Patient Centered Mobile Health Technology Enabled Atrial Fibrillation Management

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JHM IRB - eForm A – Protocol

- **Use the section headings to write the JHM IRB eForm A, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.**
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Patient Centered *m*obile health *TECH*nology Enabled Atrial Fibrillation Management (mTECH Afib): A Pilot Randomized Clinical Trial

1. Abstract

a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

Atrial fibrillation (Afib) is the most common arrhythmia.[1] Lifetime risk of Afib is one in five to one in three individuals.[2] Increased overall time spent in Afib (Afib burden) and recurrent AF episodes have been associated with higher risk of heart failure, stroke, poor quality of life, and mortality. [3] Early implementation of strategies to maintain sinus rhythm reduces cardiovascular mortality, stroke or hospitalization for heart failure or acute coronary syndrome and improves quality of life.[4, 5] Efficacy of these interventions can be limited in the setting of uncontrolled Afib risk factors. Modifiable Afib risk factors include sleep apnea, hypertension, obesity, physical inactivity, inadequate cholesterol and glycemic control, smoking, and alcohol use.[6, 7] Both observational and randomized studies have demonstrated significant reduction in Afib burden and recurrent Afib episodes with aggressive risk factor modification intervention programs delivered in-person among patients with Afib.[8-11] Risk factor modification is now recommended by American Heart Association and American College of Cardiology Afib Guidelines.[7] Such interventions are not widely implemented, due to its association with high costs and the need for trained personnel, which deprives numerous patients from this evidence-based care. Furthermore, evidence suggests poor translation of guidelines in patient care for other core aspects of AF care, including stroke prevention and rhythm control, especially among underserved minorities.[3, 12] Additionally, patients with Afib have poor quality of life[13] and report poor communication and guidance while experiencing AF episodes (IRB00230621). Mobile health technologies, including smartphone applications ("apps") and wearable devices have tremendous potential to bridge this gap and enable delivery of risk factor modification programs to patients with Afib at scale. By digitizing the processes and system of Afib management program, we will be able to increase access to guideline directed Afib care at scale and ultimately improve the quality of the service we provide to our patients as well as improve health outcomes.

We co-designed the **C**orrie **V**irtual **A**trial **F**ibrillation Management Program **"Corrie VCare Afib"** on the platform of Corrie Health in an inclusive manner together with patients, their health partners and clinicians in a way that meets their needs (IRB00230621). This comprehensive and multi-component program aims to empower patients to a) take an active role in learning about Afib management options, starting and adhering to evidence-based therapies b) help build new healthy habits for risk factor

modification c) guide them during Afib episodes which are associated with anxiety and impairment in quality of life and d) provide peer support for emotional health.

We aim to 1) evaluate the Corrie VCare Afib intervention in a pilot randomized clinical trial of 100 patients to inform feasibility - recruitment and retention rates of study participants, evaluate effect size, feasibility and acceptability of the intervention and study measurement procedures. Findings from this pilot phase will provide critical information to inform evaluation of the intervention in a larger randomized clinical trial powered for health outcomes, including measures to mitigate attrition rates 2) estimate the prevalence of Afib risk factors 3) characterize sleep symptoms and cardiovascular stress, as one of the core risk factors for Afib, sleep apnea is under characterized specifically in this population.

2. Objectives (include all primary and secondary objectives)

The primary objective of this pilot study is to inform the feasibility of conducting the study:

Primary outcome: Retention rates at 3 months (number of individuals who continue study participation (defined by App interaction, Coaching call participation or follow up survey completion) divided by the number of individuals who consent to participation in the study at 3 months after enrollment. Retention rates of at least 60% at 3 month will be considered acceptable. (https://www.cvdigitalhealthjournal.com/article/S2666-6936(22)00002-0/fulltext#figures)

As part of feasibility objective will also evaluate:
a) screen failure rates (number of individuals who are eligible for enrollment divided by number of individuals screened (meeting inclusion criteria),
b) recruitment rates (number of individuals who are eligible for participation in study divided by the number of individuals who provide consent to participate in the study) as well as number of individuals who are enrolled in a study per month,

