Sí Texas: Social Innovation for a Healthy South Texas

#MHMSíTexas

Sí Texas Portfolio Final Evaluation Report:

Methodist Healthcare Ministries of South Texas, Inc.

Prepared by:
Evaluator: Health Resources in Action, Inc.

Health Resources in Action
Advancing Public Health and Medical Research

SIF Final Evaluation Report

Overarching Project

Project Title: Sí Texas: Social Innovation for a Healthy South Texas

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EXECUTIVE SUMMARY

This final report provides an overview of findings for the evaluation of Sí Texas: Social Innovation for a Healthy South Texas, a project of the Social Innovation Fund (SIF) Grantee Methodist Healthcare Ministries (MHM) of South Texas, Inc. MHM is a member of the 2014 SIF cohort. The evaluation was conducted by external evaluation contractor Health Resources in Action (HRIA).

Program Background

There are numerous evidence-based integrated behavioral health (IBH) models in the field that demonstrate improvements in patient mental and physical health outcomes, but few have studied whether these models are effective with low-income, Hispanic populations. The South Texas border area experiences disproportionate social, economic, and health challenges. For example, in a health survey of Rio Grande Valley/Lower South Texas, 20.4% of respondents reported depressive episodes. These same respondents had an education that was less than high school and 16.7% had an income of less than $25,000 (Davila, Rodriguez, Urbina, & Nino, 2014).

Insufficient access to mental health treatment and services remains one of the most pressing issues facing Texas. The state ranks 48th in state per capita mental health funding, spending $41 per person on mental health, compared with a national average of $120 (NRI, 2015). The U.S. Department of Health & Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA) (2014) noted that approximately 62.5% of adults diagnosed with Any Mental Illness (AMI) in Texas did not receive treatment. In low-income areas like the Rio Grande Valley (RGV) and Laredo, the needs are compounded by lack of appropriate access to health care, especially for residents who are poor and uninsured. In the Sí Texas service area, there is an average of 40 primary care physicians per 100,000, ranging from none in Kenedy County to 47 in Cameron County. For the state of Texas, the ratio is 113.2 primary care physicians per 100,000. Similarly, there are even fewer mental health providers in the region, with an average of 52 mental health providers for the service area compared to 105.9 per 100,000 for the state of Texas (University of Wisconsin Population Health Institute, 2019; United Health Foundation, 2018).

To address these issues Sí Texas: Social Innovation for a Healthy South Texas, a project of the Social Innovation Fund (SIF) Grantee Methodist Healthcare Ministries (MHM) of South Texas, Inc., and a portfolio of eight subgrantee organizations, tested different approaches to integrated behavioral health (IBH) to improve the physical and mental health of the unique populations served by their organizations. IBH is a term used to describe team-based, coordinated clinical care for patients' physical and behavioral health needs (Peek & The National Integration Academy Council, 2013). These eight subgrantees are from 12 medically underserved counties in the Rio Grande Valley, Laredo, and Coastal Plains areas in South Texas and received funding to implement integrated behavioral health (IBH) models (**Figure 1**).

Figure 1. Sí Texas Project Service Area

**Each star indicates a subgrantee's primary study location, though many had more than one site.*

There are many different IBH models being implemented across the country, each with growing evidence to support them. Sí Texas focused on unique models that combined evidence-based IBH practices with innovations adapted for the South Texas population, including incorporation of non-clinical components, such as transportation. The Sí Texas grantees represented a diverse group of organizations from health clinics to academic institutions to a local mental health authority, among others. **Table 2** provides a brief description of each of the subgrantees.

Table 1. Brief Descriptions of Eight Subgrantee Programs within Sí Texas Portfolio

Subgrantee	Organization Type	Program Description	Program Model
Tropical Texas Behavioral Health (TTBH)	Local Mental Health Authority	Tropical Texas Behavioral Health's reverse co-location IBH program, Improving Access to Integrated Care for Rio Grande Valley Residents with Severe & Persistent Mental Illness, serves persons with severe and persistent mental illness by incorporating primary care into a behavioral health setting, which is facilitated by care coordination, warm-handoffs and integrated health teams.	Reverse co-location
Mercy Ministries of Laredo (Mercy)	Faith-based charity clinic	Mercy's Sí Three: Integration of 3-D Health Services program provides collaborative care to low-income patients with patient education, care coordination, and an option for faith-based or standard counseling services. Mercy's program is designed to support the health and wellness of patients' physical, behavioral, and spiritual health.	Collaborative care
Nuestra Clinica del Valle (NCDV)	Federally Qualified Health Center	NCDV's NuCare-Integrated Behavioral Health Reducing Diabetes, Obesity & Depression program is designed to provide Primary Care Behavioral Health services in a Federally Qualified Health Center (FQHC) to low-income diabetic patients. This care is supported through warm-handoffs between clinical services, community health workers working within	Primary Care Behavioral Health

