails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
- Storage of personal data on any of the following:
  - Manual files including X-rays
  - NHS computers
  - Home or other personal computers
  - University computers
  - Private company computers
  - Laptop computers

Further details:
Data will only be shared between individuals within the stated organisations (OCCUUC & NHS) who are involved in the study. All subject data will be kept under secure conditions. Hard copy material will be kept in a locked filing cabinet, and electronic data on a password protected secure site.

A40. What measures have been put in place to ensure confidentiality of personal data? Give details of whether any encryption or other anonymisation procedures have been used and at what stage:

All hard copies of any personal data of the subjects will be kept in a locked filing cabinet. Any electronic material will be kept in a password protected site. Only those with authorised access will be allowed to view this information.

Subjects will, upon acceptance onto the study, be issued with a subject number. This will be used in data analysis to identify the subjects and their personal data.

A41. Where will the analysis of the data from the study take place and by whom will it be undertaken?

The data analysis will be carried out by the researchers at OCCUUC.

A42. Who will have control of and act as the custodian for the data generated by the study?

The chief investigator (Dr K Woolf-May) at OCCUUC.

A43. Who will have access to the data generated by the study?

Researchers from OCCUUC and the NHS.

A44. For how long will data from the study be stored?

10 Years. 0 Months

Give details of where they will be stored, who will have access and the custodial arrangements for the data:
A45. How has the scientific quality of the research been assessed? (Tick as appropriate)

- Independent external review
- Review within a company
- Review within a multi-centre research group
- Internal review (e.g. involving colleagues, academic supervisor)
- None external to the investigator
- Other, e.g. methodological guidelines

If you are not in possession of any referees or other scientific critique reports relevant to your proposed study, justify and describe the review process and outcome. If review has been undertaken but not seen by the researcher, give the details of the body which has undertaken the review.

A copy of any referees’ comments or other scientific critique reports relevant to the proposed research must be enclosed with the application form.

A46. Has similar research on this topic been done before?

- Yes  ☑ No

If Yes, why should it be repeated?
Similar studies have been carried out, looking into the effect of accumulative bouts vs continuous bouts of physical activity, of similar intensity and total weekly duration. However, these studies have not looked at this with regard to Metabolic Syndrome or lipid metabolism. Since Metabolic Syndrome is becoming increasingly prevalent and blood lipid levels, in response to physical activity, are not sufficient to explain lipid metabolism during physical activity, this study is an important step forward in this area.

A47. Have all existing sources of evidence, especially systematic reviews, been fully considered?

- Yes  ☑ No

If Yes, please give details of search strategy used. If No, explain why not.
All available and relevant data bases, such as, Ovid and Medline have been reviewed.

A48. What is the primary outcome measure for the study?
Risk factors for Metabolic Syndrome (waist circumference, body fat percentage, blood insulin and fibrinogen levels, blood lipids and blood pressure) and aerobic fitness, free fatty acids, cholesterol ester transfer protein and lecithin cholesterol transferase.

A49. What are the secondary outcome measures? (If any)

A50. How many participants will be recruited? How many of these participants will be in a control group?

156 male subjects, 52 will be randomly selected into a control group.
A51. Has the size of the study been informed by a formal statistical power calculation?

☐ Yes  ☐ No

If Yes, indicate the basis upon which this was done, giving sufficient information to allow the replication of the calculation:
To determine the sample size needed to achieve a statistically significant amount of change in all the variables of interest, Clinistat statistical package was employed. Power calculations were carried out using the mean and standard deviation from previous studies looking at changes in the variables of interest after exercise intervention. In order to avoid any type I errors, subject numbers were derived from the variable that required the greatest number of subjects (OETP; mean difference 0.35±0.55 ml l−1). The results showed that in order to ensure a 90% chance of finding significant differences, at an alpha of 0.05, a total sample size of 156 subjects would be required (controls n=52, ABW n=52 and SBW n=52). These values include an estimated 20% subject drop out.

A52. Has a statistician given an opinion about the statistical aspects of the research?

☐ Yes  ☐ No

If Yes, give the name and contact details:
Dr Ray Godfrey, CCCUC.

If Yes, give a brief summary of advice offered and attach a copy of comments if available:
Dr Godfrey reviewed the statistics and made only minor changes to the statistical analysis, which was related to the order in which the statistical analysis was to be presented. This was incorporated into the proposal.

If Yes, include a copy of comments. If the comments are not available then please provide a summary of the opinion.

A53. Describe the statistical methods and/or other relevant methodological approaches (e.g. for qualitative research) to be used in the analysis of the results. Give details of the methods of randomisation process to be used if applicable:

Statistical analysis using the SPSS statistical package version 11 will be employed.
The study will be a randomised controlled trial. Subjects will be allocated at random (using computer generated sequences) to either a control group (n=50) or cumulative brisk walking (ABW) (n=50) or single daily bout of brisk walking (SBW) (n=50) group.

Multiple regressions will be used to define which factors best explain risk of Metabolic Syndrome. One way analysis of variance (ANOVA) will be also be employed to i) determine any baseline differences between the groups and ii) determine differences in the amount of change in the variables of interest between the groups. To establish whether baseline measures have any influence on the amount of change between the groups, analysis of covariance will be utilised using the baseline measures as a covariate.

A54. Where will the research take place? (Tick as appropriate)

☐ UK
☐ Other states in European Union
☐ Other countries in European Economic Area
☐ Other

Give details:

A55. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK, the European Union or the European Economic Area?
A56. In how many and what type of host organisations (NHS or other) in the UK is it intended the proposed study will take place?

Indicate the type of organisation by ticking the box and give approximate numbers if known:

<table>
<thead>
<tr>
<th>Number of organisations</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Acute teaching NHS Trusts</td>
</tr>
<tr>
<td>☒ Acute NHS Trusts 1</td>
</tr>
<tr>
<td>☐ NHS Community and/or Primary Care Trusts</td>
</tr>
<tr>
<td>☐ NHS Trusts providing Mental Healthcare</td>
</tr>
<tr>
<td>☐ NHS Care Trusts</td>
</tr>
<tr>
<td>☐ Social Care Organisations</td>
</tr>
<tr>
<td>☐ Prisons</td>
</tr>
<tr>
<td>☐ Independent hospitals 1</td>
</tr>
<tr>
<td>☐ Educational establishments</td>
</tr>
<tr>
<td>☐ Independent research units</td>
</tr>
<tr>
<td>☐ Other (give details)</td>
</tr>
</tbody>
</table>

Other:

A57. What arrangements are in place for monitoring and auditing the conduct of the research?

Regular monthly meetings will be held between the researchers at CCCUC to determine the progress of the study. The study will also be conducted under the clinical governance framework of the acute NHS trust.

Will a data monitoring committee be convened?

☐ Yes  ☐ No

If Yes, details of membership of the data monitoring committee (DMC), its standard operating procedures and summaries of reports of interim analysis to the DMC must be forwarded to the NHS Research Ethics Committee which gives a favourable opinion of the study.

What are the criteria for electively stopping the trial or other research prematurely?

Subject injury or ill health.

A58. Has funding for research been secured?

☐ Yes  ☐ No
If Yes, give details of funding organisation(s) and amount secured and duration:

<table>
<thead>
<tr>
<th>Organisation:</th>
<th>NHS Executive pending ethical clearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>Post Code:</td>
<td></td>
</tr>
<tr>
<td>UK contact:</td>
<td></td>
</tr>
<tr>
<td>Telephone:</td>
<td></td>
</tr>
<tr>
<td>E-mail:</td>
<td><a href="mailto:lumbert@liverpool.ac.uk">lumbert@liverpool.ac.uk</a></td>
</tr>
<tr>
<td>Amount (£):</td>
<td>30360.7</td>
</tr>
<tr>
<td>Duration: 24 Months</td>
<td></td>
</tr>
</tbody>
</table>

A59. Has the funder of the research agreed to act as sponsor as set out in the Research Governance Framework?

- [ ] Yes
- [ ] No
- [ ] Not Known

Has the employer of the Chief Investigator agreed to act as sponsor of the research?

- [ ] Yes
- [ ] No
- [ ] Not Known

Give details of the organisation which will act as the sponsor of the research:

| UK contact:  |                                        |
| Title:       |                                        |
| Firstname/Initials: |                                     |
| Surname:     |                                        |
| Organisation:|                                        |
| Address:     |                                        |
| Telephone:   |                                        |
| Fax:         |                                        |
| E-mail:      |                                        |

A copy of documentation indicating that the organisation has accepted the role of sponsor should be enclosed if the sponsor is not the main funder, the Chief Investigator’s employer, or an NHS body hosting the research.

A60. Has any responsibility for the research been delegated to a subcontractor?

- [ ] Yes
- [ ] No

A61. Will individual researchers receive any personal payment over and above normal salary for undertaking this research?

- [ ] Yes
- [ ] No

If Yes, indicate how much and on what basis this has been decided:

For the chief investigator 75 hours of additional work have been allocated, and a total of 3,620.70 (inclusive of national insurance and superannuation) have been calculated and accepted by the funders.

A62. Will individual researchers receive any other benefits or incentives for taking part in this research?
A63. Will the host organisation or the researcher’s department(s) or institution(s) receive any payment or benefits in excess of the costs of undertaking the research?

- [ ] Yes
- [ ] No

A64. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share-holding, personal relationship etc.) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

- [ ] Yes
- [ ] No

A65. Other relevant reference numbers if known (give details and version numbers as appropriate):

| Application/organisation’s own reference number, e.g. R&D (if available): |
| Sponsors/protoco number: |
| Funders reference number: |
| International Standard Randomised Controlled Trial Number (ISRCTN): |
| European Clinical Trials Database (EudraCT) number: |
| Project website: |

A66. Other key investigators/collaborators (all grant co-applicants should be listed)

| Title: | Mr |
| Forename/Initials: | Edward |
| Surname: | Kearney |
| Post: | Consultant Clinical Scientist |
| Qualifications: | MSc, MCB, FRCPath |
| Organisation: | EK Hospital NHS Trust |
| Address: | QEOMH, Margate |
| Telephone: | 01843 234424 |
| Fax: | |
| Postcode: | CT9 4AN |
| E-mail: | |

| Title: | Dr |
| Forename/Initials: | DW |
| Surname: | Jose |
| Post: | Clinical Scientist |
| Qualifications: | MSc, PhD |
| Organisation: | EK Hospital NHS Trust |
| Address: | Haemophilia Centre, Kent and Canterbury |
| Telephone: | 01227 778 077 |
| Fax: | |
| Postcode: | CT1 3NG |
| E-mail: | |

| Title: | Dr |
### A67. If the research involves a specific intervention, (e.g. a drug, medical device, dietary manipulation, lifestyle change etc.), what arrangements are being made for continued provision of this for the participant (if appropriate) once the research has finished?

- [ ] Not Applicable

The intervention involves brisk walking for 30 minutes a day, on 5 days of the week. This is in line with the government guidelines of levels of physical activity. Once the study is completed, the researchers will advocate the benefits of regular physical activity.

### PART A: Summary of Ethical Issues

#### A68. What do you consider to be the main ethical issues or problems which may arise with the proposed study and what steps will be taken to address these?

The main ethical issues regarding this study are related to 'safety' of the fitness assessment and walking intervention, the taking of blood, divulgence of information and the collection, storage and management of any subject data.

**Physical activity**

Any physical activity is accompanied with a heightened risk of injury or sudden cardiac death. However, in individuals that have been appropriately screened for cardiovascular disease and any potential for injury, this risk is minimal. Additionally, when the physical activity is below maximal (sub-maximal) in intensity, this risk is further reduced. During the fitness test (treadmill walking) each subject will be assessed and monitored by two staff, and in the event of any signs of distress or undue discomfort from the subject, the test will be terminated. Participants can at any point stop the test at will.

The laboratory is a British Association of Sport Science accredited and laboratory staff are accordingly trained in resuscitation and the use of a defibrillator. The defibrillator is regularly checked and placed in close proximity to the site of the testing.

The walking intervention incurs minimal risk(see above).

**Blood**

The taking of blood is invasive, but will undertaken by trained individuals using standard techniques. The blood collected will only be taken and used for the purposes stated, and with the informed consent of the subject.

### Dislosure of Information

Throughout the study measures of the subject’s blood, heart, aerobic fitness and blood pressure will be taken. If any of these measures reveal a cause for concern, the subject’s GP will be informed immediately.

Collecting, storage and management of subject data

The handling of subject data will be in accordance with the 1998 Data Protection Act.

### A69. Do you need to add further information about certain questions in Part A?

This question is not applicable for the online version of the form.
<table>
<thead>
<tr>
<th><strong>PART B: Section 4 – Use of Existing Stored Samples</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. What samples and how many will be included in the study?</strong></td>
</tr>
<tr>
<td>n/a</td>
</tr>
<tr>
<td><strong>2. What tests/techniques will be carried out on the samples?</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>3. How will samples be labelled/identified?</strong></td>
</tr>
<tr>
<td><em>Indicate if samples can be considered to be “identified”, “coded”, “de-identified”, “anonymised” or “anonymous”, and at what stage identities are removed. (See the guidance notes for definitions)</em></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>4. Has specific consent been obtained previously to use stored samples for this purpose?</strong></td>
</tr>
<tr>
<td>☑ Yes ☐ No</td>
</tr>
<tr>
<td><strong>5. Does the research involve the analysis or use of genetic material from human biological materials?</strong></td>
</tr>
<tr>
<td>☑ Yes ☐ No</td>
</tr>
<tr>
<td><strong>6. Would it be possible to link the results of any genetic analysis back to the individuals?</strong></td>
</tr>
<tr>
<td>☑ Yes ☐ No</td>
</tr>
<tr>
<td>If Yes, give details of what support or counselling service will be available to individuals:</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>7. Is it intended to link the results of any genetic analysis back to individuals?</strong></td>
</tr>
<tr>
<td>☑ Yes ☐ No</td>
</tr>
<tr>
<td><strong>8. If the samples are from an established tissue bank, give the name and location of the tissue bank, the organisation responsible for it and the name of its manager</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>9. Signature of the tissue bank manager.</strong></td>
</tr>
<tr>
<td>I confirm that I have read this research proposal. I agree to the use of samples from this tissue bank for the purposes stated in this application.</td>
</tr>
<tr>
<td>Signature: ........................................</td>
</tr>
<tr>
<td>Date: (dd/mm/yyyy)</td>
</tr>
<tr>
<td>Print Name:</td>
</tr>
</tbody>
</table>
**PART B: Section 5 – Use of Newly Obtained Human Biological Materials**

1. What samples will be collected and/or analysed and by whom will they be collected?

   A trained phlebotomist from QE0MH will collect blood samples for analysis of: Total cholesterol, triglyceride, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, lecithin cholesterol transfer protein, lipoprotein lipase, lecithing cholesterol transferase.

   A trained laboratory technician/exercise scientist from CCGUC will take finger prick samples of blood for the analysis of blood lactate.

2. Are the samples taken solely for research purposes (or are they a by-product of those taken primarily for clinical purposes, i.e. surplus to clinical requirements)?

   Yes

3. How will samples be labelled/identified?

   Indicate if samples can be considered to be "identified", "coded", "de-identified", "anonymised" or "anonymous" and at what stage identifiers are removed. (See the guidelines notes for definitions)

   The phlebotomist at QE0MH and laboratory technician/exercise scientist from CCGUC, for identification purposes, will have to know the name of the subject. Thereafter the blood samples will be coded with the subjects study identification number. All analysis will be carried out using these identification numbers.

4. Give details of where the sample(s) will be stored, for how long, who will have access and the custodial arrangements.

   The venous blood samples will be stored at QE0MH for the length of the study (6 years). The custodian of which will be Mr Edward Kearney. Other NHS professionals and academic staff will have access to these samples.

   The finger prick blood samples will only be stored at CCGUC for a maximum of 3 days, during this period the custodian of these samples will be Dr Kate Woodall-May. Other Sport Science Laboratory staff will have access to them.

5. Will the research participant retain any rights to the sample(s)?

   ○ Yes  ○ No

6. Is it known how the samples will be used in the future?

   ○ Yes  ○ No

7. Does the research involve the analysis or use of genetic material from human biological materials?

   ○ Yes  ○ No

8. Would it be possible to link the results of any genetic analysis back to individuals?

   ○ Yes  ○ No

9. Is it intended to link the results of any genetic analysis back to individuals?

   ○ Yes  ○ No
PART B: Section 7 – Declaration

– The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

– I undertake to abide by the ethical principals underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

– If the research is approved I undertake to adhere without unagreed deviation to the study protocol, the terms of the full application of which the main REC has given a favourable and any conditions set out by the main REC in giving its favourable opinion.

– I undertake to inform the main REC of any changes in the protocol, and to submit annual reports setting out the progress of the research.

– I am aware of my responsibility to keep up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer.

– I understand that research records/data may be subject to inspection for audit purposes if required in future.

– I understand that personal data about me as a researcher in this application will be held by the relevant RECs and their operational managers and that this will be managed according to the principles established in the Data Protection Act.

Signature: ........................................
Date: 31/10/2004 (dd/mm/yyyy)
Print Name: Dr Kate Wooll–May

1. Do you need to add further information about certain questions in Part B?

This question is not applicable for the online version of the REC form.

ENSURE THAT YOU COMPLETE AND SIGN THE FORM, AND ENCLOSE ANY RELEVANT ADDITIONAL DOCUMENTS.
**Site-Specific Information Form**

Does this application relate to a research site for which the NIHR (or HPSG in Northern Ireland) is responsible or to a non-NHS research site?

- NHS site
- Non-NHS site

This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.

In which country is the research site located?

- England
- Wales
- Scotland
- Northern Ireland

The data in this box is populated from Part A:

<table>
<thead>
<tr>
<th>Short title and version number:</th>
<th>The effect of 30 minutes of accumulative brisk walking on five days of</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of NI-S Research Ethics Committee to which application for ethical review is being made:</td>
<td>East Kent Research Ethics Committee</td>
</tr>
<tr>
<td>Project reference number from above REC:</td>
<td>04/Q1003/02</td>
</tr>
</tbody>
</table>

Name of NI-S REC responsible for SSA:

SSA reference (for REC office use only)

Name of NI-S care organisation to which application is being made for permission to conduct the research:

NHS organisation reference (for R&D office use only):

1. **Title of the research** (populated from A1)

   - **Full title:** The effect of 30 minutes of accumulative brisk walking on five days of the week upon metabolic syndrome risk factors and lipid metabolism
   - **Key words:** Metabolic Syndrome, brisk walking, lipid metabolism, accumulative physical activity
2. **Name of Chief Investigator (populated from A2)**
   - Title:
   - Forename/Initials:
   - Surname:

3. **Name of organisation acting as lead sponsor for the study (populated from AS9)**

4. **Research reference numbers if known (populated from A65)**
   - Applicant’s organisation’s own reference number, e.g. R&D:
   - Sponsor’s protocol number:
   - Funders reference number:
   - International Standard Randomised Controlled Trial Number (ISRCTN):
   - European Clinical Trials Database (EudraCT) Number:
   - Project website:

5. **Give the name of the trial site**
   - CCCUC, QEQMH Margate. The walking intervention will be performed outside of these premises.
   - If trial procedures are to be conducted at any other location, specify the location, department and describe the activity that will take place.
   - SE Kent, CCCUC & QEQMH Margate.

6. **Give the name of the NHS site within or through which the research will take place under the responsibility of the PI or Local Collaborator. Please give the name only. Further details of locations should be given in question 8. The name of the site is normally the name of the relevant NHS organisation. Each NHS general or dental practice is a separate site unless a formal consortium network is in place.**
   - CCCUC, QEQMH Margate. The walking intervention will be performed outside of these premises.
   - Is this a primary care site?
     - ☐ Yes  ☐ No
   - If Yes, give the name of the primary care organisation responsible for the site below:

7. **Was this site listed as a planned trial site in the original applications to the main Research Ethics Committee and the MHRA?**
   - ☐ Yes  ☐ No
   - If No, the sponsor should also submit a Notice of Amendment form to the main REC, copied to the MHRA for information.

8. **Specify all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.**
   - List of locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific locations will be required these should also be listed for each location.
   - Name the main location/department first. Include details of any contacts at other NHS organisations where potential participants may be seen or referred for inclusion in the research at this site. Give details of any research procedures to be carried out off site, for example in participants’ homes.
9. Give the name of the Site Management Organisation. This is defined as the company or other legal entity responsible for
the management of the research site.

10. Give details of the person with overall responsibility for the management and monitoring of the research at this
site.

<table>
<thead>
<tr>
<th>Title:</th>
<th>Forename/Initials:</th>
<th>Surname:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work Address:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Telephone:</td>
<td>Fax:</td>
<td></td>
</tr>
<tr>
<td>Postcode:</td>
<td>Mobile:</td>
<td></td>
</tr>
<tr>
<td>E-mail:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11. Who is the local Principal Investigator (PI) for this trial at this site?

<table>
<thead>
<tr>
<th>Title:</th>
<th>Forename/Initials:</th>
<th>Surname:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qualifications:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organisation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work Address:</td>
<td></td>
<td></td>
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<tr>
<td>Telephone:</td>
<td>Fax:</td>
<td></td>
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<tr>
<td>Postcode:</td>
<td>Mobile:</td>
<td></td>
</tr>
<tr>
<td>E-mail:</td>
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<td></td>
</tr>
</tbody>
</table>

Please provide a copy of the CV for the PI.

12. Who is the Principal Investigator or Local Collaborator for this research at this site?

<table>
<thead>
<tr>
<th>Title:</th>
<th>Forename/Initials:</th>
<th>Surname:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qualifications:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organisation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work Address:</td>
<td></td>
<td></td>
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<tr>
<td>Telephone:</td>
<td>Fax:</td>
<td></td>
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<tr>
<td>Postcode:</td>
<td>Mobile:</td>
<td></td>
</tr>
<tr>
<td>E-mail:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
13. Give details of the research team responsible to the Principal Investigator at this site:

14. Give details of all other members of the research team at this site, including academic supervisors and all people who will interact with research participants, their organs, tissue or data in a way that has a direct bearing on the quality of care.

15. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc.) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

   Yes  No

   If yes, give further details:

16. What is the proposed local start and end date for the research at this site?

   Start date:  (dd/mm/yyyy)
   Duration (Months):
   End date:   (dd/mm/yyyy)

17. Summary of the research (populated from A10.1)

   1. Type of study
   The study will be a randomised controlled trial. Subjects will be allocated at random (using computer generated sequences) to either a control group (n=52) or accumulative brisk walking (ABW) (n=52) or single daily bout of brisk walking (SBW) (n=52) group.

   2. Study subjects
   Recruitment – Volunteers will be recruited via an editorial placement in the local papers and through a poster placed within CCCULC. The aim is to successfully recruit into the study 166 subjects on a rolling programme over a period of 10 months, which is considered to be a realistic target.

   Inclusion criteria – Abdominally obese men with a waist circumference of 102 cm (~ 40 inches) and waist hip ratio equal to 1.0, aged between 40 and 65 years.

   Screening – volunteers will be screened for their suitability for the study, through a medical and activity/lifestyle screening questionnaires, and with their general practitioners approval to participate. Once cleared, subjects will be further screened from their initial venous blood samples, for diabases.

   Exclusion criteria – volunteers will be excluded if:
   a) They are symptomatic of cardiovascular disease
   b) They are diabetic
c) They smoke tobacco

d) Their waist circumference is <102 cm (~40 inches) or waist hip ratio of < 1.0.

e) Their general practitioner is unable to provide health clearance for them to participate, and

f) The subject is unable to understand the nature of the study.

3. Variables of interest

At baseline (pre-intervention), post-intervention and during detraining (for the ABW and SBW subject groups only), the variables of interest will include:

- Measures of waist circumference and waist hip ratio
- Body fat percentage (sum of skin folds)
- A fasting venous blood test to determine insulin, fibrinogen, blood lipids (total cholesterol, triglyceride, high-density lipoprotein cholesterol and low-density lipoprotein cholesterol) and markers of lipid metabolism (free fatty acids, cholesterol ester transfer protein, lecithin cholesterol ester transfer protein)
- Systolic, diastolic and mean arterial blood pressure
- Aerobic fitness (graded submaximal treadmill test)

4. Intervention

Subjects will be randomly allocated to either a group of controls or either of the ABW group (brisk walking in bouts of no less than 5 minutes and no more than 15 minutes) or the SBW (brisk walking in one single daily bout of 30 minutes) groups. Controls will carry out their usual daily lifestyle. Subjects will be asked to make no dietary or other lifestyle changes. The intervention will be over a period of 24 weeks, where, upon completion the subjects from the walking groups will undergo a further 24 weeks of detraining. Variables of interest will therefore be measured pre- and post-intervention and at 4, 12 and 24 post-intervention. The subjects from the walking groups will keep a diary of their daily physical activity.

5. Sample size

To determine the sample size needed to achieve a statistically significant amount of change in all the variables of interest, Clinical trial statistical package was employed. Power calculations were carried out using the mean and standard deviation from previous studies looking at changes in the variables of interest after exercise intervention. In order to avoid any type I errors, subject numbers were decided from the variable that required the greatest number of subjects (CETP; mean difference 0.35±0.55 ml/l/l). The results showed that in order to ensure a 90% chance of finding significant differences, at an alpha of 0.05, a total sample size of 156 subjects would be required (controls n=52, ABW n=52 and SBW n=52). These values include an estimated 25% subject drop out.

### 18. Details of clinical interventions (populated from A12 where enabled)

<table>
<thead>
<tr>
<th>Additional Intervention</th>
<th>Average number per participant</th>
<th>Average time taken</th>
<th>Details of additional intervention or procedure, who will undertake it, and what training they have received.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine Care</td>
<td>Research</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venepuncture</td>
<td>5</td>
<td>2 minutes</td>
<td>Trained phlebotomist at QEOMH, Margate</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>45 minutes</td>
<td>Trained exercise physiologists at Canterbury Christ Church University College (CCCUO) Sports Science Accredited Laboratory</td>
</tr>
</tbody>
</table>

### 19. Details of non-clinical interventions (populated from A13 where enabled)

<table>
<thead>
<tr>
<th>Additional Intervention</th>
<th>Average number per participant</th>
<th>Anticipated average time taken</th>
<th>Details of additional intervention or procedure, who will undertake it, and what training they have received.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>120+</td>
<td>30 min/day</td>
<td>Subjects are required to brisk walk for 30 minutes on 5 days of the week for 24 week. Controls carry out their usual</td>
</tr>
</tbody>
</table>

265
20. Will any aspects of the research at this site be conducted in a different way to that described in Parts A and B or the study protocol?  
☐ Yes  ☐ No  
If Yes, explain and give reasons.

21. How many research participants/samples is it expected will be recruited/obtained from this site?

22. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study?

23. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?  
The appointed PhD student will be responsible for collecting the signed informed consent from the volunteers. This will be done prior to volunteers acceptance onto the study. This procedure will be overseen by the chief investigator, who has conducted numerous NHS ethically approved research studies.

24. What local arrangements will be made to seek consent from a legal representative on behalf of adults unable to consent for themselves?

26. What is the procedure and contact point for any complaints from potential or actual participants whether before, during or after the study?

27. Is there a contact point where potential participants can seek independent advice about participating in the study?

28. Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. This must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).  
If you consider that changes should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of this study (see 26), give details below. A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.
29. What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g. translation, use of interpreters etc.) (Populated from A29)

There are not the resources to be able to accommodate those who do not adequately understand, for what ever reason, the requirements of the study. Therefore, if a volunteer is unable, for what ever reason, is unable to understand the requirements of the study they shall not be permitted to take part.

What local arrangements have been made to meet these requirements (where applicable)? There are not the resources to accommodate any subject who is unable, for what ever reason, to understand the requirements of the study. Therefore, individuals who, for what ever reason, are unable to understand the requirements of the study will not be permitted to participate.

30. What arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?

Each volunteer’s GP will be informed to their patient’s intention to partake in the study. If acknowledgement from the volunteers GP of this desire is not received by the researchers, or the volunteer's GP considers the volunteer’s participation to be detrimental to the volunteer’s health, then the volunteer will not be accepted into the study.

31. What special measures (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?

In the case of Phase 1 trials in healthy volunteers, confirm that the unit’s normal SOPs will be followed. Comment on any particular measures that may arise from this trial and outline any additional emergency measures.

In our experience the Ph.D student and the Chief Investigator will have sufficient resources to administer and conduct the research over the time permitted. Any additional work for those to the Hospital has been adequately covered in terms of finance, time and resources.

32. What measures will be in place to prevent over-volunteering?

33. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?

In our experience the Ph.D student and the Chief Investigator will have sufficient resources to administer and conduct the research over the time permitted. Any additional work for those to the Hospital has been adequately covered in terms of finance, time and resources.

34. Give details of the arrangements for the management and monitoring of the research at this site.

In the case of Phase 1 trials in healthy volunteers, confirm that the unit’s normal SOPs will be followed. Comment on any particular measures in place for this trial.

35. What are the arrangements for the supervision of the conduct of the research at this site? Give name and contact details of any supervisor not already listed in the application.
36. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the Principal Investigator, the site management organisation and other members of the research team arising from harm to participants in the conduct of the research at this site?

Please enclose a copy of all relevant documents

<table>
<thead>
<tr>
<th></th>
<th>R&amp;D Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>37. Will any external funding be provided for the research at this site?</td>
<td></td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
</tbody>
</table>

If Yes, indicate the source and details of the funding:

<table>
<thead>
<tr>
<th></th>
<th>R&amp;D Only</th>
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<tbody>
<tr>
<td>38. Which organisation will receive and manage this funding?</td>
<td></td>
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</tbody>
</table>

<table>
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<tr>
<th></th>
<th>R&amp;D Only</th>
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<tbody>
<tr>
<td>39. Authorisations required prior to R&amp;D approval</td>
<td></td>
</tr>
</tbody>
</table>

This section deals with authorisations by managers within the NHS organisation. It should be signed in accordance with the guidance provided by the NHS organisation. This may include authorisation by line managers, service managers, support department managers, pharmacy, data protection officers or finance managers, depending on the nature of the research. Managers completing this section should confirm in the text what the authorisation means, in accordance with the guidance provided by the NHS organisation. This section may also be used by university employees or research staff to provide authorisation to NHS organisations, in accordance with guidance from the university.
Declarations

Declaration by Principal Investigator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association’s Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. I undertake to comply with the Medicines for Human Use (Clinical Trials) Regulations 2004 in the conduct of this trial.
4. If the research is approved, I undertake to adhere to the study protocol, the terms of the trial application, and the terms of the main REC process for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
5. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
6. I understand and agree that study files, records and data may be subject to inspection by the main REC or the SSA REC for audit purposes.
7. I understand that personal data about me as a researcher will be held by the relevant RECs and their operational managers, and that this will be managed according to the principles established in the Data Protection Act 1998.
8. I understand that the information contained in this application, any supporting documentation and all correspondence with Research Ethics Committees or their operational managers relating to the application:
   * Will be held by the REC system until at least 3 years after the end of the study.
   * May be disclosed to the operational managers or the appointing body for the REC in order to check that the application has been processed correctly and to ensure that the application is completed.
   * May be seen by auditors appointed by the National Research Ethics Service to undertake accreditation of the REC.
   * Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made in accordance with the Acts except where statutory exemptions apply.

Signature of Principal Investigator: ..........................................................
Print Name: Dr Kate Woolf-May
Date: 01/10/2004

Declaration on behalf of Site Management Organisation

I confirm that:

* The Principal Investigator has a contract with the SMO to conduct this research.
* All insurance and indemnity arrangements described above will be in place before the study starts at the site.
* The employer’s procedures for compliance with the Ionising Radiation (Medical Exposures) Regulations 2000 will be followed in the conduct of the study.
* The arrangements described above for management and monitoring of the research will be implemented.

Signature: ..........................................................
Print Name: ..........................................................
Date: ..........................................................
Declaration by Principal Investigator or Local Collaborator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation of any amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.
8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.
9. I undertake to comply with any interim and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.
10. I undertake to maintain a project file for the research in accordance with the NHS organisation’s policy.
11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handing of adverse events.
12. I understand that information relating to this research, and about me as a researcher, will be held by the R&D office and may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
13. I understand that information relating to this research, and about me as a researcher, will be held by ECs undertaking site-specific assessment and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
14. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and the REC system relating to the application will be subject to the provisions of the Freedom of Information Acts and may be disclosed to requests made under the Acts except where statutory exemptions apply.
15. I understand that information relating to this research (including my contact details) may be publicly available through the National Research Register.

Signature of Principal Investigator or Local Collaborator: .........................................................

Print Name: Dr Kate Wollf-May
Date: 01/10/2004

Central Office for Research Ethics Committees (COREC)

NHS

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NOTICE OF SUBSTANTIAL AMENDMENT

For use in the case of all research other than clinical trials of investigational medicinal products (CTIMPs). For substantial amendments to CTIMPs, please use the EU-approved notice of amendment form (Annex 2 to ENTR/CT1) at http://eudract.emea.eu.int/document.html#guidance.

To be completed in typescript by the Chief Investigator in language comprehensible to a lay person and submitted to the Research Ethics Committee that gave a favourable opinion of the research ("the main REC"). In the case of multi-site studies, there is no need to send copies to other RECs unless specifically required by the main REC.


<table>
<thead>
<tr>
<th>Details of Chief Investigator:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong> Dr Kate Woolf-May</td>
</tr>
</tbody>
</table>
| **Address:** Department of Sport Science, Tourism and Leisure  
Canterbury Christ Church University  
Canterbury, Kent CT1 1QU  |
| **Telephone:** 01227 767700 ext. 3233  |
| **E-mail:** kw24@cant.ac.uk  |
| **Fax:**  |

<table>
<thead>
<tr>
<th>Full title of study:</th>
<th>The effect of 30 minutes of accumulative brisk walking on five days of the week on metabolic syndrome risk factors and lipid metabolism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of main REC:</td>
<td>East Kent REC</td>
</tr>
</tbody>
</table>
| REC reference number: | 04/Q1803/82  
05/Q1801/116  |
|                      | March 2005                                                                                                                                   |
Date study commenced:  

Protocol reference (if applicable), current version and date:  

| Protocol Amendment 1 – October 2005  
| Information form Amendment 3 – October 2005  

Amendment number and date:  

**Type of amendment (indicate all that apply in bold)**

(a) Amendment to information previously given on the REC application form

**Yes**

**No**

*If yes, please refer to relevant sections of the REC application in the “summary of changes” below.*

(b) Amendment to the protocol

**Yes**

**No**

*If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.*

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

**Yes**

**No**

*If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.*

Is this a modified version of an amendment previously notified to the REC and given an unfavourable opinion?
Yes  No

If yes, please explain the modifications made under “Summary of changes” below.

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

A substantial number of participants are required for this study and a substantial number of volunteers, who may gain favourable health benefits from taking part in this study, have been rejected due to the designated exclusion criteria. The waist circumference of <102 cm (~ 40 inches) or waist hip ratio of < 1.0 is a major factor in participants being ineligible for the study, and also potential participants who fit the physical characteristics are rejected due to their cardiovascular medication. Therefore, in order to overcome these recruitment problems, it is proposed that we are able to recruit participants with a waist that can be lower than 40", yet needs to have a waist:hip ratio of >0.9. Also, it is proposed that we are able to recruit volunteers who are prescribed cardiovascular medication, but do not present symptoms of cardiovascular disease. As a result of these changes in the exclusion criteria the information form also needs to be altered to reflect these changes. C-reactive protein is an emerging CVD risk factor as an inflammatory marker that is associated with metabolic syndrome. Therefore, we propose to add this parameter to those that we are currently measuring. Also, due to the number of Exercise Physiologists at CCCU trained to collect blood samples, these blood samples will now be taken at CCCU.

It is also of some concern that participants volunteer in order to perform a brisk walking programme to improve their health. However, one in three are due to take part in the control group, who have no brisk walking programme to follow. Therefore, because this study is based on 24 weeks of walking followed by 24 weeks of observation, it is proposed that the control groups do this, but in a counter–balanced way. This means they perform no extra activity during the initial 24 weeks, but perform their 24 weeks of brisk walking following this period.
Any other relevant information

Applicants may indicate any specific ethical issues relating to the amendment, on which the opinion of the REC is sought.

List of enclosed documents

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information form</td>
<td>3</td>
<td>October 2005</td>
</tr>
<tr>
<td>Revised Protocol</td>
<td>4</td>
<td>October 2005</td>
</tr>
</tbody>
</table>

Declaration

I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.

I consider that it would be reasonable for the proposed amendment to be implemented.

Signature of Chief Investigator: ...........................................

Print name: Dr Kate Woolf–May

Date of submission: 26th October 2005
A.2 Participant information document

VOLUNTEER INFORMATION FORM

The effect of 30 minutes of accumulative brisk walking on five days of the week upon risk factors for metabolic syndrome and blood fats

You are being invited to take part in a research study. Before you decide 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 others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Take time to decide whether or not you wish to take part.

What is the purpose of the study?
For health, the government recommend that each adult carry out at least 30 minutes of physical activity throughout the day, on at least 5 days of the week. The researchers are interested to see whether this would help in reducing risk of Metabolic Syndrome in a group of men with an increased waist circumference, who are known to be at high risk. Since those at risk of Metabolic Syndrome also tend to have a high blood fats and greater blood clotting, the researchers are also interested in seeing whether there is an influence on these factors.

Therefore, the purpose of the study is to determine whether 30 minutes of brisk walking a day for 24 weeks has an effect upon risk factors for Metabolic Syndrome.

What is Metabolic Syndrome?
Metabolic syndrome is a group of factors, such as high risk of diabetes, increased waist circumference, high blood glucose, high blood fats and high blood pressure. Metabolic syndrome is now extremely common and is on the increase.
**Am I a suitable subject for this study?**
The researchers are looking to recruit 156 men, between the ages of 40 and 65 years, onto the study. If you currently carry out less than 30 minutes of exercise a day, are a non-smoker, feeling overweight, and are free of symptoms for heart disease, diabetes or any disability that will make it difficult for you to walk briskly, you are probably suitable for the study.

**Do I have to take part?**
Even if you are accepted onto the study, it is up to you to decide whether or not you wish to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw from the study at any time, and without giving a reason.

**Will I get any payment for taking part?**
Unfortunately, we do not have the funding to pay for your participation in the study or to reimburse you for travel costs to any of the tests.

**What will happen to me if I take part?**
If you decide that you would like to take part in the study, you will first undergo what is called 'pre-study screening'.

**Pre-study screening**
Before you can be accepted onto the study you will have to complete two forms, and have a blood test for blood fats and clotting factors.

**Forms**
One of the forms will ask for details about your health and any medications that you are currently taking, and the other to find out your usual physical activity levels. The researchers will also ask for your permission for them to contact your GP so that they can inform him/her that you are interested in taking part in the study.

**Blood test**
The blood test will be performed at the Sport and Exercise Science Studio, Canterbury Christ Church University after an overnight fast. This will be carried out in the morning and should not take very long. Volunteers will be required not to eat or drink anything other than water for the 14 hours prior to this test (i.e. not eating between an evening meal at about 7pm and the blood test the
following morning at about 9am). Your blood will then be analysed for fats, such as cholesterol, and clotting factors.

If the researchers pick up anything that may be of concern to your health, your GP will be informed immediately.

