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Study Title: Twitter and Cardiovascular Health

NCT: NCT02806700

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Re: Study Protocol

Last update 4.10.2018

Study Protocol (Twitter and Cardiovascular Health:Twitter and Diabetes)
submitted prior to data analysis or un-blinding

Background

Cardiovascular (CV) disease remains the leading cause of morbidity and mortality in the US and is associated with significant economic burden. To advance against this major public health problem, the American Heart Association (AHA) and others have identified the need for a targeted focus on improving the CV health of populations, emphasizing “an array of new tools and competencies for implementing public health policy and population- and community-level interventions to complement the traditional, predominantly medically oriented interventions that have been promoted successfully in the past.” Social media channels like Twitter offer a new opportunity to explore health related communication generated by the public and for the public.

While effective therapies are available for diabetes mellitus (DM), disease management is often poor. Outcomes are often determined by patient activities outside of the clinical encounter such as diet, exercise, symptom monitoring, and medication adherence. Several approaches (e.g. self-care courses, home tele-monitoring) have been tested for aiding patients but are often resource intensive, and effectiveness trials have had varied results. Strategies with targeted text messaging, however, have shown promising results for improving clinical outcomes, patient satisfaction, improving health care utilization, and reducing healthcare costs.

Objective

For this study we seek to use Twitter, a public online platform to deliver health content over 6 months to participants with self-reported diabetes and evaluate the potential impact of this messaging on patient activation (a patients’ reported ability and willingness to take on the role of managing their health and healthcare).

Methods

We will identify participants with self-reported diabetes online. Participants will be identified through: self report on Twitter (e.g. “I have diabetes”), use of diabetes related hashtags and keywords on Twitter, ads posted online (e.g. Google, Reddit). Potential participants will then be “followed” on Twitter and privately direct messaged with a link to the study website. Ads would similarly include a link to the study website.

Individuals clicking on the study website would be directed to complete eligibility assessment questions. Eligibility questions include: age >21, self-report of diabetes, not pregnant (self-report), US residency.

Eligible patients who consent to participate would then complete a baseline survey and then be randomized to the control or intervention group.

Survey compensation of a \$25 dollar gift card 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), self-care practices for DM (Summary of Diabetes Self-Care Activities Measure). To assess technology use, we will also ask questions from the *Perceived usefulness*, and *Perceived ease of use* surveys.

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

Intervention: Participants randomized to the intervention group will be asked to “follow” the study team (e.g. @study handle). Once participants are “following” the study team, participants would receive 3x per week private messages via Twitter about heart health.

Twitter heart health messages will be identified via an automated program, which locates highly shared (i.e. retweets) tweets which contain the keyword “diabetes.” The 50 most retweeted in a given day (with a minimum 6 hour lag time to accumulate retweets) would then be curated by our team and 3 would be shared with participants 3x a week. We will use hand coding to describe themes associated with the curated tweets displayed to participants.

Outcome measure: The primary outcome measure will be patient activation measured by the PAM (a measure of behavior change and has been shown to be changeable over time). Predictor variables will include demographic variables (gender, age, race/ethnicity, and geographic region of residence), SF1, HbA1c. The secondary outcome will be change in self-reported HbA1c.

Sample size: Sample size estimates are based on the PAM measure. Assuming a 2-3 point change in the index PAM score (average 58) we estimate requiring 75 patients per arm to allow detection of this difference with 90% power and a type I error rate of 5%. We assume potentially 30% over-enrollment for loss to follow-up for a Twitter intervention.

Data Analysis: We will use summary statistics to compare demographics and survey responses (health status, ideal CV health status, self-practices) across groups. Summary statistics will be used to present data from the Perceived usefulness and Perceived ease of use measures for the intervention group.

For the primary outcome measure, we will use paired t-test for pre-post differences of PAM scores. In addition, multivariable linear regression models will be used to model change in PAM score with adjustment for 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.