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ORIGINAL ARTICLE

Nurse-Led Multicomponent Behavioral Activation Intervention for Patients With Atrial Fibrillation: A Randomized Controlled Trial

Polly W.C. Li, PhD; Doris S.F. Yu, PhD; Bryan P. Yan, MD

BACKGROUND: Patients with atrial fibrillation (AF) are often ill-equipped for shared decision-making. This study investigated the effects of a patient empowerment care model on patient-reported health outcomes and treatment decision-making in patients with AF.

METHODS: This randomized controlled trial prospectively randomized patients with AF to receive standard care (n=194) or a 13-week nurse-led multicomponent behavioral activation intervention (n=198). The intervention consisted of risk profile assessments, empowered shared decision-making regarding the use of oral anticoagulants (OACs), empowered AF self-management, and increased access to professional advice. The primary outcome was health-related quality of life measured after the completion of the intervention (T1), while the secondary outcomes were patient-physician decision concordance regarding OAC use, actual OAC use, AF knowledge, medication adherence, anxiety, and depression.

RESULTS: The intervention group showed significantly greater improvements in health-related quality of life (β, −6.702 [95% CI, −9.556 to −3.847]; $P<0.001$), AF knowledge (β, −1.989 [95% CI, −2.342 to −1.635]; $P<0.001$), and medication adherence (β, 0.340 [95% CI, 0.148–0.532]; $P<0.001$) at immediate post-intervention compared with the control group, and the improvements were sustained at 6 months for all outcomes. A higher proportion of patients in the intervention group were prescribed an OAC compared with the control group at 6 months (odds ratio, 5.870 [95% CI, 1.957–12.331]; $P=0.012$). No significant between-group differences were detected for patient-physician decision concordance regarding OAC use, anxiety, or depression at both time points.

CONCLUSIONS: The nurse-led multicomponent behavioral activation intervention improved patient-reported outcomes and increased OAC prescription among patients with AF.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: atrial fibrillation ■ decision making ■ empowerment ■ nurse's role ■ patient participation ■ patient education ■ self-management ■ shared

See Editorial by Parkash

Substantial evidence-practice gaps exist in the management of atrial fibrillation (AF), including the under-prescription and nonadherence to oral anticoagulants (OACs), inadequate risk factor control, and limited self-management skills.[1–4] Existing models of care for patients with AF are strongly limited by treating patients as passive care recipients. Indeed, this approach is contradictory to the Innovative Care for Chronic Conditions framework proposed by the World Health Organization as a strategy for chronic disease management,[5] and the clinical guidelines that highly emphasize involving patients in a shared decision-making process

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WHAT IS KNOWN?

- The risks and complications associated with atrial fibrillation (AF) and its treatment can be minimized by effective pharmacological treatment and disease self-management.
- Patients are suggested to be involved in the shared decision-making process to determine the optimal management plan for AF.

WHAT THE STUDY ADDS

- The nurse-led multicomponent behavioral activation intervention is effective to improve health-related quality of life, knowledge of AF, and medication adherence in patients with AF.
- The nurse-led multicomponent behavioral activation intervention is effective to increase the number of patients with AF to be prescribed with an oral anticoagulant for stroke prevention.

Nonstandard Abbreviations and Acronyms

AF	atrial fibrillation
AFEQT	Atrial Fibrillation Effect on Quality-of-Life Questionnaire
CHA2DS2-VASc	Congestive Heart Failure, Hypertension, Aged ≥75 Years, Diabetes, Stroke, Vascular disease, Aged 65–74 Years, Sex Category
HRQoL	health-related quality of life
N-MBA	nurse-led multicomponent behavioral activation
OAC	oral anticoagulant

to determine their values and preferences for AF treatment.[6] The World Health Organization's framework highlights the importance of empowering patients to become active care agents.[5] To address the complex needs of patients with AF, the model of care must shift from a traditional paternalistic approach to a patient-participatory approach. As patients with AF are their own major caregivers, successful management relies heavily on their efforts to engage in day-to-day self-management actions. For instance, decisions regarding OAC use require individuals to analyze the values of potential outcomes in a process requiring self-determination. In such cases, the active engagement of patients with AF in various stages of disease management, from initial therapeutic planning to long-term self-management, is crucial to equipping and motivating patients to participate in disease self-management.

This study aimed to address the knowledge gaps by developing and evaluating the effects of a nurse-led multicomponent behavioral activation (N-MBA) intervention on health-related quality of life (HRQoL), decision concordance between patients and physicians regarding the use of OAC, actual use of OAC, AF knowledge, medication adherence, and psychological distress among patients with AF.

METHODS

Data Sharing

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Study Design

This multisite, parallel, 2-arm randomized clinical trial was conducted to compare the effects of the N-MBA intervention and standard care in a 1:1 ratio. The trial commenced after ethical approval was obtained from the study sites. We followed the ethical principles stated in the Declaration of Helsinki. All patients provided written informed consent. The trial was registered with www.ClincialTrials.gov (REGISTRATION: URL: https://www.clinicaltrials.gov; Unique identifier: NCT03924739) before the recruitment of first participant.

