Title: RVA Breathes: A Richmond City Collaboration to Reduce Pediatric Asthma Disparities

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RVA BREATHES

CLINICAL TRIAL

PROTOCOL

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A Introduction

A1 Study Abstract

Despite the existence of several evidence-based asthma treatments, and increased understanding of effective community-based treatment approaches for high-risk pediatric populations, childhood asthma disparities persist. Richmond is often cited as the "Asthma Capital" of the U.S. by the Allergy and Asthma Foundation of America, and is consistently identified as one of the most challenging places to live with asthma. To date, however, there is no comprehensive, community-engaged asthma care program for those children at highest risk for poor asthma outcomes. To address this urgent public health concern, our investigative team conducted a year-long, mixed-methods community needs assessment (U34HL130759). Key priority areas that emerged included peer support, advocacy, treating the home as a system, increased school nurse education, and coordination with schools and providers. Our community-engaged team translated the needs assessment findings to a program, RVA Breathes, that coordinates asthma care across four sectors: the family, home, community, and medical care. RVA Breathes includes family-based asthma self-management education (delivered by Community Health Workers [CHWs] with the Institute for Public Health Innovation), home environmental remediation (with Richmond City Health Department's Healthy Homes Initiative), and a school nurse component (with elementary schools in the Richmond City Public School System). These interventions capitalize among existing resources and relationships with stakeholders in Richmond, each of which is committed to RVA Breathes. Three-hundred children with asthma and their caregivers will participate in a randomized clinical trial of RVA Breathes. After completing a baseline assessment, families will be randomized to one of three conditions: 1) asthma education + home remediation + school intervention, 2) asthma education + home remediation and 3) comparator condition (Enhanced Standard of Care, E-SOC). Families will participate in the program for 9 months and complete follow-up assessments (post-treatment and 3-, 6-, and 9-month) to measure changes in healthcare utilization and the impact of the program on child asthma outcomes. Conditions will be compared on the primary outcome of healthcare utilization, defined as a composite of the frequency of asthma-specific ED visits and hospital admissions, as well as the secondary outcomes of school absences, controller medication use, asthma control, symptoms, and quality of life. We will also evaluate the sustainability of RVA Breathes after 9 months (without active intervention), including a review of qualitative data from participants and stakeholders in the program. Findings from this trial will allow for dissemination and implementation of RVA Breathes as a sustainable program in the Richmond area.

A2 Primary Hypothesis

We hypothesize that children in the two active interventions of RVA Breathes will achieve greater reductions in healthcare utilization (e.g., a composite of the frequency of asthma-specific ED visits and hospital admissions) at post-treatment and follow-up than children in the comparator condition.

A3 Purpose of the Study Protocol

The purpose of the study protocol is to provide an overview of the RVA Breathes program and ensure that the program can be replicated in other trials.

B Background

B1 Prior Literature and Studies

Guidelines from the National Asthma Education and Prevention Program[1] outline 4 components of successful interventions to reduce asthma morbidity: assessment and monitoring of symptom control; control of environmental factors; family and patient asthma education; and appropriate pharmacologic therapy. Pediatric asthma research has shown that tailored, multi-level intervention approaches are highly effective in reducing asthma symptoms among children,[2] including interventions tailored to children's specific risk factors.[3] A range of successful interventions target asthma care across the levels of community, family, home, and medical setting. Community-based interventions can also include modification of the home environment to minimize triggers and incorporate asthma self-management education for families.[3,4] Two multisite projects, Allies Against Asthma (Robert Wood Johnson Foundation) and Merck Childhood Asthma Network (MCAN; Merck Foundation) serve as useful models for the development of a collaborative, community-based program in Richmond. Within each project, sites were selected to form a comprehensive approach to reducing asthma

morbidity. Both projects demonstrated success in reducing asthma morbidity as measured by ED visits and hospitalizations.[5-7] Long-term results over a 4 year period from the Allies Against Asthma Initiative found that policy and system changes continued as coalitions established routine care for each child.[8] Sites within each project that were able to effect change in child asthma care highlighted the importance of strong coalitions and partnerships within communities. An example from Boston Children's Hospital, the Community Asthma Initiative (CAI), began with a needs assessment and developed a program of care around each child that provided asthma education, case management, home visits to assess asthma control and risk, home environmental assessment, and community outreach.[9] Cost-benefit analyses of the CAI found a net present value of $215,100 in gains for society, taking into account savings from fewer ED visits, hospitalizations, and missed school/work days.[10] Reports from the CAI highlight the need to develop an Asthma Care Implementation Program (ACIP) that supports families with respect to culture, language, and beliefs through interventions in the home, school, and community.[11]

B2 Rationale for this Study

Currently, however, there is no well-integrated, comprehensive, sustainable program of care for children with asthma in Richmond City. Richmond, an urban center, has been named as the Asthma Capital by the Asthma and Allergy Foundation (i.e., most challenging place to live in the United States with asthma) multiple times in the last five years. Richmond's asthma hospitalization rate is the highest of any locality in Virginia. An asthma care program is critical to reducing poor asthma outcomes in this high-risk group of children.

B3 COVID-19 Pandemic

In early 2020, RVA Breathes was impacted by the Coronavirus disease 2019 (COVID-19). COVID-19 is a respiratory illness caused by a virus called SARS-CoV-2. For the health and safety of staff and families, in-person interactions between research team and families were limited beginning March 13, 2020. Additionally, schools were closed and transitioned to remote instruction in mid-March. Thus, this protocol describes procedures both pre-COVID-19 (before March 13, 2020) with 217 families, and procedures after COVID-19 began with the remaining families enrolled in RVA Breathes. Changes to procedures due to COVID-19 are noted following original procedures.

C Study Objectives

C1 Primary Aim

To evaluate a randomized control trial (RCT) of RVA Breathes.

- Conditions will be compared on the primary outcome of healthcare utilization (e.g., a composite of the frequency of asthma-specific ED visits and hospital admissions).
- Conditions will be compared on the secondary outcomes of school absences and medication usage.
- We hypothesize that children in the two active interventions will achieve greater reductions in healthcare utilization and school absences, and increases in controller medication usage at post-treatment and follow-up than children in the comparator condition.
- We will also *explore* differences in outcomes between the two active intervention conditions. This will provide important data for determining best practices in subsequent iterations of RVA Breathes.

C2 Secondary Aims

a) To evaluate the effectiveness of the RCT on secondary outcomes including asthma control, symptoms, and quality of life (QOL).

- We hypothesize that secondary outcomes of children in the intervention groups will be superior to those of the control group.

b) To identify putative mediators and moderators (e.g., caregiver asthma self-management skills, perceived stress, and depressive symptoms) of treatment outcomes.

