Invitation to take part in a research study

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you.

Please take time to read the following information carefully and discuss it with family or friends if you wish. We recognise that there is a lot of information contained within this document. If you have any further questions, please contact a member of the study team (details are on the last page of this information sheet and on the PROTECT study website).

It is important that you understand that you do not have to take part in the study and that if you do take part you are free to withdraw at any time. If you decide to take part we will ask you to read and sign the declaration on the next page of the website.

What is the purpose of the study?

This study aims to determine whether a short-term intensive online ‘brain training’ game is effective in improving brain function in people over 50. This study will test a new intensive brain training game that focuses on problem-solving. We are interested in learning whether this game improves people’s memory and other brain functions when it is played over a period of six weeks. The study is being led by Exeter University.

Why have I been invited?

We are inviting adults over 50 from across the UK to take part in this study. All the adults invited to take part in this study are already part of the Platform for Research Online to investigate Cognition and Genetics in Ageing (PROTECT). We are looking for at least 7500 people to join the study for the next six months. In order to participate, you will also need to have the ability to use a computer or device like a smartphone or tablet with internet access.

If you have an established diagnosis of dementia from your doctor then unfortunately you will not be eligible for this study.

Do I have to take part?

It is up to you whether or not to join the study. The purpose of this information sheet is to describe the study in detail to help you make your decision. If you agree to take part, you will then need to read and sign a consent form on the PROTECT website. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you
receive through your own General Practitioner or local NHS services, or your legal rights. This study does not replace those services and if you feel less well during the time you are part of this study it is important that you seek help from your doctor or local health professionals in the usual way.

**Why are we doing the study?**

As we get older our brains also begin to age, resulting in a 'slowing down' of abilities such as memory or reasoning. These mental processes are collectively known as 'cognition'. In some people, cognition declines further, leading to cognitive impairment or dementia, which affects 800,000 people in the UK. There is a growing body of evidence that indicates that people may be able to reduce their risk of dementia through certain lifestyle habits or activities.

‘Brain training’ games have been proposed as a way to maintain key cognitive abilities, such as memory, reasoning or problem-solving. Our research has shown that certain brain training games and tasks can improve these abilities. Training in reasoning tasks appear to result in very quick improvements when they are played regularly. However, it is not yet clear whether these improvements also occur in other cognitive domains such as memory or reaction time.

This study aims to test whether intensive training in one reasoning task leads to any overall change in different cognitive abilities in people over 50, compared with a separate online ‘control’ task which does not lead to any learning effects. The long-term aim is to provide a better understanding of how we can maximise brain function in adults.

**What will happen if I take part?**

If you decide to take part the following steps will happen:

1. You will be asked to sign the consent form on the next page of the website (a copy of this is at the bottom of the downloadable information sheet).
2. Once you have registered and signed the consent form you will be asked to complete a series of tests for memory, problem-solving and other cognitive abilities. You will need to complete each test once. You will also be asked about your use of brain training games. This registration phase will take around 30 minutes of your time.
3. You will also complete a scale to provide information about how you perform everyday tasks.
4. The PROTECT website will then randomly allocate you to one of two groups. The START Study will then appear in your active studies window in your ‘My Study’ area.
5. You can then get started with the START study which consists of playing one task, following the on-screen instructions. We recommend you log in and play the task at least three times a week, but you can log in as often as you like. One session will last around three minutes.
6. You are then encouraged to continue playing the task for six weeks. After two weeks and six weeks you will be asked to complete the cognitive tests once more.
7. We will also ask you to complete the tests again after six months.
8. At the end of the study we will contact you to let you know the findings of the research.
9. The DNA sample you have provided as part of the PROTECT study will be combined with all other participants to compare performance on the START task with certain genes. This analysis will be done anonymously.

All the information we collect will be kept anonymous and confidential. We will keep all data for 10 years after the study has finished. We will then destroy it.
What are the possible benefits and risks of taking part?

This is an online clinical trial that you will take part in from home. The risks associated with it are therefore very low, other than a small burden on your time to take part in the START study. All the data we collect will be stored confidentially, according to the law. Data will be analysed anonymously so no participant can be identified.

The main advantage of this research is that you will be taking part in research to move forward our understanding of how Brain Training could play a role in maintaining cognition as we age.

The South West Central Bristol Research Ethics Committee has approved this research (Ref number: 16/SW/0311) and the research will be covered by normal insurance policies at Exeter University.

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

You can withdraw from the study at any time without giving a reason. You can do this through the ‘I wish to withdraw’ link on the PROTECT website or by contacting us on the study helpline. If you withdraw from the study you can tell us whether you want us to use information collected up to the time you withdraw or whether you would like us to destroy that information. You may withdraw at any point up until the end of the study, which is the six month timepoint. We will contact you to let you know when the study has ended.

There is a very small chance that people taking part in this study may develop cognitive impairment or dementia over the six-month period. This will be monitored as usual for the PROTECT study, through your regular assessments. In the unlikely event we detect a clinically significant drop in your performance in the study tests we will contact your GP to recommend they arrange an appointment with you to carry out further tests, as agreed as part of the PROTECT study. If you receive a diagnosis of dementia unfortunately you will need to withdraw from the study.

Will my taking part in this study be kept confidential?

Research data will be collected online through the PROTECT website over the six-month period. The study database will not include your name, just a study number. Your data will be completely anonymised and it will not be possible to identify you. All anonymised data will be transferred to Exeter University and stored securely.

What will happen at the end of the study?

At the end of the study you will complete your final cognitive assessment on the PROTECT website. We will contact you to let you know the study has ended and to thank you for your contribution. The results of the study will be published in a scientific journal. We will provide you with a lay summary of our findings in the form of a newsletter. The findings will also be available on the PROTECT website. The information collected is totally confidential and no individuals will be identified in any publications.

What if there is a problem?

If you have a concern about any aspect of this study, information and Frequently Asked Questions are available on the study website. If this does not answer your query you can contact the research team by calling 0207 848 8183.
For independent advice and information you can contact the Royal Exeter & Devon NHS Foundation Trust Patient Advice and Liaison Service (PALS):
T: 01392 402093
W: http://www.rdehospital.nhs.uk/patients/help/pals.html
E: rde-tr.PALS@nhs.net

Further Information

Thank you for taking the time to read the information about this study. If you would like to take part, please register for the study through the PROTECT website at www.protect-study.org.uk. If you would like more information about the study before you decide whether or not to take part, you can contact a member of the study team at Exeter University by ringing the study help and information line (0207 848 8183).

Please note that this helpline is for general information and support for the study. It will connect you to a member of the study team who will be able to talk about the study but will not be able to provide medical advice. Please also note that we are not able to give out information about your personal performance or progress in the study.