

## TRIAL INFORMATION LEAFLET FOR PARTICIPANTS

See the YouTube video at: <https://youtu.be/B36K480uvXI>, or search for DaRe2THINK.

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



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

Before you decide, we would like you to understand why the study is being done and what it would involve for you. You will have some time (at least 48 hours) to go through this information leaflet before discussing the study with your GP. You can talk to others about it if you wish. On the last page, you will find a summary of key points and our contact details.

### 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.

Patients aged over 75 years, or those aged 65 with other health conditions usually receive blood thinning tablets to prevent blood clots. However, this may be too late to avoid dementia. A new class of blood thinning tablets are now widely used in the NHS which are more convenient for patients to take, with a lower risk of bleeding than older treatments. Using these drugs in younger patients could provide benefit, but this needs to be tested in a clinical trial. The aim of this study is to find out whether these newer blood thinning tablets can prevent serious long-term complications if used earlier in patients with AF. We are also testing a new way to run trials within the NHS, based locally in GP surgeries and without the need for patients to visit a hospital.

### Why have I been invited? Can I say no?

You have been invited by your GP as your medical record suggests you may be eligible for the trial. It is up to you to decide whether to join the study or not. If you don't take part, your NHS care will not be affected. If you agree to take part, your GP will ask you to complete a consent form (using the internet or on paper). A copy will be emailed to you, noted in your medical records and available for review by the study monitors.

### What will happen if I agree to take part?

If you take part, your GP will confirm you are eligible to join the trial and then a computer will decide at random (like tossing a coin) which group you are assigned to:

**Group 1:** You continue with your current treatment and will start a blood thinning tablet at age 75, or sooner if you have other medical conditions that lead to a high risk of stroke.

**Group 2:** In addition to any usual treatments, your GP will prescribe a blood thinning tablet called a DOAC (direct oral anticoagulant). The actual drug you start will depend on local NHS policies. In some cases, your GP may stop drugs you are already taking, such as aspirin.

Once the treatment is assigned, you and your doctor will know which group you are in. In both groups, patients will be followed up to check for strokes, blood clots, heart disease, bleeding episodes and dementia. We will do this by securely linking your NHS medical records (from your GP and any hospitals you visit), including health conditions, measurements and medications, plus information stored by NHS Digital and the Office for National Statistics.

### **How many visits are there and how long will it take?**

Using this new system for NHS trials, you will not need to make any additional visits because of the trial. Information on your health status will come from your NHS medical records. You will be asked to report your quality of life every 6 months, and memory and reaction tests every 12 months during the 5 years of the study. A further check will be made after 10 years. These tests take about 10 minutes and will be texted to your mobile phone and sent to your email address. You can complete these on your phone or any device connected to the internet. You can also use a public computer (for example at a library), however you must complete the questions yourself. You will be sent reminders by text message and email to complete these tests at the right time.

### **Are there any risks and benefits to taking part?**

We already know that AF can lead to strokes and dementia. The risk of these problems increases as you get older. Blood thinners are currently used in the NHS to prevent strokes in older patients. They could also be valuable in younger patients, but we need to test that this is the case. Your contribution is vital to helping future patients with AF receive the best treatment throughout the NHS and across the world.

Blood thinning drugs do not cause bleeding, but if bleeding is caused by another factor, for example a knock to the head, they can make the bleeding worse. The newer blood thinners used in this trial are much safer than older ones like warfarin, and are now the standard of care within the NHS. Apart from AF, doctors commonly use these drugs to treat blood clots in the leg or lung, and certain types of heart and blood diseases.

If you start a blood thinner, you will need to take extra care in day-to-day activities (for example, making sure you don't fall or cut yourself shaving). Minor bleeding occurs in around 1 in 10 patients, but isn't usually a reason to stop treatment and can be prevented by placing pressure on cuts or holding down longer after blood tests. They are established drugs, and your GP is used to prescribing and monitoring their use. Major bleeding usually only happens when there is an unknown health condition like a stomach ulcer. If you hit your head or collapse on blood thinners, you should seek medical attention.

### **What about COVID?**

You will not need to visit your doctor in person to join this study. With regards to your NHS care, government and NHS guidelines will be followed to reduce the risk of exposure to COVID-19. This may mean that non-essential NHS appointments are conducted via telephone. Where you do need to attend your practice or local hospital, safety measures will be followed according to current NHS guidance.

## **Are there broader benefits?**

This study will test a new way of running trials based at GP surgeries using routine NHS information. We aim to include patients that don't normally take part in clinical trials and follow them up without the need to revisit their GP or attend hospital. This approach could improve the health and well-being of those treated by the NHS, whilst reducing the time needed from staff and patients to engage in clinical research. We are also testing if these blood thinners can save money for the NHS in the long term.

## **Expenses and payments**

You will not receive any payment for taking part in this study.

## **Who else is taking part and why do a trial?**

We plan to include 3000 patients with AF in this study. This includes patients from GP surgeries right across England. In order to find out which way of treating patients with AF is best, we need a clinical trial to compare starting blood thinners earlier than usual. Grouping patients in a random way ensures the information we get on these drugs is impartial, and can be used to help you and future patients.

