Sí Texas: Social Innovation for a Healthy South Texas

#MHMSíTexas

Final Evaluation Report:
Texas A&M International University

THE INTERNATIONAL

TEXAS A&M
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Prepared by:
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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
AHA	American Heart Association
AIMS	Advancing Integrated Mental Health Solutions
BMI	Body Mass Index
Border	Border Region Behavioral Health Center
CLHD	City of Laredo Health Department
EMR	Electronic Medical Record
Gateway	Gateway Community Health Center
HbA1c	Hemoglobin A1c
HRiA	Health Resources in Action, Inc.
IBH	Integrated Behavioral Health
MHM	Methodist Healthcare Ministries of South Texas, Inc.
PCMU	Prevention Care Management Unit
PCP	Primary Care Physician
PHQ-9	Patient Health Questionnaire 9
RCT	Randomized Controlled Trial
SCAN	Serving Children and Adults in Need
SEP	SIF Evaluation Plan
SIF	Social Innovation Fund
TAMIU	Texas A&M International University
THCT	Traveling Health Care Teams

EXECUTIVE SUMMARY

This final report provides an overview of progress and findings for the evaluation of Texas A&M International University (TAMIU), a subgrantee of the Social Innovation Fund (SIF) grantee Methodist Healthcare Ministries of South Texas, Inc. (MHM). MHM is a member of the 2014 SIF cohort. The evaluation was conducted by an external contractor, Health Resources in Action (HRIA), at TAMIU.

Program Background

Juntos for Better Health is a partnership of four community service providers that developed a coordinated health care delivery system among multiple partners in Laredo, Texas and surrounding Webb, Zapata, and Jim Hogg counties to address the lack of centralized and comprehensive services in the region. Using a continuum of care approach to address obesity, diabetes, and depression, TAMIU and its partners implemented the Dartmouth Prevention Care Model to increase treatment compliance (Dietrich et al., 2006), traveling teams to provide screenings and referrals, supported additional personnel to increase health care capacity, created a shared system of resources, and improved patient knowledge of these three illnesses.

Juntos for Better Health, hereafter referred to as *Juntos*, was comprised of three different but interacting intervention prongs. The evaluation study for the *Juntos* initiative examined the effectiveness of creating and implementing a Prevention Care Management Unit (PCMU) to increase diabetic patient compliance through attending scheduled behavioral and primary care appointments and subsequent improvement on physical and behavioral outcomes. This is further described as part of the Prong 1 of the *Juntos* program in the Program Definition and Background subsection of the Introduction. Also, the study examined the development of the *Juntos* partnership and how the development of this partnership facilitated PCMU implementation and establishing a network of care in the area.

Prior Research

TAMIU and its partners implemented an intervention that combines the Dartmouth PCMU model, which has been validated in the scientific literature and shown to increase screening compliance (Dietrich et al., 2006) and the innovative *Juntos* model, both of which are client/community empowerment models (Staten et al., 2011). The intervention also was based on evidence from research by Watt (2009) on an integrated behavioral health (IBH)model in Austin, TX, which found that Spanish- speaking Hispanic patients had significantly greater odds of achieving a clinically meaningful improvement in depression at 3-month follow-up. Finally, The Dartmouth PMCU Model correlates with other models that place empowerment of clients and communities at the core. Empowerment programs such as *Pasos Adelante* (Spanish for Steps Forward), a lifestyle intervention model targeting chronic disease prevention and control in Mexican Americans living on the U.S.-Mexico border of Arizona (Staten et al., 2011), have proven effective in border regions. In a quasi-experimental design with pre-post tests and follow-up, program participants of *Pasos Adelante* (N = 255) demonstrated significant improvements in physiological measures linked to diabetes (TAMIU's primary outcome) and cardiovascular disease risk factors after participating in the 12-week empowerment program that combined interactive educational sessions with walking groups. Given that TAMIU's proposed intervention has multiple prongs that are adaptations of one tested model with innovative additions, the incoming level of evidence is preliminary, and the proposed evaluation targeted a moderate level of evidence.

Evaluation Design

As noted above, the second component of Prong 1 involved the use of the PCMU for non-compliant diabetic patients at Gateway Community Health Center (Gateway), and Border Region Behavioral Health Center (Border). Patients were eligible for the intervention if they were 18 years or older, resided in Jim Hogg, Webb or Zapata Counties, had a clinical diagnosis of diabetes (as defined by the 2016 American Diabetes Association guidelines) and were non-compliant with their treatment plan at time of enrollment, where compliance is defined as maintaining all follow-up appointments within 24 months prior to enrollment. TAMIU used a randomized controlled trial (RCT) design. Patients in the control group received the usual care non-compliant patient follow-up protocol. The intervention group received PCMU protocols involving a combination of the usual care non-compliant patient follow-up protocols and education, phone call, and home visits to reengage patients in the physical and behavioral health care system and increase compliance with their treatment plans. TAMIU first implemented the PCMU approach at Gateway before adding additional partner organizations. The targeted number of participants to be recruited for the study was 365 per arm (e.g., intervention and control groups), with 311 participants providing 6-month follow-up assessments accounting for 15% attrition at that time point, and 255 participants providing 12-month follow-up assessments taking into account 30% attrition.

Given the complexity of the intervention's multiple prongs and the necessity of several, varied evaluation designs, for the purposes of the Sí Texas evaluation, the PCMU model was the primary focus of the impact evaluation. PCMU participants entered the study only through Prong 1 by being a non-compliant diabetic patient at Gateway or Border. The proposed evaluation targeted a moderate level of evidence based on the incoming level of preliminary evidence.

TAMIU's recruitment target was 365 per study arm (intervention and control groups) totaling 730 participants. At 6-month follow-up, TAMIU retained 95.8% of its target for the intervention group (298 out of 366 returned, 311 targeted to maintain adequate statistical power). For 12-month follow-up, TAMIU retained 107.8% of its target (275 out of 366 returned, 255 targeted to maintain adequate statistical power). For the control group, TAMIU retained 91.6% of its target at 6-month follow-up (285 out of 367; 311 targeted) and 112.2% at 12-month follow-up (286 out of 367; 255 targeted).

The implementation evaluation measured the level of program services provided and quality of services program participants received relative to what was proposed in Prong 1 for the PCMU. Also, for Prong 1, the implementation evaluation assessed the extent to which the control group received similar program services to the intervention group. In addition, the implementation evaluation assessed the development of the *Juntos* partnership.

Description of Measures and Instruments

TAMIU collects data for the Sí Texas shared impact measures: BMI (weight/height^2), HbA1c (obtained via blood test), blood pressure (taken by provider), depression (using the Patient Health Questionnaire [PHQ-9]), and quality of life (as measured by the Duke Health Profile). The primary impact measure is improvement in HbA1c.

Research Questions

The primary impact measure for *Juntos for Better Health* is improvement in HbA1c. Below are the confirmatory and exploratory research questions:

1. Did diabetic patients who participated in the *Juntos for Better Health* PCMU intervention experience greater improvements in HbA1c measures after 12 months when compared to diabetic patients who did not participate in the intervention? *This question is confirmatory.*
2. Did patients who participated in the *Juntos for Better Health* PCMU intervention experience greater improvements in depressive symptoms, as measured by PHQ-9, after 12 months compared to patients who did not participate? *This question is exploratory.*
3. Did patients who participated in the *Juntos for Better Health* PCMU intervention experience greater improvements in quality of life after 12 months when compared to patients who did not participate in the intervention? *This question is exploratory.*
4. Did patients who participate in the *Juntos for Better Health* PCMU intervention experience greater improvements in blood pressure after 12 months when compared to patients who did not participate in the intervention? *This question is exploratory.*
5. Did patients who participate in the *Juntos for Better Health* PCMU intervention experience greater improvements in BMI after 12 months when compared to patients who did not participate in the intervention? *This question is exploratory.*

Implementation Questions

The implementation evaluation focused on measuring the level of program services provided and quality of services the intervention group received relative to what was proposed. In addition, the implementation evaluation assessed the extent to which the control group received similar program services. The following evaluation questions examine program implementation and potential for replication in other locations:

Core Implementation Evaluation Questions

1. Did the PCMU program reach its intended target population?
2. What are the components of PCMU and how did these components work "on the ground" at 6 and 12 months?
    a. Are these components different than what was planned, and why are they different?
3. What level of integrated behavioral health did the *Juntos for Better Health* partners achieve as a result of TAMIU implementing the PCMU and capacity building activities through Prong 3 of the program?
    a. To what extent did program staff adopt the components of PCMU at 6 and 12 months, and what are the facilitators and barriers to adoption?
    b. To what extent did providers buy-in to the program, and how has that buy-in affected implementation?
4. To what extent did the control group receive program-like components?
5. To what extent did TAMIU implement the PCMU intervention with fidelity?
6. How satisfied were patients with the PCMU program? How satisfied are providers with the PCMU program?

TAMIU Specific Implementation Evaluation Questions

7. Are patients who participated in the PCMU intervention more compliant with maintenance of appointments when compared to patients who did not participate in the intervention? *(Note, this question was refined following SEP approval).*
8. To what extent has the partnership played a role in the implementation of the *Juntos for Better Health* program? (Note: this question was further developed after the SEP was approved).
    a. How has the *Juntos* structure and model evolved?

b. How has the *Juntos* partnership been a mechanism for IBH? How has integration developed across partners (i.e. integration within and between organizations)?
c. How is this partnership model moving towards working as a consortium with a centralized referral system?

Impact Analysis

This report presents descriptive statistics, analysis of baseline equivalence, and analyses of impact across the study groups. All analyses were conducted based on an intention-to-treat approach. The unit of analysis was the individual patient. Impact measures are treated as continuous variables. Generalized regression analysis results are presented as final results of the modeling sequence starting with bivariate models and ending with multiple regression models. These multiple regression models are adjusted for key demographic factors, covariates, and baseline impact measures identified as relevant via review of the scientific literature or found non-equivalent at baseline. The possibility of effect modification of the intervention-outcome relationship by patients' characteristics was also explored. Specifically, interaction terms of study group and baseline impact measures as well as age were included to understand whether there were differences in intervention effect by these characteristics. Stratified linear regression models were subsequently estimated for any model that found statistically significant effect modification. For one outcome, PHQ-9 score, additional mediation analyses were examined. These are described in detail alongside the endpoint results for the research question on depressive symptoms.

Program implementation was assessed by reviewing collected measures at the identified time points to identify any opportunities to improve implementation fidelity or need for statistical adjustments in impact analysis due to problems with implementation fidelity.

Key Findings

Evaluation of the implementation of TAMIU's program shows that the program was implemented in alignment with the program logic model and that the program was implemented with moderate fidelity. Facilitators to PCMU program implementation included staffing and partners; communication; relationships; training, education, and capacity of staff; flexibility; and data systems. Implementation barriers included evaluation study implementation; communication; hiring and staff; data systems; and workflow. The evaluation study also examined development and implementation of the *Juntos* partnership. Facilitators to partnership development included: creating opportunities for partners to meet regularly to further understand services that each partner provides and how partners can better refer patients; further developing protocols and contracts to clarify agreements; and developing care referral networks. Barriers to partnership development included: evolving practices and protocols to working in partnership; communications about changes in protocols and expectations among partners; and creating shared data systems to meet patient needs.

Implementation challenges included changes in PCMU protocols during the implementation period, clinic capacity to provide systematic and reliable data on patient upcoming appointments to the PCMU, differences in clinic operations and patient populations. These challenges as well as intervention patients potentially feeling overwhelmed by the number of reminder calls they received may have discouraged them from attending appointments.

This evaluation study executed a robust RCT design, mitigating major threats to internal validity. Specifically, the following threats to internally validity were mitigated through the use of an RCT: selection,

instrumentation, and history. The RCT included participants from two clinics, both of which were implementing IBH at the study initiation; however, one clinic served a general patient population and the second served a patient population with SPMI. The use of two clinics serving populations with different physical and behavioral health needs may have compromised impact analyses. Retention targets for the study were met; however, participants with higher PHQ-9 scores and lower Quality of Life scores at baseline were less likely to have completed all study assessments.

The program was based on an incoming preliminary level of evidence which used a similar intervention in a different population. TAMIU implemented with moderate fidelity as there were significant changes in intervention and evaluation study protocols and staffing during the implementation period. As explained below, results from this study do not indicate a change in the preliminary level of evidence at this time. When controlling for baseline measures and other covariates, intervention participants did not have statistically significant improvement in the HbA1c confirmatory outcome when compared to control participants at 12 months. Further, there were no significant differences at 12 months between intervention participants and control group participants on the exploratory variables of Quality of Life, Diastolic Blood Pressure, or BMI. Among participants who were obese at baseline, intervention participants BMI increased compared to control participants at 12 months. For the exploratory variable, PHQ-9, at 12 months intervention participants had a statistically significant higher mean score, which was no longer significant when adding the mediating variable of number of behavioral health visits. Mediation analysis of the effect of the PCMU intervention indicated that there was a significant effect of the intervention on the number of behavioral health visits. The intervention was associated, on average, with a greater number of behavioral health visits which mediated the intervention effect on PHQ-9 score.

Conclusion and Next Steps

This evaluation provides insights into the implementation of a PCMU intervention to encourage compliance with recommended treatment plans among diabetics in an underserved population of Hispanic low-income residents. The PCMU was based on evidence from the Dartmouth Prevention Care Management Model, validated in the scientific literature by Dietrich et al. (2006). TAMIU implemented the PCMU at Gateway, a Federally Qualified Health Center, and at Border, a local mental health authority. Intervention participants had a higher number of visits in the Federally Qualified Health Center but not at the local mental health authority. Future research may wish to validate these findings and determine if a PCMU intervention implemented with higher fidelity or other methods will increase treatment compliance, particularly among persons with SPMI. In addition, this model was implemented to increase integration among providers through communication and collaboration as part of a larger effort to enhance care delivery in the region through development of the *Juntos* partnership.

The most significant limitations to this study were the use of populations from two different clinics with protocols that needed pilot testing, the extended participant enrollment and data collection periods, and implementation of an intervention external to the actual clinic practice. The clinic populations differed in terms of behavioral health needs with one population having diagnosed SPMI. Although, the pooled data from the two clinics did result in balanced intervention and control groups and sufficient statistical power, the SPMI sample appeared to have had much greater behavioral health needs that may have affected findings. Adding the second clinic population also extended the timeline for data collection which delayed qualitative implementation data collection and may have increased confusion among interviewees and focus group participants about the purpose of the qualitative data collection. Implementation of the PCMU call center intervention outside of clinic practice did not clearly enhance clinic usual care.

The challenges and limitations faced by the PCMU implementation have been instrumental in guiding the current implementation of the telephone referral follow-up process, interagency appointment scheduling, and documentation across the agencies as related to Prong 3 of the grant. To sustain the network of care that participating *Juntos* agencies have established, the partners have engaged in a business planning model process.

INTRODUCTION

This final report reviews the methods implemented to evaluate Texas A&M International University's program model according to the SIF Evaluation Plan (SEP), notes deviations and/or changes to the SEP, and describes final findings from the impact and implementation evaluations (including baseline data, six-month data, and twelve-month data). This report also provides a description of the reporting timeline discussed in the SEP and revised in **Appendix A: Revised Project Timeline.**

Program Definition and Background

The *Juntos for Better Health* partnership focused on the system of health care in Webb, Zapata, and Jim Hogg counties. The combined population of these counties is 286,247, most of which are in Webb County. Laredo, TX accounts for 94% of the population residing in Webb County (U.S. Census Bureau, 2013). Residents in this region suffer from disproportionate health disparities which stem from extreme poverty, lower levels of educational attainment, and inadequate access to basic health care needs. In Webb County, 95% of the population is Hispanic/Latino of Mexican Descent and nearly half (47%) of the population indicate they speak English less than "very well" (U.S. Census Bureau, 2013). Twenty-three percent of residents in Jim Hogg and 39% of Zapata residents are not able to speak English well. (U.S. Census Bureau, 2013).

Poverty is pervasive along the state's southern border with Mexico, placing border residents at high risk for poor health status. According to the U.S. Census Bureau, 31% of Webb County, 14% of Jim Hogg, and 35% of Zapata County residents live below the federal poverty level, compared to the state average of 17.6% (U.S. Census Bureau, 2013). Webb County is home to more than 60 *colonias*, which are defined as unincorporated settlement of land along Texas-Mexico border. Colonias often lack some of the most basic living necessities, such as drinking water and sewer systems, electricity, paved roads, and safe and sanitary housing. Over 25,000 *colonias* residents rely on an episodic system of care depending on funding and strained social programs with limited capacity.

The use of preventive health care services is low among the general Mexican American population, and Laredo/Webb County is not the exception (Laredo/Webb County Community Needs and Workforce Assessment, 2011). Laredo, TX and surrounding communities continue to see increasing behavioral health (including mental health, substance abuse, and domestic violence) cases with limited personnel and service-based resources to match the need. Reports estimate that the primary care provider ratio is 2,945:1 in Webb County, 7,145:1 in Zapata County, and 2,625:1 in Jim Hogg, County where the state ratio is 1,893:1. The mental health provider ratio is 3,500:1 in Webb and there is no available data on mental health providers in Zapata and Jim Hogg County (University of Wisconsin Population Health Institute, 2015). In addition, it is estimated that the uninsured population in the area ranges from 29% in Jim Hogg County to 36% in Webb County (Cadena, 2012).

The lack of public health infrastructure in Webb County further exacerbates challenges in accessing high-quality mental health care as well as primary care. While the median age of this population is relatively young (28 years of age), residents of Webb, Zapata, and Jim Hogg counties face significant health issues associated with limited access to care: 31% of adults in Webb and Zapata County report a BMI ≥ 30 (University of Wisconsin Population Health Institute, 2015), and 30% of Jim Hogg residents are obese. Twenty-eight percent of residents in Zapata County are physically inactive, and 19% of residents in the area are classified as excessive drinkers (University of Wisconsin Population Health Institute, 2015).

Estimates of the proportion of residents with diabetes are also significantly higher than the state of Texas as a whole. The 2009 Texas Department of State Health Services Health Facts profile shows the diabetes mortality in Webb County to be *more than twice* the rate of the State of Texas (47.1 per 100,000 v. 23.1 per 100,000).

In the context of an increasingly fragmented behavioral and primary health care system, uninsured individuals living in poverty in the border region of southern Texas need specialized support to access health care services. To address these health concerns, Texas A&M International University (TAMIU) of Laredo implemented *Juntos* for Better Health, a partnership of four community health care service providers that serves as the first fully coordinated comprehensive health care delivery systems among multiple partners in Laredo, TX.

The *Juntos* initiative aimed to improve the system of Integrated Behavioral Health, which provides a continuum of care for those with obesity, diabetes and depression. This coordinated health care delivery system was necessary as evidenced by a lack of centralized and comprehensive services (primary, secondary and tertiary) deliverable by any one entity because of a lack of operational resources. The need for coordinated care was reinforced by the region's designation as a health professional shortage area as well as a medically underserved area. Further, two different community needs assessments--one originally conducted in 2012 and updated in 2018 and a second conducted in 2018 –underscored these needs, specifically "access to and demand for primary and specialty care, expansion of behavioral health services and chronic disease and disease self-management initiatives as the top categories of need" (Regional Healthcare Partnership 20, 2018; Webb County Community Action Agency, 2018). Following successful coordination efforts documented in the professional health care literature, TAMIU's plan focused on prevention and compliance to improve health outcomes for South Texans. The *Juntos* initiative had three interacting prongs.

Prong 1 involved a health education activity and a treatment compliance component. The *Juntos* program offered health education on obesity, diabetes, and depression to participants in various community settings in an effort to increase prevention of these illnesses by improving knowledge. The second component of Prong 1 followed a modified version of the Dartmouth Prevention Care Management Model, which involved a Prevention Care Management Unit (PCMU). Patients with diabetes at Gateway Community Health Center (GCHC) and Border Region Behavioral Health Center (BRBHC) who previously missed appointments received phone calls, and home visits as needed, to increase participant attendance at regularly scheduled visits. This second component was the focus of the evaluation study.

Prong 2 involved traveling health care teams (THCT). These teams traveled to community sites in the region, provided services to local residents, and referred residents to partner organizations to receive appropriate services and establish a medical home as needed. The THCTs are based on a model described and tested using a quasi-experimental design by Cohen, Lemieux, Schoenborn and Mulligan (2012).

Prong 3 involved building capacity and sharing resources among and within partner organizations through the addition of staff, development of referral protocols, and developing a shared health information system to improve plans of care and facilitate referrals. The development of the partnership through Prong 3 was also examined as part of the evaluation study.

The enrollment target, calculated on the basis of HbA1c as the confirmatory outcome, was 730 total participants across the intervention and control groups. TAMIU ultimately enrolled 366 participants in the

intervention group and 367 in the control group for a total of 733 participants. Participants were recruited from two clinics.

Overview of Prior Research

The scientific literature has several examples of interventions targeting improved screening and treatment compliance among low-income populations.

The *Juntos* intervention was informed by several previous studies in the literature. Specifically, the prevention care management unit (PCMU) component of the intervention was based on evidence from the Dartmouth Prevention Care Management Model, validated in the scientific literature by Dietrich et al. (2006). Based on the Dartmouth PCMU Model, TAMIU implemented a prevention care management unit (PCMU) to support program participants to attend IBH care at Gateway Community Health Center and at Border Region Behavioral Health Center . This is a change from the SEP where additional partners were identified as sites for implementing the PCMU.

Dietrich and colleagues used a randomized controlled trial (RCT) to examine the Dartmouth PCMU model and its impact on cancer screening compliance in 11 community and migrant health centers in New York (Dietrich et al., 2006). The Preventive Care Management approach, developed to improve the cancer screening rates for ethnically diverse (Hispanic) women in New York City, focused on educating clients about the value of screening tests and motivating them to act on the information and follow up with their health care appointments and treatment plans. The trial examined telephone care management compared to usual care and the effects on cancer screening. The study showed that the PCMU model increased breast, cervical, and colorectal cancer screening rates among intervention group women at migrant and community health centers in New York City. The *Juntos* model used PCMU protocols involving education as well as phone calls and home visits to reengage patients in the physical and behavioral health care system and increase compliance with care plans. TAMIU's model also fostered integration between providers in the system, as they worked to communicate and collaborate regarding shared patients. Additionally, the PCMU model addressed several system-level barriers (difficulty making appointments and long waiting times), which also can lead to improvements in integration of services between partners in Laredo (Tobin et al., 2015).

The Dartmouth PCMU Model is similar to other models that place empowerment of clients and communities at the core. Empowerment programs such as *Pasos Adelante* (Spanish for Steps Forward), a lifestyle intervention model targeting chronic disease prevention and control in Mexican Americans living on the U.S.-Mexico border of Arizona (Staten et al., 2011), have proven effective in border regions. In a quasi-experimental design with pre-post tests and follow-up, program participants of *Pasos Adelante* (N = 255) demonstrated significant improvements in physiological measures linked to diabetes and cardiovascular disease risk factors after participating in the 12-week empowerment program that combined interactive educational sessions with walking groups.

The other IBH components of the TAMIU intervention are based on the growing body of evidence that supports the benefits of integrated behavioral health with primary care as a way to improve population health in areas demographically similar to South Texas (Bedoya et al., 2014; Camacho et al., 2015; Ell et al., 2009). In Austin, for example, People's Community Clinic used an IBH model to enable 329 adult clients diagnosed with depression and anxiety to receive psychiatric medication, counseling and education. This study sought to (1) evaluate the effectiveness of a collaborative care model with a predominantly Hispanic, low-income population in a primary care setting and (2) examine depression outcomes with a

subpopulation of preferentially Spanish-speaking patients compared with non-Hispanic white participants. A mixed methods non-experimental study showed that Spanish-speaking Hispanic patients had significantly greater odds of achieving a clinically meaningful improvement in depression at 3-month follow-up (odds ratio [OR] = 2.45, P = .013) compared to non-Hispanic whites. The finding for greater improvement in the Spanish-speaking population remained after controlling for age, sex, medical comorbidities, prior treatment, and baseline depression scores (Watt, 2009). The care model and patient populations seen in this study are similar to TAMIU's proposed integrated health care system. In addition to implementing the PCMU model, the partners developed and implemented referral protocols between their agencies and others to address clinical workflow, patient identification, treatment monitoring, and data collection and use components of integrated behavioral health (Miller, Kessler, Peek, & Kallenberg, 2011; Peek, 2013).

The health disparities and health-related challenges prevalent in Webb County and surrounding areas are not unlike those seen in other underserved and minority-prominent communities across the U.S. What makes this population unique, however, are the cultural and regional characteristics that require culturally tailored approaches. Salinas and colleagues (2013) and Rosario (2014) highlight the importance of geographic location when it comes to evaluating disease burden in Mexican Americans, in particular, in border communities. Previous epidemiologic studies demonstrate that Spanish-speaking Hispanics prefer to remain with primary care providers for treatment, the majority of whom use language services (interpreters or bilingual providers), which suggests that Spanish language adaptation of services and cultural competency are critical to facilitating access to care (Vega & Lopez, 2001). For this reason, TAMIU and the *Juntos* partners are not implementing the Dartmouth PCMU model with perfect fidelity but are adapting culturally-relevant components of the Dartmouth PCMU model to improve patient adherence to treatment. Culturally relevant components included employing bilingual staff for the PCMU, translating materials into Spanish, including home visits, and providing incentives that could be used at local stores. Since no evaluation studies have tested this adaptation, the incoming level of evidence is preliminary.

Program Components

TAMIU's program theory of change was that through increased education, screenings, coordination, and referrals, physical and behavioral health care services would be better integrated, and patients would be more compliant with care. These systems changes were designed to reduce morbidity and mortality due to chronic physical and behavioral health conditions among individuals in Laredo, TX.

The logic model in **Appendix B: Program Logic Model** visually outlines the inputs, activities, outputs, and outcomes for the program, while these elements are discussed narratively below. The activities of the TAMIU approach for prong 1 mirror those elements present in the Dietrich et al. (2006) model that have been linked to improved treatment compliance and health outcomes in the evidence base. Prongs 2 and 3 are included in the logic model but are not the focus of the impact evaluation. A portion of Prong 3 is included in the implementation evaluation.

Italicized activities and outputs (below) were part of the evaluation and were expected to influence the italicized anticipated short, intermediate, and long-term outcomes, which were measured and reported on through the implementation and impact evaluations.

Inputs: The TAMIU logic model has three inputs that include:

- *The Prevention Care Management Unit (PCMU)* – The PCMU was implemented by TAMIU Sí Texas staff which is a modification from the SEP. The PCMU staff were responsible for implementation

of the Dartmouth model through making the phone calls and home visits to reengage non-compliant patients with maintaining regularly scheduled visits. The purpose of the PCMU calls was to provide patients reminders for upcoming appointments, in addition, the caller engaged the patient in a discussion to identify barriers to attending previously missed appointments and assisted in identifying resources to overcome barriers. Patients that remained non-compliant despite receiving a reminder phone call prior to their next appointment received a home visit. The purpose of the home visit was to further discuss barriers to attending appointments and the patient was linked to clinic with the assistance of program staff.

- Traveling Health Care Teams (THCT) - Comprised of Family Nurse Practitioners (FNPs), Patient Navigators who have been trained as Qualified Mental Health Professionals, and other primary healthcare providers from Gateway, the City of Laredo Health Department, and Border, the THCT travels to community organizations who do not have primary healthcare and behavior health services to provide screenings and referrals to community residents.
- Health information system – An MS Access database was used to collect outcome measures (A1C, BP, BMI PHQ-9, & Duke Health Profile). The system was the repository for demographic variables and any other research related variables.

In the approved SEP, there was a fourth input to the logic model, TAMIU nursing students, who were initially planned as staff for the PCMU call center. During program implementation, TAMIU staff implemented the PCMU to ensure sufficient staffing of the PCMU as students were not consistently available.

There are four external program partners, to and from whom patients may potentially be referred. This is a modification from the SEP.

- Border Region Behavioral Health Center (Border) – Border was a clinical site for the *Juntos* program, and a clinical site for the Sí Texas evaluation. This is a change from the approved SEP which identified Gateway as the only clinical site for the Sí Texas evaluation. The organization serves individuals with psychiatric, behavioral, and developmental disabilities.
- City of Laredo Health Department – was a partner for the *Juntos* program. The organization also provides a Healthy Living/Viviendo Mejor program.
- Gateway Community Health Center, Inc. (Gateway)—Gateway was a clinical site for the Sí Texas evaluation and the *Juntos* program.
- Serving Children and Adults in Need (SCAN) – SCAN provided referrals for residential and outpatient substance abuse treatment services, co-occurring behavioral health issues, and case management services.

In the approved SEP, additional partners were identified. These partners were not part of the implementation of the PCMU and therefore are not mentioned here.

Activities: The activities section of the logic model provides an overview of TAMIU programmatic activities at the patient and clinic levels. Activities included in the Sí Texas evaluation are *italicized*. Please see the Implementation Evaluation and Figure 1 for full descriptions of the intervention and the intervention timeline.

- Prong 1
    - Develop health education protocols
    - Provide health education to the residents in the region
    - Develop best practice referral protocols for partner organizations

  - *Develop protocols for determining and tracking patient compliance*
  - *Develop and implement PCMU protocols*
- Prong 2
  - Establish traveling health care teams
- Prong 3
  - Develop health information system
  - *Provide partners with requested resources*

Outputs: In the course of program activities being fulfilled, outputs expected are described below.

- *Recruit 365 participants into each arm of the study (intervention and control groups)*
- *PCMU protocols developed*
- Health education protocols developed
- Referral protocols developed
- Patients engaged in health care system and enrolled in study through program partners and THCT
- THCT implemented
- Develop 3 systems to track, share, and store data This is a change from the SEP which called for a health information exchange among all partners.
- *Agreements among program partners for use of shared health information system*
- *New resources for partner capacity development*

Short-Term Outcomes: Short-term outcomes are the changes that are expected to occur during the first six months that patients are enrolled in TAMIU's program. These outcomes were assessed through analysis of quantitative implementation data after all assessments were completed and qualitatively through focus groups and interviews toward the end of the program period. Expected short-term outcomes are outlined below.

- Implementation and improvement of health education protocols
- Implementation and improvement of referral protocols
- *Implementation and improvement of patient compliance protocols*
- Increased number of patients engaged in health care system
- *Increased capacity among program personnel and partners*

Intermediate Outcomes: Intermediate outcomes are the changes that are expected to occur during the first and second years of program implementation (6 to 18 months). All intermediate outcomes were measured and reported on during the 12-month study period. Intermediate outcomes are outlined below.

- Increased patient understanding of obesity, diabetes, and depression
- *Increased patient compliance with attending regularly scheduled visits*
- Increased number of patients engaged with program partners
- *High patient satisfaction with PCMU*

Long-Term Outcomes: Long-term outcomes are the changes that are expected to occur two to three years after implementation. Follow-up over two to three years will not be possible for these measures. However, a 12-month follow-up of these outcomes is included in the current study. Long-term outcomes are outlined below.

- *Improved A1c, depression, blood pressure, BMI, and quality of life*
- *Reduced morbidity due to physical and behavioral health conditions (depression, blood pressure, diabetes, obesity)*
- *Improved integration between program partners*

Overview of Impact Study

TAMIU conducted a randomized between-groups design (targeting a moderate level of evidence based on prior evidence which includes randomized control trials (RCTs) by Dietrich et al. (2006) which provided support for the PCMU model and empowerment programs (Staten et al., 2011)). TAMIU selected a randomized control trial design because the partner organizations had the experience to randomly assign patients into treatment or control groups with minimal contamination—making implementation of a randomized experiment feasible.

Research Questions

TAMIU's evaluation plan included both implementation and impact research questions, as stated below. Implementation questions were expanded following the approval of the SEP to reflect the development of the partnership model, PCMU implementation, and availability of data from partner organizations.

Implementation Questions

The following evaluation questions examined program implementation and patient and provider satisfaction. The final implementation evaluation included qualitative focus groups and interviews as well as assessment of quantitative implementation data.

Core Implementation Evaluation Questions

1. Did the PCMU program reach its intended target population?
2. What are the components of PCMU and how did these components work "on the ground" at 6 and 12 months?
    a. Are these components different than what was planned, and why are they different?
3. What level of integrated behavioral health did the *Juntos for Better Health* partners achieve as a result of TAMIU implementing the PCMU and capacity building activities through Prong 3 of the program?
    a. To what extent did program staff adopt the components of PCMU at 6 and 12 months, and what are the facilitators and barriers to adoption?
    b. To what extent did providers buy-in to the program, and how has that buy-in affected implementation?
4. To what extent did the control group receive program-like components?
5. To what extent did TAMIU implement the PCMU intervention with fidelity?
6. How satisfied were patients with the PCMU program? How satisfied are providers with the PCMU program?

TAMIU Specific Implementation Evaluation Questions

7. Are patients who participated in the PCMU intervention more compliant with maintenance of appointments when compared to patients who did not participate in the intervention? *(Note this question was refined following SEP approval).*
8. To what extent has the partnership played a role in the implementation of the *Juntos for Better Health* program? (Note: This question was further developed after SEP approval).
    a. How has the *Juntos* structure and model evolved?
    b. How has the *Juntos* partnership been a mechanism for IBH? How has integration developed across partners (i.e. integration within and between organizations)?

c. How is this partnership model moving towards working as a consortium with a centralized referral system?

Impact Questions

The primary impact measure for *Juntos for Better Health* is improvement in HbA1c. Below are the confirmatory and exploratory research questions. The impact findings are presented later by Impact Question.

1) Did diabetic patients who participated in the *Juntos for Better Health* PCMU intervention experience greater improvements in HbA1c measures after 12 months when compared to diabetic patients who did not participate in the intervention? *This question is confirmatory.*
2) Did patients who participated in the *Juntos for Better Health* PCMU intervention experience greater improvements in depressive symptoms, as measured by PHQ-9, after 12 months compared to patients who did not participate? *This question is exploratory.*
3) Did patients who participated in the *Juntos for Better Health* PCMU intervention experience greater improvements in quality of life after 12 months when compared to patients who did not participate in the intervention? *This question is exploratory.*
4) Did patients who participate in the *Juntos for Better Health* PCMU intervention experience greater improvements in blood pressure after 12 months when compared to patients who did not participate in the intervention? *This question is exploratory.*
5) Did patients who participate in the *Juntos for Better Health* PCMU intervention experience greater improvements in BMI after 12 months when compared to patients who did not participate in the intervention? *This question is exploratory.*

Contribution of the Study

The *Juntos for Better Health* evaluation contributes to our understanding of how to increase access to health care services and treatment compliance among those individuals with chronic illnesses who are non-compliant with treatment. The evaluation targeted a moderate level of evidence based on experimental and quasi-experimental evidence supporting improved compliance with treatment and health impact.

The *Juntos* intervention is a combination of an adaptation of one model that has been validated in the scientific literature with a different population and the innovative *Juntos* model. The effectiveness of the Prevention Care Management approach was tested in an experimental study conducted in 11 community and migrant health centers in New York (Dietrich et al., 2006).

Pursuing a moderate level of evidence with an RCT design was considered appropriate and feasible for the PCMU intervention program for the following reasons:

- The *Juntos* partners implemented an evidence-based approach with a preliminary level of evidence
- TAMIU and its partners had the experience and capacity to randomly assign patients into treatment and control groups with minimal contamination—making implementation of a randomized controlled study feasible.

SIF Evaluation Plan Updates

The following changes occurred from the approved SEP during evaluation implementation.

Enrollment occurred at two clinics, rather than only Gateway, to ensure a sufficient sample was enrolled. The second clinic is a behavioral health service provider, Border Region Behavioral Health Center. The option of adding the second site to address sample size concerns was discussed with CNCS in May 2017. There was general agreement that adding a second data collection site where data collection was already occurring, and IRB approval had already been received was the best option. Given that Border serves a different population and has a behavioral health rather than primary care focus, it was agreed that data analyses would be stratified by clinic. Due to receiving notice on June 13, 2017 that SEP modifications would no longer be reviewed, a SEP modification was not submitted, and we proceeded with data collection at the Border site. All eligible participants were included in data analyses and impact analyses were stratified by clinic site.

TAMIU implemented additional strategies to increase participant enrollment and retention than those described in the SEP. First, in November 2016, TAMIU increased the budget for incentives to $20 (from $10) at 6- and 12-month follow-up assessments. Second, starting in April 2017, TAMIU recruited participants into the study from Border Region Behavioral Health Center, in addition to those recruited from the Gateway clinic, to reach the enrollment target.

TAMIU research staff, rather than faculty and students at the School of Nursing, implemented the PCMU to meet the scheduling needs of the PCMU. Also, TAMIU enrollment occurred from April 2016 through September 2017. In the SEP, enrollment was proposed for April through September 2016.

IMPLEMENTATION STUDY: STUDY APPROACH, METHODS, AND FINDINGS

Implementation Study Design

The implementation study aimed to understand how *Juntos for Better Health* was implemented. As described in the SEP, two main methods were used: 1) qualitative data collection via key informant interviews and focus groups, and 2) analysis of quantitative implementation data (e.g., patient visits, administrative data).

Qualitative Data Collection Methods and Analysis

The program's evaluator, Health Resources in Action (HRiA), conducted qualitative data collection at two-time points for the implementation study. Across the two-time points, a total of 11 TAMIU and Gateway staff members were interviewed at mid-point, 17 staff members from TAMIU and partner organizations after the conclusion of the study, and 21 program participants were involved in focus groups.

For the mid-point interviews (January 2017), a total of 11 semi-structured interviews were conducted with 11 individuals who performed a range of roles at TAMIU and Gateway including administrative, programmatic, and executive roles. Because program participants at mid-point were all recruited from the Gateway clinic, interview participants at mid-point only included TAMIU and Gateway staff. Border was added as a study site after mid-point interviews were conducted. All mid-point interviews were conducted in-person. Mid-point interviews were conducted approximately 8 months after initial study enrollment.

A total of 13 Interviews with 17 staff members were conducted in August 2018 approximately one month after 12-month assessments at Gateway were completed. Although 12-month assessment data collection was completed at Border in November 2018, all interviews and a focus group were conducted in August 2018 to ensure that all qualitative data collection was completed at the same time.

