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A Randomized Pilot Trial of a School-Based Psychoeducational Intervention
for Children with Asthma

Running title: School-based asthma intervention

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Abstract

Background: Asthma is a common childhood illness with high morbidity and mortality among minority and socioeconomically disadvantaged children. Disparities are not fully accounted for by differences in asthma prevalence, highlighting a need for interventions targeting factors associated with poorer asthma control. One such factor is psychological stress.

Objective: Here, we examine the feasibility and acceptability of “I Can Cope (ICC),” a school-based stress management and coping intervention for children with asthma. *Methods:* A parallel randomized pilot trial was conducted. One hundred and four low income children (mean age 10 years; 54% male; 70% African American) with persistent asthma were recruited from 12 urban schools and randomized to: (1) ICC or one of two control conditions: (2) “Open Airways for Schools (OAS)” – an asthma education intervention or (3) no treatment. *Results:* 71% of eligible children participated in the study, with a dropout rate of 12%. ICC was rated as highly acceptable by participating children and parents. Preliminary efficacy data suggest that when compared with no treatment, ICC resulted in decreased symptoms of depression, perceived stress, and child-reported symptoms of asthma, and improvements in sleep quality and child-reported asthma control. There were no intervention-related changes in objective measures of asthma morbidity. The magnitude of intervention effects on psychological function did not differ between the ICC and OAS groups. *Conclusions:* Results support the feasibility and acceptability of utilizing school-based interventions to access hard to reach children with asthma. Preliminary findings offer support for future, large-scale efficacy studies of school-based interventions designed to target multiple factors that contribute to asthma disparities.

Keywords: Asthma, school-based intervention, stress, education, coping.

TRIAL REGISTRATION: ClinicalTrials.gov identifier: NCT02091648.

Introduction

It is estimated that 6.2 million children in the US have asthma¹, with disproportionately high morbidity and mortality among minority and socioeconomically disadvantaged children living in urban areas²⁻⁵. Disparities in asthma morbidity are not fully accounted for by disparities in asthma prevalence, and it is accepted that multiple factors converge to make asthma worse for high risk urban children⁶. Taken together, allergen exposures and access to health care only partially account for disparities in asthma morbidity⁶⁻⁸. Hence, recent attention has turned to the contribution of psychosocial factors that often accompany socioeconomic disadvantage⁹. In this regard, evidence shows an inverse association of negative life events (e.g., job loss, family conflict), poor housing, poverty, the real or perceived threat of crime and violence, and perceived psychological stress with socioeconomic status (SES)^{10,11}, raising the possibility that psychological stress contributes to asthma disparity.

Considerable evidence shows an association between psychological stress and asthma morbidity, including more frequent asthma exacerbations^{12,13}, poorer lung function¹⁴⁻¹⁶, exacerbation of airway inflammatory response to environmental triggers¹⁷, reduced efficacy of treatment with bronchodilators¹⁸, increased hospitalization¹³, increased asthma-related school absenteeism¹³, and increased asthma mortality¹⁹. Prospective evidence also shows that stressful life events predict asthma exacerbations in children. For example, acute negative life events (moving, loss of loved one) have been shown to increase risk for an asthma episode by nearly 2-fold^{20,21}, with risk increased to 3-fold among children who also have chronic background stress²⁰⁻²². Furthermore, cross-sectional evidence suggests that psychological stress mediates links between SES and the upregulation of inflammatory processes involved in asthma exacerbation²³.

Chronic stress may also impact health beliefs and behaviors that affect asthma self-management. In this regard, socially disadvantaged children have poorer asthma problem-solving skills and self-management behaviors and lack of knowledge of asthma and its treatment than their more advantaged counterparts^{24,25}. In light of evidence that lower SES children report chronic stress and frequent stressful life events²⁶, it is widely suggested that psychological stress contributes to disparities in childhood asthma morbidity through both biological and behavioral pathways^{9,27}. These findings raise the possible health benefit of offering stress management training to this population.

One of the challenges of offering stress management to socioeconomically disadvantaged children is difficulty recruiting and retaining this population to interventions offered in traditional outpatient settings. Accordingly, we have developed a manualized stress management and coping skills training intervention called “I Can Cope (ICC),” which is designed to be administered within a school setting. To our knowledge, ICC is the first school-based intervention designed to offer stress management training to disadvantaged children with asthma. In a small proof of concept trial at one school, we provided initial evidence for the feasibility of this method of accessing high-risk urban children²⁸. The primary aim of the current trial was to extend these findings to an examination of the feasibility and acceptability of offering ICC to economically disadvantaged 8-14 year olds with physician-confirmed asthma in multiple urban schools. In secondary exploratory analyses, we also examined the efficacy of the intervention at improving psychological function and asthma health when compared with disease severity-matched peers who received education-only or standard care. Based on effect sizes from our preliminary work²⁸, secondary analyses were powered to detect significant psychological differences between ICC and standard care groups, but were underpowered to reliably detect changes in objective measures of asthma morbidity or to discriminate comparative efficacy between ICC and OAS. Based on preliminary work, it was hypothesized that the ICC intervention would be feasible, well received and associated with decreased symptoms of depression and

perceived stress, and improved asthma health when compared with education only or no treatment conditions.

