Statistical Analysis Plan
TEXTMED-FANS
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Introduction:

This statistical analysis plan contains This data analysis plan (DAP) contains definitions of study period, study groups/cohorts, data elements and statistical methods for understanding the effects of an intervention to improve diabetes specific behaviors and glycemic control among Emergency Department patients with poorly controlled diabetes.

Background:

Although diabetes is a nationwide epidemic, US Latinos are a particularly vulnerable population. Latinos are more likely than non-Latino Whites to develop diabetes and have higher rates of diabetic complications and diabetes related mortality.[1,2] This disparity is prominent in Los Angeles County, where almost half the residents are Latino, and diabetes prevalence is higher than the national average. [3,4] Patient with diabetes who rely on the Los Angeles County + University of Southern California Emergency Department for care are a high need population, with poor glycemic control, low diabetes knowledge, and limited access to care.[5] These patients are not often adequately served by the current healthcare system, and require dedicated attention to address their unique health needs and barriers to care.

Culturally and linguistically appropriate interventions can combat this disparity, especially social support interventions. Training family members and peers to support patients with diabetes has been shown to improve patient motivation, healthy behaviors and glycemic control,[6-10] and is accepted by Latino populations.[11-13] However, traditional social support interventions require in-person training for family and friends, as well as physical space and personnel for training.

Additionally, support training is often provided to the most proximate people to the patient with available time, rather than the most influential person identified by the patient. In-person training also limits scalability in populations with limited transportation and financial resources. Strategies to decrease these barriers are needed; mobile health (mHealth) may be a solution.

mHealth is the use of mobile phones to provide public health and medical solutions. mHealth interventions improve disease management of chronic illnesses, including diabetes.[14-17] However, existing app-based mHealth interventions require smartphones, which are not widely used in resource-poor communities such as safety-net emergency departments (EDs).[18] However, Latino populations have high rates of mobile phone ownership, text-message use, and access health information via mobile phones more frequently that other digital sources.[19,20] Latino patients from low-resource settings have enthusiastically joined text-message and interactive voice-recording interventions to improve diabetes self-care.[21-23]

ED care is an opportunity to reach patients and families during a health crisis, when they are susceptible to behavior change.[24] As emergency care is more expensive than healthcare in other sites,[25] ED interventions should maximize the benefit of these visits through improved behaviors and health outcomes. ED-based interventions can also bridge patients until primary care can be established for those lacking primary care, or during the wait for the next visit for patients with limited access to a primary care provider.

In this statistical analysis plan, we describe the design and analysis procedures for the randomized controlled trial TExT-MED+FANS (Trial to Examine Text-Messaging in Emergency patients with Diabetes+ Family and friends Network Support), adding a mobile social support module, FANS to the TExT-MED intervention to provide emotional context and highly personal touch. TExT-MED+FANS uses mHealth to overcome the transportation and time obstacles that social support solutions face by offering social support training via a mobile platform. Using mobile training, a patient can select the most influential person to support them, rather than the most proximate.

Study Objectives:

Primary Objective:

1. Examine the change in percent glycosylated hemoglobin at 6 months for FANS supported patients vs non-augmented support patients.

Secondary Objectives:

1. Examine the change in percent glycosylated hemoglobin at 12 months for FANS supported patients vs non-augmented support patients.
2. Examine changes in psychosocial and behavioral outcomes at 6 and 12 months for FANS supported patients vs non-augmented support patients.

Study Design:

In this twelve-month, comparative effectiveness randomized controlled trial (enrollment period July 2017 to October 2018), ED patients with poorly-controlled diabetes mellitus from an urban,

safety net medical center were randomized to one of two arms: [1] an mHealth intervention for self-management education augmented by mHealth augmented social support (TExT-MED+FANS) or [2] the same patient-oriented mHealth intervention with minimally augmented social support (TExT-MED + pamphlet).

