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A Community-Based Asthma Program: Study Design and Methods of RVA Breathes

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Abstract

Disparities in pediatric asthma morbidity and healthcare utilization exist on the basis of race, ethnicity, environment, and income; interventions are needed to address these inequities. The following protocol describes an evidence-based intervention, RVA Breathes, designed to coordinate pediatric asthma care across family, home, community, and medical sectors. Community stakeholder feedback was utilized to refine the intervention specifically for the Richmond, Virginia community. The aims of this study are to assess the effect of RVA Breathes on asthma-related healthcare utilization, as well as secondary outcomes of asthma control, asthma symptoms, and quality of life. We will enroll 300 elementary school children from the Richmond City Public School system. Participants will be between the ages of 5–11, have a diagnosis of asthma, and have had an asthma exacerbation (as indicated by an asthma-related ED visit, hospitalization, unscheduled PCP visit, or use of systemic steroids) in the last two years. Participants will be randomized to one of three groups: asthma education + home environment remediation + school intervention, asthma education + home environment remediation, or a comparator condition. Data will be collected across one baseline research visit, four intervention sessions, and four follow-up research visits over the course of 18 months. A General Linear Mixed Model (GLMM) will be used to test primary aims. We expect the findings will provide support for coordination of asthma care across sectors. Further, we hope RVA Breathes will serve as a model of community-based pediatric asthma care.

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1. Introduction

1.1 Pediatric Asthma Disparities

Pediatric asthma disparities are well documented. African American/Black children have higher rates of asthma morbidity and asthma-related hospitalizations than their White counterparts.¹ Even after adjusting for race and ethnicity, children living in urban areas experience higher rates of emergency department (ED) visits and hospitalizations for asthma.² Poor housing conditions, community violence, and limited resources are all associated with asthma morbidity in urban environments.³ In these settings, social determinants of health (e.g., housing instability, limited access to care) and increased exposure to allergens and irritants (e.g., cockroaches, dust mites, tobacco smoke) negatively impact asthma morbidity.⁴ Together, these findings suggest that African American/Black children from low-income families, living in urban settings, face detrimental environmental and social exposures that lead to poorer asthma outcomes than White children, and community-level interventions are needed to minimize these pernicious disparities.

1.2 Need for Community-Based Approaches

In response to this public health concern, the National Heart, Lung, and Blood Institute⁵ funded four Asthma Empowerment Collaborations to coordinate children's asthma management across the sectors of family, home, community, and medical care. These community-based programs were developed from evidence-based interventions refined to address the specific needs of the communities they served. RVA Breathes, one of the funded programs, was developed following a year long, mixed-methods community needs assessment.^{6,7}

RVA Breathes includes both community health workers (CHWs) and Healthy Homes assessors in the intervention arms. CHWs are paraprofessionals who live and work within the same community as their clients and have extensive knowledge of local healthcare and social service resources. They provide tailored support related to daily social and health issues (e.g., providing resources, connecting with primary care providers, assisting with medication management). Healthy Homes is an existing resource of the Richmond City Health District. Healthy Homes assessors complete home-based environmental assessments using evidence-based protocols promoted by the United States Department of Housing and Urban Development (HUD) and the National Center for Healthy Housing.^{8–10} Relevant to this study, Healthy Homes assessors conduct exterior and interior observations that pertain to the Asthma Environment Checklist from the Environmental Protection Agency (EPA; e.g., standing water, presence of tobacco smoke, mold, pests, pets).¹¹

Specifically, RVA Breathes is comprised of three evidence-based interventions: 1) asthma self-management education delivered by a CHW, 2) home environmental remediation delivered by a Healthy Homes assessor, and 3) strategies to support appropriate care in schools in partnership with school nurses. These interventions were tailored to address the priorities identified in the needs assessment^{6,7} (see Table 1). RVA Breathes differs from traditional care approaches in that it empowers children and families to adhere to daily asthma management behaviors effectively, addresses specific challenges urban families face

in managing child asthma, including those that emerged during our needs assessment (e.g., use of ED as primary source of care, poor medication routines, caregiver stress, social support), and incorporates a peer advocate model with CHWs who are also parents living within the same communities. This manuscript provides the rationale for the RVA Breathes trial, and outlines its design and methods.