Methods

Design

The trial (ClinicalTrials.gov Identifier: NCT02091648) took place at urban public schools in Pittsburgh, PA, USA between January 2013 and May 2016. Using a parallel randomized controlled design, we compared ICC (n = 36) to (1) an asthma education condition ("Open Airways for Schools (OAS)" n = 36) and (2) a no treatment (NT) condition (n = 36). Participants were allocated to condition by stratified randomization (allocation ratio: 1:1:1). Participant ID numbers and asthma severity (mild, moderate, severe) were sent to a co-investigator who was blind to all other participant information. Within each asthma severity stratum, participants were randomized to study condition. Study staff were blinded to the randomization process. Data were collected from a parent and the child with asthma at two timepoints: (T1) within the 3 weeks prior to the first intervention session and (T2) 2-3 weeks after the end of the intervention (2-4 months after T1), or at matched times for the no treatment condition. Randomization took place at the end of T1 data collection. Primary outcomes were intervention feasibility and acceptability. Secondary outcomes were asthma coping and self-efficacy, psychological function (symptoms of depression and anxiety, and perceived stress), sleep quality, and asthma health (symptoms of asthma, pulmonary function and response to bronchodilators). Study staff who conducted assessments were blind to the participants' study condition. During the trial, the age range of participants was expanded from 8-12 years to 8-14 years to offer the program to all ages enrolled at the participating schools and to facilitate recruitment.

Participants

Eligible participants were children aged 8-14 years in grades 3-8 at 12 participating public schools. All participants were eligible for the free or reduced cost school lunch program in Pennsylvania (receive food stamps or have an annual income of < \$40,900), met the American Thoracic Society (ATC) criteria for persistent asthma, as confirmed by the study physician, and had a legal parent willing to participate. Exclusion criteria were chronic illnesses other than asthma, developmental delay with function < age 8 years as assessed by the school, and inability to understand English. No exclusions were based on race, ethnicity, or sex. Written informed consent was obtained from parents and assent from child participants in accordance with guidelines of the University of Pittsburgh Institutional Review Board (Protocol # 11110591). **Recruitment.** School nurses identified children who (1) had a diagnosis of asthma on school medical records and/or who carried a bronchodilator inhaler and (2) met other study inclusion criteria. The school nurse contacted the child's parent, informed them about the study and sought permission to share contact information with study staff. Invitation letters were also sent to those identified by the nurse as possible candidates. Possible participants were screened at an assessment visit, which took place at the child's school or home, depending on parent preference.

Procedure

At the initial assessment, consent and assent was obtained and a medical evaluation was conducted (asthma and medication history, exhaled nitric oxide and spirometric assessment of lung function). The study physician, a clinical and research specialist in pediatric asthma, used the results of this assessment to confirm eligibility and determined asthma severity (mild, moderate, severe) using National Asthma Education and Prevention Program's (NAEPP) Guidelines for the Diagnosis and Management of Asthma²⁹. Eligible participants and parents then completed T1 questionnaires. For the 14 days following this

assessment, child participants completed a diary each morning and evening assessing perceived stress, sleep and asthma symptoms. Following the return of the diary, child participants were randomized to study condition. Children randomized to the active conditions received six intervention sessions during the school day over a period of 2-4 months. Post-intervention, all participants repeated the 14 days of diary assessment, followed by a school- or home-based reassessment visit to complete pulmonary function testing and T2 questionnaires. To increase diary compliance, participants received nightly telephone reminder calls during the 28 diary days. Research assistants read all questionnaires to child participants and recorded responses. Parents completed questionnaires in a separate room from the child.

Study Conditions

1. I Can Cope (ICC): ICC is a manualized intervention that involves six 50-minute individual sessions and a child workbook²⁸, with examples and exercises suitable for different developmental levels. Each session includes 15 minutes of psychoeducation, 15 minutes of related games/activities, 15 minutes of relaxation training, and 5 minutes of homework assignment and review. Content focuses on: (1) the pathophysiology of asthma; (2) the biological impact of stress on the body; (3) relationships among thoughts, feelings, actions, and asthma; (4) coping skills to help deal with asthma-related and day-to-day stressors, and (5) training in biofeedback-assisted relaxation techniques, including guided imagery, progressive muscle relaxation, diaphragmatic breathing, and mindfulness-based body awareness techniques. Children received CDs or MP3 files with the relaxation exercises and a portable CD player to enable home practice. Throughout the intervention, the therapist and child worked collaboratively to address specific challenges that the child was facing. Participants were awarded points (“coping coins”) for paying attention, participating in the session, and completing homework assignments. Coins could be cashed

in for small prizes (e.g., pencils, notepads) each session or saved for larger prizes (e.g., games, small toys). Parents of children assigned to ICC received an overview of the sessions, explanations of homework assignments, and example discussion questions to facilitate dialogue with their children. In addition, parents received a telephone call or text message after each session to review material and the child's progress, reinforce their involvement and encourage questions.

2. Open Airways for Schools: Participants randomized to OAS received a modified version of the American Lung Association (ALA) Open Airways for Schools program (<http://www.lungusa.org/lung-disease/asthma/in-schools/open-airways/open-airways-for-schools-1.html>). This program, designed for 8 to 11 year olds, includes six 40-minute sessions covering the NHLBI recommendations for asthma education²⁹. Topics covered include information about asthma, recognizing and managing asthma symptoms, using medication, avoiding asthma triggers, getting enough exercise and doing well at school. The program focuses on asthma education, but also includes some information about stress management. OAS is designed to be offered in a group format but was adapted to be offered to individuals and to last for 50 min.