The study procedures
Once accepted onto the study, you will firstly be randomly selected into one of three groups. You cannot choose which group you are allocated into.

- Control group (CON) - those who do all the tests, but carry on with their usual lifestyle and will be provided with the same brisk walking programme as the walking groups after the initial 24 weeks.
- Accumulative brisk walking (ABW) - who for 24 weeks will be asked to brisk walk for 30 minutes a day, on 5 days of the week, in bouts of no less than 5 minutes and no more than 15 minutes.
- Single brisk walking group (SBW) - who for 24 weeks will be asked to brisk walk for 30 minutes a day, on 5 days of the week, walking in one single daily bout of 30 minutes.

You will be asked to make no dietary or other lifestyle changes.

What other tests will be carried out?
Before and after the 24-weeks programmes, all subjects will carry out five tests:

- Measures of waist and hip circumference
- Blood Pressure
- Body fat percentage
- Fasted fat percentage test (see blood test above).
- Measure of aerobic fitness (treadmill walking test, see table 1)

<table>
<thead>
<tr>
<th>Table 1. Graded treadmill walking test protocol</th>
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<tbody>
<tr>
<td><strong>Speed (mph)</strong></td>
</tr>
<tr>
<td>3.0</td>
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<td>3.0</td>
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<tr>
<td>3.0</td>
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<td>3.0</td>
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</tbody>
</table>

You will walk on a treadmill and wear a facemask, through which the air that you breathe out will be collected and later analysed. A very small amount of blood will also be taken from the tip of one of your fingers to measured blood lactate levels.

The test will only start when you feel happy about what you have to do.
This is not an ‘all out’ test; you should feel no more than slightly sweaty and slightly breathless.

*Subjects are requested to wear loose clothing and not to eat or drink tea, coffee, or any drink containing caffeine within 2 hours of the test; or to drink alcohol or exercise within the 24 hours prior to any of the tests. Drinking water is permitted.*

**How often will I have to be tested?**
All subjects will complete all five tests before and after the experimental period. All tests will be performed in the Sport and Exercise Science Laboratory at Canterbury Christ Church University on the same occasion.

### Table 2. Timescale for testing

<table>
<thead>
<tr>
<th>Experimental phase</th>
<th>Week</th>
<th>Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre–experimental period</td>
<td>0</td>
<td>• ABW</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• SBW</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Controls</td>
</tr>
<tr>
<td>Post–experimental period</td>
<td>24</td>
<td>• ABW</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• SBW</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Controls</td>
</tr>
<tr>
<td>Post walk period (for those initially in the control group)</td>
<td>48</td>
<td>• Controls (ABW &amp; SBW)</td>
</tr>
</tbody>
</table>

**What are the possible benefits of taking part?**
You will have a comprehensive health and fitness assessment, and will be under the instruction of experts in their field.

**Will taking part harm my health?**
During any physical activity or exercise, there is always a slight increased risk of a cardiac event or injury; and for those without underlying heart disease, the risks to health are extremely minimal. The risk is even lower with exercise that does not go to the maximum. Since, maximal exercise will not be a part of this study, the risks to health during any prescribed physical activity is extremely minimal.

**What if something goes wrong?**
If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this
study, the normal National Health Service complaints mechanisms should be available to you.

**Will my taking part in this study be kept confidential?**
All information, which is collected about you during the course of the research, will be kept strictly confidential. Furthermore, any collected data will only be kept for the duration of the research.

**What will happen to the results of the research study?**
You will receive a copy of your own results from the study, and upon publication of the general results, you will be given a non-technical summary of the results.

**Who is organising and funding the research?**
The NHS Executive is funding the research.

**Who has reviewed the study?**
The central NHS Executive and Research Ethics Committee has reviewed the study.

**Contact for Further Information**
If you are interested in taking part in the study or require additional information. Please contact Andrew Scott on 01227 767700 x 3145 or e-mail ats5@cant.ac.uk

*Thank you for reading this.*
A.3 Informed consent document

Department of Sport Science, Tourism and Leisure,
North Holmes Road, Canterbury, Kent CT1 1QU

If you have any queries please contact Andrew Scott on 01227 767700 x 3145 or

Patient Identification Number for this trial:

CONSENT FORM

The effect of 30 minutes of accumulative brisk walking on five days of the week upon risk factors for metabolic syndrome and blood fats

Please initial box

1. I confirm that I have read and understand the information sheet dated ...................... (version 1.) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.

3. I understand that any personal information that I provide to the researchers to be kept strictly confidential.

4. I agree to take part in the above study.

5. I agree for you to contact my GP for his/her permission for me to take part

Name of Subject Date Signature

Name of Person taking consent Date Signature
(if different from researcher)

Researcher Date Signature

1 copy for the patient, 1 for researcher and 1 to be kept with subject's notes
Appendix B – 24 hour walking study

B.1 Research ethics committee proposal

This form should be completed by the Chief Investigator, after reading the guidance notes. See glossary for clarification of different terms in the application form.

| Short title and version number: (maximum 70 characters – this will be inserted as header on all forms) | The effect of single brisk walking sessions on metabolic syndrome risk |
| Name of NHS Research Ethics Committee to which application for ethical review is being made: | East Kent Research Ethics Committee |
| Project reference number from above REC: | |
| Submission date: | 01/03/2008 |

**PART A: Introduction**

**A1. Title of the research**

| Full title: | The 24 hour effect of single brisk walking at different intensities and durations on metabolic syndrome risk factors |
| Key words: | Brisk walking, metabolic syndrome, walking intensity, walking duration |

**A2. Chief Investigator**

| Title: | Mr |
| Forename/initials: | Andrew |
| Surname: | Scott |
| Post: | Postgraduate Research Student |
| Qualifications: | MSc, BSc, BA(Hons) Phase IV Instructor, Health/Fitness Instructor Certified by the ACSM, British Red Cross First Aid at Work |
| Organisation: | Department of Sport Science, Tourism and Leisure |
| Address: | Canterbury Christ Church University  
North Holmes Road  
Canterbury Kent |
| Post Code: | CT1 1QJ |
| E-mail: | ase6@cant.ac.uk |
| Telephone: | 01227 767760 ext. 3145 |
| Fax: | |

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application

**A3. Proposed study dates and duration**

| Start date: | 01/09/2006 |
| End date: | 01/03/2008 |
| Duration: | Years: 1; Months: 6 |
A4. Primary purpose of the research: (Tick as appropriate)

- Commercial product development and/or licensing
- Publicly funded trial or scientific investigation
- Educational qualification
- Establishing a database/data storage facility
- Other

A6. Does this research require site-specific assessment (SSA)? (Advice can be found in the guidance notes on this topic.)

- Yes
- No

If No, please justify:
The research will only take place at the Sport and Exercise Science Laboratory, Canterbury Christ Church University.

If Yes, Part C of the form will need to be completed for each research site and submitted for SSA to the relevant Local Research Ethics Committee. Do not submit Part Cs for other sites until the application has been booked for review and validated by the main Research Ethics Committee.

Management approval to proceed with the research will be required from the R&D Department for each NHS care organisation in which research procedures are undertaken. This applies whether or not the research is exempt from SSA.
### A7. What is the primary research question/objective? (Must be in language comprehensible to a lay person.)

Are there any decreases in metabolic syndrome risk factors (high blood pressure, high cholesterol, impaired fasting blood glucose, increased blood clotting & inflammation) due to a single brisk walking session, and if so when do these benefits occur and do they last for 24 hours?

### A8. What are the secondary research questions/objectives? (If applicable, must be in language comprehensible to a lay person.)

Does the intensity of the brisk walking session affect this relationship (see A7) and/or does the duration of the brisk walking session affect this relationship?

### A9. What is the scientific justification for the research? What is the background? Why is this an area of importance? (Must be in language comprehensible to a lay person.)

Metabolic syndrome is a cluster of related heart disease risk factors. These include increased waist circumference, pre-diabetes, high blood pressure, high cholesterol, increased blood clotting and inflammation. Participation in regular physical activity is now promoted as one of the 'best buys' in the prevention and management of physiological disorders, such as high blood pressure, high cholesterol, overweight and obesity, diabetes and heart disease, amongst others. The current recommendations for physical activity are 5 x 30 min per week at a moderate intensity. This study aims to determine whether a single brisk walking session has any immediate effect (24 hour time-course) on metabolic syndrome risk factors.

### A10. Give a full summary of the purpose, design and methodology of the planned research, including a brief explanation of the theoretical framework that informs it. It should be clear exactly what will happen to the research participant, how many times and in what order. Describe any involvement of research participants, patient groups or communities in the design of the research.

This section must be completed in language comprehensible to the lay person. It must also be self-standing as it will be replicated in any applications for site-specific assessment on Part C. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.

**Purpose**

The purpose of the study is to investigate the acute effects of brisk walking of varying intensity (45% v. 65% aerobic capacity [VO2max]) and duration (30 v. 60 minutes) on metabolic syndrome risk factors during the 24 hour period after exercise. This is to support an ongoing longitudinal brisk walking study investigating the chronic effects of regular brisk walking (5 x 30 min per week) over a 24 week period.

**Study Design**

The study will employ a repeated measures design, where each participant will take part in all four trials within a 4–10 week period.

**Methodology**

Participants will volunteer by reading the information form and completing the informed consent and pre-screening health forms. Their doctor’s approval will then be required before they are fully accepted onto the study. Following clearance, each participant will perform a graded submaximal walking test on the treadmill in order to establish their VO2max. The results from this test will be used to prescribe walking intensity during the main trials.

Prior to each trial, the participants will perform a 12 hour fast (i.e. from 7:00PM until 7:00 AM the next morning) and again that night before the 24 hour post-walk assessment the following morning. Participants will attend the Sport and Exercise Science Laboratory for the four trials. Each trial will require four assessments:

1. For the pre-walk assessment
2. For the walk and one hour post-walk assessment,
3. For the 4 hour post-walk assessment, and
4. The following morning for 24 hour post-walk assessment.

Assessments 1–3 will occur during the first visit to the Sport and Exercise Science Laboratory and participants will be observed throughout, and assessment four will occur on the following morning.
The initial assessment on the morning of the first trial will include height, body mass, waist circumference and hip circumference measurements plus the tests listed below. All subsequent assessments will include:

- Resting metabolic rate – expired air analysis using Douglas Bags
- Resting heart rate – using heart rate telemetry
- Blood pressure – assessed using an aneroid sphygmomanometer
- Blood test (using a cannula for the series of pre- & post-exercise assessments) for the analysis of blood lipids, glucose, insulin and markers of blood clotting and inflammation.

A cannula is required for the comfort of the research participant because four samples will be taken over a 5 hour period, followed by a further venepuncture the following morning. Participants will be observed throughout the duration of the trial, to maintain their safety.

**Treadmill walk**
- Prior to the brisk walk, the participants will be lead through a standardised warm up so that they are fully prepared for the walking session ahead.
- Participants will be asked to walk at the desired intensity and duration during the tests. The intensity of the brisk walk will be determined using the heart rate monitors. The gradient and speed of the treadmill will be altered accordingly so that the participants can walk comfortably (i.e. the gradient will be elevated to increase intensity if a participant cannot walk fast enough at the required intensity).

Participants will be required to fast through the first morning of each test. Following the 4 hour post-walk assessment on the morning of the first test, the participants will be required to record what they eat for the duration of the day in a food diary so that the same diet can be replicated during the following 3 trials. This is in order to reduce a confounding effect due to diet.

The trials will take place in a randomly assigned order. These trials include:
- **Trial A**: No exercise (CON) – this test acts to determine the natural changes that may naturally occur without exercise
- **Trial B**: 30 minute brisk walk at 65% VO2max
- **Trial C**: 30 minute brisk walk at 45% VO2max
- **Trial D**: 60 minute brisk walk at 45% VO2max

**Timeline for each trial**

**Day 1**
- 7:15/7:45 AM – Pre-exercise assessment – Cannula inserted
- 7:30/8:30 AM – Brisk walk on the treadmill
- 8:30 AM – Immediate post-walk assessment
- 9:30 AM – One hour post-walk assessment
- 12:30 PM – Four hour post-walk assessment – Cannula removed

**Day 2**
- 6:30 AM – 24 hour post-walk assessment – Blood sample taken with needle

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**A12. Give details of any clinical intervention(s) or procedure(s) to be received by research participants over and above those which would normally be considered a part of routine clinical care. (These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material)**

<table>
<thead>
<tr>
<th>Additional Intervention</th>
<th>Average number per participant</th>
<th>Average time taken (mins/hours/days)</th>
<th>Details of additional intervention or procedure, who will undertake it, and what training they have received.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treadmill walk</td>
<td>4</td>
<td>30-60 mins</td>
<td>Participants will perform 4 submaximal tests on a treadmill, each lasting between 10-59 minutes.</td>
</tr>
<tr>
<td>Lifestyle modification</td>
<td>4</td>
<td>6 hours</td>
<td>Participants will be fitted with a cannula by a trained practitioner that will remain patent for 4 hours. A blood sample will be taken by venepuncture 24 hours after the intervention by a trained phlebotomist.</td>
</tr>
<tr>
<td>Venepuncture</td>
<td>4</td>
<td>5 mins</td>
<td>A blood sample will be taken by venepuncture 24 hours after the intervention by a trained phlebotomist.</td>
</tr>
</tbody>
</table>
A13. Give details of any non-clinical research-related intervention(s) or procedure(s). (These include interviews, non-clinical observations and use of questionnaires.)

<table>
<thead>
<tr>
<th>Additional Intervention</th>
<th>Average number per participant</th>
<th>Average time taken (mins/hours/days)</th>
<th>Details of additional intervention or procedure, who will undertake it, and what training they have received</th>
</tr>
</thead>
</table>

A15. What is the expected total duration of participation in the study for each participant?

Each participant will be requested to attend the Sport and Exercise Science Laboratory on 9 occasions. One will be for a submaximal fitness test. The test itself will take 10 minutes and the visit no more than 30 minutes. Each of the next four trials involve 2 visits. On the first visit the participants will be asked to stay on Canterbury Christ Church University premises for observation for ~6 hours. The participants will then be asked to attend the following morning for a blood test. This visit should only require 15 minutes.

A17. What is the potential for pain, discomfort, distress, inconvenience or changes to lifestyle for research participants?

During any physical activity there is a degree of discomfort that is associated with the intensity and duration of the activity. This should not cause undue distress or cause long term changes to participants’ lifestyle. Each participant will have to give their time and follow research requirements.

This study involves taking blood, therefore there is potential for needle stick injury, fainting and, in extreme circumstances, blood loss. The chief investigator is trained to reduce the risk of these occurring. A cannula will be inserted by a trained practitioner and will remain patent for ~6 hours therefore care needs to be taken not to tamper or dislodge these by the participant. The participants also need to fast from the night before, therefore they may be at risk of hypoglycaemia and/or dehydration and will be advised to drink plenty of water to help reduce the risk of adverse reactions.

A18. What is the potential for benefit to research participants?

Participants will receive a comprehensive health and fitness assessment performed by an expert exercise physiologist. Further benefits to the research participants include being given the opportunity to find out how different types of walking (every day activity) can influence their health and be led by experts in health-related exercise.

A19. What is the potential for adverse effects, risks or hazards, pain, discomfort, distress, or inconvenience to the researchers themselves? (if any)

The only risk to the researcher may be the risk of needlestick injury, however the chief investigator is a trained phlebotomist and this should only be a slight risk.

A20. How will potential participants in the study be (i) identified, (ii) approached and (iii) recruited?

Give details for cases and controls separately if appropriate.

Potential participants will be recruited by asking volunteers, who have taken part in a previous study (04/Q1903/02), if they wish to be contacted again in the future with regards to taking part in this study. This is hoped to be the primary route of for recruitment. A poster will also be used, if necessary, and NHS healthcare professionals may also be contacted to help to find volunteers. If this proves insufficient then webpages, newspapers, TV, radio media will be used to help to advertise for volunteers.
A21. Where research participants will be recruited via advertisement, give specific details.

☐ Not Applicable

The study will only be advertised if sufficient volunteers cannot be found from approaching volunteers from a current project.

If applicable, enclose a copy of the advertisement/radio script/website/video for television (with a version number and date).

A22. What are the principal inclusion criteria? (Please justify)

Non-smoking males aged 40-65

A23. What are the principal exclusion criteria? (Please justify)

Those who smoke, those with heart disease, diabetes and those with an inability to walk for up to an hour at 3 mph. Also, participants who are prescribed with cardiovascular medication including anti-hypertensives, statins etc. Additionally, potential participants who do not understand the nature of the research will also be excluded.

A24. Will the participants be from any of the following groups? (Tick as appropriate)

☐ Children under 16
☐ Adults with learning disabilities
☐ Adults who are unconscious or very severely ill
☐ Adults who have a terminal illness
☐ Adults in emergency situations
☐ Adults with mental illness (particularly if detained under Mental Health Legislation)
☐ Adults with dementia
☐ Prisoners
☐ Young Offenders
☐ Adults in Scotland who are unable to consent for themselves
☐ Healthy Volunteers
☐ Those who could be considered to have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students
☐ Other vulnerable groups

Justify their inclusion.

The aim is to recruit ostensibly healthy participants. Although we are looking to recruit those with metabolic syndrome risk factors, we are also looking for participants who are healthy, but may be at risk of developing metabolic syndrome.

A25. Will any research participants be recruited who are involved in existing research or have recently been involved in any research prior to recruitment?

☐ Yes  ☐ No  ☐ Not Known

If Yes, give details and justify their inclusion. If Not Known, what steps will you take to find out?

Many of the volunteers for this study may have been involved in a previous study and asked to also take part in this study. This is because they will be familiar with the chief investigator and are known to be experienced brisk walkers. The aim of this study is to determine whether any effects of the related intervention study could be related to individual sessions. Therefore, it seems reasonable to use some of the same participants.
### A26. Will informed consent be obtained from the research participants?

- [ ] Yes  
- [ ] No

If Yes, give details of who will take consent and how it will be done. Give details of any particular steps to provide information (in addition to a written information sheet) e.g. videos, interactive material.

If participants are to be recruited from any of the potentially vulnerable groups listed in A24, give details of extra steps taken to assure their protection. Describe any arrangements to be made for obtaining consent from a legal representative.

If consent is not to be obtained, please explain why not.

The chief investigator will take informed consent. This will be done by providing volunteers with an information form and an informed consent form to fill in and sign.

Copies of the written information and all other explanatory material should accompany this application.

### A27. Will a signed record of consent be obtained?

- [ ] Yes  
- [ ] No

If Yes, attach a copy of the information sheet to be used, with a version number and date.

### A28. How long will the participant have to decide whether to take part in the research?

The study is due to terminate in March 2008. Therefore, if participants have not decided to take part by October 2007, then it will not be possible for them to participate.

### A29. What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g. translation, use of interpreters etc.)

There are not the resources to accommodate those who do not adequately understand, for whatever reason, the requirements of the study; they shall not be permitted to take part.

### A32a. Will the research participants’ General Practitioner be informed that they are taking part in the study?

- [ ] Yes  
- [ ] No

If Yes, enclose a copy of the information sheet/letter for the GP with a version number and date.

### A32b. Will permission be sought from the research participants to inform their GP before this is done?

- [ ] Yes  
- [ ] No

If No to either question, explain why not.

It should be made clear in the patient information sheet if the research participant’s GP will be informed.

### A33. Will individual research participants receive any payments for taking part in this research?

- [ ] Yes  
- [ ] No
A34. Will individual research participants receive reimbursement of expenses or any other incentives or benefits for taking part in this research?

- Yes
- No

A35. What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants for negligent harm?

Indemnity and compensatory insurance is covered by an Honoray NHS Research Contract

Please forward copies of the relevant documents.

A36. What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants for non-negligent harm?

As above in A35

Please forward copies of the relevant documents.

A37. How is it intended the results of the study will be reported and disseminated? (Tick as appropriate)

- Peer reviewed scientific journal
- Internal report
- Conference presentation
- Other publication
- Submission to regulatory authorities
- Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- Written feedback to research participants
- Presentation to participants or relevant community groups
- Other (e.g., Cochrane Review, University Library)

A38. How will the results of research be made available to research participants and communities from which they are drawn?

Each participant will be provided with their own results and an abstract of the overall results of the study in Layman's terms.

A39. Will the research involve any of the following activities at any stage (including identification of potential research participants)? (Tick as appropriate)

- Examination of medical records by those outside the NHS, or within the NHS by those who would not normally have access
- Electronic transfer by magnetic or optical media, e-mail or computer networks
- Sharing of data with other organisations
- Export of data outside the European Union
- Use of personal addresses, postcodes, taxes, e-mails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
A40. What measures have been put in place to ensure confidentiality of personal data? Give details of whether any encryption or other anonymisation procedures have been used and at what stage:

All records will be kept in accordance with the Data Protection Act (1998). Data will only be shared between individuals within the stated organisations (CCCU & NHS) who are involved in the study. Each participant's hard data will be stored in a locked filing cabinet and electronic data will be stored on a password protected secure site. Once data is collected from participants, it will be coded with a number to identify personal data.

A41. Where will the analysis of the data from the study take place and by whom will it be undertaken?

The data analysis will be performed by the researchers at CCCU. The clinical scientists noted as collaborators will act as advisors for the analysis of the blood samples only.

A42. Who will have control of and act as the custodian for the data generated by the study?

The Chief Investigator Andrew Scott at CCCU.

A43. Who will have access to the data generated by the study?

Researchers from CCCU.

A44. For how long will data from the study be stored?

Years: 5
Months: 0

Give details of where they will be stored, who will have access and the custodial arrangements for the data:

The data will be stored at CCCU for the duration of the study (5 years).

A45-1. How has the scientific quality of the research been assessed? (Tick as appropriate)

- Independent external review
- Review within a company
- Review within a multi-centre research group
- Internal review (e.g. involving colleagues, academic supervisor)
- None external to the investigator
- Other, e.g. methodological guidelines (give details below)
The main criticisms were to ensure complete care is to be taken for the duration that the participants’ cannot are fitted and also to maximise the potential benefits for the participants.

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

A45.2. Has the protocol submitted with this application been the subject of review by a statistician independent of the research team? (Select one of the following)

Yes – copy of review enclosed

Yes – details of review available from the following individual or organisation (give contact details below)

I was advised that the nature of the study needed to be analysed using repeated measures analysis and that I should try to recruit 15 participants by:

Dr Ray Godfrey
Department of Educational Research
Cantebury Christ Church University
Canterbury, Kent CT1 1QU
01227 782383
rg@hrw.ouk

No – justify below

A48. What is the primary outcome measure for the study?

Changes from rest to immediately post-exercise, 1 hour post-, 4 hours post- and 24 hours post-exercise in blood pressure, resting heart rate, resting metabolic rate, fat oxidation, total cholesterol, HDL-cholesterol, triacylglycerol, NEFA, glucose, insulin, fibrinogen & C reactive protein.

A49. What are the secondary outcome measures? (If any)

Changes in the differences in the measured variables between different walking intensities (45 v 65% VO2max) and durations (30 v 60 minutes)

A50. How many participants will be recruited?

If there is more than one group, state how many participants will be recruited in each group. For international studies, say how many participants will be recruited in the UK and in total.

We propose to recruit at least 12 participants in a repeated measures design.

A51. How was the number of participants decided upon?

This number was decided upon because a similar study found a significant effect using the same number of participants.

If a formal sample size calculation was used, indicate how this was done giving sufficient information to justify and reproduce the calculation.

Data from the paper below was input into CIstat by Martin Bland for power analysis:

The study used 12 young healthy males and females.

Control total area under curve = 7.40 ± 0.7 mmol/L-1/hr-1
LOW total area under curve = 6.24 ± 0.7 mmol/L-1/hr-1
MID total area under curve = 5.51 ± 0.5 mmol/L-1/hr-1

A52. Will participants be allocated to groups at random?

- Yes  
- No

If yes, give details of the intended method of randomisation:
Using computer generated number sequences

A53. Describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

The study will employ a repeated measures design, and therefore will be analysed by SPSS v.13 using repeated measures analysis.

A54. Where will the research take place? (Tick as appropriate)

- UK
- Other states in European Union
- Other countries in European Economic Area
- Other

If Other, give details:

A55. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK, the European Union or the European Economic Area?

- Yes  
- No

A56. In how many and what type of host organisations (NHS or other) in the UK is it intended the proposed study will take place?

*Indicate the type of organisation by ticking the box and give approximate numbers if known:*

- [ ] Acute teaching NHS Trusts
- [x] Acute NHS Trusts
- [ ] NHS Primary Care Trusts or Local Health boards in Wales
- [ ] NHS Trusts providing mental healthcare
- [ ] NHS Health Boards in Scotland
- [ ] HPHS Trusts in Northern Ireland
- [ ] GP Practices
- [ ] NHS Care Trusts

Number of organisations: 1
A57. What arrangements are in place for monitoring and auditing the conduct of the research?

The study will be conducted under the clinical governance framework of the acute NHS trust and regular monthly meetings will be held between the researchers at CCCU to determine the progress of the study.

Will a data monitoring committee be convened?

- Yes
- No

If Yes, details of membership of the data monitoring committee (DMC), its standard operating procedures and summaries of reports of interim analyses to the DMC must be forwarded to the NHS Research Ethics Committee which gives a favourable opinion of the study.

What are the criteria for selectively stopping the trial or other research prematurely?

- Participant injury, ill health or undue distress during the waiting trials

A58. Has external funding for the research been secured?

- Yes
- No

If No, what arrangements are being made to cover any costs of the research? If no external funding is being sought, please say so:

No external funding is being sought at this stage and Canterbury Christ Church University is funding the research.

A59. Has the funder of the research agreed to act as sponsor as set out in the Research Governance Framework?

- Yes
- No

Has the employer of the Chief Investigator agreed to act as sponsor of the research?

- Yes
- No

Sponsor (must be completed in all cases)
Name of organisation which will act as sponsor for the research:

Department of Sport Science, Tourism and Leisure, Canterbury Christ Church University

Status:

☒ NHS or HPSS care organisation ☐ Academic ☐ Pharmaceutical Industry ☐ Medical device industry ☐ Other

If Other, please specify:

Address: North Holmes Road
Canterbury
Kent
Post Code: CT1 1QU
Telephone: 01227 767700 ext. 3145
Fax:
E-mail: ojb1@sant.ac.uk

The responsibilities of the sponsor may be shared between co-sponsors. If this applies, name the lead sponsor for the REC application in this box and enclose a letter giving further details of co-sponsors and their responsibilities.

Sponsor's UK contact point for correspondence with the main REC

Title: Dr  Forename/Initials: Chris  Surname: Roll
Address: Department of Sport Science, Tourism and Leisure
Canterbury Christ Church University
North Holmes Road Canterbury Kent
Post Code: CT1 1QU
Telephone: 01227 782334
Fax:
E-mail: ojb1@sant.ac.uk

A60. Has any responsibility for the research been delegated to a subcontractor?

☒ Yes ☐ No

A61. Will individual researchers receive any personal payment over and above normal salary for undertaking this research?

☒ Yes ☐ No

A62. Will individual researchers receive any other benefits or incentives for taking part in this research?

☒ Yes ☐ No

A63. Will the host organisation or the researcher’s department(s) or institution(s) receive any payment or benefits in excess of the costs of undertaking the research?

☒ Yes ☐ No
A64. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share-holding, personal relationship etc.) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?  
☑ Yes ☒ No

A65. Other relevant reference numbers if known (give details and version numbers as appropriate):

- Applicant's/organisation's own reference number, e.g. R&D (if available):
- Sponsor's/protocol number:
- Funder's reference number:
- International Standard Randomised Controlled Trial Number (ISRCTN):
- European Clinical Trials Database (EudraCT) number:
- Project website:

A66. Other key investigators/collaborators (all grant co-applicants should be listed)

<table>
<thead>
<tr>
<th>Title</th>
<th>Fonsiname/Initials</th>
<th>Surname</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr</td>
<td>Kate</td>
<td>Woolf-May</td>
</tr>
<tr>
<td>Post</td>
<td>Research Fellow</td>
<td></td>
</tr>
<tr>
<td>Qualifications</td>
<td>BSc(Hons), MSc, PhD</td>
<td></td>
</tr>
<tr>
<td>Organisation</td>
<td>Department of Sport Science, Tourism and Leisure</td>
<td>Canterbury Christ Church University</td>
</tr>
<tr>
<td>Address</td>
<td>North Holmen Road, Canterbury, Kent</td>
<td>Telephone: 01227 767700 x 3233</td>
</tr>
<tr>
<td>Postcode</td>
<td>CT1 1OU</td>
<td></td>
</tr>
<tr>
<td>E-mail</td>
<td><a href="mailto:kew24@cant.ac.uk">kew24@cant.ac.uk</a></td>
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</tbody>
</table>

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<tr>
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<th>Surname</th>
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<tbody>
<tr>
<td>Mr</td>
<td>Edward</td>
<td>Kearney</td>
</tr>
<tr>
<td>Post</td>
<td>Consultant Clinical Biochemist</td>
<td></td>
</tr>
<tr>
<td>Qualifications</td>
<td>MSc, MCB, FRCPatn</td>
<td></td>
</tr>
<tr>
<td>Organisation</td>
<td>East Kent Hospital NHS Trust</td>
<td>Queen Elizabeth the Queen Mother Hosp.</td>
</tr>
<tr>
<td>Address</td>
<td>Margate, Kent</td>
<td>Telephone: 01843 234424</td>
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<td>Postcode</td>
<td>CT3 4AN</td>
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<tr>
<td>E-mail</td>
<td><a href="mailto:edward.kearney@ekht.nhs.uk">edward.kearney@ekht.nhs.uk</a></td>
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<tr>
<td>Dr</td>
<td>DW</td>
<td>Jones</td>
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<tr>
<td>Post</td>
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<tr>
<td>Qualifications</td>
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<tr>
<td>Organisation</td>
<td>East Kent Hospitals NHS Trust</td>
<td>Haemophilia Centre</td>
</tr>
<tr>
<td>Address</td>
<td>Kent and Canterbury Hospital</td>
<td>Telephone: 01227 779877</td>
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PART A: Summary of Ethical Issues

A68. What do you consider to be the main ethical issues which may arise with the proposed study and what steps will be taken to address these?

The two main ethical issues relating to the proposed study are the use of cannulas and data storage. The cannulas will be inserted and kept patent by trained practitioners and data will be stored in accordance with the Data Protection Act (1998).
**PART A: Student Page**

**A70. Give details of the educational course or degree for which this research is being undertaken:**

- **Name and level of course/degree:**
  - MPhil/PhD Sport Science

- **Name of educational establishment:**
  - Canterbury Christ Church University

- **Name and contact details of educational supervisor:**
  - Dr Kate Woolf-May
  - Department of Sport Science, Tourism and Leisure
  - Canterbury Christ Church University
  - North Holmes Road
  - Canterbury Kent CT1 1QL
  - 01227 767700 x 9253
  - kw24@cant.ac.uk

**A71. Declaration of supervisor**

I have read and approved both the research proposal and this application for the ethical review. I undertake to fulfill the responsibilities of a supervisor as set out in the Research Governance Framework for Health and Social Care.

- **Signature:**
- **Print Name:**
- **Note:**

*A one-page summary of the supervisor's CV should be submitted with the application*

**A72. Declaration by academic sponsor**

To be completed by an authorised person or behalf of the academic institution acting as sponsor for student research.

I can confirm on behalf of my academic institution that any necessary indemnity or insurance arrangements will be in place before this research starts, as required by the Research Governance Framework for Health and Social Care.

- **Signature:**
- **Print Name:** Chris Bull
- **Post:** Head of Department of Sport Science, Tourism and Leisure
- **Institution:** Canterbury Christ Church University
- **Date:** 20/04/2006 (dd/mm/yyyy)
### PART B: Section 5 – Use of newly obtained human biological materials

1. **What samples will be collected and/or analysed and by whom will they be collected?**
   - Trained phlebotomists will collect blood samples for the analysis of total cholesterol, high-density lipoprotein cholesterol, triglycerides, non-esterified fatty acids, glucose, insulin, fibrinogen, C-reactive protein, cholesterol ester transfer protein and lecithin:cholesterol acyltransferase.

2. **Are the samples taken solely for research purposes (or are they a by-product of those taken primarily for clinical purposes, i.e. surplus to clinical requirements)?**
   - Samples will be used for research purposes only.

3. **How will samples be labelled/identified?**
   - Indicate if samples can be considered to be "identified", "coded", "de-identified", "anonymised" or "anonymous" and at what stage identifiers are removed.
   - The participants' data will be stored in coded vials and only the chief investigator and the chief investigator's supervisor, Dr Kate Woolf-May, will know the identity of the coded samples.

4. **Give details of where the sample(s) will be stored, for how long, who will have access and the custodial arrangements.**
   - The plasma samples will be stored at CCGU for the duration of the research (up to 10 years) and in duplicate at GEOM Hospital. The samples will be looked after by Edward Keenney at GEOM. All samples will be stored in accordance with the Data Protection Act (1998).

5. **Will the research participant retain any rights to the sample(s)?**
   - Yes  No
   - If Yes, give details. If the sample is a gift, this must be clear in the information sheet. What will happen to samples if a participant withdraws from the study? Samples collected from each participant will be analysed and they will receive their own data. Incomplete data (i.e., no value in analysing) from withdrawn participants will not be analysed.

6. **Is it known how the samples will be used in the future?**
   - Yes  No
   - If Yes, give details and indicate if consent will be obtained for the future use of samples: The samples will only be used as stated.

7. **Does the research involve the analysis or use of genetic material from human biological materials?**
   - Yes  No

8. **Would it be possible to link the results of any genetic analysis back to individuals?**
   - Yes  No

9. **Is it intended to link the results of any genetic analysis back to individuals?**
   - Yes  No
PART B: Section 7 – Declaration

– The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

– I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

– If the research is approved I undertake to adhere to the study protocol, the terms of the full application of which the main REC has given a favourable opinion and any conditions set out by the main REC in giving its favourable opinion.

– I undertake to seek an ethical opinion from the main REC before implementing substantial amendments to the protocol or to the terms of the full application of which the main REC has given a favourable opinion.

– I undertake to submit annual progress reports setting out the progress of the research.

– I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer.

– I understand that research records/data may be subject to inspection for audit purposes if required in future.

– I understand that personal data about me as a researcher in this application will be held by the relevant RECs and their operational managers and that this will be managed according to the principles established in the Data Protection Act.

– I understand that the information contained in this application, any supporting documentation and all correspondence with NHS Research Ethics Committees or their operational managers relating to the application, will be subject to the provisions of the Freedom of Information Acts. The information may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

Signature: ............................

Date: 20/04/2006 (dd/mm/yyyy)

Print Name: Andrew Scott
B.2 Participant information document

Department of Sport Science, Tourism and Leisure
North Holmes Road, Canterbury, Kent CT1 1QU.

VOLUNTEER INFORMATION FORM

The 24 hour effect of brisk walking at different intensities and durations on metabolic syndrome risk factors

You are being invited to take part in a research study. Before you decide 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 others if you wish. Ask us if there is anything that is not clear or if you would like more information. **Take time to decide whether or not you wish to take part.**

What is the purpose of the study?
The purpose of this study is to investigate the acute effect of a single bout of brisk walking, of different intensity (45% v. 65% of maximal aerobic capacity) and duration (30 v. 60 minutes) on risk factors for metabolic syndrome during the 24–hour period after the exercise.

What is Metabolic Syndrome?
Metabolic syndrome is a group of risk factors, such as increased waist circumference, high blood glucose, high blood fats and high blood pressure that indicate an increase risk of developing heart disease and diabetes. Metabolic syndrome is now extremely common and is on the increase.

Am I a suitable subject for this study?
If you are male between the age of 40 to 65 years, a non-smoker, feeling overweight, and are free of heart disease, diabetes or any disability that will make it difficult for you to walk briskly, you are probably suitable.
Do I have to take part?
Even if you are accepted onto the study, it is up to you to decide whether or not you wish to take part. If you do decide to take part, you will be given this information form to keep and be asked to sign a consent form and complete a pre-screening health questionnaire. If you decide to take part, you are still free to withdraw from the study at any time, and without giving a reason.

Will I get any payment for taking part?
Unfortunately, we do not have the funding to pay for your participation in the study or to reimburse you for travel costs to any of the tests.

What will happen to me if I take part?
If you decide that you would like to take part in the study, you will first undergo what is called ‘pre-study screening’.

Pre-screening
Before you can be accepted onto the study you need to complete two forms. One of the forms will ask for your consent to take part in the study and the other will ask for details about your health and any medications that you are currently taking. The researchers will also ask for your permission for them to contact your GP so that they can inform him/her that you are interested in taking part in the study.

The tests
Once accepted onto the study, you will perform a sub-maximal treadmill walking test to establish your aerobic fitness (\(\text{VO}_{2\text{max}}\)). Afterwards, it is requested that you perform four trials (see trials A–D below), which will be randomly assigned. You do not choose the order of your trials.
Trial A: No exercise (CON) – this test acts to determine the natural changes that may naturally occur without exercise.
Trial B: 30 minute brisk walk at 65% \(\text{VO}_{2\text{max}}\)
Trial C: 30 minute brisk walk at 45% \(\text{VO}_{2\text{max}}\)
Trial D: 60 minute brisk walk at 45% \(\text{VO}_{2\text{max}}\)

These are not ‘all out’ tests. You should feel no more than slightly sweaty and slightly breathless.

Participants are requested to wear loose clothing and not to drink alcohol or exercise within the 24 hours prior to any of the tests or perform any other exercise on the day of a trial or the day before. Drinking plenty of water is advised. You should bring a packed lunch with you for the duration of the
morning of each trial. The food you eat during the first trial will be recorded in a diary so that the same diet can be followed in the subsequent three trials.

**Treadmill walk**
Prior to the brisk walks, you will be lead through a standardised warm up so that you are fully prepared for the walking session ahead. You will be asked to walk at the desired intensity and duration during the tests. The intensity of the brisk walk will be determined using a heart rate monitor. The gradient and speed of the treadmill will be altered accordingly so that you can walk briskly yet comfortably.

After the walking test on the morning of the first test, you will be required to record what you eat for the duration of the day in a diary so that this same diet can be followed during the following 3 trials.

Before the walking test on the morning of the first test your include height, body mass, waist circumference and hip circumference will be measured. All subsequent assessments will include the measurement:
- Resting metabolic rate
- Resting heart rate
- Blood Pressure
- Mouth swab, for analysis of salivary immune function
- Fasted venous blood test (see blood samples below).

