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To cite this article: Jill S. Halterman , Kristin A. Riekert , Maria Fagnano , Paul Tremblay , Susan Blaakman , Reynaldo Tajon , Honguye Wang & Belinda Borrelli (2020): Effect of the School-Based Asthma Care for Teens (SB-ACT) Program on Asthma Morbidity: A 3-Arm Randomized Controlled Trial, Journal of Asthma, DOI: [10.1080/02770903.2020.1856869](https://doi.org/10.1080/02770903.2020.1856869)

To link to this article: <https://doi.org/10.1080/02770903.2020.1856869>



Accepted author version posted online: 12 Dec 2020.



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Effect of the School-Based Asthma Care for Teens (SB-ACT) Program on Asthma Morbidity: A 3-Arm Randomized Controlled Trial

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Abstract

Urban adolescents with asthma often have inadequate preventive care. We tested the effectiveness of the School-Based Asthma Care for Teens (SB-ACT) program on asthma morbidity and preventive medication adherence. **Methods:** *Subjects/Setting-* 12-16yr olds with persistent asthma in Rochester, NY schools. *Design-* 3-group randomized trial (2014-2019). *SB-ACT Intervention-* Two core components: 1) Directly observed therapy (DOT) of preventive asthma medications, provided in school for at least 6-8 weeks for the teen to learn proper technique and experience the benefits of daily preventive therapy; 2) 4-6 weeks later, 3 sessions of motivational interviewing (MI) to discuss potential benefits from DOT and enhance motivation to take medication independently. We included 2 comparison groups: 1) DOT-only for 6-8wks, and 2) asthma education (AE) attention control. Masked follow-up assessments were conducted at 3, 5, and 7mos. *Outcomes-* Mean number of symptom-free days (SFDs)/2 weeks and medication adherence. *Analyses-* Modified intention-to-treat repeated measures analysis. **Results:** We enrolled 430 teens (56% Black, 32% Hispanic, 85% Medicaid). There were no group differences at baseline. We found no difference in SFDs at any follow-up timepoint. More teens in the SB-ACT and DOT-only reported having a preventive asthma medication at each follow-up ($p < .001$), and almost daily adherence at 3 and 5-months ($p < .001$, $p = .003$) compared to AE. By 7 months there were no significant differences between groups in adherence ($p = .49$). **Conclusion:** SB-ACT improved preventive medication availability and short-term adherence but did not impact asthma symptoms. Further work is needed to develop developmentally appropriate and effective interventions for this group.

Key Words: adherence, adolescents, motivational interviewing, symptoms, schools, urban, directly observed therapy, motivational interviewing

Introduction:

Low-income, minority adolescents have disproportionately high rates of morbidity and mortality from asthma compared to white adolescents.¹⁻³ In fact, death rates for 11-17 year olds with asthma are twice those of younger children, and Black children are six times more likely than white children to die from asthma.⁴ More than 1 in 10 children in Rochester, New York have asthma, making it the most common chronic physical disease in the community.

While inhaled anti-inflammatory medications are the most effective long-term therapy for patients with persistent asthma⁵ and are recommended by national guidelines,⁶ adherence to these guidelines is poor⁷⁻⁹ and adolescents have even poorer adherence than younger children or adults.^{10,11} Early adolescence is a developmental period marked by cognitive, social, and biological change and increased independence and responsibility. While parents often transition much of the responsibility for chronic illness management to the child by age 15 years,¹² this transition is often marked by decreased medication adherence.¹⁰ Not surprisingly, poor adherence is associated with worse disease-related outcomes.

Over the past 15 years, we have had an established partnership with the Rochester City School District to implement novel programs for urban, high risk children with asthma. Our studies in elementary schools (including children ages 3-10 years) have shown that directly observed administration of preventive asthma medications in school reduces morbidity, decreases absenteeism, and results in fewer exacerbations.^{13,14} By delivering daily preventive medications through schools, adherence is assured on the days the child attends school. There are ample data to support the feasibility of schools providing DOT for asthma.¹³⁻¹⁸

We aimed to adapt our successful school-based asthma care model in a manner that was developmentally appropriate for urban teens who are assuming increasing independence for asthma self-management. Based on a prior pilot study,¹⁵ the **School Based Asthma Care for Teens (SB-ACT)** program included two core components: 1) *directly observed therapy (DOT) of preventive medications at school to allow the teen to experience the potential benefits from adhering to guideline-based asthma treatment*, and 2) *a developmentally appropriate motivational interviewing (MI) counseling intervention that included asthma education and support for the teen to transition to independent long-term medication adherence*. MI was chosen because it can build intrinsic motivation and autonomy, and can promote adherence.¹⁹⁻²¹ Our primary hypothesis was that teens receiving the SB-ACT intervention would have more symptom-free days compared to teens in an asthma education (AE) comparison group. We also hypothesized that teens in SB-ACT would have improved medication adherence compared to AE, and would have sustained improvement in adherence compared to a third group receiving only DOT.

Materials and Methods:

Settings and participants

We recruited 430 teens from 69 secondary schools in urban Rochester, NY over 5 consecutive school years. Teen/caregiver dyads were eligible if the teen was between the ages of 12-16 years and had physician-diagnosed asthma with persistent severity or poor control according to National Heart, Lung, and Blood Institute (NHLBI) asthma guideline criteria.⁶ Exclusion criteria included an inability to speak and understand English, a lack of access to a working phone for follow-up surveys, the presence of significant medical conditions (cystic fibrosis, congenital heart disease, chronic lung disease, a developmental or intellectual disability), or living situations in which consent could not be obtained from a legal guardian.

Procedures

Study team members used school 'medical alert' forms to identify teens with asthma and called caregivers for eligibility screening. Screening procedures included a telephone survey with the caregivers, verbal consent to contact the primary care provider, and scheduling a baseline home visit.

Home visits were used to explain the study, elicit informed consent from the parent and assent from the teen, and obtain baseline measurements. Baseline evaluations included confirmation of inclusion/exclusion criteria, assessment of baseline severity, collection of demographic and health

history variables, measurement of exhaled nitric oxide (FeNO), and salivary cotinine. We also provided a diary to the teen and caregiver for symptom tracking.

Following the baseline assessment, each teen was randomly assigned to one of 3 groups: 1) the SB-ACT group (DOT plus MI counseling); 2) DOT only; or 3) an asthma education (AE) comparison group (see below). Randomization was stratified by school and use of a preventive medication at baseline (Y/N). Because enrollment occurred over a period of several months at the start of each school year, a permuted block design was used to assure approximately equal allocation of teens in each group over time. The randomization scheme was independently developed by a programmer in the Biostatistics Center. After baseline, the study coordinator assigned the subject's ID number and treatment group. Primary Care Providers (PCPs) were notified about the teen's asthma status and group assignment.

Teens and caregivers were not masked to group allocation; they were told they were randomly assigned to different methods of approaching asthma management. The University of Rochester institutional review board approved the study protocol, written informed consent was obtained from all caregivers, and assent was obtained from all teens.

SB-ACT Intervention:

Teens assigned to the SB-ACT group received a trial of DOT of preventive asthma medication at school combined with up to 3 school-based MI counseling sessions. At the start of the school year, we contacted the PCPs by facsimile or email to ensure that each teen had an inhaler of preventive medication. Prescriptions authorized by the PCP were sent to pharmacies for parent pick-up or home delivery with instructions indicating one canister of preventive medication to be dispensed for the home and a second canister for the teen's school. The school nurse and teen met at the beginning of the program to develop an individualized plan for the timing of DOT in the school, to avoid disruption of classes and allow the teen choice in this process.

