

STUDY PARTNER INFORMATION SHEET

REACTIVE: Clinical Investigation to determine the accuracy of cognitive monitoring and feedback app, REACTIVE, to detect and predict cognitive decline in older adults

Chief Investigator: Professor Anne Corbett

Invitation to take part in a research study

We would like to invite you to take part as a Study Partner in our research study, REACTIVE, which is being run at the University of Exeter. 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 we recommend that you 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 questions about this study, we would encourage you to contact a member of the study team. Our contact details are on the last page of this information sheet and on the REACTIVE app and website www.reactivestudy.org.uk

You are under no obligation to take part in the study, and 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 a statement of consent on the app or website when you register.

Why are we doing the study?

Changes in brain function such as memory, attention and problem-solving can be an early sign of dementia. These changes are subtle, and doctors do not have any tools that can pick them up, meaning that people with early symptoms do not receive any support or treatment. In fact, 99% of people with early symptoms, called Mild Cognitive Impairment (MCI), do not see a GP and do not get a diagnosis. There are promising new treatments in the pipeline, and we know much more about preventing dementia than previously. It is therefore very important that we identify people with early symptoms and make sure they are in touch with their GP. This will ensure they have the best possible chance of preventing dementia, or that they get a proper diagnosis and access to treatment and support.

We know that loss of brain function and dementia is a major fear for older adults. People need a way to check their brain health and to know when to seek help from a doctor. Doctors also need a better tool for tracking people's brain health and deciding when someone needs a full assessment. Currently they must rely on simple tests that are not good enough to detect very early symptoms.

Computerised testing is now very good at picking up changes in people's brain function. We have developed an app called REACTIVE to help people and their GP monitor their brain health. People download the app (IOS or Android) or access the website and complete regular brain tests as well as providing information about their health and lifestyle. The app will analyse this information and send feedback to the person using the app or website and their doctor to make sure they are notified, and any changes are detected early.

What is the purpose of the study?

This is a 30-month research study that will test the REACTIVE technology and see how well it performs when it is used by people at home. The trial will answer four main questions:

1. Can REACTIVE accurately detect people who are in the early stages of dementia?
2. Is the information collected on REACTIVE more accurate when it is combined with a blood and/or DNA test?
3. Will older adults use REACTIVE and find it easy to understand?
4. Do GPs find the REACTIVE information useful and easy to understand?

The study will recruit 1306 people over 65 who are experiencing concerns about their brain health. Of these, 628 participants will have MCI. They will download the app or use the REACTIVE website for 30 months, which will involve completing brain tests every six months. REACTIVE will identify people whose brain function suggests they may be developing dementia, and we will use statistical tests and clinical review to check whether REACTIVE has correctly identified the right people. Participants will also provide two saliva and blood samples through the post. We will analyse these samples to look for biological indicators of dementia risk. The saliva sample will be analysed to look for genes that are known to be linked to Alzheimer's Disease and other causes of dementia. The blood sample will be analysed to look for proteins in the blood that are linked to changes in the brain. These indicators are still being confirmed by research so we cannot be certain that the information we find will affect participants' chance of developing dementia. For this reason, we will not let participants know the results of these tests as part of the REACTIVE study.

The study is being led by the University of Exeter Medical School, in partnership with the Royal Devon University Healthcare NHS Foundation Trust and a network of NHS centres.

Why have I been invited?

You have been nominated by a friend or family member who is participating in this research study to answer some questions about them.

In order to participate, you will need to:

- Be willing and able to give informed consent for participation in the study
- Have access to and the ability to use a computer or touchscreen device with internet access
- Be a close family member or friend who have known the study participant well for at least 10 years and have contact with them regularly
- Be aged 18 or older and reside in the UK.

You will not be able to participate as a study partner if you have a diagnosis of dementia.

Do I have to take part?

It is entirely up to you to decide whether to join the study. The purpose of this information sheet is to describe the study in detail and help you make your decision. If you do wish to take part, you will then need to read and sign a consent form on the app or website. Please note that if you do join, you will be free to withdraw at any time without giving a reason.

If you decide not to join the study as a study partner, your name and email address (as provided by the study participant) will be removed from our database within a month of your receiving this invitation. You may also decline through the link provided in the email invitation or cancel your registration up to the point of enrolment.

What will happen if I take part?

