Official Title: Home-Based Health Management of COPD Patients
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Study Protocol
The study will be conducted by Dr. Benzo and his team at the Mayo Clinic. Following an initial home visit to consent the subject and ensure that all study inclusion and exclusion criteria are met, an individual appointment will be scheduled for each subject at the Mayo Clinic. The subjects will meet the health coach, receive training on using the system, and will perform one initial exercise session to ensure safety and cognitive acceptance of the intervention. The training on how to use the system will be conducted by the health coach and will include demonstration, practice, and written materials for subjects to take home. During this initial session at the Mayo Clinic each subject will also provide demographic data and complete a Chronic Respiratory Disease Questionnaire (CRDQ). For the eight week **intervention** period each subject will receive weekly health coaching plus activity monitoring. The health coaching is described below. For the activity monitoring each subject will be asked to wear the ankle and wrist monitor for the entire day, excluding bathing. Each subject will also be asked to wear a fingertip pulse oximeter while completing an exercise routine. Patients will be asked to perform the exercise routine six days a week, including at least a 5 minute walk and walking a total of 15 to 20 minutes during the day for the sole purpose of rehabilitation. The exercise routine will be the same as phase I and each participant will be provided a DVD to follow. Each participant will also have a docking station with a tablet computer. The tablet will prompt the participant daily to answer a brief series of questions on their well-being at the time of taking off the monitors at the end of the day for charging. The subject's daily steps will be available on the wrist monitor and the tablet computer. The tablet will also provide a simplified version of the report that goes to the health coach, including trend and detail data on the subject's daily activity and physiological measures.

During the eight week **control** period no health coaching will be provided or exercise prescription requested. Participants will not receive any information on their activity nor will they be asked to complete the well-being questions. During the last week of the control period all participants will be asked to wear the SenseWear Pro Armband for four days to collect data on their daily steps.

During week 9 all participants (half of whom will be in the intervention period and half in the control period) will be asked to repeat the CRDQ via telephone. At the end of week 17 each participant will be asked to complete the CRDQ via telephone and return all of the equipment.

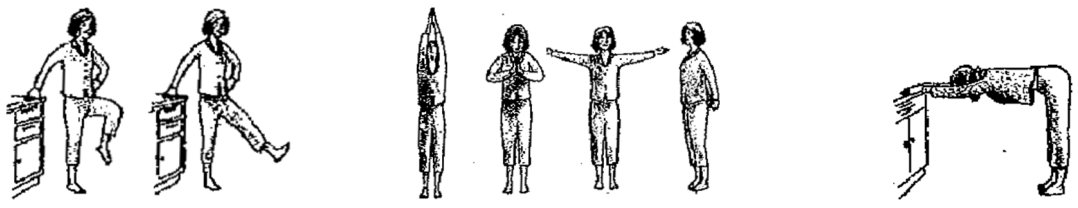

Figure 10: Diagrams showing a few representative low-dynamic exercises.

Health Coaching
Each subject will be asked in the first encounter to define a particular place and time in which they can perform rehabilitation. The environment (physical and mental) is a critical piece to adopt new behavior. Each subject will have a weekly coaching call to discuss their rehabilitation and health process with the coach. The calls will be structured using motivational interviewing

and will follow the protocol published by Dr. Benzo.[61] The coach will review with the patient the data from the activity monitoring system (daily steps, physiologic measures – oxygen saturation and heart rate, and duration, frequency, and time of day of the rehabilitation exercise). The coach will also review the daily answers to the well-being questions. Collaboratively, goals for rehabilitation exercise for the following week will be set, based on the information gathered and patients personal preferences (like modifying the exercises or the walking routine, for example, if the exercises initially proposed are not to the liking of the patient). In any case there will be a routine of upper extremity and balance exercises and a walking routine. Each call will last about 12 minutes. All calls will be taped to ensure compliance with the protocol. To complete the intervention, each subject will need to complete phone calls with a health coach at least six out of the eight weeks. At the end of the eight weeks of intervention, a qualitative semi-structured interview will be conducted with each subject by the health coach to gather information on the pros and cons of the process and intervention. This will be in addition to the CRDQ. While the monitoring of the patient will not be real time, any significant physiologic abnormality measured during rehabilitation and transmitted to the server (o2 saturation less than 80% or heart rate > 140 or <40 beats per minute) will prompt a message to the coach to initiate a call to the participant to stop the process and investigate the event. Any time such a call is initiated, the health coach will also contact the subject's health care provider at the Mayo Clinic COPD practice. Dr. Benzo will also be alerted anytime such a physiologic abnormality is measured and will ensure that the appropriate response is initiated. Detail of the training of the health coaches has been reported by Dr. Benzo.[61]

Sample Size

We calculated the sample size based on our previous published data.[62] A total sample of 104 patients (52 per group) is needed to detect a difference of 0.5 in the Chronic Respiratory Disease Questionnaire (the minimally clinical importance difference) with 80% power. See Figure 11. A sample of 104 patients is necessary to detect a difference of 1000 steps with 80% power. We plan to recruit 115 patients due to an expected attrition of 10% as seen in Dr Benzo's published research in COPD rehabilitation. See Figure 12.

