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Clinical Research

Home-Based Education and Learning Program for Atrial Fibrillation: Rationale and Design of the HELP-AF Study

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ABSTRACT

Background: Atrial fibrillation (AF) is a growing global epidemic, with its prevalence expected to significantly rise over coming decades. AF poses a substantial burden on health care systems, largely due to hospitalizations. Home-based clinical characterization has demonstrated improved outcomes in cardiac populations, but its impact on AF remains poorly defined. To test this hypothesis in AF, we developed the **H**ome-Based **E**ducation and **L**earning **P**rogram for Patients With **A**trial **F**ibrillation (HELP-AF) study.

Methods: The HELP-AF study is a prospective multicentre randomized controlled trial that will recruit 620 patients presenting to hospital emergency departments (EDs) with symptomatic AF (ANZCTR Registration: ACTRN12611000607976). Patients will be randomized to either the HELP-AF intervention or usual care. The intervention consists of 2 home visits by a nurse or pharmacist trained in the structured

RÉSUMÉ

Contexte : La fibrillation auriculaire (FA) est une épidémie en constante augmentation partout dans le monde dont la prévalence devrait, selon les prévisions, croître de façon appréciable au cours des prochaines décennies. La FA impose un lourd fardeau aux systèmes de soins de santé, principalement à cause des hospitalisations qu'elle nécessite. Il a été montré que la caractérisation clinique à domicile améliorait les résultats dans la population des patients cardiaques, mais l'incidence d'une telle méthode sur la FA reste à évaluer de façon précise. Pour tester cette hypothèse dans la FA, nous avons conçu l'étude ***Home-Based Education and Learning Program for Patients With Atrial Fibrillation (HELP-AF)***.

Méthodologie : L'étude HELP-AF est un essai multicentrique, prospectif, contrôlé et à répartition aléatoire dans le cadre duquel seront recrutés 620 patients se présentant à l'urgence d'un hôpital avec une

Introduction and Rationale

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia to affect humans, with an estimated prevalence of approximately 2% in the general population of industrialized countries. It is a major public health burden, with an estimated 33.5 million patients affected globally in 2010 and evidence suggesting that this prevalence will continue to rise exponentially.[1-3] The growing AF burden applies across the care spectrum, with AF management being associated with the second highest increase in prevalence of all diseases managed by general practitioners.[4] Consequently, AF contributes to a high health care system burden, mainly due to the increasing number of AF-related hospitalizations, with an annual cost of $3.46 billion in 2010 in the United States alone.[5,6]

Management of AF has become a complex process. Evolved evidence for the role of cardiovascular risk-factor management to reduce AF burden and treatment outcomes,[7-9] as well as new treatments for prevention of stroke, have been adopted.[10] In addition, there is evidence that structured delivery of care has

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educational visiting (SEV) method. Patients in the control group will receive usual discharge follow-up care.

Results: The primary endpoints are total unplanned hospital admissions and quality of life. Secondary endpoints include AF symptom severity and burden score; time to first hospital admission; total unplanned days in hospital; total AF-related hospital admissions (including atrial flutter); total cardiac and noncardiac hospital admissions; total AF- or atrial flutter-related; cardiac- and noncardiac-related ED presentations; and all-cause mortality. An economic evaluation will also be performed. Clinical endpoints will be adjudicated by independent blinded assessors. Follow-up will be at 24 months.

Conclusions: This study will assess the efficacy of a home-based structured patient-centred educational intervention in patients with AF.

FA symptomatique (n° d'enregistrement au registre ANZCTR : ACTRN12611000607976). Les patients seront répartis au hasard pour recevoir soit l'intervention HELP-AF, soit les soins habituels. L'intervention consiste en deux visites à domicile effectuées par une infirmière ou un pharmacien ayant reçu une formation sur la méthode de visite éducative structurée. Les patients du groupe témoin recevront les soins de suivi habituels après un congé hospitalier.