Patient recruitment

Patients were recruited from July 2017 to October 2018. IRB approval for this study was obtained prior to study initiation from the USC Health Sciences Institutional Review Board. This study enrolled ED patients with both type I and type II diabetes at LAC+USC (Los Angeles County + University of Southern California Medical Center). ED patients with diabetes in this healthcare system have been found to have poor glycemic control, poor diabetes specific knowledge, and poor access to primary care.[5]

Screening, Eligibility Criteria and Recruitment

Table 1: Eligibility criteria for participants

Exclusion Criteria
Psychiatric involuntary hold, or in police custody
Altered mental status
Clinically unstable to consent and complete baseline assessment
Inclusion Criteria
Age 18 or greater

Stable ownership of mobile phone
Able to send and receive text messages
Reads English or Spanish
A1C 8.5 or greater
Identifies a support person who can be contacted within 2 weeks to enroll

Trained research assistants (RA) conducted screening and enrollment during the daytime and evening hours in the LAC+USC ED. They surveyed the ED electronic patient tracking system for patients with diabetes. Inclusion and exclusion criteria are listed in Table 1. Only subjects with A1C ≥8.5% were enrolled in this trial, as these patients have the greatest need for intervention and potential to demonstrate beneficial intervention effect. The A1C-based eligibility requirement was verified in the emergency department during the patient's visit, using the Afinion AS-100 capillary point-of-care A1C meter (Axis-Shield PoC AS, Oslo, Norway). Patients who reported both type 1 and 2 diabetes were enrolled, as prior work with this population has shown that 30% of patients are unsure which type of diabetes they have.[5] RAs explained the purpose of the study and obtained written informed consent in the language of the patient's preference. To be eligible, patients had to identify a family member or friend to agree to serve as a supporter. Patients were aware at enrollment that the designated supporter could receive multiple text-messages per day, and would be prompted to offer increased support.

Enrollment & Randomization

The goal of this investigation is to study augmenting existing social support via mHealth, so patients were only eligible to be enrolled in the study if a supporter agreed to participate as well; however, this took up to three weeks to contact and enroll the supporter. Given the potential lag, all potentially eligible patients were registered in the SHERPA platform used by Agile Health while in the ED. Occasionally, patients lacked cellular service in the ED and were not able to text-in the Federal Communications Commission-required YES message to opt in during their initial ED visit; we texted and called these patients daily for up to one week until they texted back in YES. The supporter was not contacted until after the patient was fully registered in the system. If a supporter was not eventually enrolled as well, the patient still received the patient text-messaging program, however they were removed from further participation in the study.

Supporters were enrolled either in the ED during the initial contact with the patient or remotely by telephone if they were not present in the ED. Each patient was instructed to rank up to three family or friends who would provide them the most support. As the intervention encourages communication between a patient and a supporter, only one supporter was enrolled per patient to not overwhelm patients with suggestions for healthy living from multiple loved ones. We collected multiple contact numbers for each potential supporter from each patient. We called daily for up to three weeks to enroll supporters.

Enrolling supporters consisted of verbal consent, confirming age>18 and the ability to send and receive text messages, completion of supporter survey instruments and registration in the

SHERPA platform. Registration in the SHERPA system required a YES text back from the supporter. If the supporter did not respond with the required text-in YES message, we called them daily to remind and assist them with completing registration. After supporter enrollment was completed, the dyads were randomized to the FANS mHealth-augmented social support or pamphlet-based social support education for the supporter. All patients received the TExT-MED patient program.

Classification of Study Groups:

1] **Intervention Group:** Patients who received an mHealth intervention for self-management education augmented by mHealth augmented social support (TExT-MED+FANS) sent to an identified loved one

[2] **Active control group:** Patients who received the same patient-oriented mHealth intervention with minimally augmented social support (TExT-MED + pamphlet)

Study Measures, Definitions and Rationale for Selection:

Clinical Outcomes and Biologic Measures:

Glycemic control is measured by hemoglobin A1C collected at point-of-care from an Afinion AS100 capillary point of care machine. The Afinion machine has excellent point of care correlation with laboratory values. As a surrogate for average glycemic control over the previous 3 months and with correlation with clinical outcomes, hemoglobin A1c is a marker of overall clinical disease management.

Systolic blood pressure mmHg: Blood pressure is measured by study RAs after the patient is seated for 5 minutes, with the average of three readings used as the systolic blood pressure for that visit. Systolic blood pressure is associated with cardiovascular complications

BMI: calculated from Weight and Height. As a measure of adiposity, it correlates positively with cardiovascular disease outcomes. While imperfect, it is an easily measured and validated marker.

Weight in lbs. Participants are weighed on the same scale at enrollment and follow up assessments, without shoes or overclothes. If patient is unable to stand at time of enrollment due to pain or illness, weight as recording by nursing staff in the medical records will be used.

Height: measured by RAs at enrollment without shoes while participant is standing.

Abdominal circumference (cm): A measure of central adiposity, it correlates with cardiovascular outcomes.

