My Bridge (Mi Puente), a care transitions intervention for Hispanics/Latinos with multimorbidity and behavioral health concerns: protocol for a randomized controlled trial

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Abstract

Background: Multimorbidity affects four of ten US adults and eight of ten adults ages 65 years and older, and frequently includes both cardiometabolic conditions and behavioral health concerns. Hispanics/Latinos (hereafter, Latinos) and other ethnic minorities are more vulnerable to these conditions, and face structural, social, and cultural barriers to obtaining quality physical and behavioral healthcare. We report the protocol for a randomized controlled trial that will compare Mi Puente (My Bridge), a cost-efficient care transitions intervention conducted by a specially trained Behavioral Health Nurse and Volunteer Community Mentor team, to usual care or best-practice discharge approaches, in reducing hospital utilization and improving patient reported outcomes in Latino adults with multiple cardiometabolic conditions and behavioral health concerns. The study will examine the degree to which Mi Puente produces superior reductions in hospital utilization at 30 and 180 days (primary aim) and better patient-reported outcomes (quality of life/physical health; barriers to healthcare; engagement with outpatient care; patient activation; resources for chronic disease management), and will examine the cost effectiveness of the Mi Puente intervention relative to usual care.

Methods: Participants are enrolled as inpatients at a South San Diego safety net hospital, using information from electronic medical records and in-person screenings. After providing written informed consent and completing self-report assessments, participants randomized to usual care receive best-practice discharge processes, which include educational materials, assistance with outpatient appointments, referrals to community-based providers, and other assistance (e.g., with billing, insurance) as required. Those randomized to Mi Puente receive usual-care materials and processes, along with inpatient visits and up to 4 weeks of follow-up phone calls from the intervention team to address their integrated physical-behavioral health needs and support the transition to outpatient care.

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Background and rationale
Multimorbidity or the presence of more than one chronic condition affected four of ten US adults and eight out of ten adults ages 65 years and older in 2014 [1]. Multimorbidity is associated with premature death [2, 3], disability, poor functional status and quality of life [2, 4, 5], and high healthcare expenses [2, 6, 7]. Several studies in the elderly have demonstrated a near-exponential relationship between number of chronic conditions and healthcare costs [7], with hospital utilization expenditures contributing significantly to these trends [8, 9].

Cardiometabolic disorders such as hypertension, dyslipidemia, diabetes mellitus, heart diseases, and behavioral health concerns, including mood and anxiety disorders, are among the ten most prevalent chronic conditions in US adults [1]. Racial/ethnic minorities including Hispanics/Latinos (hereafter, Latinos) have a higher prevalence of many of these conditions, particularly certain subpopulations such as Latinos of Mexican and Puerto Rican heritage, those who are more acculturated or have lived in the USA the longest, and those with lower socioeconomic status (SES) [10–14]. Latinos with diabetes mellitus and related conditions have more frequent complications and hospitalizations, greater functional impairment, lower quality of life, and higher mortality rates when compared to non-Latino whites [15, 16].

Latinos are more likely to experience serious psychological distress [17], yet less likely to have their behavioral health needs addressed when compared to non-Latino whites [18–21]. Even in the general population, behavioral health concerns are seriously undertreated with only about four in ten adults with a mental illness receiving mental healthcare in 2016 [22]. In addition to a lack of insurance coverage, stigma, cultural factors, and language barriers can impede mental healthcare access among ethnic/racial minorities [23–25]. Unfortunately, when left untreated, mental health problems have grave implications for both quantity and quality of life. Life expectancy for individuals with a serious mental illness is 13–30 years lower than in those without such conditions [26], a pattern often linked to treatable conditions and risk factors like smoking and obesity [27]. Undertreatment of behavioral health conditions also drains the US healthcare system. Mental illnesses, including depression, represent the third most frequent cause of hospitalization in US adults ages 18–44 years [28]. Among the costliest conditions in 2012, more expenses were incurred by treatment of mental disorders (US$29.6 million) than for any other condition [29].

Individuals with multimorbidity have a two to threefold increased risk of depression [30]. In particular, mental health and cardiometabolic conditions frequently co-occur [31–34]. When present, this mental-physical disease multimorbidity predicts poorer outcomes and higher healthcare costs [31, 35], in part due to longer hospital stays and more frequent readmissions [36–38]. Importantly, hospital readmissions have been identified as a central target for improving care coordination and reducing healthcare costs in the context of healthcare reform. For Medicare alone, reducing preventable readmissions by even 10% would result in an estimated US$1 billion in healthcare savings [39].

Evidenced-based care transitions services, including patient education, medication reconciliation, follow-up phone calls, and assistance with scheduling outpatient care, can help reduce readmissions among at-risk patients. A 2016 systematic review of 30 structured discharge programs revealed positive effects on readmissions and length of stay, and on patient and provider satisfaction with care; however, cost savings (when evaluated) were not evident [40]. Another recent review found that comprehensive discharge planning reduced 30-day readmission rates in medical-surgical patients [41]. Importantly, research into the effects of such programs on patient-reported health outcomes (e.g., quality of life) is scarce, highlighting an important evidence gap. In addition, these interventions may not adequately address the specific needs of low-income, ethnic/racial-minority individuals and those with behavioral health concerns, who are at high risk of readmission. Because many programs rely on nursing, pharmacy, and other relatively highly paid staff, and often incorporate resource-intensive home visits, they may not be maximally scalable and cost effective. Although systematic reviews have reported positive effects of integrating behavioral healthcare into primary care settings [42, 43], research concerning integrated care approaches in medical inpatient settings is
limited to a few smaller studies that provide only preliminary evidence of improved outcomes, such as reduced length of stay [44]. No prior program, to our knowledge, has been developed to focus specifically on chronic cardiometabolic conditions, which are highly prevalent and associated with substantial patient and healthcare system burden. Further, much of the research on care transitions has neglected the systemic and ecological nature of the transitions process, focusing more heavily on patient knowledge and skills. A multi-level or social-ecological approach that acknowledges the interaction between the individual and his/her environment is needed to better guide provision of care for the highest-risk populations.

“My Bridge (Mi Puente) to Better Cardiometabolic Health and Well-being” is a randomized controlled trial of a culturally appropriate, interdisciplinary care transitions approach designed to support at-risk Latino adults pre and post hospital discharge as they navigate the barriers that contribute to inequities in healthcare access and perpetuate disparities in cardiometabolic and behavioral health. Mi Puente builds on a sustainable behavioral health nurse plus volunteer community mentor team-care model and strong, collaborative relationships between inpatient, outpatient, and community services, to meet the integrated (i.e., physical and behavioral) health needs of Latinos hospitalized with cardiometabolic-behavioral condition multimorbidity. Our randomized controlled trial will test the effectiveness of Mi Puente versus usual care (UC) - i.e., best-practice discharge procedures - in reducing hospital utilization, and improving patient-reported and cost-effectiveness outcomes. The chosen comparator will elucidate the extent to which Mi Puente is superior to more general evidence-based approaches that are designed to enhance care coordination for individuals with complex needs who are at risk of readmission. Ultimately, we seek to evaluate a culturally appropriate, sustainable, and scalable program that effectively addresses integrated health needs and reduces disparities in Latinos, with potential for generalizability to other at-risk populations.

Study aims
The primary objective of the current study is to determine the effectiveness of the Mi Puente care transitions intervention versus UC in reducing 30-day and 180-day hospital utilization in Latinos with multiple cardiometabolic conditions and one or more behavioral health concerns, who are hospitalized at a large safety-net hospital in South San Diego County.

The secondary aims are:

1. To test the effectiveness of Mi Puente versus UC in improving patient-reported quality of life/physical health across 180 days.

2. To test the effectiveness of Mi Puente versus UC in reducing barriers to health care, and increasing engagement with outpatient care, patient activation, and resources for chronic disease management, across 180 days.

3. To examine the cost-effectiveness of Mi Puente versus UC.

4. Guided by the reach, efficacy, adoption, implementation, and maintenance (RE-AIM) framework [45], examine the success of the Mi Puente program in:

   a. Reaching a representative population segment (reach);
   b. Achieving meaningful outcomes through a well-implemented intervention (efficacy/implementation); and
   c. Creating an intervention that can be adopted by and maintained in a real-world environment (adoption/maintenance).

Trial design
This is a randomized, controlled, single-blind parallel-group, superiority trial. Due to the nature of the intervention, participants are not blinded to condition. However, outcome assessors (i.e., individuals conducting medical records abstraction and participant interviews) are blinded to participants’ group assignments. The protocol has been developed in accordance with Good Clinical Practice, Standard Protocol Items: Recommendation for Interventional Trials (SPIRIT) (See Additional file 2 SPIRIT 2013 checklist), and Consolidated Standards of Reporting Trials (CONSORT) 2013 guidelines.

Methods: participants, interventions, and outcomes
Primary study settings
The primary study setting and participant enrollment site is Scripps Mercy Hospital, Chula Vista, which serves the South region in San Diego County, CA, USA. With nearly 500,000 residents as of 2016, the South region of San Diego adjoins the USA/Mexico border, and is home to a large number of Latino and low-income residents [46].

Relative to the broader San Diego County population, which is 33% Latino, the South region is 60.5% Latino. The patient population of Scripps Mercy Hospital, Chula Vista is 65% Latino. The hospital has 156 beds and more than 700 employees, and includes a 24-h emergency department, and intensive care unit and laboratory.

Community partners
Outpatient healthcare system
To ensure that we meet the needs of and address gaps experienced by typical receiving ambulatory healthcare settings, we have partnered with a large, federally
qualified community health center (FQHC) that serves many low-income, uninsured, and minority residents of the South San Diego region. The FQHC partner has been actively engaged in planning the research and developing and implementing the Mi Puente intervention, and will be a key collaborator in efforts to scale and disseminate the research.

