EMRG
Exercise Metabolism Research Group

UNIVERSITY OF BIRMINGHAM

PARTICIPANT INFORMATION SHEET

The effect of physical activity intervention flexibility on the time course of changes in body composition and metabolism.

Dear Participant,

Thank you for showing an interest in our study. Here is some further information regarding the nature of our investigation, along with the answers to some questions you may be wishing to ask. A member of our research team will go through this information sheet with you and answer any further questions directly. Please do ask if you wish for clarity over any matter.

Location of the study:

The study will take place in the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham. For more information about the laboratory facilities within the School please visit http://www.birmingham.ac.uk/facilities/human-performance-lab/about/index.aspx

Investigators:

Dr Andrew Blannin

Who is funding the research?

This research study is funded by Cereal Partners Worldwide.

Can I take part in the study?

We are looking for individuals who fulfill the following criteria:

- Female
- Aged 25-50 years old
- Inactive (less than 150 minutes of moderate-intensity aerobic physical activity per week)
- BMI 25-35 kg/m^2
- Good general health, as assessed by the School of Sport, Exercise and Rehabilitation Sciences' General Health Questionnaire
- Willing to strictly comply with all study procedures and restrictions
- Willing to participate, as demonstrated by voluntary written informed consent

Those who meet the following criteria will, unfortunately, be deemed unable to participate:

- Positive result from the urine sample pregnancy test
- Currently breast feeding
- Currently participating in another clinical trial deemed to potentially interfere with this study
- Current or recent (within the last 30 days) smoker
- Currently taking prescription or non-prescription medication that may interfere with metabolism (including beta-blockers, insulin, bronchodilators, anti-inflammatory agents, thyroxine and medication/supplements that in the opinion of the investigators may affect metabolism).

What is the study about?

Our goal is to optimise physical activity interventions to help previously inactive women improve their body shape and composition. Many people seeking to lose weight or improve body composition initiate an exercise programme. The most common recommendation of an exercise intervention for someone attempting to manage their weight, has been to 'prescribe' the recommended 150 minutes of exercise per week (World Health Organisation), often using one mode of exercise. An alternative approach might be to offer a portfolio of activities, from which the exerciser can pick and choose, to facilitate greater amounts of physical activity. The problem with this is how do you account for the different intensities of walking, washing the car, playing badminton, cycling, jogging, etc? In this study, we will try to overcome this barrier by allocating a number of "physical activity points" to each activity. Using this physical activity points system, participants will be provided with a points target that they can meet using any combination of activities.

Our research aim is therefore to compare this points-based system against the traditional 5x30minute prescription (and sedentary control) for their ability to help previously inactive women to drop a dress size, increase fat burning, positively change their body composition and tone their tummy.

How will I be involved?

Participation in this study will involve completing two preliminary visits to the Human Performance Laboratory, followed by the completion of a 24-week testing period. The study will conclude with a final visit to the laboratory at the end of the intervention.

<u>Preliminary visit 1: consent and familiarisation</u>

In the first of your visits to the Exercise Metabolism Laboratory, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, a member of our research team will recap the information within this document and you will be given the opportunity to ask any questions that you may have. If and when you are happy with the details of the study, a consent form will be signed. The Sport, Exercise and Rehabilitation Sciences General Health Questionnaire will be completed. You will be familiarised with the procedures of the pre-intervention testing session, with demonstrations of the muscle tonometer, ventilator hood and body silhouette equipment (all briefly described later in this document). A shortened version of the Fatmax test (described below) will be completed as a familiarisation trial for this procedure. The protocol for this test will be shorter, but will have the same endpoint, when you reach exhaustion and can no longer continue. Finally, you will receive instruction on how to accurately complete the physical activity and food diaries and how to wear the ActiGraph activity monitor system, all of which are to be used in the maintenance week.

