AuSCR Research Task Group approved projects

Title	**SAFER-AUS: Screening for Atrial Fibrillation with ECG to Reduce stroke – a randomised controlled trial**
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Submission date	24 August 2022
AuSCR role	Data provision
Approved	28 October 2022
Status	In progress
Summary	Atrial fibrillation (AF) is a heart condition that causes an irregular heartbeat. It affects up to 1 in 10 people over the age of 70. AF increases the risk of stroke five-fold, but often remans undiagnosed due to absence of typical symptoms. In fact, 10% of all ischaemic strokes are in individuals with undiagnosed AF. Early identification of AF and appropriate guideline-based treatment with oral-anticoagulants (OAC) can prevent strokes and thus reduce health costs related to AF. Organisations supporting the recommendation to screen include the European Society of Cardiology (ESC), the European Heart Rhythm Association, the Royal College of Physicians of Edinburgh, AF-SCREEN International Collaboration, and recently the Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand. Although opportunistic screening for AF is a guideline recommendation, single timepoint screening will not capture all people with the condition. In many people, AF is paroxysmal, which means it comes and goes. To capture and diagnose paroxysmal AF, multiple screens over time are required. We are therefore undertaking a large 8-year programme of work to find out if screening for AF in people aged 70 and over does prevent stroke and other problems like heart attacks, does not cause significant harm, and represents good value-for-money for the health system. The SAFER Trial (run in the United Kingdom) is a cluster randomised trial that will address these questions. We will run an Australian arm of this trial, The SAFER (AUS) Trial. This will take place in 18 GP practices and include about 1800 consented people. Practices will be randomised to control or screening (2:1). All participants on entry to the trial will provide consent for the research group to access their medical records and specified databases in order to follow up outcome data such as AF status, medication, treatment, stroke and mortality. Consented participants in screening practices will be invited to be screened for AF. Participants will use a handheld single-lead ECG recorder to record ECGs at home over a period of 3 weeks. The ECGs will be read by a validated computer algorithm, with diagnoses confirmed by a cardiologist. Participants diagnosed with AF will be directed to attend their treating GP for a review and to discuss treatment with blood thinning (anticoagulant) medication, as deemed appropriate by the treating GP. Follow up of outcome data will occur for all patients (intervention and control) at 5 years. Follow up will occur through an extraction of identified data from the general practice database for all consenting patients. These data will be linked to the state-based hospital record databases, and to the AuSCR database to cross-reference outcome data of stroke, cardiovascular events and mortality. In addition to the quantitative data, the study will include a process evaluation including qualitative interviews with patients, members of staff from the participating general practices and external stakeholders.