



## Adaptations to the RVA Breathes clinical trial due to the COVID-19 pandemic

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### ABSTRACT

RVA Breathes, a community program to improve asthma management and care coordination among children living in a low-income, urban area, is being evaluated in a randomized clinical trial. In March 2020, RVA Breathes was converted to a remote program due to the COVID-19 pandemic; this report provides an update on the modifications made to the RVA Breathes trial. Additionally, given that families in the program have been disproportionately impacted by both COVID-19 and significant social unrest at both the local and national level, strategies used to enroll and engage families in the trial who bore disproportionately high burdens during this time period are outlined. Remote sessions (telephone or video) for families enrolled in the program prior to the onset of COVID-19 began in April 2020; enrollment of new families began remotely in July 2020 using adapted consent procedures. Baseline, intervention, and follow-up sessions were delivered either via the telephone or video depending upon family preference. Strategies were implemented to engage caregivers and children in completing measures over the telephone or video versus in person. Tangible intervention materials and participant payments were dropped off at family homes using contactless procedures. Our team was able to adapt and safely continue a large, community-based clinical trial, despite the increased health risks and social isolation mandates from the pandemic, by transitioning to a remote format. Challenges remain in determining whether RVA Breathes as a remote program has had the same impact on child asthma as the face-to-face interventions that comprised its original format.

### 1. Introduction

RVA Breathes, funded by the National Institutes of Health (NIH), is a collection of evidence-based interventions, including school, family, home, and medical care components, refined to address community needs [1], with the overall aim of reducing asthma-related healthcare utilization among elementary age children [2]. The goal of the program is to minimize pediatric asthma disparities by improving asthma management and care coordination for children living in a predominantly low-income, urban area. Evaluation of the efficacy of RVA Breathes is currently ongoing via a randomized controlled trial. Participants were enrolled beginning in May 2018, and enrollment ended in December 2020. Enrolled families complete a 9-month intervention phase followed by a 9-month follow-up phase. Thus, intervention recruitment, enrollment, delivery, and follow-up assessments were all significantly affected by the coronavirus disease-2019 (COVID-19) pandemic.

Prior to the pandemic's onset in March 2020, the RVA Breathes intervention took place in families' homes and children's schools. Community health workers (CHWs) and Healthy Homes assessors delivered evidence-based asthma self-management education and home-based environmental assessments to caregivers and their children with asthma four times during the 9-month intervention phase (see details of methods [2]). School nurse partners also followed a standardized plan for responding to students' asthma symptoms in schools and documented their interactions with participants. In March 2020, when COVID-19 restrictions prohibited face-to-face clinical trial activities, and forced in-person school closures, RVA Breathes was converted to a remote trial. This manuscript provides an update on modifications made to this trial due to COVID-19, including strategies used to preserve trial integrity [3].

It is critical to note that many families in RVA Breathes were disproportionately impacted by both COVID-19, and by the significant social

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unrest that occurred both within Richmond City and nationally in the past year [4,5]. Approximately 77.6% of families enrolled in RVA Breathes identify as Black or African American, 11.2% as mixed racial/ethnic backgrounds, and 8.8% as Latinx. National data indicate that Black and Latinx individuals are three times as likely to be infected with COVID-19 as White individuals, and nearly twice as likely to die from the virus [6,7]. Within Richmond, Virginia, 80% of all COVID-19 cases occurred in Black and Latinx individuals [8]. Moreover, across Virginia, 60% of COVID-19 cases occurred in Black and Latinx individuals, although they comprised less than one-third of the state's total population [8]. Furthermore, Richmond, Virginia, the former capital of the Confederacy with numerous monuments to that history, experienced particularly intense social unrest in response to events in the summer of 2020 [9].

Social inequities, including poor access to health care and workplace exposures, have continued to drive these higher rates of COVID-19 infection and mortality among people of color [10]. Thus, this manuscript also outlines strategies used specifically to engage families who bore disproportionately high burdens during this time period. Finally, many of our CHWs, Healthy Homes assessors, and research staff also experienced increased stress during the pandemic, and we describe strategies used to address the health and well-being of our team as well.

