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The Impact of Peer Support and mp3 Messaging on Adherence to Inhaled Corticosteroids in Minority Adolescents with Asthma: A Randomized Controlled Trial

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Abstract

Background—Poor adherence to inhaled corticosteroids (ICS) is a critical risk factor contributing to asthma morbidity among low-income minority adolescents.

Objective—This trial tested whether peer support group meetings and peer asthma messages delivered via mp3 players improved adherence to ICS.

Methods—Low-income African American and/or Hispanic adolescents, ages 11–16, with persistent asthma, and poor (≤ 48%) adherence to prescription ICS during the 3-week run-in were randomized to intervention or attention control groups (ATG) for the 10-week treatment. During treatment, the intervention arm participated in weekly coping peer group support sessions and received mp3 peer-recorded asthma messages promoting adherence. The ATG participated in weekly meetings with a research assistant and received an equivalent number of mp3 doctor-recorded asthma messages. Adherence was measured using self-report and the DoserCT, (Meditrac, Inc.), an electronic dose counter. The primary outcome was the difference in adherence at 10 weeks between the two arms.

Results—Thirty-four subjects were randomized to each arm. At 10 weeks, no statistical difference in objectively measured adherence could be detected between the two arms adjusting for baseline adherence ($P = 0.929$). Adherence declined in both groups over the course of the active treatment period. Participants' in both study arms self-reported adherence was significantly higher than their objectively measured adherence at week 10 ($P < 0.0001$).

Conclusion—Improving medication adherence in longitudinal studies is challenging. Peer support and mp3-delivered peer asthma messages may not be of sufficient dose to improve outcomes.

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Keywords

Childhood asthma; medication adherence; health status disparities; outcome assessment (health care); asthma knowledge; inner-city; adolescents

Asthma is the most common chronic illness of childhood in the United States, affecting 9.3% of children.[1] Asthma prevalence in the pediatric population continues to rise, with greatest risk seen in minority racial/ethnic groups.[2] African American (non-Hispanic) and Puerto Rican Hispanic children are disproportionately affected, compared to Caucasian children, with asthma prevalence of 14.6%, 18.4%, and 8.2% for each group, respectively.[1] African American and Hispanic children experience higher rates of emergency department visits, hospitalizations, and deaths due to asthma than Caucasianchildren.[3] In particular, African American children are over twice as likely to be hospitalized for asthma, and four times as likely to die from asthma, as Caucasian children.[3] Age is a powerful predictor of negative outcomes. Across all three racial/ethnic groups, asthma death rates are approximately twice as high in 11–17 year old adolescents as 0–10 year old children.[4]

Lack of adherence to inhaled corticosteroid medications (ICS) is among the most significant risk factors associated with poor asthma outcomes.[5–12] Although ICS reduce the frequency of asthma symptoms and severity of asthma attacks,[13–15] adherence to this class of medications is dismally low and the benefits of ICS are often not received. In a city-wide Chicago cohort, only 11.9% of children with moderate or severe persistent asthma self-reported use of a controller medication.[16] A large-scale community-wide intervention in Chicago was able to increase adequate ICS use in 5–9 year olds, but not in 10–17 year olds.[17] Objective measurement of medication adherence—especially among African American and Hispanic youth—is rare.[18–20] Interventions to improve adherence have not been rigorously tested in this population.[7]

A difficulty in the design of interventions for adolescents is that they must fit easily into adolescents existing lifestyles and peer group.[21–25] Coping peers have been shown to be a valuable source of information, companionship, mutual understanding, and support in helping adolescents to face and manage their asthma.[26–27] Technology-based interventions directed at adolescent adherence have begun to emerge and offer distinct advantages. Media consumption among adolescents overall is high, with two groups of youth standing out for exploding levels of media use: (1) those in the early teen years (11–14 year olds); and (2) African Americans and Hispanics.[28] iPod/mp3 player ownership has increased from 18% to 76% among all 8–18 year olds between 2004 and 2009.[28] Guided by social cognitive theory,[21] the investigators sought to leverage this existing use of technology, specifically the iPod/mp3 player, and the coping peer model to deliver a culturally sensitive intervention aimed at improving medication adherence in minority adolescents with asthma.[28]

This randomized controlled trial assessed the efficacy of a coping peer support plus mp3 technology-assisted behavioral intervention, relative to an attention control, in improving adherence among non-adherent African American and Hispanic adolescents with persistent asthma.

