COVER PAGE

Text2Breathe: Enhance Parent Communication to Reduce Pediatric Asthma Disparities (T2B)

NCT03032159

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C.5. Statistical Analyses

C.5.a: Preliminary Descriptive Analysis of Data

We will summarize all baseline variables overall and by study arm to assess the balance achieved by randomization and to check assumptions such as normality and equality of variances. The distributions of continuous variables will be summarized using means, standard deviations, medians, and ranges. Categorical variables will be summarized using frequency distributions. Non-parametric tests (e.g., Wilcoxon rank-sum and Fisher's exact) will be used in subsequent analyses as needed. Cronbach alpha reliabilities will be estimated for 12 all standardized instruments to assess whether the instruments are as reliable in our target population as in the population on which the instruments were validated. Frequency of missing data for each outcome variable will be determined at each time point. Baseline characteristics of missing and non-missing respondents at the 3, 6, 12 and 24 month time points will be compared to assess for attrition bias. We will employ multiple imputation to account for missing data, if necessary.84, 85 We will examine counts of mobile interactions captured by Rip Road (e.g., number of messages received and sent by each participant; See section 5.1.d.) to assess engagement with the intervention, overall and by participant characteristics.

C.5.b: Analysis Plan for Addressing Specific Aims

In **Aim 1**, to assess the intervention effect on the primary and secondary distal outcomes (i.e., the number of ED visits for asthma care during the 12-month interval following randomization, and the number of days of impairment during the two weeks prior to the 12-month interview, respectively), we will utilize negative binomial regression, a generalization of Poisson regression which yields unbiased inference even if the outcome variable is over-dispersed (i.e., the variance exceeds the mean) to estimate incidence rate ratios (IRRs) and 95% confidence intervals (CIs) for count data. The single independent variable in each model will be study group, and the exponentiated form of its regression coefficient will reflect the relative difference between groups in the annual rate of ED visits or frequency of impaired days.

In **Aim 2**, we will implement a negative binomial regression model to estimate the IRR and 95% CI for number of follow-up visits with the PCP for asthma care over 12 months in the intervention group compared to the usual care group. In addition to the group variable, the model will include a covariate to account for PCP visit frequency prior to randomization. The exponentiated form of the coefficient of the group term will reflect the relative difference between groups in annual rate of PCP follow-up visits for asthma care. We will use linear regression models to examine the intervention effect on knowledge of self-management (continuous scale score). The model independent variables will include study group and pre-randomization level of knowledge of self-management. The magnitude of the group coefficient will provide an estimate of the size and direction of difference between groups controlling for differences in pre-randomization levels.

We will also assess whether primary care utilization (annual rate of follow-up visits) and increased knowledge of self-management mediate the relationship between the assigned communication intervention and child asthma outcomes (defined as frequency of ED and urgent care visits for asthma care and days of impairment). To do so, we will use path analysis models at baseline and each follow-up time separately. To test these hypotheses using longitudinal data, growth trajectories of each outcome will be modeled using multi-process latent growth models (LGM) of these

proximal and distal outcomes. The hypothesized mediating effects of the proximal outcomes will be tested by relating the intervention condition, the latent slope growth factors of the multiple growth processes, and the distal outcomes.[86]

In **Aim 3**, we will use linear regression models, as above, to evaluate the intervention effect on measures of self-efficacy and outcome expectations. We will then use path analysis to assess whether parental self-efficacy and outcome expectations (defined using the three validated instruments) mediate intervention effects on PCP follow-up rates and knowledge of self-management. Although the data collected at the 12-month time point will be used as our primary indicator of intervention effectiveness, we will also utilize data collected through the full 24-month follow-up period to evaluate sustainability of the hypothesized effects of the intervention in the same series of analyses. The above analyses estimate the impact of the intervention at observed levels of acceptance of the intervention and thus estimate the expected average effectiveness of the intervention if implemented in a similar population. We will also estimate the magnitude of the effect on each outcome under alternative levels of engagement in the intervention to provide a range of estimated effects based on greater and lesser levels of engagement. Moreover, we will examine potential moderating effects of race/ethnicity on the intervention effects.

C.5.c: Sample Size Estimate

All sample size and power analyses are based on a 2-tailed type 1 error of 5% in final analyses based on 12 month follow-up results. For the primary outcome under **Aim 1** (number of ED visits for asthma care during a 12-month interval), we calculated that a sample size of 125 per study group provides at least 90% power to detect a clinically important 35% reduction in the T2B group compared to the estimated average rate of 1.28 ED visits per year in the usual care group (based on 2012 ED records). For the primary outcome under **Aim 2** (number of PCP visits for asthma care during a 12-month interval), we calculated that a sample size of 120 participants per group provides 90% power to detect an increase to the recommended 3 annual visits in the T2B group over the observed rate of 1.8/year in the previous IMPACT DC sample.7 For the other outcomes under Aim 3 (self-efficacy and outcome expectation), a sample size of 85 per group provides 90% power to 13 detect a 0.5 SD effect size difference between study groups. A feasible **analytic sample size of 110** ensures >80% power in all aforementioned analyses.

In prior studies, we have been able to maintain a 90% retention rate over a 6-month follow-up period. We will employ retention strategies that have been successful in this population in previous studies. Conservatively estimating a retention rate of 80% at the 12-month assessment, we must enroll 138 participants in each group (total N=276). The Seattle Children's ED currently serves approximately 1400 2-12 year old asthma patients per year, 40% (n=530) of whom are Medicaid insured. We estimate that 70% of this total will meet the remaining eligibility criteria (n=371). If 40% of these patients consent to the trial, which is much less than the 60-70% participation rates for Seattle Children's ED-based studies, we will yield our projected sample size of 276 in the proposed 24 month enrollment period. Thus, we estimate that we will need to approach 5-7 parents to recruit at least 3 participants per week, with an estimated recruitment of approximately 12 participants per month (minimum of 6 and maximum of 18 in any given month to assure there is not seasonal over-representation in the study sample).