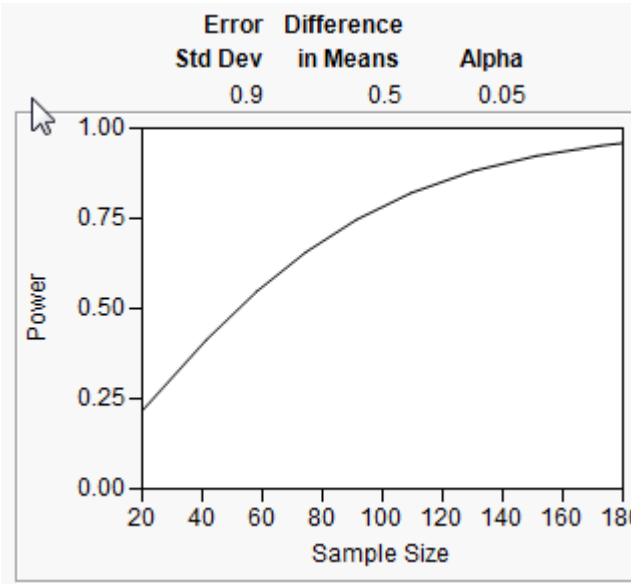

Figure 11: Diagram for power sample size for quality of life outcome

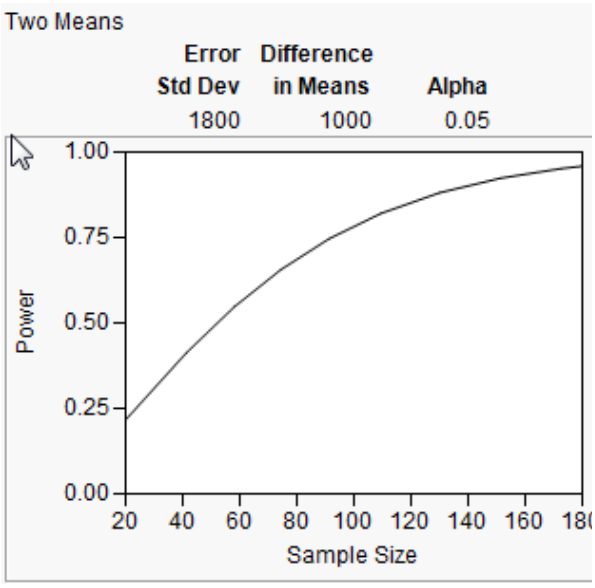

Figure 12: Diagram for power sample size for steps outcome

Analysis Plan

The primary outcomes of the study are: change in daily steps and change in quality of life between the intervention and control conditions. Change in daily steps will be measured by comparing the mean number of daily steps in weeks 1, 9, and 17 as measured by the activity monitoring system and the SenseWear Pro Armband. Quality of life will be measured by the CRDQ, which consists of 20 items across four dimensions. A change in the score of .5 on the 7 point scale reflects a clinically significant change.

Quantitative analysis: Descriptive and inferential statistics will be used. For daily steps descriptive statistics such as means, standard deviations, medians, ranges, and frequency distributions will be examined and calculated by condition (baseline versus intervention versus control period). The mean number of daily steps of each measurement period (baseline, 9 weeks and 17 weeks in all subjects: intervention, and control) will be compared for differences. A difference of 1000 steps is considered clinically meaningful across all severities of COPD.[63] We will also compare quality of life measured by the CRDQ (baseline versus intervention versus control period). The CRDQ data will be examined for each question, domain, and the entire instrument. We will also analyze daily steps and quality of life trajectories from weeks 1, 9, and 17 using repeated measures models. Regression equations and correlations will be performed to determine the impact of the system/coaching and adherence on outcomes adjusted by the most pertinent variables in COPD (age, dyspnea level, lung function, exacerbations and comorbidities measured by the Charlson comorbidity index).

Multivariate, repeated-measures ANOVA will be used to analyze the main pre- and postintervention effects and interactions both between and within groups. If the overall ANOVA value was significant at the $p < .05$ level, post hoc independent-samples t tests will be conducted on the subscales of CRDQ

Qualitative analysis: We will conduct semi-structured interviews in the last week of the intervention period with all subjects. These interviews will collect data on the participant's experiences, opinions, perceived benefits and barriers, and impact on self-efficacy for behavior change and actual behavior change. An inductive coding approach will be used to condense these data and to identify themes. These data will be collected to identify potential improvements to study protocol or the system.