Title: Efficacy of a Health Belief Model Based Intervention for Anticoagulation Adherence

NCT number : NCT03864900

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Study Protocol

BACKGROUND: Inconsistent anticoagulation therapy in AF patients is associated with a higher risk of stroke and abnormal bleeding. However, control of oral anticoagulation therapy in AF patients has been frequently reported as inadequate. Few theoretical based interventions have been tested for enhancing medication adherence in this population. Previous studies showed that the health belief model may offer some advantage over other behavior change theories for enhancing medication adherence in adult with chronic conditions.

PURPOSE: The purpose of the study is to investigate the efficacy of a health belief model based self-management of oral anticoagulant therapy intervention on the outcome of medication adherence and the mediators of knowledge, professional support, health belief, and self-efficacy in patients treated with oral anticoagulants for atrial fibrillation.

METHODS: The study is a randomized clinical trial with repeated measurements. A convenient sample of 72 adults who were treated with anticoagulants for atrial fibrillation was recruited from two teaching hospitals in northern Taiwan. Participants were randomly assigned 1:1 to either the control group (n = 36) or the intervention group (n = 36) after completion of baseline questionnaires. Allocation was balanced by site by using a minimization method. The health belief model based self-management intervention comprised two main components: a 60-minute individual face-to-face instruction and six follow-up telephone calls. Participants in the control group received regular medication education, 10-minute individual instruction for health knowledge and six follow-up telephone calls for concerning health. Data were collected at baseline, third month, and sixth month in both groups, by using self-administered questionnaires. The investigator administered the study questionnaire after obtaining informed consent from each subject. The data collection took place at the waiting areas outside the outpatient clinics during the patients' visits to the clinics. For subjects who were unable to read the questionnaire due to vision or other problems, the investigator read each question to help them complete the questionnaire. The instruments include the Atrial Fibrillation Knowledge Scale, Satisfaction Scale about Service and Warfarin Treatment, Belief about Anticoagulation Survey, and Self-Efficacy for Appropriate Medication Use Scale.

DATA ANALYSIS: Data were analyzed using the Statistical Package for Social Sciences 20.0 (SPSS, Inc., Chicago, IL, USA). Descriptive analyses were used to describe study variables. Independent t-tests and one-way analysis of variance (ANOVA) were performed to analyze the baseline equivalent between study groups. The generalized estimating equations were used to analyze the efficacy of the intervention for enhancing knowledge, knowledge, perceived benefits, perceived barriers, self-efficacy, and adherence to anticoagulant therapies in patients treated with oral anticoagulants for atrial fibrillation.

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Participant Flow Data Preparation Checklist

Overview: The Participant Flow module is a tabular summary of participants' progress through each stage of a study by assignment group. Use this checklist with the Participant Flow Template and Results Data Element Definitions to complete this module of the results section.

Select	Information to have available for Participant Flow	Data Element
☒	• Conceptual overview of the study design, including the type (e.g., single group, cross-over, parallel) and any distinct stages (e.g., double-blind then open-label) ◦ Tip: Have a CONSORT flow diagram available.	
☒	• Description of any significant study events that occurred after participants were enrolled, but before they were assigned to a study group (e.g., run-in phase or washout)	[*]Pre-assignment Details
☒	• Number of groups that accurately describes the study design from participant assignment to completion ◦ Tip: The number of groups is typically equal to the number of unique paths (participant experiences) in a CONSORT flow diagram, from beginning to end. Each group will be reported as a table column.	*Arm/Group Information
☒	• For each group: ◦ Title—Descriptive label for the group ▪ Tip: Use informative labels (e.g., "Placebo"), not generic labels (e.g., "Group 1"). The label will become the header for that table column. ◦ Description—Detailed explanation of the interventions administered or the groups observed during each stage of the study ▪ Tip: Include details about the intervention (e.g., dosage, dosage form, frequency and duration of administration) or observation.	*Arm/Group Title *§Arm/Group Description
☒	• Number of discrete stages or intervals of activity in the study	*Period(s)
☒	• Descriptive title for each period (the default for one Period is "Overall Study") ◦ Tip: A Period Title should describe what happened during that period of the study. For example, "Double-blind (0 to 24 weeks)" and "Open-label (24 to 48 weeks)" are more descriptive than "Period 1" and "Period 2."	*Period Title
☒	• Number of participants that Started and Completed each period: ◦ Started—Participants initiating each period (e.g., the number of participants assigned or randomized to each group for that period) ▪ Tip: If the number of participants starting the first period is different from the total enrolled in the study, explain why in Pre-assignment Details. ◦ Completed—Participants still in the study at the end of the period ◦ Tip: If the unit of assignment is a unit other than participants, specify the name of the unit (e.g., eyes, lesions, implants) and provide the number of units. ◦ Tip: Each unit of assignment (participants or units other than participants) should only be represented in one group. For example, if the unit of assignment is participants, do not count a participant more than once by including them in more than one group. ◦ Tip: Use the Additional Milestone field to record any specific events or time points in the study between the Started and Completed milestones.	*Started *Completed [*]Type of Units Assigned Additional Milestone