Methods

Eligibility Criteria

Eligibility criteria specified that participants would be: 11 to 16 years of age and self-identified as African American or Hispanic, diagnosed with persistent asthma, and possessing an active prescription for a daily ICS for asthma. Persistent asthma was defined

as asthma symptoms (e.g. cough, wheeze, shortness of breath, chest tightness) more than two days per week or nighttime awakenings more than twice a month; or being on a prescribed daily ICS for asthma.[29] The latter requirement was met when the adolescent had, within the last 12 months: 1) an outpatient visit to Rush University Medical Center with asthma listed as a diagnosis code for that visit, and 2) a prescription for ICS. To verify that the ICS prescription was active, the participant had to either bring in the medication with his or her name on the pharmacy label, or have the pharmacy verify availability of an active prescription. Exclusion criteria included: a caregiver or child unable to speak English, the presence of co-morbidities that could interfere with study participation, or ≥ 48% adherence over 2 weeks during the run-in period. Participants with ≥ 48% adherence were excluded as the aim of the study was to target children with poor adherence (i.e. who could benefit most from this behavioral intervention). Observational studies that electronically monitored adherence to daily ICS in diverse samples of adolescents report rates between 40–50% as being typical. [18–19, 30–31] The most common dosing schedule for ICS administered via metered dose inhaler is two puffs twice daily (for a total of 56 puffs over a 2-week period). Thus, the investigators set the cutpoint for adherence eligibility as taking ≤ 26 puffs per 2-week period, or ≤ 48% adherence.

Recruitment and Study Follow-up

Patients were recruited between May 24, 2011 and February 28, 2012 from three primary care practices at Rush University Medical Center in Chicago, Illinois. All three practices have been recognized as level 3 (highest recognition awarded by the National Committee for Quality Assurance) Patient-Centered Medical Homes. The majority of pediatric patients in these practices receive public insurance through Medicaid or the State Children's Health Insurance Program (SCHIP). The study protocol was approved by the Rush University Medical Center Institutional Review Board. After obtaining Request for Access to Personal Health Information for Reviews Preparatory to Research, eligible patients were identified by an electronic medical records search. Written consent and assent were obtained from eligible patients as well as their parent or guardian.

Figure 1 illustrates the flow of participants from recruitment through final data collection. Figure 2 shows the design of the study. Upon providing written consent, participants entered a 3-week run-in phase in which medication adherence eligibility was determined. Each participant was provided an electronic medication monitor (Doser CT, MediTrack, Inc., South Easton, MA) that was placed on their ICS. Participants and their caregivers were fully informed that the electronic monitor would record the number of times that they actuated their ICS on a daily basis, but were kept blind to the specific purpose of the monitoring.

At the end of the 3-week run-in phase, eligible participants entered a pre-active treatment phase in which they attended weekly individual sessions until a cohort of 8 to 12 participants could be formed. Once a cohort of 8–12 participants was formed, the group was randomized (blocked group randomization, using a computer-generated allocation schedule) to receive either the active intervention or the attention control. A total of 7 cohorts were enrolled, resulting in a total of 68 participants. Participants were followed for 10 weeks after being randomized.

Study Interventions

During the run-in phase, all participants received: 1) medical supervision (provision of spacers and peak flow meters, as well as education on proper use of each);[32] 2) an iPod shuffle 2GB (4th Generation) (Apple, Cupertino, CA) locked at 70% volume to protect participant's hearing[33–34] and set in shuffle mode to ensure all contents had an equal chance of being played; and 3) clean and/or radio-edited mp3 music tracks.

During each of the 10 weeks of the active treatment phase, participants received music tracks and were to attend scheduled weekly sessions. Those in the active intervention group attended coping peer group sessions led by social workers during weeks 1 through 4 and 6 through 9. The session leaders were trained to use a motivational interviewing approach and to follow a topic guide designed specifically for this study. [35–38] During the sessions, participants discussed barriers to taking daily ICS and strategies to overcome them. The social workers received equivalent training in using motivational interviewing as a behavior change therapy, and asthma education[39] prior to leading the coping peer groups. At the conclusion of each group session, participants developed and recorded 2 to 4 messages gleaned from the discussions at that visit and focused on encouraging each other to take their daily ICS. These messages were then produced with background music chosen by the participants and placed as selections on their iPods to be shuffled at random between the music tracks. In contrast, those in the attention control group met individually with a research assistant during weeks 1 through 4, and 6 through 9. The research assistant did not engage in conversation with the participants to promote adherence. At each of these sessions, the attention control group adolescents received the same number of iPod messages as their active intervention group counterparts, with content promoting adherence to daily controller medications. However, their messages were developed and recorded by an asthma doctor rather than by peers. These messages were placed on participants' iPods to be shuffled at random between the music tracks.

