REACH Intervention:
Improving Medication Adherence Among Underserved Patients With Type 2 Diabetes

NCT02409329

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NCT02409329 – Statistical Analysis plan

REACH treatment effects – any REACH vs. Control

All analyses were performed using R v.3.5.1. We employed multiple imputation with chained equations to address missing data (m=1,000 imputed datasets). Statistical significance for each hypothesis test was determined at the α=0.05 level. All analyses compare those receiving the REACH intervention (i.e., REACH or REACH + FAMS) to control except for the subgroup analyses estimating additional effects of also receiving FAMS.

We used generalized estimating equations (GEE) with a working-exchangeable correlation structure and identity link (1), adjusting for baseline and allowing a time-treatment interaction. We 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. For each outcome, we performed an omnibus test of the treatment effect using a robust variance-covariance based Wald statistic. We used ordinary least squares linear regression with Huber-White heteroscedasticity-consistent standard errors (2) to obtain point estimates and 95% CIs for the intervention effect on each outcome at each time point.

REACH only and REACH+FAMS vs. Control

Half of the intervention group received REACH only and the other half received REACH+FAMS for the first 6 months. Both intervention groups received REACH only during months 6-12. Data visualizations suggested effect modification by baseline HbA1c, in which those with a higher baseline HbA1c demonstrate a larger estimated effect at 3 and 6 months than those with a lower baseline HbA1c. To increase our power to detect any differential effects for REACH only as compared to REACH+FAMS, we conducted analyses with a subset of data including participants with a baseline HbA1c≥8.5% (69 mmol/mol; n=219), which was the approximate mean value for baseline HbA1c. With this reduced dataset, we conducted the same GEE model described above for REACH only vs. control and, separately for REACH+FAMS vs. control. We used ordinary least squares linear regression with Huber-White heteroscedasticity-consistent standard errors (2) to obtain point estimates and 95% CIs for the intervention effect on each outcome at each time point.

References:

1. Diggle P, Diggle PJ, Heagerty P, Liang K-Y, Heagerty PJ, Zeger S: *Analysis of longitudinal data*. Oxford University Press, 2002.

2. White H: A heteroskedasticity-consistent covariance matrix estimator and a direct test for heteroskedasticity. Econometrica: journal of the Econometric Society 1980:817-838