**Blood samples and mouth swabs**
The study involves the use of cannulas and venepuncture. A cannula is a plastic device, used to take blood, which remains in your arm for the duration of the first morning. Venepuncture is the process of taking blood that occurs when you have your blood taken with a needle and is removed once the blood has been collected. You will be required not to eat or drink anything other than water for the 12 hours prior to each trial (i.e. not eating between an evening meal at about 7pm and the blood test the following morning at about 7am). A cannula will be inserted in a forearm vein. This will be carried out early in the morning and should not take very long. This is in readiness for a series of four blood collection periods. Your blood will then be analysed for fats, such as cholesterol, and clotting factors. You will need to remain under observation by the sport and exercise research team for the duration of the first morning (~5 hours). If the researchers pick up anything that may be of concern to your health, your GP will be informed immediately. A mouth swab (small sponge) will be chewed for a few minutes in order to collect saliva for the later analysis of immune function.
## Timescale for each trial

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<tr>
<th>Day 1</th>
<th>(see ‘what tests will be carried out?’)</th>
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<tr>
<td>7.30/8.30 AM</td>
<td>Pre–exercise assessment – cannula inserted</td>
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<tr>
<td>8 –7.30/8.30 AM</td>
<td>Brisk walk on the treadmill</td>
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<tr>
<td>9.00 AM</td>
<td>Immediate post–walk assessment</td>
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<td>10.00 AM</td>
<td>One hour post–walk assessment</td>
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<td>1.00 PM</td>
<td>Four hour post–walk assessment &amp; then cannula removed</td>
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</table>

### Day 2

| 8.30 AM | Follow–up assessment – sample taken with needle |

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**How often will I have to be tested?**

You will be asked to complete all four trials. All tests will be performed in the Sport and Exercise Science Laboratory at Canterbury Christ Church University during separate weeks (all within ~two month period). Each trial will require two visits:

1. The walk and three post–walk assessment, and
2. The following morning for the next day assessment (15–30 minutes).

**What are the possible benefits of taking part?**

You will find have a comprehensive health and fitness assessment performed by experts in health–related exercise. If anything untoward is found during your assessment, you may be advised to consult your GP.

**Will taking part harm my health?**

During any physical activity or exercise, there is always a slight increased risk of a cardiac event or injury; however the risks to health are extremely minimal for those without underlying heart disease. The risk is even lower with exercise that does not go to the maximum. Since maximal exercise will not be a part of this study, the risks to health during any prescribed physical activity are extremely minimal. All staff from the Sport and Exercise Physiology Laboratory are trained in defibrillation, resuscitation and first aid and there is access to a portable defibrillator.

**What if something goes wrong?**

*If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any*
aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you.

Will my taking part in this study be kept confidential?
All information and data that is collected about you during the course of the research will be kept strictly confidential in accordance with the 1998 Data Protection Act and kept for the duration of the research. The blood samples will be coded and the accompanying physical data that will be collected will be stored anonymously for a maximum of 10 years. All data and samples will be stored securely in locked cabinets/freezers and on secure computer files.

What will happen to the results of the research study?
You will receive a copy of your own results and a non-technical summary of the results on completion of the study.

Who is organising and funding the research?
Canterbury Christ Church University.

Who has reviewed the study?
The East Kent NHS Research Ethics Committee has reviewed the study.

Contact for Further Information
If you are interested in taking part in the study or require additional information. Please contact Andrew Scott on 01227 767600 x 3145, 07909 586514 or e-mail ats5@cant.ac.uk
B.3 Informed consent document

Department of Sport Science, Tourism and Leisure
North Holmes Road, Canterbury, Kent CT1 1QU.

If you have any queries please contact Andrew Scott on 01227 767700 x 3145

CONSENT FORM

The 24 hour effect of different intensities and durations of brisk walking on metabolic syndrome risk factors

Please initial box

1. I confirm that I have read and understand the information sheet dated ....................... (version 1.) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

3. I understand that any personal information that I provide to the researchers to be kept strictly confidential.

4. I agree to take part in the above study.

5. I agree for you to contact my GP for his/her permission for me to take part

Name of Subject Date Signature

Name of Person taking consent Date Signature
(if different from researcher)

Researcher Date Signature

1 copy for the patient, 1 for researcher and 1 to be kept with subject’s notes

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### B.4 24 week walking study mean data

#### Walking data

##### Mean heart rate

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<td>Mean</td>
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<td>SD</td>
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| 6045 | 5 | 10 | 15 | 20 | 25 | 30 | 35 | 40 | 45 | 50 | 55 | 60 |
|------|---|----|----|----|----|----|----|----|----|----|----|----|----|
| Mean | 93.3| 94.4 | 95.3 | 96.1 | 96.9 | 97.9 | 99.3 | 99.2 | 100.4 | 101.5 | 102.4 | 103.3 |
| SD   | 11.0 | 8.9  | 9.4  | 8.9  | 8.6  | 9.9  | 9.9  | 9.1  | 9.2  | 9.8  | 10.1  | 9.8   |

##### Mean percentage of age-predicted maximum heart rate

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| 6045 | 5 | 10 | 15 | 20 | 25 | 30 | 35 | 40 | 45 | 50 | 55 | 60 |
|------|---|----|----|----|----|----|----|----|----|----|----|----|----|
| Mean | 58.3 | 59.0 | 59.5 | 60.0 | 60.6 | 61.2 | 62.0 | 62.0 | 62.7 | 63.4 | 64.0 | 64.6 |
| SD   | 6.4  | 5.3  | 5.5  | 5.2  | 5.4  | 5.9  | 5.6  | 5.4  | 5.6  | 5.8  | 6.1  | 5.9  |

##### Mean ratings of perceived exertion

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| 6045 | 5 | 10 | 15 | 20 | 25 | 30 | 35 | 40 | 45 | 50 | 55 | 60 |
|------|---|----|----|----|----|----|----|----|----|----|----|----|----|
| Mean | 8.92 | 9.77 | 10.1 | 10.3 | 10.9 | 11.0 | 11.2 | 11.4 | 11.5 | 11.9 | 12.2 | 12.3 |
| SD   | 1.8  | 1.7  | 1.7  | 1.5  | 1.7  | 1.7  | 1.8    | 2.0   | 1.7   | 1.6   | 1.8   | 1.8   |
### Mean cardiovascular and metabolic measures

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Appendix C – Pre-screening health procedures

C.1 Pre-screening health questionnaire

PRE-SCREENING HEALTH QUESTIONNAIRE
**Strictly Confidential**

PART 1. Personal Details

Full Name: ___________________________ Age: ________ D.O.B: __________

Address:
____________________________________________________________
____________________________________________________________
____________________________________________________________
____________________________________________________________

Tel No: Home ________________
Mobile ________________
Email ________________

GPs Name: ___________________________ Permission to contact GP - Yes / No

Address:
____________________________________________________________
____________________________________________________________
____________________________________________________________

Tel No: ________________________

Emergency Contact
Name: _____________________________

Tel No: ________________________
PART 2. Medical History

1. Circle any of the relatives below who died of a heart attack before age 50:
   Father  Mother  Brother  Sister  Grandparent

2. Date of last medical exam by your GP ________ (year)  Details ______________________
   Date of last physical fitness test (if any) ______ (year)  Details ______________________

3. Circle operations you have had: (please put approximate date)
   Back _______  Heart ________  Kidney ________  Eyes _______
   Joint ________  Neck ______  Ears ________  Hernia ________
   Lungs ________  Other ______________________________

   Further details overleaf:

4. Please circle any of the following for which you have been diagnosed or treated by a GP or other health professional (please put approximate date)
   Alcoholism  Diabetes  Kidney Problems  Anaemia  Emphysema
   Mental Illness  Asthma  Epilepsy  Neck Strain  Back strain
   Eye Problems  Obesity  Hearing Loss  Gout  Osteoarthritis
   Bronchitis  Rheumatoid arthritis  Phlebitis  Cancer
   Heart Problems  Stroke  Cirrhosis
   High Blood Pressure  Thyroid Problems  Concussion  Low Blood Sugar
   Ulcer  Osteoporosis  High Cholesterol  TB
   Other ______________________________

   Further Details ______________________________

5. Medications
Please list below all the medications that you are currently taking. This includes any vitamins, minerals and/or food supplements.

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Any of the health symptoms listed below that occur frequently are the basis for medical attention. Circle the number, indicating how often you have each of the following.


a. Cough up blood
   1  2  3  4  5

g. Swollen joints
   1  2  3  4  5

b. Abdominal pain
   1  2  3  4  5

h. Feel faint
   1  2  3  4  5

c. Low-back pain
   1  2  3  4  5

i. Dizziness
   1  2  3  4  5

d. Leg Pain
   1  2  3  4  5

j. Breathless with slight exertion
   1  2  3  4  5

e. Arm or shoulder pain
   1  2  3  4  5

k. Palpitation or fast heart beat
   1  2  3  4  5

f. Chest pain
   1  2  3  4  5

l. Unusual fatigue with normal activity
   1  2  3  4  5

Further Details______________________________________________________
PART 3:  Health Related behaviour

8. Do you smoke?  Yes  No

9. If so, how many do you smoke a day:
   Cigarettes:  40 or more   20-39   10-19   1-9
   Cigars or pipes only:
   5 or more or any inhaled   Less than 5, none inhaled

10. How many units of alcohol do you consume each week?
(1 unit = ½ pint or 1 wine glass)
   21 or more   14-21   7-14   1-7   None

11. Do you exercise regularly?  Yes  No
   If yes, please give details

12. How many days a week do you accumulate 30 minutes of moderate activity?
   (activity which makes you slightly breathless)
   0  1  2  3  4  5  6  7  days per week

13. How many days per week do you normally spend at least 20 minutes vigorous exercise?
   (activity which makes you hot, sweaty and out of breath)
   0  1  2  3  4  5  6  7  days per week

14. Can you walk 4 miles briskly without fatigue?  Yes  No

15. Weight now: ____________  One year ago ____________
   Age 21 ____________
PART 4: Health Related Attitudes

16. Do you consider yourself?

<table>
<thead>
<tr>
<th></th>
<th>Impatient</th>
<th>Time Conscious</th>
<th>Competitive</th>
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<tbody>
<tr>
<td>1. Strongly agree</td>
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<td>2. Moderately agree</td>
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<td>3. Slightly agree</td>
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<td>5. Moderately disagree</td>
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<td>6. Strongly disagree</td>
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17. Do you have any other physical condition or injury that are not covered by the above questions? Yes  No

If yes, please give details: __________________________________________

18. How did you hear about this research ____________________________

I HAVE READ, UNDERSTOOD AND COMPLETED THIS QUESTIONNAIRE. ALL QUESTIONS HAVE BEEN ANSWERED TO THE BEST OF MY KNOWLEDGE.

Signature ___________________________ Date ________________

Signature of person if not a researcher ________________ Date ________________

Signature of Researcher ___________________________ Date ________________

This information will be kept on a confidential computerised database (in accordance with the Data Protection Act 1998).
C.2 Physical activity questionnaire


**Examples of Activities in Each Category**

**Moderate activity**

Occupational tasks: 1) delivering mail or patrolling on foot; 2) house painting; and 3) truck driving (making deliveries, lifting and carrying light objects).

Household activities: 1) raking the lawn; 2) sweeping and mopping; 3) mowing the lawn with a power mower; and 4) cleaning windows.

Sports activities (actual playing time): 1) volleyball; 2) Ping-Pong; 3) brisk walking for pleasure or to work (3 miles/hour or 20 minutes/mile); 4) golf, walking and pulling or carrying clubs

**Hard activity**

Occupational tasks: 1) heavy carpentry; and 2) construction work, doing physical labour

Household tasks: 1) scrubbing floors

Sports activities (actual playing time): 1) tennis doubles; and disco or folk dancing

**Very hard activity**

Occupational tasks: 1) very hard physical labour, digging or chopping with heavy tools; and 2) carrying heavy loads such as bricks and lumber

Sports activities (actual playing time): 1) jogging or swimming; 2) singles tennis; 3) squash; and 4) football
Now we would like to know about your physical activity during the past 7 days. But first, let me ask you about your sleep habits.

1. On the average, how many hours did you sleep each night during the last five weekday nights (Sunday-Thursday)? _____ hours

2. On the average, how many hours did you sleep each night last Friday and Saturday nights? _____ hours

Now I am going to ask you about your physical activity during the past 7 days, that is, the last 5 weekdays, and last weekend, Saturday and Sunday. We are not going to talk about light activities such as slow walking, light housework, or un-strenuous sports such as bowling, archery or darts. Please look at this list, which shows some examples of what we consider moderate, hard, and very hard activities. (Interviewer: allow subject time to read over the Examples of Activities in Each Category sheet.) People engage in many other types of activities, and if you are not sure where one of your activities fits, please ask me about it.

3. First, let's consider moderate activities. What activities did you do and how many total hours did you spend during the last 5 weekdays doing these moderate activities or others like them? Please tell me to the nearest half hour. _____ hours

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4. Last Saturday and Sunday, how many hours did you spend on moderate activities and what did you do? (Probe: Can you think of any other sports, job, or household activities that would fit into this category?) _____ hours

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<th>Type of activity</th>
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</table>
5. Now, let’s look at hard activities. What activities did you do and how many total hours did you spend during the last 5 weekdays doing these hard activities or others like them? Please tell me to the nearest half hour. _____ hours

<table>
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<tr>
<th>Type of activity</th>
<th>Duration of activity</th>
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</tbody>
</table>

6. Last Saturday and Sunday, how many hours did you spend on hard activities and what did you do? (Probe: Can you think of any other sports, job, or household activities that would fit into this category?) _____ hours

<table>
<thead>
<tr>
<th>Type of activity</th>
<th>Duration of activity</th>
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</table>

7. Now, let’s look at very hard activities. What activities did you do and how many total hours did you spend during the last 5 weekdays doing these very hard activities or others like them? Please tell me to the nearest half hour. _____ hours

<table>
<thead>
<tr>
<th>Type of activity</th>
<th>Duration of activity</th>
</tr>
</thead>
<tbody>
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<td></td>
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</tbody>
</table>

8. Last Saturday and Sunday, how many hours did you spend on very hard activities and what did you do? (Probe: Can you think of any other sports, job, or household activities that would fit into this category?) _____ hours

<table>
<thead>
<tr>
<th>Type of activity</th>
<th>Duration of activity</th>
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</table>
9. Compared with your physical activity over the past 3 months, was last week’s physical activity more, less, or about the same?

1. More   2. Less   3. About the same

Interviewer: Please list below any activities reported by the subject that you don’t know how to classify. Flag this record for review and completion.

Activity (brief description)  Hours: workday  Hours: weekend day

----------------------------------------  ----------  ----------
C.3 GP approval documents

C.3.1 24 week walking study

General Practitioner Form

*Strictly confidential*

Dear Dr

Your patient Mr (DOB ) has volunteered to participate in a randomised controlled study looking into the effect of 30 minutes of brisk walking on 5 days of the week on risk factors for Metabolic Syndrome and lipid metabolism. The experimental period is over 24-weeks (see table 1)

Table 1. Timescale for testing

<table>
<thead>
<tr>
<th>Experimental phase</th>
<th>Week</th>
<th>Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-walk assessment</td>
<td>0</td>
<td>• Walkers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Controls</td>
</tr>
<tr>
<td>Post-walk assessment</td>
<td>24</td>
<td>• Walkers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Controls</td>
</tr>
<tr>
<td>Post walk period (for those initially in the control group)</td>
<td>48</td>
<td>• Controls (ABW &amp; SBW)</td>
</tr>
</tbody>
</table>

The assessments include weight, height, BMI, body composition analysis, aerobic fitness (sub-maximal treadmill walking test), blood pressure, waist circumference, hip circumference and a fasted venous blood test. These tests will be performed in the Sport and Exercise Science Laboratory at Canterbury Christ Church University. The blood samples will then be analysed for blood lipids, glucose and fibrinogen.

Do you know of any reason why this patient should not participate in this study?

Please circle as appropriate Yes / No.

Name (block print)

Signed

Date

Please return this form in the SAE as soon as possible to Andrew Scott in the Department of Sport Science, Tourism and Leisure. If you have any questions please do not hesitate to contact me on (01227) 767700 ext. 3145

The NHS Executive funds this research
C.3.2 24 hour walking study

Dear Dr,

Your patient Mr (DOB) has volunteered to participate in a study investigating the effect of brisk walking intensity and duration on metabolic syndrome risk factors over a 24 hour period. Participants will be requested to visit the Sport and Exercise Science Laboratory at Canterbury Christ Church University on 5 occasions. The first visit will be a submaximal walking treadmill test. This will be used to prescribe the required intensities during the subsequent tests. The next 4 visits are part of the main study and their order will be randomised. One will involve walking at 45% aerobic capacity (VO2max) for 30 minutes, the 2nd at 65% VO2max for 30 minutes, the 3rd will be for 60 minutes at 45% VO2max and the 4th is the non-exercising control. Participants will be fitted with a patent cannula by a trained practitioner before each walk and this will be removed 4 hours post-walk. Participants will be observed throughout the period of the cannula being fitted.

The assessments include height, body mass, BMI, aerobic fitness (sub-maximal treadmill walking test), blood pressure, resting heart rate, resting metabolic rate and fasted venous blood samples. These tests will be performed in the Sport and Exercise Science Laboratory at Canterbury Christ Church University. The blood samples will then be analysed for blood lipids, glucose, fibrinogen and lipid enzymes.

Do you know of any reason why this patient should not participate in this study?

Please circle as appropriate  **Yes / No.**

Name (block print)

Signed Date

Please return this form in the SAE as soon as possible to Andrew Scott in the Department of Sport Science, Tourism and Leisure. If you have any questions please do not hesitate to contact me on (01227) 767700 ext. 3145.
Appendix D – Record diaries

D.1 Walking diaries

D.1.1 Accumulative sessions walking diary

Department of Sport Science, Tourism and Leisure, North Holmes Road, Canterbury, KENT CT1 1QU

Diary for accumulating 30 minutes of brisk walking per day programme

Participant name .................................................................
Participant number .............................................................

This diary is to be returned to Andrew Scott at the Department of Sport, Tourism & Leisure, Canterbury Christ Church University for analysis at the end of the walking programme.
Introduction

- Thank you for volunteering to take part in the brisk walking study. We are extremely grateful for your interest and hope that you will enjoy your involvement in the project.

- We aim to give you all the advice and support you need to enable you to complete the 24 weeks of the walking programme.

- We would be grateful if you could complete this daily physical activity diary and returned to us at the end of the 24 week period for analysis.

- The information contained in this booklet should help you out fill out the diary and inform you how to warm up, monitor your heart rate, cool down, and tell you what to do if you have any problems with your walking programme.

- There is a sheet for the post walking testing appointments at the back of the diary. It is essential for the success of the research that you attend the retesting appointments. If you have any problems regarding appointment dates or times please contact Andrew Scott as soon as possible.

- Your recommended heart rate range is recorded below. This is your specific range and determines your exercise intensity. This is intended only as a guide, however if your heart rate is 15 beats less or more than the recommended range on a regular basis please contact Andrew.

- TARGET HEART RATE taken over 15 seconds should be………………………….. beats.
Training programme for accumulative 30 minute brisk walking group

- Brisk walking sessions during each day should be **no less than five minutes** and **no more than 15 minutes**, e.g. three × 10 minutes or two × 15 minutes etc
  - Sessions outside of these limits may affect the overall results of the research
  - Additionally you must leave **at least 120 minutes** between each walking session

- The accumulated duration of brisk walking should ideally be **30 minutes per day** and this should be performed on **five days of the week**

- The weekly time expenditure for brisk walking should be **2.5 hours per week**

- During the walking programme you will be expected to walk in your own time

- Please remember to perform a warm up and a cool down each day (see p 5: Warming up & cooling down)
  - Performing a warm up prior to each session will not be practical due to the nature of this particular walking programme, therefore perform your warm up before your first session of each day and perform the cool down following the last session of the day
  - Warm up and cool down time should **not** count in the total walking time allocated

- Any readings such as heart rate and perceived exertion (Borg scale chart) should be for the **last minute** of brisk walking and not during the cool down

- Walking must be continuous and at a brisk pace, making you breathe more heavily and feel slightly sweaty

- Wear loose comfortable clothing and comfortable supportive footwear
• It is **important** to fill out your training diary after each session and to subjectively rate the intensity of each session using the Borg scale, e.g. *Monday, 30 mins, 12, and heart rate values*

• It is important for you to record your heart rate during the last minute of walking before your cool down (See p  7: *Heart rate monitoring*)

• Try to maintain your target heart rate while you are performing your brisk walking. Do not become overly concerned with your heart rate and record your value in the diary

• **Remember** to record the time spent walking, your heart rate (see page 7: *Heart rate monitoring*) and subjective intensity (see page 8: *Borg scale*) during the last minute of your brisk walking session

• If you find the recommended programme too much or you cannot keep to it for any reason please do not hesitate to contact Andrew. It is important for any problems or queries to be sorted out otherwise this may have an effect on the results of the project

• The programme is 24 weeks long, after which you will be retested as soon as possible

Andrew Scott (01227) 767700 x 3145 – CCCU
07909 586514 – mobile
Warming up and cooling down

- It is important that you warm up before you exercise and cool down afterwards
  - The warm up helps to prepare the body for exercise and reduces the risk of injury
  - Cooling down will help to reduce any stiffness and increase mobility

_The warm up_

- You should begin by either walking for 200 yards or march on the spot for two minutes
- While moving you should perform exercise 1, followed by exercise 2 as shown in the following diagrams
- Then stop and perform exercises 3-7 before commencing your walking session (hold each stretch for 8-10 seconds without bouncing)

_The cool down_

- After you have taken your heart rate during the last minute of brisk walking reduce your walking speed and perform exercises 1 & 2 again.
- Then stop walking and perform exercises 3-7 (hold these stretches for at least 20 seconds)
**Mobility & stretches for Warming up and cooling down**

**Warm up** – hold each stretch for 8-10 seconds. These are static stretches and do not involve bouncing.

**Cool down** – same as for warm up, but hold stretches for 20 seconds

<table>
<thead>
<tr>
<th>Exercise</th>
<th>Description</th>
<th>Diagram</th>
</tr>
</thead>
</table>
| 1. Shoulder shrugs | • While marching on the spot or walking 200 yards, raise both shoulders towards your ears and then lower  
• Repeat eight times | ![Diagram](image1) |
| 2. Shoulder rotations | • Still walking, rotate shoulders forwards, up, back and down  
• Repeat eight times | ![Diagram](image2) |
| 3. Calf stretch | • Now standing still. Stand with feet shoulder width apart, with the right foot forward and left foot behind  
• Lean forward so that right knee is directly over your right ankle and press your left heel into the ground with your toes facing forwards  
• Place hands on front leg | ![Diagram](image3) |
| 4. Hamstring stretch (Back of upper leg) | • From your position in stretch 3  
• Lean back onto your left foot and straighten your right leg  
• Your left leg should be bent  
• As you lean forward make sure your back is straight and tip your bottom up  
• Place hands on bent leg | ![Diagram](image4) |
| 5. Quadriceps stretch (front of upper leg) | • Standing on your right leg, bring your left knee up and grasp your left ankle with your hand  
• If you cannot reach use your trouser leg or heel of your shoe  
• Bring your left foot to your bottom, keeping your knees together  
• For balance lean against a wall or hold a chair *etc* | ![Diagram](image5) |
| 6. Repeat exercises 3-6 with your opposite leg | | |
| 7. Ankle mobility | • Standing on your right leg, extend your left leg and make clockwise circles with your foot then anticlockwise  
• Repeat with your other foot | ![Diagram](image6) |
Heart rate monitoring

- Turn your hand so that the palm is facing upwards
- Place the tips of your index and middle fingers towards the outside of the tendons that run down the centre of your wrist (closest to your thumb)
- Apply light pressure
- You may need to move your fingers either slightly up or down until you successfully find your pulse (measure of heart rate)
- Taking your own pulse effectively requires practice, therefore practice taking your pulse until you feel confident you can measure your pulse whilst walking
- When taking your pulse during walking it is best to count the first beat as zero and count the beats for a period of 15 seconds. Remember this number and record it in your walking diary
- Remain standing when taking your pulse at the end of the walk and do not sit down
Borg’s Rating of perceived exertion scale

6
7 — Very very light
8
9 — Very light
10
11 — Fairly light
12
13 — Somewhat hard
14
15 — Hard
16
17 — Very hard
18
19 — Very very hard
20
Training diary for *accumulative 30 minutes brisk walking group*

Name ................................................................. Age .................

<table>
<thead>
<tr>
<th>Official use only</th>
<th>Target HR range =</th>
<th>% HR_{max} =</th>
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</table>

**Week ……**

<table>
<thead>
<tr>
<th>Day</th>
<th>Date</th>
<th>Duration</th>
<th>Last minute HR</th>
<th>Borg scale</th>
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Target minutes walked per week = 150

Total minutes walked this week =

Target weekly HR =

Actual weekly HR =

Weekly comments


Exercise test information sheet

- In order for the results of your sub-maximal exercise test to be as accurate as possible it is essential that you follow certain guidelines prior to testing

- **On the day of your test:**
  - Do not exercise on the day prior to the testing
  - Do not drink any caffeinated drinks, e.g. tea or coffee
  - Do not drink alcohol 24 hours prior to testing
  - Do not eat anything after 7.00 PM the day before the assessment
  - You are encouraged to drink water

- **What to wear**
  - Rubber soled shoes, either trainers or comfortable walking shoes
  - Loose light clothing, preferably either shorts & T-shirt or track suit
  - **NB** – it is essential that we attach a heart rate monitor to your chest when testing, therefore relatively loose clothing is required

**Post-exercise test date**

Your post-24 week assessment will take place in the Sport and Exercise Science Laboratory at Canterbury Christ Church University at on …………………….AM on ………………………
D.1.2 Single session walking diary

Department of Sport Science, Tourism and Leisure, North Holmes Road, Canterbury, KENT CT1 1QU

Walking diary for one single 30 minute brisk walk per day programme

Participant name………………………………………………

Participant number…………………………………………

This diary is to be returned to Andrew Scott at the Department of Sport, Tourism & Leisure, Canterbury Christ Church University for analysis at the end of the walking programme.
Introduction

• Thank you for volunteering to take part in the brisk walking study. We are extremely grateful for your interest and hope that you will enjoy your involvement in the project

• We aim to give you all the advice and support you need to enable you to complete the 24 weeks of the walking programme

• We would be grateful if you could complete this daily physical activity diary and returned to us at the end of the 24 week period for analysis

• The information contained in this booklet should help you out fill out the diary and inform you how to warm up, monitor your heart rate, cool down, and tell you what to do if you have any problems with your walking programme

• There is a sheet for the post walking testing appointments at the back of the diary. It is essential for the success of the research that you attend the retesting appointments. If you have any problems regarding appointment dates or times please contact Andrew Scott as soon as possible

• Your recommended heart rate range is recorded below. This is your specific range and determines your exercise intensity. This is intended only as a guide, however if your heart rate is 15 beats less or more than the recommended range on a regular basis please contact Andrew

• TARGET HEART RATE taken over 15 seconds should be……………………………beats
Training programme for single 30 minute brisk walking group

- The duration of brisk walking should ideally be **30 minutes per day** and this should be performed on **five** days of the week

- The weekly time expenditure for brisk walking should be **2.5** hours per week

- During the walking programme you will be expected to walk in your own time

- Please remember to perform a warm up before and a cool down after each walking session (see warm up & cool down section)

  - Warm up and cool down time should **not** count in the total walking time allocated

- Any readings such as heart rate and perceived exertion (Borg scale chart) should be for the **last minute** of brisk walking and not during the cool down

- Walking must be continuous and at a brisk pace, making you breathe more heavily and feel slightly sweaty

- Wear loose comfortable clothing and comfortable supportive footwear

- It is **important** to fill out your training diary after each session and to subjectively rate the intensity of each session using the Borg scale, e.g. **Monday, 30 mins, 12 and heart rate values**

- It is important for you to record your heart rate approximately halfway through your walk as well as during the last minute of walking before your cool down (See section on ‘taking your heart rate’)

333
• Try to maintain your target heart rate while you are performing your brisk walking. Do not become overly concerned with your heart rate and record your value in the diary.

• **Remember** to record the time spent walking, your heart rate (see page 7: *Heart rate monitoring*) and subjective intensity (see page 8: *Borg scale*) at both halfway and during the last minute of your brisk walking session rates during each of your brisk walking sessions.

• If you find the recommended programme too much or you cannot keep to it for any reason please do not hesitate to contact Andrew. It is important for any problems or queries to be sorted out otherwise this may have an effect on the results of the project.

• The programme is 24 weeks long, after which you will be retested as soon as possible.

Andrew Scott (01227) 767700 x 3145 – CCCU
07909 586514 – mobile
Warming up and cooling down

- It is important that you warm up before you exercise and cool down afterwards
  - The warm up helps to prepare the body for exercise and reduces the risk of injury
  - Cooling down will help to reduce any stiffness and increase mobility

**The warm up**

- You should begin by either walking for 200 yards or march on the spot for two minutes
- While moving you should perform exercise 1, followed by exercise 2 as shown in the following diagrams
- Then stop and perform exercises 3-7 before commencing your walking session (hold each stretch for 8-10 seconds without bouncing)

**The cool down**

- After you have taken your heart rate during the last minute of brisk walking reduce your walking speed and perform exercises 1 & 2 again.
- Then stop walking and perform exercises 3-7 (hold these stretches for at least 20 seconds)
Mobility & stretches for Warming up and cooling down

Warm up – hold each stretch for 8-10 seconds. These are static stretches and do not involve bouncing.

Cool down – same as for warm up, but hold stretches for 20 seconds

<table>
<thead>
<tr>
<th>Exercise</th>
<th>Description</th>
<th>Diagram</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Shoulder shrugs</td>
<td>• While marching on the spot or walking 200 yards, raise both shoulders towards your ears and then lower&lt;br&gt;• Repeat eight times</td>
<td><img src="image1.png" alt="Diagram" /></td>
</tr>
<tr>
<td>2. Shoulder rotations</td>
<td>• Still walking, rotate shoulders forwards, up, back and down&lt;br&gt;• Repeat eight times</td>
<td><img src="image2.png" alt="Diagram" /></td>
</tr>
<tr>
<td>3. Calf stretch</td>
<td>• Now standing still. Stand with feet shoulder width apart, with the right foot forward and left foot behind&lt;br&gt;• Lean forward so that right knee is directly over your right ankle and press your left heel into the ground with your toes facing forwards&lt;br&gt;• Place hands on front leg</td>
<td><img src="image3.png" alt="Diagram" /></td>
</tr>
<tr>
<td>4. Hamstring stretch (Back of upper leg)</td>
<td>• From your position in stretch 3&lt;br&gt;• Lean back onto your left foot and straighten your right leg&lt;br&gt;• Your left leg should be bent&lt;br&gt;• As you lean forward make sure your back is straight and tip your bottom up&lt;br&gt;• Place hands on bent leg</td>
<td><img src="image4.png" alt="Diagram" /></td>
</tr>
<tr>
<td>5. Quadriceps stretch (front of upper leg)</td>
<td>• Standing on your right leg, bring your left knee up and grasp your left ankle with your hand&lt;br&gt;• If you cannot reach use your trouser leg or heel of your shoe&lt;br&gt;• Bring your left foot to your bottom, keeping your knees together&lt;br&gt;• For balance lean against a wall or hold a chair etc</td>
<td><img src="image5.png" alt="Diagram" /></td>
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<tr>
<td>6. Repeat exercises 3-6 with your opposite leg</td>
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<tr>
<td>7. Ankle mobility</td>
<td>• Standing on your right leg, extend your left leg and make clockwise circles with your foot then anticlockwise&lt;br&gt;• Repeat with your other foot</td>
<td><img src="image6.png" alt="Diagram" /></td>
</tr>
</tbody>
</table>
**Heart rate monitoring**

- Turn your hand so that the palm is facing upwards

- Place the tips of your index and middle fingers towards the outside of the tendons that run down the centre of your wrist (closest to your thumb)

- Apply light pressure

- You may need to move your fingers either slightly up or down until you successfully find your pulse (measure of heart rate)

- Taking your own pulse effectively requires practice, therefore practice taking your pulse until you feel confident you can measure your pulse whilst walking

- When taking your pulse during walking it is best to count the first beat as zero and count the beats for a period of 15 seconds. **Remember this number** and record it in your walking diary

- Remain standing when taking your pulse at the end of the walk and do not sit down
Borg’s Rating of perceived exertion scale

6
7 Very very light
8
9 Very light
10 Fairly light
11
12
13 Somewhat hard
14
15 Hard
16
17 Very hard
18
19 Very very hard
20
Training diary for *single* 30 minutes brisk walking group

Name ……………………………………………………………… Energy ………………

<table>
<thead>
<tr>
<th>Official use only</th>
<th>Target HR range =</th>
<th>% HR&lt;sub&gt;max&lt;/sub&gt; =</th>
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</thead>
</table>

Week ……

<table>
<thead>
<tr>
<th>Day</th>
<th>Date</th>
<th>Duration</th>
<th>Halfway HR</th>
<th>Last minute HR</th>
<th>Borg scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday</td>
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</table>

Target minutes walked per week = 150

Total minutes walked this week =

<table>
<thead>
<tr>
<th>Target weekly HR =</th>
<th>Actual weekly HR =</th>
<th>Weekly comments</th>
</tr>
</thead>
</table>

Week ……

<table>
<thead>
<tr>
<th>Day</th>
<th>Date</th>
<th>Duration</th>
<th>Halfway HR</th>
<th>Last minute HR</th>
<th>Borg scale</th>
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</table>

Target minutes walked per week = 150

Total minutes walked this week =

<table>
<thead>
<tr>
<th>Target weekly HR =</th>
<th>Actual weekly HR =</th>
<th>Weekly comments</th>
</tr>
</thead>
</table>
Exercise test information sheet

- In order for the results of your sub-maximal exercise test to be as accurate as possible it is essential that you follow certain guidelines prior to testing

- **On the day of your test:**
  - Do not exercise on the day prior to the testing
  - Do not drink any caffeinated drinks, e.g. tea or coffee
  - Do not drink alcohol 24 hours prior to testing
  - Do not eat anything after 7.00 PM the day before the assessment
  - You are encouraged to drink water

- **What to wear**
  - Rubber soled shoes, either trainers or comfortable walking shoes
  - Loose light clothing, preferably either shorts & T-shirt or track suit

**NB** – it is essential that we attach a heart rate monitor to your chest when testing, therefore relatively loose clothing is required

**Post-exercise test date**

Your post-24 week assessment will take place in the Sport and Exercise Science laboratory at Canterbury Christ Church University at on …………………….AM on ……………………………
D.2 Food diary

FOOD RECORD DIARY

Name: _____________________________________________ 

Dates:

Please complete the following one day weighed intake record. Your help is very much appreciated.

The following instructions may be useful:

• Do not change what you eat because it is easier to weigh, or choose ‘healthier’ foods than you would normally consume
• Record foods eaten at the time that you eat them
• Please give the most accurate description of the foods as possible
  (e.g. Heinz reduced salt and sugar baked beans)
• Include any comments and information about vitamin supplements etc that you feel are relevant in the notes section at the bottom of the sheet and on the back
• Please record all food wasted e.g. weigh the apple and then weigh the core and record both
• Use as many diet sheets as you need
• Please bring this sheet with you when you attend the laboratory
Feel free to contact Andy on 01227 767700 ext 3145 (office), 07909 586514 (mobile) or email ats5@cant.ac.uk if you have any problems.

Thank you.
Name:       Date:         /         /

Please use a separate line for each item eaten; leave a line between different meal entries.

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>Office Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>Brand name of each item (except fresh food)</td>
<td>Full description of each item including: -whether fresh, frozen, dried, canned -cooked: boiled, grilled, fried, roasted. -what type of fat food fried in</td>
<td>Weight served (gms)</td>
<td>Weight of leftovers (gms)</td>
<td>Actual Weight (gms)</td>
</tr>
<tr>
<td>am/pm</td>
<td></td>
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GENERAL COMMENTS:
Appendix E – Blood collection and analysis procedures

Blood collection

Whole blood was collected for the assessment of selected blood parameters as part of both of the main studies presented in this thesis (See sections 3.0 & 4.0). In the 24-hour walking study, blood was collected from a cannula placed in a forearm vein while the participants were in a semi-supine position and blood samples were collected after the participants rested >5 minutes. In the 24-week walking study and for the 24-hour post-walk assessment in the 24-hour walking study, blood was collected via venepuncture from an antecubital vein while the participants were in a seated position following >5 minute rest. The blood was collected into specific tubes for the formation of either plasma or serum and the blood was always collected into these tubes in a specific order. The serum tube was always the first to be used, which allowed the formation of serum. The second tube to be used to collect plasma was a tube containing sodium citrate. Sodium citrate was present in these tubes prior to use, which prevents clotting activity in the collected sample, and the tubes were completely filled to ensure a blood:sodium citrate ratio of 9:1. The third tube used to collect blood for the formation of plasma contained fluoride oxalate, which is a powder-form substance that prevents oxidative activity of the red blood cells contained in the sample tube, which maintains the integrity of the sample to prevent artificially low levels of substrates such as non-esterified fatty acids (NEFA) and glucose.
Blood analysis

Following the collection of the blood samples these were allowed to rest in an upright position prior to being centrifuged. The blood samples were centrifuged for 30 minutes at 2000 revolutions per minute at room temperature to facilitate the separation of plasma/serum from the red blood cells. Following centrifugation the plasma/serum rose to the top, which allowed these to be pipetted into smaller micro-tubes and these were closed with a screw top and placed in storage boxes in a -70°C freezer. The samples were frozen so that samples from the same participants could be analysed within the same series in order to reduce measurement error. The serum samples were analysed for total cholesterol (TC), triacylglycerol (TAG), high-density lipoprotein-cholesterol (HDL-C), insulin, cholesterol ester transfer protein (CETP) and lecithin-cholesterol acyltransferase (LCAT), the sodium citrate plasma samples were analysed for fibrinogen, and the fluoride oxalate plasma samples were analysed for glucose and NEFA. The biochemistry analysers were each calibrated prior to use and were checked for validity using at least low concentration quality control samples, with medium and high concentration quality control samples also used for insulin. The lipid transfer enzyme (CETP & LCAT) activity assays incorporated known concentrations into the stand curves from which the unknown research samples were calibrated to on each fluorimetry plate that was analysed and also acted as quality control.

The majority of the samples were analysed within the Sport and Exercise Biochemistry Laboratory, Department of Sport Science, Tourism and Leisure, Canterbury Christ Church University by the process of enzymatic colorimetry, including TC, TAG, HDL, glucose and NEFA. Serum LDL-C was calculated using the Friedewald equation (Friedewald et al., 1972), which retains accuracy providing that serum TAG is \( \leq 5 \text{ mmol·L}^{-1} \):
LDL-C = TC – HDL-C – (TAG/2.2)

The serum samples were analysed for insulin by the process of chemiluminescence in the Department of Clinical Biochemistry, Queen Elizabeth the Queen Mother Hospital, Margate, fibrinogen was assayed using the Clauss clotting technique (Clauss, 1957) in the Haemophilia Department, Kent and Canterbury Hospital, Canterbury and the lipid transfer enzymes (CETP & LCAT) were assayed using fluorimetry to determine the activity of these enzymes in the Department of Clinical Biochemistry, Queen’s University, Belfast.