Interview participants at summative evaluation included TAMIU, Gateway, Border, SCAN, and City of Laredo staff to ensure PCMU program implementation and partner development questions were explored. Interview participants included clinical providers (both primary and behavioral care) and other program clinic staff.

The goal of the interviews was to assess program fidelity and understand in greater depth the context, facilitators, and challenges to program implementation. Program fidelity was assessed with clinic personnel interviewees by asking questions about program implementation from a clinic staff, program, and organizational level:

- ***Staff level:*** The implementation evaluation measured programmatic implementation including clinical and programmatic staff perceptions, attitudes and perceived barriers in care delivery for the target population.
- ***Program and organizational level:*** Interviews were also conducted with program managers and staff to obtain information about the operational level workflow and adherence to the original design of the program, and facilitators and barriers to implementation.

The interviews also aimed to capture information on clinical and administrative staff members' perceptions of barriers and facilitators to the program adoption, perceptions of program successes, challenges and opportunities for improvement, and perceived staff and patient satisfaction. Staff members were asked about their experiences with the program and perceptions of patient satisfaction both with the process of participating in the program as well as the outcomes. **Appendix C: Sí Texas Mid-Point Implementation Evaluation: Key Informant Interview General Guide** and **Appendix D: Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide** present the semi-structured interview guides used to conduct the interviews at the mid-point and final data collection periods.

In addition to these semi-structured interviews, HRiA conducted two focus groups with intervention group participants after participants completed 12-month follow-up. The goal of the focus groups was to better understand the influence the program had on participants' health and wellbeing. **Appendix E: Sí Texas Summative Implementation Evaluation: Focus Group Guide** presents the semi-structured focus group guide used to conduct the focus groups at the final data collection period. **Appendix F: Implementation Evaluation Measures** presents all implementation program components/activities, outputs, and outcomes that were measured using the qualitative data collection.

There was a total of 21 intervention participants in TAMIU's summative focus groups. One focus group had 12 participants and the other had 9 participants. **Table 1** describes participant demographics for the two focus groups (n=21). Most participants lived in Webb county (90.5%) and were female (61.9%). A majority of participants were between 45 and 64 years of age (71.4%). All participants were Hispanic or Latino (100.0%). Most participants were White (57.1%) and spoke Spanish as a primary language (64.7%). Almost half of participants had less than a high school diploma (45.0%). Over half did not have health insurance (55.6%).

Table 1. Juntos for Better Health Pre-Focus Group Demographics Survey

	TAMIU (n=21)	
Measure	n	%
County		
Jim Wells*	1	4.8
Webb	19	90.5
Willacy*	1	4.8
Sex		
Male	8	38.1
Female	13	61.9
Age		
<35	1	4.8
35-44	1	4.8
45-54	10	47.6
55-64	5	23.8
65+	4	19.1
Ethnicity		
Hispanic/Latino	21	100.0
Non-Hispanic/Non-Latino	0	0.0

Measure	TAMIU (n=21) n	%
Primary Language		
Spanish	11	64.7
English	5	29.4
Other	1	5.9
Missing	*4*	--
Education		
Less than a high school diploma	9	45.0
High school degree or equivalent (e.g., GED)	4	20.0
Some college, junior college, or vocational school	4	20.0
College degree or more	3	15.0
Missing	*1*	--
Health Insurance		
None	10	55.6
Medicaid	2	11.1
Medicare	5	27.8
Other	1	5.6
Missing	*3*	--

**These participants may have moved to these counties after initial enrollment where participants were only eligible if they resided in Webb, Jim Hogg, and Zapata counties.*

All interviews and focus groups were conducted by experienced and trained qualitative researchers from the HRiA evaluation team. A lead moderator conducted the interviews or focus groups and a research assistant took detailed notes. The interviews were conducted in English, one focus group was conducted in Spanish, and the other focus group was conducted in English and Spanish (bilingual) to match the primary language spoken at home by many participants.

All interviews and focus groups were recorded digitally and transcribed. For the summative interviews and focus groups, two trained team members initially reviewed transcripts to develop a mutually-agreed upon codebook using a grounded theory approach. They then independently coded each transcript for themes using NVivo qualitative data analysis software (NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 12) and met to discuss concordance and discordance between their coding schemes. Differences were reconciled through discussion until a consensus on the first-level of coding was reached (average kappa=0.62). Themes were identified by discussion frequency and intensity. Mid-point interviews were coded using NVivo software by one coder using detailed notes. The mid-point interviews were analyzed with this approach due to the importance of expediency to complete the interim report and to provide findings to the subgrantee quickly for continuous quality improvement. Mid-point data were not re-coded for the summative analysis, but themes from the mid-point and summative data collection were synthesized together, and findings were summarized in narrative descriptions organized by theme with illustrative quotes. If qualitative findings changed from mid-point data collection to summative data collection, it is noted.

Quantitative Data Collection Methods and Analysis

Implementation data of patient participation in the *Juntos for Better Health* PCMU intervention were analyzed. These mainly comprised of de-identified patient records from PCMU records that included

information on intervention and control group participants' behavioral health and primary care visits. Descriptive statistics on these services are provided in this section, including the mean, median, and range of number of completed and missed visits related to behavioral health and primary care for both groups. This information provides insights into fidelity and dose of the intervention.

Implementation Study Findings

The following presents the implementation study findings by research question as presented in the SEP. Note that throughout this section, except for Questions 3 and 8, the focus of the implementation evaluation was on the PCMU component. Due to the interrelated nature of all *Juntos* activities, however, additional information on other *Juntos* activities are provided. Most of this information is found later in this section under Additional Findings.

Question 1. Did the PCMU program reach its intended target population?

All patients who met eligibility criteria and voluntarily consented to participate in the *Juntos* program were offered the opportunity to participate in the intervention research study at Gateway and Border at the time of baseline data collection.

As described in the SEP, individuals were eligible for the intervention if the following was met:

- Resided in Jim Hogg, Webb, or Zapata Counties
- Provider diagnosis of diabetes following American Diabetes Association 2016 guidelines, which includes a baseline measurement of A1c≥6.5% (Notes: The original SEP eligibility criteria was A1c > 6.5%, this was clarified to >= during study enrollment. Also, See **Appendix I: ADA Guidelines**)
- Non-compliant with attending appointments (non-compliance is defined as having missed an appointment within the past 24 months).

TAMIU enrolled 733 participants into the intervention (n=366) and control groups (n=367). Most of the participants enrolled in the study were female (69.5%) and spoke Spanish as their primary language (75.4%) Almost all participants were Hispanic (97.9%) and over half had less than a high school education (58.0%) The average age across the study was 54.5 years. All participants met the study eligibility criteria; therefore, the program reached the intended audience. The prevalence of the individual eligibility criteria among the enrolled sample is provided in **Table 2**. All participants enrolled in the study met the eligibility criteria. The demographic characteristics of the study sample can be found in **Table 17** later in the report.

Table 2. Prevalence of Eligibility Criteria in *Juntos* Intervention and Control Group Participants

Eligibility Criteria	Prevalence in Enrolled Sample
Resided in one of the following counties: ▪ Jim Hogg, ▪ Webb, or ▪ Zapata	100%
Provider diagnosis of diabetes and HbA1c equal to or greater than 6.5%	100.0%
Non-compliant with treatment plan at enrollment or within 1 month following enrollment	100.0%

Question 2. What are the components of PCMU and how do these components work "on the ground" at 6 and 12 months?

TAMIU staff provided thorough descriptions of the PCMU development and implementation. The PCMU included two activities, calls and home visits. The purpose of the PCMU calls were to provide patients reminders for upcoming appointments. In addition, the caller engaged the patient in a discussion to identify barriers to previously missed appointments and assisted in identifying resources to overcome barriers. Patients that remained non-compliant despite receiving a reminder phone call prior to their next appointment received a home visit. The purpose of the home visit was to discuss participant barriers to attending appointments and link the patient to the clinic with the assistance of program staff. It was believed that a home visit would establish the clinic's commitment and investment to the patient's health, thus serving as an external motivator for treatment compliance. PCMU calls were initiated in April 2016 and home visits were initiated in December 2016. Please see Figure 1 for an implementation timeline of the *Juntos* program components.

Intervention participants received one phone call per week for three weeks from the PCMU in advance of a rescheduled appointment. If the patient continued to miss appointments, the patient received a home visit from the PCMU in an effort to assess barriers that result in decreased compliance. PCMU calls were made in addition to each clinic's practice of making reminder calls to patients in advance of upcoming appointments. Both intervention and control group participants received reminder calls from the respective clinic for upcoming appointments.

Through the course of the program *Juntos* has utilized three systems for tracking, sharing, and data storage. Syncplicity is the encrypted shared repository used to store records generated by the THCT and referrals generated by the providers. TAMIU utilizes Syncplicity to securely manage the sharing of records with providers. Acuity Scheduling is an online appointment scheduling solution used by *Juntos* to facilitate the scheduling of appointments with *Juntos* staff across providers whether appointments are generated by the THCT or *Juntos* navigators/case managers at each agency. Microsoft databases were designed to store PCMU baseline and follow-up data, PCMU phone call and appointment data, and more recently agency referral follow-up / outreach data. These storage systems meet security requirements as per HIPAA.

Question 2a. Are these components different than what was planned, and why are they different?

The Prevention Care Management Unit (PCMU) (one of three prongs) was designed to reengage diabetic patients who did not maintain regular appointments by way of phone calls and home visits by TAMIU staff. The study recruitment site was initially Gateway. Due to a variety of factors as outlined in Enrollment Log presented in **Appendix G: PCMU Evaluation Enrollment Log** and further detailed in **Appendix H: PCMU Implementation Challenges Summary**, Border also enrolled participants into the program. The addition of Border as a site to enroll participants is a deviation from the approved SEP. Specific program components and activities are presented in **Appendix B: Program Logic Model** and in the Program Components section.

How Components Work "On the Ground"

At the mid-point of the *Juntos* program, partner and staff interviewees demonstrated varied understandings of its goals and components including the PCMU. While some interviewees described the program as being about tracking and re-engaging non-compliant patients, others understood the program

as being about increasing patients' knowledge of their health regarding diabetes and depression. One partner interviewee at the mid-point had a broader understanding of the *Juntos* program as the "integration of agencies."

At the summative evaluation, interviewees similarly described the PCMU program in both pragmatic and high-level terms. Clinical staff interviewees discussed engaging previously unconnected individuals in both preventive and condition-specific care (referring to the conditions of diabetes or behavioral health). A partner interviewee discussed that the PCMU goal was to "*implement a telephone-based intervention model that would allow us to improve patient compliance with keeping their appointments*" through both reminders and discussion of ways to address individual patients' barriers to keeping these appointments. Another partner interviewee described the high-level goal of improving behavioral health services delivery and its integration into primary care, with an additional emphasis on "*disease health management*." One partner interviewee noted an additional goal of proving the worth of such an intervention through changed patient behavior and feelings about their health. A partner interviewee commented that the "*main overarching goal is bringing together a network organization in the community to share the resources in order to maximize the limited resources..., limit the amount of duplicative services, [and] increase the communication between these local entities*."

Workflow

Prior to its involvement in *Juntos*, Gateway interviewees reported they had co-located primary care and behavioral health services and were developing and adapting some of their processes through *Juntos*. As of the midpoint, they shared that the PHQ-9 was being administered to all patients and that patients with high scores were automatically referred to an LPC. This reflects a partnership wide protocol of providing behavioral health referrals or services for all patients with an elevated PHQ-9 score. Gateway staff also said they were working to create standing orders for elevated blood pressure, and BMI, so that patients would automatically receive specific services if elevated readings were observed. Several said the *Juntos* program was facilitating integration by encouraging clinic-wide screening for the aforementioned outcomes and facilitating the development of patient care protocols for elevated scores.

Enrollment in Evaluation Study

At the summative evaluation, partner and clinical staff interviewees described that patients were eligible for enrollment in the PCMU if their HbA1c at the time of screening was above a given threshold and the patient was not in compliance with the treatment plan, meaning that they had missed scheduled appointments for 24 months prior to enrollment or within a month following enrollment. Gateway interviewees described an earlier part of the study in which there was no HbA1c minimum for eligibility (only that the patient was a diagnosed diabetic), and that at some point they were instructed to begin using a specific threshold. *(Note: During the sample recruitment period, eligibility for participation was clarified as a participant having an A1c of 6.5% or higher at baseline measurement, see Appendix G for further details).* These interviewees shared that subsequently their pool of eligible patients was far smaller than estimated and the number of new enrollees plateaued, and that *Juntos* administrators then elected to add Border as an enrollment site. (Note: While Gateway staff may have perceived that *Juntos* administrators made this decision; in fact, MHM, TAMIU, and HRiA arrived at this decision jointly in consultation with the CNCS Research and Evaluation department). As reported by interviewees, this also meant that many patients who had already been recruited were no longer eligible for the program, and that Gateway was no longer able to meet the enrollment goals in which they had initially been confident. One partner interviewee stated, "*You don't change from one week to the next or one month to the next to decide to now change the population, or it's the same population but with different requirements. At the end, honestly, we ran out of patients because, out of the close to fifteen hundred patients that were*

recruited, they only used about five hundred and some and then they came in and they said, 'Well, now, we're going to have to recruit another partner because you were not able to make the numbers.' Wait a minute. It wasn't that we were not able to make the numbers. It was all the changes. We have the patients. We provided you with the patients. So, I was kind of frustrated at the moment."

An additional factor described by partner interviewees as influencing the expansion to Border for enrollment was the presence of a new and separately-funded MHM program at Gateway that offered participation to patients with similar morbidities. One partner interviewee described worry about "*our people being siphoned over to that other program…because [it] was more attractive [with] more [gift] cards or whatever it was.*" Ultimately, enrollment was expanded from being conducted solely at Gateway to include Border to meet enrollment targets. To ensure that existing *Juntos* participants did not enroll in another program, specifically the Lado a Lado program, or other program participants did not enroll in the *Juntos* program, staff members from the *Juntos* and Lado a Lado programs received training for the proper identification of participants to prevent dual enrollment. Gateway utilized documentation in the patient's electronic health record to avoid duplicate enrollment. For *Juntos* participants, the electronic health record contained two identifiers that were included to document participation in the program. These identifiers were the patient's study number and the expiration date (date of the patient's last 12 month follow up visit). In the patient's electronic health record, entering a patient's DOB or patient/chart number and selecting the corresponding patient would trigger a pop-up alert stating that the patient is enrolled in an MHM program. If a participant was flagged as being enrolled in the *Juntos* program, they would not be considered for Lado a Lado enrollment until the expiration of the 12 month date.

At endpoint interviews, partner and clinical staff interviewees also noted enrollment challenges attributed to limited staff availability to conduct enrollments at Gateway the start of the study. They described this being due to a delay in hiring a medical assistant dedicated to the evaluation study (during which time *Juntos* partners stepped in to help with enrollment sessions).

Partner and clinical staff interviewees described that upon enrollment, patients agreed to receive reminder phone calls from the PCMU in addition to the one they might receive as a regular patient, and to potentially be visited at their home if they missed an appointment. They indicated that enrollees were screened for depression using the PHQ-9 tool and referred for behavioral health services within the primary care setting or to a clinic closely connected to that setting. Clinical staff interviewees from Gateway described the following steps for engaging with patients for the evaluation study of the *Juntos* program:

"These patients were enrolled based on a report that we run. The patient was invited via a phone call. After the first session that the patient attends, then we would contact the patient once again…It's a total of three visits: the initial, the six months, and then the twelve months…After we officially meet them, they sign the consent forms. The program is explained that they are in this for twelve months. We do invite them back in after six months to repeat their A1C—because they get their A1C drawn at the beginning of the program—and then we invite them back for the six months, and they get an A1C voucher to get their lab work done. And they also have an incentive: they get a $10 gift card. And then after that, we invite them one last time, which would be the year from the first time they came in. And same thing—their A1C is drawn and they do get their vitals, PHQ, just like every visit. The last gift card will be given as well, and we do explain to them that it is the end of the program."

According to TAMIU staff, these same processes were used at the Border clinic to enroll patients.

Implementation as Planned

During the summative evaluation, all partner interviewees reported that several aspects of the PCMU program had been expanded or refined during implementation. A partner interviewee reported that appointment reminder phone calls to diabetic patients were broadened to include calls for services beyond primary care (podiatry, dental, etc.) in order to fully support patient wellbeing. They said that this led to the logistic challenge of more calls needing to be made, and an acknowledgment that a *Juntos* goal was to "*really give the client or the patient a sense that somebody is looking out for their treatment and sort of giving them an extra reminder to say, 'You have some stuff coming up and we're here to remind you about that.'"* Regarding home visits, one partner interviewee reported that these were conducted "*when a number of calls were made for [PCMU participants] to come in for services and they failed to do so*." This interviewee explained that these visits were preceded by a phone call to the participant from staff asking for "*permission to go visit you in your home to identify anything that may be preventing you from…coming in for the appointment that was scheduled*." Clinical staff shared that they enjoyed conducting home visits, and that this option "*made it way easier for some [participants].*" Clinical staff also mentioned that they were aware of the associated travel expense for home visits.

With regards to the goal of creating a method of inter-agency monitoring of patient care and compliance, multiple partner and clinical staff interviewees reported that a change was made to locate the PCMU call center and an associated database centrally at TAMIU rather than at each clinic site. According to one partner interviewee, this effort also led to considering an overall systematic approach to effectively maintaining connections with previously unengaged patients beyond those enrolled in the evaluation study.

Question 3. What level of integrated behavioral health did the *Juntos for Better Health* partners achieve as a result of implementing the PCMU and capacity building activities through Prong 3 of the program?

Implementation of Integrated Behavioral Health

According to the World Health Organization (2008), behavioral health integration encompasses the management and delivery of health services so that individuals receive a continuum of preventive and restorative mental health and addiction services, according to their needs over time, and across different levels of the health system. Quality integrated care requires a well-functioning, well-organized primary care practice as well as key behaviors at the organizational, practice, interpersonal, and individual clinician levels (Cohen et al. 2015).

There are many ways to assess how components of IBH are practiced in different settings. The Advancing Integrated Mental Health Solutions (AIMS) IBH checklist was developed by IBH experts to assess five core principles of collaborative care (AIMS Center, 2011). These principles include: (1) patient-centered care, (2) population-based care, (3) measurement-based treatment to target, (4) evidence-based care, and (5) accountable care. The checklist details core components and tasks for each of these principles that are self-assessed on a scale of "None," "Some," or "Most/all." **Appendix J: Patient-Centered Integrated Behavioral Health Care Checklist** presents the core descriptions of the Patient-Centered Integrated Behavioral Health Care Principles and Tasks Checklist as defined by the AIMS Center.

Gateway IBH Checklist Results

Table 3 and **Table 4** on the following pages present the results from Gateway clinic staff assessment of IBH implementation prior to and following implementation of the *Juntos* program. According to Gateway staff, the clinic moved 1 principle and 4 tasks to the Most/All category by the end of implementing the *Juntos* program. Also, staff reported that 1 task moved from the Most/All category to the Some category by the end of implementation. Gateway staff reported that this reflected a change in reviewing clinic procedures such that at baseline the rating was made for the pool of patients eligible for the PCMU intervention and the post-intervention rating was made for all patients in the clinic. This indicates that Gateway may not be implementing all IBH principles and tasks clinic wide at the end of the intervention.

Table 3. Gateway Clinic IBH Checklist Baseline to 12 months: Core Principles

We apply this principle in the care of (none, some, most/all) of our patients.			
	None	**Some**	**Most/All**
Patient-Centered Care Primary care and behavioral health providers collaborate effectively using shared care plans.			•✓
Population-Based Care Care team shares a defined group of patients tracked in a registry. Practices track and reach out to patients who are not improving, and mental health specialists provide caseload-focused consultation, not just ad-hoc advice.		•	✓
Measurement-Based Treatment to Target Each patient's treatment plan clearly articulates personal goals and clinical outcomes that are routinely measured. Treatments are adjusted if patients are not improving as expected.			•✓
Evidence-Based Care Patients are offered treatments for which there is credible research evidence to support their efficacy in treating the target condition.			•✓
Accountable Care Providers are accountable and reimbursed for quality care and outcomes.			•✓

• Response at baseline ✓ Response at 12 months

Table 4.Gateway Clinic IBH Checklist Baseline to 12 months: Core Components and Tasks

We apply this principle in the care of (none, some, most/all) our patients.			
	None	**Some**	**Most/All**
Patient Identification and Diagnosis			
Screen for behavioral health problems using valid instruments			•✓
Diagnose behavioral health problems and related conditions			•✓
Use valid measurement tools to assess and document baseline symptom severity			•✓

We apply this principle in the care of (none, some, most/all) our patients.	None	Some	Most/All
Engagement in Integrated Care Program			
Introduce collaborative care team and engage patient in integrated care program			•✓
Initiate patient tracking in population-based registry			•✓
Evidence-Based Treatment			
Develop and regularly update a biopsychosocial treatment plan	•		✓
Provide patient and family education about symptoms, treatments, and self-management skills			•✓
Provide evidence-based counseling (e.g., Motivational Interviewing, Behavioral Activation)			•✓
Provide evidence-based psychotherapy (e.g., Problem Solving Treatment, Cognitive Behavior Therapy, Interpersonal Therapy)			•✓
Prescribe and manage psychotropic medications as clinically indicated		✓	•
Change or adjust treatments if patients do not meet treatment targets			•✓
Systematic Follow-up, Treatment Adjustment, and Relapse Prevention			
Use population-based registry to systematically follow all patients			•✓
Proactively reach out to patients who do not follow-up			•✓
Monitor treatment response at each contact with valid outcome measures			•✓
Monitor treatment side effects and complications			•✓
Identify patients who are not improving to target them for psychiatric consultation and treatment adjustment			•✓
Create and support relapse prevention plan when patients are substantially improved			•✓
Communication and Care Coordination			
Coordinate and facilitate effective communication among providers			•✓
Engage and support family and significant others as clinically appropriate			•✓
Facilitate and track referrals to specialty care, social services, and community-based resources		•	✓
Systematic Psychiatric Case Review and Consultation			
Conduct regular (e.g., weekly) psychiatric caseload review on patients who are not improving	•		✓
Provide specific recommendations for additional diagnostic work-up, treatment changes, or referrals			•✓

We apply this principle in the care of (none, some, most/all) our patients.			
	None	Some	Most/All
Provide psychiatric assessments for challenging patients in-person or via telemedicine	•		✓
Program Oversight and Quality Improvement			
Provide administrative support and supervision for program			•✓
Provide clinical support and supervision for program			•✓
Routinely examine provider- and program-level outcomes (e.g., clinical outcomes, quality of care, patient satisfaction) and use this information for quality improvement			•✓

• Response at baseline ✓ Response at 12 months

Border Region Behavioral Health Center IBH Checklist Results

Table 5 and **Table 6** present the results from Border clinic staff assessment of IBH implementation prior to and following implementation of the *Juntos* program. According to Border staff, the clinic moved 2 principles and 2 tasks to the Most/All category from the None or Some categories by the end of implementing the *Juntos* program. Note that Border staff completed both assessments at the end of the intervention period; staff did not complete an assessment prior to intervention implementation.

Table 5. Border Region Behavioral Health Center IBH Checklist Baseline to 12 months: Core Principles

We apply this principle in the care of (none, some, most/all) of our patients.			
	None	Some	Most/All
Patient-Centered Care Primary care and behavioral health providers collaborate effectively using shared care plans.			•✓
Population-Based Care Care team shares a defined group of patients tracked in a registry. Practices track and reach out to patients who are not improving, and mental health specialists provide caseload-focused consultation, not just ad-hoc advice.	•		✓
Measurement-Based Treatment to Target Each patient's treatment plan clearly articulates personal goals and clinical outcomes that are routinely measured. Treatments are adjusted if patients are not improving as expected.	•✓		
Evidence-Based Care Patients are offered treatments for which there is credible research evidence to support their efficacy in treating the target condition.		•	✓
Accountable Care Providers are accountable and reimbursed for quality care and outcomes.			•✓

• Response at baseline ✓ Response at 12 months

Table 6. Border Region Behavioral Health Center IBH Checklist Baseline to 12 months: Core Components and Tasks

We apply this principle in the care of (none, some, most/all) our patients.			
	None	Some	Most/All
Patient Identification and Diagnosis			
Screen for behavioral health problems using valid instruments			•✓
Diagnose behavioral health problems and related conditions	•✓		
Use valid measurement tools to assess and document baseline symptom severity			•✓
Engagement in Integrated Care Program			
Introduce collaborative care team and engage patient in integrated care program			•✓
Initiate patient tracking in population-based registry			•✓
Evidence-Based Treatment			
Develop and regularly update a biopsychosocial treatment plan	•✓		
Provide patient and family education about symptoms, treatments, and self-management skills	•✓		
Provide evidence-based counseling (e.g., Motivational Interviewing, Behavioral Activation)		•	✓
Provide evidence-based psychotherapy (e.g., Problem Solving Treatment, Cognitive Behavior Therapy, Interpersonal Therapy)	•✓		
Prescribe and manage psychotropic medications as clinically indicated	•✓		
Change or adjust treatments if patients do not meet treatment targets	•✓		
Systematic Follow-up, Treatment Adjustment, and Relapse Prevention			
Use population-based registry to systematically follow all patients		•	✓
Proactively reach out to patients who do not follow-up			•✓
Monitor treatment response at each contact with valid outcome measures	•✓		
Monitor treatment side effects and complications	•✓		
Identify patients who are not improving to target them for psychiatric consultation and treatment adjustment	•✓		
Create and support relapse prevention plan when patients are substantially improved	•✓		

We apply this principle in the care of (none, some, most/all) our patients.	None	Some	Most/All
Communication and Care Coordination			
Coordinate and facilitate effective communication among providers			•✓
Engage and support family and significant others as clinically appropriate	•✓		
Facilitate and track referrals to specialty care, social services, and community-based resources			•✓
Systematic Psychiatric Case Review and Consultation			
Conduct regular (e.g., weekly) psychiatric caseload review on patients who are not improving	•✓		
Provide specific recommendations for additional diagnostic work-up, treatment changes, or referrals			•✓
Provide psychiatric assessments for challenging patients in-person or via telemedicine	•	✓	
Program Oversight and Quality Improvement			
Provide administrative support and supervision for program			•✓
Provide clinical support and supervision for program			•✓
Routinely examine provider- and program-level outcomes (e.g., clinical outcomes, quality of care, patient satisfaction) and use this information for quality improvement			•✓

• Response at baseline ✓ Response at 12 months

Question 3a. To what extent have providers and program staff adopted the components of PCMU at 6 and 12 months, and what are the facilitators and barriers to adoption?

Program Adoption

Partner and clinical staff interviewees and focus group participants were asked about factors that facilitated or hindered program implementation and participant participation in the program. Presented in the following section are adoption facilitators and barriers that emerged from interviews with staff and partners and from focus groups with study participants. *(Note that in some cases, interviewees and focus group participants provide insights beyond the implementation of the PCMU).*

Adoption Facilitators

At mid-point, partner and clinical staff interviewees cited several successes to early program implementation of the *Juntos* program, including: patient access to increased screening, health education, and additional services at Gateway; increased communication and coordination between TAMIU and Gateway via frequent emails, phone calls, and in-person meetings between staff and leadership at many levels; increased patient recruitment and retention were attributed in part to adding a gift card incentive in addition to a voucher for the A1C test; the movement of behavioral health providers within the Gateway clinic to a space closer to patient education services resulted in increased privacy and integration; and

staff training was conducted on using the PHQ-9 and Duke Health Profile instruments. During summative evaluation interviews, adoption facilitators included staffing and partners; communication; relationships; training, education, and capacity of staff; flexibility; and data systems.

Staffing and Partners

Interviewees reported that staffing needed to implement the PCMU project, and *Juntos* in general, was found through existing employees and new hires. Interviewees said that case managers from different sites were trained in the PCMU program, and that specialized evaluation/study staff—such as a compliance officer, research analyst, etc.—were hired or reassigned from other jobs within partner agencies. For the traveling healthcare teams, a key hire was an individual familiar with the community and its institutions, and who was crucial in identifying and coordinating with possible visit sites. In some cases, staff were added to bolster existing services. For example, clinical staff interviewees from Border described expanding on their existing primary care capacity by hiring a nutritionist and an additional skills trainer: *"With expansion capacity we can provide skills training and nutritional assessments for clients that didn't have the opportunity to have that in the past. It's a more complete care for them at Border because we already have a primary care clinic, but we didn't have a nutritionist in the past. We did have skills training but only one person and there's about 300 plus clients in the center."*

One partner interviewee noted that in the initial team-building phase, there was ongoing assessment of individuals regarding "*the kinds of skills and the kind of background and experience that we were bringing. We were always kind of learning…what kind of contribution we would be making, and that really has evolved over time.*" For example, the same interviewee shared that they were initially hired to facilitate data collection and cleaning, but they were then asked to use their background knowledge in research to help shape and carry out the evaluation study. Partner and clinical staff interviewees indicated that this process yielded strong teams, which multiple interviewees complimented. One partner interviewee stated that Gateway staff, for instance, "…*did some absolutely fabulous work in treating as many patients as they could. I think overall they ended up screening something like between twelve to fifteen hundred people to find the sample that we ended up with*." The *Juntos* partnership also provided staffing support for sites when they were occasionally short-staffed. A partner interviewee relayed a period when Gateway needed a medical assistant to help conduct *Juntos* enrollment due to a change to the original plan of having nursing students on-board for this task. According to this interviewee, rather than cancel enrollment sessions, staff from partnering agencies came as needed to assist with collecting BMI and blood pressure while Gateway staff completed remaining enrollment tasks.

Communication

Multiple interviewees stated that the addition of monthly meetings in May 2017 for all *Juntos* stakeholders greatly improved the collaborative's efforts to implement the PCMU and other *Juntos* activities. Partner and clinical staff interviewees suggested that being with one another in person on a regular basis simplified the troubleshooting process because all the players were able to discuss challenges in real time, often leading to quicker opportunities for realistic solutions. One partner interviewee shared that this increased communication has helped in tracking patients referred between agencies: "*There's better communication now, and better connection for continuum of care. And I think that's one thing Sí (Texas) did assist with is enhancing that continuum, whether we do it directly, or in partnership with one of the other partners*." Also, as indicated below, communication between partner agencies improved knowledge of what each site provides, as well as personal relationships with contacts at each site, which further enabled referral-making and follow-up.

Relationships with Partners

Clinical staff interviewees at multiple agencies observed that the *Juntos* partnership facilitated far greater knowledge of programming and inter-agency relationships among staff, which enhanced IBH, inter-agency integration, and coordinated care for patients. More information is provided in response to Question 8 later and visually depicted in **Figure 1**. As one clinical staff interviewee said, "*There were all separate agencies and I think with the partnership…we're able to kind of join together and it's been really important, especially for the community because we should work together in general, not just for Region, Gateway, SCAN, and City*." Interviewees suggested that relationships were built through face-to-face monthly meetings, presenting to one another on each agency's work, sorting out the nuts and bolts of inter-agency travel healthcare teams, etc. Multiple interviewees indicated that this increased knowledge of programming at other sites and familiarity with specific contacts at these sites led to increased IBH referral and integration. For example, a clinical staff interviewee commented that the City of Laredo Health Department offers multiple structured physical activity opportunities, "*…but we never knew when they were going to be. You go to their website, you can't find the information. So, then that's where Sí Texas comes in and you're able to talk to the caseworker over there, email them, and create a flyer—come together so that people know what's out there for them*."

Training, Education, and Capacity of Staff

Clinical staff interviewees reported pride and utility in gaining new skills through their work with *Juntos*, especially those who worked with the travelling healthcare teams. Several of these interviewees appreciated PCMU-related trainings to ensure consistent communication and documentation. One partner interviewee described Gateway staff as engaging clients successfully and being very successful at bringing clients back in for follow-ups. *"I don't know how much of it is the relationship that they have with the clients or the engagement that the clients have with the clinic, but they did a very good job…and that's something tremendous because of the number of people that we were working with."* Border staff were also noted as being fundamentally engaged with clients, effectively directing them to services, and having the benefit of their existing integrated behavioral health specialist and primary care unit. One partner interviewee said of these staff that "*They multitask. They're cross-trained. They can pretty much do anything*."

Flexibility

Related to the section above on "Training, Education, and Capacity of Staff," clinical staff interviewees also mentioned the benefit of their flexibility due to cross-training and their willingness to conduct work in the field rather than only in the clinic. One interviewee shared, "*We still get along, so that made it so much easier for us to learn, and even if I don't know what you're talking about—then teach me or show me what can I help you with. Somebody was doing something, then the other one would do the paperwork, and one was arranging the gift cards. Even those little things, yes everyone helped.*" Some clinical staff interviewees stated they were hired for a specific job but ended up in a slightly different role based on how their skills would best help implement the program. Lastly, clinical staff interviewees explained they required flexibility to keep up with changes to protocols along the way: "*First it was starting off and making sure we understood what the program was about, our duties, etc., getting familiar with the center, too, with Border and its policies. Then once we got the hang of it, it changed. Which is great, like I was saying—it challenges you in ways and you're successful.*"

Data Systems

Though multiple interviewees commented that there were challenges to finalizing a dynamic data-sharing system between agencies to track referrals, they also provided examples within *Juntos* of using data

systems to facilitate implementation. A partner interviewee explained that there were "…*monthly reports that we put together that [clinics] submitted to us where they reported their performance and the numbers and the number of visits, the number of clients that they were seeing, and how many of them were unduplicated, duplicated, how well they were doing with their six-month and twelve-month follow-ups.*" (Note: These reports from clinics were uploaded into a TAMIU-based database for central tracking and the data sharing system was finalized in December 2016). A partner interviewee also described how one clinic site successfully used a tracking form for patients during clinic appointments where participants were seen by multiple providers to ensure that they received all appropriate services.

Adoption Barriers

At the mid-point, interviewees described several adoption barriers, including initial staffing challenges, meeting enrollment targets due to trouble identifying eligible patients and difficulties in data collection and reporting. During summative evaluation interviews, interviewees named the following barriers to adoption: evaluation study implementation; communication; hiring and staff; data systems; and workflow.

Evaluation Study Implementation

A primary adoption barrier described by partner and clinical staff interviewees was changes in implementation protocols, such as reporting procedures from clinics to TAMIU, by grant leadership at TAMIU that were meant to be immediately carried out by partnering clinics. Partner and clinical staff interviewees observed that these changes were challenging in both the partnership process and the resulting lack of time to train and prepare direct service staff for changes. One partner interviewee commented that "*Some of the challenges that we started seeing since the beginning was all the different changes. So for us, especially for me, because I was the one dealing with the report and dealing directly with TAMIU…it was difficult. But we wanted to help, we wanted to make it work*." One example described was the introduction of multiple iterations of referral tracking forms to be used by *Juntos* staff. This is described further in the "Communication" and "Data Systems" sections immediately below; interviewees providing direct services noted that the swiftness with which new versions of these forms were expected to be implemented was difficult to keep up with.

Communication

As noted above, communication of changes between partners was noted as a barrier to implementation. Another reported example was the ways that PCMU referrals were tracked across agencies. Partner interviewees indicated that while each agency had its own referral system, there was need for a common system across agencies. Clinical staff interviewees who worked most closely with these systems shared that ongoing changes to the developing *Juntos* system made it very difficult to keep up with all requirements and led to some participants seeming to fall through the cracks. These interviewees indicated that this was frustrating to their own sense of professionalism and made the PCMU study itself a challenge. This example is described further in the "Data Systems" section below.

Hiring and Staff

As mentioned previously, some interviewees suggested that when initiating *Juntos* programming, there were periods of trial and error to matching existing and recruiting new staff to the needed roles. Some partner interviewees said that the staffing challenge was especially pronounced for the traveling healthcare team, as staff from each partner agency were needed who were both dedicated to the outreach mission and who could work in the field without direct supervision. One partner interviewee also indicated that some sites could still make improvements to staffing in order to better implement the

IBH goal: "*We hope that they begin to implement case managers or navigators because they don't provide case management, and I think that's where they have the difficulty with the true integration.*"

Data Systems

At the midpoint, neither TAMIU nor Gateway reported having data systems in place to collect and share evaluation outcome measure data. In addition, they explained that data collection requirements changed several times as both organizations worked on implementation; midpoint interviewees stated that this challenged both organizations to communicate and implement collaborative systems to meet grant requirements for data reporting. As seen above in the "Communication" section, interviewees cited ongoing challenges to sharing referral and compliance data across agencies. The amount of documentation needed to employ the system that was eventually established was described as time-consuming by a clinical staff interviewee, noting, "*Minimizing the documentation we have to keep track of, finding a better way of gathering the referrals would be easier…I can handle it, but sometimes I'm like—Gateway, for example, has so many. I can see how they might get overwhelmed with forms and filling out and going back and forth with Acuity and Syncplicity. I know they are trying to make it easier, but at the same time they find things like incorporating this form, but it's more work that way*." Partner interviewees also described challenges in drawing relevant reports from within their internal agency data systems, which were sometimes exacerbated by a relative dearth of technical resources. One partner interviewee commented that it was a lot of work to successfully comply with the reporting requirements: "*A lot of people were involved besides the Juntos staff…There was a lot of time that we provided to the program and we continue to. But we understand the value of it in the long run. We can see the big picture idea*."

