STUDY PROTOCOL

Using Question Prompt Lists during Pediatric Asthma Visits to Increase Adolescent Involvement

NCT02498834

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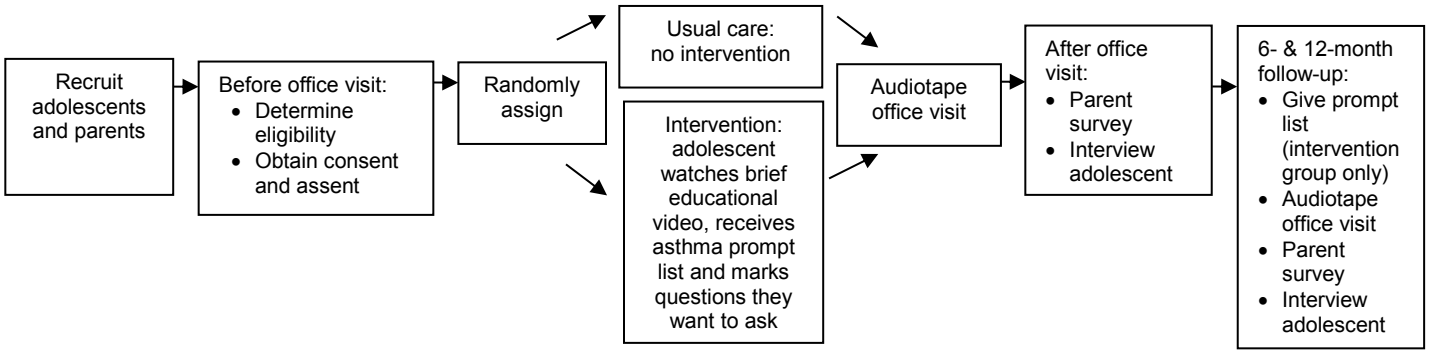
Study Design/Approach

Study overview: This study is a randomized controlled trial testing the effectiveness of an asthma question prompt list with short video intervention compared to usual care to increase adolescent involvement during visits and improve asthma outcomes. We conducted the study at four pediatric clinics in rural and suburban North Carolina. Forty providers and 359 English- or Spanish-speaking adolescents and their caregivers participated. Adolescents were randomized to the intervention or usual care. Their visits were audio-recorded. Adolescents were interviewed after their visits and their caregivers completed questionnaires. Participants were followed for 12 months.

Study design: This study is a randomized controlled trial testing the effectiveness of an asthma question prompt list with short video intervention compared to usual care to increase adolescent involvement during visits and improve asthma outcomes (ClinicalTrials.gov ID: NCT02498834, protocol ID 14–2628). Figure 1 contains our study protocol.

Figure 1



Study setting: Participants were recruited from four pediatric clinics in suburban and rural areas in North Carolina. Three clinics were private practices and one was an academic practice. Clinics were chosen because they served large numbers of adolescents with persistent asthma from diverse racial/ethnic backgrounds.

Participants: Our target population was adolescents with persistent asthma because we wanted to examine whether we could improve adolescent involvement during visits and asthma outcomes. Our target sample size was 360 adolescents ages 11-17. Research assistants were hired and placed at each clinic.

Clinic staff referred potentially eligible patients who were interested in learning more about the study to a research assistant. During pre-visit wait time, the research assistant explained the study, obtained written caregiver consent and adolescent assent, and administered an eligibility screener. Children were eligible if they were: ages 11 to 17 years; spoke and read English or Spanish; had persistent asthma; were present for an acute or follow-up asthma visit or a well-child visit; and had previously visited the clinic at least once for asthma. Adolescents' caregivers were eligible if they were at least 18 years of age, spoke and read English or Spanish, and were the legal guardian of the adolescent. The research assistant recorded the reasons why individuals declined to participate.

The study statistician prepared the randomization envelopes for the research assistants to use. Adolescents were randomized within providers and opaque envelopes were prepared for the research assistants at each site. A group of envelopes was prepared for each enrolled provider. Eligible adolescents of participating providers were then randomized to the intervention or usual care group. Adolescents in the intervention group watched the video with their caregivers on an iPad. Depending on the clinic, they either watched it in a private area before the visit or they watched it with earphones in the waiting area. The adolescents then received the one-page asthma question prompt list to complete before their visits. Providers were blinded to the adolescent's group assignment. All adolescents' visits were audio-tape recorded. All adolescents were interviewed at baseline after their medical visits by a research assistant while their caregivers completed questionnaires. Research assistants reviewed the caregiver questionnaires before

families left the clinics to ensure data quality. The project manager traveled to the clinics regularly to pick up and review data to ensure quality. Adolescents and caregivers each received $25 for their time.

Interventions and comparators or controls: Our goal was to increase adolescent involvement during pediatric asthma visits. Adolescents in the intervention group received the asthma question prompt list with video intervention in the clinic before their medical visits. The video was eleven minutes in length and had six themes (asthma triggers, staying active with asthma, how to get mom off your back, tracking asthma symptoms, how to talk to your doctor, and having confidence with asthma). Each theme had its own video that ranged in length from one to two minutes. The final one-page asthma question prompt list had 14 questions about asthma medications, eight questions about triggers and asthma in general, and an area where adolescents could write in questions. The question prompt list took adolescents in the intervention group less than four minutes to complete.