2. Specific Aims & Hypotheses

The primary aim of this study is to evaluate a randomized controlled trial (RCT) of RVA Breathes (registered as [NCT03297645](#)). In this RCT, 300 families (parent-child dyads) will be assigned to one of three conditions: 1) asthma education + home environmental remediation + school intervention, 2) asthma education + home environmental remediation, or 3) comparator condition (Enhanced Standard of Care, E-SOC). Families will participate for 9 months and complete follow-up assessments (post-treatment and 3-, 6-, and 9-months) to measure potential changes in healthcare utilization (e.g., ED visits and hospitalizations), our primary outcome. In addition to healthcare utilization, we will also consider changes in school absences and controller medication use between conditions. We hypothesize that children in the two active interventions will achieve greater reductions in asthma-related healthcare utilization and school absences, and increases in controller medication usage at follow-up than children in the comparator condition. We will also explore differences in outcomes between the two active intervention conditions.

A secondary aim is to evaluate the effectiveness of RVA Breathes on secondary outcomes including asthma control, symptoms, and quality of life. We hypothesize that secondary outcomes of children in the intervention groups will be superior to those of the control group. Finally, in our third aim, we will examine putative mediators and moderators (e.g., caregiver asthma self-management skills, perceived stress, and depressive symptoms) of treatment outcomes.

3. Study Design and Methods

3.1 Participants

Families will be recruited from Richmond City, which is diverse in terms of socioeconomic status (SES) and race/ethnicity: 49.4% of Richmond residents are non-Latinx Black (40.6% non-Latinx White; 6.5% Latinx), and 25% of families live in poverty.¹² In Virginia, 13.4% of non-Latinx Black children (versus 7.6% of non-Latinx White children) report lifetime asthma.¹³ Moreover, 75% of students in the school district from which we are recruiting (Richmond Public Schools, RPS) are African American/Black, 13% Latinx, and 9% non-Latinx White; 81% of elementary students receive free or reduced lunch; 88% of RPS elementary schools are Title I. Richmond is consistently ranked as one of the most challenging places to live in the United States with asthma¹⁴ and is an ideal location for studying pediatric asthma disparities. Children will be recruited from the community (including primary healthcare providers), from hospitals in Richmond City, and from schools.

3.1.1. Inclusion criteria.—Children must be between the ages of 5–11 years, have physician-diagnosed asthma, and have had an asthma-related ED visit, hospitalization, unscheduled PCP visit, or use of systemic steroids for asthma in the last two years. Given that we will randomize by school (see 3.2 Randomization), children must also be enrolled in RPS. Enrolled caregivers must be the child’s legal guardian (and live in the same home with them for the last 6 months). Families can be English or Spanish speaking. At least one CHW will be bilingual, and we will translate all study materials for non-English speaking families.

3.1.2. Exclusion criteria.—We will exclude children 12 years as issues related to asthma management among adolescents and caregivers may differ. Also, we will exclude children and caregivers with a medical or psychiatric condition that precludes effective study participation. Families will only enroll one child in the program; thus, sibling pairs are excluded.

3.2 Randomization

Given that we are including a school component in RVA Breathes, families will be randomized at the school level. We will match elementary schools based on: (1) demographics, (2) location, and (3) whether their assigned school nurse travels among schools; 8–9 schools will be included in each condition. Efforts will be made to balance recruitment of families across schools in the district. Enrollment at each school will be tracked and recruitment efforts will be shifted to facilitate these efforts.

3.3 Procedures

3.3.1 Baseline session.—Once a family has screened eligible, a baseline session will be scheduled within two weeks (see Figure 1). Two RAs will conduct this visit; no personnel involved with the active intervention arms (CHWs or Healthy Homes) will be present. Caregivers and children will complete the consent/assent process and questionnaires assessing: healthcare utilization, asthma symptoms and control, home environment, demographic information, and psychosocial characteristics (see 3.4 Measures). Information regarding the child’s primary care physician (PCP), asthma provider, and school will also be obtained. Caregivers will complete a release to allow us to interact with school nurses and the child’s PCP and/or asthma provider. After the visit is complete, the project coordinator will randomize the family to one of the three conditions based on the child’s school. Families will receive compensation for completing the baseline session.

