Author’s response to reviews

Title: Effects of the Home-based Educational Intervention on Health Outcomes among Primarily Hispanic Children with Asthma: A Quasi-Experimental Study

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Response to Reviewer Comments:

We would like to thank the reviewers for their feedback and valuable comments on our manuscript and for the opportunity to address their comments. Below are our responses to the comments from each reviewer. Page and line numbers are also provided (when applicable) to indicate the locations of addition and changes in the revised manuscript. We believe that the manuscript has improved significantly after addressing comments and suggestions offered by the reviewers.
Reviewer reports:

Leslie Allsopp, MSN, MPH. (Reviewer 1): Summary Comments:

The work has numerous strengths and may make an important contribution to the health of a vulnerable population of children and families. At the same time, there are numerous points to consider for revision. Individually, most of the recommended revisions are minor; taken as a whole they represent an opportunity to substantially strengthen the manuscript and the impact of the work. I also recommend careful editing throughout to correct numerous errors in grammar and sentence structure. One example is the frequent use of "Health Homes" rather than "Healthy Homes". Other examples are highlighted throughout the annotated PDF.

Response: Thank you very much for reviewing our manuscript. We corrected all of the words and sentence structures that you highlighted.

Background:

The authors have generally done a good job of synthesizing the literature. However, I noted an error in presentation of one study I am familiar with. On line 35 it states "Moreover, the total cost of asthma for the pooled sample of about 214,000 was about $82 billion in 2013." In fact this is an estimate for the entire US based on the pooled sample. I am not sure if this is an error in writing or author interpretation, but it would strengthen the manuscript to correct this and assure there are not similar instances.

Response: Thank you for your comment. We revised this part as follows (Background section, lines 13-14, page 4):

“Moreover, the estimated total cost of asthma in the U.S. based on the pooled sample of about 214,000 was about $82 billion in 2013.”

Methodology:

Important strengths of the study include the Difference in Differences design, the use of a validated tool for the pre and post-test survey, and a standardized curriculum. These strengths support the study's important potential contribution to the health and well-being of vulnerable children and families.

Response: We really appreciate your positive feedback.
Blinded, school level, randomization was done to create intervention and control groups and demographic characteristics of each group are measured and controlled for. This approach has strengths. At the same time, within a single ISD there may be substantial school level variation in factors that are not reported. Specifically, school attendance zones may vary with respect to neighborhood level factors that are relevant to study outcomes. Examples include transportation, age and quality of housing stock, accessibility of health services, and ambient air quality. These factors could potentially mediate outcomes and response to the intervention, especially given the statistically significant higher income among intervention families. While such neighborhood level factors may or may not be important in this specific study location, acknowledging this possibility would support interpretation of findings and suggest future investigations.

Response: Thank you for your comments. We agree with your opinion that the neighborhood level factors can affect asthma-related outcomes of children. However, we could not include them in this study unfortunately since data (residential information) was not available. So we focused on individual factors. As you mentioned, the future research will include potential neighborhood level factors. We added this information as one of the study limitations (Discussion section, lines 17-19, page 15).

“Fourth, this study did not deal with neighborhood factors, such as traffic-related air pollution, accessibility to healthcare, and ambient air quality, which may affect asthma-related outcomes. Future study will have to include potential neighborhood factors in the regional level.”

The intervention being assessed is the "60-90 minutes of direct education;" further characterization of the intervention would be extremely helpful. What was the content and how was the "direct education" delivered by CHW? What was the training and experience of these CHW and was there training specific to this intervention? Given the authors make recommendations regarding training of CHWs in the conclusions, this is especially important information.

