Study Protocol

Aides in Respiration (AIR) Health Coaching for Patients with COPD

NCT02234284

Last Updated September 8, 2014

Uploaded March 7, 2019

Each document must include a cover page with the Official Title of the study, NCT number (if available), and date of the document.

A. Goals and Aims

The goal of the Aides in Respiration (AIR) study was to evaluate the effectiveness of a health coach model for improving outcomes for low-income urban patients with COPD. We conducted a randomized trial comparing 9 months of health coaching plus usual care (health coached arm) to usual care (usual care arm) alone for patients with moderate to severe COPD cared for at 7 federally qualified health centers (FQHCs). The specific aims of the study were:

Specific Aim 1. To compare disease specific quality of life for patients randomized to receive 9 months of health coaching plus usual care to those randomized to usual care alone. Our hypothesis was that mean quality of life, assessed by the Chronic Respiratory Disease Questionnaire total score and dyspnea domain score at 9 months, would be greater in patients in the health-coached arm when tested against the null hypothesis of no difference between health-coached and usual care patients.

Specific Aim 2. To compare the number of exacerbations of COPD experienced by patients in the health coached arm to those in the usual care arm during the 9 month period starting at enrollment. COPD exacerbation was defined as an emergency department visit or hospitalization for COPD-related diagnosis or the outpatient prescription of oral steroids for COPD-related diagnosis. Our hypothesis was patients in the health-coached arm would experience fewer exacerbations when tested against the null hypothesis of no difference between health-coached and usual care patients.

Specific Aim 3. To compare exercise capacity at 9 months for patients in the health-coached arm to those in the usual care arm. Our hypothesis was that patients in the health-coached arm would have greater exercises capacity as measured by the 6-minute Walk Test when tested against the null hypothesis of no difference between health-coached and usual care patients.

Specific Aim 4. To compare self-efficacy for management of their COPD for health-coached versus usual care patients at 9 months. Our hypothesis was that mean self-efficacy, as measured by Stanford Chronic Disease Self-Efficacy Scale would be greater in patients in the health coached arm when tested against the null hypothesis of no difference in self-efficacy between health-coached and usual care patients.

B. Study Design
Nine-month randomized controlled parallel trial, single-blinded.

C. Setting
This study was conducted at seven urban county-operated primary care clinics designated as federally qualified health centers (FQHCs) that primarily serve a low-income, publically insured patient population. Two of these sites are large academic residency teaching practices based at the public hospital that is part of the county-owned system. Pulmonary specialty care is available through the public hospital that is part of the health network. Clinic sites have integrated behavioral health services. All sites have had prior exposure to health coaching for diabetes, hypertension, and/or as part of complex care management programs**.**

D. Participants
The study enrolled low income and vulnerable patients receiving care FQHCs because these patients experience disparities in quality of care and disease burden and have been underrepresented in clinical research studies of COPD. Multiple clinic sites were necessary to obtain an adequate sample size.

E. Inclusion and exclusion criteria*:*
In addition to meeting diagnostic criteria for COPD, clinical inclusion for having moderate to severe COPD required at least one of the following:

- At least one hospital admission due to COPD-related diagnosis in the last 12 months;
- At least two emergency department visits due to COPD-related diagnosis in the last 12 months;
- Prescription of short term oral steroids (at least 40 mg for at least 5 days but <21 days) for respiratory symptoms in the last 12 months;
- Current prescription of anticholinergic inhaler;
- Current prescription of combination long-acting bronchodilator and corticosteroid inhaler;
- Prescription of home oxygen therapy (ever);
- Post-bronchodilator forced expiratory volume over 1 second (FEV1) < 80% of predicted (ever);
- Resting O2 Saturation <= 88% as an outpatient (ever);
- Arterial blood gas (ABG/PPO2) <=55 mm Hg as an outpatient (ever).

