BreatheOut: Effectiveness and Feasibility of a Pharmacist-Led Culturally-Tailored Tobacco Cessation Program for Transgender and Gender Diverse Patients

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Residents and their preceptors

Introduction:
An estimated 1.4 million adults in the United States identify as transgender.[1] Transgender and gender diverse individuals are those whose gender identity, or internal sense of oneself in relation to gender, differs from the sex they were assigned at birth. Though studies assessing tobacco use in the trans population is lacking, currently available literature suggests a disproportionate burden of smoking across all tobacco and e-cigarette products.[2–4] In addition, this population faces health care access barriers that may reduce opportunities for smoking cessation intervention, such as financial strain, lack of knowledgeable and culturally sensitive providers, or mistreatment by medical providers and staff.[5]

Another factor contributing to increased uptake of tobacco and nicotine products in this community is the influence of tobacco marketing. There is a long history of targeted tobacco marketing in the LGBTQ+ community. These deep-seated ties are still prevalent today, with tobacco companies maintaining a strong presence at community events such as Pride, advertising in LGBTQ+ publications, and marketing through social media.[6]

For populations with unique factors contributing to smoking behaviors, culturally-tailored cessation programs have been proposed a way to mitigate these disparities. One approach to cultural-tailoring is through use of the PEN-3 Model, a framework for health promotion and disease prevention interventions that centers culture in the determinants of health behavior.[7,8] The PEN-3 Model explores the relationships between an individual's cultural identityas it relates to a certain health behavior. This approach has been used to identify perceptions, behaviors, and practices that either encourage or discourage a particular health behavior. This model has been used to address a number of issues in health care that impact minority and medically underserved populations, including HIV care, cancer screening, diabetes management, nutrition, and smoking cessation.[8] Previous studies have developed and assessed the effectiveness of culturally-tailored smoking cessation programs in populations with increased burden of tobacco use, including racial minority groups and the broader LGBTQ+ community.[9-14] No studies to our knowledge have described the design or evaluation of a culturally-tailored smoking cessation program specifically for transgender and gender diverse individuals.

Evidence supports that pharmacist-led interventions in tobacco cessation improve abstinence rates compared to control groups.[15] However, there are no interventions described in the literature to date in which pharmacists have led a culturally-tailored tobacco cessation program or service. As some of the most accessible healthcare providers, pharmacists have untapped potential to address health disparities. In addition, pharmacists practicing under collaborative practice may be able to prescribe medications that assist in smoking cessation, which can expand access to and reduce cost for these agents. The culturally-tailored smoking cessation programs for LGBTQ+ individuals such as Bitch to Quit® and The Last Drag® took place in a community setting and did not integrate access to smoking cessation medication support within their programs[16].

Practice Site:
This study and program were developed and implemented at Equitas Health, a Federally Qualified Health Center (FQHC) look-alike serving the LGBTQ+ community. Providers, clinic staff, and pharmacy

staff are trained to create a healthcare home for patients and provide additional support such as financial assistance, case management, and social support networks. These supports aim to address social determinants of health, the conditions in individuals' environments and settings that affect their health and quality of life. Resources that address social determinants include access to affordable housing, education, availability of healthy foods, transportation access, and affordability of health care.

Objectives

The objective of this study is to develop, implement, and assess the feasibility and effectiveness of a culturally-tailored smoking cessation program for transgender and gender diverse patients led by a pharmacist in a community ambulatory setting. This study aims to provide a potential model for pharmacist involvement in the interdisciplinary healthcare team for transgender patients.

Methods:

Participants were recruited using three methods. Those meeting eligibility criteria were onboarded into the guided program, which consisted of three content areas over three or more visits. Visits were designed to deliver evidence-based smoking cessation interventions that were culturally-tailored using established techniques.

Study Population:
Participants were deemed eligible if they met the following criteria in their electronic health record: age 18 years or older, currently smoking tobacco products or e-cigarettes, and a non-cisgender gender identity. Participants were ineligible for this study if they were pregnant or planning to become pregnant within the next 3 months or required language translation for smoking cessation visits. The study team excluded any participant who could not give consent that they understood the treatment protocol.