For the first 6-8 weeks after enrollment the teen visited the school nurse once a day to receive a dose of preventive asthma medication. The purpose of this intervention component was for teens to establish a relationship with the school nurse, learn proper medication technique, and experience potential benefits of consistent preventive therapy. If more frequent medication dosing was needed, the teen was responsible for taking additional doses at home. The teen also used his/her home inhaler for doses on weekend days and other days in which he/she did not attend school. School nurses instructed teens to rinse their mouth with water after each medication dose, and a medication dispensing log was used for tracking purposes. Guideline-based medication adjustments ('step-ups') were recommended to the PCP after the first follow-up survey if persistent symptoms continued.

Since the goal of SB-ACT was to ultimately support the teen's transition to independent, sustained use of preventive medications, MI counseling, the second component of the intervention, started 4-6 weeks after the commencement of DOT (see below). A brief survey was administered by the school nurse following the first 6 weeks of DOT, to help determine collaboratively with teens if they were ready to transition to independent medication use.^{15,20} The teen reported their motivation to use preventive medications independently,¹⁵ their confidence in adhering to the treatment plan, and whether they had obtained needed refill medications for ongoing use. While the goal of the counseling sessions was to help the teen move towards autonomy with medications, some teens requested to continue DOT for a longer time period. We deliberately provided this choice to support teens' autonomy in decision-making, which is appropriate for this developmental stage.

The **Motivational Interviewing** component was developed based on prior studies²¹⁻²³ and consisted of an evidence-based self-management program to help the teen transition to independence with preventive medication use. A trained staff member (nurse or psychologist) conducted up to

three in-person MI sessions with the teen at school to enhance the teen's motivation to adhere to their guideline-based asthma treatment plan (developed during the DOT phase). All sessions took place in a quiet location at a mutually agreed upon time that limited interference with classes and activities. The three sessions consisted of an initial 30-40 minute counseling session (4-6 weeks after the start of DOT), and two 20-30 minute follow-up sessions 2 and 6 weeks later.

a) Initial MI visit

The focus of the first visit was to address ambivalence about and build motivation for asthma medication adherence. Within the context of MI counseling delivery, asthma education was provided in a non-prescriptive and collaborative manner using the MI technique of "elicit-provide-elicit".²¹ Topics included lung physiology and asthma basics, symptoms and warning signs, medications, and triggers. The MI counselor elicited the teen's knowledge about the importance of proper medication adherence and offered recommendations in a non-confrontational manner that supported autonomous decision-making. Teen-endorsed goal setting and problem-solving strategies were utilized. The counselor used open-ended questions and reflections to explore the teen's ambivalence towards taking medications (e.g., pros and cons). The teen was encouraged to reflect on his/her experience with DOT in school, and the benefits gained from taking medicine consistently. The counselor inquired about things the teen felt was important (values, goals, interests), and where appropriate addressed discrepancies between the teen's current behaviors (e.g., not taking medicine) and goals (e.g., being on basketball team).

Follow-up sessions occurred approximately 2 and 6 weeks following the initial session. These sessions focused on building motivation and confidence for adherence in general and for independent adherence, and included assessing the teen's perspectives and choices regarding asthma management, offering continued support for autonomous decision making regarding medication adherence, and identifying any benefits associated with ongoing preventive asthma care. The teens were asked about any anticipated obstacles (e.g., getting medication refills, making a follow-up visit with the provider). If the teen was not using medications, additional motivational enhancement was provided.

The MI sessions were targeted towards the adolescent, however the counselor also called the caregiver following each session to reinforce the strategies discussed with the teen, as well as potential barriers to adherence such as obtaining medications from the pharmacy. Using MI-compatible strategies, the counselor assessed asthma control from the caregiver perspective, and the caregiver's role in supporting or hindering the teen's asthma self-management.

Dr. Borrelli trained 4 staff members over 2 days in techniques of MI and on the study and the manualized intervention. All counselors had prior counseling experience with teens. Achievement of training goals was assessed using the MITI (Motivational Interviewing Treatment Integrity Coding 3.1.1). Prior to implementing the intervention with study participants, counselors had to demonstrate proficiency in MI and in the study protocol with 3 'mock' participants and 3 pilot participants. For ongoing supervision, Dr. Borrelli listened to 20% of the audiotaped counseling sessions and provided feedback during weekly meetings with counselors on adherence to the protocol and motivational interviewing skills.^{24,25}

DOT-Only Group: As with the teens in the SB-ACT group, we contacted the PCP of those in the DOT-only group at the start of the school year to ensure each teen had preventive medications at home and school. Teens in the DOT-only group received 6-8 weeks of directly observed administration of preventive asthma medications from the school nurse (with medication adjustments as needed), but did not receive MI counseling. The school nurse used the same survey as for the SB-ACT group to help determine with the teen if they were ready to transition to independent

medication use. As in the SB-ACT group, teens could ask the nurse to continue DOT beyond the initial trial period.

Asthma Education (AE) Comparison Condition: We notified PCPs that teens in the AE group had persistent asthma symptoms that warranted use of effective guideline-based preventive medications. We also provided an in-school asthma education program, based on an established curriculum designed for this age group (Kickin' Asthma).²⁶ The program included similar content and matched the time and attention of the MI counseling portion of SB-ACT. Sessions were delivered at school by trained staff members (different from the MI counselors) using a developed protocol, in a similar structure and time-schedule to the MI intervention (each teen received three 1-on-1 educational sessions at school). As in SB-ACT, caregivers were called after each session to reinforce key points and answer questions. Teens in the AE group did not receive DOT in school.

Outcomes Assessment and Measures:

Outcomes were assessed 3-, 5-, and 7-months after baseline by research assistants masked to treatment allocation. We used structured telephone interviews separately with the teen and caregiver for follow-ups. We also collected FeNO and cotinine measurements at home visits at specific time-points (see below). Teens and caregivers each received a \$20 gift card following baseline, \$10 after each telephone follow-up, and \$50 at the 7-month (end of school-year) home visit assessment.

The primary outcome measure was the mean number of symptom-free days (SFDs) at the 3, 5, and 7 month follow-ups. This outcome measure is consistent with national guidelines⁶ and was used in our prior studies.^{13,14} At each follow-up, caregivers and teens reported the number of days the teen experienced no symptoms of asthma (defined as 24 hours with no coughing, wheezing, shortness of breath, and no need for rescue medicine) in the past 2 weeks. We referred them to symptom diaries to assist with recollection. Secondary measures included ED visits, hospitalizations, and urgent care visits for asthma. We also measured the number of nights with asthma symptoms, days needing rescue medications, and days with limited activity.

To measure adherence teens were asked to answer the following statement: "In the past 2 weeks, I took my controller medicine: Not at all, A few days (1-3 days), Several days (4-7 days), Most days (8-11 days), Almost every single day (12-13 days), and Every single day (14 days)." We dichotomized responses to 'Almost every single day and Every single day' versus all other responses. We also used a 10-point rating scale to assess teen's sense of confidence, importance, and motivation to take preventive medications consistently.²⁰ We measured teen and caregiver quality of life using the Pediatric Asthma Quality-of-Life Questionnaire²⁷ and the Pediatric Asthma Caregiver's Quality of Life Questionnaire.²⁸ School absenteeism was assessed by teen and caregiver report.