## 2. Methods

The RVA Breathes program is comprised of three evidence-based interventions that were adapted for the Richmond community based on our prior work [1]. Families are randomized to one of three groups in the RVA Breathes trial: 1) family-based asthma self-management education (delivered by CHWs), home environmental remediation (partnering with a local health district), and school nurse support (in collaboration with elementary schools), 2) CHW education and home components only, or 3) an enhanced standard of care group. Families are in the intervention/control phase for 9 months and then complete follow up assessments immediately after completing the intervention/control phase and at 3-, 6-, and 9-month follow ups. Participant enrollment was from May 2018 to December 2020; trial participation will be complete by June 30, 2022.

Our primary outcome is asthma-related healthcare utilization (e.g., composite of frequency of emergency department [ED] visits and hospitalizations). Our prior work suggests that in a sample of 55 African American children (7–12 years) living in Richmond, 42% had experienced 1–2 asthma-related ED visits in the last 12 month, and 27% had experienced 3 or more visits [11]. We hypothesize that children in the two active intervention conditions will experience less asthma-related healthcare utilization than the control group in the 9 months after the RVA Breathes program as compared to 9 months before enrollment. Briefly, our statistical analyses will use Generalized Linear Mixed Models (GLMM) to determine within person changes in healthcare utilization across time, and then differences in healthcare utilization between groups (e.g., intervention vs. control). Thus, our main outcome is change in healthcare utilization at the individual level as an average of individuals (see more details in Ref. [2]).

All changes made to the RVA Breathes protocol due to COVID-19 were approved by the Institutional Review Board (IRB) and by the NIH-appointed Data Safety Monitoring Board overseeing the trial (registered as NCT03297645). Given the uncertainty of the pandemic's impact on social isolation at the onset in mid-March (i.e., how long restrictions would be in place), recruitment and enrollment activities were temporarily halted on March 13, 2020. We were initially hopeful in-person enrollment could be resumed shortly so as not to disrupt the consent/assent process or rapport building with new families. For families already enrolled in RVA Breathes, we worked with the research team, IRB, and our NIH Program Officer to adapt intervention sessions (delivered by CHWs, Healthy Homes assessors, and school nurses) and fol-

low-up assessments (completed by the research team) to be delivered remotely via telephone or video. We began implementing these changes in April 2020. When it became clear in early summer 2020 that social isolation mandates would continue, we proceeded with changes that would allow us to restart enrollment of new families remotely in July 2020. However, with in-person schools closing in March 2020 for the academic year, our school nurse component of the intervention did not resume in a remote format until the 2020–2021 academic year in September 2020. We outline specific adaptations to each phase of the study below.

### 2.1. Adaptations to recruitment, enrollment, and baseline sessions

#### 2.1.1. Recruitment

Prior to March 13, 2020 (when research activities were halted due to COVID-19), we had enrolled 217 participants in the clinical trial. According to our study timeline, enrollment needed to be complete by December 2020. We were able to enroll an additional 43 families between July and December 2020, bringing our final enrollment to 250 families. Because of the pandemic, we had to cease in-person recruitment activities at community events, primary care provider offices, and at schools. We continued to contact primary care provider offices over the telephone to remind them that we were still available as a resource to families during the pandemic. We offered to email or mail our flyer for distribution at their offices. We were also able to continue receiving lists of potentially eligible children with asthma from local health systems. With appropriate approvals, our study flyer was distributed at COVID-19 testing sites, at school lunch distribution sites, and on buses that delivered school lunches to neighborhoods. We also partnered with Richmond Public Schools on community walks that used socially distanced protocols to deliver materials about virtual school resources to families (i.e., how to receive a laptop and/or Wi-Fi services, where to receive school lunches); our flyer was distributed during these walks as well. School nurses continued to refer families to the program if they interacted with them over the telephone or in a virtual clinic. We provided school nurses with electronic materials to use when describing the study to families.