Outcome Measures

Outcomes data were collected at baseline and at 5 and 10 weeks post-randomization (during the active treatment phase) by research assistants blinded to the participants' group assignment. The primary study outcome was ICS adherence measured using the electronic medication monitor to ICS. Daily adherence was calculated as the following over a given 24-hour period: percentage of prescribed puffs = (puffs actuated/prescribed puffs) * 100%.[6] Daily adherence was truncated at 100% of the prescribed dose because true adherence to ICS may be distorted by intentional overuse (medication dumping).[40] To use a standard electronic monitoring system to measure adherence in all study participants, the investigators switched participants on different ICS formulations to a best approximation dose of Flovent HFA 110 mcg Inhalation Aerosol (provided by GlaxoSmithKline) for the duration of the study. If a participant declined the switch, he or she was allowed to continue to participate in the study as long as the Doser CT tracking cap fit onto his or her current ICS medication. Adherence was monitored continuously during study follow-up. The primary study outcome was measured using the average daily adherence over the previous 14 days. This measure was determined at baseline (using data obtained during the run-in phase) and post-randomization at 5 weeks and at 10 weeks.

Assessments at baseline included: demographics, asthma history, media use, asthma control, and depression. Asthma history included questions about currently prescribed controller and quick-relief medications for asthma as well as tobacco smoke exposure. Asthma control was assessed using questions that addressed domains of risk and impairment from the NHLBI EPR3 guidelines, specifically: recall of previous 2–4 weeks of daytime symptoms, nighttime awakenings, interference with normal activities, use of short-acting bronchodilator medication for symptom control; and number of asthma exacerbations requiring oral systemic steroid use in the prior year.[29] The Children's Depression Inventory 2[41] was used to evaluate levels of depression.

The following were assessed at baseline, as well as at weeks 5 and 10 of the active treatment period: 1) asthma knowledge;[42] 2) ICS knowledge;[40] 3) ICS self-efficacy;[43] 4) social support;[44] 5) asthma social support;[44] and 6) asthma exacerbations.[29] In addition, at the week 5 and week 10 visits only, participants were asked to self-report their ICS medication

use over the past 14 days. Asthma knowledge was measured by the ZAP Asthma Knowledge Instrument. This 39-item questionnaire was adapted from the ZAP Caregiver Asthma Knowledge Survey Instrument.[42] Asthma exacerbations included self-reported: missed school days; oral prednisone bursts; unscheduled urgent visits to the doctor's office; emergency room visits; hospitalizations; intensive care unit admissions; and intubations.

Statistical Methods

This study employed a two-arm design in which participants were randomized to either the intervention arm or attention control arm. Whenever a cohort of 8–12 individuals met all eligibility criteria, the study biostatistician effected the randomization process. A 1:1 ratio block randomization scheme was used. Group membership was maintained and reinforced within the active intervention arm; however, the attention control was delivered individually. Thus, clustering was a potential confounder within the active intervention arm, but not within the control arm. Linear mixed effects modeling was used to assess the influence on outcomes of the clustering within the active intervention arm. This approach allows analysis of within- and between-cluster variance as well as estimation of the intraclass correlation.[45] If the resulting model estimates are non-significant ($P > 0.05$), the effect of clustering can be assumed negligible and cluster-adjusted analyses not required.

Baseline demographic and assessment variables were compared between treatment groups to assess balance. The t-test or Wilcoxon rank sum test was used, depending on the appropriateness of the normality assumption, to compare continuous variables. Discrete variables were compared using the chi-square test or fisher exact test, depending on the pertinent sample size. Cluster-adjusted versions of these tests were used when analyses indicated a significant (at the 0.05 level) effect due to clustering within the intervention arm.

The primary outcome measure was adherence to ICS, computed as the average daily adherence rate over the previous 14-days. For each participant, this measure was taken at baseline and weeks 5 and 10 post-randomization. The primary analysis compared mean adherence at 10-weeks post-randomization between the two treatment groups. To assess the influence of missing data on this comparison, the analysis was also performed with missing outcomes values replaced with the maximal observed value (the so-called 'best case' scenario) and then with the missing outcomes replaced by the minimal observed value (the so-called 'worst case' scenario). To adjust for potentially meaningful pre-specified covariates (treatment group, visit attendance, asthma control, depression, music listening, and asthma severity), multilevel modeling was used.[46] For the model, objectively measured 10-week adherence was the dependent variable, the covariates mentioned above were included as fixed-effects, and a random intercept was employed. All statistical analyses were performed using SAS v.9.2 software.