Study Settings and Population

Participants were recruited via AF screening with single-lead electrocardiography in the community and clinical settings. Screened positive cases were confirmed with a 12-lead electrocardiography. All patients meeting the following eligibility criteria were invited to join the study: (1) aged ≥60 years, (2) community-dwelling, (3) confirmed diagnosis of AF, (4) not using OAC therapy, and (5) a Congestive Heart Failure, Hypertension, Aged ≥75 Years, Diabetes, Stroke, Vascular Disease, Aged 65–74 Years, Sex Category (CHA_2DS_2-VASc) score of ≥1 in men and ≥2 in women. The CHA_2DS_2-VASc score is a risk prediction model to estimate patients' risk of stroke. Patients with impaired communication or cognition hindering participation in research activities were excluded. We also identified potential participants who were under the care of noncardiology specialty outpatient clinics of a public hospital in Hong Kong. Their electronic health records were screened to identify patients with documented AF who met the aforementioned criteria, were approached for further screening according to the eligibility criteria.

Randomization, Allocation Concealment, and Blinding

Block randomization with randomly varying block sizes of 8, 10, or 12 was used. The block size and study group allocation sequence were determined using a computer-generated sequence. Chronologically recruited patients were allocated to the study groups according to the computer-generated sequence by the research nurse. To ensure allocation concealment, sealed envelopes were used and opened by the participants. Given the explicit nature of the intervention, blinding of the participants and the nurses delivering the intervention was not possible, but the post-intervention data collector was blinded to the group allocation.

Study Interventions

Control Group: Standard Care

Upon randomizing to the control group, we provided a brief advice about the disease and encouraged the patients to discuss with their attending doctor for the AF treatment. Otherwise, participants in the control group received standard care provided by the health care system, which did not include any structured education regarding AF, but with occasional and unstructured information provided by the health care providers.

Intervention Group: N-MBA Intervention

On top of the standard care, participants in the intervention group received the N-MBA intervention. A full description of the N-MBA intervention has been published.[7] In brief, it consisted of 4 components: a risk profile assessment and empowered shared decision-making regarding OAC use, patient empowerment on AF self-management, and increased access to professional advice.

The risk assessments and empowered shared decision-making sessions were arranged 1–2 weeks before the participants' medical consultations. This component aimed to increase participants' awareness of their increased stroke risk with and without the use of OACs and of their bleeding risk if they used OACs, and empower them to engage proactively in the treatment planning for OAC use. First, the risk estimation for stroke was based on the CHA_2DS_2-VASc score, and the bleeding risk was determined by the Hypertension, Abnormal Liver or Renal Function, Stroke, Bleeding, Labile International Normalized Ratio, Elderly (Aged >65 Years), Drugs or Alcohol score to calculate the risk of major bleeding for patients with AF receiving OAC therapy. A decision aid booklet was provided to facilitate the patients in understanding their risks, the pros and cons of different OACs. To empower their proactive engagement in the treatment planning for OACs during the medical consultation, interactive training on how to communicate assertively with the physicians about their concerns and preferences regarding AF treatment was provided. The skills included asking questions, expressing concerns, and stating opinions and preferences regarding AF management.

Then, a 5-week patient empowerment module was offered, which comprised weekly active learning sessions on major topics related to AF self-management: (1) medication management, (2) symptom monitoring, (3) crisis management, (4) activities and exercise, and (5) risk factor management. The empowerment educational approach was adopted, as it emphasizes the use of interactive teaching strategies, experiential learning, and self-reflection during the educational process.[8] First, the nurse delivered a structured educational session about the topic of the week, then encouraged patients to share their self-management practices and facilitated them in identifying discrepancies between their own self-management and the guideline-based recommendations. The nurse then highlighted the possible health consequences of these discrepancies to motivate the patients to set self-directed goals. A subsequent interactive skill-building session was conducted to ensure that patients had acquired the skills for self-monitoring heart rhythm and lifestyle modification. The nurse discussed the patients' performances, provided feedback, and worked with the patients to mutually develop action plans for achieving goals.

Upon completion of the patient empowerment module, the nurse provided regular telephone calls (4× over 6 weeks) to monitor patients' goal attainment, adherence to suggested self-management actions, treatment efficacy in symptom control, and adverse effects. Further health counseling was provided to resolve any barriers to self-management.

The participants were provided with telephone access to the nurse for inquiries regarding AF management. The participants in the control group were given brief information about AF and advised to discuss the treatment with a doctor during a face-to-face encounter. Beyond this, they received standard care provided by their health care providers.

Outcome Measures

All outcomes were measured at 3 time points: baseline (T0), immediately after the completion of the intervention (T1), and 6 months thereafter (T2), except for the decision concordance between patients and physicians regarding the use of OACs and the actual prescription of OACs, which were measured at T2. We have chosen HRQoL at T1 as the primary outcome, as this patient-reported outcome could best capture the effect of the intervention, which emphasized on valued-based health care and shared decision-making.[9] The disease-specific HRQoL was measured using the Atrial Fibrillation Effect on Quality-of-Life Questionnaire (AFEQT),[10] the only recommended patient-reported outcome measure for patients with arrythmias.[9] AFEQT consists of 20 items and 4 subscales, including patients' symptoms, daily activities, treatment concerns, and treatment satisfaction. Each item is rated on a 7-point Likert scale, ranging from the most severe symptom/limitation to no symptom/limitation. The calculation of the overall and subscale scores was transformed to a 0 to 100 scale, based on actual responses and adjusting for the missing responses. A higher score represents better health status. Excellent reliability (Cronbach α=0.94; intraclass correlation coefficients=0.68–0.92) and concurrent validity have been reported.[10]

The key secondary outcomes were decision concordance between patients and physicians regarding the use of OACs and the actual prescription of OACs. We asked the patients to indicate their intention to use and their preferences regarding OACs upon the completion of the empowered shared decision-making session. After their medical appointments, they were contacted by telephone and asked whether they had discussed their concerns about AF and OAC use with their doctors. Prescriptions for OACs were monitored by checking with the patients and confirmed by reviewing their electronic medical records to determine the concordance between the patients' and physicians' decisions regarding OAC treatment options at T2.

