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Statistical Analysis Plan

Title: Improving Technology-Assisted Recording of Asthma Control in Children (iTRACC)

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Statistical Analysis:

Demographic and baseline characteristics:

Demographic and baseline characteristics including gender, age, race, ethnicity, and co-morbidities will be summarized for each treatment group and overall. The demographic and baseline characteristics summary will be based on all randomized subjects.

Baseline values for efficacy parameters (ACT, quality of life score, PAMSE) will also be presented for each treatment group and overall based on all randomized subjects.

For continuous variables, non-missing will be used to calculate the mean, median, SD, IQR, minimum and maximum by treatment group and overall. For categorical variables, the count and percentages of each possible value will be tabulated by treatment group and overall.

All comparisons of baseline characteristics between treatment groups will be adjusted for potential household clustering using robust standard errors. For continuous variables, comparability of treatment groups will be assessed using general linear models. For discrete variables, comparability will be assessed using the Cochran-Mantel-Haenszel general association test. P-values will be displayed as descriptive statistics of comparability in order to identify potential baseline imbalances with an alpha level of 0.05.

AIM 1. Determine factors influencing clinical and psychosocial outcomes.

Clinical and psychological outcomes of interest include the 12-month rate of asthma-related oral corticosteroid use, ED visits, and hospitalizations, as well as change in mean ACT scores (range of 0 to 27) from baseline to end line (12 months). Psychological outcomes of interest include quality of life score (range of 1 to 7), parental self-efficacy score, and the number of school days missed due to asthma. Potential predictors of outcomes include age (4 to 7 years vs. 8 to 17 years), gender (M vs. F), race/ethnicity (non-Hispanic white, non-Hispanic Black, Hispanic, vs. others), insurance status (private/public), and co-morbidities.

Each count variable (asthma-related oral corticosteroid use, ED visits, and hospitalizations) will be analyzed by mixed negative binomial regression analysis adjusting for treatment, all potential predictors, and including maximal random effect structures (i.e., slope and intercept as allowed by the model) of family and clinic. VIFs (variance inflation factors) will be computed for each predictor.

Highly correlated predictors (i.e. predictors that can be well-explained by other predictors) will be dropped from the model to avoid multicollinearity issues. Model fit criteria, parameter estimates, and precision of parameter estimates will all be evaluated to select the most parsimonious model.

For each continuous primary outcome variable (i.e., ACT score), change-from-baseline score at each visit will be analyzed using mixed linear regression models, adjusting for treatment , time point, baseline score, all potential predictors, and including random effects (i.e., both slope and intercept) of family and clinic. A treatment by time interaction will be included to evaluate whether the effect of the treatment on the primary outcome varies by time point. VIFs will be investigated for each predictor, and those with high VIFs (VIF>=10) will be dropped from the model to avoid multicollinearity issues.

An unstructured covariance (UN) matrix will be assumed. Model fit criteria, parameter estimates, and precision of parameter estimates will also be used to select the most parsimonious model.

Model diagnostics will be performed to check model assumptions.
All analyses will be performed using statistical analytic software Stata Version 15.1.

Missing data and sensitivity analyses:
Missing data will be handled using Multiple Imputations. Sensitivity analyses will be conducted using SAS procedures PROC MI and PROC MIANALYZE. Other sensitivity analyses may be performed if appropriate.

AIM 2. Enhance parental management through improved inhaler use.
After the patient's enrollment visit, parents will be contacted via email or phone at 1, 3, 6, 9, and 12 months to complete a REDCap survey. Descriptive statistics (frequencies and percentages) of each quantitative question will be summarized at each time point and associations between outcomes and demographic predictors will be analyzed by Chi-squared test. Qualitative data will be coded and analyzed by theme analysis.

AIM 3. Improve management by physician and clinical team.
On a biweekly basis, we will collect quantitative data from clinics on the number of time physicians' follow-up with patients and the follow-up outcome. The research team will know exactly how many alerts physicians are receiving, and how physicians are following-up with patients from the Propeller dashboard. The data from the Propeller dashboard will be summarized and associations between outcomes and clinic predictors will be analyzed by Chi-squared test. Clinicians will also be contacted at 1, 3, 6, 9, and 12 months through REDCap surveys to determine if the data is helping them with management and aspects of the platform they like and dislike. Descriptive statistics (frequencies and percentages) from surveys will be summarized at each time point and associations between outcomes and clinic predictors will be analyzed by Chi-squared test.
Qualitative data will be coded and analyzed by theme analysis.