Self-care decision-making: Feasibility of the BREATHE asthma intervention trial

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STUDY PURPOSE AND RATIONALE

Study Purpose

The **overall goal** of this study is to develop and to preliminarily validate a novel intervention delivered by primary care providers (PCPs) to their Black adult patients with uncontrolled asthma in federally qualified health centers (FQHCs). We recently developed and rigorously tested a brief questionnaire, the Conventional and Alternative Management for Asthma (CAM-A) tool[1,2], that screens patients for beliefs about asthma self-care and inhaled corticosteroid (ICS) treatment and prompts PCPs to discuss ICS adherence at office visits based on personalized patient CAM-A responses[3]. In over 300 adults (80% Black; 67% uninsured or government-insured) with high rates of uncontrolled asthma (69%), the validated CAM-A identified that erroneous personal health beliefs and negative ICS beliefs were commonly endorsed (93% and 68%, respectively)[1]. Importantly, erroneous personal health beliefs were significantly associated with uncontrolled asthma, likely driven by ICS non-adherence. In this feasibility trial we will develop the intervention by adapting an evidence-based brief shared decision-making strategy with proven efficacy[4-6], for use with our validated CAM-A tool using community-based participatory research and delivered by PCPs. As such, this project has three ***specific aims***:

Specific Aims:

1. **To develop an intervention to improve asthma control in Black adults receiving care in FQHCs;**
2. **To evaluate the feasibility and acceptability of the intervention procedures; and**
3. **To assess the preliminary evidence of intervention effects on asthma control (primary outcome), ICS adherence, forced expiratory volume in one second (FEV_1) – an objective lung function measure – and asthma quality of life (secondary outcomes) over a 3-month follow-up period.**

Please note, at this time we are submitting for IRB approval for Aim #1 (Phase I - focus group and PCP review only), which will be carried out in Study Year #1. Aims #2 and #3 (Phase II-pilot intervention) will be conducted later; as we develop/refine the pilot study we will submit for approval for Aims #2 and #3.

Background / Rationale

Uncontrolled asthma due to ICS non-adherence is common among Black adults. Nearly every asthma-related hospitalization and death could be prevented with appropriate self-management that achieves and maintains disease control[7-10]. However, as many as 64% of adults have uncontrolled asthma[11]; minorities are disproportionately represented within that population[12]. While inhaled corticosteroids (ICS) are a safe and effective treatment for uncontrolled asthma, relative to Whites, Blacks have lower rates of ICS adherence (74% vs. 29%)[13-17].

Health beliefs are associated with ICS non-adherence. Erroneous personal beliefs about asthma and its pharmacologic treatment are among the most significant factors contributing to ICS non-adherence[18-21]. ICS non-adherence, a primary cause of uncontrolled and/or fatal asthma[7], is lower in Blacks relative to Whites[13-17] due, in part, to higher rates of erroneous personal health beliefs regarding asthma self-care[1] (e.g., coffee is a safe, effective asthma treatment) and negative ICS beliefs[13-15,22-29] (e.g., ICS is addicting). These beliefs have been shown to be associated with ICS non-adherence[22,23,27], more asthma attacks[22,30] and delays in seeking care[23].

There are unique challenges to achieving asthma control in FQHCs. PCPs deliver up to 80% of asthma care. However, compared to specialists, uncontrolled asthma is more common in their patients[31]. There are unique challenges to achieving asthma control in FQHCs a particular type of primary care setting designated to receive enhanced Medicaid reimbursement because their clientele are underserved, underinsured, and uninsured Americans who receive more episodic primary care[32]. In these settings PCPs have limited time to evaluate asthma control, to assess ICS non-adherence, and to identify beliefs associated with ICS non-adherence[33]. This speaks to the pressing need for novel brief interventions that facilitate evidence-based guideline-directed asthma self-management.