Other secondary outcomes included AF knowledge, medication adherence, anxiety and depression. The 11-item Atrial Fibrillation Knowledge Scale was used to measure patients' knowledge about AF in general, symptom recognition, and treatment. Patients respond by choosing 1 of 3 options as the answer. One point was given for the correct answer, no point is deducted for incorrect ones. A total score was calculated by summing the correct items, a higher score represents better knowledge about AF. Sufficient psychometric properties have been reported.[11] The 4-item Morisky-Green-Levine Adherence Scale was used to measure medication adherence.[12] Patients self-reported on a dichotomous scale (yes or no) on 4

medication-taking misbehaviors. The sum of items rated as yes yield a total score. A higher score indicates greater medication nonadherence. Good reliability, concurrent and predictive validity have been reported.[13] The Hospital Anxiety and Depression Scale was used to measure psychological distress. Hospital Anxiety and Depression Scale consists of 14 items to evaluate anxiety and depression. All items are rated on a 4-point Likert scale, with higher scores indicate more anxious and depressed. Good internal consistency (Cronbach α=0.86) and satisfactory factorial, concurrent, and criterion validity have been reported.[14]

Sample Size

Similar interventional studies targeting patients with other chronic conditions showed the effect sizes of the empowerment interventions on HRQoL ranged from 0.09 to 1.17,[15–17] depending on the HRQoL domains. Based on these findings, this study aimed to yield adequate power for the detection of at least a small to medium effect size[18] on the primary outcome. We assumed a 10% dropout rate; 392 participants were needed to yield 80% power at a 5% significance level for the detection of an effect size as small as 0.3 on our primary outcome when comparing the 2 study groups at the postintervention time points.

Statistical Analyses

Data were analyzed on an intention-to-treat basis. Study group homogeneity at baseline was determined by performing χ^2 tests or independent *t* tests to compare the patients' characteristics and outcome measures at baseline. Generalized estimating equation modeling was used to compare the differential changes between the study groups and across the study time points for the following continuous outcome variables: HRQoL, AF knowledge, medication adherence, anxiety, and depression. Time points and group status were included as interaction terms. Generalized estimating equation modeling can account for intracorrelated repeated measures data and accommodate missing data caused by incomplete visits or dropout, provided that the data are missed at random, and thus are particularly suitable for intention-to-treat analysis without the need of imputation for missing data. Little's Missing Completely at Random test was performed to check the nature of data missingness. The between-group mean differences in the changes of scores in terms of Hedges' *g* from baseline to each time point were calculated to indicate the effect sizes. Hedges' *g* values of 0.15, 0.40, and 0.75 corresponded to small, medium, and large effects, respectively.[19] Logistic regression models with generalized estimating equation modeling were used to examine the effects of the intervention on the binary outcomes,[20] including the decision concordance between patients and physicians regarding OAC use and the actual use of OACs at T2. The following factors were adjusted as a priori confounders in the analysis: educational level, newly diagnosed or established AF, CHA_2DS_2-VASc score, and Hypertension, Abnormal Liver or Renal Function, Stroke, Bleeding, Labile International Normalized Ratio, Elderly (Aged >65 Years), Drugs or Alcohol score at baseline. IBM SPSS (version 28) was used for data analysis. The significance level was set at 0.05, and all of the statistical tests were 2-sided.

RESULTS

Patient Characteristics

The study was conducted from July 2019 to December 2022. Of the 5341 individuals who underwent eligibility evaluation, 4949 were excluded. The primary reason was that they did not have AF. Among those with confirmed AF (n=529), reasons for exclusion from the study were having a low CHA_2DS_2-VASc score, being younger than 60 years, and having cognitive impairment. Fifty-eight patients (11.0%) met the eligibility criteria but declined to join, mostly because of scheduling, willingness, or being physically unfit to travel. The remaining 392 participants were randomized into the intervention (n=198) or control group (n=194). The CONSORT flowchart is shown in Figure 1. The attrition rates immediately after the completion of the intervention (T1) and at the 6-month follow-up (T2) were 11.7% and 14.3%, respectively. The baseline characteristics in terms of sociodemographic and clinical factors and outcome variables were comparable between the participants who retained in the study and those who were lost to follow-up, implying the attrition bias is minimal. All of the participants were included in the analysis based on the intention-to-treat principle. The adherence rate for the intervention sessions was 89%.

The mean age of the participants was 71.2 years (SD, 5.4 years). Over half of the participants were identified from community screening (61.0%), and the rest were identified from screening the electronic health records in noncardiac specialty clinics. The majority of the participants (88.3%) had a CHA_2DS_2-VASc score ≥2 for male patients and ≥3 for female patients, indicating a high risk of stroke. The sample characteristics are presented in Table 1. There were no significant between-group differences in any of the sociodemographic and clinical characteristics at baseline (Table 1).