'Required

'§ Required if Primary Completion Date is on or after January 18, 2017

[*] Conditionally required

Participant Flow Template

Recruitment Details	Patients with AFib were recruited from the cardiology clinics of two general hospitals in northern Taiwan. Potential participants were referred by cardiologists and screened by one of the investigators to determine their eligibility
[*] Pre-assignment Details	

Period ①

*	Overall Study ①			
	*	EG	CG	
	*§ Arm/Group	Intervention Group	Control Group	
		Number of Participants ④	**Number of Participants ④**	**Number of Participants**
	* Started	36	36	
	[*] Milestone			
	[*] Milestone			
	[*] Milestone			
	* Completed	33	30	
	Not Completed	*(automatically calculated)*		
	Reason Not Completed Type ③			
	[*] Adverse Event			
	[*] Death			
	[*] Lack of Efficacy			
	[*] Lost to			
	[*] Physician			
	[*] Pregnancy			
	[*] Protocol			
	[*] Withdrawal by	1	2	
[*] Other	Change Medication	1	2	
[*] Other	Operation	1	0	

Baseline Characteristics Template — Age* (use at least one) — ClinicalTrials.gov

* Arm/Group Title	EG	CG		Total
*§ Arm/Group Description ①	Intervention group	Control Group		
* Overall Number of Baseline Participants ②	36	36		③
[*] Baseline Analysis Population Description	Age 20 years and over, diagnosis with AFib by a physican and receving anticoagulation therapy			
Age, Categorical				
<=18 years	0	0		③
Between 18 and 65 years	13	13		③
>=65 years	41	42		③
* Unit of Measure: Participants				
Age, Continuous				
* Measure Type / * Measure of Dispersion				
(Select One) Mean, Median, Least Squares Mean (LSM), Geometric Mean, Geometric LSM / (Select One) Standard Deviation, Inter-quartile Range, Full Range	69.3 / 7.5	73.3 / 10		
* Unit of Measure: years old				
Age, Customized				
* Measure Type / * Measure of Dispersion				
(Select One) Count of Participants ④, Mean, Median, Least Squares Mean (LSM), Geometric Mean, Geometric LSM, Number, Count of Units ④ / (Select One) Not Applicable ⑤, Standard Deviation, Inter-Quartile Range, Full Range				
[*] Row/Category Title ⑥	④⑤	④⑤	④⑤	③ ④⑤
[*] Row/Category Title ⑥	④⑤	④⑤	④⑤	③ ④⑤
* Unit of Measure				

* Required *§ Required if Primary Completion Date is on or after January 18, 2017 [*] Conditionally required

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ Total values are automatically calculated for Overall Number of Baseline Participants and for data reported with a Measure Type of Number, Count of Participants, or Count of Units.
④ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Baseline Participants/Units Analyzed. The percentage can be hidden (display is optional).
⑤ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion value is needed if Measure of Dispersion is Not Applicable.
⑥ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Baseline Measure Data are required for each row.

Baseline Characteristics Template — *Sex/Gender* (use at least one)* — *ClinicalTrials.gov*

* Arm/Group Title	EG	CG		Total
*§ Arm/Group Description ①	Intervention Group	Control Group		
* Overall Number of Baseline Participants ②	36	36		③
[*] Baseline Analysis Population Description				
Sex: Female, Male				
Female	12	17		③
Male	24	19		③
* Unit of Measure: Participants				
Sex/Gender, Customized				
* Measure Type: (Select One) Count of Participants ④, Mean, Median, Least Squares Mean (LSM), Geometric Mean, Geometric LSM, Number, Count of Units ④	* Measure of Dispersion: (Select One) Not Applicable ⑤, Standard Deviation, Inter-Quartile Range, Full Range			
[*] Row/Category Title ⑥		④⑤	④⑤	④⑤	③	④⑤
[*] Row/Category Title ⑥		④⑤	④⑤	④⑤	③	④⑤
[*] Row/Category Title ⑥		④⑤	④⑤	④⑤	③	④⑤
* Unit of Measure				

* Required *§ Required if Primary Completion Date is on or after January 18, 2017 [*] Conditionally required

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ Total values are automatically calculated for Overall Number of Baseline Participants and for data reported with a Measure Type of Number, Count of Participants, or Count of Units.
④ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Baseline Participants/Units Analyzed. The percentage can be hidden (display is optional).
⑤ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion value is needed if Measure of Dispersion is Not Applicable.
⑥ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Baseline Measure Data are required for each row.