3.3.2 Participation in active trial.—Two weeks after the baseline session, families will complete the first of four home-based sessions. For children in the CHW + Healthy Homes + school intervention arm, and children in the CHW + Healthy Homes intervention arm, this will be the first home visit that includes both family-based asthma education and a home assessment by Healthy Homes. Home visits will last about 2 hours and include both the CHW and Healthy Homes assessor. For children in the CHW + Healthy Homes + school intervention arm, CHWs and the project coordinator will begin the process of communicating with the schools to ensure that children have the necessary forms and medication in place. School nurses and PCPs will be alerted to the child’s participation in an active arm of RVA Breathes. School nurses will follow a standardized protocol in their

interactions with students, which will be documented and relayed to the project coordinator (see 4.3 School intervention). After each home visit, the project coordinator will update the child's PCP and/or asthma provider on the child's participation in the intervention and information related to asthma symptoms and control. Families will receive compensation after Sessions 2 and 3.

3.3.3 Post-intervention and follow-up sessions.—Within 2 weeks of completing the 9-month program, children and caregivers will complete a post-intervention session of measures collected at baseline. Feasibility and family satisfaction with the program will be ascertained in semi-structured interviews. This session will last one hour and RAs will administer questionnaires to the child and parent. At 3-, 6-, and 9-month intervals, families will complete a similar session without the semi-structured interview. These sessions will last about 45 minutes. Families will receive compensation after each follow-up session.

3.3.4. Protocols for windows of eligibility and reaching families.—The team will develop protocols to monitor study visits and ensure visits occur following the study timeline. In general, visits occurring 30 days after the expected date will be considered outside of the window; actual time since the expected date will be documented and considered in interpretation of findings. Because this sample might be hard to reach, protocols will also be developed for study staff to follow in handling multiple no shows or rescheduled visits. Typically these protocols include how many times the team should reschedule a visit, how many times families should be called following a no show, and at what point a family is considered disengaged and withdrawn from the study.

3.4 Measures

Demographics.—At baseline, caregivers will report on caregiver and child's race/ethnicity, age, sex, monthly family income, caregiver education, family structure, and relationship to child.

Healthcare utilization.—Data from our hospital partners' billing systems will be collected at baseline, end of the intervention phase, and at the 9-month follow-up to assess number of ED visits and hospitalizations due to asthma. Caregivers will also report on the child's asthma-related ED visits and hospitalizations at each research and intervention session. This is our primary outcome of interest.

Medication usage.—Caregivers will report on their child's current asthma medications, including dose and refill history. We will use these reports to determine controller medication use.

Asthma school absences.—Caregivers will report on the number of asthma-related child school absences in the interval since the last assessment.

Asthma control.—Children and caregivers will complete the Childhood Asthma Control Test,¹⁵ which measures the frequency of daytime and nighttime asthma symptoms, activity limitations, and perception of disease control.

Symptom free days.—Caregivers will report number of symptom free days in the last 7 days.¹⁶

Asthma-related quality of life (QOL).—Parents will complete the Pediatric Asthma Caregiver QOL Questionnaire¹⁷ to assess their level of QOL related to child asthma. Children 7–11 years will complete the Pediatric Asthma QOL Questionnaire (PAQLQ);¹⁸ children 5–6 years will complete the pictorial version of the PAQLQ.¹⁹

Asthma self-management skills.—Caregivers will complete the Asthma Self-Management Questionnaire,²⁰ which assesses proper use of preventive strategies and understanding differences between medications.

Stress.—Caregivers will complete the Perceived Stress Scale,²¹ a well-validated measure of global stress appraisal and an individual's ability to cope with stress.

Depressive symptoms.—Caregivers will complete the 20-item Centers for Epidemiologic Studies Depression Scale,²² which assesses depressive symptoms in the last 7 days.

Metrics from home visits.—CHWs and Healthy Homes assessors will complete electronic reports regarding their productivity on the study as staff, including time spent on each session component, content covered (or not covered, with reasons noted). Families' questions and barriers described will also be entered in reports. CHWs will also be prompted to administer a series of paper questionnaires to caregivers at each visit. Questionnaires address asthma symptoms, control, medication use and changes, healthcare utilization, and missed school days. In their productivity reports, Healthy Homes will note observations of the home environment according to the Asthma Environment Checklist from the EPA, as well as document education shared with and materials provided to families.

Metrics from school nurses.—Nurses will record data related to interactions with each enrolled student, including reason and length of visit, actions during and following visit, and whether the child had medication, a spacer, and asthma action plan in the nurse's office.

Intervention fidelity.—Fidelity will be tracked by a member of the research team as adherence to the protocol, including feasibility of completing the intervention material in the time allotted. Intervention staff and caregivers will complete a checklist separately at the end of each session to determine which intervention components were completed. Congruency in responses will be compared to determine fidelity.