Primary Outcome

Table 2 and Figure 2 present the findings on primary and secondary outcomes. Little's Missing Completely at Random test showed a nonsignificant result, indicating the data were missing at random. The intervention group showed significantly greater improvements in AF-specific HRQoL measured using the AFEQT compared with the control group at T1 (β, −6.702 [95% CI, −9.556 to −3.847]; P<0.001), and this positive effect was sustained at T2 (β, −5.593 [95% CI, −8.491 to −2.695]; P<0.001). The Hedges' *g* values at T1 and T2 were 0.346 and 0.281, respectively, indicating small effect sizes (Figure 2; Table 2). Table 3 illustrates the changes in AFEQT global and domain scores at T1 and T2 from baseline. The major contribution to the significant improvements in the AFEQT global score at both time points were due to the improvements in the daily activity and treatment concerns domains, rather than the symptom domain.

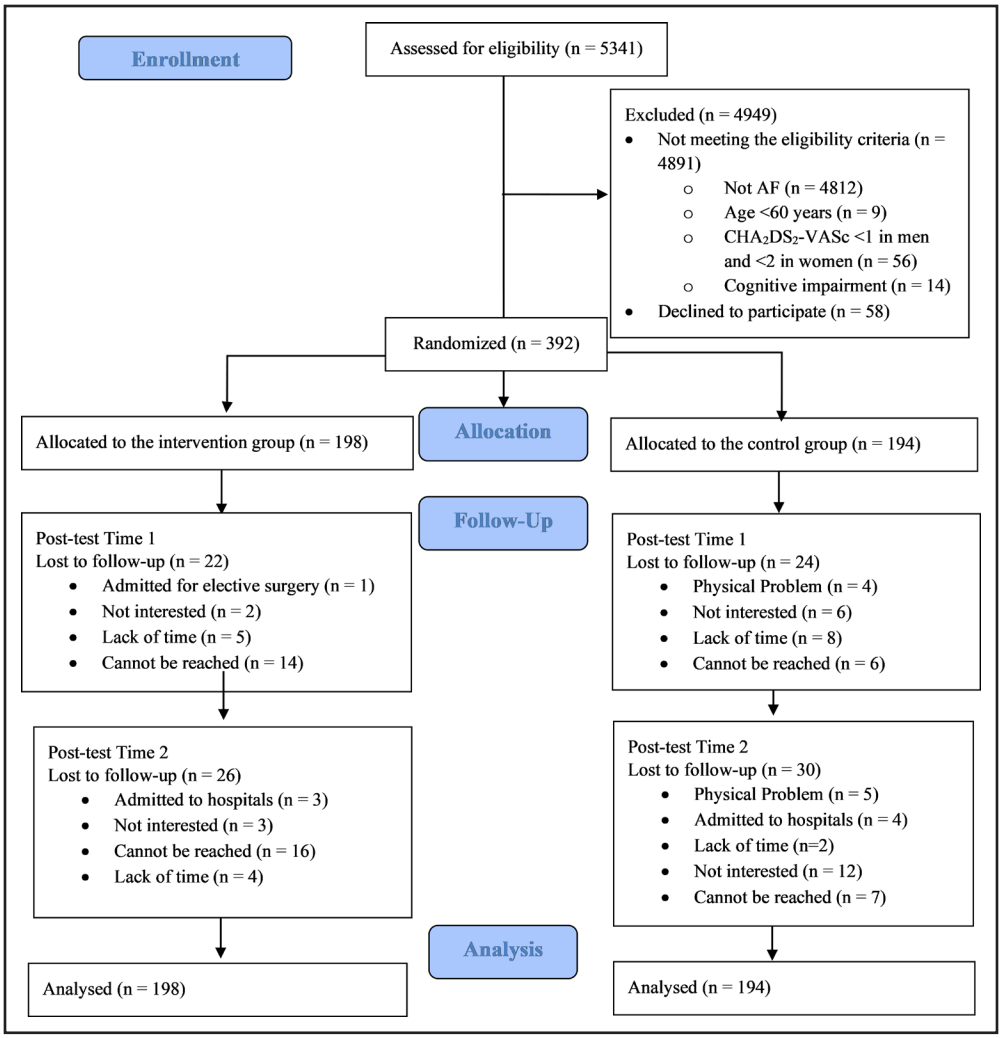

Figure 1. The CONSORT flowchart.
AF, atrial fibrillation; CHA2DS2-VASc, Congestive heart failure, Hypertension, Age ≥ 75, Diabetes, Stroke, Vascular disease, Age 65–74, Sex category score.

Secondary Outcomes

No significant between-group differences were found for decision concordance between patients and physicians regarding the use of OAC (Table 4). A higher proportion of participants in the intervention group were prescribed an OAC (odds ratio, 5.870 [95% CI, 1.957–12.331]; *P*=0.012) and self-reported adherence to OAC (odds ratio, 5.224 [95% CI, 1.013–9.882]; *P*=0.015) compared with those in the control group at T2 (Table 4).

Compared with the control group, the intervention group showed a statistically significant improvement in AF knowledge from T0 to T1 (β, −1.989 [95% CI, −2.342 to −1.635], *P*<0.001; Hedges' *g*=1.211), and T2 (β, −1.783 [95% CI, −2.123 to −1.443], *P*<0.001; Hedges' *g*=1.126) with large effect sizes. The intervention group demonstrated significantly better medication adherence than the control group at T1 (β, 0.340 [95% CI, 0.148–0.532]; *P*<0.001) and T2 (β, 0.265 [95% CI, 0.081–0.449]; *P*=0.005), with small effect sizes at both time points (Hedges' *g*=−0.228 and −0.151, respectively). No significant between-group differences were found in anxiety and depression at T1 or T2 (Figure 2; Table 2).