**Chula Vista Community Collaborative**
The mission of the Chula Vista Community Collaborative (CVCC) is “enhancing community partnerships to develop and implement coordinated strategies and systems for future generations.” The CVCC works to integrate existing resources and assets to develop coordinated strategies and systems that promote the health, safety, and wellness of local residents. For the current study, CVCC members have consulted on study components such as participant recruitment, intervention materials, and methods for disseminating study findings. In particular, the CVCC has provided significant input on the Community Resource Manual, used by volunteer community mentors.

**Scripps Mercy Hospital Chula Vista Well-Being Center**
The Scripps Mercy Hospital Chula Vista Well-Being Center (CVWBC) provides Scripps patients and the community with health and wellness resources, support groups and health promotion education. The mission of the CVWBC is to improve access to and quality of care, increase health awareness, and guide services for the underserved. The CVWBC offers a wide variety of programs in senior health, maternal and child health, and chronic disease education, support, and management. The CVWBC is also committed to supporting Scripps Mercy patients post-discharge to help reduce readmissions and aid in their continuum of care. For the current trial, the CVWBC refers members to consult on study and intervention components, has provided input on the community resource manual, and is listed in the community resource manual as a resource for patients in need of more intensive support.

**Community Advisory Board**
*Mi Puente* study and intervention significance, design, and implementation have been informed by ongoing input from a Community Advisory Board (CAB) composed of diverse stakeholders. The CAB includes representation by Scripps Health and outpatient healthcare system personnel, CVWBC and CVCC staff, and Scripps Mercy hospital patients. The CAB met yearly during the initial project years and has received updated study reports by email. In the final year of the trial, we will conduct in-person CAB meetings to discuss study findings, dissemination to stakeholders, and methods to sustain, disseminate, and scale the intervention.

**Eligibility criteria**
The target population for this trial is Spanish-speaking and/or English-speaking Latino adult patients (ages 18 years and older), hospitalized at Scripps Mercy Hospital for any reason, with two or more cardiometabolic conditions (including obesity, diabetes mellitus, hypertension, dyslipidemia, ischemic heart disease, congestive heart failure, peripheral vascular disease, stroke, or other chronic coronary conditions; see Table 1 for eligible International Statistical Classification of Diseases and Related Health Problems (ICD) 10 codes). Participants are also required to have at least one behavioral health concern, defined broadly to include psychological distress (elevated depression or anxiety symptoms, or disease-related distress), chronic stress in central life domains, health risk behaviors (smoking, at-risk levels of alcohol consumption), medication non-adherence, and/or lack of outpatient healthcare access and regular preventive visits. Exclusion criteria include pregnancy; a serious life-threatening condition with life expectancy < 6 months; psychiatric morbidity or cognitive impairment that precludes informed consent or intervention participation; discharge to a location other than home (e.g., skilled nursing facility (SNF)); and language other than Spanish or English. In addition, participants without access to a telephone are excluded, since part of the intervention is delivered by telephone.

**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 [47] assuming a statistical significance level of .05 (two-tailed), and targetting at least 80% power. Sample size estimates were adjusted to accommodate expected drop-outs/attrition of 10% between each assessment time point (up to 20% total attrition across 6 months). For the primary aim of examining between-group differences in readmission rates, power analyses were based on published effect sizes [48] for hospital utilization, defined as number of hospital readmissions plus emergency department visits. Specifically, a base rate of 0.37 for the UC group was used, and an incidence rate ratio of 0.70 was selected to represent a meaningful decrease in the *Mi Puente* group relative to the UC group. Enrollment ratios were kept equivalent between groups in determining the necessary sample size. Power analyses indicated that a sample size of 558 is needed at baseline to find a statistically significant incidence rate ratio of this magnitude given the base rate with 80% power, and allowing for expected attrition of up to 20% over 6 months. We estimated an effect size of *d* = 0.50 as a clinically significant difference or change in a patient-reported
| Cardiometabolic condition                  | ICD 10 code ranges |
|-------------------------------------------|--------------------|
| Peripheral vascular disease (PVD)         | 443.9 - 443.99     |
|                                          | 441.0 - 441.99     |
|                                          | 785.4 - 785.49     |
|                                          | V43.4 - V43.49     |
|                                          | I71.0 - I71.999    |
|                                          | I79.0 - I79.099    |
|                                          | I73.1 - I73.199    |
|                                          | I73.8 - I73.899    |
|                                          | I73.9 - I73.999    |
|                                          | R02.0 - R02.999    |
|                                          | Z95.8 - Z95.899    |
|                                          | Z95.9 - Z95.999    |
|                                          | K55.1 - K55.199    |
|                                          | K55.8 - K55.899    |
|                                          | K55.9 - K55.999    |
|                                          | I70.0 - I70.999    |
|                                          | I77.1 - I71.199    |
|                                          | I79.2 - I79.299    |
| Congestive heart failure (CHF)            | 428.0 - 428.99     |
|                                          | I50.0 - I50.999    |
|                                          | I09.9 - I09.999    |
|                                          | I11.0 - I11.099    |
|                                          | I13.0 - I13.099    |
|                                          | I13.2 - I13.299    |
|                                          | I25.5 - I25.599    |
|                                          | I42.0 - I42.099    |
|                                          | I42.2 - I42.999    |
|                                          | I43.0 - I43.999    |
|                                          | P29.0 - P29.099    |
| Myocardial infarction                     | 410.0 - 410.99     |
|                                          | 412.0 - 412.99     |
|                                          | I21.0 - I22.999    |
|                                          | I25.2 - I25.2999   |
| Obesity                                  | 278.0 - 278.999    |
|                                          | E66.0 - E66.999    |
| Diabetes                                 | 250.0 - 250.399    |
|                                          | 250.7 - 250.799    |
|                                          | 250.4 - 250.699    |
|                                          | E10.0 - E10.099    |
|                                          | E10.1 - E10.199    |
|                                          | E10.6 - E10.699    |
|                                          | E10.8 - E10.899    |
|                                          | Hypertension       |
|                                          | 401.9 - 401.999    |
|                                          | I10.0 - I10.999    |
|                                          | Dyslipidemia       |
|                                          | 272.4 - 272.499    |
|                                          | E78.5 - E78.599    |
|                                          | Ischemic heart diseases |
|                                          | 410.0 - 414.999    |
|                                          | I20.0 - I25.999    |
|                                          | Other coronary conditions |
|                                          | 429.2 - 429.299    |
|                                          | I25.10 - I25.099   |
|                                          | Stroke             |
|                                          | 433.01 - 433.019   |
|                                          | 433.1 - 433.199    |
|                                          | 433.11 - 433.119   |

Table 1 (Continued)
outcome such as quality of life/perceived health [49]. Using the same parameters outlined above, a total of 280 participants is needed to find a statistically significant difference between groups in a patient-reported outcome, with 93% power. Thus, the target baseline sample size of 560 participants is sufficient to detect statistically significant differences of clinically meaningful magnitude across 6 months both in the primary outcome of hospital utilization and in the secondary, patient-reported outcomes.

Recruitment, screening, and enrollment

Patient eligibility is determined through a multi-step process as shown in Table 2. Recruitment is conducted by trained, bilingual and bicultural research staff. Step 1 (pre-screening) determines demographic and health-related eligibility through the examination of electronic medical records (EMR). The research team collaborated with Scripps Health analysts to develop an automated EMR-based patient identification report that includes a list of all potentially eligible patients (based on Latino ethnicity, age ≥ 18 years, and diagnosis of two or more cardiometabolic health conditions) admitted during the previous 24 h. Once generated, the EMR-derived patient identification report is manually screened by a research assistant to exclude any patients known to be ineligible based on previous involvement with the study (e.g., Table 1 International Statistical Classification of Diseases (ICD)-Version 10 codes utilized to identify patients eligible for the Mi Puente trial (Continued)

| Cardiometabolic condition | ICD 10 code ranges |
|---------------------------|---------------------|
| 433.21 – 433.219          |                     |
| 433.31 – 433.319          |                     |
| 433.81 – 433.819          |                     |
| 433.91 – 433.919          |                     |
| 434.00 – 434.009          |                     |
| 434.01 – 434.019          |                     |
| 434.1 – 434.109           |                     |
| 434.11 – 434.119          |                     |
| 434.91 – 434.919          |                     |
| 436.0 – 436.999           |                     |
| 430.0 – 430.999           |                     |
| 431.0 – 431.999           |                     |
| 435.8 – 435.899           |                     |
| 435.9 – 435.999           |                     |
| 437.3 – 437.399           |                     |
| I60.0 – I69.999           |                     |

Table 2 Steps for Mi Puente in-hospital screening and consenting

| Screening steps | Data source | Screening criteria | Data collected |
|-----------------|-------------|--------------------|----------------|
| Step 1 pre-screening | EMR and admission notes | Inclusion: (1) Hispanic ethnicity; (2) ≥ 18 years of age; (3) ≥ 2 cardiometabolic conditions Exclusion: (1) pregnancy; (2) serious life-threatening condition with life expectancy ≤ 6 months; (3) psychiatric morbidity or neurological/cognitive impairment of sufficient severity to preclude consent or participation in the intervention; (4) discharging to location other than home (e.g., SNF); (5) does not speak Spanish or English | Medical information, including previous emergency department admission, chronic condition diagnoses, and LACE index Patient identifying information including name, demographics, contact information, and medical record number |
| If pass step 1, Step 2 approach in person | Bedside nurse | Patient is available for screening. Yes - approach patient. No - e.g., not currently in room or has already been discharged; document reasons and research assistant will return if applicable | New demographic information (e.g., language preference), screening status, qualitative enrollment data to facilitate future approaches/recruitment efforts |
| If pass step 2, step 3 in-person screening approach | Patient | Confirmation of patient name and language preference. Verbal consent to administer screener No - declined Yes - complete Behavioral Health Screener: ≥ 1 behavioral health concern(s) (i.e., related to mental health, life stressors, medication adherence, healthcare use); telephone access (see Table 3) | Reason(s) for patient eligibility/inelegibility |
| If pass step 3, step 4 consenting | Patient | Yes – agreed No - declined No - consent not obtained → study was introduced but no decision was made about participation | Complete consent form Reasons for refusals and “hard” refusals (patient explicitly declined enrollment and will not be approached in the future) or “soft” refusals (patient may be approached in a future hospital readmission) Reasons for no decision |

EMR electronic medical records, SNF skilled nursing facility, LACE “length of stay”, “acuity of the admission”, “comorbidity of the patient”, and “emergency department use in the 6 months before admission”
enrolled in the past 6 months, previously declined participation, exclusionary condition) or based on other EMR information (e.g., cognitive impairment, life expectancy ≤ 6 months, plans to discharge to a SNF). Verified eligible patients are then assigned screening identification numbers for tracking purposes.

