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Document:

Protocol and Statistical Analysis Plan

Official Study Title:

Mi Puente: My Bridge to Better Cardiometabolic Health and Well-Being

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Mi Puente Protocol

The proposed randomized controlled trial will enroll 560 individuals according to the inclusion and exclusion criteria that follow and randomly assign them to a study group in order to test the effectiveness of Mi Puente, a nurse and volunteer peer team intervention (n=280) versus Usual Care, a best practices comparison (n=280) in Hispanics with multiple chronic physical and behavioral conditions.

Inclusion criteria:
1. Hispanic ethnicity (any race)
2. Is currently inpatient at Scripps Mercy Hospital Chula Vista
3. Age 18 years and older
4. Two or more cardiometabolic conditions (e.g., obesity, diabetes, hypertension, ischemic heart disease, congestive heart failure, other chronic coronary conditions, dyslipidemia)
5. One or more behavioral health concern(s) (e.g., broadly defined and related to mental health, medication adherence, life stressors, healthcare use, substance use
6. Access to telephone (mobile or landline)

Exclusion criteria:
1. Pregnancy
2. Serious life-threatening condition with life expectancy <6 months.
3. Psychiatric morbidity or neurological/cognitive impairment of sufficient severity to preclude participation in the intervention.
4. Plans to discharge to location other than home (e.g., inpatient rehabilitation or nursing care)
5. Does not speak Spanish or English

Patients who are potentially eligible (based on demographics, diagnoses) will be identified through a daily review of electronic medical records (EMR) and asked by their bedside nurse if they are willing to discuss the study with research staff. Those who agree will be approached by a trained bilingual research assistant, who will obtain verbal informed consent and administer an evidence-based behavioral health screener. Patients with one or more behavioral health needs identified either via screening or EMR review (e.g. documented, pre-existing mental health diagnosis) will be deemed eligible, provided with a detailed description of the study and if interested will be asked to provide written informed consent.

Behavioral Health Screener will comprise of the following parameters:
1. Emotional Well-being, measured by the PROMIS Anxiety and Depression forms,
2. Smoking, measured by number of cigarettes smoked per day
3. Alcohol consumptions (AUDIT-C)
4. Stress, measured by means of the Perceived Stress Scale, 4-item
5. Medication Adherence, measured by how many days/weeks the recommended medications are taken, reported by the patient
6. Healthcare access, patients' report on where they normally seek medical care.

After informed consent is obtained, assignment will be unveiled to the participant by the consenting research assistant and the participant will be assigned also with an ID number which will be used in all

procedures using de-identified data.

Participants assigned to the Usual Care (UC) group will be treated using best practice evidence-based discharge procedures, involving a team-based approach to enhance coordination of care for individuals at high risk for readmission.

Participants assigned to the Mi Puente group will be receiving usual care along with the Mi Puente discharge procedure. The latter involves individualized support from a Behavioral Health Nurse while inpatient, a follow-up call from the Behavioral Health Nurse during post-discharge week 1 and weekly supportive phone calls from a Volunteer Peer Mentor during post-discharge weeks 1-4. The intervention will focus on building resources, skills, knowledge and on empowering patients and connecting them with appropriate outpatient services.

EMR of all study subjects will be audited for specific information relevant to the trial (e.g. diagnoses, medication, complications, readmissions, length of stay) at baseline and for readmissions at 30-days and 180-days after baseline.

All study subjects will participate in three assessments of approximately 30-60 minutes duration at baseline and at 3 months and 6 months after baseline. Baseline assessment will be performed prior to hospital discharge in person and the month-3 and month-6 assessments will be conducted by telephone.

Data collected during these assessments will involve the following patient-reported indicators:
1. Demographic information (study-specific/standard item)
2. Physical symptoms, measured via the PHQ-15
3. Quality of life, measured by the PROMIS General Health Scale
4. Healthcare access and barriers, measure adapted from the HCHS/SOL
5. Patient activation, measured by the Patient Activation Measure
6. Support resources for disease management, measured by means of the Chronic Illness Resources Survey.

