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ORIGINAL RESEARCH

A Novel Model of Integrated Care of Older Patients With Atrial Fibrillation in Rural China

Mingfang Li, MD,[a,*] Ming Chu, MD,[a,*] Youmei Shen, MD,[a] Shimeng Zhang, MD,[a] Xuejun Yin, PhD,[b] Shu Yang, MD,[a] Gregory Y.H. Lip, MD,[c,†] Minglong Chen, MD,[a,†] the MIRACLE-AF Trial Investigators

ABSTRACT

BACKGROUND An integrated management approach is essential to improving outcomes for patients with atrial fibrillation (AF). China's rural health care system, primarily reliant on village doctors, falls short of providing optimal management of AF in rural populations with limited resources and access to health care. To support village doctors in providing integrated care for AF, we have developed a digital health support platform.

OBJECTIVES This study aims to evaluate the effectiveness of this telemedicine-based, village doctor–led, multifaceted care model.

METHODS The MIRACLE-AF (a novel Model of IntegRAted Care of oLdEr patients with Atrial Fibrillation in rural China) trial is a prospective cluster-randomized clinical trial. Thirty village clinics in Jiangdu County, Jiangsu Province, were randomly assigned to village doctor-led telemedicine integrated care or enhanced usual care in a 1:1 ratio. All the patients diagnosed with AF who resided in this rural area and were aged ≥65 years were eligible for enrollment. The primary outcome in stage 1 was the proportion of patients who met all 3 criteria for the atrial fibrillation better care pathway at 12 months, and in stage 2, a composite of cardiovascular death, all strokes including ischemic stroke and hemorrhagic stroke, worsening of heart failure or acute coronary syndrome, and emergency visits due to AF over 36 months.

RESULTS In total, 1,039 participants were recruited from December 1, 2020, to May 9, 2022, with 524 in the telemedicine care arm and 515 in the enhanced usual care arm. All the enrolled patients are under scheduled follow-up.

CONCLUSIONS The MIRACLE-AF trial will provide evidence for this novel integrated care model for treating rural older patients with AF. (New Model of Integrated Care of Older Patients with Atrial Fibrillation in Rural China; NCT04622514) (JACC Asia. 2024;4:764–773) © 2024 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

From the [a]Division of Cardiology, The First Affiliated Hospital of Nanjing Medical University, Nanjing, China; [b]School of Population Medicine and Public Health, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; and the [c]Liverpool Centre for Cardiovascular Science, University of Liverpool, Liverpool John Moores University and Liverpool Heart & Chest Hospital, Liverpool, United Kingdom; and the Department of Clinical Medicine, Aalborg University, Aalborg, Denmark. *Drs Li and Chu contributed equally to this work. †Drs Lip and Chen are co-senior authors of this work.
The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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Atrial fibrillation (AF) is the most commonly encountered cardiac arrhythmia in clinical practice. It increases the risk of stroke, heart failure, and mortality.[1,2] Hence, AF poses a major public health challenge worldwide, with major implications for health care costs.[3]

Stroke prevention is a major pillar of AF management, and oral anticoagulants (OACs) can significantly reduce the incidence of strokes and stroke-related deaths.[4] Despite the use of OACs, a residual risk of stroke and other major cardiovascular events remains.[5] This reflects the clinical complexity of these patients with AF that leads to a higher prevalence of adverse outcomes; yet, suboptimal treatment is common.[6] Hence, a more holistic or integrated care approach in characterizing and managing AF beyond OAC per se is necessary.[7-12]

Current guidelines have recommended the Atrial fibrillation Better Care (ABC) pathway as a simplified approach to implementing integrated care for patients with AF.[13-15] The components of the ABC pathway are defined as follows: A, Avoiding stroke with anticoagulation, B, Better symptom management, with patient-centered and symptom-directed decisions on rate or rhythm control, and C, Cardiovascular and other comorbidity risk reduction, including proactive management of associated lifestyle and patient-centered risk factors. Adherence to the ABC pathway is associated with improved clinical outcomes in patients with AF in different clinical settings and patient populations.[16]