Research assistants then consult with hospital staff (step 2) to confirm that each patient is available to be approached and if so, they proceed with step 3 (screening). Research staff confirm that the patient speaks English or Spanish, introduce the study, verify telephone access, and obtain verbal consent to administer the Behavioral Health Screener.

Table 3 Mi Puente Behavioral Health Screener and Eligibility Determination

| Measure                        | Number of Items | Description                                                                                           | Eligibility Determination |
|-------------------------------|-----------------|-------------------------------------------------------------------------------------------------------|---------------------------|
| Proactive Health Management   |                 |                                                                                                       |                           |
| Medication adherence          | 1 item          | This study-specific item asks patient to indicate the number of days recommended medication doses were missed in the past 7 days. | Missed “sometimes,” “often,” or “always” |
| Healthcare utilization        | 5 items         | This study-specific measure assesses routine medical care access/use in the past 3 months. Lack of routine medical care is defined as: No routine medical exam, or patient unable to recall date of last routine medical exam; patient not able to receive health care when needed, or; patient endorses uses emergency room or hospital outpatient department for routine medical care. | Lack of routine medical care |
| Substance Use                 |                 |                                                                                                       |                           |
| Alcohol                       | 4 items: Alcohol Use Disorders Identification Test-C (AUDIT-C) | This measure screens for risky drinking behaviors based on sex-specific cut scores. Scores ≥ 5 for men (i.e., consuming ≥ 14 drinks per week or ≥ 5 drinks in one occasion ≥ 1 times per month) and ≥ 4 for women (i.e., consuming ≥ 7 drinks per week or ≥ 4 drinks in one occasion ≥ 1 times per month), may be indicative of hazardous drinking. This measure has demonstrated validity in both men and women in primary care settings [50] and has been recommended for use in general health screening [51]. | Women: score ≥ 4 Men: score ≥ 5 |
| Smoking                       | 1 item          | This item assesses if patient currently smokes cigarettes (Yes/No).                                       | Endorses current smoking  |
| Emotional Well-Being          |                 |                                                                                                       |                           |
| Anxiety symptom screener      | 2 items: Generalized Anxiety Disorder-2 (GAD-2) | This scale assesses the frequency of anxiety symptoms experienced over the past 2 weeks [52].Scores ≥ 3 may be indicative of an anxiety disorder. This measure has demonstrated validity across diverse primary care patients ([52], including Spanish-speakers [53]. | Score ≥ 3 |
| Depression symptom screener   | 2 items: Patient Health Questionnaire (PHQ-2) | This scale assesses the frequency of depressed mood and anhedonia over the past 2 weeks. Scores ≥ 3 may be indicative of clinical depression. This measure has demonstrated validity in primary care [54] and general medical outpatients [55]. | Score ≥ 3 |
| Chronic stress                | 12 items: Chronic Burden Scale | Assesses the number of current ongoing problems of at least 6 months duration in major life domains (i.e., financial, work, relationship, health problems in self or close other, drug or alcohol problems in close other, caregiving, other chronic stressor) [56]. This measure has been used in prior multi-ethnic and Hispanic cohort studies [57, 58], and scores shown to relate to cardiometabolic disorders and risk factors [58–60]. | Score ≥ 1 chronic stressor |
| Chronic health problem distress| 2 items         | Diabetes Distress Screener [61], adapted to assess distress associated with chronic health problems experienced in the past month. Specifically, the participant felt “overwhelmed by the demands of living with chronic health problems” or felt he/she was “failing with health care regimen.” | Score ≥ 6 |
| Telephone Access              | 1 item          | Assesses if patient has access to a United States based telephone number that can be used for the duration of the study. | Telephone access endorsed |
shown in Table 3. If eligibility is confirmed and the patient expresses interest in participation, the research assistants proceed with step 4 (informed consent).

Informed consent
Research assistants review a paper copy of the informed consent document with the patient in his/her preferred language. The patient’s comprehension is monitored and the consent process is halted if a patient demonstrates difficulty understanding the content of the study or the informed consent document. Where questions about ability to consent arise, research assistants consult bedside nurses to determine if the difficulties are temporary or are unlikely to be resolved. If it is determined that a patient will have continued difficulties providing informed consent, the patient is categorized as ineligible. If the patient has difficulties reading, the consent form is read aloud word for word in the presence of a witness (e.g., family member). Once ample opportunity to ask questions about the study has been provided, participants are asked to provide written consent. Reasons for refusal to participate will be recorded where possible.

Interventions
The two-group parallel design compares UC discharge procedures to the Mi Puente specially trained behavioral health nurse plus volunteer community mentor team intervention.

Group 1, usual care (UC)
Patients in this group receive the hospital’s UC approach as documented in the discharge instructions. This includes education materials, appointments to see outpatient medical providers (e.g., primary care, cardiology), and referrals to other community-based providers (e.g., home care). The UC condition reflects evidence-based discharge approaches that enhance coordination of care for individuals with complex needs who are at risk of readmission. UC components are individually tailored and provided by hospital inpatient navigators and case management representatives who troubleshoot difficult aspects of discharge planning, including arranging outpatient follow-up appointments and/or diagnostic tests and resolving insurance or billing issues. Patients receiving UC are provided with printed behavioral health services information as appropriate. Patients with acute psychiatric needs are referred to the inpatient psychiatric consultation-liaison team for triage and evaluation.

Group 2, Mi Puente (My Bridge)
In addition to the processes described for UC, patients assigned to the Mi Puente group receive an innovative, team-based intervention to address their integrated health needs during the transition to home. The format and content of the Mi Puente intervention were guided by input from inpatient and outpatient care providers and administrators, community organizations, patients, and patient caregivers, collected during the pre-trial formative phase, and using experience gained during a pilot intervention [62]. The building blocks of the Mi Puente intervention strategy are a specially trained behavioral health nurse (inpatient “anchor”), a volunteer community mentor (“connecting archway”), and partnerships with outpatient medical facilities (outpatient “anchor”) and community organizations (see Fig. 1). In line with

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**Fig. 1** Conceptual overview of Mi Puente intervention. Behavioral health nurse and volunteer community mentor provide bridging support, which is enhanced by strong relationships between inpatient facility and community partners in order to achieve reduced hospital utilization and improved patient-reported outcomes.
the cultural relevance of interpersonal relationships among Latinos [63] and the importance of involving caregivers and family as key members of the care transition process, support person(s) are included in the intervention whenever possible. The overarching goal of Mi Puente is to provide care transition support to patients and their caregivers for up to 30 days following discharge. The specific intervention components are tailored to the patient and caregiver needs and preferences.

Mi Puente is based on three complementary frameworks for effective chronic disease management interventions (see Fig. 2). First, the social ecological model [64, 65] asserts that influences on health and behavior exist across multiple levels of society – i.e., individual, interpersonal, organizational, community, and policy – and that interventions must consider health-related barriers and resources at each of these levels to achieve desired outcomes. Mi Puente addresses these multi-level factors through the 6 components of the resources and supports for self-management model (RSSM) [66, 67]: (1) individualized assessment; (2) collaborative goal-setting; (3) skills enhancement; (4) ongoing follow-up and support; (5) community resources; and (6) continuity of quality care. These RSSM components are targeted in the interventions delivered by the Mi Puente behavioral health nurse and volunteer community mentor. As research has shown that interventions based on the transtheoretical model (TTM) [68, 69] effectively enhance RSSM components 1–3 [70], the TTM is used to guide the behavioral health nurse’s specific intervention strategies. In brief, the TTM posits that “readiness for behavior change” exists on a continuum, ranging from pre-contemplation to action and maintenance, and individuals can move back and forth between these stages over time. By assessing the location of an individual on this spectrum, the behavioral health nurse can “meet the patient where he/she stands” and choose stage-appropriate behavior change tools. Finally, the Mi Puente volunteer community mentor addresses RSSM components 4–6 by serving as a trusted bridge, support person, and cultural liaison to promote better links with ambulatory healthcare and community resources.

**Behavioral health nurse intervention**

After enrollment, Mi Puente participants are visited in the hospital by a specially trained, bilingual behavioral health nurse. The behavioral health nurse holds a BSN and RN qualification, and has received specific training in cardiometabolic conditions, behavioral health, and related interventions. The behavioral health nurse is supported by, and integrated with the Scripps inpatient advanced practice nurses in diabetes, cardiology, and behavioral health. The behavioral health nurse provides an in-person intervention and follow-up phone support encompassing as many intervention components as deemed necessary and for which time allows. Table 4 provides a detailed description of the intervention components conducted by the behavioral health nurse. The intervention content and materials were informed by previously established evidence-based discharge support programs, including the Coleman care transitions intervention [71–73] and project re-engineered discharge (RED) [48, 74], by our pilot intervention program [62], and by input from patient, healthcare system, and community stakeholders.