Non-clinical inclusion criteria were all of the following:

- Age $\geq$ 40 years;
- Able to be reached by telephone;
- Speaking Spanish or English;

Currently a patient at one of the 7 participating clinic sites with at least 1 outpatient visit within the last 12 months and planning to continue care at clinic for the next 9 months;

Planning to be in San Francisco area for at least 6 of the next 9 months, including at the end of study

Willing to attempt spirometry.

Exclusion criteria were any of the following:

Unable to participate in the study as judged by their PCP

Unable to travel to their primary care clinic

Unable to complete the enrollment process.

Spanish speaking patients were recruited by a bilingual research assistant. To maximize participation of from under-represented groups, we minimized exclusion criteria. Specifically, we did not exclude patients who were homeless, had substance abuse, mental illness, or other conditions as long as they were able to receive health coaching and participate in the study.

F. Health coaching intervention

Health coach training. The two study health coaches were college graduates without medical training or certification but who had previously worked with patients in the public health clinic system, one as a research assistant and the other as a volunteer health coach. Both received over 100 hours of training over 3 months using a COPD health coaching curriculum specific to the study. The curriculum was comprised of two primary domains: health coaching techniques and COPD-specific knowledge. The health coaching curriculum [CEPC website] focused on five areas: (1) active listening and non-judgmental communication, (2) helping patients create self-management goals and action plans, (3) healthcare navigation, (4) medication reconciliation and adherence and (5) closing the loop (checking for comprehension by asking patients to describe the key messages in their own words). COPD-specific training covered the physiology of COPD, related comorbidities, care recommended by the Global Initiative for Chronic Obstructive Lung Disease (GOLD),[5] prevention and management of exacerbations, and lifestyle management. Upon completion of training, coaches were required to score at least 90% on three exams assessing content knowledge and to demonstrate mastery of coaching skills through simulated role-plays and observed health coaching sessions.

Health coaching activities. Patients received health coaching for 9 months. Each health coach worked with a total of 50 patients over the two-year duration of the study, with a maximum caseload of thirty patients at any given time. Patient needs and preferences guided the frequency of contact, with a suggested minimum frequency of connecting with the patient once every three weeks. Health coaches were expected to complete an initial visit within 2–3 weeks of enrollment, to meet in person with the patient at least 3 additional times over the course of the study and to have a phone check-in call at least every 3 weeks, including within two weeks after each medical visit. Coaches were also expected to conduct at least one in-depth consultation with the study pulmonary nurse practitioner specialist (PNPS) to optimize patient care and to attend at least one medical visit between the patient and their primary care provider

(PCP). Coaches provided patient education, worked with patients to set goals and develop action plans to reach those goals, facilitated patient access to clinical care and resources, and supported communication between patients, their PCP, and the PNPS.

As summarized below, coaches interacted with patients in one-on-one in person meetings, by telephone and during medical visits. Coaches also presented patients to the PNPS for consultation.

Initial meeting. The purpose of the initial meeting was to build rapport building and understand the patients' motivations, strengths, and barriers to self-management.

Subsequent meetings. Subsequent meetings occurred in person at the clinic or at the patient's home when possible, or by phone if an in-person meeting was not feasible. The purpose of these meetings, which generally lasting 15 to 90 minutes, was to set goals or address barriers to carrying out goals to assess patient knowledge, share information about target conditions, review inhaler use technique, and to assist with navigation of health and community resources (including making and keeping appointments, accessing classes and smoking cessation resources and meeting with a member of the behavioral health team). Home visits were utilized most frequently by patients that had difficulties with public transportation or general mobility. Home visits were also used to identify COPD/asthma triggers within the home, acquire accurate knowledge of what medications a patient has in the home, including any duplicate or expired medications, identify barriers to medication adherence, and ensure patients on oxygen have the necessary equipment.

Phone check-ins. Phone check-ins were done to provide on-going support for patient self-management, check for barriers to self-management and provide reminders for up-coming appointments.