Despite the various analyses being performed in different departments the principal researcher (A Scott) was present and involved in the processes of the assays. The samples were stored in a freezer within the Sport and Exercise Biochemistry Laboratory at Canterbury Christ Church University, therefore transportation of these samples was not an issue. The samples that were analysed at the other laboratories were placed in a polystyrene box along with frozen blocks and then placed in freezers on arrival at the respective laboratories. This procedure successfully retained the frozen status of the samples, since the samples remained frozen even following a six hour journey between Canterbury and Belfast. Prior to the samples being analysed or transported to the various laboratories they were arranged so that each participants’ samples could be analysed in series together. When the samples were ready to be analysed at their respective laboratories they were then placed on polystyrene racks and floated in 37°C water baths to allow the samples to gently defrost. Once the samples had defrosted they were inverted twice to decrease the effects of sedimentation and then transferred by pipettes into the appropriate measuring vessel for the various analysers that were used in the different laboratories. For the CETP and LCAT samples that were assessed in Belfast a micro-volume of serum was pipetted into the pre-mixed solution rather than an empty vessel as with the other assays.
At the Sport and Exercise Biochemistry Laboratory, CCCU, serum samples were analysed for TC, TAG, HDL-C and C-reactive protein (CRP) together in the same batches of samples, while glucose and NEFA were analysed together from the fluoride oxalate plasma samples. This procedure was a time-effective and successful method for analysing the TC, TAG, HDL-C, glucose and NEFA concentrations, however there were difficulties associated with the CRP immuno-assay. There were two separate issues for the two studies: it appeared that the standard curve calibrated correctly, however the levels could not be detected in the serum samples collected in the 24-week walking study, and; the calibration of the standard curve was instable due to a problem with the ‘blank’ solution, therefore <50 samples were analysed out of the available 260.

The analysis of the sodium citrate plasma samples for fibrinogen content was also a challenge. The principal researcher acquired the skills necessary to conduct enzyme-linked immuno-sorbent assays (ELISA), which in this case was a technique based on fibrinogen-specific immunoglobulins (antibodies). However, after many analyses of the ELISA plates it was determined that this particular assay over-estimated fibrinogen concentration, possibly due to a lack of specificity of the immunoglobulins. The process of discovering that the assay would not work took one month, however all of the samples were analysed within a single run in a morning using the clotting technique that was eventually used, which was based on the principle that the more quickly a solution incorporating the plasma samples clots the greater the concentration of fibrinogen. Conversely, there were no such problems associated with the insulin assays, conducted in the Department of Clinical Biochemistry, QEQM, Margate, or with the CETP and LCAT activity assays conducted at Queens University, Belfast. Insulin resistance and pancreatic insulin secretion were calculated from serum insulin and plasma glucose concentrations using the Homeostasis
Model of Assessment (HOMA); HOMA-IR and HOMA-β for insulin resistance and insulin secretion, respectively.

\[
\text{HOMA-IR} = \frac{\text{fasting serum insulin (} \mu \text{IU·mL}^{-1} \times \text{fasting plasma glucose (mmol·L}^{-1})}{22.5}
\]

\[
\text{HOMA-β} = \frac{\text{fasting serum insulin (} \mu \text{IU·mL}^{-1} \times 20 \text{/fasting plasma glucose (mmol·L}^{-1}) - 3.5}{\text{}}
\]

These indices of glucose homeostasis were used rather than being directly measured using techniques such as the hyperglycaemic/euglycaemic clamp techniques because specialised equipment is required to infuse and measure quantities of insulin and glucose entering the circulatory system. The majority of the samples collected in this thesis were fasting samples and infusing glucose may affect some of the other fasting parameters being measured and a greater degree of invasive measures would have been experienced by the participants with the glycaemic clamp technique. Furthermore, evidence suggests that these models for estimating insulin dynamics exhibit a high degree of validity compared to euglycaemic/hyperglycaemic clamps and oral glucose tolerance tests (Matthews et al., 1985).

In both of the walking studies it was also necessary to collect finger prick blood samples for the assessment of blood lactate at the end of the exercise tests in the pre- and post-walking assessments in the 24-week walking study and for the assessment of haematocrit and haemoglobin concentration to account for changes in plasma volume during the 24-hour walking study using the method of Dill & Costill (1974). Details of the analytical principles of each of the assays can be found in Appendix F.1.
Appendix F – Raw data analysis

F.1 Assay principles

F.1.1 Glucose assay method

Principle of the test

Enzymatic determination of glucose using the following reactions:

\[
\text{Glucose} + \text{O}_2 \xrightarrow{\text{Glucose oxidase}} \text{Glucose acid} + \text{H}_2\text{O}_2
\]

\[
2\text{H}_2\text{O}_2 + \text{Phenol} + \text{4AAP} \xrightarrow{\text{Peroxidase}} \text{Glucose acid} + \text{H}_2\text{O}_2
\]

\(\text{4AAP = 4-aminoantipyrine}\)

Materials

Reagent: Phosphate buffer, pH 7.40 13.8 mmol·L\(^{-1}\)

- Phenol 10.0 mmol·L\(^{-1}\)
- 4-aminoantipyrine 0.3 mmol·L\(^{-1}\)
- Glucose oxidase \(\geq 10,000\) U·L\(^{-1}\)
- Peroxidase \(\geq 700\) U·L\(^{-1}\)
- Sodium azide < 0.1 %

Calibrator (Multical)

Controls: N control and P control

Automated clinical chemistry analyser

Source

Glucose PAP kit insert provided by Horiba ABX Diagnostics, Cambridge, UK.
F.1.2 Cholesterol assay method

**Principle of the test**

Cholesterol enzymatic photometric test: Determination of cholesterol after enzymatic hydrolysis and oxidation. The colorimetric indicator is quinoneimine which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase.

\[
\text{Cholesterol ester} + \text{H}_2\text{O} \xrightarrow{\text{CHE}} \text{Cholesterol} + \text{Fatty acid}
\]

\[
\text{Cholesterol} + \text{O}_2 \xrightarrow{\text{CHO}} \text{Cholesterol-3-one} + \text{H}_2\text{O}_2
\]

\[
2\text{H}_2\text{O}_2 + \text{O}_2 + 4\text{-aminoantipyrine} \xrightarrow{\text{POD}} \text{Quinoneimine} + 4\text{H}_2\text{O}
\]

(CHE = Cholesterol esterase, CHO = cholesterol oxidase, POD = Peroxidase)

**Materials**

Reagent: Good’s buffer, pH 6.70 \(50.0 \text{ mmol·L}^{-1}\)

- Phenol \(5.0 \text{ mmol·L}^{-1}\)
- 4-aminoantipyrine \(0.3 \text{ mmol·L}^{-1}\)
- Cholesterol esterase \(\geq 200 \text{ U·L}^{-1}\)
- Glucose oxidase \(\geq 50 \text{ U·L}^{-1}\)
- Peroxidase \(\geq 3 \text{ kU·L}^{-1}\)
- Sodium azide \(< 0.95 \text{ g·L}^{-1}\)

Calibrator (Multical)

Controls: N control and P control

Automated clinical chemistry analyser

**Source**

Cholesterol kit insert provided by Horiba ABX Diagnostics, Cambridge, UK.
F.1.3 HDL-C assay method

**Principle of the test**

The method is based on accelerating the reaction of cholesterol oxidase (CO) with non-HDL-C unesterified cholesterol and dissolving HDL-C selectively using a specific detergent. In the first reagent, non-HDL-C unesterified cholesterol is subject to an enzyme reaction and the peroxide generated is consumed by a peroxidise reaction with DSBmT yielding a colourless product. The second reagent consists of a detergent capable of solubilising HDL-C specifically, cholesterol esterase (CE) and chromagenic coupler to develop colour for the quantitative determination of HDL-C.

\[
\text{HDL-C, LDL-C, VLDL-C, chylomicrons} \xrightarrow{\text{Accelerator + CO}} \text{Non-reactive LDL-C, VLDL-C, chylomicrons}
\]

\[
\begin{align*}
\text{HDL-C} & \xrightarrow{\text{HDL specific}} \text{HDL-C undisrupted} \\
& \xrightarrow{\text{DSBmT + peroxidase}} \\
\text{HDL-C} \xrightarrow{\text{Cholesterol esterase}} \Delta^4 \text{Cholestenone + H}_2\text{O}_2 \\
\text{H}_2\text{O}_2 + \text{DSBmT} + 4\text{-AAP} \xrightarrow{\text{Peroxidase}} \text{Colour development}
\end{align*}
\]

(4-AAP = 4-aminoantipyrine, CO = Cholesterol oxidase, DSBmT = N,N-bis(4-sulphobutyl)-m-toluidine-disodium)

**Materials**

Reagent: Good’s buffer, pH 6.70 50.0 mmol·L\(^{-1}\)
- Phenol 5.0 mmol·L\(^{-1}\)
- 4-aminoantipyrine 0.3 mmol·L\(^{-1}\)
- Cholesterol esterase \(\geq 200\) U·L\(^{-1}\)
- Glucose oxidase \(\geq 50\) U·L\(^{-1}\)
- Peroxidase \(\geq 3\) kU·L\(^{-1}\)
- Sodium azide < 0.95 g·L\(^{-1}\)

Calibrator (HDL-Cal)

Controls: N control and P control

Automated clinical chemistry analyser

**Source** HDL-C kit insert provided by Horiba ABX Diagnostics, Cambridge, UK.
F.1.4 Triacylglycerol assay method

**Principle of the test**

Enzymatic determination of triacylglycerol according to the following reactions:

\[
\text{Triacylglycerol} + \text{H}_2\text{O} \xrightarrow{\text{Lipoprotein lipase}} \text{Glycerol} + \text{fatty acids}
\]

\[
\text{Glycerol} + \text{ATP} \xrightarrow{\text{Glycerokinase}} \text{Glycerol-3-phosphate} + \text{ADP}
\]

\[
\text{Glycerol-3-phosphate} + \text{O}_2 \xrightarrow{\text{Glycerol-3-phosphate oxidase}} \text{H}_2\text{O}_2 + \text{DHAP}
\]

\[
2\text{H}_2\text{O}_2 + 4\text{-AAP} + \text{p-Chlorophenol} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + 4\text{H}_2\text{O}
\]

(DHAP = Dihydroxyacetone phosphate, 4-AAP = aminoantipyrine)

**Materials**

- Reagent: Pipes free acid 50.0 mmol·L\(^{-1}\)
- Sodium hydroxide 3.36 g·L\(^{-1}\)
- Triton X-100 1.0 mL·L\(^{-1}\)
- Magnesium salt 14.8 mmol·L\(^{-1}\)
- P-chlorophenol 2.69 mmol·L\(^{-1}\)
- ATP 3.14 mmol·L\(^{-1}\)
- Sodium azide 7.99 mmol·L\(^{-1}\)
- Potassium ferrocyanide 9.94 µmol·L\(^{-1}\)
- 4-aminoantipyrine 0.31 mmol·L\(^{-1}\)
- Lipoprotein lipase 1.90 U·L\(^{-1}\)
- Glycerokinasease 0.5050 kU·L\(^{-1}\)
- Glycerol phosphate oxidase \(\geq 4.15\) U·L\(^{-1}\)
- Peroxidase 0.4950 kU·L\(^{-1}\)
- Distilled water qs 1l·L\(^{-1}\)

Calibrator (Multical)

Controls: N control and P control

Automated clinical chemistry analyser

ABX Clean-chem (tip cleaner)

**Source**

Triacylglycerol kit insert provided by Horiba ABX Diagnostics, Cambridge, UK.
F.1.5 NEFA assay method  

**Principle of the test**  
The NEFA test kit utilises an *in vitro* enzymatic colorimetric method for the quantification of NEFA collected in serum and plasma samples.

\[
\text{RCOOH} + \text{ATP} + \text{CoA-SH} \xrightarrow{\text{ACS}} \text{Acyl-CoA} + \text{AMP} + \text{PPi} \\
\text{Acyl-CoA} + \text{O}_2 \xrightarrow{\text{ACOD}} 2,3\text{-trans-Enonyl-CoA} + \text{H}_2\text{O}_2 \\
2\text{H}_2\text{O}_2 + 4\text{-aminophenazone} + \text{MEHA} \xrightarrow{\text{POD}} \text{Quinoneimine-colour} + 4\text{H}_2\text{O}
\]

The intensity of the red pigment is proportional to the concentration of NEFA in the sample. Ascorbic acid is removed by ascorbate oxidase from the sample.

**Materials**

**Reagent 1:** Solvent A 65mL  
- Phosphate buffer, pH 6.9 50 mmol·L⁻¹  
- Magnesium chloride 3.0 mmol·L⁻¹  
- Surfactant  
- Stabilisers  
- Colour reagent A for 10 mL  
- Acyl-CoA-Synthetase 0.3 kU·L⁻¹  
- Ascorbate oxidase 3.0 kU·L⁻¹  
- Coenzyme A 0.6 g·L⁻¹  
- ATP 5.0 mol·L⁻¹  
- 4-aminophenazone 1.5 mmol·L⁻¹  
- Sodium azide 1.4 %

**Reagent 2:** Solvent B 130 mL  
- MEHA 1.2 mmol·L⁻¹  
- Surfactant  
- Colour reagent B  
- Acyl-CoA-Oxidase 6.6 kU·L⁻¹  
- Peroxidase 7.5 kU·L⁻¹  
- NEFA C standard solution 10 mL  
- Oleic acid (28.2 mg·dL⁻¹; 1 mmol·L⁻¹)

**Source**
NEFA-C kit insert provided by Wako Ltd, Neuss, Germany.
F.1.6 CRP assay method

C-reactive protein (CRP) is an acute phase protein whose concentration is seen to increase as a result of the inflammatory process, most notably in response to pneumococcal infections, histolytic disease and variety of other disease states. Originally discovered in 1930 in patient sera with acute infection, CRP has now come to be used as a marker of inflammation.

Principle of the test

When an antigen-antibody reaction occurs between CRP in a sample and anti-CRP antibody, which has been sensitised to latex particles, agglutination occurs. The agglutination is detected as an absorbance change, with the magnitude of the change being proportional to the quantity of CRP in the sample. The true CRP concentration of the sample is determined by interpolation from the calibration curve of known quantities.

Materials

Reagent 1: Buffer solution and Glycine buffer solution
Reagent 2: Latex suspension – 0.20% w/v suspension of latex particles sensitised with rabbit anti-CRP antibodies
Calibrators: NaCl solution (9 g·L$^{-1}$), 2.5 mg·L$^{-1}$, 10 mg·L$^{-1}$, 40 mg·L$^{-1}$, 80 mg·L$^{-1}$ and 160 mg·L$^{-1}$.
Control solutions (low/high controls)
Automated clinical chemistry analyser

Source

C-reactive protein kit insert provided by Horiba ABX Diagnostics, Cambridge, UK.

THE DATA FROM THIS ASSAY WAS NOT INCLUDED IN THE THESIS DUE TO PROBLEMS WITH THE ASSAY
F.1.7 Insulin assay method

**Principle of the test**

The Advia Centaur Insulin assay is a two-site sandwich immunoassay using direct chemiluminescent technology which uses constant amounts of two antibodies. The first antibody, in the Lite Reagent, is a monoclonal mouse anti-insulin antibody labelled with acridinium ester. The second antibody, in the Solid Phase, is a monoclonal mouse anti-insulin antibody, which is covalently coupled to paramagnetic particles. A direct relationship exists between the amount of insulin present in the patient sample and the amount of relative light units detected by the system.

The system automatically performs the following steps:

- Dispenses 25 µL of sample into a cuvette
- Dispenses 50 µL of Lite Reagent and incubates for 5 minutes at 37°C
-Dispenses 250 µL of Solid Phase and incubates for 2.5 minutes at 37°C
- Separates, aspirates, and washes the cuvettes with reagent water
- Dispenses 300 µL each of acid reagent and base reagent to initiate the chemiluminescent reaction

**Source**

Bayer Advia Centaur Insulin immunoassay kit insert provided by Bayer Healthcare, Diagnostics Division, Tarrytown, NY.
F.1.8 Fibrinogen assay method

**Principle of the test**

Thrombin is added to plasma, diluted with assay buffer, and the clotting time is measured, which is a modification of the Clauss clotting technique (Clauss, 1957). The test result of the ‘unknowns’ is compared with a pre-prepared calibration curve by clotting a series of 6 known plasma concentrations, reporting the result in g·L$^{-1}$. With the photo-optical method, increased fibrin formation results in a change in optical density, where the greater the formation the decreased light transmission and increased scattered light.

**Materials**

- Sysmex CA-1500, Sysmex UK Ltd, Milton Keynes, UK
- Coagulation low control, Technoclone, Surrey, UK
- Fibriquik Thrombin Reagent, Biomerieux, Hampshire, UK
- Owren’s veronal buffer, Dade Behring, Eschborn, Germany

**Source**

F.1.9 Fibrinogen ELISA method

**Principle of the test**

Microtitre plates are coated with antibodies obtained from rabbits directed against human fibrinogen, and dilutions of standard and test samples are added. After incubation, during which time fibrinogen within the plasma binds to the antibody, the plates are washed in buffer and a further HRP (horse radish peroxidase) conjugated antibody obtained from sheep directed against the human fibrinogen is added to the plate. After incubation, during which time the fibrinogen already bound to the rabbit antibody binds to the HRP conjugated antibody, the plates are washed in buffer. A substrate for peroxidase is added generating a blue colour, the greater the colour the more anti human rabbit antibody is bound to the fibrinogen present on the plate.

**Materials**

- 10-5000 µL pipettes and disposable tips
- Multi-channel pipette
- Microtitre 96 well plates - immunoglobulin G absorption plates (Maxi-sorp™, Nunc, Denmark)
- Distilled water
- 0.05M sodium carbonate buffer pH 9.6 – diluted 50:50 with distilled water
- ELISA buffer B (pH 7.2) – 5 L:
  - 146.1 g NaCl
  - 6.055 g Trizma base
  - 10 mL Tween 20
  - 1 g Thiomersal
  - Hydrochloric acid
  - Diluted with distilled water
- Capture antibody – polyclonal rabbit anti-human fibrinogen antibody (Dako, Denmark)
- Fibrinogen standard (2.85 g·L⁻¹) – diluted with 1 mL distilled water and allowed to dissolve for 15 minutes
- Fibrinogen low quality control
- Detection antibody – polyclonal sheep anti-human fibrinogen antibody with HRP conjugate (Biogenesis, Poole, UK)
- K-Blue (Skybio, Beds., UK) – ELISA reaction solution
- Sulphuric acid – reaction stop solution
- Spectrophotometer microplate reader (SPECTRAMax® 340, Molecular Devices, Sunnyvale, CA) & SOFTmax® PRO (Sunnyvale, CA) software for result calculation
Method
The wells of the plates were coated with 100 µL of the capture antibody, diluted 1:400 with the carbonate buffer, and incubated overnight at 4°C. Following the overnight incubation, the plates were emptied and each well was washed 3 times with 200 µL of ELISA buffer B using a 12-channel pipette. The fibrinogen standard curve was then constructed using ELISA buffer B for the following serial dilutions:

- 1:4,000 (5.70 g·L⁻¹)
- 1:6,000 (4.28 g·L⁻¹)
- 1:8,000 (2.85 g·L⁻¹)
- 1:12,000 (2.14 g·L⁻¹)
- 1:16,000 (1.43 g·L⁻¹)
- 1:24,000 (1.08 g·L⁻¹)
- 1:32,000 (0.72 g·L⁻¹)
- 100 % ELISA buffer B (0.00 g·L⁻¹)

The plasma samples to be analysed were diluted 1:8000 with ELISA buffer B. The standards and the samples were analysed in duplicate on the plate; the first 16 wells on each plate were used for the standards and the remaining wells were used for 40 samples in duplicate and the plates were incubated for 1 hour at room temperature.

The plates were then washed, as before, and 100 µL of the HRP conjugate, diluted 1:600 with ELISA buffer B, was added to each well of the plates to detect fibrinogen concentrations. The plates were again incubated for 1 hour at room temperature and then washed as before for a final time. The ELISA reaction was initiated by adding 100 µL of K-Blue and 15 minutes later this reaction was stopped using 100 µL of 1M sulphuric acid. The plates were then read by the plate reader at 450 nM and analysed using the Softmax Pro programme.

THE DATA FROM THIS ASSAY WAS NOT INCLUDED IN THE THESIS AND THE PREVIOUS PRO-THROMBIN TIME TECHNIQUE WAS USED INSTEAD.
F.1.10 Cholesteryl Ester Transfer Protein activity assay method

**Principle of the test**

CETP is present in normal human plasma and transfers neutral lipids from HDL-C to LDL-C and LDL-C during reverse cholesterol transport. The assay uses a proprietary substrate that enables the detection of CETP-mediated transfer of neutral lipid from the substrate to a physiological acceptor. The transfer activity results in an increase in fluorescence intensity.

**Materials**
- Fluorimeter
- 37 °C water bath/incubator
- Assay buffer (150 mM NaCl, 10 mM Tris, 2 mM EDTA, pH 7.4) – diluted 1:10 with distilled water
- Serum samples diluted 1:20 with assay buffer
- Donor particle
- Acceptor particle
- Black thermo electron U-bottom Microtitre plates

**Method**

The 1:20 dilution of the plasma samples (5 µL) were each combined with 4 µL of the donor particle and 4 µL of the acceptor particle, together with 187 µL of assay buffer, for a total volume of 200 µL per sample. The blank for the standard curve was prepared using µL of the donor particle and 4 µL of the acceptor particle, together with 192 µL of assay buffer. The standard curve was made using serial dilutions of the standard provided in the kit for 130, 65 pmoles·hr⁻¹, 32.5 pmoles·hr⁻¹, 16.3 pmoles·hr⁻¹, 8.1 pmoles·hr⁻¹ and 4.1 pmoles·hr⁻¹. Each sample (including standards) was prepared in duplicate on the microtitre plate, which was incubated at 37°C for 3 hours. The increase in the fluorescence of the samples were measured using the fluorimeter (excitation: 465 nm; 535 nm) and then subtracting the fluorescence of the blank from each sample and the results were reported in pmoles·hr⁻¹.

**Source**
CETP activity kit insert provided by Roar Biomedical Inc, New York, USA.
F.1.11 Lecithin-Cholesterol AcylTransferase activity assay method

**Principle of the test**

Lecithin-cholesterol acyltransferase (LCAT) mediates the formation of cholesteryl esters in human plasma. LCAT transfers an acyl chain from the sn-2 position of phosphatidylcholine to cholesterol.

**Materials**

- LCAT substrate reagent (240 µL) sufficient for 240 assays
- LCAT assay buffer (150 mM NaCl, 10 nM Tris, 1 nM EDTA, 4 mM 2-mercaptoethanol, pH 7.4)
- READ reagent – 1 mL concentrate X100

**Method**

The read reagent was reconstituted using 99mL of 150 mM NaCl, 10 nM Tris, 1 nM EDTA, pH 7.4. A cocktail with a ratio of 1 µL of LCAT substrate and 200 µL of assay buffer was mixed, and 201 µL of this solution was added to 5 µL of the 1:20 diluted serum samples. The sample cocktails were incubated at 37°C for 4 hours, and following this period 100 µL of each sample was added to 300 µL of the read reagent and vortexed. Each sample was added to the microtitre plate in duplicate and the standard curve was constructed using serial dilutions of the provided standard. The fluorescent labels were read at an emission intensity of 390 nm (hydrolysed substrate) and 470 nm (unhydrolysed substrate). The ratio (470/390nm) indicated the increase in concentration of hydrolysed substrate and a decrease in unhydrolysed substrate in proportion to the quantity of LCAT present in the sample.

**Source**

LCAT activity kit insert provided by Roar Biomedical Inc, New York, USA.
F.1.12 Blood lactate analysis method

**Principle of the test**
A 20 µL whole blood sample is collected from a finger prick into a capillary tube. The capillary tube is then placed into a 1.5 mL safe-lock microcentrifuge tube containing 1 mL of haemolysing solution. Lactate is determined with the aid of the enzyme electrode in the BIOSEN 5030 l according to the enzymatic amperometric principle of measurement. The measuring chamber, which is limited by the enzyme membrane, is located in the sensor block. The enzyme lactate oxidase (LOD) required for the determination of lactate is present in the membrane in an immobilised form. The measuring cycle begins with the lifting of the sample for aspiration. The lactate in the sample penetrates the measuring chamber during aspiration and encounters the immobilised LOD and is converted into pyruvate and hydrogen peroxide (H₂O₂). After diffusing through the secondary boundary layer of the membrane H₂O₂ is quantitatively determined using a platinum electrode sensor. After measurement, the sensor system is rinsed automatically and prepared for the next measurement.

**Materials**
- Softclix gun and lancets
- 20 µL capillary tubes
- Safe-lock microcentrifuge tubes
- Lactate standard (12 mmol·L⁻¹)

**Source**
Biosen 5030 L lactate analyser handbook, EKF Industrie-Elektronik GmbH, Madgeburg, Germany.
F.1.13 Haemoglobin method

Principle of the test

Whole blood was collected onto a measuring slide and inserted into the Hemocue photometer. The test follows the method of Vanzetti (1966), whereby sodium deoxycholate hemolyses the erythrocytes and haemoglobin is released. Sodium nitrite converts haemoglobin to met-haemoglobin which, together with sodium azide, gives azide-met-haemoglobin. The absorbance is measured at two wavelengths (570 & 880 nm) in order to compensate for the turbidity in the sample. The measuring range for the test is 0-256 g·L⁻¹ and linearity between 50-180 g·L⁻¹ and 181-256 g·L⁻¹.

Materials

Softclix gun and lancets

Hemocue microcuvettes, containing sodium deoxycholate, sodium nitrite, sodium azide and non-reactive ingredients.

Haemoglobin quality control (130 g·L⁻¹)

Hemocue photometer

Source

Hemocue photometer operating manual, HemoCue AB, Ängelholm, Sweden.

F.1.14 Haematocrit method

Principle of the test

The distribution of erythrocytes and plasma collected in a capillary tube is proportional to that in the whole body and can thus be measured using centrifugal force.

Method

A 40-60 mm of capillary blood was collected from whole blood into a 75 mm heparinised capillary tube. The end of the tube where the blood was collected was placed onto the plasticine tray to seal the end keep the blood in the tube during centrifugation. The tube was centrifuged for 2 minutes to allow the erythrocytes and the plasma to separate and then placed on to the reading plate for the percentage of erythrocytes to be determined manually.

Materials

Softclix gun and lancets (Accuchek, Roche Diagnostics GmbH, Germany & Kunststoff-Kapillaire, EKF Diagnostics, Germany, respectively)

Heparinised capillary tubes (Brand GMBH, Wertheim, Germany)

Cristaseal tray (Brand GMBH, Wertheim, Germany)

Hawksley microcentrifuge (LSI Ltd, Hants, UK)

Haematocrit reader (LSI Ltd, Hants, UK)

Source

Hawksley microcentrifuge operating manual, YSI Ltd, Hants, UK.
## F.2 Servomex spreadsheet

The calculation spreadsheet used to analyse the data gained from the Douglas bags via the Servomex.

<table>
<thead>
<tr>
<th>Expired air analysis</th>
<th>% O₂</th>
<th>% CO₂</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant</td>
<td>Vol(L)</td>
<td>Ex air Temp (°C)</td>
</tr>
<tr>
<td>Date</td>
<td>P H₂O =ROUND(E8<em>0.03783+6.25012+0.0264</em>E8^2,3)</td>
<td>Ve BTPS =E7/C13*60</td>
</tr>
<tr>
<td>Pb (mmHg)</td>
<td>Ve STP =ROUND(E10* ((C11-E9)/(760*(1+0.00367*E8))),3)</td>
<td>True O₂ =ROUND((100-E5-E6)*0.265-E5,3)</td>
</tr>
<tr>
<td>Collection time (secs)</td>
<td>True CO₂ =E6-0.04</td>
<td>RER =ROUND(E13/E12,3)</td>
</tr>
<tr>
<td>Body mass (kg)</td>
<td>VO₂ (L·min⁻¹) =ROUND((E11*E12)/100,3)</td>
<td>VO₂ (mL·kg⁻¹·min⁻¹) =ROUND((1000*E15)/C15,3)</td>
</tr>
<tr>
<td></td>
<td>VCO₂ (L·min⁻¹) =ROUND((E11*E13)/100,3)</td>
<td></td>
</tr>
</tbody>
</table>
Appendix G – Methodology

G.1 Walking measurement

G.1.1 Physical activity measurement: Walking diaries compared to accelerometry

Introduction

Physical activity has been considered to be a central factor in the aetiology, prevention and treatment of chronic diseases, particularly obesity, and in the 21st Century is increasingly being viewed as a complementary treatment to traditional medicine (Williams & Franklin, 2007). However, accurately measuring physical activity (PA) without participant self-report methods can require expensive equipment, such as doubly-labelled water, accelerometers, pedometers, and heart telemetry, which for large scale studies may be impractical and/or expensive. Therefore, many studies involving PA intervention may look to ‘paper and pencil’ methods such as PA diaries in order to quantify individual exercise volume, such as frequency, intensity and duration. The main criticisms of this method is that the individuals being tested become the measurement device, and as such the measures being recorded may not necessarily be as accurate compared to quantitatively measured PA. During certain intervention studies, such as this study, the variables of interest may primarily investigate PA data whereas other studies, such as the 24 week walking intervention in the next section, may primarily investigate health outcomes, such as blood pressure, insulin sensitivity and waist circumference in response to increased PA. Studies that primarily involve activity data need valid and reliable measurement techniques in order to satisfactorily assess the collected data. Studies that use physical activity as an intervention to improve health outcomes are not primarily concerned with activity measurement, however it is useful that this is monitored in some way. Therefore, depending on the particular study being carried out differing standards of activity
measurement may be deemed appropriate when evaluated in terms of study costs and practicality for the participants volunteering and taking part in such studies.

There are a number of methods available for monitoring activity levels, each involving various degrees of expense, validity & reliability, practicality and different levels of data. These include PA record diaries (Sallis et al., 1985), pedometry (Tudor-Locke et al., 2002), heart telemetry (Keytel et al., 2005), accelerometry (Crouter et al., 2006), indirect calorimetry (Ferrannini, 1988), global positioning systems (GPS) (Le Faucheur et al., 2007) and doubly-labelled water technique (Ainslie et al., 2003), however not only do these separate techniques use different measurement principles, they also record different units of measurement for PA, which need to be calculated into energy expenditure (kcals). Pedometers only quantify the number of steps taken and not the intensity, duration or type of PA, heart rate telemetry can be used to estimate energy expenditure, however the HR-VO2 relationship needs to be individually calibrated during an incremental exercise test, indirect calorimetry uses oxygen consumption to derive energy expenditure, however even portable online systems can be restrictive and expensive, GPS are useful for tracking exact ambulatory PA patterns for a number of people, including time taken to move a certain distance, and the doubly-labelled water technique is possibly the gold standard for assessing PA in free-living individuals, however it only measures gross activity and cannot measure the duration, intensity or frequency of PA. PA record diaries may be used to record the duration, intensity, frequency and type of PA, however they rely self-monitoring and reporting and accelerometry can be used to measure the duration and intensity of ambulatory activity without the need for participants to be directly involved in the measurement process, however purchasing large numbers of accelerometers can be expensive. Due to the expense and impracticality of some of the PA measurement
methods, record diaries are commonly used in PA interventions and record diaries as short as three days may predict weekly PA (Tudor Locke et al., 2005b). The two main advantages of motion sensors such as accelerometers are that they require no input from participants, as with PA diaries, and can measure the frequency, intensity and duration of ambulatory activity (Westerterp, 1999). Accelerometers are worn on the waist, near to the centre of gravity, and measure activity counts within epochs, where each epoch can be programmed to different durations – usually one minute – and the greater the number of activity counts recorded in each epoch the greater the PA level (Chen & Bassett, 2005).

Due to the accelerometer being an objective measure of PA it was selected as the criterion measure of PA to compare the walking diaries to in the present study.

A previous study of the relationship between PA determined by the Actigraph accelerometer used in this study and a PA diary determined that three days of activity were significantly correlated (\(r=0.51; P \leq 0.05\)). However, one of the differences between that study and the present study was that the record diary was used as the criterion measure (Sirard et al., 2000). A further study similar to the present study found that although there was a tendency for the PA diary to overestimate PA compared to accelerometer-determined PA, the criterion measure, the diaries provided “reasonable self-reported estimates of activity levels across a day” (Wickel et al., 2006). The difference between the methods appeared to be heteroscedastic in nature, where the greater the levels of PA that were performed the greater the difference between methods. These previous studies have investigated the relationship between record diary and accelerometer determined total free-living PA in cross-sectional studies rather than as tools to record increases in PA in an intervention study. In study 1 (section 3) in this thesis PA diaries were used to record walking activities, therefore the purpose of this study was to compare walking activities
self-reported by participants in record diaries to walking activities monitored using accelerometry in an intervention study to increase PA levels. Furthermore, the study also aimed to determine whether being instructed to perform single or accumulative patterns of walking would affect this relationship.
Method

Introduction
Thirty four males (age 56.2 ± 8.5 years; height 1.77 ± 0.06 m; mass 89.8 ± 10.8 kg) volunteered and gave their written informed consent to take part in the study, which was approved by the Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University (Appendix G.1.2). The participants were advised of the procedures (Appendix G.1.3) and then signed the informed consent form (Appendix G.1.4) and a pre-screening health questionnaire (Appendix C.1).

Procedures
Prior to the brisk walking interventions, height and mass were measured using a stadiometer and beam balance scales (both Seca, Hamburg, Germany) to the nearest 1 cm and 100 g, respectively. The participants were allocated into one of two groups by random number sequences. One group were required to complete their daily 30 min walking in one single brisk walking (SBW) session and the other group were instructed to accumulate brisk walking (ABW) in 3 × 10 min, or 2 × 15 min, sessions over the course of the day. The participants recorded their walking activities in a diary (APPENDIX H), which included: the date, duration, HR and rating of perceived exertion score (Borg 6-20 scale). The intensity of the walking was intended to be ≥65% HR_{max}, calculated by 220 \text{ beats-min}^{-1} \times 0.65. The participants monitored their heart rate during the walk using their radial pulse and recording for 15 sec, which was multiplied by 4 to derive \text{beats-min}^{-1}. Those in SBW recorded their HR half way through the 30 min period and again during the final min of the 30 min session (the mean of these was later recorded), whereas those in ABW recorded their HR only during the final minute of their shorter walks. In addition to the walking diaries, the participants were requested to wear an accelerometer (Model 7164, Manufacturing Technologies Inc, Shalimar, FL) on their right hip when they performed
their walking for a 7 day period in order to assess the accuracy of the information recorded in the diaries.

Statistical analysis
The data are presented as mean ± SD and were analysed using coefficient of variation, intra-class correlations, Pearson product-moment correlations and 95% limits of agreement.
Results

Full data

Walking frequency data

There were few differences in the number of sessions performed during the week recorded in the walking diaries compared with that measured with the accelerometers (Figure G1.1), despite there being a few exceptions. Mean walking frequency reported in the diaries was \( 6.84 \pm 3.01 \text{ sessions·wk}^{-1} \) compared with \( 6.46 \pm 2.87 \text{ sessions·wk}^{-1} \) recorded using the accelerometers.

![Figure G1.1](image_url)

**Figure G1.1**  The 95% limits of agreement for mean weekly walking sessions assessed by accelerometry vs. diaries
Walking volume data
The unexpected finding was that there was a strong tendency for the walkers to under-report their walking volume in the diaries compared to that recorded by the accelerometers, particularly in those who performed extra walking above the recommended 150 min·wk$^{-1}$. Mean walking volume recorded in the walking diaries was 147.17 ± 39.57 min·wk$^{-1}$ compared to 178.65 ± 82.97 min·wk$^{-1}$ measured using the accelerometers (Figure G1.2).

**Figure G1.2** The 95% limits of agreement for mean weekly walking volume assessed by accelerometry vs. diaries
Walking intensity data

There appeared to be little agreement between walking intensity assessed by accelerometry (counts per min) and HR or %HR$_{\text{max}}$, where both correlations appear to be poor (figures G1.3 & G1.4).

**Figure G1.3** The relationship between walking intensity assessed by accelerometry vs. diaries

**Figure G1.4** The 95% CIs for walking intensity assessed by accelerometry vs. diaries
ABW and SBW data

Walking frequency data

Generally there were little differences between walking sessions per week reported in the walking diaries and that measured using the accelerometers (Figure G1.5). However, as demonstrated by the tighter limits of agreement, the diaries were more accurate for recording the number of sessions performed by SBW in comparison to ABW when measured using the accelerometers. Mean walking sessions per week performed according to the diaries were 4.76 ± 0.96 sessions·wk\(^{-1}\) & 8.93 ± 2.90 sessions·wk\(^{-1}\) compared to 4.86 ± 1.22 sessions·wk\(^{-1}\) & 8.06 ± 3.18 sessions·wk\(^{-1}\) measured by the accelerometers in SBW and ABW, respectively.

Figure G1.5 The 95% limits of agreement for mean weekly walking sessions in ABW & SBW assessed by accelerometry vs. diaries: – SBW , – ABW
Walking volume data

The walking diaries tended to under-estimate weekly brisk walking volume in both walking patterns (Figure G1.6). Mean weekly walking volume performed according to the diaries were 153.95 ± 36.71 mins·wk\(^{-1}\) & 140.38 ± 42.23 mins·wk\(^{-1}\) compared to 175.23 ± 55.82 mins·wk\(^{-1}\) & 182.07 ± 105.15 mins·wk\(^{-1}\) measured by the accelerometers in SBW and ABW, respectively. Furthermore, the \(R^2\) values indicated that greater volumes of walking were associated with greater disagreement between measurement methods.

**Figure G1.6** The 95% limits of agreement for mean weekly walking volume in ABW & SBW assessed by accelerometry vs. diaries: – SBW , – ABW
Walking intensity data
The intensity data for the SBW and ABW sub-groups both demonstrate a similar pattern to the full data (Figure G1.7), with no discernible relationship between activity counts and \( \%HR_{\text{max}} \) for both groups.

Figure G1.7 The relationship between walking intensity assessed by accelerometry vs. diaries: – SBW, – ABW
Discussion

The purpose of this study was to compare the walking activities recorded in diaries and that collected using accelerometry and also whether single or accumulative patterns of daily walking affected this relationship. There were few differences in the number of sessions performed during the week recorded in the walking diaries compared with that measured with the accelerometers, despite there being a few exceptions. Mean walking frequency reported in the diaries was $6.84 \pm 3.01$ sessions wk$^{-1}$ compared with $6.46 \pm 2.87$ sessions wk$^{-1}$ recorded using the accelerometers. However, the unexpected finding was that far from over-reporting walking volume there was a strong tendency for the walkers to under-report their walking volume in the diaries compared to that recorded by the accelerometers, particularly in those who performed extra walking above the recommended 150 min wk$^{-1}$. Mean walking volume recorded in the walking diaries was $147.17 \pm 39.57$ min wk$^{-1}$ compared to $178.65 \pm 82.97$ min wk$^{-1}$ measured using the accelerometers. When the data was separated to distinguish between walking activity carried out by SBW and ABW, there appeared to be more pronounced differences between the diaries and the accelerometers for ABW, where participants did not fully report all of their walking that was recorded by the accelerometers, which was more pronounced as weekly walking volume increased.