- We hypothesize that intervention effects will be mitigated in families with caregivers with lower levels of asthma self-management skills at baseline, as well as in those with higher baseline levels of stress and depressive symptoms.

C3 Rationale for the Selection of Outcome Measures

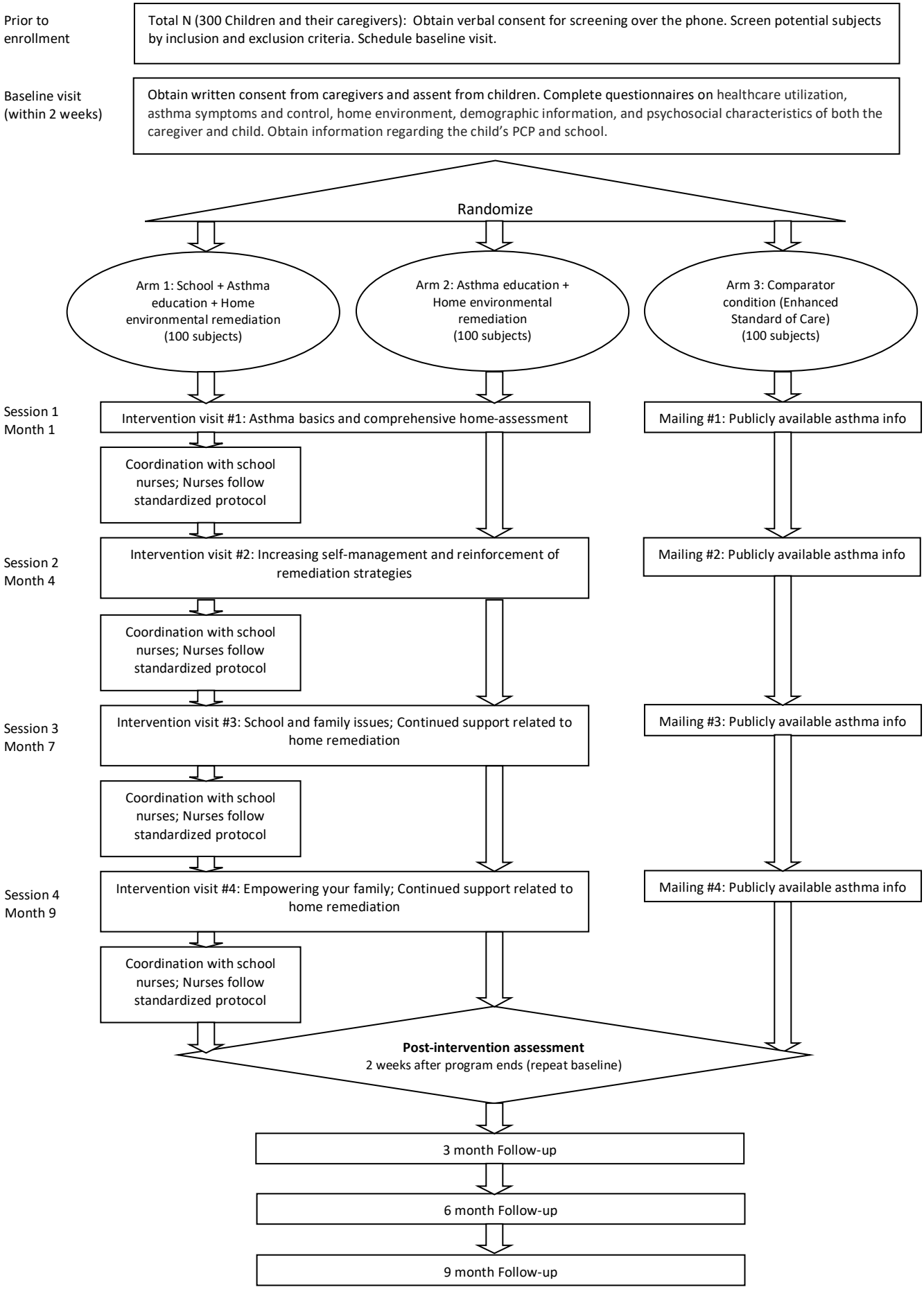
Outcome measures were informed by the Social-Ecological Model and Interactive Systems Framework and drawn from recommendations by the Asthma Outcomes Steering Committee.

C4 Rationale and Risk/Benefits

Given that pediatric asthma disparities are a serious public health problem, the significance of this research project is high. As the study risks are small, the benefit to society outweighs subject risk. New information learned from this intervention study has the potential to improve the health and lives of urban children with asthma, as well as their families.

D Study Design

D1 Overview of Study Design



D2 Subject Selection and Withdraw

2.a Inclusion Criteria

Children and their caregivers must meet all of the inclusion criteria in order to be eligible to participate in the study:

- Child between the ages of 5 and 11
- Physician diagnosed asthma in child
- Child has had an asthma-related hospitalization or emergency department visit, an unscheduled asthma-related PCP visit, or systemic steroid use for asthma exacerbation in the last 2 years
- Family resides in Richmond City
- Child attends an elementary school in Richmond City Public School System
- Parent or caregiver is child's legal guardian
- Parent or caregiver has lived with child in same home for last 6 months
- Provide relevant signed consent and assent

2.b Exclusion Criteria

A child or caregiver who meets any of the following criteria will be excluded from participation in this study:

- Severe psychiatric, developmental, or medical condition that would preclude effective study participation
- Anything that would place the individual at increased risk or preclude the individual's full compliance with or completion of the study.

2.c Ethical Considerations

All data will be collected and maintained in accordance with legal and ethical standards. These materials are being collected for the research purposes of this study. Study staff will be required to complete the Collaborative Investigator Training Initiative (CITI) course in human subjects' protection offered by VCU's Office of Research Subjects Protection. PI Everhart will ensure that this study is conducted in full conformity with the principles set forth in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.