The secondary objective of the study is to evaluate feasibility of implementing study procedures, measurement tools and collecting study data. We will evaluate secondary objectives by examining:

a) Completion rates for study interventions (e.g. survey completion rates, coaching call completion rates
b) App engagement (Total number of interactions in the smartphone app and overall amount of time spent using the smartphone app per participant, collected via the Corrie Health Platform User Analytics), rhythm check log rates, vital sign log rate)
c) User satisfaction – System Usability Scale modified for Corrie Afib

We will conduct exploratory analysis of the results of the following effectiveness measurements as well as metrics that may be relevant to heterogeneity of treatment effects and intervention's mechanism of action:

- ❑ **Quality of Life - measured by Atrial Fibrillation Effect on Quality-of-Life (AFEQT),** validated disease specific measure which consists of 20 items. Score ranges from 0 to 100 with higher scores signifying better quality of life. [14]**Error! Hyperlink reference not valid.**At least 5 point change in AFEQT score is considered clinically meaningful.[15]

- ❑ Atrial Fibrillation episode burden, symptom burden and healthcare utilization – measured by the **Atrial Fibrillation Severity Scale (AFSS)** – validated 19 item questionnaire.[16]
- ❑ Berlin Sleep Questionnaire- 10 item questionnaire assessing sleep apnea risk through 3 different categories, and classifies patients as high or low risk.[17]
- ❑ Brief Sleep Characterization – Team designed Afib specific questions to characterize sleep apnea in patients with atrial fibrillation
- ❑ Social Support **–** measured by **Medical Outcomes Social Support Survey Instrument (MOS Social Support Scale) -** Is a 19 item questionnaire with final score ranging between 0 – 100 with higher scores suggesting more support [18]**Error! Hyperlink reference not valid.**
- ❑ Skills in applying electronic health information to health problems– measured by 8-item questionnaire **eHealth Literacy Scale (eHEALS) [19, 20]**
- ❑ Depressive symptoms – Patient Health Questionnaire 8 (PHQ – 8) - 8-item measure with (≤4: no depressive symptom, 5–9: mild, ≥10: moderate to severe depressive symptoms)[21]
- ❑ Generalized Anxiety Disorder 7 (GAD 7) – score ranges from 0 to 21 with higher scores indicating more anxiety [22]
- ❑ Perceived Stress Score (PSS-10). In this 10 item questionnaire score ranges from 0-40 with higher scores indicating higher level of anxiety.[23]
- ❑ AF Episode Burden as assessed by the ratio of 30 second single lead ECG recordings (via Apple Watch) reporting Afib divided by total number of 30 second single lead ECG recordings
- ❑ Physical Activity – As assessed by The Rapid Assessment of Physical Activity (RAPA)[24]
- ❑ Diagnosis of Sleep Apnea, Continuous positive airway pressure (CPAP) therapy
- ❑ Alcohol use – as assessed by The Alcohol Use Disorders Identification Test (AUDIT), 10-item questionnaire. The score range is from 0 to 40 with 0 referring to abstainer with no history of alcohol abuse and higher scores indicate gradually higher and hazardous alcohol dependence. [25, 26]
- ❑ Smoking status – as assessed by study team developed questionnaire responses and evaluating the ratio of participants who report quitting smoking at 12 week f/u divided by number of participants who report smoking at baseline
- ❑ Diet – Rate Your Plate. A 27 item scale administered at 12 weeks with the following scoring system: 27-45: There are many ways you can make your eating habits healthier. 46-63: There are some ways you can make your eating habits healthier. 64-81: You are making many healthy choices.[27, 28]
- ❑ Blood pressure Attainment of BP less than 130/80 mmHg, averaged over two measurements per time point[29]
- ❑ Body Mass Index

Safety Outcomes:

- ❑ Hospitalization, Emergency room visits, myocardial infarction, Stroke - as reported in electronic health records or via patient/caregiver report, verified by health records.
- ❑ Death – as reported in electronic health records or via caregiver report, verified by death certificates or health records

To further characterize sleep apnea patterns and assess validity of Afib specific sleep apnea questionnaire we aim to conduct one time home sleep apnea testing (FDA approved Itamar WatchPAT device) in

patients enrolled in usual care arm after they complete 12 week follow up assessments. WatchPAT devices will be mailed to patients home address and results of the study will be shared with patients and their cardiologist/care team.