Prior to initiating the in-person intervention, the behavioral health nurse conducts a needs assessment to determine the severity and nature of the patient’s behavioral health concerns and important contextual factors (e.g., language barriers, health literacy, education, social or financial...
Table 4 Mi Puente intervention components

| Interventionist component | Content | Rationale | RSSM component | Mode, timing, and frequency of delivery |
|---------------------------|---------|-----------|----------------|-----------------------------------------|
| Behavioral health nurse   | Needs assessment | The BHN will gather information from recruiting staff, and review the Study-Specific Patient Report and EMR to complete the Needs Assessment Form. The BHN will also use this information to begin completing the Ready Set Action Plan form, highlighting possible areas for discussion and goal setting during the in-person visit (See Study-Specific Patient Report, Needs Assessment Form, and Ready Set Action Plan in Additional file 1) | To determine the severity and/or underlying causes (e.g., language barriers, health literacy, education, social or financial circumstances) of the patient's behavioral health concerns. To help the BHN tailor information-seeking, education, action planning, problem-solving and behavioral change techniques | Individualized assessment | Forms completed before and during inpatient visit, with patient (and caregiver if available) |
| Behavioral health nurse   | Create patient-specific personal health record (My Personal Health Record) | The BHN and participant will complete the “My Personal Health Record” (MPHR), a written document containing CM and BHN contact information; reasons and dates of admission and discharge; brief medical history summary (including list of current chronic health diagnoses, most recent laboratory results, and recent vaccinations); primary care provider, specialist, and pharmacy information (i.e., name and contact information, reasons for appointment(s), and questions for the provider); medication log (including previously and newly prescribed prescriptions, purpose, dosage, and timing); follow-up medical appointment calendar; and list of relevant resources (see My Personal Health Record in Additional file 1). The participant is encouraged to take their MPRH to their outpatient appointment(s). The MPRH is also copied and shared with the assigned CM | To help educate patients on their health conditions and self-management. To help patients organize information relevant to their care transition and healthcare, including their personalized action plans and goals, post-discharge medication regimens, and follow-up medical appointments | Skills enhancement | MPRH completed before and during inpatient visit, with patient (and caregiver if available) |
| Behavioral health nurse   | Engage patient in goal setting and action planning (My Action Plan) | Guided by the TTM, motivational interviewing is used to explore stage of change, motivation, elicit change talk, and empower patients to take goal-oriented action to manage their health. The BHN will utilize the Ready Set Action Plan to guide the patient in formulating goals and creating an action plan shaped by the participant’s individual strengths and the multi-level barriers he/she may experience. Action plan goals will use the evidence-based specific, measurable, attainable, relevant, time-bound (SMART) formulation. The participant will complete a My Action Plan form with his/her stated goals, steps, and confidence level in achieving the stated goal for each domain for which he/she is ready to set goals (see My Action Plan in Additional file 1). All My Action Plans will be photocopied and stored in the participant’s file for future intervention contents. The BHN will reinforce the action plan and SMART goals during the post-discharge telephone call and upon readmission, if relevant. | To aid participant in formulating and taking action towards improving self-management for chronic condition(s) in an evidence-based format | Collaborative goal-setting | During inpatient visit with patient (and caregiver if available) During follow-up telephone call/s if necessary. During readmission visit if necessary |
| Behavioral health nurse   | Medication review | The BHN will review the participant’s pre-hospital medication and discharge medication lists and help the participant complete the medication log section of their MPRH, explain refill information, and explore beliefs, barriers, or concerns around medication. The MPRH medication log will include previously and newly prescribed medications, their purpose, dosage, and timing. Last, the BHN will emphasize the importance of bringing all medications to the outpatient appointment to guide the patient in formulating and taking action towards improving self-management for chronic condition(s) in an evidence-based format | To help patients understand and organize post-discharge medication regimen To address any barriers or concerns regarding medications | Skills enhancement | During inpatient visit with patient (and caregiver if available) During follow-up telephone call/s During readmission visit if necessary |
| Interventionist Intervention component | Content | Rationale | RSSM component | Mode, timing, and frequency of delivery |
|----------------------------------------|---------|-----------|----------------|----------------------------------------|
| Behavioral health nurse Health education | The BHN will provide participants with a health education handout on proactive and reactive behavior, and will discuss and explain chronic conditions and the need for ongoing self-management (see Living with Chronic Illness Handout in Additional file 1) | To provide education surrounding patient’s current chronic conditions (e.g., mechanisms, rationale behind self-care) | Skills enhancement | During inpatient visit with patient (and caregiver if available) During follow-up telephone call/s if necessary During readmission visit if necessary |
| Behavioral Health Nurse Condition red flags | The BHN will discuss how to distinguish between medical emergency situations and when it is appropriate to utilize outpatient care. The BHN will also review steps to take in the case of a medical emergency | To reduce unnecessary emergency service utilization and encourage appropriate use of outpatient care | Skills enhancement | During inpatient visit with patient (and caregiver if available) During follow-up telephone call/s if necessary During readmission visit if necessary |
| Behavioral Health Nurse Provide referrals | The BHN will confirm which referrals were already provided by hospital staff (e.g., case manager) and assist with any of the following referrals deemed appropriate: condition specific education; nutrition services; outpatient navigator; pharmacist; short-term SNF; social services; wellness center; behavioral health; and substance abuse. If patient is discharged before intervention can be completed, the BHN may also provide a Resource Page containing information on commonly used community resources (see Community Resource Page in Additional file 1). Any additional referrals will be made by assigned CM | To provide patient with additional referrals, not already addressed by the hospital staff | Individualized assessment | During inpatient visit with patient (and caregiver if available) During follow-up telephone call/s if necessary During readmission visit if necessary |
| Behavioral Health Nurse Ensure understanding of discharge plan | The BHN will discuss discharge plans with participant (when available) to ensure instructions are well understood | To ensure participant understands necessary action following discharge | Skills enhancement | During inpatient visit with patient (and caregiver if available) |
| Behavioral Health Nurse Outpatient appointment coordination | The BHN will help the patient complete the medical records release form for the primary care physician (PCP) and specialist visits, encourage patients to follow through with appointments, help the patient compose questions to ask their PCP or specialists, and support a proactive approach to healthcare visits; to facilitate more effective and efficient | To expedite the transfer of medical records to the participant’s PCP, specialists, and/or personal address, and support a proactive approach to healthcare visits; to facilitate more effective and efficient | Skills enhancement | During inpatient visit with patient (and caregiver if available) During follow-up telephone call/s if necessary |
| Interventionist         | Intervention component | Content                                                                                                                                                                                                 | Rationale                                                                 | RSSM component | Mode, timing, and frequency of delivery |
|------------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|----------------|----------------------------------------|
| Volunteer community mentor | In-person hospital visit | If the BHN and CM schedules align with the participant's availability, the BHN will provide a "warm hand-off" after they conduct their inpatient visit, introducing the CM to the participant as part of the team. Depending on schedules, the CM may need to conduct an in-person introduction without the BHN present, or may need to meet the patient before the BHN conducts the in-person visit (see CM In-Person Visit Checklist in Additional file 1). During this in-person meeting, the CM and the participant will decide on a time for the first telephone appointment. If a PCP appointment has already been scheduled, an appointment with the CM is set before this appointment and noted on the participant's MPHR. If a PCP appointment has not yet been scheduled, the first telephone call is scheduled for a time during the first week post-discharge. | To reinforce the team-care model, build rapport between the CM and participant, and ensure patient understanding of CM role. | On-going follow up and support | During inpatient visit, with patient (and caregiver if available) |
| Volunteer community mentor | Support follow-up calls | At minimum, CMs place follow-up calls to patients during post-discharge weeks 1 and 2. Participants who have not completed their outpatient medical appointments, and/or who would benefit from additional support (per the CMs' discretion), will receive additional calls during post-discharge weeks 3 and 4. For patients who are readmitted to the hospital or sent to a skilled nursing facility (SNF) during this 30-day period, the CM has the flexibility to extend phone support. The two primary goals of CM follow-up calls are to (1) foster accountability as the patient makes progress towards his/her goals and (2) help the patient problem-solve around multi-level barriers to implementation (see CM Phone Call Checklist in Additional file 1). To achieve goal 1, CMs utilize skills such as motivational interviewing and active listening to guide conversations about behavior change with patients. For goal 2, CMs utilize a Community Resource Manual to provide participants with information on how/where to get assistance needed (see "referrals" section). | To foster accountability as the patient makes progress towards his/her goals and to help the patient problem-solve and overcome multi-level barriers to implementation | On-going follow up and support | By telephone, once per week for up to 4 weeks post discharge |
| Volunteer community mentor | Provide referrals (as needed) | The CM will refer patients to local community resources listed within the Resource Manual, depending on individual patient needs. This manual was created and is regularly updated. | To provide referrals to outside community agencies and resources that may aid the patient in addressing | On-going follow up and support | By telephone, once per week for up to 4 weeks |

The BHN will aid the participant in completing the MPHR appointment calendar. The BHN will encourage and assist the participant to complete a medical records release form to expedite the transfer of medical records to the participant’s PCP, specialists, and/or personal address. Participants who cannot complete the form while inpatient will be provided with instructions on what items must be included and where they must submit the completed form (see Medical Records Release Form and Medical Records Release Form Guide in Additional file 1). The BHN will inquire about follow-up appointments and transfer of medical records during readmission visit if necessary.
circumstances, fatalistic beliefs toward health) and any other information that may guide the post-discharge plan (e.g., hospital discharge orders, medication). The behavioral health nurse communicates with recruitment staff, reviews the Mi Puente patient report, which highlights behavioral health concerns identified during the screening and baseline assessment (see Table 4 and Additional file 1), and consults the patient EMR, including case manager notes, to inform the needs assessment. This information is then summarized using the Needs Assessment Form and Ready Set Action Plan (see Table 4 and Additional file 1) and used to tailor education, information-seeking, action planning, problem-solving, and behavior change techniques throughout the intervention.

