Official Title of the study: “Data-driven shared decision-making to reduce symptom burden in atrial fibrillation”

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Study Protocol

OVERALL AIMS

- **Aim 2: Evaluate the atrial fibrillation (AF) decision aid in a single-arm feasibility study (n=75).** We hypothesize that patients who have viewed the decision aid after an AF ablation consultation will report reduced decisional conflict three months post-decision compared to baseline. We will also evaluate decision-related outcomes (decision regret) and health-related outcomes (HRQOL, AF symptom burden, AF recurrence) at multiple timepoints throughout the decision-making process.
- **Aim 3: Identify predisposing, enabling, and reinforcing factors of implementing web-based decision aids in clinical settings.** We will conduct qualitative interviews with patients (n=15), clinicians (n=10), and other key stakeholders (n=5) to evaluate facilitators and barriers to adoption, implementation, and maintenance using the established RE-AIM framework.

STUDY DESIGN AND SETTING

We will conduct a single-arm feasibility trial with 75 adults with AF at Columbia University Irving Medical Center (CUIMC) and NewYork Presbyterian-Queens hospital (NYP-Q).

PARTICIPANT ELIGIBILITY CRITERIA

We will recruit adults with symptomatic, paroxysmal AF immediately after consultation visits for ablation. Eligibility criteria are described in **Table 1**.

Table 1. Participant eligibility criteria

Inclusion criteria	**Exclusion criteria**
1. Diagnosis of symptomatic AF confirmed by the treating cardiologist and/or in the EHR. 2. Scheduled consultation at CUIMC or NYP-Q to discuss ablation. 3. Age 18 years and older. 4. Able to read and speak English. 5. Willing and able to provide informed consent.	1. Prior history of ablation to treat AF. 2. Concomitant terminal illness, psychiatric illness, or cognitive impairment that would prevent the ability to provide informed consent or participate in the study. 3. No working email address.

INTERVENTION OVERVIEW

The interview involves viewing a web-based decision aid, the Atrial Fibrillation Rhythm Control Decision Aid. The decision aid explains what AF is, two common treatment options (including risks and benefits of each), personal values to consider, and evidence on the outcomes after each treatment option. The decision aid can be viewed on a computer, tablet, or mobile phone. It has been iteratively developed following expert guidelines for decision aid development, with input from clinicians, patients, and other stakeholders in multiple stages. Participants who have a scheduled consultation for ablation to treat AF will view the decision aid before the appointment. They may view the decision aid at any point thereafter if desired. Participants will complete surveys about AF symptoms, quality of life, and levels of decisional conflicts before and after viewing the decision aid.

MEASURES

All survey data will be collected using Research Electronic Data Capture (REDCap). In addition to the surveys described in Table 2, at baseline participants will also provide demographic and socioeconomic information, and complete surveys about health literacy, subjective numeracy, and control preferences. Participants will receive $50 upon enrollment and $50 upon study completion including all follow-up surveys.

Table 2. Measurement of key constructs in the feasibility study (Aim 2)

Construct	Measurement	T1	T2	T3
Primary outcome				
Decisional conflict	Decisional Conflict Scale	X	X	
Secondary outcomes				
Decision self-efficacy	Decision self-efficacy scale	X	X	
Decision regret	Decision regret scale			X
Exploratory outcomes				
Acceptability of decision aid	Acceptability of decision aid scale		X	
Perceived AF burden	Atrial Fibrillation Severity Scale	X		X
AF-related quality of life	Atrial Fibrillation Effect on Quality of Life scale	X		X
RE-AIM analysis (Aim 3)				
Adoption, implementation, maintenance of decision aid	Qualitative semi-structured interviews			X

T1: Baseline pre-intervention, T2: One week post-intervention, T4: 3 months post-intervention

STUDY PROCEDURES

Recruitment/screening: The CUIMC and NYP-Q electrophysiology practices will provide weekly lists of patients coming in for their first consultation for ablation. We will review the medical records of each patient on the list to confirm eligibility. We will then call each patient, describe the study, and invite them to participate in the study. Participants who agree will be given the option to immediately sign up or schedule a separate phone call to undergo the enrollment process. They will be told that it will take approximately 20-30 minutes to complete all of the enrollment steps.

Enrollment and T1 surveys: At the time of enrollment, we will email a REDCap link to the participant. When they click the REDCap link, they will view the informed consent document while the recruiter verbally explains the consent form via phone. They will sign the consent form virtually in REDCap. They will then proceed to complete the baseline series of surveys (T1 in **Table 2**).