We obtained FeNO measurements at baseline and the 7-month assessment. We used a NIOX AERO Airway Inflammation Monitor; a portable device that measures FeNO using the electrochemistry method (range 5-300ppb). FeNO is elevated with airway inflammation and decreases with inhaled steroid treatment.²⁹

We collected caregiver-reported measures of demographic, personal, and community factors known to be associated with asthma morbidity in high risk children or to influence response to interventions. These included demographics (age,^{9,30} race/ethnicity,^{7,31,32} sex, insurance,^{7,9,33} caregiver's education⁹), and caregiver and teen-reported depressed mood,^{34,35} using the Center for Epidemiologic Studies-Depression Scale³⁶ and the Center for Epidemiological Studies Depression Scale for Children.^{37,38} Since smoke exposure is associated with asthma morbidity,^{39,40} we also collected teens' salivary cotinine levels.^{41,42}

Analysis:

This study was designed to have adequate power to test the primary hypothesis that teens receiving SB-ACT will have more symptom-free days at 3, 5, and 7-months compared to AE. Based on our prior data, we estimated a pooled standard deviation (SD) of SFD to be 2.6 and within-subject correlation (ICC) of 0.3-0.4. We calculated power for the intervention effect on SFD while justifying repeated assessments for outcomes.^{43,44} A sample size of 123 subjects per group would obtain 94-96% power to detect a difference of 0.9 in SFD at a two-sided 5% significance level. We anticipated <15% attrition, and therefore planned to enroll 430 teens.

Analyses were carried out under the modified intention-to-treat principle, including all subjects with post-intervention data. We compared demographic characteristics, baseline symptoms, healthcare utilization, medications and adherence between the three study groups. Categorical variables were compared using Chi-Square or Fisher's exact test and continuous variables were compared using Kruskal-Wallis one-way analysis of variance test. Repeated measure analyses testing the overall treatment effect were performed by fitting the Generalized Estimating Equation (GEE) with SFD at the three follow-up time points (3, 5, 7 months) as the dependent variable and treatment as independent variable. Normal error and identity link was specified and standard error was calculated using Sandwich estimator. Baseline SFDs, poverty level, and the presence of smokers in the home were controlled in the regression model. We also tested the interaction effect between treatment and time. Stratified analyses by preventive medication and baseline symptom severity were carried out to test whether the treatment effects in each stratum were different. The analyses for other continuous outcome variables were performed in a similar manner. Binary outcome variables such as hospitalization/ED visits, medications and adherence were analyzed by fitting Generalized Estimating Equation models with a logit link function and a Binomial error specified. We also examined all missing data and performed a sensitivity analysis based on multiple imputation and weighted GEE to assess whether the treatment effect was affected, implementing the inverse probability-weighted method to account for dropouts under MAR assumption.^{45,46}

Results:

We screened 3,312 teens and 545 were eligible (Figure 1). We enrolled 430 teens (149 SB-ACT, 142 DOT-only, 139 AE) from 69 schools for a participation rate of 79%.

Intervention Implementation:

For the teens in the SB-ACT group, 141 of the 149 subjects initiated directly observed therapy (DOT) of preventive asthma medications in school, and 81% continued DOT for at least 6 weeks. Fifty-seven teens were prescribed a new preventive medication, 44 continued a previous prescription of preventive medication as DOT at school, 40 restarted a previously prescribed preventive medication through DOT (that they hadn't been taking at home). In the DOT-only group, 132/142 initiated DOT; 58 teens were prescribed a new preventive medication, 39 continued a previous prescription as DOT at school, and 35 restarted a previously prescribed preventive medication as DOT. Teens in the SB-ACT group and DOT-only groups received preventive medications at school on 72% of all possible school days and 89% of the days they attended school, with no difference between groups. In both the SB-ACT and DOT-only groups, half (51%) chose to continue DOT until the end of the school year.

Motivational Interviewing (MI) counseling sessions completion rates for teens in SB-ACT were as follows: Session 1 – 89%; Session 2 – 86%; Session 3 – 72%. Completion rates for the AE counseling sessions were as follows: Session 1 – 95%; Session 2 – 88%; Session 3 – 89%.

Outcomes:

Data were available for more than 80% of participants at each follow-up assessment; almost all (98%) had at least 1 follow-up for the primary outcome. Twelve teen/caregiver dyads withdrew from the study after randomization (4 from SB-ACT, 7 from DOT-only, 1 from AE).

Table 1 shows the demographic characteristics of teens in the study. Among the teens enrolled, 56% were male, 56% Black, and 32% were Hispanic. The mean age was 13.4 years. The majority (85%) had public health insurance, 28% had depressive symptoms, and more than half lived in a home with one or more smokers. There were no differences in any of the demographic characteristics or exposure to smoke among teens in the three treatment groups.

At the time of the baseline assessment, teens had an average of 7.7 symptom-free days over two weeks (sd=4.8), and >25% reported an emergency department visit, urgent care visit, or hospitalization in the prior year. Approximately 2/3 (69%) reported having a preventive medication prescription. There were no differences between groups at baseline in asthma symptoms, FeNO levels, healthcare utilization, or preventive medication prescription.

Table 2 shows the main study outcomes by group. For the primary outcome of mean symptom-free days averaged over 3, 5, and 7 months, we found no differences between teens assigned to SB-ACT (11.5, sd= 2.9) compared to DOT (11.4, sd=2.9) or AE (11.6, sd=2.8) based on the GEE analyses. The analysis stratified by preventive medication prescription and symptom severity at baseline showed similar results (data not shown), as did the weighted GEE analysis to account for missing data. There were no differences between groups in days absent from school, emergency visits or hospitalizations, or quality of life. Change in FeNO was not different between groups (SB-ACT -2.1 ppb, DOT-only -6.3 ppb, AE 1.7 ppb, $p=.201$).

Table 3 shows teen ratings of confidence, motivation, and sense of importance for using preventive medications over the follow-up time periods. There was a significant difference in motivation and importance scores among the three groups, with teens in SB-ACT having an overall higher motivation scores (overall $p<.001$) as well as a higher sense of importance (overall $p=.042$) to adhere to daily medications compared to AE. The confidence scores were higher for teens in SB-ACT vs. DOT-only at 5-months with no significant overall differences between groups across the follow-ups.

Figure 2a shows a longitudinal analysis of symptom-free days. Teens in all three groups improved significantly over time ($p<.001$), from a baseline average of 7.7 symptom-free days over two weeks to a peak of 12.0 at the time of the 7-month survey; there were no differences between groups for this outcome at any time point. Teens in all three groups also had improved days with symptoms and nights with symptoms over time (data not shown). Figures 2b and 2c show preventive medication prescription as well as ‘daily or almost daily’ adherence over time for the teens in the three groups. For teens in the SB-ACT and DOT-only groups, almost all teens reported a preventive medication prescription by the three-month survey, and this persisted over time. For teens in the AE group, preventive medication prescription did not change over time from the baseline value of 69% and was significantly lower than the SB-ACT and DOT-only groups at 3, 5, and 7 months ($p<.001$). Importantly, while adherence increased for the SB-ACT and DOT-only groups around the time that teens were receiving school-based DOT (from 22% and 29% at baseline to 69% and 71% at 3 months, and 70% and 63% at 5 months), the increase did not persist for any of the groups beyond the 5-month time period when almost ½ had chosen to discontinue DOT. By the 7-month assessment, adherence was close to baseline levels (30-40%) for all 3 groups.