Response: We appreciate your feedback. The direct education (60-90 minutes) is conducted by the curriculum. This curriculum is accredited by the Texas Department of State Health Services (DSHS) with 3 CEU’s, and a Community Health Worker Instructor (CHWI) provide CHW training with the curriculum. The specific components of the curriculum are presented in ‘Intervention’ part of Methods section (lines 1-7, page 8). As part of the curriculum, there are three case studies that are discussed during the training, a pre-test done at baseline and a post-test done three months after the education. The CHWs are certified by the DSHS and have many years working on this hard-to-reach Hispanic population in Texas-Mexico Border. We included the information about training for CHWs in the ‘Intervention’ part as follows (Methods section, lines 8-14, page 8):
“The Asthma and Healthy Homes Curriculum Manual (not published) includes details of all the steps needed to provide the training for the participants accurately and focusing on the same topics included in the curriculum. CHWs are trained by a Community Health Worker Instructor (CHWI) using a holistic asthma and healthy homes curriculum training modules that enable them to provide participants with the same training in the targeted communities (25). The training for CHWs consists of lecture, discussion, class participation/exercise and Question & Answer sessions.”

Additionally, is there any information regarding fidelity in delivering the intervention?” This type of information is necessary for interpretation of the results, dissemination and implementation, potential scaling, and recommendations to policy makers that are included in the conclusion. If the information is available it should be included. If it is not, it should be a recommendation for future study.

Response: Thank you for your valuable comments. We are working on a methodology for implementation on fidelity delivering the information for future studies. Unfortunately, it was not implemented in this study. According to your comments, we added the recommendation for future study (Discussion section, lines 1-3, page 16).

“Lastly, this study was limited to evaluate fidelity for the educational intervention by CHWs. A methodology for fidelity in delivering the intervention would be recommended for future study.”

Although studies referencing the curriculum used are referenced, I do not see a reference for the curriculum itself. This would be helpful.

Response: Since the curriculum used in this study has not been published yet, we did not include it in the manuscript. However, we mentioned “not published” for the curriculum and included additional information about the curriculum in the intervention part (Methods section, lines 8-14, page 8).

A dichotomous, family reported measure of income < 15,000 is used for participants that does not incorporate number of household members. Incorporation of household number and income are usually used in measures of poverty; the absence of household number is considered a limitation in measuring this important variable.

Response: Thank you for your comment. We could not incorporate them since the data for the number of household members was not available unfortunately. As you said, it may be a limitation in measuring this variable. We will consider collecting the data for the number of household next time.
Results:

It is important to understand what proportion of families invited to participate in the study consented to do so; the proportion completed the study is important as well. These questions are important to identify potential selection bias and determine validity of findings.

Response: Thank you for your comment. We mentioned the total number of school included in this study (n=19) in the Methods section (line 3, page 7). And we included this information in the results section (lines 2-5, page 11).

“Of 1,272 potential participants who were invited by a school nurse, 313 people submitted the consent form and enrolled in the study. Of the 313 enrolled participants, the intervention group included 139 participants and the control group had 174 participants, and 130 (93.5%) and 160 (92.0%) completed the study, respectively.”

Asthma prevalence based on the number of students identified as having asthma would be helpful. As school studies commonly find there is under-identification of students with asthma, they generally present how students are identified as having asthma. Additionally, it may be important to consider how expected and observed asthma prevalence compare in schools randomized to control vs. schools randomized to intervention.

Response: We appreciate your comment. A healthcare provider diagnoses all students and their parents who consent for this study with asthma. The number of children diagnosed with asthma is provided to the program staff, so at later date consent forms are delivered to the school nurse to send home. The parental consent forms that are return signed are those that are contacted for a household appointment for education, and their children are educated at school. Based on the number of students identified as having asthma and the total number of students in schools, we calculated the asthma prevalence (7.4%).

The authors state, "the control and intervention groups were not statistically different except for household income (p=0.027), indicating that the two groups were comparable.” While the point estimate of income difference is not large, income is of substantial potential importance to study outcomes. As a result, I do not see the statement of comparable groups is adequately supported and warrants some caution in interpretation. For example, a higher income family may have greater capacity to implement Healthy Homes’ recommendations; higher income may be associated with higher education or other family level characteristics, which might also be relevant to outcomes. Another factor to consider is the limitation in self-reported income noted in methodology comments. Acknowledging the income difference between the intervention and control group and considering its potential importance in this instance would strengthen interpretation of results.
Response: Thank you for your comment. We agree with your opinion that the income would be one of the important factors. To address this, we included this variable in all of the regression models (Table 3) to control its effect. It helps us to see the impact of the intervention on outcomes, controlling for potential confounders including the household income. In addition, we mentioned a limitation of some biases from the self-reported survey.

