A novel shared decision-making (SDM) tool for anticoagulation management in atrial fibrillation: protocol for a prospective, multicenter, cluster randomized controlled trial

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Research Article

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Running title: A SDM tool for anticoagulation management

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Abstract

**Background:** Atrial fibrillation (AF) is a common arrhythmia that requires anticoagulation therapy to prevent stroke. However, there is still a significant under-/over-treatment in stroke prevention for patients with AF. The adherence and the risk of bleeding associated with oral anticoagulation therapy (OACs) are a major concern. Shared decision-making (SDM) is an approach that involves patients and healthcare providers in making decisions about treatment options. This study aims to assess the effectiveness of a novel SDM tool for anticoagulation management in AF.

**Methods:** The study will be a prospective, multicenter, cluster randomized controlled trial involving 440 patients with AF in 8 community health service centers (clusters) in Shanghai, China. The SDM group will receive anticoagulation management through the novel SDM tool, while the control group will receive standard care. The follow-up period will be at least 1 year. The primary outcome will be any bleeding event, while secondary outcomes include the accordance of stroke prophylaxis for AF according to current guidelines, time in therapeutic range (TTR), the occurrences of major bleeding and thrombosis events, and patient knowledge, adherence, and satisfaction.

**Discussion:** This study will provide evidence on the effectiveness of shared decision-making in improving the appropriateness of OAC use in Chinese AF patients. The findings may inform the development of guidelines and policies for the management of AF and anticoagulation therapy in China and other countries.
**Trial registration:** ChiCTR, ChiCTR2200062123. Registered 23 July 2022.

**Keywords:** Atrial fibrillation, Shared decision-making, Net clinical benefit, Anticoagulation, Warfarin, Non-vitamin K antagonist oral anticoagulants

**Background**

Atrial fibrillation (AF) is a chronic cardiac arrhythmia that is prevalent worldwide, affecting 2% to 4% of the population [1]. In China alone, it affects more than 10 million patients [2]. It is crucial to note that AF substantially increases the risk of stroke by five-fold [3]. Several studies have established that oral anticoagulants (OAC), including warfarin or non-vitamin K antagonist oral anticoagulants (NOACs), are essential for preventing stroke in AF patients [4-7]. However, in clinical practice, suboptimal OAC usage is a common occurrence [8]. Over a third of AF patients who are eligible for OAC treatment receive antiplatelet therapy instead [9]. Additionally, more than a quarter of patients receiving OAC are underdosed or overdosed [10]. Patient adherence is also a significant factor affecting anticoagulation quality. After one year, medication adherence is at 70% among AF patients, dropping to 50% at two years and only 35% after five years [11]. Collectively, inappropriate usage and non-adherence to OAC can result in poor outcomes and high costs for AF patients [11, 12].

Shared decision-making (SDM), is a crucial process that involves both medical professionals and patients in treatment decision-making, leading to improved rationality, reduced decision conflict, and increased patient satisfaction and adherence [1]. This approach is now recommended as a class I recommendation for patient
management in clinical guidelines for AF [1]. Although several online tools have been developed to facilitate SDM in AF patients [13-16], most of them use outdated or nonspecific data and lack support for full-process follow-up, making it challenging to achieve optimal individualization of anticoagulation and sustainable management [16]. In response to these challenges, our team developed a SDM tool called I-Anticoagulation, which comprises two functional modules - an anticoagulation decision support system and a full-process patient management system - to enhance the decision-making and patient management of stroke prevention in AF [17]. In a pilot study, the use of I-Anticoagulation improved rationality, adherence, and satisfaction in both medical professionals and patients [17]. However, the pilot study had a limited sample size, and only patients using I-Anticoagulation were included in the analyses. Therefore, this study aims to evaluate the effectiveness of the SDM tool in improving the quality, patient adherence, and satisfaction of anticoagulation therapy in AF patients through a prospective, multicenter, cluster randomized controlled trial.

**Methods**

**Study design**

This study will be a cluster randomized controlled trial conducted from October 2022 to April 2024 in eight community health service centers in Shanghai, China. The trial will compare the efficacy of using the shared decision-making (SDM) tool, I-Anticoagulation, versus the usual care in treating patients with AF. The clusters will
be randomly assigned to either the SDM or control group, as depicted in Figure 1. Consecutive patients with AF will be enrolled in the study, with those in the SDM group being treated using the I-Anticoagulation tool, while those in the control group receiving standard care. The study was registered on July 23, 2022, in the Chinese Clinical Trial Registry, with the registration number of ChiCTR2200062123. This protocol was designed and described according to the standard protocol item-Recommendations for Interventional Trials–Artificial Intelligence (SPIRIT-AI) extension published in 2019[18] (see Additional file 1).