Maintenance week:

After completing preliminary visit 1 you will complete a maintenance week, where you will be asked to maintain your usual activities. During this week, you will wear a small unobtrusive piece of apparatus called an ActiGraph activity monitor. This will consist of a heart rate monitor strap that is to be worn around your chest and a small accelerometer that is worn on your waist (see image below).

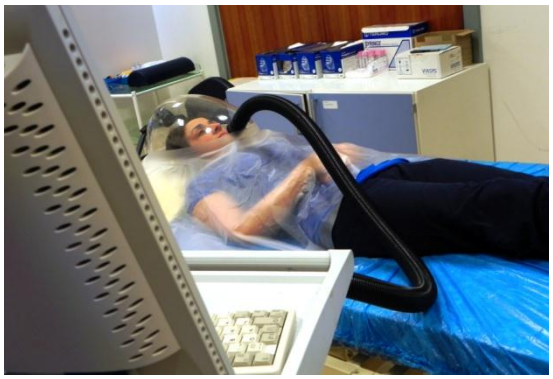
You will also be asked to complete a comprehensive 3-day food diary and begin to keep a physical activity diary, which you will continue doing for the whole study (24 weeks). It is important that you maintain a normal level of activity during this week and also carry out your normal eating habits.

Preliminary visit 2: pre-intervention testing

On this visit, you will arrive at the Exercise Metabolism Laboratory, School of Sport and Exercise Sciences between 07:30 and 08:00am following an overnight fast (nothing from 10pm the night before, except water) and after abstaining from exercise the day before. In addition, you will be asked to complete a food diary for the day prior to the testing day. You will then be asked to replicate this diet on the day prior to the three subsequent testing days. The first few measurements need to be taken both fasted and rested, so we will ask you to travel by car or public transport and to take the lift inside the building to the laboratory, to keep activity to a minimum. Once in the laboratory, you will complete a number of tests, in the sequence shown below. The procedure for each is as follows:

Fasting blood sample (optional – approximately 15 minutes): This is an optional measure, as we are aware that many people are not fond of needles. If you are willing to donate a blood sample, a 5ml sample will be obtained from the antecubital vein in the arm by a trained and experienced member of our research team.

Resting metabolic rate, resting fat oxidation rate and blood pressure (approximately 30 minutes): In order to measure resting metabolic rate and resting fat burning capacity we will measure the amount of oxygen you consume and carbon dioxide you produce while lying down. At approximately 8:30am you will be asked to lay supine for 30 minutes. A ventilated hood will be placed over your head, as shown in the image opposite, which will be connected to a breath-by-breath automated gas analysis system. Using a ventilated hood system allows you to lay and breathe freely while expired gas is collected and analysed.



Before placing you under the ventilated hood, we will attach a blood pressure cuff to your upper arm. We will then measure blood pressure using an automated blood pressure monitor immediately after the end of the resting metabolic rate measurement.

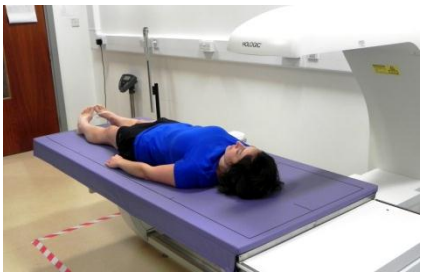
Fat_{max} and VO_{2max} test (approximately 30 minutes):

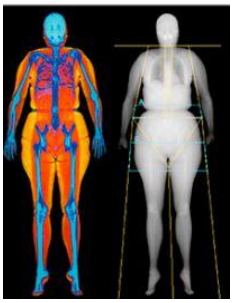
At approximately 9:00am you will begin the exercise test. We recommend you wear something comfortable for exercising indoors, such as a T-shirt, shorts and trainers. You will begin by walking on a treadmill at a slow walking pace (3.5km/h) and gradient of 1% for three minutes while we measure oxygen uptake and carbon dioxide production (to subsequently calculate rate of fat oxidation). For this measure, you will be asked to wear a small face mask that allows for the collection of your exhaled air. The speed of the treadmill will then increase by 1km/h every 3 minutes until a speed of either 6.5 km/h or 7.5 km/h is reached; equivalent to brisk walking or slow jogging. Thereafter the gradient will be increased by 2% every 3 min until you are using 100% carbohydrate to fuel the activity (the point where the amount of oxygen you consume is equal to the amount of carbon dioxide you produce). At this point, the speed will be increased every minute until you are exhausted and can no longer continue.