<u>Healthy behavior measures:</u>

Summary of Diabetes Self-care Activities [26]. The Summary consists of 6 subscales representing different domains of diabetes related healthy behaviors and self-care. It has been validated in over 10 studies, with the results published in two manuscripts: one with three studies [27], and

one with seven studies[26]. Each measure ranges from Each range from 0-7, indicating number of days per week patient reports engaging in these behaviors.

1. Following a generally healthy diet
2. Following a disease specific diet plan
3. Spacing carbohydrates throughout the day
4. Getting sufficient physical activity
5. Checking feet daily for wounds
6. Self-monitoring blood glucose as advised by a healthcare provider

Medication adherence (Wilson 3 item Medication Adherence scale) [28]. The three-item medication adherence scale is a self-report measure that assesses the number of days of medication missed in the last month, the frequency of medication taking, and asks patients self-rate their medication adherence. Initially developed in HIV research, it has been validated for non-HIV medications with electronic drug monitoring and other adherence measures [29]. An individual's total score ranges from 0-100. It is the combination of three sub-scores (days missed dose (negative scored), self-rating, days taking medications as indicated).

Healthcare utilization by the patients' report of clinic appointments, ED visits and hospitalizations with in the 6 months prior to enrollment at each follow up visit. This self-report will be confirmed by a manual review of the electronic medical record.

<u>Psycho-social measures:</u>

Self-efficacy (Diabetes Empowerment Scale Short Form) [30], is a measure of a patient's overall diabetes related self-efficacy, shortened by the original from 37 to an 8 item scale. It has reliability of alpha=0.84; and has been shown to be sensitive to change in multiple populations and is correlated with improved glycemic control measured by A1C [30]. It ranges from 8-40 points; higher score indicates higher self-efficacy.

Diabetes related distress (Diabetes Distress Scale) [31], is a 17 item scale measuring distress related to emotional burden, physician-related distress, regimen-related distress, and diabetes-related interpersonal issues. It has a Cronbach's alpha of 0.88-0.93 in various studies. Higher scores are negatively correlated with several healthy behaviors. Each question is a Likert scale ranking of how serious a particular issue is from 1-6, 6 indicating a more significant problem. The scores are then averaged across all item, with final scores ranging from 1-6, with 6 indicating higher levels of distress.

Depression as measured by the PHQ-9 [32], is a widely used scale of depression used in clinical practice and research. The Cronbach's alpha ranges from 0.86-0.89, and it has been validated in multiple languages. Higher levels of depression are associated with fewer healthy behaviors and worse glycemic control.

Fatalism is measured by the Diabetes Fatalism Scale [33], which measures three subscale emotional distress, religiosity and coping and perceived self-efficacy. The total score has a

Cronbach's alpha of 0.80 and ranges from 12-72, higher score indicates higher fatalism. The score is associated with glycemic control, depression, self-care behaviors and social factors.

Quality of life (World Health Organization WHO-5 Well Being Index) [34] is a widely used measure of quality life, validated in many languages and consists of only 5 items.

Social support measures:

Diabetes-related supportive and obstructive family behaviors are measured by patient report on the Diabetes Family Behavior checklist [35]. Family behaviors: supportive and non-supportive sub-scores of the Diabetes Family Behavior Checklist: supportive ranges from 4-45, non-supportive ranges from 7-35.

Diabetes-specific social support is measured by the Diabetes Care Profile Support Questions,[36] with sub-scores for perceived disease specific support needs and perceived disease specific support received. Diabetes Care Profile support questions: Support wanted, and support received. Each range from 5 to 30, high scores indicating high desire for support and higher support received.

General social support is captured by the Norbeck Social Support Questionnaire Emotional and Tangible subscales.[37] General social support: Norbeck Social Support Questionnaire, emotional sub score (ranges 0-16, with higher scores indicating higher perceived emotional support) and tangible sub score (0-8, higher score indicating higher perceived tangible support). While the

sub scores are highly correlated, the authors do not recommend Cronbach's alpha as a test of internal validity. However the Pearson correlations between the emotional support items was 0.96 and the tangible support items was 0.89. (http://eileengigliotti.com/uploads/1/1/0/2/110241155/nssq-psychometric.pdf)

Supporter diabetes-related distress is measured by response to the Partner Distress Scale[38], which was initially developed for partners of patients with type 1 diabetes, but is used in this expanded support context with permission of the scale author. The self-report scale consists of 21 items in four domains: "my partner's diabetes management", "how best to help", "diabetes and me", and "hypoglycemia". The Cronbach's alpha was 0.76. It has not been previously validated in Spanish speaking population. For this study, the scale was translated and back translated by separate 2-person native Spanish speaking teams. Greater partner distress is correlated with higher A1C among patients and worse self-care, as is lower satisfaction with relationship with the partner

Report of frequency of patient-supporter contact and proportion of communication that is about diabetes is collected from the patients and confirmed by collecting this information from the supporter as well.

