



Participant information sheet

A pedometer intervention to increase walking in adults

PACE-UP trial

We are inviting you to take part in our research study. Before you decide, you need to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully. A research assistant will go through this information sheet with you and answer any questions. Talk to others about the study if you wish.

- *Part 1 tells you the purpose of this study and what will happen to you if you take part.*
- *Part 2 gives you more detailed information about the study.*

Ask us if there is anything that is not clear or if you would like more information.

Part 1

What is the purpose of the study?

Most adults are less physically active than they need to be to stay healthy. We want to find out if people aged 45-74 years can become more active if they are given a pedometer (a monitor that counts steps) with a physical activity diary and guidance on a 12-week programme to increase their walking. The programme will be tailored to their individual baseline physical activity level. We are also interested in testing whether offering individual support from a practice nurse will increase any benefits.

Why have I been chosen?

We are inviting people aged 45-74 years at random, through their GP. We want approximately 1000 people in total to take part, about 170 each from 6 practices in South West London.

How physically active do I need to be to take part?

The study is for adults who do not currently do the recommended amount of physical activity weekly. If you already do at least 30 minutes per day, most days per week of moderate or vigorous exercise (such as brisk walking or a sport) then the study is not for you. However, you do need to be able to walk outside the home in order to take part.

Do I have to take part?

No, it is up to you to decide. If you do not want to take part your care from the practice will not be affected in any way. If you decide to join in, you can change your mind later and leave at any time. This will not affect your future health care. However, we may use information that you have already given us. If you have any difficulties reading, understanding or speaking in English, we suggest that you bring a relative or friend to help you when meeting the researcher. We also have this participant information sheet translated into other languages, please ask for one if this would be helpful to you.

What will happen to me if I take part?

You will be invited to meet with our researcher at your GP's practice. This meeting will take around 30-45 minutes. They will make sure that the study is suitable for you. You will be asked to:

- Sign a consent form and fill in a questionnaire about your health and physical activity.
- Have your weight, height and waist measurement taken.
- Record your physical activity in a diary for a week.
- Wear a belt with two small monitors on, an accelerometer and a pedometer, during the day for a week. (The monitors will accurately record your physical activity levels, but will be sealed for the baseline measurement, so that they do not give you any direct feedback).
- You will need to hand the belt with the monitors on back to your practice when you have finished wearing it.

There will be 3 groups of people taking part in the study.

- One group will carry on with their usual activity (the 'usual physical activity group').
- One group will be sent a pedometer, a physical activity diary and instructions for a 12-week walking programme through the post ('pedometer by post group')
- One group will meet with the practice nurse and will receive their pedometer, physical activity diary and 12-week walking programme instructions from her (the 'pedometer plus nurse support group').

The groups will be decided randomly, like tossing a coin. If two people from your household are invited you will both be in the same group.

If you are in the usual physical activity group

- We will contact you by post 3 months after your first visit and ask you to wear the accelerometer to monitor your activity again for 7 days and then to post it back.
- We will contact you by telephone, text or email (according to your preference) 6 months and 9 months after your first visit to check on your progress.
- We will ask you to visit the practice 12 months after your first visit and to monitor your activity with the accelerometer for 7 days before that visit.
- We will offer you a pedometer to keep and guidance on a 12-week walking programme, tailored to your own activity level, at the end of the study. You will have the choice about whether you receive this through the post or from a practice nurse.
- In total you will make 2 practice visits for the research and you will be asked to record your activity levels with an accelerometer 3 times for 7 days each time.

If you are in the pedometer by post group

- We will send you a pedometer through the post with a physical activity diary and instructions for a 12-week walking programme, based on your individual baseline step-count from the accelerometer.
- The research assistant will contact you a week after she has posted out the pedometer to ensure that it is working and that you understand the 12-week walking programme instructions.
- A few people in this group will be invited to talk with a researcher about taking part in the study. This will take approximately 20-30 minutes and will be audio-recorded.
- The researcher will contact you at 3 months, 6 months, 9 months and 12 months, exactly as above for the usual physical activity group.

- At the end of the study you can keep the pedometer and you will be offered a consultation with the practice nurse to discuss your physical activity if you would like this.
- In total you will be asked to make 2 practice visits for the research (A few people will make an additional visit to be interviewed). You will record your activity levels with an accelerometer 3 times for 7 days each time.