Résultats : Les paramètres d'évaluation principaux sont le nombre total d'admissions à l'hôpital non planifiées et la qualité de vie. Les paramètres d'évaluation secondaires sont notamment la gravité et le score du fardeau des symptômes de la FA et, le temps écoulé avant la première admission à l'hôpital; le nombre total de journées d'hospitalisation non planifiées; le nombre total d'admissions à l'hôpital liées à la FA (y compris le flutter auriculaire); le nombre total d'admissions à l'hôpital pour un problème d'origine cardiaque ou non cardiaque; le nombre total de visites à l'urgence liées à la FA ou au flutter auriculaire et pour un problème d'origine cardiaque ou non cardiaque; ainsi que la mortalité toutes causes confondues. On procédera également à une évaluation économique. L'arbitrage des paramètres d'évaluation cliniques sera effectué à l'insu par des évaluateurs indépendants. Un suivi sera réalisé après 24 mois.

Conclusions : Cette étude évaluera l'efficacité d'une intervention à domicile éducative, structurée et centrée sur le patient chez les personnes atteintes de FA.

improved clinical outcomes.[11] Indeed, this mandates the requirement of a multifactorial, integrated approach focusing on the treatment of the arrhythmia, prevention of thromboembolic complications with appropriate oral anticoagulation therapy according to risk of stroke, detection and treatment of underlying cardiovascular disease, and management of modifiable cardiovascular risk factors.[12] Importantly, successful management depends on patients having good understanding of their health problems and the role of complex medication regimens. Poor understanding and illness beliefs may be a contributing factor to the patterns of repeat hospitalization, poor quality of life (QoL), and inadequate adherence to medication currently associated with AF.

Models of home-based interventions and behavioural change

Congestive heart failure (CHF) has been the primary cardiac disease target for coordinated chronic disease-management interventions in attempts to improve outcomes of rehospitalization and QoL. Initial studies used intensive clinical and allied health professional outpatient-based interventions that demonstrated lower hospital readmission rates and fewer patients with multiple readmissions.[13,14] Stewart et al. were the first to model this type of intervention with their initial study demonstrating an effective reduction in total hospitalizations.[15] However, the intervention did not yield a significant improvement in QoL at 6 months. In a larger sample, home-based intervention demonstrated a longer time to first hospitalization and an all-cause mortality benefit (when adjusted for other covariates).[16] In addition, patients undergoing home-based intervention had had fewer hospitalizations at reduced total cost compared with those undergoing usual care.[16] However, QoL was not reported in this study.

The intervention in these studies predominantly involved home visits at 7 to 14 days after discharge from hospital by qualified cardiac nurses and repeat visits as deemed necessary.[16] The aims of the visit were to provide educational material to the patients in addition to a clinical assessment and identification of other factors likely to lead to rehospitalization. A report was written and sent to all treating physicians with a combination of possible short- and long-term strategies. In addition, the cardiac nurses acted as intermediaries throughout the duration of the trial, coordinating and optimizing their patients' clinical management. Superior outcomes from home-based clinical interventions may therefore be mediated from greater patient knowledge or a superior clinical characterization and networking during the intervention phase of the trial.

Detailed clinical profiling and home visits by cardiac nurses were also used in the **S**tandard versus **A**trial **F**ibrillation-Sp**e**cific Manageme**n**t Stud**y** (SAFETY) study.[17] The intervention also included the development of a care plan, education, and a variety of management strategies and follow-up, depending upon the patient's clinical status and risk profile. The intervention was delivered by a cardiac nurse in the patient's home following admission to hospital, together with additional telephone support (mean of 12.6 calls per participant). In 26% of people, home visits were repeated because of clinical issues requiring direct intervention. In the intervention group (n = 168), 337 brief in-home assessments of heart rate and rhythm occurred within 6 months after enrollment in the study, and an additional 48 comprehensive home visits were performed during follow-up. After a follow up of 2 years, there was no significant difference in the primary endpoint, which was a composite of all-cause unplanned hospitalizations and mortality. However, in the coprimary endpoint, there were proportionately more days alive and out of hospital in the intervention group compared with controls.