In China, the prevalence of AF is high and is expected to increase in the coming years.[17] A most recent nationwide epidemiologic study showed that about 20 million adults in China were estimated to have AF, with similar prevalence rates between urban and rural areas (1.6% in urban areas vs 1.7% in rural areas) in China.[18] However, older residents in rural China are particularly vulnerable, given their much lower awareness of AF compared with urban residents.[19] Our ongoing Jiangsu Province Rural Community AF Project showed that the detection rate of AF in the rural elderly (aged ≥65 years) was 4.3%, whereas the proportion of patients with AF with a CHA_2DS_2-VASc score ≥3 in women or ≥2 in men was 92%.[20] Among the 50% of patients with known AF, the overall anticoagulation rate was only 11%, with suboptimal blood pressure and glucose control.[21] The low awareness of AF and the large treatment gap in this rural population can be attributed to factors such as low educational level, limited pension coverage, poor disease knowledge, and lack of health consciousness.[22-24] Additionally, senile frailty, limited support from adult children, and inefficient transportation systems further impede older patients in rural areas from seeking better medical care in township or higher-level hospitals.[25,26]

Village clinics represent the most accessible medical resources for rural residents. However, according to on our findings from the Jiangsu Province Rural Community AF Project, only 7% of the village doctors reported having the ability and knowledge to provide integrated care for AF management.[27] How to overcome the barriers faced by rural elderly and implement guidelines-recommended integrated AF management in this population is therefore a substantial public health challenge, and finding a way to empower village doctors might be an effective solution.

To support village doctors in providing integrated care management for AF, we have developed a digital health support platform. The MIRACLE-AF (a novel Model of IntegRAted Care of oLdEr patients with Atrial Fibrillation in rural China) trial aims first to determine whether this telemedicine-based village doctor-led multifaceted care model will improve compliance with the ABC pathway components and second to assess its impact on clinical outcomes in rural elderly patients with AF.

ABBREVIATIONS AND ACRONYMS

ABC = atrial fibrillation better care

AF = atrial fibrillation

OAC = oral anticoagulant

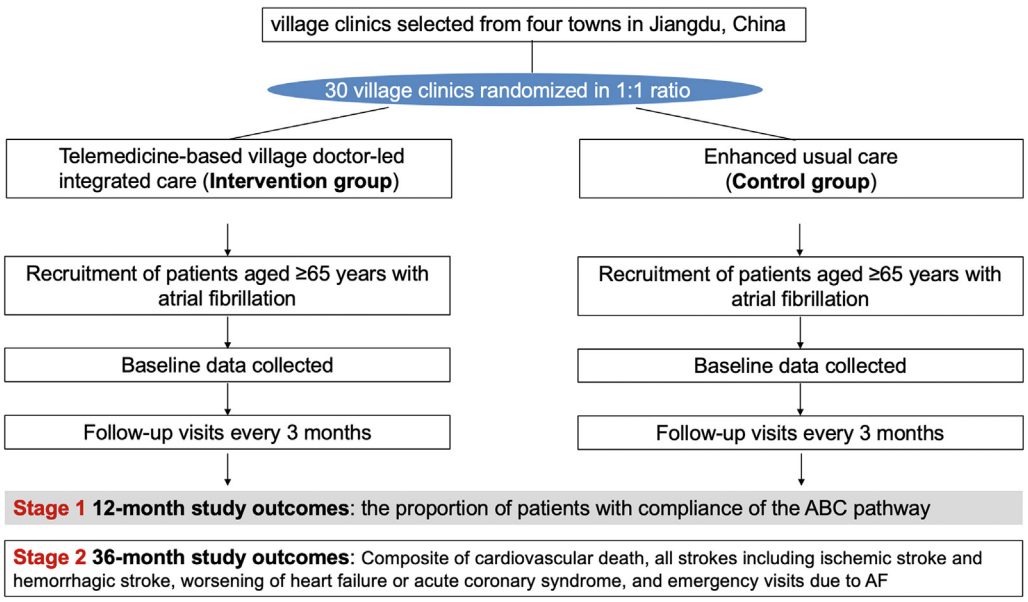
MATERIALS AND METHODS

This study was approved by the local ethics committee (ID 2020-SR-027), and the study protocol is registered on ClinicalTrials.gov (NCT04622514).