The data for intensity were more difficult to analyse because neither HR nor $\%HR_{max}$ correlated with the activity counts recorded by the accelerometers and the intensity data for the SBW and ABW sub-groups both demonstrated a similar pattern to the full data, with no discernible relationship between activity counts and $\%HR_{max}$. Two conclusions may be draw from this: physiological measures of walking intensity are incompatible with activity counts or; participants were incorrectly palpating their pulse rate. Both of these
explanations are plausible, since there was a relatively narrow range of HR or $\%HR_{\text{max}}$ responses compared to a wider range of activity counts. Therefore, it may be speculated that some of the participants may have been a little inexperienced in self-monitoring their HR whilst walking and either over or under-estimating HR combined with economical HRs at higher activity counts and less economical HR at lower activity counts between participants may have lead to the lack of association between HR and activity counts.

For the diaries and accelerometers to be fully compared, and remove discrete measures of frequency, intensity and duration from the equation, the data recorded from each could be reported as kcal·wk$^{-1}$, which may help to clear up the apparent lack of agreement between measures indicated by the different units used to indicate intensity – counts·min$^{-1}$ and beats·min$^{-1}$ for accelerometers and diaries, respectively. In summary, despite the lack of agreement for measuring intensity between the walking diaries and the accelerometers, 7-day walking diaries are effective for encouraging study participants to adhere to a walking programme. However, the walking diaries appear to under-report actual walking volume more so as walking volume increases. Furthermore, recording accumulative walking volume during the day appears to be less well reported in the diaries relative to the accelerometers than reporting single daily sessions.
G.1.2 Research ethics committee proposal

FACULTY RESEARCH ETHICS COMMITTEE (FREC)
Request for Ethics Approval

For official use only

REC Protocol No: ..........................
Date rec'd: ..........................

APPLICATION FOR FREC APPROVAL

Please type your application. Remember that applications must be printed out, authorised, and then sent, with X copies, to the FREC office,

1. TITLE OF YOUR STUDY
The accuracy of self-recorded walking patterns in diaries compared with actual walking patterns measured by accelerometry

2. NATURE OF PROJECT
Studying the health and fitness benefits of a brisk walking intervention involves recruiting many participants and allowing them to perform the walking in their own time. Therefore, this precludes structured walking sessions led by an instructor and therefore the walking intensity and weekly volume must be recorded in diaries. This study aims to look the validity of trusting participants to accurately record their weekly brisk walking sessions when correlated with data recorded by the accelerometers (pedometer).

3. INVESTIGATORS
3a. Principal Investigator

Name: Andrew Scott

Post: Postgraduate research student
**Department:** Department of Sport Science, Tourism and Leisure

**Qualifications:** BSc(Hons.) Sport, Recreation & Physical Education  *with* Human and Applied Biology
- MSc Exercise Physiology
- Health/Fitness Instructor certified by the American College of Sports Medicine
- Phase IV instructor certified by the British Association of Cardiac Rehabilitation
- British Red Cross Trained First Aider

**Previous experience of Research on Human Subjects:**
- BSc final year dissertation - The influence of caffeine on endurance capacity
- MSc Thesis - The influence of carbohydrate–electrolyte solutions on performance and metabolism during intermittent high intensity exercise

**3b. Other investigators/collaborators** (please note their employer if they are not employees of CCCUC)
- Dr Kate Woolf-May
- Dr Ian Swaine

4. **TIMETABLE**

4a. **Intended start date:** April 2006

4b. **Projected date of project's submission:** July 2007

5. **RESEARCH SPONSOR / OTHER ORGANISATIONS INVOLVED**

If your study involves another organisation, please provide details. Evidence that the relevant authority has given permission will be needed (ie. a letter).

6. **OTHER REC APPROVAL**

6a. **Has the proposed study been submitted to any other reviewing body?** If so, please provide details.

   No

7. **PURPOSE OF THE STUDY**

   The purpose of the study is to investigate the validity of using walking diaries to record weekly brisk walking activity when compared to measurements taken from accelerometers.
8. STUDY DESIGN, METHODOLOGY AND DATA ANALYSIS
One group of participants will be asked to walk briskly for 30 minutes per
day in a single session on five days of the week for 24 weeks and a second
group will accumulate 30 minutes of brisk walking per day, i.e. 3 × 10 or 2
× 15 minute sessions. The participants will wear an accelerometer and fill
in a walking diary for seven consecutive days during two random periods
during the brisk walking intervention. The data collected using the
accelerometers will then be correlated with the data recorded by the
participants in their walking diaries. This will determine whether the
walking diaries are accurate measures of the walking that is being
performed, and whether there are any changes depending on which groups
the participants have been randomly allocated.

9. ETHICAL CONSIDERATIONS
Participants taking part in the study will be screened using a health
questionnaire and their GP’s permission will also be required to ensure that
they a suitable to take part and their data will be stored in lockable files.

10. SUBJECTS TO BE STUDIED
50 males

Number of volunteers:
Lower age limit: 40
Upper age limit: 65

11. SELECTION CRITERIA
Previously sedentary males aged 40–65 without cardiovascular disease,
diabetes or any disability that impairs walking.

12. RECRUITMENT
Through posters, media campaign and GP encouragement.

13. CONSENT
13a. How is consent to be obtained (attach copies of any information sheet(s)
and consent forms that will be used)?
Potential participants will be provided with written information about the
study and will fill in an informed consent form.

13b. Will the participants be from any of the following groups? (Tick as
appropriate.)
Children under 18
Children in care
Those with learning disability
Those suffering from dementia
Prisoners
Young Offenders (16–21 years old)
Those who could be considered to have a particularly dependent relationship with the investigator, eg those in care homes, students

Other vulnerable groups
How will you ensure that participants in the groups listed above are competent to consent to take part in this study? Please attach any correspondence to parents, guardians, carers, keyworkers etc.

13c. Are there any special pressures that might make it difficult for people to refuse to take part in the study (e.g. the potential participants are students or colleagues of the investigator)? How will you address this?
No

14. PARTICIPANT'S INVOLVEMENT: RISKS, REQUIREMENTS AND BENEFITS
This is a simple brisk walking study using previously sedentary males aged 40–65 who will be pre-screened for their health status prior to taking part. Therefore, the risk to participants is minimal. Participants are required to record their walking activity for 7 days in diaries and also to wear the accelerometer for 2 random 1 periods week during the study. The benefit to the participants is that they may improve their health-related fitness during the course of the study.

14a. What potential hazards, risks or adverse effects associated with the study?
None. See above.

14b. Does your study involves invasive procedures such as blood taking, muscle biopsy or drug administration?
No

If so, please provide details:

14c. Does your study involve genetic analysis or manipulation?
No

If so, please provide details,
14d. Please list the experience of the investigators in the use of these procedures.

14e. If medical devices are to be used on any subject, do they comply with the requirements of the Medical Devices Directives?

14f. Please describe how you would deal with any adverse reactions or untoward incidents.
This is an observational study involving minimal contact between the investigator and the participants, therefore no untoward situations are foreseen.

14g. Please name the locations or sites where the work will be done (room number, etc.)
Sport and Exercise Science Studio (AG50) and in the participants’ own time.

14h. Can women of child-bearing potential participate without significant risk?
N/A

14i. Can lactating women participate without significant risk?
N/A

14j. What is the potential for participants' suffering pain, discomfort, distress, inconvenience or changes to lifestyle as a result of participation?
Participants will suffer no pain, discomfort, distress or inconvenience and changes to their sedentary lifestyle will not be great.

14k. Will group or individual interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting? If so, please list these topics and explain how you will prevent, or respond to, volunteer discomfort.
No

14l. Is it possible that criminal or other disclosures requiring action (e.g. evidence of professional misconduct) could take place during the study? If yes, give details of what procedures will be put in place to deal with these issues. The information sheet should make it clear under which circumstances action may be taken by the researcher.
14m. Please describe any expected benefits to the research participant.
They will have their activity measured by two methods for a total of three weeks.

14n. What circumstances might lead a participant not continue with the study?
Lack of adherence to the walking programme in the first place.

14o. What circumstances might lead to termination of the study in part or as a whole?
None

15. FINANCIAL INCENTIVES, EXPENSES AND COMPENSATION
15a. Will travelling expenses be given? If so, an appropriate comment should be included on the Information Sheet
No

15b. Is any financial or other reward, apart from travelling expenses, to be given to participants? If yes, please give details and justification.
No

15c. Will the study result in financial payment or payment in kind to the department? Please specify, including the amounts involved.
No

15d. If this study is being carried out in collaboration with a pharmaceutical company or an equipment manufacturer, please give the name of the company and indicate what arrangements exist for compensating patients or healthy volunteers for adverse effects resulting from their participation in the study (The Committee is unlikely to approve protocols if the pharmaceutical company involved fails to confirm, in writing, that it abides by ABPI guidelines).

16. CONFIDENTIALITY, ANONYMITY AND DATA STORAGE
16a. What steps will be taken to ensure confidentiality? Give details of the anonymisation procedures to be used, and at what stage they will be introduced.
Participants will be recognized by a number and this will be introduced when their data are stored.
16b. Who will have access to the records and resulting data?

Myself and my supervisors, Dr Woolf-May and Dr Swaine will have access to the records and resulting data.

16c. Where, and, for how long, do you intend to store the consent forms and other records?

I intend to store the consent forms and other records in locked filing cabinets for the duration of the research.

17. INFORMATION SHEET AND CONSENT FORM
The information sheet for participants should be designed according to the given guidelines and submitted alongside this protocol. The standard consent form should also be used and submitted with the name of your project added. Details of how these documents should be used are provided in the guidelines for applicants.

The following, where applicable, are attached to this form (please tick):

- Participant Information Sheet
- Consent Form

AUTHORISING SIGNATURES

The information supplied above is to the best of my knowledge and belief accurate. I have read the notes to investigators and clearly understand my obligations and the rights of subjects/study participants, particularly in so far as to obtaining valid consent.

Signature of Principal Investigator

.......................................................... .................................................... ... ... Date............

Signature of Head of Department

.......................................................... .................................................... Date............

Communications about this application should be addressed to:
Name: Andrew Scott

Address: Department of Sport Science, Tourism and Leisure
Canterbury Christ Church University College
North Holmes Road
Canterbury
Kent
CT1 1QU

Telephone No: 01227 767700 ext. 3145

E mail: ats5@cant.ac.uk
VOLUNTEER INFORMATION FORM

The accuracy of self–recorded walking patterns in diaries compared with actual walking patterns measured by accelerometry

You are being invited to take part in a 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 others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Take time to decide whether or not you wish to take part.

What is the purpose of the study?
Studying the health and fitness benefits of a brisk walking intervention involves recruiting many participants and allowing them to perform the walking in their own time. This precludes structured walking sessions led by an instructor and therefore the walking intensity and weekly volume must be recorded in diaries. This study aims to look the validity of trusting participants to accurately record the weekly brisk walking sessions when correlated with data recorded by accelerometers (like pedometers).

Am I a suitable subject for this study?
The researchers are looking to recruit non–smoking males, aged 40 to 65 years of age, who are free of symptoms for heart disease and diabetes.

Do I have to take part?
Even if you are accepted onto the study, it is up to you to decide whether or not you wish to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw from the study at any time, and without giving a reason.
**Will I get any payment for taking part?**
Unfortunately, we do not have the funding to pay for your participation in the study or to reimburse you for travel costs to any of the tests.

**What will happen to me if I take part?**
If you decide that you would like to take part in the study, you will first undergo what is called 'pre-study screening'.

**Pre-study screening**
Before you can be accepted onto the study you will have to complete two forms. One of these forms will ask for details about your health and any medications that you are currently taking, and the other to determine your habitual physical activity levels. Once this information has been received you will be given an appointment.

**The study procedures**
You will be asked to walk briskly for 30 minutes per day, in a single session, on five days of the week for 24 weeks. You will be required to wear an accelerometer for seven consecutive days during two random weeks of the brisk walking intervention. The data collected using the accelerometers will then be correlated with the data recorded by the participants in their walking diaries. This will determine whether the walking diaries are accurate measures of the walking that is being performed, and whether there are any changes from week one through to week 24.

**How often will I have to be tested?**
You will be tested for seven consecutive days during two random weeks of the walking intervention. These will take place in your own time.

**What are the possible benefits of taking part?**
The benefits of taking part in this study are that you may improve your health-related fitness through brisk walking.

**Will taking part harm my health?**
During any physical activity or exercise, there is always a slight increased risk of a cardiac event or injury; and for those without underlying heart disease, the risks to health are extremely minimal. For instance, is has been reported that when testing large numbers of individuals, during 'all out' maximal exercise there were only 5 incidence for every 100,000 tests being carried out.

**What if something goes wrong?**
*If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it.*
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 strictly confidential. Furthermore, any collected data will be kept for the duration of the research and used even if you withdraw from the study.

What will happen to the results of the research study?
You will receive a copy of your own results from the study.

Who has reviewed the study?
The Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University, has reviewed this study.

Contact for Further Information
If you are interested in taking part in the study or require additional information. Please contact Andrew Scott on 01227 767700 x 3145 / 07909 586514 or ats5@cant.ac.uk

Thank you for reading this.
G.1.4 Informed consent document

Department of Sport Science, Tourism and Leisure
North Holmes Road, Canterbury, Kent CT1 1QU

If you have any queries please contact Andrew Scott on 01227 767700 x 3145

Participant Identification Number for this trial:

CONSENT FORM

The accuracy of self-recorded walking patterns in diaries compared with actual walking patterns measured by accelerometry

Please initial box

1. I confirm that I have read and understand the information sheet dated .........................□
   (version 1.) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time □
   without giving any reason, without my legal rights being affected.

3. I understand that any personal information that I provide to the researchers
   to be kept strictly confidential.

4. I agree to take part in the above study.

Name of Subject Date Signature

Name of Person taking consent Date Signature
(If different from researcher)

Researcher Date Signature

1 copy for the patient, 1 for researcher and 1 to be kept with subject’s notes
G.2 Ergospirometry validity and reliability

G.2.1.1 Validity and reliability of a sub-maximal walking test

Introduction
Tests of aerobic fitness (\( \dot{V}O_2_{\text{max}} \)) are routinely performed by sport and exercise scientists in health-related studies as well as scientific support for athletes. \( \dot{V}O_2_{\text{max}} \) is the greatest rate of oxygen consumption that can be taken in and used by the active musculature for the purposes of energy production and is expressed relative to body mass per minute (\( \text{mL} \cdot \text{kg}^{-1} \cdot \text{min}^{-1} \)) during weight-bearing exercise. The assessment of \( \dot{V}O_2_{\text{max}} \) is essential when diagnosing disease states (myocardial ischaemia) in conjunction with 12-lead electrocardiogram (Lauer et al., 2005), monitoring changes in participants’ health-related fitness and also prescribing exercise intensities. The ‘gold standard’ is the laboratory-based maximal test to exhaustion, however actual \( \dot{V}O_2_{\text{max}} \) tests involve exercising to exhaustion and may be inappropriate for the sedentary/low active population for reasons such as the test being terminated by the performer before they have attained their maximal effort, putting off participants from returning for follow-up assessment, or in rare circumstances, such tests may prove fatal (Willich et al., 1993). For these reasons maximal tests are usually only performed using athletes, with less active participants performing sub-maximal fitness tests to estimate \( \dot{V}O_2_{\text{max}} \) using sub-maximal measures (Bird et al., 1998).

Attainment of actual \( \dot{V}O_2_{\text{max}} \) is confirmed by certain criteria, including a ‘plateau’ in oxygen consumption despite an increasing workload (primary criterion), blood lactate [La\(^-\)] >7.9 mmol·L\(^{-1}\), an R value ≥1.15 indicating the degree of lactacidosis and/or the attainment of age-adjusted HR\(_{\text{max}}\), otherwise the maximal rate may only be deemed as peak oxygen consumption (\( \dot{V}O_2_{\text{peak}} \)) (Howley et al., 1995). However, the nature of \( \dot{V}O_2_{\text{max}} \) testing has created much debate (Myers et al., 1989; Noakes, 1997; Bassett & Howley, 1997; Noakes,
1998; Bergh et al., 2000) since the initial tests were developed (Taylor, 1944; Taylor et al., 1955) and there appears to be little consensus on the criteria for establishing that VO$_{2\text{max}}$ has been achieved (Shephard, 1984; Howley et al., 1995). Evidence also exists to suggest that there is a more profound learning effect with repeated maximal tests from untrained individuals rather than those who are trained (Bingisser et al., 1997). Evidently, if the ‘gold standard’ for VO$_{2\text{max}}$ testing is debatable, what does this indicate for tests that estimate VO$_{2\text{max}}$?

The majority of tests for the estimation of VO$_{2\text{max}}$ are based on the premise that during moderate intensity exercise the ‘fitter’ the individual the lower their heart rate response. There are a range of such tests – laboratory-based and field-based – using treadmills, cycles, steps or circuits. Laboratory-based submaximal tests include step tests and cycle ergometer tests, with the most simple tests involving the measurement of HR following a single stage, i.e. the Harvard step test (Brouha et al., 1943) and the Åstrand-Ryhming cycle test (Åstrand & Ryhming, 1954). Unfortunately, due to their simplicity tests of this nature are the most prone to estimation error. More elaborate tests include the multi-stage fitness test (‘Bleep’ test), involving several submaximal workloads (Ramsbottom et al., 1988). Field-based submaximal tests include the Cooper 12 minute walk/run test (Cooper, 1968) and the less vigorous shuttle walking test (Singh et al., 1992).

The submaximal test presently being studied involved walking on a treadmill at 3 mph for 10 min, where the gradient increased by 2.5% during each 2 min stage with oxygen consumption (VO$_2$) being measured in addition to heart rate (HR). The premise of the test is based on the work of Maritz et al. (1961), which involves measuring the HR-VO$_2$ response to graded moderate intensity exercise and then extrapolating this relationship up
to the participants’ age-predicted maximum heart rate (HR$_{\text{max}}$) (220-age). Using this method the lower the participants’ HR at a given VO$_2$, the greater the HR reserve for extrapolation up to the age-related maximum, therefore the greater their estimated VO$_{2\text{max}}$.

When measuring participants in an intervention it is crucial to limit measurement error from the test methodology and the equipment used in order to ensure that any differences are solely due to the fitness intervention. Sources of methodological error may occur from the assumptions that the test is based on, such as i) the essentially linear HR-VO$_2$ relationship, ii) homogenous HR$_{\text{max}}$ for all participants, iii) constant mechanical efficiency, and iv) limited inter-day variations in submaximal HR. The linear relationship of HR-VO$_2$ is over simplified because this relationship becomes curvilinear at very low, and towards maximal exercise, intensities (Davies, 1968), there is a heterogeneity of 8-12 beats·min$^{-1}$ in HR$_{\text{max}}$ between individuals (Miller et al., 1993) and day-to-day HR measurement variability can occur.

Even though VO$_2$ is measured during this protocol to account for variations in mechanical efficiency during walking, the process of extrapolation may still induce measurement error. Further error may also arise from equipment, such as HR telemetry devices, automated metabolic analysers or the exercise machine. However, the technology of HR telemetry has been greatly developed for more than 20 years and has been found to be highly accurate (Laukkanen & Virtanen, 1998; Achten & Jeukendrup, 2003; Foss & Hallén, 2005) and the same can also be said of metabolic analysis systems. The system used in the present study has been validated against the Douglas bag technique, with the only difference being that the data retrieval was more rapid (Rietjens et al., 2001; Carter & Jeukendrup, 2002), and
the speed and gradient of the treadmill that was used has also been validated (Appendix G.7.1).

Therefore, with the previous information in mind, and using a hybrid of the ‘Stanford’ submaximal test and the ‘Bruce’ protocol (American College of Sports Medicine [ACSM], 2000; p98), the purpose of this study was a) to validate a submaximal walking protocol for the estimation of $\text{VO}_2\text{max}$ when compared to the participants’ true $\text{VO}_2\text{max}$ values, and b) to determine whether there were variations in the estimation of $\text{VO}_2\text{max}$ between repeated submaximal tests.
Methods
Participant characteristics
Ten males (age 55.2 ± 5.92 years; height 1.75 ± 0.04 m; mass 89.9 ± 8.1 kg; WC 101.1 ± 7.7 cm) volunteered and gave their written informed consent to take part in the study, which was approved by the Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University (Appendix G.2.1.2). The participants were advised of the procedures (Appendix G.2.1.3) and then signed the informed consent form (Appendix G.2.1.4) and a pre-screening health questionnaire (Appendix C.1).

Procedures
Prior to the test the participants were requested to wear loose clothing and not to eat, or drink tea, coffee, or any caffeinated drink within 2 hours before the test; or to drink alcohol or exercise within the 24 hours prior to any of the tests. Drinking sufficient water was strongly advised. The test itself involved measuring the participants’ height and body mass were also measured and recorded. Height was measured to the nearest 1 cm using a stadiometer (Seca, Hamburg, Germany) and body mass was measured to the nearest 100g using beam balance scales (Seca, Hamburg, Germany). WC was measured using a self-tightening tape (Seca, Hamburg, Germany). The study involved two tests, which were performed on a motorised treadmill (Mercury Med., HP Cosmos, Nussdorf-Traunstein, Germany) and the participants were informed that the test would start off at a low intensity and then increase to a jog/run as the test progressed. The protocol for the treadmill tests is shown in table G2.1.
Table G2.1: Treadmill test

<table>
<thead>
<tr>
<th>Test</th>
<th>Stage</th>
<th>Speed (mph)</th>
<th>Grade (%)</th>
<th>Time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUB</td>
<td>One</td>
<td>3.0</td>
<td>2.5</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Two</td>
<td>3.0</td>
<td>5.0</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Three</td>
<td>3.0</td>
<td>7.5</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Four</td>
<td>3.0</td>
<td>10.0</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Five</td>
<td>3.0</td>
<td>12.5</td>
<td>2</td>
</tr>
<tr>
<td>MAX</td>
<td>Six</td>
<td>3.4</td>
<td>14.0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Seven</td>
<td>4.2</td>
<td>16.0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Eight</td>
<td>5.0</td>
<td>18.0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Nine</td>
<td>5.5</td>
<td>20.0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Ten</td>
<td>6.0</td>
<td>22.0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Eleven</td>
<td>6.5</td>
<td>24.0</td>
<td>3</td>
</tr>
</tbody>
</table>

The participants wore a chest strap to be used to monitor HR with a radio-telemetry system (Polar Beat, Polar Electro OY, Finland) and a facemask for the collection of expired gases using an automated metabolic analyser (Oxycon-Pro, Jäeger, Würzburg, Germany). HR and VO₂ were recorded every 5 sec during the test and RPE (Borg 6-20; Borg, 1982) was recorded at the end of each stage. No warm up was required because of the relatively low intensity of the first stage and the gradual nature of the test. The shaded area (stages 1-5) in table 1 indicates the sub-maximal walking test (SUB), which all of the participants completed. The maximal component of the test occurred from stage 6 onwards (MAX), where the participants were expected to perform until volitional exhaustion. Using the HR-VO₂ relationship collected during the sub-maximal component (SUB) this was extrapolated up to the participants’ age predicted maximum heart rate (220 beats·min⁻¹·age) to estimate VO₂max (Maritz et al., 1961).

Actual VO₂max following MAX was calculated from the mean values taken during the final minute of exercise before volitional exhaustion. On termination of each test, a finger prick blood [La⁻] sample was collected using a Softclix lancet gun (Accuchek, Roche Diagnostics GmbH, Germany) and collected in two 20μL capillary tubes (Kunststoff-Kapillaire, EKF Diagnostics, Germany) and analysed using a Biosen 5030L (Industrie-Elektronik GmbH,
Madgeburg, Germany). These procedures were then completed on a second occasion and the results from the two tests were compared (SUB 1 & 2 and MAX 1 & 2).

**Statistical analyses**

The data are presented as mean ± SD and were analysed using Pearson product-moment correlations, 95% confidence intervals (95% CI), 95% limits of agreement (95% LoA), coefficient of variation (CV) and intraclass correlation coefficients (ICC).
**Results**

**Validity**

Figure G2.1 indicates that for 9 out of the 10 participants, SUB over-estimated \( \bar{V}O_{2\text{max}} \) and the line of best fit was at the upper-most level of the 95% CIs. However, despite the over-estimation of \( \bar{V}O_{2\text{max}} \) by SUB this appeared to be systematic as evidenced by the strong ICC \((r=0.852)\) and the parallel slope of the line of best-fit to the line of equality.

![Figure G2.1](image)

**Figure G2.1**  The 95% CIs for \( \bar{V}O_{2\text{max}} \) from SUB and MAX
The mean values for SUB and MAX were $35.92 \pm 3.90$ & $32.75 \pm 3.93$ mL·kg$^{-1}$·min$^{-1}$ respectively (Figure G2.2), where mean $\text{VO}_{2\text{max}}$ was over-estimated using SUB by a mean $3.16 \pm 4.17$ mL·kg$^{-1}$·min$^{-1}$ (9.65% of the MAX value) compared to MAX. The 95% LoA indicate that for the whole population this discrepancy may be up to $-7.54$ mL·kg$^{-1}$·min$^{-1}$ more than attained during a maximal test.

**Figure G2.2**  The 95% limits of agreement for $\text{VO}_{2\text{max}}$ between SUB and MAX.
Table G2.2: $\dot{V}O_{2\text{max}}$ criterion attained during MAX 1

<table>
<thead>
<tr>
<th>Criterion met</th>
<th>VO$_2$ plateau</th>
<th>RER</th>
<th>HR$_{\text{max}}$</th>
<th>[La$^-$]</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>8</td>
<td>9</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

Table G2.2 demonstrates the criterion for the attainment of $\dot{V}O_{2\text{max}}$. The participants were deemed to have achieved their ‘apparent’ $\dot{V}O_{2\text{max}}$ if their VO$_2$ plateaued, their RER reached ≥1.15, their HR$_{\text{max}}$ was within ≤10 beats·min$^{-1}$ of their age-predicted HR$_{\text{max}}$ or their [La$^-$] was >7.9 mmol·L$^{-1}$. The mean value for actual HR$_{\text{max}}$ following MAX 1 was 164.3 ± 9.0 beats·min$^{-1}$ compared to 164.8 ± 5.9 beats·min$^{-1}$ for predicted HR$_{\text{max}}$. Mean RER was 1.21 ± 0.06 and mean [La$^-$] was 8.14 ± 1.41 mmol·L$^{-1}$, ranging from 6.03 to 10.61 mmol·L$^{-1}$. 
Reliability

The estimated $\dot{V}O_{2\text{max}}$ values from SUB 1 & SUB 2 were $35.92 \pm 3.90$ & $35.36 \pm 4.24$ mL·kg$^{-1}$·min$^{-1}$ respectively (Figure G2.3), indicating that the submaximal test has strong repeatability, with an intraclass correlation of 0.974 and a relatively low CV of $1.80 \pm 1.41\%$. The 95% confidence intervals were also relatively tight, indicating little variation between tests.

![Figure G2.3](image)

**Figure G2.3** The 95% CIs for the test-retest reliability of SUB
The values for the repeated MAX tests were 32.75 ± 3.93 & 32.77 ± 3.64 mL·kg\(^{-1}\)·min\(^{-1}\) (figure G2.4), with a mean CV of 0.93 ± 0.64%, indicating that MAX was slightly more reliable than SUB (CV = 1.80 ± 1.41%).

**Figure G2.4** The 95% CIs for the test-retest reliability of MAX
Discussion

The aims of the study were to determine the accuracy of a submaximal walking test for the estimation of $\dot{V}O_{2\max}$ and also the reliability of these estimated measures. The data suggests that although SUB systematically over-estimated $\dot{V}O_{2\max}$ by $3.16 \pm 4.17$ mL·kg$^{-1}$·min$^{-1}$, SUB estimated similar $\dot{V}O_{2\max}$ values ($35.92 \pm 3.90$ vs. $35.36 \pm 4.24$ mL·kg$^{-1}$·min$^{-1}$) when SUB was repeated. Furthermore the CV between SUB 1 and SUB 2 ($1.80 \pm 1.41\%$) was only marginally greater than that between MAX 1 and MAX 2 ($0.93 \pm 0.64\%$). The mean difference between the SUB 1 values and the MAX 1 values was $9.65\%$, and was as could be expected since the deviation between actual and predictive tests may be up to $10\%$ (Shephard, 1984). In well-performed $\dot{V}O_{2\max}$ tests the maximum intra-individual variation has been reported to be between 4-6% (Shephard, 1984), which indicates the relative strength of the test-retest reliability not only for the MAX ($0.93 \pm 0.64\%$) but also for SUB ($1.80 \pm 1.41\%$).

Figure G2.1 indicated that for 9 out of the 10 participants, SUB over-estimated $\dot{V}O_{2\max}$ and the line of best fit is at the upper-most level of the 95% CIs. However, despite the over-estimation of $\dot{V}O_{2\max}$ by SUB this appears to be systematic as evidenced by the strong ICC ($r=0.852$) and the slope of the line of best-fit in comparison with the line of equality. The 95% LoA were particularly large between SUB and MAX (Figure G2.2), which may have been due to the relatively small sample size ($n=10$) and thus it may be speculated that the 95% limits of agreement may have been closer to the overall mean value if more than 10 participants had been studied. The main reasons for choosing the present submaximal test were that it was used to assess changes in $\dot{V}O_{2\max}$ and to prescribe exercise intensity when investigating the acute and chronic effects in walking studies. The SUB test is also useful because it should remove any motivational issues from the particular ‘low active’ population that was recruited and also to minimise potential health risks associated with
higher intensity tests. For those participants taking part in the maximal test they all appeared to reach their ‘apparent’ $\dot{V}O_{2\text{max}}$ without any undue distress or after-effects, however it cannot be presumed for sure that this would have been the case for all participants in the related studies.

As expected from the physiological responses to exercise of increasing intensity until maximal exercise capacity, SUB slightly over-estimated $\dot{V}O_{2\text{max}}$ in comparison to MAX, possibly due to an inaccurate premise because the data in table 2 indicates that they achieved their ‘apparent’ $\dot{V}O_{2\text{max}}$ during the MAX test. The premise most in question is the essentially linear relationship between HR and $\dot{V}O_2$ during exercise of increasing intensity. In reality the relationship becomes more curvilinear towards $\dot{V}O_{2\text{max}}$ and plateaus rather than continuing to increase linearly until exhaustion. However, even though maximal $\dot{V}O_{2\text{max}}$ tests are considered the ‘gold standard’, there is much criticism since there is equivocal evidence to demonstrate that a plateau in oxygen consumption exists during maximal exercise intensity (Hill & Lupton, 1924; Noakes 1988; Day et al., 2003), thus it is still debatable whether to accept the MAX score as valid. The ‘plateau’ phenomenon was proposed by Hill & Lupton (1924) and has become dogma since this time, despite not being fully substantiated. The possible alternatives for this are that the plateau is due to methodological error, with the exerciser merely reaching steady state rather than being taken to absolute maximum (Noakes, 1997) or due to the sampling rate (Myers et al., 1989; Myers et al., 1990). Low sampling rates can produce a plateau effect whereby the rate of change in $\dot{V}O_2$ is transiently negative and predominantly due to tidal volume variation. In the present study the plateau in $\dot{V}O_2$ was generally apparent for $\geq$30 seconds before volitional exhaustion.
For many people $\dot{V}O_{2\text{max}}$ might be an elusive quantity, thus not providing an adequate index of cardiorespiratory function (Noakes, 1988), making the interpretation of $\dot{V}O_{2\text{max}}$ tests is not straightforward, with studies showing those achieving a plateau are reported to be 90-100%, 60-80% and even as little as $\leq$50% of participants (Howley et al., 1995). Therefore, a variety of factors must be considered, including the specific population being studied, the protocol and also motivation to perform. These considerations have led researchers to use secondary criteria for establishing $\dot{V}O_{2\text{max}}$ in the absence of a plateau. The variety associated with predicted HR$_{\text{max}}$ makes it an awkward criterion for establishing $\dot{V}O_{2\text{max}}$, maximally and submaximally. Taylor et al., (1955) proposed a limit for the plateau in $\dot{V}O_2$ of $\leq$2.1 mL·kg$^{-1}$·min$^{-1}$ (150 mL·min$^{-1}$) for the participants in their classic study, which had a similar protocol in terms of time and gradient at each stage to the present study, with the exception that their test was discontinuous.

The mean $3.16 \pm 4.17$ mL·kg$^{-1}$·min$^{-1}$ difference between estimated and maximal values in this study is not that much greater than the 2.1 mL·kg$^{-1}$·min$^{-1}$ maximum increase in $\dot{V}O_2$ required for a ‘plateau’. This suggests that the majority of the error of the HR-$\dot{V}O_2$ extrapolation may come from the disparity between the linear prediction and the curvilinear nature of $\dot{V}O_2$ during progressive exercise until exhaustion. Evidence of attaining a valid $\dot{V}O_{2\text{max}}$ in most participants is presented in Table G2.2, which indicates that a lack of motivation on the part of the participants was generally not the cause of the lower $\dot{V}O_{2\text{max}}$ values compared with the estimated values. Ten participants achieved a plateau in VO$_2$, indicated by a lack of rise in VO$_2$ for 4 consecutive 5 sec measurements, 8 achieved an RER $\geq$1.15, 9 were within $\leq$10 beats·min$^{-1}$ of the predicted HR$_{\text{max}}$ prior to volitional exhaustion and only 5 participants attained a [La$-$] $>$7.9 mmol·L$^{-1}$ at exhaustion (Table 2). The failure of 50% of the participants to achieve satisfactory [La$-$] is not just
confined to the findings of the present study. In fact, previous tests of a continuous nature have failed to elicit the \(7.9 \text{--} 8.8 \text{ mmol·L}^{-1}\) criterion standard in some participants, with \([\text{La}^-]\) responses ranging from 4.9 to 10.0 mM (Howley et al., 1995). The variety in attaining these criteria by each participant provides further evidence to the controversy regarding the achievement of \(\text{VO}_2\text{max}\) rather than a \(\text{VO}_2\text{peak}\).

From a study of the pattern of \(\text{VO}_2\text{max}\) criteria during maximal tests, Duncan et al. (1997) concluded that a combination of RER and \([\text{La}^-]\) are sufficient for defining \(\text{VO}_2\text{max}\) due to the plateau effect rarely being observed. Furthermore, following Noakes’ (1988; 1997) criticisms of the \(\text{VO}_2\) plateau, Snell et al. (2007) compared the \(\text{VO}_2\text{max}\) values from graded maximal tests to \(\text{VO}_2\) values gained during supramaximal exercise. The findings were that despite the supramaximal intensity, and thus an apparent increase in \(\text{VO}_2\) demand beyond \(\text{VO}_2\text{max}\), the actual \(\text{VO}_2\) values for the two tests were similar (63.3 ± 6.3 mL·kg\(^{-1}\)·min\(^{-1}\) & 62.9 ± 6.2 mL·kg\(^{-1}\)·min\(^{-1}\), for maximal & supramaximal, respectively) indicating an upper limit for \(\text{VO}_2\).

Ramped protocols, i.e. more frequent small increments in intensity, are gaining in popularity, replacing the Bruce protocol, to provide greater measurement sensitivity (Myers & Bellin, 2000). The ‘Bruce’ protocol is a commonly used exercise stress test, however the choice of appears to make little difference providing that an increase in gradient is involved in untrained individuals (Kang et al., 2001). This was not the case for trained individuals, where a running protocol with small increments in gradient was considered most effective for eliciting \(\text{VO}_2\text{max}\). Indeed, Paavolainen et al. (2000) found that although maximal velocity was greatest when a \(\text{VO}_2\text{max}\) test was performed on a treadmill.
at $0^\circ$ in endurance trained athletes, $VO_{2\text{max}}$ and $[La^-]$ values were significantly greater when the same incremental test was performed at $7^\circ$.

Speculation for the elevated $VO_{2\text{max}}$ values following uphill running suggests that increased muscle mass activation and/or altered efficiency with increasing gradient (Paavolainen et al., 2000). In contrast, Kasch et al. (1986) have previously noted that at fast running speeds, $VO_{2\text{max}}$ values were not significantly different following an incline test (I) or a horizontal test (H), however the mean running speed in the incline test was only marginally less than for the horizontal test indicating that exhaustion may have occurred before sufficient gradient could be reached to attain $VO_{2\text{max}}$, with little data provided to substantiate attainment of $VO_{2\text{max}}$ with mean maximal respiratory quotient values of only $1.09 \pm 0.03$ for I and $1.07 \pm 0.03$ for H.

The ‘Bruce’ protocol is one of the most widely used maximal tests with $VO_{2\text{max}}$ usually derived from the final stage achieved rather than measured $VO_2$, however $VO_2$ was measured in this study to improve accuracy because mechanical efficiency may vary by 10% during treadmill exercise (Shephard, 1984). Maritz et al. (1961) were one of the first groups to utilise the HR-$VO_2$ relationship in order to extrapolate this to $VO_{2\text{max}}$ and found that there was a 6% underestimation of $VO_{2\text{max}}$ values. Estimated $VO_{2\text{max}}$ can often show systematic error of up to 10% (Shephard, 1984). Myocardial workload greatly increases during near maximal due to alterations in blood flow, such as increased afterload, increased preload and increased myocardial contractility (Shephard, 1984). In older participants submaximal tests may over-estimate $VO_{2\text{max}}$ due to age-related difficulties in maintaining stroke volume and thus increasing HR disproportionately to $VO_2$. 

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Macsween (2001) performed a similar study to this one investigating the Åstrand-Ryhming nomogram for estimating VO$_{2\text{max}}$ compared with the Bruce protocol to assess the validity and reliability of the nomogram and HR extrapolation techniques. The participants in that study were younger and with a higher mean VO$_{2\text{max}}$ (50.14 ± 8.75 mL·kg$^{-1}$·min$^{-1}$) than the present study. The extrapolation method was found to be the most preferable method for estimating VO$_{2\text{max}}$ with an ICC of 0.9433, similar to that of their Bruce protocol, which was 0.9443, with a mean bias of -1.1 mL·kg$^{-1}$·min$^{-1}$, implying a 2.19% underestimation by extrapolation. Also, during a study involving 71 participants, VO$_{2\text{max}}$, VO$_{2\text{peak}}$ and extrapolated VO$_{2\text{max}}$ were not found to differ significantly and the authors concluded that a plateau in VO$_2$ is not necessarily required to determine the maximal rate of VO$_2$ (Day et al., 2003). Furthermore, this supports the notion that the extrapolation method is also a reasonable method for measuring (estimating) VO$_{2\text{max}}$. This is in contrast to the findings of Greiwe et al. (1995), who found that the ACSM submaximal ergometer test significantly overestimated VO$_{2\text{max}}$ and also had a mean CV of 25.7% between repeated tests.

In summary, irrespective of the aetiology of VO$_{2\text{max}}$, which has instigated the recent debate over VO$_{2\text{max}}$ testing (Noakes, 1988; Noakes, 1997; Noakes, 1998; Bassett & Howley, 1997; Bergh et al., 2000; Howley, 2007), it appears there is a measurable maximum rate no matter whether this is due to central and/or peripheral factors. Furthermore, the data presented suggest that VO$_{2\text{max}}$ can be estimated with a strong degree of reliability, however the validity of the estimations is more questionable, which is in agreement with some researchers (Shephard, 1984; McArdle et al., 2001) and in disagreement with others (Skinner et al., 1999; Macsween, 2001; Day et al., 2003).
G.2.1.2 Research ethics committee proposal

FACULTY RESEARCH ETHICS COMMITTEE (FREC)
Request for Ethics Approval

For official use only
REC Protocol No: ..........................
Date rec'd: ............................

