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Study Protocol

The PuSHCon study was a randomized controlled trial of health coaching-facilitated pulmonary specialist consultations added to usual care (HC arm) versus usual care alone (UC arm) for patients with a diagnosis of asthma and/or COPD. The protocol is available at clinicaltrials.gov (NCT03695276). The study was approved by the UCSF Institutional Review Board (18-26335). Written informed consent was obtained from all study participants.

Setting

The PuSHCon study was conducted between October 2020 and January 2025 at ten urban Federally Qualified Health Centers (FQHCs) or "FQHC look-alikes" by the Health Services Resources and Services Administration. Eight participating study clinics were in the community and two were located at the county hospital medical campus.

Participants

Patients were eligible for enrollment if they had been seen in primary care at least once but had not been seen by pulmonary specialty care in the past 12 months, spoke Spanish or English, and had a diagnosis of COPD and/or asthma. To be eligible, they also had to report a high level of symptoms as measured by the COPD Assessment Test[1] or the Asthma Control Test,[2] or to have had two exacerbations or one hospitalization due to an exacerbation within the last year. While this was a pragmatic trial with eligibility based on presence of a diagnosis in the medical record, diagnoses were reviewed by a study physician (MK) and pulmonologist (GS) blinded to allocation arm, who reviewed spirometric and imaging data as well as other clinical criteria.

Recruitment, enrollment, and randomization within clinics

Potentially eligible patients were identified primarily through review of electronic medical records (EMR) from the previous 12 months for the 10 clinics and the county hospital and emergency department (ED). Patients with a COPD- or asthma-related diagnosis (ICD-10 parent codes J41 – J45) were assessed by review of electronic health records and their primary care provider (Figure 1). A research assistant (RA) attempted to contact the patients not excluded by telephone and mail to describe the study and conduct additional eligibility screening. Eligible patients interested in the study met with the RA remotely or at their primary care clinic for informed consent and study enrollment. Within each clinic, patients were randomized 1:1 to HC or UC, in blocks of 10, using a random generator (Microsoft Excel 360). Randomization by the individual, rather than by

clinic, was chosen when a pilot phase of the study found a higher ICC than anticipated, such that clinic-level randomization would require a sample size nearly 80% larger than individual-level randomization. In addition, individual level randomization enhanced recruitment of clinics by enabling the study team to offer coaching for some patients at each participating clinic. After obtaining baseline survey measurements, the RA activated a lookup feature to reveal the participant's study arm assignment.

Blinding

Blinding of patients and clinical teams was not feasible due to the nature of the intervention. While RAs were trained to gather unbiased data, it was not possible to completely blind them to study arm, as we could not prevent patients from revealing they worked with a health coach.

Health coaching (HC) training and fidelity

We used a health coaching model developed by the Center for Excellence in Primary Care[3] to train unlicensed health workers to support patient self-management using evidence-based patient-centered techniques such as motivational interviewing and action planning.[4, 5] The study Health Coach was a high school graduate with a diploma from a medical assistant program, bilingual in Spanish and English without medical licensure. The coach received approximately 30 hours of training over four weeks. COPD- and asthma-specific training was delivered to HC by two pulmonary specialists and covered the physiology of the conditions, related comorbidities, international disease management guidelines, and self-management skills that the HC would teach the patients. The coach shadowed the Pulmonary Specialist Nurse Practitioner (PSNP) in her specialty clinic and took part in existing educational classes on obstructive lung disease. The PSNP met weekly with the health coach to review cases, reinforce skills, and troubleshoot interventional activities.

Usual care (UC) arm

Patients randomized to usual care continued to have visits with their primary care provider over the course of their 4-month intervention period. They had access to any resources their provider and their clinic offered as part of standard care, including access to asthma or COPD educators, breathing education classes, pulmonary rehabilitation, assessment for co-morbidities, smoking cessation classes and pulmonary specialist referrals by the primary care clinician.

Pulmonary-specialist - Health coach Consultation (HC) arm

Patients randomized to the intervention arm continued to have access to all resources available through usual care. In addition, they received a health coach-facilitated consultation and support for 16 weeks, as our protocol previously described.[6] Health coaches first reviewed the EMR and met with the patient to complete the Pulmonary Specialist Consultation Form, a tool to organize patient information for the PSNP. HCs 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 HC then presented the patient's information to the PSNP who could gather additional information from the medical record if needed. The PSNP created a set of recommendations for changes in care using the GOLD/GINA guidelines without needing to see the patient.