STUDY DESIGN. The MIRACLE-AF trial is a prospective, cluster randomized clinical trial conducted in 30 village clinics in 4 towns in Jiangdu County, Jiangsu Province. The village clinic serves as a fundamental unit in which village doctors deliver primary health care to rural residents. China guarantees 1 village clinic for each administrative village (consisting of ≥1 natural villages). In this study, village clinics (clusters) were randomly assigned to receive village doctor-led telemedicine integrated care (the intervention arm) and enhanced usual care (the control arm). Study participants are followed up every 3 months for their compliance with the ABC pathway components and other study outcomes (**Figure 1**).

RECRUITMENT OF VILLAGE CLINICS. The village clinics are eligible for enrollment if their village doctors meet all the following criteria: 1) willing and able to provide integrated care to their patients with AF; 2) willing to serve all patients with AF from 3 to 5 nearby natural villages through their village clinic; and 3) well trained to have a fundamental understanding of telemedicine. The recruitment process for

FIGURE 1 Study Design of the MIRACLE-AF Trial



In this prospective cluster-randomized clinical trial, village clinics were randomly assigned to village doctor-led telemedicine integrated care or enhanced usual care in a 1:1 ratio. All the patients with diagnoses of AF who resided in this rural area and were aged ≥65 years were eligible for enrollment. AF = atrial fibrillation; ABC pathway = Atrial fibrillation Better Care pathway.

village clinics is described in the Supplemental Material.

RECRUITMENT OF STUDY PARTICIPANTS. In the MIRACLE-AF trial, patients with diagnoses of AF who reside in this rural area and are aged ≥65 years or older are eligible for enrollment. Furthermore, all patients enrolled in this study should agree to receive medical care from their village doctors and provide written informed consent. Confirmation of AF diagnosis was established through an electrocardiogram, a report from an AF specialist, or a hospital discharge letter. We exclude patients from this study if they meet any of the following criteria: 1) moderate to severe rheumatic mitral stenosis or prior heart valve replacement; 2) an existing implantable cardioverter-defibrillator or cardiac resynchronization therapy device; 3) cardiac ablation or surgery within 3 months before enrollment; 4) prior pulmonary vein isolation or left atrial appendage occlusion or a plan to receive any of these interventions; 5) a life expectancy <1 year; and 6) current participation in other clinical trials.

RANDOMIZATION PROCEDURES. To minimize treatment "contamination" between participants in the intervention and those in the control group, cluster randomization was used in this study, with village clinics serving as the clusters. Village clinics were stratified on the basis of certain characteristics, such as their geographic locations and their capacity to treat patients with AF. The economic level of township territories has a direct impact on the capacity of their grassroots medical services. Inasmuch as the economic level varies across different towns, we first stratified based on the township territory where village clinics are located, and then further stratified based on the capacity of each village clinic to treat patients with AF, ranging from 10 to 60 patients per village clinic. Village clinics (clusters) were randomly assigned to either the intervention or the control group in a 1:1 ratio, which was designed to assign an equal number of village clinics to each group while maintaining the stratification criteria. Using a computer-generated random number system, an independent statistician who was blind to the identities of the village clinics conducted the

randomization. Village allocation was done only after all participants in the villages had been recruited and the baseline survey had been completed for all. Therefore, the village doctors, the participating patients, and the local investigators who undertake participant recruitment and data collection remain unaware of the group allocation until the start of the intervention.

INTENSIFIED EDUCATION BEFORE RANDOMIZATION. Before randomization, all the village doctors received intensified training regarding integrated care management of AF according to the ABC pathway. The offline courses were delivered by the AF specialists over a 2-day workshop. A hard copy of the handouts was provided to the village doctors. In addition, intensified education was provided to all the patients with AF and their family members.

INTERVENTION. In the intervention arm, a new technology-based model of AF care was introduced to empower village doctors. A digital health support platform was developed by our research team, and a collaborative network of teams consisting of village doctors and AF specialists from our research team was established. With the aid of this telemedicine platform, village doctors can receive more support from AF specialists in providing integrated AF care to the rural elderly with AF. AF specialists in our study refer to cardiologists who specialize in the diagnosis, management, and treatment of AF from tertiary hospitals, namely, the First Affiliated Hospital of Nanjing Medical University and Jiangdu County Hospital.