Workflow

When discussing workflow challenges, interviewees were often referring to THCT implementation. The use of additional paperwork required by *Juntos* was described as a workflow challenge for both the referring agencies and the agencies providing referred services with regards to whether a given patient should be documented as part of the *Juntos* program. Due to multiple referring agencies and multiple service referrals, adding the *Juntos* paperwork when staff weren't clear as to what referrals were for and why added to workflow challenges. One interviewee shared that when patients were referred into their clinic from elsewhere, it was challenging to learn whether it was a *Juntos*-related referral: "*Somebody comes in…and says, 'Oh, I got sent to see you.' 'By who?' 'I don't know.' And that'll be a typical answer: 'I don't know. They just told me to see you.' And they'll be a little bit upset… And by the time we realize, "Oh, it might have been a Sí Texas, it might not," he has already seen a therapist. So, that becomes a challenge that they don't come with the paperwork."*

Participant Facilitators

Program participant focus group members were asked to identify factors that supported their participation in *Juntos*. Reported facilitators included relationships and improved health outcomes, and transportation. (*Note that many of these facilitators reflect factors that helped participants within the clinic itself and may not reflect implementation of the PCMU.)*

Relationships with Providers and Peers

Many PCMU focus group participants mentioned liking their providers (i.e., physicians, counselors, nutritionists, case managers, etc.), citing that they received good, attentive care. For example, a focus group participant stated that she appreciated getting primary care at the clinic despite having insurance (Medicaid/Medicare) that could be used elsewhere because "*I like how [the doctor here] takes care of me and how she advises me…She tells you, You're higher in these, lower in that. Take this, take that, or walk or whatever…I like her.*" Program participant focus group members said they appreciated frequent monitoring of their diabetes and other chronic health conditions, noting that providers in other settings

don't track their conditions as frequently. One focus group participant contrasted her care through *Juntos* with care elsewhere, saying that the *Juntos* doctor will "*…check my diabetes every four months…When I would go to another doctor, sometimes it takes a year to recheck all that, when they know you're diabetic. And what I like about [the doctor here], she would go ahead and check everything, your high blood pressure, your sugar, and we've got cholesterol. And some of the other doctors don't even do that."* Focus group participants also described the pleasure and benefits of socializing with peers through their *Juntos*-related care and classes: "*It's also good for socializing, right! To get to know more people, well at least I like it. Wherever I talk, wherever my kids tell me 'Mommy, you chat in the store, you know her, wherever you go you always make friends.'*"

Improved Health Outcomes

Juntos enrollees reported improvements in their physical and mental health and noted that these outcomes made it both appealing and meaningful to return for scheduled care. Cited improvements included weight loss, better understanding of diet and health, and emotional relief. One program participant focus group member reported losing two pounds a month due to twice weekly exercise classes and "*a half hour of talking where they are talking about…how to count calories in each meal*." Another focus group participant observed that she was "*…always quiet until I said, 'Why? Everyone's talking, and I can too.' I started to talk, and I learned to talk in front of people...One learns many things if one wants to."* In reference to the emotional and practical benefits of a support class, one participant said they "*…got rid of the problems we were carrying around. A weight was lifted and one left here very tranquil, different…It helped me a lot, and I didn't like to miss any class because I learn a lot and I understand a lot of things and I try to control myself."*

Participant Barriers

Program participant focus group members were asked to discuss barriers that participants faced during the program. Participant barriers that emerged included scheduling, cost, relationships, wait times, and patient health or health literacy. (*Note that the barrier presented reflects participant experience within the clinic itself (i.e. clinic operations) and may not reflect implementation of the PCMU. Other barriers are presented in the Additional Implementation Findings subsection.)*

Scheduling

Program participant focus group members described the challenge of scheduling appointments and then having unanticipated obligations arise that prevented them from coming into the clinic (i.e. family emergencies or work demands). They noted that at times this led to being chastised by a provider at subsequent appointments or being told that if they miss more appointments they may be removed from these services and put onto a waiting list. One focus group participant described frustration after following his caseworker's advice of calling ahead to let them know he couldn't make an appointment due to a family emergency and being told he would have to wait three months for a rescheduled appointment. He said, "*Why are you going to make me wait when you tell us [to] call and let us know what's going on, so when you come back, why they say, No you have to redo everything, and then they make you wait three months later, and I ended up being at the hospital for two weeks because I hadn't took my medication*." Another participant stated that when cancelling an appointment, "*…sometimes you might lose your services because there's a lot of people on the waiting list.*" Additionally, with regards to receiving reminder calls from the PCMU program, some focus group participants commented that if they worked a day job or had obligations at their child's school, they would likely miss the reminder call and had no opportunity to get full advantage of the PCMU program (i.e. talking through barriers to making appointments if needed, etc.). Educational and skills sessions were also described as difficult for some

participants to attend as scheduled (early morning) because of the long bus ride to the clinic, work, or childcare responsibilities.

Question 3b. To what extent do providers buy-in to the program, and how has that buy-in affected implementation?

Provider and Staff Buy-In

Partner and clinical staff interviewees from clinic sites and at TAMIU were asked about their support and buy-in for the *Juntos* program, as well as their perceptions of their colleagues' buy-in. Interview participants described the role of IBH culture and buy-in from frontline staff and administration and leadership.

Clinic Culture

In general, interviewees characterized their organizational cultures as receptive to integrating primary care and behavioral health via the *Juntos* collaborative. One partner interviewee suggested that the *Juntos* work, especially the traveling healthcare teams, was in line with their organizational mission of working with the indigent and uninsured population, and "*taking care of the patient the way you'd want anybody to take care of the patient*." Many partner interviewees reported that clinics had been collaborating to different degrees already, thus indicating an openness to the process. In some sites, *Juntos* tools such as the PHQ-9 were reported to have already been in use and had revealed high frequency of depression among their patients, which one interviewee cited as "*reinforcing the need of implementing more behavioral health services now*." One partner interviewee explained that Border has a history of integration and multiple strategies in place to support it, such as their method of routing patients through multiple-appointment visits using a tracking sheet and ensuring that staff are trained in its effective use. This interviewee suggested that Gateway has historically not had this depth of integration in place, but that the *Juntos* program had newly introduced the Border-style tracking system in all sites. On the challenge of collaboration and new approaches in terms of meshing with other agencies, another partner interviewee shared that *"We've got certain ways of doing things. You also have personalities. That comes into play. But at the end, our [goal] has always been—at least at our end to our staff—it's what's best for the patient. If we need to work hand in hand with [other clinics], we've got to do it."*

Frontline Clinical Staff

On the topic of clinical staff satisfaction, one partner interviewee said, *"My staff, they love it. I could see they're so proud of it. You talk to my staff, they'll tell you that they're amazed that they've been here going on three years, and how much they've done and how much they've learned."* As seen in the "Adoption Facilitators" section, many clinical staff reported being enthusiastic about learning new ways of engaging patients. Some clinical staff, as mentioned above in "Adoption Barriers," found changes in PCMU documentation to be challenging, though they spoke positively about *Juntos* on the whole. One partner interviewee, in observation of clinic partners' pushback against some changes made along the way by TAMIU, noted, "*I think everybody has worked together, but it has come with some moments, some challenging, difficult moments where there's been some degree of resistance. I think that TAMIU's relationship with Methodist has helped a lot."*

Leadership and Administration

Partner and clinical staff interviewees characterized clinic leadership and administration as supportive. Partner interviewees frequently described the *Juntos* collaboration as being in line with what they were already doing or wanted to do in their sites. For example, one partner interviewee saw this opportunity as a good fit, saying, "*Before the Juntos, we had already implemented that…integration of services with*

primary care as…Patient-Centered Medical Home that's recommended by HRSA…We had diabetes support groups for patients with diabetes. We had already started all of that." Additionally, partner interviewees indicated that varying levels of collaboration existed between clinic sites prior to this grant opportunity, and that this presented an opportunity to structure and formalize these relationships. One partner interviewee stated that "*Juntos has improved that relationship with the partner [organizations], even though we already had it."* Conversely, there was some concern about whether the PCMU prong in particular was "*doing more wrong than good"* or *"may have created some degree of agitation*" based on feedback that some patients expressed annoyance by multiple reminder phone calls. (Note: Border and Gateway staff placed appointment reminder calls to all participants, intervention and control, as part of usual care protocols). Some partner and clinical interviewees identified turnover in *Juntos* staff as a barrier to implementation.

Question 4. To what extent did the control group receive program-like components?

Quantitative implementation data submitted by TAMIU for both intervention and control participants included visit and follow-up call data. Based on this information, there was no evidence of control participants receiving program-like components. No control participant received any follow-up calls from the PCMU. See **Table 7** below for implementation results of the PCMU intervention.

Qualitative implementation data revealed it is difficult to ascertain the extent to which the control group received program-like components. By moving the location for making reminder calls to PCMU patients from individual clinics to the TAMIU call center, the project introduced a centralized data entry point to document the study-related content of these calls (i.e. patient compliance and barriers, etc.). One partner interviewee shared a concern that the number and content of calls to the control group were not tracked in the same way as the intervention group, making it difficult to confidently assess whether they received program-like components. This interviewee said that, "*The piece that was difficult is when you don't have control of [documentation] in terms of the control group in terms of really being sure about how many telephone calls were made, exactly what was said, and those kinds of things…* "*Thinking back on it, it would have been nice maybe that we did the interventions in the call center at one time, and the control group follow ups on different days*."

Question 5. To what extent did the partners implement the PCMU intervention with fidelity?

TAMIU implemented the intervention with moderate fidelity due to changes in PCMU program implementation, particularly with respect to enrollment processes (as described above in question 2A), staffing and scheduling, and data systems. At the midpoint, most interviewees commented that there had been change in what they had initially envisioned for program implementation. Several new protocols and procedures, such as changing eligibility criteria, as well as new staffing, scheduling, and data systems facilitated implementation. Interviewees from both Gateway and TAMIU described making some adjustments, such as increasing incentives for patients and new reporting mechanisms, along the way as they worked to continuously improve their processes. In terms of the PCMU, interviewees acknowledged challenges with implementing the home visit component in a timely manner. While some patients did receive a home visit, others re-engaged with providers at Gateway and Border.

Interviewees reported several other implementation changes. One partner interviewee shared his/her perception that the initial plan was to roll out the program to other agencies, and that there was a change to only have evaluation study participants come from Gateway; however, once enrollment at Gateway became challenging (as seen above), the Border site was added as an evaluation study site. One partner

interviewee suggested that this presented a small but manageable hurdle. Additionally, partner interviewees noted that the home visiting aspect of the PCMU was not fully implemented during the entire intervention period as planned due to staffing issues.

TAMIU placed PCMU calls to intervention participants for upcoming clinical visits. For the Gateway clinic, PCMU calls were made to remind participants primarily about upcoming primary care appointments. At the Border clinic, these PCMU calls were made for both upcoming primary care and behavioral health/psychiatric appointments. When participants were called to be reminded of a primary care or behavioral health appointment, they were also reminded of any upcoming appointments scheduled for the next 30 days.

Table 7 below describes the intervention services relating to PCMU calls and home visits. A total of 1,500 calls were placed to intervention participants over the 12-month study period. About half (49%) were completed meaning the clinic staff successfully reached the participant; the other half of the placed calls were incomplete. These not completed calls were primarily unanswered (72%) while other reasons were related to inaccurate contact information, technical issues, and the availability of the participant. For those who were non-compliant after the PCMU calls, clinic staff worked to schedule a home visit. Over the course of the study, 13 home visits were scheduled and 8 were completed.

Table 7. Number of PCMU Calls Placed, Completed Calls, and Reasons for Incomplete Calls

	Number of PCMU Calls
Call Placed	1500
Call Complete	731
Call Incomplete	769
Unanswered Call	554
Non-working Number	40
Unavailable Participant	145
Technical Issue	26
Reason Not Indicated	4
Number of Home Visits Scheduled	13
Number of Home Visits Completed	8

Table 8 and **Table 9** and provide details on the number of calls attempted and completed by the two types of visits requiring PCMU calls, primary care and behavioral health, by clinic. Of the 366 intervention participants across both clinics, the PCMU attempted to contact 47 participants about a behavioral health visit, completing 20 of those calls. An average of 2.9 calls per participant were attempted with about half that (1.5 calls) completed. Contact regarding primary care visits was attempted for 303 participants and, of those, 252 were completed. On average, 4.5 attempted calls were placed to intervention participants with 2.8 of those considered complete. (Note that the average is based on the number of calls attempted rather than the total number of intervention participants).

Table 8. Receipt of PCMU Call Data for Intervention Participants, Gateway Clinic

	Number of Participants Receiving a PCMU Call	Average Number of PCMU Calls per Participant	Median Number of PCMU Calls per Participant	Minimum Number of PCMU Calls per Participant	Maximum Number of PCMU Calls per Participant
Behavioral Health					
Call Attempted	--	--	--	--	--
Call Completed	--	--	--	--	--
Primary Care					
Call Attempted	280	4.8	4.0	1.0	16.0
Call Completed	242	2.8	3.0	1.0	10.0

Table 9. Receipt of PCMU Call Data for Intervention Participants, Border

	Number of Participants Receiving a PCMU Call	Average Number of PCMU Calls per Participant	Median Number of PCMU Calls per Participant	Minimum Number of PCMU Calls per Participant	Maximum Number of PCMU Calls per Participant
Behavioral Health					
Call Attempted	47	2.9	2.0	1.0	6.0
Call Completed	20	1.6	1.5	1.0	4.0
Primary Care					
Call Attempted	23	1.4	1.0	1.0	3.0
Call Completed	10	1.2	1.0	1.0	2.0

Table 10 and **Table 11** describe the number and type of services received by both the intervention and control groups for each study clinic. At the Gateway Clinic, participants in both groups mostly received primary care services (see **Table 10**). For intervention participants, over half of the scheduled primary care visits were complete (52.2%) with 10.0% no shows. Control participants had a lower show rate (49.8%) and higher no-show rate (11.2%) for primary care. The additional primary care visits at the Gateway Clinic were either rescheduled or canceled. The most common visit type for Border participants was for behavioral health services (see **Table 11**). The intervention participants at Border had a show rate of 57.3% for behavioral health services. Over a third (35.1%) were no shows. The control group had a show rate of 73.0% and a no-show rate just under a quarter of visits (24.1%).

Table 10. Number of Juntos Clinical Services Provided, Gateway Clinic

	Number of Participants Receiving Service	Number of Scheduled Visits[a]	Number of Completed Visits	Show Rate	Number of No Shows	No Show Rate	Number of Rescheduled Visits	Number of Canceled Visits
INTERVENTION								
Behavioral Health	28	54	28	51.9%	10	18.5%	11	5
Primary Care	289	3196	1669	52.2%	320	10.0%	775	380
Other Services[b]	203	1562	637	40.8%	185	11.8%	436	251
CONTROL								
Behavioral Health	14	37	17	45.9%	9	24.3%	6	3
Primary Care	286	2969	1478	49.8%	346	11.7%	726	382
Other Services[b]	201	1437	572	39.8%	155	10.8%	418	251

[a]this includes visits labeled as "pending" where a specific visit has not yet occurred [b]this category includes all services not covered by primary care or behavioral health

Table 11. Number of Juntos Clinical Services Provided, Border

	Number of Participants Receiving Service	Number of Scheduled Visits[a]	Number of Completed Visits	Show Rate	Number of No Shows	No Show Rate	Number of Rescheduled Visits	Number of Canceled Visits
INTERVENTION								
Behavioral Health	63	684	392	57.3%	240	35.1%	49	3
Primary Care	33	273	161	59.0%	89	32.6%	21	2
Other Services[b]	56	329	166	50.5%	118	35.9%	30	15
CONTROL								
Behavioral Health	66	315	230	73.0%	76	24.1%	3	6
Primary Care	32	182	136	74.7 %	42	23.1%	0	4
Other Services[b]	58	158	98	62.0%	47	29.7%	3	10

[a]this includes visits labeled as "pending" [b]this category includes all services not covered by primary care or behavioral health

Of the 302 intervention participants at Gateway clinic, 289 received primary care services with an average of 5.8 visits per participant over the course of the study (see **Table 12**). Of the 296 control participants at the Gateway clinic, 286 received primary care services, with an average of 5.2 visits per participant. The average number of primary care visits between intervention and control participants was statistically significantly different ($p = 0.03$). The average number of behavioral health visits was also statistically significantly different with control participants having 1.2 visits and intervention participants having 1.0 visits ($p = 0.02$).

Table 12. Receipt of Juntos Clinical Services for Intervention and Control Participants, Gateway Clinic

	Number of Participants Receiving a Visit[a]	Average Number of Visits per Participant	Median Number of Visits per Participant	Minimum Number of Visits per Participant	Maximum Number of Visits per Participant
INTERVENTION					
Behavioral Health	28	1.0	1.0	1.0	1.0
Primary Care	289	5.8	5.0	1.0	22.0
Other Services[b]	203	3.1	2.0	1.0	16.0
CONTROL					
Behavioral Health	14	1.2	1.0	1.0	2.0
Primary Care	286	5.2	5.0	1.0	20.0
Other Services[b]	201	2.8	2.0	1.0	13.0

[a]this includes only visits that occurred [b]this category includes all services not covered by primary care or behavioral health

Almost all the intervention participants at Border, apart from one participant, received a behavioral health care visit during this study with an average of 6.2 visits per participant (see **Table 13**). Of the 71 control participants enrolled at Border, 66 received a behavioral health visit during the study, with an average of 3.5 visits per participant**.** The average number of behavioral health visits between intervention and control participants was statistically significantly different ($p < 0.001$). The average number of primary care visits was not significantly different between intervention and control participants.

Table 13. Receipt of Juntos Clinical Services for Intervention and Control Participants, Border Clinic

	Number of Participants Receiving a Visit[a]	Average Number of Visits per Participant	Median Number of Visits per Participant	Minimum Number of Visits per Participant	Maximum Number of Visits per Participant
INTERVENTION					
Behavioral Health	63	6.2	6.0	1.0	21.0
Primary Care	33	4.9	3.0	1.0	21.0
Other Services[b]	56	3.0	2.0	1.0	12.0
CONTROL					
Behavioral Health	66	3.5	3.0	1.0	11.0
Primary Care	32	4.3	3.0	1.0	19.0
Other Services[b]	58	1.7	1.0	1.0	5.0

[a]this includes only visits that occurred [b]this category includes all services not covered by primary care or behavioral health

Question 6. How satisfied are patients with the PCMU program? How satisfied are providers with the PCMU program?

Program participant focus group members indicated that they were mostly satisfied with the *Juntos* program, citing services provided, relationships with program staff and peers, improved health knowledge and health behaviors, and improved health outcomes as reasons for being satisfied. (*Notes: Patient satisfaction surveys were part of the approved SEP. However, due to the use of participants from several clinics which use different patient satisfaction protocols, data from patient satisfaction surveys are not included in this report. (Many of the ways in which participants expressed satisfaction with services were related to clinic services rather than the PCMU intervention*).

Services Provided
Program participant focus group members shared satisfaction with many of their providers through *Juntos*, and a feeling that they were receiving attentive, personalized care. This was exemplified by the participant previously quoted who was pleased to have her blood sugar levels and other conditions monitored regularly. Participants were especially positive about their experiences with behavioral health treatment, whether individualized or in a group setting. One participant explained that she had been "*…closed off from the world. Then I started coming and all and talking with them, and you left a different person. Here you would cry, hear everything, and you left a different person. And besides, well, they take care of you.*" There were also reports of great satisfaction with classes on nutrition for diabetics.

There were also reports of dissatisfaction with services by focus group participants. The majority of these reports were related to a dislike of what they perceived as an often-changing set of providers and staff, especially in relation to behavioral health care. A participant noted disliking the telemedicine provision of psychiatric care because "s*ometimes it's not even the same one, and…everybody has a different mind and different way to interpret how you feel, what you're going through and all that, making changes and all that.*" Another participant added that they generally distrusted the telemedicine method because "*The person that's on the television can't tell you want's really wrong with you, okay? So it's not the same thing. Looking into somebody based on a camera and look into somebody here in person. You can't see the defects on that person, and that's not right."* In relation to primary care and diabetes management, a focus group participant said that though the doctor was nice, they perceived her to be "absolutely clueless" at controlling diabetes: "*When I used to go to a real doctor, they gave me 80 [pills]." [Instead, this doctor will] start me with ten. I'm like, really? Oh, you've got to prove the 80. I've got to bring the old bottles? I hoard my pills, so I have my old bottles, but they're just fighting with her all the time. She's a very nice person, but yeah."* Lastly, one participant stated indifference to the program by saying that he wouldn't participate if they didn't pay him.

Improved Outcomes
Several focus group participants cited improved health outcomes as shaping their satisfaction with *Juntos*. When asked what they liked about the program, one focus group participant shared, "*I used to eat a lot of bread and a lot of tortillas. So that's helping me out now, where I only eat…one bread or one tortilla a day, and my sugar really levels.*" Focus group participants indicated satisfaction with weight loss in relation to improved diet. Additionally, as seen above, participants described great benefits from behavioral health skills training sessions, such as approaches to coping with grief or feeling overwhelmed.

Relationships
As seen in the "Services Provided" section above, relationships with staff and providers were closely related to focus group participants' satisfaction or dissatisfaction with the *Juntos* program. Key to the level

of satisfaction, regardless of outcomes, was often whether the participant was able to establish an ongoing relationship with a provider (more satisfied) versus seeing different providers at each visit (less satisfied). One satisfied participant stated that she got "*…the skills training, the counseling. She asks me, how is your counseling doing? Are you doing okay? And the nutritionist, I like her too. She's a very good lady."* As described elsewhere, relationships with peers were also a source of participant satisfaction in the *Juntos* program.

Health Literacy
As seen above, focus group participants mentioned learning about diabetic self-care through blood sugar monitoring and its significance, carbohydrates and food choices, and exercising. One participant shared: *"It's teaching me more—[I] at least test myself in the morning, and then sometimes I test myself at night again to make sure I'm okay because sometimes if you don't test yourself at night, you never know your sugar's too low as you sleep."* Similarly, as noted above, participants gained actionable insights and relief from behavioral health programming through *Juntos*.

Partner and clinical staff interviewees indicated that they were generally satisfied with the PCMU program, as detailed above in Question 3b. Most interviewees reported that the *Juntos* program meshed well with their clinic cultures—and in some cases, existing protocols—and built on existing relationships between organizations. Clinical staff interviewees reported overall enthusiasm for *Juntos* activities, though they also noted challenges related to PCMU documentation and to unexpected changes in protocols. Partner interviewees similarly viewed *Juntos* programming as aligned with their existing organizational missions and contributing to improved relationships with partner organizations. Many partner and clinical staff interviewees cited the introduction of monthly *Juntos* meetings as an important contributor to their successes. In addition to these themes, they described improved referrals as a key point of satisfaction.

Improved Referrals
Clinical staff interviewees mentioned great satisfaction with their improved capacity to make quality referrals as a result of increased familiarity with services and specific point people at neighboring agencies. For example, one clinical staff interviewee observed that they were better equipped to provide a supported referral for primary or specialized care to insured patients: "[*Before Juntos,] whenever someone would say they have insurance, I think we would just be like, OK, you can get your primary care physician. But now we have compiled a directory of different primary care physicians in Laredo and urgent care clinics and emergency rooms, dermatologists, just to make sure we have a healthcare community here in Laredo."* Clinical staff interviewees indicated that familiarity with other agencies' programming enabled them to be more helpful in providing IBH referrals.

TAMIU Specific Implementation Evaluation Questions

Question 7. Are patients who participate in the PCMU intervention more compliant with maintaining appointments when compared to patients that do not participate in the intervention?

Compliance is defined as not missing scheduled appointments; therefore, any participant having missed either a behavioral health or primary care visit was considered non-compliant. These incomplete visits include no shows, canceled, and rescheduled visits. Visits reported as having occurred were considered successful and indicated a participant was compliant. All 366 intervention participants began the study non-compliant by missing appointments in the 24 months prior to the study or within 1 month of enrolling into the study. Among intervention participants, 72% had a successful PCMU call where the participant

was reached to remind him or her of a primary care visit in either clinic or behavioral health for Border participants. Over half of participants who received a PCMU call were compliant as of their last reported scheduled appointment (58%). In other words, the status of these participants last reported scheduled appointment was having occurred.

Among those intervention participants for whom a PCMU call was not successful, who had primary care or behavioral health visit data reported (n=62), the compliance rate was 39% based on their last scheduled appointment. The remaining 39 intervention participants did not have any behavioral health or primary care visit data reported during the study. The 8 home visits were received by 5 study participants. Based on the status of their last reported scheduled appointment, none of those participants who received home visits were compliant (**Table 14**).

Table 14. Status of Intervention Participants through Study Period

	Number of Participants
Non-compliant at Baseline	366
Received PCMU Call	265
Compliant After PCMU Call	153
Received Home Visit	5
Compliant After PCMU Home Visit	0

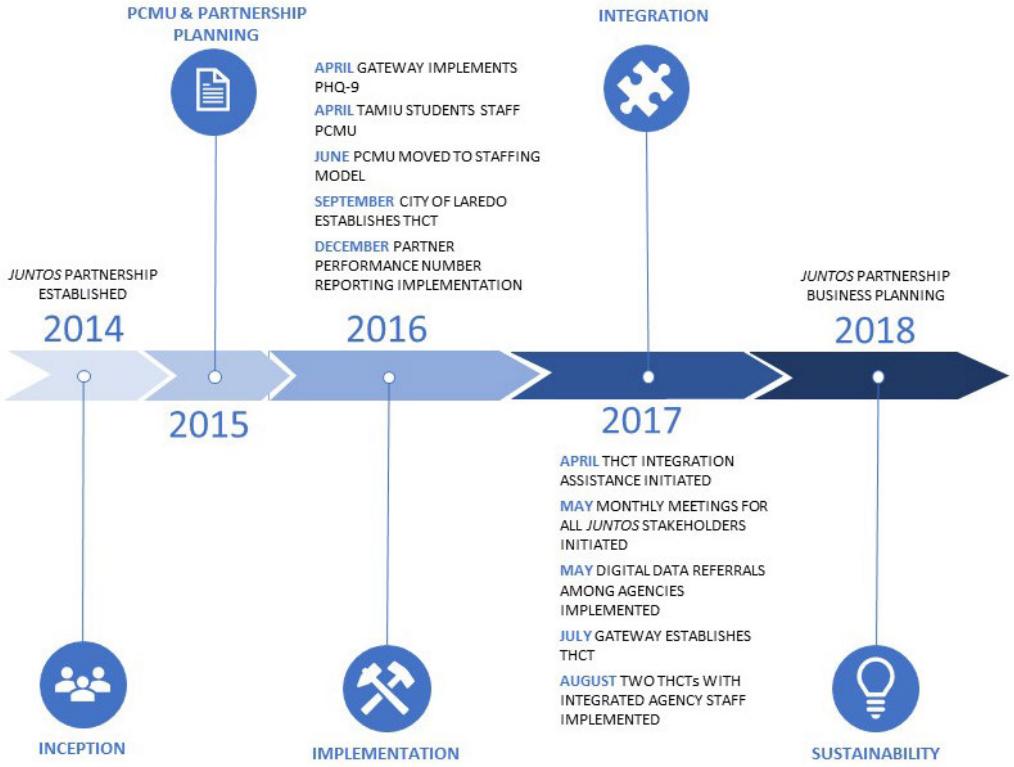
The compliance rates among intervention participants with a successful PCMU call varied by clinic. Among Gateway intervention participants with a successful PCMU call, 60% were compliant based on their last reported scheduled appointment. Among Border, intervention participants with a successful PCMU call, the compliance rate was 39% based on their last reported scheduled appointment.

Among control group participants, 360 (98%) had data on the primary care and behavioral health visits received during the study period. Of these, 64% were compliant at the end of the study. Just over a third (34%) had statuses of “no show”, “canceled”, or “rescheduled” for their last reported appointment in the study period. The compliance rates in the control group varied by clinic. Based on their last reported scheduled appointment, 62% of Gateway control participants were compliant. Among Border’s control group, 74% were compliant based on the status of their last reported scheduled appointment.

Question 8. To what extent has the partnership played a role in the implementation of the *Juntos for Better Health* program?
(Note: Specific subquestions were added to this implementation question during the development and preparation for summative qualitative data collection).

As stated previously, the *Juntos* program involved 3 prongs with Prong 3 intended to build capacity and share resources among and within partner organizations through the addition of staff, development of referral protocols, and developing a shared health information system to improve plans of care and facilitate referrals. **Figure 1** presents a timeline of the development and implementation of the *Juntos* program strategies.

Figure 1. Juntos Development and Implementation



According to summative evaluation interviews, the partnership between all participating organizations was crucial to the effective implementation of the *Juntos* program. As described by interviewees, the *Juntos* program has required intensive collaboration amongst agencies that previously had varying degrees of existing connection. One partner interviewee commented that *"It was a good model…because we were already partners…We've always worked with [the other organizations]. This just formalized a way of partnering which we already did informally and set the groundwork for the future."* The partnership, as noted elsewhere, was greatly supported by the introduction of monthly meetings in May 2017 in which staff and administrators from different agencies were in direct contact, and in which problem solving was done with greater efficiency. One clinical staff interviewee described a deeper inter-agency connection resulting from these meetings, saying, *"I don't think that it was as it is now. I think everybody was kind of aware, OK, this clinic, this clinic, but not really aware of what services they offer…I mean there were all separate agencies and I think with the partnership, with Juntos, we're able to kind of join together and…it's been really important especially for the community because we should work together in general…It should be more agencies involved in this, but I think it was different in the beginning but it's good now that we work together that way."*

Interviewees shared that over the course of the *Juntos* program, there was an ongoing process of clarification of the goals, expectations, and terms of partnership. They noted that their satisfaction with it increased as they felt they could implement the programming successfully, and subsequently saw positive results among patients regarding their health and engagement with health care. Partner interviewees described a range of perspectives and practices at partnering agencies with regards to sharing resources across organizations. However, they noted that through the process of working

together via *Juntos*, the agencies saw how beneficial this practice could be, and they reported that they were working more towards shared goals. One partner interviewee summarized the process by saying that *Juntos* "*has really worked to raise that awareness of integrated health as it sort of applies to each agency because everyone is at a different place and on top of that, we really work on creating connections amongst the agencies so that there is a system in place where they are. There is some active communication happening between [all partner sites] where we're not just sending clients off for services just kind of cold, with no contact on the other end."*

Question 8a. How has the *Juntos* structure and model evolved?

As noted elsewhere, interviewees shared that the *Juntos* PCMU structure and model shifted over the course of the program. Question 5 addresses fidelity to the original plan, and details reported shifts in the details of implementation. Of these shifts, those that relate to the PCMU's program's structure and model include: eligibility criteria; number of enrollment sites; and fewer home visits than anticipated. Additionally, as seen elsewhere in this report, interviewees described multiple iterations of referral documentation and tracking data systems. *Juntos* partner agencies expanded services as the partnership developed. For example, Border began offering skills training to all clients, nutrition counseling, and classes on skills and nutrition. See **Appendix N: Expanding Capacity Summary** for a list of expanded services that partners implemented as the partnership developed.

Regarding development of the *Juntos* partnership, interviewees indicated that collaboration, information sharing and communication, and opportunities for complementary activities were key issues.

Collaboration
Some interviewees described bumps in the road as the *Juntos* collaboration got underway, such as the need for clarity and documentation of expectations and agreements between partners. One partner interviewee stated, "*One of the things that we learned as an organization and myself is before we get into any contracts, make it even clearer. I thought it was clear at the beginning but, I guess, I don't know, it was also new for them and it's a huge initiative and we recognize that they took on such a huge, huge job to get all this—the network and all the partners—working."* As previously reported, enhancements to collaboration included the introduction of monthly, in-person meetings and purposeful presentations from each agency to introduce one another to their programming and staff. Another partner interviewee observed that there were ongoing efforts to encourage the clinics to communicate directly with one another regarding requests, rather than going through another agency. This partner interviewee described a recent situation: *"[The clinic had] a situation where they needed help. I told them, you need to call across the street…and ask them if they can help you…I need to start stepping back and you need to start doing it on your own. You need to build that relationship where you have enough where you can call and just say, Hey, I need your help for this one…I think the trust between them has gotten better but I do think it's at a point where it depends on who you're talking about."* The same interviewee framed this reliance on one another as something that must be practiced: "*You've got to learn how to do it. If you don't practice it, you don't know how to do it…It's just an issue of putting your personality and your self-interest to one side and doing it for the well-being of the team.*"

Information Sharing and Communication
Interviewees described their success in communicating about available services to both the public at large and to other providers. One partner interviewee commented that *"The things that we have done well is to continue to be engaged and really try and understand what's happening with the community, and really*

engage in some research that has not really been done in our community before, and I think that will be helpful in many different ways."

Additional or Complementary Activities
During summative evaluation interviews and focus groups, participants and staff had several recommendations for additional or complementary activities that *Juntos* partners could provide to participants. These suggestions included provision of free counseling; transportation and medication assistance; enabling the traveling health care teams to prescribe and dispense initial amounts of medication in order to initiate the relationship to a clinic; and explicitly addressing addiction.

Question 8b. How has the *Juntos* partnership been a mechanism for IBH? How has integration developed across partners (i.e. integration within and between organizations)?

As described in Question 3a in the section on "Adoption Facilitators," the *Juntos* partnership has been a mechanism for IBH in multiple ways. This is notably highlighted in adoption facilitators such as "Staffing and Partners," "Communication," and "Relationships." Crucially, partner and clinical staff interviewees indicated that the partnership has facilitated far greater knowledge of programming and relationships between staff at the sites, which has enhanced both IBH and inter-agency integration. One partner interviewee stated that *Juntos* enhanced inter-agency relationships, communication, and networking "*…to improve services so no one falls through the cracks, because some would...But there's better communication now, and better connection for continuum of care. And I think that's one thing Sí (Texas) did assist with is enhancing that continuum, whether we do it directly, or in partnership with one of the other partners. I think that's what it tested and that's easier said than done."* Noted activities that were said to have led to this integration included face-to-face monthly meetings, presenting to one another on each agency's work, sorting out the nuts and bolts of inter-agency travel healthcare teams. Interviewees shared that in some cases IBH referrals were already in place across agencies pre-*Juntos* (for example, Gateway's medical providers were already referring as indicated to in-house LPCs, to Border, or to SCAN for substance use issues). In other cases, interviewees made note that increased knowledge of programming at other sites and familiarity with specific contacts at these sites led to increased IBH referral and integration.

Question 8c. How is this partnership model moving towards working as a consortium with a centralized referral system?

The *Juntos* partners reported they began making phone calls to clients from a single location at TAMIU rather than from each individual clinic. At the summative evaluation, clinical staff interviewees reported varying degrees of integration with the centralized call center. One clinic staff member, for example, reported they had begun training on scripts to use at the call center, but not yet made calls from there. A staff member from another site noted that going to TAMIU to make calls may be challenging because it rules out spontaneously speaking to their home agency clinic staff in person to request appointment openings for clients. They noted that working from TAMIU instead requires calling their home agency clinic in hopes of reaching a specific person. They stated, "*I'm hoping that it will work, but I don't know yet…I don't know how that process is going to work to be honest with you*."

With regards to creating a system for electronically sharing information across systems within the consortium, interviewees noted that this was a more challenging task that had not yet come to fruition. One partner interviewee explained: *"That was a pillar activity for us to develop a network of reminders and outreach to make sure people came in…I don't think we did a good enough job in that action, in that*

activity…The health information sharing never got off the ground, and that's critical for our patients that go back and forth."

Additional Implementation Findings

In addition to data to answer the *a priori* implementation questions presented in the SEP, the qualitative implementation evaluation also yielded additional findings related to perceived successes and impacts, information-sharing, program replication/scalability, funding, and additional or complementary activities. Presented here are key themes that emerged during the interviews and focus groups not directly asked by the implementation research questions outlined above but that are still available to provide context for the *Juntos* program.

Program Successes, Impact, and Barriers

Partner and clinical staff interviewees and focus group participants were asked to speak about their perceived successes and impacts of the PCMU program. Successes identified at the midpoint included: patient access; increased communication and coordination; patient incentives; clinic space; and staff training. At the summative point, successes identified included: staff, partners, and consumer capacity; integration; mental health; health literacy; chronic disease; and clinical space as relating to travel health care teams.

Staff, Partners, and Consumer Capacity
As described above in Question 3, interviewees observed that clinical staff at both clinic sites grew from their respective baselines to demonstrate a recognizably excellent level of care for and interaction with patients, as well as close tracking of patient wellbeing via A1C levels and the PHQ-9 instrument. Clinical staff were cited by an interviewee as engaging clients well and successfully bringing clients back in for follow-ups: *"I don't know how much of it is the relationship that they have with the clients or the engagement that the clients have with the clinic, but they did a very good job…and that's something tremendous because of the number of people that we were working with."* Other clinical staff were also observed as being fundamentally engaged with clients, effectively directing them to services, and utilizing the clinic's existing integrated behavioral health specialist and primary care unit. One partner interviewee commented that *"There's different things that each of [the agencies] weren't doing before that because of this project are now doing. And so, in essence, even if there isn't continued funding for exactly what we're doing right now, they have…begun to make changes to how they engage with their patients to provide a better service."*

Integration
Interviewees remarked on clinic providers' increased capacity to provide needed, integrated care to patients due, in part, to increased integration of information on patients' behavioral health status within the primary care setting via the PHQ-9. As one partner interviewee noted, *Juntos* enabled the partners to "*…come together to improve behavioral health. But also, to integrate into primary care, which in public health we've been talking about that for 20 years that we need to make it a standard and incorporate two things: incorporate disease health management and behavioral health.*"

Behavioral Health
Program participant focus group members expressed gaining behavioral health benefits from skills training sessions; as noted in Questions 3a and 6a above, they described positive outcomes that included feeling a burden lifted and having skills to navigate difficult circumstances and emotions.

Health Literacy
It was observed by program participant focus group members that their health literacy improved via *Juntos* education—both individual and group—on the topics of weight management, diet, diabetes, and mental health. As described elsewhere in this report, participants explained that this information was gained through educational sessions, individual and group therapy, and provider education during medical appointments.

Chronic Disease
Observations of improved chronic disease status were made by program participant focus group members and partner and clinical staff interviewees, as seen throughout this report. These observations included primary improvements for diabetic patients, such as lower A1C levels, weight loss, increased exercise, and a general decrease in the severity of diabetes-related risks. Additionally, interviewees commented on *Juntos* participants' greater connection to primary care within a medical home as a benefit to their chronic disease management, which may have previously been untreated.

Traveling Health Care Teams
Though the traveling health care teams from Prong 2 were not included in the formal implementation evaluation, many partner and clinical staff interviewees commented on this prong of the *Juntos* program. They described the challenges and successes of forming inter-agency teams to deliver health screenings and connections to care in community settings. Highlights of this experience from the provider perspective included learning how to work together across agencies with varying protocols and cultures and staffing the teams with self-motivated individuals who would function well without direct supervision in the field. From the patient care perspective, interviewees highlighted the importance of meeting community members where they work, live, study, and pray. They also noted making successful contact with otherwise unreachable patients and facilitating their connection to a medical home. One partner interviewee stated, "*My experience has been that people really like for us to be going to places where they feel more comfortable…I've got nothing but very positive reviews*" from sites hosting the travel team.

