

Title: Improving Asthma Care Together (IMPACT): A Shared Management Pilot Study

NCT #: NCT04908384

Document Date: 03/19/2020

Statistical Analysis Plan

## **Data Analysis.**

**Feasibility.** Eligibility, enrollment, and retention (number who complete study) data will be summarized in a study flowchart. A priori feasibility benchmarks include  $\geq 60\%$  recruitment (eligible dyads who enroll) and  $\geq 80\%$  retention; these benchmarks are based on our previous research (80% recruitment, 86% retention) and similar studies.<sup>106-111</sup> Study withdrawal reasons and timing will also be reported.

**Acceptability.** Participants will rate IMPACT acceptability via Acceptability of Intervention (AIM) survey and semi-structured interview. The a priori acceptability benchmark will be  $\geq 60\%$  of participants rating IMPACT as acceptable (4 or 5 on AIM, table 3).<sup>106-108,111</sup> Additional participant acceptability feedback will be documented via an exit interview. Quantitative data will be summarized using descriptive statistics whereas qualitative data will undergo thematic analysis, described above.

**Analysis of the primary outcomes** (asthma responsibility score, self-efficacy). Descriptive summaries of de-identified data will be transferred into SPSS 24 (IBM Corp, Armonk, NY) for analyses. Distributions of interval and ratio level variables will be checked for normality and transformed as necessary. We will compare characteristics of those who completed the study to those who did not to inform the generalizability of findings. We expect an increase in asthma management responsibility scores and increased dyadic interdependence (i.e. nonindependence of scores between dyads)<sup>103</sup> between parent and child-reported outcomes over time in the intervention group, suggesting true shared management.

**Secondary outcome analyses** will use mixed model ANCOVAs to assess whether the primary outcome variable means, adjusted for baseline scores, differ between intervention and control groups. We predict a group x time interaction such that shared management and health outcome variables (asthma responsibility score, self-efficacy, medication adherence, control, QOL) will increase to a greater extent in the intervention group. Also pursuant to Aim 2, the dyadic effect of the intervention will be tested with the Actor-Partner Interdependence Model<sup>103,112</sup> using structural equation modeling with full information maximum likelihood estimation (FIML). First, the pattern of missing data will be tested to determine if it is missing at random. The FIML method is superior to listwise deletion of missing data points in terms of producing less biased estimates. Next, intraclass correlations (ICC) will be examined for parent and child asthma responsibility, self-efficacy, and general health scores. The APIM produces estimates of actor effects (Person A's pretest  $\rightarrow$  Person A's posttest) and partner effects (Person A's pretest  $\rightarrow$  Person B's posttest). Actor effects are estimated while controlling for partner effects, and vice versa. In these analyses, dyadic interdependence is indicated by statistically significant **partner effects** (e.g., parent pretest  $\rightarrow$  child posttest, controlling for child pretest). Intervention condition will be entered into the model as a dummy coded variable. For each measure taken from both parent and child (i.e., self-efficacy, asthma responsibility) two APIMs will be compared; one in which all of the paths from child variables are constrained equal to their respective paths from the parent variables, and one in which all paths are unconstrained and thus free to vary. Comparison of the fit of these two models indicates whether the effects emanating from the parent are significantly different from those emanating from the child. Parent-child dyads in IMPACT are expected to show stronger **partner effects** than those in the comparison group.