The control intervention was usual care, meaning that the adolescent received no intervention before their medical visits. All adolescent visits were audio-taped and transcribed so we could examine communication during visits.

All audiotapes of the medical visits were transcribed verbatim. Three research assistants were trained to code the transcripts using a detailed coding tool developed and used in prior asthma communication studies. The three coders coded thirty-four of the same transcripts throughout the study period to assess inter-rater reliability.

Study outcomes: Our primary outcomes were (a) asthma control, (b) adolescent asthma management self-efficacy, and (c) asthma quality-of-life at 12 months. Asthma control was measured using the 5-item Asthma Control Test which is a valid and reliable measure of asthma control. Using a 5-point Likert scale, responses are summed to indicate a score ranging from 5 (poor asthma control) to 25 (complete asthma control). Scores above 19 are considered “well controlled”, 16 to 19 are considered not well controlled, and scores 15 or below are considered “very poorly controlled.” Studies have shown the Asthma Control Test to be reliable, valid, and responsive to temporal changes in asthma control. We measured asthma as being controlled if adolescents scored above 19 on the Asthma Control Test. Adolescent asthma management self-efficacy was measured as a summary score using a 14-item scale that has been shown to have a reliability of 0.87. Prior work in asthma has found asthma management self-efficacy to change in response to an intervention. Adolescent quality-of-life was measured as a mean score on the standardized version of the Juniper pediatric asthma quality-of-life questionnaire. The questionnaire contains 23 items organized in three domains: symptoms, activities, and emotional impact of asthma, and has a reliability of 0.84.

Data collection and sources: After enrollment at baseline, caregivers completed a contact information sheet that contained information on the date of initial contact, the caregiver’s name and contact information, including postal address, home/cell number, email address and alternative contact information. The research assistant kept in contact with the patient to determine when their 6- and 12-month follow-up visits would occur. The research assistant called first; if the research assistant could not speak to the caregiver directly she would leave a voice message (caregiver was always asked for permission to leave voice messages during initial meeting). If the research assistant did not hear back from the caregiver within a couple of days she would proceed to text, send an email and/or mail a letter. The research assistant would reach out to the alternative contact as the last resort.

When an adolescent came back to the clinic at the 6-month follow-up visit, their visit was audio-taped, the research assistant interviewed the adolescent, and the caregiver completed a questionnaire. If an adolescent did not have a clinic visit at the 6-month data collection point, the research assistant met the family for a follow-up visit at the location of their choice. If a family withdrew from the study at 6 months, the research assistant recorded the reason why.

If patients did not withdraw from the study, we still attempted to conduct the 12-month follow-up visits. When an adolescent came back to the clinic at the 12-month follow-up visit, their visit was audio-taped, the research assistant interviewed the adolescent, and the caregiver completed a questionnaire. If an adolescent did not have a clinic visit at the 12-month data collection point, the research assistant met the family for a follow-up visit at the location of their choice. If a family withdrew from the study at 12 months, the research assistant recorded the reason why. Adolescents and caregivers each received $25 at 6 and 12-month follow-up. The adolescent’s medical records were reviewed for the period of 12 months before and after the intervention.

Analytical and statistical approaches

Sample Size Calculations: Our planned enrollment was 360 adolescents. We expected a 20% attrition rate over 12 months based on our prior work. Assuming the same attrition rate, 288 patients, or about 144 patients each in the experimental and usual care groups, would complete the study. We expected to go from 50% of the adolescents in the intervention group being well controlled according to the Asthma Control Test at baseline to 70% of adolescents in the intervention group being well controlled at 12 months. An intervention study conducted with adults with asthma found that an educational intervention increased the percent of adults controlled according to the Asthma Control Test from 50% to 65% over a 6-month period. From past studies, we expected an average self-efficacy score of around 3.7 to 3.8 and average quality of life scores of 5.7 to 5.8 for the adolescents. With 143 families in each group and an expected increase of 20% in asthma control, as well as an expected increase in adolescent self-efficacy and adolescent's quality of life by at least one half of a point, which equates to effect sizes of 0.45 to 0.6, the study is powered at 80% with a type I error rate of 5% for each of the between-group differences for these outcome variables. Our estimates for the control group come from our prior work.

Analytical Approach: All analyses were performed using SPSS. Generalized estimating equations, (i.e., the GEE method) were used to analyze the data, which allowed families to be nested within providers. The GEE method was used to detect clinically significant differences in our primary outcome variables: asthma control, adolescent self-efficacy in asthma management, and adolescent quality-of-life. Primary analysis used the 12-month follow-up data. Our multivariable models for the primary outcomes were nested by provider and included several covariates. For all of our models, we examined relevant interaction terms. For scale items that were missing, we imputed missing scale items using overall sample mean scores.