3. No treatment control condition: Participants randomized to NT received no intervention until after the trial, when they were offered the OAS program.

Interventionists were a doctoral level clinical psychologist, a master's level counseling psychologist, and 3 graduate students in clinical or counseling psychology programs. All had basic training in cognitive behavior therapy. For ICC, they received an additional four weeks (> 25 hours) of didactic and experiential training to conduct the intervention and provide biofeedback-assisted relaxation. For OAS, all interventionists received the standard training and certification offered by the American Lung Association.

Primary Outcome Measures

Feasibility: Feasibility was assessed by (1) the proportion of eligible children who (a) agreed to screening and (b) consented to participate, (2) attrition rates, (3) measures of adherence (completion of sessions and homework assignments), (4) child and parent-reported program satisfaction, and (5) barriers to offering the intervention in selected schools. Child participants and their parents responded on a 4-point scale (poor to excellent) to 6 questions assessing acceptability, enjoyment and usefulness of the interventions (Table 2).

Child psychological function: Questionnaires completed by the child at T1 and T2 included: (1) The Perceived Stress Scale (PSS-10)³⁰, which assesses the degree to which children perceive situations in their lives as stressful (Cronbach's coefficient alpha = .85)³⁰. The diary also included 3 items from the PSS, assessing daily stress, which were averaged across the 2 week period. (2) The Child Depression Index (CDI)³¹, which is a measure of depressive symptoms. Internal reliability coefficients are generally >.80, with test-retest reliability coefficients ranging from .38 to .87³². (3) The State-Trait Anxiety Inventory for Children (STAIC)³³, a 40-item measure of state and trait anxiety symptoms that has high split-half reliability ($r=.89$ for State and $r=.88$ for Trait) and moderate test-retest reliability ($r=.63$ for State and $r=.44$ for Trait at 3 months)³⁴.

In addition, child participants and parents completed the Children's Health Survey for Asthma (CHSA (parent version) and CHSDA-C (child version)³⁵. This measure provides a valid and reliable assessment of asthma-related quality of life^{36,37}. Responses were summed to derive measures of Physical Health, Activity, and Emotional Health Quality of Life.

Child sleep quality: To derive a measure of perceived sleep quality, the diary included two questions previously used in diary assessments of children's sleep^{38,39}: (1) "Last night, the quality of my sleep was:" rated on a 10 point scale from "very bad" to "very good." And (2) "This morning, waking up was:" rated on a 10-point scale from "very hard" to "very easy." Scores on the 2 questions were correlated ($r = .78$ at T1 and $.93$ at T2). Thus, they were summed and averaged across the 2-week period to provide an index of sleep quality, with higher scores reflecting better perceived sleep. Internal reliability coefficients of this measure were $.90$ at T1 and $.92$ at T2.

Child Asthma Health Measures: (1) Pulmonary Function: Pulmonary function testing was conducted at T1 and T2 using a portable spirometer (KoKo Legend, Grace Medical Marketing Inc., GA), following American Thoracic Society testing guidelines⁴⁰. Measures were taken pre- and post-administration of a short-acting bronchodilator (two puffs of Albuterol). Forced vital capacity (FVC) and forced expiratory volume in one second (FEV1) were obtained from the full expiratory flow-volume-time curve. Percentiles were calculated by comparing this value to reference values based on child age, height, sex and race. (2) Peak Expiratory Flow (PEF) was also recorded twice a day on diary days using an electronic peak flow meter (PiKo, nSpire Health Inc, CO), which records values along with a data and time stamp. Child participants were trained to record three PEF measurements on each measurement occasion (6/day). Values were downloaded at the end of each two-week period. PEF values are expressed as a percentage of a predicted mean for the child's age, sex, race, and stature. (3) Symptoms of Asthma: The CHSA and CHSA-C include questions about the intensity of asthma symptoms over the past two weeks, with the amount of time each symptom was experienced recorded on a five-point scale (5 (none of the time) to 1 (all of the time)). Scores were summed to derive parent- and child-rated recalled symptoms over the past two weeks, with higher scores reflecting less frequent symptoms. In addition, intensity of five symptoms (wheezing, coughing, shortness of breath, chest tightness, and

night time awakening) taken from the National Asthma Education and Prevention Program guidelines^{29,41} were assessed by the child on a scale from (0-none to 4 – bothersome and functionally limiting) on all diary days. Intensity of symptoms was averaged across each two-week diary period. (4) Use of as needed asthma medications: Frequency of use of short-acting beta agonists was reported twice a day on diary days. Scores were summed across the two week period. (5) Asthma Control: Answers on the CHSA and CHSA-C were used to derive separate parent- and child-measures of asthma control. Guided by the NHLBI guidelines for the assessment of asthma control, responses on questions that asked about frequency of school absences, wheezing symptoms, asthma attacks or trouble breathing and asthma-related medical visits in the past two weeks were summed. (6) Asthma-Self Efficacy: Parent and child participants completed the Asthma Self-Management Scale (ASMS)⁴², which assesses beliefs that they can perform behaviors to prevent and manage asthma symptoms. This scale has been validated for use with 7-15 year olds and has adequate reliability (Cronbach's alpha = 0.76-0.87) and validity⁴².