The THCT model did result in workflow challenges as noted by clinical staff interviewees related to differing responsibilities of travelling healthcare team members. Specifically, there was a concern noted regarding the protocol that all team members remain present if crisis management is needed: "*Staff from Border take over the crisis—that's what we do. [But staff from other sites] don't understand why they have to stay there, because the whole team needs to stay. That's kind of hard for them sometimes.*" This specific challenge may reflect the nature in which the THCTs were implemented. Several agencies implemented THCTs with staff only from their agency. Later in partnership development, two THCTs that integrated staff from multiple agencies were implemented.

Cost for Patients
Focus group participants commented that having no-cost care through some *Juntos* clinics made it possible for them to make use of that care. For instance, a focus group participant described having previously been charged twenty dollars for care at a clinic, "*…and you don't have the money. And here now we're doing it for free, and now that's helping us out.*" One focus group participant also shared that she's glad not to be charged fees for missed appointments, as she has experienced previously: *"At least they don't charge you the $5 for not coming to be checked. Because there are times that you say, "Well yes, I have time for the appointment," and at the very time you wasted it or…you were without money. Well, now they charged you. Now I owe almost $200…[for] treatments that haven't come and the children…Truth to tell, better I cancel it a day before and that's all, because sometimes you forget, and there it goes increasing and it goes increasing."* Focus group participants also made note of the value of

learning about less expensive options for buying medications, support for housing expenses, etc., and the consequences of not having affordable options. In one instance, a participant explained that "*This year I didn't have money and my husband was unemployed for almost two months, and they didn't give me a prescription because I didn't have the $35 to buy the prescription."* Cost was also mentioned as a barrier to specialist care and to following nutrition suggestions "…*if we're barely making ends meet. Then we have tried for food stamps, and we only got $18 coming*."

Transportation
Program participant focus group members indicated that assistance with transportation costs provided by specific clinics made it more feasible for them to come in for appointments. One participant said, "*Let's say we wanted to come [to the clinic], they looked for the way to bring us or something like that now."* Some focus group participants suggested that support from *Juntos* staff and the use of Medicaid travel assistance enabled them to make use of free transport for medical appointments.

Wait Times
Program participant focus group members explained the challenges of wait times once they were in the clinics for appointments. In some cases, they were there as scheduled, but observed that an emergency for another patient led the clinic to reschedule their appointment for another day. Participants also noted that long wait times in the clinic were challenging for diabetics needing to manage their blood sugar; they note that sometimes the clinic provided sugary snacks, which weren't a healthy option for them. Additionally, participants observed that at times the staff would visibly eat food (including snacks put out for patients) and the participants would feel frustrated and hungry: "*You have me there since this morning, I need to eat breakfast—look at what time it is. You are going to eat and I'm sitting here*."

Participant Health Condition
Health conditions made coming to the clinic challenging, according to some program participant focus group members. For example, as seen in the "Wait Times" section above, diabetic participants reported that managing their blood sugar levels made long wait times at the clinic especially difficult. Physically navigating the clinic setting for *Juntos* programming was described as hard for focus group participants with physical disabilities; one disabled participant commented that in at least one instance, staff were unable to assist her in traversing from the waiting area to another room for *Juntos* programming. Some participants reflected that ongoing changes to medications were physically and mentally taxing. A focus group participant shared that "*with the medication, when they do switch it and stuff, it's like sometimes some others might feel like we're here being a guinea pig. Because they'll sometimes give you one medication, and then the following week, you know what? We're going to change this because this ain't working out. And then the following week you're doing okay, maybe you've been with this for two years, and all of a sudden they change to another medication.*" In regard to health literacy and understanding the *Juntos* program itself, a small number of participants stated at the endpoint that they didn't understand what the program was. A participant said, "*I don't know what we're doing. That's why I say if they don't pay me, I wouldn't come. It's kind of a waste of time. I don't get it.*"

Relationships with Staff and Providers
Program participant focus group members reported frustration at relationships disrupted, in their view, by ongoing changes in clinic staff, and perceived short notice regarding these changes. One participant said that the woman working at the front desk was the only consistent staff person: *"The providers, the counselors, the caseworkers—anywhere you go, they're all different people."* As noted elsewhere, some focus group participants expressed dissatisfaction both with telemedicine psychiatry, which occurred at Border, and seeing different providers from visit to visit, suggesting that it's not consistent, quality care.

A participant shared, *"You have things and you're showing her every time you move to another doctor, and it's wrong…[You see] any psychiatrist that's available, and…sometimes they just go by what the first one wrote. They don't change what's really wrong with you. They just go one by one by one, and that's it."*

Sustainability and Lessons Learned

Overall, results from interviews with *Juntos* partners and clinical staff as well as focus group participants indicated that implementation of TAMIU's *Juntos* program has been generally successful. Several lessons learned and opportunities for improvement emerged. At the mid-point, lessons learned related to program scale-up; grant management; and relationships. During the summative evaluation interviews and focus groups, lessons learned and opportunities for improvement focused on program replication and scalability; funding; staffing; leadership buy-in; outreach; workflow; training; and socio-political and natural environment. Presented below are themes that emerged from interviews and focus groups.

Program Replication and Scalability
A clinical staff interviewee indicated that there were plans to expand PCMU reminder phone calls to patients brought into care via the traveling health care teams in addition to diabetic patients who qualified for the original PCMU intervention. Some clinical staff interviewees expressed interest in expanding the work of the traveling health care teams. A partner interviewee noted that implementing IBH has been a longtime CDC recommendation, stressing the importance of scaling up this work. Additionally, another partner interviewee expressed hope that other providers would implement similar programming if the *Juntos* outcomes are positive. One partner interviewee observed that in the final project year the team was *"…taking all of our lessons and really doing our best to implement that model...We're also finding that we are having to adapt to find the best way to carry out these things, especially because we're dealing with such a high volume of patients or clients that we have to work with and all of them have their own—they all have their own challenges, they all have their own cases, specifically why they need services and what kind of services they need on top of what challenges they're facing to come in."*

Funding
Multiple interviewees expressed interest in securing funding to continue and expand *Juntos* programming to "*other counties and [clinic] services*" and for improved data systems, as well as active efforts to do so. Some suggested that the *Juntos* program provided a great boost in advocating for similar services: "*We're the demonstration site to say it works. Now what I see as important is to sustain it…I think Juntos has facilitated the opportunity to implement better behavioral health services and given us the opportunity to discuss options for sustainability.*" Partner and clinical staff interviewees also discussed the need for funding to provide patients assistance with medication and transportation, both of which were named by patients as barriers to maintaining care. Clinical staff interviewees who conducted home visits remarked upon the expense of this travel.

There were also critiques of the *Juntos* funding mechanism due to its restrictions on some spending seen as necessary by interviewees. One partner interviewee shared that prohibitions included "*a cell phone for the staff who are on outreach, not being able to cover some mileage…not being funded if you don't meet the number of patients you're supposed to*." They described this as challenging because there were instances of not being fully reimbursed despite best efforts to meet all requirements while serving a population that struggles to keep appointments.

Staffing

Some partner and clinical staff interviewees observed the importance of dedicated case managers whose primary goal is to connect with patients and assist in engaging them in services and who are networked with one another. Interviewees expressed enthusiasm for the sharing of staff across agencies to carry out common work, saying "*If we're consortia, we're partners, so ours is let's work together, let's get patient care done, let's do the outreach together, let's make sure persons come and stay in care. It doesn't matter who does it. We all have to do it.*" One example shared of a newly enacted staffing-related change was bringing in representatives from multiple agencies to participate in interviewing for a consortium-related hire within one agency. As mentioned previously, interviewees also described the value of learning to share staff across agencies as needed for *Juntos* work.

Leadership Buy-In

As explained by multiple interviewees in previous sections, having the right staffing in place, including supportive leadership, was key for navigating the described challenges to achieve success. Many of the partner interviewees articulated their support for the goal of implementing IBH. For example, one partner interviewee said: "*Our diabetic population is a group…[that needs] behavioral health because almost every diabetic has some degree of depression that we need to deal with. You got to treat both to improve."* Another partner interviewee described their own role as protecting "premium pay" for field workers, stating, "*That's where I come in because that's what I've been authorized to do to make sure the program succeeds. Having the right people and having the right incentives, and getting it done, because it's so important that we try to continue this project way into the future*." Clinical staff interviewees also expressed appreciation for the openness of supervisors and other leaders to providing the opportunity to learn and do something new and be a part of troubleshooting along the way.

Outreach

Many interviewees echoed the observation that outreach into communities to provide assessments and facilitate connection to both individual and group-based care—including the PCMU prong of providing multiple appointment reminders and supports—was key to bringing in more patients for care at the clinics. One partner interviewee said of the importance of outreach for the travelling health care team via external relationships that "*it will never work unless you have a trusting relationship [because the potential patients] …do not know any of us; they know the person who set it up, and it was that person that they trust.*" It was also suggested by a partner interviewee that greater outreach is needed to the "*community at large—we need to spread the word around*" to ensure that even more of the public know what services are available to them.

Workflow

There have been many references to workflow in previous report sections, both within and across organizations. Interviewees mentioned multiple workflow facets, including how patients with complex needs are moved through a clinic on a given day; how referrals are given, received, and tracked; the roles of traveling health care teams; and many other examples. Interviewees described examples of more and less successful methods for these processes, and efforts throughout the *Juntos* program to improve aspects of workflow across the partnership. An example of a lesson learned regarding workflow has been the confusion associated with iterative efforts to document and track referrals; specifically, the challenge faced by staff in different settings to ensure that all associated paperwork is completed to meet multiple internal and external requirements. A productive lesson learned is the effectiveness of Border's internal tracking sheet for patients with multiple appointments during a single visit, and the goal of introducing this approach to other sites.

Training

Training was described by partner and clinical staff interviewees as both satisfying and crucial to carrying IBH implementation using common protocols across sites. For example, Border staff indicated that after *Juntos* training, when they saw patients with specific A1C levels or high blood pressure, they would be "*…sure to refer them to primary care…and making sure we refer them to the nutritionist or to these lifestyle [classes].*"

Socio-Political and Natural Environment

Interviewees described the need for improved access to IBH and care in general in terms of distinct populations that were not receiving consistent or any services. In addition to local indigent, very poor, and isolated populations, one partner interviewee also mentioned the example of area employees whose companies did not provide health care coverage and whom were in need of care. The interviewee described the challenge of offering *Juntos* programming via the traveling healthcare team at such worksites, where they estimated access was granted half of the time: "*At the beginning, I thought it was going to be a piece of cake because you are taking them a free service. It's something that they could offer their people that work there. But little did I anticipate that there are some businesses that it's all about productivity, it's not about the person's wellbeing.*" The impact of the natural environment was mentioned in some cases as well. One clinical staff interviewee noted that "*With everything that's been going with hurricanes and stuff, we get half the people out from Houston who were staying here,*" and that they were being served by area clinics amidst complex circumstances—one example cited was an out-of-care pregnant woman in need of obstetric services at the start of the third trimester. Summative interviews also revealed descriptions of some community members' hesitance to come to clinics for fear they would be asked for citizenship documentation, although it was highlighted in interviews that *Juntos* providers would not ask for that: "*There are so many pockets of folks that need our services that will not venture even out here in the community…They're going to be very, very cautious to come out here because of what's happening in our current situation nationally.*" Some interviewees also discussed the politics present in their small city in relation to how care is provided, whether it is integrated, and challenges to collaboration. This partner interviewee commented, "*I try to stress the civic-minded commitment that all of us should have because everyone is a part of this puzzle as far as bringing in additional thing to Laredo.*"

IMPACT STUDY – APPROACH AND METHODS

Overview of Impact Study Design

For this study, TAMIU implemented a PCMU in clinics providing integrated behavioral health services with a three-pronged approach focused on health education, treatment compliance, utilization of traveling health care teams (THCT), and building capacity and shared resources with partner organizations. The PCMU implemented followed a modified version of the Dartmouth Prevention Care Management Model, which involved the PCMU. Patients with diabetes at Gateway and Border who missed appointments received one phone call per week for three weeks in advance of a rescheduled appointment. If the patient continued to miss appointments, the patient received a home visit from the PCMU in an effort to assess barriers that result in decreased compliance and link patients with the appropriate clinic. In addition to literature previously cited in the Prior Research section (Dietrich et al., 2006; Staten et al., 2012; Watt et al., 2009), the PCMU also was largely based on the theory of learned helplessness, the view that depression and other behavioral health conditions may result from a real or perceived absence of control over the outcome of a situation. The *Juntos* model responded to this theory with an empowerment-based approach to educate patients and identify and respond to their barriers to increase treatment compliance (Seligman, 1975).

This study used an RCT to compare intervention participants who received usual clinic care with an enhanced patient compliance protocol, with control participants who received only usual care with standard compliance protocols. For the purposes of the Sí Texas initiative, the impact research questions focus on the PCMU component of the *Juntos for Better Health* program. The impact evaluation examined the effectiveness of the PCMU designed to improve diabetic patient compliance with maintaining appointments. There was the potential for community members who received general community education through the Juntos program also could have been eligible for the PCMU intervention. An RCT design was used and, therefore, the effect of that education should not impact the evaluation design as both intervention and control patients were equally likely to receive that education. Participants enrolled in the study and were followed through 12 months. The study hypothesis was that using the PCMU model in combination with usual care would result in improved treatment compliance and ultimately improved physical and behavioral health of participants. The evaluation targeted a moderate level of evidence with an RCT based on the incoming level of preliminary evidence.

Impact Study Design and Methods

Study Design

The study's impact evaluation used data from the RCT to evaluate the impact of integrating a PCMU into clinics operating with integrated behavioral health models by comparing intervention participants to control participants. Participants enrolled in the study were followed for approximately 12 months. Quantitative program implementation data related to participation in intervention components is also reported in this report (see Implementation Evaluation section).

Randomization Procedure

Randomization was accomplished by *Juntos* grant staff using SAS 9.4 Proc Plan. A block design was used in the random assignment to avoid the control and intervention groups being markedly different in size. The literature on medical sociology indicates that gender is an important social determinant of health (Cockerham, Cockerham, & C., 2014), and that men and women have different socialization experiences which result to variations in their perceptions of risk, sensibilities about health, attitudes and behaviors

toward health care compliance/non-compliance. These socialization experiences in regards to feminine and masculine roles also result in differences in the incidence and prevalence of chronic diseases such as diabetes and heart disease (Gorman & Read, 2006). For example, women are more likely than men to access health services; men may avoid accessing preventive care because such behavior is perceived as feminine and is counter masculine sensibility of a "macho" image (National Center for Health Statistics, n.d.; Springer & Mouzon, 2011). Although there are other important social determinants of health such as age, social class, and race/ethnicity, gender presents the largest heterogeneity in TAMIU's target population. To control for this heterogeneity, male and female participants were stratified and randomized separately (Chow & Liu, 2004). In terms of analysis, TAMIU proposed to perform both combined and separate analyses by gender (the stratification variable). Given that TAMIU's target population was predominantly female, and since TAMIU allocated their sample proportionate to the subpopulation size for men and for female, TAMIU did not anticipate equal number of men and women to be recruited in their study.

One disadvantage of block randomization was that the allocation of participants may have been predictable and resulted in selection bias when the study groups were unmasked. That is, the treatment assignment that had so far occurred least often in the block likely would have been the next chosen. Selection bias was reduced by using random block sizes according to predetermined factors and keeping the investigator blind to the size of each block.

Per study eligibility requirements, non-compliant patients were consented and enrolled into the study. Noncompliance was defined as missing a clinic appointment in the 12 months prior to the study period. Upon enrollment, participants were randomized to either the intervention or usual care groups. Intervention group participants received the PCMU intervention combined with Gateway CHC or Border usual care services, and participants randomized to the control group received Gateway or Border usual care services. In addition, to meet study target enrollments, diabetic compliant patients were consented to the study and, if they became non-compliant by not attending an appointment during a 30-day window after enrollment into the study, these patients were then randomized into either the intervention or control group.

Assessment of Baseline Equivalence

Examining baseline equivalence evaluates whether the intervention and control groups are statistically equivalent in regard to a specified set of characteristics at study enrollment. At baseline, a series of sociodemographic characteristics were captured for all participants using a standardized set of questions including age, gender, ethnicity, primary language, and education level. These sociodemographic characteristics were selected because they are potential covariates routinely collected by Gateway and Border and captured in their EMR.

There were no statistically significant differences detected between the intervention and control groups on any of the demographic characteristics presented in **Table 15**.

Table 15. Tests of Baseline Equivalence for Demographic Measures

Measure	Full Sample (n=733)		Intervention (n=366)		Control (n=367)		p-value
	N	%	N	%	N	%	
Sex							
Male	223	30.5	112	30.6	111	30.3	0.94
Female	509	69.5	254	69.4	255	69.7	
Missing	*1*	--	--	--	*1*	--	
Ethnicity							
Hispanic/Latino	712	97.9	356	97.5	356	98.3	0.44
Non-Hispanic/Non-Latino	15	2.1	9	2.5	6	1.7	
Missing	*6*	--	*1*	--	*5*	--	
Age							
18-34	29	4.0	11	3.0	18	4.9	0.60
35-44	107	14.6	53	14.5	54	14.7	
45-54	214	29.2	112	30.6	102	27.8	
55-64	249	34.0	120	32.8	129	35.2	
65+	134	18.3	70	19.1	64	17.4	
Mean (SD)	54.5 (11.0)		54.9 (10.8)		54.1 (11.2)		0.32
Education							
Less than high school	419	58.0	211	58.8	208	57.3	0.69
High school or more	303	42.0	148	41.2	155	42.7	
Missing	*11*	--	*7*	--	*4*	--	
Primary Language							
English	130	17.7	63	17.2	67	18.3	0.06
Spanish	553	75.4	270	73.8	283	77.1	
Other	50	6.8	33	9.0	17	4.6	

For the six impact measures in TAMIU's study, the intervention and control groups were statistically equivalent on all measures (see **Table 16**).

Table 16. Tests of Baseline Equivalence for Impact Measures

	Full Sample (n=733) Mean (SD)	Intervention (n=366) Mean (SD)	Control (n=367) Mean (SD)	p-value
BMI[b]	32.8 (6.8)	33.1 (7.3)	32.3 (6.3)	0.20
Systolic	134.3 (19.4)	134.6 (19.7)	134.0 (19.1)	0.67
Diastolic	78.3 (10.9)	78.8 (11.0)	77.7 (10.7)	0.17
Nonparametric Tests[a]	Median (IQR)	Median (IQR)	Median (IQR)	p-value
HbA1c	8.1 (2.6)	8.2 (2.6)	8.1 (2.5	0.87
PHQ-9	4.0 (8.0)	4.0 (8.0)	4.5 (7.0)	0.10
General Health	73.3 (30.0)	73.3 (26.7)	70.0 (30.0)	0.22

Note: Bold denotes statistical significance (p-value < 0.05); [a] The Wilcoxon rank sum test was used to examine non-normally distributed data [b] A log transformation was used

Propensity score matching was considered as an option in the analytic phase for this final report in case baseline equivalence was not established. However, due to the RCT design and application of the block design randomization procedure, matching strategies were not needed. Participants were statistically equivalent on the randomized characteristic, gender, as well as all other sociodemographic measures. Additionally, all health outcomes were balanced between the groups at baseline. There is no evidence that randomization was done improperly as all procedures were followed and documented. If there were problems with the randomization, we would expect to find imbalance in the randomized characteristics and/or more patient level variables, which was not the case in our assessment.

Intervention and Control Group Conditions

Treatment compliance was defined as attending all follow-up appointments with the patient's medical or behavioral health care provider. Participants randomized to the treatment group received Gateway or Border clinic usual integrated behavioral health care combined with the PCMU model, which included follow-up phone calls reminding patients of their appointments and assessing any barriers to compliance with follow-up. PCMU staff made one reminder phone call per week for the three weeks prior to a scheduled appointment. If the patient failed to make the provider follow-up appointment after three calls, then the patient received a home visit from program staff if the client agreed. During the home visit, barriers to treatment compliance were discussed and TAMIU staff would call clinic from patient's home to link patient with another appointment. Patients continued to be monitored for compliance throughout the intervention period. Gateway and Border provided appointment information through semi-automated, encrypted weekly uploads to TAMIU for tracking purposes. This procedure was developed and initiated in early 2017 following SEP approval as the technology became available. The initial protocol involved contacting patients when they were non-compliant. If the patient showed for the most recent visit, the patient was moved to the bottom of the list and contacted only if he or she became non-compliant again. The protocol was subsequently revised to contact all intervention participants in advance of all appointments regardless of the show status at the previous appointment. This protocol modification addressed inconsistency in reporting appointment outcomes and to ensure that all intervention patients were up to date on all upcoming appointments.

Providers would send TAMIU weekly updates via CSV files uploaded to Syncplicity, including upcoming appointment information and appointment outcomes from the previous weeks. The data were uploaded to the respective databases and added to the participants profile for upcoming calls or for outcome review. The technical nature of this process required that the Research and Reporting Analyst conduct this process. The complexity and eventual refinement of this process impacted the implementation of home visits.

All participants were scheduled to return to Gateway and Border for reassessment of study measures at 6 and 12 months.

Participants randomized to the control group received the standard follow-up care from Gateway or Border. At Gateway, a missed appointment triggered an alert to the provider who then reviewed the medical record and created a disposition (e.g., critical lab results, medication change) which included a call and letter from the Medical Office Assistant to the patient for follow-up. There were no additional follow-up steps if patients continue to be non-compliant. Border reminded clients of upcoming appointments. When a patient missed an appointment, s/he was called to reschedule the appointment. When a client was not able to be reached by phone, a letter was sent to the client. Border kept cases open

up to 6 months if no contact was achieved. Client cases were then closed and, if a patient returned, the file was reopened.

Study Sample

The following section describes the final data on the composition, eligibility, recruitment, enrollment, retention, and attrition of the study sample. There were two deviations from the SEP. First, patients were enrolled in the study from a second study site, Border. Second, TAMIU increased incentives for participants to return for follow-up assessments.

Study Sample Composition

Table 17 presents participant demographics for intervention and control groups at baseline. Most of the participants enrolled in the study were female (69.5%) and spoke Spanish as their primary language (75.4%) Almost all participants were Hispanic (97.9%) and over half had less than a high school education (58.0%) The average age across the study was 54.5 years.

Table 17. Participant Demographic Measures for Full Sample and by Intervention Group

Measure	Full Sample (n=733)		Intervention (n=366)		Control (n=367)		p-value
	N	%	N	%	n	%	
Sex							
Male	223	30.5	112	30.6	111	30.3	0.94
Female	509	69.5	254	69.4	255	69.7	
Missing	*1*	--	--	--	*1*	--	
Ethnicity							
Hispanic/Latino	712	97.9	356	97.5	356	98.3	0.44
Non-Hispanic/Non-Latino	15	2.1	9	2.5	6	1.7	
Missing	*6*	--	*1*	--	*5*	--	
Age							
18-34	29	4.0	11	3.0	18	4.9	0.60
35-44	107	14.6	53	14.5	54	14.7	
45-54	214	29.2	112	30.6	102	27.8	
55-64	249	34.0	120	32.8	129	35.2	
65+	134	18.3	70	19.1	64	17.4	
Mean (SD)	54.5 (11.0)		54.9 (10.8)		54.1 (11.2)		0.32
Education							
Less than high school	419	58.0	211	58.8	208	57.3	0.69
High school or more	303	42.0	148	41.2	155	42.7	
Missing	*11*	--	*7*	--	*4*	--	
Primary Language							
English	130	17.7	63	17.2	67	18.3	0.06
Spanish	553	75.4	270	73.8	283	77.1	
Other	50	6.8	33	9.0	17	4.6	

Table 18 presents participant impact measures at baseline for the intervention and control groups. As previously presented in the assessment of baseline equivalence section, the intervention and control groups were statistically equivalent on all outcome measures and therefore the average values are similar across the two groups.

Table 18. Descriptive Statistics for Baseline Impact Measures

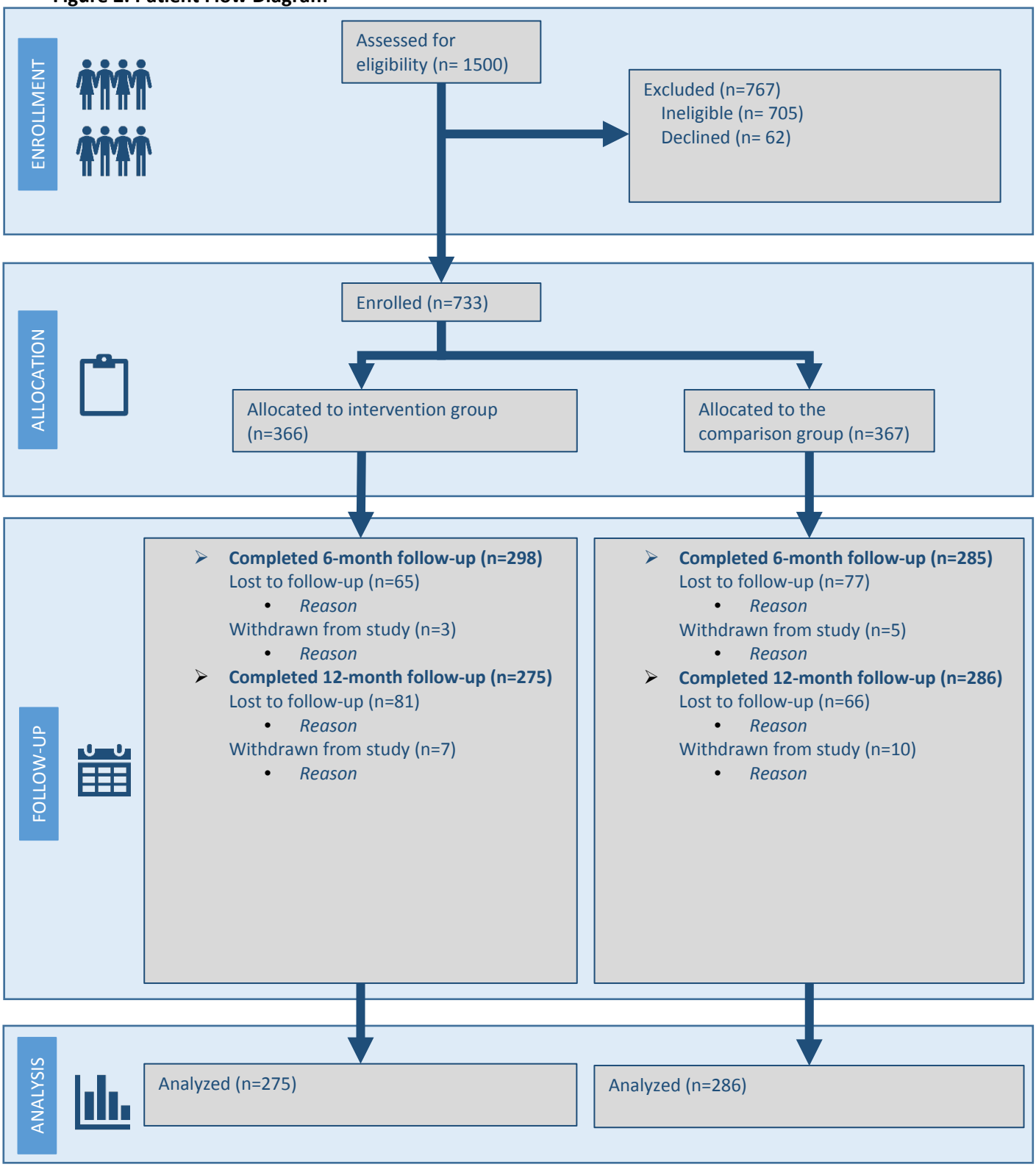
	Full Sample[c] (n=733) Mean (SD)	Intervention (n=366) Mean (SD)	Control (n=367) Mean (SD)	p-value
BMI[b]	32.8 (6.8)	33.1 (7.3)	32.3 (6.3)	0.20
Systolic	134.3 (19.4)	134.6 (19.7)	134.0 (19.1)	0.67
Diastolic	78.3 (10.9)	78.8 (11.0)	77.7 (10.7)	0.17
Nonparametric Tests[a]	Median (IQR)	Median (IQR)	Median (IQR)	p-value
HbA1c	8.1 (2.6)	8.2 (2.6)	8.1 (2.5	0.87
PHQ-9	4.0 (8.0)	4.0 (8.0)	4.5 (7.0)	0.10
General Health	73.3 (30.0)	73.3 (26.7)	70.0 (30.0)	0.22

[a] The Wilcoxon Signed Rank test was used to examine non-normally distributed data; these results aligned with t test results; [b] A log transformation was used and then exponentiated [c] Baseline equivalence tests on impact measures were conducted within clinic samples between intervention and control groups. No differences were found.

Patient Flow Description

A patient flow diagram following the CONSORT structure (Schulz et al., 2010) is presented in **Figure 2.** This diagram depicts the study process from assessment of eligibility, to enrollment and group selection, ending with retention and analysis. Sample sizes are provided throughout to show timing of participant attrition. Qualitative reasons for any ineligibility, withdrawal, or lost-to-follow-up are provided where applicable. In the "enrollment" stage, 705 participants who were excluded did not meet one or more of the eligibility criteria and could not be allowed to participate. An additional 62 participants were assessed for eligibility but did not enroll for other reasons. In the "follow-up" stage, those participants categorized as "lost to follow-up" did not complete an assessment at that time point but did not formally withdraw from the study. Due to the lack of official withdrawal from the study, those who were lost to follow-up at 6 months remained in the study and were still eligible to complete a 12-month assessment.

Figure 2. Patient Flow Diagram



Sample Recruitment, Retention and Attrition

Participant Eligibility and Recruitment

The study sample was recruited among all adult diabetic patients who are out of treatment compliance at Gateway and Border. Patients who met the following criteria were eligible to participate in the study:

- Resided in Jim Hogg, Webb, or Zapata Counties
- Provider diagnosis of diabetes following American Diabetes Association 2016 guidelines, which includes a baseline measurement of A1c≥6.5% (Notes: The original SEP eligibility criteria was A1c > 6.5%, this was clarified to >= during study enrollment. Also, See **Appendix I: ADA Guidelines**)
- Non-compliant with attending appointments (non-compliance is defined as having missed an appointment within the past 24 months).

Patients who expressed suicide ideation upon intake were not approached for enrollment but may have been enrolled during the study recruitment period if stabilized. If a potential participant or participant was found to be suicidal at any time during the study, the patient was immediately referred to a Gateway or Border provider or to Border for assessment and treatment. Other exclusion criteria include enrollment in another research study, particularly another Sí Texas study, or if a patient did not speak either English or Spanish as a primary or secondary language.

Gateway and Border staff identified existing patients who met study inclusion criteria through record review of 24 months prior to the enrollment start date. Gateway navigators and promotoras contacted and invited eligible participants to attend a health information session where they were informed of the study and invited to participate. Staff at both clinic sites also invited patients to participate in the study at the patient's regular clinic visit or through telephone contact. Please note, the study did not differentiate between newly diagnosed or patients with existing diagnoses of diabetes because the focus was on treatment compliance not length of diagnosis. Newly diagnosed diabetics may have already started a pattern of non-compliance after initially being diagnosed. In addition, no restrictions on how long participants were patients at the clinic were implemented as an eligibility consideration.

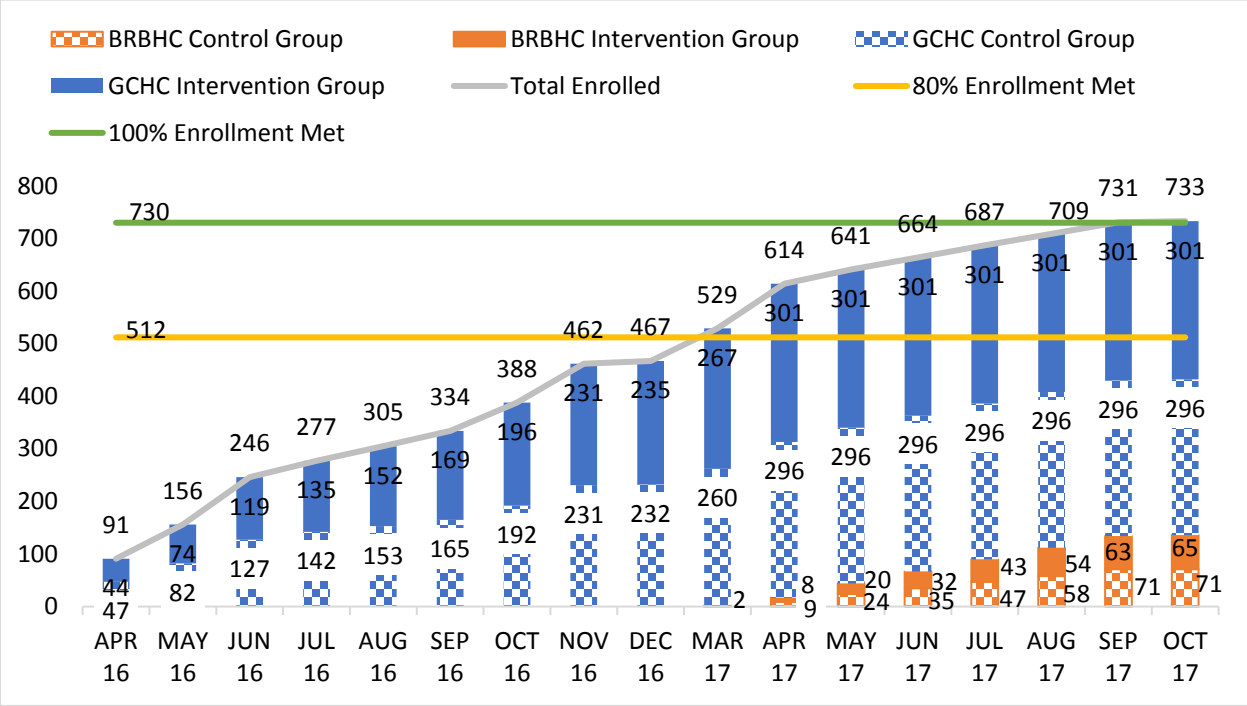
The study recruited non-compliant and compliant patients to ultimately ensure the study had a sufficiently powered sample of non-compliant patients. Noncompliance was defined as having missed one appointment (Dietrich et al., 2006). Compliance was defined as a patient keeping all scheduled appointments. Non-compliant patients who attended health information sessions were automatically given an informed consent form and asked to enroll. Compliant patients were asked to consent at a health information session or their scheduled appointment, invited to enroll and then monitored for compliance for one month. Gateway clinic primarily enrolled non-compliant patients. It was expected that a small number of newly non-compliant patients (patients who were compliant at time of enrollment and then become non-compliant after missing a scheduled appointment) would be enrolled in the study. Therefore, participants were not differentiated based on this definition of non-compliance.

Sample Enrollment and Retention

Participant enrollment began at Gateway in April 2016 and continued through April 2017. Border began recruitment in March 2017 and continued through September 2017. As previously noted, the addition of enrollment at the Border clinic was a change to the SEP. Enrollment at Border was initiated as the available pool of participants at Gateway diminished. Please see the SIF Evaluation Plan Update section in the Introduction for a full description of the process through which the Border site was added as an evaluation study site and **Appendix G: PCMU Evaluation Enrollment Log** for an accounting of enrollment at the two

clinics. The final timeline is presented in **Appendix A: Revised Project Timeline.** The enrollment target was 365 participants each for the intervention and control groups; a total of 366 participants were enrolled into the intervention and 367 participants in the control groups (see **Figure 3**), meeting the enrollment target for both the intervention and control groups.

Figure 3. Cumulative Enrollment, by Intervention Group and Clinic (note: enrollment was completed October 31, 2017).



GCHC – Gateway Community Health Center; BRBHC – Border Region Behavioral Health Center

Table 19 presents subgrantee-reported information on the number of participants who returned for 6-month and 12-month follow-up through April 2018 and October 2018 respectively, overall and for each clinic, by study arm. TAMIU retained 95.8% of the 6-month target in the intervention group (298 out of 366 returned for a 6-month follow-up assessment, 311 needed to maintain adequate statistical power). The retention target was exceeded in the intervention group at 12 months, with TAMIU retaining 107.8% of the 12-month target (275 out of 366 returned for a 12-month follow-up assessment, 255 needed to maintain adequate statistical power). The control group reached 91.6% of the 6-month retention target (285 out of 367 returned for a 6-month follow-up assessment, 311 needed to maintain adequate statistical power). The retention rate in the intervention exceeded the 12-month retention target by 12.2% (286 out of 367 returned for a 12-month follow-up assessment, 255 needed to maintain adequate statistical power).

Gateway retained 84.1% of those enrolled in the intervention group at 6 months and 79.4% at 12 months. The clinic also retained 78.0% of those enrolled in the control group at 6 months and 81.1% at 12 months. Border retained 69.2% of those enrolled in the intervention group at their clinic at 6 months and 55.4% at 12 months. The clinic also retained 76.1% of those enrolled in the control group at 6 months and 64.8% at 12 months.