Medical visits. Coaches also meet with patients at the time of their medical visits to conduct medication reconciliation, gather clinical information including administration of the COPD Assessment Tool, identify gaps in care and help patient to establish priorities and goals for the visit prior to the patient seeing the PCP. With the patient's permission, the health coach was present during the medical visit and could offer clarifications and support as needed. After the visit, the health coach reviewed the PCP's recommendations with patient to ensure patient understanding, and helped patients choose attainable goals and create an action plan for making changes to achieve those goals. The health coach called the patient approximately 2 weeks later to follow-up on action plans.

Consultations with the PNPS. The Health Coach consultation with the PNPS had several steps. Health coaches recorded patient medical history and co-morbidities, smoking history, risk and symptom assessment, COPD and asthma medications and treatment history, environmental triggers and screens for symptoms of sleep apnea, from review of the EMR and information supplied by the patient. The health coach then presented the patient's information to the PNPS who could gather additional information from the medial record if needed. The PNPS created a set of recommendations for changes in care using the GOLD guidelines, generally

without the need to see the patient. Recommendations could include changes to inhaler therapy, further diagnostic testing, and referrals to pulmonology, pulmonary rehabilitation, physical therapy, and other appropriate programs. Recommendations were communicated to the patient's PCP via the EMR and/or through secure email. The Health Coach followed-up with the patient to see if the recommendations had be accepted by the primary care provider and to provide education and support to the patient for implementing the recommendations.

G. Usual care control group

Patients randomized to usual care continued to have visits with their primary care provider over the course of the 9-month period. They received any resources their provider and their clinic offer as part of standard care, including: access to COPD educators, respiratory therapists, COPD education classes, pulmonary rehabilitation, or smoking cessation classes.

H. Recruitment and enrollment

Electronic billing records for the seven clinics and for the county hospital and ED were screened for patients with a COPD-related diagnosis (ICD-9 codes 491, 492, 496, 490+305.1, 493+305.1, 786+305.1) in the past year. Trained research assistants conducted chart reviews for patients identified by ICD-9 codes to gather clinical measures to determine eligibility criteria based on the previously stated criteria. Primary care providers received a list of their patients who appeared to be eligible after chart review and were asked to exclude those with severe physical or cognitive impairment, or who were known not be otherwise be eligible (e.g. deceased, no longer seen at clinic, or did not speak English or Spanish). The research associates then attempted to contact the remaining patients to confirm eligibility and, if eligible, to offer the chance to enroll in the study. Patients who did not have a COPD diagnosis confirmed by spirometry but who otherwise appeared to be eligible were offered spirometry. Eligible patients interested in enrolling in the study were scheduled to meet with a research assistant at their primary care clinic and were enrolled with informed consent. Baseline measurements, which included a survey, a 6 minute walk test and spirometry, were obtained prior to the patient being randomized.

