Cover Page
Study Title: Twitter and Cardiovascular Health
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Re: Statistical analysis plan
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Protocol (Twitter and Cardiovascular Health: Twitter and Hypertension)

Background

Cardiovascular (CV) disease remains the leading cause of morbidity and mortality in the US and is associated with significant economic burden. While there is effective medical treatment for hypertension (HTN) in the form of prescription medications, blood pressure management is likewise dependent on several lifestyle choices. A patient's diet, exercise, monitoring of symptoms and adherence to medication (activities that occur outside of the physician's office), have an effect on clinical outcomes. Social media channels like Twitter offer a new opportunity to explore health related communication generated by the public and for the public about areas such as HTN and its management.

Objectives

This project leverages Twitter, a public online platform, to study if there is a potential benefit of tweeting regularly about health. We will ask patients with a diagnosis of HTN and elevated BP to regularly tweet about health content and evaluate if this intervention will improve their perceived disease management and their systolic blood pressure over a six-month timeframe.

Methods

We will identify patients greater than or equal to 21 years of age, with known HTN (ICD-9 code 401.9) from a single health system. These patients will then be contacted via email. Eligibility questions include: greater than or equal to 21 years of age, not pregnant (self-report), a diagnosis of hypertension and a Twitter account or willingness to create an account for the study.

Eligible patients who consent to participate would then complete a baseline survey and be randomized to the control or intervention group. Randomization will occur via a computerized randomization program in a 1:1 allocation ratio not accessible until after collection of baseline data.

Survey compensation of a gift card worth $25 would be provided for completion of the final survey at 6 months. Baseline and follow-up surveys will include questions regarding patient activation (PAM-13), self-rated health (SF-1), ideal CV health (BRFSS), HTN self-care practices and demographics. To assess technology use, we will also ask questions from the *Perceived usefulness*, and *Perceived ease of use* surveys. Patients will also consent to having their electronic health records accessed to validate clinical data (e.g. blood pressure (BP), BMI).

Control: The control group study participation would include completing a baseline survey and a survey 6 months later.

Intervention: Participants randomized to the intervention group will be asked to follow the study Twitter account, tweet or retweet health content twice per week using #health and complete a survey at study initiation and 6 months later. Participants will be sent weekly reminders to tweet.

Outcome measures: The primary outcome measure will be change in systolic blood pressure (5mm). The secondary outcome will be patient activation measured by the PAM (a measure of behavior change that has been shown to be changeable over time). Baseline variables will include demographic variables (gender, age, race/ethnicity, and geographic region of residence).

Sample size: Sample size estimates based on the ability to detect a 5mmHg difference in systolic blood pressure at 90% power and type I error of 0.05. We planned to enroll approximately 240 in each control and intervention group, for a total of 480 participants, accounting for a 35% lost to follow up for an online Twitter intervention (total up to 648).

Data analysis: We will use summary statistics to compare demographics and survey responses (health status, ideal CV health status, self-practices perceived usefulness/ease of use) between groups. Categorical variables will be presented as frequencies and percentages and continuous baseline variables will be presented as means and standard deviations (if skewed these will be presented as medians and interquartile ranges).

Our primary outcome will be a 5mmHg change in systolic blood pressure from baseline to study end at 6 months. We will conduct an intent-to-treat analysis. We will use paired t-tests to compare the mean difference in SBP between the intervention and control groups. We will also conduct a multiple linear regression analysis for change in SBP adjusting for covariates which may be imbalanced even after randomization to improve efficiency of our estimates. We will also adjust for baseline SBP. The distribution of change in SBP will be assessed and if it is non-normal (skewed) we will use an appropriate transformation (such as natural log) or we will use a generalized linear model with appropriate family and link choices to model our outcome.
For the secondary outcome measure, we will use paired t-test for pre-post differences of PAM scores. A multiple linear regression model will also be used to account for additional imbalances in demographic and baseline health characteristics not evenly distributed by arm. In all models, a binary indicator for control/intervention group will be included. Baseline PAM score will also be adjusted for in the model. Covariates with missing data will be assessed for patterns of missingness and non-ignorability and will be multiply imputed if deemed necessary and reasonable.