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

Our study team has conducted inclusive design sessions (Human Centered Design Sessions) in collaboration with Johns Hopkins Center for Health Equity with support from American Heart Association to identify challenges that diverse group of patients and their health partners with Afib face in everyday life and similarly challenges that clinicians face while managing Afib (IRB00230621). Guidance with evidence based Afib care, peer support, Afib episode management and risk factor modification were identified as top problems patients and clinicians wish to be addressed via digital toolkit. These challenges are in line with well established gaps in care suggested in literature.

In order to bridge the gap in Afib care and provide access to guideline recommended Afib management to patients, we have designed virtual Afib care model "Corrie VCare Afib" on Corrie Health platform. Program leverages digital health technologies, namely Corrie Health patient facing app, Clinician Dashboard, FDA approved wearable devices providing data generation (Apple Watch, Bluetooth enabled blood pressure cuffs (Omron) and Itamar Watch PAT home sleep apnea testing. The role of the industry collaborators is hardware and software donation and advice on technology best practices. There is no expectation for data sharing.

The app, Corrie, is the same platform used in IRB00099938, QI project (IRB00148849), Human Centered Design Studies (IRB00266731 and IRB 00230621). App owners will have access to limited PII and PHI (name and email). Core app functions include: 1) medication tracking; 2) CPAP use tracking via patient logs 3) vital signs and heart rhythm and physical activity tracking; 4) patient education; 5) summary report for care team; 6) assistance in organization of care, 7) connecting with care team and Johns Hopkins nurse-led patient coaching 8) access to already established social media patient led support groups.

Furthermore, one of the core risk factors for atrial fibrillation is sleep apnea. Sleep is an essential period for cardiovascular system as during this time heart rate and blood pressure are reduced allowing restoration and recovery of cardiovascular system.[30] In patients with sleep disorders, such as sleep apnea however, sleep is a significant source of cardiovascular stresses related to periods of hypoxemia, changes in intrathoracic pressure and surges of sympathetic activity during arousals.[31] However true prevalence and characterization of sleep apnea is lacking in patients with atrial fibrillation. By deploying sleep assessment to all patients enrolled in the trial (at baseline for individuals in intervention arm and at follow up in control group) as well as deploying sleep characterization questionnaires we will be able to bridge this gap and characterize sleep among patients with sleep apnea (detailed sleep apnea testing and treatment plan is uploaded in Section 20.2 as part of Corrie VCR program document.

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

General Overview:

We will conduct a pilot, parallel arm randomized clinical trial in a convenience sample of 100 patients with paroxysmal atrial fibrillation (diagnosed not more than 12 months prior to randomization) who presents for evaluation (Afib at Johns Hopkins Outpatient Cardiology Clinic, Johns Hopkins Bayview cardiology or electrophysiology clinics, or Medical Pavilion at Howard County electrophysiology clinic). We will evaluate feasibility and preliminary efficacy of multi-component Corrie VCare AF Program in addition to usual care vs usual care alone.
Given proven benefits on cardiovascular outcomes with 12-week rehabilitation programs for patients with range of other cardiovascular diseases we will deploy digital AF program for 12 weeks.

Table 1.