Eligible Gender Identity entries within the health record include: Transgender Female/Male-to-Female, Transgender Male/Female-to-Male, Non-binary/genderqueer, Questioning Additional eligible Gender Identity entries include: Female (if Assigned Male at Birth) and Male (if Assigned Female at Birth).

Participant Recruitment:
Participants were identified through 3 pathways using the gender identity and sex assigned at birth demographic fields and tobacco use fields. Identification could be provider-initiated as part of standard care to the clinical pharmacy team through internal referral, pharmacy resident-initiated through a report in the electronic health record, and patient-initiated through advertising materials in the clinic and pharmacy at the two practice sites.

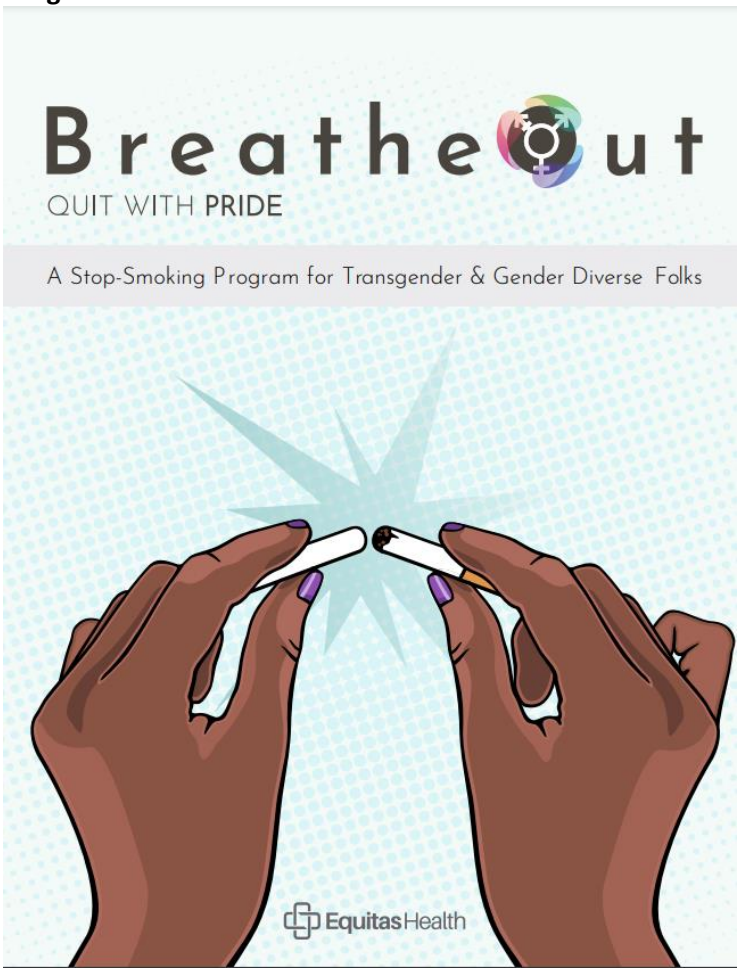
Patient-initiated identification was completed through a QR code on study advertisements posted in the clinic and pharmacies. This QR code linked to a secure online form where individuals may attest to their eligibility for the study and list their name and phone number for study recruitment.

Program Design:
BreatheOut is a new program designed for this study that delivers commonly used and research-validated techniques as part of the standard of care for smoking cessation through a lens that emphasizes factors specific to transgender and gender diverse individuals.

Counseling techniques and assessments used in this program followed clinical guidelines and United States Preventative Services Task Force (USPSTF) recommendations. These include the following: review of smoking history and motivation to quit, identification of high-risk situations and the generation of problem solving strategies, support and encouragement, and discussion of health benefits and strategies for planning a quit attempt. A newly-created and culturally-tailored program book containing visit activities and reflective prompts were given to patients at the start of the program to work through during their quit attempt.

The lens through which this program was designed and delivered is based on the PEN-3 model, a framework for health promotion and disease prevention interventions that centers culture in the determinants of health behavior.[7,8] This lens informs the aesthetic and design, terminology and phrasing, and sociocultural context of the delivery of the BreatheOut program. A literature review, institutional knowledge, and prior focus group data was used to identify peripheral, evidential, linguistic, and sociocultural strategies.[17] The result is emphasizing the impact of tobacco use in the LGBTQ+ community, incorporating cultural values and beliefs into evidence-based cessation strategies, and reinforcing individual strength identification and development in relation to the subject's transgender or gender diverse identity to build relevancy with study subjects.