Sensitivity Analysis

A sensitivity analysis was conducted by including participants with a CHA_2DS_2-VASc score ≥2 for male patients and ≥3 for female patients, as the clinical guidelines suggest OAC as a Class 1A recommendation for these patients.[6] The analyses indicated consistent results with the main analyses for all primary and secondary outcomes (Table S1; Supplemental Material).

DISCUSSION

This trial attempted to improve patient-reported outcomes through enabling their self-management and engagement in the decision-making for OAC use during medical consultations. The most unique finding was that

Table 1. Participant Characteristics at Baseline

Characteristics	Total sample, n (%; n=392)	Intervention group, n (%; n=198)	Control group, n (%; *n*=194)
Age, y; mean (SD)	71.18 (5.44)	70.88 (5.13)	72.84 (5.15)
Sex			
Men	268 (68.4)	129 (65.2)	139 (71.6)
Women	124 (31.6)	69 (34.8)	55 (28.4)
Education*			
Nil/primary	92 (23.5)	42 (21.2)	50 (25.8)
Secondary 1–3	137 (34.9)	76 (38.4)	61 (31.4)
Secondary 4–7	119 (30.4)	63 (31.8)	56 (28.9)
≥ Tertiary	44 (11.2)	17 (8.6)	27 (13.9)
Occupation			
Unemployed/Retired/Housewife	380 (96.9)	191 (96.5)	189 (97.4)
Employed	12 (3.1)	7 (3.5)	5 (2.6)
Monthly income†			
HKD <$5000	232 (59.2)	119 (60.1)	113 (58.2)
HKD $5000–$10 000	89 (22.7)	43 (21.7)	46 (23.7)
HKD $10 001–$20 000	23 (5.9)	14 (7.1)	9 (4.6)
HKD >$20 001	48 (12.2)	22 (11.1)	26 (13.4)
Clinical characteristics			
Body mass index, mean (SD)	24.56 (4.38)	24.42 (4.32)	24.94 (4.66)
Smoking status			
Current smoker	16 (5.0)	9 (4.5)	7 (3.6)
Ex-smoker	63 (25.0)	36 (18.2)	27 (13.9)
Nonsmoker	319 (70.0)	153 (77.3)	160 (82.5)
CHA_2DS_2-VASc score, mean (SD)	3.40 (1.63)	3.09 (1.64)	3.45 (1.61)
1 (male patients only)	39 (9.9)	23 (11.6)	16 (8.2)
2	21 (5.4)	13 (6.6)	8 (4.1)
3	251 (64.0)	117 (59.1)	134 (69.1)
4	67 (17.1)	36 (18.2)	31 (16.0)
≥5	14 (3.6)	9 (4.5)	5 (2.6)
HAS-BLED score	2.18 (0.96)	2.15 (.97)	2.25 (0.97)
<3	290 (74.0)	157 (79.3)	133 (68.6)
≥3	102 (26.0)	41 (20.7)	61 (31.4)
Medical history			
Hypertension	276 (70.4)	151 (76.3)	125 (64.4)
Diabetes	98 (25.0)	41 (20.7)	57 (29.4)
Coronary artery disease	165 (42.1)	89 (44.9)	76 (39.2)
Heart failure	14 (3.6)	5 (2.5)	9 (4.6)
Stroke or transient ischemic attack	9 (2.3)	4 (2.0)	5 (2.6)
Peripheral artery disease	28 (7.1)	12 (6.1)	16 (8.2)

Remarks: absolute values do not always match the group total because of missing data at baseline. CHA_2DS_2-VASc indicates Congestive Heart Failure, Hypertension, Aged ≥75 y, Diabetes, Stroke, Vascular Disease, Aged 65–74 y, Sex Category; and HAS-BLED, Hypertension, Abnormal Liver or Renal Function, Stroke, Bleeding, Labile International Normalized Ratio, Elderly (Aged >65 y), Drugs or Alcohol.

*Education: primary level corresponds to elementary school; Secondary 1–3 corresponds to middle school; Secondary 4–7 correspond to high school; Tertiary correspond to university level of education.

†1 US dollar=$7.8 HK dollars.

a comprehensive intervention which focused on empowering patients' proactive engagement in decision-making and communication on OAC use with physicians and optimizing AF self-management, resulted in improved HRQoL, increased prescription of OAC, improved medication adherence, and self-management knowledge in patients with AF.

Although the concordance between patients' and physicians' decision regarding OAC use was comparable between the study groups, the increased prescription of

Table 2. Main Results on Primary and Secondary Outcomes (n=392)