APPLICATION FOR FREC APPROVAL

Please type your application. Remember that applications must be printed out, authorised, and then sent, with X copies, to the FREC office.

1. TITLE OF YOUR STUDY
   The validity and reliability of predicting cardiorespiratory fitness from a sub–maximal treadmill walking test

2. NATURE OF PROJECT
   Tests of aerobic fitness (VO$_2$max) are essential when monitoring changes in participants’ health–related fitness and the ‘gold standard’ is the maximal laboratory–based test. However, maximal tests may be inappropriate in some circumstances. Therefore, this study intends to look at the validity & reliability of a submaximal aerobic fitness test.

3. INVESTIGATORS
3a. Principal Investigator

   Name: Andrew Scott
   Post: Postgraduate Research Student
   Department: Department of Sport Science, Tourism and Leisure
Qualifications: BSc (Hons.) Sport, Recreation and Physical Education with Human and Applied Biology
MSc Exercise Physiology
Health/Fitness Instructor certified by the American College of Sports Medicine
Phase IV instructor certified by the British Association of Cardiac Rehabilitation
British Red Cross Trained First Aider

Previous experience of Research on Human Subjects:
Final year undergraduate dissertation – The influence of caffeine on endurance capacity
MSc Thesis – The influence of carbohydrate–electrolyte solutions on performance and metabolism during intermittent high intensity exercise

3b. Other investigators/collaborators (please note their employer if they are not employees of CCCU)
Dr Kate Woolf–May
Dr Ian Swaine

4. TIMETABLE

4a. Intended start date: August 2006

4b. Projected date of project's submission: January 2007

5. RESEARCH SPONSOR / OTHER ORGANISATIONS INVOLVED
If your study involves another organisation, please provide details. Evidence that the relevant authority has given permission will be needed (ie. a letter).

6. OTHER REC APPROVAL
6a. Has the proposed study been submitted to any other reviewing body? If so, please provide details.
A large-scale study has been approved by the local NHS research ethics committee with a sub-maximal exercise test being used to predict aerobic fitness

7. PURPOSE OF THE STUDY
The purpose of the study is to assess the validity and reliability of a submaximal treadmill walking protocol for the prediction of VO$_2$max. A further purpose is to investigate the influence of storing blood lactate samples at $-70^\circ$C on the accuracy of measurement compared with immediate analysis.
8. STUDY DESIGN, METHODOLOGY AND DATA ANALYSIS

The study will have a repeated measures design, where each participant will perform a maximal treadmill test twice within 7 days (see tables 1 & 2). The first maximal test will act as a habituation test. Expired air will also be analysed and heart rate recorded throughout each test. The exercise test will consist of walking at 3 mph for 10 minutes, with the gradient beginning at 2.5% being raised 2.5% after each stage until stage 6 (Table 1). As the test progresses the speed will increase, as will the gradient. The test is designed to be maximal, therefore the participant will exercise until volitional fatigue. Blood lactate samples will be collected in duplicate at the beginning and at the end of both treadmill tests, therefore two levels will be measured; resting and exhaustive blood lactate concentrations. The samples will be collected by an exercise physiologist and trained phlebotomist, and handled according to British Association of Sports and Exercise Sciences guidelines.

Table 1: Bruce protocol

<table>
<thead>
<tr>
<th>Stage</th>
<th>Speed (miles·hr⁻¹)</th>
<th>Gradient (%)</th>
<th>Time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>3.0</td>
<td>2.5</td>
<td>0–2</td>
</tr>
<tr>
<td>Two</td>
<td>3.0</td>
<td>5.0</td>
<td>3–4</td>
</tr>
<tr>
<td>Three</td>
<td>3.0</td>
<td>7.5</td>
<td>5–6</td>
</tr>
<tr>
<td>Four</td>
<td>3.0</td>
<td>10.0</td>
<td>7–8</td>
</tr>
<tr>
<td>Five</td>
<td>3.0</td>
<td>12.5</td>
<td>9–10</td>
</tr>
<tr>
<td>Six</td>
<td>3.4</td>
<td>14</td>
<td>11–13</td>
</tr>
<tr>
<td>Seven</td>
<td>4.2</td>
<td>16</td>
<td>14–16</td>
</tr>
<tr>
<td>Eight</td>
<td>5.0</td>
<td>18</td>
<td>17–19</td>
</tr>
<tr>
<td>Nine</td>
<td>5.5</td>
<td>20</td>
<td>20–22</td>
</tr>
</tbody>
</table>

The test is a combination of a submaximal VO₂max test and a maximal VO₂max test, both of which are described in the American College of Sports Medicine, 2000, Guidelines for exercise testing and prescription. 6th edition, Philadelphia: Lippincott, Williams & Wilkins, and the participants are able to stop the tests at any point. The tests are maximal, therefore the participants may be stopped if any participant is showing any signs of undue distress. The validity of the submaximal test for the prediction of VO₂max will be determined using limits of agreement (95%; mean difference ± (SD × 1.96)).
9. ETHICAL CONSIDERATIONS
Ethical considerations of the study include ensuring that participants fill in a health screening questionnaire, and storing data in accordance with the Data Protection Act (1998).

10. SUBJECTS TO BE STUDIED
Number of volunteers: 10 males
   Lower age limit: 40
   Upper age limit: 65

11. SELECTION CRITERIA
   Negative health questionnaire

12. RECRUITMENT
   Through direct contact

13. CONSENT
13a. How is consent to be obtained (attach copies of any information sheet(s) and consent forms that will be used)?
   Through information forms and an informed consent document

13b. Will the participants be from any of the following groups? (Tick as appropriate.)
   Children under 18
   Children in care
   Those with learning disability
   Those suffering from dementia
   Prisoners
   Young Offenders (16–21 years old)
   Those who could be considered to have a particularly dependent relationship with the investigator, eg those in care homes, students
   Other vulnerable groups

   How will you ensure that participants in the groups listed above are competent to consent to take part in this study? Please attach any correspondence to parents, guardians, carers, keyworkers etc.
13c. Are there any special pressures that might make it difficult for people to refuse to take part in the study (e.g. the potential participants are students or colleagues of the investigator)? How will you address this?
Any people I contact are free to say no. If they are sure I will supply them with the informed consent and information forms to let then make up their own mind

14. PARTICIPANT’S INVOLVEMENT: RISKS, REQUIREMENTS AND BENEFITS
During any physical activity there is a heightened risk of injury or sudden cardiac death, however for those without underlying cardiovascular disease the risk of sudden cardiac death during physical activity and exercise is minimal. Stuarts & Ellestad (Stuarts, RJ & Ellestad, MH, 1998 National Survey of Exercise Stress Testing Facilities. Chest 77: 94–7) observed only 5 incidences per 100,000 (0.0005%) maximal aerobic fitness tests. Risk is further reduced when accompanied by health questionnaires (ACSM, 2000). The participants are required to report to the Sport and Exercise Science laboratory and exercise maximally on two occasions. The benefits to the participants are that they receive 2 free aerobic fitness assessments.

14a. What potential hazards, risks or adverse effects associated with the study?
As above

14b. Does your study involves invasive procedures such as blood taking, muscle biopsy or drug administration?
No

14c. Does your study involve genetic analysis or manipulation?
No

14d. Please list the experience of the investigators in the use of these procedures.
The principal researcher has received training in maximal and submaximal exercise tests as part of my undergraduate and postgraduate training as well as being part of his Personal Trainer award.

14e. If medical devices are to be used on any subject, do they comply with the requirements of the Medical Devices Directives?
14f. **Please describe how you would deal with any adverse reactions or untoward incidents.**
Participants will be screened for any potential health risks, i.e. Hypertension, high cholesterol, diabetes etc, using a health questionnaire and are therefore presumed apparently healthy. Any participants with a positive questionnaire will be ineligible to take part. The principal investigator is a trained exercise physiologist and a certified personal trainer. To prevent anything untoward happening during the test, heart rate, oxygen consumption, respiratory exchange ratios and ratings of perceived exertion will be used to monitor participants' ability to continue exercising. Signs and symptoms of undue distress will be monitored, such as undue heavy breathing, pale faced, dizziness or disorientated movements. If this level of monitoring proves insufficient then all staff from the Sport and Exercise Science Laboratory are trained first aiders and trained in the use of automated debrillation.

14g. **Please name the locations or sites where the work will be done** (room number, etc.)
AG50

14h. **Can women of child-bearing potential participate without significant risk?**
N/A

14i. **Can lactating women participate without significant risk?**
N/A

14j. **What is the potential for participants' suffering pain, discomfort, distress, inconvenience or changes to lifestyle as a result of participation?**
Potential for any of the above are minimal because the participants will be exercising under the supervision of a trained exercise physiologist.

14k. **Will group or individual interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting?** If so, please list these topics and explain how you will prevent, or respond to, volunteer discomfort.

14l. **Is it possible that criminal or other disclosures requiring action (e.g. evidence of professional misconduct) could take place during the study?** If yes, give details of what procedures will be put in place to deal with these issues. *The information sheet should make it clear under which circumstances action may be taken by the researcher.*
14m. Please describe any expected benefits to the research participant.
   Benefits to the participant include 2 free aerobic fitness assessments

14n. What circumstances might lead a participant not continue with the study?
   Some participants may not want to complete the maximal fitness test

14o. What circumstances might lead to termination of the study in part or as a whole?
   None

15. FINANCIAL INCENTIVES, EXPENSES AND COMPENSATION
15a. Will travelling expenses be given? If so, an appropriate comment should be included on the Information Sheet
   No

15b. Is any financial or other reward, apart from travelling expenses, to be given to participants? If yes, please give details and justification.
   No

15c. Will the study result in financial payment or payment in kind to the department? Please specify, including the amounts involved.
   No

15d. If this study is being carried out in collaboration with a pharmaceutical company or an equipment manufacturer, please give the name of the company and indicate what arrangements exist for compensating patients or healthy volunteers for adverse effects resulting from their participation in the study (The Committee is unlikely to approve protocols if the pharmaceutical company involved fails to confirm, in writing, that it abides by ABPI guidelines).

16. CONFIDENTIALITY, ANONYMITY AND DATA STORAGE
16a. What steps will be taken to ensure confidentiality? Give details of the anonymisation procedures to be used, and at what stage they will be introduced.
   Participants will be recognized by a number and this will be introduced when their data is stored
16b. Who will have access to the records and resulting data?
The principal investigator will have access to the records and resulting data

16c. Where, and, for how long, do you intend to store the consent forms and other records?
For the duration of the research

17. INFORMATION SHEET AND CONSENT FORM
The information sheet for participants should be designed according to the given guidelines and submitted alongside this protocol. The standard consent form should also be used and submitted with the name of your project added. Details of how these documents should be used are provided in the guidelines for applicants

The following, where applicable, are attached to this form (please tick):
- Participant Information Sheet  √
- Consent Form  √

AUTHORISING SIGNATURES

The information supplied above is to the best of my knowledge and belief accurate. I have read the notes to investigators and clearly understand my obligations and the rights of subjects/study participants, particularly in so far as to obtaining valid consent.

Signature of Principal Investigator

................................................................. ... ...  Date...........

Signature of Head of Department

.................................................................  Date...........

Communications about this application should be addressed to:

Name: Andrew Scott

Address: (full postal address please)

Department of Sport Science, Tourism and Leisure

416
Canterbury Christ Church University College
North Holmes Road
Canterbury
Kent
CT1 1QU

Telephone No: 01227 767700 ext. 3145

E mail: ats5@cant.ac.uk
G.2.1.3 Participant information document

VOLUNTEER INFORMATION SHEET

The validity and reliability of predicting cardiorespiratory from a sub-maximal treadmill walking test

You are being invited to take part in a research study. Before you decide 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 others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Take time to decide whether or not you wish to take part.

What is the purpose of the study?
The purpose of the study is to determine the validity and reliability of predicting cardiorespiratory fitness (VO₂max) from a sub-maximal test.

Do I have to take part?
Even if you are accepted onto the study, it is up to you to decide whether or not you wish to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw from the study at any time, and without giving a reason.

Will I get any payment for taking part?
Unfortunately, we do not have the funding to pay for your participation in the study or to reimburse you for travel costs to any of the tests.

What will happen to me if I take part?
If you decide that you would like to take part in the study, you will attend the Sport and Exercise Science laboratory on two occasions to perform a sub–
maximal walking test, shortly followed by a maximal fitness test, which you are free to stop at any point.

**Pre-study measurements**

Pre-study recordings include age, height and weight and waist and hip circumferences.

**The study procedures**

Once accepted onto the study you will perform the aerobic fitness tests in the Sport and Exercise Science laboratory. The protocols are outlined below:

- Allow 45 minutes to include instructions
- You will exercise on the treadmills and wear a facemask, through which the air that you breathe out will be collected and analysed
- The test will only start when you feel happy about what you have to do
- The exercise test will take between 10–20 minutes, however you can terminate the test at any point (See figure 1: Treadmill test below).
- Finger prick blood lactate samples will be collected in duplicate immediately prior to, and following, each treadmill test.

**You are requested to wear loose clothing and not to eat, or drink tea, coffee, or any caffeinated drink within 2 hours before the test; or to drink alcohol or exercise within the 24 hours prior to any of the tests. Drinking water is recommended.**

**Figure 1: Treadmill test**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Speed (mph)</th>
<th>Grade (%)</th>
<th>Time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>3.0</td>
<td>2.5</td>
<td>2</td>
</tr>
<tr>
<td>Two</td>
<td>3.0</td>
<td>5.0</td>
<td>2</td>
</tr>
<tr>
<td>Three</td>
<td>3.0</td>
<td>7.5</td>
<td>2</td>
</tr>
<tr>
<td>Four</td>
<td>3.0</td>
<td>10.0</td>
<td>2</td>
</tr>
<tr>
<td>Five</td>
<td>3.0</td>
<td>12.5</td>
<td>2</td>
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<tr>
<td>Six</td>
<td>3.4</td>
<td>14.0</td>
<td>3</td>
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<tr>
<td>Seven</td>
<td>4.2</td>
<td>16.0</td>
<td>3</td>
</tr>
<tr>
<td>Eight</td>
<td>5.0</td>
<td>18.0</td>
<td>3</td>
</tr>
<tr>
<td>Nine</td>
<td>5.5</td>
<td>20.0</td>
<td>3</td>
</tr>
<tr>
<td>Ten</td>
<td>6.0</td>
<td>22.0</td>
<td>3</td>
</tr>
<tr>
<td>Eleven</td>
<td>6.5</td>
<td>24.0</td>
<td>3</td>
</tr>
</tbody>
</table>

**What tests will be carried out?**

Two treadmill fitness tests
How often will I have to be tested?
Twice – Preferably within 7–14 days

What are the possible benefits of taking part?
Receiving two free aerobic fitness assessments

Will taking part harm my health?
Taking part will not harm your health

What if something goes wrong?
You will be under the instruction of an experienced exercise physiologist and personal trainer. These tests have been piloted and there have been no accidents. As long as you are experienced in the use of treadmills, have no cardiovascular disease or related illness and are of moderate fitness, you should not experience any undue discomfort. If you do feel any discomfort, trained first aiders will be on hand.

Will my taking part in this study be kept confidential?
All information, which is collected about you during the course of the research, will be kept strictly confidential. Furthermore, any collected data will only be kept for the duration of the research.

What will happen to the results of the research study?
You will receive a copy of your own results from the study.

Who has reviewed the study?
The Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University, has reviewed the study.

Contact for Further Information
If you are interested in taking part in the study or require additional information. Please contact Andrew Scott on 01227 767600 x 3145 or e-mail ats5@cant.ac.uk

Thank you for reading this.
G.2.1.4 Informed consent document

Department of Sport Science, Tourism and Leisure
North Holmes Road, Canterbury, Kent CT1 1QU.

If you have any queries please contact Andrew Scott on 01227 767700 x 3145

Participant Identification Number for this trial:

CONSENT FORM

The validity and reliability of predicting cardiorespiratory from a sub-maximal treadmill walking test

Please initial box

1. I confirm that I have read and understand the information sheet dated ....................... (version 1.) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected. ☐

3. I understand that any personal information that I provide to the researchers to be kept strictly confidential. ☐

4. I agree to take part in the above study. ☐

Name of Subject Date Signature

Name of Person taking consent Date Signature (if different from researcher)

Researcher Date Signature

1 copy for the patient, 1 for researcher and 1 to be kept with subject’s notes
G.2.2.1 Intra- & inter-day reliability of measures of resting metabolic rate

**Introduction**
Metabolism is the overall process involving cellular catabolism and anabolism within the body. Metabolic rate is contributed to by three main factors: resting metabolic rate (RMR); physical activity thermogenesis, and the thermic effect of food. RMR is the minimum rate of metabolism required by the body to maintain cellular processes when the body is at rest. Physical activity thermogenesis is the elevation of metabolic rate above RMR caused by the increased energy needs of muscular contractions during physical activity and is proportional to the intensity and duration of the activity. The thermic effect of food is the influence of food consumption on metabolic processes, which arises from the energy required for mastication, movement through the gastro-intestinal tract, digestion, absorption and cellular processing of macronutrients in the body, and is usually ~10% of the calorific value of the food consumed.

The basis for measuring metabolic rate is indirect calorimetry, which makes use of oxygen consumption (VO\textsubscript{2}) from which metabolic rate can be derived. There are various methods of indirect calorimetry, such as room calorimeters, micro-environment hoods, Douglas bags and online gas analysers. These systems use the principle that ambient air contains 20.9% oxygen, therefore VO\textsubscript{2} may be derived from the difference between inspired and expired oxygen. Oxygen is consumed in order to drive respiration, and therefore VO\textsubscript{2} proportional to cellular energy requirements, where at rest one litre of oxygen is required to generate 5 kilocalories (kcal) of energy (Montoye *et al.*, 1996). Using this principle, VO\textsubscript{2} (litres per minute; L·min\textsuperscript{-1}) may be multiplied by five in order to calculate resting metabolic rate in kcal per minute (kcal·min\textsuperscript{-1}).
When using the Douglas bag technique to obtain expired air samples, participants breathe into a facemask or a mouthpiece with a peg over nose. Exercising samples are usually collected for 1 minute, however due to low flow rates at rest five minute samples are more appropriate. The samples are collected for a specified duration to allow the calculation of VO\textsubscript{2}, which is measured per minute. Once the air sample is collected, a unit containing an oxygen and carbon dioxide analyser measures the proportions of oxygen and carbon dioxide within the bag for a duration of 1-3 minutes at a flow rate of 1 litre per minute until the concentrations stabilise. In order to calculate the volumes of oxygen and carbon dioxide, the bag is evacuated to measure the volume of expired air (V\textsubscript{E}) along with the temperature of the contents. These measurements are then used to calculate VO\textsubscript{2} whereby the percentage of oxygen within the bag is applied to the total volume, which is corrected for the temperature, to gain the volume of oxygen present in the bag. The greater the oxygen present in the bag indicates a lower oxygen consumption, whereas the lower the oxygen present the greater the oxygen consumption. An issue with the Douglas bag technique is that it is time intensive and the sequence of samples that can be measured is limited, whereas online systems can analyse each breath.

Gas analysis equipment needs to be calibrated before it is used and most systems use a three point calibration involving a zero gas, a known concentration of oxygen and carbon dioxide and also an analysis of ambient air. The zero gas usually contains only nitrogen, the known gases usually contain 15% oxygen and 5% carbon dioxide and using ambient air as the final calibration point allows the assessment of the accuracy of the calibration.

Collecting expired air samples using the Douglas bag technique has been traditionally viewed as the gold standard, however with the development of more reliable online
systems it is now possible to generate accurate breath by breath analyses rather than using the time consuming Douglas bag technique to generate a single value. When making measurements in intervention studies it is important for measurements to be both valid and reliable. Therefore, the purpose of this study was to investigate the comparability of the Douglas bag technique with an online gas analysis system, and also determine the intra-day and inter-day reliability of measuring RMR using the Douglas bag technique.
Method

Introduction
Thirteen males (age 59.9 ± 6.6 years; height 1.79 ± 0.05 m; mass 94.1 ± 17.2 kg) volunteered and gave their written informed consent to take part in the study, which was approved by the Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University (Appendix B.1). The participants were advised of the procedures (Appendix B.2) and then signed the informed consent form (Appendix B.3).

Procedures
Each participant performed the three tests within a single visit on the first day and a further test the following day at the same time. Height and mass were measured using a stadiometer and beam balance scales (both Seca, Hamburg, Germany) to the nearest 1 cm and 100 g, respectively. After resting for 5 minutes in a supine position a 5 minute resting expired air sample was collected using Douglas bags (Harvard Apparatus Ltd, Kent, UK) and then a second 5 minute expired air sample was recorded using a breath by breath metabolic analyser (Oxycon-Pro, Jäeger, Würzburg, Germany). The mean value recorded over the 5 minute period by the breath by breath system was used for resting VO$_2$. A second expired sample was then collected using the Douglas bag technique. The first and second Douglas bag samples were used to indicate intra-day reliability, while counter-balancing of the Douglas bag was achieved for the determination of cross-comparison by randomly using the first and second Douglas bag samples to use in comparison to the online gas analysis system. A further a 5 minute Douglas bag sample was collected at the same time the following day for the purpose of demonstrating inter-day reliability of RMR.

The DB were immediately analysed using a Servomex gas analyser (Series 1440, Servomex Group Ltd, Crowborough, UK) for oxygen concentrations and the volumes
measured by a dry gas meter (Harvard Apparatus Ltd, Kent, UK). These values, plus ambient air temperature and barometric pressure were input into an MS Excel spreadsheet (Appendix F.2) for the calculation of VO$_2$ (mL·kg$^{-1}$·min$^{-1}$) and RMR was calculated by multiplying VO$_2$ (L·min$^{-1}$) by 5 (Montoye et al. 1996) and expressed as kcal·day$^{-1}$.

Statistical analyses
The data are presented as mean ± SD and were analysed using 95% confidence intervals, 95% limits of agreement and Pearson’s product-moment correlation coefficients.
Results

Comparisons

Resting oxygen consumption

Mean VO$_2$ appears to be measured homoscedastically lower using DB compared with BB, with the mean difference being $-0.52 \pm 0.40$ mL·kg$^{-1}$·min$^{-1}$ and the 95% limits of agreement suggest that some measurements may be 1.29 mL·kg$^{-1}$·min$^{-1}$ different (Figure G2.5).

\[ \text{Mean difference} = -0.52 \pm 0.40 \text{ mL·kg}^{-1} \cdot \text{min}^{-1} \]
\[ \text{Mean CV} = 12.08 \pm 10.68\% \]
\[ R^2 = 0.0009 \]

**Figure G2.5** The 95% limits of agreement for resting VO$_2$ between DB and BB
Daily resting metabolic rate

Figure G2.6 demonstrates a similar relationship to the previous figure, with DB under-estimating RMR by $336 \pm 237 \text{kcal·day}^{-1}$ compared to BB and the 95% limits of agreement suggest that this may be up to -800.96 kcal·day$^{-1}$ for some measurements.

![Figure G2.6](image)

**Figure G2.6** The 95% limits of agreement for the estimation of daily RMR between DB and BB
Reliability

Intra-day reliability of RMR

The intra-day reliability of RMR, calculated from VO$_2$ that was collected by DB, was relatively strong with the line of best-fit and 95% CIs generally following the line of equality and with a strong ICC (r=0.907) (Figure G2.7).

**Figure G2.7**  The 95% CIs for the reliability of the intra-day estimation of daily RMR
Inter-day reliability of RMR

The inter-day reliability of RMR, calculated from VO$_2$ collected by DB, was relatively strong with the 95% CIs generally following the line of equality and with a strong ICC ($r=0.964$). The line of best-fit almost followed the line of equality, however an outlier at the lower end appears to have affected the overall relationship (Figure G2.8).

**Figure G2.8** The 95% CIs for the reliability of the inter-day estimation of daily RMR
Discussion
The purpose of this study was to investigate the comparability of the Douglas bag technique with an online gas analysis system, and also determine the intra-day and inter-day reliability of the Douglas bag technique. Mean oxygen consumption (VO$_2$) was measured homoscedastically lower using Douglas bag technique (DB) compared with the online analysis system (BB), with the mean difference being -0.52 ± 0.40 mL·kg$^{-1}$·min$^{-1}$ and the 95% limits of agreement suggest that some measurements may be ≥1.29 mL·kg$^{-1}$·min$^{-1}$ lower using DB than BB. However, there is no gold standard in this study therefore it cannot be ascertained whether BB was measuring high, DB was measuring low or both. Daily RMR demonstrated a similar relationship to VO$_2$, with DB under-estimating daily RMR by 336 ± 237 kcal·day$^{-1}$ compared to BB and the 95% limits of agreement suggest that this may be up to -800.96 kcal·day$^{-1}$ for some measurements using DB compared to BB, which amounts to nearly one-third of the the daily recommended energy consumption for adult males. These data indicate that the two systems cannot be used interchangeably for the purpose of measuring resting VO$_2$ and deriving RMR from this measure, however the heteroscedastic error between methods suggests that these methods may have more agreement at greater exercise intensities rather than at rest.

The intra-day reliability of daily RMR, calculated from VO$_2$ measured by DB, was relatively strong with the line of best-fit and 95% CIs generally following the line of equality and with a strong ICC (r=0.907). Furthermore, the inter-day reliability of daily RMR was even stronger, with the 95% CIs generally following the line of equality and with a strong ICC (r=0.964). The line of best-fit almost followed the line of equality, however an outlier at the lower end appeared to affect the overall relationship. Strong reliability is important for this measurement because the smallest mean difference for RMR in study 2 (Section 4.0) was 23 kcal·day$^{-1}$, therefore in order to gain strong statistical
power from such a small difference, measurement error needs to be kept to a minimum. In summary, there was a large degree of disagreement in the measurement of VO₂ and daily RMR between the Douglas Bag technique and the online gas analysis system, with the DB method consistently measuring lower than BB. However, there was a high degree of intra- and inter-day reliability for RMR as measured by DB.
G.3 Body composition cross-comparison

G.3.1 Sum of skin folds vs. air displacement plethysmography

Introduction
Elevated body fat is not an independent risk factor for health, however it is associated with an increased risk of diseases such as diabetes, hypertension, stroke and heart disease, and is therefore often used as a physical marker of health-related fitness. Therefore measures of overweight/obesity are often employed by health professionals in health screening procedures. Direct measurement of body composition is impractical, because the body needs to be dissected and the individual constituents weighed, therefore various methods of body composition assessment have been developed to estimate body composition based on models derived from cadaver research. In terms of body composition, the body has two compartments; fat mass and fat free mass. Fat mass is the total amount of fat carried by the body and fat free mass includes all of the facets of the body that are not fat, such as bones, muscle, organs and the blood.

Hydrostatic densitometry (HD) is currently, the ‘Gold Standard’ for estimating body composition, also known as underwater weighing, where participants are weighed on dry land and then submerged underwater. The under-pinning principle is that the greater the fat mass the more buoyant the participant will be therefore the lighter they will be when weighed underwater compared to dry land, and the lower their fat mass the more dense they are and the nearer to their dry-land measurement they will be under water. This technique involves a full exhalation to minimise the effect of lung volume on buoyancy and full water submersion and also requires a large space to accommodate the water tank. Dual-energy x-ray absorptiometry (DEXA) is a more straightforward process in terms of demands on the participant. Indeed, this method is capable of discerning between the
different volumes of lean mass, such as bone and muscle (Ellis, 2000). However, the equipment is expensive and requires sizeable laboratory space.

Bioelectrical impedance analysis (BIA) is based on the principle that fat is hydrophobic to water and that electrolytes are dissolved in bodily fluids. These are significant because fat will not carry water and water helps to carry current. The technique works by passing a small electric current through the body to a receiver. The electric current is carried by the electrolytes in the body’s water, which is contained in the FFM, and impeded by fat mass (no water). Therefore, the greater the fat mass the greater the current is impeded, indicating higher body fat %. Conversely, the lower the body fat the larger percentage of water in the body and the greater the flow of current through the body, indicating a lower body fat %. The air displacement technique (Bod Pod; BP) has been marketed as a more practical, method to HD, which relies on air displacement. The basic assumption is because fat is less dense than lean tissue then the greater the fat mass of the person the more air they will displace because their volume is larger for a given mass. These tests have varying degrees of accuracy. Unfortunately, access to elaborate methods of body composition analysis, such as HD, DEXA, BIA or BP can be unpleasant, expensive or limited. However, the use of sum of skin fold thickness measurements (SoS) for the estimation of body composition by trained practitioners is a less expensive and more accessible method.

The SoS method requires the use of skin fold callipers to ‘pinch’ the dermis and the underlying fat layer at specific sites on the body, depending on the estimation model being used. Skin fold estimations use the principle that subcutaneous fat deposition is proportional to total body fat, i.e. higher levels of subcutaneous fat are present when total body fat levels are higher, and vice versa. Skin fold measurements rely on participant-
specific estimation equations, which are selected based on the gender, ethnicity and age of
the participant, and are used to estimate body fat % from the sum of skin fold measures
(mm). Therefore, the purpose of this study was to compare the fat percentage (fat%) and
body fat mass (FM) values derived from both sum of skin fold thicknesses (SF) and air
displacement plethysmography (BP).
Method

Introduction
Thirty males (age 50.23 ± 11.83 years; height 1.78 ± 0.07 m; mass 87.35 ± 14.54 kg) volunteered and gave their written informed consent to take part in the study, which was approved by the Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University (Appendix G.3.2). The participants were advised of the procedures (G.3.3) and then signed the informed consent form (G.3.4).

Procedures
Each participant performed a single trial. The participants’ height and mass were measured using a stadiometer and beam balance scales (BB) (both Seca, Hamburg, Germany) to the nearest 1 cm and 100 g, respectively. Body composition was estimated using both sum of skin fold thicknesses (SF) and air displacement plethysmography (Bod Pod, Life Measurement Inc., CA, USA; BP). The SF measures were always measured first and calculated afterwards so that the readings from the BP could not influence the size of SF taken. For the SF measures, body density (Db) was estimated using 7-site sum of skin fold thicknesses [Chest, midaxillary, triceps, subscapular, suprailliac, abdomen and thigh] for men (ACSM, 2000) using skin fold callipers (Harpenden, British Indicators Ltd, Beds., UK) whilst the participants were in the anatomical neutral position. Three skin fold measures were taken at each site and the mean value was recorded, then body composition was calculated using the Siri (1961) equation for white males aged 20-80 years [495/Db-450] (ACSM, 2000). This calculation provided a value for body fat percentage (BF%), which was then applied to the body mass of the participant for the determination of absolute fat mass (FM).

BP was used in the absence of a ‘Gold Standard’ in this cross-comparison because of its similarity of accuracy for measuring body composition to hydrostatic densitometry.
BP measured body mass (kg), using internal scales, and measured body volume (L). The measurement of body volume involved the participants remaining seated within the BP chamber for 5 minutes, where they were instructed not to talk and to seat still and breathe normally. The test involved 3 measurements of body volume during the measurement period. In between each measurement the door of the BP was opened to equilibrate the air within the chamber and then closed. Each test lasted 40-50 seconds. Following the measurement of body mass and volume, the BP then derived Db from these values [volume/mass], and then derived fat/lean % from Db using the Siri equation (Siri, 1961).

Statistical analysis
The data are presented as mean ± SD and were analysed using, 95% limits of agreement and intraclass correlation coefficients, Pearson product-moment correlation coefficients and coefficient of variation.
Results

Body mass

Figure G3.1 demonstrates that the error of body mass measurement between the BB and the Bod Pod scales played little role in any differences between the two measures of body composition. There was a slight tendency for the beam balance scales to measure BM slightly greater than the Bod Pod scales, however the 95% LoA suggest that this was very small and the intra class correlation was very strong (r = 1.000).

Figure G3.1  The 95% limits of agreement for body mass measured on BB vs. the BP
Fat percentage

Figure G3.2 indicates that there was a strong relationship between the SoS estimates of BF% compared with the Bod Pod. There seemed to be a tendency for the SoS measures to under-estimate BF% slightly according to the mean values, in the order of $-0.46 \pm 4.81\%$. However, these differences were relatively small as the strong intra class correlation indicates ($r=0.837$).

![Figure G3.3](image)

**Figure G3.3** The 95% limits of agreement between SF and BP for estimating fat %
Fat mass
Figure G3.4 demonstrates that the estimations of FM using both methods were very similar. Both methods provided similar mean values, with SoS (23.33 ± 9.43 kg) slightly under-estimating the values estimated by Bod Pod (23.97 ± 11.63 kg) by -0.64 ± 4.17 kg. The strength of the relationship between the two methods was illustrated by the strong correlation (ICC=0.923).

![Figure G3.4](image)

**Figure G3.4** The 95% limits of agreement for fat mass estimated by SF vs. BP
Discussion

The aim of this study was to compare the body composition measures estimated from SoS compared with BP. The results demonstrate that the error of body mass measurement between the BB and the BP scales played little role in any differences between body mass measured by SoS or Bod Pod. Even though there appeared to be a slight tendency for the beam balance scales to measure greater the BP scales the 95% LoA suggest that this was very small and the correlation is very strong (ICC = 1.000).

There was a strong relationship between the SoS estimates of BF% compared with the Bod Pod. There seemed to be a tendency for the SoS measures to under-estimate BF% slightly compared to Bod Pod according to the mean values, in the order of -0.46 ± 4.81. However, these differences were relatively small as the strong correlation indicates (ICC=0.837). And as would be expected from similar BF% estimations for both methods, the estimations of FM using both methods were very similar. Both methods provided similar mean values, with SoS (23.33 ± 9.43 kg) slightly under-estimating the values estimated by Bod Pod (23.97 ± 11.63 kg) by -0.64 ± 4.17 kg. The strength of the relationship between the two methods is illustrated by the strong correlation (ICC=0.923). There is a general expectation that estimating body composition using technology such as the Bod Pod decreases the potential error of estimating total body composition from subcutaneous adiposity only, where devices such as the Bod Pod estimate based on the density of body volume to take visceral adiposity into consideration, which cannot be ‘pinched’ by callipers. However, in summary the high ICC and low mean differences between percentage body fat and fat mass values indicate a strong degree of agreement between sum of skin fold and air displacement plethysmography methods of body composition estimation.
G.3.2 Research ethics committee proposal

FACULTY RESEARCH ETHICS COMMITTEE (FREC)
Request for Ethics Approval

For official use only
REC Protocol No: _______________________
Date rec'd: _______________________

APPLICATION FOR FREC APPROVAL
*Please type your application. Remember that applications must be printed out, authorised, and then sent, with X copies, to the FREC office,

1. **TITLE OF YOUR STUDY**
A cross-comparison of body composition estimated by 7-site sum of skin fold thicknesses and air displacement plethysmography

2. **NATURE OF PROJECT**
Access to elaborate methods of body composition analysis, such as hydrostatic densitometry, dual energy x-ray absorptiometry (DEXA), air displacement plethysmography (Bod Pod) or bioelectrical impedance analysis (BIA) can be limited, expensive or unpleasant. However, the use skin fold thicknesses for the estimation of body composition by trained practitioners may be a cheap and more practical method to assess body composition. Therefore, the purpose of this study is to compare body the fat percentage and body fat mass values derived from both sum of skin fold thicknesses and air displacement plethysmography.

3. **INVESTIGATORS**
3a. Principal Investigator

Name: Andrew Scott
Post: Postgraduate Research Student
Department: Department of Sport Science, Tourism and Leisure

Qualifications: BSc (Hons.) Sport, Recreation and Physical Education with Human & Applied Biology

- MSc Exercise Physiology
- Health/Fitness Instructor certified by the American College of Sports Medicine
- Phase IV instructor certified by the British Association of Cardiac Rehabilitation
- British Red Cross Trained First Aider

Previous experience of Research on Human Subjects:
Final year undergraduate dissertation – The influence of caffeine on endurance capacity
MSc Thesis – The influence of carbohydrate–electrolyte solutions on performance and metabolism during intermittent high intensity exercise

3b. Other investigators/collaborators (please note their employer if they are not employees of CCCUC)
Dr Kate Woolf–May
Dr Ian Swaine

4. TIMETABLE

4a. Intended start date: January 2006

4b. Projected date of project's submission: March 2006

5. RESEARCH SPONSOR / OTHER ORGANISATIONS INVOLVED
If your study involves another organisation, please provide details. Evidence that the relevant authority has given permission will be needed (ie. a letter).
N/A

6. OTHER REC APPROVAL
6a. Has the proposed study been submitted to any other reviewing body? If so, please provide details.
A large-scale study has been approved by the local NHS research ethics committee, and the estimation of body composition was included in the approval
7. PURPOSE OF THE STUDY
The purpose of the study is to compare estimates of body composition provided by 7-site sum of skin fold thicknesses with those provided using air displacement plethysmography. This is because body composition is being estimated by sum of skin fold measures in large-scale studies leading to the award of PhD and these measures need to be accurate. Air displacement will be used as the ‘Gold standard’ because it is the next best to the true gold standard – under-water weighing – but is more participants friendly and practical.

8. STUDY DESIGN, METHODOLOGY AND DATA ANALYSIS
Each participant will have their body composition assessed using skinfold calipers and the Bod Pod, therefore the study will have a repeated measures design. For the SF measures, body density (Db) will be estimated using 7-site sum of skin fold thicknesses [Chest, midaxillary, triceps, subscapular, suprailiac, abdomen and thigh] for men using skin fold callipers whilst the participants stand in the anatomical neutral position. Three skin fold measures will be taken at each site and the mean value recorded. A Bod Pod will also estimate body composition using the principle of air displacement plethysmography. This will be used as the ‘Gold Standard’ in this cross-comparison because of its similar accuracy of measurement of body composition to hydrodensitometry. The measurement of body volume will involve the participants remaining seated within the BP chamber for ~5 minutes, where they will not to talk, sit still and breathe normally. The similarity of estimating body composition using skin fold thicknesses and air displacement plethysmography will be determined using limits of agreement (95%: mean difference ± (SD × 1.96)).

9. ETHICAL CONSIDERATIONS
Ethical considerations of the study include maintaining the privacy of the subjects by reporting their data anonymously using participant numbers and only disclosing their measurements to that person.

10. SUBJECTS TO BE STUDIED
Number of volunteers: 30 males
Lower age limit: 40
Upper age limit: 65

11. SELECTION CRITERIA
None specific
12. **RECRUITMENT**
   Through direct contact

13. **CONSENT**
   13a. How is consent to be obtained (attach copies of any information sheet(s)
        and consent forms that will be used)?
        Through information forms and an informed consent document

   13b. **Will the participants be from any of the following groups?** (Tick as appropriate.)
        
