



The **AGILITY** Study

Participant Information Sheet

We invite you to join in a research study

This leaflet explains why this research is being done and what it will involve. Discuss it with friends, relatives and your GP if you wish.

About this study

We do not yet know the best way to support people to stay active as they get older. We want to find out which approach works best and offer the best value for the NHS. The Agility study will compare two approaches:

1. The Agility programme (three-month walking app programme)
2. Standard care (a leaflet about being active)

This is a small study to check everything works before a larger study.

Why am I being asked to take part?

We are looking for 80 people across the UK aged 55 or over who aren't active enough (doing less than 150 minutes a week of exercise that makes you breathe faster and feel warmer). Your GP practice has offered to take part in the study. You are being asked to take part because you recently completed an NHS Health Check or are about to. If you decide to take part, you can still drop out at any time without giving a reason. Your decision will not affect the care you receive at your general practice. You need a smartphone and an email address to take part.

What will happen and how will I be involved?

Screening and consent

If you are interested in taking part in the study, please click on the link at the end of this form. This will take you to the eligibility form to fill out. Alternatively, you can contact us by email. In the form, you will be asked to fill out some questions to check if you are able to take part. If you are eligible, we will send you a link to give your consent online.



How to contact us

If you have any questions or would like to take part in this study, please talk to:

Dr Dharani Yerrakalva
MRC Epidemiology Unit
University of Cambridge

Email:
AGILITY.study@ims.cam.ac.uk

If you have a formal complaint

Contact the University of Cambridge
Clinical School Secretary:
Tel: 01223 333543
Email: SchoolSec@medschl.cam.ac.uk

Study measures

We will ask you to complete the following measures at the start of the study and at three months after you start the study:

1. **Online questionnaires:** We will ask questions about your health, physical activity levels, your height and weight and how you use healthcare services. This should take approximately 15-20 minutes.
2. **A device to measure your activity:** We will post you a device to wear on your wrist that measures your activity levels and how fast you walk. This device is called an accelerometer. We will ask you to wear it for 7 days and then send it back to us.

Sharing of Walking Data from your smartphone

Smartphones track and store data on how much walking you do each day. We are interested in how much walking participants did on average in the month before you are randomised to a group, and during the study. We will ask you to download an app called AfterSurg which will allow us to get this information from your phone.

In order for AfterSurg to be able to get information on how much you walk from your phone, there are a few extra steps that we will need you to do at the beginning of the study.

1. If you have an android phone, we will ask you to check if you have a walking-tracker app downloaded on your phone already (for example, Health Connect, Samsung Health or Google Fit apps). Most phones already have these installed. If you don't have one of these apps already, we will ask you to download the Health Connect app. If you have an Apple phone, you will have the Apple Health app installed.



2. At three months into the study, we will ask you to download the AfterSurg app. You will be asked to enter a 4-digit access code, which the study team will provide, and your participant ID on the AfterSurg app.
3. You will be asked to accept the AfterSurg App Terms and Conditions. You will then be asked to allow the AfterSurg app to look at the walking data in the walking-tracker app already on your phone (for example, Health Connect or Apple Health). This will allow the AfterSurg app to collect information on how much you walked in the month before you were randomised, and during the study.
4. The AfterSurg App will only look at your walking data. This set-up should take 5 minutes.

You will be offered £10 as thank-you once we receive this walking information.

At the end of the study, we will use these measures to compare whether the AGILITY group or the Standard care group worked best.

How is it decided who gets the new intervention?

A computer programme will choose which group you are assigned to at random (like throwing dice); we can't control which group is selected.

Study groups

Group 1: The AGILITY programme. You will receive an exercise plan, the intervention walking tracker app and progress summary emails. We will ask you to accept the app Terms and Conditions.

Group 2: Standard care. You will receive a link to a leaflet about being active.

Optional Interviews

Some participants will be invited to a phone or video interview about their experience. This will be about 45 minutes long. They will be offered £20 as thank-you for this. The discussions will be digitally recorded.

Access to Data on How You Use the App

If you are chosen to be in Group 1, we will collect data on how you use the walking tracker app (for example, how often you have opened it). With your consent, we will receive this information from the team that run the app at the Department for Health & Social Care.

Possible benefits and disadvantages

You may become more active and improve your health. You will also help research into preventing inactivity-related health problems.

Disadvantages or risks

Other than the time it takes you to complete the questionnaires, there should be very little risk or disadvantage to taking part.



How will my information be looked after?

Information we collect during the study will be kept strictly confidential.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your:

- Name
- Date of birth
- Contact details (postal address, telephone number and email address)

Researchers 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 data will have a code number instead.

The University of Cambridge is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- I. Collaborator organisations (for example The Department of Health & Social Care, United Kingdom and the

University of New South Wales,
Australia)

2. An external company who will type up interviews under an appropriate confidentiality agreement

We will keep all information about you safe and secure by:

- Storing data securely on a secure computer network accessible only by the study team.
- All data will be held confidentially on our Secure Research Drive (SRD) which is password protected and accessed by 2 Factor Authentication.

The walking data collected from your smartphone will be processed by the company that runs the app (AfterSurg). They will then send it securely to the research team and delete any copies of the data that they held.

The contact information you provide such as email address and phone number(s) will be used by the research team to keep you informed about your participation in the study. In the event it becomes necessary for the study team to use an external company to manage this process, for example an SMS service, the company will be GDPR compliant.



How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results.

We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised (taking out any data that could identify a person) and securely archived or destroyed.

What are your choices about how your 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 ask us not to).
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.
- We may ask if you would be willing to be contacted again in the future about further follow up for this study or any future research.

International Transfers

We may share or provide access to data about you outside the UK for research related purposes with collaborator organisations. If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible.

If your data is shared outside the UK, it will only be with specific universities with collaboration agreements with the research team. We will make

sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/>
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/report-a-breach>



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

You can find out more about how we use your information:

- by contacting the research team (email or phone number)
- on the 'How we use your personal information (for medical research participants)' page on the University website <https://www.information-compliance.admin.cam.ac.uk/data-protection/medical-research-participant-data>

Who is organising and funding the study?

This study is organised and sponsored by the University of Cambridge. The study is funded by the National Institute for Health and Care Research (NIHR).

Who has reviewed the study?

The study has been reviewed and approved by the Health Research Authority (HRA) UK, and the Cambridgeshire and Hertfordshire Research Ethics Committee (REC Ref: 25/EE/0245).

Occasionally our studies may be monitored by our Sponsors. This is to ensure our research is conducted appropriately and in the best interests of the participants. Your research records may be made available for this purpose to inspectors from the University of Cambridge. It has already been reviewed by the National Institute for Health and

Care Research, who awarded the funding for this study.



[LL](#) using the passcode sent to you by text message. For more information, please email the research team on AGILITY.study@ims.cam.ac.uk

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the University of Cambridge Clinical School Secretary: Tel: 01223 333543

Email: SchoolSec@medschl.cam.ac.uk

The University of Cambridge have provided insurance cover for this study. In the unlikely event that you are harmed by taking part in the study, you can make a claim in writing to the chief investigator (Email: AGILITY.study@ims.cam.ac.uk). The Chief Investigator will then pass the claim to the University of Cambridge's Insurance Department for further investigation.



Would you like to take part?

You can register your interest at this link

<https://redcap.mrc-epid.cam.ac.uk/surveys/?s=PHHXTNN9W9AKEL>