Results

Enrollment and Follow-up

See Figure 1. A total of 373 potentially eligible patients were identified from the electronic medical record. Two hundred and sixty-six participants did not meet study criteria. Of the 107 participants who completed informed consent and assent procedures, 39 failed the run-in, and 68 were randomized (34 to the treatment, and 34 to the attention control). Three participants randomized to the active intervention group did not attend any study visits due to: (n=1) declined to participate and (n=2) becoming lost to follow up. Three participants randomized to the attention control group did not attend any study visits, having become lost to follow up (n=3). Fifty-six percent (19/34) and 62% (21/34) of the treatment and attention control group participants, respectively, attended > 6 study visits. To be included in the data

analysis, participants had to have either week 5 or week 10 data available with respect to adherence or asthma knowledge. A total of 57 participants, 29 (85%) and 28 (82%) in the treatment and attention control groups respectively, completed the 5 week follow-up visit. A total of 58 participants, 29 (85%) in each study arm, completed the 10 week follow up visit.

Baseline Characteristics

Baseline characteristics of the 68 randomized participants are presented in Table I. There were no differences between arms on any baseline characteristics except listening to music ≥ 1 hour/day where the control group listened more (97.1%) than the treated (76.5%) (P = 0.027). The sample is remarkable for a high rate of uncontrolled asthma (80.9%) and poor adherence to ICS (26.8%), despite all being prescribed ICS by their physician. There is also a high rate of participation in the Patient Centered Medical Home (75% of all participants) within this study cohort.

Primary Outcomes

The mixed effects modeling indicated no significant effects of the clustering within the active intervention arm; thus, cluster adjusted statistical analysis methods were not used. Adherence to ICS and Asthma Knowledge at 5 weeks and 10 weeks are presented in Table II. Study participants in both arms did not demonstrate clinically or statistically significant differences in objectively measured adherence at weeks 5 and 10. Adherence in both groups was well below the clinically significant target of ≥70% throughout the study [9,40] With respect to the missing data analysis, the analysis under the 'best case' scenario produced similar results, indicating that the inability to achieve significance was not due to missing data. Additionally, adherence in both groups declined over time during study follow up. The multilevel modeling that allowed for group comparisons while adjusting for meaningful covariates produced similar results of no significant difference between groups in adherence at weeks 5 or 10.

General asthma knowledge remained largely unchanged between baseline and weeks 5 and 10 of active follow up treatment, both within and between the treatment and attention control groups. Compared to baseline, at 10 weeks the treatment group percent items correct improved by 2.56% and the attention control group improved by 0.0% (P = 0.407 for the between group comparison).

Secondary Outcomes

Both active intervention (treatment) and attention control group participants' self-reported adherence was significantly (P < 0.0001) higher than their objectively measured adherence at weeks 5 and 10 of the active treatment period (See Table III). For the treatment group, at week 5, the median objectively measured adherence was 16.1% and the median self-reported adherence was 50%. For the attention control group, at week 5, the median objectively measured adherence was 16.1% and the median self-reported adherence was 63.4%. For the treatment group, at week 10, the median objectively measured adherence was 6.3% and the median self-reported adherence was 50.0%. For the attention control group, at week 10, the median objectively measured adherence was 14.3% and the median self-reported adherence was 61.6%.

Discussion

The active intervention under investigation combined weekly face-to-face coping peer support and coping peer asthma messages delivered between favorite music tracks on an mp3 player during the course of participants' daily lives. Neither this intervention nor an attention control consisting of doctor asthma messages delivered via mp3 player

demonstrated improvement in objectively measured adherence to ICS or asthma knowledge in our study population of low-income minority adolescents with persistent asthma. Adherence decreased and asthma knowledge did not change throughout study follow up in both groups.

There are several possible explanations for this lack of demonstrated efficacy. The original recruitment goal for this study was 90 participants, with 45 in each group, to achieve 80% power to detect at least a 25% difference in adherence rates between the two study groups while allowing for attrition and intraclass correlation within the treatment group. Recruitment was to be accomplished via school-based health centers, a strategy that proved to be unproductive. After eventually modifying the recruitment strategy to focus on use of the electronic medical record and Patient Centered Medical Home Project at Rush University Medical Center, remaining time and resources allowed for the enrollment of only 68 participants. The investigators note, however, that the study's lower than expected attrition rate and intraclass correlation results in this sample size still meeting the 80% power criterion.

Although the clinically significant target adherence goal of ≥ 70% would be ideal, [9] the investigators consider it to be unrealistic for this minority adolescent population. The study targeted minority adolescents with low adherence (≤ 48%) because the investigators thought that the children with the most need could derive the greatest benefit from this intervention. A cutpoint of ≤ 48% adherence was chosen as: 1) observational only studies monitoring adherence to ICS in diverse samples of adolescents publish rates between 40–50%;[18–19, 30–31] 2) the typical dosing schedule for ICS delivered via metered dose inhaler is two puffs twice daily (for a total of 56 puffs over a 2-week period); and 3) the investigators sought to set the cutpoint just under 50% (which amounts to 26 out of 56 puffs per 2 weeks, or ≤ 48%).