Baseline Characteristics Template — *Race*§, Ethnicity*§, and Region* — *ClinicalTrials.gov*

* Arm/Group Title		EG	CG		Total
*§ Arm/Group Description ①		Intervention Group	Control Group		
* Overall Number of Baseline Participants ②		36	36		72 ③
[*] Baseline Analysis Population Description					
Race (NIH/OMB) ④					
American Indian or Alaska Native					③
Asian		36	36		72 ③
Native Hawaiian or Pacific Islander					③
Black or African American					③
White					③
More than one race					③
Unknown or Not Reported					③
* Unit of Measure	Participants				
Ethnicity (NIH/OMB) ④					
Hispanic or Latino					③
Not Hispanic or Latino					③
Unknown or Not Reported					③
* Unit of Measure	Participants				
Region of Enrollment					
United States					③
Region/Country Name ⑤	Taiwan	36	36		③
Region/Country Name ⑤					③
Region/Country Name ⑤					③
* Unit of Measure	Participants				

* Required *§ Required if Primary Completion Date is on or after January 18, 2017 [*] Conditionally required

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ Total values are automatically calculated for Overall Number of Baseline Participants and for each Baseline Measure.
④ If not using NIH/OMB categories, use Race/Ethnicity, Customized (not shown); if not collected, use Race and Ethnicity Not Collected (not shown).
⑤ [Optional] Region of Enrollment Baseline Measure is optional, but at least one Region/Country is required if reporting Region of Enrollment. Add as many Regions/Countries as needed.

Baseline Characteristics Template *Study-Specific Measure**§* *ClinicalTrials.gov*

* Arm/Group Title		EG		CG				Total	
*§ Arm/Group Description ①		Intervention Group		Control Group					
* Overall Number of Baseline Participants ②		36		36				③	
[*] Baseline Analysis Population Description		Patients with AFib currently receving anticoagulation therapy							
[*] Study-Specific Baseline Measure Title		History of anticoagulation therapy							
Baseline Measure Description									
* Measure Type	* Measure of Dispersion								
(Select One) Count of Participants ④ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ④	(Select One) Not Applicable ⑤ Standard Deviation Inter-Quartile Range Full Range								
[*] Row/Category Title ⑥	Disease duration	65.6	45 ④⑤	70.9	66.2 ④⑤		④⑤	③	④⑤
[*] Row/Category Title ⑥			④⑤		④⑤		④⑤	③	④⑤
* Unit of Measure	month								

* Required *§ Required if Primary Completion Date is on or after January 18, 2017 [*] Conditionally required

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ Total values are automatically calculated for Overall Number of Baseline Participants and for data reported with a Measure Type of Number, Count of Participants, or Count of Units.
④ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Baseline Participants/Units Analyzed. The percentage can be hidden (display is optional).
⑤ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion value is needed if Measure of Dispersion is Not Applicable.
⑥ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Baseline Measure Data are required for each row. Row/Category Titles are only required if more than one row.

Outcome Measure Template

* Outcome Measure	(Select One) **Primary** **Secondary** **Other Pre-specified** **Post-Hoc**
* Outcome Measure	Anticoagulant medication adherence
[*] Outcome Measure Description	~~Participants were monitor for up to 24 weeks, These is the score of participants who had been monitor for medication~~ adherence. The study adapted Adherence to Refills Medications Scale (ARMS) assess the participants' medication adherence when taking anticoagulants
* Outcome Measure Time	Ups to 24 weeks

More details available in the Results Data Element Definitions. April 2017

	* Arm/Group	EG		CG			
	*§ Arm/Group Description	Intervention group		Control group			
*	Number of Participants Analyzed	36		36			
	[*] Analysis Population	All participants with baseline and at least fellow up for 24 weeks					
* Measure Type	* Measure of						
(Select One) **Count of Participants** ③ **Mean** **Median** **Least Squares Mean**	(Select One) **Not Applicable** ④ **Standard deviation** **Standard Error** **Inter-Quartile Range**						
[*] Row/Category Title	Medication adherence	8.1	1.4	9.2	2.2		③④
[*] Row/Category Title			③④		③④		③④
* Unit of	score						