<u>Potential modifiers at baseline</u>

Mobile technology use: Mobile technology use will be measured by questions modeled after the Pew Hispanic Center survey[19] with the addition of questions about frequency of contact between the patient and supporter, and the proportion of communication that is about diabetes. Supporter mobile usage is also captured with the Pew questions.

Health literacy: Health literacy is measured by the Brief Health Literacy Screen developed by Chew, et al.[39] This screen has been validated in English and Spanish speakers.

Age: collected from medical records

Ethnicity: Collected by patient self-report, with option for decline to state

Race: collected by patient self-report, with option for more than one race and decline to state

Statistical Analysis

Primary and Secondary Outcomes

The primary outcome in this trial is the change in A1C from baseline to six-months, with a priority secondary outcomes of change in A1C from six to twelve months, with the exposure of interest of TExT-MED+FANS.

Preliminary Analysis

Normality of the outcome variable (six-month change) will be graphically evaluated.

Hypothesis Analysis

Initial changes in outcomes (primary and secondary) will be compared between groups with paired t-tests. This will be following by a longitudinal methods with a mixed effects regression model to account for correlated outcome data (zero-six month and six-twelve month changes) and loss to follow up. Analyses will be conducted by intent-to-treat, with participants analyzed according to their randomized intervention regardless of adherence.

Because change in A1C is the outcome, participants who drop out prior to six-months will not be included in the analysis. All participants who complete the twelve-month study will provide two outcome measures of six-month change: a zero-six month measure of treatment efficacy, and a six-twelve month measure of sustainability of treatment effect. The linear mixed effects model will include a random intercept term for participants. Fixed effects will include treatment allocation, initial level of A1C (zero month measure for treatment efficacy, six-month measure for sustainability), and a covariate of study period (zero-six month, six-twelve month). The main effect of treatment will test for group differences over both zero-six and six-twelve month periods. An interaction term of treatment by study period will test for differences in treatment effects by study period; treatment effects will be estimated and tested for differences by study period in this interaction model. Model assumptions including normality of model residuals and homogeneity of variance will be evaluated. A sensitivity analysis confined to adherent participants (those who have not opted out of messages and have received 75% or greater of messages confirmed by message delivery platform) will be conducted. Mixed effects linear regression models will be conducted on secondary outcomes as detailed above.

Planned Subgroup Analysis:

To determine if subgroups of participants are differentially affected by the intervention, secondary analyses evaluating intervention moderators are planned. For A1C and each of the secondary outcomes, interaction terms (randomized intervention-by-moderator product terms) will be added to the mixed effects linear models described above. Variables evaluated as moderators will include gender, language preference, years with diabetes, baseline frequency of mobile usage, physically proximity to supporter, baseline social connectedness, and baseline support. If any of these factors indicate significant moderation, intervention effects will be estimated by levels of the moderator. Secondary analyses of the primary A1C outcome will use structural equation modeling to evaluate the secondary behavior and efficacy outcomes as mediators of the TEXT-MED+FANS intervention. Initial analyses will evaluate the associations of changes in behavior and efficacy variables with change in A1C using mixed effects models as detailed above. The A1C mediating model will then include randomized intervention, baseline A1C, any moderating variables detected above, and change in a behavior or efficacy outcome as a possible mediator. Mediation will be tested with bootstrapped samples, evaluating the direct and indirect (mediated) effects of changes in behavior and efficacy outcomes.[40,41] The final model will include significant moderators and mediators of the TEXT-MED+FANS effect on A1C.

Additionally, after completion of enrollment, substantial differences in baseline support and contact between patients and their selected supporters became evident, as some supporters took up to three weeks to enroll. We now plan on conducting a sub-analysis based on

supporter immediate availability for enrollment versus delayed enrollment.

Study Limitations:

There are several limitations in this study:

1. Assessing “dose” of messaging may be difficult, as per current report from Agile Health, there have been no messages bounced back. They believe this is due to the lower tier cell phone providers used by some participants, which do not accurately report incoming and dropped messages.
2. Healthy behaviors are measured by self-report.
3. We did not include a social desirability measure in baseline data, so assessing for potential social desirability bias in responses would be difficult.
4. The setting of this study is very specific and limits generalizability to larger populations.

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