Take Action for Asthma Control Study - Developing pictorial asthma action plans to promote self-management and health in rural youth with asthma

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**Study Protocol**

**Title**: Take Action for Asthma Control Study - Developing pictorial asthma action plans to promote self-management and health in rural youth with asthma

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**Background:** Asthma, the most common chronic illness in children, is characterized by symptoms of wheezing, coughing, chest tightness, and shortness of breath. When poorly managed, asthma can be associated with negative social and health outcomes (Akinbami, Moorman, & Liu, 2011; Akinbami, & Schoendorf, 2002). Asthma action plans (AAPs) are individualized treatment plans, arranged in a stoplight format, that specify daily asthma care activities as well as instructions for adjusting medication or seeking emergency medical help in response to symptoms. Regular use of an AAP has been associated with improved outcomes such as adherence to daily inhaler use and fewer symptomatic days and nights (Bhogal, Zemek, & Ducharme, 2006). However, written AAPs are targeted at a $7^{th}$ to $9^{th}$ grade reading level and are dense with text, which significantly constrains their utility and may contribute to health disparities. Rural families with literacy issues are particularly at risk. A critical need exists to develop a simpler format for AAPs.

**Overall Aim:** The overall aim of this pilot RCT is to develop a symptom-based, computer-generated pictorial AAP (PAAP) and to investigate acceptability and feasibility in a pilot randomized controlled trial (RCT). The PAAP will be comprised primarily of images, with minimal words or phrases, to direct the family regarding the child's asthma regimen.

**Specific Aim # 1 – Determine the relative of pictorial & written AAPs.** Our working hypothesis is that relative to usual care (Written AAP), Pictorial AAP will produce superior clinical and behavioral outcomes: (a) better treatment plan knowledge for caregiver and patient; (b) higher daily adherence rates to preventive medication (via electronic monitoring); and (c) better health outcomes (i.e., report of better asthma control & higher *lung functioning* or spirometry scores). This hypothesis is based in part on research findings indicating that use of pictures in health education markedly increases recall of information through simpler and more salient cues.

**Specific Aim # 2 – Evaluate provider and family acceptability of pictorial AAP.** Based on existing literature, we expect that the Pictorial AAP will be easy and user-friendly for providers to offer as well as patients and families to use. Consequently, our working hypothesis is that patient and caregiver satisfaction (e.g., perceived ease of use, benefits) survey scores will be significantly higher for the Pictorial AAP than for the Written AAP group.

**Specific Aim # 3: Identify whether parent health literacy and youth literacy levels are associated with treatment outcome.** Pearson (parametric) or Spearman (non-parametric) correlations will be used as appropriate to assess the association between parent health literacy and youth literacy to changes in knowledge, adherence, and health outcome, as well as caregiver and patient satisfaction, within and between AAP groups. Given that research suggests the use of graphics and images improves comprehension of medical information, it is anticipated that rural youth, particularly with lower literacy levels, will benefit significantly from a simpler, "image rich" pictorial AAP.

**Design:** Pilot Randomized Controlled Trial

Young people aged 8-17 were randomly assigned to one of two groups (pictorial vs. written AAP, i.e. usual care) for 6 months. The Written AAP (WAAP) group received a personalized, text-based AAP. The WAAP is consistent with national practice guidelines [5] and recommended as standard care for patients with asthma. The proposed study will use the written AAP published by the National Heart Lung and Blood Institute (NHLBI) (Available at: https://www.nhlbi.nih.gov/files/docs/public/lung/asthma_actplan.pdf). Providers (not researcher) completed the WAAP with the child's prescribed medications and specific asthma care regimen. The provider reviewed the WAAP with the child and caregiver.

The Pictorial AAP (PAAP) group received a largely pictorial version of their AAP (with only brief & simple text). Its content was personalized to their prescribed regimen and comparable to that of the written AAP (e.g., asthma regimen divided into stoplight-color zones); however, it used conventional pictures and symbols to represent what, when and how medications should be taken. Providers accessed the PAAP software program in clinic, after evaluating the patient, and selected options from dropdown menus to tailor the PAAP to the particular patient's asthma regimen. The PAAP was provided to the participant, another was be saved in the participant's online medical record, and a third was be kept in their research record. The provider reviewed the PAAP with the child and caregiver.

