Title: Coordinating Pragmatic Primary Care Population Management for Obesity

Clinical Trials Record Number: NCT03998046

Date: 6/1/2021

Analysis Plan

Data Sources & Collection: The primary outcome of interest was the percent of eligible patients who commit to a weight goal and reach 5% or greater weight loss at 6 months. Key secondary outcomes include the percent of eligible patients who set a weight goal (regardless of weight loss), and mean changes in pragmatically collected cardiometabolic risk factors. As a feasibility study, we also estimated costs per person per year for intervention delivery.

We assessed the feasible capture of body weight measures from two pragmatic data sources: electronic health records and cellular-enabled, wireless body weight scales (eScales), which were provided to all participants at the time of randomization. We extracted the date and value of all body weight recordings in the electronic health record of each eligible patient participant during the 12 months before his/her study randomization date (each occurred between 12/16/2019 and 1/6/2020). We also extracted the date and value for all body weight measures available from either the electronic health record or from eScale transmissions during the 15-month period after each individual's study randomization. The last electronic health record weight measure prior to the randomization date served as the baseline body weight for constructing the primary weight change outcome variable. The electronic health record weight measure closest to the date of randomization plus 180 days (6 months) was selected for the follow up body weight measure for the primary outcome analysis. For patients who did not have a follow up weight value in the electronic health record between 6 months +/- 3 months, we searched the electronic health record for a weight value between 12 months +/- 3 months. For participants missing 6-month weight values, we imputed their 6-month value as equal to one half the distance between the baseline and 12 month value. For participants missing both a 6- and 12-month weight value in the electronic health record, we used the eScale weight value closest to 6 months +/- 3 months. Finally, if individuals were missing all of these weight values, we assumed conservatively for the primary outcome analysis that the participant failed to reach the 5% weight loss threshold. All blood pressure, A1c, and cholesterol test results were extracted similarly from the electronic health record. As this was a small pilot trial, when analyzing mean change at different time points, we analyzed only those patients with available outcome measures and did not use advanced imputation approaches for replacing missing values.

Statistical Analysis: We examined univariate and bivariate descriptive statistics and conducted chi-square or Fisher exact tests to compare all patients randomized to intervention and control arms on the proportion that reached the dichotomous primary outcome of clinically meaningful weight loss at 6 months. We conducted t-tests to compare all patients with available outcome measures in each study arm with respect to all pre-specified, continuous outcomes (e.g., mean changes in body weight, systolic blood pressure, hemoglobin A1c, total cholesterol, and non-HDL cholesterol). Multivariate models (ANCOVA and multivariate logistic regression) were used to estimate adjusted means (continuous variables) or proportions (categorical variables) for each pre-specified outcome. We explored stratified analyses by age and by sex to understand if preliminary outcome differences appeared to vary with these biologic variables.

Input from health system leaders and study team members were used to identify the principal "ingredients" of study interventions. Inputs included personnel, supplies, contract services, and facility and administrative costs, all from the perspective of the health system. Administrative data on the number and type of contacts made between nurses and study participants, as well as interviews with staff to identify time spent in other activities was used to estimate %FTE spent with patients in each study arm over 6 and 12 months. Costs of eScales and community intervention program fees were estimated from the invoice amounts to estimate cost per person and overall. One-time development or startup costs for health IT was estimated from contract amounts and invoiced payments for work performed. Operational or maintenance costs for IT support was estimated from interviews of IT staff members, who were asked to estimate hours per week spent supporting the intervention components. Research-only costs were excluded from intervention cost estimations. Since many health payers currently reimburse for lifestyle interventions costing between $400 and $800 per person annually, preliminary estimates for intervention costs equal or less than this were considered supportive of health system sustainability and were used as a threshold for proceeding to a larger future trial that will include a more intensive net cost and cost-effectiveness analysis.