Optimally, each patient meets with the behavioral health nurse for 30–45 min before they are discharged. Caregivers are encouraged to participate, as desired by the patient. During the in-person visit, the behavioral health nurse reviews and ensures the participant’s understanding of their discharge plan, reviews current medications, helps the patient complete the “My Personal Health Record” (MPHR) for future medical visits, helps the patient create a “My Action Plan” containing one or more specific, measurable, achievable, relevant, and time-bound (SMART) goals, provides health education, highlighting chronic health condition “red flags” and a health education handout (see Additional file 1, “Living with Chronic Illness”) and/or provides referrals.

The behavioral health nurse uses the Behavioral Health Nurse Checklist to guide the visit and ensure that all relevant content and materials are covered. At the conclusion of the in-person visit, the behavioral health nurse schedules and explains the purpose of the post-discharge follow-up phone call. If the participant is discharged prior to completion of the in-person intervention, the behavioral health nurse mails intervention documents, a Medical Release Form and Medical Release Form Guide, and a Resource Page containing information on commonly used community resources to the patient’s home address to facilitate intervention completion via phone. These forms can be viewed in Additional file 1.

The behavioral health nurse follow-up call is approximately 30 min in duration and is scheduled to occur before the participant’s outpatient primary care appointment and within 3 days of discharge. All Mi Puente participants receive one follow-up call; however, if in-person intervention components were not completed before discharge, additional phone calls may be required. During the follow-up call, the behavioral health nurse asks about the patient’s transition home and recent primary care provider visit. The behavioral health nurse also reinforces any My Action Plan SMART goals, discusses post-hospital discharge medication regimens, and encourages use of the MPHR. The behavioral health nurse answers participants’ clinically relevant questions (e.g., about medications and symptoms) and

| Interventionist component | Content | Rationale | RSM component | Mode, timing, and frequency of delivery |
|--------------------------|---------|-----------|---------------|----------------------------------------|
| Behavioral health nurse and community mentor, Readmission follow-up visit | The intervention team is provided a list of patients who are currently enrolled in Mi Puente and have been readmitted to the hospital on a daily basis. Based on interventionist availability, either the CM or the BHN, or both, will meet with the patient in person. The interventionist will utilize past CM and BHN notes to gather information that may inform the readmission follow-up visit (e.g., content of past follow-up calls, past SMART goals, resources provided). The goal of this visit is to review patient progress and provide additional support and resources as needed (see Re-admit Checklist in Additional file 1). | To provide support to patients who have been readmitted to the hospital during their time in the study | post discharge | During readmission follow-up visit if necessary |

CM community mentor, BHN behavioral health nurse, emr electronic medical records, pcp primary care physician, smart specific, measurable, achievable, time-bound, MPHR My Personal Health Record, TTM transtheoretical model, SNF skilled nursing facility.
provides or reinforces health education when relevant. Additional details about the behavioral health nurse follow-up call is provided in Table 4.

After the behavioral health nurse completes his/her follow-up call, he/she may reengage by phone with the participant if a clinical issue (e.g., questions about symptoms or medications) arises during a volunteer community mentor call. If readmitted within 6 months of enrollment, patients are visited by the behavioral health nurse (and/or volunteer community mentor) while hospitalized, when possible (see “Re-admit Checklist” in Additional file 1). During these visits, the intervention team provides a new Medical Release Form, discusses the reason(s) the participant was readmitted, and briefly reviews and reinforces intervention components most relevant to the participant.

**Volunteer community mentor intervention**

Volunteer community mentors are Spanish-English bilingual, bicultural individuals with “lived experience” who reside in, or are familiar with the South San Diego community. Persons with “lived experience” are those who have experienced the condition(s) of interest personally or in others, and have accessed or are familiar with the healthcare system. The volunteer community mentor serves as an advocate and support resource to the patient for up to 30 days post discharge as he/she embarks on his/her journey to better health and well-being. The components of the volunteer community mentor intervention are detailed in Table 4.

Ideally, the patient is introduced to the volunteer community mentor by the behavioral health nurse via a “warm hand off” (personal introduction) in the hospital. The warm hand-off fits with the cultural relevance of interpersonal relationships and personal, face-to-face interactions in the Latino population [63]. The goal of the volunteer community mentor’s in-person visit is to build rapport, explain his/her supportive role, and discuss the plan for telephone follow-up after discharge. If the participant has already scheduled a primary care appointment, a phone call with the volunteer community mentor is scheduled before the appointment and noted on the patient’s MPHR. If a primary-care appointment has not yet been scheduled, the first phone call is scheduled during the first week post discharge, in part to ensure that the initial follow-up appointment is made in a timely manner. To enhance communication and transparency, the behavioral health nurse provides both the patient and the community mentor with a copy of the Ready Set Action Plan form with the patient’s chosen action plan(s) and SMART goal(s). Thereafter, the volunteer community mentor fosters accountability as the patient makes progress towards his/her goals and is available to help the patient problem-solve around multi-level barriers to implementation via follow-up phone calls.

At minimum, volunteer community mentors place follow-up calls to patients during post-discharge weeks 1 and 2. Participants who have not completed their post-discharge primary care appointment and/or who would benefit from additional support will receive additional calls during weeks 3 and/or 4. If patients are readmitted to the hospital during this 30-day period or discharged to a SNF, the volunteer community mentor may extend phone support or see the patient in the hospital.

The volunteer community mentors use a Community Resource Manual to guide participants on how to obtain assistance needed, based on areas identified in the behavioral health nurse’s needs assessment. The Community Resource Manual was created with assistance from the study community partners and contains resources in the following areas: housing and food security, behavioral health, transportation, insurance/benefits, emergency services, health education, and services related to chronic health conditions (e.g., cancer, HIV). All information related to patient referrals for services are documented in a secure, web-based, Research Electronic Data Capture (REDCap) database [63].

As noted above, participants who are readmitted to the hospital within 6 months of discharge are visited by the behavioral health nurse and/or volunteer community mentor, if available. The interventionist references past volunteer community mentor and behavioral health nurse notes to inform the readmission follow-up visit. The goal of this visit is to review patient progress and provide additional support and resources, and in turn, prevent additional preventable readmissions.

Due to his/her non-clinical role, the volunteer community mentor does not advise participants on any clinical issues that are raised during calls or visits (e.g., questions about medications, symptoms), but refers them to the behavioral health nurse (or emergency services if urgent), who will then contact the patient for triage and assistance with follow-up care as needed. Patients with severe social, cultural, emotional, financial, and other non-clinical barriers that are outside of the volunteer community mentors’ scope of assistance are referred to the CVWBC.

Additional information about the volunteer community mentor intervention content and materials is available in Table 4 and Additional file 1.

**Intervention monitoring, adherence, and withdrawals**

**Behavioral health nurse selection, training, and supervision**

The behavioral health nurse holds a BSN and RN qualification and is selected based on specific criteria. He/she is required to be bicultural and bilingual in English and Spanish, currently licensed in the state of CA, and to have at least one year of experience working in an inpatient,
hospital setting. Additionally, the candidate should have experience caring for and providing education to patients with chronic health condition(s), such as diabetes mellitus and cardiovascular disease, familiarity with discharge planning, connection with ambulatory care and other community resources, and experience identifying/addressing behavioral health concerns. For the current study, the behavioral health nurse received training and ongoing supervision by the primary investigators, a board-certified endocrinologist (APT), CA-licensed clinical psychologist (LCG), and clinical psychologist (ALF).

Prior to study initiation, the behavioral health nurse received 2-day training in “Principles in Health Coaching” led by a national expert and 1-day training in “Motivational Interviewing” led by a CA-licensed clinical psychologist. The behavioral health nurse also received study-specific training (e.g., on forms, procedures) and completed the Collaborative Institutional Training Initiative (CITI) Protection of Human Subjects and the Society of Behavioral Medicine (SBM) Good Clinical Practice certifications. The behavioral health nurse receives biannual “refresher” trainings consisting of seminars on psychosocial support for patients, and formal system-wide clinical/educational training in cardiometabolic treatment advances led by Scripps Health. Weekly case consultation from licensed clinical psychologists was provided in years 1 and 2 of the study, and tapered to monthly (or more frequently as needed) in subsequent years.

The behavioral health nurse receives ongoing support from the Scripps inpatient advanced practice nurses in diabetes, cardiology, and behavioral health to assist with disease-specific clinical issues. Additionally, the behavioral health nurse has access to Scripps inpatient certified diabetes educators who may assist patients with significant disease-specific knowledge deficits. The behavioral health nurse also attends ongoing role-specific and clinical-care-specific training for continuing medical education units.

**Volunteer community mentor selection, training and supervision**

The research team recruits, screens, and selects the volunteer community mentors according to pre-specified criteria - Latino bilingual individuals with lived experience who reside in, and are familiar with the South San Diego community. All volunteer community mentors become Scripps (unpaid) contractors, which includes receiving general volunteer training and ensuring medical clearance and Health Insurance Portability and Accountability Act (HIPAA) compliance. The research team provides additional training and oversight that is specific to the volunteer community mentor role, which includes 1-day Motivational Interviewing training that teaches interviewing skills to assess stage of change and elicit change talk/behaviors. The volunteer community mentors also complete CITI and SBM Good Clinical Practice certification. Weekly supervision is provided by the project manager and clinical psychology doctoral students, supervised by one of the principle investigators (LCG).