#### 2.1.2. Consent process and enrollment/baseline

Our consent process was adapted to be performed either over the telephone or via video/Zoom depending upon family preference. The consent process was done prior to a baseline session with families that consisted of completion of a series of study questionnaires (see Table 1 and Section 2.3). If the enrollment/baseline session was scheduled as a Zoom session, the project coordinator read a video information sheet to the caregiver over the telephone that reminded the family that this session was voluntary, that they should not show anyone or any parts of their home on camera that they were not comfortable with the team seeing, and that the research team would call from a place where no one else could see or hear the family. Families were then emailed a link to a HIPAA compliant Zoom session.

We received IRB and DSMB approval to waive documentation of written consent and child assent. Rather, we obtained verbal consent from caregivers (for both their participation and that of their child) and completed a consent documentation form at the time of the consent discussion. This form recorded that consent was given, date/time it was given, and the staff member conducting the discussion. On the same form, we also documented that child assent was waived. Families were mailed or emailed a copy of the consent form depending upon their preference.

After the consent discussion was completed and the family was enrolled in the program, research assistants documented the caregiver's physical location and alternative contact methods prior to administering questionnaires. Research assistants asked for the caregiver's address in case it was necessary to call emergency services for critical situations

**Table 1**  
Adaptations to research measures.

	Measure	When collected?	Changes
Asthma-related ED visits and hospitalizations	Data received from hospital partners' billing systems	Baseline, end of intervention session, 9-month follow up session	None
	Caregiver-reported ED visits and hospitalizations	Baseline, post-intervention session, 3, 6, and 9 month follow ups	Collected over the telephone/video
Medication usage	Caregivers report on child asthma medications, including dose and refill history	Baseline, post-intervention session, 3, 6, and 9 month follow ups	Collected over the telephone/video
Asthma school absences	Caregiver-reported school absences since last assessment	Baseline, post-intervention session, 3, 6, and 9 month follow ups	Collected over the telephone/video; Absences from virtual school assessed
Asthma control	Children and caregivers completed Childhood Asthma Control Test [22]	Baseline, post-intervention session, 3, 6, and 9 month follow ups	Collected over the telephone/video; Caregiver reports as proxy for child if child not present
Symptom free days	Caregivers report number of symptom free days in last 7 days [23]	Baseline, post-intervention session, 3, 6, and 9 month follow ups	Collected over the telephone/video
Asthma-related quality of life	Caregivers complete the Pediatric Asthma Caregiver QOL Questionnaire [24]	Baseline, post-intervention session, 3, 6, and 9 month follow ups	Collected over the telephone/video
	Children 7–11 years complete the Pediatric Asthma QOL Questionnaire (PAQLQ) [25]	Baseline, post-intervention session, 3, 6, and 9 month follow ups	Collected over the telephone/video; Caregiver reports as proxy for child if child not present
	Children 5–6 years complete the pictorial version of the PAQLQ [12]	Baseline, post-intervention session, 3, 6, and 9 month follow ups	Not administered in remote setting (child responds by marking answer on a line)
Asthma self-management skills	Caregivers complete the Asthma Self-Management Questionnaire [26]	Baseline, post-intervention session, 3, 6, and 9 month follow ups	Collected over the telephone/video
Stress	Caregivers complete the Perceived Stress Scale [27]	Baseline, post-intervention session, 3, 6, and 9 month follow ups	Collected over the telephone/video
Depressive symptoms	Caregivers complete the Centers for Epidemiologic Studies Depression Scale [28]	Baseline, post-intervention session, 3, 6, and 9 month follow ups	Collected over the telephone/video

that might be discussed or overheard during the research session (e.g., child abuse/neglect, active domestic violence, suicidal thoughts/plan, medical emergency). Caregivers were told that emergency services might be contacted if the research assistant was concerned about the safety of any household member. Caregivers were also reminded that if they felt uncomfortable answering a question in the presence of other household members, they should find a private location before responding. Alternative contact methods were gathered in case the telephone call or Zoom session disconnected before completion. Research assistants then read the questionnaires to families either over the telephone

or during the Zoom session. Caregivers were emailed questionnaires if they requested to enable them to follow along as a research assistant read the questions to them and their child.