Satisfaction with the program was high for all groups of teens and caregivers, with the majority stating that the program was helpful (98% teens, 98% caregivers), and that they would be happy to participate again in a similar study (84% teens, 94% caregivers). There were no significant adverse events for any of the teens.

Discussion:

The goal of this intervention was to reduce asthma morbidity by fostering sustained use of preventive medications by teens, using motivational interviewing (MI) as the vehicle to counsel teens through the transition from DOT to independence. Our prior studies have consistently shown that school-based therapy can improve outcomes for elementary age children with persistent asthma.^{13,14} For the adolescent group, we felt it was appropriate to support their transition to independence regarding taking their medication, and we therefore incorporated a counseling program into the intervention.¹⁵ MI was chosen because it can help build intrinsic motivation,^{47,48} and includes promotion of autonomy as one of its core components, which is critical for teens. We hypothesized that teens in the SB-ACT group would have sustained improvement in symptom-free days compared to the other two groups. However, we found no difference between groups in our primary outcome. There also were no differences in other asthma morbidity outcomes including emergency visits and hospitalizations, as well as quality of life. For both groups of teens receiving preventive medications at school (SB-ACT and DOT-only), we were able to successfully achieve high rates of reported preventive medication prescriptions that lasted throughout the duration of the study. However, adherence dropped off around the time that DOT at school was discontinued for many teens.

The MI intervention was designed to capitalize on the teens' experience with DOT through school, and the benefits they experienced from consistently taking their asthma medication. MI is a person-centered approach applied to health behavior change that helps individuals resolve their ambivalence about change and enhance their intrinsic motivation for change.⁴⁹ Teens who report high levels of motivation to follow the treatment plan also report better medication adherence.¹¹ Thus, enhancing motivation is a critical component of adherence promoting interventions. The lack of a difference in primary outcomes for this intervention may be related to insufficient intensity with a population of very high-risk teens. There were several factors that may have mitigated the impact of the treatment, including varying levels of teen engagement with school, and alternative living arrangements and school absences that interfered with the ability to provide consistent school-based DOT as well as focused counseling. In fact, while the SB-ACT intervention was associated with improved motivation and a greater sense of importance for using daily medications in the short term, we did not see sustained improvement in these constructs over time. It is possible that the substantial competing priorities for many of these teens interfered with their ability to reflect on their asthma control and how it might relate longer-term to their own asthma self-management behaviors.⁵⁰

We also note that teens' reported adherence to preventive medications continued to be high during the time of their receipt of directly observed therapy at school, but seem to drop once DOT was discontinued for many teens. It is possible that more intensive and prolonged counseling is necessary for this group to help them continue to self-manage over time. Further, since the DOT component was well received by the majority of teens (i.e.; 91% agreed that they were comfortable with the nurse giving them medications and 85% agreed that it was easy to go to the school health office to take their medication each day), it is also possible that maintaining DOT throughout the school year (and/or adding twice daily dosing) may be beneficial for teens while also recognizing that many in this age group are looking for increased independence.

Interestingly, all three groups of teens improved significantly over time. While it's not completely clear why this is the case, it is possible that the attention given to the teens either through school-based directly observed therapy and the connection with the school nurse or with asthma education that was delivered to the teens in the AE group, helped them better manage their asthma and led to improved outcomes. In addition, we and others have found both regression to the mean as well as improvement in symptom-free days over time directly related to participation in asthma studies (regardless of intervention status).^{51,52} Regardless of the reason, it is encouraging that many of these teens had improved by the end of the study, and the majority endorsed the value of participation in the study.

This study has several limitations. It was conducted in a single city among disadvantaged teens and may not be generalizable to other age groups or settings. Second, we utilized an intention-to-treat analysis and not all teens and caregivers participated fully in all intervention components. There were many circumstances among this high-risk group that created challenges to intervention implementation. Third, by design there was heterogeneity in the study groups and the intervention components that were received. Lastly, our main focus was on one core component of asthma care, medication use, and we did not provide specific resources to address other factors such as environmental triggers that can influence asthma outcomes.

In conclusion, we found that a school-based program combining DOT and motivational interviewing can be implemented in an urban school setting. While teens receiving DOT as part of the program were more likely to report using a preventive medication, we did not find differences in symptoms between groups. While we believe school-based programs have promise in improving the delivery of guideline-based care, further research is needed to identify the components of care that are most useful and developmentally appropriate for this population of adolescent patients.

Acknowledgments

We would like to thank all our study participants, including the teens and their caregivers, our partners in the city school district and the school health program, and the Preventive Care Program for Urban Teens with Asthma in Rochester, NY.

This work was funded by a grant from the National Heart, Lung, and Blood Institute of the National Institutes of Health (R18HL116244).

Declaration of Interest Statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

REFERENCES

1. Akinbami LJ, Moorman JE, Simon AE, Schoendorf KC. Trends in racial disparities for asthma outcomes among children 0 to 17 years, 2001-2010. *Journal of Allergy and Clinical Immunology*. 2014;134(3):547-553.
2. Milligan KL, Matsui E, Sharma H. Asthma in Urban Children: Epidemiology, Environmental Risk Factors, and the Public Health Domain. *Current allergy and asthma reports*. 2016;16(4):33.
3. Asthma Disparities in America: A Roadmap to Reducing Burden on Racial and Ethnic Minorities. *Asthma and Allergy Foundation of America (2020)* aafa.org/asthmadisparities, 2020.
4. Moorman JE, Zahran H, Truman BI, Molla MT. Current asthma prevalence - United States, 2006-2008. *MMWR Surveill Summ*. 2011;60 Suppl:84-86.
5. Wennergren G, Kristjansson S, Strannegard IL. Decrease in hospitalization for treatment of childhood asthma with increased use of antiinflammatory treatment, despite an increase in prevalence of asthma. *J Allergy Clin Immunol*. 1996;97(3):742-748.