2.d Subject Recruitment Plans and Consent Process

Children with asthma will be recruited from the community, from hospitals in Richmond City (e.g., Bon Secours Health System [BSHS], VCUHS), and from schools. High risk children will be defined as those that have had an asthma-related hospitalization or ED visit, unscheduled PCP visit, or systemic steroid use for asthma exacerbation in the past 2 years. The Office of Health Innovation at VCU and VCUHS has developed a system to identify excessive healthcare utilizers; we will use hot spotting methodology to recruit children who have had at least 1 hospitalization and/or 1 ED visit for asthma in the past 2 years and have been seen at area hospitals. Analysts will work with the Health Systems' Information technology programs to provide a daily list of children meeting our high-risk definition for asthma who are currently in the ED or hospital. Existing CHWs already present in the resource centers of public housing developments will also assist with recruitment given their established relationships with families in the community. Recruitment from hospitals throughout BSHS and VCUHS will occur through clinic referrals, hospital inpatient units, and the ED. School recruitment includes school nurses calling families and referring them to the program, sending home flyers and consent to contact forms in student backpacks and through teacher distribution, providing small prizes for children who return a consent to contact form, and recruiting at school events such as health fairs, PTA meetings, and other school festivals. Letters will also be sent from primary care provider offices to potentially eligible families.

Contact information for potentially eligible participants will be given to study RAs and the project coordinator. Families will then be contacted by study staff by phone to determine eligibility and interest. During their initial contact, potential participants will complete a screening questionnaire (which confirms their family's eligibility). Participants will be asked to provide their verbal consent prior to beginning the screening interview. Similarly, prior to beginning the baseline assessment, adult participants will be asked to provide written consent for both their participation, and their child's (via the parental consent form). Children will also be asked to provide their

written assent. All consent and assent forms will be IRB approved. Prior to beginning the baseline assessment, consent and assent forms will be reviewed with parents and children in detail. Participants will be given a signed and dated copy of the consent/assent form. Either the PI or a Research Assistant will obtain consent. Consent will be obtained prior to any study related procedures. Participants will be provided as much time as they need to make their decision. They will be offered the opportunity to take the consent form home with them to review with other family members prior to committing to the program. All consent forms include information about the following: a) the purpose of the research, b) a description of human subjects' involvement, c) the types of data being collected and how records will be maintained, d) the anticipated number of participants, e) potential risks and benefits, f) compensation for participation, g) methods used to ensure the confidentiality of the data, h) compensation for injury, and i) details on participants' right to withdraw from the study at any point, or refuse to answer any specific interview or survey question(s). In addition, the consent form encourages participants to ask questions should they not understand any word included in the consent/assent forms. In addition, these forms will be reviewed with them in detail. Participants will be given a signed and dated copy of the consent form, which includes contact information for the PI and Co-PI, and for the VCU Office of Research Subjects Protection. If the caregiver is non-English speaking, a translated consent document will be available and a bilingual RA will be present to conduct the consent process.

2.d.i. Changes to recruitment and consent process due to COVID-19: Recruitment in the community will be limited to remote options (e.g., as a part of virtual newsletters or emailed flyers). School nurses will still call potentially eligible families, we will still receive lists of children seen at VCU and BSHS, and letters will be mailed from provider offices. Families will be screened using our IRB approved screening materials. If a family screens eligible, the caregiver will be told that, "Due to COVID-19 and recommendations from the Health Department, and for the safety of families and our staff, we are now conducting RVA Breathes remotely. This means that the consent process and all research and intervention sessions will be conducted over the phone or video." A phone or video session will then be scheduled to conduct the verbal consent process and complete baseline measures. Questions will be asked to the parent and then to the child separately. If the child is not available or is not comfortable answering questions, these will be marked as missing data. IRB has approved a waiver of documentation of consent for parents in RVA Breathes. This is for their participation in the study and for the participation of their child. We will instead obtain verbal consent and will document in our research record using a consent documentation form that records that consent was given, what day/time it was given, and who was present for the discussion. We are also approved to waive child assent, which is recorded on the consent documentation form.

2.e Randomization Method and Blinding

Families will be randomized at the school level. In consultation with RPS, we will match elementary schools based on demographics and location, and whether school nurses travel among schools; 8-9 schools will be included in each condition. We will use a block randomization scheme. After the baseline session is complete, the project coordinator will randomize the family to one of the 3 conditions based on the child's school. Given the nature of our program, it will not be possible to blind participants or study staff to their condition. Analysts collecting data from insurance companies will be blind to condition.

2.f Risks and Benefits

Perceived risks for participating in this study are minimal (see Data Safety and Monitoring Plan for detailed description of risks and mitigation of risks). Participants may find some of the questionnaires upsetting or may be uncomfortable answering questions. Participants will be told that they can choose not to answer any questions and can stop participating in the study at any time without penalty. Breach in confidentiality is another potential risk, however safeguards will be in place to deter this potential. Paper-based records will be kept in a secure location and accessed only by authorized study personnel. Electronic records will be made available only to those personnel in the study through the use of access controls and password-protected files. Personal identifying information will be removed from study-related data and data will be coded. A Data Safety and Monitoring Board will be in place to ensure the safety of subjects.

We expect that families enrolled in the intervention arms of RVA Breathes will experience benefits in that their children's asthma will be better controlled and managed through a comprehensive asthma care plan. Our proposed research will make a significant contribution to minimizing pediatric asthma disparities by implementing evidence-based interventions that have been directly informed by the Richmond community.

Further, data collected from this trial will inform subsequent iterations of RVA Breathes, which will benefit more children with asthma.

In-person visits were paused in mid-March 2020 to reduce participant risk.

2.g Early Withdrawal of Subjects

Efforts to minimize attrition will include graduated incentives (i.e., increased compensation throughout study to increase retention) and phone calls/text reminders. However, families are free to withdraw from participation at any time upon request. A subject's participation may also be terminated if the family's participation in the project is not in their best interest (i.e., placing too much stress on the family system).

2.h When and How to Withdraw Subjects

Families will be withdrawn as soon as they request to do so or the project team (e.g., CHWs and their supervisor, Healthy Homes assessors, the project coordinator, community liaison) determines that their participation is not in their best interest. Written documentation for the reason for termination will be recorded. The PI will speak with the family if the family's participation is deemed not to be in their best interest. Moreover, if home circumstances are deemed physically unsafe for CHWs or other study staff, subjects will be withdrawn from the study; this also implies that the appropriate calls to Child Protective Services will be made. Given that evidence-based interventions for asthma are being used in this program, we do not have any other specific stopping guidelines for efficacy or safety.

2.i Data Collection and Follow-up for Withdrawn Subjects

If the parent/caregiver member of the caregiver-child dyad withdraws from the study at their request, we will determine whether another caregiver is able to participate in the study. If so, this caregiver will be consented for their participation in the study. If not, then the dyad will be withdrawn from the study. Every effort will be made to meet with the family one last time to repeat data collection of measures completed at baseline. Participants would be paid for participating in this final session. Exit interview data, including feasibility and acceptability, will also be collected from the family at this time if they agree to do so. Depending on when in the study timeline a participant withdraws (e.g., still in recruitment phase), replacement of withdrawn subjects will occur if we are still actively recruiting participants into the trial. If we are no longer recruiting participants, then the withdrawn subject will not be replaced.