Outcomes	Time point	Intervention group (n=198)	Control group (n=194)	Time×group interaction effect		Treatment effect	
		Mean (SD)	Mean (SD)	β (95% CI)	*P*	Between-group mean difference in change (95% CI)	Effect size (Hedges' *g*)
AFEQT	Baseline	64.96 (18.56)	65.73 (18.61)	…	…	…	…
	T1	73.57 (16.10)	68.03 (15.88)	−6.702 (−9.556 to −3.847)	<0.001	5.54 (2.34 to 8.74)	0.346
	T2	73.68 (14.79)	69.06 (17.79)	−5.593 (−8.491 to −2.695)	<0.001	4.62 (1.32 to 7.93)	0.281
AFKS	Baseline	6.45 (1.69)	6.22 (1.67)	…	…	…	…
	T1	7.99 (1.68)	5.78 (1.97)	−1.989 (−2.342 to −1.635)	<0.001	2.22 (1.85 to 2.58)	1.211
	T2	7.73 (1.67)	5.72 (1.89)	−1.783 (−2.123 to −1.443)	<0.001	2.01 (1.66 to 2.37)	1.126
MGLS	Baseline	3.15 (0.86)	3.02 (0.86)	…	…	…	…
	T1	2.98 (0.89)	3.18 (0.83)	0.340 (0.148 to 0.532)	<0.001	−0.20 (−0.37 to −0.02)	−0.228
	T2	3.05 (0.82)	3.18 (0.88)	0.265 (0.081 to 0.449)	0.005	−0.13 (−0.30 to −0.04)	−0.151
HADS anxiety	Baseline	5.09 (4.54)	5.13 (3.30)	…	…	…	…
	T1	5.51 (3.48)	5.41 (3.21)	−0.136 (−0.760 to 0.488)	0.670	0.09 (−0.57 to 0.76)	0.028
	T2	5.35 (3.07)	5.23 (2.88)	−0.165 (−0.703 to 0.373)	0.548	0.12 (−0.47 to 0.71)	0.041
HADS depression	Baseline	5.41 (3.63)	5.60 (2.97)	…	…	…	…
	T1	5.65 (3.29)	5.78 (3.43)	−0.057 (−0.774 to 0.660)	0.876	−0.13 (−0.80 to 0.54)	−0.039
	T2	5.01 (1.70)	5.23 (2.05)	0.028 (−0.440 to 0.496)	0.908	−0.22 (−0.66 to 0.23)	−0.097

Measurement: AFEQT covers patients' symptoms, daily activities, treatment concerns, and treatment satisfaction. The total score was transformed to a 0–100 scale and adjusted for missing responses. A higher score represents better health status. AFKS consists of 11 items measuring patients' knowledge of AF. The total score is calculated by summing the correct items, and a higher score indicates better knowledge of AF; MGLS consists of 4 items measuring medication adherence. Patients self-reported on 4 medication-taking misbehaviors on a dichotomous scale (yes or no). The sum of items rated yes yield the total score. A higher score indicates greater medication nonadherence; HADS measure psychological distress, including 7 items measuring anxiety and 7 items measuring depression. Higher scores indicate greater anxiety and depression. AFEQT indicates Atrial Fibrillation Effect on Quality-of-Life Questionnaire; AFKS, Atrial Fibrillation Knowledge Scale; HADS, Hospital Anxiety and Depression Scale; MGLA, Morisky-Green-Levine Adherence Scale; N-MBA, Nurse-led Multicomponent Behavioral Activation; T1, time point 1 (immediate post-intervention); and T2, time point 2 (6 mo post-intervention).

OAC among the N-MBA intervention group attracted attention. This finding may imply that patients' proactive communication of their guided decision-making on OAC use plays an important role to optimize its use in AF management. This reinforces that physicians' overemphasis of the hesitance of patients to receive OAC because of its side effects explain their suboptimal compliance to the guidelines to prescribe this drug.[21] Achieving this breakthrough in increasing OAC prescription requires effective aids to guide patients' decision-making on this therapy. However, 2 recent systematic reviews indicated that the sole use of such aids could only improve patients' knowledge and reduce decisional conflicts, but less promising in optimizing OAC prescription.[22,23] Our study showed that preparing patients to take an active role in communicating their decision to their physicians was a crucial step to enact the patient-centered care. More specifically, the participants were drilled in assertive communication skills using a scenario-based approach and role-play to facilitate skill consolidation. Such skills are essential, particularly in a paternalistic health care system in which the power dynamic of the physician-patient relationship often makes patients reluctant to raise their concerns and discuss their preferences with doctors.[24] The comparably high concordance between patients' and physicians' decisions regarding OAC use in both study groups is probably also due to the power dynamics of the physician-patient relationship, as patients tend to think that doctors will make the best decision for them. Nevertheless, the interactions between patients and physicians during the consultations were not directly observed in our study, and we were unable to ascertain whether the N-MBA intervention could enhance patients' involvement in the shared decision-making process.

Patient-reported outcomes are considered an essential metric to inform AF management.[25] The recent clinical management guidelines specified HRQoL as an important patient-reported metric to capture the impacts of disease and treatment on the AF population.[26] As compared with previous studies which used integrated care models to enhance this patient-reported outcome,[27,28] the N-MBA intervention used in our study demonstrate significant and sustainable benefits, with the change in AFEQT score at T1 greater than the minimum clinically important difference (ie, ±5 points).[29] Two major reasons may explain the difference, including the empowerment strategies and risk profile of the patients. First, empowerment is a patient-centered philosophy of care in which interactive teaching strategies and experiential learning are used to strengthen patients' inherent capacities to gain control over their decision-making and behaviors regarding their health problems.[30] We enabled patients