Our village doctor-centered digital health support platform served as a hub for streamlined health care resource utilization. After randomization, a training program on the use of our digital health support platform was delivered to the village doctors assigned to the intervention group. An instruction manual was also provided to these village doctors. Village doctors use this digital health support platform to treat patients with AF. This platform is also used to store patients' baseline and follow-up data. Importantly, our digital health support platform can be used by AF specialists to conduct remote consultations with rural elderly patients with AF assisted by village doctors. On the basis of the quality of the data uploaded on the platform by village doctors, AF specialists periodically evaluate the performance of village doctors. The results of this evaluation are used to inform the allocation of financial resources, including incentives and special subsidies to recognize and reward the performance of village doctors. Our digital health support platform also provides educational materials and training resources to further augment the knowledge and skills of village doctors.

In the intervention group, village doctors are responsible for implementing integrated AF care using the ABC pathway to the rural elderly with AF. Village doctors can have a tight link with patients with AF and AF specialists through the digital health support platform we developed. This enables them to receive more support from AF specialists in providing integrated AF care to rural elderly with AF. Meanwhile, the village doctors have access to educational materials available on the digital health support platform at any time.

All the patients in the intervention group are asked to visit their village clinics at least once a month. For those facing physical challenges or having limited mobility, village doctors extend their care to home visits. During each visit, village doctors inquire about the symptoms and medication adherence of the patients and monitor their blood pressure, heart rate, and blood glucose levels. We have devised a protocol to guide village doctors in adjusting medication types or dosages if blood pressure is not well controlled (**Figure 2**). Village doctors can post their questions online, and AF specialists respond in a timely manner. If village doctors still have difficulty managing some AF cases, a real-time face-to-face remote consultation can be provided by the AF specialists to them on the digital health support platform every Friday. Patient participation is encouraged when remote consultation is requested by village doctors.

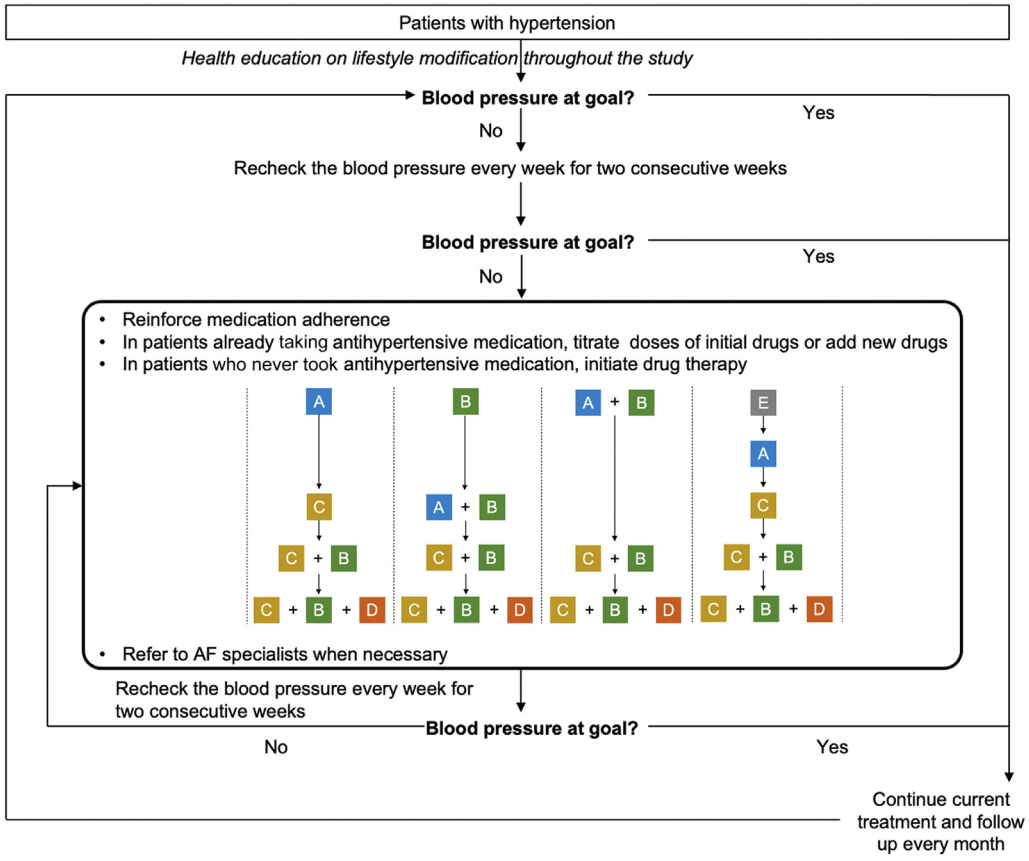
CONTROL. On the basis of the work we conducted with the village doctors and patients before randomization, we refer to the usual care received by patients in the control arm as enhanced usual care. In the control group, village doctors are also responsible for implementing integrated AF care using the ABC pathway to the rural elderly with AF. However, they do not have access to the telemedicine platform.