### 2.1.3. Strategies for increasing engagement of families

In recognizing that families may be experiencing additional stress and uncertainty due to the pandemic and issues related to social unrest, our staff spent time at the beginning of the consent process (and each session) checking in with the caregiver about whether this was still a good time for them to complete the task at hand (i.e., consent, session, assessment). Staff emphasized to the caregiver that it would be fine to reschedule at a more convenient time for the family, and that their participation was valued whenever they were able to participate in the study. Given that many families in the program used minute-restricted cell phones, staff would also let caregivers know that it was acceptable if they needed to reschedule the call to the beginning of the month, when they had more minutes available.

As a research team, we also paid attention to issues related to social injustice at the community and national level. When we engaged with families, we offered community mental health referrals knowing that many were experiencing increased stress, loneliness, and isolation. We remained aware of the potential impact of social unrest on the families in this study and did not engage in recruitment calling or enrollment/baseline sessions for several days after media-reported incidences of police brutality against people of color, while waiting for election 2020 results, or immediately following the Capitol attack in January 2021. Conscious efforts were made to ensure that team members understood that while meeting our enrollment goals was important, families in the community had more pressing priorities than research participation during the pandemic. Thus, in team meetings, we checked in regularly about how families were responding to our recruitment calls and the consent process, and ensured that we were continuing with our research in a way that was respectful of families' needs.

## 2.2. Adaptations to interventions

### 2.2.1. Asthma self-management education and home-based environmental assessments

Adaptations to interventions provided by CHWs and Healthy Homes assessors were made primarily in delivery format rather than session content (see Table 2). We completed 471 virtual visits with 174 participants after the onset of COVID-19. Approximately 89% of these visits occurred over the telephone due to either families' preference or families' lack of video capabilities. As with the enrollment/baseline session, when sessions were scheduled, families were given the option of completing the session over the telephone or via a Zoom video session. While we considered it ideal for the Healthy Homes assessor to see parts of the family's home, families were told to choose whichever delivery format felt most comfortable to them. If sessions occurred toward the end of a month, when caregivers might not have sufficient cell minutes remaining, CHWs and Healthy Homes assessors offered the opportunity to continue the session at a later date, when they had more minutes. For telephone sessions, Healthy Homes assessors asked detailed questions about the interior spaces, and families sent pictures of areas of concern. If the visit was held on Zoom, the family was reminded that they should not show anyone or any parts of their home on camera that they were not comfortable with the team seeing, and that the CHW and Healthy Homes assessor would call from a place where no one else could see or hear the family. Families were emailed a link to a HIPAA compliant Zoom session.

### 2.2.2. Strategies to engage families in the intervention phase

CHWs and Healthy Homes assessors worked to engage families in the program and intervention materials over the telephone, particularly for families that did not complete a video session or had never com-

**Table 2**  
Adaptations to RVA Breathes interventions.

Components	Adaptations due to COVID-19
<b>CHW intervention</b>	<ul style="list-style-type: none"> <li>- Evidence-based asthma education delivered to caregiver and child</li> <li>- Monthly telephone call checks ins between sessions</li> <li>- Ensure required forms and medications are at schools</li> </ul>
<b>Healthy Homes intervention</b>	<ul style="list-style-type: none"> <li>- Home assessment with appropriate remediation strategies in response</li> <li>- Low-cost intervention materials provided</li> </ul>
<b>School intervention</b>	<ul style="list-style-type: none"> <li>- Asthma education sessions for school nurses</li> <li>- Standardized plan for responding to students' asthma in schools</li> <li>- Complete data form on interaction in clinic</li> </ul>
<b>Enhanced SOC (control)</b>	<ul style="list-style-type: none"> <li>- Publicly available materials mailed throughout intervention period</li> <li>- Family continues with usual asthma care</li> </ul>