Table 19. Study Retention at 6 and 12 Months by Intervention Group and Clinic

Group	Number Enrolled	Retention Target[a]	Number Retained[b]	Percent Retention of the Enrolled Sample	Percent of Retention Target
OVERALL					
6-month Retention					
Intervention Group	366	311	298	81.4%	95.8%
Control Group	367	311	285	77.7%	91.6%
12-month Retention					
Intervention Group	366	255	275	75.1%	107.8%
Control Group	367	255	286	77.9%	112.2%
GATEWAY					
6-month Retention					
Intervention Group	301	--	253	84.1%	--
Control Group	296	--	231	78.0%	--
12-month Retention					
Intervention Group	301	--	239	79.4%	--
Control Group	296	--	240	81.1%	--
BORDER					
6-month Retention					
Intervention Group	65	--	45	69.2%	--
Control Group	71	--	54	76.1%	--
12-month Retention					
Intervention Group	65	--	36	55.4%	--
Control Group	71	--	46	64.8%	--

[a]These targets anticipate 15% attrition at 6 months and 30% at 12 months [b]These data are the number that completed an assessment at 6 and 12-month follow-ups

Sample Attrition Analyses

The study anticipated 70% retention of the sample at 12 months. At 12 months, the study retained 75% of the intervention group and 78% of the control group. TAMIU exceeded the set targets for each group. To examine whether the 3% difference in attrition between intervention and control groups was statistically significant, a chi-square test was performed comparing the proportion of participants who were lost to follow-up in the intervention to those who were lost to follow-up in the control group. The results of this analysis were not statistically significant at the 0.05 level (p=0.37). Given these results, we conclude that the two study groups did not have significantly differing attrition rates at 12 months of follow-up.

Bivariate analyses were conducted to examine whether participants lost to follow-up were significantly different from those who remained in the study across demographic characteristics and baseline health measures, for each study arm. T-tests were used for continuous measures and chi-square tests for categorical data. Fisher's Exact Test was utilized if the expected cell counts were less than 5 and nonparametric tests were performed on non-normally distributed data. **Appendix M: Loss to Follow-Up / Attrition Table** presents the results from these analyses.

There were no statistically significant differences in health measures at baseline between those who were lost to follow-up and those who remained in the study at 12 months within the control group. Within the intervention group, however, there was a statistically significant difference in baseline PHQ-9 and Duke General Health scores between those who completed the study and those who did not. Those who dropped out of the study had a higher median PHQ-9 score and a lower median Duke General Health score than those who remained through their 12-month assessment. Regarding demographic measures, there was a statistically significant difference in language within the intervention group; a higher proportion of English-speaking participants in the intervention group did not complete the study. For the control group, there was a statistically significant difference in sex; a higher proportion of males in the control group did not complete the study.

A multivariate logistic regression model was then utilized to understand the independent influence of these four significant differences identified in predicting a participant's likelihood to drop out of the study. In this model, none of the predictors were found to significantly influence the likelihood of a participant completing the study, mitigating any concern of potential bias due differential attrition.

Sample Retention Strategies

Post-recruitment, sample retention was addressed using a variety of retention strategies validated in the scientific literature for use with similar populations (Priebe, et al., 2013). In addition, TAMIU provided intervention and control returning participants with gift cards and lab vouchers with a combined cash value of $20 as an incentive at both 6- and 12-month follow-up assessments. This is a change from the SEP where participants were to receive a lab voucher or gift card for a cash value of $10. TAMIU changed the incentives to increase return rates among an already non-compliant population. TAMIU worked with Gateway and Border staff to ensure that intervention and control participants at each clinic were identified as needing a 6- or 12-month follow up assessment and contacted to return for the assessment appointment.

Non-Response Bias and Missing Data

All data (e.g., blood pressure, height, weight) were collected, scanned, and uploaded into the patient's health record on a computer. Gateway and Border navigators assisted patients with completing the PHQ-9 questionnaire and the Duke Health Profile as needed. Blood draws for HbA1c were done on-site at the clinic and results were input to the EMR. Clinical staff collected the data and shared it with *Juntos* grant staff and PCMU team members, who conducted follow-up (phone calls, education, home visits) with the intervention group patients.

Missing data on covariates is a potential issue that could lead to biased results. The data collection team made all efforts to minimize missing data through training and use of standard practice measures within the clinic settings captured by the EMR. Imputation approaches were noted as an option if there were missing data on important covariates (Rubin, 1996). However, the data collected and submitted by TAMIU were largely complete and therefore multiple imputation methods were not used in any analyses of TAMIU's data.

Regarding the five study impact measures for the primary end-point analysis, there were minimal missing baseline data in both study groups for blood pressure, BMI, PHQ-9 score, and Duke General Health score. Complete data were collected for HbA1c at baseline for intervention and control participants. There were 8 participants missing baseline PHQ-9 score, 3 missing Duke General Health, 1 missing blood pressure, and 2 missing BMI. There were also missing data at 12 months for all measures in both the intervention and control groups. At the end of the study, 17 participants were missing HbA1c, 19 were missing a PHQ-

9 score, 10 were missing a Duke General Health score, 6 did not have blood pressure, and 5 did not have BMI data. While the missing data were greater at 12 months, these data represent no more than 3% of the total study sample at 12 months. Therefore, as previously noted above, multiple imputation was not necessary as the potential bias due to missing data was minimal. There were missing sociodemographic data for some characteristics. At baseline, 1 participant did not have sex data, 6 were missing ethnicity, and 11 were missing education.

Measures

The measures collected for the impact analysis aligned with the planned set of measures**.** The impact measures assessed were HbA1c, blood pressure, BMI, depression, and quality of life. There were no changes to the measures described in TAMIU's amended SEP and interim report. Information on the number of respondents and tests of normality are provided here (see **Table 20**). PROC UNIVARIATE in SAS was used to understand the distributions of these measures at baseline. Q-Q plots and histograms were used to determine if the measure should be treated as normal, be transformed, or treated as non-normal data. Descriptive statistics for each of these measures, including number of participants with or without the impact measures, are included in this final report.

Table 20. Impact Measure Sample Size by Follow-up

Measure	Sample Size		
	Baseline	6-month	12-month
HbA1c	733	571	544
PHQ-9	725	572	542
Duke Health Profile	730	565	551
Systolic Blood Pressure	732	580	555
Diastolic Blood Pressure	732	580	555
BMI	731	578	556

HbA1c: HbA1c levels are routinely measured in the monitoring of people with diabetes. HbA1c levels depend on the blood glucose concentration. That is, the higher the glucose concentration in blood, the higher the level of HbA1c. Levels of HbA1c are not influenced by daily fluctuations in the blood glucose concentration but reflect the average glucose levels over the prior six to eight weeks. Therefore, HbA1c is a useful indicator of how well the blood glucose level has been controlled in the recent past (over two to three months) and may be used to monitor the effects of diet, exercise, and drug therapy on blood glucose in people with diabetes (American Diabetes Association, 2016).

For HbA1c, there were 733 respondents with complete data at baseline, 571 respondents at 6 months, and 544 respondents at 12 months for the intervention and control groups. The distribution of responses for HbA1c at baseline was determined to be non-normal. The log transformation was examined but did not normalize the distribution of HbA1c; therefore, nonparametric tests were used in bivariate analyses.

Depression: Depression is characterized by depressed or sad mood, diminished interest in activities which used to be pleasurable, weight gain or loss, psychomotor agitation or retardation, fatigue, inappropriate guilt, difficulties concentrating, as well as recurrent thoughts of death. Diagnostic criteria established by the American Psychiatric Association dictate that five or more of the above symptoms must be present for a continuous period of at least two weeks. In addition to being a chronic disease in its own right, the burden of depression is further increased as depression appears to be associated with behaviors linked to

other chronic diseases. In most studies, it is difficult to determine whether depression is the result of an unhealthy behavior or whether depression causes the behavior (American Psychiatric Association, 1994).

- **Administration method:** Depression was measured via provider interview or self-assessment using the PHQ-9 assessment tool. The PHQ-9 is a multipurpose instrument for screening, monitoring and measuring the severity of depression.
- **Administration time:** The assessment was administered to participants as part of their intake process at their medical home agency.
- **Intended respondent:** The PHQ-9 was administered to all adult patients as part of their assessment at their medical home agency.
- **Potential score/response range:** The PHQ-9 total possible score of 27. The PHQ-9 scoring criteria is categorized as minimal (0-4), mild (5-9), moderate (10-14), moderately severe (15-19) and severe (20-27) depression (Kroenke & Spitzer, 2002). Gateway and Border reviewed PHQ-9 scores and provided appropriate referrals to internal or external providers per a standard protocol (available upon request). The PHQ-9 score for all patients in the study were included in the analysis for this study.

See **Appendix K: Patient Health Questionnaire – 9 (PHQ-9)** to view the PHQ-9 assessment tool.

For PHQ-9 score, there were 725 respondents with complete data at baseline, 572 respondents at 6 months, and 542 respondents at 12 months for the intervention and control groups. The distribution of responses for PHQ-9 at baseline was determined to be non-normal. The log transformation was examined but did not normalize the distribution of PHQ-9. Therefore, nonparametric tests were used in bivariate analyses.

Quality of Life (QOL): QOL is a broad multidimensional concept that usually includes subjective evaluations of both positive and negative aspects of life. Health serves as one of several domains for overall QOL. Aspects of culture, values, and spirituality are also key aspects of overall quality of life that add to the complexity of its measurement (CDC, 2011).

- **Administration method:** Quality of life was measured via the self-administered Duke Health Profile. The Duke Health Profile instrument contains six health measures (physical, mental, social, general, perceived health, and self-esteem), and five dysfunction measures (anxiety, depression, anxiety-depression, pain, and disability) (Parkerson, Broadhead, & Tse, 1990).
- **Administration time:** The Duke Health Profile assessment tool was administered to the patient as part of their assessment at their medical home agency.
- **Intended respondent:** The Duke Health Profile assessment tool was administered to all adult patients who have consented to participate in the study, as part of their assessment at their medical home agency.
- **Potential score/response range:** The Duke Health Profile has 11 scales, six of which measure function (physical health, mental health, social health, general health, perceived health, self-esteem) and five of which measure dysfunction (anxiety, depression, anxiety-depression, pain disability). Scores range from 0 to 100. For scales measuring function, the higher the score, the more functional the person being evaluated. For scales measuring dysfunction, the higher the score, the more dysfunctional the person being evaluated. The general health domain score, a composite of the physical health, mental health and social health domain scores, was utilized as the primary quality of life indicator in our analyses.

See **Appendix L: Duke Health Profile** to view the Duke Health Profile (English and Spanish).

For the Duke General Health score, there were 730 respondents with complete data at baseline, 565 respondents at 6 months, and 551 respondents at 12 months for the intervention and control groups. The distribution of responses for the Duke General Health score at baseline was determined to be non-normal. The log transformation was examined but did not normalize the distribution of Duke General Health. Therefore, nonparametric tests were used in bivariate analyses.

Blood Pressure: Blood pressure is usually expressed in terms of the systolic pressure over diastolic pressure and is measured in millimeters of mercury (mm Hg). Blood pressure varies depending on situation, activity, and disease states. Blood pressure that is low due to a disease state is called hypotension, and pressure that is consistently high is hypertension. Both have many causes which can range from mild to severe (American Heart Association, 2015).

Blood pressure was measured by the primary care provider for all patients, manually or automatically using a Manometer and following clinically-established practice guidelines (National Guidelines Clearinghouse, 2011). For the purposes of this evaluation, patients with a blood pressure greater than or equal to 140/90 mm Hg (AHA 2015) were considered hypertensive, though clinical diagnosis is not based on one reading. In addition, the primary care provider determined the need/appropriateness of medication.

For blood pressure, there were 732 respondents with complete data at baseline, 580 respondents at 6 months, and 555 respondents at 12 months for the intervention and control groups. The distributions of responses for systolic and diastolic at baseline were determined to both be normal and therefore parametric tests were used for bivariate analyses.

Body Mass Index (BMI): Excessive weight may be serious because it places individuals at greater risk for developing obesity-related conditions, such as Type 2 Diabetes, high blood pressure, and coronary artery disease. In this study, obesity was captured using body mass index (BMI), a calculation of the ratio of height and weight.

The clinic staff calculated BMI using a clinical weight scale and height measurement instrument following clinically-established practice guidelines (National Guideline Clearinghouse, 2014).

For BMI, there were 731 respondents with complete data at baseline, 578 respondents at 6 months, and 556 respondents at 12 months for the intervention and control groups. The distribution of responses for BMI at baseline was determined to be slightly skewed in the sample. The log transformation was examined and found to normalize the distribution of BMI. Therefore, parametric tests were used in bivariate analyses.

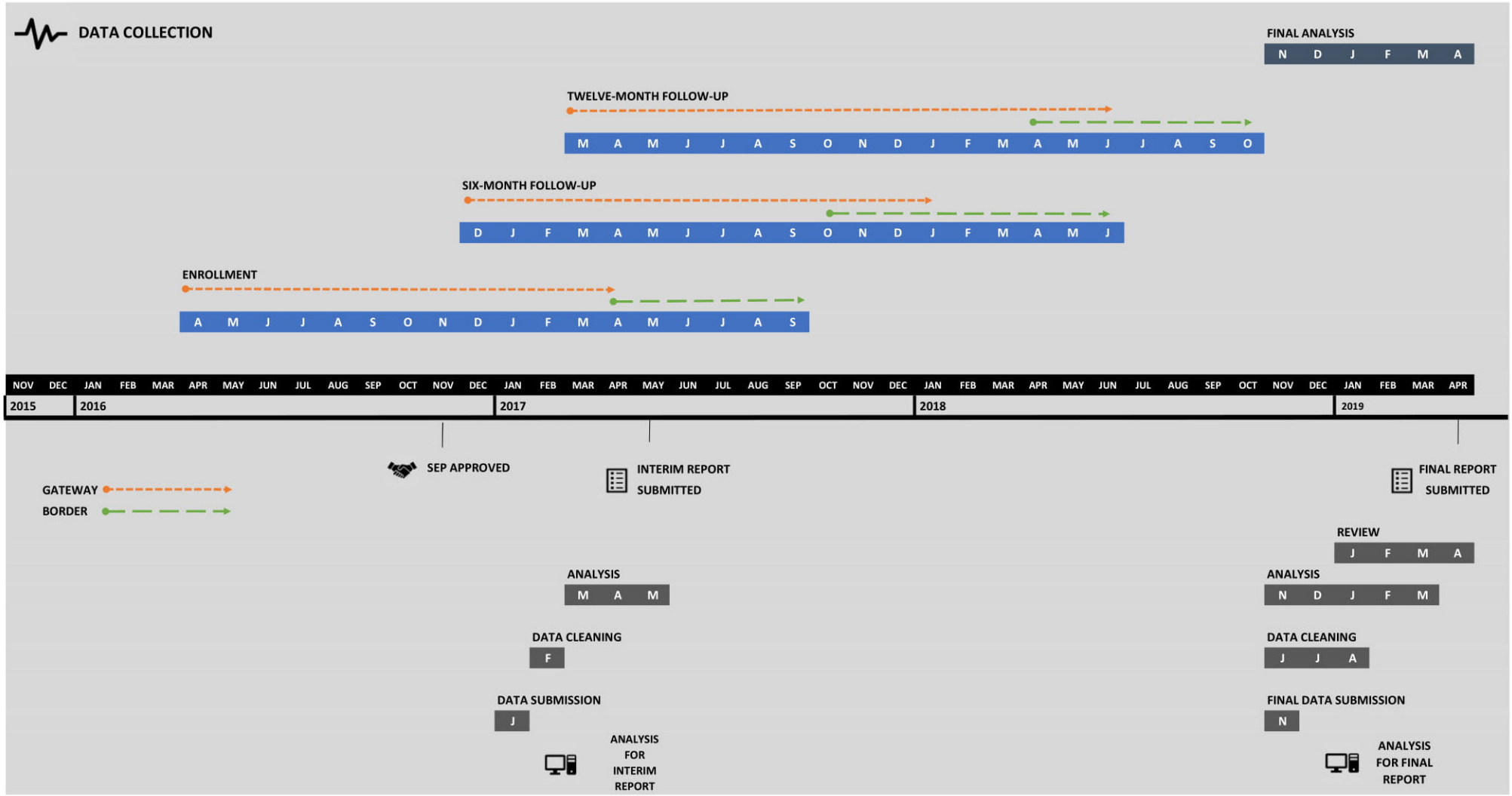
Patients were primarily Spanish speaking. All PCMU data collection was assisted by a patient navigator or case manager. All instruments were validated in Spanish language for use with Spanish speakers.

Data Collection Activities

TAMIU collected data starting in April 2016 and enrolled through September 2017. **Appendix A: Revised Project Timeline** provides further details on the enrollment timeline. **Figure 4** depicts the data collection timeline as it relates to SEP approval and analyses completed for this final report. Six-month follow-up began in December 2016 and continued through June 2018. Twelve-month follow-up began in March 2017 and ended in October 2018. This timeline is approximately one year longer than the timeline in the SEP due to delays in recruiting the sample needed for analytic power.

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Figure 4. Timeline for Data Collection and Analyses for the Final Report



IMPACT STUDY – ANALYSIS AND RESULTS

Final impact study results for the intervention and control groups at 12 months are presented by research question. This section also details the statistical methods used, noting any deviations from what was planned in the SEP based on field conditions and analytic judgment at the time of analysis, and presents findings for the final assessment of data collected for the TAMIU study.

Descriptive statistics for complete data are presented in this final report for the intervention and control groups. These statistics summarize patients' demographics and other key covariates. These covariates were examined to assist in identifying potential factors that may result in nonequivalence between the two groups. To examine baseline equivalence, Chi-square tests and Fisher's Exact Tests, when necessary based on cell counts, were used for categorical data while two sample t-tests were used for normally distributed continuous data, and the Wilcoxon Signed Rank test was used for non-normally distributed data. Because an RCT design was used for the study, intent-to-treat analyses were conducted for the final analysis. While this study was balanced on all health and demographic measures at baseline, adjustment for some covariates was performed to increase the precision of study results. The decision was made not to perform secondary power calculations as the final sample size exceeded the target and prior research indicated that these tests are not necessarily helpful in the interpretation of observed results (Goodman and Berlin, 1994).

All descriptive, baseline equivalence, bivariate, multivariate, and longitudinal analyses reported in this final report were performed with SAS version 9.4 (Cary, NC). PROC GLM was utilized for the primary linear regression models. To confirm this was an appropriate approach given the non-normal distributions for some outcomes, the distribution of errors was examined for each outcome. The residual errors were determined to be normally distributed for all outcome measures and therefore the use of linear regression as our primary approach was suitable. Differences were considered statistically significant at $p<0.05$.

Effect sizes were calculated for the confirmatory outcome regardless of statistical significance of model results and for any exploratory outcome with a statistically significant result. Results are presented in the "Findings" section under research questions when applicable. The statistic utilized for these calculations was Cohen's d using the following equation:

$$d = \frac{\bar{x}_1 - \bar{x}_2}{s} = \frac{\mu_1 - \mu_2}{s}$$

Unit of Analysis and Overview of Analyses Performed

The unit of analysis was the individual patient. An end-point analysis was our primary analytic approach. This end-point analysis approach is a conventional approach to analyze clinical trial data collected from individuals with both baseline data and end-point data of primary interest (Liebschutz, et al., 2017). We employed generalized regression analysis following a modeling sequence from bivariate models to multiple regression models adjusting for baseline levels of outcome measures and covariates that were assessed to be relevant based on review of the scientific literature. The parameter of interest was the dichotomous variable that differentiates the treatment status (i.e., intervention vs. control). Between-group comparison of baseline and single follow-up outcomes were assessed by end-point analyses that accounted for the baseline level of impact measures. Additionally, because multiple follow-up impact measures form individual trajectories, we conducted longitudinal analyses assessing whether the impact

measure trajectories differed by intervention status (Fitzmaurice et al., 2004). A time measure was developed and applied to denote baseline, 6-month, and 12-month follow-up measures.

In addition to adjusting for key covariates, we also assessed potential collinearity and its impact on the standard error estimates for the covariates in the model by examining the variance inflation factor when necessary. We stated in the SEP that in areas where multiple comparisons are necessary, we would employ adjustment of the p-value to account for multiple comparisons, such as the Bonferroni correction. This step was ultimately not applied for executed analyses since we did not address multiple comparisons.

To evaluate the intervention effect, a multiple linear regression model approach was used following a sequence of models. The analysis sequence began by developing a bivariate model regressing the follow-up outcome measure on intervention status (intervention vs. control) followed by the estimation of an adjusted model accounting for the baseline measure of interest and further adjustment for key covariates. Parametric two sample t-tests were used for bivariate analysis of exploratory study outcomes (blood pressure and BMI). The confirmatory variable and other exploratory outcomes (HbA1c, PHQ-9, and Duke General Health) were found to be non-normally distributed. In these bivariate analyses, nonparametric Wilcoxon Rank Sum tests were conducted due to the increased sensitivity to detect a difference in non-normally distributed data. The nonparametric results are presented throughout this report; however, additional parametric t-tests were performed for these measures to align with linear regression methods for the final analyses. Though the bivariate parametric results are not presented, both the nonparametric and parametric bivariate analyses produced consistent results.

Following bivariate comparisons, multivariate and longitudinal analyses were performed separately to answer each research question. As previously mentioned, multiple imputation methods were not needed due to the complete nature of the submitted data. It was also decided propensity score matching methodology was not necessary as randomization successfully led to statistically equivalent groups at baseline. The primary adjusted multivariate analysis models the outcome of interest on intervention status with relevant covariates included. The longitudinal analysis evaluates whether the impact measure trajectories differ by intervention status across the 12-month study. Effect modification of the intervention-outcome relationships were also examined by including interactions terms between sample characteristics and intervention group status in the regression models. Possible effect modification of baseline health condition was explored for the corresponding impact measure (e.g. baseline depression as an effect modifier for impact on PHQ-9 score at 12 months. Age was considered as a potential effect modifier for each model; age was divided into under 55 years and 55 years or older based on the average age in the full study population. The effect modification of sex, male and female, was also assessed.

The SEP indicated a set of planned covariates for adjustment in the models. Of those listed, age (continuous), sex, ethnicity, language, education, and time were included in one or more of the analyses. Categorical age was operationally defined by the following categories: 18-34 years, 35-44 years, 45-54 years, 55-64 years, and those who are 65 years or older. Education was recoded to a dichotomous variable of “less than high school” and “high school or higher”. Race was noted as a possible covariate in the SEP but was not included in the analyses as it was not collected at baseline.

A backward elimination modeling selection procedure was employed for the end-point analysis approach where covariates with a p-value larger than 0.15 were excluded from the final model for parsimony. A priori selection was considered, particularly for age and sex due to the known biological influence of these characteristics on health outcomes. However, in response to the baseline equivalence on all demographic measures, it was decided a priori selection was not appropriate. All variables were still included for

possible selection in the model based on the p-value of 0.15. When testing for effect modification, interaction terms between intervention group and variables of interest were included in the model for possible selection using the same criteria of a p-value ≤0.15.

Because Border serves a patient population with SPMI and Gateway serves a general population with unknown psychiatric diagnosis, three analytic samples were created and analyzed. We first analyzed all participants combined, regardless of the clinic at which they received services. In these models, the participant's clinic was included as a covariate for possible selection. We then conducted stratified analyses examining the intervention effect on health outcomes in each clinic population separately. Apart from the clinic covariate, all analyses included the same covariates for possible selection and employed the same backwards selection approach. The addition of the stratified analyses was not planned in the SEP. However, based on the known differences between the two study clinics, examining the intervention effect separately was warranted and responsive to the study sample recruited. Results from all analyses are presented under each research question.

HbA1c Level

Question 1. **Do diabetic patients who participate in the Juntos for Better Health PCMU intervention experience greater improvements in HbA1c measures after 12 months when compared to diabetic patients that do not participate in the intervention? This question is confirmatory.**

Overview of Analysis
To answer this confirmatory question about intervention impact on HbA1c level, data were collected on patient HbA1c levels. As previously stated, eligibility for participation in the study required an HbA1c of 6.5% or higher at baseline and HbA1c data were collected for all participants at all time points. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for HbA1c level. The sample sizes for the presented analyses of HbA1c in the combined TAMIU sample are as follows: bivariate analyses (n=544), primary linear regression analyses (n=532), and longitudinal analyses (n=641). For the Gateway clinic, the sample sizes were: primary linear regression analyses (n=455) and longitudinal analyses (n=530). For the Border clinic, the sample sizes were primary linear regression analyses (n=77) and longitudinal analyses (n=111).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 48** presents the mean HbA1c level data in each study period for the overall sample as well as the intervention and control groups. The overall study sample had a mean HbA1c of 8.7% at baseline. For those who returned for a follow-up assessment, the average was 8.5% at 6-month follow-up and at 12-month follow-up. The intervention group began with a mean of 8.7%. For those participants in the intervention group who returned for a follow-up visit, mean HbA1c at 6-month follow-up was 8.6% and 8.5% at 12 months. The control group participants also began the study with a baseline HbA1c of 8.7%. For those participants in the control group who returned for a follow-up visit, the mean HbA1c at 6 months and 12 months was 8.4%. As previously noted in **Table 16**, the intervention and control groups were statistically equivalent on HbA1c level at baseline.

Bivariate analyses were performed within each study group, testing the statistical significance of any difference between impact measures at baseline and 12-month follow-up without controlling for any additional covariates (**Table 46**). The difference observed in HbA1c level from baseline to 12-month follow-up was statistically significant within the control group (p=0.01), but not in the intervention group.

Bivariate analyses were also performed between the intervention and control groups comparing HbA1c levels at 12-month follow-up, without controlling for any additional covariates (**Table 47**). Based on a p-value greater than 0.05 for HbA1c when comparing the intervention and control group median scores at 12 months, the null hypothesis cannot be rejected. The HbA1c level was not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, HbA1c level. Covariates were removed from the model if their p-value was found to be greater than 0.15. The initial covariates that were input into the models for HbA1c level were: age, sex, primary language, education, baseline HbA1c level, number of comorbidities at baseline, and clinic.

$$Y_{(HbA1c)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 Education + \beta_6 BL\_HbA1c + \beta_7 BL\_Comorbidities + \beta_8 Clinic + \varepsilon$$

As previously stated, multiple imputation approach was considered but not performed due to the near completeness of the evaluated data.

For the full study sample, the final model of HbA1c level included those covariates with p-value of 0.15 or less: age, sex, baseline HbA1c level, and clinic. Age was modeled as a continuous variable for parsimony. The final model specification was:

$$Y_{(HbA1c)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 BL\_HbA1c + \beta_5 Clinic + \varepsilon$$

For the Gateway clinic sample, the final model of HbA1c level included those covariates with p-value of 0.15 or less: age, sex, baseline HbA1c level, and number of comorbidities at baseline. Age was modelled as a continuous variable for parsimony. The final model specification was:

$$Y_{(HbA1c)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 BL\_HbA1c + \beta_5 BL\_Comorbidities + \varepsilon$$

For the Border clinic sample, the final model of HbA1c level included those covariates with p-value of 0.15 or less: sex, language, and baseline HbA1c level. The final model specification was:

$$Y_{(HbA1c)}=\beta_0 + \beta_1 StudyArm + \beta_2 Sex + \beta_3 Language + \beta_4 BL\_HbA1c + \varepsilon$$

Findings

Estimates for the final model of HbA1c level, for the full TAMIU sample, are presented in **Table 21**.

Mean HbA1c level at 12 months did not differ significantly by intervention status (p=0.38) when analyzing the full sample; the effect size (using Cohen's d) is 0.06.

$$Y_{(HbA1c)}=3.20 + 0.11(Intervention) + -0.02(Age) + -0.42(Male) + 0.69(Gateway) + 0.65(BL\_HbA1c) + \varepsilon$$

Table 21. Effect of IBH Intervention on Twelve Month HbA1c Value, Full TAMIU Sample

Variable	HbA1c (n=532)		
	Estimate (β)	Standard Error	p-value
Intervention	0.11	0.12	0.38
Control (ref)	--	--	--
Age (continuous)	-0.02	0.01	0.004
Male	-0.42	0.14	0.003
Female (ref)	--	--	--
Gateway clinic	0.69	0.18	<0.001
Border clinic (ref)	--	--	--
Baseline HbA1c	0.65	0.03	<0.001

Note: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Estimates for the final model of HbA1c level for the Gateway clinic sample are presented in **Table 22**.

Mean HbA1c level at 12 months did not differ significantly by intervention status (p=0.47) when analyzing the Gateway clinic sample; the effect size (using Cohen's d) is 0.05.

$$Y_{(HbA1c)}=4.06 + 0.10(\text{Intervention}) + -0.02(\text{Age}) + -0.41(\text{Male}) + 0.68(\text{BL\_HbA1c}) + -0.13(\text{BL\_Comorbidities}) + \varepsilon$$

Table 22. Effect of IBH Intervention on Twelve Month HbA1c Value, Gateway Clinic Sample

Variable	HbA1c (n=455)		
	Estimate (β)	Standard Error	p-value
Intervention	0.10	0.13	0.47
Control (ref)	--	--	--
Age (continuous)	-0.02	0.01	0.003
Male	-0.41	0.15	0.01
Female (ref)	--	--	--
Baseline HbA1c	0.68	0.04	<0.001
Baseline number of comorbidities	-0.13	0.08	0.09

Note: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Estimates for the final model of HbA1c level for the Border clinic sample are presented in **Table 23**.

Mean HbA1c level at 12 months did not differ significantly by intervention status (p=0.86) when analyzing the Border clinic sample; the effect size (using Cohen's d) is 0.04.

$$Y_{(HbA1c)}=3.80 + -0.06(\text{Intervention}) + -0.54(\text{Male}) + 0.61(\text{English}) + -0.34(\text{OtherLang}) + 0.47(\text{BL\_HbA1c}) + \varepsilon$$

Table 23. Effect of IBH Intervention on Twelve Month HbA1c Value, Border Clinic Sample

Variable	HbA1c (n=77)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.06	0.33	0.86
Control (ref)	--	--	--
Male	-0.54	0.34	0.11
Female (ref)	--	--	--
English	0.61	0.35	0.08
Other language	-0.34	0.50	0.49
Spanish (ref)	--	--	--
Baseline HbA1c	0.47	0.09	<0.001

Note: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Additional Analyses

When examining effect modification between intervention participation and select participant characteristics at baseline on HbA1c level, significant effect modification was identified by sex and mean age. However, when stratifying, the intervention was not found to have a statistically significant effect on HbA1c level for either sex or age group.

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differed by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For HbA1c level, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.62, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for HbA1c level (see **Table 24**). Adjusting for the covariates that were selected in the primary model—age, sex, and clinic —did not alter these results. Longitudinal analyses were also not statistically significant when examining the Gateway clinic (interaction term p-value=0.83) and Border clinic (interaction term p-value=0.85) separately (full results not presented).

Table 24. Effect of IBH Intervention on Trajectory of HbA1c Value Across Twelve Month Study, Full TAMIU Sample

Variable	HbA1c (n=641)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	0.07	0.13	0.62
Time*Control (ref)	--	--	--
Time	-0.29	0.09	0.002
Intervention	0.03	0.14	0.84
Control (ref)	--	--	--

Note: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Limitations
For the stratified analyses, particularly within the Border clinic population, the reduced sample sizes, compared to the full combined sample, may have had insufficient power to detect a difference in health outcomes between the two study groups.

Depressive Symptoms

Question 2. **Do patients who participate in the Juntos for Better Health PCMU intervention experience greater improvements in depressive symptoms, as measured by PHQ-9, after 12 months compared to patients who do not participate? This question is exploratory.**

Overview of Analysis
To answer this exploratory question about intervention impact on depressive symptoms, data were collected using the PHQ-9. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for the PHQ-9 scale. The sample sizes for the presented analyses of PHQ-9 score in the combined TAMIU sample are as follows: bivariate analyses (n=542), primary linear regression analyses (n=526), and longitudinal analyses (n=639). For the Gateway clinic, the sample sizes were: primary linear regression analyses (n=449) and longitudinal analyses (n=529). For the Border clinic, the sample sizes were: primary linear regression analyses (n=77) and longitudinal analyses (n=110).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 48** presents the mean PHQ-9 values in each study period for the overall sample as well as the intervention and control groups. The overall study sample had a mean PHQ-9 score of 6.0 at baseline. For those who returned for a follow-up assessment, mean PHQ-9 was 5.2 at 6-month follow up and 4.6 at 12-month follow-up. The intervention group began the study with a mean PHQ-9 of 5.7. For those participants in the intervention group who returned for a follow-up, mean PHQ-9 was 4.9 at 6-month follow up and 4.6 at 12-month follow-up. The control group began the study at mean PHQ-9 of 6.4. For those participants in the control group who returned for follow-up, mean PHQ-9 was 5.4 at 6-month follow-up and 4.6 at 12-month follow-up. As previously noted in **Table 16**, the intervention and control groups were statistically equivalent on baseline PHQ-9 score.

Bivariate analyses were performed within each study group, testing the statistical significance of any difference in impact measures between baseline to 12-month follow-up without controlling for any additional covariates (**Table 46**). For PHQ-9 score, the difference from baseline to 12-month follow-up was statistically significant within the control group ($p<0.001$), but not within the intervention group.

Bivariate analyses were also performed between the intervention and control groups comparing PHQ-9 at 12-month follow-up, without controlling for any additional covariates (**Table 47**). Based on a p-value greater than 0.05 for PHQ-9 score when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. PHQ-9 score was not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process
A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, PHQ-9. Covariates were removed from the model if their p-value was found to be greater than 0.15. The initial covariates that were input into the models for PHQ-9

score were: age, sex, primary language, education, baseline PHQ-9, number of comorbidities at baseline, and clinic.

$$Y_{(PHQ9)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 Education + \beta_6 BL\_PHQ9 + \beta_7 BL\_Comorbidities + \beta_8 Clinic + \varepsilon$$

As previously stated, multiple imputation approach was considered but not performed due to the near completeness of the evaluated data.

For the full study sample, the final model of PHQ-9 included those covariates with a p-value of 0.15 or less: age, baseline PHQ-9 score, and clinic. The final model specification was:

$$Y_{(PHQ9)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 BL\_PHQ9 + \beta_4 Clinic + \varepsilon$$

For the Gateway clinic sample, the final model of PHQ-9 included those covariates with a p-value of 0.15 or less: language and baseline PHQ-9 score. The final model specification was:

$$Y_{(PHQ9)}=\beta_0 + \beta_1 StudyArm + \beta_2 Language + \beta_3 BL\_PHQ9 + \varepsilon$$

For the Border clinic sample, the final model of PHQ-9 included those covariates with a p-value of 0.15 or less: baseline PHQ-9 score only. The final model specification was:

$$Y_{(PHQ9)}=\beta_0 + \beta_1 StudyArm + \beta_2 BL\_PHQ9 + \varepsilon$$

Findings

Estimates for the final model of depressive symptoms for the full TAMIU sample are presented in **Table 25.**

Mean PHQ-9 score at 12 months differed significantly by intervention status (p=0.03) when analyzing the full sample; the effect size (using Cohen's d) is 0.14. On average, when examining all TAMIU participants regardless of clinic, those in the intervention group have a PHQ9 score 0.76 points higher than those in the control group.

$$Y_{(PHQ9)}=4.35 + 0.76(Intervention) + -0.02(Age) + 0.54(BL\_PHQ9) + -2.19(Gateway) + \varepsilon$$

Table 25. Effect of IBH Intervention on Twelve Month PHQ-9 score, Full TAMIU Sample

Variable	PHQ-9 (n=526)		
	Estimate (β)	Standard Error	p-value
Intervention	**0.76**	**0.35**	**0.03**
Control (ref)	--	--	--
Age (continuous)	-0.02	0.02	0.15
Gateway clinic	-2.19	0.56	<0.001
Border clinic (ref)	--	--	--
Baseline PHQ-9	0.54	0.03	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Estimates for the final model of depressive symptoms, for the Gateway clinic sample, are presented in **Table 26.**

Mean PHQ-9 score at 12 months did not differ significantly by intervention status (p=0.12).

$$Y_{(PHQ9)}=0.95 + 0.55(\text{Intervention}) + -0.87(\text{English}) + 1.24(\text{Other language}) + 0.55(\text{BL\_PHQ9}) + \varepsilon$$

Table 26.Effect of IBH Intervention on Twelve Month PHQ-9 score, Gateway Clinic Sample

Variable	PHQ-9 (n=449)		
	Estimate (β)	Standard Error	p-value
Intervention	0.55	0.36	0.12
Control (ref)	--	--	--
English	-0.87	0.58	0.13
Other language	1.24	0.88	0.16
Spanish (ref)	--	--	--
Baseline PHQ-9	0.55	0.04	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Estimates for the final model of depressive symptoms for the Border clinic sample are presented in **Table 27.**

Mean PHQ-9 score at 12 months did not differ significantly by intervention status (p=0.32).

$$Y_{(PHQ9)}=3.04_0 + 1.21(\text{Intervention}) + 0.53(\text{BL\_PHQ9}) + \varepsilon$$

Table 27. Effect of IBH Intervention on Twelve Month PHQ-9 score, Border Clinic Sample

Variable	PHQ-9 (n=77)		
	Estimate (β)	Standard Error	p-value
Intervention	1.21	1.22	0.32
Control (ref)	--	--	--
Baseline PHQ-9	0.53	0.09	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Additional Analyses

When examining effect modification between intervention participation and select participant characteristics at baseline on PHQ-9 score, no significant effect modification was detected.

To further understand the significant results produced in the primary analysis, additional analyses of the potential impact of the intervention on health outcomes were conducted. Using the same linear regression modeling approach as the primary analyses in both the full sample and the two study clinics separately, a continuous covariate for the number of visits received over the study period was added for

possible selection. One set of models included the number of primary care appointments a participant completed and the other included the number of completed behavioral health visits.

For models of PHQ-9 score, number of primary care visits was not selected for the Gateway clinic sample. The variable was selected for the PHQ-9 score model within the Border clinic sample, but inclusion did not alter the lack of significance between the intervention and PHQ-9 score found in the primary linear regression. For the full study sample, the number of primary care visits was selected and, with its inclusion, the intervention effect on PHQ-9 score was no longer statistically significant as in the primary linear regression model (see **Table 28).**

Table 28. Effect of IBH Intervention on Twelve Month PHQ-9 score Adjusting for Primary Care Visits, Full TAMIU Sample

Variable	PHQ-9 (n=526)		
	Estimate (β)	Standard Error	p-value
Intervention	0.66	0.35	0.06
Control (ref)	--	--	--
Gateway clinic	-2.31	0.59	<0.001
Border clinic (ref)	--	--	--
Baseline PHQ-9	0.54	0.03	<0.001
Number of Primary Care Visits	0.08	0.05	0.13

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

For models of PHQ-9 score, number of behavioral health visits was selected for the separate Gateway clinic and Border clinic samples, but inclusion did not significantly alter results found in the primary linear regression. For the full study sample, the number of behavioral health visits was selected and, with its inclusion, the intervention effect on PHQ-9 score was no longer statistically significant as in the primary linear regression (see **Table 29**Table 33).