E Study Procedures

E1 Screening for Eligibility

Contact information for potentially eligible participants will be given to study RAs and the project coordinator. Families will then be contacted by study staff to determine eligibility and interest. During their initial contact, potential participants will complete a screening questionnaire (which confirms their family's eligibility). Caregivers will be asked to provide their verbal consent prior to beginning the screening interview. This over the phone screening questionnaire will include questions regarding child age, school, parent/caregiver and child relationship, and questions regarding the child's asthma diagnosis. If the caregiver and child are eligible and interested, a baseline visit will be scheduled within two weeks of the screening phone call.

E2 Schedule of Measurements

This table includes all measure content, including in which visit they are collected. Exact measure names are presented in the description of sessions.

Forms	Content	Administered by	When/How Often
Potential Participant Information	Contact information for potential participants (includes caregivers and children who are and are not selected to participate)	Project coordinator	Pre-enrollment
Eligibility and Enrollment	Inclusion and exclusion criteria for the study; Assignment into intervention arms and wave; IRB consent/assent	Project coordinator	Pre-enrollment
Caregiver Release	Signature of caregiver authorizing study personnel to contact the child's school nurses, PCP and/or asthma provider	Research assistants (RA)	Baseline session
Demographic Information	Caregiver and child race, ethnicity, gender	RA	Baseline session

Psychosocial Characteristics	Caregiver and child characteristics on social determinants of health, stress, and depressive symptoms	RA or CHW	Baseline, post intervention, 3-month, 6-month, and 9-month follow up sessions
Health Care Utilization	Inpatient and emergency department utilization	RA or CHW	
Medication Usage	Prescription medication history and refills	RA or CHW	
Asthma Symptoms and Control	Asthma control, symptoms, quality of life, self-management skills	RA or CHW	
School Nurse Log	School attendance, visit to nurse, medication given at school	RN or RA	
Month 1 Session – CHW	Documenting info on asthma basics	CHW	Month 1 Session
Month 1 Session – HH	Comprehensive home environment assessment	HH	
Month 4 Session – CHW	Documenting info on increasing self-management	CHW	Month 4 Session
Month 4 Session – HH	Education and strategies provided/reinforced and referrals	HH	
Month 7 Session – CHW	Documenting school and family issues	CHW	Month 7 Session
Month 7 Session – HH	Education and strategies provided/reinforced and referrals	HH	
Month 9 Session – CHW	Documenting Empowerment to family	CHW	Month 9 Session
Month 9 Session – HH	Education and strategies provided/reinforced and referrals	HH	
Between Session Log	Track contacts between participants and CHW/HH outside of the four sessions	CHW/HH	Intervention
E-SOC Mailing Log	Track mailing of asthma information	Project coordinator	Quarterly

E3 Changes to study sessions due to COVID-19

Due to COVID-19 (mid-March 2020), we have converted RVA Breathes to a remote program for families. Families are given the option of completing the research and intervention sessions as phone sessions or video sessions through Zoom. If the family chooses Zoom, all privacy and confidentiality protocols will be followed. Control families are emailed or mailed educational materials during the intervention phase. We have developed "contactless" procedures to drop off intervention materials and cash payments at participants' homes. These procedures include calling the family ahead of time, maintaining a distance of at least 10 feet, wearing a mask, placing items in front of the home, and waiting for retrieval before leaving the area. Intervention materials include pillowcase covers, air purifiers, cleaning products, filters, and supplies for pest removal. These materials will be dropped off after the intervention session.

As we are able to complete follow up sessions remotely with families, we will plan to continue remote follow up sessions with families that have moved out of state. Research staff will conduct these sessions via phone or video depending on family preference. Payments will be made with an e-gift card.

Given the relevance of COVID-19 to participants' lives and its potential impacts/interactions with the study interventions, we have also added the following items to study questionnaires:

- To the beginning of the data forms used at each intervention session: "How has the COVID-19 pandemic impacted you and your family?"
- To the end of the data forms used at each intervention session: "What did you think of the phone/video session today instead of an in-person visit?"
- To baseline/follow-up session questionnaires: "How has COVID-19 impacted your family?," "How has COVID-19 impacted your child's asthma care?," "What has it been like not being able to access your child's school nurse for asthma care?"

Change in school nurse intervention due to COVID-19: Per RPS protocol, school nurses will be contacting all students with a health condition at least once over the phone during the fall semester. This will include RVA Breathes participants. When a school nurse speaks with an RVA Breathes family, the school nurse will complete a modified data form that has been adapted for a non-clinic setting. This interaction could happen at any time throughout 2020.

E4 Baseline Session

Two RAs will attend the baseline session, which will last about 90 minutes. Caregivers will be compensated $30 for their time and children will be given a parent-approved prize. At this visit, RAs will:

- Obtain and document consent from subject on study consent form, as well as child assent. This includes parental consent for their own participation and their child's participation.
- Verify inclusion/exclusion criteria.
- Administer the following measures:
    - Caregivers will report on family demographic information including caregiver and child's race/ethnicity, age, sex, monthly family income, education level, information on family structure, and their relationship to child.
    - Caregivers will report on the duration and number of times the child has been hospitalized due to asthma or visited the ED because of asthma in the last 12 months. This information will be verified by hospitalization and ED visit information from insurance companies and health systems.
    - Caregivers will report on the number of times their child missed school due to asthma in the last 12 months. This information will be verified by absentee data from the child's school.
    - Caregivers will report on the child's asthma medication name, dose, and refill information. We will also collect pharmacy refill data.
    - Caregivers and children will complete the Childhood Asthma Control Test (cACT) jointly, which measures the frequency of daytime and nighttime asthma symptoms, activity limitations, and perception of disease control.
    - Caregivers will report on number of symptom free days in the last 14 days on the Asthma Assessment Form.
    - Children will complete the Pediatric Asthma Quality of Life Questionnaire (PAQLQ).
    - Caregivers will complete the Pediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ) and report on their own quality of life.
    - Caregivers will complete the Asthma Self-Efficacy Management Questionnaire (ASMQ), Perceived Stress Scale (PSS), Centers for Epidemiologic Studies Depression Scale (CES-D), and Stressful Life Events and Conditions Checklist (SLECC).