        - Children under 18
        - Children in care
        - Those with learning disability
        - Those suffering from dementia
        - Prisoners
        - Young Offenders (16–21 years old)
        - Those who could be considered to have a particularly dependent
          relationship with the investigator, eg those in care homes, students
        - Other vulnerable groups

How will you ensure that participants in the groups listed above are competent to
consent to take part in this study? *Please attach any correspondence to parents,
guardians, carers, keyworkers etc.*

13c. Are there any special pressures that might make it difficult for people to refuse to take part
in the study (e.g. the potential participants are students or colleagues of the investigator)? How will you address this?
Any potential participants that are contacted are free to say no. If they accept then they will be supplied with the information forms and informed consent to let then make up their own mind

14. **PARTICIPANT'S INVOLVEMENT: RISKS, REQUIREMENTS AND BENEFITS**
   14a. What potential hazards, risks or adverse effects associated with the study?
        Some participants may find the Bod Pod a little claustrophobic, therefore
        those at risk are advised of this. However, the there is a button that may
        be pressed by the participant to terminate the test at any point.
14b. Does your study involves invasive procedures such as blood taking, muscle biopsy or drug administration?  
No

14c. Does your study involve genetic analysis or manipulation?  
No

14d. Please list the experience of the investigators in the use of these procedures.  
The principal investigator is trained in assessing blood pressure through undergraduate studies and also as part of his Personal Trainer award.

14e. If medical devices are to be used on any subject, do they comply with the requirements of the Medical Devices Directives?  
N/A

14f. Please describe how you would deal with any adverse reactions or untoward incidents.  
The principal investigator is a trained first aider (Red Cross First Aid at Work) and so are the other employees and research students in the sport and exercise science laboratory.

14g. Please name the locations or sites where the work will be done (room number, etc.)  
AG50

14h. Can women of child-bearing potential participate without significant risk?  
N/A

14i. Can lactating women participate without significant risk?  
N/A

14j. What is the potential for participants' suffering pain, discomfort, distress, inconvenience or changes to lifestyle as a result of participation?  
None

14k. Will group or individual interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting? If so, please list
these topics and explain how you will prevent, or respond to, volunteer discomfort.

141. **Is it possible that criminal or other disclosures requiring action** (e.g. evidence of professional misconduct) **could take place during the study?** If yes, give details of what procedures will be put in place to deal with these issues. *The information sheet should make it clear under which circumstances action may be taken by the researcher.*

14m. **Please describe any expected benefits to the research participant.**

   Benefits to the participant include two free blood pressure assessments in a short space of time

14n. **What circumstances might lead a participant not continue with the study?**

   People may not want themselves or other people to know what their blood pressure is, or the inflatable cuff may be slightly uncomfortable

14o. **What circumstances might lead to termination of the study in part or as a whole?**

   None

15. **FINANCIAL INCENTIVES, EXPENSES AND COMPENSATION**

15a. **Will travelling expenses be given?** If so, an appropriate comment should be included on the Information Sheet

   No

15b. **Is any financial or other reward, apart from travelling expenses, to be given to participants?** If yes, please give details and justification.

   No

15c. **Will the study result in financial payment or payment in kind to the department?** Please specify, including the amounts involved.

   No

15d. **If this study is being carried out in collaboration with a pharmaceutical company or an equipment manufacturer, please give the name of the company and indicate what arrangements exist for compensating patients or healthy volunteers for adverse effects resulting from their participation in the study** *(The Committee is unlikely to approve protocols if the*
pharmaceutical company involved fails to confirm, in writing, that it abides by ABPI guidelines).

16. **CONFIDENTIALITY, ANONYMITY AND DATA STORAGE**

16a. **What steps will be taken to ensure confidentiality?** Give details of the anonymisation procedures to be used, and at what stage they will be introduced.
Participants will be recognized by a number and this will be introduced when their data is stored.

16b. **Who will have access to the records and resulting data?**
The principal investigator will have access to the records and resulting data.

16c. **Where, and, for how long, do you intend to store the consent forms and other records?**
Records will be kept in locked cabinets for the duration of the research.

17. **INFORMATION SHEET AND CONSENT FORM**
The information sheet for participants should be designed according to the given guidelines and submitted alongside this protocol. The standard consent form should also be used and submitted with the name of your project added. Details of how these documents should be used are provided in the guidelines for applicants.

The following, where applicable, are attached to this form (please tick):
- Participant Information Sheet  
- Consent Form  

**AUTHORIZING SIGNATURES**

The information supplied above is to the best of my knowledge and belief accurate. I have read the notes to investigators and clearly understand my obligations and the rights of subjects/study participants, particularly in so far as to obtaining valid consent.

Signature of Principal Investigator

.......................................................... ................................................................. ... ... ... Date.............

Signature of Head of Department
Communications about this application should be addressed to:

Name: Andrew Scott

Address: (full postal address please)

Department of Sport Science, Tourism and Leisure
Canterbury Christ Church University
North Holmes Road
Canterbury
Kent
CT1 1QU

Telephone No: 01227 767700 ext. 3145

E mail: ats5@cant.ac.uk
G.3.3 Participant information document

Canterbury Christ Church University

Department of Sport Science, Tourism and Leisure
North Holmes Road, Canterbury, Kent CT1 1QU.

VOLUNTEER INFORMATION SHEET

A comparison of seven-site sum of skin folds with the Bod Pod

You are being invited to take part in a research study. Before you decide 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 others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Take time to decide whether or not you wish to take part.

What is the purpose of the study?
The purpose of the study is to determine the validity of using 7 skinfold sites for the estimation of body composition compared with air displacement plethysmography (Bod Pod).

Do I have to take part?
Even if you are accepted onto the study, it is up to you to decide whether or not you wish to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw from the study at any time, and without giving a reason.

Will I get any payment for taking part?
Unfortunately, we do not have the funding to pay for your participation in the study or to reimburse you for travel costs to any of the tests.
What will happen to me if I take part?
If you decide that you would like to take part in the study, you will have your body composition measured by skinfolds (7–site, 3 at each site) and in the Bod Pod in the Sport and Exercise Science laboratory.

Pre-study measurements
Pre study recordings include age, height and weight.

The study procedures
On arrival in at the Sport and Exercise Science laboratory you will have your body composition assessed by seven-site sum of skinfolds (chest, under the arm, back of the arm, below the shoulder blade, above the hip, to the right of the navel and middle of the front of the thigh). Assessment of body composition in the Bod Pod will require you to sit in a small enclosed space, a little like a helicopter cockpit, for $3 \times 40$ seconds. The Bod Pod is a small chamber and assesses body composition using air displacement. If you are claustrophobic it is wise not to take part. Once these tests have taken place you can receive your measurements immediately.

What tests will be carried out?
Automated body composition measurement (Bod Pod) and 7–site sum of skinfolds.

How often will I have to be tested?
Once only

What are the benefits of taking part?
Receiving two free body composition assessments in ~30 minutes

Will taking part harm my health?
Taking part will not harm your health

What if something goes wrong?
*If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it.*
Will my taking part in this study be kept confidential?
All information, which is collected about you during the course of the research, will be kept strictly confidential. Furthermore, any collected data will only be kept for the duration of the research.

What will happen to the results of the research study?
You will receive a copy of your own results from the study.

Who has reviewed the study?
The Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University, has reviewed the study.

Contact for Further Information
If you are interested in taking part in the study or require additional information. Please contact Andrew Scott on 01227 767600 x 3145 or e-mail ats5@cant.ac.uk

Thank you for reading this.
G.3.4 Informed consent document

Department of Sport Science, Tourism and Leisure
North Holmes Road, Canterbury, Kent CT1 1QU.

If you have any queries please contact Andrew Scott on 01227 767700 x 3145

Participant Identification Number for this trial:

CONSENT FORM

A comparison of seven-site sum of skin folds with the Bod Pod

Please initial box

1. I confirm that I have read and understand the information sheet dated ......................... □
   (version 1.) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time,
   without giving any reason, without my legal rights being affected. □

3. I understand that any personal information that I provide to the researchers to be kept strictly confidential. □

4. I agree to take part in the above study. □

Name of Subject Date Signature

Name of Person taking consent Date Signature
(if different from researcher)

Researcher Date Signature

1 copy for the patient, 1 for researcher and 1 to be kept with subject’s notes
G.4 Body composition reliability

G.4.1 Reliability of waist circumference, waist:hip ratio and sum of skin folds

Introduction

Waist circumference (WC), waist:hip ratio (WHR) and body mass index (BMI) are often used as simple anthropometric measures of body fat in relation to health risk. These are usually employed by health practitioners because access to elaborate methods, such as hydrostatic densitometry, dual energy x-ray absorptiometry (DEXA), air displacement plethysmography (Bod Pod), bioelectrical impedance analysis (BIA) or skin fold methods.

Individuals with an increased WC are more at risk of metabolic diseases, such as insulin resistance, metabolic syndrome, diabetes and heart disease. The metabolic syndrome is a cluster of cardiovascular disease risk factors, characterised by hypertension, insulin resistance and dyslipidaemia in the presence of abdominal obesity. As individuals increase in age their risk of metabolic syndrome increases, therefore males aged 40-65 were encouraged to volunteer for the study. Waist circumference is one of the major risk factors of metabolic syndrome as a measure of visceral obesity. Visceral obesity is the adipose tissue that accumulates around the abdominal organs and is more hazardous to metabolic health than subcutaneous adipose tissue. This type of obesity is associated with the development of metabolic syndrome. There has been controversy regarding the use of waist indices for the determination of body fat. Many studies have used BMI, WC alone or WHR, with debate over which is the most suitable method.

Body composition can be estimated using elaborate techniques, such as those already discussed, however it can also be estimated or inferred using anthropometric techniques, such as SoS, WC and WHR. These are relatively simple to use providing they are being applied by trained practitioners. As mentioned previously, the SoS method requires the use
of skin fold callipers to ‘pinch’ the dermis and the underlying fat layer at specific sites on
the body and employ participant-specific estimation equations to derive fat% from SoS.
WC is another indicator of obesity and also abdominal adiposity, an indicator of cardio-
metabolic risk due to the dangerous nature of visceral adiposity. Visceral adipose tissue is
fat that accumulates around the waist particularly around the organs contained within the
abdomen, such as the stomach, intestines, kidneys and liver. Waist circumference can be
measured at the narrowest circumference between the lowest rib portion and the iliac crest,
at the level of the umbilicus or at the mid-point between the lowest rib portion and the iliac
crest. The WHR was developed to take lean mass into account in order to avoid larger or
more muscular physiques being classified as overweight/obese using WC alone. WHR is
determined by dividing WC by the circumference at the hip, with hip circumference being
measured as the greatest circumference around the hips above the gluteal fold. However,
an issue with using hip circumference as a measure of lean mass is that as human’s
abdominal fat depots grow, as do those around the buttock area, thus over-estimating lean
mass and giving a skewed picture of obesity status.

When measuring participants in an intervention study, where repeated measures are usually
employed, it is crucial to limit any error of measurement to be confident that any
differences are solely due to the intervention itself and not complicated by measurement
error. This means that the measuring instrument, either human or mechanical/electronic
equipment, or both, must contain substantially less error than the expected effect size of the
intervention. To maximise confidence, it is prudent to assess the repeatability of the
prospective measuring technique being employed. Therefore, the purpose of this study was
to determine the reliability of SoS, including estimated fat%, and WC and WHR when
measured on two separate days.
Method

Introduction
Ten males (age 59.92 ± 6.64 years; height 1.79 ± 0.05 m; mass 94.11 ± 17.17 kg) volunteered and gave their written informed consent to take part in the study, which was approved by the Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University (Appendix G.4.2). The participants were advised of the procedures (Appendix G.4.3) and then signed the informed consent form (Appendix G.4.4).

Procedures
Each participant performed two identical trials. During the first trial height and body mass were also measured using a stadiometer and beam balance scales (both Seca, Hamburg, Germany) to the nearest 1 cm and 100 g, respectively. Body composition was estimated using sum of skin fold thicknesses (SoS). Body density (Db) was estimated using 7-site sum of skin fold thicknesses [Chest, midaxillary, triceps, subscapular, suprailiac, abdomen and thigh] for men (ACSM, 2000) using skin fold callipers (Harpenden, British Indicators Ltd, Beds., UK) whilst the participants stood in the anatomical neutral position. Three skin fold measures were taken at each site and the average recorded, then body composition was calculated using the Siri (1961) equation for white males aged 20-80 years [495/Db-450] (ACSM, 2000). This calculation provided a value for body fat percentage (BF%), which was then applied to the body mass of the participant for the determination of absolute fat mass (FM).

While remaining in the anatomical neutral position the participants’ WC was measured at the level of the umbilicus and HC was measured at the largest circumference of the hips above the gluteal fold both to the nearest 1 mm using a self-tightening circumference tape.
measure (Seca, Hamburg, Germany). Three waist circumference and three hip circumference measures were recorded and the mean values were recorded and waist:hip ratio (WHR) was then derived from these measures. These procedures were then repeated a week later.

Statistical analysis
The data are presented as mean ± SD and were analysed using 95% confidence intervals, intra-class correlations and coefficient of variation.
Results

Sum of skin fold reliability

Figure G4.1 shows that there was a strong intra class correlation (r=0.9979) between SoS measured on two separate occasions, furthermore the CV between the two measures was satisfactory and the 95% CI confirm this relationship.

![Graph showing the relationship between the measurement of sum of skin fold thicknesses on two separate days.](image)

**Figure G4.1** The relationship between the measurement of sum of skin fold thicknesses on two separate days
Fat percentage reliability
As with the SoS values, the data for fat%, derived from the SoS measures, demonstrated a similar relationship ($r=0.957$, $CV=2.35\%$), thus illustrating that these measures are highly reliable. The 95% CI were also strongly in agreement (Figure G4.2).

**Figure G4.2** The relationship between the estimation of body fat % from sum of skin fold thicknesses on two separate days
Waist circumference reliability

Figure G4.3 indicates that there was a strong relationship between the WC measurements on the two separate occasions, which both the ICC value ($r=0.990$) and the mean CV (0.71 ± 0.64 %) demonstrated. This relationship was also confirmed by the tight 95% CI.

Figure G4.3 The 95% CIs for the measurement of waist circumference on two separate days
Waist:hip ratio reliability

Figure G4.4 demonstrated a strong relationship (ICC=1.000) between waist:hip ratios measured on two separate occasions with a CV of 0.71 ± 0.62 % between trials. The 95% CI also reinforced this fact, demonstrating identical figures.

**Figure G4.4** The test-retest relationship between waist:hip ratios measured on two separate occasions
Discussion

The aim of this study was to investigate the repeatability of anthropometric estimates of body composition, including SoS, WC and waist:hip ratio, therefore the data presented include the relationship between SoS, fat%, WC and waist:hip ratio measured on two separate days. There was a strong relationship \((r=0.9979)\) between SoS measured on two separate occasions, furthermore the CV between the two measures was satisfactory and the 95\% CI confirmed this relationship. Not surprisingly, the data for fat\%, derived from the SoS measures, demonstrated a similar relationship \((r=0.957, \text{CV}=2.35\%)\), thus illustrating that these measures were highly reliable, while the 95\% CI were also indicated strong agreement. There was also a strong relationship between the WC measurements on the two separate occasions, which both the ICC value \((r=0.990)\) and the mean CV \((0.71 \pm 0.64 \%)\) demonstrated. This relationship was also confirmed by the tight 95\% CI. There was a strong relationship \((r=1.000)\) between waist:hip ratios measured on two separate occasions with a CV of 0.71 ± 0.62 \%\% between trials. The 95\% CI also reinforce this fact, demonstrating identical figures.

These anthropometric measures of body composition demonstrate low degrees of variation, which is important for increasing statistical power in measurements that may be unlikely to change by a large degree, such as WHR. Therefore despite relatively small mean differences for WC, w:h ratio and BF\% in study 1 (Section 3.0), there was a strong statistical power (WC 0.998; WHR 0.991; BF\% 0.959). In summary, the inter-day repeatability of measures of waist circumference, waist:hip ratio and sum of skin folds was high, demonstrating low coefficient of variation and high intra-class correlations between measures on two consecutive days.
G.4.2 Research ethics committee proposal

FACULTY OF BUSINESS & SCIENCES
FACULTY RESEARCH ETHICS COMMITTEE

APPLICATION FOR FREC APPROVAL

Please type your application. Remember that applications must be printed out, authorised, and then one hard copy sent to: Roger Bone, FREC Administrator, c/o Research Office together with an emailed copy to rtb2@canterbury.ac.uk. Please ensure that you have answered all questions.

<table>
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1. RESEARCHERS

1a. Principal Researcher

<table>
<thead>
<tr>
<th>Name:</th>
<th>Andrew Scott</th>
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<tr>
<td>Post:</td>
<td>Postgraduate Research Student</td>
</tr>
<tr>
<td>Department:</td>
<td>Department of Sport Science, Tourism and Leisure</td>
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</tbody>
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| Qualifications:| BSc(Hons.) Sport, Recreation and Physical Education with Human and Applied Biology  
                 | MSc Exercise Physiology  
                 | Health/Fitness Instructor certified by the American College of Sports Medicine  
                 | Phase IV instructor certified by the British Association of Cardiac Rehabilitation  
                 | British Red Cross Trained First Aider |
Previous experience of Research on Human Participants:
Final year undergraduate dissertation – the influence of caffeine on endurance performance
MSc thesis – the influence of carbohydrate–electrolyte solutions on metabolism and performance during intermittent intensity exercise
Ongoing research as part of MPhil/PhD investigating the influence of brisk walking on metabolic syndrome risk

1b. Other researchers/kollaborators (please note their employer if they are not employees of CCCUC)
Dr Kate Woolf–May
Dr Ian Swaine

2. TITLE OF YOUR STUDY
The reliability of waist and hip circumferences and sum of skinfolds

3. LAY SUMMARY (no more than 300 words)
As part of research leading to a PhD, waist and hip circumferences and sum of skinfolds are to assess body composition in a repeated measures design. These measures are used in a cross-sectional study and also in a longitudinal study. Therefore, it needs to demonstrated that the measurements are reliable. In order to do this, three measures of waist circumference, three of hip circumference and 7 site sum of skinfolds using calipers with three measures at each site will be performed. These measures will then be replicated the next day to see if the measures are the same.

4. TIMETABLE
4a. Intended start date: January 2006

4b. Projected date of project's submission: July 2006

5. RESEARCH SPONSOR / OTHER ORGANISATIONS INVOLVED
If your study involves another organisation, please provide details. Evidence that the relevant authority has given permission will be needed (ie. a letter).
N/A

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6. **OTHER REC APPROVAL**

6a. Has the proposed study been submitted to any other reviewing body? If so, please provide details.

N/A

7. **PURPOSE OF THE STUDY**

The purpose of the study is to demonstrate that anthropometric measures taken by the principal investigator, such as waist & hip circumference, and sum of skinfolds, are reliable.

8. **STUDY DESIGN, METHODOLOGY AND DATA ANALYSIS**

The study has a repeated measures design. Each participant will undergo three waist circumference measures, three hip circumference measures and seven site sum of skinfolds (chest, midaxillary, subscapular, triceps, suprailiac, abdomen & thigh), with three measures at each site. These tests will then be repeated on a separate day. Waist circumference will be measured at the narrowest part of the abdomen between the lowest partial rib and the iliac crest. Hip circumference will be measured around participants underwear at the widest part of the hips above the gluteal fold. Reliability of these measures will be assessed using coefficient of variation.

9. **ETHICAL CONSIDERATIONS**

Ethical considerations of this study include ensuring that each participant is capable of understanding the study and performing the walking test. All data will be kept in accordance with the 1998 Data Protection Act.

10. **PARTICIPANTS TO BE STUDIED**

    Number of volunteers: 10 males
    Lower age limit: 18
    Upper age limit: 65

11. **SELECTION CRITERIA**

    Apparently healthy males who understand the requirements of the procedures

12. **RECRUITMENT**

    Through direct contact
13. CONSENT

13a. How is consent to be obtained (attach copies of any information sheet(s) and consent forms that will be used)?
Informed consent will be obtained by issuing potential participants with a copy of the approved information sheet and consent forms (encl.)

13b. Will the participants be from any of the following groups? (Tick as appropriate.)

- Children under 18
- Children in care
- Those with learning disability
- Those suffering from dementia
- Prisoners
- Young Offenders (16–21 years old)
- Those who could be considered to have a particularly dependent relationship with the researcher, e.g. those in care homes, students
- Other vulnerable groups

13c. How will you ensure that participants in the groups listed above are competent to consent to take part in this study? Please attach any correspondence to parents, guardians, carers, keyworkers etc.

N/A

13d. Are there any special pressures that might make it difficult for people to refuse to take part in the study (e.g. the potential participants are students or colleagues of the Researcher)? How will you address this?
Potential participants will not be coerced into taking part in this study. They will be provided with the informed consent documents, and if they do not wish to take part then they will not take part.

14. PARTICIPANT'S INVOLVEMENT: RISKS, REQUIREMENTS AND BENEFITS

14a. What potential hazards, risks or adverse effects associated with the study?
The principal researcher is trained in the use of tape measures and skinfold calipers. There may be some transient red markings where the calipers have squeezed, however this will fade very quickly.
14b. Does your study involves invasive procedures such as blood taking, muscle biopsy or drug administration?

No

If so, please provide details:

14c. Does your study involve genetic analysis or manipulation?

No

If so, please provide details,

14d. Please list the experience of the Researchers in the use of these procedures.

N/A

14e. If medical devices are to be used on any participant, do they comply with the requirements of the Medical Devices Directives?

N/A

14f. Please describe how you would deal with any adverse reactions or untoward incidents.

It is not envisaged that any untoward incidents will take place. To ensure this, the principal researcher is not recruiting females and all tests will be conducted in a private room

14g. Please name the locations or sites where the work will be done (room number, etc.)

Sport and Exercise Science Laboratory (AG50)

14h. Can women of child-bearing potential participate without significant risk?

N/A

14i. Can lactating women participate without significant risk?

N/A
14j. What is the potential for participants’ suffering pain, discomfort, distress, inconvenience or changes to lifestyle as a result of participation?
None, other than slight nipping from the calipers

14k. Will group or individual interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting? If so, please list these topics and explain how you will prevent, or respond to, volunteer discomfort.
N/A

14. Is it possible that criminal or other disclosures requiring action (e.g. evidence of professional misconduct) could take place during the study? If yes, give details of what procedures will be put in place to deal with these issues. The information sheet should make it clear under which circumstances action may be taken by the researcher.
No

14n. What circumstances might lead a participant not to continue with the study?
Nothing

14o. What circumstances might lead to termination of the study in part or as a whole?
Insufficient volunteers

15. FINANCIAL INCENTIVES, EXPENSES AND COMPENSATION

15a. Will travelling expenses be given? If so, an appropriate comment should be included on the Information Sheet
No

15b. Is any financial or other reward, apart from travelling expenses, to be given to participants? If yes, please give details and justification.
No

15c. Will the study result in financial payment or payment in kind to the department? Please specify, including the amounts involved.
No
15d. If this study is being carried out in collaboration with a pharmaceutical company or an equipment manufacturer, please give the name of the company and indicate what arrangements exist for compensating patients or healthy volunteers for adverse effects resulting from their participation in the study (The Committee is unlikely to approve protocols if the pharmaceutical company involved fails to confirm, in writing, that it abides by ABPI guidelines).
N/A

16. CONFIDENTIALITY, ANONYMITY AND DATA STORAGE

16a. What steps will be taken to ensure confidentiality? Give details of the anonymisation procedures to be used, and at what stage they will be introduced.
Records will be kept in locked drawers

16b. Who will have access to the records and resulting data?
The principal researcher and his supervisor Dr Kate Woolf–May

16c. Where, and for how long, do you intend to store the consent forms and other records?
For the duration of the research

17. INFORMATION SHEET AND CONSENT FORM

The information sheet for participants should be designed according to the given guidelines and submitted alongside this protocol. The standard consent form should also be used and submitted with the name of your project added. Details of how these documents should be used are provided in the guidelines for applicants.

The following, where applicable, are attached to this form (please tick):

- Participant Information Sheet ✓
- Consent Form ✓
- Letter to general practitioners
- Letter to parents/guardians/key carer/social services
- Copy of email recruitment circular/poster/press advertisement
AUTHORISING SIGNATURES

The information supplied above is to the best of my knowledge and belief accurate. I have read the notes to Researchers and clearly understand my obligations and the rights of study participants, particularly in so far as to obtaining valid consent.

Signature of Researcher:

............................................................  ..................................................  ..................................................  ..................................................  ..................................................  Date.............

Signature of Supervisor/Head of Department [staff] :

............................................................  ..................................................  ..................................................  ..................................................  ..................................................  Date.............

Signature of Medical Supervisor (if appropriate) :

............................................................  ..................................................  ..................................................  ..................................................  ..................................................  Date.............

Communications about this application should be addressed to:

Name: Andrew Scott
Address: (full postal address please)
Department of Sport Science, Tourism and Leisure
Canterbury Christ Church University
North Holmes Road
Canterbury
Kent CT11QU
Telephone No: 01227 767700 ext. 3145
E mail: ats5@cant.ac.uk
G.4.3 Participant information document

Department of Sport Science, Tourism and Leisure
North Holmes Road, Canterbury, Kent CT1 1QU.

VOLUNTEER INFORMATION SHEET

The reliability of waist and hip circumferences and sum of skin folds

You are being invited to take part in a research study. Before you decide 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 others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Take time to decide whether or not you wish to take part.

What is the purpose of the study?
The purpose of the study is to determine the reliability of my measurement of seven-site sum of skinfolds and waist and hip circumferences.

Do I have to take part?
Even if you are accepted onto the study, it is up to you to decide whether or not you wish to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw from the study at any time, and without giving a reason.

Will I get any payment for taking part?
Unfortunately, we do not have the funding to pay for your participation in the study or to reimburse you for travel costs to any of the tests.

What will happen to me if I take part?
If you decide that you would like to take part in the study, you will have your waist and hip circumferences measured and your body composition measured by skinfolds (7-site, 3 at each site).
Pre–study measurements
Pre study recordings include age, height and weight.

The study procedures
On arrival in at the Sport and Exercise Science laboratory you will have your body composition assessed by seven–site sum of skinfolds (chest, under the arm, back of the arm, below the shoulder blade, above the hip, to the right of the navel and middle of the front of the thigh). Waist circumference will be measured at the narrowest part of the abdomen between the lowest partial rib and the iliac crest. Hip circumference will be measured around participants underwear at the widest part of the hips above the gluteal fold. The assessment will last ~30 minutes.

How often will I have to be tested?
On two occasions

What are the benefits of taking part?
Receiving a repeated basic anthropometric health assessment

Will taking part harm my health?
Taking part will not harm your health

What if something goes wrong?
There is no potential for anything going wrong in this study. The tests use basic anthropometric measures – tape measure and skinfold callipers.

Will my taking part in this study be kept confidential?
All information, which is collected about you during the course of the research, will be kept strictly confidential. Furthermore, any collected data will only be kept for the duration of the research.

What will happen to the results of the research study?
You will receive a copy of your own results from the study.

Who has reviewed the study?
The Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University, has reviewed the study.

Contact for Further Information
If you are interested in taking part in the study or require additional information.
Please contact Andrew Scott on 01227 767600 x 3145 or e-mail ats5@cant.ac.uk

Thank you for reading this.
**CONSENT FORM**

The reliability of waist and hip circumferences and sum of skin folds

Please initial box

1. I confirm that I have read and understand the information sheet dated ....................... (version 1.) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

3. I understand that any personal information that I provide to the researchers to be kept strictly confidential.

4. I agree to take part in the above study.

Name of Subject Date Signature

Name of Person taking consent Date Signature (if different from researcher)

Researcher Date Signature

1 copy for the patient, 1 for researcher and 1 to be kept with subject’s notes
G.5 Blood pressure measures cross-comparison

G.5.1 Aneroid sphygmomanometry vs. automated oscillometric monitoring

Introduction

Measurements involved with health-related fitness assessment can provide important information regarding the health of individuals, including blood pressure (BP), body fat (BMI and/or body composition estimations), serum cholesterol and aerobic fitness. Therefore, it is essential to ensure that such measurements are valid; in this case assessment of BP. Blood pressure is measured in millimetres of mercury (mm Hg) and systolic blood pressure (SBP) is measured as the greatest pressure exerted by the heart and the vasculature on the blood during ventricular contractions and diastolic blood pressure (DBP) is the residual pressure of the vasculature during ventricular relaxation. The most direct and accurate method for the assessment of BP is by using an aortic catheter, which directly measures the measures from within the lumen of the aorta. However, this method is impractical, extremely invasive and can only be performed by trained practitioners. Mercury column sphygmomanometers were traditionally used by health practitioners, in conjunction with stethoscopes, to assess systolic and diastolic BP. However, for health and safety precautions these have been replaced by manual aneroid sphygmomanometers, which have an aneroid dial instead of a mercury column.

The principles of the two methods make use of the disturbances in blood flow through the brachial artery in the when a force is applied. This force is applied by a sphygmomanometer cuff, which constricts the brachial artery until no or little blood flow is apparent and is then gradually loosened, which causes turbulent blood flow. The turbulent flow within the artery results in the blood beating and making sounds against the walls of the artery in rhythm with each heart beat. The practitioner listens for these ‘Korotkoff
sounds’ by applying the stethoscope to the brachial artery in the cubital fossa. SBP is recorded at the point where the pulse becomes apparent again. When the cuff is loosened sufficiently to allow the artery to fully dilate, the blood flow reverts to the normal laminar flow and the sounds disappear, thus indicating DBP. There are five Korotkoff sounds: 1) the first sound heard on releasing the cuff represents the systolic pressure, 2) the murmurs heard for most of the area between the systolic and diastolic pressures, 3 & 4) pressures within 10 mmHg above the diastolic blood pressure can be described as "thumping" and "muting", with the fourth sound being used on occasions to represent the diastolic pressure if number five is undecipherable, and 5) silence as the cuff pressure drops below the diastolic blood pressure and this sound denotes the diastolic pressure. Mean arterial pressure (MAP) is the mean pressure within the cardiovascular system and can be calculated from the mean of the difference between SBP and DBP and then added to DBP and corrected using a factor. In this thesis MAP was calculated using 0.33 of the difference between SBP and DBP: \((\text{SBP} – \text{DBP}) \times 0.33 + \text{DBP}\). Pulse pressure (PP) is the additional pressure exerted during ventricular systole above the diastolic pressure and is measured as the difference between SBP and DBP.

Since using the aortic catheter technique is difficult to administer and is impractical when more simple BP measurement techniques were available, an automated oscillometric BP monitor was used as a means of comparison for the aneroid sphygmomanometer method. The process of oscillometric blood pressure determination is similar to aneroid sphygmomanometry, where the cuff is pressurised to 160 mm Hg for the first reading, or if further readings are taken ~30 mm Hg above the previous SBP reading or ~65 mm Hg above the previous MAP reading (Ramsey, 1991). The cuff is then deflated in a stair step fashion, where the time at each pressure step is determined by the time it takes for two
consecutive cardiac contractions to produce two equal pressure oscillations in the cuff and these oscillations are monitored by a microprocessor, from which SBP, DBP and MAP are analysed by reading the cuff pressure at parameter pressure points. Individuals untrained in manual sphygmomanometry may prefer to use automated systems, such as automated oscillometric monitoring, to measure blood pressure. However, those trained in the use of manual sphygmomanometry may prefer to use aneroid sphygmomanometry to measure the blood pressure of participants due to the error that may occur with automated systems. Therefore, the purpose of the study was to compare SBP, DBP, MAP and PP readings using an aneroid sphygmomanometer and an automated oscillometric monitor.
Method

Introduction
Thirty males (age 50.23 ± 11.83 years; height 1.78 ± 0.07 m; mass 87.35 ± 14.54 kg) volunteered and gave their written informed consent to take part in the study, which was approved by the Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University (Appendix G.5.2). The participants were advised of the procedures (G.5.3) and then signed the informed consent form (G.5.4).

Procedures
Each participant performed a single trial. The participants’ height and mass were measured using a stadiometer and beam balance scales (both Seca, Hamburg, Germany) to the nearest 1 cm and 100 g, respectively. After remaining seated for at least 5 minutes in a seat with an arm rest, each participants’ systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and pulse pressure (PP) were assessed from the participants’ right arm using both an aneroid sphygmomanometer (AS; Accoson Limpet, A.C. Cossor & Son Ltd, London, UK) and then an automated oscillometric monitoring (AOM; Dinamap Pro 200, GE Healthcare, Bucks, UK). The AS method was employed first during each trial in order to ensure that the readings from the AS measurements could not be influenced by the AOM readings.

Three SBP and three DBP measures were recorded using the AS and AOM methods plus AOM also calculated MAP, and the mean was derived for each. MAP was calculated using (SBP-DBP)*0.33 + DBP from the mean of the SBP and DBP measures for the AS method. PP was calculated in both methods by the difference between the mean SBP values and mean DBP values.
Statistical analysis
The data are presented as mean ± SD and were analysed using 95% confidence intervals, limits of agreement and intraclass correlation coefficients.
Results

Systolic blood pressure

The mean values from both methods indicate that the SBP values were virtually the same for this group (Figure G5.1). The intra-class correlation demonstrates that even though there were minor discrepancies between the two methods for some of the participants, the relationship was still strong (ICC=0.898).

![Figure G5.1](image-url)

The 95% limits of agreement for SBP assessed by AS vs. AON

- **Mean difference**: 3.65 ± 2.85 mm Hg
- **Mean CV**: 2.83 ± 2.07%
- **ICC**: 0.898
- **R²**: 0.0089

Figure G5.1  The 95% limits of agreement for SBP assessed by AS vs. AON
Diastolic blood pressure

The mean values measured by both measures indicate that AS slightly over-estimates DBP relative to AOM (Figure G5.2). The relationship between AS and AOM between for the measurement of DBP was almost as strong as that for SBP (ICC=0.824), however the 95% limits of agreement indicate a greater lack of agreement than for SBP.

**Figure G5.2** The 95% limits of agreement for DBP assessed by AS vs. AON
Mean arterial pressure
Due to the similarity of the relationships between AS and AOM for both SBP and DBP, the measurement of MAP is also similar between methods (Figure G5.3). Mean MAP was similar for both methods, as are the 95% CIs and the correlation also shows a strong relationship (ICC=0.816).

**Figure G5.3** The 95% limits of agreement for MAP assessed by AS vs. AON
Pulse pressure

The mean PP values indicate there was a slight difference in the magnitude of the PP between the two methods. This is likely to be an artefact of the very minor differences between the measurement of SBP and DBP between the methods, particularly for the measurement of DBP (Figure G5.4).

**Figure G5.4** The 95% limits of agreement for PP assessed by AS vs. AON
Discussion

The purpose of the study was to compare SBP, DBP, MAP and PP readings using an aneroid sphygmomanometer and an automated oscillometric monitor. The mean values from both methods indicate that the SBP values were virtually the same for this group, apart from three clear outliers. The intra-class correlation demonstrates that even though there were minor discrepancies between the two methods for some of the participants, the relationship was still strong (ICC=0.898). The mean values measured by both measures indicate that AS slightly over-estimates DBP relative to AOM. The relationship between AS (aneroid sphygmomanometry) and AOM (automated oscillometric monitoring) between for the measurement of DBP was almost as strong as that for SBP (ICC=0.824), however due to AS tending to overestimate DBP relative to AOM there was less agreement for DBP than SBP between the two methods according to the 95% limits of agreement. Due to the slight differences between AS and AOM for DBP, the measurement of MAP was also slightly different between methods according to the 95% limits of agreement, however the CV and the correlation coefficients also shows a strong relationship (ICC=0.816). The mean PP values indicate there was a slight difference in the magnitude of the PP between the two methods. This is likely to be an artefact of the very minor differences between the measurement of SBP and DBP between the methods, even though these were not great. In summary, there was a strong degree of agreement between aneroid sphygmomanometry and automated oscillometry for systolic blood pressure, diastolic blood pressure, mean arterial pressure and pulse pressure. However, it would be advisable not to use these methods interchangeably due to different blood pressure readouts that occurred at times.
G.5.2 Research ethics committee proposal

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FACULTY RESEARCH ETHICS COMMITTEE (FREC)

Request for Ethics Approval

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APPLICATION FOR FREC APPROVAL

*Please type your application. Remember that applications must be printed out, authorised, and then sent, with X copies, to the FREC office.*

1. **TITLE OF YOUR STUDY**
   A comparison of an aneroid sphygmomanometer with an automated oscillometric blood pressure monitor

2. **NATURE OF PROJECT**
   The common measure of arterial blood pressure is the mercury column sphygmomanometer. Using this device requires the palpation of the radial pulse to determine systolic blood pressure and the use of a stethoscope to listen for the fifth Karotkoff sound to determine diastolic blood pressure. Using this method requires training and skill. However, the use of an automated system negates the requirement of skill and the machine does all the work. The aim of this study is to determine the validity of the measurements provided by the automated blood pressure monitor, and hence whether the easier method is outweighed by invalid measurements

3. **INVESTIGATORS**
   3a. Principal Investigator

   **Name:** Andrew Scott
   **Post:** Postgraduate Research Student
**Department:** Department of Sport Science, Tourism and Leisure

**Qualifications:** BSc (Hons.) Sport, Recreation and Physical Education with Human and Applied Biology
MSc Exercise Physiology
Health/Fitness Instructor certified by the American College of Sports Medicine
Phase IV instructor certified by the British Association of Cardiac Rehabilitation
British Red Cross Trained First Aider

**Previous experience of Research on Human Subjects:**
- Final year undergraduate dissertation – The influence of caffeine on endurance capacity
- MSc Thesis – The influence of carbohydrate–electrolyte solutions on performance and metabolism during intermittent high intensity exercise

3b. **Other investigators/collaborators** (please note their employer if they are not employees of CCCUC)
Dr Kate Woolf–May
Dr Ian Swaine

4. **TIMETABLE**

4a. **Intended start date:** January 2006

4b. **Projected date of project's submission:** March 2006

5. **RESEARCH SPONSOR / OTHER ORGANISATIONS INVOLVED**
If your study involves another organisation, please provide details. Evidence that the relevant authority has given permission will be needed (ie. a letter).

6. **OTHER REC APPROVAL**
6a. **Has the proposed study been submitted to any other reviewing body?** If so, please provide details.
A large-scale study has been approved by the local NHS research ethics committee, and the measurement of blood pressure was included in the approval
7. PURPOSE OF THE STUDY
The purpose of the study is to compare blood pressure measurements provided by an aneroid sphygmomanometer with those provided by an automated oscillometric blood pressure monitor (Dinamap). This is because the principal researcher will be using the aneroid sphygmomanometer to assess blood pressure in studies leading to the award of PhD and the need to compare such devices is necessary in the absence of intra-aortic measurement expertise.

8. STUDY DESIGN, METHODOLOGY AND DATA ANALYSIS
Each participant will have their blood pressure assessed through automated oscillometry and sphygmomanometry, therefore the study will have a repeated measures design. Participants will be seated and their blood pressure will be measured three times using the sphygmomanometer and three times using the automated oscillometer on the same occasion. The mean score of each of the three measures will be calculated and used for comparison. The validity of measuring blood pressure by automated oscillometry will be determined using limits of agreement (95%: mean difference ± (SD × 1.96)).

9. ETHICAL CONSIDERATIONS
Ethical considerations of the study include maintaining the privacy of the subjects by reporting their data anonymously using participant numbers and only disclosing their measurements to that person.

10. SUBJECTS TO BE STUDIED
Number of volunteers: 30 males
Lower age limit: 40
Upper age limit: 65

11. SELECTION CRITERIA
None specific

12. RECRUITMENT
Through direct contact

13. CONSENT
13a. How is consent to be obtained (attach copies of any information sheet(s) and consent forms that will be used)?
Through information forms and an informed consent document
13b. Will the participants be from any of the following groups? (Tick as appropriate.)