Shared decision-making interventions to promote asthma control in this vulnerable population are lacking. The study is guided by the theoretical model of Shared Decision-Making in evidence-based practice[34], which posits that the best treatment decisions are informed by patient's preferences, the best available evidence, and practitioner expertise. The PCP's role is to facilitate discussion of the risks and merits associated with specific options in the context of patient's goals and preferences, and in a manner that activates patients to engage in self-management. PCPs offer options to consider jointly[35] with the goal of reconciling differences and reaching mutually agreed upon higher quality decisions that align patients' needs with evidence-based guideline-directed care[36,37]. Prior research has demonstrated that with repeated lengthy engagement (1+ hour), highly-trained interventionists in settings other than primary care can increase medication adherence[38-40], this intervention model improves disease control[39,41-43], identifies health beliefs that conflict with evidence-based care[44] and reduces risky behaviors[4-6]. The framework's application to asthma has been limited to children[39,47] and to White privately insured adults[40]. Sustained implementation of effective shared decision-making interventions has been restricted, in part, by burdensome protocols requiring multiple visits, lengthy engagement, highly-trained interventionists, and by protocols inappropriate for populations like those served in FQHCs.

Implementation research is underutilized in asthma intervention research. Evidence-based interventions may be difficult to sustain[8-10], in part, because factors associated with implementation are overlooked. To close this gap between research and practice, researchers should conduct formative assessments with the target audience and program providers during development, and evaluate the program features that enhance a program's reach. Further, FQHCs are overlooked in asthma intervention research.

Impact. Black adults with uncontrolled asthma experience profound health disparities. Despite data that point to the critical need for enhanced asthma self-management, we continue to see rates of controlled asthma well below *Healthy People 2020* targets[48], particularly among vulnerable populations[49]. Our **Brief Evaluation of Asthma Therapy (BREATHE)** intervention has the potential to offer a new avenue to asthma control via shared decision-making that supports ICS adherence.

STUDY DESIGN AND PROCEDURES

This R21 proposal will proceed in two major phases: (1) a development phase (Year 1) where **BREATHE** is developed using iterative community-based participatory research (CBPR) approaches with feedback from PCPs; and (2) a pilot randomized trial phase (end of Year 1 and Year 2) that will allow estimation of parameters crucial for a larger randomized control trial (RCT) including final content specification, participant recruitment rates, and potential intervention effect sizes.

PHASE I ONLY

Development Phase. While the final intervention content will be determined by results of an iterative process with asthma patients, their family/support person, PCPs and our Patient Advocate, based on our collective clinical and research experiences[1-3,5,6,13,23,24,50-54], we anticipate the new manualized intervention will consist of one-time, brief (7-minute), tailored shared decision-making intervention session using motivation interviewing

to address personal health beliefs and negative ICS beliefs associated with ICS non-adherence (see manual attached-Brief intervention adapted for asthma). To adapt **BREATHE**, the PI will use a 2-step process.

Study Procedures

PHASE I ONLY **Step 1. CBPR with Adults with Persistent Asthma and their Family/Support Person to Adapt Intervention Content.** We will conduct up to 6 focus groups composed of ~10 participants each: (a) two groups of only adults with persistent asthma; (b) two groups of only family/support persons of adults with persistent asthma unique from group a; and (c) two combined groups of adults with persistent asthma and/or their family/support persons who did not participate in group a or b.

Participants will be recruited from the partner FQHCs. These are Spectrum Health Services (SHS) and Greater Philadelphia Health Alliance (GPHA). Letters of support for this project are attached to this application.

PI George will conduct the focus groups using grounded theory approaches, collecting qualitative data using an open-ended interview guide adapted from our preliminary studies[1-6,13,23,24,50-54] to obtain suggestions for responses PCPs will use with patients who endorse CAM-A beliefs associated with uncontrolled asthma. Responses will be used to design the brief intervention. Focus groups will be audiotaped and transcribed verbatim. A member of the research team will take field noted.

Step 2. PCP Review. We will further refine the intervention prior to piloting by presenting the focus group results to four PCPs who are working in settings similar to our partner FQHCs; we chose not to use PCPs from our partnering FQHCs in order to avoid contamination. PCPs will provide input into the application of the intervention to their practice, which we will use to revise the intervention.

STATISTICAL PROCEDURES

Qualitative analysis. Qualitative data analysis will focus on developing the intervention. De-identified transcripts will be entered into NVivo 11.0 for coding and analysis. Three coders working independently of each other will systematically read the transcripts to identify emerging themes; the Patient Advocate consultant will serve as one coder. Themes will be compared between coders and disagreements will be reconciled by consensus. As we have done in the past, we will employ an iterative process in which themes from the initial focus groups will be presented to subsequent focus groups to ascertain if they resonate with that group; unendorsed themes will be discarded. This iterative process will continue until no new essential information is obtained, an endpoint known as data saturation. Typically data saturation occurs when between two and five focus groups per category (e.g., patient, family/support person) are held[55]; we have over-estimated by planning for 6 focus groups. If we find that we have reached data saturation with fewer focus groups we will end this phase of data collection. All retained responses that are similar will be grouped together by code words to form the final thematic categories. Transcripts, field notes and codes will serve as points of triangulation.