Subgrantee	Organization Type	Program Description	Program Model
		the clinic, and provision of community-based wellness services.	
The University of Texas Health-Brownsville Campus (UT Health SPH)	University with multiple clinical and community partners	UT Health SPH's Salud y Vida 2.0 program builds off an established community-wide chronic care program, Salud y Vida 1.0, to increase services and support to uncontrolled, low-income diabetic patients in the lower Rio Grande Valley. Key additional services available through Salud y Vida 2.0 include medication therapy management, diabetes friendly cooking classes, and behavioral health services.	Integrated community continuum of care (community chronic care model)
The Rural Economic Assistance League, Inc. (REAL)	Transportation-focused organization with multiple clinical and community partners	REAL's Transportation for Rural Integrated health Partnership (TRIP) for Salud y Vida program addresses the unique challenges of rural patients with severe and persistent mental illness in accessing integrated behavioral healthcare within a five-county service area. This program works in partnership with the Local Mental Health Authority, that provides reverse co-location IBH services, to provide transportation that is customized to meet a patient's medical and health needs, care coordination, and community-based services tailored to increase patient knowledge, self-efficacy, and social support.	Reverse co-location
The University of Texas Rio Grande Valley (UTRGV)	University family medicine residency with clinical partners	UTRGV's Primary Care Behavioral Health (PCBH) Implementation program replicates the well-established Primary Care Behavioral Health model, which integrates a behavioral health consultant into a primary care clinic to provide consultation to primary care physicians and brief patient interventions, within two family practice residency clinics that serve low-income patients in the lower Rio Grande Valley.	Primary care behavioral health
Hope Family Health Center (HFHC)	Non-profit charity clinic	HFHC's Sí Texas Hope program provides collaborative primary care and behavioral health services to low-income and uninsured patients living in the lower Rio Grande Valley within a charity care setting utilizing volunteer primary care providers.	Collaborative care
Texas A&M International University (TAMIU)	University with multiple clinical and community partners	TAMIU's Juntos for Better Health Program is a community-wide initiative representing a multi-organizational commitment to improving patient health through system-wide integrated healthcare. Non-compliant, low-income individuals with diabetes living in Webb, Zapata, and Jim Hogg counties receive outreach and screening services, integrated behavioral healthcare, and standardized follow-up to increase treatment compliance. The latter was the focus of their study.	Integrated community continuum of care (integrated network)

The overarching evaluation examines the effectiveness of these IBH models across the portfolio while also aiming to understand the facilitators, barriers, and lessons learned in implementing IBH-related practice changes in various settings in the region.

Prior Research

IBH models implemented across Sí Texas are cited in the literature and have an evidence base with findings of effectiveness across multiple populations. The portfolio of interventions within Sí Texas represent a range of evidence-based approaches such as primary care and behavioral health approach in IBH ((Ray-Sannerud et al., 2012b; Bryan, Morrow, & Appolonio, 2009; Goodie, Isler, Hunter, & Peterson, 2009), collaborative care (Guide to Community Preventive Services, 2010; Sanchez & Watt, 2012; Watt, 2009; Gilbody et al., 2006), and reverse co-location (Wagner, 1998; Druss et al., 2001), among other studies.

There is limited research within the integrated behavioral health field that examine a portfolio of different IBH program in its entirety. A 2013 RAND study of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Primary and Behavioral Health Integration (PBHCI) grant program examined results from 56 programs with a core set of intervention components plus varying optional components (Scharf et al., 2014). The evaluation pooled a smaller sub-set of study participant outcome data to examine differences by the various core features of the interventions. Participants in the interventions had improvements in some physical health measures (such as diastolic blood pressure, total cholesterol, LDL cholesterol and fasting plasma glucose). Compared with participants served at control sites, participants served through PBHCI showed no benefit in terms of indicators related to behavioral health which included binge drinking, substance use, social connectedness, and self-reported overall health. Additionally, in a 2013 cross-site evaluation of clinical implementation grantees of the Maine Health Access Foundation Integration Initiative, system-level, rather than patient-level data, were aggregated to examine level of organizational change and integration at the clinic setting over the course of the study period ("Maine Health Access Foundation Integration Initiative: Cross-Site Evaluation of Clinical Implementation Grantees," n.d.).

The Sí Texas overarching evaluation aims to examine the effectiveness of enhanced IBH on improving patient health outcomes on measures of depressive symptoms, quality of life, BMI, HbA1c, and blood pressure compared to participants engaged in standard of care. To achieve this, the overarching evaluation utilizes a research synthesis approach to 1) conduct an individual-level pooled QED approach to take into account individual-level differences among participants and 2) conduct a meta-analysis to examine study-level effects across the portfolio from the randomized control trials (four subgrantees) or quasi-experimental designs (four subgrantees) among the subgrantee-level studies.

SIF Evaluation Plan Updates

The overarching Sí Texas evaluation study experienced several deviations from the SIF Evaluation Plan (SEP). First, the original impact analyses in the SEP described the meta-analysis as the primary impact analysis, and the pooled individual-level regression as a secondary analysis. However, given the richness of the individual-level patient data and the limited number of studies for the meta-analysis (only seven met the inclusion criteria), our analytic focus shifted, and the pooled individual-level regression became the primary analysis for the impact study to leverage the large sample size for analyses across the portfolio and by sub-populations of interest (e.g., those with chronic conditions).

