Statistical Analysis Plan

Official Title: Family-Centered Tailoring of Pediatric Diabetes Self-Management Resources

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Data Source

Children aged 8-16 years were recruited from 2 large multidisciplinary diabetes clinics serving both urban and rural populations. We collected A1c data at routine diabetes clinic visits at 9 time points (quarterly during the intervention and for a year after the intervention). Quality of life (QOL) data were collected from parents and children at 5 time points: at baseline, at 3 months after the first intervention session, and at 3, 6, and 9 months after the intervention ended. Fear of Hypoglycemia data were collected from parents at 4 time points: at baseline, at 3 months after the first intervention session, and at 3 and 9 months after the intervention ended.

Analysis Objectives

Applying an intention to treat approach, the primary hypothesis was that outcome trajectories differ between the intervention and usual care arms.

Outcomes

Primary outcomes were trends in A1c for the child, as well as child and parent quality of life. Trend in fear of hypoglycemia was a secondary outcome.

Handling of Missing Values and Other Data Conventions

Rates of missingness were low. Mixed effects regression models were fit via maximum likelihood and were hence robust to non-informative missingness. The influence of informative missing data was evaluated via pattern mixture models. Our evaluations indicated that missing data have no substantial impact on the results of our analyses, so we report results without imputing or modeling missing data.

Statistical Procedures

The primary analytic technique was mixed effects models with repeated measures to capture time trends in intervention and usual care groups via linear terms. Intervention effect was tested via interaction terms between treatment group and time trend, as initially proposed. Trajectories were fit for child's A1c and for QOL for child and parents, as well as fear of hypoglycemia. Preliminary analyses indicated that trajectories differed

between the period during the intervention and post-intervention, so the models allowed the slope of the trajectories before and after the intervention to differ. Outcomes were modeled as continuous, with normally distributed residuals, and within-individual random intercepts and slopes to capture within-individual correlation. Models assuming equal variance of these components in both groups were compared with those allowing unequal variances via likelihood ratio tests. Fixed effects were included in the models to represent block randomization factors (clinic site and age group), and their interactions with time trend were tested.

Measures to Adjust for Multiplicity, Confounders, Heterogeneity, etc.

Two additional variables (i.e., whether the child used an insulin pump and whether the participating parent was the child's mother) were included in the model to correct for imbalance between usual care and intervention arms at baseline. We estimated the average treatment effect for all participants as well as by site and age sub-groups in consideration of potential heterogeneity of treatment effects.

Sensitivity Analyses

Additional covariates (e.g., baseline demographics, healthcare utilization, and comorbidities) were evaluated for inclusion in our models to improve precision. Ultimately, these adjustments for precision made no substantive difference in the study findings, so we report our findings without these covariates.