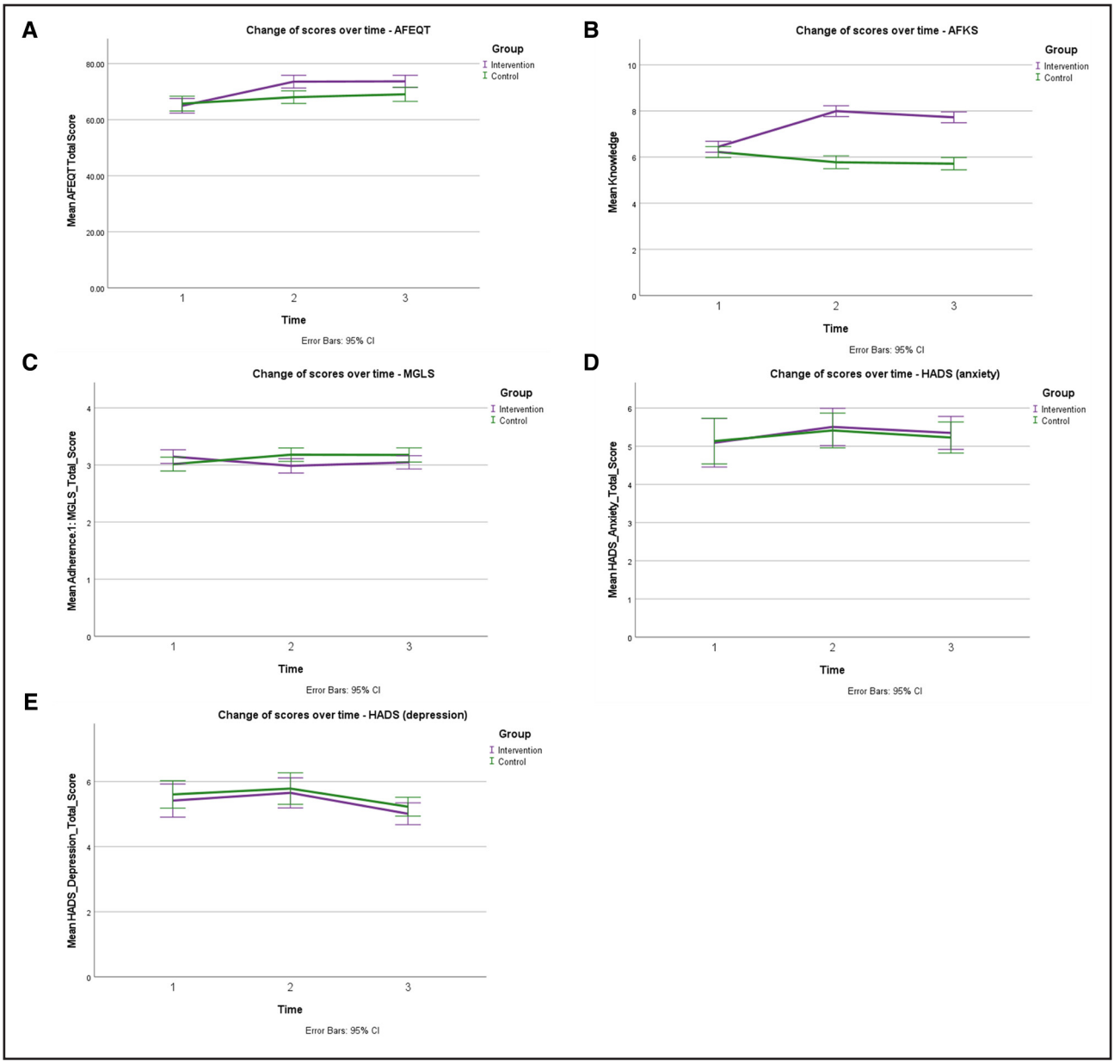

Figure 2. Changes in primary and secondary outcomes over time.
A, Health-related quality of life measured by the Atrial Fibrillation Effect on Quality-of-Life Questionnaire (AFEQT); **B**, Atrial fibrillation knowledge measured by the Atrial Fibrillation Knowledge Scale; **C**, Medication adherence measured by the Morisky-Green-Levine Adherence Scale (MGLS); **D** and **E**, Anxiety and depression measured by the Hospital Anxiety and Depression Scale (HADS). AFKS indicates Atrial Fibrillation Knowledge Scale.

by using a decision aid and training them in assertive communication and self-management skills using a scenario-based approach, which increased their sense of control and thus positively affected their HRQoL.[31] The empowerment model has been successfully used to improve patient outcomes in other populations.[32] Its success is further supported by our findings in this study that the N-MBA intervention significantly improved patients' knowledge of AF with large effect sizes. Second, the design of our study to target patients with AF with high risk of stroke might also explain our greater intervention effect. The participants in previous studies reported only a slightly suboptimal HRQoL at baseline, as compared with the norm value.[27,28] A significant proportion of their samples (43% and 56%)[27,28] had a lower risk of stroke (ie, CHA_2DS_2-VASc score ≤1) which were not indicated for any stroke prevention treatment. Our study targeted high-risk patients, and nearly 90% of our participants had a high risk of stroke as evidenced by a CHA_2DS_2-VASc score ≥2 for male patients and ≥3 for female patients. The CHA_2DS_2-VASc score also reflects patients' comorbidities, which are a predictor of poor HRQoL in the AF patient population.[33] Nevertheless, only a small effect size was detected for our intervention, implying an uncertain