MEDICAL TREATMENT IN THIS STUDY. The medical treatment plan of every patient in this study was developed by the AF specialists after randomization. Information about essential medication use is in the Supplemental Material.

FOLLOW-UP AND STUDY OUTCOMES. During follow-up visits every 3 months, trained research staff collected study data from all the patients (**Table 1**). A clinical events committee adjudicated the clinical events that occurred during follow-up.

STAGE 1 OUTCOME MEASURES. The primary outcome measure for stage 1 was the proportion of patients who met all 3 criteria for the ABC pathway of

FIGURE 2 Medication Adjustment Protocol for Uncontrolled Blood Pressure



(A) Calcium channel blocker 1 tablet daily. (B) Angiotensin-converting enzyme inhibitor/angiotensin II receptor blocker 1 tablet daily. (C) Calcium channel blocker 2 tablets daily. (D) Thiazide-type diuretic 0.5 tablet daily. (E) No antihypertensive drugs.

integrated AF care at 12 months. The secondary outcome measures were the proportions of patients who met every individual criterion for the ABC pathway components at 12 months. The definitions of the A, B, and C criteria are in the Supplemental Material. Patients who met all 3 criteria were defined as ABC compliant.

STAGE 2 OUTCOME MEASURES. The stage 2 primary outcome measure was the composite of cardiovascular death, all strokes including ischemic stroke and hemorrhagic stroke, worsening of heart failure or acute coronary syndrome, and emergency visits due to AF over 36 months. Secondary outcome measures over 36 months included all-cause mortality, cardiovascular death, ischemic or hemorrhagic stroke, worsening of heart failure or acute coronary syndrome, emergency visits due to AF, major bleeding, clinically relevant nonmajor bleeding, and the proportion of patients who met all 3 criteria for the ABC pathway at 36 months. Definitions of the clinical outcomes are in the Supplemental Material.

SAMPLE SIZE AND POWER CALCULATIONS. The minimum sample size required in stage 2 of this study was substantially larger than that in stage 1. Therefore, the overall sample size was calculated for the primary outcome in stage 2 of this study. The overall minimum sample size was 962 participants (13 clusters in each group and 37 participants in each cluster). The sample size was determined using the following assumptions: the annual rate of the composite endpoint in the AF population aged >65 years in eastern rural China by usual care was 7.78%, which

TABLE 1 Schedule of Study Visits

Data Collection	BL	Follow-Up Visits, mo											
		3	6	9	12	15	18	21	24	27	30	33	36
Demographic information	X												
Lifestyle status	X	X	X	X	X	X	X	X	X	X	X	X	X
Medical history	X				X				X				X
Physical examination													
A	X				X				X				X
B	X	X	X	X	X	X	X	X	X	X	X	X	X
AF symptom assessment	X	X	X	X	X	X	X	X	X	X	X	X	X
Risk assessment	X				X				X				X
Concomitant medical therapy	X	X	X	X	X	X	X	X	X	X	X	X	X
12-lead electrocardiogram	X				X				X				X
Echocardiogram	X				X				X				X
Carotid ultrasound	X				X				X				X
ABI and PWV	X				X				X				X
Brain MRI	X				X				X				X
Biochemistry profile	X				X				X				X
CHA_2DS_2-VASc score	X				X				X				X
HAS-BLED score	X				X				X				X
MMSE	X				X				X				X
OAC adherence		X	X	X	X	X	X	X	X	X	X	X	X
Compliance of the ABC pathway components	X				X				X				X
Clinical events		X	X	X	X	X	X	X	X	X	X	X	X