**Intervention fidelity**

Intervention content and “dosage” data for Mi Puente are ascertained via the (1) Behavioral Health Nurse Checklist, (2) Ready Set Action Plan forms (intervention) and My Action Plans (goal setting), (3) Volunteer Community Mentor Checklists (i.e., date and duration of call/s, main topics, resources information provided). All fidelity data are collected in a REDCap database and reviewed on a regular basis by supervising research staff, who provide informative feedback to the interventionists on adherence to protocols and areas for improvement (forms can be viewed in Additional file 1).

**Participant withdrawals**

Participants who request to no longer receive the intervention are closed out at that time. These participants are referred to as voluntary withdrawals from the intervention but are still tracked for outcomes via medical records abstraction and telephone interviews if contactable. The intervention is permanently discontinued if the participant dies or requests to be withdrawn from the study completely. These participants are referred to as administrative withdrawals and do not receive further contact.

**Concomitant interventions**

Mi Puente is conducted in the context of usual care provided by Scripps Mercy Hospital and any outpatient healthcare encounters. The trial provides adjunct services and all participants continue to receive inpatient and outpatient care as usual. There is no restriction placed on concomitant interventions that may be obtained.

**Outcomes assessments**

Details on assessment of primary and secondary outcomes, demographic factors, and other variables are shown in Table 5.

**Primary outcome**

The primary outcome is hospital utilization (readmissions plus emergency department visits) within the first 30 and 180 days following discharge from the initial, index admission. Informed consent includes HIPAA compliant forms and permission to audit the EMR. Subsequent emergency department visits and hospital readmissions across the 180-day follow-up period are abstracted from electronic health records. Audits will examine 30-day and 180-day rates and other information. It is anticipated that most readmissions will occur at the study setting where the participants are enrolled. However, to ensure that ascertainment of the primary outcome is as complete as
possible, hospital utilization is also assessed by self-report during the telephone follow-up interviews conducted at 90 days and 180 days following the baseline assessment. It is anticipated that some hospital visits will be missed, because they do not occur at the primary study setting and participants cannot be reached by phone. However, these missing data will occur in both Mi Puente and UC participants, and are therefore unlikely to bias the primary outcome assessment. Analyses will include evaluation of missingness and variables that are associated with missing data in a systematic manner will be controlled for in analyses. The primary outcome of hospital utilization is chosen as a clinically relevant indicator of improved quality of care and patient safety, which maps onto the national goal of reducing readmissions as a means to stem rising healthcare costs [82].

### Table 5

| Domain                          | Description                                      | Time of assessment | Number of items |
|---------------------------------|--------------------------------------------------|--------------------|-----------------|
| **Primary outcome**             |                                                  |                    |                 |
| Hospitalizations                | EMR data for hospital utilization                | X X X n/a          |                 |
| **Secondary outcomes**          |                                                  |                    |                 |
| Physical symptoms/quality of life| PROMIS Global-10 Health Scale [76]               | X X X 10           |                 |
| Patient activation              | Patient Activation Measure [77, 78]              | X X X 13           |                 |
| Support resources for disease management | Chronic Illness Resources Survey [67] | X X X 13           |                 |
| Healthcare utilization          | Health Utilization Questionnaire                 | X X X 12           |                 |
| Healthcare access and barriers  | Study-adapted measure                            | X X X 5            |                 |
| **Behavioral health concerns**  |                                                  |                    |                 |
| Medication Adherence            | Medication adherence                             | X                  | 1               |
| Smoking                         | Smoking status                                   | X                  | 1               |
| Alcohol use                     | Alcohol screener (AUDIT-C) [51]                  | X                  | 4               |
| Chronic stress                  | Chronic Burden Scale [56]                        | X                  | 12              |
| Health-related distress         | Study-adapted Diabetes Distress Screener [61].   | X                  | 2               |
| Depression                      | Patient Health Questionnaire 2-item [54]         | X                  | 2               |
| Anxiety                         | Generalized Anxiety Disorder 2-item [52].        | X                  | 2               |
| **Demographic and social contextual factors** | Age, sex, race, ethnicity, nativity, language, employment, income, education, marital status, housing | X                  | 11              |
| Social support                  | Single Item Measure of Social Support [79]       | X X X 1            |                 |
| Fatalism                        | Fatalism scale [80]                              | X X X 10           |                 |
| Health literacy                 | Single Item Literacy Screener [81]              | X X X 1            |                 |

*EMR electronic medical records, PROMIS Patient-Reported Outcomes Measurement Information System, AUDIT-C Alcohol Use Disorders Identification Test*

### Secondary outcomes

Measures of secondary outcomes are collected in the hospital during the baseline assessment, and by telephone at 90 and 180 days after baseline (see Table 5). For measures anchored to a specific timeframe, participants are asked about the past 3 months to allow congruent assessment at baseline, 90 days, and 180 days. Quality of life and perceived physical health are assessed using the Patient-Reported Outcomes Measurement Information System (PROMIS®) Global-10 Health Scale [76]. PROMIS is a National Institutes of Health (NIH) initiative to develop state-of-the-science standardized item banks that offer efficient, flexible, and precise measurement of common patient-reported outcomes. The measures were developed using item response theory, are available in Spanish and English (among other languages), and have shown
evidence of reliability (internal consistency), validity (ability to discriminate individuals with/without chronic conditions, construct validity, content validity, factorial validity and invariance across age and gender groups) in numerous studies (e.g., [83–86]). The PROMIS Global-10 consists of 10 items that assess physical health, mental health, social health, pain, fatigue, and perceived quality of life, at the time of the assessment, and which are summarized into two subscale scores assessing general mental and physical health. Scores on the measures are calibrated using a T-score metric with the mean of the US general population equal to 50 and standard deviation fixed at 10. The scale is internally consistent, and valid in respect to factor structure and magnitude and direction of association with conceptually relevant constructs [87].

Patient activation is an important intermediate process in improved disease self-management and health outcomes [77, 78]. Further, patient activation is believed to be a critical element in efforts to address disparities in health and healthcare quality [88, 89]. We are administering the 13-item version of the Patient Activation Measure (PAM), which assesses patient knowledge, skill, and confidence in self-management activities. The measure queries patient activation in general at the time of the assessment. The PAM has been shown to have strong psychometric properties, including reliability, content, construct, and criterion validity [77, 78]. The measure was translated into Spanish by a bilingual team of translators for a study of US and foreign-born Latinos and was shown to be reliable in both languages [89].

To assess the relative effectiveness of Mi Puente versus UC in helping participants to build and capitalize on available resources, participants complete an abbreviated version of the Chronic Illness Resources Survey (CIRS), a measure of resources and supports for self-management over the past 3 months [67]. The CIRS has good psychometric properties [67], is appropriate for use in Spanish-speaking Latinos [90], and emphasizes the importance of building resources for optimal health across multiple levels of the social-ecological model. Participants complete CIRS subscales measuring support resources received over the past 3 months from the participant (personal support, similar to self-efficacy), family and friends, healthcare providers, and community. In a prior trial with a similar population, this 13-item CIRS version was shown to be internally consistent (α = 0.86), and higher resource scores were related to more effective disease self-management and glycemic control [91].

A study-specific measure is used to assess healthcare utilization in the past 3 months. This measure queries participants’ healthcare behaviors including their use of outpatient services, emergency room or urgent-care visits, inpatient stays, inpatient and outpatient surgeries, home health visits, 911 calls, ambulance travel, use of medical equipment and devices, and use of prescription and non-prescription medications. In addition, participants complete a measure of perceived barriers to accessing healthcare needed in the past 3 months. Barriers include difficulty reaching the service by telephone, difficulty obtaining a timely appointment, waiting too long for an appointment, clinic/service not open when

| Table 6 RE-AIM guided process evaluation framework |
|---------------------------------------------|
| **Reach**                                  |
| a) Examine enrollment rate; compare characteristics of eligible participants who enroll versus those who decline |
| b) Examine generalizability by comparing sample demographics with those of the target population |
| c) Compare participants who received at least 75% of the intended intervention with those who did not and examine differences between these groups |
| d) Record detailed information about reasons for, and time of drop-out; compare participants retained versus lost-to-follow-up to examine reasons for attrition |
| **Efficacy**                               |
| a) Assess improvement in primary and secondary outcomes between baseline and month 6 and examine dose-response association (i.e., whether dosage received relates to changes over time) |
| b) Examine unintended negative outcomes     |
| **Adoption**                               |
| a) Using semi-structured interviews approach, assess Scripps’ stakeholders’ perceptions of the perceived feasibility and efficacy of intervention strategies |
| b) Difficulties with implementation        |
| c) Satisfaction with the intervention, and |
| d) Additional benefits derived             |
| **Implementation**                         |
| a) Examine intervention dose and fidelity via checklists completed by behavioral health nurse (Ready, Set, Action forms) and volunteer community mentors (Community Mentors Checklists) for each patient interaction and across the intervention |
| b) Assess participants’ engagement in the intervention through brief self-reports evaluating satisfaction with the intervention and number of scheduled calls completed |
| c) Assess Mi Puente participants’ subjective impressions of the content/format of the intervention and materials, satisfaction with knowledge gained, and challenges/barriers experienced via two focus groups (n = 20) to be conducted with participants following their completion of the 6-month study protocol |
| d) Assess volunteer community mentors’ self-report of satisfaction and conduct in-depth discussions to examine intervention acceptability, and barriers and enabling factors to program implementation |
| **Maintenance**                            |
| a) Assess number of Mi Puente participants involved throughout the study period |
| b) Reassess stakeholders’ support for more broadly implementing the intervention |
| c) Meet with community partners and other stakeholders to discuss dissemination of findings and intervention |
healthcare was needed, lack of transportation, lack of access to an interpreter, inability to take time off work, inability to leave caregiving responsibilities, financial obstacles, or legal concerns.

