The Chinese University of Hong Kong, Department of Medicine & Therapeutics, Division of Cardiology and

The University of Hong Kong, LKS Faculty of Medicine,School of Nursing

Information Sheet and Consent Form

Project title:
A nurse-coordinated integrated care model to support decision-making and self-care in patients with atrial fibrillation: A randomized controlled trial

Purpose of the study:

The aim of this study is to develop and examine the effects of a nurse-coordinated care model on health outcomes in patients with atrial fibrillation (AF) using a patient empowerment-based approach to enhance shared decision-making about treatment planning and self-care. Findings from this study would be highly important in informing the development of effective health care service to improve the self-care ability of AF patients.

Target group:

Patients attending medical follow-ups at cardiac clinics will be invited to undergo a rapid, single-lead ECG device to screen for AF. A 12-lead ECG will be performed to confirm the diagnosis for suspected cases. Patients with confirmed diagnosis of AF, who are ≥60 years of age, community dwelling, and with no use of oral anticoagulants (OAC) will be invited to participate in this study.

Study Content:

The study will consist of 2 phases.

Phase 1: Participants will be randomly allocated to join Programme 1 or Programme 2. Participants of Programme 1 will undergo a baseline assessment conducted by a research nurse to give basic information on self-care ability and health condition. A pre-consultation session will be provided 1–2 weeks before participants' next medical clinic consultation. This session will comprise of two components: an individualized assessment and a group-based session. The individual assessment will address multiple aspects, including stroke risk, bleeding risk, quality of anticoagulation with warfarin and symptom assessment. After the risk assessment, the research nurse will conduct a face-to-face session in a small-group (6–8 patients/group) format to empower participants regarding decision-making and communication with physicians. The same group of participants will attend an empowerment-based educational module beginning 1 week after their medical appointments. The module will comprise five weekly educational sessions covering the following major topics related to AF self-care: i) medication management, ii) symptom monitoring, iii) crisis management, iv) activities and exercise, and v) risk factor management to reduce risks of stroke and bleeding. After finishing five educational sessions, the research nurse will make regular phone calls to participants to ask for participants' self-care conditions on AF and to provide them with health advices. In addition, the participants will be provided with telephone access to the nurse for inquiries regarding disease management during office hours.

Participants of Programme 2 will continue to receive conventional care as arranged by the hospital.

Phase 2: A small group of participants will be invited to join an exploratory qualitative study to determine how and why the intervention works.

Procedure:

If you are willing to join this study, please sign on the consent form and complete the baseline assessment to provide us with your personal particulars, information on your self-care ability and health condition. You will be allocated to Programme 1 or 2 according to a computer-generated sequence. Telephone interviews will be conducted upon completion of the intervention and 6 months thereafter for follow-up assessment. Your medical record will also be reviewed for reference.

Risks and benefits:

The study intervention will not cause any pain, discomfort or harm to you. The major potential benefit is to develop a high quality and effective health service to enhance the self-care ability of patients with AF and enhance their overall quality of life.

Anonymity, confidentiality and nature of participation:

All collected data will be subject to strict anonymity and confidentiality. Your name will not appear on any data record sheets. All data will be locked up in a secure location and only the researcher can have access to it. All data will be destroyed after use. Your participation is voluntary. You may refuse to participate in or withdraw from the study at any time. Your decision will not affect the quality of present or future care you are receiving in the hospital.

Inquiry:

This study is undertaken by:

Prof. Bryan Yan, Division of Cardiology, Dept. of Medicine & Therapeutics, CUHK (Tel: 3505 3942)

Dr. Polly Li, School of Nursing, LKS Faculty of Medicine, HKU (Tel: 3917 6686).

For any inquiry, please feel free to contact them.

For matters concerning research ethics, please contact The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee at 35053935.

You are cordially invited to participate in this study.

The Chinese University of Hong Kong, Department of Medicine & Therapeutics, Division of Cardiology and

The University of Hong Kong, LKS Faculty of Medicine, School of Nursing

Consent Form

Code No: _____

Date: _____

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I confirm that I have read and I was informed of the purpose of the study, the procedures that I will undergo, the risks and the benefits that I may receive. Alternatives to my participation in the study have also been discussed. All my queries and personal concerns regarding the above issues have been asked and had been fully explained by the research nurse. I understand that The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee will be one of the authorized parties to access my records related to the study for ethics review purpose. I acknowledge that I can contact The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee for any inquiries. I have read this consent form and I understand the particulars. Therefore, I agree to give my consent to participate in this study.

Signature of Participant	Name of Participant	Date of Signature
Signature of Research Assistant	Name of Research Assistant	Date of Signature