Table 29. Effect of IBH Intervention on Twelve Month PHQ-9 score Adjusting for Behavioral Health Care Visits, Full TAMIU Sample

Variable	PHQ-9 (n=526)		
	Estimate (β)	Standard Error	p-value
Intervention	0.47	0.35	0.18
Control (ref)	--	--	--
Baseline PHQ-9	0.53	0.03	<0.001
Number of Behavioral Health Visits	0.44	0.09	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

To further understand the differing results of the primary and additional analyses, mediation analyses were explored. The number of primary care visits and the number of behavioral health visits were considered in separate models for possible mediation of the intervention effect on PHQ-9 score. This assessment required four separate analyses, all adjusting for the selected covariates in the primary

analysis. First, there needed to be an established effect of the intervention on PHQ-9 score. Next, there needed to be an association between the intervention and number of visits. Third, the number of visits needed to be associated with PHQ-9 score. If these relationships were confirmed, a model was conducted to assess the effect of the intervention on PHQ-9 score while adjusting for the effect of visits on PHQ-9 score.

When assessing the possible mediation of primary care visits, there was a significant association between the intervention and number of primary care visits, with those in the intervention completing more visits throughout the study period. However, there was no significant effect of the number of primary care visits on PHQ-9 score, though the results were marginal (see **Table 30**).

For possible mediation by behavioral health visits, there was a significant effect of the intervention on number of behavioral health visits, with those in the intervention completing more visits. There was also a significant association of number of behavioral health visits and PHQ-9 score, with those receiving more visits having higher PHQ-9 scores. Because of these significant associations (see **Table 30**) and the lack of statistical significance of the intervention on PHQ-9 score with the inclusion of behavioral health visits in the model, we conclude that the number of behavioral health visits mediates the effect of the intervention on PHQ-9 score.

Table 30. Mediation Analyses of the Effect of IBH Intervention on Twelve Month PHQ-9 score by Clinic Visits, Full TAMIU Sample

Association	Primary Care Visits Estimate (p)	Behavioral Health Visits Estimate (p)
PCMU calls → PHQ-9	**0.71 (0.04)**	**0.71 (0.04)**
PCMU calls → Visits	**0.91 (0.001)**	**0.62 (<0.001)**
Clinic visits → PHQ-9	0.10 (0.06)	**0.39 (0.003)**
PCMU calls → PHQ-9 (with clinic visits → PHQ-9)	0.62 (0.07)	0.47 (0.18)

Notes: Bold denotes statistically significant difference between intervention and control groups (p-value<0.05); Above models adjusted for baseline PHQ-9, age, and clinic

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differ by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For PHQ-9 score, only adjusting for intervention status and time, there was a significant time/group interaction with a p-value of 0.02, indicating that the trajectories from baseline to 6 months, and then to 12 months differed between the two study arms for PHQ-9 score (see **Table 31**). Adjusting for the covariates that were selected in the primary model— age and clinic – did not alter these results. Longitudinal analyses were also statistically significant when examining the Gateway clinic (interaction term p-value=0.04), but not for Border clinic (interaction term p-value=0.22) separately (full results not presented).

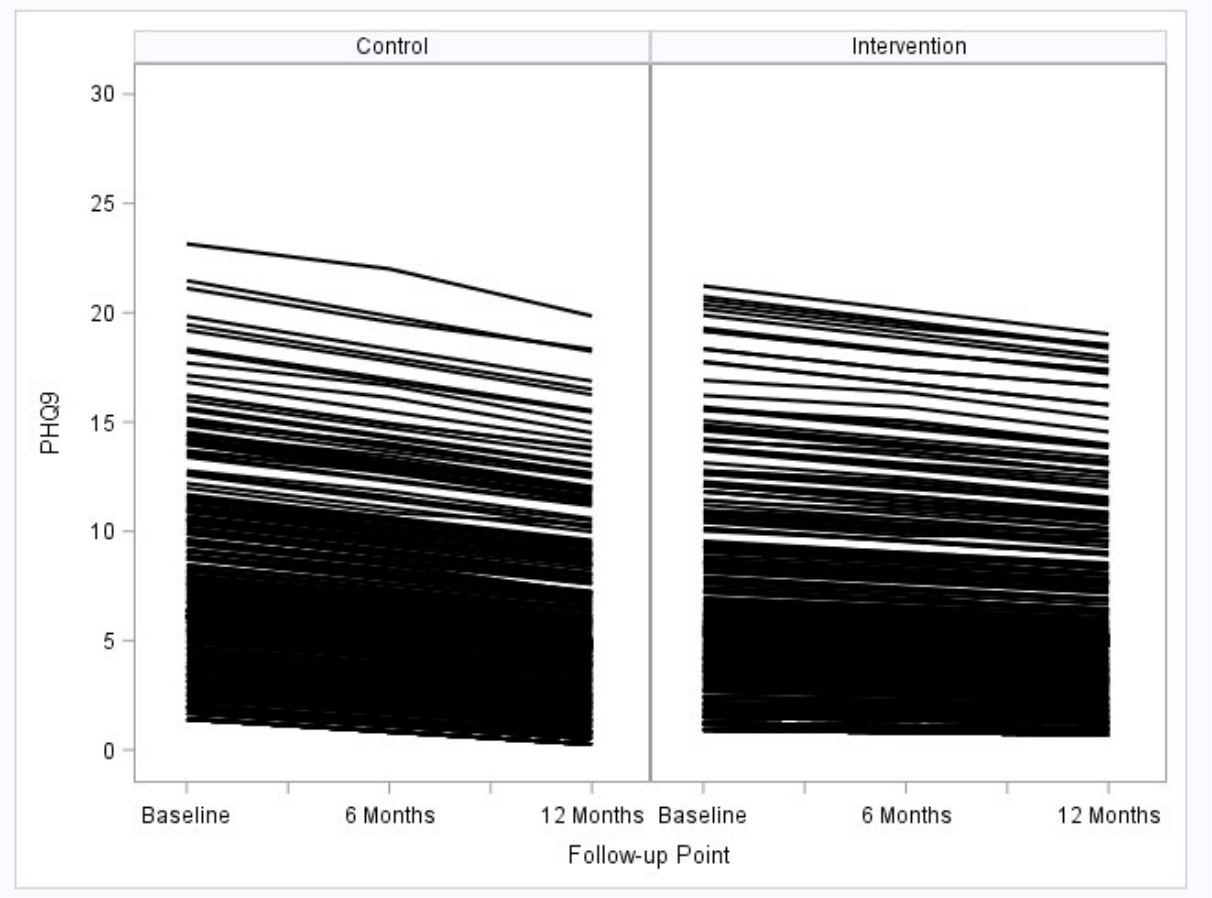
Table 31. Effect of IBH Intervention on Trajectory of PHQ-9 score Value Across Twelve Month Study, Full TAMIU Sample

Variable	PHQ-9 (n=639)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	0.95	0.39	0.02
Time*Control (ref)	--	--	--
Time	-1.64	0.27	<0.001
Intervention	-0.74	0.44	0.09
Control (ref)	--	--	--

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

To visualize the longitudinal effect of the intervention on PHQ-9 score, we produced a two-panel spaghetti plot using PROC SGPANEL. Figure 5 displays the control group trajectory in the left panel and the intervention group trajectory in the right panel. The trajectory figure visually displays the differences identified in the longitudinal statistical model, illustrating the decreasing PHQ-9 score in both groups and the control group's steeper decrease in PHQ-9 score from baseline to 12 months compared to the intervention group.

Figure 5. Individual Trajectories of PHQ-9 Across 12-Month Study Period by IBH Intervention and Control Group



Limitations
For the stratified analyses, particularly within the Border clinic population, the reduced sample sizes, compared to the full combined sample, may have had insufficient power to detect a difference in health outcomes between the two study groups.

Functioning and Quality of Life

Question 3. **Do patients who participate in the Juntos for Better Health PCMU intervention experience greater improvements in quality of life after 12 months when compared to patients that do not participate in the intervention? This question is exploratory.**

Overview of Analysis
To answer this exploratory question about intervention impact on quality of life, data were collected using the Duke Health Profile, specifically the General Health score. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for the Duke General Health score. The sample sizes for the presented analyses of Duke General Health score in the combined TAMIU sample are as follows: bivariate analyses (n=551), primary linear regression analyses (n=529), and longitudinal analyses (n=631). For the Gateway clinic, the sample sizes were: primary linear regression analyses (n=454) and longitudinal analyses (n=526). For the Border clinic, the sample sizes were: primary linear regression analyses (n=75) and longitudinal analyses (n=105).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 48** presents the mean Duke General Health index values in each study period for the overall sample as well as the intervention and control groups. The overall study sample had a mean General Health score of 67.9 at baseline. For those who returned for a follow-up assessment, mean General Health score was 71.9 at 6-month follow-up and 74.4 at 12-month follow-up. The intervention group began the study with a mean Duke General Health score of 68.9. For those participants in the intervention group who returned for a follow-up, mean Duke General Health score was 72.6 at 6-month follow up and 75.4 at 12-month follow-up. The control group began the study with a mean Duke General Health score of 66.9. For those participants in the control group who returned for follow-up, mean Duke General Health score was 71.1 at 6-month follow-up and 73.4 at 12-month follow-up. As previously noted in **Table 16**, the intervention and control groups were statistically equivalent on Duke General Health score at baseline.

Bivariate analyses were performed within each study group, testing the statistical significance of any difference in impact measures between baseline and 12-month follow-up without controlling for any additional covariates (**Table 46**). For Duke General Health, the differences between baseline and 12-month follow-up were statistically significant within both the intervention and control groups ($p<0.001$).

Bivariate analyses were also performed between the intervention and control groups comparing quality of life at 12-month follow-up, without controlling for any additional covariates (**Table 47**). Based on a p-value greater than 0.05 for Duke General Health score when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. Duke General Health score was not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, Duke General Health score. Covariates were removed from the model if their p-value was found to be greater than 0.15. The initial covariates that were input into the models for Duke General Health score were: age, sex, primary language, education, baseline Duke General Health score, number of comorbidities at baseline, and clinic.

$$Y_{(GeneralHealth)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 Education + \beta_6 BL\_GenHlth + \beta_7 BL\_Comorbidities + \beta_7 Clinic + \varepsilon$$

As previously stated, multiple imputation approach was considered but not performed due to the near completeness of the evaluated data.

For the full study sample, the final model of Duke General Health score included those covariates with a p-value of 0.15 or less: education, baseline Duke General Health score, and clinic. The final model specification was:

$$Y_{(GeneralHealth)}=\beta_0 + \beta_1 StudyArm + \beta_2 Education + \beta_3 BL\_General + \beta_4 Clinic + \varepsilon$$

For the Gateway clinic sample, the final model of Duke General Health score included those covariates with a p-value of 0.15 or less: education, baseline Duke General Health score, and number of comorbidities at baseline. The final model specification was:

$$Y_{(GeneralHealth)}=\beta_0 + \beta_1 StudyArm + \beta_2 Education + \beta_3 BL\_General + \beta_4 BL\_Comorbidities + \varepsilon$$

For the Border clinic sample, the final model of Duke General Health score included those covariates with a p-value of 0.15 or less: baseline Duke General Health score only. The final model specification was:

$$Y_{(GeneralHealth)}=\beta_0 + \beta_1 StudyArm + \beta_2 BL\_General + \varepsilon$$

Findings

Estimates for the final model of quality of life, for the full TAMIU sample, are presented in **Table 32.**

Mean Duke General Health score at 12 months did not differ significantly by intervention status (p=0.80).

$$Y_{(GeneralHealth)}=43.41 + -0.28(Intervention) + 2.06(High\ school\ or\ higher) + 0.64(BL\_General) + -10.80(Gateway) + \varepsilon$$

Table 32. Effect of IBH Intervention on Twelve Month Duke General Health score, Full TAMIU Sample

Variable	Duke General Health (n=529)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.28	1.12	0.80
Control (ref)	--	--	--
High school or higher	2.06	1.15	0.07
Less than high school (ref)	--	--	--
Gateway clinic	-10.80	1.84	<0.001
Border clinic (ref)	--	--	--
Baseline General Health	0.64	0.03	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Estimates for the final model of quality of life, for the Gateway clinic sample, are presented in **Table 33**.

Mean Duke General Health score at 12 months did not differ significantly by intervention status (p=0.64).

$$Y_{(GeneralHealth)}=40.09 + -0.55(Intervention) + 2.58(High\ school\ or\ higher) + 0.56(BL\_General) + -1.44(BL\_Comorbidities) + \varepsilon$$

Table 33. Effect of IBH Intervention on Twelve Month Duke General Health score, Gateway Clinic Sample

Variable	Duke General Health (n=454)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.55	1.17	0.64
Control (ref)	--	--	--
High school or higher	2.58	1.20	0.03
Less than high school (ref)	--	--	--
Baseline General Health	0.56	0.04	<0.001
Baseline number of comorbidities	-1.44	0.74	0.05

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Estimates for the final model of quality of life, for the Border clinic sample, are presented in **Table 34**.

Mean Duke General Health score at 12 months did not differ significantly by intervention status (p=0.80).

$$Y_{(GeneralHealth)}=7.66 + 0.84(Intervention) + 0.92(BL\_General) + \varepsilon$$

Table 34. Effect of IBH Intervention on Twelve Month Duke General Health score, Border Clinic Sample

Variable	Duke General Health (n=75)		
	Estimate (β)	Standard Error	p-value
Intervention	0.84	3.30	0.80
Control (ref)	--	--	--
Baseline General Health	0.92	0.09	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Additional Analyses

When examining effect modification between intervention participation and select participant characteristics at baseline on Duke General Health score, no significant effect modification was detected.

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differed by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For Duke General Health score, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.45, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for Duke General Health score (see **Table 35**). Adjusting for the covariates that were selected in the primary model—education and clinic – did not alter these results. Longitudinal analyses were also not statistically significant when examining the Gateway clinic (interaction term p-value=0.36) and Border clinic (interaction term p-value=0.82) separately (full results not presented).

Table 35. Effect of IBH Intervention on Trajectory of Duke General Health Score Value Across Twelve Month Study, Full TAMIU Sample

Variable	Duke General Health (n=631)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	-0.89	1.19	0.45
Time*Control (ref)	--	--	--
Time	5.76	0.84	<0.001
Intervention	1.89	1.57	0.23
Control (ref)	--	--	--

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Limitations

For the stratified analyses, particularly within the Border clinic population, the reduced sample sizes, compared to the full combined sample, may have had insufficient power to detect a difference in health outcomes between the two study groups.

Blood Pressure

Question 4. **Do patients who participate in the Juntos for Better Health PCMU intervention experience greater improvements in blood pressure after 12 months when compared to patients that do not participate in the intervention? This question is exploratory.**

Overview of Analysis

To answer this exploratory question about intervention impact on blood pressure, data were collected on patient systolic and diastolic blood pressure levels. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for blood pressure. The sample sizes for the presented analyses of blood pressure in the combined TAMIU sample are as follows: bivariate analyses (n=555), primary linear regression analyses (n=542), and longitudinal analyses (n=645). For the Gateway clinic, the sample sizes were: primary linear regression analyses (n=467) and longitudinal analyses (n=535). For the Border clinic, the sample sizes were: primary linear regression analyses (n=75) and longitudinal analyses (n=110).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 48** presents the mean systolic and diastolic blood pressure values in each study period for the overall sample as well as the intervention and control groups. The overall study sample had a mean blood pressure of 134.3/78.2 mmHg at baseline. For those who returned for a follow-up assessment, mean blood pressure was 133.3/79.5 mmHg at 6-months and 128.2/76.4 mmHg at 12-month follow-up. The intervention group began the study with a mean blood pressure of 134.6/78.8 mmHg. For those participants in the intervention group who returned for a follow-up, mean blood pressure was 134.7/80.4 mmHg at 6-month follow-up and 129.5/76.7 mmHg at 12-month follow-up. The control group began the study with a mean blood pressure of 134.0/77.7 mmHg. For those participants in the control group who returned for follow-up, mean blood pressure was 131.9/78.6 mmHg at 6 months and 126.8/76.1 mmHg at 12 months. As previously noted in **Table 16**, the intervention and control groups were statistically equivalent on systolic and diastolic blood pressure at baseline.

Bivariate analyses were performed within each study group, testing the statistical significance of the change in impact measures from baseline to 12-month follow-up without controlling for any additional covariates (**Table 46**). The changes observed within systolic blood pressure from baseline to 12-month follow-up were statistically significant within both the intervention ($p<0.001$) and control ($p<0.001$) groups. The changes observed within diastolic blood pressure from baseline to 12-month follow-up were statistically significant within both the intervention ($p=0.02$) and control ($p=0.03$) groups.

Bivariate analyses were also performed between the intervention and control groups comparing systolic and diastolic blood pressure at 12-month follow-up, without controlling for any additional covariates (**Table 47**). Based on a p-value greater than 0.05 for both systolic and diastolic blood pressure when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. Systolic and diastolic blood pressure were not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcomes, systolic and diastolic blood pressure. Covariates were removed from the model if their p-value was found to be greater than 0.15. The initial covariates that were input into the models for systolic and diastolic blood pressure were: age, sex, primary language,

education, baseline systolic blood pressure, baseline diastolic blood pressure, number of comorbidities at baseline, and clinic.

$$Y_{(SBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 Education + \beta_6 BL\_SBP + \beta_7 BL\_DBP + \beta_8 BL\_Comorbidities + \beta_{12} Clinic + \varepsilon$$

$$Y_{(DBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 Education + \beta_6 BL\_DBP + \beta_7 BL\_SBP + \beta_8 BL\_Comorbidities + \beta_{12} Clinic + \varepsilon$$

As previously stated, multiple imputation approach was considered but not performed due to the near completeness of the evaluated data.

For the full study and Gateway clinic samples, the final models of systolic blood pressure included those covariates with a p-value of 0.15 or less: age, sex, baseline systolic blood pressure, baseline diastolic blood pressure, and number of comorbidities at baseline. Age was modelled as a continuous variable for parsimony. The final model specification for each was:

$$Y_{(SBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 BL\_SBP + \beta_5 BL\_DBP + \beta_6 BL\_Comorbidities + \varepsilon$$

Because diastolic blood pressure was selected for inclusion into the final model of systolic blood pressure, and systolic and diastolic blood pressure are known to be related, we conducted an additional test to quantify any multicollinearity between systolic and diastolic blood pressure. The variance inflation factor of systolic blood pressure in the diastolic blood pressure model was 1.7 in the full study sample and 1.6 in the Gateway clinic sample, below the accepted cutoff of 5 representing a minimal influence on the variance from the correlation of these two variables (Belsley et al., 1980; O'Brien, 2007; Lasser, et al. 2017).
For the Border clinic sample, the final model of systolic blood pressure included those covariates with a p-value of 0.15 or less: baseline systolic blood pressure only. The final model specification was:

$$Y_{(SBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 BL\_SBP + \varepsilon$$

For both the full study and Gateway clinic samples, the final models of diastolic blood pressure included those covariates with a p-value of 0.15 or less: age, baseline diastolic blood pressure, and number of comorbidities at baseline. Age was modelled as a continuous variable for parsimony. The final model specification for each was:

$$Y_{(DBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 BL\_DBP + \beta_4 BL\_Comorbidities + \varepsilon$$

For the Border clinic sample, the final model of diastolic blood pressure included those covariates with a p-value of 0.15 or less: baseline diastolic blood pressure only. The final model specification was:

$$Y_{(DBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 BL\_DBP + \varepsilon$$

Findings
Estimates for the final model of blood pressure, for the full TAMIU sample, are presented in **Table 36**.

Mean systolic blood pressure at 12 months did not differ significantly by intervention status (p=0.05).

$Y_{(SBP)}$=71.56 + 2.51(Intervention) + 0.12(Age) + -2.80(Male) + 0.24(BL_SBP) + 0.18(BL_DBP) + 1.29(BL_Comorbidities) + ε

Mean diastolic blood pressure at 12 months did not differ significantly by intervention status (p=0.27).

$Y_{(DBP)}$=57.66 + 0.82(Intervention) + -0.13(Age) + 0.29(BL_DBP) + (1.22)BL_Comorbidities + ε

Table 36. Effect of IBH Intervention on Twelve Month Systolic and Diastolic Blood Pressure, Full TAMIU Sample

Variable	Systolic Blood Pressure (n=542)		
	Estimate (β)	Standard Error	p-value
Intervention	2.51	1.30	0.05
Control (ref)	--	--	--
Age (continuous)	0.12	0.07	0.07
Male	-2.80	1.45	0.05
Female (ref)	--	--	--
Baseline systolic blood pressure	0.24	0.05	<0.001
Baseline diastolic blood pressure	0.18	0.08	0.02
Baseline number of comorbidities	1.29	0.86	0.13
Variable	Diastolic Blood Pressure (n=542)		
	Estimate (β)	Standard Error	p-value
Intervention	0.82	0.74	0.27
Control (ref)	--	--	--
Age (continuous)	-0.13	0.03	<0.001
Baseline diastolic blood pressure	0.29	0.04	<0.001
Baseline number of comorbidities	1.22	0.45	0.01

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Estimates for the final model of blood pressure for the Gateway clinic sample are presented in **Table 37**.

Mean systolic blood pressure at 12 months did not differ significantly by intervention status (p=0.10).

$Y_{(SBP)}$=74.39 + 2.23(Intervention) + 0.15(Age) + -3.02(Male) + 0.22(BL_SBP) + 0.15(BL_DBP) + 1.61(BL_Comorbidities) + ε

Mean diastolic blood pressure at 12 months did not differ significantly by intervention status (p=0.35).

$Y_{(DBP)}$=57.37 + 0.73(Intervention) + -0.12(Age) + 0.28(BL_DBP) + 1.50(BL_Comorbidities) + ε

Table 37. Effect of IBH Intervention on Twelve Month Systolic and Diastolic Blood Pressure, Gateway Clinic Sample

Variable	Systolic Blood Pressure (n=467)		
	Estimate (β)	Standard Error	p-value
Intervention	2.23	1.35	0.10
Control (ref)	--	--	--
Age (continuous)	0.15	0.07	0.03
Male	-3.02	1.52	0.05
Female (ref)	--	--	--
Baseline systolic blood pressure	0.22	0.05	<0.001
Baseline diastolic blood pressure	0.15	0.08	0.07
Baseline number of comorbidities	1.61	0.92	0.08
Variable	Diastolic Blood Pressure (n=467)		
	Estimate (β)	Standard Error	p-value
Intervention	0.73	0.78	0.35
Control (ref)	--	--	--
Age (continuous)	-0.12	0.04	0.001
Baseline diastolic blood pressure	0.28	0.04	<0.001
Baseline number of comorbidities	1.50	0.49	0.002

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Estimates for the final model of blood pressure, for the Border clinic sample, are presented in **Table 38**.

Mean systolic blood pressure at 12 months did not differ significantly by intervention status (p=0.48).

$$Y_{(SBP)}=69.50 + 3.10(\text{Intervention}) + 0.43(\text{BL\_SBP}) + \varepsilon$$

Mean diastolic blood pressure at 12 months did not differ significantly by intervention status (p=0.47).

$$Y_{(DBP)}=49.99 + 1.63(\text{Intervention}) + 0.36(\text{BL\_DBP}) + \varepsilon$$

Table 38. Effect of IBH Intervention on Twelve Month Systolic and Diastolic Blood Pressure, Border Clinic Sample

Variable	Systolic Blood Pressure (n=75)		
	Estimate (β)	Standard Error	p-value
Intervention	3.10	1.35	0.48
Control (ref)	--	--	--
Baseline systolic blood pressure	0.43	0.10	<0.001
Variable	Diastolic Blood Pressure (n=75)		
	Estimate (β)	Standard Error	p-value
Intervention	1.63	2.24	0.47
Control (ref)	--	--	--
Baseline diastolic blood pressure	0.36	0.09	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Additional Analyses

When examining effect modification between intervention participation and select participant characteristics at baseline on systolic blood pressure, no significant effect modification was detected.

When examining effect modification between intervention participation and select participant characteristics at baseline on diastolic blood pressure, significant effect modification was identified by baseline hypertension (interaction term p=0.05). When stratifying by baseline hypertension, there was no statistically significant intervention effect on diastolic blood pressure among those who were hypertensive at baseline. Among those who were not hypertensive at baseline, the diastolic blood pressure at 12 months was higher in the intervention group than in the control group (see **Table 39**).

Table 39. Effect of IBH Intervention on Twelve Month Systolic and Diastolic Blood Pressure, Full TAMIU Sample, by Hypertensive Status

	Not Hypertensive			Hypertensive		
Variable	Diastolic Blood Pressure (n=328)			Diastolic Blood Pressure (n=214)		
	Estimate (β)	Standard Error	p-value	Estimate (β)	Standard Error	p-value
Intervention	**2.28**	**1.00**	**0.02**	-0.74	1.24	0.55
Control (ref)	--	--	--	--	--	--
Age	-0.16	0.04	0.001	-0.25	0.06	<0.001
Gateway clinic	-2.60	1.49	0.08	--	--	--
Border clinic (ref)	--	--	--	--	--	--
Number of baseline comorbidities	1.56	0.71	0.03	1.99	0.91	0.03

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differ by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS.

For systolic blood pressure, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.17, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for systolic blood pressure (see **Table 40**). Adjusting for the covariates that were selected in the primary model— sex and baseline diastolic blood pressure – did not alter these results. Longitudinal analyses were also not statistically significant when examining the Gateway clinic (interaction term p-value=0.12) and Border clinic (interaction term p-value=0.96) separately (full results not presented).

For diastolic blood pressure, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.77, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for systolic blood pressure (see **Table 40**). Adjusting for the covariates that were selected in the primary model— age and number of comorbidities at baseline – did not alter these results. Longitudinal analyses were also not statistically significant when examining the Gateway clinic (interaction term p-value=0.80) and Border clinic (interaction term p-value=0.99) separately (full results not presented).

Table 40. Effect of IBH Intervention on Trajectory of Systolic and Diastolic Blood Pressure Across Twelve Month Study, Full TAMIU Sample

Variable	Systolic Blood Pressure (n=645)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	2.22	1.62	0.17
Time*Control (ref)	--	--	--
Time	-7.10	1.14	<0.001
Intervention	0.91	1.40	0.52
Control (ref)	--	--	--
Variable	Diastolic Blood Pressure (n=645)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	-0.27	0.94	0.77
Time*Control (ref)	--	--	--
Time	-1.49	0.66	0.02
Intervention	1.43	0.79	0.07
Control (ref)	--	--	--

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Limitations
For the stratified analyses, particularly within the Border clinic population, the reduced sample sizes, compared to the full combined sample, may have had insufficient power to detect a difference in health outcomes between the two study groups.

Body Mass Index

Question 5. **Do patients who participate in the Juntos for Better Health PCMU intervention experience greater improvements in BMI after 12 months when compared to patients that do not participate in the intervention? This question is exploratory.**

Overview of Analysis
To answer this exploratory question about intervention impact on body mass index, data were collected on patient weight and height, from which body mass index was calculated. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for weight or height. The sample sizes for the presented analyses of BMI in the combined TAMIU sample are as follows: bivariate analyses (n=556), primary linear regression analyses (n=543), and longitudinal analyses (n=645). For the Gateway clinic, the sample sizes were: primary linear regression analyses (n=468) and longitudinal analyses (n=535). For the Border clinic, the sample sizes were: primary linear regression analyses (n=75) and longitudinal analyses (n=110).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 48** presents the mean body mass index values in each study period for the overall sample as well as the intervention and control groups. The overall study sample had a mean body mass index of 32.8 kg/m^2 at baseline. For those who returned for a follow-up assessment, mean body mass index was 32.6 kg/m^2 at 6-month follow-up and 32.8 kg/m^2 at 12-month follow-up. The intervention group began the study with a mean body mass index of 33.1 kg/m^2. For those participants in the intervention group who returned for a follow-up, mean body mass index was 33.2 kg/m^2 at 6-month follow-up and 32.9 kg/m^2 at 12-month follow-up. The control group began the study at mean body mass index of 32.4 kg/m^2. For those participants in the control group who returned for follow-up, mean body mass index was 31.9 kg/m^2 at 6-months and 32.7 kg/m^2 at 12 months. As previously noted in **Table 16**, the intervention and control groups were statistically equivalent on body mass index at baseline.

Bivariate analyses were performed within each study group, testing the statistical significance of the change in impact measures from baseline to 12-month follow-up without controlling for any additional covariates (**Table 46**). The slight changes observed within body mass index from baseline to 12-month follow-up were not statistically significant within both the intervention and control groups.

Bivariate analyses were also performed between the intervention and control groups comparing body mass index at 12-month follow-up, without controlling for any additional covariates (**Table 47**). Based on a p-value greater than 0.05 for body mass index when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. Body mass index was not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process
A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, body mass index. Covariates were removed from the model if their p-value was found to be greater than 0.15. The initial covariates that were input into the models

for body mass index were: age, sex, primary language, education, baseline body mass index, number of comorbidities, and clinic.

$$Y_{(BMI)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 Education + \beta_6 BL\_BMI + \beta_7 BL\_Comorbidities + \beta_8 Clinic + \varepsilon$$

As previously stated, a multiple imputation approach was considered but not performed due to the near completeness of the evaluated data.

For the full study sample, the final model of body mass index included those covariates with p-value of 0.15 or less: age, sex, language, and baseline body mass index:

$$Y_{(BMI)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 BL\_BMI + \varepsilon$$

For the Gateway clinic sample, the final model of body mass index included those covariates with p-value of 0.15 or less: age, sex, and baseline body mass index:

$$Y_{(BMI)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 BL\_BMI + \varepsilon$$

For the Border clinic sample, the final model of body mass index included those covariates with p-value of 0.15 or less: language and baseline body mass index:

$$Y_{(BMI)}=\beta_0 + \beta_1 StudyArm + \beta_2 Language + \beta_3 BL\_BMI + \varepsilon$$

Findings

Estimates for the final model of body mass index for the full TAMIU sample are presented in **Table 41**. Mean body mass index at 12 months did not differ significantly by intervention status (p=0.93).

$$Y_{(BMI)}=5.29 + -0.03(Intervention) + -0.03(Age) + 0.54(Male) + 0.84(English) + -0.14(Other\ Language) + 0.88(BL\_BMI) + \varepsilon$$

Table 41. Effect of IBH Intervention on Twelve Month BMI, Full TAMIU Sample

Variable	BMI (n=543)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.03	0.30	0.93
Control (ref)	--	--	--
Age (continuous)	-0.03	0.01	0.07
Male	0.54	0.34	0.11
Female (ref)	--	--	--
English	0.84	0.43	0.05
Other language	-0.14	0.66	0.83
Spanish (ref)	--	--	--
Baseline BMI	0.88	0.02	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Estimates for the final model of body mass index for the Gateway clinic sample are presented in **Table 42**.

Mean body mass index at 12 months did not differ significantly by intervention status (p=0.94).

$$Y_{(BMI)}=5.66 + 0.02(\text{Intervention}) + -0.03(\text{Age}) + 0.69(\text{Male}) + 0.86(\text{BL\_BMI}) + \varepsilon$$

Table 42. Effect of IBH Intervention on Twelve Month BMI, Gateway Clinic Sample

Variable	BMI (n=468)		
	Estimate (β)	Standard Error	p-value
Intervention	0.02	0.32	0.94
Control (ref)	--	--	--
Age (continuous)	-0.03	0.02	0.07
Male	0.69	0.37	0.06
Female (ref)	--	--	--
Baseline BMI	0.86	0.02	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Estimates for the final model of body mass index for the Border clinic sample are presented in **Table 43**.

Mean body mass index at 12 months did not differ significantly by intervention status (p=0.33).

$$Y_{(BMI)}=3.01 + -0.82(\text{Intervention}) + 1.56(\text{English}) + -0.76(\text{Other language}) + 0.92(\text{BL\_BMI}) + \varepsilon$$

Table 43. Effect of IBH Intervention on Twelve Month BMI, Border Clinic Sample

Variable	BMI (n=75)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.82	0.84	0.33
Control (ref)	--	--	--
English	1.56	0.90	0.09
Other language	-0.76	1.25	0.54
Spanish (ref)	--	--	--
Baseline BMI	0.92	0.06	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

Additional Analyses

When examining effect modification between intervention participation and select participant characteristics at baseline on BMI, significant effect modification was identified by sex, mean age, and baseline obesity. When stratifying by age and sex, the intervention was not found to have a statistically significant effect on BMI for either sex or age group. There was effect modification detected by baseline obesity (interaction term p=0.07). When stratifying by baseline obesity, there was no statistically significant intervention effect among those who were not obese at baseline. Among those who were

obese at baseline, the BMI at 12 months was higher in the intervention group than in the control group (see **Table 44**).

Table 44. Effect of IBH Intervention on Twelve Month BMI, Full TAMIU Sample, by Obese Status

	Not Obese			Obese		
Variable	BMI (n=216)			BMI (n=327)		
	Estimate (β)	Standard Error	p-value	Estimate (β)	Standard Error	p-value
Intervention	-0.19	0.44	0.66	**1.54**	**0.69**	**0.03**
Control (ref)	--	--	--	--	--	--
Age	--	--	--	-0.08	0.03	0.02
Gateway clinic	-1.43	0.80	0.07	-1.87	0.93	0.05
Border clinic (ref)	--	--	--	--	--	--
High school or more	--	--	--	1.06	0.71	0.13
Less than high school (ref)	--	--	--	--	--	--

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and control groups (p-value<0.05).

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differed by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For body mass index, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.62, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for body mass index (see **Table 45**). Adjusting for the covariates that were selected in the primary model— age, sex, and language – did not alter these results. Longitudinal analyses were also not statistically significant when examining the Gateway clinic (interaction term p-value=0.86) and Border clinic (interaction term p-value=0.45) separately (full results not presented).

Table 45. Effect of IBH Intervention on Trajectory of BMI Across Twelve Month Study, Full TAMIU Sample

Variable	BMI (n=645)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	-0.15	0.30	0.62
Time*Control (ref)	--	--	--
Time	0.05	0.21	0.79
Intervention	0.86	0.50	0.09
Control (ref)	--	--	--

Limitations

For the stratified analyses, particularly within the Border clinic population, the reduced sample sizes, compared to the full combined sample, may have had insufficient power to detect a difference in health outcomes between the two study groups.

Table 46. Within Group Bivariate Analyses Comparing Impact Measures from Baseline to 12 Months, by Intervention Group

INTERVENTION GROUP				
	12-Month (n=275) Mean (SD)	Baseline (n=366) Mean (SD)	12-month (–) Baseline Mean Difference (SD)	p-value
BMI[b]	32.9 (6.9)	32.9 (7.2)	0.01 (3.7)	0.97
Systolic Blood Pressure	**129.5 (17.2)**	**134.5 (19.6)**	**-5.0 (20.4)**	**<0.001**
Diastolic Blood Pressure	**76.7 (9.5)**	**78.4 (10.8)**	**-1.7 (11.7)**	**0.02**
Nonparametric Tests[a]	12-Month Median (IQR)		Baseline Median (IQR)	p-value
HbA1c	8.0 (2.7)		8.1 (2.6)	0.06
PHQ-9	2.0 (6.0)		3.0 (6.0)	0.05
General Health	**80.0 (23.3)**		**76.7 (23.3)**	**<0.001**
CONTROL GROUP				
	12-Month (n=286) Mean (SD)	Baseline (n=367) Mean (SD)	12-month (–) Baseline Mean Difference (SD)	p-value
BMI[b]	32.7 (6.9)	32.6 (6.2)	0.13	0.84
Systolic Blood Pressure	**126.8 (16.2)**	**133.8 (19.4)**	**-7.0 (19.5)**	**<0.001**
Diastolic Blood Pressure	**76.1 (9.7)**	**77.4 (10.5)**	**-1.4 (10.8)**	**0.03**
Nonparametric Tests[a]	12-Month Median (IQR)		Baseline Median (IQR)	p-value
HbA1c	**8.0 (2.6)**		**8.0 (2.5)**	**0.01**
PHQ-9	**3.0 (6.0)**		**4.0 (6.0)**	**<0.001**
General Health	**78.3 (30.0)**		**73.3 (33.3)**	**<0.001**

Note: Bold denotes statistical significance (p value < 0.05); [a] The Wilcoxon Signed Rank test was used to examine non-normally distributed data; these results aligned with t test results; [b] A log transformation was used and then exponentiated

Table 47. Between Group Bivariate Analyses Comparing Intervention to Control at 12-Month Follow-Up

	Full Sample (n=561) Mean (SD)	Intervention (n=275) Mean (SD)	Control (n=286) Mean (SD)	p value
BMI[b]	37.8 (6.9)	32.9 (6.9)	32.7 (6.9)	0.83
Systolic	128.2 (16.7)	129.5 (17.2)	126.8 (16.2)	0.06
Diastolic	76.4 (9.6)	76.7 (9.5)	76.1 (9.7)	0.46
Nonparametric Tests[a]	Median (IQR)	Median (IQR)	Median (IQR)	
HbA1c	8.0 (2.7)	8.0 (2.7)	8.0 (2.6)	0.75
PHQ-9	3.0 (6.0)	2.0 (6.0)	3.0 (6.0)	0.21
General Health	80.0 (26.7)	80.0 (23.3)	78.3 (30.0)	0.18

[a] The Wilcoxon Signed Rank test was used to examine non-normally distributed data; these results aligned with t test results; [b] A log transformation was used and then exponentiated

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Table 48. Impact Measures by Study Arm and Follow-up Period, Overall and by Study Group

	Full Sample			Intervention			Control		
	Baseline	6-Mo	12-Mo	Baseline	6-Mo	12-Mo	Baseline	6-Mo	12-Mo
	n=733	n=582	n=561	n=366	n=297	n=275	n=367	n=285	n=286
Measure		Mean (SD)			Mean (SD)			Mean (SD)	
HbA1c									
HbA1c	8.7 (1.9)	8.5 (2.0)	8.5 (1.9)	8.7 (1.9)	8.6 (2.0)	8.5 (2.0)	8.7 (1.9)	8.4 (2.0)	8.4 (1.9)
Missing	0	11	17	0	5	9	0	6	8
PHQ-9									
PHQ-9 Score	6.0 (6.1)	5.2 (5.8)	4.6 (5.3)	5.7 (5.9)	4.9 (6.0)	4.6 (5.7)	6.4 (6.3)	5.4 (5.6)	4.6 (4.9)
Missing	8	10	19	5	4	10	3	6	9
Duke Health									
General Health	67.9 (21.4)	71.9 (20.6)	74.4 (19.7)	68.9 (21.0)	72.6 (21.1)	75.4 (19.8)	66.9 (21.9)	71.1 (20.1)	73.4 (19.7)
Missing	3	17	10	2	8	6	1	9	4
Mental Health	75.2 (27.1)	81.0 (22.9)	83.2 (23.2)	76.2 (27.4)	82.5 (22.8)	84.7 (21.5)	74.2 (26.9)	79.4 (22.9)	81.8 (24.6)
Missing	3	8	5	2	5	4	1	3	1
Physical Health	55.8 (28.4)	57.1 (29.4)	58.7 (28.0)	56.6 (28.2)	57.4 (29.4)	59.2 (28.6)	54.9 (28.7)	56.8 (29.4)	58.3 (27.4)
Missing	3	4	4	2	2	2	1	2	2
Social Health	72.3 (21.7)	76.6 (22.4)	81.1 (20.5)	73.5 (20.5)	77.0 (22.6)	82.3 (21.4)	71.1 (22.8)	76.2 (22.3)	80.0 (19.6)
Missing	3	6	1	2	1	0	1	5	1
Blood pressure									
Systolic	134.3 (19.4)	133.3 (18.6)	128.2 (16.7)	134.6 (19.7)	134.7 (19.1)	129.5 (17.2)	134.0 (19.1)	131.9 (18.0)	126.8 (16.2)
Diastolic	78.2 (10.9)	79.5 (11.2)	76.4 (9.6)	78.8 (11.0)	80.4 (10.6)	76.7 (9.5)	77.7 (10.7)	78.6 (11.8)	76.1 (9.7)
Missing	1	2	6	1	1	2	0	1	4
BMI									
BMI	32.8 (6.8)	32.6 (6.9)	32.8 (6.9)	33.1 (7.3)	33.2 (7.4)	32.9 (6.9)	32.4 (6.3)	31.9 (6.2)	32.7 (6.9)
Missing	2	4	5	2	1	2	0	3	3

CONCLUSION – SUMMARY OF FINDINGS, LESSONS LEARNED, AND NEXT STEPS

This final report provides an overview of findings for the evaluation of Texas A&M International University. TAMIU and its partners implemented an intervention that combines the Dartmouth PCMU model and the innovative *Juntos* model in Webb County. TAMIU implemented an RCT to compare intervention participants receiving the PCMU services in addition to usual care services at two clinics with a control group who received only usual care services at the same clinics. All participants were diagnosed diabetics who, within the last 24 months, were non-compliant with their treatment plans due to not attending all scheduled appointments. All participants from the second clinic population sample had an SPMI diagnosis at enrollment. PCMU services included contacting intervention participants once a week for three weeks in advance of an upcoming appointment and, if a participant did not attend that appointment, the participant was offered home visiting services to address barriers to attending scheduled appointments and linking intervention participants with their home clinic.