**Patient and public involvement**

Neither the public nor the patients were engaged in the proposal of the research question, the design or implementation of the study or patient recruitment. The results will be dispersed to the study participants via public reports and academic papers.

**Settings and participants**

This study will enroll patients who are 18 years or older and have received a new diagnosis of paroxysmal, persistent, or permanent AF confirmed by electrocardiogram (ECG) or 24-hour Holter monitors, and are willing to participate in the study and sign the informed consent (Additional file 2). Patients who meet any of the following criteria will be excluded: those who are pregnant, have experienced therapeutic or subtherapeutic bleeding complications in the last 6 months, have severe renal insufficiency (creatinine clearance rate, CrCl ≤ 20 ml/min), have severe hepatic insufficiency (Child-Pugh ≥ 10 points), have severe heart failure (cardiac function
New York Heart Association, NYHA grade IV and above), have severe infection and respiratory failure, or are unable to comply with the study requirements. Patients can reserve the right to drop out due to any reason or without reason and at any time during the study. If any incident happens to the patients, such as death, disability, or dementia, they could withdraw from the study after applying by their legal representatives and evaluating by researchers. The full eligibility criteria are listed in Table 1.

Randomization and blinding

To avoid any risk of contamination between the SDM and control groups, cluster randomization will be implemented in this trial. The intervention provided to patients with AF will be grouped by clinicians in a single hospital. Computer-generated randomization will be used to allocate the intervention and control groups in a 1:1 ratio following AF confirmation. The allocation results of each community health center were told to the administrators by telephone. Each administrator only knows the result of his or her own site. The researchers, participants, and data analysts will not be blinded, but the participants will not be allowed to know the outcomes of this study.

Interventions

Introduction

Hospitals that are randomized to the SDM group will utilize the SDM tool to manage AF patients. The medical specialists involved in this study will have access to the
SDM tool. The anticoagulation regimens for AF patients will be determined through communication between the clinicians and patients based on the suggestions and information provided by the SDM tool. This includes anticoagulation strategies that have a corresponding net clinical benefit (NCB), cost of each anticoagulant, blood examination of warfarin, and other relevant considerations. Clinicians will prescribe dosage regimens and order appropriate laboratory monitoring based on the recommendations of the SDM tool. Furthermore, this SDM tool can also assist clinicians with anticoagulation regimes in AF patients with specific circumstances, such as adjuvant bridging therapy, periprocedural anticoagulation recommendations, and drug regimen adjustments for end-organ function, weight, and concomitant interactions. With the help of the SDM tool, pharmacists can provide comprehensive patient education, including indications for the therapy, medication intake, medication interactions, laboratory monitoring, activity, diet, side effects, pregnancy, procedures, safety precautions, and self-care. The SDM tool will also enable the tracking of bleeding and other adverse events relevant to anticoagulation, as well as assessing patients' knowledge, adherence, and satisfaction with anticoagulation therapy. The tool will automatically schedule the follow-up scheme, and the anticoagulation therapy will be reassessed based on the follow-up data of the patients. The records and information of the patients will be obtained from the SDM tool cloud platform. In contrast, the control group will receive the usual care based on the clinicians' usual approach.

*Introduction of the anticoagulation SDM tool (I-Anticoagulation)*
In a previous study, a novel anticoagulation Shared Decision Making (SDM) tool was developed with the input of healthcare professionals including physicians, pharmacists, and nurses [17]. To facilitate optimal anticoagulation management, a WeChat Mini application-based tool called I-Anticoagulation was created, which offers a flexible and efficient communication platform for healthcare professionals and AF patients. The tool is composed of two modules: an anticoagulation decision support system and a full-process patient management system.

The anticoagulation decision support system requires the input and recording of baseline information of patients with AF, such as age, weight, gender, smoking, alcohol consumption, diagnosis, complications, comediations, history of stroke and bleeding, blood pressure, liver and kidney function, and heart function [17]. Liver function will be assessed using the Child-Pugh score, and renal function will be calculated using the Cockcroft-Gault formula based on creatinine clearance. The tool can automatically calculate CHA2DS2-VASc and HAS-BLED scores to evaluate the patient's stroke and bleeding risks, respectively, based on incidence data for Asian AF patients [19-21]. The anticoagulation strategies with NCB values will also be presented on I-Anticoagulation.