If you are in the pedometer plus nurse support group

- We will invite you to see your practice nurse 3 times over 3 months. Each visit will last around 20-30 minutes.
- A few patients will be asked their consent for one of their visits with the nurse to be audio-recorded, so that the nurse's trainer on the PACE-UP study can listen to it. If you are asked and you prefer not to be recorded, this is fine.
- The practice nurse will give you a pedometer, a physical activity diary and a 12-week walking plan based on your individual baseline step-count from the accelerometer. She will go through this with you and make a physical activity plan with you, based on increasing walking and other activities that you already do. She will encourage you to monitor your activity, set goals, overcome barriers and increase your confidence to be more active.
- A few people will be invited to talk with a researcher about taking part in the study. This will take approximately 20-30 minutes and will be audio-recorded.
- The researcher will contact you at 3 months, 6 months, 9 months and 12 months, exactly as above for the usual physical activity and pedometer by post groups.
- In total you will be asked to make 5 practice visits (2 with the researcher, 3 with the nurse). (A few people will make an additional visit to be interviewed). You will record your activity levels with an accelerometer 3 times for 7 days each time.

How long will the study take and what if I plan to go away?

The active part of the study will last 3 months. We will also ask you to come for an assessment at the practice at 12 months. If you are away for a few weeks we can book the appointments for when you return. We will not be having any visits or contact over Christmas and New Year.

Are there any benefits from taking part?

We cannot promise that the study will help you, but there are many health benefits from walking more and becoming more active. Everybody will be offered feedback on their individual activity levels and a pedometer to keep at the end of the study and a physical activity consultation with the practice nurse, if they would like one.

Are there any risks from taking part?

This is a very low risk study. The usual activity group will not be advised to make any changes. The pedometer by post group and the pedometer plus nurse support group will be advised to gradually increase their walking in a safe way. However, there is a small risk that you could fall or get pain from unaccustomed walking, or you could make a condition that you already have, like arthritis, worse. If you develop new symptoms, these should be reported to your GP. Walking more can slightly increase your risk of having a fall if you have problems with your balance, but if this is the case for you, we will teach you how to reduce this risk.

How can the risks be minimised?

You should not take part if you have had previous falls, have very poor vision or balance, or if you have had a heart attack or a heart operation in the last 3 months. If you are unsure, you can discuss this with your GP.

Are there any expenses or payments?

If you take part in the study it will not cost you any money and you do not need to buy any special equipment. You will receive a £10 gift token for returning the physical activity monitor after your baseline, 3 month and 12 month assessments (£30 in total).

What if there is a problem?

We will respond to any complaint about the way you have been dealt with during the study or any possible harm you might suffer. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal rules. All information about you will be handled in confidence. The details are included in Part 2.

Contact Details:

Main investigator: Dr Tess Harris, email: tharris@sgul.ac.uk . PACE-UP office telephone: 0208 7255601.

Part 2

Will my General Practitioner (GP) be informed?

If you choose to take part in the study, we will seek your consent to inform your GP that you are doing so. No individual results will be fed back to your GP.

Will my taking part in this study be kept confidential?

Yes, all information that is collected about you during the study will be kept strictly confidential.

- Information will be collected about you from questionnaires, accelerometers and pedometers. If you consent to an individual interview with a researcher to discuss the study, this will be audio-recorded. A few individuals in the pedometer plus nurse support group will be asked by the nurse if one of their consultations with her can be audio-recorded. You have the right to check the accuracy of any data held about you.
- Data (including audio-recordings) will be stored securely & disposed of securely after 7 years. Dr Tess Harris is the data custodian.
- Data that could identify you will only be accessed by nurses from your general practice and researchers from St George's University of London (main investigator Dr Tess Harris and research assistants under her direct supervision). Audio-recorded interviews will be anonymised by the research assistant. Some data may be looked at by authorized people from the Primary Care Trust, for research monitoring. All have a duty of confidentiality. Nothing that could reveal your identity will be disclosed outside the practice or St George's University of London.

Complaints

If you are concerned about any part of this study, you can contact the main investigator, Dr Tess Harris email: tharris@sgul.ac.uk. If you want to complain formally, you can do this through the NHS Complaints Procedure. You can get their details from your surgery.

Harm

The monitors are safe. If something happens to you that may be related to you increasing your walking (e.g. a fall, sprain) you should seek medical attention at the practice if required and report the event to the nurse at your next visit or to the research assistant (*name of research assistant and telephone and email contact details*). Any serious problem (e.g. fracture, hospital admission) should be reported immediately to Dr Tess Harris (mobile: 07807494977). In the unlikely event that something goes wrong and you are harmed during the study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, you may have grounds for a legal action against St George's, University of London, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you

What will happen to the results of the research study?

You will receive a newsletter with the study results. A report will be sent to the Department of Health and to your local Primary Care Trust to help them promote physical activity. The results will be published as papers in medical journals and you can have a copy of these papers if you would like.

Who is organising and funding the research?

The research is organised by South West London Primary Care Trust and St George's, University of London. It is funded by the National Institute of Health Research under the Health Technology Assessment Programme.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the London Hampstead Research Ethics Committee.

Thank you for taking the time to read this information.