This evaluation study executed a robust RCT design, mitigating major threats to internal validity. Specifically, the following threats to internally validity were mitigated through the use of an RCT: selection, instrumentation, and history. The RCT included participants from two clinics, both of which were implementing IBH at the study initiation; however, one clinic served a general patient population and the second served a patient population with SPMI. The use of two clinics serving populations with different physical and behavioral health needs may have compromised the impact analyses. Retention targets for the study were met; however, participants with higher PHQ-9 scores and lower Quality of Life scores at baseline were less likely to have completed all study assessments.

The program was based on an incoming preliminary level of evidence which used a similar intervention in a different population. TAMIU implemented with moderate fidelity as there were significant changes in intervention and evaluation study protocols and staffing during the implementation period. As explained below, results from this study do not indicate a change in the preliminary level of evidence at this time. When controlling for baseline measures and other covariates, intervention participants did not have statistically significant improvement in the HbA1c confirmatory outcome when compared to control participants at 12 months. Further, there were no significant differences at 12 months between intervention participants and control group participants on the exploratory variables of Quality of Life, Diastolic Blood Pressure, or BMI. Among participants who were obese at baseline, intervention participants BMI increased compared to control participants at 12 months. For the exploratory variable, PHQ-9, at 12 months intervention participants had a statistically significant higher mean score, which was no longer significant when adding the mediating variable of number of behavioral health visits. Intervention participants also had a statistically significantly higher systolic blood pressure at 12 months compared to control group participants.

The implementation and impact of the PCMU evaluation study must be placed within the larger context of the development of the *Juntos* partnership. As discussed in the Implementation Findings section and below, the partners were striving to develop a system of care in Webb county where no system had previously existed. Developing this system entailed creating and trying out new protocols within a fragmented health care structure.

Summary of Implementation Findings

The implementation evaluation examined fidelity to TAMIU's program model by conducting focus groups and interviews, examining PCMU call center implementation, and patient visit data. A delayed timeline in data collection was a deviation from the SEP; mid-point interviews were conducted 8 months post-enrollment rather than 6 months, and final interviews and focus groups were conducted 2 months after study conclusion with one clinic and immediately prior to study conclusion at the second clinic rather than immediately after.

Evaluation of the implementation of TAMIU's program shows that the program was implemented in alignment with the program logic model and that the program was implemented with moderate fidelity. TAMIU met the enrollment target for the study and exceeded the overall 12-month retention target (final sample was 286 total participants compared to a target of 255 participants.)

All participants enrolled in the intervention met study eligibility criteria, and all who remained in the study for the 12 months received the phone call intervention as designed including physical and behavioral health referrals and services. Intervention group participants received reminder calls in advance of upcoming primary care and behavioral health appointments in addition to usual care reminder procedures at the two clinics. PCMU staff placed more than 1500 reminder calls to participants, less than half of these calls were completed to remind participants of upcoming appointments. The home-visit component of the intervention was not implemented as planned. Only 13 home visits were scheduled and eight of these were completed.

The effectiveness of the PCMU intervention on patient compliance with treatment can be examined by participant show rate to scheduled appointments, patient compliance with treatment by attending the last scheduled appointment, and through the impact analysis of the PCMU on number of completed visits. Due to sequential implementation in Gateway and Border clinics, data on show rates and compliance should be examined by clinic. Gateway intervention participants had higher show rates than control participants for all services, including behavioral health (52 vs 46%) and primary care (52 versus 50%). Among Border participants, the control group had higher show rates than intervention participants for behavioral health (73 versus 57%) and primary care (75 versus 59%) services. Regarding compliance, 60% of Gateway and 39% of Border intervention participants, who received a successful PCMU call, were compliant based on their last scheduled appointment. Among the control group, 62% of Gateway and 74% of Border participants were compliant as of their last scheduled appointment.

Mediation analysis of the effect of the PCMU intervention indicated that there was a significant effect of the intervention on the number of primary care and behavioral health visits. The intervention was associated, on average, with a greater number of behavioral health visits which mediated the intervention effect on PHQ-9 score as described in the *Summary of Impact Findings* below. Potential reasons for differences in results of PCMU implementation, show and compliance rates as well as number of visits, include the changes in PCMU protocols during the implementation period, clinic capacity to provide systematic and reliable data on patient upcoming appointments to the PCMU, differences in clinic operations and patient populations, and intervention patients potentially feeling overwhelmed by the number of reminder calls they received which may have discouraged them from attending appointments.

Further exploration of within clinic data shows that Border intervention participants received more visits but had lower show rates. Although the Border participants were balanced on outcome measures at baseline, it is plausible that intervention participants were scheduled for a greater number of behavioral

health visits due to higher need for care to address depression or other SPMI symptoms, which may also have resulted in lower show rates.

Facilitators to PCMU program implementation included staffing and partners; communication; relationships; training, education, and capacity of staff; flexibility; and data systems. Implementation barriers included evaluation study implementation; communication; hiring and staff; data systems; and workflow.

Due to the fact that participants were patients in partner clinics which conduct satisfaction measures separate from the PCMU program, it was difficult to ascertain participant satisfaction with the PCMU program.

The evaluation study also examined development and implementation of the *Juntos* partnership. Facilitators to partnership development included: creating opportunities for partners to meet regularly to further understand services that each partner provides and how partners can better refer patients; further developing protocols and contracts to clarify agreements; and developing care referral networks. Barriers to partnership development included: evolving practices and protocols to working in partnership; communications about changes in protocols and expectations among partners; and creating shared data systems to meet patient needs.

Summary of Impact Findings

The RCT was implemented with the following modifications from the SEP. Due to enrollment challenges at the first clinic, a second clinic sample was added to ensure sufficient statistical power for data analysis. Although the combined samples were balanced between intervention and control groups, the second clinic population had diagnosed SPMI. The second modification was the extension of the enrollment and follow up periods for an additional year. This modification accommodated an extended enrollment period at the two clinics. Third, incentives to encourage study participants to return for follow up assessments were increased for both the 6- and 12-month follow up assessments.

The RCT did not demonstrate that the PCMU intervention resulted in improved behavioral or physical health for the intervention participants. After 12 months in the program, intervention participants did not see improvements on key outcomes compared to control group participants. For BMI, intervention patients who were obese at baseline had a higher BMI at 12 months than control obese patients.

For PHQ-9, at 12 months intervention participants had a statistically significant higher mean score, which was no longer significant when adding the mediating variable of number of behavioral health visits. Examining the longitudinal trajectories of PHQ-9 scores over time revealed that the PHQ-9 scores of both intervention and control participants improved over time and that the control participants experienced greater improvements than the intervention participants. This may be due to several factors. Although the groups were balanced on PHQ-9 at baseline, the control group had a slightly higher mean PHQ-9 score, particularly among the Border control group participants. This may have resulted in greater room for improvement among control participants compared to the intervention participants who may have experienced a “floor effect” for improvement. In other words, the intervention group may have had limited opportunity to improve their PHQ-9 score.

As explained above, the PCMU was implemented in the context of the larger *Juntos* effort with minimal pilot testing of PCMU protocols which may have limited the effectiveness of the intervention. The PCMU

was implemented outside of clinic practice in the two clinics where the evaluation study participants received care. The intervention was designed to enhance usual care reminder protocols. It is unclear as to whether the additional reminder calls from the PCMU supported usual care reminders. Also, as discussed previously, the use of two clinic population samples and expanded timeline for enrollment and follow-up may have affected intervention implementation and effectiveness. Furthermore, these findings should be placed in the context of the population that the *Juntos* partnership serves as well as the actual development of the partnership during PCMU implementation. Partners, including the agencies where the evaluation study occurred, expanded services. As described in the Introduction, the *Juntos* partnership serves a three-county area with limited services for basic living conditions, such as water and housing, as well as high poverty rates.

Lessons Learned

This evaluation provides insights into the implementation of a PCMU intervention to encourage compliance with recommended clinic visits among diabetics in an underserved population of Hispanic low-income residents. The PCMU was based on evidence from the Dartmouth Prevention Care Management Model, validated in the scientific literature by Dietrich et al. (2006). TAMIU implemented the PCMU at Gateway, a Federally Qualified Health Center, and Border, a local mental health authority. Intervention participants had a higher number of visits in the Federally Qualified Health Center but not in the local mental health authority. Future research may wish to validate these findings and determine if a PCMU intervention implemented with higher fidelity or other methods will increase treatment compliance, particularly among persons with SPMI. In addition, this model was implemented to increase integration among providers through communication and collaboration as part of a larger effort to enhance care delivery in the region through development of the *Juntos* partnership.

Sustainability

To sustain the network of care that participating Juntos agencies have established, the partners have engaged in a business planning model process.

As the *Juntos* partnership learned about what the PCMU could achieve along with other partnership efforts, the PCMU has been repurposed to facilitate patient connection with participating agencies after being seen at a THCT visit. Patients who were seen at a THCT visit and given appointments at participating agencies will be called to remind them of the upcoming visit.

Evaluation Lessons

While results from this evaluation study are limited, several lessons emerged that could inform other organizations interested in implementing a similar PCMU model. The first is that eligibility criteria be as explicit as possible prior to enrolling participants. The first clinic to enroll participants had met the enrollment target with the initial criteria. Once the criteria were further specified to ensure appropriate analyses could be conducted, a sufficient pool was no longer available at that first clinic to meet the target enrollment. Second, several implementation challenges might not have occurred had PCMU protocols and processes for data submission and participant monitoring from clinic partners been pilot tested prior to full implementation. While not always feasible within timelines and funding constraints, pilot testing these processes could have made implementation much smoother.

Study Limitations and Implications for Future Research

The most significant limitations to this study were the use of populations from two different clinics with protocols that needed pilot testing, the extended participant enrollment and data collection periods, and implementation of an intervention external to the actual clinic practice. The clinic populations differed in terms of behavioral health needs with one population having diagnosed SPMI. Although, the pooled data from the two clinics did result in balanced intervention and control groups and sufficient statistical power, the SPMI sample appeared to have had much greater behavioral health needs that may have affected findings. Adding the second clinic population also extended the timeline for data collection which delayed qualitative implementation data collection and may have increased confusion among interviewees and focus group participants about the purpose of the qualitative data collection. Implementation of the PCMU call center intervention outside of clinic practice did not clearly enhance clinic usual care.

Next Steps

The challenges and limitations faced by the PCMU implementation have been instrumental in guiding the current implementation of the telephone referral follow-up process, interagency appointment scheduling, and documentation across the agencies as related to Prong 3 of the grant. To sustain the network of care that participating Juntos agencies have established, the partners have engaged in a business planning model process.

OTHER ASPECTS OF STUDY LOGISTICS AND FEASIBILITY

Human Subjects Protection

TAMIU received Institutional Review Board approval from TAMIU IRB for a duration of 12 months beginning February 26, 2016. In accordance with TAMIU procedures, TAMIU submitted a Continuing Review/Progress report on January 10, 2017 which was approved on January 17, 2017 for a duration of one year. An additional approval was received for one year on January 8, 2018. and again on December 20, 2018 No deviations in research protocol have occurred to date.

Timeline

Program recruitment and baseline data collection began April 2016 and concluded in September 2017; this program had an 18-month enrollment period and utilized a rolling recruitment. Twelve-month follow up occurred between March 2017 and October 2018. Participant de-identified data was sent quarterly to HRiA (July 2016 – November 2018). An annual report was generated by HRiA and sent to SIF/CNCS in May 2017. This final report is being submitted April 2019.

Evaluator/Subgrantee Role and Involvement

No major changes were made to the evaluator and subgrantee personnel listed in the SIF Evaluation Plan during the project period. The Principal Investigator of record for the study under the IRB protocol is Glenda Walker, PhD, Dean of the School of Nursing, TAMIU.

Budget

The only change made to the SIF Evaluation Plan budget was to increase funding for incentives to accommodate double incentives in November 2016.

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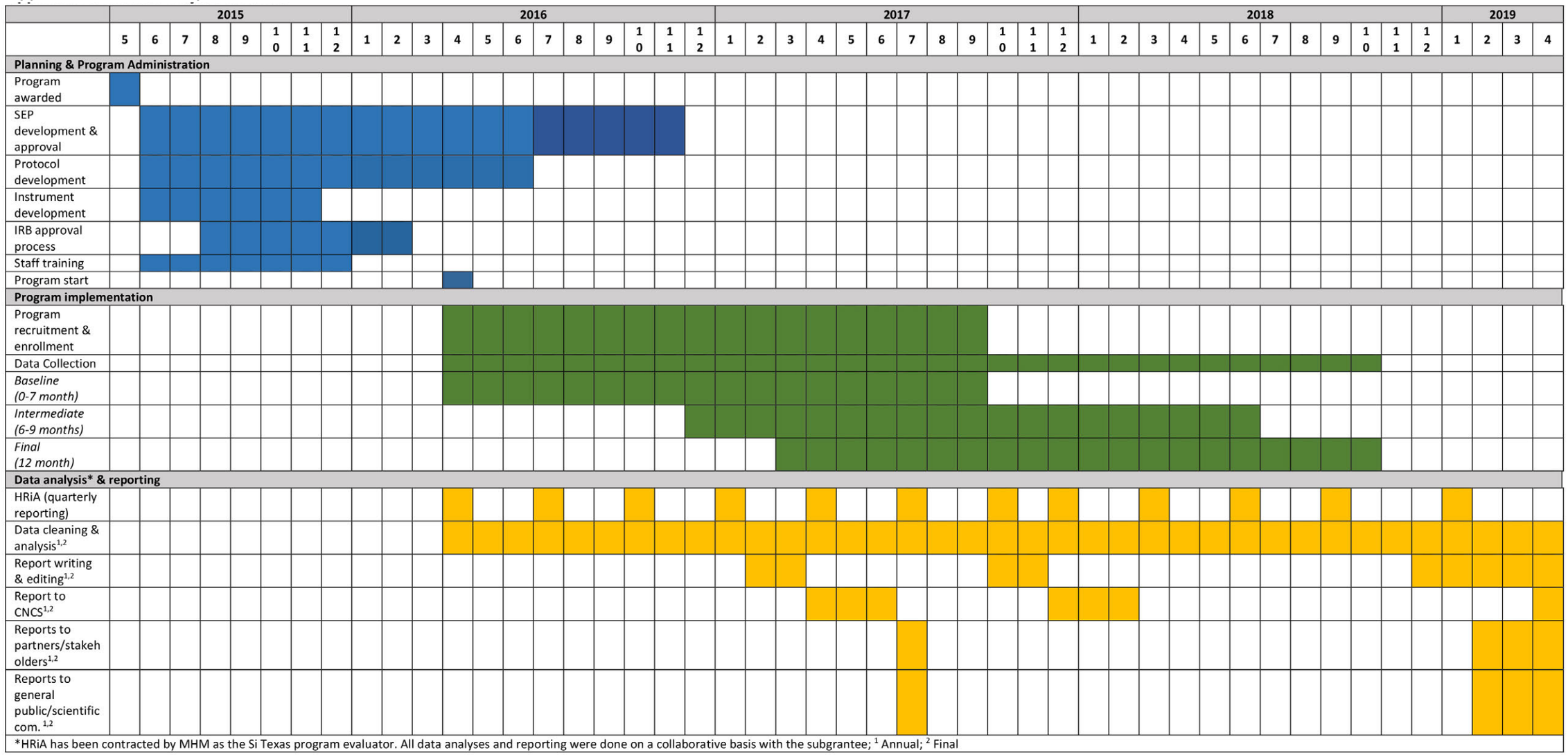
APPENDICES

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Appendix A: Revised Project Timeline



Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Appendix B: Program Logic Model

Inputs	Activities	Outputs	Outcomes		
			Short-term	**Intermediate**	**Long- term**
Program personnel: • *Prevention Care Management Unit (PCMU)* • *TAMIU staff and outreach personnel* • Traveling Health Care Teams (THCT) **Program partners:** • Border Region Behavioral Health Center • City of Laredo Health Department • *Gateway Community Health Center, Inc.* • Serving Children and Adults in Need (SCAN) **Program funders:** Methodist Healthcare Ministries **Other resources:** • Health information system—MS Access database to collect outcome measures	• **Prong 1** ▪ Develop health education protocols ▪ Develop best practice referral protocols ▪ *Develop protocols for determining and tracking patient compliance* ▪ *Develop PCMU call center protocols* • **Prong 2** ▪ Establish traveling health care teams • **Prong 3** ▪ Develop health information system ▪ Provide partners with requested resources • *Recruit 365 participants into each arm of the study*	• Health education protocols developed • Referral protocols developed • *Patient compliance protocols developed* • Patients engaged in health care system and enrolled in study through program partners and THCT • THCT implemented • Health information system developed • Agreements among program partners for use of shared health information system • New resources for partner capacity development	• Implementation and improvement of health education protocols • Implementation and improvement of referral protocols • *Implementation and improvement of patient compliance protocols* • Increased number of patients engaged in health care system • *Increased capacity among program personnel and partners*	• Increased patient understanding of obesity, diabetes, and depression • *Increased patient compliance with treatment plans* • Increased number of patients engaged with program partners • *High patient satisfaction with PCMU* • Increased coordination and referrals among program partners	• *Improved A1c, depression, blood pressure, BMI, and quality of life* • *Reduced morbidity from physical and behavioral health conditions (depression, blood pressure, diabetes, obesity)* • *Improved integration between program partners*

Italicized text indicates the focus for the Sí Texas evaluation.

Appendix C: Sí Texas Mid-Point Implementation Evaluation: Key Informant Interview General Guide

INTERVIEW GOALS
• To collect qualitative information about the implementation of the Sí Texas initiative
• To understand whether the intended target population has been reached at each subgrantee site
• To learn whether what was planned for implementation was actually implemented, and to identify facilitators and barriers of adoption
• To learn what has gone well during the initial phase of the Sí Texas project at the subgrantee level and what needs improvement, and to understand plans for making improvements in the future

INTRODUCTION/INFORMED CONSENT

- Thank you for taking the time out of your day to meet with us. My name is [name] I am a researcher at Health Resources in Action, and today I am joined by my colleague [name] who will assist me during our interview.

- Our goal today is to collect perspectives about the implementation of your Sí Texas project. We hope to learn what has gone well during this initial phase of the project. We are also interested in learning about any challenges that may have been encountered during this period, and your perspectives about what's ahead for the program.

- The interview should last approximately 45 minutes to one hour. I want to remind you that this interview is voluntary and confidential. What we talk about in this space stays in this space so feel free to share your opinion openly and honestly without worrying that it will be repeated. You may choose not to answer any questions during the interview and we can stop at any time. Your interview answers will be summarized in a report along with the interviews from other interview participants.

- I will not identify [name of subgrantee], your name, or your organization's name with your responses in any publication. At the end of the study, we will return to many of our interviewees and ask to re-interview them after the program period has ended. However, participating in this interview does not mean you have to participate in a subsequent interview. The final interview is also voluntary.

- Do you have any questions about the study or how your responses will be used? I would also like to record our session today to make sure our notes are complete and correct, but we will delete the recording after we verify and save our notes. We won't use names in our notes. Are you okay with me recording our discussion?

- As a reminder, when you answer a question, please do not use client's/patient's names. We would appreciate you provide more general examples if you would like to describe a specific situation.

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

INTERVIEW QUESTIONS

1. Key Informant Background
   - What is your current role, and how long have you served in this role? How long have you been with your organization?
   - What are your responsibilities at [subgrantee/organization]?
   - Do you have any responsibilities for running the [name of subgrantee Sí Texas program]? If so, would you tell us about those responsibilities?
   - What was your involvement in the [name of subgrantee Sí Texas program] planning process? What was that process like?

For the remaining questions, the interviewer will select questions to ask based on the person being interviewed and the subgrantee's specific needs/implementation questions. It is recommended that those questions be selected prior to interview.

2. Level of Integrated Behavioral Health
   - What do you understand the goals of the Sí Texas project to be?
   - Prior to the program's implementation, did your program offer both primary care and behavioral health services?
     - What did that look like? To what extent were primary care and behavioral health services connected/coordinated/combined, if at all?
     - [For programs with other integration goals]: To what extent are [services] integrated?
       - Probes: in what way are services integrated? Coordinated? (e.g., IT, workflow)
   - Now that the [name of subgrantee Sí Texas program] has been implemented, to what extent are primary care and behavioral health services connected/coordinated/combined, if at all?
     - How feasible has it been to integrate these services? (If applicable)

3. Program Components and Population
   - How are participants identified for the program? What is/was the enrollment process like?
     - How were participants assigned to the intervention or control group? (For randomized control trials, ask the participant to describe the randomization process.)
     - When a participant enrolls in the program, what happens to them next? Take me through the services and activities that an enrollee receives in the program.
       - Probe: Are warm hand offs between providers a component of the services participants receive? How do those hand offs work? (If applicable)
     - How are behavioral health/health coaches accessed or how do they become involved in patient care?
   - Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention? (Ask those who had a role in planning the program)
   - Since the program started, has anything changed about the services that intervention group participants received or activities they have access to at your clinic? In what way?
   - To what extent/Have any adjustments been made to program operations or offerings based on your early experience implementing the program?
   - How would you describe the population that your program is serving?

- What are they like in terms of demographics generally? Is this the population it intended to serve?

4. Adoption
   - To-date, what have been the most successful parts of the program? Why?
   - To-date, what have been the least successful parts of the program? Why?
   - Please describe any barriers you or your organization has experienced in implementing the program.
     - In what ways did these barriers affect program implementation? In what ways have you been able to address these barriers?
   - Please describe anything that has helped your organization implement the program.
     - Probes: Is the staff, the facilities, the data systems, outside partners, or other things?
   - What kind of training did you develop/participate in as part of the program?
     - Did this training prepare you for your responsibilities in the program? If not, what was missing from the training?
   - What, if any, concerns have program staff raised about the program? How about non-program staff (if relevant)?
     - What has been the response, if any, to those concerns?

5. Control Group Program-Like Components (if applicable)
   - When a participant is randomized/enrolled in the control/comparison group of your program, what can they expect to receive or participate in terms of services or activities?
   - Since the program started, has anything changed about the services that control group participants received or activities they have access to at your clinic? In what way?
     - Have those changes been experienced by the intervention group? If no, why not?

6. Operations (Choose Clinic or Community as appropriate)

Clinic-based Operations

- In what ways have clinic operation workflow changed due to implementation of your project?
- What do you see as the impact of this workflow change, if any?
  - Have these changes had any effects on patient care for those participants <u>not</u> enrolled in the study? In what way?
- To what extent have information/data systems/your EMR been changed to support the program? Have you added any information/data systems for the project?

Community-based Operations

- How, if at all, has your agency operation workflow changed due to implementation of your project?
- What do you see as the impact of this workflow change, if any?
  - How, if at all have these workflow changes affected client care for those participants <u>not</u> enrolled in the study? In what way?
- To what extent have information/data systems been changed to support the community program? Have you added any information/data systems for the project?

7. Patient and Provider Satisfaction

   [Remind respondent not to identify participants by name or to use any identifying information when giving examples]

- What do you think participants in general would say about the program? Would you mind sharing any general themes from feedback you have heard from participants about the program?
- Have you heard any feedback from providers about program implementation? What are some of the general themes from their feedback been?
- To what extent have there been challenges to retaining primary care, behavioral health, or community-based staff during the course of the [name of subgrantee program]? Why do you think there have been challenges, and what has been done to address those challenges?

8. External Partnerships (if applicable)
    - How would you describe your partnership(s) with external organizations related to this program? What role have these partnerships played in early implementation?
    - How has the partnership been helpful in promoting implementation of program activities?
    - To what extent have there been challenges in building and maintaining productive partnerships to-date?
    - Are there any gaps in program activities that were the responsibility or role of a partner? Would you share with me any steps your organization has taken (or will take) to overcome this gap?

9. Sustainability and Lessons Learned
    - If you could go back in time and change anything about getting the program started, what would that change be? Why?
    - What changes, if any, would you want to make at this point in the program?
    - What lesson have you learned to-date from the early experiences of your program that you would want to share with other organizations thinking of implementing your program in their setting?

10. Closing

Thank you so much for your time. That's it for my questions. Is there anything else that you would like to mention that we didn't discuss today?

Appendix D: Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide

Sí Texas Summative Implementation Evaluation:
Key Informant Interview General Guide

CORE INTERVIEW GOALS
• To understand how primary care and behavioral health services are integrated (in various settings) from the perspective of staff (clinic and non-clinic) • To identify perceived facilitators and barriers to adoption of the IBH model, including external factors • To identify program successes, challenges, opportunities for improvement, and lessons learned for sustainability • To better understand the perceived impact of the program on participants' health and wellbeing.

INTRODUCTION/INFORMED CONSENT (2 MIN)

- Hi, my name is [name] and I am a researcher at Health Resources in Action. I am also joined by my colleague [name] who will assist me during our interview. Thank you for taking the time to speak with us today.

- We are speaking with a variety of people to better understand the implementation of [name of subgrantee Sí Texas program]. We are interested in learning what has worked well, challenges that may have been encountered, and any advice or lessons learned that could inform future planning or sustainability of programs like [name of subgrantee Sí Texas program].

- The interview should last approximately [INSERT TIME: 30-60 minutes]. I want to remind you that this interview is voluntary and confidential. What we talk about in this space stays in this space so please feel free to share your opinions openly and honestly. You may choose not to answer any questions during the interview and we can stop at any time. We are conducting several interviews such as this one and will be writing a summary report that pulls out common themes. We will not identify you in our report or any future publication.

- Do you have any questions about the study or how your responses will be used? I would also like to record our session today to make sure our notes are complete and correct, but we will delete the recording after we verify and save our notes. We won't use names in our notes. Are you okay with me recording our discussion?

- As a reminder, when you answer a question, please do not use client's/patient's names. We would appreciate you provide more general examples if you would like to describe a specific situation.

INTERVIEW QUESTIONS

[**NOTE:** IF INTERVIEWEE PARTICIPATED IN MID-POINT DATA COLLECTION, PLEASE FRAME CONVERSATION AS NEEDED TO ACKNOWLEDGE PREVIOUS DISCUSSION (E.G., since we last interviewed you, what additional changes were made to better connect or coordinate services?)]

Key Informant Background (3 MIN)

1. I'd like to start by asking you a few questions about yourself. Can you tell me about your role in [name of subgrantee Sí Texas program]?
    a. How long have you been involved with the [name of subgrantee Sí Texas program]?
        i. Has anything about your role in the project changed since you started working with [name of subgrantee Sí Texas program]?

Integrated Behavioral Health Program Goals and Activities (10-15 MIN)

2. Now I'd like to talk about the program's goals and its specific activities. What do you see as the goals of [name of subgrantee Sí Texas program]? What were you hoping to achieve for participants?
    a. [SUBGRANTEE SPECIFIC PROBES: How about goals or desired outcomes for the wider community—for example, family members or care givers? Operational goals for [name of subgrantee Sí Texas program] (e.g., improving show rates to appointments, reducing wait times, etc.)]?

3. Can you walk me through the program: after a participant enrolled in the intervention group, what services or activities did they receive?
    a. After a participant enrolled in the control/comparison group, what services or activities did they receive?
    b. What changes, if any, were made to the services or activities offered to intervention participants? How about comparison/control group participants? Why?
        i. How did these changes affect the program?

4. Since implementing the [name of subgrantee Sí Texas program], to what extent have primary care and behavioral health services been connected or coordinated? How have these services been connected or coordinated?
    a. How easy or hard has it been to connect or coordinate these services? Why? (If applicable)
        i. What has made services more or less connected or coordinated?
        ii. What changes were made to better connect or coordinate services?
    b. [SUBGRANTEE SPECIFIC PROBE: How are primary care providers involved in patient care? [OR] How are behavioral health providers/health coaches involved in patient care?]
    c. [SUBGRANTEE SPECIFIC PROBE: Do warm handoffs occur between primary care and behavioral health? How do warm hand offs work? Since the program started, have any changes been made to how warm hand offs work?]

Adoption Facilitators and Barriers (15 MIN)

[NOTE TO INTERVIEWER: FOCUS ON FACILITATORS/BARRIERS TO IMPLEMENTATION NOT OUTCOMES]

5. Next I'd like to talk about your experience with implementing the program or putting it into practice. What worked well about putting the program into practice? Why? [PROBE ON ALL: LEADERSHIP, STAFF, COMMUNICATION, DATA SYSTEMS, EMR, PARTNERSHIPS, TRAINING, AND OTHER SUBGRANTEE SPECIFIC AREAS]
    a. What helped you/your organization implement the program?

6. On the flip side, what has not worked well about putting the program into practice? Why? [PROBE ON ALL: LEADERSHIP, STAFF, COMMUNICATION, DATA SYSTEMS, EMR, PARTNERSHIPS, TRAINING, AND OTHER SUBGRANTEE SPECIFIC AREAS]
    a. What barriers or challenges did you/your organization experience in implementing the program? [PROBE ON EXTERNAL FACTORS (e.g., natural disasters, legislation, funding shifts, political events, etc.)]
        i. In what ways have you been able to address these barriers?

7. [IF NOT YET MENTIONED:] Since the start of the [name of subgrantee Sí Texas program], what changes were made to how the program was implemented? Why? [PROBE ON: WORKFLOW, STAFFING, DATA SYSTEMS/EMR, POLICY, OTHER SUBGRANTEE SPECIFIC AREAS]
    a. How did these changes affect the program?

Provider and Patient Satisfaction (5 MIN)

8. [IF NOT YET MENTIONED:] I'm also interested in your perspective on others' experiences with implementing the program. What feedback have you heard from providers or staff about the process of implementing the program?
    a. How satisfied were providers or staff with the program?
    b. [SPECIFIC SUBGRANTEE PROBE: To what extent did providers or staff buy in to the program? How did this affect implementation?]

9. What feedback have you heard from participants about the process of participating in the program?
    a. [SPECIFIC SUBGRANTEE PROBE: How satisfied were participants with the program?]

Program Impact (5 MIN)

10. In your opinion, how effective was the program at achieving its goals?
    a. How do you think the program affected participants' health?
    b. To what extent do you think the program made an impact on participants' health?
        i. What was the program's impact on participant…? [PROBE ON SPECIFIC IMPACT MEASURES (e.g., diabetes, depression, BMI, etc.)]

11. What events or trends did you see as affecting program impact? (e.g., natural disasters, legislation, funding shifts, political events, etc.)

Sustainability and Lessons Learned (10 MIN)

12. Lastly, I'd like to talk about the future of [name of subgrantee Sí Texas program]. As the Sí Texas project draws to a close, what is the plan for [name of subgrantee Sí Texas program]?[PROBE ON PROGRAM CONTINUATION, REPLICATION, SCALING UP]

   a. Moving forward, how does [subgrantee] plan to improve or enhance the integration of primary care and behavioral health services?

13. If you could start over and implement this program from the very beginning, what changes would you make for the program to be more successful? Why? [PROBE ON DATA SYSTEMS, STAFFING, TRAINING, CLINIC SPACE, FUNDING]
    a. If a similar organization were planning to implement your program from the ground up, what advice would you give them?

14. What suggestions/recommendations do you have to help continue/sustain the positive efforts of [name of subgrantee Sí Texas program]? [PROBE ON PROGRAM REPLICATION, SCALING UP, FUNDING, POLICY CHANGE]

Closing (2 MIN)

Thank you so much for your time. That's it for my questions. Is there anything else that you would like to mention that we didn't discuss today?

Appendix E: Sí Texas Summative Implementation Evaluation: Focus Group Guide

Sí Texas Summative Implementation Evaluation:
Participant Focus Group Core Guide
October 11, 2017

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CORE FOCUS GROUP GOALS

- To better understand the perceived impact of the program on participants' health and wellbeing.
- To assess how satisfied participants are with the services they have received (Note: Included in most but not all subgrantee SEPs)
- To identify perceived facilitators and barriers to participating in the program, including external factors
- To identify participant perceptions of program successes, challenges, and opportunities for improvement

INTRODUCTION (5 MIN)

- My name is [name] and this is my colleague [name] and we are from Health Resources in Action an organization working with [subgrantee name] that provides the [name of program/service/study]. Thank you for taking the time to speak with us today.

- We are talking with a variety of people involved in [name of subgrantee program/service/study] to better understand how the [program/services/study] worked. We are interested in hearing about your experience participating in the [program/services/study] and your ideas about how to make [program/services/study] better in the future. I want everyone to know there are no right or wrong answers to our questions. We want to know your opinions, and those opinions might not all be the same. This is fine. Please feel free to share your opinions, both positive and negative. What you share with us today will in no way affect the care you receive.

- I want to remind you that talking with us in this group is voluntary. You can leave anytime or choose not to answer any question we ask. We also want to do everything we can to make sure what we talk about in the group stays private, so we ask that you not share anything you hear today with anyone outside of the group. This is to make sure everyone feels comfortable sharing their opinions. We will definitely not share anything we hear today with anyone outside the group, but we can't be sure that something you say in the group won't be repeated by someone else in the group.

- We are speaking with several different groups such as this one and will be writing up a report of the general ideas we hear across all of the group. No one's name will be used in our summary. When we write our report we will mention that "some people said this" or "other people said that." No one will be able to tell it was you who said something in our report.

- Our conversation will last about an hour and a half. If you have a cell phone, please turn it off or use vibrate mode. If you need to go to the restroom during the conversation, please feel free to leave, but we'd appreciate it if you would go one at a time.

- [IF INCENTIVE IS OFFERED, OTHERWISE OMIT: Each of you will receive a [$amount] gift card for completing today's group conversation. To receive the gift card, you will need to put your initials

on a receipt for our records and we will give you a copy of that receipt. Our copy of the receipt will be kept private.]

- We would also like to record our session today to make sure our notes are complete and correct, but we will delete the recording after we verify and save our notes. We won't use names in our notes. Is everyone okay with me recording our conversation?

- Do you have any questions before we begin our introductions and conversation?

INTRODUCTION AND WARM-UP (5 MIN)

1. First let's spend a little time getting to know one another. Let's go around the table and introduce ourselves. Please tell me: 1) Your first name; 2) how long you've been in the [program/service/study] and 3) something about yourself – such as what you like to do for fun with your family. [AFTER ALL PARTICIPANTS INTRODUCE THEMSELVES, MODERATOR TO ANSWER QUESTIONS]

PROGRAM RECRUITMENT (10 MIN)

2. Let's get started by talking about how you first found out about the [name of subgrantee program/service/study]. Tell me a little bit about how you were introduced to this [program/service/study].
    a. How did you hear about the [program/service/study]?
    b. Who talked to you about it?
    c. How easy or hard was it to understand the information provided to you about the [program/service/study]?

3. Why did you join the [program/service/study]?
    a. What concerns, if any, did you have about joining the program/service/study?