Components of Corrie VCare Afib Program Multi Component Intervention
Corrie Afib App, Apple Watch, Itamar WatchPAT Home Sleep Apnea Test, BP cuff, scale, Nurse-coach for Corrie Afib (guidance document uploaded in Section 20.2) and contextual motivational messages (document uploaded in Section 20.2), voluntary access to public patient led Facebook AF support group (**https://www.facebook.com/groups/AtrialFibrillationSupportForum**)

Enrollment, Randomization and Measurements:

1. The list of patients in the cardiology and electrophysiology outpatient clinics at Johns Hopkins Hospital (JHH), Johns Hopkins Bayview Medical Center (JHBMC), and Medical Pavilion at Howard County (MPHC) will be reviewed daily by study team member. Furthermore, flyers will be placed at JHH and JHBMC cardiology outpatient clinician work rooms to increase visibility of the study and allow clinicians to refer patients to the study. Patients who meet the inclusion criteria (see below in section 5) will be entered into REDCap (Research Electronic Data Capture) dataset.
2. Study team members will subsequently screen patient charts for exclusion criteria.
3. Before approaching eligible patients for consent, study team members will ask the attending physician of the patient to obtain permission from patients for study team to approach them. Study team members will also assess whether treating clinicians deem Corrie VCare Afib program safe for patients
4. Patients will be approached in the outpatient clinic either before or after their scheduled clinic visit. Once patients are approached, further questions will be asked to screen for exclusion criteria including visual, motor, and/or auditory impairment limiting digital health technology use (precludes meaningful use of intervention technology).
5. Research team member will provide patients with detailed information and consent form to review prior to starting further discussion.
6. Confirmation about having as much time as necessary will be done by allowing the patient to read the consent form with unlimited time and a repeat of information
7. Patients will be given the opportunity to ask any questions of research team before considering consenting to participate in study.
8. After consent is obtained, patients will be randomized at a 1:1 ratio, stratified by location of enrollment (JHH vs JHBMC vs MPHC) and practice (Cardiology vs Electrophysiology) to the **VCare Afib** program along with usual care or usual care alone. Usual care is defined by care delivered by patients clinical team.

9. We will use a web-based tool for randomization using variable-sized blocks (2-6). We will minimize bias by concealed allocation.
10. Once randomization arm is determined, a study team member will inform each patient of their allocation.

11. Individuals randomized to the Corrie Afib Virtual Program will receive onboarding from a study team member. Patients will receive step by step guidance on how to download the Corrie Afib app onto the phone, use Apple Watch device, blood pressure cuff [Omron Blood pressure cuff (FDA cleared)], which will be paired with the smartphone via Bluetooth and scale. They will also be instructed on the use of one-time Itamar Watch PAT home sleep apnea testing (Detailed description of sleep apnea testing and treatment is uploaded in Section 20.2 as part of the Corrie VCare Afib Program description document). We will ask patients to keep WatchPAT on for the entire night. For a study to be considered acceptable, we will require a minimum recording duration of 4 hours, which is standard of care. If a recording does not meet minimum duration requirement, then the participant would be asked to repeat the sleep study. Patients will be able to keep Apple Watch, BP cuffs and scale after the study if they will plan to use the equipment, otherwise they will be provided with return mailers for Apple Watch device. The research team will have access to data collected via these devices and will review them on a weekly basis. Patients will be provided with an email to allow them to contact study investigators in case they have questions about technology use. They will also be able to submit feedback or questions regarding app use directly via the app. Patients will be encouraged to start using the app immediately; they will be able to receive education and log medication use and CPAP wearing time via the app as soon as the app is downloaded. Patients will be instructed to record single lead (Apple watch) ECG twice a day and when they experience symptoms concerning for Afib.
12. To promote privacy of health information, a login will be required to access the app (created upon onboarding). Additionally, the iPhone will be set to password protected mode / face ID activated.
13. After obtaining consent, app permissions will be given. In order for an app to access any information on an iOS smartphone, the app must ask the user for permission and only if that permission is granted, can the app access that information. This is inherently enforced on all apps by the operating system. In our case we only will ask for permissions to access:
    - Relevant digital health data from iOS HealthKits, in particular: physical activity, blood pressure and heart rate.
    - Photos to store an insurance card or other cards like a stent card. Even if the access-permission is granted, it is limited to the images specified by the user.
    - Display notifications, such as an alert to take medications.
    - Send email function to allow users to send a PDF of their consent form or a PDF of relevant health info (e.g., medication list, progress report) to their care providers. No app is allowed to read any data from the mail app.