At the end of the test, you will have the opportunity to shower and you will be provided with a breakfast snack.

Muscle Tone (approximately 25 minutes): At approximately 9:50am you will undergo an assessment of muscle tone using a muscle tonometer. The muscle tonometer probe is pressed into the muscle and measures the resistance (tone) of the muscle. The probe does not pierce the skin and this measure is completely painless. We will use this technique to quantify the degree of muscle tone in the abdominal muscles, buttocks and triceps. Triplicate measures will be performed at each site.

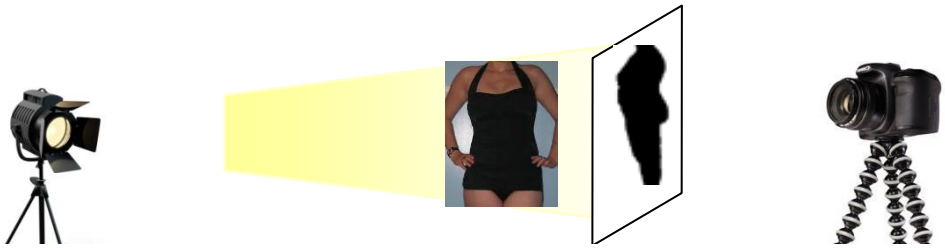
DEXA scan, body weight and waist circumference (approximately 30 minutes): At approximately 10:15am, the DEXA scan will be completed in order to determine your body composition.





You will be asked to lay supine on the DEXA scanner bed, wearing something comfortable like a T-shirt and shorts, but whatever you wear it must not contain any metal such as rivets or eyelets (this also includes underwire bras). Once correctly positioned, the scan, which takes approximately 7 minutes, will commence. Again, this is a completely painless procedure. Upon completion of the scan, we will measure your weight, height and hip and waist circumferences.

Body Shape (approximately 30 minutes): The penultimate task is to obtain a measure of body shape. This will be done through taking an image of your figure. Wearing a swimsuit, you will stand between a light source and translucent screen. A silhouette image of your body shape will be cast on to the screen and a photographic image will be taken from the opposite side of the screen (see diagram below).



Light source You Silhouette image Camera

A front-on and a side-on image will be taken. At the end of the study your silhouette images will be viewed by you and independent researchers (this will be done on separate occasions and the independent researchers will not know any information about you or your involvement in the study). Before and after-intervention images will be shown side-by-side, with viewers asked to state whether they consider the images to be different images or replicas of one another. If they are deemed different images, they will be asked which body shape they would find preferable, or most aesthetically desirable.

Body self-perception, self-esteem and motivation questionnaires (approximately 30 minutes): At approximately 11:15am, you will undertake your final task of completing a series of questionnaires. These will be used to assess your self-perception of your body, your self-esteem and your motivation towards physical activity.

At approximately 11:45am the testing sessions will be completed. To ensure that you do not leave us hungry, you will be provided with a lunch meal, consisting of sandwiches and fruit, as well as hot and cold drink options.

12-week intervention

Once the maintenance week and baseline data have been completed, you will be allocated to one of three trial conditions: Prescribed exercise (PresEx), Points-based system of physical activity (PBS) or a control condition (CON) in which you would be asked to maintain your usual behavior.