4. Interventions

RVA Breathes consists of three interventions adapted from evidence-based approaches to address priority areas identified in our needs assessment.^{6,7} These interventions include family-based asthma self-management education (delivered by CHWs), home environmental remediation (partnering with a local health district), and school nurse support (collaborating with elementary schools). We will test one intervention arm with all 3 components against

an intervention arm with asthma self-management education + home environmental remediation, and a comparator condition, enhanced standard of care (E-SOC). The interventions and E-SOC condition are described further in the following paragraphs (see also Table 2).

Additionally, the interventions comprising RVA Breathes (asthma education, home environmental remediation, and school nurse support) were chosen based on their application of behavioral change theory in targeting specific asthma outcomes.^{23,24} For instance, components of all three interventions are designed to elicit improved self-management of asthma in caregivers, children, and school nurses. This will be achieved through mechanisms of behavior change such as goal setting with CHWs, collecting information on child asthma symptoms at CHW sessions and school nurse visits, using that information to determine whether changes are needed in treatment plans and in the home environment, and working collaboratively in teaching and reinforcing asthma knowledge. Thus, through RVA Breathes, families will learn to sustain such behavioral changes and actions, leading to improvements in asthma management and ultimately, decreases in asthma-related healthcare utilization.

4.1 Family-based, self-management education.

CHWs will deliver evidence-based asthma education to parents and children. This will be an interactive process, tailored to the family's prior knowledge, strengths, and challenges. We used the evidence-based You Can Control Asthma,^{25,26} content on asthma management from the National Cooperative Inner City Asthma Study,²⁷ and from the Seattle-King County Healthy Homes project²⁸ as our guides in developing lesson plans for this component of RVA Breathes. Educational topics include: asthma etiology, symptoms, triggers, medications, asthma action plans, and psychosocial concerns related to asthma. Families will participate in four home-based sessions across 9 months. Material will be delivered to parents and children together, with appropriate visuals and worksheets for children. We contemplated separating parents and children; parents strongly preferred children attend with them to ensure that they could apply the knowledge gained to settings (e.g., schools) in which parents are not present.

Overall, we made a number of adaptations to the education sessions based on the results our needs assessment (see Table 3 for session outline). The order of session topics follows that of previously published asthma education programs,²⁹ and also covers the basics of asthma first before moving into empowering families in discussions with schools and providers. Between sessions, CHWs will call parents at least monthly to check in and assess family asthma management, including healthcare utilization since the last contact. CHWs will problem solve with parents to address relevant barriers, provide additional asthma education, and offer needed support or encouragement in between sessions. Additionally, in their monthly phone calls, CHWs will answer questions that might have arisen about the material covered in previous sessions, and reinforce any previously learned material that might be beneficial for the caregiver.

Throughout the four home sessions, CHWs will also work with caregivers to empower them in managing their child's asthma. During the first session, caregivers and CHWs will

collaboratively set goals and develop an action plan for their time together. This will include identifying skills and knowledge that caregivers want to improve in order to better care for their child's asthma. CHWs will utilize the teach-back method throughout the education modules to ensure that the caregiver has mastered the material and can use it without the CHW's assistance in the future. For instance, caregivers will be asked to describe the purpose of their child's asthma medications to the CHW, demonstrate that they can instruct their child in proper inhaler use, and describe the connection between asthma triggers in the home and their child's symptoms. In these ways, material from intervention sessions will be reinforced across the nine months. Caregivers will develop greater independence throughout the program and build the necessary skills required to manage their child's asthma without CHW involvement once the program ends.

4.2 Home environmental remediation.

This component of RVA Breathes will be delivered in conjunction with the family-based asthma education. A CHW and a Healthy Homes assessor from the local health district will attend all intervention sessions jointly as a team; the 4 home-based sessions will last approximately 2 hours each. During our needs assessment, focus group members emphasized their desire for efficient home visits, with material condensed into as few visits as possible. Thus, having both CHW and Healthy Homes in their home at the same time was considered more acceptable to community stakeholders. Healthy Homes will complete home assessments that include: family smoking habits, use of the dwelling, housing attributes (e.g., structural, mechanical, plumbing), non-intrusive observations for signs of problems, and use of environmental sampling equipment (temperature and relative humidity gauge, moisture meter, and/or CO/methane sniffer) to help detect and define problems. Healthy Homes will also provide real-time education and share information about their findings and recommendations for actions. Tenant education, specifically on rights and responsibilities based on the VA Landlord Tenant Residential Act, is a key educational component. CHWs will serve an important role in advocating for families with landlords and housing authorities based on recommendations from Healthy Homes.