I. Collection of baseline data

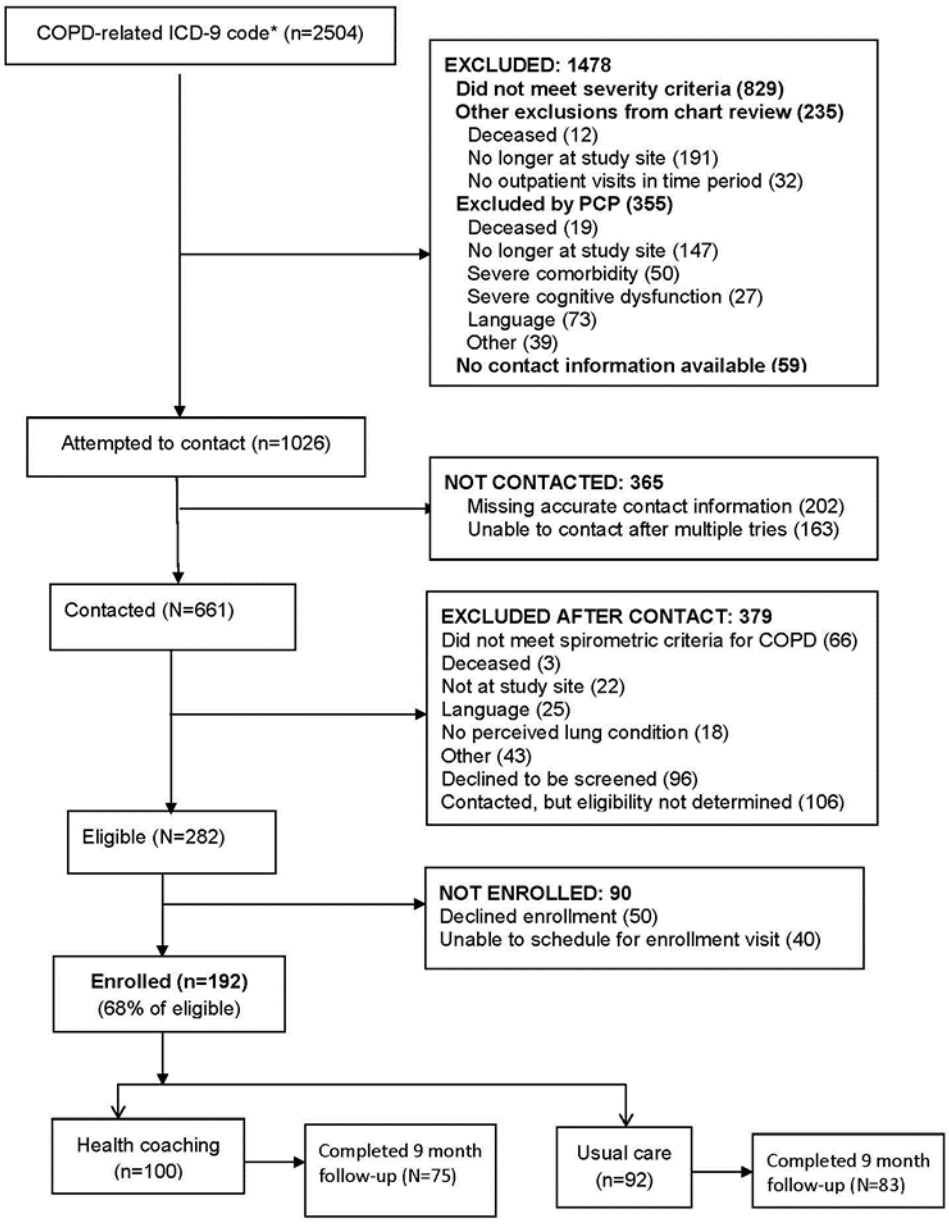
All study participants met with a research assistant (RA) at their primary care clinic. The research assistant administered the Patient Baseline Survey (see Attachments) either in English or in Spanish, based on the patient's preference. The RA also administered spirometry (see Attachments) the 6-minute walk test (see Attachments), and recorded weight, height, blood pressure, pulse and O2.

J. Randomization

A random binary sequence, stratified by site, was used to order study arm assignment into sequentially numbered envelopes. Once baseline measures are complete, the research

assistant asked the patient to open a sealed envelope with a randomization card indicating whether the patient will be assigned to the usual care or health coaching arm.

CONSORT Diagram for AIR Health Coaching Study for COPD



K. Outcomes

Study outcomes and references for the measures are shown in Table 1 below. All outcomes were measured at baseline and 9 months. Additional phone surveys at 3 and 6 months ask about smoking status, COPD-related quality of life (CRQ-SF) and bed days in past 4 weeks due to COPD. The 3 and 6 month surveys also asked about any ED visits or hospitalization at sites other than the county hospital. Medical records were then requested for these visits. Participants

receive $10 for each measure (survey, exercise capacity test, and spirometry) at baseline, $10 for each survey at 3 and 6 months, and $20 for each measure completed at 9 months in acknowledgement of their participation in the study.