Changes due to COVID-19:
- Baseline sessions occur over the phone or via video (see Section E3)
- Verbal consent is obtained with documentation (see Section D2, 2.d.i.)
- Question added to packet:
    - "How has COVID-19 impacted your family?," "How has COVID-19 impacted your child's asthma care?," "What has it been like not being able to access your child's school nurse for asthma care?"
- Payment occurs via contactless payment drop-off (see Section E3)

E5 Session 1, Month 1

Within 2 weeks after the baseline session, families in the two active intervention arms will complete the first of 4 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 2-2.5 hours, and include both the CHW and a representative from Healthy Homes.

After the first visit, CHWs in consultation with the care management committee, will update providers with a summary of information covered at the session. Data from family interactions with the PCP will be communicated back to CHWs.

For children in the CHW + Healthy Homes + school intervention arm, CHWs will begin the process of communicating with the schools to ensure that children have the necessary forms and medication in place. Caregivers will complete a release to allow us to contact school nurses and the child's PCP and/or asthma provider. School nurses and PCPs will be alerted to the child's participation in an active arm of RVA Breathes. School nurses will follow the standardized protocol in their interactions with the student; interactions will be documented and relayed to CHWs.

For children in the E-SOC group the project coordinator will mail the first set of publicly available information on asthma.

Intervention Session 1:

- CHW and Healthy Homes assessor describe program aims for the year. Work with parent and child to outline their goals for the year as an RVA Breathes participant.

- CHW role: Lesson plans focus on the basics of asthma, highlighting what the parent and child know about asthma and what knowledge gaps exist. Content includes:
    - Physiology of asthma: where lungs are located and what happens when an asthma attack occurs
    - Review of child's current asthma symptoms and what they are able to do/not able to do because of their asthma
        - Keep list and highlight what child would like to be able to do with asthma
        - Define for parent and child what is meant by asthma control
    - Describe asthma triggers: focus on differences between allergens and irritants
        - Review child's own asthma triggers
    - Focus on what child's asthma looks like: triggers, symptoms, medications, and how the family manages the child's asthma daily

- Healthy Homes role: Complete a comprehensive home assessment. Evaluation includes:
    - Family smoking habits, general use of the dwelling, housing attributes (e.g., structural, mechanical, plumbing), and non-intrusive observations for signs of problems.
    - Use environmental sampling equipment (temperature and relative humidity gauge, moisture meter, and/or CO/methane sniffer) to help detect and define problems.
    - Provide real-time education, and share information about these findings and recommendations for actions with the parent, child, and CHW.
    - Review family's priorities related to minimizing triggers in the home. Work with families to decide which area they can reasonably and successfully improve. (Maintain a non-judgmental perspective and highlight the family's strengths)
        - Generate a clear, written plan for family with a plan of action.
    - Provide family with low-cost intervention materials (e.g., filters, pillow covers).
    - Provide list of behavioral modifications to aid in the reduction of asthma triggers in the home. Focus on the family's priorities.
    - Provide tenant education, specifically on rights and responsibilities based on the VA Landlord Tenant Residential Act, as well as referrals to *Medical-Legal Partnership* when those requests are not/or have not been met.

- CHWs and Healthy Homes assessors complete a session checklist of material covered; caregivers also independently complete a checklist.
- Schedule the next session, Session 2 before leaving the family's home. Schedule a follow up phone call for each month before the next session. Remind the family that the CHW will be calling then. Make sure the family has all contact information for RVA Breathes.
- Answer any questions the family has and thank them for their time.

Changes due to COVID-19:

- Session occurs over the phone or via video (see Section E3)
- Questions added to packet:
    - "How has the COVID-19 pandemic impacted you and your family?"
    - "What did you think of the phone/video session today instead of an in-person visit?"
- Intervention materials dropped off using contactless procedures (see Section E3)

E5.a. Changes to home assessment due to COVID-19: The comprehensive home assessment will be done remotely, if possible (if the family does not have video capabilities or does not want to do a video, then it will occur as a phone session). The session will be scheduled as a Zoom video session by our project coordinator. Families will be emailed a link to the HIPAA compliant Zoom session (through VCU) with both the CHW and Healthy Homes assessor. A video session will allow the family to walk the home assessor through their home

and determine areas of concern in the home that might be triggering the child's asthma. Prior to beginning the session, the Healthy Homes assessor will remind the caregiver that this session is voluntary, and that no one other than the consented parent and child should appear on the video. Moreover, the CHW and Healthy Homes assessor will confirm that they are in a private location and no one else can see or hear their video. We will document the method of delivery and fidelity to the components of the HHA assessment (rate the quality of the video, and document whether the HHA was able to see the parts of the home they needed to see). Stakeholder feedback will also include how CHWs and HHAs think the remote visits are going and whether they see comparable participant engagement in these sessions.

E6 ***All groups:*** School nurses across the district will receive evidence-based asthma education in the standing meeting with the supervisor of nursing services for RPS. This education will occur four times across the academic year and cover the following evidence-based topics:

- Recognizing and managing symptoms
- Understanding the importance of an asthma action plan
- Responding in the event of an emergency
- Tracking school absences
- Communicating with families
- Encouraging physical activity
- Reducing exposure to triggers during the school day

Due to COVID-19, this education will occur remotely with school nurses.

E7 Session 2, Month 4

During Month 4 of study participation, families in the two active intervention arms will complete the second of 4 sessions. For children in the CHW + Healthy Homes + school intervention arm and children in the CHW + Healthy Homes intervention arm, this will be the second home visit that includes both family-based asthma education and a home assessment by Healthy Homes. Home visits will last 2-2.5 hours, and include both the CHW and a representative from Healthy Homes.

CHWs in consultation with the care management committee, will continue to update providers on the family's participation in the intervention. Data from family interactions with the PCP will be communicated back to CHWs.

For children in the CHW + Healthy Homes + school intervention arm, CHWs will continue to communicate with the schools to ensure that children have the necessary forms and medication in place. School nurses will continue to follow the standardized protocol in their interactions with the student; interactions will be documented and relayed to CHWs.

For children in the E-SOC group the project coordinator will mail the second set of publicly available information on asthma.

<u>Intervention Session 2:</u>

- CHW and Healthy Homes worker summarize the information that was covered in the first visit.
- The caregiver and child are asked for an update on any changes in medication, and any asthma-related sick visits, scheduled visits, hospitalizations, ED visits, or absenteeism.

