Physical Activity and Pacemaker Study

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Overview of approach: Based upon our previous work, the overall experimental design of this study is a small pragmatic randomized controlled trial (RCT). A general study diagram of events and procedures is present in Figure 2. Potential subjects who fit inclusion/exclusion criteria will be approached for enrollment once they are identified as candidates for permanent pacemaker implantation or as patients with already implanted Medtronic Revo or EnRhythm pacemakers. Individuals with, on average, less than 2 hours/day of active minutes over the prior 3 months (based in the pacemaker's internal accelerometer daily active minute reading) will be eligible for randomization. For individuals enrolled at the time of pacemaker implantation, the average active minutes for the time period of 3-6 months following implantation will be used to assess eligibility for randomization. At the time of enrollment all subjects will have a detailed medical history obtained. Thirty participants will be randomized across 2 parallel groups: an intervention group (n=15), or a Patient Usual Care (PUC) group (n=15). The PAC intervention follows the 5 A's (Assess, Advise, Agree, Assist, Arrange) model, which has been shown to be an effective clinical counseling tool for other health behaviors.14 Implanted Medtronic Pacemaker accelerometer data will be used to Assess physical activity levels. Subjects in the low active group will be referred to an intervention expert on the study staff. Eligible patients will then be Advised of their activity levels, and migrate through the 5 A's intervention model for 12 weeks. A fuller description of the intervention is included below. At the end of the 12 week active intervention, subjects in the intervention arm will enter a maintenance phase for an additional 3 months. During the study, pacemakers will be interrogated remotely or at clinic visits every 3 months. All subjects in the intervention arm will be contacted every 2 weeks to assess how they are doing with respect to the intervention. The study schema is shown in Figure 1, described in accordance with the CONSORT statement's recommendations for randomized clinical trials. An outline of study procedures is presented in Table 1.

Study setting.

Subjects will be recruited from individuals who require permanent pacemaker placement at Froedtert Hospital and Zablocki VA Medical Center, both located in Milwaukee, WI.

Participant eligibility and recruitment.

Criteria for Enrollment and Randomization.

Inclusion Criteria:

1) Age ≥ 55 years old

2) Clinical indication for placement of permanent pacemaker or currently implanted pacemaker

3) LVEF of ≥ 50% by most recent echocardiogram.

4) Able to ambulate

5) Average active time of ≤ 2 hours/day based on Revo or EnRhythm Accelerometer read out for the 3 month period prior to enrollment

6) Able to take 650 steps over 10 minutes following pacemaker implantation (~2-2.5 mph walking speed)

Exclusion Criteria:

1) Follow up for implantation planned at a non-study center at the time of implantation.

2) Individuals with and expected life span of 1 year or less at the time of implantation

3) Known history of cognitive impairment or inability to follow study procedures

4) Lack of stable internet access

Randomization. Randomization will occur at the patient level. Upon potential eligibility being identified, subjects will be randomized in 3 blocks of 10 participants and randomized 1:1 to each study arm. We will enroll until we reach 15 subjects in each study arm who complete all study procedures. Randomization will be delivered via a random number generation sequence. Due to the nature of the trial, research staff, clinicians, and patients will not be blinded to patient assignment.

Physical Activity Counseling Intervention Group: The 12 week intervention is a multifaceted intervention that follows the 5 A's (Assess, Advise, Agree, Assist, Arrange) model, designed to be both simple to implement and follow for patients. It mimics a referral for education model that is used for patients who require a nutritionist or other specialist for behavioral modification. The intervention includes the following elements.

1) Assess: Subjects will undergo a physical activity assessment, utilizing the implanted Medtronic Pacemaker accelerometer data.

2) Advise: Eligible patients will be shown the graph from our recent publication demonstrating the relationship between decreased active minute time and mortality to help build the case that an intervention is necessary.

3) Agree: Those patients who agree enter into a shared decision making process to behavior change – in this case modifying physical activity behavior in an effort to decrease sedentary time.

4) Assist: The patient will receive a written prescription that includes their baseline Medtronic Pacemaker accelerometer data, and a target to increase their activity. Activity will be increased using the following:

a. Self-regulatory monitoring: A pedometer with a target to increase steps by 10% per week, to a target of 10,000 steps/day. A calendar will be given for patients to write down daily amounts.

b. Brief printed support materials – on different behavioral strategies to increase active behaviors

c. A list of freely available internet-resources

d. Bi-weekly telephone support: A member of the study staff will call each participant randomized to the PAC intervention group every other week. Calls will be limited to 5 minutes and used to offer support, advice, and solicit feedback.

5) Arrange: A follow-up visit will be arranged for week 12, to retrieve outcome data for physical activity from the implanted Medtronic Pacemaker accelerometer. Alternatively, data will be obtained through convenient methods.

Overall, our approach employs key strategies proven to increase the adoption and retention of lifestyle integrated habitual physical activity in older adults.15,16 These strategies included the use of frequent feedback,15 self-regulation of activity,17,18 education and practice in realistic behavioral change strategies and goal setting,16 and rewarding.19

Patient Usual Care (PAC) Group: The PAC group will undergo Implanted Medtronic Pacemaker Accelerometer data retrieval, but this data will not be shown to the patient, nor used to alter behavior. This group will follow their typical clinical routine, and therefore represent a usual care approach.

Communication of Physical Activity information: All individuals with pacemakers will undergo interrogation of their device every 3 months during entire study period, including intervention phase and follow-up phase.

Outcomes: The primary outcome for this study is the number of active minutes as measured by the Medtronics Implanted Pacemaker accelerometer.

Statistical Methods: Baseline demographic and clinical data will be compared between groups by unpaired t-tests, Chi-squared tests, or non-parametric equivalents as appropriate. The primary outcome will be compared between

Data Analyses

SPSS 24 and SigmaStat 12.5 were employed for data analyses. Data will be analyzed on a per protocol basis given that the goal of this pilot. Baseline characteristics will be compared between groups using unpaired t-tests, chi-

square, or Fisher's Exact test as. Differences in step counts and pedometer determine active time over the study period will be investigated using general linear models for repeated measures with the randomization group assignment as the between subjects variable and a three factor within subjects comparisons representing the three measurement time points with the Tukey test applied for post-hoc comparisons if significance of the overall models was detected. Correlations between step count measurements and PDAH measurements were performed using Pearson's r test. $P < 0.05$ were considered significant.