    Participants will be given the option to take a photo in which they are identifiable using the app and can specify authorization for internal or external use via the standard media consent form.
14. All patients in the Corrie VCare Afib program will receive weekly check-in calls from Johns Hopkins Cardiology Nurse (Stephney Blair or Courtney Eddy) – Corrie Afib coach to guide patients with individualized risk factor modification. If during conversation with the Corrie Afib health coach patients report concerning symptoms, including chest pain, shortness of breath and more, the health coaches will follow study Standard Operating Procedure Protocol to handle the different scenarios (attached in supplementary documents in Section 20.2 Patients will be informed that the Corrie Afib team cannot replace their care teams and patients should contact

their clinicians, call 911 or go to emergency room when experiencing symptoms or abnormal vital signs.

15. Patients in the Corrie VCare AF program will also receive messages tailored to their risk factor to facilitate lifestyle modification. Text messages which will be sent as push notifications via an app. Corrie Message Bank has been developed by combining validated messages from mACTIVE trial, American Heart Association's Care Pathway messages and patient generated messages. (Attached as supplemental document in Section 20.2). There are slight modifications in the message bank for Afib version compared to cardiac rehabilitation version approved by the IRB (IRB00308410) with addition of sleep apnea messages and modified physical activity messages. Patient specific risk factors will be reviewed by the chart review and confirmed with patients. Then based on patients' goals for each risk factor messages promoting building healthy habits for patient preferred risk factor will be sent to them with patient desired frequency.
16. Through the app patients in Corrie VCare AF program will be able to record ECG (using Apple Watch device), log CPAP wear times, record their vital signs, symptoms and perceived triggers. They will be able to alert their clinician via app and receive guidance for episode management. They will also be able to alert health partner (pre-specified in the app) that they are experiencing Afib episode. App will alert patients that if they are experiencing medical emergency, they should call 911.
17. At 12 weeks follow up, all study participants will receive a survey via REDCap to report any adverse events - stroke, emergency room visit, heart attack or hospital readmission. If a patient is readmitted to a Hopkins affiliated hospital their record will be searched for confirmation and cause of readmission. If the person is readmitted to an outside hospital, we will email them an Authorization for Release of Health Information form asking for permission to obtain their records of readmission. If patients cannot be reached, we will contact their emergency contact to identify whether the patient is alive and also search electronic health records, if death is reported it will be verified by death certificates or health records.
18. Study measurements and their timing is summarized in Table 2. Detailed list of data elements collected is uploaded in Section 20.2

Table 2. Study visits and variables obtained (comprehensive list of variables uploaded in Section 20.2)

Visit 1. Baseline visit	Virtual Visit at 3 months
From Chart (day of enrollment)	
sex	
age	
race/ethnicity	
insurance type	
contact information (email, phone)	
Enrollment location	
smartphone ownership	
height	
hypertension	
diabetes	
dyslipidemia	
left ventricular ejection fraction (latest within 6 months)	
aortic dissection	
icd	

cardiac surgery within 12 months	
hypertrophic cardiomyopathy with >25mmHg resting gradient	
cardiac arrest or ventricular arrhythmia	
Untreated high grade atrioventricular block	
Severe valvular disease (any)	
Mitral stenosis	
Presence of artificial heart valve or valve repair	
Coronary artery disease	
Congestive heart failure	
Atrial fibrillation type	
TIA/stroke	
CHADSVASC Score	
Vascular disease	
Sleep Apnea	
Incomplete revascularization of coronary artery disease	
pregnancy	
Implanted cardiac device	
Cholesterol panel (within 6 month of enrollment)*	Cholesterol panel (within 1 month of follow up)*
Hb A1c (within 6 month of enrollment)*	Hb A1c (within 1 month of follow up)*
Determined upon enrollment	
iPhone ownership	
Apple watch ownership	
Access to wifi	
Health Metrics	
Weight	Weight**
Blood Pressure	Blood Pressure**
From Corrie Health Analytic Platform & Devices (for individuals in Corrie VCare Afib Program)	
Heart rate	Heart rate
Average Weekly Step Count	Average Weekly Step Count
	User Engagement - Total number of interactions in the smartphone app and overall amount of time spent using the smartphone app per participant, collected via the Corrie Health Platform User Analytics
	Rhythm Check Proportion
	BP check proportion
	HR check proportion
	Medication log proportion
	Exercise log proportion
	Proportion of AF Episodes
	Number of times called nurse team
	Number of nurse coaching completed