pleted an in-person visit. Specifically, CHWs and Healthy Homes assessors spent time getting to know the family and learning how they were adjusting to the pandemic before jumping into the asthma education modules or discussing triggers in the home environment. Intervention materials (e.g., education binder, air purifier, pillowcase covers, cleaning products) were dropped off to families using contactless procedures that ensured both team members and families remained safe and followed social distancing guidelines. These procedures included calling the family ahead of time, maintaining a distance of at least 10 feet, wearing a mask and gloves, placing items in front of the home, and waiting for retrieval before leaving the area. This also allowed for families to briefly see their CHW or Healthy Homes assessor in person, albeit from a safe distance.

To determine whether our program was acceptable to families as a remote session, CHWs asked the caregiver at the end of the session what they thought about completing a remote session instead of an in-person session, and if they had suggestions for improving the session. Additionally, CHWs asked caregivers at the beginning of each session: "How has the COVID-19 pandemic impacted you and your family?" This question allowed us to have a broader understanding of how the pandemic was affecting families of children with asthma in our study and ensure that we were not overburdening families at this difficult time. We also continued to check in with CHWs and Healthy Homes assessors during team meetings about how families were responding to these remote sessions, as well as how the process was going for interventionists.

To minimize uncertainty about how our program would proceed during the pandemic, we sent a letter to all families describing changes to the RVA Breathes protocol due to COVID-19. This outlined the fact

that families would complete home sessions either over the telephone or via Zoom (video) during this period of social distancing, to keep families and staff safe. We also noted that, prior to beginning a telephone or video session, our staff would review privacy and confidentiality information to ensure families were comfortable with the new process. Families were also reminded that our program was voluntary and available to them even if they needed to reschedule a visit or had missed a session. The letter closed with our contact information (telephone and email) and encouragement to reach out with any questions or concerns about the program or their involvement.

### 2.2.3. Strategies to support team members

Our team members, which include CHWs, Healthy Homes assessors, and research staff, are Black, African American, Latinx, and White and have other identities as well; many experienced additional stress and uncertainty due to the pandemic and issues related to social unrest. In supporting our team members, we implemented several strategies. We began each of our weekly meetings (which were conducted via Zoom), by discussing how everyone was doing in general and if there were any team concerns or celebrations. We also discussed the importance of self-care and team members were given permission to miss meetings if they needed time to themselves or to take care of something that would minimize their overall level of stress. A virtual group workshop on trauma and resilience during COVID-19 was provided by an outside group and was open to all team members. Finally, we made sure to respond to concerns expressed by some team members who questioned their roles on the project, given that they could no longer interact in-person with families. For instance, CHWs noted that their job, by definition, involved their physical presence in the community; consequently, several of them questioned whether their work as a CHW was equally as important in a virtual setting. Thus, we spent time discussing strategies for rapport building over the telephone or video session with families. Additionally, at each meeting and throughout the week, a deliberate effort was made by the Principal Investigator to validate team members' contributions to families of children with asthma and to recognize what they were accomplishing, particularly within the context of the pandemic.

### 2.2.4. School intervention components

We partnered with Richmond Public School nursing leadership to determine the best way to adapt the school nurse intervention components for the virtual setting. Given that school nurses would be in contact with students via telephone or in a virtual clinic during the school year, they were given a modified data form to record their interactions with participants. Prior to COVID-19, when children were in school and seen at the clinic for asthma, school nurses recorded on a data form what steps they took (following a standardized action plan) in response to the child's asthma symptoms. Given that nurses were not managing child asthma symptoms in school, we adapted the clinic data form for the remote setting to capture information about: 1) how the child's asthma was at home, 2) if the family had any concerns about the child's asthma, 3) whether the family had an asthma action plan at home, 4) whether the family had the appropriate medications at home, and 5) if the school nurse felt the child needed to follow up with their asthma provider. This form was then sent to the project coordinator, and the research team and family's CHW followed up with the family as appropriate. We also found that, although the school nurses appreciated having RVA Breathes to help support families, they were overwhelmed with other priorities in the virtual school setting. Thus, by adapting our school intervention to require no additional meetings between school nurses and participants, it was feasible for school nurses to continue their participation during the pandemic. We also continued to provide asthma education to school nurses remotely throughout the school year as requested, either through handouts or virtual meetings.