Analytic Methods: Feasibility and acceptability was assessed by: (1) willingness to participate as measured by number of eligible families who consented, (2) dropout rates between the ICC and control groups by Chi Square analysis, (3) adherence to intervention sessions and homework, and (4) program satisfaction. To conduct an initial examination of the efficacy of ICC, analyses were conducted in SPSS (Version 24) and Stata (Version 14). First, one-way analysis of variance was employed to examine mean differences in pre-intervention levels of psychological and asthma health. Next, mixed effects regression models were performed in Stata (program "xtmixed") to examine intervention-related changes in psychological and asthma health measures, with school-level random intercepts to account for nesting of children in schools. More specifically, children's post-intervention outcomes were regressed on indicators for ICC group and OAS group (NT group reference group) along with pre-intervention measures of the corresponding outcome measures. Maximum likelihood estimation was used to estimate the models. It was expected that

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subjects in the ICC group would show greater improvements in psychological function and asthma health than those randomized to OAS group or the control group. The statistical significance of the ICC group indicator in the model assessed whether this group differed from the control group (reference group). A Wald test was used after the model was estimated to compare the coefficients for the ICC and OAS groups, which tested whether children in the ICC condition performed better than those assigned to the OAS condition. Standardized mean differences (d's) were estimated using the pooled pretest standard deviation for weighting the differences of pre-post means as recommended by Morris⁴³. Power to detect group differences: Power calculations were performed using G-Power. Based on effect sizes from our proof of concept trial²⁸ and using an alpha of .05 and a group size of 30, we had 80% power to detect significant differences between ICC and standard controls for perceived stress and symptoms of depression. We were underpowered to reliably detect changes in objective measures of asthma morbidity or to discriminate comparative efficacy between ICC and OAS. For this reason, results of analyses that examine asthma health outcomes or compare the efficacy of the two interventions should be considered preliminary and only interpreted with caution.

Results

Table 1 shows baseline demographic and asthma characteristics of the sample.

Participants were 104 children ages 8-14 years ($M = 10.6$ ($SD = 1.5$) years, 54% male; 70% African American) and a legal parent (101 female; 3 male; 70% African American) aged 23 to 60 ($M = 39.8$ ($SD = 7.2$) years. Ninety one percent of child participants lived with their biological mother (48% with mother only, 20% with both biological parents, and 23% with mother and another partner); 7% with adoptive parent(s) and 2% with related parents. At baseline, 26 children (25%) endorsed elevated depression symptoms ($CDI > 13$) and 62 children (60%) endorsed elevated anxiety symptoms ($STAI-C$ trait scale > 34).

Feasibility

Our goal was to recruit 108 economically disadvantaged children with asthma. In total, school nurses identified and contacted parents of 220 possible participants; 26 of whom were not interested and 67 did not meet screening eligibility criteria (see Figure 1). The remaining 111 consented to participate (111/153; 73%). Of this group, seven were dropped prior to randomization (see Figure 1). Thus, 71% of eligible children (104/146) were recruited, providing support for the feasibility of the approach. Dropout rates were also low, with 11 children (11%) dropping out prior to the T2 evaluation. Of these 11 children, 5 withdrew (3 from the NT group, 1 from ICC because they moved school and 1 from OAS because of missing gym class) and 6 were lost to follow-up (3 from the NT and 3 from the active interventions due to moving school). In regard to adherence, 93% of the 69 participants completed all intervention sessions and T1 and T2 questionnaires. In addition, 60% completed more than 80% of the 4 weeks of daily diary records. The majority of child participants reported completing homework assignments, but this was difficult to confirm.

Acceptability

For both interventions, qualitative feedback from participants, parents, interventionists, school nurses and administrators was uniformly positive, and therapists were able to adhere to the protocols consistently. Mean ratings from the satisfaction survey supported child and parent satisfaction with the two programs (See Table 2). For example, child participants scored a mean of 2.9/3.0 (SD = 0.4) and parents scored a mean of 2.3/3.0 (SD = 0.6) on an item asking “To what extent has participation in “I Can Cope” helped you (or your child)?” Child participants rated the whole program 2.7/3.0 (SD = 0.6) and parents rated it as 2.5 /3.0 (SD = 0.5). Satisfaction scores were similar for the two interventions.

Preliminary Efficacy Data.

There were no significant differences between the ICC (N = 35), OAS (N = 34) or NT (N = 35) groups in demographic, psychological or asthma characteristics at T1 except individuals in the OAS group lived in larger households than the other two groups (See Tables 1 and 3).

Psychological function: Table 3 shows results of the mixed effect regression models. Participants in both interventions showed significantly lower symptoms of depression when compared with the NT group (Figure 2). Controlling for baseline depression, the ICC group scored 2.68 points lower (SE = 1.29; $d = -0.40$; Wald's $Z = -2.08$, $p = 0.04$) and the OAS group 3.15 lower (SE = 1.31; $d = -0.61$ Wald's $Z = -2.41$, $p = 0.02$) following treatment than the NT condition. The magnitude of this effect did not significantly differ between the two interventions. On the perceived stress measure, the OAS group scored 3.93 points lower than NT controls (SE = 1.60; $d = -0.72$; Wald's $Z = -2.46$ $p = 0.01$). Although the ICC group scored 1.24 points (SE = 1.55) lower than NT after controlling for