	Symptom/AF episode concordance
	Identified AF trigger (self-report)
	User Satisfaction – System Usability Scale (Modified for Corrie Afib)
Surveys delivered via email through REDCap* **	
e-Health Literacy scale	e-Health Literacy scale
AFEQT	AFEQT
AFSS	AFSS
Medical Outcomes Social Support Survey Instrument (MOS Social Support Scale)	
Rate Your Plate	Rate Your Plate
Rapid Assessment of Physical Activity	Rapid Assessment of Physical Activity
minutes of exercise per week and perceived exertion score combination	minutes of exercise per week and perceived exertion score combination
Patient Health Questionnaire (PHQ-8)***	Patient Health Questionnaire (PHQ-8)
Generalized Anxiety Disorder 7 (GAD 7)	Generalized Anxiety Disorder (GAD 7)
Perceived Stress Score -10	Perceived Stress Score -10
Sociodemographic survey (education level, income level)	
Smoking Status	Smoking Status, quitting attempts
Alcohol use status, AUDIT questionnaire	Alcohol use status, AUDIT questionnaire
Sleep Apnea diagnosis, CPAP use	Sleep Apnea diagnosis, CPAP use
Sleep Characterization tailored for Afib patients	
Berlin Questionnaire (sleep apnea screening)	
	Adverse Outcome Survey
** Patients will be advised to complete those surveys within 48 hours of enrollment. The standard email greeting is included as a Supplemental Study Document. Survey responses will be recorded electronically via REDCap. All surveys are uploaded in supplementary data material section.	
	The hospital costs (in US dollars) for emergency department (ED) visit, hospital readmission, and acute myocardial infarction (MI) will be compared between Corrie Virtual Afib Program and usual care groups.
*If available ** Blood pressure cuff and scale will be mailed to patients at 12 weeks to obtain self-assessment at 12 weeks *** If PHQ 8 score is ≥10 and patient is randomized to Corrie VCare Afib program, study team member will ask patient to obtain permission from patients primary care clinician to exercise at home and won't be allowed to engage in exercise portion of the intervention until patient confirms permission from the treating clinician."	

b. If your study involves data/biospecimens from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies. Please note: Certificate of Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016. If this situation applies, Section 36, question 6 in the application will need to be answered "Yes" and "Hopkins Faculty" should be selected in question 7. No other documents are required.

N/A

c. Study duration and number of study visits required of research participants.

Each participant will be enrolled in the study from the time of enrollment for 12 weeks. Study visits will occur at baseline only, 3 months follow up visits will be virtual limited to data collection remotely as above (Table 2).

d. Blinding, including justification for blinding or not blinding the trial, if applicable.

Although blinding participants or study team members enrolling patients is not possible, outcome assessors will be blinded to intervention allocation.

e. Justification of why participants will not receive routine care or will have current therapy stopped.

All participants will continue to receive usual care.

f. Justification for inclusion of a placebo or non-treatment group.

All participants will continue to receive usual care.

g. Definition of treatment failure or participant removal criteria.

For participants with Corrie VCare Afib program: If an individual stops using platform for >30 days or does not respond to phone calls from study team or after failing to complete the study surveys after 7 days without response to phone calls the participant will be considered lost to follow up.