Figure 1: BreatheOut Program Book Cover

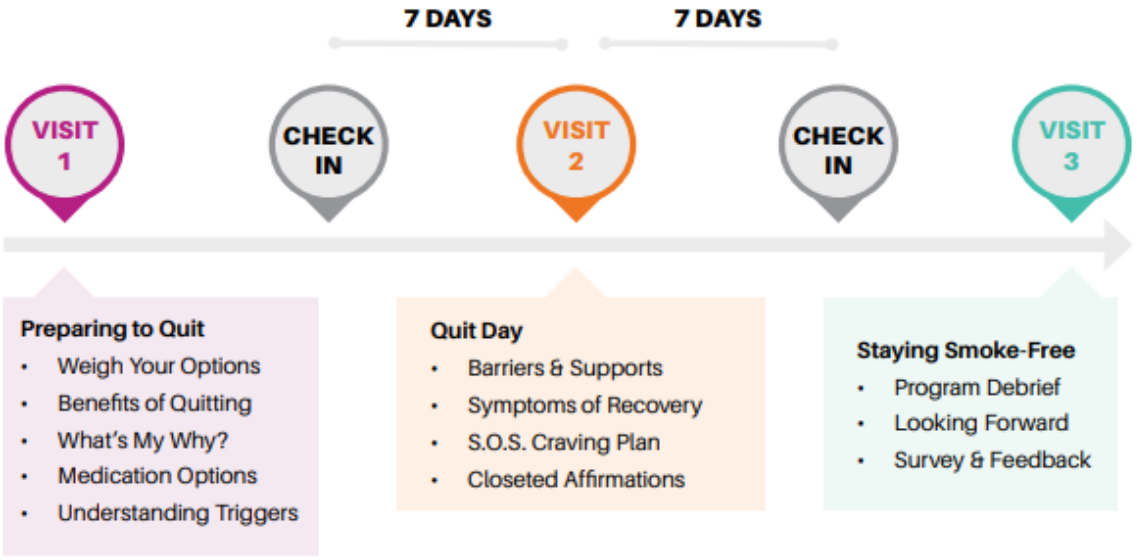


The program consisted of three 30-45 minute office or telemedicine (video or phone) visits with the pharmacy resident as well as two phone check-ins before and after the patient's quit date. These visits and check-ins could be repeated based on patient preference and progress toward smoking cessation. Smoking cessation medications were provided to the patient through collaborative decision-making and support for financial access if needed.

Study Design:
This is a prospective, observational pilot study to evaluate a culturally-tailored smoking cessation service for transgender and gender diverse patients.

Participants completed three smoking cessation visits with the resident pharmacist following a guided program. At the first visit, patients were offered medication assistance in accordance with guideline-directed therapy. Visit 2 was scheduled on the patient's selected quit date. Two phone check-ins were scheduled 7 days prior to and following Visit 2 to assess progress, medication access and side effects, and determine if adjustments to the program schedule were needed. At the patient's one-month follow up (Visit 3), maintenance of smoking cessation was assessed, and participants had an opportunity to complete an anonymous survey about the program.

Figure 2: Program Outline



Within the BreatheOut program, standard of care smoking cessation activities include tobacco use assessments, motivational interviewing to promote smoking cessation, assessment for medications to promote smoking cessation, and addressing barriers to care and social determinants of health.
The following assessments and activities within the BreatheOut program are within the standard of care for primary care of transgender and gender diverse patients: discussion of self-perception of gender, discussion of experiences of minority stress and discrimination, and addressing barriers to care and social determinants of health.

The primary effectiveness outcome for this study was smoking cessation: patient-reported abstinence at the 1-week and 1-month follow-up from the patient's quit date. Cessation rates for this program were compared to published literature to assess comparative efficacy. Secondary effectiveness outcomes include reduction in tobacco use from baseline and proportion of patients retained through the completion of the program. To assess long-term feasibility of the program, medical billing revenue and time spent at each visit was tracked to calculate cost using a pharmacy resident versus a clinical pharmacist to provide the service. Patient acceptability was assessed using a post-program survey (Likert scale and free-response questions).