Structured educational visits

Structured educational visits (SEVs), informed/underpinned by the principles of academic detailing, are a means of implementing evidenced-based patient education that is focused on influencing behaviour in accord with key messages that are determined *a priori* and informed by the best available evidence. Patient-centred SEV (PC-SEV) adapts the method of clinical-centred educational visits, known as academic detailing (educational visiting, educational outreach visiting),[18] for use in the home of the patient. Like academic detailing for clinicians, PC-SEV is conducted as close to the point at which the person makes decisions about his or her care and where that care is delivered. For ambulatory patients, it is their home. Randomized trials have documented the success of academic detailing in influencing health professional behaviour-prescribing patterns, disease management, cancer screening, and use of transfusions.[19-21] Three to 4 key messages are framed around the behavioural goals for the intervention. PC-SEV is based on the principle of "exchange" and uses a social marketing framework to develop the key messages. Social marketing includes procedures derived from commercial marketing to modify behaviour of individuals and populations by recognizing and appreciating perceptions, motivations, values, and behaviour of the population involved.[22-24]

PC-SEV has been designed, implemented, and tested within a large randomized controlled trial in the Palliative Care Trial (PCT).[25] The PCT trial concluded that a single case conference or patient/caregiver SEV about pain management—which included 2 home visits by a palliative care nurse, conducted at a time when the patient's physical performance status was declining—better maintained function by 5% to 10% compared with the control group; $P = 0.01$ and $P = 0.02$ for case conference and SEV, respectively. In addition, the mean number of hospital admissions was lower for case conferencing (mean 1.26 vs 1.70, $P < 0.007$) and patient educational visiting (mean 1.36 vs 1.61, $P = 0.1197$) compared with usual care. Health outcomes for PC-SEV have also been evaluated in a randomized controlled trial of carer training for patients receiving domiciliary oxygen therapy for advanced respiratory disease, in which carers were visited twice at home by research nurses.[26] Mortality was significantly higher for patients in the intervention group compared with the control group (31% vs 11%, $P = 0.0008$). The intervention was associated with significant improvements in carer QoL and chronic respiratory QoL of patients.

The HELP-AF study

The **H**ome-Based **E**ducation and **L**earning **P**rogram for Patients With **A**trial **F**ibrillation (HELP-AF) study uses home-based PC-SEV and clinical characterization. Strengths of the HELP-AF intervention include the potential for community-based delivery, workforce availability in both regional and urban areas, and adaptability to changes in practice—such as the introduction of the newer oral anticoagulants—during the study. The intervention is undertaken in the home environment to empower patients to take ownership of their management. The self-management strategies in the intervention are compatible with other chronic disease programs in primary care. We chose to study this intervention in patients presenting to hospital EDs, as they are highly symptomatic and are likely to already be using significant health care resources (eg, hospital outpatient and emergency services) in the management of the arrhythmia.

The planning for the HELP-AF study started in 2011, supported by research grants awarded by the National Heart Foundation of Australia and the Government of South Australia. Recruitment started in 2013, and 24-month follow-up was completed in 2018. The research team is led by the Centre for Heart Rhythm Disorders (CHRD) at the University of Adelaide and Royal Adelaide Hospital.

Hypothesis

We hypothesize that a home-based education intervention, combining clinical characterization with patient-centred SEV, will result in a reduction in all-cause hospital admissions and improved health-related QoL in patients with AF.

Methods and Study Design

The HELP-AF study is a multicentre prospective randomized controlled trial, which was powered to recruit 620 patients with a primary diagnosis of AF from 6 hospitals in Adelaide, South Australia. Figure 1 outlines the design of the study. Ethical and Governance approval has been obtained from the relevant Ethics Committees for the respective recruiting sites (additional information in the Supplementary Material). The study is registered at the Australian New Zealand Clinical Trials Registry (www.anzctr.org.au), with trial ID ACTRN12611000607976.

Patient recruitment and population

Patients have been recruited within 2 months of their presentation to the ED of the participating hospitals, located in South Australia. We elected to study a population of patients with symptomatic AF, as they are likely to have the greatest contribution to recurrent hospitalization and therefore the growing AF-related health care burden. Patients have been followed for 2 years. Table 1 outlines the inclusion and exclusion criteria for the study.