Patients on anticoagulant therapy can be enrolled in the full follow-up management system, with patient information updated at each follow-up visit, including adjusted dose, INR value (if warfarin was used), the reason for unstable INR, thromboembolic/bleeding events during anticoagulation, and other changing characteristics. The risks of stroke and bleeding will be dynamically reassessed
according to changes in patient characteristics, and the NCB for each anticoagulant
drug will also be recalculated, with dynamic recommendations for appropriate
anticoagulation regimens.

In addition, the SDM tool includes a series of questionnaires, such as the
Anticoagulation Knowledge Tool (AKT) [22], Medication Adherence Reporting Scale
(MARS-5) [23], and Anti-Clot Treatment Scale (ACTS) [24], to evaluate medication
knowledge, adherence, and satisfaction of AF patients receiving anticoagulation.

Clinicians can search for recommended anticoagulation strategies based on the latest
guidelines or consensus for patients with AF affected by renal/liver impairment,
coronary artery disease (CAD), perioperative period or switching to a different type of
anticoagulant.

**Outcomes**

The study's primary outcomes comprise any bleeding events, both major and minor.
Major bleeding events [25] include fatal haemorrhage, life-threatening bleeding, and
severe bleeding requiring treatment or assessment. Severe bleeding can manifest as
gastric intestinal haemorrhage, joint haematoma, retroperitoneal haemorrhage, fundus
haemorrhage, urine, haemoptysis, or require blood transfusion of at least two units. In
contrast, minor bleeding events, such as mild nasal hemorrhage, endoscopic
haematuria, skin stasis, or mild hemorrhoids, do not lead to serious consequences
[26].
The study's secondary outcomes include the accordance of stroke prophylaxis for AF according to current guidelines, the percentage of time in the target INR range for patients using warfarin, the occurrences of major bleeding and thrombosis events, and the OAC knowledge, adherence, and satisfaction of AF patients receiving anticoagulation therapy. The study will evaluate stroke prophylaxis for AF using a flow chart (Figure 2) and guidelines for dabigatran, rivaroxaban, and edoxaban (Table 2). The anticoagulation quality of warfarin will be assessed using the TTR, and the therapeutic range of INR for patients with AF is set between 1.8-3.0 [27]. The study considers TTR levels of 65% or higher as good anticoagulation quality. Thrombosis events, including ischaemic stroke, systemic embolism, and transient ischaemic attacks, will be confirmed by imaging methods such as ultrasound, CT, or MRI. To evaluate patients' knowledge, adherence, and satisfaction with anticoagulation therapy, the study will use AKT, MARS-5, and ACTS. The AKT comprises 28 items assessing general anticoagulation knowledge for all available OAC and a specific section for VKAs therapy. The MARS-5 assesses common patterns of nonadherent behavior, and the ACTS evaluates the burdens and benefits of anticoagulation treatment and its overall impact (see Additional file 3).

**Enrollment and follow-up**

In this study, each patient enrolled will be monitored for at least one year, regardless of whether they meet the study's endpoint or not. For the SDM group, the follow-up plan will be automatically arranged using the SDM tool. Patient anticoagulation therapy will be re-evaluated based on follow-up data, and information on patients'
records and past data will be retrieved from the SDM tool's cloud platform. At each follow-up time point, patients will complete questionnaires within the tool. In the control group, patients must undergo follow-ups on the 1st, 3rd, 6th, 9th, and 12th months through outpatient clinic visits. At the follow-up time points, researchers will complete the clinical case report form (CRF). A designated medical staff member will send text reminders to patients to attend follow-ups. Patients in the control group who cannot attend scheduled follow-ups at the hospital can be followed up by telephone.

**Data collection and management**

All pertinent information of clinical patients in the group will be documented after enrollment, which includes demographic details, diagnosis, drug usage, test outcomes, and follow-up results. All data will be collected in accordance with standard procedures outlined in Table 3. This study has no composition of data monitoring committee (DMC) because other data will be reserved in the information security department as parts of patients’ medical records. Throughout the study period, the researchers will regularly inspect the completeness of subjects' records, accuracy of data input, and patients' adherence to the study protocol. They will monitor the progression of the group and ensure that all activities are carried out in compliance with the program's rules. The medical information of each patient enlisted in the SDM tool, which is a WeChat mini-program-based model, will be saved in a monitoring database. Professionals will ensure that patients' personal information is secure and that all files remain confidential. If there are any bugs or data leakage, all people will stop using the SDM until the problem is solved and the ethics committee approves
resumption. The users can contact the researchers at any time if they encounter any difficulties and a response will be given within 24 h. For severe adverse events, researchers will report them to the ethics committee within 24 h. If it is attributed to the SDM, the ethics committee, and the principal investigator (PI) can terminate prematurely and conduct interim analyses.