- CHW role: Lesson plans focus on increasing asthma self-management and efficacy. Content includes:
    - Discuss role of stress and mood in asthma.
        - Discuss parent and child stress: Identify stressors and problem solve strategies for minimizing (e.g., self care, organization).
        - Repeat process for parent and child mood, include ways to improve mood (e.g., behavioral activation, social support)
    - Review child's current asthma medications

    - Focus on difference between controller and rescue inhalers: differences in mechanisms of action between two medications
        - Reinforce with child visuals regarding medications (pictures of controller medications, role of controller medication in reducing mucus in lungs)
        - Use child's own medications as examples
    - Skills-based education around using a spacer and inhaler. This includes a demonstration by the CHW and the child, as well as a discussion about why a spacer is important. The CHW will correct and reinforce the child's technique in a developmentally appropriate manner.
    - Review of the child's asthma action plan. By this point, the CHW will have retrieved the asthma action plan for the child's PCP to review with the family.
    - Review of child's medications and importance of using them as prescribed.
        - Barriers to using medications for family will be reviewed. CHW and caregiver will problem solve ways to increase adherence.
        - Issues with insurance coverage, prescription payments, and refills are also discussed, as well as strategies for minimizing these issues.

- Healthy Homes role: Review changes that family has made (if any) based on first assessment. Session content includes:
    - Praise for successful changes. Review how family was able to make these important changes.
    - Problem solve issues that have prevented any changes that family wanted to make.
    - Review new priority areas and how family can make these changes.
    - Assess whether follow up with landlord or referral to Medical-Legal Partnership is needed.
    - Address any additional needs that family may have related to home environmental remediation.
    - Set goals for any behavioral modifications/changes in the home that are needed between now and the next visit.

- CHWs and Healthy Homes assessors complete a session checklist of material covered; caregivers also independently complete a checklist.
- Schedule the next session, Session 3, before leaving the family's home. Schedule a follow up phone call for each month before the next session. Remind the family that the CHW will be calling then. Make sure the family has all contact information for RVA Breathes.
- Answer any questions the family has and thank them for their time.

Changes due to COVID-19:

- Session occurs over the phone or via video (see Section E3)
- Questions added to packet:
    - "How has the COVID-19 pandemic impacted you and your family?"
    - "What did you think of the phone/video session today instead of an in-person visit?"
- Intervention materials dropped off using contactless procedures (see Section E3)

E8 Session 3, Month 7

During Month 7 of study participation, families in the two active intervention arms will complete the third of 4 sessions. For children in the CHW + Healthy Homes + school intervention arm and children in the CHW + Healthy Homes intervention arm, this will be the third home visit that includes both family-based asthma education and a home assessment by Healthy Homes. Home visits will last 2-2.5 hours, and include both the CHW and a representative from Healthy Homes. The intervention component related to home environmental remediation will reduce in intensity with each session.

CHWs in consultation with the care management committee, will continue to update providers on the family's participation in the intervention. Data from family interactions with the PCP will be communicated back to CHWs.

For children in the CHW + Healthy Homes + school intervention arm, CHWs will continue to communicate with the schools to ensure that children have the necessary forms and medication in place. School nurses will

continue to follow the standardized protocol in their interactions with the student; interactions will be documented and relayed to CHWs.

For children in the E-SOC group the project coordinator will mail the third set of publicly available information on asthma.

Intervention Session 3:

- CHW and Healthy Homes worker summarize the information that was covered in the first and second visits.
- The caregiver and child are asked for an update on any changes in medication, and any asthma-related sick visits, scheduled visits, hospitalizations, ED visits, or absenteeism.

- CHW role: Lesson plans focus on communication with providers, school and family issues related to asthma. Content includes:
    - Review child and caregiver's experiences and relationship with asthma care provider.
    - Discuss the role of school nurses and how families can communicate with schools about their children's asthma.
    - CHW reviews how asthma interferes with child's functioning throughout the school day, including during recess, gym, or walking through the halls. Discussion also focuses on how child handles such occurrences and how having asthma symptoms during the school day can make it harder to pay attention.
    - Strategies to improve preventive actions, such as using daily controller, will be reviewed.
    - Management of asthma within the family is reviewed, including which family members are responsible for which aspects of daily asthma care.
    - Decisions regarding when child is taken to the emergency department are reviewed.
    - Review of caregiver functioning and stress. Focuses on importance of parent caring for him or herself in order to provide child with best care possible.

- Healthy Homes role: Review changes that family has made (if any) based on first and second visits. Session content includes:
    - Praise for successful changes. Review how family was able to make these important changes.
    - Problem solve issues that have prevented any changes that family wanted to make.
    - Review new priority areas and how family can make these changes.
    - Assess whether follow up with landlord or referral to Medical-Legal Partnership is needed.
    - Address any additional needs that family may have related to home environmental remediation.
    - Set goals for any behavioral modifications/changes in the home that are needed between now and the next visit.

- CHWs and Healthy Homes assessors complete a session checklist of material covered; caregivers also independently complete a checklist.
- Schedule the next session, Session 4, before leaving the family's home. Schedule a follow up phone call for each month before the next session. Remind the family that the CHW will be calling then. Make sure the family has all contact information for RVA Breathes.
- Answer any questions the family has and thank them for their time.

Changes due to COVID-19:

- Session occurs over the phone or via video (see Section E3)
- Questions added to packet:
    - "How has the COVID-19 pandemic impacted you and your family?"
    - "What did you think of the phone/video session today instead of an in-person visit?"
- Intervention materials dropped off using contactless procedures (see Section E3)

E9 Session 4, Month 9

During Month 9 of study participation, families in the two active intervention arms will complete the final intervention sessions. For children in the CHW + Healthy Homes + school intervention arm and children in the

CHW + Healthy Homes intervention arm, this will be the fourth home visit that includes both family-based asthma education and a home assessment by Healthy Homes. Home visits will last 2-2.5 hours, and include both the CHW and a representative from Healthy Homes. This session will focus on reinforcing previously learned material and setting goals for sustaining change and preventive behaviors.

CHWs, in consultation with the care management committee, will continue to update providers on the family's participation in the intervention. Data from family interactions with the PCP will be communicated back to CHWs.

For children in the CHW + Healthy Homes + school intervention arm, CHWs will continue to communicate with the schools to ensure that children have the necessary forms and medication in place. School nurses will continue to follow the standardized protocol in their interactions with the student; interactions will be documented and relayed to CHWs.

For children in the E-SOC group the project coordinator will mail the fourth set of publicly available information on asthma.

Intervention Session 4:

- The caregiver and child are asked for an update on any changes in medication, and any asthma-related sick visits, scheduled visits, hospitalizations, ED visits, or absenteeism.
- CHW and Healthy Homes worker summarize the information that has been covered in the last three sessions.
- Time is spent reviewing any lessons that have been challenging for the family to master.