baseline PSS, this difference was not statistically significant ($d = -0.13$; Wald's $Z = -0.80$, $p = 0.43$). There was also a trend towards a larger effect in response to OAS than ICC ($\chi^2 = 2.99$, $p = 0.08$). There were no intervention-related changes in state or trait anxiety. On the Children's Health Survey for Asthma, both interventions tended to associate with an improvement in physical health-related quality of life when compared with the NT group (ICC group: $d = 0.15$; Wald's $Z = 1.81$, $p = 0.07$; OAS group: $d = 0.37$; Wald's $Z = 1.96$, $p = 0.05$) (See Figure 2). There was no significant difference between the two interventions in the magnitude of this effect. There were no parallel improvements in emotional or activity-related quality of life scores. Finally, sleep quality, as assessed by the child across the 14 days pre- and post-intervention, showed significant improvements for both intervention groups when compared with the NT condition (ICC: $d = 0.88$; Wald's $Z = 3.25$, $p = 0.001$; OAS: $d = 0.94$; Wald's $Z = 3.71$, $p < 0.001$) (Figure 2), with no significant between group difference in the magnitude of this effect.

Asthma health: Analyses examining asthma health outcomes were underpowered and the presented results should be considered preliminary. On average, child participants in the active treatment groups recalled fewer symptoms of asthma over the past two weeks on the CHSDA-C than the NT group (ICC: $d = 0.61$; Wald's $Z = 2.32$, $p = 0.02$; OAS: $d = 0.34$; Wald's $Z = 2.03$, $p = 0.04$) (See Table 3). They also reported an intervention-related increase in level of asthma control (ICC: $d = -0.71$; Wald's $Z = -2.58$, $p = 0.01$; OAS: $d = -0.69$; Wald's $Z = -2.36$, $p = 0.02$) and, for those in the ICC group, a trend towards lower reported use of beta agonist inhalers (ICC: Wald's $Z = -1.36$, $p = 0.15$; OAS: Wald's $Z = -0.50$, $p = 0.62$). In contrast, there were no significant intervention-related changes in mean asthma symptoms as reported in the daily diary. Parents also did not perceive any intervention-related changes in their child's symptoms or level of asthma control. There were no significant intervention-related changes in measures of lung function, pulmonary response to bronchodilators, or peak expiratory flow across diary days. Finally, on the

asthma self-management scale, children in the OAS program reported greater confidence that that could perform behaviors to manage their asthma ($d = 0.42$; Wald's $Z = 2.03$, $p = 0.04$). A similar effect was not observed for ICC.

Discussion

Attention has focused on the possibility that psychological stress may contribute to higher asthma morbidity among socioeconomically disadvantaged children living in urban communities^{3,5,6,27,44}. Accordingly, the primary goal of the current study was to examine the feasibility and acceptability of offering a school-based stress management program to vulnerable urban children with asthma. In secondary analyses, we also examined preliminary evidence in support of the efficacy of the intervention at improving psychological function and asthma health.

The recruitment approach was effective and successfully accessed minority and economically disadvantaged children with persistent asthma from 12 different urban schools. Of eligible families, 71% agreed to participate, with 70% of the sample being African-American, all participants meeting state criteria for subsidized school lunches, and 34% falling below the federal poverty level. Retention was acceptable, with only 7.2% dropping out of the intervention groups. The interventions were well accepted by child participants, parents and school personnel. In sum, the trial provided support for the feasibility and acceptability of offering interventions to economically disadvantaged children in schools.

Relative to control subjects, participation in ICC or OAS was associated with improvements in psychological wellbeing, with similar decreases in symptoms of depression and improvements in sleep quality. Levels of perceived stress also decreased following both interventions, with some suggestion that this effect was larger for OAS than ICC. Consistent with our “proof of concept” findings²⁸, there were no intervention-related decreases in symptoms of anxiety. Based on power analyses that used effect sizes from our earlier

findings, the current trial was adequately powered to detect intervention-related changes in psychological outcomes.

Failure to find a difference in the magnitude of intervention effects on psychological function between ICC and OAS was unexpected. OAS is weighted towards education and asthma symptom management and ICC to stress management and psychological coping. Thus, it was anticipated that ICC would associate with greater improvements in psychological health than OAS. Although we were underpowered to reliably discriminate comparative efficacy, the current results suggest that the psychological effect sizes of OAS and ICC are similar. OAS is less labor intensive, takes less time and is therefore cheaper to implement. However, before it is concluded that OAS is the intervention of choice, further research is warranted. Our anecdotal observations suggest that younger participants (~8-10 year olds) engaged more with the OAS materials than with ICC, whereas the reverse appeared true for older participants (~11-14year olds). It is also possible that a more comprehensive approach that combines asthma education with stress management training would be more effective than either intervention alone.

The finding that participants in ICC showed improvements in psychological function when compared with no treatment is consistent with our preliminary work²⁸ and with results from some prior trials of psychosocial interventions for children with asthma^{45,46}. However, not all findings are consistent and reviews of this literature conclude that many studies are of poor general quality, which makes it difficult to form conclusions⁴⁷. The current study is one of the first to examine feasibility of a school-based intervention that targets emotional health among lower income children with persistent asthma and preliminary results are promising. In addition to intervention-related decreases in symptoms of depression and perceived stress, participants showed improvements in sleep quality. Up to 66% of children with asthma present with sleep disturbance⁴⁸, which is likely related to breathing difficulty and poor sleep habits⁴⁹. Indeed, children living in low-income households show more emotional and sleep problems than their more affluent peers^{48,50,51}. Given that lack of sleep negatively

affects cognitive function, predicts poorer general mental and physical health, and associates with poorer asthma management and asthma health among school age children^{48,52,53}, the current results may translate to improved asthma health outcomes over time.