- Children under 18
- Children in care
- Those with learning disability
- Those suffering from dementia
- Prisoners
- Young Offenders (16–21 years old)
- Those who could be considered to have a particularly dependent relationship with the investigator, eg those in care homes, students
- Other vulnerable groups

How will you ensure that participants in the groups listed above are competent to consent to take part in this study? Please attach any correspondence to parents, guardians, carers, keyworkers etc.

13c. Are there any special pressures that might make it difficult for people to refuse to take part in the study (e.g. the potential participants are students or colleagues of the investigator)? How will you address this?

Any people I contact are free to say no. If they are sure I will supply them with the informed consent and information forms to let them make up their own mind.

14. PARTICIPANT'S INVOLVEMENT: RISKS, REQUIREMENTS AND BENEFITS

14a. What potential hazards, risks or adverse effects associated with the study?

There are no potential hazards, risks or adverse effects associated with the study.

14b. Does your study involves invasive procedures such as blood taking, muscle biopsy or drug administration?

No

14c. Does your study involve genetic analysis or manipulation?

No
14d. Please list the experience of the investigators in the use of these procedures.
   The principal investigator is trained in assessing blood pressure through undergraduate studies and also as part of my Personal Trainer award.

14e. If medical devices are to be used on any subject, do they comply with the requirements of the Medical Devices Directives?

14f. Please describe how you would deal with any adverse reactions or untoward incidents.
   The principal investigator is a trained first aider (Red Cross First Aid at Work) and so are the other employees and research students in the sport and exercise science laboratory.

14g. Please name the locations or sites where the work will be done (room number, etc.)
   AG50

14h. Can women of child-bearing potential participate without significant risk?
   N/A

14i. Can lactating women participate without significant risk?
   N/A

14j. What is the potential for participants' suffering pain, discomfort, distress, inconvenience or changes to lifestyle as a result of participation?
   None

14k. Will group or individual interviews, questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting? If so, please list these topics and explain how you will prevent, or respond to, volunteer discomfort.

14l. Is it possible that criminal or other disclosures requiring action (e.g. evidence of professional misconduct) could take place during the study? If yes, give details of what procedures will be put in place to deal with these issues. The information sheet should make it clear under which circumstances action may be taken by the researcher.
14m. Please describe any expected benefits to the research participant.

Benefits to the participant include two free blood pressure assessments in a short space of time

14n. What circumstances might lead a participant not continue with the study?

People ay not want themselves or other people to know what their blood pressure is, or the inflatable cuff may be slightly uncomfortable

14o. What circumstances might lead to termination of the study in part or as a whole?

None

15. FINANCIAL INCENTIVES, EXPENSES AND COMPENSATION

15a. Will travelling expenses be given? If so, an appropriate comment should be included on the Information Sheet

No

15b. Is any financial or other reward, apart from travelling expenses, to be given to participants? If yes, please give details and justification.

No

15c. Will the study result in financial payment or payment in kind to the department? Please specify, including the amounts involved.

No

15d. If this study is being carried out in collaboration with a pharmaceutical company or an equipment manufacturer, please give the name of the company and indicate what arrangements exist for compensating patients or healthy volunteers for adverse effects resulting from their participation in the study (The Committee is unlikely to approve protocols if the pharmaceutical company involved fails to confirm, in writing, that it abides by ABPI guidelines).

16. CONFIDENTIALITY, ANONYMITY AND DATA STORAGE

16a. What steps will be taken to ensure confidentiality? Give details of the anonymisation procedures to be used, and at what stage they will be introduced.

Participants will be recognized by a number and this will be introduced when their data is stored
16b. Who will have access to the records and resulting data?
The principal investigator will have access to the records and resulting data

16c. Where, and, for how long, do you intend to store the consent forms and other records?
Records will be kept in locked cabinets for the duration of the research

17. INFORMATION SHEET AND CONSENT FORM
The information sheet for participants should be designed according to the given guidelines and submitted alongside this protocol. The standard consent form should also be used and submitted with the name of your project added. Details of how these documents should be used are provided in the guidelines for applicants

The following, where applicable, are attached to this form (please tick):
- Participant Information Sheet √
- Consent Form √

AUTHORIZING SIGNATURES

The information supplied above is to the best of my knowledge and belief accurate. I have read the notes to investigators and clearly understand my obligations and the rights of subjects/study participants, particularly in so far as to obtaining valid consent.

Signature of Principal Investigator
................................................................. ................................ .................................. Date..............

Signature of Head of Department
................................................................. ................................ .................................. Date..............

Communications about this application should be addressed to:

Name: Andrew Scott
Address: (full postal address please)
  Department of Sport Science, Tourism and Leisure
  Canterbury Christ Church University College
  Canterbury Kent CT1 1QU
  Telephone No: 01227 767700 ext. 3145

E mail: ats5@cant.ac.uk
G.5.3 Participant information document

Department of Sport Science, Tourism and Leisure
North Holmes Road, Canterbury, Kent CT1 1QU.

VOLUNTEER INFORMATION SHEET

A comparison of an aneroid sphygmomanometer with an automated oscillometric blood pressure monitor

You are being invited to take part in a research study. Before you decide 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 others if you wish. Ask us if there is anything that is not clear or if you would like more information.

*Take time to decide whether or not you wish to take part.*

What is the purpose of the study?
The purpose of the study is to determine the validity of using an automatic blood pressure monitor for the measurement of blood pressure compared with a manual blood pressure monitor.

Do I have to take part?
Even if you are accepted onto the study, it is up to you to decide whether or not you wish to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw from the study at any time, and without giving a reason.

Will I get any payment for taking part?
Unfortunately, we do not have the funding to pay for your participation in the study or to reimburse you for travel costs to any of the tests.
What will happen to me if I take part?
If you decide that you would like to take part in the study, you will undergo six blood pressure measurements (3 with each method) in the Sport and Exercise Science laboratory. After this you will be provided 2 blood pressure measurements recorded by each method.

Pre-study measurements
Pre study recordings include age, height and weight.

The study procedures
On arrival in at the Sport and Exercise Science laboratory you will have your blood pressure taken 6 times (3 with each method). The mean will be calculated for each method and you will receive your mean blood pressure measurement immediately.

What tests will be carried out?
Automated oscillometric blood pressure measurement ×3 and mercury column sphygmomanometer blood pressure measurement ×3.

How often will I have to be tested?
Once only

What are the benefits of taking part?
Receiving two free blood pressure assessments in ~10 minutes

Will taking part harm my health?
Taking part will not harm your health

What if something goes wrong?
If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it.

Will my taking part in this study be kept confidential?
All information, which is collected about you during the course of the research, will be kept strictly confidential. Furthermore, any collected data will only be kept for the duration of the research.

What will happen to the results of the research study?
You will receive a copy of your own results from the study.
Who has reviewed the study?
The Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University, has reviewed the study.

Contact for Further Information
If you are interested in taking part in the study or require additional information. Please contact Andrew Scott on 01227 767600 x 3145 or e-mail ats5@cant.ac.uk

Thank you for reading this.
CONSENT FORM

A comparison of an aneroid sphygmomanometer with an automated oscillometric blood pressure monitor

Please initial box

1. I confirm that I have read and understand the information sheet dated ....................... (version 1.) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

3. I understand that any personal information that I provide to the researchers to be kept strictly confidential.

4. I agree to take part in the above study.

Name of Subject Date Signature

Name of Person taking consent Date Signature
(If different from researcher)

Researcher Date Signature

1 copy for the patient, 1 for researcher and 1 to be kept with subject's notes
G.6 Aneroid sphygmomanometry reliability

G.6.1 Intra- and inter-day reliability of aneroid sphygmomanometry

Introduction

Blood pressure (BP) is one of the most common measures of cardiovascular disease risk, where elevations in BP are associated with coronary heart disease and stroke. Due to the health risks associated with increased BP in epidemiological or cross-sectional studies, intervention studies, such as medication, diet and/or physical activity, are often used to determine whether reductions in blood pressure may be gained. In the case of this thesis, the method of intervention was physical activity, specifically walking. The influence of both acute and chronic bouts of walking on factors associated with metabolic syndrome (MetS), such as BP, was investigated.

In performing intervention studies the reliability of the measurement method is crucial in order to ensure that any differences are due to the intervention being studied rather than error on the part of the method. When measuring BP using aneroid sphygmomanometry, as previously described in the previous section, investigator error is most likely to occur rather than instrument error when performing the BP measurements. Furthermore, BP can fluctuate greatly in some individuals without explanation and both investigator and natural error may adversely affect the outcomes of research involving series of measurements, such as the 24 week and 24 hour intervention studies included in this thesis. Therefore, the purpose of this study was to determine the intra-day and inter-day reliability of SBP, DBP, MAP and PP measures using aneroid sphygmomanometry.
Method

Introduction

Thirteen males (age 59.9 ± 6.6 years; height 1.79 ± 0.05 m; mass 94.1 ± 17.2 kg) volunteered and gave their written informed consent to take part in the study, which was approved by the Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University (Appendix B.1). The participants were advised of the procedures (Appendix B.2) and then signed the informed consent form (Appendix B.3).

Procedures

Each participant performed two trials, two on the first visit and one more the following day. The participants’ height and mass were measured using a stadiometer and beam balance scales (both Seca, Hamburg, Germany) to the nearest 1 cm and 100 g, respectively. On the day of the first trial the participants’ BP was recorded twice, with 30 minutes separation (intra), and BP was measured again 24 hours after the first measurement (inter). During each test the participants were instructed to remain still for at least 5 minutes in a semi-supine position while systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and pulse pressure (PP) were assessed from the participants’ right arm using an aneroid sphygmomanometer (AS; Accoson Limpet, A.C. Cossor & Son Ltd, London, UK). Three SBP and three DBP measures were recorded, MAP was calculated using (SBP-DBP)*0.33 + DBP from the mean of the SBP and DBP measures and PP was calculated by the difference between the mean SBP values and mean DBP values.

Statistical analysis

The data are presented as mean ± SD and were analysed using coefficient of variation, 95% confidence intervals and intraclass correlation coefficients.
Results

Systolic blood pressure

There was a tendency for both intra and inter SBP values to rise slightly compared to the initial measurement, with the 95% CIs demonstrating an upward shift above the line of equality (Figure G6.1). The ICCs and CVs also indicate a similar degree of variation for inter- and intra-day measurements. Mean SBP was $120.4 \pm 17.0$ mm Hg for the initial measurement, $125.8 \pm 18.8$ mm Hg for the second intra-day measurement and $127.3 \pm 23.1$ mm Hg for the second inter-day measurement.

**Figure G6.1** The 95% CIs for intra and inter SBP measurements: – Intra , – Inter
Diastolic blood pressure

There was a tendency for both intra and inter DBP values to rise slightly compared to the initial measurement, with the 95% CIs demonstrating an upward shift above the line of equality (Figure G6.2). The ICCs and CVs also indicate that there was greater variation for the inter-day than the intra-day measurements, however the variation with DBP was less so than that of SBP. Mean DBP was 78.5 ± 8.5 mm Hg for the initial measurement, 80.4 ± 6.3 mm Hg for the second intra-day measurement and 80.4 ± 10.5 mm Hg for the second inter-day measurement.

![Figure G6.2](image)

**Figure G6.2** The 95% CIs for intra and inter DBP measurements: – Intra , – Inter
Mean arterial pressure
There was a tendency for intra MAP values to rise slightly compared to the initial measurement, with the 95% CIs demonstrating an upward shift above the line of equality (Figure G6.3). The 95% CIs for the inter-day measurements followed the line of equality, despite the apparent greater variation suggested by the ICC. The ICCs and CVs also indicate that there was greater variation for the inter-day than the intra-day measurements. Average MAP was 92.3 ± 10.9 mm Hg for the initial measurement, 95.4 ± 9.9 mm Hg for the second intra-day measurement and 95.9 ± 14.4 mm Hg for the second inter-day measurement.

**Figure G6.3** The 95% CIs for intra and inter MAP measurements: – Intra, – Inter
Pulse pressure

There was much greater variation in intra- and inter-day variation for PP values compared with the initial measurement with the ICCs indicating that there was variation for both the inter-day and intra-day measurements, despite the lines of best-fit and the 95% CIs generally following the line of equality (Figure G6.4). Mean PP was $41.9 \pm 10.7$ mm Hg for the initial measurement, $45.4 \pm 14.2$ mm Hg for the second intra-day measurement and $46.9 \pm 13.6$ mm Hg for the second inter-day measurement.

**Figure G6.4** The 95% CIs for intra and inter PP measurements: – Intra , – Inter
Discussion

The purpose of this study was to determine the intra-day and inter-day reliability of SBP, DBP, MAP and PP measures using aneroid sphygmomanometry. There was a tendency for both intra and inter SBP and DBP values to rise slightly compared to the initial measurement, with the 95% CIs demonstrating an upward shift above the line of equality. The ICCs and CVs also indicated a similar degree of variation for inter- and intra-day measurements. Mean SBP was $120.4 \pm 17.0$ mm Hg for the initial measurement, $125.8 \pm 18.8$ mm Hg for the second intra-day measurement and $127.3 \pm 23.1$ mm Hg for the second inter-day measurement, while mean DBP was $78.5 \pm 8.5$ mm Hg for the initial measurement, $80.4 \pm 6.3$ mm Hg for the second intra-day measurement and $80.4 \pm 10.5$ mm Hg for the second inter-day measurement. Consequently, there was a tendency for intra-day MAP values to rise slightly compared to the initial measurement, with the 95% CIs demonstrating an upward shift above the line of equality. The 95% CIs for the inter-day measurements followed the line of equality, despite the apparent greater variation suggested by the ICC. The ICCs and CVs also indicate that there was greater variation for the inter-day than the intra-day measurements.

Mean MAP was $92.3 \pm 10.9$ mm Hg for the initial measurement, $95.4 \pm 9.9$ mm Hg for the second intra-day measurement and $95.9 \pm 14.4$ mm Hg for the second inter-day measurement. There was much greater variation in intra- and inter-day variation for PP values compared with the initial measurement with the ICCs indicating that there was variation for both the inter-day and intra-day measurements, despite the lines of best-fit and the 95% CIs generally following the line of equality. Mean PP was $41.9 \pm 10.7$ mm Hg for the initial measurement, $45.4 \pm 14.2$ mm Hg for the second intra-day measurement and $46.9 \pm 13.6$ mm Hg for the second inter-day measurement. It is difficult to explain why
blood pressure results were greater on the second day, where both SBP and DBP tended to increase from day one, however the variety of the PP results indicate that SBP and DBP did not rise uniformly. The rise in blood pressure during the intra-day measures may be explained by the 30 minutes spent lying on the couch by the participants between measurements, and reducing vasodilation in normally active muscles.

In summary, there was generally a moderate degree of reliability for intra and inter-day measurements of blood pressure, however the variation in these measures may have been sufficient to decrease the statistical power for blood pressure in the two main studies included in this thesis (Sections 3.0 & 4.0), particularly study 1 in section 3.0, where there were no significant differences in blood pressure despite favourable trends.
G.7 HP-Cosmos treadmill validation

G.7.1 Validity and reliability of treadmill gradient, distance and speed

Introduction

Many ergometers are available on the market for the assessment of human work or means of simulating outdoor activities within the laboratory setting, such as treadmills, stationary cycles, rowing machines and arm-crank ergometers. There are many types of treadmill on the market at present, ranging from small domestic treadmills with no gradient options to hi-tech machines that can accommodate competitive cyclists. Due to the differences in the quality of the treadmill being used there may be error in their measurements or calibrations. Error can occur systematically or randomly. Systematic error is where the error is constant irrespective of the measurement, in the case of a treadmill belt speed whether the speed is 5 k·hr\(^{-1}\) or 15 k·hr\(^{-1}\) the error would be 0.1 k·hr\(^{-1}\) at both speeds if it were systematic. Conversely, if the error was random there would be no distinct pattern with the error, and this may depend on other factors than the treadmill, such as the participants’ body mass.

Some types of ergometers or parameters are more simple than others to calibrate/validate. In the case of the treadmill, the gradient was relatively straightforward to validate using an electronic inclinometer, however validating treadmill distance/speed can require an intricately designed system. In the case of this mini-study a method for attaching a measuring wheel to the treadmill was specifically created. The main aspect of this thesis was to investigate walking and the impact on cardio-metabolic health. The purpose of this study was to assess the validity of the gradient, distance and speed of the console display on a Mercury Medical treadmill (HP-Cosmos, Nussdorf-Traunstein, Germany) that was used in the main studies.
Method

Introduction
Ten habitually active participants (8 males and 2 females aged 33.90 ± 9.27 yrs, height 1.76 ± 0.09 m and mass 73.68 ± 10.56 kg) volunteered and gave their written informed consent to take part in the study, which was approved by the Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University (Appendix G.7.2). The participants were advised of the experimental procedures (Appendix G.7.3) and then signed the informed consent form (Appendix G.7.4).

Procedures
The participants’ height and mass were measured and recorded prior to the validation tests. Height was measured to the nearest 1 cm using a stadiometer (Seca, Hamburg, Germany) and body mass was measured to the nearest 100g using beam balance scales (Seca, Hamburg, Germany). Participants walked on the treadmill (Mercury Med., HP-Cosmos, Nussdorf-Traunstein, Germany) throughout the gradient test and the slow distance/speed tests, and ran during the 10 & 15 k·hr\(^{-1}\) distance/speed tests.

Gradient validation
The gradient of the treadmill was validated using an inclinometer (Clinomatic, Wyler AG, Winterthur Switzerland). This was situated on the foot rail of the treadmill to the side of the treadmill belt whilst the participants walked on the treadmill at 5 km·hr\(^{-1}\). The gradient validation test involved walking at this speed as the gradient on the treadmill was increased from 0\(^o\) to 13.5\(^o\), however the measurement at 13.5\(^o\) was not recorded yet went up this far to allow the actual gradient at 13\(^o\) to be measured twice The actual gradient of the treadmill was recorded at every 1\(^o\) increment according to the treadmill console display.
Distance/speed validation

The validation of the speed and distance displayed by the treadmill console was performed using a fixed measuring wheel (Measure Meter, Trumeter, York, UK) which was fixed to the treadmill using a home-made arrangement (Figure G.7.1).

![Figure G.7.1 Measuring wheel arrangement for the validation of distance/speed](image)

The participants were required to walk, jog and run at 5 km·hr⁻¹, 10 km·hr⁻¹ and 15 km·hr⁻¹, respectively, for 1000m according to the treadmill console display whilst the actual distance covered was measured using the measuring wheel. During the walk at 5 km·hr⁻¹ the actual distance covered at 200m, 400m, 600m and 800m on the treadmill console display was also recorded from the measuring wheel display. The treadmill belt speed was then determined from the actual distance covered by multiplying the actual distance the treadmill belt covered in metres by the speed that the console displayed (i.e. 979 m × 5 km·hr⁻¹ = 4895 m·hr⁻¹) and then dividing this number by 1000 to give  km·hr⁻¹.
Statistical analyses
The data are presented as the mean ± SD and were analysed using coefficient of variation, ICC, Pearson’s product-moment correlation coefficient, 95% confidence intervals and 95% limits of agreement.
Results

Gradient

The HP Cosmos display slightly under-estimated the actual gradient by $0.01 \pm 0.01^\circ$.

However, it is clear from figure G7.2 that there variation was very slight and that the main source of variation arose from $9^\circ$ onwards, whereas there was much more limited variation below this threshold. The CV between methods (0.15%) and individuals (0.67%) were relatively small and both the 95% LoA ($0.01 \pm 0.01^\circ$) and ICC ($r=1.000$) were very tight.

**Figure G7.2** The 95% limits of agreement for HP Cosmos displayed values and actual gradient
Distance

The treadmill belt distance was 3.97 ± 0.10 m behind the console display every 200 m. This equated to a mean percentage loss of 1.99 ± 0.05%. The actual distance covered by the treadmill belt every 200 m had a mean CV of only 0.45% between participants. The actual distance covered by the treadmill belt when the console displayed 1000 m was 980.20 ± 4.21 m, 992.10 ± 3.75 m and 977.50 ± 8.54 m at 5, 10 and 15 km·hr⁻¹, respectively. Therefore distance covered at increasing speed was relatively uniform (Figure G7.3).

Figure G7.3  The 95% limits of agreement for HP Cosmos displayed values and measured distance
Speed

Figure G7.4 indicates that the speed on the treadmill console over-estimates the speed of the treadmill belt when compared to the speed measured using a measuring wheel. This difference varies according to the belt speed, with losses of $-0.17 \pm 0.14 \text{ km/hr}^{-1}$. These findings demonstrate that the treadmill speed is consistent over a variety of running speeds (ICC=1.000).

**Figure G7.4** The 95% limits of agreement for treadmill speed between the console display and that measured by a measuring wheel.
Discussion

The purpose of this study was to determine whether the gradient, distance and speed displayed on the console on the treadmill satisfactorily compared to the same parameters measured independently using a measuring wheel and an electronic inclinometer. Gradient, compared to the electronic inclinometer, was relatively similar, with the difference being ~0.01° up until a gradient of 9°, after which the difference increased to 0.020-0.045°. The CV between methods (0.15%) and individuals (0.67%) indicated that there was limited variation between the values displayed on the console and that measured by the inclinometer and also between various participants. The 95% LoA (0.01 ± 0.01°) indicated that the mean difference between measures was very small and the ICC (r=1.000) demonstrates that the two measures were highly proportional to each other.

The mean difference between distance on the console display and that recorded by the measuring wheel was -3.97 ± 0.10 m, which equated to a mean percentage loss of 1.99 ± 0.05% (Figure ). The actual distance covered by the treadmill belt when the console displayed 1000m was 980.20 ± 4.211 m, 992.10 ± 3.755 m and 977.50 ± 8.541 m at 5, 10 and 15 km·hr⁻¹, respectively. Therefore distance covered at increasing speed was relatively uniform (Figure G7.3). The actual distance covered by the treadmill belt every 200 m had a mean CV of only 0.45% between participants, also indicating the systematic error over increasing treadmill speeds and between participants. However, it must be stated that the console may not have over-estimated actual distance because the measuring wheel may have been systematically biased, where although the best efforts were made to secure the measuring wheel to the treadmill that the bouncing belt may have caused the wheel to skip a few cm, thus under-estimating the actual treadmill belt speed.
The measuring wheel method indicates that the speed displayed on the treadmill console over-estimates the speed of the treadmill belt, with the mean difference being $0.17 \pm 0.14 \text{k}\cdot\text{hr}^{-1}$. The mean CV between speed displayed on the console and that measured by the wheel was $0.56 \pm 0.27\%$ and the ICC ($r=1.000$) indicate that the difference between measurements was small. These findings indicate that the treadmill speed is consistently slightly slower than the console indicates over a variety of running speeds, however this may also be due to potential error in the fixing of the measuring wheel to the treadmill.

The data included in this mini study suggest that the treadmill – Mercury Med., HP-Cosmos, Nussdorf-Traunstein, Germany – is relatively accurate for displaying the gradient, distance covered and the treadmill belt speed whilst being walked/ran on by participants.
G.7.2 Research ethics committee proposal

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**FACULTY OF BUSINESS & SCIENCES**  
**FACULTY RESEARCH ETHICS COMMITTEE**

**APPLICATION FOR FREC APPROVAL**

*Please type your application. Remember that applications must be printed out, authorised, and then one hard copy sent to: Roger Bone, FREC Administrator, c/o Research Office together with an emailed copy to rtb2@canterbury.ac.uk. Please ensure that you have answered all questions.*

<table>
<thead>
<tr>
<th>For official use only</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>FREC Protocol No:</td>
<td><strong>06/B&amp;S/015</strong></td>
</tr>
<tr>
<td>Date rec’d:</td>
<td>.........................</td>
</tr>
</tbody>
</table>

---

1. **RESEARCHERS**

1a. **Principal Researcher**

**Name:**  Andrew Scott  
**Post:**  Postgraduate Research Student  
**Department:**  Department of Sport Science, Tourism and Leisure  
**Qualifications:**  BSc(Hons.) Sport, Recreation and Physical Education with Human and Applied Biology  
- MSc Exercise Physiology  
- Health/Fitness Instructor certified by the American College of Sports Medicine  
- Phase IV instructor certified by the British Association of Cardiac Rehabilitation  
- British Red Cross Trained First Aider

**Previous experience of Research on Human Participants:**  
Final year undergraduate dissertation – the influence of caffeine on endurance performance
MSc thesis – the influence of carbohydrate-electrolyte solutions on metabolism and performance during intermittent intensity exercise
Ongoing research as part of MPhil/PhD investigating the influence of brisk walking on metabolic syndrome risk

1b. Other researchers/collaborators (please note their employer if they are not employees of CCCUC)
   Dr Kate Woolf-May
   Dr Ian Swaine

2. TITLE OF YOUR STUDY
   The validity of speed and gradient on the Mercury Med treadmill

3. LAY SUMMARY (no more than 300 words)
   As part of research leading to a PhD a treadmill will be used as a vehicle to determine the cardiorespiratory fitness of the participants. These treadmill tests include increasing both the speed and gradient of the treadmill. In order to be sure that the indications on the treadmill console represent the actual speed and gradient of the treadmill, the treadmill needs to be validated.

4. TIMETABLE
4a. Intended start date: January 2006
4b. Projected date of project's submission: June 2006

5. RESEARCH SPONSOR / OTHER ORGANISATIONS INVOLVED
   If your study involves another organisation, please provide details. Evidence that the relevant authority has given permission will be needed (ie. a letter).
   N/A

6. OTHER REC APPROVAL
6a. Has the proposed study been submitted to any other reviewing body? If so, please provide details.
   N/A

7. PURPOSE OF THE STUDY
   The purpose of the study is to validate the speed and gradient of the treadmill to ensure accuracy

8. STUDY DESIGN, METHODOLOGY AND DATA ANALYSIS
   Participants will be required to provide ~45 minutes of their time on a single occasion. On this occasion the participants will first be asked to walk at 5 km·hr⁻¹ while the gradient of the treadmill is increased from 0° to 13.5°, 1° at a time and
then back down to $0^\circ$ again $1^\circ$ at a time. During this time an electronic goniometer will measure the gradient of the treadmill between $1-13^\circ$. Following this the participants will be asked to walk 1000 metres at a speed of $5\text{ km}\cdot\text{hr}^{-1}$, jog 1000 metres at $10\text{ km}\cdot\text{hr}^{-1}$ and run 1000 metres at $15\text{ km}\cdot\text{hr}^{-1}$. During the walk at $5\text{ km}\cdot\text{hr}^{-1}$ the distance the treadmill belt has travelled will be measured every 200m using a trundle wheel attached to the treadmill frame and the distance covered when the console reads 1000m will also be recorded. At treadmill speeds $10$ & $15\text{ km}\cdot\text{hr}^{-1}$, just the distance covered by the treadmill belt when the console reads 1000m will be recorded. Belt speed can then be calculated from the distance travelled by the belt by using the following formula:

\[(\text{actual distance covered}/1000) \times \text{console speed} = \text{actual treadmill belt speed}\]

\[i.e. \ (979/1000) \times 10\text{ km}\cdot\text{hr}^{-1} = 9.79\text{ km}\cdot\text{hr}^{-1}\]

The mean values for speed and gradient will be calculated and presented as the mean ± SD, and coefficient of variation and 95% confidence intervals will also be calculated.

9. **ETHICAL CONSIDERATIONS**

Ethical considerations of this study include ensuring that each participant is capable of understanding the study and performing the validation tests. All data will be kept in accordance with the 1998 Data Protection Act.

10. **PARTICIPANTS TO BE STUDIED**

<table>
<thead>
<tr>
<th>Number of volunteers:</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower age limit:</td>
<td>18</td>
</tr>
<tr>
<td>Upper age limit:</td>
<td>50</td>
</tr>
</tbody>
</table>

11. **SELECTION CRITERIA**

Fit and healthy adults (males and females) absent of disease or disability that prevents them using a treadmill.

12. **RECRUITMENT**

Direct contact

13. **CONSENT**

13a. **How is consent to be obtained (attach copies of any information sheet(s) and consent forms that will be used)?**

Informed consent will be gained using an information form and a consent form.

13b. **Will the participants be from any of the following groups? (Tick as appropriate.)**

- Children under 18
- Children in care
- Those with learning disability
- Those suffering from dementia
- Prisoners
- Young Offenders (16-21 years old)
- Those who could be considered to have a particularly dependent...
relationship with the researcher, e.g. those in care homes, students
Other vulnerable groups

13c. How will you ensure that participants in the groups listed above are competent to consent to take part in this study? Please attach any correspondence to parents, guardians, carers, keyworkers etc.
N/A

13d. Are there any special pressures that might make it difficult for people to refuse to take part in the study (e.g. the potential participants are students or colleagues of the Researcher)? How will you address this?
Students, colleagues etc will not be coerced into taking part

14. PARTICIPANT’S INVOLVEMENT: RISKS, REQUIREMENTS AND BENEFITS

14a. What potential hazards, risks or adverse effects associated with the study?
During any physical activity there is a heightened risk of injury or sudden cardiac death, however for those without underlying cardiovascular disease the risk of sudden cardiac death during physical activity and exercise is minimal (Stuarts, RJ & Ellestad, MH, 1980 National Survey of Exercise Stress Testing Facilities. Chest 77: 94-7) observed only 5 incidences per 100,000 (0.0005%) during maximal aerobic fitness tests. Risk is further reduced when accompanied by health questionnaires (ACSM, 2000). During the tests the participants will be monitored by heart rate, perceived exertion and also their ability to converse during exercise. If at any time the participants show signs of undue distress then the test will be terminated immediately.

Some pilot work has already been performed involving the principal researcher and colleagues, some of whom even tried running at 20 kph. A possible risk with this study is the suitability of the volunteers to perform the runs. Only those that are habitually active and are familiar with a treadmill will be selected. Many recreational runners will “jog” at 15 kph for hours, whereas this task only requires 4 minutes. The principal researcher will be present throughout the test recording the belt speed and the gradient. The participants may terminate the test at any point. The principal researcher is a trained first aider, exercise physiologist and a certified personal trainer by the American College of Medicine, who can recognize signs of distress during exercise and will terminate a test if participants are uncomfortable. All-in-all these procedures will minimize the risk of a stumble or cardiac failure.

14b. Does your study involves invasive procedures such as blood taking, muscle biopsy or drug administration?
No

If so, please provide details:

14c. Does your study involve genetic analysis or manipulation?
No
If so, please provide details,

14d. Please list the experience of the Researchers in the use of these procedures. 
N/A

14e. If medical devices are to be used on any participant, do they comply with the requirements of the Medical Devices Directives? 
N/A

14f. Please describe how you would deal with any adverse reactions or untoward incidents. 
All staff from the Sport and Exercise Science Laboratory are trained first aiders and are therefore able to deal with any situation related to these tests.

14g. Please name the locations or sites where the work will be done (room number, etc.) 
Sport and Exercise Science Laboratory (AG50)

14h. Can women of child-bearing potential participate without significant risk? 
Yes

14i. Can lactating women participate without significant risk? 
No

14j. What is the potential for participants' suffering pain, discomfort, distress, inconvenience or changes to lifestyle as a result of participation? 
The potential for any of these events is minimal. If any participant suffers pain, discomfort or distress the test will be stopped immediately, and the test lasts ~45 minutes and therefore should not be an inconvenience.

14k. Will group or individual interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting? If so, please list these topics and explain how you will prevent, or respond to, volunteer discomfort. 
No

14l. Is it possible that criminal or other disclosures requiring action (e.g. evidence of professional misconduct) could take place during the study? If yes, give details of what procedures will be put in place to deal with these issues. The information sheet should make it clear under which circumstances action may be taken by the researcher. 
No

14m. Please describe any expected benefits to the research participant. 
None, other than taking part in research
14n. What circumstances might lead a participant not to continue with the study?
If they are uncomfortable with the requirements of the treadmill tests

14o. What circumstances might lead to termination of the study in part or as a whole?
In the unlikely event that insufficient participants volunteer

15. FINANCIAL INCENTIVES, EXPENSES AND COMPENSATION
15a. Will travelling expenses be given? If so, an appropriate comment should be included on the Information Sheet
No

15b. Is any financial or other reward, apart from travelling expenses, to be given to participants? If yes, please give details and justification.
No

15c. Will the study result in financial payment or payment in kind to the department? Please specify, including the amounts involved.
No

15d. If this study is being carried out in collaboration with a pharmaceutical company or an equipment manufacturer, please give the name of the company and indicate what arrangements exist for compensating patients or healthy volunteers for adverse effects resulting from their participation in the study (The Committee is unlikely to approve protocols if the pharmaceutical company involved fails to confirm, in writing, that it abides by ABPI guidelines).
N/A

16. CONFIDENTIALITY, ANONYMITY AND DATA STORAGE
16a. What steps will be taken to ensure confidentiality? Give details of the anonymisation procedures to be used, and at what stage they will be introduced.
Records will be kept in accordance with the Data Protection Act (1998)

16b. Who will have access to the records and resulting data?
The principal researcher and supervisors will have access to the records will have access to the records

16c. Where, and, for how long, do you intend to store the consent forms and other records?
For the duration of the research

17. INFORMATION SHEET AND CONSENT FORM
The information sheet for participants should be designed according to the given guidelines and submitted alongside this protocol. The standard consent form
should also be used and submitted with the name of your project added. Details of how these documents should be used are provided in the guidelines for applicants.

The following, where applicable, are attached to this form (please tick):

- Participant Information Sheet ✓
- Consent Form ✓

**AUTHORISING SIGNATURES**

*The information supplied above is to the best of my knowledge and belief accurate. I have read the notes to Researchers and clearly understand my obligations and the rights of study participants, particularly in so far as to obtaining valid consent.*

Signature of Researcher:

.......................................................... ................................................ Date............

Signature of Supervisor/Head of Department [staff] :

.......................................................... ................................................ Date............

Communications about this application should be addressed to:

**Name:** Andrew Scott  
**Address:** Department of Sport Science, Tourism and Leisure  
Canterbury Christ Church University  
North Holmes Road  
Canterbury  
Kent CT1 1QU

Telephone No: 01227 767700 ext. 3145  
E mail: ats5@cant.ac.uk
G.7.3 Participant information document

Department of Sport Science, Tourism and Leisure
North Holmes Road, Canterbury, Kent CT1 1QU.

VOLUNTEER INFORMATION SHEET

The validity of speed and gradient on the Mercury Med treadmill

You are being invited to take part in a research study. Before you decide 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 others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Take time to decide whether or not you wish to take part.

What is the purpose of the study?
The purpose of the study is to determine the validity of the validity of the gradient and speed of the Mercury Med treadmill when compared with an electronic goniometer and a fixed trundle wheel.

Do I have to take part?
Even if you are accepted onto the study, it is up to you to decide whether or not you wish to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw from the study at any time, and without giving a reason.

Will I get any payment for taking part?
Unfortunately, we do not have the funding to pay for your participation in the study or to reimburse you for travel costs to any of the tests.

What will happen to me if I take part?
If you decide that you would like to take part in the study, you will attend the Sport and Exercise Science laboratory only once to perform a sub-maximal walking/running test, which you are free to stop at any point.
Pre-study measurements
Pre-study recordings include age, height and weight.

The study procedures
Once accepted onto the study you will perform the aerobic fitness tests in the Sport and Exercise Science laboratory. The protocols are outlined below.

Gradient validation – walk at 5 km·hr⁻¹ through the sequence of gradients shown below

<table>
<thead>
<tr>
<th>Stage</th>
<th>0°</th>
<th>Stage</th>
<th>9°</th>
<th>Stage</th>
<th>8°</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0°</td>
<td>10</td>
<td>10°</td>
<td>20</td>
<td>7°</td>
</tr>
<tr>
<td>2</td>
<td>1°</td>
<td>11</td>
<td>10°</td>
<td>20</td>
<td>7°</td>
</tr>
<tr>
<td>3</td>
<td>2°</td>
<td>12</td>
<td>11°</td>
<td>21</td>
<td>6°</td>
</tr>
<tr>
<td>4</td>
<td>3°</td>
<td>13</td>
<td>12°</td>
<td>22</td>
<td>5°</td>
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<td>5</td>
<td>4°</td>
<td>14</td>
<td>13°</td>
<td>23</td>
<td>4°</td>
</tr>
<tr>
<td>6</td>
<td>5°</td>
<td>15</td>
<td>12°</td>
<td>24</td>
<td>3°</td>
</tr>
<tr>
<td>7</td>
<td>6°</td>
<td>16</td>
<td>11°</td>
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<td>2°</td>
</tr>
<tr>
<td>8</td>
<td>7°</td>
<td>17</td>
<td>10°</td>
<td>26</td>
<td>1°</td>
</tr>
<tr>
<td>9</td>
<td>8°</td>
<td>18</td>
<td>9°</td>
<td>27</td>
<td>0°</td>
</tr>
</tbody>
</table>

You will be asked to walk at 5 km·hr⁻¹ at each of the gradients until the goniometer has settled enough to record a reading.

Speed validation

<table>
<thead>
<tr>
<th>Speed</th>
<th>Time</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walk 1000 metres – 5 km·hr⁻¹</td>
<td>12 minutes</td>
<td>calling out every 200 metres until 1000m so that the belt distance can be recorded from the trundle wheel</td>
</tr>
<tr>
<td>Jog 1000 metres – 10 km·hr⁻¹</td>
<td>6 minutes</td>
<td>at the completion of 1000m on the treadmill console, the distance on the trundle wheel will be recorded</td>
</tr>
<tr>
<td>Run 1000 metres – 15 km·hr⁻¹</td>
<td>4 minutes</td>
<td>at the completion of 1000m on the treadmill console, the distance on the trundle wheel will be recorded</td>
</tr>
</tbody>
</table>

How often will I have to be tested?
Once only

Will taking part harm my health?
If you are ready and able to run 1000m in four minutes, this should not be harmful to your health.
Will my taking part in this study be kept confidential?
All information, which is collected about you during the course of the research, will be kept in accordance with the Data Protection Act (1998). Furthermore, any collected data will only be kept for the duration of the research.

What will happen to the results of the research study?
The results will be used as part of research contributing to a PhD.

Who has reviewed the study?
The Faculty of Business and Sciences Research Ethics Committee, Canterbury Christ Church University, has reviewed the study.

Contact for Further Information
If you are interested in taking part in the study or require additional information. Please contact Andrew Scott on 01227 767600 x 3145 or e-mail ats5@cant.ac.uk

Thank you for reading this.
G.7.4 Informed consent document

Department of Sport Science, Tourism and Leisure
North Holmes Road, Canterbury, Kent CT1 1QU.

If you have any queries please contact Andrew Scott on 01227 767700 x 3145

Participant Identification Number for this trial:

CONSENT FORM

The validity of speed and gradient on the Mercury Med treadmill

Please initial box

1. I confirm that I have read and understand the information sheet dated ......................... (version 1.) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

3. I understand that any personal information that I provide to the researchers to be kept strictly confidential.

4. I agree to take part in the above study.

Name of Subject Date Signature

Name of Person taking consent Date Signature
(if different from researcher)

Researcher Date Signature

1 copy for the patient, 1 for researcher and 1 to be kept with subject’s notes