Intervention: After completing the surveys, participants will automatically receive the hyperlink to the decision aid. They will be free to navigate the decision aid independently and may visit the decision aid as many times as they desire. The RA will also mail the baseline incentive at this time.

Follow-up surveys: One week after the intervention, participants will receive an automated email with a hyperlink to a set of surveys (T2 in **Table 2**). The first survey will ask if they have viewed the decision aid. If they respond yes, they will be directed to a series of surveys measuring decisional conflict, decision self-efficacy, and overall acceptability of the decision aid. They will also report whether they viewed the decision aid multiple times, if they had their consultative appointment yet, and if so, whether they discussed the decision aid during the appointment. Participants will be asked to complete surveys again three-months after the intervention (T3 in **Table 2**). Surveys will ask about the decision they ultimately made (whether they opted for ablation or not), as well decision regret, AF symptoms, and quality of life. They will also indicate whether they would like to be contacted for a semi-structured interview (Aim 3). After completing the 3 month surveys, the RA will mail the second incentive.

Aim 3: Identify predisposing, enabling, and reinforcing factors of implementing web-based decision aids in clinical settings.

Framework: Prior studies have noted significant implementation challenges with decision aids, specifically around integrating decision aids into the clinical workflow and engaging patients with variable literacy levels, technology comfort, and control preferences. We will apply a widely used implementation science framework, "RE-AIM," to evaluate factors that support decision aid implementation. RE-AIM focuses on an intervention's reach to a representative sample of the target population, effectiveness in improving specified outcomes, adoption in a desired setting, and details of implementation and maintenance in clinical settings.

Data collection: We will collect quantitative and qualitative data. We will evaluate the reach of the intervention using baseline characteristics of the Aim 2 feasibility study sample; this will allow us to identify potential sources of inequity in the reach of the decision aid. We will evaluate effectiveness using the primary outcome evaluated in Aim 2, decisional conflict. We will evaluate adoption using quantitative usage metrics, such as the number of visits to the decision aid website. We will also collect qualitative data about adoption, implementation, and maintenance through semi-structured interviews at the end of the feasibility study with 30 participants (**Table 2**). Specifically, we will conduct qualitative semi-structured interviews with a random subsample of Aim 2 feasibility study patient participants (n=15), clinicians (n=10), and other key stakeholders (n=5). All interviews will be audio recorded and transcribed verbatim. Study patients will come from the pool of participants who indicated on their final surveys that they would be interested in participating in an interview.

RECRUITMENT SCHEDULE

We aim to recruit 75 participants.

STATISTICAL ANALYSIS PLAN

Feasibility study: We will describe variables of interest at each timepoint using descriptive statistics of frequency, central tendency, and dispersion. The primary outcome is the change in decisional conflict from baseline to three months-post decision, measured using the Decisional Conflict Scale. This primary outcome and timeframe were selected based on the protocol for a similar decision aid trial. We will conduct pairwise comparisons using the appropriate statistical test (t-test, Wilcoxon signed-rank test) to evaluate the primary outcome, as well as secondary and exploratory outcomes at the three follow-up timepoints (post-receipt of DA, post-decision, and three-months post-decision) compared to baseline. The randomness of missing data will be evaluated to determine risk of bias by comparing the characteristics of participants with complete and incomplete data. Finally, given recent studies showing racial bias in provider characterizations of patients in EHRs, we will take advantage of the simultaneous access to PROs and provider reports (via EHR) about symptoms to measure agreement between the two data sources. We will determine whether EHR documentation patterns are different for underserved patients, which may be associated with disparities in symptom management. All quantitative data will be analyzed using R statistical software.

RE-AIM: Qualitative data will be analyzed in NVivo 11 using directed content analysis in which the RE-AIM framework will form the initial coding scheme. A minimum of 2 coders will review and analyze each transcript, meeting regularly to achieve consensus until agreeing upon a final set of themes and subthemes. To establish trustworthiness and credibility, we will member check during the interviews, share an audit trail, cross-check emerging concepts with the participants' original statements, and record detailed notes outlining the analysis. Quantitative data will be summarized using descriptive statistics of frequency, central tendency, and dispersion. We will evaluate possible differences by patient sociodemographic or clinical

characteristics by comparing unadjusted estimates of reach, effectiveness, and adoption using two-sided student's t-tests or Wilcoxon's Rank Sum tests depending on whether the data are non-normally distributed. Unadjusted estimates for categorical data will be compared using $\chi 2$ tests. Quantitative and qualitative data will be analyzed concurrently, and findings will be interpreted together, in keeping with a classic mixed-methods analysis.