## **How will I receive the medication if I am randomly assigned to the blood thinner group?**

Your GP will prescribe your medication in the normal way, which you can pick up or get delivered from your local pharmacy as usual. You should take the study medication regularly as directed, and continue all of your other medications as advised by your GP. Although there are no blood tests needed specifically for the study, most GPs will do blood tests every 6 months for patients on blood thinners.

## **Are the medications and tests safe?**

The treatments we are using have been prescribed for many years as part of the normal treatment for patients with AF. The tests are simple questions about your quality of life every 6 months, and tests to check your memory and reaction times every 12 months. The results of the tests will not be available to you or your GP, so you should still report any health problems to your GP as usual, or seek advice from NHS 111.

## **What happens when the research study stops?**

After the study finishes, your GP or any hospital teams you see will decide on your future treatment. The treatments you have started may continue, or you may change to other treatments if these prove to be better. If we find that starting blood thinners earlier is better, then this may become standard practice in the NHS.

## **What if new information becomes available?**

Sometimes we get new information about the treatments being studied. If this happens, your GP will tell you and discuss whether you should continue in the study. If the study is stopped for any reason, we will tell you. Your GP will then arrange your continuing care.

## **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 any other treatment you are receiving. However if you do withdraw, then your GP may stop

any blood thinning medication started within the trial. If you change your GP, you may also be withdrawn. The information collected from your medical records up to the point of your withdrawal can still be used. You are able to opt out of the following future study activities by contacting the study coordinator:

- 1) No longer receive any further health questionnaires.
- 2) Cancel future access to your health records.
- 3) Completely withdraw from all future aspects of the trial.

### **What if there is a problem?**

You should ask to speak to your GP if you encounter any problems. If you have a concern about any aspect of this study, you can also speak to the researchers (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) via your NHS Trust. 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](mailto:dataprotection@contacts.bham.ac.uk).

In the event that something goes wrong and you are harmed during routine treatment, you should seek advice from your NHS practice, and if as a result of the study intervention, then through the University of Birmingham. The NHS complaints mechanism is also available.

### **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. This study has been reviewed and given favourable opinion by the North East - Tyne & Wear South Committee (project 21/NE/0021). Any studies linked to DaRe2THINK would only continue after further review by this committee. In addition, two independent groups of experts will help to ensure the trial is run correctly, and to ensure the safety of all participants.

### **Will my details be kept confidential?**

All information which is collected about you, including your medical records and contact details, will be kept strictly confidential. We will take all reasonable steps available in order to protect your privacy. Personal and research information will be stored for up to 25 years. Any future use of this information will follow the same principles as discussed above, and only shared within the research team. Outside of this team (including in any articles we publish about the research), all reports will refer to groups of patients without any identifying details. 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.

### **How will my medical records be accessed?**

We are working with the Clinical Practice Research Datalink (CPRD), part of the UK Department of Health and Social Care. CPRD works with around 1 in 5 GPs across the UK to improve how routine health information can be used to benefit all patients. The secure system does not collect any identifying information, but can link to NHS hospital records and information from the Office for National Statistics. We will use this system so that you and your GP do not have to spend time completing lengthy study forms.

When you join the study, we will ask for your consent to use this system periodically throughout your life to look for health issues related to this study. With your consent, the

research team will record your NHS number so we can obtain information about any stays in hospital. By joining the study, this supersedes any data opt-out you may have completed, but only for the purposes of this study.

### **What are your choices about how your information is used?**

You can stop being a part of this study at any time, without giving a reason, but we will keep information about you that we already have collected. We will need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

There may be additional studies either as part of this study or others where your contribution could be helpful. When you join, you will be asked for your consent to contact you about future research approved by the Ethics Committee. You can refuse without consequence to this study or your NHS care.

### **What will happen to the results of the research?**

At the end of the study, we plan to publish the study findings in a medical journal. You will not be identified in any publication. We will send a summary of the findings to your mobile phone and email address once the study has been published.

### **Who is organising and funding the research?**

The study is sponsored by the University of Birmingham and is funded by the National Institute for Health Research (NIHR; part of the UK Department of Health and Social Care). Other members of the research team are CPRD, University Hospitals Birmingham NHS Foundation Trust, the University of Oxford and London School of Economics. No member of the research team is being paid for including you in this study.

#### ***Key points about this research:***

- Patients with atrial fibrillation have a higher risk of stroke, blood clots and memory problems in later life that can lead to dementia.
- We don't currently know whether giving blood thinning medication can reduce this risk if given to patients earlier than they would normally receive.
- This trial will randomly assign patients to either continuing their current care (starting blood thinners when they are older) or given a blood thinning medication at a younger age.
- If you participate in this study, you will not need extra visits to your doctor. You will be sent a questionnaire every 6 months to complete on your mobile phone or any internet connected device.
- Our aim is to improve the care of patients with atrial fibrillation and help doctors choose the right medication to prevent long term complications.

Thank you for taking the time to read this information leaflet and for considering to take part in this research.

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

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