Guided by the RE-AIM framework, the program evaluation will examine the success of Mi Puente versus Usual Care in 1) Reaching a representative segment of the population (Reach); 2) Achieving meaningful outcomes through a well-implemented intervention (Efficacy/Implementation); and 3) Creating an intervention that can be adopted by and maintained in a real-world environment (Adoption/ Maintenance). As part of the evaluation, 20 participants will be invited to attend focus groups to share their experiences with the intervention (2-3 groups). The Behavioral Health Nurse and Volunteer Peer Mentors will also serve as “participants” via their involvement in evaluating the treatment fidelity of and their experiences with Mi Puente.

Cost-effectiveness Analysis (CEA) of the Mi Puente intervention relative to Usual Care only will be conducted focusing on services delivered by the two care partners (Scripps/San Ysidro Health center) and Mi Puente coordination over the 6-month study period. Cost-effectiveness will be estimated using the Incremental Cost Effectiveness Ratio (ICER). The estimated ICER will be compared to CEA standards

and similar interventions to provide context for the cost-effectiveness of Mi Puente.

Timeline: The study will be conducted over 5 years, 07/01/15 – 06/30/20. The first 6 months will be devoted to start-up. Eligible patients will be enrolled between months 7 and 46 and the recruitment target is approximately 28 patients per month during this period, with post-discharge telephone intervention for Mi Puente group participants concluding in month 47. Follow-up telephone assessments of patient-reported outcomes will be completed between months 10 and 52. Focus groups will follow in months 53-54 and the last 6 months will be devoted to statistical analyses and report preparation.

Study participants will be offered gift cards as an incentive to complete all assessments. Study participants will receive compensation after baseline ($20), month-3 ($20) and month-6 ($25) assessments in the form of gift cards. The total incentive for participants who will complete all assessments will be $65. Gift cards will be given after completion of each assessment; that is at baseline, 3-months and 6 months.

Patients interested in the study will be approached by a trained bilingual staff member while inpatient. The bilingual staff member will introduce the study to the participant and obtain verbal consent to administer evidence-based behavioral health screening. Patients who are deemed eligible to participate in the study will be provided with a copy of the consent form and will review all content together with the staff member both in Spanish and English. Adequate opportunity will be provided to the potential participant to consider all options and ask questions; care will be taken to ensure that all participants understand the information and that their participation is voluntary. Prior to each follow-up appointment, research staff will remind participants of the procedures and the voluntary nature of their participation.

Statistical Analysis Plan

Sample size

Power and Sample Size

The target study sample size is 560 participants allocated equally to the two groups (n = 280/group). Sample size estimates were calculated based on the primary outcome of hospital utilization at 30 and 180 days, and the secondary outcome of changes in patient-reported outcomes. All estimates were generated using RMASS2 assuming a statistical significance level of .05 (two-tailed), and targeting at least 80% power. Sample size estimates were adjusted to up to 20% total attrition. Power analyses indicated that a sample size of 558 is needed at baseline to find a statistically significant incidence rate ratio of expected magnitude with 80% power. For patient-reported outcomes, we estimated an effect size of d = 0.50 as a clinically significant change. Using parameters defined above, 280 participants are needed to find a statistically significant difference between groups.

Analytic Plan

All analytic strategies will follow intent-to-treat principles. Preliminary data screening and cleaning will be conducted, and statistical testing and effect size consultation will be used to determine if random assignment has resulted in statistical equivalence between groups. Significant covariates will be added to adjust for nonequivalence. Analyses of hospital utilization (primary outcome) and patient-reported

outcomes will be conducted using multi-level modeling and the appropriate link function for a target outcome. Analyses will include “group” (Mi Puente or Usual) as the between-subjects factor, “time” (assessment dates) as the within-subjects factor, and a cross-level, “group-by-time” interaction effect. Analyses will be conducted in IBM SPSS Statistics 22.0 (IBM, Inc., Armonk, NY, UK) and MPLUS (Muthen & Muthen, Los Angeles, CA, USA. Effect size indicators and confidence intervals will also be examined and reported.