Title: Retail Outlet Health Kiosk Hypertension Trial (ROKHyT)
Registration#: NCT03515681
Protocol Version Date: 15APR2019

Statistical Analysis Plan

The overall goal of the R34 pilot grant is to develop pilot data for an application for a fully powered trial. The intervention using interactive text messaging will be compared to current information provided in the context of higi installation (usual care). The primary endpoint will be hypertension control defined as < 149/90 mmHg at 12 months post randomization. Measurements will also be obtained at 3- and 6-, months post randomization.

The specific aims are shown in table 1.

Table 1. Specific Aims
1. Develop and pre-test the intervention text messages
2. Pilot the enrollment, consent, randomization, and data collection procedures at baseline and 3, 6, and 12 months and document participation and completion rates in a randomized pilot study of N=70 per group.
3. Obtain demographic data on potentially eligible participants using an on-line questionnaire.
4. Pilot test the text messaging intervention and document blood pressure control rate in response to the intervention.
5. Pilot test secure data transfer and other data coordinating center (DCC) functions.

Aim 1. No statistical analysis.
Aim 2. The numbers enrolled, consented, and randomized will be tabulated.
Aim 3. Demographic characteristics will be tabulated.
Aim 4. The proportion in each group (intervention and control) achieving blood pressure control at 12 months will be tabulated and the difference between these proportions will be calculated. Control will be defined as systolic blood pressure <140 mmHg and diastolic blood pressure <90 mmHg. A Mantel-Hanzel relative risk with adjustment for stratification will be calculated comparing the two groups. In addition, the proportions achieving blood pressure control at 3-months and 6-months follow-up will also be tabulated. Formal statistical testing will not be done because the pilot study is not powered for hypothesis testing.
Aim 5. No statistical analysis.