The health coach was assigned 165 patients over the course of the study with a maximum caseload of 30 patients at any given time. The HC was expected to conduct at least one in-depth consultation with the study PSNP, ideally within the first 2-3 weeks of randomization, and to attend medical visits between the patient and their primary care provider (PCP) throughout the intervention period, whenever possible. Health coaches were expected to meet in person with the participant at least 2 additional times over the course of the study and to conduct a phone check-in call at least every 3 weeks, including within two weeks after each medical visit, resulting in at least 5 points of contact over 16 weeks. Additional contacts were guided by patient needs and preferences. Health coaching focused on helping patients identify and achieve self-care goals for their COPD using techniques from motivational interviewing and adult learning models. Specific content included asthma or COPD education, action planning for exacerbations, practicing optimal inhaler use, and facilitating consultation with a PSNP. The Health Coach documented interactions in a study-specific database.

Protocol Modifications

The original PuSHCon protocol planned for at least three in-person meetings between the health coach and participant during the 16-week intervention, with the health coach present at one or more primary care visits to facilitate implementation of recommendations. Due to COVID-19–related restrictions beginning in March 2020, the intervention was adapted to rely primarily on telephone and video visits. Health coaches received additional training to support patients with limited digital literacy in accessing video visits, although uptake remained low. When video was not feasible, education and skills training (e.g., inhaler technique review) were conducted via telephone using teach-back methods, supplemented with mailed or electronic educational materials and links to demonstration videos. The pandemic also reduced the availability of in-person primary care visits, limiting opportunities for the health coach to coordinate directly with

the patient's clinician during visits. To address this, health coaches used secure messaging within the electronic health record to communicate recommendations to primary care providers and to request approval for referrals, prescriptions, and other orders. These adaptations were documented in the study database, and fidelity monitoring accounted for both planned and adapted delivery modes.

Data Safety and Monitoring

A Data Safety and Monitoring Board (DSMB) was established prior to recruitment. The DSMB consisted of a pulmonary nurse specialist, a primary care physician and an epidemiologist. As directed by the DSMB, the research team reported ED visits and hospitalizations twice yearly and participant deaths within 30 days over the course of the study.

Data Collection

The study survey was administered remotely or in person by an RA at baseline and again at 16 weeks. Medical records were reviewed for receipt of guideline-based care (e.g., recommended medications, smoking cessation support as needed, immunizations, screening or treatment for comorbidities). Patients received a $40 gift card or cash for completion of measures at baseline and 16 weeks, for a total of up to $80.

Outcome Measures

Primary outcomes, as defined in ClinicalTrials.gov (NCT03695276) prior to the study launch, were the receipt of guideline-based care and the receipt of recommended medications. For *Receipt of guideline-based care*, we identified 13 guideline-based care recommendations (Table E1) based on international GOLD and GINA guidelines. For each participant, we identified the items for which the participant had an unmet recommendation ("care gap") at baseline. The outcome was the proportion of those care gaps that were addressed by 16 weeks, as documented in the electronic health record.

Table E1. Recommended care defined for Specific Aim 1

Recommended care	Condition	Gap closure defined as
Vaccines		
Influenza	All	No influenza vaccine within last year
COVID-19	All	No COVID-19 vaccine within last year