Based upon observations documented in the comprehensive home assessment, families are provided with low-cost intervention materials (e.g., filters, pillow covers), as well as behavioral modifications to aid in the reduction of identified asthma triggers in the home. If more costly home environment issues are identified, with the family's permission, the Healthy Homes assessor will contact the tenant's landlord or make referrals to the local housing authority. The City of Richmond often has small grants that could help a family with major repairs or issues; the Healthy Homes team is well-versed in these resources.

In response to issues raised in our needs assessment, families will be asked to identify which of the specific environmental barriers noted by the Healthy Homes assessor is their top priority. This iterative and individually tailored approach to addressing environmental barriers was considered preferable by stakeholders, compared with addressing multiple environmental issues simultaneously, which families perceived as overwhelming and unrealistic. Healthy Homes will also build on family's strengths and priorities in a non-judgmental way (another important program feature, according to focus group participants).

The CHW will be present at these assessments to facilitate a team atmosphere among family, CHW, and the Healthy Homes assessor. The first session will be most intensive; sessions 2–4 will focus on changes made and those still needed, barriers to change, and issues that may have arisen related to home-based asthma triggers.

4.3 School intervention.

For children in the school component of RVA Breathes, CHWs will ensure that families submit required health paperwork (e.g., asthma action plan, medication release form). Parents in our focus and advisory groups had concerns that school nurses were not equipped to provide appropriate asthma care as needed, but also noted that they often did not turn in required forms to support such care.⁶ Parents stated that it can be confusing and challenging to determine which forms to complete, and to follow through with submitting the appropriate forms to schools. Barriers to paperwork completion included: lack of time, forgetfulness, and challenges in having the forms completed by PCPs. Nurses cited their inability to provide appropriate care in the absence of information from parents. In RVA Breathes, CHWs will assist families with this process and confirm with school nurses that children have the appropriate forms and medications at school. CHWs will also reach out the child's school nurse directly to further coordinate asthma care.

Additionally, school nurses in the intervention will be given a standardized protocol to follow with clear guidelines for caring for students with asthma. This includes a plan to respond to the needs of children with acute asthma symptoms, as well as one to follow if the child is chronically symptomatic or has asthma-related school absences. The project coordinator will monitor school nurse reports and check in with the child's PCP if the child has no medication or asthma action plan on file, or if the school nurse is concerned about the child's asthma symptoms during the school day.

The evidence base for these interventions comes from a variety of school-based asthma programs that highlight the need for asthma education, comprehensive action plans for school personnel, and coordination among families, nurses, and physicians.^{30–33} We focused on building a sustainable program that improves school nurses' management of asthma, empowers families in advocating for children's needs at schools, and increases communication among families, schools, and providers. We will not deliver intervention sessions in schools given concerns related to missed instructional time and issues with sustaining a program in Title I schools with competing priorities. The school component of RVA Breathes is flexible regarding when children enroll in the program, supporting a more feasible, sustainable model. Coordination and a standardized response from nurses will be important regardless of when a child enrolls.

4.4 Enhanced standard of care (E-SOC).

Health disparities in pediatric asthma treatment persist; it would be a disservice, therefore, to enroll a control group that is usual care without an active component. Given the unique infrastructure of school nursing in RPS, our E-SOC condition will include the usual asthma care children receive, as well as education for school nurses. The monthly school meeting targets all school nurses (elementary, middle, and high) in RPS, which allows for

dissemination at the district level. An E-SOC that includes nursing education addresses a priority area highlighted in our needs assessment. Thus, nurses in each school for children in the E-SOC (as well as the other conditions) will receive asthma education in the group meetings. There will only be follow up, however, among CHWs, school nurses, and child medical homes in the arm with all interventions; E-SOC families will not work with a CHW throughout the program. Families in the E-SOC group will also receive 4 mailings throughout the 9 months (Months 1, 3, 6, 9) that contain publicly available information about asthma. Our E-SOC will not contain any of the tailored, individual components that comprise the two treatment conditions. Consistent with the other groups, families will complete baseline, post-intervention, and follow-up assessments, and receive similar compensation.

