Table of Planned Analyses
Breathe with Ease: A Unique Approach to Managing Stress (BEAMS)
PI: Stephen J. Teach, MD, MPH
Final 11.25.16

Primary Outcome	
Symptom-free days	• In last 14 days; symptom-free days are defined as a 24-hour period with no coughing, wheezing, chest tightness, or shortness of breath and no need for rescue medications
Secondary Outcomes	
Asthma morbidity	• In last 14d: daytime/nighttime symptoms, activity limitation, use of quick relief meds, changed plans, and missed school.
Asthma medication adherence	• Medication use in past 2d • Medication beliefs (difficulty following med plan, concerns re side effects, belief that med use prevents exacerbations)
Health care utilization	• ED visits, • hospital admissions, • ICU admissions, • primary care visits
Asthma exacerbations	• Courses of systemic steroids or hospitalizations in 12m prior to enrollment and during 12m follow up period (independent courses ≥7d apart)
Parental stress	• Perceived Stress Scale • Stressful Life Events
Parental depression	• CES-D
Child anxiety	• PROMIS Parent Proxy Anxiety
Child depression	• PROMIS Parent Proxy Depressive Symptoms
Quality of life	• Pediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ)
Safety data	• AEs/SAEs
Exploratory Outcomes	
Coping strategies	• Brief COPE
Mindfulness	• Interpersonal mindfulness of parenting
Parental Resilience	• LOT-R
Economic data	• Analysis of costs of care in both groups
Environmental smoke exposure	• Child smoke exposure • Parent smoking behavior
Use of existing ancillary services	• Use of psychological support (parent/child/other family members) • Use of mental health resources • Participation in stress reducing activities (exercise, dance, yoga, breathing, other)
Control Variables	
Baseline Sociodemographic factors	Age, gender, race, ethnicity, insurance type, parent education, household income, family medical history, parent health literacy, parental resilience
Intervention uptake, satisfaction, and fidelity	Completion of 1:1 session, completion of group sessions, location/format of sessions, use of stress management techniques, use of techniques with children
Asthma severity	• NAEPP classification, as determined by IMPACT DC clinician
Asthma control	• NAEPP classification, as determined by IMPACT DC clinician • ACT score

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We will examine interactions between primary and secondary outcomes and

- baseline asthma variables (severity/control, health care utilization, exacerbations),
- baseline psychosocial variables (parental stress and depression, resilience, child anxiety and depression, quality of life)
- baseline demographic factors

In addition, we will examine interactions between primary and secondary outcomes and intervention uptake within the intervention group.

Key planned analyses include:

- Interaction between primary outcome and parental age, education, household income, child age and gender
- Interaction between primary outcome and baseline child asthma severity, control, and history of unscheduled healthcare utilization
- Interaction between primary outcome and baseline parental depression
- Interaction between primary outcome and baseline parental stress
- Interaction between primary outcome and baseline parental resilience
- Interaction between primary outcome and baseline child depression
- Interaction between primary outcome and baseline child anxiety
- Interaction between primary outcome and baseline asthma severity/control
- Dose-response analysis of intervention uptake (session completion and parent report of technique utilization)

Sample Size Calculation: The sample size was recalculated on September 14, 2015 based on the baseline data collected from the first 60 participants, which showed the following:

- mean = 10.25 days
- standard deviation = 4.12
- median = 11.5 days.

The sample distribution is not normal and approximated a Poisson distribution. Based on this distribution, the calculated sample size is 188 to achieve 80% power at a 0.05 significance level to detect a response rate ratio of 1.15 with baseline response rate of 10.25. Therefore, with 10% percent attrition rate, we planned to enroll 207 participants.

The primary analyses for this study will be conducted at 6m FU, and the same analyses will be completed with the 12m FU data.

The primary analysis for this study will be by intention to treat.

A per-protocol analysis will also be conducted. Per protocol will be defined as completion of all four one-on-one sessions.