Data Collection:
The study was approved by The Ohio State University Investigational Research Board (IRB).
The data listed in Table 1 was collected during program visits. Program cost (estimated cost of personnel time), program revenue (estimated medical and pharmacy billing revenue), proportion of patients retained from consent to Visit Three, and results of a post-program survey were collected and presented as aggregate data.

Table 1: Study Data	
Onboarding Visit	**Baseline Participant Data:** Age, BMI, Gender Identity, Sex Assigned at Birth, Sexual Orientation, Race, Tobacco Smoking Status, E-Cigarette Use Status **Smoking Assessment:** Age of first tobacco use, Age started smoking regularly, Average cigarettes/day, First cigarette timing, Modified Fagerstrom Score, Menthols (Y/N), Other tobacco product use, E-cigarettes use (If yes: E-cig Device Name, E-cig Strength, E-cig Pod size, E-cig Pod Duration), Number of past quit attempts, Longest quit, Other household members smoke, Readiness to Quit (scale of 1-10)
Visit One **(Preparing to Quit)**	Desire to quit, Confidence in quitting **Nicotine Dependence Assessment:** Psychological Dependence (Y/N), Physical Dependence (Y/N) **Previous Quit Strategies:** Medication Effectiveness, Stress Management/Mindfulness Effectiveness, Social Support Effectiveness, Other Effectiveness, Medication Name/Strength
Visit Two **(Quit Day)**	Desire to quit, Confidence in quitting **Medication Use Assessment:** Med Name/Strength, Medication Adherence (PDC), PRN Medication Usage **Nicotine Withdrawal/Cravings:** Withdrawal Symptoms (Y/N), Craving Frequency
Visit Three **(Staying Smoke-Free)**	**Abstinence from Smoking:** Smoking 7 day Point Prevalence Desire to stay smoke-free, Confidence in staying smoke-free **Medication Use Assessment:** Med Name/Strength, Medication Adherence (PDC), PRN Medication Usage **Smoking Assessment (if applicable):** Average cigarettes/day, First cigarette timing, Modified Fagerstrom Score, Menthols (Y/N), Other tobacco product use, E-cigarettes use (If yes: E-cig Device Name, E-cig Strength, E-cig Pod size, E-cig Pod Duration)

BMI: Body Mass Index; PDC: Percent Days Covered

Data Analysis:
Descriptive statistics were used to characterize and present participant data. For the post-program survey, questions utilizing a 5-point Likert scale were summarized by frequency of point selection.

Results:

Participants
Baseline demographics of study participants are summarized in Table 2.

Though the potential participant pool was reasonably diverse with regard to gender identity, the majority (3/5) of participants were white transgender men in this pilot study. Baseline tobacco use varied among participants, with some reporting low use (<1/2 pack per day (ppd)) and others reporting an average of 1 ppd or concomitant nicotine vaping devices. The average Fagerstrom Nicotine Dependence Score among participants was 4.4 out of 10, indicating mild to moderate physical nicotine dependence. 2 of 5 of participants reported smoking menthol cigarettes, and 1 participant reported co-occurring use of e-cigarettes or vaping products with cigarettes. Concomitant mental health conditions were common amongst participants, with all subjects presenting with a nonzero PHQ-2 or GAD-2 at baseline.

Table 2: Baseline Participant Characteristics		
	Contacted Potential Participants (n=27)	**Study Participants (n=5)**
Demographics		
Mean age	30.9 yrs *(21-48)*	35.4 yrs *(26-48)*
Gender Identity		
Man/Transgender Man	14	4
Woman/Transgender Woman	8	-
Non-binary/Genderqueer	5	1
Race		
White	21	4
Black/African American	2	1
Multiracial	3	-
Unknown/No Entry	1	-
Tobacco Smoking Status		
Current Every Day Smoker	17	3
Current Some Day Smoker	8	2
Former Smoker (Current E-Cig User)	2	-
E-Cigarette Use Status		
Current Every Day User	4	1
Current Some Day User	1	-
Never User/Former User	15	3
Other *(No Entry, Unknown)*	7	1
Co-occurring Mental Health Conditions		
Mean PHQ-2 Score *(range: 0-6)*		2.2 *(range: 0-6)*
Mean GAD-2 Score *(range: 0-6)*		3.4 *(range: 1-6)*
SBIRT: At-Risk *(Y/N)*		Yes: 4 No: 1
Baseline Smoking Assessment		
Mean age started regularly smoking		17.8 yrs *(range: 12-27)*
Mean FTND Score *(range: 0-10)* 7-10 = highly dependent 4-6 = moderately dependent <4 = minimally dependent		4.4 (range: 1-8) 1 2 2
Menthols *(Y/N)*		Yes: 2 No: 3
Other tobacco *(Y/N)*		No: 5
E-cigarette with Nicotine Use *(Y/N)*		Yes: 1 No: 4
Mean number of past quit attempts		2.67 *(range: 2-4)*
Mean longest past quit duration		7 weeks *(range: 2-17)*
Mean readiness to quit (range: 1-10)		8 *(range: 7-9)*