- CHW role: Lesson plans focus on empowering families. Content includes:
    - Discuss issues in the school or community that impact childhood asthma.
    - Outline strategies for family to focus efforts on appropriate self-management behaviors, including using medications correctly, recognizing symptoms, communicating with providers, and enhancing preventive care.
    - Summarize family's strengths and how they can work together as a team in managing child's asthma.
    - Encourage continued communication between family and primary care providers.
    - Address any other issues that the family raises.

- Healthy Homes role: Review any changes that family has made and/or maintained since the last sessions. Session content includes:
    - Praise for successful changes. Review how family was able to make these important changes.
    - Problem solve issues that have prevented any changes that family wanted to make.
    - Review new priority areas and how family can make these changes. Focus on empowering the family to continue to implement changes in their home.
    - Assess whether follow up with landlord or referral to Medical-Legal Partnership is needed.
    - Address any additional needs that family may have related to home environmental remediation.
    - Set clear plans for maintaining these changes.

- CHWs and Healthy Homes assessors complete a session checklist of material covered; caregivers also independently complete a checklist.
- Wrap up with a review of everything that was accomplished in the year long program. Make sure that the parent and child will keep their RVA Breathes binders in a safe place for easy reference.
- Provide a certificate of completion to both the parent and child.
- Schedule the post-intervention session before leaving the family's home.
- Answer any questions the family has and thank them for their time. Stress the importance of continued participation for the next 9 months, even though they have completed the four intervention sessions.

Changes due to COVID-19:

- Session occurs over the phone or via video (see Section E3)

- Questions added to packet:
    - "How has the COVID-19 pandemic impacted you and your family?"
    - "What did you think of the phone/video session today instead of an in-person visit?"
- Intervention materials dropped off using contactless procedures (see Section E3)

E10 Post-intervention

Two RAs will complete the post-intervention session (within 2 weeks of last session), which will last about 60 minutes. Caregivers will be compensated $50 for their time and children will be given a parent-approved prize. At this visit, RAs will:

- Administer the following measures:
    - Caregivers will report on any changes in monthly family income, education level, or in the family structure.
    - Caregivers will report on the duration and number of times the child has been hospitalized due to asthma or visited the ED because of asthma in the last 12 months. This information will be verified by hospitalization and ED visit information from insurance companies and health systems.
    - Caregivers will report on the number of times their child missed school due to asthma in the last 12 months. This information will be verified by absentee data from the child's school.
    - Caregivers will report on the child's asthma medication name, dose, and refill information. We will also collect pharmacy refill data.
    - Caregivers and children will complete the Childhood Asthma Control Test (cACT) jointly, which measures the frequency of daytime and nighttime asthma symptoms, activity limitations, and perception of disease control.
    - Caregivers will report on number of symptom free days in the last 14 days on the Asthma Assessment Form.
    - Children will complete the Pediatric Asthma Quality of Life Questionnaire (PAQLQ).
    - Caregivers will complete the Pediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ) and report on their own quality of life.
    - Caregivers will complete the Asthma Self-Efficacy Management Questionnaire (ASMQ), Perceived Stress Scale (PSS), Centers for Epidemiologic Studies Depression Scale (CES-D), and Stressful Life Events and Conditions Checklist (SLECC).

- Complete a brief semi-structured interview with the parent and child. Questions will ascertain:
    - Family satisfaction with the intervention sessions
    - Whether they would recommend the program to a friend
    - Perceived usefulness of the interventions
    - What behavioral changes they made because of the program
    - Changes they have seen in their child's daily asthma symptoms (if any)

Changes due to COVID-19:

- Session occurs over the phone or via video (see Section E3)
- Question added to packet
    - How has COVID-19 impacted your family?," "How has COVID-19 impacted your child's asthma care?," "What has it been like not being able to access your child's school nurse for asthma care?"
- Payment occurs via contactless payment drop-off (see Section E3) or via e-gift card.

E11 3-month follow-up

Two RAs will complete the 3-month follow-up session in the family's home. Caregivers will be compensated $70 for their time and children will be given a parent-approved prize. At this visit, RAs will:

- Administer the following measures:
    - Caregivers will report on the duration and number of times the child has been hospitalized due to asthma or visited the ED because of asthma since the post-intervention session. This information will be verified by hospitalization and ED visit information from insurance companies and health systems.

- Caregivers will report on the number of times their child missed school due to asthma in the last 3 months. This information will be verified by absentee data from the child's school.
- Caregivers will report on the child's asthma medication name, dose, and refill information. We will also collect pharmacy refill data.
- Caregivers and children will complete the Childhood Asthma Control Test (cACT) jointly, which measures the frequency of daytime and nighttime asthma symptoms, activity limitations, and perception of disease control.
- Caregivers will report on number of symptom free days in the last 14 days on the Asthma Assessment Form.
- Children will complete the Pediatric Asthma Quality of Life Questionnaire (PAQLQ).
- Caregivers will complete the Pediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ) and report on their own quality of life.
- Caregivers will complete the Asthma Self-Efficacy Management Questionnaire (ASMQ), Perceived Stress Scale (PSS), Centers for Epidemiologic Studies Depression Scale (CES-D), and Stressful Life Events and Conditions Checklist (SLECC).

Changes due to COVID-19:
- Session occurs over the phone or via video (see Section E3)
- Question added to packet
  - How has COVID-19 impacted your family?," "How has COVID-19 impacted your child's asthma care?," "What has it been like not being able to access your child's school nurse for asthma care?"
- Payment occurs via contactless payment drop-off (see Section E3) or via e-gift card.

E12 6-month follow-up

Two RAs will complete the 6-month follow-up session in the family's home. Caregivers will be compensated $80 for their time and children will be given a parent-approved prize. At this visit, RAs will:
- Administer the following measures:
  - Caregivers will report on the duration and number of times the child has been hospitalized due to asthma or visited the ED because of asthma in the last 3 months. This information will be verified by hospitalization and ED visit information from insurance companies and health systems.
  - Caregivers will report on the number of times their child missed school due to asthma in the last 3 months. This information will be verified by absentee data from the child's school.
  - Caregivers will report on the child's asthma medication name, dose, and refill information. We will also collect pharmacy refill data.
  - Caregivers and children will complete the Childhood Asthma Control Test (cACT) jointly, which measures the frequency of daytime and nighttime asthma symptoms, activity limitations, and perception of disease control.
  - Caregivers will report on number of symptom free days in the last 14 days on the Asthma Assessment Form.
  - Children will complete the Pediatric Asthma Quality of Life Questionnaire (PAQLQ).
  - Caregivers will complete the Pediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ) and report on their own quality of life.
  - Caregivers will complete the Asthma Self-Efficacy Management Questionnaire (ASMQ), Perceived Stress Scale (PSS), Centers for Epidemiologic Studies Depression Scale (CES-D), and Stressful Life Events and Conditions Checklist (SLECC).