6. National Asthma Education and Prevention Program (NAEPP). Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma-Summary Report 2007. *J Allergy Clin Immunol*. 2007;120(5 Suppl):S94-138.
7. Bauman LJ, Wright E, Leickly FE, et al. Relationship of adherence to pediatric asthma morbidity among inner-city children. *Pediatrics*. 2002;110(1 Pt 1):e6.
8. Diaz T, Sturm T, Matte T, et al. Medication use among children with asthma in East Harlem. *Pediatrics*. 2000;105(6):1188-1193.
9. Halterman JS, Aligne CA, Auinger P, McBride JT, Szilagyi PG. Inadequate therapy for asthma among children in the United States. *Pediatrics*. 2000;105(1 Pt 3):272-276.
10. McQuaid EL, Kopel SJ, Klein RB, Fritz GK. Medication adherence in pediatric asthma: reasoning, responsibility, and behavior. *J Pediatr Psychol*. 2003;28(5):323-333.
11. KyngAs HA, Kroll T, Duffy ME. Compliance in adolescents with chronic diseases: a review. *J Adolesc Health*. 2000;26(6):379-388.
12. Wade SL, Islam S, Holden G, Kruszon-Moran D, Mitchell H. Division of responsibility for asthma management tasks between caregivers and children in the inner city. *J Dev Behav Pediatr*. 1999;20(2):93-98.
13. Halterman JS, Fagnano M, Tajon RS, et al. Effect of the School-Based Telemedicine Enhanced Asthma Management (SB-TEAM) Program on Asthma Morbidity: A Randomized Clinical Trial. *JAMA pediatrics*. 2018;172(3):e174938.
14. Halterman JS, Szilagyi PG, Fisher SG, et al. Randomized controlled trial to improve care for urban children with asthma: results of the School-Based Asthma Therapy trial. *Arch Pediatr Adolesc Med*. 2011;165(3):262-268.
15. Halterman JS, Riekert K, Bayer A, et al. A pilot study to enhance preventive asthma care among urban adolescents with asthma. *J Asthma*. 2011;48(5):523-530.
16. Gerald L, McClure L, JM M, et al. Increasing adherence to inhaled steroid therapy among schoolchildren: Randomized, controlled trial of school-based supervised asthma therapy. *Pediatrics*. 2009;123:466-474.
17. Trivedi M, Patel J, Lessard D, et al. School nurse asthma program reduces healthcare utilization in children with persistent asthma. *J Asthma*. 2018;55(10):1131-1137.
18. Salazar G, Tarwala G, Reznik M. School-based supervised therapy programs to improve asthma outcomes: current perspectives. *J Asthma Allergy*. 2018;11:205-215.
19. Gesinde B, Harry S. The use of motivational interviewing in improving medication adherence for individuals with asthma: a systematic review. *Perspect Public Health*. 2018;138(6):329-335.
20. Riekert KA, Borrelli B, Bilderback A, Rand CS. The development of a motivational interviewing intervention to promote medication adherence among inner-city, African-American adolescents with asthma. *Patient Educ Couns*. 2011;82(1):117-122.

21. Borrelli B, Riekert KA, Weinstein A, Rathier L. Brief motivational interviewing as a clinical strategy to promote asthma medication adherence. *J Allergy Clin Immunol*. 2007;120(5):1023-1030.
22. Borrelli B, McQuaid EL, Becker B, et al. Motivating parents of kids with asthma to quit smoking: the PAQS project. *Health Educ Res*. 2002;17(5):659-669.
23. Borrelli B, McQuaid EL, Novak SP, Hammond SK, Becker B. Motivating Latino caregivers of children with asthma to quit smoking: a randomized trial. *J Consult Clin Psychol*. 2010;78(1):34-43.
24. Borrelli B, Sepinwall D, Ernst D, et al. A new tool to assess treatment fidelity and evaluation of treatment fidelity across ten years of health behavior research. *Journal of Consulting and Clinical Psychology*. 2005;73(5):852-860.
25. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol*. 2004;23(5):443-451.
26. Magzamen S, Patel B, Davis A, Edelstein J, Tager IB. Kickin' Asthma: school-based asthma education in an urban community. *J Sch Health*. 2008;78(12):655-665.
27. Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring quality of life in children with asthma. *Qual Life Res*. 1996;5(1):35-46.
28. Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring quality of life in the parents of children with asthma. *Qual Life Res*. 1996;5(1):27-34.
29. Beck-Ripp J, Griesse M, Arenz S, Koring C, Pasqualoni B, Bufler P. Changes of exhaled nitric oxide during steroid treatment of childhood asthma. *Eur Respir J*. 2002;19(6):1015-1019.
30. Nelson BW, Awad D, Alexander J, Clark N. The continuing problem of asthma in very young children: a community-based participatory research project. *J Sch Health*. 2009;79(5):209-215.
31. McDaniel M, Paxson C, Waldfogel J. Racial disparities in childhood asthma in the United States: evidence from the National Health Interview Survey, 1997 to 2003. *Pediatrics*. 2006;117(5):e868-877.
32. Gupta RS, Carrion-Carire V, Weiss KB. The widening black/white gap in asthma hospitalizations and mortality. *J Allergy Clin Immunol*. 2006;117(2):351-358.
33. Halterman JS, Montes G, Shone LP, Szilagyi PG. The impact of health insurance gaps on access to care among children with asthma in the United States. *Ambul Pediatr*. 2008;8(1):43-49.
34. Bartlett SJ, Krishnan JA, Riekert KA, Butz AM, Malveaux FJ, Rand CS. Maternal depressive symptoms and adherence to therapy in inner-city children with asthma. *Pediatrics*. 2004;113(2):229-237.

35. Weil CM, Wade SL, Bauman LJ, Lynn H, Mitchell H, Lavigne J. The relationship between psychosocial factors and asthma morbidity in inner-city children with asthma. *Pediatrics*. 1999;104(6):1274-1280.
36. McCallum J, Mackinnon A, Simons L, Simons J. Measurement properties of the Center for Epidemiological Studies Depression Scale: an Australian community study of aged persons. *J Gerontol B Psychol Sci Soc Sci*. 1995;50(3):S182-189.
37. Weissman MM, Orvaschel H, Padian N. Children's symptom and social functioning self-report scales. Comparison of mothers' and children's reports. *J Nerv Ment Dis*. 1980;168(12):736-740.
38. Faulstich ME, Carey MP, Ruggiero L, Enyart P, Gresham F. Assessment of depression in childhood and adolescence: an evaluation of the Center for Epidemiological Studies Depression Scale for Children (CES-DC). *Am J Psychiatry*. 1986;143(8):1024-1027.
39. Mannino DM, Homa DM, Redd SC. Involuntary smoking and asthma severity in children: data from the Third National Health and Nutrition Examination Survey. *Chest*. 2002;122(2):409-415.
40. Chilmonczyk BA, Salmun LM, Megathlin KN, et al. Association between exposure to environmental tobacco smoke and exacerbations of asthma in children. *N Engl J Med*. 1993;328(23):1665-1669.
41. Bernert JT, Jr., McGuffey JE, Morrison MA, Pirkle JL. Comparison of serum and salivary cotinine measurements by a sensitive high-performance liquid chromatography-tandem mass spectrometry method as an indicator of exposure to tobacco smoke among smokers and nonsmokers. *J Anal Toxicol*. 2000;24(5):333-339.
42. Willers S, Axmon A, Feyerabend C, Nielsen J, Skarping G, Skerfving S. Assessment of environmental tobacco smoke exposure in children with asthmatic symptoms by questionnaire and cotinine concentrations in plasma, saliva, and urine. *J Clin Epidemiol*. 2000;53(7):715-721.
43. Diggle P, Liang K, Zeger S. Chapter 2. *Analysis of Longitudinal Data*. New York, New York: Oxford University Press; 1994.
44. Liu H, Wu T. Sample size calculation and power analysis of time-averaged difference. *Journal of Modern Applied Statistical Methods*. 2005;2:1-9.
45. Preisser JS, Lohman KK, Rathouz PJ. Performance of weighted estimating equations for longitudinal binary data with drop-outs missing at random. *Stat Med*. 2002;21(20):3035-3054.
46. Robins JM, Rotnitzky A, Zhao LP. Analysis of Semiparametric Regression-Models for Repeated Outcomes in the Presence of Missing Data. *J Am Stat Assoc*. 1995;90(429):106-121.
47. Deci E, Ryan RM. *Intrinsic motivation and self-determination in human behavior*. New York: Plenum; 1985.

48. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *American Psychologist*. 2000;55:68-78.
49. Miller WR, Rollnick S. *Motivational interviewing, third edition: helping people change*. 3 ed. New York, NY: The Guilford Press; 2012.
50. Blaakman SW, Cohen A, Fagnano M, Halterman JS. Asthma medication adherence among urban teens: a qualitative analysis of barriers, facilitators and experiences with school-based care. *J Asthma*. 2014;51(5):522-529.
51. Frey SM, Goldstein NPN, Fagnano M, Tajon RS, Halterman JS. Considering the Control Group: The Influence of Follow-Up Assessments on Asthma Symptoms. *Acad Pediatr*. 2020;20(1):63-72.
52. Teach SJ, Shelef DQ, Foushee N, et al. Randomized clinical trial of parental psychosocial stress management to improve asthma outcomes. *J Asthma*. 2019:1-12.

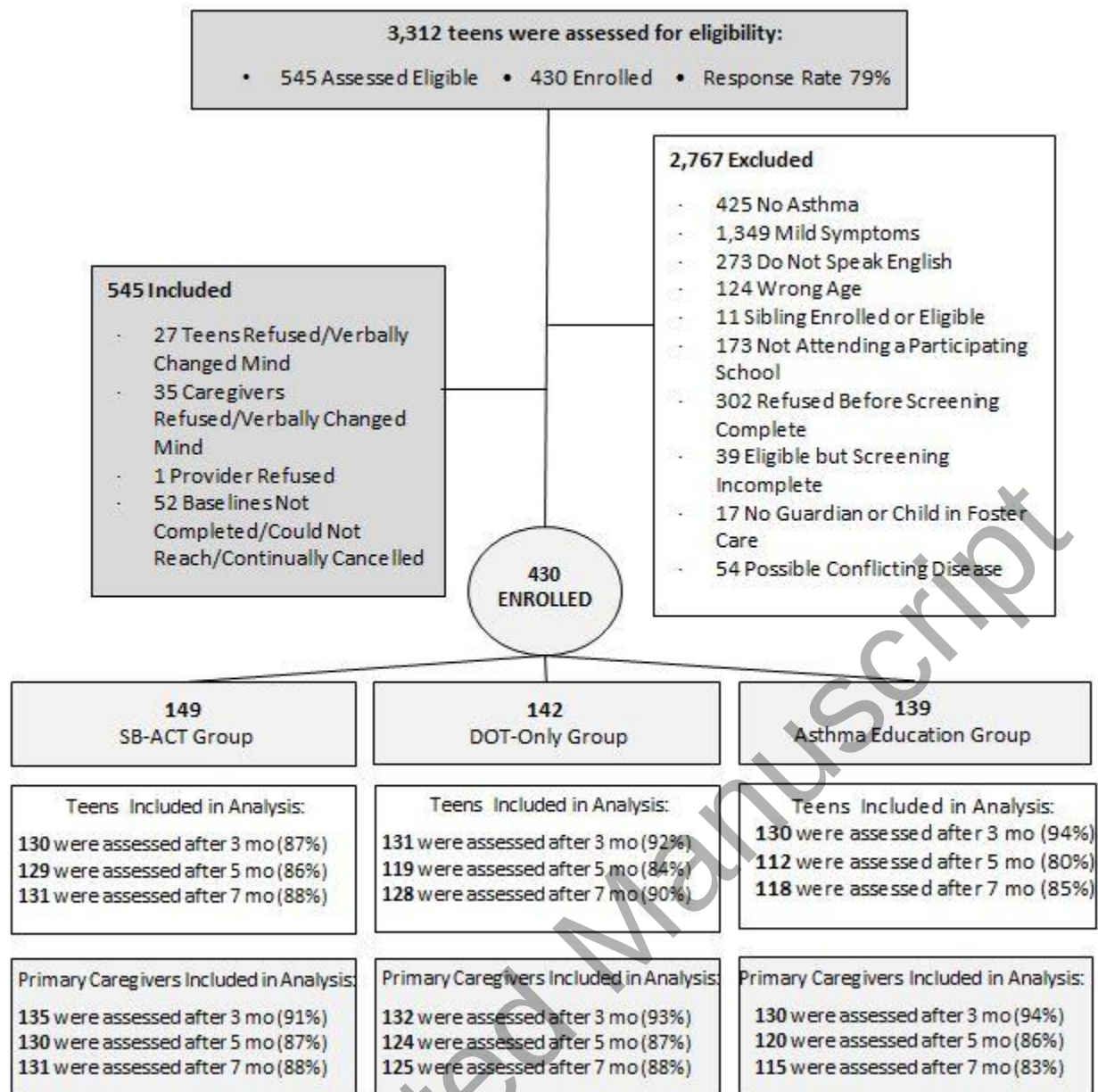
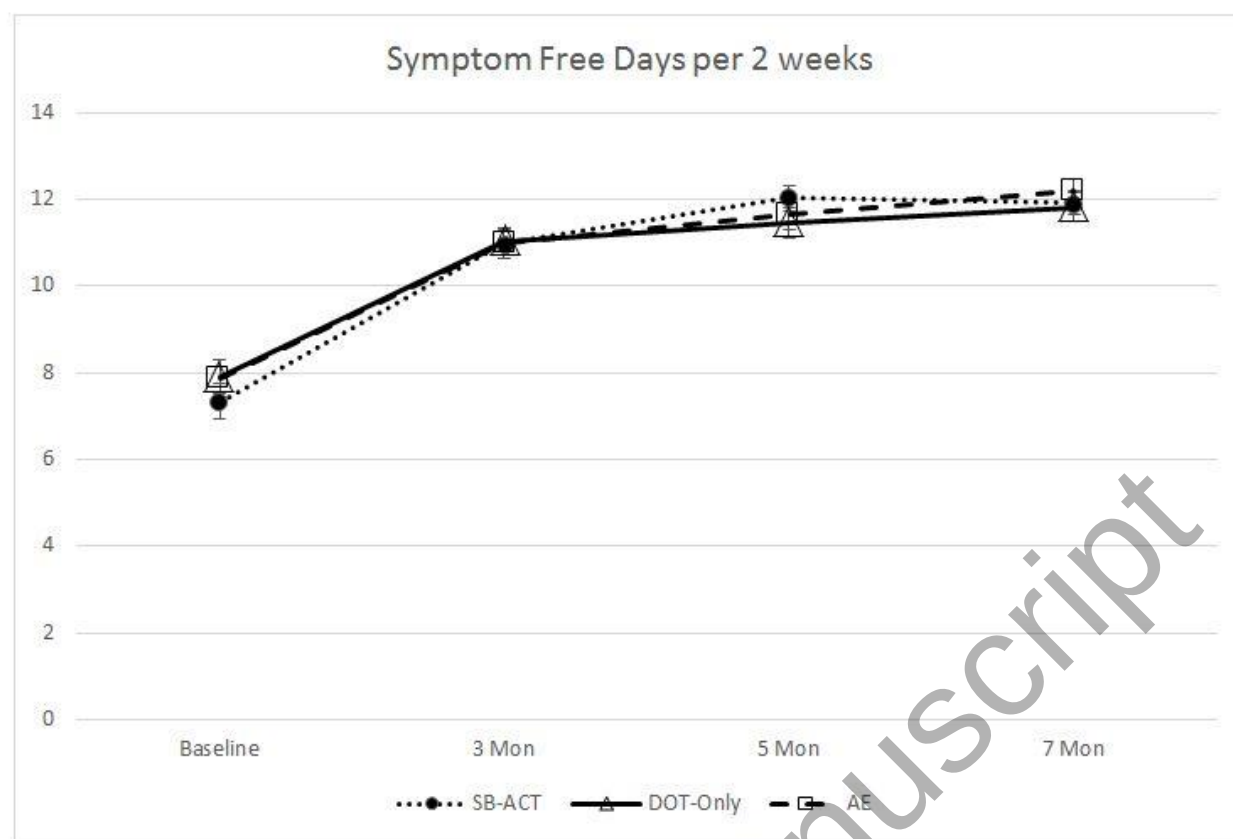


