

Citizen Science to Promote Sustained Physical Activity in Low-Income Communities

NCT03041415

5/5/2022

Abby C King, Principal Investigator
Stanford University
Stanford, California 94305

Steps for Change Statistical Analysis Plan

Sample size calculation and data analysis plan

Sample size estimates have been developed to test the study's primary question evaluating the potential superiority of the ALED+Our Voice intervention in increasing 12-month weekly walking minutes relative to those achieved in the ALED+health education comparison intervention. Using a two-tailed 95% confidence interval on the effect size (Cohen's d), we will evaluate how the estimated true effect size compares with a critical effect size magnitude, set a priori, reflecting the threshold of clinical significance between the two interventions.

The effect size (Cohen's d) is the standardized difference between the rates of change in total walking minutes/week over the 12-month period. The critical effect size value is based on a clinically meaningful difference between arms of 30 min of total walking per week and a within-arm standard deviation of 90. In enrolling at least 140 subjects per study arm, our final total sample size of 300 will provide greater than 80% power to determine 12-month superiority between the two study arms. Because standard imputation methods will be used for missing data in this intent-to-treat trial, all enrolled participants will in actuality contribute to the study analyses.

Analysis of the primary outcome and secondary outcomes of interest

The data will be analyzed using mixed-effects linear regression models. Mixed-effects linear regression effectively addresses both missing data and early dropout in "intent-to-treat" analysis. Change in 12-month weekly walking minutes is the primary outcome, with centered arm assignment as the independent variable, and the centered baseline value, community housing site, and sex as covariates. To account for the cluster randomization design, community housing site will be included as a random intercept term. Multiple imputations will be performed by replacing missing 12-month values with a set of plausible values using the option of imputation by fully conditional specification methods (ten imputations will be done). Imputation results will then be combined. All reported out-comes will use intent-to-treat (ITT) principles. The 12-month time point was chosen for the primary analysis given that 12 months provides sufficient time for the multi-level intervention to have impacts on local environmental and policy outcomes in addition to person-level out-comes; provides enough time to evaluate program maintenance effects; and controls for seasonal effects given that it occurs during the same time of the year as baseline measurement.

Similar mixed-effects linear regression techniques will be used to address the secondary outcomes of interest, e.g., intervention impacts on additional physical activity variables, clinical measures, physical function, and rated well-being variables, as well as impacts of the interventions at the other assessment time points (6, 18, and 24 months).