Randomization

Patients with primary separation diagnoses of AF by ICD-9 or ICD-10 coding, presenting to emergency departments of participating hospitals, were eligible for inclusion in the trial. All individuals with a primary separation diagnosis of AF by ICD coding were identified from each participating hospital. Preliminary screening of individuals occurred to ensure that age criteria were met, participants were living independently and had a home address within the geographical catchment area defined by the study. Eligible participants were then sent an introductory letter by post containing brief information about the study. At this stage, participants were able to opt in or out prior to telephone contact with researchers. Those who opted in or did not respond to this letter were contacted by phone to provide brief information on the study. Interested

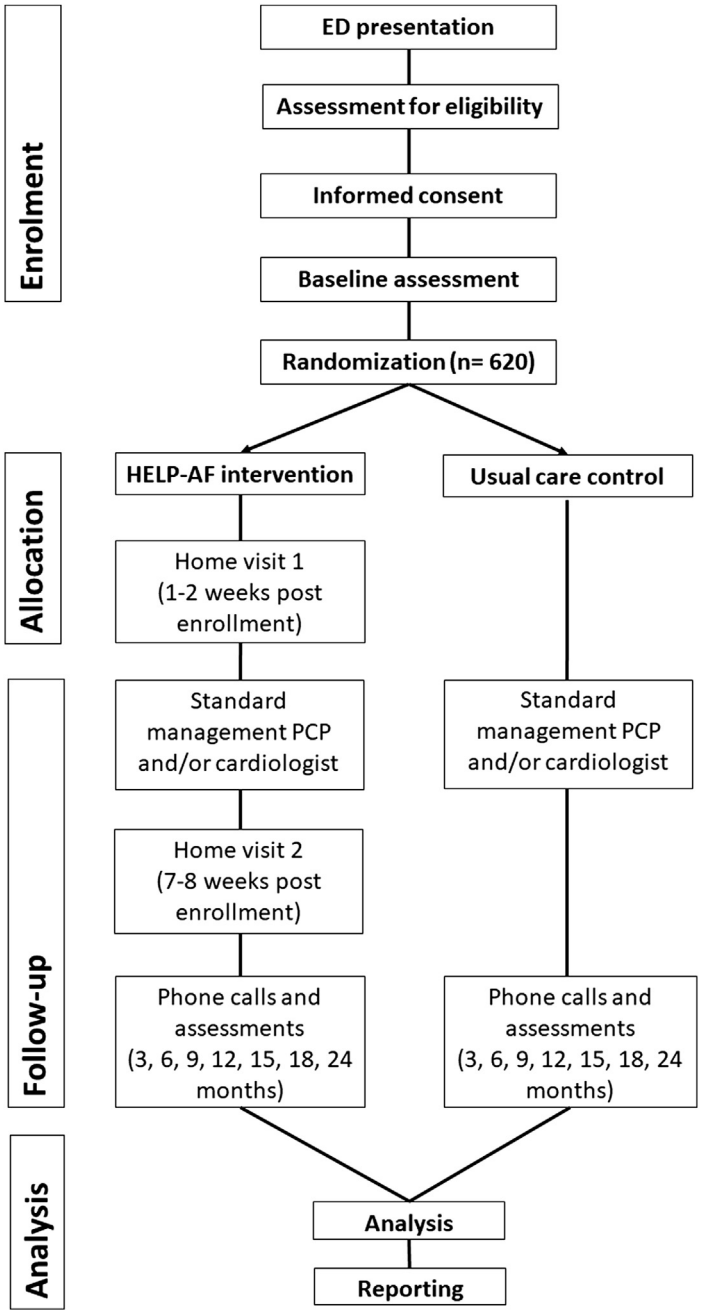

Figure 1. **H**ome-Based **E**ducation and **L**earning **P**rogram for Patients With **A**trial **F**ibrillation (HELP-AF) study design scheme. ED, emergency department; PCP, primary care physician.