**Sample size**

This multicenter, cluster randomized clinical trial aims to evaluate the occurrence of bleeding events as the primary outcome. The anticoagulation bleeding rate of patients with AF in our hospital was previously found to be 20%, and we set the power at 80% with a bilateral two-tailed significance of 5%. To achieve a sample size of 88 cases in both the intervention and control groups, with a 20% loss to follow-up rate, we estimated a minimum of 110 cases in each group. However, taking the clustering into account, we increased the sample size to account for the design effect to achieve the required statistical power under cluster randomization. Therefore, using the bleeding rate as the calculating target and a design effect of 2, we estimated a sample size of 440, which was calculated using PASS software version 15.

**Statistical analyses**

In accordance with standard practice, continuous variables will be presented as means ± standard deviation, while categorical variables will be expressed as proportions. The Kolmogorov-Smirnov test will be utilized to determine the normality of the data. Student's t-test or Mann-Whitney's U-test will be applied to compare two groups,
depending on the distribution of the data. For categorical data, comparisons between groups will be performed using the Chi-square or Fisher's exact tests. Time in therapeutic range (TTR) will be evaluated for patients on warfarin. Statistical significance will be assumed for p values less than 0.05. All statistical analyses will be conducted with IBM SPSS version 22.0 software.

**Discussion**

A multicenter, cluster randomized trial will be conducted to evaluate the effectiveness of a novel SDM tool in reducing bleeding events and improving guideline compliance for stroke prophylaxis in AF patients, anticoagulation quality, adherence, and satisfaction.

With the increasing usage of online resources to access healthcare information, SDM applications and tools have immense potential for patients to communicate with their doctors and obtain timely clinical diagnosis and treatment recommendations [28, 29]. Several mobile health tools have been developed to manage AF patients, including the AFib 2gether™ app [14] that facilitates SDM for patients who are not receiving anticoagulation therapy, and another SDM tool [30] that provides individualized stroke risk estimates for different anticoagulation therapy options. However, most of these tools are based on international studies that have limited representation of Asian and Chinese participants, despite the higher risks of stroke and bleeding in Asian AF patients [31]. In the I-Anticoagulation tool, risk estimation for stroke and bleeding is based on Asian patient data, and the corresponding NCB of each optimal
anticoagulation strategy are calculated. Clinicians and patients can use this tool to gain a clear understanding of the risks of anticoagulation therapy and engage in a conversation to analyze the advantages and disadvantages of available recommendations and make a shared decision. During the follow-up period, the CHA2DS2-VASc score and the HAS-BLED score are updated with changes in patient risk factors, and the NCB for each anticoagulant and corresponding recommendations also change dynamically. Accurate recognition of patient risk and precise recommendations for anticoagulation can improve the rationality of anticoagulation therapy, as well as patient adherence and satisfaction.

In previous publications from China, oral anticoagulant (OAC) therapy was underutilized in patients with AF, despite the fact that AF is recognized as a major risk factor for ischemic stroke. The Shanghai cross-sectional survey revealed that only 29.5% of AF patients received anticoagulation, and 40.1% were treated with antiplatelet agents for stroke prevention [32]. In addition, the inappropriate prescription of OACs was commonly observed, particularly in Asians, with over 90% of the study population in Taiwan receiving a lower dosage of NOACs [33]. A Korean national study showed that 40%-60% of patients were also provided with lower doses of NOACs [34]. Our epidemiological meta-analysis of 23 studies involving 162,474 AF patients found that the overall prevalence of off-label DOAC doses was 24%, with underdosing accounting for 20% and overdosing for 5% [35]. Off-label underdosing NOACs were associated with a significantly higher risk of stroke and systemic embolism, while off-label overdosing NOACs were associated with a substantially
higher risk of major bleeding [36]. The inappropriate use of OACs can be attributed to various factors, including clinicians' lack of understanding of the indications and recommended use of OACs and patients' excessive concerns about the bleeding risk associated with OACs [36-38]. To address these issues, we provide clinicians with guideline-based anticoagulation recommendations and a shared decision-making platform to help both patients and physicians understand the benefits and risks of anticoagulation therapy and make shared decisions based on the patient's condition. In our previous pilot study, we observed good adherence and satisfaction in 120 AF patients receiving anticoagulants [17].

