DaRe2THINK Information leaflet for participants

See the YouTube video at: <https://youtu.be/yKylFgWXL9A>, or search for DaRe2THINK.

****Website: [www.birmingham.ac.uk/d2t](http://www.birmingham.ac.uk/d2t)

# Thank you

Thank you for taking part in the DaRe2THINK trial.

As you live in or near the West Midlands, we would like to invite you to join an additional study that will take scans of your brain and eyes to understand why patients with atrial fibrillation develop dementia (trouble remembering, concentrating or making every-day decisions). This research will address a major public health problem that affects many patients in the NHS.

You will not be put on any new medicines as part of this study. You do not have to join this extra study, and saying no will not affect the DaRe2THINK trial, or any NHS care you receive.

# What is the purpose of the study?

Atrial fibrillation (AF) is a common condition where the heart rhythm is irregular. AF leads to a higher risk of blood clots which can cause a stroke if they occur in the brain, and other problems elsewhere in the body. In addition, patients with AF have a higher chance of developing problems with their memory or making every-day decisions (cognitive decline) that can eventually lead to dementia.

In the DaRe2THINK trial, we are testing if using blood thinning tablets earlier in patients with AF, before they develop other health conditions, can lower the risk of developing blood clots. As part of the trial, your GP will have assigned you by random to one of two groups: either taking a blood thinning tablet now, or continuing your normal medications until you reach the age of 75 years (or 65 with other health conditions).

This extra study in 160 patients will help us to understand why some patients with AF develop dementia, and if blood thinners work by preventing damage to the brain or if they impact on blood vessels throughout the body. It is essential that we include patients in both groups in the trial, so we are asking all patients to join if they are within distance of the Queen Elizabeth Hospital in Birmingham where the scans will take place.

# We would like to invite you to take part in this research

You have indicated before that you are happy for the study team to contact you. Before we call you, we would like you to understand why the study is being done and what it would involve for you. You will have time to go through this information leaflet before discussing the study with the research team (at least 5 days). Feel free to talk to others about it if you wish.

If you agree to join this extra study, you will be asked to complete a consent form on your phone, tablet or computer, similar to the one you completed for the main DaRe2THINK trial. A copy of your consent form will be emailed to you, noted in your medical record in the hospital, and available for review by the study monitors.

# What will happen if I agree to take part?

If you agree to take part, you will be invited to attend the Queen Elizabeth Hospital in Birmingham. Your first visit must happen within a few months of you starting in the DaRe2THINK trial. A further visit will happen in 3 years’ time. Apart from these two visits, there is nothing else you need to do. However, you will still need to complete the questionnaires on your phone every 6 months for the main trial.

Each of the two visits will include:

1. A **brain magnet scan** (MRI) which is painless with no x-rays; this will take around an hour.
2. **Scans of your eyes** taking photographs of the blood vessels with a special camera; this is also painless and will take around 30 minutes.
3. **Blood** taken from your arm for routine tests and markers of heart function (1-2 teaspoons).
4. A **heart tracing** that records for about 15 seconds (electrocardiogram).
5. Simple tests of your **memory and reaction times** on a tablet; this will take 10-15 minutes.

# Is there anyone who can’t take part?

All patients taking part in DaRe2THINK can join this study, as long as this is within 3 months of them starting the trial. There are a few patients who will not be able to take part because of the brain magnet scan if:

1. You are claustrophobic (fear of confined spaces).
2. You have implanted metal clips or devices (such as a cochlear implant, aneurysm clips and certain heart pacemakers).
3. Your weight is above 190 kilograms or 30 stone (the limit for the scanner).

We will check all of these when we contact you, before arranging your visit.

# Are there any benefits or risks to taking part?

We already know that AF can lead to dementia. This may be due to silent ‘micro-strokes’ that gradually damage the brain over time. The scans will allow us to see these changes over time in your brain and also the eyes, which are a great window to the rest of your blood vessels.

The aim of the study is to help future patients with AF receive the best treatment throughout the NHS and across the world. Unless there is major problem found on your scans (such as a brain tumour or major bleed), the results will not be sent back to your doctor or contribute to your NHS care. If anything is found, the brain, eye or heart teams at the Queen Elizabeth Hospital will arrange for further NHS tests and keep you informed. Sometimes, incidental findings are revealed which need further investigation. So although there may be some benefit to you from taking part, that is not the aim of the study. We are most interested in comparing scans across the 3 years, so we can understand why patients with AF develop dementia.

There is no specific risk to you in taking part – blood tests and the scans can cause a little discomfort, but these are all simple tests that are routinely used in the NHS to investigate people with strokes, dementia, eye and heart problems.

# What about COVID?

Government and NHS guidelines will be followed at the Queen Elizabeth Hospital in Birmingham to reduce the risk of exposure to COVID-19. You may be required to wear a mask or face covering; please see <https://www.uhb.nhs.uk/coronavirus-public> for up-to-date details. Your visit will need to be re-arranged if you develop any coronavirus symptoms or are isolating.

# Expenses and payments for visits

To cover your travel costs and any other expenses, each patient who takes part will receive £50 per visit. This will be mailed to you after the visit, so there may be a short delay in receiving it. You do not have to collect any receipts from taxis or other transport to receive this. We will coordinate each visit so you only have to visit the hospital once for the tests – the scans need to fit around usual NHS work, but there will be flexibility in date and time for your convenience.

# What happens when the research study stops?

After your 3-year scan, the research team will spend the next year looking at the differences between your scans and putting together a scientific summary. The outcomes from the main DaRe2THINK trial will be used, so no additional effort is needed on your part. The scientific report will be published in a medical journal, with all results referring to groups of patients without identifying any individuals. Your information will have a code number instead, with your name and other details removed so that no-one can work out that you took part in the study. You can find out more about how we use your information by going to the study website or contacting the study team. Our public involvement team (which includes patients with AF) will put together a plain English summary which will be emailed to you after study completion.

# What will happen if I don’t want to carry on?

You can withdraw from the study at any time without giving a reason and this will not affect your participation in the main DaRe2THINK trial, or any other treatment you are receiving. However, we hope you will agree to complete the 3-year visit if you are able, so that we can see changes over time and contribute to research on the prevention of dementia. If you do wish to withdraw, please contact the study coordinator. Any information collected up to the point of your withdrawal can still be used.

# Who has reviewed and is monitoring the study?

To protect your interests, all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. The DaRe2THINK trial and this study have been reviewed and given favourable opinion by the North East - Tyne & Wear South Committee (project number: 21/NE/0021).

# What else do I need to know?

Please see the main DaRe2THINK patient information leaflet for details on who is overseeing the study, how your medical records are accessed, and what steps we take to keep your details confidential. The study is sponsored by the University of Birmingham and is funded by the National Institute for Health Research (part of the UK Department of Health and Social Care).

# What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the research team (see below). If you are not satisfied with their response or wish to make a complaint, you can contact the Patient Advice and Liaison Service (PALS) at the University Hospitals Birmingham NHS Trust (pals@uhb.nhs.uk). If you wish to make a complaint about how your information has been handled, you can contact the University of Birmingham’s Data Protection Officer on dataprotection@contacts.bham.ac.uk.

**Thank you for considering taking part in this research.**

**If you have any questions, please contact the national coordinator, Alastair Mobley:** **dare2think@trials.bham.ac.uk** **or 07867 551957 (office hours).**