Changes due to COVID-19:
- Session occurs over the phone or via video (see Section E3)
- Question added to packet
  - How has COVID-19 impacted your family?," "How has COVID-19 impacted your child's asthma care?," "What has it been like not being able to access your child's school nurse for asthma care?"
- Payment occurs via contactless payment drop-off (see Section E3) or via e-gift card.

E13 9-month follow-up

Two RAs will complete the 9-month follow-up session in the family's home. Caregivers will be compensated $100 for their time and children will be given a parent-approved prize. At this visit, RAs will:

- Administer the following measures:
    - Caregivers will report on the duration and number of times the child has been hospitalized due to asthma or visited the ED because of asthma in the last 6 months. This information will be verified by hospitalization and ED visit information from insurance companies and health systems.
    - Caregivers will report on the number of times their child missed school due to asthma in the last 6 months. This information will be verified by absentee data from the child's school.
    - Caregivers will report on the child's asthma medication name, dose, and refill information. We will also collect pharmacy refill data.
    - Caregivers and children will complete the Childhood Asthma Control Test (cACT) jointly, which measures the frequency of daytime and nighttime asthma symptoms, activity limitations, and perception of disease control.
    - Caregivers will report on number of symptom free days in the last 14 days on the Asthma Assessment Form.
    - Children will complete the Pediatric Asthma Quality of Life Questionnaire (PAQLQ).
    - Caregivers will complete the Pediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ) and report on their own quality of life.
    - Caregivers will complete the Asthma Self-Efficacy Management Questionnaire (ASMQ), Perceived Stress Scale (PSS), Centers for Epidemiologic Studies Depression Scale (CES-D), and Stressful Life Events and Conditions Checklist (SLECC).

Changes due to COVID-19:

- Session occurs over the phone or via video (see Section E3)
- Question added to packet
    - How has COVID-19 impacted your family?," "How has COVID-19 impacted your child's asthma care?," "What has it been like not being able to access your child's school nurse for asthma care?"
- Payment occurs via contactless payment drop-off (see Section E3) or via e-gift card.

E14 Metrics from CHWs, Healthy Homes, and PCPs

Program-specific data will be gathered from CHWs, Healthy Homes, school nurses, and child medical homes. All metrics will be entered directly into REDCap. This information will be used to assess the implementation of the project, including whether short-term outcomes were achieved.

Metrics from home visits. CHWs and Healthy Homes assessors will complete electronic productivity reports regarding their productivity on the study as staff, including time spent on each component of the session, content that was covered, and content that was not (and reason). Information on family questions and barriers described will also be entered in reports. CHWs will also be prompted to ask caregivers a series of paper questionnaires at each visit related to symptoms, asthma control, medication use and changes, healthcare utilization, and missed school days. In their productivity reports, Healthy Homes will note observations of the home environment, as well as document education shared, materials provided to the family, and referrals to MLP-R. Visual observations about the home environment include exterior and interior observations that pertain to the Asthma Environment Checklist from EPA (e.g., standing water, presence of tobacco smoke, mold, pests, or pets).

Metrics from nurses. Nurses will record data on paper forms or in an electronic file if preferred related to interactions with student, any reported health care utilization from student, school absences (for CHW follow-up), and care coordination activity (with family and/or PCP).

Metrics from health systems. Information from health systems (area hospitals) will contain patient identifying information. Data will include information related to units, duration, and frequency of ED visits and hospitalizations due to asthma in the last year.

Metrics from medical homes. CHWs and the project coordinator will document children's visits to their primary care provider or other physician for asthma care. CHWs will ask caregivers to report on any child asthma-related visits to a provider throughout their time in the study; number of visits and reason for visit will be recorded, including whether it was a preventative or an urgent visit. If the child is enrolled in the school intervention group, CHWs or the project coordinator will communicate with the provider's office to ensure that the school has an asthma action plan and medication release form on file at the school.

Metrics from insurers. Frequency, length, and cost for asthma-related inpatient and ED visits, as well as information on asthma medication prescriptions and refill data will be collected.

F References

1. National Asthma Education and Prevention Program. *Expert Panel Report 3: guidelines for the diagnosis and management of asthma.* Bethesda MD: US Department of Health and Human Services, National Institutes of Health;2007.
2. Evans R, Gergen PJ, Mitchell H, et al. A randomized clinical trial to reduce asthma morbidity among inner-city children: Results of the National Cooperative Inner-City Asthma Study. *Journal of Pediatrics.* 1999;135:332-338.
3. Morgan WJ, Crain EF, Gruchalla RS, O'Connor GT, Kattan M, Evans R, et al. Results of a home-based environmental intervention among urban children with asthma. *New England Journal of Medicine.* 2004;351:1068-1080.
4. Krieger JW, Takaro TK, Song L, Weaver M. The Seattle-King County Healthy Homes Project: a randomized, controlled trial of a community health worker intervention to decrease exposure to indoor asthma triggers. *American Journal of Public Health.* 2005;95:652-659.
5. Coughey K, Klein G, West C, et al. The Child Asthma Link Line: a coalition-initiated, telephone-based, care coordination intervention for childhood asthma. *Journal of Asthma.* 2010;47:303-309.
6. Findley S, Rosenthal M, Bryant-Stephens T, et al. Community-based care coordination: practical applications for childhood asthma. *Health Promotion Practice.* 2011;12(6 Suppl 1):52S-62S.
7. Lara M, Bryant-Stephens T, Damitz M, et al. Balancing "fidelity" and community context in the adaptation of asthma evidence-based interventions in the "real world". *Health Promotion Practice.* 2011;12 (6 Suppl 1):63S-72S.
8. Clark N, Lachance L, Benedict M, et al. Improvements in health care use associated with community coalitions: long-term results of the allies against asthma initiative. *American Journal of Public Health.* 2013;103:1124-1127.
9. Woods E, Bhaumik U, Sommer S, et al. Community Asthma Initiative: Evaluation of a Quality Improvement Program for Comprehensive Asthma Care. *Pediatrics* 2012;129:465-472.
10. Bhaumik U, Norris K, Charron G, et al. A Cost Analysis for a Community-Based Case Management Intervention Program for Pediatric Asthma. *Journal of Asthma.* 2013;50:310-317.
11. Sommer S, Bhaumik U, Tsopelas B, et al. *Boston Children's Hospital Community Asthma Initiative Replication Manual: Needs Assessment, Implementation, and Evaluation.* Boston Children's Hospital; 2013.