While no validated instrument was used to measure asthma control, asthma control assessment followed the NHLBI EPR3 asthma guidelines and addressed both impairment and risk domains.[29] Asthma exacerbation data was collected at baseline, 5 weeks, and 10 weeks, but impairment data were only collected at baseline. The investigators plan to measure outcomes during the active treatment phase, and use validated instruments to assess asthma control, in future studies.

A larger "dose" of the intervention may be needed. Adolescents may need two to three, rather than one, face-to-face coping peer support sessions per week to demonstrate improvement in adherence to ICSs. Within our study, much of the coping peer support sessions were devoted to providing group support to participants coping with stressful concerns for individual and familial health and well-being (e.g. grief for the recent loss of a friend or family member due to asthma or neighborhood violence). It was difficult to focus participants on discussions of barriers to adherence and strategies to overcome them given other compelling distractions. Asthma exacerbations are a systems problem; this study targeted only one piece of that system.

In addition, technological limitations did not allow effective tracking of their mp3 use. In particular, it was not possible to track which selections (e.g. songs, coping peer asthma messages, or doctor messages) were skipped, played ≤ 12 seconds in total duration, or listened to entirely. Thus, we do not know to what extent the active intervention was actually delivered.

The investigators' conceptual model, based on social cognitive theory, led to an intervention aimed at increasing social support for and self-efficacy toward medication taking behavior. This model may need to be re-evaluated. If low-income minority adolescents with asthma

have urgent competing needs, or are experiencing invulnerability[47] and denial[48] characteristic of this period of development, it may be ineffectual to attempt to increase social support and self- efficacy to promote a behavior that they are not at all interested in fostering.[21,49]

Participants were not provided with feedback on medication taking behavior. Study participants were kept blind to their electronically measured adherence to ICS throughout the 10-week active treatment period. In three studies successfully demonstrating improved adherence to ICS, participants were provided feedback and made accountable for their medication taking behavior.[50–52] Studies objectively measuring adherence to ICS generally show a decline in adherence over time.[50–51] Without the provision of feedback, participants' may have been unaware that their adherence was poor.

An important finding from this research is the large discrepancy between objectively measured and self-reported adherence. This study confirms findings from other pediatric studies, that patient self-report exceeds objectively measured adherence to ICS[10,53] In a study by Milgrom and colleagues, median electronic metered-dose inhaler monitor use was 58.4%, and median diary reported use was 95.4%.[10] The Childhood Asthma Management Program ancillary clinical trial measured adherence in 140 children randomized to receive ICS or placebo using both self-report (daily diary cards) and objectively measured adherence (number of doses remaining in study inhalers). Self-reported adherence generally surpassed objectively measured adherence (93.6% vs. 60.8%, $P < 0.0001$).[53] National asthma guidelines recommend physician assessment of patient adherence before stepping up therapy in patients not adequately controlled on their current controller medication regimen.[29] While health care providers often believe they are able to ascertain their patients' level of medication adherence, discordance between patient reports and objectively measured adherence should raise concerns.

The investigators have learned important lessons from this study in planning for future behavioral interventions aimed at increasing adherence to ICS in low income minority adolescents with persistent asthma. First, technology is attractive to inner-city teens and could potentially be a powerful way to intervene. Second, more immediate positive feedback could increase the potency of the messages. Collaborating with computer scientists, electrical engineers, and media arts experts to develop a mobile phone technology platform with mobile applications, ICS medication sensors, advanced analytics and feedback, would allow for continuous real time monitoring of asthma medication taking behavior and instant feedback. However, a randomized controlled trial of adolescents and adults with poorly controlled asthma did not demonstrate benefits of mobile phone supported self-monitoring and immediate feedback for asthma.[54] Perhaps immediate positive feedback combined with back-up reinforcers would be more effective for changing medication taking behavior in this target population.[55]

Despite receiving asthma care at a hospital highly ranked for primary care, participation in a level 3 Patient-Centered Medical Home, and all having been prescribed the gold standard treatment for persistent asthma, 81% of our population had uncontrolled asthma, poor adherence to ICS, and a high rate of emergency room visits (51%). Poor adherence declined further throughout the study. Optimal medical care, coping peer support, and technology assisted intervention delivery were not sufficient to change behavior in this population.

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Abbreviations

ICS	Inhaled corticosteroids
ATG	Attention control group
mp3	Music file (MPEG Layer 3)

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Highlights

What is already known about this topic?

Lack of adherence to inhaled corticosteroids is a significant risk factor for poor asthma outcomes among low-income African American and Hispanic adolescents with persistent asthma.