participants then received written information packages, consent form, and baseline questionnaires via postal mail and were requested to sign the consent form, complete the baseline questionnaires, and return these documents to the research team. After obtaining informed consent, a researcher conducted a medical record review and screening telephone call to ensure individuals met eligibility criteria. Following the confirmation of eligibility, further baseline data was collected during an enrollment phone call, at the end of which patients were randomized to either the HELP-AF intervention group or the usual-care control group, based on a 1:1 computerized randomization schedule. An online study database, maintained by the Data Management and Analysis Centre (DMAC) of the University of Adelaide, was used for management of patient data and study workflow tasks including screening, randomization, and follow-up assessments.

Control group

Patients in the control group received usual discharge follow-up care, which may have been provided by a primary care physician and/or a cardiologist. AF treatment, including rate and/or rhythm controlling agents, electrical cardioversion, AF ablation, management of thromboembolic risk, treatment

Table 1. Eligibility for the HELP-AF study: inclusion and exclusion criteria

Inclusion criteria
Patients visiting the emergency department meeting the following criteria:
• A primary diagnosis of atrial fibrillation, detected on electrocardiogram (< 12 months) or at index presentation
• Age ≥ 30 years
• Living within the catchment area of the participating hospitals
• English literacy
• Ability to provide informed consent
Exclusion criteria
• Age < 30 years
• Home address outside the catchment area of the participating hospitals
• Absence of electrocardiographic documentation of atrial fibrillation during index presentation
• End-stage heart failure (New York Heart Association class IV, left ventricular ejection fraction < 20%)
• Cardiac surgery < 2 months prior to index presentation
• Patients with a terminal malignancy
• End-stage renal dysfunction (history of dialysis or > stage 3 chronic kidney disease)
• Documented thyrotoxicosis or acute pneumonia at index presentation
• Poor English literacy
• Nonindependent living
• Inability to provide informed consent

HELP-AF, **H**ome-Based **E**ducation and **L**earning **P**rogram for Patients With **A**trial **F**ibrillation.

of underlying cardiovascular morbidity and risk factors, as well as the follow-up frequency, was left to the discretion of the treating physicians.

HELP-AF intervention group

Patients in the HELP-AF intervention group also received usual discharge follow-up care. The HELP-AF intervention consists of 2 essential components: 2 home PC-SEVs using the principles of established SEV and PC-SEV informed by clinical characterization. The home visits were conducted by nurses or pharmacists trained in the methods of SEV.

Home visits were scheduled at 1 to 2 weeks and 7 to 8 weeks after enrollment. The trained nurses or pharmacists who conducted the home visits built on the rapport established with individual patients during pre-home visit phone calls. Also, the trained nurses or pharmacists used enrollment information to conduct broad characterizations of patients' AF burden, symptomatology, medication use, social/support networks, lifestyle risk factors, and comorbid diseases. This information informed the clinical characterization and the PC-SEV. The trained nurses or pharmacists engaged in communication that is responsive to patients' preferences and discussed target behaviours and/or risk factors and, if clinical interventions were indicated, the patient was advised to see appropriate health professionals for further guidance and monitoring. A graphical PC-SEV aid, in the form of an illustrated booklet that highlights self-management behaviours, was used to assist interaction with patients and was left with patients for their future reference. The booklet provides comprehensive information about AF including basic pathophysiology, causes, treatment options, potential complications, and cardiovascular risk-factor management. Oral anticoagulation information booklets and medication lists were provided when needed. The presence of carers or family members was encouraged.