Table 3. Baseline and Follow-Up Changes in AFEQT Global and Domain Scores

	Intervention group (*n*=198)					Control group (*n*=194)				
	Baseline mean (SD)	T1 mean (SD)	T2 mean (SD)	Change at T1 from baseline	Change at T2 from baseline	Baseline mean (SD)	T1 mean (SD)	T2 mean (SD)	Change at T1 from baseline	Change at T2 from baseline
AFEQT global score	65.0 (18.6)	73.6 (16.1)	73.7 (14.8)	8.6 (12.6)	8.7 (13.6)	65.7 (18.6)	68.0 (15.9)	69.1 (17.8)	2.3 (7.1)	3.4 (6.2)
AFEQT domains										
Symptom	80.4 (19.8)	82.7 (21.6)	83.3 (19.2)	2.3 (7.0)	2.9 (7.2)	78.4 (16.2)	79.8 (17.1)	80.3 (21.4)	1.4 (9.1)	1.9 (9.3)
Daily activity	71.9 (13.3)	78.5 (16.3)	76.4 (11.8)	6.6 (12.7)	4.5 (8.4)	73.4 (14.7)	74.5 (18.9)	78.3 (20.1)	1.1 (7.2)	4.9 (8.8)
Treatment concern	42.7 (9.0)	59.6 (12.6)	61.4 (9.8)	16.9 (13.6)	18.7 (11.2)	45.3 (9.8)	49.7 (12.1)	48.7 (11.9)	4.4 (8.9)	3.4 (7.5)
Treatment satisfaction	50.2 (10.1)	67.7 (9.8)	63.4 (14.2)	17.5 (13.1)	13.2 (11.9)	52.9 (13.3)	54.1 (16.3)	51.3 (12.9)	1.2 (7.2)	−1.6 (8.2)

Remarks: AFEQT global score includes symptoms, daily activities, and treatment concern domains only. AFEQT indicates Atrial Fibbrilation Effect on Quality of Life questionnaire.

clinical significance. Our sample mainly consisted of patients identified from AF screening conducted in the clinical and community setting, and they were asymptomatic or with mild AF symptoms only. Future studies are warranted to evaluate the clinical benefits of this intervention among the symptomatic population with AF.

The N-MBA intervention had no significant effects on patients' anxiety and depression levels, probably because of the low levels of anxiety and depression at baseline in our community sample with AF. Indeed, this result could be considered favorable, as the intervention did not increase patients' psychological distress when they were exposed to information about AF and its potential health risks. Psychological distress in patients with AF is associated with poorer HRQoL and greater perceived symptom severity and AF recurrence,[34] and it has negative impacts on patients' self-management behaviors.[35] Future studies are thus encouraged to address such patient needs.

The dropout rates at both timepoints (11.7% and 14.3% at T1 and T2, respectively) were higher than expected (10%). The implementation of this study was negatively influenced by the COVID-19 pandemic, which jeopardized patients' willingness to engage in this study. Because this historical hallmark event influenced participants in both study groups, and the fact that there were no significant differences in terms of the baseline characteristics of participants who retained in the study and those who withdrew, we believed the attrition bias was limited.

It is noteworthy that nearly two-thirds of the participants were recruited through community screening, and most of them were asymptomatic. Consequently, the types of patients included in this study differed from those under the care of cardiologists in a hospital setting. Therefore, the study findings are more generalizable to the patient cohort encountered in a primary care setting.

Limitations

This study has several limitations. First, we used convenience sampling to recruit participants in the community and clinical settings. Older adults who were more active and socially engaged were more likely to be recruited, which limits the generalizability of the study findings to more isolated older adults. Second, because of the explicit nature of the intervention, study participants could not be blinded, which might have led to more favorable participant-reported health outcomes. Third, we tested the effects of a multicomponent intervention, and such a complex intervention design did not permit us to evaluate which components worked or did not work in a two-arm

Table 4. Between-Group Differences on Decision Concordance, Prescription of and Adherence to OAC at T2

	Intervention group	Control group	Multivariate analysis	
Outcomes	Number (%)	Number (%)	Adjusted OR (95% CI)	*P*
Decision concordance	114 (57.6)	102 (52.6)	0.943 (−1.453 to 7.342)	0.431
Prescription of OAC	72 (36.4)	19 (9.8)	5.870 (1.957 to 12.331)	0.012
Adherence to OAC	69 (34.8)	16 (8.2)	5.224 (1.013 to 9.882)	0.015

Remark: age, sex, education level, diagnosis of AF (newly or established AF diagnosis, CHA_2DS_2-VASc score and HAS-BLED score were adjusted in the multivariate analysis.

AF, atrial fibrillation; OAC, oral anticoagulant; CHA2DS2-VASc, congestive heart failure, hypertension, age 75 years and older, diabetes, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, and sex category; HAS-BLED, hypertension, abnormal kidney and liver function, stroke, bleeding, labile international normalized ratio, elderly, and drugs or alcohol; OR, odds ratio.

randomized clinical trial. A future factorial randomization trial would be able to elucidate this. Fourth, because of practical limitations, we did not directly observe the encounters between patients and physicians. The lack of this process data rendered us unable to ascertain how the intervention activated patients' behaviors. Fifth, we did not consider the minimum clinically meaningful difference for the change in primary outcome for calculating the required sample size, which might result in inadequate power. Nevertheless, the change in the primary outcome of our study had reached the clinically important changes in patients' health reported in the population with AF.[29] Finally, limited funding precluded us from examining the intervention effects on longer-term outcomes, such as OAC persistence, hospital service utilization, AF-related and treatment-related complications, and mortality.

Conclusions

An empowerment-based multicomponent intervention to optimize the use of OAC and improve AF self-management in patients with AF resulted in significant improvements in their HRQoL, use of OAC, AF knowledge, and medication adherence. This intervention has the potential to improve the health outcomes for patients with AF around the world.

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None.

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