MEASURES

Immediately prior to the focus groups, but after obtaining HIPAA and informed consent, we will administer surveys. These can be found under separate attachment.

Adults with asthma will complete:	Family/support person of adult with asthma will complete:
Demographics	Demographics
Asthma History Patient version	Asthma History Family Version
Conventional and Alternative Management for Asthma (CAM-A) Patient version	Conventional and Alternative Management for Asthma (CAM-A) Family Version
Newest Vital Sign	Newest Vital Sign
Medication Adherence Record Scale – Asthma	Medication Adherence Record Scale – Asthma

Asthma Control Questionnaire (without item #7-spirometry)	_
Asthma Quality of Life Questionnaire	_

PERSONNEL

In addition to the PI, two other Columbia personnel are investigators. They are

1. Dr. Haomiao Jia, statistician for the project,
2. Dr. Jean-Marie Bruzzese, in-kind effort for behavioral science expertise.

Four investigators are from the University of Pennsylvania School of Nursing (SON) and/or the University of Pennsylvania School of Medicine (SOM) serve as key personnel:

1. Dr. Marilyn Sommers (SON) is an expert on brief interventions targeting risk-taking behaviors in urban populations and will contribute health and culture expertise to tailor the intervention (phase II) in the target population. As an expert in training and fidelity for behavioral interventions, she will also lead the evaluation of the fidelity to the interventions, which includes designing the fidelity plan and supervising the blinded assessors. She will also review the planned analysis and make suggestions for additional statistical reports and will participate in the preparation of reports and manuscripts for this project.
2. Dr. Karen Glanz (SON/SOM) is a public health expert and Director of the Center for Health Behavior Research at the University of Pennsylvania. Her primary role will be to provide consultation as needed regarding the public health aspects of the trial, trial design and implementation and the planned analysis. She will review and contribute to the design, results and discussion sections of all manuscripts.
3. Dr. Shreya Kangovi (SOM) will provide in-kind effort for her expertise in health and culture. She works one day a week at Spectrum, one of the federally-qualified health centers that will serve as a performance site for this trial. Her primary role will be to provide access to patients and primary care colleagues, to assist George and the Consultant Pantalon with provider training and to provide expert consultation, as needed, on chronic disease management in primary care. She will also review the planned analysis and make suggestions for additional statistical reports and will participate in the preparation of all manuscripts.
4. Mr. Jesse Chittams (SON) will have primary responsibility for the creation of the REDCap data management system and data security with the PI. He will also assist the PI on the execution of the SMC. In Year 01 he will review the training in all data entry and management procedures; overseeing the double data entry, data cleaning, and preliminary analyses. He will supervise the final analysis of the cleaned and validated database and assist Jia in the writing of the statistical methods section for the primary results and secondary results papers.

There are two consultants on the project. Dr. Michael Pantalon, Yale School of Medicine, is a psychologist with expertise in training health care professionals to deliver brief interventions using motivational interviewing approaches. On this project, he will supervise the training of the health care providers in the delivery of brief intervention techniques (Phase II). As a Consultant, he will also be one of the blinded personnel responsible for reviewing the audio files to determine if fidelity to the **BREATHE** intervention has been maintained and making recommendations for additional training, if needed, until consistency and fidelity is achieved.

5. Ms. Coleman is a 30 year old female with lifelong persistent asthma who receives asthma care at GPHA, one of the federally-qualified health centers that will serve as a performance site for this trial. She has agreed to serve as the Patient Advocate and has been involved in every aspect of this application. In Year 01, Ms. Coleman will be involved in coding of the focus groups, adapting the draft intervention and piloting of the protocol. In addition, in Year 02 she will have primary responsibility for contributing to the design, planned analysis and preparation of reports, presentations and manuscripts for this project. Ms. Coleman will assist in analyzing the qualitative data from post-trial interviews for final refinement of the protocol.

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