The *a priori* key messages developed for the PC-SEV intervention include the following:

- *Take your AF medications as prescribed to reduce your symptoms and risk of stroke.* The trained nurses or pharmacists engaged with patients to enhance understanding about their current treatment. The discussion was tailored to patients' needs and informed by the clinical characterization and covered rate and rhythm control strategies as well as stroke-prevention therapy. The importance of medication adherence was discussed, in addition to a brief review of any upstream medication therapy related to AF.
- *Stroke-preventing medications can reduce your risk of stroke by up to 60% to 70%.* The association between AF and the increased risk of stroke was discussed. The use of oral anticoagulation was outlined, individualized to their risk of stroke. Advice was also provided on self-management interventions that aim to improve persistence and adherence to medication regimens.
- *You can reduce the risk of AF becoming more severe and reduce risk of stroke by choosing a healthy lifestyle.* Cardiovascular risk factors and lifestyle aspects that may predispose to the worsening of AF were discussed. Individual risk factors were identified, and lifestyle modification was discussed to empower patients to undertake self-management interventions in this area and to assist in reducing future cardiovascular risk.
- *AF episodes are not usually medical emergencies. Follow your personal action plan during an AF episode with usual symptoms.* Patients were provided with written action plans to use during AF episodes with patients' usual symptoms and were asked to seek advice from their primary care physicians or treating cardiologists to individualize plans. The plan includes the option of additional 24-hour phone advice from on-call cardiologists. Participants were taught how to measure their pulses to assist in recognition of AF episodes.

The duration of the visit was scheduled for 90 minutes but was flexible, depending on patient risk factors, clinical history, and expressed and perceived patient needs. Second home visits were used to check patients' understanding of their personal action plans, assess and discuss changes in behaviour or medications since the first visit, reinforce key messages, and answer any questions. The duration of this visit was 30-45 minutes. The aim of this approach is to encourage and assist patients to adopt self-management behaviours and to focus on actions ("What should I do?") rather than feelings (eg, "I feel anxious/scared") when experiencing their usual AF symptoms. The intervention is tailored to the individual's understanding, level of health literacy, motivation for current behaviour, and personal barriers to behavioural change. The trained nurses and pharmacists were upskilled on management of AF and in the technique of academic detailing, including an understanding of how to identify and address barriers and enabling factors relevant to desired behavioural change. For example, this may include beliefs about medicines and barriers to persistence with long-term drug therapy or lifestyle changes.

Follow-up

Patients in both groups received posted questionnaires and 3 monthly structured follow-up phone calls from blinded research staff to assess for study end points (Fig. 1).

Sample Size Calculation

Miyasaka et al.[27] reported 6993 cardiovascular readmissions during a 5.5-year follow-up in 4498 patients with new AF. Assuming a constant event rate over time, conservatively, 2542 events would be expected to occur in 2 years (0.57 events per patient per 2 years). To approximate the all-cause rehospitalization from the data of Miyasaka and colleagues on cardiovascular events, we have increased the estimate by 40%, so that the expected 2-year all-cause rehospitalization is 0.79 events per patient per 2 years. A home-based intervention in patients with heart failure reported a 36% reduction in rehospitalization associated with home-based clinical characterization and patient education at 9 months and overall: a 16% linear reduction over a 6-year follow-up.[16] Assuming a Poisson distribution, 310 patients in each arm of the study will enable us to discriminate a ±30% change (0.55 to 1.02 events per patient per 2 years in the intervention) in event rate with 0.80 power, and an α of 0.05. In total, 620 patients will be enrolled in the trial.

Study Endpoints

Primary and secondary study endpoints are summarized in Table 2.

Primary endpoint

Total unplanned all-cause hospital admissions. Admissions were identified initially by patient self-report, and were then verified by screening of patient records. Additional admissions identified in hospital records were included. The date, reason, and duration of hospital admission was assessed, to enable the calculation of secondary endpoints as well as generation of time-to-event curves. Total unplanned hospital admissions will be compared among treatment groups using the Poisson regression model, in which we estimate the total number of unplanned admission by treatment group. Planned hospital admissions (eg, for elective or planned medical interventions) will be excluded from the primary endpoint. Subgroup analysis will be undertaken to examine the impact of the intervention on the primary endpoint for newly diagnosed patients with AF compared with those who had diagnoses before their emergency department (ED) presentations.

Health-related QoL has been selected as a coprimary endpoint, given its natural importance for this patient category, and will be assessed through the SF-36 Questionnaire (4-week recall)[28] at baseline, 3, 6, 12, and 24 months. Each of 8 domains, as well as physical and mental component summary scores and the utility weight, will be analyzed using the linear mixed-effects model with patient ID as the random effect and treatment group, time point, and the interaction between treatment group and time as the fixed effects.