What does this article add to our knowledge?

Face-to-face coping peer support and mp3-delivered peer asthma messages do not appear to influence adherence to inhaled corticosteroids among inner-city minority adolescents with persistent asthma.

How does this study impact current management guidelines?

Asthma guidelines recommend monitoring patient adherence to his/her pharmacotherapeutic regimen at each visit. Reliance on self-report of adherence to inhaled corticosteroid medications among urban minority adolescents may give clinicians inadequate information to adjust their treatment regimens.

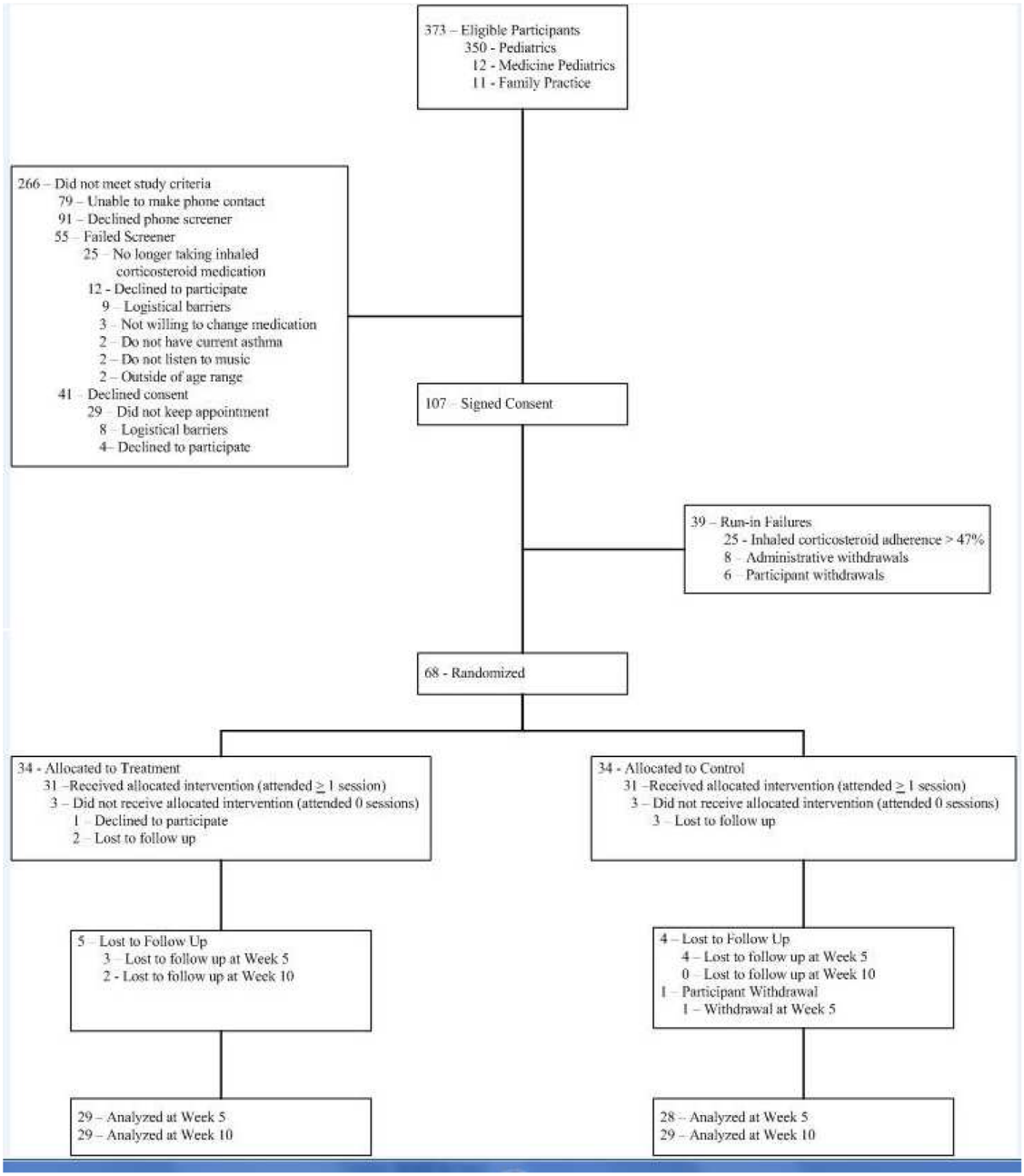

Figure 1. CONSORT Diagram

The CONSORT flow diagram illustrates the flow of participants from eligibility to completion of treatment.