Statistical Analysis Template — *ClinicalTrials.gov*

Statistical Analysis Overview	* Comparison Group Selection ①	☐ ✓Arm/Group 1 ☐ ✓Arm/Group 2 ☐ Arm/Group 3
	Comments ②	
	* Type of Statistical Test	**(Select One)** Superiority; Non-inferiority; [Equivalence]; Other (for example, single group or other descriptive analysis)
	[*] Comments ③	
Statistical Test of Hypothesis	[*] P-Value (if applicable)	0.05 *(calculated value, not the a priori threshold for statistical significance)*
	Comments ②	
	[*] Method (required if p-value entered)	**(Select One)** ANCOVA; ANOVA; Chi-Squared; Chi-Squared, Corrected; Cochran-Mantel-Haenszel; Fisher Exact; Kruskal-Wallis; Log Rank; Mantel Haenszel; McNemar; Mixed Models Analysis; Regression, Cox; Regression, Linear; Regression, Logistic; Sign Test; t-Test, 1-Sided; [t-Test,2-Sided]; Wilcoxon (Mann-Whitney); Other (_____)
	Comments ②	
Method of Estimation	[*] Estimation Parameter (if applicable)	**(Select One)** Cox Proportional Hazard; Hazard Ratio (HR); Hazard Ratio, Log; [Mean Difference (Final Values)]; Mean Difference (Net); Median Difference (Final Values); Median Difference (Net) (generalized estimating equation); Odds Ratio (OR); Odds Ratio, Log; Risk Difference (RD); Risk Ratio (RR); Risk Ratio, Log; Slope; Other
	Estimated Value	0.5 *(calculated value)*
	Confidence Interval (if applicable)	**Level:** 95 % Confidence Interval **Number of Sides: (Select One)** [2-sided] 1-sided **Lower Limit:** _____ **Upper Limit:** _____
	Parameter Dispersion	**Type: (Select One)** Standard Deviation; Standard Error of the Mean **Value:** _____
	Estimation Comments ②	
Other Statistical Analysis ④		A generalized estimating equation (GEE) [28] was used to model each outcome variable as a function of group effect, time effect, and group by time interaction effect.

* Required [*] Conditionally required

① Use the checkboxes to select the Arms/Groups (pre-populated from the Outcome Measure) involved in the statistical analysis.
② (Optional) Include any relevant information about the row above (e.g., the null hypothesis, details of the power calculation, adjustment for multiple comparisons, the *a priori* threshold for statistical significance, the direction of the comparison). Do not include written results or conclusions.
③ If a non-inferiority or equivalence analysis, information on the definition of the non-inferiority or equivalence margin is required.
④ If the statistical analysis cannot be submitted using the Statistical Test of Hypothesis or Method of Estimation options, provide a description and the results

All-Cause Mortality and Serious Adverse Events Template — ClinicalTrials.gov

*§ Time Frame	non applicable
[*] Adverse Event Reporting Description	
Source Vocabulary Name for Table Default ①	
*§ Collection Approach for Table Default ①	(Select One) Systematic Non-Systematic

* Arm/Group Title			
*§ Arm/Group Description ②			

*§ All-Cause Mortality

	*§ Number Participants Affected	*§ Number Participants at Risk	*§ Number Participants Affected	*§ Number Participants at Risk	*§ Number Participants Affected	*§ Number Participants at Risk
*§ Total						

* Serious Adverse Events

	* Number Participants Affected	* Number Participants at Risk	Number Events	* Number Participants Affected	* Number Participants at Risk	Number Events	* Number Participants Affected	* Number Participants at Risk	Number Events
* Total									

* Adverse Event Term	* Organ System									
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	

* Required *§ Required if Primary Completion Date is on or after January 18, 2017 [*] Conditionally required

① If entered, the table default values apply to all Adverse Event Terms. The values may be changed for any single Adverse Event, if different from the table default.
② Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
③ Organ System must be selected from a pick-list of high-level categories. See the Results Data Element Definitions for details.
④ Number of Participants at Risk for an Adverse Event Term is only required when the value differs from the Total Number of Participants at Risk.

Other (Not Including Serious) Adverse Events Template — ClinicalTrials.gov

*§ Time Frame	non applicable
[*] Adverse Event Reporting Description	
Source Vocabulary Name for Table Default ①	
*§ Collection Approach for Table Default ①	(Select One) Systematic Non-Systematic

* Arm/Group Title			
*§ Arm/Group Description ②			

*** Other (Not Including Serious) Adverse Events**

* Frequency Threshold for Reporting Other Adverse Events (0–5%) _____%		* Number Participants Affected	* Number Participants at Risk	Number Events	* Number Participants Affected	* Number Participants at Risk	Number Events	* Number Participants Affected	* Number Participants at Risk	Number Events
* Total										
* Adverse Event Term	* Organ System									
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	

* Required *§ Required if Primary Completion Date is on or after January 18, 2017 [*] Conditionally required

① If entered, the table default values apply to all Adverse Event Terms. The values may be changed for any single Adverse Event, if different from the table default.
② Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
③ Organ System must be selected from a pick-list of high-level categories. See the Results Data Element Definitions for details.
④ Number of Participants at Risk for an Adverse Event Term is only required when the value differs from the Total Number of Participants at Risk.