Demographic information includes age, sex, education level, and marriage status. Lifestyle status includes smoking and alcohol drinking. Medical history includes heart failure, hypertension, diabetes mellitus, coronary artery disease (myocardial infarction, percutaneous coronary intervention, and coronary artery bypass graft surgery), peripheral artery disease, stroke, transient ischemic attack, systemic embolism, chronic obstructive pulmonary disease, chronic kidney disease, chronic liver disease, thyroid disease, and major bleeding event. Physical examination includes A, height, weight, and waist circumference; and B, blood pressure and heart rate. The European Heart Rhythm Association score of atrial fibrillation is used to assess cardiac function. Risk assessment tools used in this study includes the CHA_2DS_2-VASc score and the HAS-BLED score. Biochemistry profile includes fasting blood glucose, fasting cholesterol, fasting triglycerides, hemoglobin A1c, liver function, serum creatinine, complete blood count, and hemoglobin. Clinical events include all-cause death, thromboembolism, hemorrhage, worsening heart failure, acute coronary syndrome, and emergency visit due to AF occurring since last visit.

ABC = Atrial fibrillation Better Care; ABI = ankle-brachial index; ADL = activities of daily living; BL = baseline visit; MMSE = Mini-Mental State Examination; MRI = magnetic resonance imaging; OAC = oral anticoagulants; PWV = femoral-ankle pulse wave velocity.

was based on our previous unpublished observation of rural elderly in China. Our novel integrated care AF management model is projected to reduce this rate by 50% during an expected 3-year follow-up based on our theoretical framework, a superiority margin of 3%, an intracluster correlation of 0.01, possible loss to follow-up of10% of patients, a 1-sided significance level of 0.05, and a statistical power of 90%. The sample size was calculated using the procedure Superiority by a Margin Tests for the Difference of Two Proportions in a Cluster-Randomized Design with PASS, version 15.0.5.

STATISTICAL ANALYSIS. All statistical analyses will be performed using SAS version 9.4 based on the intention-to-treat principle. The study outcomes will be compared between participants according to the randomization assignment of their village clinics, regardless of whether participants adhered to the intervention.

In stage 1, the proportions of patients who meet all 3 criteria for the ABC pathway of integrated AF care at 12 months will be analyzed using a generalized estimating equation with exchangeable correlation structure. The model response of the generalized estimating equation model is a variable of 0 or 1 that indicates whether an individual meets the criteria, and the link function is specified as the Logit. The estimated intervention effect will be reported as net difference with 95% confidence intervals and *P* values between the intervention and control groups.

In stage 2, the cumulative event rates of the primary outcome will be tested using a clustered log-rank test. Marginal Cox proportional hazards model will be used to estimate the HRs and 95% CIs. Owing to inherent randomness, even with the same intervention, variations exist between different villages and among individuals within the same village. To account for this variability, we use random effects to characterize such randomness and fixed effects to delineate the impact of intervention. Therefore, this marginal Cox proportional hazards model will include fixed effects for the intervention and time, as well as random effects for clusters.

Secondary outcomes are analyzed using generalized estimating equation with exchangeable correlation structure.

SUBGROUP ANALYSIS. Subgroup analyses will be performed to examine whether the therapeutic effect remain consistent across all patients, or if it varies depending on some specific characteristics of patients. The prespecified subgroups of interest in this study include those defined by age strata, sex, educational level, newly detected or previously known AF, and CHA_2DS_2-VASc strata.

MISSING DATA AND SENSITIVITY ANALYSES. Missing efficacy data will be treated as missing at random, and multiple imputations will be conducted using the Markov chain Monte Carlo method with an arbitrary missing pattern. The findings from the primary analysis without imputation will be compared with those with imputation in the sensitivity analyses.

Covariables will not be adjusted in the primary analysis. In a sensitivity analysis, important unbalanced covariables between the 2 comparison groups will be adjusted. The results from primary and sensitivity analyses will be compared.

Information about trial organization and administration is in the Supplemental Material.

DISCUSSION. The MIRACLE-AF trial aims to test the efficacy of a telemedicine-based village doctor-led, multifaceted care model in enhancing clinical outcomes among elderly patients with AF living in rural areas. The impact of this novel model on the compliance of the ABC pathway of integrated AF care will also be examined, along with its impact on clinical outcomes (**Central Illustration**).