Recommended care	Condition	Gap closure defined as
Pneumococcal	All	No pneumococcal vaccine OR No second dose if older than 65 and at least 5 years since first
Medications		
Rescue inhaler	All	No short acting beta agonist OR No ICS (e.g. budesonide) for asthma patients
Inhaled corticosteroid (ICS)	Asthma	No ICS No high dose ICS for Moderate to Severe persistent asthma
Long-acting beta agonist (LABA)/ Long-acting muscarinic agent (LAMA)	COPD Moderate to severe asthma	Medications based on severity*
Self-management support		
Chronic lung disease (CLD) education	All patients at baseline	Referral to any CLD class or asthma home visit Patient-reported education on exacerbation management, breathing techniques, staying active
Smoking cessation support	Smoking at baseline	Smoking cessation or reduction OR Prescription of smoking cessation medications OR Patient-reported receipt of cessation support
Assessment or management of condition/co-morbidities		
Pulmonary function testing (PFTs)	No record of PFT	Had received PFT at follow up
Allergies	Positive screen on Respiratory Allergy Prediction Test†	Any of: New diagnosis, referral for consultation/testing, new allergy medication, patient-reported allergy management support
Gastroesophageal reflux disease (GERD)‡	Positive screen on GERDQ (score of >=8)	Any of: New diagnosis, new medication, patient-reported support for lifestyle management, referral for assessment
Sleep apnea	Positive screen on STOP-BANG (score of >=3)	Any of: New diagnosis, referral for testing or treatment, education received on impact of sleep apnea or use of positive airway pressure device
Any evidence of diagnosis clarification	Identified by pulmonary specialist	Any of: Change in asthma or COPD diagnosis, new testing (e.g., Chest CT, exertional oximetry, nocturnal oximetry), referral cardiology

* Medications based on severity based on GOLD or GINA guidelines.
COPD GOLD Group B: LAMA or LABA
Group D: LAMA, LAMA + LABA, or ICS + LABA
From 2024 onward: Groups B/E: LABA + LAMA
Moderate to severe asthma patients: LABA

† The Respiratory Allergy Prediction Test, a single item question associated with allergic rhinitis: “Have you ever been told by a doctor or nurse that you have allergies that may affect your breathing?” Source: Galimberti M, Passalacqua

G, Incorvaia C, Castella V, Costantino MT, Cucchi B, Gangemi S, Nardi G, Raviolo P, Rottoli P, Scichilone N. Catching allergy by a simple questionnaire. World Allergy Organization Journal. 2015 Dec;8(1):1-7.

‡The GERD-Q is a 6-item screening tool validated for identification of gastro-esophageal reflux disease. Source: Jones R, Junghard O, Dent J, Vakil N, Halling K, Wernersson B, Lind T. Development of the GerdQ, a tool for the diagnosis and management of gastro-oesophageal reflux disease in primary care. Alimentary pharmacology & therapeutics. 2009 Nov;30(10):1030-8.

For *Receipt of recommended medications*, we compared received medications to the minimal medications recommended based on their GOLD or GINA classification and coded each participant's care (0=Not receiving all recommended medications; 1= Receiving all recommended medications) based on previously described methods,[7] at enrollment and at 16 weeks (Table E2). For example, a patient with moderate persistent asthma who was not on at least a low dose inhaled corticosteroid at baseline was considered not to be receiving recommended medications; if they received the medication during the 16 weeks post baseline, they would be considered to have received recommended medications at 16 weeks.

Table E2. Defining receipt of guideline-based medications

Condition	Classification	Guideline for minimal medications
COPD	Prior to 2024	
	Class A	Rescue inhaler: Short acting beta agonist (SABA)
	Class B	Rescue: SABA AND Controller: Long-acting beta agonist (LABA) OR Long-acting muscarinic agent (LAMA)
	Class C	Rescue: SABA AND Controller: Long-acting muscarinic agent (LAMA)
	Class D	Rescue: Short acting beta agonist AND Controller: Long-acting muscarinic agent (LAMA) OR LAMA + LABA OR ICS + LABA
	After 2024:	
	Class B	Rescue: SABA AND Controller: LAMA AND LABA
	Class E (formerly C/D)	Rescue: SABA AND Controller: LABA AND LAMA

Asthma	Steps 1-2 (formerly intermittent or mild persistent asthma)	SMART Therapy: Inhaled corticosteroid (ICS) + LABA as needed OR Rescue: ICS + SABA together
	Step 3 (formerly moderate persistent asthma)	SMART Therapy with low dose ICS + LABA
	Steps 4 – 5 (formerly severe persistent asthma)	SMART Therapy with moderate dose ICS for