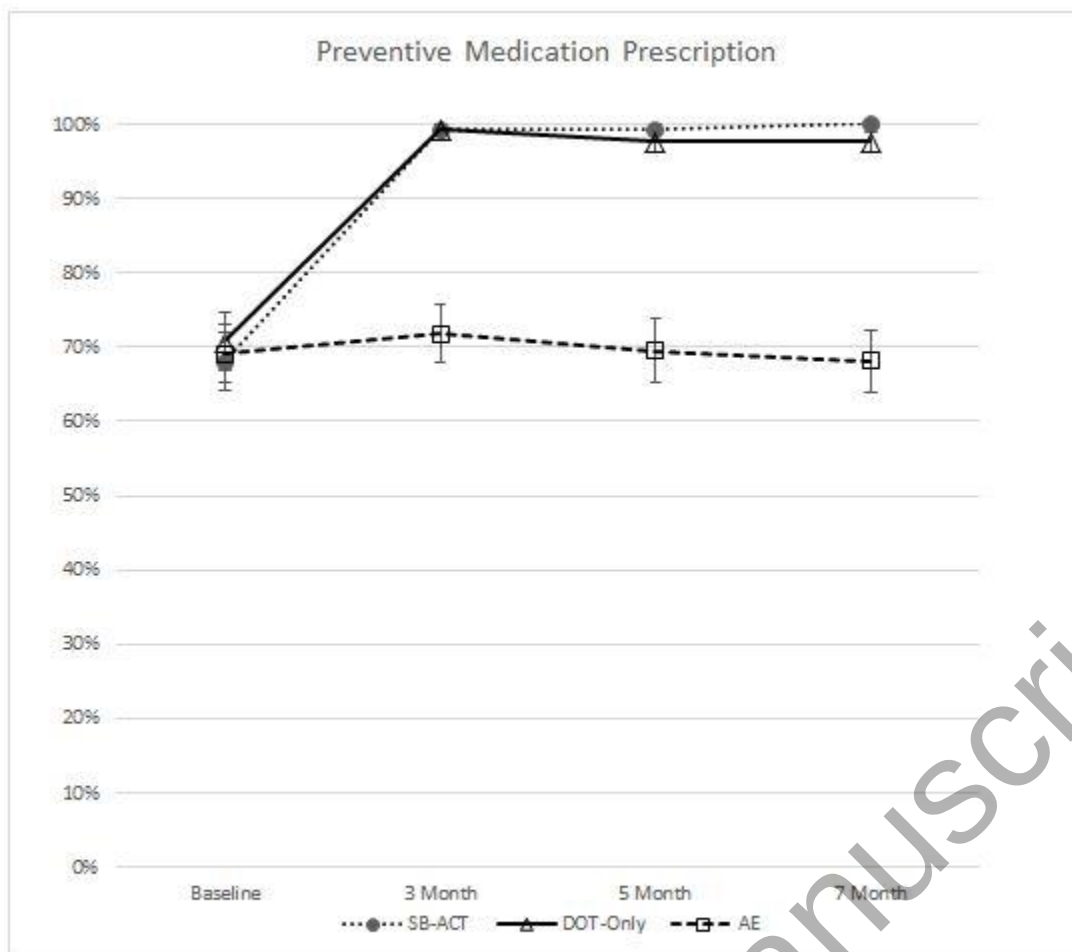
Figure 1: Consort Diagram

Figure 2: Symptom Free Days, Preventive Medication Prescription, and Adherence Over Time



p=NS at each time point

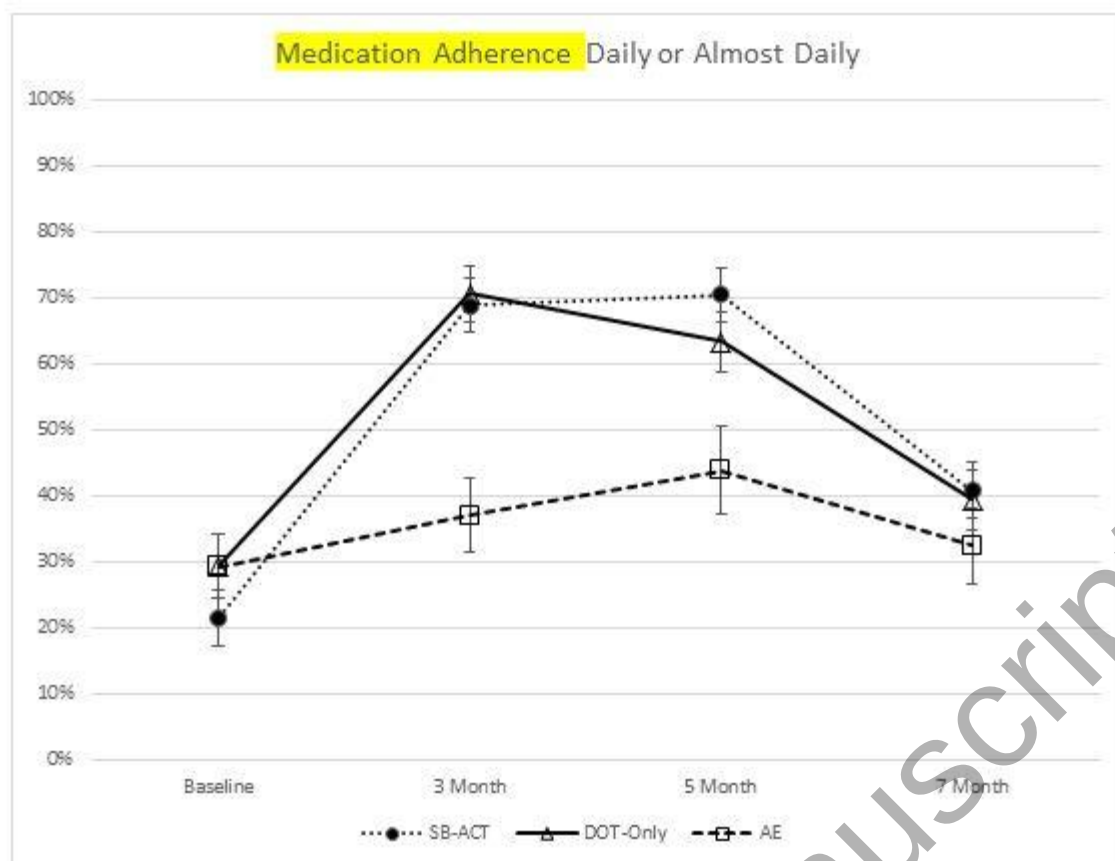
Figure 2a: Symptom Free Days



$p = .88$ at baseline

$p < .001$ at 3, 5, and 7 months

Figure 2b. Preventive Medication Prescription



$p = .39$ at baseline

$p < .001$ at 3 months

$p = .003$ at 5 months

$p = .49$ at 7 months

Figure 2c. Medication Adherence

Table 1: Population Demographic Information and Baseline Asthma Symptom Variables

