

ACE: Active, Connected, Engaged (known in Wales as ACTIF)

A multi-centre randomised controlled trial of a peer volunteer led active ageing programme to prevent decline in physical function in older people at risk of mobility disability

Participant Information Sheet

This document explains exactly what would happen if you decide to take part in the ACE study. If you would prefer one of our researchers to go through all this information with you, please call Katie Chatwin on 07442989155 or email k.chatwin@bham.ac.uk

What is this study about?

ACE is a study which is looking at ways we can support people who are 65 years and older to stay mobile and maintain their independence for longer. The way we plan to do this is by matching older adults with volunteers who are themselves over 55 years old so they can get out and about and enjoy taking part in local activities together.

Why have I been chosen?

We are asking adults aged 65 and above from Stoke-on-Trent, Greater Manchester and South Wales, who have some difficulty doing daily activities such as walking, getting out of a chair, and climbing stairs to take part in the ACE research project. Altogether about 515 people will be taking part.

Who is organising the study?

The study is being organised by the School of Sport, Exercise and Rehabilitation Sciences, at the University of Birmingham, and it is being paid for by the National Institute for Health Research, Public Health Research Programme.

Who is conducting this study?

The researchers who will be conducting this study are Professor Afroditi Stathi (A.Stathi@bham.ac.uk; 0121 415 8389) and Dr Janet Withall (J.Withall@bham.ac.uk) University of Birmingham, Dr Helen Hawley-Hague, University of Manchester (Helen.Hawley-Hague@manchester.ac.uk; Tel 0161

3067890) and Professor Diane Crone (dmcrone@cardiffmet.ac.uk; 0290 416998), Cardiff Metropolitan University

What will happen to me if I take part?

If you agree to take part in the ACE study you will be asked to sign a consent form and given a copy of this information leaflet. The research team will be available to answer any questions you may have.

There are a number of things we will ask you to do.

Some things we'd like to find out about you

First of all, with your consent and prior to you taking part in the study, we would carry out a screening interview over the telephone. We would ask some questions about your health and any medical conditions you have to make sure taking part in ACE would be suitable for you. This would take 10-15 minutes. If ACE was suitable for you, and you decided to take part we would ask you to wear a small movement monitor on your wrist for 16 days so that we can measure how physically active you are. We would give you a reply-paid envelope so that after 16 days you can return it to us easily. We would also arrange to spend some time with you asking some questions about you and your everyday life, your health and wellbeing. Finally, we would like to measure your height and weight and ask you to do some simple physical function tests. This would mean walking 4 metres, doing some simple balance tests and sitting in a chair and then standing up. We would also test your grip strength. We



would do all these things at the beginning of the study and again after 6 months and 18 months. After 12 months we will send you a short questionnaire to complete at home and a movement monitor to wear.

In order to carry out these measures a researcher would meet you in a local community centre or volunteering organisation's facilities. If you need it, we can arrange for transport to get you there. Before we do anything, we would ask you to complete a consent form with the researcher so that you know exactly what we are asking you to do and you can confirm if you are happy to go ahead. We will then do the physical function tests with you, show you how to wear the movement monitor and go through the questions with you. We will give you an envelope so that you can send the monitor back to us after 16 days). After 12 months in the study we will telephone you and

ask a few questions over the phone and send you the movement monitor to wear again.

Each session should take around 60-75 minutes.

Some things we'd like you to take part in

For this part of ACE, we will separate our participants into 2 groups. This will be done randomly so neither you, nor the researchers, will be able to control which group you are in. If you are in Group 1 you will be matched with a volunteer. Our volunteers are managed by the Royal Voluntary Service. With your consent, we will share your contact details and a small amount of information about you, such as your interests and hobbies and the language(s) you speak, with RVS. This will help them match you with a volunteer with similar interests. You will be asked to meet with your volunteer regularly, choose some local activities you would like to try out together. These can be anything from joining a choir or a walking group to starting to knit and natter or trying out short mat bowls. Your volunteer will support you in person and after a few months over the phone to keep going to the activities. If you are in Group 2 you will be given an information pack on healthy ageing and we will invite you to two social events over the course of the study with presentations about ageing well. People in both Groups 1 and 2 are crucial to the success of the study as comparing the two groups is the only way to understand whether the ACE programme has benefits for older adults



Some things we might ask you to help us with

At 6 and 18 months into the study we will ask some people in Group 1 to tell us about their experiences of taking part in Group 1 of the ACE study with a view to making possible improvements. We would arrange for you to attend an interview or a small group to discuss this with 5 or 6 other people who have also taken part in ACE. This will take place in a local venue and we will record the discussion. Interviewees will be asked not to use their own name or any information that would identify them during the interviews. These recordings will then be transcribed (written up) using ID numbers, not names, to maintain confidentiality. These recordings will be stored securely at your local research site, The University of Birmingham. You will get a chance to tell us about what you feel about your involvement in ACE and how it might have affected your life. We may also record a few of the meetings between some people and their volunteer. Some of the things people say in these meetings or interviews may be used when we write reports about the study. We will always anonymise these comments so

participants' names will never be used. People in Group 2 would not need to attend any interviews or focus groups.