Contrary to expectations, intervention-related improvements in psychological function were not accompanied by improvements in objective measures of asthma health. However, in this regard, the current pilot study was underpowered and larger trials are warranted before firm conclusions are drawn. Our preliminary findings suggest that participants in OAS or ICC did not differ from the NT group in lung function, response to bronchodilators, or peak expiratory flow across the diary period. Similarly, parent assessment of the child's asthma symptoms and level of asthma control, and child report of symptoms across the diary days did not differ significantly in comparison to the NT group. In contrast, child participants in both interventions recalled fewer symptoms in the past two weeks, and endorsed a higher level of asthma control, and better physical health-related quality of life post intervention than those in the control condition. Participants in the OAS program, but not ICC, also reported an increase in their belief that they could manage their asthma. Overall, this pattern of results is consistent with existing literature, with school-based asthma education interventions resulting in increased knowledge of asthma and its management, but not improvements in asthma health⁵⁴. Findings regarding effects on self-reported quality of life, asthma symptoms and asthma control are more mixed⁵⁴ and a meta-analysis of educational interventions concluded that they were not sufficient alone to improve asthma health outcomes⁵⁵. Studies that incorporate psychological interventions, like ICC, into asthma education programs, may be more efficacious, with preliminary evidence suggesting that they are associated with reduced asthma morbidity⁵⁶.

Reasons why interventions, such as ICC, may not result in improvements in objective indices of asthma health are unclear. It is likely that these interventions are insufficient to address the many factors that associate with asthma morbidity among lower

SES children in urban communities⁵⁷, including environmental exposures (e.g., allergens/irritants/pollutants and violence), family challenges (e.g., parenting stress, harsh/inconsistent parenting, reduced parental engagement), child behaviors (e.g., poor diet, low levels of physical activity, medication non-adherence) and low access to quality medical care^{6,58}. In this case, better outcomes may result from an integrated treatment approach that considers the complex social and physical systems in which the child resides and addresses patient education, mental health, and family function, along with more traditional medical management^{57,59}. The current findings suggest that schools provide an effective setting for this coordinated healthcare, providing reliable access to high risk children with asthma.

Another possible explanation for our failure to observe intervention-related changes in objective measures of asthma health may relate to large number (50%) of children in the study with mild asthma. Among this group, 52% experienced no symptoms in the prior two weeks and the average percent predicted FEV1 was 91% at baseline, limiting our ability to detect intervention-related changes in these measures. Future work would benefit from targeting a sample with more severe asthma who have been shown to derive greater physical health benefit from school-based intervention⁶⁰.

The current pilot trial was designed to assess feasibility and acceptability and was underpowered to examine comparative efficacy or moderators that may influence magnitude of treatment response. In addition to asthma characteristics, these factors include the age and sex of the child and the level of parental engagement in the program. Anecdotal reports from the interventionists suggest that younger children in the trial had difficulty retaining intervention material and were less compliant with homework than older participants, particularly if they did not have a supportive parent at home. Given these observations, the study age range was changed from 8-12 years to 8-14 years early in the trial. In future work implementing cognitive-behavioral stress management, it may be more effective to target older children who are better able to recall and utilize the cognitive and emotion regulation skills. Given the significance of caregiver adjustment to the child's asthma health⁶¹, future

work may also benefit from the greater engagement of parents in the program. Despite attempts to engage parents in the current program, level of engagement was low. In this regard, home-based family interventions may be more effective and have a greater impact on the child's asthma health^{62,63}.

Finally, we encountered a number of barriers to offering interventions in a school setting. General issues surrounded finding acceptable times to release children from school activities. School-specific issues included lack of dedicated space to meet with the child. Future work would benefit from exploring the feasibility of adapting the intervention to be offered in a group format by members of the school community who receive training and supervision from qualified health practitioners. The ICC intervention could also be offered at a school-based health center as part of a general health education program. Evidence shows that embedding health centers within schools provides greater access to vulnerable families, promotes preventative and supportive interventions, and improves a range of health outcomes, including for children with asthma⁶⁴.

In sum, the current findings support the feasibility and acceptability of utilizing school-based interventions to access hard to reach children with asthma. Initial efficacy results suggest that both active interventions, ICC and OAS, improve psychological function, sleep quality and physical health-related quality of life in ways that could translate to future improvements in asthma health and physical function. Consistent with results of other school-based asthma management programs⁶⁵, the interventions were not associated with improvements in objective measures of asthma health. It is likely that multi-modal programs that target children with moderate-severe asthma, include parents and health care providers, and involve both asthma education and stress management will be necessary to improve the asthma health of urban minority and economically disadvantaged children.

The Authors have no conflicts of interest to declare.

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Figure Legends

Figure 1. Consort Trial Flow Diagram

Figure 2. Scores on measures of depression (Child Depression Inventory), sleep quality (mean scores on diary measures of sleep quality), and physical health quality of life (Children's Health Survey for Asthma – Child Version) at pre- and post-intervention (T1 and T2) among children assigned to "I Can Cope (ICC)," "Open Airways for Schools (OAS)," and the no treatment control (NT) group.