In the current healthcare landscape, pharmacists have become a vital link in the chain of patient care, as they are able to provide patients with critical support when it comes to managing their chronic illnesses and medications, especially when it comes to anticoagulation decisions [39, 40]. Studies have shown that when pharmacists are involved in shared decision-making, patients benefit from better medication appropriateness and adherence [41, 42] In our research, we will be incorporating pharmacists as part of the patient care team in a combined pharmacy clinic. We will be investigating the role of pharmacists in ensuring that anticoagulant prescriptions for the management of AF are appropriate and in line with guidelines.

**Strengths and Limitations**

This study has significant advantages, as it is a large-scale multicenter cluster randomized controlled trial involving a substantial number of participants. However,
there are some limitations to this research. Firstly, the 12-month period may not be long enough to assess the effect on clinical outcomes such as thromboembolic events. Therefore, future studies should consider longer follow-up periods to evaluate the effects of the intervention over an extended period. Secondly, it is possible that those who agreed to participate in the research might be more interested in their own health, leading to a higher adherence to medication therapy than the general population with AF. This could potentially affect the generalizability of the study findings.

**Trial status**

This publication is based on version 3.0 of the trial protocol dated Jun. 16, 2022. Patient enrollment started October 2022. We anticipate enrollment will be completed by April 2024.

**Abbreviations**

SMD, shared decision-making; AF, atrial fibrillation; OAC, oral anticoagulant; NOACs, non-vitamin K antagonist oral anticoagulants; VKA, vitamin K antagonist oral anticoagulant; TTR, the percentage of time in the target INR range; ECG, electrocardiogram; NCB, net clinical benefit; AKT, Anticoagulation Knowledge Tool; MARS-5, Medication Adherence Reporting Scale; ACTS, Anti-Clot Treatment Scale; CAD, coronary artery disease.

**Figure legends**

**Fig. 1** Flow chart of the study. AF, atrial fibrillation; ECG, electrocardiogram; SMD, shared decision-making; TTR, the percentage of time in the target INR range; AKT,
Anticoagulation Knowledge Tool; MARS-5, Medication Adherence Reporting Scale; ACTS, Anti-Clot Treatment Scale.

**Fig. 2** Evaluation flow chart. AF, atrial fibrillation; TTR, the percentage of time in the target INR range.

**Additional file:**

Additional file 1. SPIRIT-Al checklist.

Additional file 2. Informed consent.

Additional file 3. Questionnaire.

Additional file 4. Copy of the original funding documentation.

Additional file 5. Ethical approval document.

**Acknowledgments**

Not applicable.

**Protocol amendments**

If any, the important protocol modifications would be communicated to relevant parties, such as the ethics committee, trial registry, and trial participants.

**Authors’ contribution**

ZCG, MMP and CZ designed the trial. ZCG is the lead researcher of this trial critically and had reviewed the article for important intellectual content. MMP and CZ are responsible for the execution of the project and had written the first draft. ZCG,
MMP, CZ, JJS, HS and JW are responsible for the execution of the project. ZCG, LS, JJS, HS, YDY, JW and HWL provided technical supports. All the authors read and approved the final manuscript.

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**Availability of data and materials**

No additional data are available.

**Ethics approval and consent to participate**

This study will be conducted according to the Declaration of Helsinki, ethical principles of medical research involving human subjects (revision Fortaleza, Brazil, October 2013). All of the participants will sign written informed consent before initiating data collection and implementation of the intervention. The protocol has been approved by Ethics Committee of Ren Ji hospital (KY2022-105-B) *(Additional file 5)* and other participating institutions. The study has been registered in Chinese Clinical Trial Registry (No.ChiCTR 2200062123). The results of this study will be disseminated through publication in peer-reviewed journals. The access to study data will be made available by providing anonymized datasets after the agreement of
Ethics Committee of Ren Ji hospital. Written, informed consent to participate will be obtained from all participants.

**Consent for publication**

Not applicable.

**Competing interests**

The authors declare no competing interests.

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**References**


Figure 1

Flow chart of the study. AF, atrial fibrillation; ECG, electrocardiogram; SMD, shared decision-making; TTR, the percentage of time in the target INR range; AKT,
Anticoagulation Knowledge Tool; MARS-5, Medication Adherence Reporting Scale; ACTS, Anti-Clot Treatment Scale.

Figure 2

Evaluation flow chart. AF, atrial fibrillation; TTR, the percentage of time in the target INR range.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Additionalfile1.SPIRITchecklist.pdf
- Additionalfile2.Informedconsent.pdf
- Additionalfile3.Questionnaire.pdf
- Table1.pdf
- Table2.pdf
- Table3.pdf