### 2.2.5. Communication with child's asthma provider

Finally, communication with the child's asthma provider continued in the virtual setting using the procedures already in place. The project coordinator updated the child's primary care provider and/or asthma care provider on the family's participation in the program, the child's current asthma symptoms, and the child's asthma control following intervention sessions. This was accomplished either via a telephone call, mailed letter, or faxed letter depending upon the office's preference.

## 2.3. Adaptations to follow-up sessions

After completing the 9-month intervention phase, families complete a post-intervention research session within 2 weeks, and then research sessions 3-, 6-, and 9-month intervals after the final intervention session. At each of these assessment points, families complete the same research measures that were completed at baseline (see Table 1). As with the intervention sessions, these were all converted to remote delivery via telephone or video depending upon family preference. Procedures were again in place to ensure families felt comfortable with using telephone or video to complete the research sessions.

### 2.3.1. Assessment measures

Changes to assessment measures can be found in Table 1. Specifically, no changes were made to the wording or content of the measures. Rather, strategies were used to engage caregivers and children in completing measures over the telephone or video versus in person. This included spending more time on the response options and repeating them throughout the administration of a questionnaire, asking questions to ensure caregivers and children understood certain items, and providing more opportunities for caregivers and children to ask questions. Additionally, because caregivers often completed sessions at times when children were not home with them (or the caregiver was in another location), we used caregivers' report for measures of child asthma control and symptoms when needed. This decision was made after considering the burden on families to attend a separate session for their child simply for the purpose of completing a few items related to their asthma. Any change in respondents on these measures was clearly documented in the study database. We also had to eliminate the pictorial quality of life measure for 5- and 6-year-olds [12]. To use this measure, children are instructed to mark their response to an item anywhere on a line between three thermometers representing "not at all" to "a lot;" this marking is then converted to a score using a scoring template. This was not possible over the telephone or during a video session. We chose to continue administering questionnaires in a remote setting versus emailing a survey link to respondents to minimize additional variability and technological issues that a new administration format may have introduced.

Given the relevance of COVID-19 to participants' lives, and its potential impact on study interventions, we added three open-ended items to follow-up sessions to assess COVID-19 impact. These brief items included: "How has COVID-19 impacted your family?," "How has COVID-19 impacted your child's asthma care?," and "What has it been like not being able to access your child's school nurse for asthma care?" Caregivers answered these questions prior to completing the regular follow-up session measures.

### 2.3.2. Participant payments

Finally, we adapted our procedures for paying families following research sessions. Families were given the choice of receiving an electronic gift card or a cash payment that would be dropped off using our contactless procedures (see section 2.2.2). We found that more families preferred the cash payment over the electronic gift card. Thus, we adapted research assistants' schedules to allow for more travel time in the community.

## 2.4. Adaptations to retention and engagement strategies

In the 9 months after the onset of COVID-19 (April to December 2020), we saw a temporary increase in the rate of visit rescheduling. Prior to the pandemic, the average reschedule rate was 35%; from April to December 2020, it increased to 43.9% (8.9% increase). To mitigate the number of rescheduled visits, the team used several strategies to maintain engagement of families. We developed a "retention task force," a group of research team members who met weekly to review the list of participants whom we were having difficulties reaching. They determined next steps for contacting the family based on the timing of their last contact, and discussed optimal communication strategies (e.g., telephone call, text, letter). We also reached out to participants' primary care physicians/asthma providers and school nurses to obtain up to date contact information (as we already had the appropriate releases to do so). Research assistants also delivered "RVA Breathes information bags" to participants' homes following IRB-approved, contactless procedures. These bags include prizes for children, contact information, and a newsletter. We piloted this method with 30 families who we were initially having difficulties reaching and were able to reengage 6 of them (20%). After the implementation of these targeted retention efforts, the average rate of rescheduled visits declined to 33.4% (January to May 2021).