Table 2. Primary and secondary endpoints in the HELP-AF study

Primary endpoints
1. Total unplanned all-cause hospital admissions
2. Health-related quality of life

Secondary endpoints
1. Health care utilization:
   - Proportion of patients with more than 1 hospital admission
   - Time to first hospital admission
   - Total unplanned days in hospital
   - Total atrial fibrillation-related hospital admissions (including atrial flutter)
   - Total cardiac hospital admissions, including admissions related to AF, congestive heart failure, thromboembolic events, bleeding events, peripheral or coronary events, other cardiovascular events
   - Total noncardiac hospital admissions
   - Total atrial fibrillation- or atrial flutter-related ED presentations
   - Total cardiac-related ED presentations
   - Total noncardiac-related ED presentations
2. Atrial Fibrillation Severity and Burden Score (AFSS)
3. All-cause mortality
4. Cost effectiveness

ED, emergency department; HELP-AF, **H**ome-Based **E**ducation and **L**earning **P**rogram for Patients With **A**trial **F**ibrillation.

Secondary endpoints

Health care utilization. The primary endpoint of total unplanned all-cause hospital admissions will be further investigated to determine (1) the proportion of patients with more than 1 admission (using a logistic regression model); (2) time to first hospital admission (using a log rank test); (3) total unplanned days in hospital (using the Poisson regression model); (4) total AF-related hospital admissions including atrial flutter; (5) total cardiac admissions; (6) total noncardiac admissions; (7) total AF-related ED presentations (including atrial flutter); (8) total cardiac-related ED presentations; and (9) total noncardiac-related ED presentations. All hospital admission types and ED presentations will be analyzed using a Poisson regression model.

AF severity and burden score. The Atrial Fibrillation Severity Scale (AFSS)[29] is a disease-specific scale that aims to capture subjective and objective values of AF disease burden, incorporating frequency, duration, and severity of episodes. This also includes questions evaluating the number of cardioversions and a measure of well-being ranging from 1 (worst well-being) to 10 (best well-being). The 7-item questionnaire to measure total AF burden comprises common AF symptoms at rest (such as palpitations, dyspnea, fatigue, dizziness, and chest pain) as well as during exercise (dyspnea, fatigue). The severity of symptoms is evaluated using a 6-point scale, with scores from 0 to 5 points. Hence, scores range from 0 to 35 points, with increased scores indicating a higher AF symptom severity. AF severity and burden score will be compared among groups using the mixed-effects model with treatment group, time point, and the interaction between treatment group and time point as fixed effects and patient ID as the random effect.

Disease-specific QoL. The **A**trial **F**ibrillation **E**ffect on **Q**uali**t**y-of-Life (AFEQT) questionnaire [29] will be used to examine the arrhythmia specific changes in quality of life at the same time points. Each of the 4 domain scores, as well as

the overall score, will be analyzed using the linear mixed-effects model with patient ID as the random effect and treatment group, time point, and the interaction between treatment group and time as the fixed effects.

All-cause mortality. All-cause mortality will be assessed for the duration of the trial, with cause of death obtained from death certificates/medical records, cross-referenced with family contact when necessary. This will be analyzed using a Cox proportional hazard model.

Economic analysis and cost effectiveness. The economic analysis will assess the incremental cost per patient to the Australian health system of adding HELP-AF to current AF patient-management strategies, and hence the incremental cost effectiveness in terms of quality-adjusted life-years (QALYs) gained. Health state utilities (QALY weights) will be obtained from the SF-36 data, using Brazier's method.[30] Individual patient costs will be measured from the time of randomization. These costs will usually be measured as unit cost by occasions of service and will include hospitalization, outpatient, and ED visits. The costs of the HELP-AF intervention per patient will include salaries (trained nurses and pharmacists, on-call cardiologists), travel, educational materials, and SEV training but not research protocol costs. Direct costs of informal care and indirect costs (ie, productivity costs) will not be considered. Inpatient costs will be estimated from public and private Australian Refined Diagnosis Related Groups (AR-DRG) estimates. Outpatient and ED costs will be estimated via the respective national classification and the hospital accounting systems.

