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Management of Atrial fibriLLation INcluding anticoagulation in primary care - study protocol of the cluster randomized controlled trial ALL-IN

Carline van den Dries(1), R Oudega(1), F Rutten(1), Svan de Leur(2), A Elvan(3), K Moons(1), G-J Geersing(1)
(1) Julius Center, University Medical Center Utrecht, The Netherlands
(2) Isala Hospital, Thrombosis Service, Zwolle, The Netherlands
(3) Isala Hospital, Department of Cardiology, Zwolle, The Netherlands

Corresponding author: PhD Fellow Carline Van Den Dries, Julius Center, UMC Utrecht, Clinical Epidemiology, Utrecht, The Netherlands. E-mail: c.j.vandendries@umcutrecht.nl

Background & Aim: Atrial fibrillation (AF) is the most common cardiac arrhythmia with an increased risk of stroke and mortality. It often involves frail, elderly patients, requiring adequate care for cardiac and non-cardiac comorbidities, lifestyle and tailored anticoagulation treatment. Given the expected increase in prevalence of AF, transition of care for AF patients from secondary care to primary care is desired. However, data on the safety and (cost)effectiveness are lacking. This study evaluates if integral management of patients with AF by the practice nurse and general practitioner, including care for comorbidities and anticoagulation, is non-inferior to usual care.
Method. The ALL-IN study is a cluster randomized trial that will be performed in approximately 60 primary care practices in the region of Zwolle, The Netherlands, with more than 1000 AF patients aged 65 years or over. Patients from primary care practices randomized to the intervention arm will receive integral AF management, consisting of a) visits to the practice nurse three times a year and once yearly to the general practitioner, b) INR measurements performed by the practice nurse, and c) easy access consultation from secondary care through the establishment of an Expert Center for Anticoagulation and an Expert Center Cardiology. Patients from practices randomized to the control arm will receive care as usual by the Dutch Thrombosis Service, cardiologist and/or general practitioner.
Results: The study will start in 2016 with a follow-up time of 24 months. Primary endpoint is all-cause mortality. Secondary endpoints are cardiovascular mortality, (non)cardiovascular hospitalization, Major Adverse Cardiac Events (MACE), stroke, major bleeding, quality of life and cost-effectiveness.
Conclusions. The ALL-IN trial is the scientific evaluation of a health care innovation that - due to the delegation of tasks to the practice nurse and the establishment of the Expert Centers for Anticoagulation and Cardiology- aims for sustainable and accessible care, close to the AF patient.