Table 1: Demographic and asthma characteristics for subjects randomized to the 3 conditions. Baseline group differences were assessed using one-way analysis of variance or chi square tests.

Characteristic	I Can Cope (n = 35)	Open Airways (n = 34)	No Treatment control (n = 35)	P for group difference
Child Age (years)	10.8 (1.67)	10.5 (1.61)	10.5 (1.31)	F (2,103)= .34; P = .71
Child sex (male)	17 (49%)	19 (56%)	20 (57%)	Chi Sq = .60; P=.74
Child Race				Chi Sq = 4.32 P = .63
African American	28 (80%)	23 (68%)	22 (65%)	
White	4 (11%)	5 (15%)	7 (21%)	
Mixed Race	3 (9%)	5 (15%)	5 (15%)	
Other	0	1 (3%)	0	
Total Household Income				Chi Sq = 8.06; P = .43
<\$11,999	3 (9%)	4 (12%)	7 (20%)	
\$12,000-\$24,999	7 (20%)	9 (26%)	10 (35%)	
\$25,000-\$49,999	15 (43%)	14 (41%)	9 (26%)	
\$50,000-\$74,999	8 (23%)	5 (15%)	3 (9%)	
\$75,000-\$99,999	1 (3%)	0	0	
>\$100,000	0	0	0	
No response	1 (3%)	2 (6%)	6 (17%)	
Maternal Education (years)	13.82 (2.01)	13.21 (1.85)	13.32 (2.21)	F(2,100) = .87; p = .42
# people in household	3.77 (1.26)	4.64 (1.69)	3.80 (1.37)	F(2,102) = 3.88, p =.02
# days missed school in 12 mos.	2.09 (3.19)	5.75 (13.21)	4.22 (8.29)	F(2,97) = 1.35; p = .26
Asthma Severity				Chi Sq = 1.81, p = .77
Mild persistent	17 (49%)	19 (56%)	16 (46%)	
Moderate persistent	17 (49%)	13 (38%)	16 (46%)	
Severe persistent	1 (3%)	2 (6)	3 (9%)	
Asthma control – Child report	19.42 (3.95)	19.61 (3.95)	19.43 (4.16)	F(2,102) = .022; p = .98
Child symptoms in past 2 weeks - parent report	28.85 (5.42)	26.03 (6.73)	26.71 (6.22)	F (2,102) = 1.94; p = .15
Short-Acting Beta agonist use	34 (100%)	31 (91%)	33 (94%)	Chi Sq = .59; p = .74
Inhaled steroid in past 12 mos.	13 (37%)	13 (38%)	20 (57%)	Chi Sq = 3.92; p = .14
Oral steroids in past 12 mos.	14 (40%)	21 (62%)	17 (49%)	Chi Sq = 3.83; p = .15
Rescue Nebulizer treatment in past 12 mon (yes/no)	14 (40%)	13 (38%)	18 (51%)	Chi Sq = 1.98. p = .37
Unscheduled Dr/ER visits for asthma in past 12 mon (yes/no)	17 (49%)	22 (65%)	22 (63%)	Chi Sq = 17.68; p = .13
FeNO (ppb)	26.37 (29.00)	29.09 (32.35)	20.97 (21.92)	F (2,99) = .71; p = .50

Table 2: Means and standard deviations for child and caregiver responses on post-intervention satisfaction surveys for “I Can Cope” and “Open Airways for Schools” intervention groups.

Questions	I Can Cope Intervention		Open Airways for Schools	
	Child (n = 31)	Parent (n = 27)	Child (n = 30)	Parent (n = 23)
To what extent has participation in the program helped you (your child)?	2.9 (.40)	2.3 (.59)	2.7 (.52)	2.4 (.51)
How would you rate the quality of the whole program?	2.7 (.60)	2.5 (.51)	2.7 (.60)	2.5 (.59)
Would you tell a friend (a friend's child) with asthma that he/she should take part in this program?	2.6 (.66)	2.6 (.49)	2.7 (.55)	2.5 (5.9)
Have the things you (your child) learned in this program helped you (your child) deal with upsetting events (stress) in your life?	2.6 (.55)	2.6 (.49)	2.4(.77)	2.4 (.65)
Are you happy with the help you (your child) received in this program?	2.8 (.55)	2.6 (.69)	2.8 (.50)	2.6 (.65)
Did you enjoy the training?	2.5 (.81)	-	2.7(.71)	-
Sum Score	16.13 (2.59)	12.59 (1.94)	15.93 (2.83)	12.37 (2.68)

Scores are based on a 0 (poor) to 3 (excellent) rating scale.

Table 3. Psychological and asthma measures at T1 and T2 for subjects in the I Can Cope (ICC), Open airways for Schools (OAS), and no treatment groups; comparison of mean differences at T1; and results of mixed effects regression models examining intervention-related changes and the Wald test comparing the coefficients among the ICC and OAS groups.