PHQ-2: Patient Health Questionnaire-2 item; GAD-2: Generalized Anxiety Disorder-2 item; SBIRT: Screening, Brief Intervention and Referral to Treatment; FTND: Fagerstrom Test for Nicotine Dependence

Effectiveness

At the end of the pilot period (12 weeks), all 5 participants had completed a 1-week follow-up from their quit date, and 2 participants had completed a 1-month follow-up appointment. At 1-week follow-up, 3 of 5 participants reported abstinence from smoking, and the remaining 2 participants elected to reschedule their quit date. At 1-month follow up, both of the 2 participants reported a reduction in smoking but not complete abstinence, citing triggering factors causing intermittent smoking.

At the close of the pilot study period, all participants were retained within the program. Both participants who had not successfully maintained abstinence at their 1-month follow-up elected to schedule additional visits with a clinical pharmacist for continued support toward complete abstinence from smoking. 2 participants had 1-month follow-ups scheduled but not yet completed by the end of the pilot period. 1 participant had rescheduled their quit date at their 1-week follow-up and had not yet completed this visit.

As part of their quit plan, 4 of 5 participants used a short-acting form of nicotine replacement therapy, and 3 of 5 subjects used both a long-acting and short-acting form of nicotine replacement therapy. 2 of 5 participants entered the study on bupropion, which they continued. 1 participant did not use any medication as part of their quit plan. No participants elected to use Chantix.

Feasibility

During the pilot study period, 15 hours were spent in face-to-face or virtual appointments with patients. In order to estimate cost of personnel time, pharmacy resident and clinical pharmacist hourly pay were estimated. The salary for a pharmacy resident was estimated as $46,958 ($22.58 /hour) from the average of available stipend records for PGY-1 Community programs in the American Society of Health Systems Pharmacists Residency Directory. According to the Bureau of Labor Statistics, the average salary for pharmacists in the state of Ohio was $117,890 ($56.68/hour). Marketing time and program book printing were not factored into the cost calculation due to the support of grant funding to cover these costs.

Visits were billed as HCPCS Code 99213: outpatient office visit for established patient (20-29 minutes). Revenue from medical billing was estimated as $89 using the Physician Fee Schedule from the Centers for Medicare and Medicaid Services (CMS) using the Ohio Medicare Administrative Contractor (MAC) Locality payment at Non-Facility (outpatient) Price. Following anti-trust laws, pharmacy revenue was estimated using the National Average Drug Acquisition Cost (NADAC) and Average Wholesale Price available on UpToDate in June of 2021.

No anonymous survey data was submitted by the end of the pilot study period, so patient acceptability was not able to be formally assessed. Informal positive feedback provided during visits included praise for the design of the guided program book and learning new strategies that participants had not considered before to help with smoking cessation. Informal constructive feedback provided during visits included that an online interactive format may be preferable to a printed program book.

