

FAMS Mobile Health Intervention for Diabetes Self-care Support
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NCT 02481596 - Statistical analysis plan

Targeted mediators were helpful family/friend involvement, and harmful family/friend involvement. The primary outcomes were dietary behavior and physical activity and the secondary outcome was diabetes self-efficacy. Analyses followed intention-to-treat principals. Regression models examine change in the outcome of interest adjusted for the baseline value of the outcome of interest with restricted cubic splines (three knots) to allow for a nonlinear effect of the baseline value. We ran separate models to examine the 3-month effects and the 6-month effects. Missing data were imputed using multiple imputation using chained equations to generate m=20 datasets. Between groups analysis compared improvements in the REACH+FAMS group to the control group on primary and secondary outcomes at 3- and 6-months.