## 3. Discussion

In the wake of COVID-19, our research team was able to adapt and safely continue a large, community-based clinical trial, despite the increased health risks and social isolation mandates from the pandemic, by transitioning to a remote format. We implemented numerous strategies to maintain participant engagement in the program, and attend to the health and well-being of our own team members. The extent of the physical and psychological burden of COVID-19 on individuals, and especially people of color is not yet fully known [13]. Reports suggest that parents and parents of children with pre-existing medical conditions are experiencing additional burden related to COVID-19 [14,15]. With respect to asthma, this might include disruptions in medical care, or increased exposure to indoor allergens [16]. Taken together, and within the context of a period of high social unrest, families likely had other life-altering priorities after March 2020 that might not have included participating in a clinical trial. However, our asthma program remained available to families during the pandemic, and we made every effort to continue addressing families' needs related to their children's asthma. Through consultation with the IRB, NIH, our Data Safety Monitoring Board, the research team, and community members, we were able to convert RVA Breathes to a format acceptable to families and study partners (e.g., schools, primary care providers, CHW interventionists), and that could continue in a virtual setting within the context of a pandemic.

### 3.1. Limitations

Adapting a clinical trial to a remote format is not without limitations. First and foremost, the success of our adaptations in terms of the validity of a remote versus in-person clinical trial is not yet known. In essence, it is not clear whether our virtual intervention has had the same impact on child asthma as the community, face-to-face intervention that comprised its original format. Although RVA Breathes was adapted quickly to a virtual program in March 2020, it was done with the utmost attention to maintaining the scientific rigor of a clinical trial with pediatric populations [17]. However, its success as a remote program will not be known until we have completed the trial in June 2022 and are able to complete our statistical analyses. There is evidence to suggest that telemedicine is as effective as in-person visits for improving child asthma control, at least within a clinic setting [18].

Another limitation includes the fact that questionnaires at baseline and follow-up sessions were completed over the telephone or video. This might have introduced additional reporting bias. For example, participants might have been less likely to report accurately in their homes if other people could hear their responses. We did encourage participants to complete assessments in a private location, but this was not always feasible. When in person, research assistants would often ask parents to point to their answers on measures that were more sensitive, such as those assessing stress or mental health, if they were more comfortable doing so. In this way, other family members in the home, including the child participant, were not privy to the caregiver's responses. This was not possible over the telephone or video and thus, caregivers might have reported in a more favorable light on these questionnaires. It also is not clear how well children understood the response options for the child quality of life measures over the telephone versus in person. Although research assistants administering the measure repeated the response option multiple times, children might have benefited from being able to see the range of responses from 1 "none of the time" to 7 "all of the time." While we continued to receive caregiver reports of asthma-related school absences during virtual instruction, it is not clear whether these reports were completely comparable to pre-pandemic absenteeism. It is possible that the threshold for a child experiencing asthma symptoms and missing school was different in the in-person vs. virtual setting. For example, a child with mild symptoms might have continued with virtual learning, but perhaps would have missed in-person learning.

Finally, retention of families in the trial after the onset of the COVID-19 pandemic may have been compromised. Several families moved out of state due to financial changes in the home, and others noted being "too overwhelmed" or "too stressed" to continue with the study due to the pandemic. We also were not able to enroll our target sample size of 300 within the context of the pandemic. This may again have been due to other family priorities with the onset of COVID-19, as well as within the context of heightened social unrest (particularly in our city) and a challenging 2020 election period. We were able to enroll 250 of the expected 300 families (83%). Given we were initially overpowered and our enrollment target allowed for 20% attrition, we are likely still powered to evaluate our primary hypothesis. We were not able to extend our recruitment period past December 2020 given that clinical trial participation must be completed by June 30, 2022. Thus, with a 9-month follow up period, we enrolled our last participants by the end of December 2020.