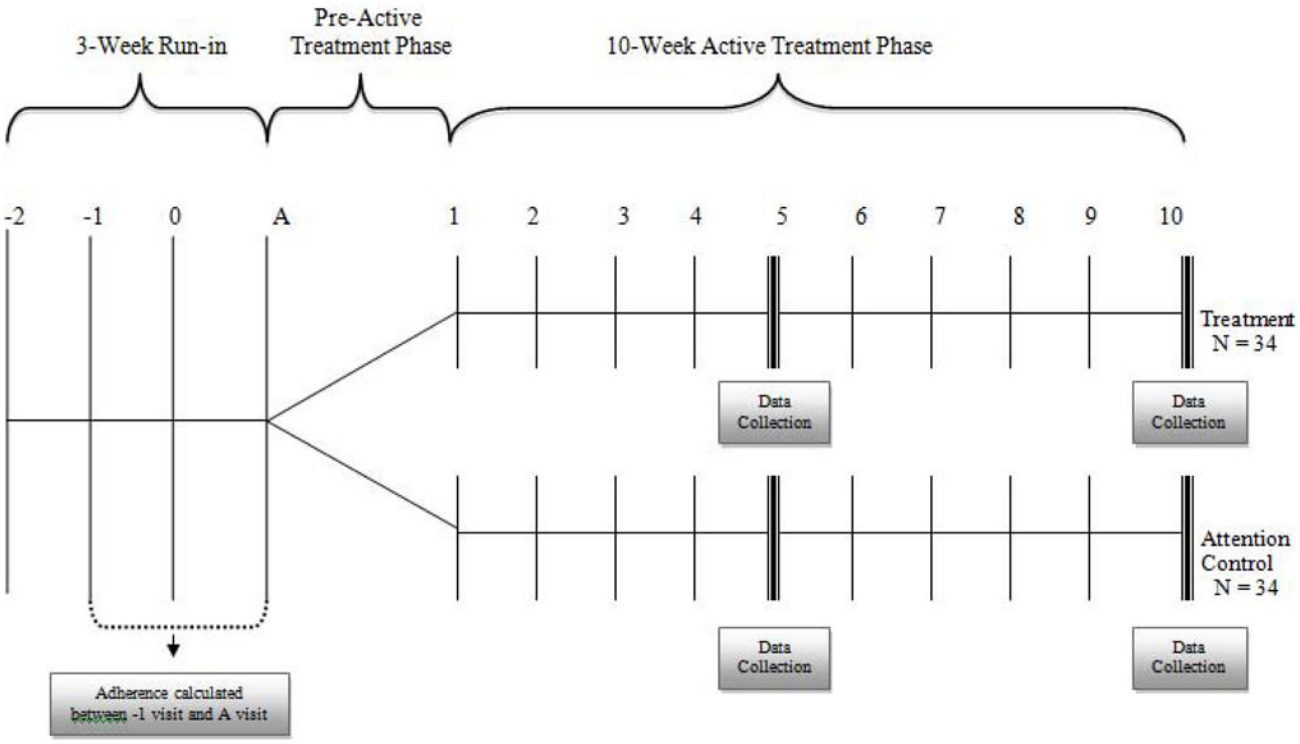

Figure 2. Study Timeline

The study timeline illustrates the run-in, pre-active treatment, and active treatment phases. Data collection occurred at weeks 5 and 10 of the active treatment phase.

