



The Active Brains Study

An online programme for brain and body health

We invite you to take part in a study

It is up to you to decide whether or not to take part. Saying no will not affect the care you receive from your doctor. This leaflet tells you why the study is being done and what it will involve. After you read it you can choose whether or not you want to take part. Please contact us if anything is unclear or you would like to ask any questions.

A quick summary of the study

- This study is testing an interactive programme (called 'Active Brains') to help people aged 60-85 with lifestyle changes and brain training activities which may help with memory and thinking skills.
- If you take part, the study will last for five years.
- We ask everyone who takes part to complete 4 online puzzle games and answer some questions about how they are when they start the study, and then again each year after that. Doing these online puzzle games each year is a really important part of the study, and only takes about 10 minutes.
- About two thirds of people will be in a group who can use Active Brains straight away and one third of people will carry on with usual care and get brief advice about a healthy lifestyle.
- Which group you are in will be decided by chance.
- Everyone in the study will carry on receiving their usual NHS care.
- The activities recommended by Active Brains can nearly all be done at home. They are all activities that are likely to be good for staying fit and healthy in general. However, it is very important to follow current government advice about how to stay safe and healthy during the Coronavirus (COVID-19) outbreak.
- Active Brains is not designed to treat the type of memory and thinking problems that can be caused by COVID. If you feel as if your thinking skills are *currently* being affected by COVID unfortunately this study will not be suitable for you.
- The study is being run by the University of Southampton and is funded by the National Institute for Health Research, the main funder of research in the NHS.

What is the aim of the study?

The aim of the study is to find out if using Active Brains is useful for people aged 60-85 to keep their

brain healthy. We want to know if it can help with things like memory, thinking skills, and quality of life.

How do I take part?

If you're interested, please visit our website or get in touch with us if you have any questions.

- Find out more and see if you can take part on our website at www.activebrains.online
- Email us at ActiveBrainsEnquiries@soton.ac.uk

Why am I being asked to take part?

You have been invited because you are aged 60-85. We would like people to take part whether or not they have any trouble with their memory or thinking skills. You will need to be able to access the internet on a computer, laptop or tablet to take part. You will only be able to take part if no one else in your household is taking part in the study. We hope that about 20,000 people will take part in this study.

What will happen if I take part?

1. The first step is to sign-up on our website to check if the study is right for you. You can get in touch with us if you have any questions.
2. On the website, you will be asked to answer some questions to make sure you want to take part and that the study is right for you. You will be told straight away if you can take part.
3. The website will put you into one of three groups by chance (the same as flipping a coin), so either:
 - You will be in the group who can use Active Brains as much as you like during the study.
 - Or, you will be in the group who can use the Active Brains programme as much as you like plus you will get some extra support by phone or email from someone trained in how to help people make healthy lifestyle changes.
 - Or, you will carry on with your normal healthcare, but you will also get some brief information about some simple ways to look after your brain and body health.

If you are in one of the groups who can use Active Brains then you can use it as much as you like. You can choose which bits of Active Brains you would like to see and use. We will record which parts of the website people use in the study.

4. Each year, you will be asked to go online to complete the 4 puzzle games and to answer some questions on the website about how you are. The puzzle games only take about 10 minutes to do, but they are important because the information from these will let us know whether Active Brains is helpful for people. We know that lots can change over time so if we don't hear from you or if we're not sure you still want to take part then we'll get in touch with your contact person to check and make sure we're not bothering you. Your contact person could be a friend, family member or neighbour that we will ask you to tell us about (name and contact details) at the start.

What are the possible pros and cons of taking part?

Taking part in the study and using Active Brains might improve your memory and thinking skills and general well-being. In our other studies, people have enjoyed taking part and learning new things.

A while after the study has finished we will tell everyone who took part about what the study found out. If Active Brains is shown to be helpful for people's memory and thinking skills, we will try to make it available for everyone to use. As someone who took part we would let you know how you could access Active Brains.

Taking part in the Active Brains study will take up some of your time. It will take about 30 minutes to fill in the questions about how you are. You will be asked to complete these questions every year.

What will happen if I don't want to carry on with the study?

You can change your mind and stop taking part in the study any time without giving a reason. This will not affect the medical care you receive in any way. If you decide to stop taking part then the information you have given us up to that point would be used in study results, unless you tell us not to. This information would not include any of your personal details (e.g. your name, or any other details that could let people know who you are).

Will my taking part in this study be kept confidential?

The Active Brains website is secure. Only people on the study team will be able to see your data. We will have your contact details and the ones for your contact person so that we can keep in touch. Your GP will know that you are taking part in the study. After years 1 and 5, relevant parts of your medical records will be checked by the research team. All personal data will be deleted at the end of the study. Once analysis and reporting our results are complete, study data will be archived in a sponsor approved facility for 10 years. After this time all data will be destroyed. The findings from this study will be used in research reports, but no names will be included in the report. Any feedback you give us will be anonymous. You can find out more at www.activebrains.online/page/privacy-policy.

What will happen to the results of the research study?

The results will be presented at medical conferences, published in medical journals, used to educate students and develop the Active Brains programme. None of this will include names or personal details.

Who has reviewed the study?

The study has been reviewed and given approval by Bradford Leeds NHS Research Ethics Committee (Ref 20/YH/0018).

What if there is a problem?

If you have any concerns you can contact the study team (ActiveBrainsEnquiries@soton.ac.uk) who will be happy to answer any questions. If you are still not happy about anything or want to complain you can contact the Research Governance office at the University of Southampton (email

rgoinfo@soton.ac.uk). If you are still unhappy and wish to complain formally you can do this through the NHS complaints procedure. Details are available from your GP practice. The study is insured by the University of Southampton.

What do I do now?

If you would like to take part, please go to www.activebrains.online to sign-up and find out if you can take part in the study. Please contact us if you have any questions. If you do not want to take part then you don't need to do anything.

Another small optional study - you can still take part in the main study without doing this part:

There will be an option to talk to someone from the study team about Active Brains. We might get in touch with you later to see if you would like to tell us what you think about the Active Brains programme and the study. If you'd like to do this then we will speak to you, usually on the phone, for about 30-60 minutes, depending on how much feedback you have. We will record and then write up what you say but all of your personal details will be removed from the write-up so no-one can tell who you are. We will look at what people have said to find out how they are using the website and we will write research reports about it.

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION