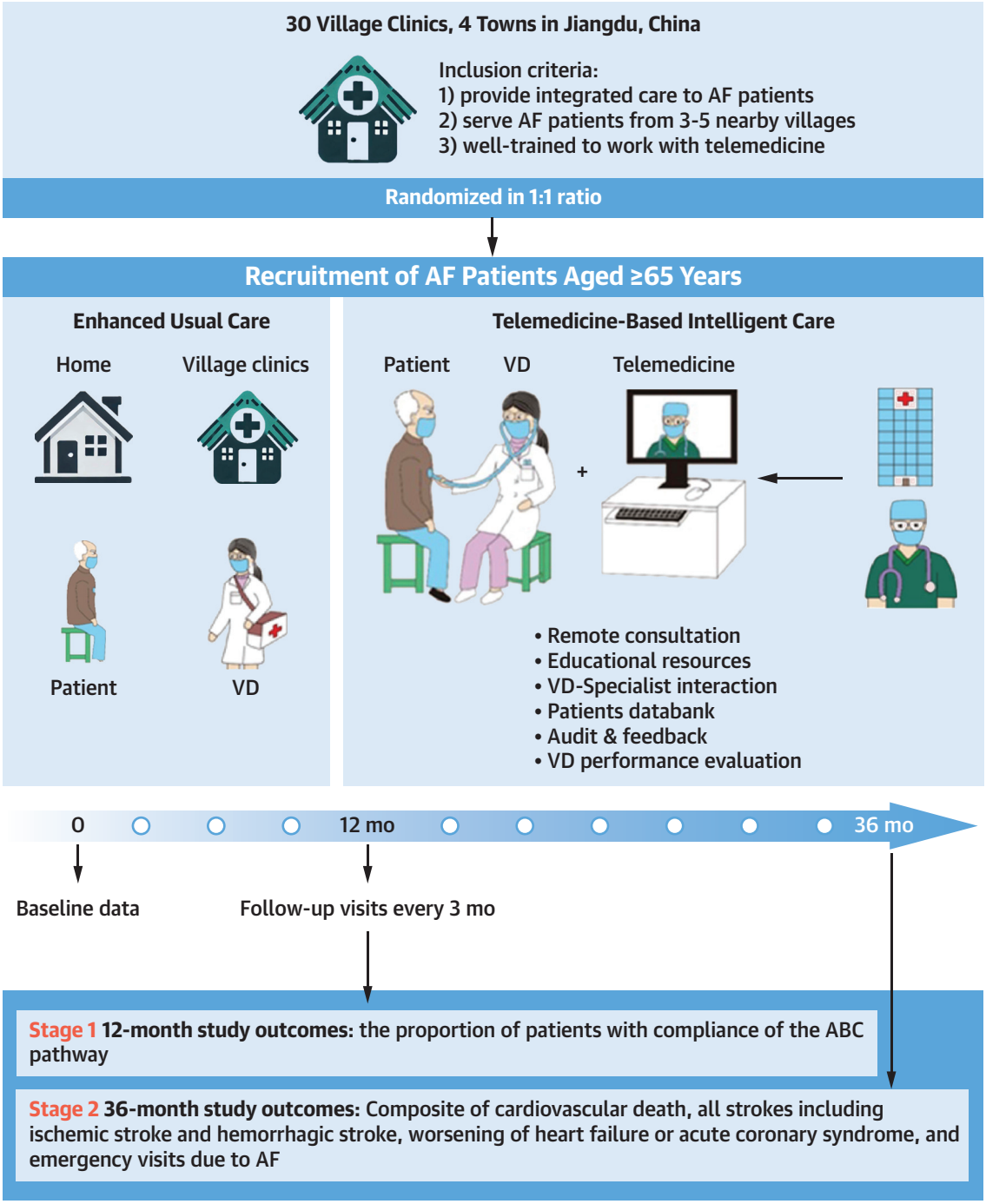
In recent years, the concept of integrated AF management has been more widely accepted. The evidence-based ABC pathway has been advocated as a simplified approach to implementing integrated care for patients with AF, according to current guidelines. Despite the increasing use of lower-cost generic non-vitamin K antagonist oral anticoagulants and new AF intervention technologies, such as cryoballoon ablation, pulsed field ablation, and left atrial appendage occlusion, the management of AF remains suboptimal, particularly among vulnerable populations, such as the rural elderly in China. Indeed, clinical complexity is evident among patients with AF and is closely related to suboptimal management. Even if evidence-based treatments such as OACs are started, there is a high rate of discontinuation.[6] Therefore, the implementation of integrated AF management in this high-risk AF population has become a critical issue.

Given that most young adults in rural China have migrated to urban areas in search of better job opportunities, it is unlikely for the rural elderly to rely on their adult children for care. In addition, it is also challenging for the rural elderly to access upper-tier hospitals without their accompanying children. Intensified health education has been shown to be beneficial in the management of AF.[28] However, the rural elderly may struggle to absorb new knowledge because of their low education level. The Huawei Heart Study and the mAFA II randomized trial have revealed that mobile health technology can support integrated AF management, reducing hospitalizations and clinical adverse events in patients with AF.[29,30] The mAFA app used in the MAFA trials is patient centered, and given that patient involvement is a key element, a highly intellectual and motivated population benefits the most. However, because only a few elderly people in rural areas know how to use smartphone apps, the feasibility and impact on clinical outcomes of the mAFA strategy may be low in these rural populations.

Village doctors are the most accessible medical resource for the rural elderly.[31] However, their ability to provide high-quality AF care is limited. Therefore, finding a solution to strengthen the delivery of primary care in rural settings is essential. The telemedicine platform we built in our MIRACLE-AF trial is village doctor centered. With the aid of this novel platform, we have established a collaborative network management model. Through this telemedicine system, medical experts can be invited by village doctors to check on patients online, eliminating the need for patients to travel long distances to larger hospitals alone, without the company of their family members. This approach also helps them save on travel expenses. Although this is a different type of interaction and a different dynamic, patients do not feel anxious or fearful when using the telemedicine platform with the assistance of their village doctors.

STUDY LIMITATIONS. We speculate that if the novel model in the MIRACLE-AF trial proves successful, this approach could be extended to the management of other cardiovascular diseases such as hypertension and myocardial infarction. Moreover, this approach could be easily scaled up to address health delivery problems in other countries, especially among rural communities. However, further external validation of the generalizability of MIRACLE-AF is warranted. In addition, the village doctors involved in the

CENTRAL ILLUSTRATION **Village Doctor-Led Telemedicine Integrated Care: The MIRACLE-AF Cluster Randomized Trial**



Li M, et al. JACC Asia. 2024;4(10):764–773.

The MIRACLE-AF (a novel Model of IntegRAted Care of oLdEr patients with Atrial Fibrillation in rural China) trial: a novel model of integrated care of older patients with atrial fibrillation in rural China. AF = atrial fibrillation; VD = village doctor.

MIRACLE-AF trial already possessed a fundamental understanding of telemedicine before their participation. Consequently, there is a need to explore solutions to empower village doctors who lack proficiency in using telemedicine.

CONCLUSIONS

In MIRACLE-AF, we hypothesized that this telemedicine-based, village doctor-led, multifaceted care model could empower village doctors to deliver integrated management to older patients with AF in rural areas. In this trial, we will therefore evaluate whether this novel model can effectively reduce the incidence rate of AF-related adverse events.

TRIAL STATUS

The recruitment of this study began on December 1, 2020, and ended on May 9, 2022. In total 1,039 participants were recruited: 524 from 15 village clinics in the telemedicine care arm and 515 from another 15 village clinics in the usual care arm. All the enrolled patients are under scheduled follow-up.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

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ADDRESS FOR CORRESPONDENCE: Dr Gregory Y. H. Lip, Liverpool Centre for Cardiovascular Science, University of Liverpool, Liverpool John Moores University and Liverpool Heart & Chest Hospital, 6 West Derby Street, William Henry Duncan Building, Liverpool L7 8TX, United Kingdom. E-mail: gregory.lip@liverpool.ac.uk. OR Dr Minglong Chen, Division of Cardiology, The First Affiliated Hospital of Nanjing Medical University, 300 Guangzhou Road, Nanjing 210029, China. E-mail: chenminglong@njmu.edu.cn.

PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: Outcomes of the MIRACLE-AF trial are poised to contribute valuable evidence for the effectiveness of a telemedicine-supported village doctor–led model in managing AF in resource-limited rural populations.

TRANSLATIONAL OUTLOOK: Future studies are needed to assess the generalizability of the telemedicine-based, village doctor–led integrated care model demonstrated in the MIRACLE-AF trial.

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KEY WORDS **atrial fibrillation, integrated management, older patients, rural area, telemedicine**

APPENDIX **For supplemental material, please see the online version of this paper.**