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

1. You will be asked to register as a study partner with the REACTIVE study and confirm that you have read this Study Partner Information Sheet. A downloadable copy of this is available on the app and the website www.reactivestudy.org.uk
2. You will be asked to read a consent form and provide your consent to a series of statements on the app or website to confirm you understand what the study involves and that you are happy to participate as a study partner in the study.
3. Once you have registered and confirmed your consent, we will let your friend or family member know you have accepted their invitation to become their study partner.
4. You will then be asked to complete two online questionnaires about how your friend or family member's behaviour might have changed over the past years and how they have been performing day-to-day tasks. These will take a total of 15-20 minutes to complete.
5. We will ask you to complete these questionnaires again every six months until the end of the study. We will send you an email and/or SMS reminder when your questionnaires are ready and if you are taking part through the app you will receive app notifications as well. This way we will be able to track any changes you may have observed in your friend or family member.

6. At the end of the study, we will contact you to let you know that REACTIVE is closing. We will make the findings of the research available through the study website, app, and a newsletter.

How will we use information about you?

We will need to use information about you for this research project including

- Name and Initials
- Contact details (email address)

People 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.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep your 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.

What are the possible benefits and risks of taking part?

This study is aiming to improve how we detect the early symptoms of dementia in people who are not yet in touch with their GP about their brain health. By taking part in this study, it could help move forward our understanding of MCI and dementia and how it should be managed and supported.

This is a clinical study of an online cognitive test system. This means it is of low risk to all participants. We only wish to observe how your friend or family member progresses over the period of the trial.

The main advantage of this research is that participants and study partners will be taking part in an important research study that could provide valuable new knowledge about how to support people with mild cognitive impairment and those at risk of dementia.

There is a chance that the participant that you are supporting as their study partner may receive a message telling them that they may have problems with their brain health. This may be distressing and may cause anxiety for you and your loved ones. We will support the participant during this process and ensure they understand what this information and what happens next.

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. 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.

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

You can find out more about how we use your information

- at <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-for-all-sponsors/#GDPRtemplate>
- our leaflet available from www.reactivestudy.org.uk
<https://www.exeter.ac.uk/about/oursite/privacy/research/#a5http://www.hra.nhs.uk/patientdataandresearch>
- by asking one of the research team
- by emailing dataprotection@exeter.ac.uk
- by sending an email to Suzy Wignall, Senior Clinical Research Governance Manager (Contact details at the end of this information sheet), or
- by ringing us on 01392 727581.

Who is organising and funding the research?

The study is funded by the National Institute for Health & Care Research and is sponsored by the University of Exeter. You will not receive payment for participating in this study.

Who has reviewed and approved this study?

The study has been reviewed by a UK Health Department's NHS Research Ethics Committee (**Yorkshire & The Humber – Leeds West Research Ethics Committee**), **the Medicines and Healthcare products Regulatory Agency**, and the Health Research Authority who are the regulatory authority for research involving the NHS.

What will happen at the end of the study?

At the end of the study period, you will complete your final questionnaires on the app or website. We will then 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 study website. The information collected will be totally confidential and no individuals will be identified in any reports/publications or presentations. A description of this clinical study will be available at <https://www.isrctn.com/>

What if there is a problem?

If you have a concern or complaint about any aspect of this study contact the research team or the Sponsor using the details below.

Additional information and [Frequently Asked Questions](#) are available on the study website and app. If this does not answer your query, please contact the research team on 01392 727581 or email us on reactive@exeter.ac.uk.

For independent advice and information, you can contact the PALS Service at the Royal Devon University Healthcare NHS Trust.

Patient Advice and Liaison Service (PALS)

Royal Devon University Healthcare NHS Trust PALS:

- Telephone: 01392 402093
- Email: rde-tr.PALS@nhs.net

University of Exeter

Sponsor Representative
Suzy Wignall
Senior Clinical Research Governance Manager
University of Exeter
Research Ethics, Governance and Compliance
University Corporate Services
Lafrowda House, St Germans Road
Exeter, EX4 6TL
Tel: 01392 726621
Sponsor mailbox: res-sponsor@exeter.ac.uk

REACTIVE Study Team Contact (Study Helpline)

Email: reactive@exeter.ac.uk

Tel: 01392 727581

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 app or website at www.reactivestudy.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 by ringing the study help and information line 01392 727581.

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.

Thank you for your interest in taking part.