For participants in the Control group: If the participant does not respond to phone calls after failing to complete the study surveys after 7 days, the participant will be considered lost to follow up.

h. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

When the study ends or a participant's participation in the study ends prematurely, participants in the Corrie VCare AFib program who have received loaned smartphone will be expected to return the device, if they chose to continue using devices they will be allowed to keep the rest of the study equipment. Otherwise we will ask patients to return Apple Watch device.

Participants may be given the option to participate in future research studies

i. If biological materials are involved, please describe all the experimental procedures and analyses in which they will be used.

N/A

5. Inclusion/Exclusion Criteria

Inclusion Criteria

- 18 years or older
- Paroxysmal Atrial Fibrillation

Exclusion Criteria

- Non-English speaking
- Does not own an iPhone 5 or newer
- Moderate to severe mitral stenosis
- Presence of Artificial Heart Valve
- Severe valvular disease (any)
- Physical disability that would preclude technology use, safe and adequate exercise performance
- Hearing or Visual Impairment that would preclude technology use
- History of fall one or more times in the last year
- Hypertrophic obstructive cardiomyopathy with peak resting left ventricular outflow gradient of >25 mmHg
- Known aortic dissection
- Severe resting arterial hypertension (SBP >200 mmHg or diastolic BP >110mmHg) upon enrollment (obtained during clinic visit)
- Mental impairment leading to inability to cooperate with study procedures
- Untreated high degree atrioventricular block
- History of cardiac arrest, sudden death
- History of MI
- Left ventricular ejection fraction <40%

- Clinically significant depression
- Presence of implanted cardiac device
- Incomplete revascularization procedure
- Pregnancy (pregnancy status will be determined by self report and at enrollment patients will be asked to report if they become pregnant in which case they will be asked to stop participating in the study and their data will be excluded from the intention to treat analysis. Of note, Afib generally affects older individuals with only <0.1% prevalence of Afib in women under age of 55).
- Previous open-heart surgery
- Unsafe to participate in the program as per treating clinician

6. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used.
b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.
c. Justification and safety information if non-FDA approved drugs without an IND will be administered.

1. The Corrie app is available on iPhone platforms. In discussion with an FDA-consultant, because the functionality of the app is as an organizational and navigational tool for patients, it does not require pre-approval from the FDA before use with patients. It falls within the category of mobile apps for which the FDA is exercising enforcement discretion.
2. Apple Watch, Itamar Watch PAT, and Omron blood pressure cuff all have received FDA clearance and are safe for patient use (see supplementary documents).

7. Study Statistics

a. Primary outcome variable.
b. Secondary outcome variables.
c. Statistical plan including sample size justification and interim data analysis.
d. Early stopping rules.

In this two-arm, parallel group RCT we will evaluate feasibility (primary outcome) of a 12-week Corrie AF digital toolkit intervention. We will recruit a convenience sample of 100 patients with paroxysmal atrial fibrillation. With 100 patients enrolled we would be able to detect difference in quality of life measured by AFEQT of ~ 19 points with 80% power and 0.05 alpha but it would be unlikely to see such large effect size with 12 week intervention. Similarly, we will be able to detect 10% difference in AF burden, previous studies have shown 7.6% point reduction in AF burden with 12 week exercise program and given our comprehensive approach we anticipate that we will achieve at least 10% difference in AF burden from baseline to follow up in the intervention group.

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.
b. Steps taken to minimize the risks.
c. Plan for reporting unanticipated problems or study deviations.
d. Legal risks such as the risks that would be associated with breach of confidentiality.
e. Financial risks to the participants.

Risks include feeling tired with filling out surveys. Other risks include risk of adverse events with diet and exercise. However weight loss is class I recommendation by American Heart Association and American College of Cardiology guidelines for atrial fibrillation patients. We will not ask patients to do extreme diet or engage in exercise that is beyond what they can safely tolerate. Furthermore, we have implemented the following interventions to further minimize the risk (1) We will exclude patients who are not deemed fit for study participation by treating clinician (2) We will only enroll participants in the study who have significant comorbidities (see exclusion criteria) (3) We will provide nurse led weekly check-ins with patients to guide them accordingly if their vitals are not within normal range or if patients report concerning symptoms. The guide for these check-ins has been compiled based on the Johns Hopkins cardiac rehabilitation program and atrial fibrillation clinic protocols and is attached in supplementary document section.