4.5 Strategies to promote engagement.

We will implement a graduated incentive structure to minimize attrition such that higher compensations will be associated with later follow-up visits. Specifically, families will be offered incentives (\$30 baseline; \$50 post-intervention; \$70, \$80, and \$100 for 3-, 6-, and 9-month follow-ups, respectively) and children will receive parent-approved prizes (e.g., pencils, books) at each assessment. Phone calls and texts from CHWs in between sessions (and as needed) will further enhance retention for families in the intervention arms. Finally, the project coordinator will send postcard and email reminders to families regarding their upcoming visits.

5. Statistical Analysis

5.1 Evaluation of specific aims.

Descriptive statistics (e.g., frequency distributions, contingency tables) will be calculated prior to conducting any hypothesis testing. For the first aim of this study, we hypothesize that children in the two active interventions will achieve greater reductions than the comparator condition in the primary outcome of healthcare utilization (e.g., composite of frequency of ED visits and hospitalizations) from a 9-month follow-up to 9 months prior to the intervention period. We will also evaluate changes in school absences and controller medication usage at follow-up compared to baseline. We will also *explore* differences in outcomes between the two active intervention conditions to determine the value of adding a school-based component. These outcomes will be tested using a Generalized Linear Mixed Model (GLMM). GLMM models will be fit to multiple types of dependent variables including, Gaussian/Normal, Binomial, Poisson and Negative Binomial. The GLMM model fit will include a between-subject factor (Group, representing the control group and the two intervention groups) and will also include a random effect for the cluster. These models will be modified in longitudinal assessments by the inclusion of a within-subject factor (Time, baseline, additional time point assessment) and the interaction between Group and Time variables. The inclusion of the interaction terms allows for a formal test of differing courses between the groups over time.

Next, we will evaluate whether secondary outcomes (asthma control, symptoms, QOL) of children in the intervention groups are superior to those of the control group (Aim 2). These

outcomes will be tested using the GLMMs described under Aim 1 utilizing the proper distribution and link functions for the outcome variable examined.

To assess whether intervention effects are mitigated in families with caregivers who have poor asthma self-management skills, and experience high levels of stress and depressive symptoms (Aim 3) we will use the GLMMs described under Aim 1 utilizing the proper distribution and link functions for the outcome variable examined that have been modified by the inclusion of additional effects measuring caregivers' self-management skills, as well as stress and depressive symptoms. The inclusion of these covariates will allow us to adjust the intervention effects and increase the generalizability of the findings based upon caregivers' characteristics. We will also account for demographic factors and seasonality as covariates in our models. Given the possibility that we may have unequal cells by school within each group, we will also consider whether findings differ by school and will modify our models accordingly. Data from home sessions regarding environmental observations, Healthy Homes assessors' remediation plans, and CHWs' referrals for resources will be used in contextualizing processes that may have elicited positive change among families. Home session data will not be used directly to address our hypotheses, but will instead provide information supporting mechanisms of change within the RVA Breathes program.

5.2 Sample size.

We have a fixed number of clusters (24 schools). We anticipate that within each of these clusters there will be 50 children with asthma, 10 of whom we can expect to recruit; we conservatively assume 10 children in each cluster. Although we are interested in an overall test of group differences among the 3 study arms, we are even more interested in post-hoc tests of the group arms. To adjust for the multiple comparisons among the 3 study arms, rather than using $\alpha=0.05$ significance level, we applied a Bonferroni correction to the desired significance level, and have assumed a desired $\alpha=0.01$ significance level. Based on published data that reasonably represent our population and intervention effects,¹⁰ we assumed that in Group 1, 70% will have had at least 1 ED visit; in Group 2, 40% will have had at least one ED visit; in Group 3, 30% will have had at least one ED visit. Assuming 80% power, sample size calculations show that 16 clusters with an average cluster size of 10 and an ICC 0.02 will result in over 80% power for Group 1 vs. 3 comparison, and 80% power for Group 1 vs. 2 comparison. Given the expected small effect size for Group 2 vs. 3 comparison, we recognize that we are underpowered. This comparison, however, will provide information to power future studies and select best practices. With 240 children (24 clusters of 10) we have sufficient power to test for 1) an overall difference between the 3 study arms, and 2) a difference between the control arm and each intervention arm. We will enroll 300 children to allow for 20% attrition.