Do I have to take part?

Not at all, it's up to you. Even if you agree to take part you can drop out at any time. If you change your mind about any aspect of taking part, at any stage, you just need to let us know. If you decide not to take part, this will have no effect on your medical care.

What are the possible risks of taking part?

Getting out and about more has been shown to increase levels of physical activity in older adults. A recent UK Chief Medical Officer's report said that "engaging in physical activity carries very low health and safety risks for most older adults. In contrast, the risks of poor health as a result of inactivity are very high". ACE is designed to help people who take part to gradually become more active. Government safety guidelines in relation to COVID-19 will be followed at all times for any face to face meetings.



If the research team becomes concerned that a participant may be at risk of harm or that there is a risk to their safety and wellbeing, safeguarding procedures will be followed and the participants healthcare provider will be made aware.

What are the possible benefits of taking part?

If you are allocated to ACE Group 1 you will get out and about more, with a volunteer to support and encourage you. This will help you to become more active, which could help you improve your ability to perform your daily activities, increase your strength and stamina and help maintain the physical function you need to continue living independently. It also means you will have the chance to socialise with other people. Our aim is to make taking part in ACE sociable and fun. Older adults often find being involved in research a positive experience, finding it interesting and stimulating. You will also be contributing to a large pioneering study that will provide very important information for the NHS and, if successful, may improve the health of many other older adults in the future.

Will I be reimbursed for taking part?

We appreciate the time that you are giving up for us and in addition to paying your travelling expenses we will give you a shopping voucher for £15 at both the 6 and

18 month measurement sessions (after the first baseline session). Refreshments will be served and you will have a chance to meet other people who are taking part.

Confidentiality and data protection

All data will be collected in accordance with the Data Protection Regulations including the General Data Protection Regulation (GDPR)

How we will use information about you?

We will use information we collect from you for this research project to compare people in Group 1 and Group 2 to see if taking part in the ACE intervention has made a difference. This data will include that described above in the section called '**Some things we'd like to find out about you**' and will also include information such as your name, contact details and date of birth. Authorised staff will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details.

Your involvement in the research, anything you say and all the information you give us, is confidential. Any electronic data will be anonymised with a code so that the results cannot be linked back to you. Data collected during the study may be analysed by individuals from the Universities involved in the study (Birmingham, Manchester, Cardiff Metropolitan, Cardiff and Exeter) and the Royal Voluntary Service. All your data are kept on password-protected computers and any paper information (such as your contact details and any research questionnaires) will be stored safely in lockable cabinets in locked rooms and would only be accessed by the research team. Authorised staff at the University of Birmingham may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines. With your consent, we will keep your personal information on a secure database in order to contact you for future studies. If you would like more information about how your data will be used please contact Afroditi Stathi.



What are my choices about how my information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have unless you do not wish us to do so.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use participant's information:

- At www.hra.nhs.uk/information-about-patients/
- By asking a member of the research team
- By emailing the University of Birmingham's Data Protection Officer via dataprotection@contacts.bham.ac.uk

Who do I contact if I have any complaints?

If you have any concerns about how the study is being conducted please speak to a member of the research team in the first instance. If you remain unhappy with their response or wish to make a complaint you can contact the University's Head of Research Governance, Dr Birgit Whitman on researchgovernance@bham.ac.uk

If you wish to make a complaint about how your data has been dealt with by the University please contact the University of Birmingham's Data Protection Officer on dataprotection@contacts.bham.ac.uk

Any complaints made to the University will be dealt with through the standard complaint procedures at the University.

Who has reviewed and approved this study?

This study is sponsored and insured by the University of Birmingham, and has been reviewed and received favourable opinion by London-Surrey Research Ethics Committee.

What next?

Before you decide whether to take part, we would be happy to answer any questions. If you are attending one of our ACE sessions just ask one of our researchers any questions you have, or if you received this information at home please call Katie Chatwin 07442989155 or email k.chatwin@bham.ac.uk

With warm thanks from: The ACE research team at the Universities of Birmingham, Manchester, Cardiff Metropolitan, Cardiff and Exeter