Endpoint event committee

All clinical events (eg, ED presentation, hospital admission, and mortality) were adjudicated according to the study protocol, by an independent panel of specialists consisting of cardiologists and electrophysiologists. The panel will be blinded to randomized group assignment. The panel members will independently perform a review of events and assign events to a study endpoint. Each event will be adjudicated by 2 committee members. In the event of discrepancy, a meeting will be arranged to discuss and achieve consensus. If the panel remains in disagreement, a chair decision will be made. Further information is available in the Supplementary Material.

Data safety monitoring board

Although educational and behavioural interventions are generally considered to have minimal risk for harm, some studies of interventions using SEV or action plans for management of acute symptoms in other populations have been associated with increased mortality.[26,31] Data-safety monitoring has been recommended for clinical trials involving behavioural or self-management interventions[26,32] and was considered to be an important safeguard for patients in the HELP-AF study. The Data and Safety Monitoring Board (DSMB) was responsible for safeguarding the interests of study participants, assessing the safety of the study intervention, and for monitoring the overall conduct of the study. The DSMB consisted of an independent professional panel comprising 3 clinicians with expertise in biostatistics and clinical research.

Statistical Analysis

Continuous variable data will be assessed for normality assumptions and analyzed using appropriate statistical tests. Categorical variables will be summarized using count (numerator/denominator) and percentages. All analyses will be performed based on the "intention-to-treat" principle. The primary outcome variables (total unplanned hospital admissions and QoL) will be compared across groups, using linear and Poisson regression models, respectively. Statistical significance will be 2 sided and set at $P < 0.05$.

Significance of the Study

Projected estimates have suggested that the prevalence of AF will rise to epidemic levels in the near future. AF-related hospitalizations have increased significantly over the last decades. It is likely that many of these hospitalizations may be preventable. However, there has been a distinct lack of strategies targeting ways in which the growing health care burden of AF could be curtailed; the HELP-AF study aims to address this significant gap. This is the first study to examine the efficacy of SEV for cardiac patients and the efficacy of a personalized action plan for use during AF episodes. The structured approach around *a priori* key messages will facilitate consistent replication of the home-visit intervention, which may be difficult to achieve with other educational and behavioural approaches. Hence, this study is of substantial importance on numerous levels.

At the patient level, the focus on the provision of education and empowering patients to self-manage and monitor their conditions is crucial, with the PC-SEV delivered in patients' own home environments. This will lead to improved treatment uptake, improved patient knowledge on how to self-manage, and more appropriate use of health care resources. This study is expected to result in reduced unplanned hospital admissions and improved QoL in patients with AF. Home-based interventions have been applied successfully in other cardiac patient populations. This study aims to build on this previous research to deliver a home-based education and learning intervention in the AF population. Study results should provide data on the efficacy of this patient-centred, structured educational intervention in enhancing patient outcomes, improving QoL, and reducing health care resource utilization.

From a health-policy standpoint, this structured intervention could be seamlessly translated to other health care systems worldwide. The focus on patient centeredness and involvement may reduce preventable health care utilization and consequently reduce the significant and growing burden that AF currently places on health care systems worldwide.

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Disclosures

Dr Hendriks reports that the University of Adelaide has received on his behalf lecture and/or consulting fees from Medtronic and Pfizer/BMS. Dr Sanders reports having served on the advisory board of Medtronic, Abbott Medical, Boston Scientific, CathRx, and Pacemat. Dr Sanders reports that the University of Adelaide has received, on his behalf, lecture and/or consulting fees from Medtronic, Abbott Medical, and Boston Scientific. Dr Sanders reports that the University of Adelaide has received, on his behalf, research funding from Medtronic, Abbott Medical, Boston Scientific, and Microport. Dr Brooks accepted a continuing position at Microport CRM (formerly LivaNova Australia Pty Limited) subsequent to the design and commencement of the study.

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Supplementary Material

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