COPD-related quality of life (Specific Aim 1) was The Chronic Respiratory Disease Questionnaire (CRQ) which generates scores in four domains (dyspnea, fatigue, physical function and mastery) and an overall score, has been validated in multiple studies. The CRQ has the advantage of having a near normal total score distribution and of being sensitive to change. and has establish minimal clinically important differences for total score and for each of its 4 domain scores (dyspnea, fatigue, physical function and mastery) We chose to use the standardized, self-administered version of the CRQ due to its ease of administration and superior discriminant validity.

A COPD exacerbation (Specific Aim 2) was defined as worsening of respiratory symptoms resulting in prescription of an antibiotic and/or steroid medication, an unscheduled or emergency visit, or a hospitalization. Similar utilization-based definitions have been used in previous studies for moderate to severe exacerbations and is consistent with guideline definition.

Exercise capacity (Specific Aim 3) was measured by the standardized 6 minute walk test (6MWT) which measures how far a patient can walk in 6 minutes, was administered by the RA using an established protocol recommended by the American Thoracic Society. The distance a patient is able to walk in 6 minutes, is a well-recognized and widely used measure of exercise capacity. The MICD for the 6MWT is generally considered to be 25 to 50 meters. Previous studies have documented the 6MWT is sensitive to measuring change over time.

Self-efficacy (Specific Aim 4) has been shown to predict functional capacity and quality of life for patients with COPD. We chose to measure self-efficacy using the 6 item scale developed by Dr. Kate Lorig and others at Stanford.

Patient-reported **quality of care** was measured using the short form of the Patient Assessment of Chronic Illness Care (PACIC)

Level of **COPD symptoms** was assessed using the COPD Assessment Test (CAT).

Lung Function was assessed by spirometry conducted by the research assistant using the VMAX Vyntus SPIRO with SentrySuite. All spirometry results were reviewed by the Director of the Community Spirometry program to determine quality based on American Thoracic Society (ATS) guidelines. To be used, spirometry had to receive a grade of C or higher. Patients were allowed a maximum of 10 attempts at either pre- or post-bronchodilator spirometry. If a patient felt unable to complete the test, the RA terminated the attempt and referred the patient to the pulmonary function testing (PFT) lab or to a respiratory therapist for testing.

Smoking status was ascertained by patient self-report. Patients who reported having smoking at all in the past 30 days were considered to be current smokers.

Patient-reported **medication adherence** was assessed using the Morisky Medical Adherence Scale (MMAS4)

COPD knowledge was assessed using 10 questions developed for the current study.

Inhaler use was observed by research assistants and documented using checklists specific to each type of inhaler (see Attachments). Checklists were based on published checklists and consistent with manufacturers' directions for inhaler use.
Symptoms of depression in the previous 4 weeks was measured using the Patient Health Questionnaire 8-item version (omitting the question asking about suicidal ideation).
Functional status was measured by patient-self report of number of days unable to do usual activities due to COPD (bed days).
Utilization was assessed at the end of the study by review of EMR and of all records obtained from outside hospitals.
Guideline concordant care included prescription for COPD medication corresponding to GOLD recommendation by COPD category (A=low symptoms, low risk; B=high symptoms, low risk, C=low symptoms, high risk and D=high symptoms, high risk).

