

Location-based Smartphone Technology to Guide College Students Healthy Choices (Healthy Detours)
Statistical Analysis Plan
NCT02996864
8/16/2016

H1 (Primary): College students randomized to the Healthy Detours app will have greater improvements in their dietary intake quality compared to college students randomized to the control app at 12-week post-test. HEI index is the outcome. Must be calculated from the ASA24 Secondary interest: the nutritional content tracked by the app

H2 (Secondary): College students randomized to the HD app will report greater increases in their physical activity compared to college students randomized to the control app at 12-week post-test.

IPAQ-SF outcomes – standard scoring Secondary: PA (minutes/day) entered into app Phone accelerometry (any additional wearable data from FitBit)

H3 (Secondary): College students randomized to the HD app will report greater improvements in their sleep compared to college students randomized to the control app at 12-week post-test.

PSQI – standard scoring Secondary - Sleep quality (rating of 0-10 of their daily sleep quality) from app Phone accelerometry (any additional wearable data from FitBit)

H4 (Secondary): College students randomized to the HD app will report greater improvements in their quality of life (QOL) compared to college students randomized to the control app at 12-week post-test.

SF-12

Additional analyses will (1) evaluate immediate changes in the diet, PA, and sleep measures at 6 weeks; (2) assess mediators at 6-weeks for a mediational analysis on 12-week outcomes; and (3) evaluate app usage data (e.g., number of log-ins, number of “check-ins”, EMA responses for likability and satisfaction with the app).

The analyses are heavily descriptive in nature for this feasibility trial. Means (standard deviations), medians (Interquartile range), distributions, frequencies and percentiles, etc. will be used to characterize the major outcome measures. Tests will be performed as per the design using simple t-tests followed by analysis of covariance to assess the outcome results adjusted for baseline (rather than change from baseline). Multivariate analyses will be conducted to assess the simultaneous direction of changes between the treatment arms. We will test the four outcomes simultaneously and examine the correlation amongst them within treatment arms. Hotelling’s T2 will be used to test the overall mean vector of responses. This analysis will utilize the pre and post measures, but additional analyses will be conducted using generalized least squares regression (PROC MIXED in SAS ver 9.3 or higher) to account for missing data (drop outs between 6 weeks and 12 weeks).

Characteristics of dropouts will be intensively examined to shed light on potential weaknesses of the app (differential dropout overall or within certain subgroups). The evaluation of the control app will include its impact using the pre-post data. This will provide information on the choice of this app as the relevant control population. As noted, examination of the correlation matrices along with the mean changes will inform whether the variables appear to move similarly in both groups. Thus, one might argue that it not necessarily the best control choice since we would then be measuring the intensity of intervention. Alternatively, very different correlation structures will inform us about how the interventions are working and may provide information on appropriate controls and or strengths and weaknesses.

Utilization data will be examined to understand the acceptability and intensity of interactions with the apps. The penetration of the apps into this young at-risk population is very important in potentially understanding, not only market share, but also potential impact. Complier average causal effect models²¹⁷ will be used to examine the intensity of the intervention app's utilization. Mediation models using the latest bootstrapping methods^{218,219} will be examined to enhance evidence that the changes induced by the treatment effects are consistent with the changes being mediated via the app and the Healthy Detours intervention.