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Document:

Protocol and Statistical Analysis Plan

Official Study Title:

Dulce Digital-COVID Aware (DD-CA) Discharge Texting Platform for US/Mexico Border Hispanics With Diabetes + COVID-19

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DD-CA Protocol

The Dulce Digital-COVID Aware (DD-CA) study will enroll a total of 172 COVID + and – Hispanic patients with type 2 diabetes according to the inclusion and exclusion criteria outlined below. This study compares discharged patients requiring on-going glucose management who receive a proven texting platform with added COVID-related messages versus discharged patients requiring on-going glucose management who do not receive COVID educational messaging using a digital texting platform.

Inclusion criteria:

- Are a patient admitted to a Scripps Mercy Hospital
- Self-identify as Hispanic/Latino
- Are 18 years of age or older
- Speak English or Spanish
- Have type 2 diabetes diagnosis and A1c ≥ 7% in the last 30 days
- Have a cellphone that can receive/send text messages

Exclusion criteria:

- Are pregnant
- Are currently participating in another diabetes or COVID-19 related study
- Do not meet all eligibility inclusion criteria

Research staff review automated electronic health record (EHR) reports to identify potentially eligible patients. Once a patient is determined eligible according to EHR-based study criteria, the attending physician is contacted to approve inclusion in the study. If the nursing staff approved and indicate anticipated discharge to home in <24 hours, the patient is asked if he/she is willing to discuss the study with the research staff. Patients interested in the study are approached by a trained bilingual staff member while inpatient. Patients who are deemed eligible to participate in the study are provided with a copy of the consent form and review all content together with the staff member in Spanish or English (depending on potential participant's language preference). Adequate opportunity is provided to the potential participant to consider all options and ask questions; care is taken to ensure that all participants understand the information and that their participation is voluntary.

After consent is obtained and the patient is enrolled to the study, research staff verbally administer the baseline survey, then unveil the group assignment (enclosed in sealed envelopes by the statistician) to the patient: Intervention group (DD-CA + DTS) or Usual Care group (DTS). Each participant is assigned a unique ID number for de-identification purposes.

For all participants, a routine referral is placed to the Diabetes Transition Service (DTS) program, which is a standard service offered to patients with diabetes approaching discharge from Scripps Mercy Hospital. As part of DTS, participants receive pre-discharge diabetes education from a certified diabetes care and education specialist (CDCES). Within 10 days of discharge, participants are contacted by a DTS health coach using a standardized protocol to coordinate care with outpatient health and other community resources to collaborate with participants in overcoming barriers to accessing these resources. The DTS health coach also provides important training on glucose pattern and excursion recognition. For participants in the Intervention group, the glucose control review/feedback is informed by glucose data that is wirelessly transmitted via the study meter and populated in the study dashboard. In Usual Care

this review/feedback is based on participants' self-report of recent glucose values. Aside from this difference, standard DTS delivery is otherwise constant across intervention groups.

In addition to the DTS program described above, participants assigned to the Intervention group (DD-CA) receive an evidence-based text message-based diabetes self-management education and support in their language of preference (Spanish or English), which consists of educational, motivational and medication adherence messaging. The messaging is supplemented by COVID-related support content and is tailored to address identified barriers in Hispanic underserved communities (e.g., obtaining testing supplies and medications, accessing routine medical care, and completing other important diabetes self-management behaviors such as healthful eating, exercise, social distancing, quarantine, and stay-at-home/lockdown guidelines).

The EHR of all study participants will be audited for specific information relevant to the trial including hospital readmission rates within 30 (primary outcome), 90 and 180 days, length of stay for 30-day readmissions, healthcare costs, patient descriptives, and other relevant clinical metrics (e.g., HbA1c).

All participants are asked to complete three assessments of approximately 15-20 minutes duration at baseline/prior to hospital discharge, and at 90 days and 180 days by telephone.

Data collected during all assessments will include the following patient-reported indicators:

1. Demographic information (study-specific/standard item)
2. Diabetes distress, measured using the Diabetes Distress Scale
3. Diabetes self-management behaviors, measured using the Summary of Diabetes Self-Care Activities Survey
4. Patient-reported physical and mental health, measured using the Patient-Reported Outcomes Measurement Information System Global-10 Health Scale (PROMIS)
5. Knowledge and attitudes towards COVID-19 and COVID-19 diagnosis status, measured using the COVID-19 Patient Survey (Phenix toolkit).