Prescribed Exercise: If in this group, you will be asked to choose one activity and stick to it for the duration of the intervention. You will be able to choose between brisk walking/slow jogging or cycling. The intervention will require you to do 30 minutes of your chosen activity on 5 days of the week, which you will be asked to

record in a physical activity diary. To check compliance to the programme, we will contact you via telephone, text or email daily for the first week, on a weekly basis until the end of week 4 and on a fortnightly basis thereafter.

Points-based System: If in this group, you will be asked to achieve a pre-set, individualised points target for physical activity each week. Points are acquired through the completion of a minimum 10 minutes of activity, choosing from the extensive list of activities provided; for example, 10 minutes of jogging achieves 4.5 points, whereas 10 minutes of washing a car achieves 1.5 points. The target will be 35-40 points per week, which equates to approximately 6 points per day. Any combination of activity, duration and frequency can be selected. Also, a total weekly target allows for your activity level over the course of the week to fluctuate, providing the weekly target is met; daily points targets can be carried over to following days within the same week, or conversely, the weekly target can be achieved within the first few days of the week. You will be asked to record all activity undertaken in a physical activity diary. To check compliance to the programme, we will contact you via telephone, text or email daily for the first week, on a weekly basis until the end of week 4 and on a fortnightly basis thereafter.

Control condition: If allocated to this condition, you will be asked to maintain your normal activities and diet. You will be added to a waiting list to receive either exercise intervention after completing the 24-week trial period, so that you do not miss out on the opportunity to receive the exercise intervention. You will be able to choose with intervention you wish to follow, with post-intervention measures available, should you wish.

12-week follow-up period

During this period, you will be asked to maintain your exercise intervention, just as in the previous 12-week period. The only difference will be that you will receive no contact from us, nor will we obtain any intermediary measures. You will, however, still be asked to log all physical activity undertaken in your physical activity diary.

During- and post-intervention testing session:

The procedure of the pre-intervention testing session will be repeated on one day during week 4, week 12 and week 24. Also, during these weeks, the 3-day food diary will be once again completed and the ActiGraph apparatus will be worn. Please see final page for a procedure-timeline matrix to illustrate the timing of the various tasks and procedures.

How do I benefit from participation?

By taking part in this study, you will undertake a supported, structured exercise intervention which, if adhered to should improve fitness and health. You will also receive a vast range on physiological, metabolic, and anthropometric information about yourself and your body. Such information is not only of great interest, but could help guide you toward improving aspects of fitness and health in the future.

You will also receive £150 (plus reasonable travel expenses) for completing the study.

Are there any risks involved in participation?

The most obvious risks to you will involve the Fat_{max} exercise test, the body composition scan (DEXA) and the optional blood sample.

Exercise Test

You will experience fatigue towards the end of the test. This will however be short lived and you should have fully recovered within a few minutes. However during such vigorous exercise there is a very small risk of a cardiovascular event (e.g., a heart attack). The absolute risk that an acute cardiovascular event will occur during vigorous exertion has been estimated to be 1 in 2,600,000 hours of exercise. In addition, intense physical activity may increase the chance of you fainting, or experiencing a stress fracture. However, as you are healthy (as screened by the General Health Questionnaire) the risk is extremely small and these procedures are regularly conducted within the laboratory. At least one investigator trained in first aid procedures (St. Johns Ambulance) and CPR will be 'on hand' during all exercise testing sessions.

Body Composition (DEXA) Scan

Body composition will be assessed using a DEXA scan that involves exposure to X-ray radiation. It is known that exposure to large doses of radiation can cause damage to living tissue, and can result in mutation, radiation sickness, birth defects and cancer. The total of four DEXA scans to be used in this study will expose you to a very low dose of X-ray radiation. The dose of radiation from each scan is likely to increase your risk of developing cancer by between 0.001 – 0.0001%. Nonetheless, to put this in perspective, the dose of radiation you will experience from each scan is approximately equivalent to 2 days normal background radiation in the UK, or a 150 mile aeroplane flight. Furthermore, risks will be minimised by safe practise and testing will be conducted by trained members of the research team.