Characteristic <i>Mean (SD), N (%)</i>	Overall N=430	SB-ACT N=149	DOT-Only N=142	AE N=139	P-value
TEEN					
Age, mean (SD), years	13.4 (1.2)	13.4 (1.2)	13.4 (1.2)	13.5 (1.2)	.723
Male	240 (56%)	79 (53%)	87 (61%)	74 (53%)	.278
Race:					
White	22 (5%)	5 (3%)	7 (5%)	10 (7%)	.598
Black	239 (56%)	82 (55%)	78 (55%)	79 (57%)	
Other	169 (39%)	62 (42%)	57 (40%)	50 (36%)	
Hispanic Ethnicity	139 (32%)	47 (32%)	50 (35%)	42 (30%)	.649
Public Insurance	363 (85%)	121 (81%)	121 (86%)	121 (87%)	.347
Depressive Symptoms	121 (28%)	41 (28%)	37 (26%)	43 (31%)	.612
≥1 Smoker in Home	228 (53%)	72 (49%)	73 (51%)	83 (60%)	.130
Salivary Cotinine Level, mean (SD), ng/ml	9.4 (39.5)	9.9 (34.8)	11.0 (40.0)	7.2 (43.6)	.318
Asthma Severity over 14 days, mean (SD):					
Symptom-free days	7.7 (4.8)	7.3 (5.0)	7.9 (4.6)	7.9 (5.0)	.627
Days with daytime symptoms	4.8 (4.4)	5.2 (4.7)	4.6 (4.0)	4.6 (4.5)	.663
Nights with nighttime symptoms	2.5 (3.5)	2.8 (3.7)	2.1 (3.1)	2.5 (3.8)	.293
Days with limited activity	2.8 (3.8)	3.0 (3.7)	2.5 (3.4)	3.0 (4.2)	.385
Days with rescue medication use	3.3 (4.0)	3.4 (3.2)	3.2 (3.9)	3.4 (4.2)	.927
FeNO (ppb)	38.3 (38.4)	38.6 (39.8)	39.3 (37.9)	36.8 (38.4)	.631
Persistent Asthma Symptoms	303 (71%)	107 (73%)	102 (72%)	94 (68%)	.597
Preventive medication prescription	295 (69%)	100 (68%)	99 (71%)	96 (69%)	.884
≥1 ED, Urgent Care or Hospitalization in prior year	113 (26%)	40 (27%)	39 (28%)	34 (24%)	.833
CAREGIVER					

Education: <High School	158 (37%)	61 (41%)	47 (33%)	50 (36%)	.372
Marital Status: Single	304 (71%)	95 (64%)	106 (75%)	103 (74%)	.070
Income: <Federal Poverty Level	263 (62%)	87 (59%)	86 (61%)	90 (65%)	.617
Depressive Symptoms	132 (31%)	43 (30%)	45 (32%)	44 (32%)	.891

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Table 2: Main Study Outcomes (3, 5, and 7 months)

Outcome <i>Mean (SD); N (%)</i>	Overall	SB-ACT	DOT-Only	AE	P-value
Symptom-free days, mean (SD)	11.5 (2.9)	11.5 (2.9)	11.4 (2.9)	11.6 (2.8)	.757
Secondary outcomes, mean (SD):					
Days with daytime symptoms	1.8 (2.3)	1.8 (2.4)	2.0 (2.3)	1.7 (2.0)	.804
Nights with nighttime symptoms	1.0 (1.8)	1.0 (2.0)	1.0 (2.0)	0.9 (1.5)	.496
Days with limited activity	1.2 (2.0)	1.3 (2.2)	1.3 (1.9)	1.2 (1.8)	.583
Days with rescue medication use	1.8 (2.5)	1.9 (2.7)	1.7 (2.3)	1.2 (1.8)	.450
≥1 Day absent from school due to asthma (baseline to 7 mos)	155 (37%)	51 (35%)	58 (43%)	46 (33%)	.528
≥1 ED, urgent care or hospitalization (baseline to 7 mos)	54 (13%)	17 (12%)	22 (16%)	15 (11%)	.672
Change in FeNO level (baseline to 7 mos)	-2.4 (31.5)	-2.1 (23.2)	-6.3 (32.2)	1.7 (38.0)	.201
Change in Teen Quality of Life (baseline to 7 mos)	0.81 (1.2)	0.82 (1.3)	0.80 (1.1)	0.83 (1.3)	.662

Repeated Measures, GEE statistics including: Baseline SFD, Smokers in home, Income level <FPL

Table 3: Teen's Confidence, Importance and Motivation regarding Preventive Medication Adherence over Time

Outcome <i>Mean (SD)</i>	SB-ACT	DOT-Only	AE	P-value
Confidence in Medication Adherence				
Baseline	5.9 (2.0)	6.2 (2.0)	6.1 (2.1)	.476
3 Month	7.2 (2.0)	7.0 (2.0)	7.0 (1.8)	.472
5 Month	7.6 (2.0)	6.9 (2.3)	7.0 (2.2)	.017^a
7 Month	7.0 (2.2)	6.7 (2.4)	6.8 (2.3)	.763
Mean Score at 3, 5, and 7 Months	7.2 (1.8)	6.9 (2.0)	6.9 (2.0)	.188*
Motivation in Medication Adherence				
Baseline	5.8 (1.9)	6.2 (2.1)	5.8 (2.3)	.185
3 Month	7.6 (2.1)	7.2 (2.2)	6.4 (2.3)	<.001^{b,c}
5 Month	7.9 (2.0)	7.3 (2.3)	6.9 (2.4)	.002^b
7 Month	6.9 (2.4)	6.7 (2.4)	6.6 (2.2)	.563
Mean Score at 3, 5, and 7 Months	7.4 (1.8)	7.1 (2.0)	6.6 (1.9)	<.001*
Importance in Medication Adherence				
Baseline	7.1 (1.7)	7.2 (2.0)	7.0 (2.1)	.683
3 Month	8.5 (1.7)	8.1 (1.9)	7.9 (2.1)	.043^b
5 Month	8.8 (1.5)	8.4 (1.8)	8.3 (2.0)	.028^b
7 Month	8.0 (2.2)	8.0 (2.0)	7.9 (1.9)	.985
Mean Score at 3, 5, and 7 Months	8.4 (1.6)	8.1 (1.6)	8.0 (1.7)	.042*

Scales range 1-10, higher scores indicating better outcome

Individual time point comparisons based on ANOVA.

^a SB-ACT vs DOT-Only significantly different

^b SB-ACT vs AE significantly different

^c DOT-Only vs AE significantly different

*GEE analyses accounting for repeated measures at 3, 5, and 7 month after adjusting for Baseline SFD, Smokers in home and income level