**Process evaluation outcomes**

The RE-AIM model [45, 92] will be used as a framework to evaluate feasibility, acceptability, sustainability, and dissemination and scaling potential of the *Mi Puente* intervention. The evaluation will also be used to guide program revisions prior to dissemination. An overview of the indicators to be assessed from the RE-AIM guided process evaluation is shown in Table 6.

**Participant timeline**

A summary of the expected timeline for participant involvement is shown in Fig. 3. Enrollment occurs during the inpatient hospital stay. After providing written informed consent, the baseline assessment is performed,

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**Fig. 3** Theoretical mapping of *Mi Puente*. Using the transtheoretical model (TTM) to assess readiness for change, and targeting resources and supports for self-management (RSSM) components 1–3 (behavioral health nurse (BHN)) and 4–6 (volunteer community mentor), the *Mi Puente* intervention will increase resources and decrease barriers across multiple socioecological levels. The operationalization of all RSSM components in intervention content is monitored using behavioral health nurse “Ready, Set, Action” forms and volunteer community mentor checklists (See Additional file 1). Primary outcomes (d, e) and proposed mechanisms (a–c) are operationalized with the following measures: (a) Patient Activation Measure, (b) Chronic Illness Resources Survey, (c) measure adapted from the Hispanic Community Health Study/Study of Latinos, (d) hospital utilization assessed by electronic medical record (EMR) and self-report, (e) Patient-Reported Outcomes Measurement Information System (PROMIS) General Health Scale. **SEM** Social-ecological model.
following which randomization occurs. If randomized to UC, the participant continues to receive inpatient care as usual, followed by UC discharge procedures. For participants assigned to the Mi Puente intervention, the behavioral health nurse begins the needs assessment and inpatient component of the intervention as soon as possible. Following his/her visit, whenever possible, the behavioral health nurse introduces the participant to the community mentor via a “warm handoff.” The intervention continues by phone for up to 30 days following discharge, with one call from the behavioral health nurse (within 3 days of discharge) and two to four calls from the volunteer mentor (once per week during weeks 1 and 2 post discharge, and possibly during weeks 3 and/or 4). EMR abstraction is conducted to investigate hospital utilization 30 days post hospital discharge and 180 days post discharge. These follow-up periods were chosen because they are commonly used as indicators of quality of hospital care.

Methods: assignment of interventions
Randomization and blinding
The target number of patients to be randomized is 560, equally allocated between the Mi Puente and UC conditions (n = 280/group). Randomization is unveiled by the research assistant who performs the screening, consenting, and baseline assessment in the hospital, immediately following the baseline assessment. Sequence generation is performed using a computer-generated complete randomization design conducted by the study statistician (SCR), and conveyed to the study project manager. Allocations are indicated by sequential participant number and placed within sealed, opaque envelopes by the study project manager, who is not involved in participant screening, enrollment, or assessment. After the baseline assessment is complete, assignments are opened and revealed by the research staff. Participants and interventionists are not blinded to group assignment, given the nature of the intervention. Research personnel who conduct telephone-based follow-up assessments and EMR abstraction are blinded to group assignment.

Methods: data collection, management, and analysis
Data collection methods
Data are collected primarily from participants, and as part of the process aim, from stakeholders such as the behavioral health nurse, volunteer community mentors, community stakeholders, and Scripps staff and administrators. Patient data include hospitalization utilization from the EMR, self-report data collected through in-person and telephone interviews, and qualitative data collected through end-of-study patient focus groups.

Electronic medical records abstraction
Baseline clinical data, information on the index hospital admission, and hospital utilization for 180 days following the baseline hospital admission will be abstracted from the EMR by trained research personnel. The data to be abstracted include demographics (e.g., age, race/ethnicity, sex), insurance status, medical history, comorbidities, risk factors, and clinical or laboratory assessments. For each emergency room visit and hospital admission, contextual information such as length of stay, surgeries and procedures needed, medication prescriptions, and admission and discharge diagnosis/es will be collected. The data abstraction report will be developed jointly by study investigators and hospital analysts. To ensure accuracy and completeness of data extraction, two research staff will quality check and verify the extracted data report by spot checking multiple sections of data against live EMR records to evaluate inter-rater reliability. A third staff member will perform the final validation to compile a list of data report feedback to analysts. Analysts will evaluate data discrepancies and troubleshoot extraction procedural issues to produce an updated accurate report. Research staff will perform the quality control-feedback loop until no data discrepancies are found. A REDCap database will be developed to store data abstracted from the EMR for the planned analyses.

Patient-reported assessments
The baseline interview is conducted in person while the participant is hospitalized and prior to randomization. Follow-up interviews are conducted by telephone, 90 and 180 days after baseline. All assessments are administered in the participant’s preferred language (English or Spanish), by interview, in order to accommodate the range of literacy levels and health statuses. All interviews are conducted by trained bilingual, bicultural research assistants using a standardized protocol to ensure maximal data quality. Self-report measures were chosen based on evidence of reliability and validity, availability in English and Spanish, and appropriateness to the target population and constructs of interest.

Data management
All study data are entered into a secure REDCap database, which includes web-based data entry platforms for research staff to enter screening, in-person and telephone-assessment data, and electronic health records abstraction. Study personnel use secure passwords to access the database. Where possible, data fields are preprogrammed to prevent entry of out-of-range or implausible data, and missing data are minimized by requiring that a response is entered before transitioning to the next item. Separate databases are maintained for participant tracking, recruitment, and
screening, EMR abstraction, intervention fidelity, and interview/self-report data. The REDCap databases are stored on servers within environments that conform to HIPAA, CITI, and NIH data security regulations and are backed up on a daily basis, with external backups stored off site and exchanged weekly.

Data quality control procedures

Staff training
All research staff are trained and certified in interviewing, questionnaire administration, recruitment procedures, consenting, database use, CITI Protection of Human Subjects, and SBM Good Clinical Practice certification. Research staff also become Scripps contractors, which includes receiving general volunteer training and ensuring medical clearance and HIPAA compliance.

Quality control checks
All databases containing study data are checked for completeness and accuracy at least weekly. The number of behavioral health screeners completed and relevant enrollment statuses are cross-checked with the recruitment and screening database to verify accuracy and ensure that coding of patient data is consistent across databases. Baseline, follow-up assessments, and fidelity data are manually checked for completeness and accuracy. Additionally, the number of follow-up surveys completed and appropriate coding of patients (e.g., refusal, deceased) are verified and confirmed. Research staff indicate their name with each survey completed, and are contacted when discrepancies, errors, or omissions of data are identified.

Cohort retention procedures
To maximize retention and data quality, participants receive an appointment reminder letter with instructions to contact the study if they need to re-schedule approximately one week prior to follow-up assessments. In addition, approximately 24 h before their appointment, participants receive a reminder phone call. If a participant cannot be reached during three consecutive calls, we attempt to reach alternative contacts if provided. If this does not result in successful contact, public directories are searched. If participants cannot be reached within a month of their 90-day telephone assessment, the data are marked as missing. Participants are then contacted again for their 180-day follow-up assessment, with all retention procedures repeated as outlined above.

Statistical methods

Primary analyses
All analytic strategies will follow published standards, including intent-to-treat principles [93]. Preliminary data screening and cleaning will require examination of distributions for normality, outliers, and missing data patterns at both the univariate and multivariate level. Preliminary inferential 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. Multi-level models are especially appropriate for nested data (i.e., time points nested within participants) where missing data and non-normally distributed variables are present [94, 95]. Analyses will include “group” (Mi Puente or UC) as the between-subjects factor, “time” (assessments) as the within-subjects factor, and a cross-level, “group-by-time” interaction effect. Follow-up analyses to determine the nature of the differential change between groups will follow recommended procedures [96]. To determine if outcomes differ relative to baseline values, two dummy-coded time variables will be created and specified as level-1 predictors of the target outcome(s) [95]. The baseline assessment will be specified as the referent time point with each follow-up time point, respectively, specified as the comparison time point. Finally, the association between the intervention dosage with the magnitude of change in the target outcomes will be evaluated in the Mi Puente group. All analyses will use an intent-to-treat approach, and will be conducted in IBM SPSS Statistics 22.0 (IBM, Inc., Armonk, NY, UK) and MPLUS (Muthen & Muthen, Los Angeles, CA, USA) [97]. Due to the number of statistical tests being conducted, alpha correction will be used to minimize the potential impact of type I error. Effect size indicators and confidence intervals will also be examined and reported. For the primary study aim, additional analyses will be undertaken to fully address the question of interest. Differences in hospital utilization between the Mi Puente and UC intervention groups at 30 days and 180 days will be tested using Poisson and proportion tests. Cumulative hazard curves will also be generated and statistically compared using the log-rank test.

Cost effectiveness analysis
We will estimate the short-term, within-study cost effectiveness of Mi Puente relative to UC from (1) the societal perspective and (2) the healthcare system perspective. Costs will include both the costs of healthcare coordination through Mi Puente and the costs of healthcare services received during the study period. Effectiveness will be measured by quality-adjusted life years. The cost effectiveness of Mi Puente relative to UC will be estimated using the incremental cost effectiveness ratio, or the difference in costs between the study groups divided by the difference in quality-
adjusted life years. The sensitivity of the incremental cost effectiveness ratio to assumptions and estimated parameters will be investigated using a series of one- and two-way sensitivity analyses [98].