Lines 33 -51 report results using Acronyms of outcomes that are not defined. I only identify EC and EF being defined in the abstract. This is necessary to address. Given the conclusions stated about emotional well-being of families, it would be important to have more information about the EF and other scores. It may also be of interest to consider why the intervention was associated with improvement in EF but not EC.

Response: We appreciate your feedback. We included the definitions of these five scores in the Measurement part of the Methods section (lines 7-10, page 9). In addition, we added a citation of ‘User’s Guide: Children’s Health Survey for Asthma (CHSA).’ This document shows how to calculate these five scales based on the survey questions.

Discussion and Conclusions:

While the conclusions are in-line with the evidence provided, I recommend greater acknowledgement of limitations including those identified in this review and more cautious interpretation of the results and conclusions. This is the reasoning behind the "No" response to the question regarding adequate support for conclusions.

Specific contributors to this response include the limited information provided regarding the nature of the "direct education" intervention, CHW training, and the CHSA scores, especially as the authors conclude that "the study emphasizes the importance of caring for children and their families emotionally in training of health care professionals like CHWs" (page 15, lines 49-54). Also important is information regarding the proportion of students/families with identified asthma that consented to participate, and the proportion that completed the study.

Response: Thank you for your comments. According to your previous comments, we added the information, including components of the intervention, CHW training, and a citation for the calculation of CHSA scores. In addition, we included the information about the numbers of the people invited and people enrolled, respectively, and completion rates in the intervention and control groups as we mentioned above.
Relatively minor changes in the wording would bring the conclusions in better alignment with the strength of evidential support. The study makes important contributions and identifies areas where additional research is needed so that modifiable risks for vulnerable children can be effectively addressed. At the same time greater caution is warranted regarding recommendations for policy makers and dissemination and implementation of this program. This is necessary to assure that benefits suggested by this study are provided if the intervention is expanded, and to understand if and how the interventions may support sustainable improvement in health and well-being of this important group of children and families.

Response: We appreciate your feedback. We clarified some sentences according to your specific comments.

Emily Adlparvar, MPH (Reviewer 2): - Authors mention that childhood asthma rates are higher among minorities and Hispanics, however, they only share general population national and state of Texas rates - no rates are provided for Hispanic nor minority groups at any level. Therefore, it is hard to properly assess how big the problem is, as there is no point of comparison. It would also be helpful to get a sense of rates in the Hidalgo County and/or surrounding counties - both general population and minority rates.

Response: Thank you very much for your comments. We included some information about the current child asthma prevalence for Hispanic and Black compared to that for White as follows (Background section, lines 3-5, page 4):

“The current child asthma prevalence for Black (14.1%) and Hispanic (7.4%) were higher than White (7%) in the U.S.”

In addition, we added the childhood asthma prevalence for Hidalgo County as follows (Methods section, line 22 page 6 – lines 1-2, page 7):

“The childhood asthma prevalence for Hidalgo County in 2016 was about 9.4%, higher than the national (8.3%) and state (7.6%) prevalence.”
- Study was only implemented in Hidalgo County. Should the name of this article more closely reflect this? Perhaps the Texas Gulf Coast? The "US-Mexico border region" alludes to a much larger study area that includes at least more than one county, if not more than one border state.

Response: Thank you very much for your comment. We eliminated the location in the title, but explained the place where the study took place in the text.

- Minor revision of sentence. Original: "A comparison of the changes of asthma attack between two groups, the intervention group showed a significantly larger decrease than the control group."

Suggested: A comparison of the changes of asthma attack between the two groups showed that the intervention group had a significantly larger decrease than the control group. OR: In comparing the changes of asthma attack between the two groups, the intervention group showed a significantly larger decrease than the control group.

Response: Thank you for your suggestion. We revised it according to your first suggestion (Results section, lines 4-6, page 12).

“A comparison of the changes of asthma attacks between two groups showed that the intervention group had a significantly larger decrease than the control group (p=0.049).”