Table 3: Results	
Effectiveness	
Smoking Cessation	
Cessation at 1-week follow-up: 7-day point prevalence (Y/N)	3/5
Cessation at 1-month follow-up: 7-day point prevalence (Y/N)	0/5 (0/2 completers)
Reduction in smoking (reduction in mean FTND score at 1-month follow-up)	-1.5 *(range: 1-2)*
Program Retention	
Retention to Visit 2 (Quit Day)	5/5
Retention to end of 12-week Pilot Period	5/5
Feasibility	
Cost	
Total Clinic Visit Time	15 hours
Resident Cost	$338.70
Clinical RPh Cost	$850.20
Income*	
Estimated Medical Billing	$1,335.00
Estimated Pharmacy Billing	$280.32
Revenue	
Based on Resident Salary	$1,276.62
Based on RPh Salary	$765.12

*Visits were billed as HCPCS Code 99213: outpatient office visit for established patient (20-29 minutes). Revenue from medical billing was estimated as $89 using the Physician Fee Schedule from the Centers for Medicare and Medicaid Services (CMS) using the Ohio Medicare Administrative Contractor (MAC) Locality payment at Non-Facility (outpatient) Price.
Due to anti-trust laws, actual pharmacy revenue could not be reported. Pharmacy revenue was estimated using the National Average Drug Acquisition Cost (NADAC) and Average Wholesale Price available on UpToDate in June of 2021.

Discussion:

This pilot study is the first study to assess the effectiveness and feasibility of a culturally-tailored smoking cessation program for transgender and gender diverse individuals that is led by a pharmacy resident in a community ambulatory care setting. Preliminary results suggest that a culturally-tailored program was effective in promoting short-term smoking cessation. Further study is needed to compare this program to other culturally-tailored smoking cessation programs for LGBTQ+ patients that have been evaluated in the literature (32% ITT quit rate at one month following the quit date)[21]. Program retention and informal feedback support patient acceptability, though no anonymous survey data was available at the end of the pilot study period.

Using an estimate for medical and pharmacy revenue as a result of billable program visits and prescribed medications, this program was found to be fiscally feasible for both a pharmacy resident and clinical pharmacist salary. These estimates were based on the ability to bill for pharmacist-provided services in a clinic setting. This was dependent on provider status laws in the state of Ohio which are not yet present

in every state. Prior to payer-recognized provider status in the state of Ohio, these visits would be billed at a 99211, which would result in this program not being financially feasible when administered by a clinical pharmacist.

Strengths
This study expands upon the current literature by focusing on a high-risk subset of a community with an increased burden of tobacco use. Incorporation of institutional knowledge and study personnel who identify within the transgender community provided unique insights when interpreting the available literature on the needs of this community related to smoking cessation. In addition, the location for this study is a FQHC with a strong reputation for serving the LGBTQ+ community and established staff training in cultural competence and cultural humility. The design of this study mimicked clinical practice, with an ability to repeat content if needed.

Limitations
Due to the limited time course of this study as a resident project, extended follow up with patients for sustained abstinence was limited to a 1-month follow-up. 3 participants were not able to complete their 1-month follow-up visit prior to the end of the data collection period. In addition, the study population was predominantly white transgender men. This limits the ability to extrapolate the information collected to transfeminine individuals as well as those with intersecting racial or cultural identities that may increase burden of smoking and tobacco use.

For program feasibility, the reduction of restrictions and expanded reimbursement opportunities for telehealth during the COVID-19 pandemic may have increased access to telehealth for study participants which may limit applicability. The impact of FQHC reimbursement for medical billing and 340b drug pricing, pre-existing cultural competence and cultural humility training for staff, and the grant support for startup costs associated with this program may also inflate the feasibility of implementation at a different site where this support and training does not already exist.

Conclusion:

This pilot study implementing a culturally-tailored smoking cessation program for a population with a high burden of smoking was found to be effective in promoting short-term smoking cessation and feasible when administered by a pharmacy resident or clinical pharmacist. The results of this pilot study support the further expansion of this program as a clinical service implemented in a community health center. Due to the limitations of this pilot phase, higher-quality studies are needed to confirm or refute these findings over a longer study period and compare to existing smoking cessation programs.

Incentive Grant Budget

BreatheOut Program Pilot Phase Budget		
	Description	**Amount**
Marketing Consultant Time	○ Design of flyers, program book	$140
Resident Training	○ Courage to Quit tobacco cessation training (Respiratory Health Association)	$125
Patient Education Materials	○ Printing for 50 booklets	$285
Spanish Translation of Patient Materials	○ Professional translation of written materials ($973 total)	$450 $523*
Conference Presentation and Manuscript Submission	○ Registration for APhA Annual Meeting ○ Poster printing	$400**
*Support provided by Equitas Health **Support provided by The Ohio State University Additional administrative and technical support provided by Equitas Health	**Total**	$1923

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