**Healthcare coordination costs: Mi Puente**

The *Mi Puente* intervention is conducted by an inpatient behavioral health nurse and a volunteer community mentor. Volunteers are employed in this model in part to promote sustainability and scaling. Costs for the behavioral health nurse will be included in both the societal and health system perspectives, while costs of the volunteer community mentor will be included only in the societal perspective. Time spent by the behavioral health nurse and the volunteer community mentor in supporting study participants will be measured using time-logs tracked in the interventionist checklists (Additional file 1). Time spent by the behavioral health nurse will be valued at the current wage plus benefits, while time spent by volunteer community mentors will be valued at the wage of a community health worker, plus benefits. Overhead, administrative, and phone costs will also be estimated and included in healthcare coordination costs.

**Healthcare service costs**

Costs of healthcare services will be measured using a combination of administrative and self-reported data. Hospital utilization will be measured using administrative data from the participating hospitals (i.e., those in the Scripps system). The resource intensity of each emergency room visit or readmission will be measured using diagnostic related groupings, and the costs will be estimated by applying a national price schedule to these. Non-inpatient services will be measured via telephone follow up at 90 days and 180 days using a self-report as-

| Protocol domain | Protocol revision                                                                 | Rationale                                                                                      | Date approved               |
|-----------------|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|-----------------------------|
| Behavioral Health Screener | Added items to behavioral health screener to increase sensitivity in detecting potential behavioral health issues. | We expanded the screener to detect other behavioral health concerns that we felt the original screener was missing, thus increasing the pool of eligible patients who can benefit from the program | The amendment was approved on 10/27/2016 |
| Retention       | Began sending a letter to participants in our intervention group when unable to contact for telephone follow up | When unable to contact participants through other means, we send a letter reminding them of available services, and asking them to contact us if desired | The amendment was approved on 10/27/2016 |
| Baseline and follow-up surveys | Housing status item added to baseline and follow-up (3 and 6 month) surveys | Housing and homelessness are important factors that may affect program outcome | The amendment was approved on 1/24/2017 |
| Retention       | Began using a public search directory to update phone numbers and contact information when not available from medical records | This change was enacted to maximize participants’ benefit from the intervention, which takes place in part by phone, and to maximize data quality and completeness for outcome assessment | The amendment was approved on 1/24/2017 |
completion rates of key processes including inpatient visits, behavioral health nurse and volunteer community mentor support calls, and completion of 90-day and 180-day patient-reported outcome assessments.

The study follows a data and safety monitoring plan approved by the funding agency and the Institutional Review Board (IRB). The data and safety monitoring plan includes oversight by a three-member external data and safety monitoring committee. The safety monitoring committee is responsible for safeguarding the interests of study participants, assessing the safety and efficacy of study procedures, reviewing the data, and monitoring the overall conduct of the study. The safety monitoring committee is required to provide recommendations about starting, continuing, and stopping the study. In addition, the safety monitoring committee is asked to make recommendations, as appropriate, about the efficacy of the study intervention; benefit/risk ratio of procedures and participant burden; selection, recruitment, and retention of participants; adherence to protocol requirements; completeness, quality, and analysis of measurements; amendments to the study protocol and consent forms; participant safety; and notification of adverse events. Safety monitoring committee meetings are held yearly and are preceded by the distribution of a report of study progress, adverse events, and other issues of note.

Harms
The primary study-related risk to participants is the potential loss of confidentiality. Our data management approach includes protections to mitigate this risk. An additional risk is increased distress that could occur as a result of the assessment of behavioral health concerns and/or in response to the intervention. The behavioral health nurse and volunteer community mentors are trained to remain alert to participant distress and provide urgent (e.g., crisis support services, appropriate use of 911 services) and routine psychiatric and medical care referrals (e.g., sources for outpatient healthcare) if needed. All adverse events and other unintended effects of the research and intervention, including loss of confidentiality, are monitored and will be reported to the safety monitoring committee as part of the data and safety monitoring plan.

Auditing
No outside auditing is conducted as part of the trial.

Ethics and dissemination
Research ethics approval
The research protocol and the informed consent form contained in Additional file 1 have been reviewed and approved by the reviewing IRB (Scripps Health, i.e., the IRB of record performing review on behalf of one or more institutions, also referred to as the single IRB and/or central IRB), with respect to scientific content and compliance with applicable research and human subjects regulations. In addition, all procedures, recruitment, assessment, and intervention materials have been reviewed. All approved documents have been submitted and approved in both English and Spanish language versions. Initial IRB approval was obtained on 29 April 2015. All modifications subsequent to the initial approval have been or will be submitted and approved by the reviewing IRB. The responsible IRBs receive yearly progress reports, including information on the total number of participants enrolled and summaries of each safety and monitoring committee report, and review and approve the study protocol at least annually.

Protocol amendments
Any protocol modifications that impact the study conduct, and/or participant risk-benefit profile, including changes in objectives, design, sample size, participant characteristics, staff changes, or significant administrative aspects, require a formal amendment to the protocol. Such amendments are submitted for approval by the relevant IRBs prior to implementation. Minor protocol corrections and/or clarifications that do not affect study conduct or the participant risk/benefit profile are viewed as administrative changes and are documented internally. There have been no protocol changes that would necessitate reporting to the funding agency (i.e., changes that would affect the scope of work or fulfillment of study aims). For a summary of key protocol modifications see Table 7.

Informed consent
Initial informed consent is obtained in writing, after review of the study, informed consent form, and ample time to address all questions. The informed consent form is presented in the participant’s preferred language (English or Spanish) by trained bilingual, bicultural research personnel. Informed consent is considered an ongoing process and participants are reminded of the voluntary nature of their participation at each assessment point. The informed consent form has been approved by relevant IRBs, and is shown in Additional file 1.

Confidentiality
Participant confidentiality is considered of utmost importance by the study investigators. Steps taken to mitigate possible loss of confidentiality include the use of participant identification numbers to label all forms and data, data entry in secure password-protected REDCap data systems, and storage of all hard-copy personal health information in secured, locked file cabinets within
Discussion

Multimorbidity has reached alarming levels in US adults, and is expected to further increase in prevalence as the population ages and chronic diseases are increasingly diagnosed in younger individuals [100, 101]. The current randomized controlled trial will compare Mi Puente, a special care transitions intervention designed to reduce hospital utilization and improve patient-reported outcomes in Latinos with multiple chronic health conditions complicated by behavioral health concerns, to UC, best-practice discharge processes. By conducting the trial at a large safety net hospital that is typical of similar settings across the USA, the study has potential to inform dissemination and scaling of the program if Mi Puente is shown to be effective. The Mi Puente behavioral health nurse and volunteer community mentor team-based intervention is designed to be cost-efficient, scalable, and to help meet the specific socio-cultural needs of the large and growing US Latino population, while also being adaptable to other conditions and populations. Innovations of the program include the focus on integrated physical-behavioral health care within an inpatient setting, close partnerships with community and outpatient healthcare organizations to ensure maximization of acceptability, feasibility, and uptake, and the use of volunteers as a cost-effective means of broadening the program reach. Importantly, the trial will include a thorough process evaluation and cost-effectiveness analysis. Economic evaluations, and cost-effectiveness studies in particular, in people with multimorbidity will provide critical evidence to inform care models and
policies of resource allocation. Identifying resource-efficient interventions that effectively address multimorbidity is one of most important challenges facing our healthcare system today. By introducing the Mi Puente care transitions intervention, we seek to contribute to efforts to address the growing and complex healthcare needs of our diverse, high-risk patient populations.

Trial status
Recruitment started in July 2016 and is ongoing. We expect to complete recruitment in December 2019.

Protocol version 5 (24 January 2017)
Substantive amendments to the original protocol (approved April 2015) are outlined in Table 7.

Supplementary information
Supplementary information accompanies this paper at https://doi.org/10.1186/s13063-019-3722-8.

Additional file 1. Mi Puente forms and materials.
Additional file 2. SPIRIT 2013 checklist.

Abbreviations
CIRS: Chronic Illness Resources Survey; CITI: Collaborative Institutional Training Initiative; CVCC: Chula Vista Community Collaborative; CVWBC: Chula Vista Well Being Center; EMR: Electronic medical records; FQHC: Federally Qualified Community Health Center; HIPAA: Health Insurance Portability and Accountability Act; IRB: Institutional Review Board; NIH: National Institutes of Health; PROMIS: Patient-Reported Outcomes Measurement Information System; RE-AIM: Reach, efficacy, adoption, implementation, and maintenance; REDCap: Research Electronic Data Capture; RSM: Resources and support for self-management model; SBM: Society of Behavioral Medicine; SES: Socioeconomic status; SMART: Specific, measurable, achievable, relevant and time-bound; TTM: Transtheoretical model; UC: Usual care; US: United States.

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Authors’ contributions
LCG, ALF, APT, SCR, GAT, and TG contributed to study conception, design, and implementation, and manuscript writing. JIB, TLC, KLS, JE, DLL, and HS contributed to study design, data acquisition, and manuscript writing. All authors read and approved the final manuscript. All authors agree to be accountable for their contributions, the accuracy, and integrity of the research.

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Availability of data and materials
The de-identified datasets used and/or analyzed during the current study will be made available from the study investigators following completion of study activities, on reasonable request, and with appropriate data use agreements. Materials not included in this protocol will be made available by request to the study investigators following completion of all study activities.

Ethics approval and consent to participate
All procedures and materials for the current study were approved by the Scripps IRB (#IRB-15-6585), which served as the reviewing IRB, or the IRB of record performing review on behalf of one or more institutions, also referred to as the single IRB and/or central IRB. All participants provided written informed consent.

Consent for publication
No individual data will be reported.

Competing interests
The authors declare that they have no competing interests.

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