Risks also include patient relaying on study clinician during the Afib episode that is causing medical emergency. To minimize this risk, we will have disclaimer that if patients are experiencing medical emergency, they should call 911. Otherwise patients will be connecting with healthcare team as they would in usual care team, except they will have option to use the App to make the connection.

Another risk is breach of confidentiality. The Corrie Health digital platform uses a high level of personal security password protection and encryption to meet privacy standards. The study team will disclose to the participant and IRB if a breach of confidentiality occurs.

There are no study procedures that would put patient at financial risk.

9. Benefits

a. Description of the probable benefits for the participant and for society.

Overall, the participants in the intervention group will be given access to a Corrie Vcare Afib program. Through this intervention they may benefit from greater knowledge about their diagnosis, risk factors, how to modify their risk factors and develop self-efficacy to continue risk factor modification after completion of the program. Furthermore, they may benefit from physical activity and develop skills that help them manage their medications as well as follow-up appointments with their clinicians. Patients enrolled in usual care may not derive significant direct benefit. Moreover, the data that they contribute as a research participant could help others in the future.

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

The Corrie App, Apple Watch, One time Itamar Watch PAT home sleep study, blood pressure monitor, and scale will be provided to participants if they do not own one at no cost to the them. If participants opt to continue using devices after the completion of the program they will be allowed to do so. Participants randomized to usual care arm will be provided with blood pressure cuff, scale as well as home sleep study test after the completion of 12 week follow up surveys.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

Costs associated with hardware and software support for Apple Watch and Watch PAT single use home sleep study will be covered by companies, Apple and Itamar.

12. Transfer of Materials

Transfer of biospecimens from Johns Hopkins to another organization for research purposes and receipt of biospecimens from an outside organization for your research must adhere to JHU policies for material transfer (https://ventures.jhu.edu/faculty-inventors/forms-policies/) and biospecimen transfer (https://hpo.johnshopkins.edu/enterprise/policies/176/39187/policy_39187.pdf?_=0.622324232879).

Please complete this section if your research involves transfer or receipt of biospecimens.

a. Will you **receive** biospecimens from an external entity for this research? [Yes/No].
If "Yes", please confirm you will secure an MTA/research agreement from the appropriate office (JHTV/ORA) prior to transfer.
See: https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/ .

b. Will you **transfer** biospecimens to an external entity as part of this research? [Yes/No]
If "Yes", please address each of the following:

1) Describe the nature of the research collaboration with the external entity and the rationale for the transfer. (Include an explanation of your intellectual contribution to the design of the research study, resulting data and sharing, and participation in the planned publications.)

2) Please confirm you will secure an MTA through the appropriate office (JHTV or ORA) prior to transfer.
(See: https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/.)

3) If the biospecimens you intend to transfer were obtained through clinical or research procedures at Johns Hopkins and "Other" is selected in Item 4, Section 23, please submit the following items in that Section:

a. A pdf version of a completed JHTV Online "Material Transfer Agreement Request Form for Outbound Material" https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/ **OR** a copy of the COEUS PD (Proposal Development Summary).
b. A completed Biospecimen Transfer Information Sheet https://www.hopkinsmedicine.org/institutional_review_board/forms/.
c. A signed and dated "De-identified Human Subject Certification" https://www.hopkinsmedicine.org/institutional_review_board/forms/
d. Approval documents from recipient site, if applicable.
e. Copies of the consent forms associated with the IRB protocols under which the biospecimens were collected, with language appropriate to this transfer highlighted.
f. The name of the specialist you are working with in ORA to complete a contract/MTA.

Please see the following website for more information about transferring human biospecimens to outside entities:
https://www.hopkinsmedicine.org/institutional_review_board/news/announcement_transfer_human_biospecimens_outside_entities.html/ .

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