



## Rationale and design of a comparative effectiveness trial of home- and clinic-based self-management support coaching for older adults with asthma



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### ABSTRACT

Older adults with asthma face numerous barriers to effective self-management and asthma control, and experience worse outcomes than younger asthmatics. Yet, there have been no controlled trials of interventions specifically designed to improve their care and outcomes. Through a multi-stakeholder collaboration (patients, academia, community-based organizations, a state department of health, and an advocacy organization) we developed a multi-component asthma self-management support intervention to address the myriad psychosocial, functional, health status, and cognitive barriers to effective asthma self-management in adults ages 60 and older. We are recruiting 425 New Yorkers in Manhattan and the Bronx for a pragmatic randomized controlled trial with 3 arms: the intervention delivered in primary care settings or in their home, or usual care. In the intervention, care coaches use a novel screening tool to identify the specific barriers to asthma control and self-management they experience. Once identified, the coach and patient choose from a menu of actions to address it. The intervention emphasizes efficiency, flexibility, shared decision making and goal setting, communication strategies appropriate for individuals with limited cognition and literacy skills, and ongoing reinforcement and support. Additionally, we introduced asthma-specific enhancements to the electronic health records of all participating clinical practices, including an asthma severity assessment, clinical decision support, and a patient-tailored asthma action plan. Patients will be followed for 12 months and interviewed at baseline, 3, 6, and 12 months and data on

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emergency department visits and hospitalizations will be obtained through the New York State Statewide Planning and Research Cooperative System.

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## 1. Introduction

Older adults with asthma experience worse asthma related quality of life [1–3] and have a 4-fold greater rate of mortality compared to younger asthmatics in age-adjusted analyses [4]. A 2011 National Institutes of Health expert panel on asthma in the elderly highlighted the scarcity and urgent need for research on interventions to improve care and outcomes for this population [5].

Consistent and accurate self-management behaviors are crucial to achieving and maintaining asthma control. There are five self-management behaviors that are central to asthma control: 1) medication adherence, 2) avoidance of triggers, 3) self-monitoring, 4) use of written action plans, and 5) keeping regular appointments with their clinician [6]. Older adults face challenges in sustaining asthma control similar to younger individuals, such as language and cultural barriers, health literacy, and the environmental factors of poor housing and air quality that disproportionately affect lower socioeconomic groups. But older adults are more commonly subject to other impediments to asthma control, such as frailty and long term changes to the lung and immune system [7], multimorbidity [8,9], and declines in cognitive function [10–12], as well as financial barriers that may limit access to care [13,14]. Often social support is limited and unable to keep up with increasing burdens of physical and mental decline [15,16]. Alone or in combination, these factors pose real barriers for older adults striving to keep their asthma in check.

Interventions to improve asthma outcomes among young children, adolescents, and adults have been extensively described, but few have been specifically designed for older adults and or designed to comprehensively address the barriers to asthma control commonly found in the elderly [5,7,17–19]. Moreover, asthma programs often aim to broadly educate patients about asthma and its management rather than tailoring to the patient's specific needs [20–34]. Such broad-stroke, unfocused approaches may unduly complicate patient learning and distract attention from the key information and skills needed to improve asthma control, especially among older adults who often have cognitive limitations that affect their health literacy and self-management behaviors [11,35–38].

Two promising strategies exist for chronic disease management among older adults: clinic- and home-based self-management support using care coaches. In primary care settings, self-management support programs for conditions other than asthma have been used extensively and effectively for older adults [39–41]. Similar programs have been tested in the home, and in the case of asthma, may be particularly helpful owing to the opportunity home visits present for remediation of environmental triggers of asthma [42]. Informed by the Chronic Care Model [43–46] and existing asthma interventions, we designed a new intervention to address the dearth of research on approaches to assist older adults with their asthma self-management and improve outcomes.

## 2. Design and methods

### 2.1. Study overview

We are comparing the effectiveness of a home- and clinic-based asthma care coordination and self-management support program to improve quality of care and asthma related outcomes for older adults with poorly controlled asthma. We hypothesize that compared to usual care, patients receiving either home- or clinic-based support will have better asthma outcomes and self-management behaviors. A secondary hypothesis is that patients with more severe asthma or physical and cognitive impairments will more likely benefit from the home-based intervention.

With funding from the Patient Centered Outcomes Research Institute (PCORI, AS-1307-05584), we developed the Supporting Asthma self-Management Behaviors among Aging Adults (SAMBA) program which provides asthma self-management support to older adults (ages 60 years and older) in the home or in the outpatient clinical setting. The intervention has 4 core elements: (1) clinical decision support tools to assist primary care physicians in managing older adults with asthma, (2) a screening tool to identify patients' specific barriers to asthma control, (3) targeted "mini" interventions to address the specific barriers identified, and (4) reinforcement over time through repeated follow up encounters with the patient and close communication between the asthma coach and the patient's primary care provider. We launched the trial in January 2015.

### 2.2. Stakeholder engagement

Stakeholders across multiple organizations with expertise in asthma, care coaching, and care management were involved in developing the program, including its content and procedures, pre-testing and refinement of materials and procedures, developing training materials and protocols, and training of coaches and their certification. These stakeholders included patients, non-profit service organizations, and clinical and university partners.

We convened a patient advisory board consisting of 5 older asthmatics (ages ≥60 years) from the communities in which the intervention would be tested. Advisory board meetings took place on a monthly basis and were used to generate feedback on materials and procedures as they evolved during development. Union Settlement, a multiservice community services provider based in East Harlem, helped organize and support the patient advisory board.

Little Sisters of the Assumption (LSA) Family Health Service and City Health Works, East and Central Harlem based non-profit organizations, respectively, injected the community health worker service perspective into the SAMBA program in addition to contributing heavily to the development of SAMBA materials, protocols, and procedures. LSA conducts environmental assessments and facilitates remediation of triggers in the homes of asthmatic children. City Health Works provides chronic disease management and care coordination services for adults, with specific expertise in diabetes. Both LSA and City Health Works provide the community health workers who conduct SAMBA home-based self-management support, a major adaptation of the focus of their work prior to the SAMBA program's inception (children with asthma and adults with diabetes, respectively).

Clinical stakeholders included physicians from the Mount Sinai Hospital Internal Medicine Associates practice (part of a tertiary care academic medical center), from the Institute for Family Health (a federally qualified health center with a family medicine residency program), and the non-teaching outpatient primary care practices of St. Luke's Hospital, an inner-city community hospital. Other stakeholders included employees of the New York State Department of Health and the Greater New York Hospital Association with expertise relevant to the focus of this study. We utilized a committee approach to organize individuals with relevant expertise and divided tasks.

### 2.3. SAMBA program

#### 2.3.1. Focusing on older adults

The SAMBA program includes a number of features which target the needs and vulnerabilities more often found in older adults than in younger ones, which fall into 4 domains: (1) sociodemographic (e.g., limited

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