Blood sample

The insertion of a needle, used to obtain the blood samples can sometimes cause mild discomfort; however all of the researchers involved are trained, skilled phlebotomist, and will do their utmost to prevent this. Once the needle is positioned, you should be largely unaware of its presence and the extraction of blood is a painless process. After the removal of the needle, there is a chance that a small amount of bruising, at the point of insertion, may occur. Application of pressure to this site by the researcher, after removing the needle, will help reduce this risk.

Finally, if at any point during the protocol you feel uncomfortable or unable to continue, testing will be ceased immediately.

Can I change my mind?

If at any point you wish to withdraw from the study, you may do so without providing a reason. Also, you may withdraw your data at any point, up to 1 week after completion of your study testing. Participation is NOT compulsory, however before you commit we do ask that it should be considered carefully, i.e. do you have the time to spare? Are you afraid of laboratory environments? If you do not wish to participate, you will continue to be treated as before.

What happens to my information?

Research data stored in paper form, such as your age, weight, height, address and medical information will be stored in a locked filling cabinet in the principal researcher's office. You will be assigned a unique study ID and experimental data will be stored using this unique ID number on a password protected computer for analysis purposes. Data will only be accessed by the principal investigator or members of the research team. Blood samples will be stored in the Human Performance Laboratory freezers at the School of Sport, Exercise and Rehabilitation Sciences. In line with the University's guidelines on records management, research data will be retained intact for a period of ten years from the date of collection. Should you withdraw from the study, your research data will be destroyed, and subsequently your data will not be included in any publications. The result of the study is expected to be published in a scientific journal, but your name will never be published. All data will remain completely confidential at all times.

What happens if something goes wrong on the day of a trial?

All procedures have been included within the University of Birmingham Liability Insurances and if you are harmed in any way by taking part in this research project your normal rights apply and you may have grounds for legal action.

Complaints procedure:

If you have any complaints regarding the way you have been treated or anything else relating to the study you can write to Dr Sean Jennings who is independent from the research team and will investigate the matter fully.

Dr Sean Jennings
Research Governance Officer
Room 119, Aston Webb Building
The University of Birmingham
Birmingham
B15 2TT
United Kingdom
Tel: 0121 415 8011
Email: s.jennings@bham.ac.uk

What do I do next?

If you feel you would like to be involved in our study, have any questions, or would like some further information, please contact Dr Andrew Blannin so we can arrange a meeting. If you confirm that you do wish to participate, a time and date for the initial visit will be arranged, where you will be asked to complete an informed consent form to confirm that you are happy to participate in this study.

Contacts:

Dr Andrew Blannin
Phone: 0121 414 7353 (office)
Email: A.K.Blannin@bham.ac.uk

Procedure-timeline matrix for the study. Note the intervention and follow up phases require adherence to your trial demands, exercising or inactive control, depending on your trial assignment. Data capture laboratory visits are highlighted in the red boxes.

	Initial visit	Baseline week	Baseline lab visit	Week 1	Week 2	Week 3	Week 4	Week 4 lab visit	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12	Week 12 lab visit	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20	Week 21	Week 22	Week 23	Week 24	Final lab visit
				Intervention														Follow up phase												
Consent form	✓																												
General Health Questionnaire	✓																												
3 day food diary		✓					✓									✓												✓	
7 day physical activity data collection		✓					✓									✓												✓	
Physical activity diary		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Blood sample			✓					✓									✓												✓
Resting metabolic rate			✓					✓									✓												✓
Resting BP and heart rate			✓					✓									✓												✓
Exercise test			✓					✓									✓												✓
DEXA scan			✓					✓									✓												✓
Body silhouette			✓					✓									✓												✓
Muscle tone			✓					✓									✓												✓
Self-perception questionnaires			✓					✓									✓												✓