### 3.2. Next steps and conclusion

Next steps for the RVA Breathes program include an in-depth analysis of our open-ended questions regarding COVID-19's impact on families and their children's asthma for a future publication. This will allow us to assess for themes related to how family asthma management was impacted during the pandemic, and importantly, whether our program continued to meet families' needs. Issues related to social determinants of health and the impact of COVID-19 on these factors may also emerge in these analyses. We will also be able to determine how acceptable and feasible families found our program in a remote setting. It might be that families find it easier to engage in a remote program, and thus, future iterations of RVA Breathes might be successfully implemented as a hybrid model. A recent study found that video telemedicine was the most highly used asthma encounter modality after March 17, 2020, and telephone encounters also increased [19]. Thus, for a future model of RVA Breathes, we might consider an initial in-person visit with the family, in which they meet their CHW and Healthy Homes assessor, complete a home assessment, and receive several educational modules in person. Subsequent intervention sessions could then occur in person or in a remote setting depending upon family preference. Not only might this be a cost saving model in terms of staff travel (e.g., time, mileage), but

families might also be better able to maintain engagement in a program that provides remote sessions as needed.

One of the biggest challenges we face is determining how best to account statistically for the impact of COVID-19 on our intervention effects. Although all three groups (two active intervention and a control group) were impacted by COVID-19, our trial began before the onset of COVID-19. Thus, most families received a mix of in-person and remote visits; some were in the follow up phase when COVID-19 hit, and others had only completed a baseline or few intervention sessions prior to March 2020. We will need to determine how best to represent the impact of COVID-19 in our statistical models, as well as in our interpretation of findings. This includes not only the delivery of program content (e.g., in-person, video, telephone) and measure informant (i.e., parent reporting on child measure), but also the impact of COVID-19 on caregiver and child psychological functioning and challenges related to managing asthma in the context of COVID-19 (i.e., financial limitations, indoor triggers).

Additionally, during the pandemic, there has been a dramatic decline in asthma-related healthcare utilization, specifically emergency department (ED) visits. A report from the Children's Hospital of Philadelphia, an urban area with similar demographics to Richmond, found that in the first 4 weeks after the onset of COVID-19, the mean daily asthma ED visit rate was 76% lower than pre-COVID utilization [20]. Making this finding even more striking is that the period of time between mid-March and mid-April is often a time of high pollen counts and respiratory viruses that can increase asthma symptoms [21]. Reasons for this drop in ED visits are not entirely known, but researchers speculate it might have to do with school closures and limited exposure to other children with respiratory viruses, families being more vigilant in managing a child's asthma in order to minimize trips to the hospital, and reduced exposure to outdoor seasonal allergens and air pollution [20]. Given that asthma-related healthcare utilization, primarily ED visits and hospitalizations, is our primary study outcome, we will also need to consider how to account for changes in healthcare utilization across the pandemic. Furthermore, it is not clear whether these declines will persist as social isolation mandates are removed, and children return to in-person school in Fall 2021. It is likely that our analyses will need to capture time since the pandemic onset in considering the impact of the intervention on asthma outcomes.

In sum, our study serves as a model for adapting a community-based program to a remote program, with consideration given to engaging families experiencing heightened social and health inequities. We suggest that researchers continue to determine how best to develop and implement research studies within the context of COVID-19 and its aftermath, recognizing that some families have been placed at greater harm during the pandemic and impacted significantly by issues related to social injustice at the community and national level. Opportunities to support child asthma management across multiple sectors of a child's life persist, but model delivery and sensitivity to issues related to social inequity are needed.

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### Author declaration

Michael Schechter reports personal fees for a Data Monitoring Board from Astra-Zeneca. No other authors have conflicts to disclose.

## Declaration of competing interest

M.S.S. reports personal fees for a Data Monitoring Board from Astra-Zeneca. No other authors have conflicts to disclose.

## Data availability

Data will be made available on request.

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