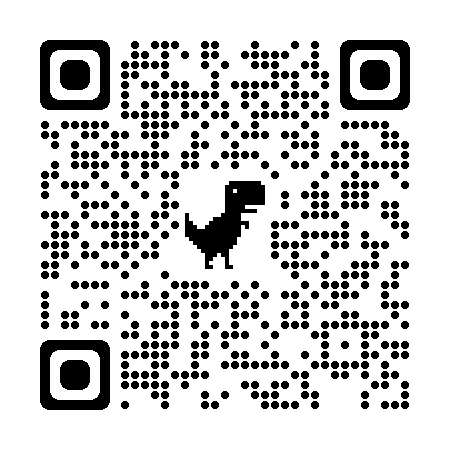
**Research Information Sheet for Practices (RISP)**

**Study contacts:**

| **Study Co-ordinator:** **Alastair Mobley**  **Tel:** 07867551957  **E-mail:**  [dare2think@trials.bham.ac.uk](file:///C:\Users\mobleya\University%20of%20Birmingham\DaRe2THINK%20-%20Documents\12.0%20GENERAL%20CORRESPONDENCE\12.3%20Promotional%20Materials%20for%20Meetings,%20Events,%20Publications\DaRe2THINK%20RISP\dare2think@trials.bham.ac.uk) | **CRN Study Lead: Sue Elwell**  **Phone:** 07920531254  **Email:** [sue.elwell@nihr.ac.uk](mailto:sue.elwell@nihr.ac.uk) |
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| **Study** **Title** | DaRe2THINK |
| --- | --- |
| **IRAS Number** | 290420 |
| **Sponsor** | University of Birmingham, UK |
| **Funders** | National Institute for Health Research (HTA 19/109 - NIHR130280) |
| **Chief Investigator** | Dipak Kotecha (Chief Investigator), Professor of Cardiology, Institute of Cardiovascular Sciences, University of Birmingham & Institute of Translational Medicine, University Hospitals Birmingham NHS Foundation Trust; Email: [d.kotecha@bham.ac.uk](mailto:d.kotecha@bham.ac.uk)  David Shukla (Deputy Chief Investigator), General Practitioner & Lead for the West Midlands Primary Care CRN team, Institute of Applied Health Research, University of Birmingham; Email: [david.shukla@nihr.ac.uk](mailto:david.shukla@nihr.ac.uk) |
| **Study Design** | DaRe2THINK is an NHS embedded individual-patient, randomised, parallel-group, open-label, event-driven superiority trial with 1:1 allocation to either direct oral anticoagulant (DOAC) or no added therapy.  DaRe2THINK uses routinely collected healthcare data to automatically pre-screen patients, and conduct no visit follow-up. Combined with remote e-consent this trial aims to make research accessible to busy primary care staff. |
| **Primary Study Aim & Objectives** | DaRe2THINK will test the hypothesis that DOACs are effective at reducing thromboembolic events and vascular dementia compared to no treatment, in patients with AF and a low or intermediate expected risk of stroke. Using a healthcare data approach to reduce the burden on both NHS staff and patients. |
| **Total Recruitment Target** | 3000 Nationally |
| **Practice/Site Target** | No target |
| **Recruitment Period** | 01/06/2021 to 01/06/2023. [Study follow up will be conducted through yearly data extraction from the patient's electronic health records by CPRD.  Follow up will continue for 5 years after recruitment] |
| **Criteria for Primary Care staff to review** | 1. Currently receiving an anticoagulant. 2. Any clinical indication for anticoagulation. 3. Active clinically-significant bleeding. 4. Life expectancy estimated <2 years. 5. Participant unable or unwilling to provide informed consent for access and linkage of past and future electronic healthcare records. 6. Currently participating in another clinical trial.   Women of childbearing potential. |
| **Criteria Checked by electronic search** | Inclusion Criteria   1. Diagnosis of AF (previous, current or chronic). 2. Age at enrolment ≥60 years to ≤73 years.   Exclusion Criteria   1. Diagnosis of AF (previous, current or chronic) 2. Age at enrolment ≥55 years to ≤73 years 3. Prior documented stroke, transient ischaemic attack or systemic thromboembolism. 4. Combination of multiple known risk factors for stroke where oral anticoagulation would ordinarily be started, including: Heart failure; Hypertension; Age 65 years or older; Diabetes mellitus; Previous myocardial infarction, peripheral artery disease or aortic plaque; and/or Female gender. 5. Any prior history of intracranial bleeding. 6. Prior major bleeding requiring hospitalisation in the last 3 years. 7. Condition that poses a significant risk for bleeding (within 12 months) including gastrointestinal ulceration, brain/spinal/ophthalmic injury or surgery, arteriovenous malformations or vascular aneurysms, major intraspinal or intracerebral vascular abnormalities, hepatic disease associated with coagulopathy, known or suspected oesophageal varices, and cancers with high bleeding risk. 8. Estimated glomerular filtration rate <30 mL/min/1.73m2 measured within the last 12 months. 9. Patients receiving systemic treatment with azole-antimycotics within the last 3 months (ketoconazole, itraconazole, voriconazole and posaconazole). 10. Documented diagnosis of dementia. 11. Hypersensitivity or known intolerance to direct oral anticoagulants. |
| **Core Practice/Site Activities and Requirements** | 1. Review a list of pre-screened patients. 2. Invite eligible patients to take part, using a letter and text message. 3. Countersign a patients e-consent form. 4. Use EMIS to start a DOAC of your choice if the patient is randomised to the intervention arm (no added therapy in the control arm). 5. Report any protocol-defined Serious Adverse Events (SAEs) during the 5-year length of the trial. |
| **Core Patient Activities** | * Review study information * Complete remote informed consent * Randomised to either direct oral anticoagulants (DOACs intervention group) or to continue without oral anticoagulation (control; standard of care). * There is no follow up visits and patient reported cognitive functions will be collected through web-based interface. Similarly, Quality of life is collected every 6 months, a questionnaire will be sent either as text message or to patient’s nominated email address. |
| **Benefits to the Site/Resources provided by the study team and WM CRN** | * Training and general study Q&A session are available for all sites/delegates that have signed up for the study * Completely remote trail with no need for direct patient contact * Automated SAE safety net with sites notified of any potential events in their patients * CRN Nurse support is also available * DaRe2THINK is an Associate PI scheme registered study |
| **Financial Arrangements** | Research Costs (Provide by CPRD)   * Site set-up fee - £268.35 * Per patient - £101.43   Study Support Costs (provided by the CRN)   * Site set-up fee - £180.00 * Per patient - £15.00 * Extra RSI payment - £1300.00 |

If you would like to find out more about the trial please book a introduction meeting with a member of the trial team: <https://calendly.com/dare2think/introduction>



# TRIAL FLOW CHART

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