	ICC		OAS		No Treatment		T1 mean difference	ICC effect compared with control group ^a	OAS effect compared with control group ^a	Test for difference of ICC and OAS effect sizes
	Mean (SD)		Mean (SD)		Mean (SD)					
Measure	T1	T2	T1	T2	T1	T2		Coefficient (SE)	Coefficient (SE)	Wald Chi ²
Psychological Function										
Perceived Stress (PSS)	13.48 (8.12)	12.36 (8.15)	16.30 (5.26)	11.53 (5.95)	14.12 (7.54)	14.03 (8.98)	F (2,102) = 1.03; NS	-1.24 (1.55)	-3.94 (1.60)*	2.99 [†]
Symptoms of Depression (CDI)	9.0 (6.82)	7.45 (5.57)	9.87 (5.94)	7.35 (5.95)	9.25 (5.09)	10.11 (6.99)	F (2,103) = 0.76; NS	-2.68 (1.279)	-3.15 (1.31)*	0.14
State Anxiety (STAIC)	29.06 (5.60)	28.48 (5.29)	29.77 (5.10)	28.84 (5.52)	29.21(6.40)	28.46 (5.32)	F(2,103) = .02; NS	0.38 (1.23)	0.56 (1.245)	0.02
Trait Anxiety (STAIC)	36.58 (8.09)	34.58 (7.72)	37.00 (7.00)	33.74 (8.44)	35.52 (7.18)	34.10 (7.01)	F(2,103) = .09; NS	-.10 (1.67)	-1.16 (1.69)	0.42
Physical Health Quality of Life (CHQ)	76.80 (15.39)	83.33 (16.93)	69.51 (21.48)	81.22 (18.07)	69.58 (21.16)	73.28 (17.82)	F(2,103) = .61; NS	7.36 (4.06) [†]	7.97 (4.07)*	0.02
Activity Quality of Life (CHQ)	80.81 (16.14)	84.04 (15.03)	72.74 (24.86)	81.48 (18.10)	75.86 (19.36)	76.78 (24.46)	F(2,103) = .79; NS	4.79 (4.15)	6.26 (4.20)	0.13
Emotional Health Quality of Life (CHQ)	77.97 (19.94)	83.27 (17.02)	71.98 (19.05)	84.54 (19.51)	75.29 (18.59)	82.40 (17.15)	F (2,103) = .67; NS	0.14 (3.61)	4.27 (3.66)	1.33

Asthma Health										
Symptoms past 2 weeks – Child	26.61 (4.42)	30.84 (3.91)	26.80 (5.81)	29.87 (5.10)	26.48 (5.93)	27.52 (4.99)	F (2,100) = .50; NS	2.56 (1.10)*	2.24 (1.10)*	0.09
Symptom past 2 weeks –Parent	28.79 (5.35)	30.71 (3.73)	27.21 (6.48)	31.04 (3.47)	26.56 (6.82)	29.85 (4.21)	F(2,102) = 1.94; NS	0.22 (0.91)	1.00 (0.93)	0.71
Symptoms (mean diary)	2.16 (2.75)	2.52 (5.68)	2.66 (3.80)	1.98 (4.95)	3.02 (2.52)	4.19 (8.48)	F (2,89) = .70; NS	-0.69 (1.56)	-1.91 (1.58)	0.65
Asthma control – parent rated	1.56 (1.65)	1.15 (1.29)	1.26 (1.76)	1.39 (2.08)	3.40 (3.88)	1.72 (2.19)	F (2,98) = 1.75; NS	-0.28 (0.52)	0.01 (0.55)	0.32
Asthma control – child rated	2.12 (2.12)	1.21 (2.01)	2.33 (2.32)	1.40 (2.14)	2.00 (1.95)	2.55 (2.30)	F (2,103) = .08; NS	-1.40 (0.54)*	-1.31 (0.56)*	0.02
FVC (% predicted)	86.63 (17.56)	96.25 (17.94)	89.14 (14.92)	96.86 (18.89)	91.10 (26.24)	97.93 (24.49)	F (2,103) = .25; NS	113.97 (84.40)	16.79 (84.73)	1.31
FEV1 (% predicted)	88.28 (18.37)	95.91 (16.92)	89.52 (15.36)	97.14 (16.04)	90.38 (24.96)	96.31 (22.54)	F (2,103) = .05; NS	105.65 (84.44)	18.83 (84.86)	1.04
FEV1 Response to bronchodilators	8.56 (14.41)	3.44 (7.93)	10.59 (13.65)	7.17 (10.80)	7.21 (16.50)	4.97 (19.27)	F(2,103) = .81; NS	86.91 (79.90)	2.92 (80.67)	1.09
PEF (Diary; %predicted)	79.12 (15.39)	75.60 (17.23)	74.12 (25.52)	74.37 (28.89)	67.65 (23.76)	64.64 (22.98)	F(2,90) = 1.28; NS	2.38 (4.84)	4.89 (4.90)	0.29
Frequency of β agonist use	6.65 (9.37)	3.23 (6.99)	5.96 (7.70)	4.13 (7.24)	7.43 (10.23)	5.86 (9.67)	F(2,90) = .42; NS	-2.14 (1.57)	-0.80 (1.60)	0.78

Asthma Self Management	3.48 (.76)	3.72 (.76)	3.48 (.84)	3.92 (.81)	3.50 (.78)	3.60 (.78)	F(2,102) = .03; NS	0.10 (0.16)	0.34 (0.17)*	2.16
Sleep (Diary)	15.45 (3.00)	16.47 (3.03)	15.63 (3.52)	17.07 (3.10)	15.52 (3.49)	13.66 (3.89)	F (2,90) = .14; NS	2.85 (0.88)**	3.34 (0.90)**	0.33

* p < .05; **p<.005; [†]p<.10; ^a Coefficients from mixed effects models controlling for age, sex, and baseline measure of the outcome variable