PARTICIPANT EXPERIENCE: INTERVENTION/CONTROL GROUP (20-30 MIN)

4. I'd now like you to think about your experience as a participant of [name of program/service/study]. If you had to describe the [program/service/study] to a neighbor, what would you say? How would you describe the [name of program/service/study]?
    a. In your own words, what is the purpose/goal of the [name of program/service/study]?
    b. Who is the program/service for (e.g., for people who have diabetes or want to lose weight)?
    c. What services did you receive? What activities did you participate in? [ADD SUBGRANTEE SPECIFIC PROBES HERE]
        i. How often?
    d. How was this program/service/study similar or different to health services you received before the program/service/study?

5. What did you think about the program/service/study? On a scale of 1-10 [USE VISUAL SCALE], how would you rate your experience with the program/service/study? Why? [ADD PROBES ON INTERVENTION/CONTROL COMPONENTS HERE (E.G., CLINIC/COMMUNITY SERVICES, REFERALLS, CARE COORDINATION, COMMUNICATION BETWEEN PROVIDERS, ETC.]
    a. What did you <u>like best</u> about the program/service/study? Why?
        i. In what ways has the program/service/study met your needs?

ii. What was helpful to you?

b. What did you <u>like least</u> about the program/service/study?
c. What could have made your experience better?

6. What did you think about the program/clinic staff (e.g., how they treated you, how comfortable you felt around them, etc.)?
7. How easy or hard was it to participate in the program/service/study?
    a. What made it <u>easier</u> to participate in the program/service/study?
        i. What helped you participate in the program/service/study? [PROBE: COST, SCHEDULE, LANGUAGE, TRANSPORTATION, INCENTIVES, ETC.]
    b. What made it <u>harder</u> to participate in the program/service/study? [PROBE: COST, SCHEDULE, LANGUAGE, TRANSPORTATION, POLITICAL EVENTS, HURRICANE HARVEY, ETC.]

PROGRAM VALUE/IMPACT (10-15 MIN)

8. How did participating in [name of program/service/study] affect you/your health?
    a. How about other parts of your life? [PROBE ON: WORK, RELATIONSHIPS WITH FAMILY, STRESS, SLEEP, ETC.]

9. How can the program/service/study be improved?
    a. What else could the program/service/study do to improve participants' health?
    b. What could have improved your experience in the [name of program/service/study]?
    c. What's missing? What kinds of services or activities would you want to see offered by the program/service/study?

10. Thinking about your experience in the [name of program/service/study], would you sign up for the program/service again? Why or why not?
    a. Would you recommend this [name of program/service/study] to someone else? Why or why not?

CLOSING/INCENTIVE DISTRIBUTION (2 MIN)

Thank you so much for your time. That's it for my questions. Is there anything else that you would like to mention that we didn't discuss today?

[OPTIONAL: OMIT THE FOLLOWING SECTION IF INCENTIVES NOT BEING USED:
I want to thank you again for your time. To express our thanks to you, we have [$amount] gift cards from [name of vendor, e.g., H-E-B]. [Name of HRiA staff person] has a receipt for you to initial and then he/she will give you your gift card. [DISTRIBUTE INCENTIVES AND HAVE RECEIPT FORMS SIGNED].]

Thank you again. Your feedback is very helpful, and we greatly appreciate your time and for sharing your opinion.

Appendix F: Implementation Evaluation Measures

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
REACH: Did the PCMU's program reach its intended target population?				
	Demographic characteristics of participants	Eligibility criteria data	• How would you describe the population that your program is serving? • What are they like in terms of demographics generally? • Is this the population it intended to serve?	None
FIDELITY: What are the components of PCMU's program and how do these components work "on the ground" at 6 and 12 months? Are these components different than what was planned? If so, why? To what extent did the TAMIU implement the PCMU model with fidelity?				
What are the resources of the program?	Input: Prevention Care Management Unit (PCMU)	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
What are the resources of the program?	Input: TAMIU nursing students and outreach personnel	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
What are the resources of the program?	Input: Traveling Health Care Teams (THCT)	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
What are the resources of the program?	Input: The Mid Rio Grande Border Area Health Education Center (AHEC)	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Border Region Behavioral Health Center	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: City of Laredo Health Department	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Doctors Hospital of Laredo	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Gateway Community Health Center, Inc.	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Holding Institute Community Center	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: The Human Services Commission – Office of Border Affairs	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Serving Children and Adults in Need (SCAN)	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
What are the resources of the program?	Input: TAMIU Stress Center	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
What are the resources of the program?	Input: Methodist Healthcare Ministries	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Health information system	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
What are the program activities and how have they been operationalized?	Activity: Develop health education protocols	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No, protocol developed
What are the program activities and how have they been operationalized?	Activity: Develop best practice referral protocols	• Number of patients referred to PCMU • Referrals to behavioral health services	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No, protocol developed
What are the program activities and how have they been operationalized?	Activity: Develop protocols for determining and tracking patient compliance	• Show compliance rate for primary care services	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No, protocol developed

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
What are the program activities and how have they been operationalized?	Activity: Establish traveling health care teams	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No, team established
What are the program activities and how have they been operationalized?	Activity: Develop health information system	--	• To what extent have information/data systems/your EMR been changed to support the program? • Have you added any information/data systems for the project?	Yes/No, health system developed
What are the program activities and how have they been operationalized?	Activity: Provide partners with requested resources	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No, what kind and how many resources provided to whom

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
What are the program activities and how have they been operationalized?	Activity: Recruit 365 participants into each arm of the study	• Number of target participants • Number of patients screened for participation in the study • Compliant • Non-compliant • Number of patients consented to participate in the study • Number of patients who choose not to participate in the study • Number of patients randomized into the study – intervention and control groups • Number non-compliant at enrollment • Number compliant at enrollment	--	None

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
Are the components different than what was planned? If so, why?	Output: Health education protocols developed	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
Are the components different than what was planned? If so, why?	Output: Referral protocols developed	• Number of patients referred to PCMU • Referrals to behavioral health services	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
Are the components different than what was planned? If so, why?	Output: Patient compliance protocols developed	• Show compliance rate for primary care services	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
Are the components different than what was planned? If so, why?	Output: Patients engaged in health care system and enrolled in study through program partners and THCT	• Show compliance rate for primary care services • Show rate for behavioral health services	When a participant enrolls in the program, what happens to them next? Take me through the services and activities that an enrollee receives in the program.	Patient satisfaction survey
Are the components different than what was planned? If so, why?	Output: THCT implemented	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
Are the components different than what was planned? If so, why?	Output: Health information system developed	--	• To what extent have information/data systems/your EMR been changed to support the program? • Have you added any information/data systems for the project?	Yes/No
Are the components different than what was planned? If so, why?	Output: Agreements among program partners for use of shared health information system	--	How would you describe your partnership(s) with external organizations related to this program? What role have these partnerships played in early implementation?	Documentation of agreements
Are the components different than what was planned? If so, why?	Output: New resources for partner capacity development	--	How would you describe your partnership(s) with external organizations related to this program? What role have these partnerships played in early implementation?	Yes/No, what kind, how many resources, provided to whom
INTEGRATION: What level of Integrated Behavioral Health did PCMU achieve as a result of implementing the program?				
What level of Integrated Behavioral Health did HFHC achieve as a result of implementing the program?	IBH Level	Score (measured by IBH Checklist)	--	None

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
To what extent have providers and program staff adopted the components of HFHC's program at 6 and 12 months?	--	--	• Now that the program has been implemented, to what extent are primary care and behavioral health services connected, coordinated, combined, if at all?	Staff satisfaction/knowledge survey
What are the facilitators and barriers to adoption?	--	--	• Please describe any barriers you or your organization has experienced in implementing the program. • In what ways did these barriers affect program implementation? In what ways have you been able to address these barriers? • Please describe anything that has helped your organization implement the program. • Probes: Is the staff, the facilities, the data systems, outside partners, or other things?	Staff/Administration satisfaction surveys
To what extend do providers buy-in to the program, and how has that buy-in affected implementation?	--	--	• Have you heard any feedback from providers about program implementation? • What are some of the general themes from their feedback been?	Staff satisfaction surveys

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
To what extent did the comparison groups receive program-like components?				
--	--	• Number of control group patients that received PCMU services or other program-like components	• When a participant is randomized/enrolled in the control/comparison group of your program, what can they expect to receive or participate in terms of services or activities? • Since the program started, has anything changed about the services that control group participants received or activities they have access to at your clinic? In what way? • What do you see as the impact of this workflow change, if any? • Have these changes had any effects on patient care for those participants not enrolled in the study? In what way?	None

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
How satisfied are PCMU patients with the services they have received? How satisfied are providers with the PCMU program?				
--	--	--	• What do you think participants in general would say about the program? Would you mind sharing any general themes from feedback you have heard from participants about the program? • Have you heard any feedback from providers about program implementation? What are some of the general themes from their feedback been? • To what extent have there been challenges to retaining primary care, behavioral health, or community-based staff during the course of the [name of subgrantee program]? Why do you think there have been challenges, and what has been done to address those challenges?	Provider and participant satisfaction surveys

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
Are patients who participate in the PCMU intervention more compliant with treatment plans when compared to patients that do not participate in the intervention?				
--	--	• Number of intervention patients that received follow-up phone calls for compliance • Number of intervention patients in compliance after receiving phone calls • Number of intervention patients that received a follow-up home visit for compliance • Number of intervention patients in compliance after receiving home visit • Show compliance rate for primary care services	--	None

Sí Texas Subgrantee: TAMIU
Program Title: Juntos for Better Health

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
To what extent has the partnership played a role in the implementation of the Juntos for Better Health program?				
--	--	--	• How would you describe your partnership(s) with external organizations related to this program? What role have these partnerships played in early implementation? • How has the partnership been helpful in promoting implementation of program activities? • To what extent have there been challenges in building and maintaining productive partnerships to-date? • Are there any gaps in program activities that were the responsibility or role of a partner? Would you share with me any steps your organization has taken (or will take) to overcome this gap?	None

Appendix G: PCMU Evaluation Enrollment Log

Date	Clinic	Event	Procedures/Explanation
April 14, 2016	Gateway	Enrollment initiated	24 mo record review to identify non-compliant patients, patients invited to information session to learn about study and provide baseline assessments
December 15,2016	Gateway	Enrollment paused	Gateway reached enrollment target with participants who were diagnosed as diabetic (participants not verified for baseline A1c > 6.5%)
March 7, 2017	Gateway	Enrollment re-opened	Enrollment re-opened due to 116 not meeting threshold for baseline A1c, 129 not providing blood draw for A1c in 30 days, and 20 in both categories. Total not meeting eligibility criterion n = 262 Potential additional participants identified through 1. Review of Gateway records to identify additional non- compliant patients using 24 mo window 2. Re-enroll participants who did not have validated blood draw within 30 days of initial enrollment (comparison first, intervention participants if they had not received any PCMU contacts). 3. Offer participation to all diabetics with a next day appointment and verify eligibility through baseline measures 4. Contact all diabetic patients for enrollment into study at patient convenience
April 2017	Gateway	2nd Intervention Enrollment	MHM funded Lado a Lado also enrolling patients. Similar intervention with higher incentives. Less than 10 Gateway participants switched from Sí Texas to Lado a Lado.
April 25, 2017	Border	Enrollment Initiated	Due to insufficient target participants available at Gateway, TAMIU and Border start enrolling patients at Border. All eligibility criteria verified at baseline data collection. 1. Newly enrolled patients 2. Any participant with data collected up to 30 days prior to April 25, 2017 was approached for consent to study enrollment. Last data collected became the baseline assessment for consented participants.
April 28, 2017	Gateway	Enrollment Ends	TAMIU, MHM, and HRiA agreed that additional enrollment efforts at Gateway would not be beneficial.
October 2017	Border	Enrollment Ends	Enrollment target reached.

Appendix H: PCMU Implementation Challenges Summary

PCMU IMPLEMENTATION SUMMARY

TEXAS A&M INTERNATIONAL UNIVERSITY
SÍ TEXAS | JUNTOS FOR BETTER HEALTH

October 10th 2017

In April 2016, Texas A&M International University (TAMIU) began recruiting patients at Gateway Community Health Center (Gateway CHC) for the Si Texas – Juntos for Better Health randomized control trial that is being evaluated by Health Resources in Action (HRiA) on behalf of Methodist Healthcare Ministries of South Texas (MHM). TAMIU's objective was to recruit a sample of 730 patients that met qualifying criteria which included an historical record of missed appointments at the clinic. Enrolled patients that were randomly assigned to the intervention group were to begin receiving reminder phone calls from the Prevention Care Management Unit (PCMU) about upcoming appointments at the clinic. Reminder phone calls would be made as much as three weeks in advance to provide patients with three weekly reminders about their upcoming appointment and to provide patients with the opportunity to reflect and discuss barriers to keeping their appointments. Patient's that failed to show for their appointment after having been successfully contacted by the PCMU would be offered a home visit to discuss the reason and barriers that lead to missing their last appointment in anticipation of a newly rescheduled appointment.

To accomplish this, multiple elements needed to be developed, implemented, and refined to achieve a system for carrying out the PCMU intervention. First, TAMIU created the PCMU call center by leveraging an existing Computer Assisted Telephone Interview (CATI) lab as the hub of PCMU call activity and translating PCMU materials into a format conducive to scripted telephone interviewing and digital data collection. Between April and June 2016, TAMIU finalized the composition of the PCMU call team with dedicated Special Program Aides. Special Program Aides were hired by TAMIU and assigned to the PCMU for consistency and continuity of care that logistically could not be coordinated for the Canseco School of Nursing undergraduate students. The PCMU data collection documents were developed into a reminder script and home visit script, translated to Spanish, and approved by the Institutional Review Board.

In addition to collecting data from enrollees, in July 2016 Gateway CHC began manually compiling upcoming and outcome appointment reports for patients enrolled in the intervention group and control group. Compiling these reports for the PCMU activity continued to be a manual process for Gateway CHC staff until February of 2017. The limitations of a manual process slowed the turnaround time of appointment reports to the degree that carrying out the PCMU intervention as originally intended was not possible. During this time TAMIU also faced staffing issues leading to the prioritization of the phone component of the PCMU intervention over the home visit component.

In February of 2017, together TAMIU and Gateway CHC identified and implemented an appointment reporting mechanism that utilized the clinic's internal reporting software to auto generate a list of upcoming appointments and their outcome. TAMIU developed an MS Access database that would import appointment information in CSV format delivered weekly by Gateway CHC. To date TAMIU and Gateway CHC have worked together to improve the data management of PCMU related activity to ensure the completeness and accuracy of appointment information. This serves to avoid providing outdated appointment information to the intervention group via the PCMU and to enable the intervention to be implemented as intended.

The following steps have been taken to improve the fidelity of the PCMU intervention. Gateway CHC and Border Region staff have been trained and instructed on the timeline and process for extracting upcoming appointments and appointment outcome data from the agency's reporting system. TAMIU's appointment database has been simplified and arranged to allow faster linkage of appointment outcomes and PCMU call activity to facilitate the timely coordination of home visits. Additional staff have been trained in organizing PCMU data at TAMIU. TAMIU's Integrated Behavioral Health coordinator has been assigned to carry out home visits for the remainder of the PCMU activity. TAMIU's Compliance Officer will conduct regular reviews of the PCMU implementation, provide feedback, and request corrective action(s) as deemed necessary.

TAMIU, Gateway CHC, and Border Region continue working together to carry out the PCMU intervention as an example of interagency outreach, to generate evidence, and to serve the community.

Appendix I: ADA Guidelines

2016 American Diabetes Association (ADA) Diabetes Guidelines
Summary Recommendations from NDEI

Source: American Diabetes Association. Standards of medical care in diabetes—2016. *Diabetes Care*. 2016;39(suppl 1):S1-S106. Available here.

Refer to source document for full recommendations, including level of evidence rating.

1. Diabetes Diagnosis

Criteria for Diabetes Diagnosis: 4 options
FPG ≥126 mg/dL (7.0 mmol/L)* Fasting is defined as no caloric intake for ≥8 hours
2-hr PG ≥200 mg/dL (11.1 mmol/L) during OGTT (75-g)* Using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water
A1C ≥6.5% (48 mmol/mol)* Performed in a lab using NGSP-certified method and standardized to DCCT assay
Random PG ≥200 mg/dL (11.1 mmol/L) In individuals with symptoms of hyperglycemia or hyperglycemic crisis
***In the absence of unequivocal hyperglycemia results should be confirmed using repeat testing**
• **No clear clinical diagnosis? Immediately repeat the same test using a new blood sample.** • **Same test with same or similar results? Diagnosis confirmed.** • **Different tests above diagnostic threshold? Diagnosis confirmed.** • **Discordant results from two separate tests? Repeat the test with a result above diagnostic cut-point.**

Testing for Type 2 Diabetes and Prediabetes in Asymptomatic Adults

Type 2 diabetes screening should be performed in adults of any age who are overweight or obese, and who have one or more diabetes risk factor (*See Diabetes Risk Factors*)

- Testing should begin at age 45
- If test is normal? Repeat it at least every 3 years (*See Diabetes Risk Factors*):

Screening for prediabetes can be done using A1C, FPG, or 2-hr PG after 75-g OGTT criteria

- CVD risk factors should be identified and treated
- Testing may be considered in children and adolescents who are overweight or obese and have two or more risk factors for diabetes (*See Diabetes Risk Factors*)

Type 2 Diabetes Risk Factors

- Physical inactivity
- First-degree relative with diabetes
- High-risk race/ethnicity
- Women who delivered a baby >9 lb or were diagnosed with GDM
- HDL-C <35 mg/dL ± TG >250 mg/dL
- Hypertension (≥140/90 mm Hg or on therapy)
- A1C ≥5.7%, IGT, or IFG on previous testing
- Conditions associated with insulin resistance: severe obesity, acanthosis nigricans, PCOS
- History of CVD

Appendix J: Patient-Centered Integrated Behavioral Health Care Checklist

Patient-Centered Integrated Behavioral Health Care Principles & Tasks

AIMS CENTER
Advancing Integrated Mental Health Solutions

About This Tool

This checklist was developed in consultation with a group of national experts (http://bit.ly/IMHC-experts) in integrated behavioral health care with support from The John A. Hartford Foundation, The Robert Wood Johnson Foundation, Agency for Healthcare Research and Quality, and California HealthCare Foundation. For more information, visit: http://bit.ly/IMHC_principles.

The core principles of effective integrated behavioral health care include a patient-centered care team providing evidence-based treatments for a defined population of patients using a measurement-based treat-to–target approach.

Principles of Care	We apply this principle in the care of ... of our patients: None	Some	Most/All
1. Patient-Centered Care			
Primary care and behavioral health providers collaborate effectively using shared care plans.	☐	☐	☐
2. Population-Based Care			
Care team shares a defined group of patients tracked in a registry. Practices track and reach out to patients who are not improving and mental health specialists provide caseload-focused consultation, not just ad-hoc advice.	☐	☐	☐
3. Measurement-Based Treatment to Target			
Each patient's treatment plan clearly articulates personal goals and clinical outcomes that are routinely measured. Treatments are adjusted if patients are not improving as expected.	☐	☐	☐
4. Evidence-Based Care			
Patients are offered treatments for which there is credible research evidence to support their efficacy in treating the target condition.	☐	☐	☐
5. Accountable Care			
Providers are accountable and reimbursed for quality care and outcomes.	☐	☐	☐

Page 2

Core components and tasks are shared by effective integrated behavioral health care programs. The AIMS Center Integrated Care Team Building Tool (http://bit.ly/IMHC-teambuildingtool) can help organizations build clinical workflows that incorporate these core components and tasks into their unique setting.

Core Components & Tasks	None	Some	Most/All
	of our patients receive this service		
1. Patient Identification and Diagnosis			
Screen for behavioral health problems using valid instruments	☐	☐	☐
Diagnose behavioral health problems and related conditions	☐	☐	☐
Use valid measurement tools to assess and document baseline symptom severity	☐	☐	☐
2. Engagement in Integrated Care Program			
Introduce collaborative care team and engage patient in integrated care program	☐	☐	☐
Initiate patient tracking in population-based registry	☐	☐	☐
3. Evidence-Based Treatment			
Develop and regularly update a biopsychosocial treatment plan	☐	☐	☐
Provide patient and family education about symptoms, treatments, and self management	☐	☐	☐
Provide evidence-based counseling (e.g., Motivational Interviewing, Behavioral Activation)	☐	☐	☐
Provide evidence-based psychotherapy (e.g., Problem Solving Treatment, Cognitive Behavior Therapy, Interpersonal Therapy)	☐	☐	☐
Prescribe and manage psychotropic medications as clinically indicated	☐	☐	☐
Change or adjust treatments if patients do not meet treatment targets	☐	☐	
4. Systematic Follow-up, Treatment Adjustment, and Relapse Prevention			
Use population-based registry to systematically follow all patients	☐	☐	☐
Proactively reach out to patients who do not follow-up	☐	☐	☐
Monitor treatment response at each contact with valid outcome measures	☐	☐	☐
Monitor treatment side effects and complications	☐	☐	☐
Identify patients who are not improving to target them for psychiatric consultation and	☐	☐	☐
Create and support relapse prevention plan when patients are substantially improved	☐	☐	
5. Communication and Care Coordination			
Coordinate and facilitate effective communication among providers	☐	☐	☐
Engage and support family and significant others as clinically appropriate	☐	☐	☐
Facilitate and track referrals to specialty care, social services, and community-based resources	☐	☐	☐
6. Systematic Psychiatric Case Review and Consultation			
Conduct regular (e.g., weekly) psychiatric caseload review on patients who are not improving	☐	☐	☐
Provide specific recommendations for additional diagnostic work-up, treatment changes, or	☐	☐	☐
Provide psychiatric assessments for challenging patients in-person or via telemedicine	☐	☐	☐
7. Program Oversight and Quality Improvement			
Provide administrative support and supervision for program	☐	☐	
Provide clinical support and supervision for program	☐	☐	
Routinely examine provider- and program-level outcomes (e.g., clinical outcomes, quality of care, patient satisfaction) and use this information for quality improvement	☐	☐	

Appendix K: Patient Health Questionnaire – 9 (PHQ-9)

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 +_____+_____+ _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all D | Somewhat difficult D | Very difficult D | Extremely difficult D

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

Appendix L: Duke Health Profile

FORM A: FOR SELF-ADMINISTRATION BY THE RESPONDENT (revised 4-2000)

DUKE HEALTH PROFILE (The DUKE)

Date Today:_____ Name: _____ ID Number:_____
Date of Birth:_____ Female____ Male____

INSTRUCTIONS: Here are some questions about your health and feelings. Please read each question carefully and check (√) your best answer. You should answer the questions in your own way. There are no right or wrong answers. (Please ignore the small scoring numbers next to each blank.)

		Yes, describes me exactly	Somewhat describes me	No, doesn't describe me at all
1.	I like who I am	12	11	10
2.	I am not an easy person to get along with	20	21	22
3.	I am basically a healthy person	32	31	30
4.	I give up too easily	40	41	42
5.	I have difficulty concentrating	50	51	52
6.	I am happy with my family relationships	62	61	60
7.	I am comfortable being around people	72	71	70

TODAY would you have any physical trouble or difficulty:

		None	Some	A Lot
8.	Walking up a flight of stairs	82	81	80
9.	Running the length of a football field	92	91	90

DURING THE PAST WEEK: How much trouble have you had with:

		None	Some	A Lot
10.	Sleeping	102	101	100
11.	Hurting or aching in any part of your body	112	111	110
12.	Getting tired easily	122	121	120
13.	Feeling depressed or sad	132	131	130
14.	Nervousness	142	141	140

DURING THE PAST WEEK: How often did you:

		None	Some	A Lot
15.	Socialize with other people (talk or visit with friends or relatives)	150	151	152
16.	Take part in social, religious, or recreation activities (meetings, church, movies, sports, parties)	160	161	162

DURING THE PAST WEEK: How often did you:

		None	1-4 Days	5-7 Days
17.	Stay in your home, a nursing home, or hospital because of sickness, injury, or other health problem.	172	171	170

MANUAL SCORING FOR THE DUKE HEALTH PROFILE

Item	Raw Score*
8 =	_____
9 =	_____
10 =	_____
11 =	_____
12 =	_____
Sum =	_____ x 10 =

PHYSICAL HEALTH SCORE ☐

Item	Raw Score*
1 =	_____
4 =	_____
5 =	_____
13 =	_____
14 =	_____
Sum =	_____ x 10 =

MENTAL HEALTH SCORE ☐

Item	Raw Score*
2 =	_____
6 =	_____
7 =	_____
15 =	_____
16 =	_____
Sum =	_____ x 10 =

SOCIAL HEALTH SCORE ☐

GENERAL HEALTH SCORE

Physical Health score = _____
Mental Health score = _____
Social Health score = _____
Sum = _____ ÷ 3 = ☐

PERCEIVED HEALTH SCORE

Item	Raw Score*
3 =	_____ x 50 =

☐

Item	Raw Score*
1 =	_____
2 =	_____
4 =	_____
6 =	_____
7 =	_____
Sum =	_____ x 10 =

SELF-ESTEEM SCORE ☐

To calculate the scores in this column the raw scores must be revised as follows:
If 0, change to 2; if 2, change to 0; if 1, no change.

Item	Raw Score*	Revised
2 =	_____	_____
5 =	_____	_____
7 =	_____	_____
10 =	_____	_____
12 =	_____	_____
14 =	_____	_____
	Sum =	_____ x 8.333 =

ANXIETY SCORE ☐

Item	Raw Score*	Revised
4 =	_____	_____
5 =	_____	_____
10 =	_____	_____
12 =	_____	_____
13 =	_____	_____
	Sum =	_____ x 10 =

DEPRESSION SCORE ☐

Item	Raw Score*	Revised
4 =	_____	_____
5 =	_____	_____
7 =	_____	_____
10 =	_____	_____
12 =	_____	_____
13 =	_____	_____
14 =	_____	_____
	Sum =	_____ x 7.143 =

ANXIETY-DEPRESSION (DUKE-AD) SCORE ☐

PAIN SCORE

Item	Raw Score*	Revised
11 =	_____	_____ x 50 =

☐

DISABILITY SCORE

Item	Raw Score*	Revised
17 =	_____	_____ x 50 =

☐

* Raw Score = last digit of the numeral adjacent to the blank checked by the respondent for each item. For example, if the second blank is checked for item 10 (blank numeral = 101), then the raw score is "1", because 1 is the last digit of 101.

Final Score is calculated from the raw scores as shown and entered into the box for each scale. For physical health, mental health, social health, general health, self-esteem, and perceived health, 100 indicates the best health status, and 0 indicates the worst health status. For anxiety, depression, anxiety-depression, pain, and disability, 100 indicates the worst health status and 0 indicates the best health status.

Missing Values: If one or more responses is missing within one of the eleven scales, a score cannot be calculated for that particular scale.

SPANISH (UNITED STATES) FORMULARIO A: PARA AUTO-ADMINISTRACIÓN POR LA PERSONA QUE RESPONDE (revisado 4-2000)

PERFIL DE SALUD DE DUKE (El Duke)

Fecha de hoy:_____ Nombre: _____Número de identificación: _____

Fecha de nacimiento: _____ Sexo: Femenino ☐ Masculino ☐

INSTRUCCIONES: Estas son algunas preguntas sobre su salud y sus sentimientos. Por favor, lea cada pregunta cuidadosamente y marque (✓) la respuesta más apropiada para usted. Usted debe contestar las preguntas a su manera. No hay respuestas correctas ni incorrectas. (Por favor, ignore los pequeños números al lado de cada línea).

	Sí, me Describe exactamente	Me describe más o menos	No, no me describe de ninguna manera
1. Me gusta quien soy	12	11	10
2. No me llevo bien con otros fácilmente	20	21	22
3. Soy básicamente una persona saludable	32	31	30
4. Me doy por vencido(a) muy fácilmente	40	41	42
5. Tengo dificultad en concentrarme	50	51	52
6. Yo estoy contento(a) con mis relaciones familiares	62	61	60
7. Me siento cómodo(a) alrededor de otras personas	72	71	70

¿Tendría HOY alguna dificultad o problema físico:	Ninguna	Alguna	Mucha
8. Al subir un tramo de escaleras?	82	81	80
9. Al correr la distancia de un campo de fútbol americano (100 yardas / 91 metros)?	92	91	90

DURANTE LA ÚLTIMA SEMANA: ¿Cuánta dificultad ha tenido con:	Ninguna	Alguna	Mucha
10. Dormir?	102	101	100
11. Dolor en alguna parte de su cuerpo?	112	111	110
12. Cansarse fácilmente?	122	121	120
13. Sentirse deprimido(a) o triste?	132	131	130
14. Nerviosismo?	142	141	140

DURANTE LA ÚLTIMA SEMANA: ¿Con qué frecuencia:	No, en absoluto	A veces	Muchas veces
15. Pasó tiempo con otras personas (por ejemplo, hablar o visitar con amigos o parientes)?	150	151	152
16. Participó en actividades sociales, religiosas, o recreativas (por ejemplo, reuniones, iglesia, cine, deportes, fiestas)?	160	161	162

DURANTE LA ÚLTIMA SEMANA: ¿Con qué frecuencia:	No, en absoluto	1-4 días	5-7 días
17. Se quedó en su casa, en la casa de ancianos, o en el hospital debido a enfermedad, lesión, o cualquier otro problema de salud?	172	171	170

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Appendix M: Loss to Follow-Up / Attrition Table

Table 49. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Demographic Characteristics among the Intervention and Control

Measure	Full Sample (n=733)		Completed Study (n=561)		Did Not Complete Study (n=172)		p-value
	N	%	N	%	N	%	
Sex							
Male	223	30.5	161	28.8	62	36.1	0.07
Female	509	69.5	399	71.3	110	64.0	
Missing	*1*	--	*1*	--	*0*		
Ethnicity							
Hispanic/Latino	712	97.9	546	98.0	166	97.7	0.76
Non-Hispanic/Non-Latino	15	2.1	11	2.0	4	2.4	
Missing	*6*	--	*4*	--	*2*	--	
Age							
≤ 34	29	4.0	22	3.9	7	4.1	0.21
35-44	107	14.6	88	15.7	19	11.1	
45-54	214	29.2	159	28.3	55	32.0	
55-64	249	34.0	197	35.1	52	30.2	
65+	134	18.3	95	16.9	39	22.7	
Mean (SD)	54.5 (11.0)		54.3 (10.9)		54.9 (11.5)		0.53
Education							
Less than high school	419	58.0	323	58.7	96	55.8	0.50
High school or more	303	42.0	227	41.3	76	44.2	
Missing	*11*	--	*11*	--	*0*	--	
Primary Language							
English	130	17.7	86	15.3	44	25.6	**<0.001**
Spanish	553	75.4	442	78.8	111	64.5	
Other	50	6.8	33	5.9	17	9.9	

Table 50. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Demographic Characteristics among the Intervention

Measure	Full Intervention Group (n=366)		Completed Study (n=275)		Did Not Complete Study (n=91)		p-value
	N	%	N	%	N	%	
Sex							
Male	112	30.6	83	30.2	29	31.9	0.76
Female	254	69.4	192	69.8	62	68.1	
Missing	--	--					
Ethnicity							
Hispanic/Latino	356	97.5	269	97.8	87	96.7	0.70
Non-Hispanic/Non-Latino	9	2.5	6	2.2	3	3.3	
Missing	*1*	--	*0*	--	*1*	--	
Age							
≤ 34	11	3.0	8	2.9	3	3.3	0.15
35-44	53	14.5	44	16.0	9	9.9	
45-54	112	30.6	76	27.6	36	39.6	
55-64	120	32.8	96	34.9	24	26.4	
65+	70	19.1	51	18.6	19	20.9	
Mean (SD)	54.9 (10.8)		54.9 (10.6)		54.8 (11.6)		0.96
Education							
Less than high school	211	58.8	160	59.7	51	56.0	0.54
High school or more	148	41.2	108	40.3	40	44.0	
Missing	*7*	--	*7*	--	*0*	--	
Primary Language							
English	63	17.2	36	13.1	27	29.7	**<0.001**
Spanish	270	73.8	218	79.3	52	57.1	
Other	33	9.0	21	7.6	12	13.2	

Table 51. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Demographic Characteristics among the Control

Measure	Full Control Group (n=367)		Completed Study (n=286)		Did Not Complete Study (n=81)		p-value
	N	%	N	%	N	%	
Sex							
Male	111	30.3	78	27.4	33	40.7	**0.02**
Female	255	69.7	207	72.6	48	59.3	
Missing	*1*	--	*1*	--	*0*	--	
Ethnicity							
Hispanic/Latino	356	98.3	277	98.2	79	98.8	0.99
Non-Hispanic/Non-Latino	6	1.7	5	1.8	1	1.3	
Missing	*5*	--	*4*	--	*1*	--	
Age							
≤ 34	18	4.9	14	4.9	4	4.9	0.37
35-44	54	14.7	44	15.4	10	12.4	
45-54	102	27.8	83	29.0	19	23.5	
55-64	129	35.2	101	35.3	28	34.6	
65+	64	17.4	44	15.4	20	24.7	
Mean (SD)	54.1 (11.2)		53.8 (11.2)		55.0 (11.4)		0.37
Education							
Less than high school	208	57.3	163	57.8	45	55.6	0.72
High school or more	155	42.7	119	42.2	36	44.4	
Missing	*4*	--	*4*	--	*0*	--	
Primary Language							
English	67	18.3	50	17.5	17	21.0	0.55
Spanish	283	77.1	224	78.3	59	72.8	
Other	17	4.6	12	4.2	5	6.2	

Table 52. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Health Impact Measures among the Intervention and Control

	Full Sample (n=733) Mean (SD)	Completed Study (n=561) Mean (SD)	Did Not Complete Study (n=172) Mean (SD)	p-value
BMI[b]	32.8 (6.8)	32.7 (6.7)	32.8 (7.0)	0.99
Systolic	134.3 (19.4)	134.1 (19.5)	135.0 (19.1)	0.63
Diastolic	78.3 (10.9)	77.9 (10.7)	79.3 (11.6)	0.15
Nonparametric Tests[a]	Median (IQR)	Median (IQR)	Median (IQR)	p-value
HbA1c	8.1 (2.6)	8.1 (2.6)	8.6 (2.8)	0.16
PHQ-9	4.0 (8.0)	4.0 (7.0)	6.0 (9.0)	**0.003**
General Health	73.3 (30.0)	73.3 (23.3)	66.7 (43.3)	**0.002**

Note: Bold denotes statistical significance (p value < 0.05); [a] The Wilcoxon rank sum test was used to examine non-normally distributed data [b] A log transformation was used

Table 53. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Health Impact Measures among the Intervention

	Full Intervention Group (n=366) Mean (SD)	Completed Study (n=275) Mean (SD)	Did Not Complete Study (n=91) Mean (SD)	p-value
BMI[b]	33.1 (7.3)	32.9 (7.2)	33.9 (7.5)	0.24
Systolic	134.6 (19.7)	134.5 (19.6)	135.1 (20.1)	0.81
Diastolic	78.8 (11.0)	78.4 (10.8)	79.8 (11.8)	0.30
Nonparametric Tests[a]	Median (IQR)	Median (IQR)	Median (IQR)	p-value
HbA1c	8.2 (2.6)	8.1 (2.6)	8.5 (2.8)	0.36
PHQ-9	4.0 (8.0)	3.0 (6.0)	6.0 (10.0)	**0.001**
General Health	73.3 (26.7)	76.7 (23.3)	66.7 (43.3)	**0.01**

Note: Bold denotes statistical significance (p value < 0.05); [a] The Wilcoxon rank sum test was used to examine non-normally distributed data [b] A log transformation was used

Table 54. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Health Impact Measures among the Control

	Full Control Group (n=367) Mean (SD)	Completed Study (n=286) Mean (SD)	Did Not Complete Study (n=81) Mean (SD)	p-value
BMI[b]	32.3 (6.3)	32.6 (6.2)	31.6 (6.3)	0.15
Systolic	134.0 (19.1)	133.8 (19.4)	134.8 (18.1)	0.66
Diastolic	77.7 (10.7)	77.4 (10.5)	78.7 (11.5)	0.36
Nonparametric Tests[a]	Median (IQR)	Median (IQR)	Median (IQR)	p-value
HbA1c	8.1 (2.5	8.0 (2.5)	8.7 (2.3)	0.27
PHQ-9	4.5 (7.0)	4.0 (6.0)	5.5 (9.5)	0.35
General Health	70.0 (30.0)	73.3 (33.3)	66.7 (36.7)	0.07

Note: Bold denotes statistical significance (p value < 0.05); [a] The Wilcoxon rank sum test was used to examine non-normally distributed data [b] A log transformation was used

Appendix N: Expanding Capacity Summary

Expanding Capacity / Expanding Services Summary

As part of prong 3 of the Juntos for Better Health grant activity, TAMIU worked closely with Gateway Community Health Center (GCHC), Border Region Behavioral Health Center (BRBHC), City of Laredo Health Department (CLHD), and Serving Children and Adults in Need (SCAN) to enhance each agency's capacity to expand existing lines of service or create new lines of service. The following is a list of providers that were funded by the project for the purpose of fulfilling the goals of prong 3.

GCHC

Physician's Assistant – Expanded the clinic's capacity for primary care services five days a week.
Family Nurse Practitioner - Expanded the clinic's capacity for primary care services two days a week.
Nutritionist – Expanded the clinic's capacity for one-to-one nutrition counseling and class sessions five days a week.

BRBHC

Rehab Workers – Added new lines of service in one-to-one rehab and skills training for all clients five days a week and class sessions (e.g. Yoga, Gardening).
Nutritionist – Added new lines of service in one-to-one nutrition counseling five days a week and class sessions.

CLHC

Physician's Assistant – Added new line of service at the clinic in primary care services for registered and non-registered patients two days a week.
Medical Assistant – Assisted PA in new line of service at the clinic in primary care for registered and non-registered patients two days a week.
Case Worker – Added new line of service at the clinic for service navigation for registered and non-registered patients five days a week.

SCAN

Licensed Chemical Dependency Counselors – Expanded the center's capacity for one-to-one and group counseling sessions 5 days a week.
Co-occurring Psychiatric and Substance Use Disorders Case Manager – Expanded the center's capacity for co-occurring case management 5 days a week.
Case Manager – Expanded the center's capacity for intake screenings and case management 5 days a week.