Table I

Baseline Characteristics of 68 Randomized Participants

	Total (n=68)	Treatment (n=34)	Control (n=34)	*P* value
Age, Mean (Min, Max)	13.4 (11, 16)	13.3 (11, 16)	13.6 (11, 16)	0.530
Gender, n (%)				
Male	32 (47.1)	17 (50)	16 (47.1)	0.808
Female	36 (52.9)	17 (50)	18 (52.9)	
Ethnicity: Hispanic/Latino, n (%)	9 (13.3)	7 (20.6)	2 (5.9)	0.149
Race, n (%)				
Black/African American	58 (85.2)	26 (83.9)	32 (94.1)	0.083
Mixed African American*	1 (1.5)	1 (3.2)	0 (0)	
Other	9 (13.3)	7 (20.6)	2 (5.9)	
Child insurance status, n (%)				
Public	54 (79.4)	28 (82.4)	26 (76.5)	0.765
Private	14 (20.6)	6 (17.6)	8 (23.5)	
Receive free or reduced school lunch, 3 n (%)	53 (80.3)	27 (81.8)	26 (78.8)	0.757
Patient Centered Medical Home Participant, n (%)	51 (75.0)	24 (70.6)	27 (79.4)	0.576
≥ 1 hour daily music listening, n (%)	59 (86.8)	26 (76.5)	33 (97.1)	0.027
Smoking behavior reported by adolescent, n (%)				
Current smoker	2 (2.9)	2 (5.9)	0 (0)	0.492
Exposed to second hand smoke at home	5 (7.4)	3 (8.8)	2 (5.9)	>0.999
Asthma controller medications, n (%)				
ICS monotherapy	53 (77.9)	25 (73.5)	28 (82.4)	0.559
ICS and long-acting bronchodilator combination therapy‡	15 (22.1)	9 (26.5)	6 (17.7)	
Uncontrolled Asthma, n (%)	55 (80.9)	29 (85.3)	26 (76.5)	0.539
Asthma exacerbation in the last 12 months				
≥ 2 Requiring oral systemic corticosteroids, n (%)	19 (27.9)	9 (26.5)	10 (29.4)	0.787
≥ 1 Requiring emergency room visit or hospitalization, n (%)	34 (50.8)	19 (57.6)	15 (44.1)	0.332
Children's Depression Inventory 2, n (%)				
Very elevated	3 (4.4)	2 (5.9)	1 (2.9)	0.323
Elevated	5 (7.4)	4 (11.8)	1 (2.9)	
High average	4 (5.9)	3 (8.8)	1 (2.9)	
Average or lower	56 (82.4)	25 (73.5)	31 (91.2)	
ICS Knowledge Questionnaire, median (Q1, Q3)	24.0 (22.0, 26.5)	25.0 (22.0, 28.0)	24.0 (21.0, 26.0)	0.374
ICS Self-Efficacy Questionnaire, median (Q1, Q3)	51.0 (44.5, 59.0)	50.5 (44.0, 58.0)	52.0 (45.0, 59.0)	0.370
Social Support Questionnaire, median (Q1, Q3)	33.0 (30.0, 35.0)	33.0 (30.0, 35.0)	33.0 (30.0, 35.0)	0.792
Asthma Social Support Questionnaire median (Q1, Q3)	27.0 (24.0, 29.0)	26.5 (22.0, 29.0)	27.0 (24.0, 31.0)	0.512

*Mixed African American: Self-identified as a combination of African American and another race.

†Criteria for Free and Reduced School Lunch in Chicago Public Schools July 1, 2011 – June 30, 2012.[56]

‡Inhaled corticosteroid and long-acting bronchodilator: Two participants who were taking inhaled corticosteroid and long acting bronchodilator combination therapy were also taking inhaled corticosteroid monotherapy.

Table II

Primary Outcomes

This table depicts objectively measured adherence and asthma knowledge at baseline, week 5 and week 10 of the active treatment phase. There was 8% missing data at weeks 5 and 10.

	Adherence to ICS % Adherence					ZAP Asthma Knowledge Instrument % Items Correct				
	Treatment		Control			Treatment		Control		
Evaluation	N	Median (Q1, Q3)	N	Median (Q1, Q3)	*P* value	N	Median (Q1, Q3)	N	Median (Q1, Q3)	*P* value
Baseline	34	27.4 (14.3, 35.0)	34	25.9 (14.0, 37.5)	0.670	34	67.9 (59.0, 76.9)	34	70.5 (61.5, 76.9)	0.825
5 Weeks	24	18.8 (5.4, 24.2)	22	16.1 (7.14, 19.6)	0.534	29	74.4 (59.0, 84.6)	28	73.1 (56.4, 79.4)	0.655
10 Weeks	24	7.1 (0.9, 21.4)	25	14.3 (5.4, 21.4)	0.929	29	71.8 (59.0, 82.1)	29	69.2 (61.5, 74.4)	0.487

Table III

Objectively Measured and Self-Reported Adherence to Inhaled Corticosteroids

This table shows differences in objectively measured versus self-reported adherence at week 5 and week 10 of the active treatment phase for treatment and attention control groups. Only participants whose self-reported data was available for the same two weeks as their objectively measured data were included.

	Week 5					Week 10				
	Objectively Measured		Self-Reported			Objectively Measured		Self-Reported		
Group	N	Median (Q1, Q3)	N	Median (Q1, Q3)	*P* value	N	Median (Q1, Q3)	N	Median (Q1, Q3)	*P* value
Treatment	19	16.1 (3.6, 23.2)	23	50.0 (30.4, 82.1)	0.0007	18	6.3 (1.8, 14.3)	21	50.0 (35.7, 78.6)	<.0001
Control	17	16.1 (14.3, 19.6)	20	63.4 (49.1, 79.5)	<.0001	21	14.3 (5.4, 21.4)	22	61.6 (48.2, 82.1)	<.0001
Total	36	16.1 (7.1, 22.3)	43	57.1 (41.1, 82.1)	<.0001	39	7.1 (1.8, 21.4)	43	57.1 (39.3, 78.6)	<.0001