6. Discussion

RVA Breathes is designed to minimize pediatric asthma disparities and will be tested in a sample of predominately low-income children who identify as African-American/Black. Our intervention program is innovative given that it was developed from a community needs assessment, and evidence-based interventions have been refined for use specifically with our

targeted population. Pediatric asthma research has shown that tailored, multi-level intervention approaches are highly effective in reducing asthma symptoms among children, ³⁴ including interventions tailored to children's specific risk factors.⁹ Thus, RVA Breathes offers significant potential to improve the lives of children with asthma and their families living in Richmond, an urban center with disproportionately high rates of this chronic condition.¹³

6.1 Limitations and challenges.

Despite the strengths of RVA Breathes, there are some potential challenges involved in testing the program in an RCT. First and foremost, we are enrolling families who are often harder to reach and retain in intervention research. Moreover, eligible children may experience more severe asthma symptoms, suggesting the need for the program, but also making it harder for families to prioritize research participation. Barriers to participation might include competing priorities, lack of time, inconsistent phone service, and mistrust of research.³⁵ Strategies to mitigate these potential barriers will include working to establish a presence in the community by assisting at community events. For instance, we will provide asthma education at school events and community health fairs, assist with tours of a new market and health center opening in the community, and contribute in other ways so that our program begins to gain the trust of the community. We will also work with community partners and residents to optimize community members' trust and enhance our understanding of best practices for engaging and retaining families in the Richmond community in our asthma program.³⁵ Often mistrust is historical and thus, it might take time for our program to be established and trusted in the community.

Additionally, families often have transient living situations which can make it challenging to keep contact information current.³⁶ We will ensure that we have multiple contact numbers for families, including phone numbers and email addresses. We will also ask caregivers their preferences for being contacted via phone, text, or email. It is likely that caregivers will prefer to be reminded of a study visit via text as this is less disruptive. We will also ask caregivers for permission to visit their home for a scheduled session even if we have not been able to confirm the visit with them the day before. Finally, if we have enrolled a family, and have the proper releases signed, we will reach out to the school for additional contact information if needed.

Another potential challenge is that we may have a high number of screen fails due to children not meeting the school inclusion criterion. When recruiting from area PCP offices or health systems, it is likely that while participants might meet our asthma criterion, they might not attend a public elementary school within Richmond City. Geographically, parts of Richmond City are very close to surrounding counties; however, we are not working with school nurses in other school districts. Thus, we will try to maximize recruitment within the schools and build off our established partnership with RPS by asking schools to place flyers in students' backpacks, and to highlight RVA Breathes in newsletters and other communications from principals. Additionally, we will ask school nurses to assist with identifying potentially eligible children and referring families to the study. We will also consider compensating school nurses for referring participants to the program.

Based on developmental differences between younger children and adolescents, we decided to target children between the ages of 5 and 11 years in the program. This will allow us to enroll children in kindergarten through 4th grade in the program. Given that children are in the program for 9 months and then followed for 9 months, this will ensure that child participants can complete all interventions activities and assessments while still in an elementary school setting. However, we recognize that an asthma program is needed for adolescents as well. Thus, our next steps include developing a similar RVA Breathes program for middle and high school students. The program will likely address different asthma education topics, as families of middle and high school students face developmentally-specific barriers to daily asthma management.³⁷

We have modeled our program off other existing asthma programs that have conducted 3–4 home sessions across a 9 to 12 month period.^{28,38} In RVA Breathes, families receive intervention sessions every 2 to 3 months, with monthly phone calls from CHWs in between (and more frequently if needed). However, it might be that families prefer receiving intervention sessions more frequently and in a shorter amount of time. This is something that we will evaluate in the semi-structured interview that families complete in the first post-intervention session. We will use this feedback to refine RVA Breathes for future iterations. Finally, we acknowledge that our study design is limited in that many assessments will be measured via caregiver self-report. Although our primary outcome, healthcare utilization, will be measured via objective health encounter data, we recognize that future studies should incorporate other objective indices of asthma status, such as pulmonary function tests.