The RE-AIM framework will be used to evaluate the success of the DD-CA versus Usual Care in 1) Reaching a representative segment of the population (Reach); 2) Achieving meaningful outcomes through a well-implemented intervention (Efficacy/Implementation); 3) Creating an intervention that can be adopted by and maintained in a real-world environment (Adoption/Maintenance). As part of the process evaluation, participants from both groups are invited to participate in a telephone-based survey to assess patient experiences and satisfaction related to specific aspects of the study (e.g., content of text messages, receiving and responding to text messages, follow-up phone calls from health coach and diabetes educator) at the conclusion of their 6-month participation in the study. After verbal consent is obtained, study staff interview the patient using a survey script that will take approximately 20-25 minutes to complete by telephone.

Study participants will be offered gift cards as an incentive for completing all follow-up assessments. Participants will receive a $30 gift card for completing the surveys and labs after 90 days and $40 gift card for completing the surveys and labs after 180 days. The total incentive for each participant who complete all follow-up assessments (at 90 and 180 days) is $70. In addition, participants will be offered a $30 gift card for participating in the telephone-based process evaluation survey.

Statistical Analysis Plan

The statistical software G*Power was used to estimate the sample size needed to detect differences between groups (DD-CA vs. Usual Care) for the primary outcome, rate of readmission within 30 days post discharge in the proposed randomized-controlled trial. From a pilot study in a similar population, we determined that an absolute reduction of 20% of patients readmitted within 30 days between the two groups would be clinically meaningful based on an estimated 40% readmissions rate within 30-days in the UC arm. Participants will be 1:1 randomized between the study arms, and group assignments will be determined by a random number generator and provided in sealed envelopes to prevent selection bias. Additional assumptions include one-sided alpha = 0.05, and power = 0.80. We estimate maximum of 15% of participants being excluded from analyses due to loss to follow up or request to withdraw. Given these assumptions, *N* = 172 participants are needed to detect a difference in readmission rates of this magnitude between study arms by a Fisher's Exact test.

The statistical software R and SPSS will be used for all analyses. Patient-reported indicators and clinical will be compared between groups to assess randomization among study arms by Chi-squared tests of proportions to compare categorical variables and student's *t*-tests to compare continuous variables. For our first aim we will compare rates of readmissions between the DD-CA and Usual Care groups within 30 days of discharge following study enrollment. The electronic medical records will be used to identify admissions for any patients in the study during each patient's unique follow up period. Unadjusted between-group differences will be analyzed by comparing proportion of patients with any hospital readmissions within the 30-day period by a Fisher's exact test.. For our second aim we will compare glycemic control between groups through HbA1c measurements captured for each study participant 90-days post discharge. Unadjusted group mean differences in HbA1c at each of the two timepoints will be assessed with a student's *t*-test.

Our secondary outcomes will be measured through self-report assessments. Baseline patient-reported outcome surveys will be administered immediately after enrollment and prior to randomization. At 90-days, research assistants will obtain the patient-reported outcomes assessment during the follow-up visits and changes from baseline will be compared between groups by *t*-tests at each time point. An additional secondary outcome will compare rates between groups of new COVID-19 infections over the 90-day follow-up window via the COVID-19 Patient Survey. Differences in proportions of patients experiencing new infections per group will be compared by Fisher's exact tests. Similar to our primary outcome, we will also examine differences in 90-day hospital readmissions between groups. Unadjusted between-group differences will first be analyzed by comparing proportion of patients with any hospital readmissions within the 90-day period by a Fisher's exact test.

Process outcomes to be assessed following the RE-AIM evaluation framework, and quantitative outcomes will be assessed as follows: To examine enrollment rate, EMR-derived demographic and characteristics of eligible patients will be compared between those who enroll versus decline; where continuous measures will be compared between groups by student's *t*-tests and categorical measures will be compared between groups by Chi-Square tests. To examine generalizability of our sample, distribution of demographics in our sample will be compared to expected distributions of our target population through Chi-square tests. Results of semi-structured interviews will be descriptively analyzed to reveal perceptions of implementation efficacy, challenges, satisfaction, and benefits. Physicians' pre- and post-study perceptions and knowledge of, and identified barriers to successful implementation of a

transitions texting program-DD-CA will also be descriptively analyzed. To quantify successful start-up and continuation of the texting program post-discharge after initial hospital training prior to discharge, text messaging rates will be tracked longitudinally within the DD-CA arm. Participants' satisfaction with the texting program (modified and abbreviated for the current study) will be descriptively compared between groups. Participants' impressions of the program, satisfaction, and challenges/barriers experienced via post-discharge will be further qualitatively analyzed following telephone interviews (*n* = 5-7). Stakeholder and CAB member's feedback will be descriptively analyzed and quantified where appropriate.