Pre-specified secondary outcomes included the proportion of patients in each arm who received chronic lung disease education, defined as referral to any class or one-on-one education on chronic lung conditions or patient-reported receipt of education on identifying and responding to signs of exacerbations, staying active, or breathing training. In addition, we measured several patient-reported outcomes, including disease-specific quality of life, as measured by the St. George Respiratory Questionnaire (SGRQ)[8, 9] and symptoms, as measured by the symptom subscale of the SGRQ. Patient-reported quality of care was measured using the short form of the Patient Assessment of Chronic Illness Care (PACIC) (mean item score 1-8).[10, 11] Self-reported adherence to inhaler therapy was defined as the proportion of patients taking all doses of controller medications as prescribed in at least five of the last seven days.[12] For the intervention arm, provider acceptance of recommended care was defined as the proportion of PSNP recommendations for which the provider took action, including placing of referrals, orders for new prescriptions, or approval for the health coach to follow up.

Additional outcomes not pre-specified in ClinicalTrials.gov included exacerbations and utilization of acute and primary care services were identified through the electronic medical records from participating clinics, the county hospital, and outside facilities for ED visits and hospitalizations that were viewable through the Care Everywhere feature in Epic. A study physician (MK) blinded to study arm reviewed cases to identify exacerbations with blinded consultation from the study pulmonologist (GS) as needed.

Analysis Methods

We summarize by arm the demographic and clinical characteristics of participants in the PushCon study using descriptive statistics but, following convention, do not compare characteristics between arms using statistical tests. To examine differential dropout by arm, affecting Week-16 survey outcomes only, we compare characteristics of participants with and without missing outcomes using chi-square or Wilcoxon rank-sum tests.

To analyze study outcomes, we used generalized estimating equation (GEE) models to estimate the mean (95% CI) ratio of arm-specific rates (for binomial or count outcomes) or geometric means (for continuous outcomes) and to generate 2-sided p-values, while accounting for correlated outcomes within study clinics. For longitudinal outcomes, assessed at baseline (after consent but before randomization; Week 0) and at the end of the intervention period (Week 16), we fit time and time*arm as fixed effects, and nest correlated outcomes within study clinics; for cross-sectional outcomes we exclude the time effect from the model. In the setting of RCTs, the constrained longitudinal data analysis (cLDA) approach, used here, estimates a common mean across arms at baseline; in contrast, the LDA approach would include a fixed effect for arm to estimate distinct mean outcomes at baseline. The cLDA model is equivalent to the ANCOVA model when no data are missing; however, participants with some missing values, for example, at follow-up only, contribute to the cLDA model but not the ANCOVA model, increasing the cLDA's relative power.

Receipt of guideline-recommended care was calculated as a single proportion that can be modeled cross-sectionally. Each participant's outcome arises from a ratio of two counts, *p_care = x/d,* where *d* is the number of gaps in care noted over the 12-month pre-baseline (denominator, see Appendix A), and *x* is the number of these gaps that were noted as addressed during the 16-week intervention (numerator). To estimate the rate ratio (RR) (95% CI) we modeled *x* as a function of arm, specified a negative binomial distribution for *x* and used a log link with *log(d)* as an offset.

Receipt of all guideline-recommended medications is a binary longitudinal outcome. All medications recommended by GOLD/GINA guidelines for each participant were identified prior to the start of the study. The outcomes at Week 0 (using EHR data the 12 months prior to randomization) and at Week 16 (using EHR data from the 16-week intervention period) are scored *y=1*, if all were prescribed, and *y=0,* otherwise. Using a constrained longitudinal data analysis (cLDA) approach, which estimates equal rates by arm at baseline, we modeled *y* as a function of time and the time*arm interaction,[13] specified that *y* is binomial, and used a log link to estimate RRs at Week 16. Other binomial outcomes modeled analogously.

The *Saint George Respiratory Questionnaire,* a patient-reported outcome, is also measured longitudinally. It consists of 51 items in three domains: symptoms, activity, and impact, and has a total **score** ranging from 0 to 100, with higher scores indicating greater disability. The analysis method is the same for the overall score and its domains. Using the cLDA approach, we modeled *z* as a function of time and time*arm, used a log link, and specified that *y* has a negative binomial distribution. The model estimates geometric means (95% CI) and estimates the relative mean (RM) (95% CI) to compare the HC and UC arms at Week 16. Another outcome using this model is *PACIC*.

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