6.2 Conclusion.

In sum, pediatric asthma disparities persist and refinements to existing evidence-based interventions are needed to reduce asthma-related healthcare utilization among low-income, children from African American/Black backgrounds living in an urban setting. Interventions must reach children and families in their daily lives and aim to minimize barriers to coordinating care across multiple sectors of a child's asthma care including family, home, community, and medical. RVA Breathes is an innovative and comprehensive care program for children with asthma that will use CHWs to coordinate care among families, schools, and medical providers. Furthermore, with specific tailoring to the Richmond community based on direct stakeholder feedback, RVA Breathes has the potential to become a sustainable program; in fact, sustainability is built into the goals of the grant. Given the complexity of the program, discussions will occur with insurance companies and health systems to determine models of payment that could continue to support RVA Breathes. Additionally, different program aspects might be best supported by varying funders. For example, interventions with school nurses might be best sustained by the school district with additional assistance from the local health district. Discussions regarding sustainability of RVA Breathes will be ongoing throughout the course of the study, especially after results are analyzed and indicate the optimal strategy for resource allocation. Findings from this RCT will be disseminated at local community events, as well as outside of the Richmond area. The RVA Breathes program will likely serve as community-based model of asthma care for other urban centers aiming to minimize pediatric asthma disparities in their communities.

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Figure 1.
Timeline of RVA Breathes RCT

Table 1.

Community's identified needs addressed in RVA Breathes

Sector	Identified Needs	Intervention	Stakeholder	How being addressed in intervention?
Family and child	Support from another parent; issues with remembering to take medications; parent stress	Family-based, self-management education	Community health workers (CHWs)	CHWs will be parents (peer advocate model); education includes establishing routines to remember medications, strategies for managing stress
Home	Mold and other triggers within the home; difficulty advocating with landlords	Environmental remediation	Home environmental assessors	Use of established community program to conduct home assessments; referrals to legal assistance when needed
Community	Lack of asthma knowledge among school nurses; absence of appropriate asthma medications/ confusion about permission to administer medications in schools	School nurses	School district	Intervention with school nurses around asthma and coordination with families; standardized protocol for school nurses to follow
Medical Care	Mistrust of physicians; difficulty refilling prescriptions on time; not understanding differences between quick-relief and controller meds; need to reduce reliance on ED and increase use of medical home	School nurses; continued feedback between CHWs and PCPs (and schools)	School district; CHWs	Facilitating communication between families, school nurses, and PCPs; self-management education focuses on communicating with physicians, differences among medications, and other preventive strategies

Table 2.

Intervention components of RVA Breathes

	Components
CHW intervention	<ul style="list-style-type: none"> • Evidence-based asthma education delivered to caregiver and child • Monthly phone call checks ins between sessions • Ensure required forms and medications are at schools
Healthy Homes intervention	<ul style="list-style-type: none"> • Home assessment with appropriate remediation strategies in response • Low-cost intervention materials provided
School intervention	<ul style="list-style-type: none"> • Asthma education sessions for school nurses • Standardized plan for responding to students' asthma in schools
Enhanced SOC (control)	<ul style="list-style-type: none"> • Publicly available materials mailed throughout intervention period • Family continues with usual asthma care

Table 3.

Adaptations to evidence-based asthma education

	Evidence-based content from published research	Adaptations based on needs assessment
Session 1 (Month 1)	<u>Asthma Basics:</u> <ul style="list-style-type: none"> • Physiology • Review child's current asthma symptoms and level of control • Review types of asthma medications • Asthma triggers and ways to minimize exposures • Getting to know the child's asthma 	<ul style="list-style-type: none"> • Raising expectations about life with asthma (i.e., not waking up at night, not coughing every day, being able to attend school) • What is meant by well-controlled asthma? • More emphasis on purpose of controller medication and its importance in reducing symptoms and use of emergent care • Focus on stress and mood as asthma triggers
Session 2 (Month 3)	<u>Increasing self-management:</u> <ul style="list-style-type: none"> • Asthma device skills are taught (using spacers, inhalers) • Asthma action plans, taking medications as prescribed • Communicating with physicians 	<ul style="list-style-type: none"> • Barriers to using medications as prescribed (introduce brief motivational interviewing) • Concerns related to patient-provider communication (e.g., distrust)
Session 3 (Month 6)	<u>School and family issues:</u> <ul style="list-style-type: none"> • Communication with school nurses • Handling your asthma in school • Balancing asthma care within the family • When to seek emergency care 	<ul style="list-style-type: none"> • Reducing feelings of "ED security/reliance" by increasing preventive strategies, including enhancing relationship with PCP • Minimizing caregiver stress • Advocating for your child at school and in the community
Session 4 (Month 9)	<u>Empowering your family:</u> <ul style="list-style-type: none"> • Review what has been learned • Questions and issues still remaining 	<ul style="list-style-type: none"> • Review strategies for minimizing asthma management barriers • Focus on empowerment