Table 1. Outcomes with reference to specific aim (SA) if relevant

Outcomes	Measure used	Source	Reference
Primary (SA 1)			
COPD-related quality of life	Short Form Chronic Respiratory Disease Questionnaire (SF-CRQ)	Patient survey	1-10
Dyspnea	SF-CRQ dyspnea sub-scale	Patient survey	1-10
Secondary outcomes			
COPD exacerbations **(SA 2)**	Review of medical records		11
Exercise capacity **(SA 3)**	6 Minute Walk Test	Administered by RA	12-16
Self-efficacy for managing COPD **(SA 4)**	Stanford Self-Efficacy for Managing Chronic Disease	Patient survey	17
Other pre-specified outcomes			
Patient-reported quality of care	Patient Assessment of Chronic Illness Care (PACIC)	Patient survey	18
COPD symptoms	COPD Assessment Test (CAT)	Patient survey	19-21
Lung function	Force Expiratory Volume at 1 second (FEV1) by spirometry	Administered by RA	
Smoking status	Smoked cigarette in past 30 days	Patient survey	NA
Medication adherence	Morisky Medication Adherence Scale	Patient survey	22,23
Knowledge of COPD	Individual questions	Patient survey	NA
Correct use of inhalers	Inhaler checklist for each type of inhaler (adapted)	Observed by RA	24-26

Functional status	Bed days due to respiratory problems	Patient survey	27, 28
Utilization by type of visit	Outpatient, urgent care, emergency department and hospitalizations	Review of EMR	NA
Post-hoc outcomes			
Symptoms of depression	Patient Health Questionnaire (PHQ-8)		29
Guideline concordant care	GOLD recommendations	Patient-report and review of EMR	5

L. Follow-up

Participant contact information, including phone numbers, address and emails, were obtained at enrollment the best way(s) to contact the participant was established. Participants in both study arms were contacted every 3 months by the RA and asked to complete a brief interval survey (see attachments) which asked about recent exacerbations, and current smoking status. Participants were paid $10 for each interval survey. To the extent possible, the same RA follow-up with participant each time to help build trust. For the 9-month, end of study measures, which required an in person visit, RAs met with the patient at the patients primary care clinic, helping to arrange transportation if needed. The proportion of patients completing surveys were similar between study arms at 3 and 6 months, was but higher in usual care arm at 9 months. Reasons for withdrawal from the study was documented to the extent possible, based on contacting the patient and reviewing the medical record.

M. Sample size

The original target sample size for enrollment was 250 patients allocated in a 1:1 ratio between study arms. Sample size and power estimates for comparison of the health-coached and usual care groups assumed a target power of .80 or higher and significance to be defined by a two-sided a = 0.05. Expected effect sizes and minimum clinically important differences (MCIDs) for each outcome, were derived from previous studies for the primary measures for the first 3 aims: COPD-related quality of life,[30] number of exacerbations,[31] and the 6-minute walk test.[32] Expected differences and minimal clinically important differences were not available for the fourth specific aim, patient self-efficacy of COPD management. Based on our previous experience in conducting randomized controlled trials in this population,[33] (Willard Grace) we assumed an attrition rate of 20%, resulting in 200 patients available for analysis at the end of the study. We further assumed an intraclass correlation coefficient (ICC) of 1% between clinic sites based on our previous experience. The target sample size gave us sufficient power to detect the anticipated differences between groups for each outcome variable, which are at least as large as the MCIDs previously established, as shown in the following table.

Table 2. Original study power based on 100 participants in each arm at end of study

Outcome	MCID*	Power of study to detect MCID	Difference expected based on previous studies	Minimum difference for which study has >80% power
CRQ-SF total	1.0	.99	.73-2.00	0.33
CRQ-SF dyspnea	0.5	.88	.76-1.06	0.45
# of exacerbations	22%	.90	20-26%	20%
6 minute walk test	50 m	.97	48-85 m	25 m

As detailed in section F18 below, we were not able to meet our initial goal of 250 patients and had modify our enrollment goal to 190 patients that, with a 20% attrition, was expected to yield 152 patients at the end of the study. The power for the revised sample size is presented below.

Table 3. Revised study power based on 76 participants in each arm at end of study

Outcome	MCID*	Power of study to detect MCID	Difference expected based on previous studies	Minimum difference for which study has >80% power
CRQ-SF total	1.0	.96	.73-2.00	0.45
CRQ-SF dyspnea	0.5	.78	.76-1.06	0.51
# of exacerbations	22%	.81	20-26%	22%
6 minute walk test	50 m	.92	48-85 m	35 m

O. References

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