

Insul-In This Together Program: Optimizing Family-based Interventions for Adolescents With Type 1 Diabetes and Their Parents

Statistical Analysis Plan

NCT04589689

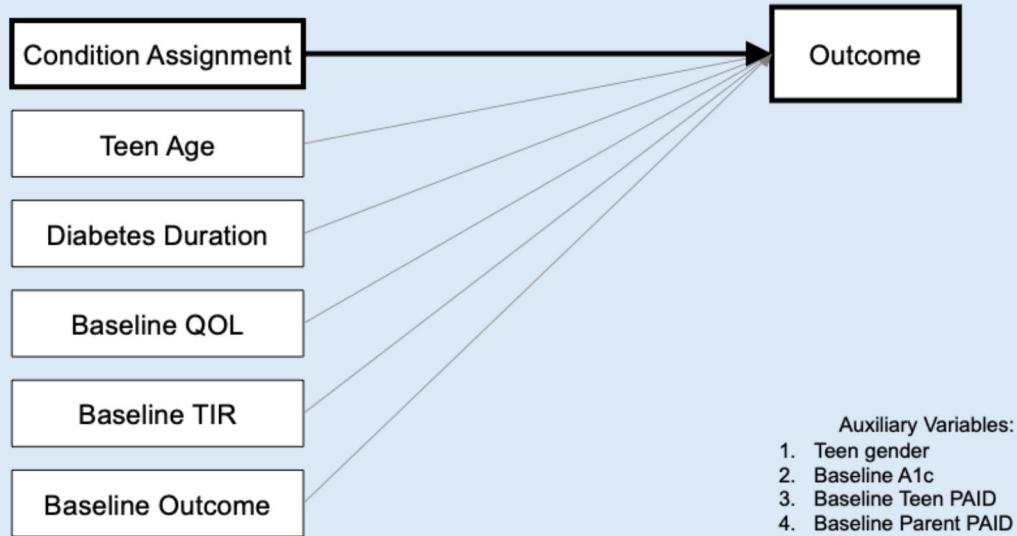
May 11, 2021

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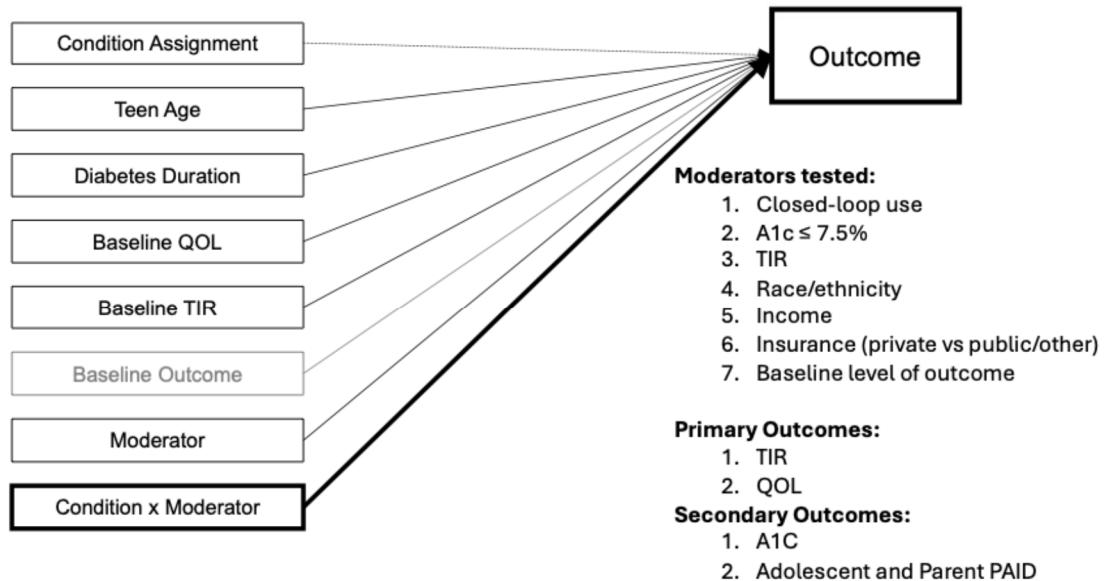
1. Planned sample size was 150 enrolled parent-adolescent dyads. The final sample included 157 parent-adolescent dyads.
2. Basic two-sided t-tests for primary and secondary outcomes using a p-value cutoff of <.05. Compared participants based on condition assignments: intervention versus waitlisted control.
3. Simple regression models: test main effects on outcomes at 3-month and 6-month follow-ups (in Mplus)
 - a. Covariates: Teen age, diabetes duration, baseline TIR, baseline QOL, and baseline outcome (if other than TIR or QOL)
 - b. Auxiliary variables (to inform data imputation, but not directly included in model): Teen gender, baseline A1c, Teen PAID, and Parent PAID
4. Moderation analyses: separate regression models for each outcome that include set of covariates and an interaction term of condition x moderator.
 - a. Covariates: age, diabetes duration, baseline QOL, and baseline TIR
 - b. Outcomes: QOL, TIR, A1c, Teen PAID, and Parent Paid
 - c. Moderators (at baseline):
 1. Closed loop
 2. A1c \leq 7.5%
 3. TIR \geq 70%
 4. Race/ethnicity
 5. Income
 6. Insurance
 7. Baseline level of corresponding outcome
5. Mediation analyses: single mediator models
 - a. Mediator: immediate posttest
 - b. Outcomes: 3-month and 6-month follow-ups
6. 12-month follow-up – combine both conditions and look through 6-months (but for control the 6-month value 12-month value)

Regression Model

6-Month Follow-Up



Moderation Models



Single Mediator Model