It is hypothesized that the use of the PAAP will produce better AAP knowledge, higher objectively measured adherence rates to daily asthma medication, and better health outcomes, such as asthma control.

**Methods:**

This pilot RCT began data collection in May 2017 and continued through May 2018. A total of 45 youths and their families were recruited. Data was collected at four time points: baseline (recruitment), 1-month, 3-months, and 6-months. At baseline, caregivers completed a general information form on demographics and medical history, as well as measures to assess health status (Asthma Control Test), and health literacy (S-TOFHLA and Asthma Numeracy Questionnaire). Patients completed measures to assess health status (Asthma Control Test), health literacy (S-TOFHLA) and reading comprehension (WIAT-III), and complete pulmonary function testing (spirometry). Qualitative methods were used to gather acceptability and feasibility data. Participants in both groups were provided with their first canister or diskus of medication in order to attach the electronic adherence monitor at baseline. Participants refilled with medications they purchase as needed for the remainder of the study. One month after initial visit, families were called to complete the Asthma Control Test and study-specific satisfaction survey. Three months after initial visit, families returned to clinic for follow up with the physician and to complete the Asthma Control Test, AAP knowledge interview, and pulmonary function testing (patient only). Six months after initial visit, families returned to clinic for follow up with the physician and to complete the Asthma Control Test, AAP knowledge interview, satisfaction survey, spirometry (patient only), and to review adherence data and return the inhaler monitor. Six families completed follow up measures at 3 months due to time constraints.

The findings of this study will be relevant to research and practice with rural youths with asthma, as well as families with significant literacy issues. A novel and innovative stakeholder-led approach was used in this study to develop a more accessible and effective approach to asthma education in pediatric settings. The process and findings of this study will be widely disseminated and guide improvements to the PAAP for use in future research and practice, including the possible development of an "app" version of the PAAP.

**Study Analysis Plan**

All analysis was conducted using SAS 9.4. Descriptive analysis was conducted on baseline measures for both the total sample, and by treatment group. Frequency and valid percentages were used to describe categorical data, means and standard deviations for continuous data, and medians and interquartile range for non-normal continuous data. Group differences were tested by chi-square, Fisher's exact, Mann-Whitney, or t-test as appropriate for variable type, with odds ratios (OR) and 95% CI of the OR, means by group and t-statistic, or mean score ranks and Z-statistic reported.

Generalized linear mixed model (GLIMMIX) with multinomial response distribution and a cumulative logit link function were used to analyze the daily adherence data, in order to model the ordinal outcome measure (0%, 25%, 50%, 75%, and 100% adherence) over time. Multiple covariance structure models were tested, with an unstructured matrix best fitting by AIC. Because adherence changed depending on prescription, the models were tested by both interaction of prescription and by stratification. Sensitivity analysis was also run for 3 months or less data and compared to the full 6 month dataset. Fixed effects were reported. Generalized linear mixed model (GLIMMIX) with binary response distribution was also conducted for the binary outcome of ACT cut-off >= 19.

Linear mixed models with restricted estimation maximum likelihood estimation and Kenward-Richardson adjustment for the degrees of freedom were used for the continuous outcome data. Pre-post analysis included combining 3 month and 6 month time points for outcome measures where the final time point was 3 instead of 6 months. Time was treated as categorical for these pre- post- time points; otherwise time was treated as continuous variable. Time, Group, and Time by Group interaction effects were included in the model. Random effects statement included the time, with participants listed by ID. Different covariance structures and intercept inclusion were tests; AIC was used to determine best model fit with the best fitting model including no intercept and an unstructured covariance matrix. Fixed effects are reported. Sensitivity analysis was also run by including days in the study for those post-outcomes where some participants have 3 months or less data and compared to the full 6 month dataset.

Finally, equivalence testing was conducted for all continuous outcomes, assuming that results that fall within an SD unit difference would indicate that PAAP is as good as guideline-recommended care (WAAP) with sufficient power. The overall stability of the effect of the treatment response was demonstrated utilizing the F test for equivalence of the effect of psi-squared, a standardized measure of difference between groups/time point means and an overall (across groups and time points) mean. This was be assessed utilizing output from the best-fitting general linear mixed model and by testing whether this psi-squared effect size measure falls in the critical region [6].

## References


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