Additionally, there were two original implementation research questions proposed in the SEP that were not answered in the study. These included a question examining how principles of Collective Impact were operationalized in the portfolio and one about understanding the system-level changes in IBH that occurred across the region. These research questions were not explored so that evaluation efforts could

focus on more action-oriented data for future planning. Additionally, as interventions were implemented, it became clear that many of the interventions were site-specific and varied dramatically by setting and context, and thus were not necessarily engaging with other institutions across the larger area to achieve regional systems changes. Therefore, this question was not formally part of the data collection process so that efforts could focus more on understanding the site-specific practice changes and IBH implementation barriers and facilitators. A social network analysis was proposed in the SEP to examine organizational connectedness among subgrantees and their partners. Since the SEP was not approved until one year into the program, it was not possible to collect data to capture a true baseline to answer this question. Additionally, there has been staff turnover across all the subgrantees. This question, instead, was explored during key informant interviews.

Lastly, an impact question about what type of integrated behavioral health model improves participants' physical and mental health outcomes controlling for sociodemographic and patient population characteristics is not answered in this report. The original expectation was for analyses to pool study samples together of similar interventions to better understand the effectiveness of specific components. However, the standard of care received by comparison group participants varied dramatically. This variation occurred within studies that utilized similar IBH models, so that pooling smaller study samples together would not be able to appropriately answer the question of what type of IBH model improved participant health outcomes. Other deviations from the SEP are noted throughout the report.

Evaluation Design

The overarching impact evaluation used a two-pronged approach: linear regression analysis of pooled individual-level Sí Texas cohort data and a conventional meta-analysis. These analyses aimed to examine the effectiveness of IBH programs on physical and mental health outcomes among intervention participants compared to comparison participants during a 12-month study period. The implementation evaluation examined the extent to which the Sí Texas subgrantees reached their target populations, the extent to which the projects were implemented to fidelity, the changes in their IBH practices, and the barriers and facilitators to all these components.

Description of Measures and Instruments

The Sí Texas overarching evaluation used data collected within each of the Sí Texas subgrantee studies. Five shared outcomes were used across the Sí Texas portfolio. These five outcomes included: depressive symptoms (using PHQ-9), HbA1c, body mass index, blood pressure, and quality of life (using the Duke Health Profile). **Of these five, PHQ-9 score was the primary impact measure for the overarching impact evaluation.** In addition to these measures, several subgrantees also captured program-specific outcome measures of interest such as anxiety, cholesterol, and waist circumference, which were specific to their own intervention and were not part of the overarching evaluation. Data were also captured on participant demographic characteristics such as ethnicity, age, primary language, and geography.

The implementation evaluation examined the extent to which the Sí Texas subgrantees implemented IBH in their clinic and community settings. To do so, data were collected via the Behavioral Health Integration Checklist at the subgrantee level and qualitative discussions occurred with providers and clinic staff to further understand IBH implementation and practice. In addition, administrative data on patients screened, enrolled, and assessed were examined to identify the extent to which subgrantees reached their target populations.

Implementation Research Questions

The following questions aim to assess factors that have facilitated or hindered implementation of the various IBH models in the portfolio. These research questions are answered in this report and are associated with the activities, outputs and short-term outcomes presented in the logic model. Questions 5 and 6 from the SEP are not listed in this section as they are not addressed in this report, as previously described.

1. To what extent did the Sí Texas subgrantees reach their intended target population?

2. To what extent did the Sí Texas subgrantees implement their projects to fidelity?
    a. What were the facilitators and barriers to adoption?

3. To what extent did the Sí Texas subgrantee sites improve their level of Integrated Behavioral Health during the period of the Sí Texas initiative?
    a. What components of integrated behavioral health were most successfully achieved, and which were not?

4. How have organizational partnerships and connectedness changed over the Sí Texas period between subgrantees and community partners?

Impact Research Questions

Evaluating the effectiveness of various IBH models implemented in a predominantly low-income and minority population in South Texas.

The primary impact measure for the overall impact evaluation is PHQ-9. Below are the confirmatory and exploratory research questions for the impact evaluation.

1. Did intervention participants who participated in a Sí Texas intervention significantly reduce their depressive symptoms after 12 months compared to participants who receive the standard of care? *(This question is confirmatory)* Did the impact vary based on the population served? *(This question is exploratory)*

2. Did intervention participants who participated in a Sí Texas intervention obtain significantly improved blood pressure readings after 12 months compared to participants who receive the standard of care? *(This question is exploratory)* Did the impact vary based on the population served? *(This question is exploratory)*

3. Did intervention participants who participated in a Sí Texas intervention obtain significantly improved HbA1c readings after 12 months compared to participants who received the standard of care? *(This question is exploratory)* Did the impact vary based on the population served? *(This question is exploratory)*

4. Did intervention participants who participated in a Sí Texas intervention obtain significantly improved BMI scores after 12 months compared to participants who received the standard of care? *(This question is exploratory)* Did the impact vary based on the population served? *(This question is exploratory)*

5. Did Sí Texas intervention participants report significant improvements in their quality of life after 12 months compared to participants who receive the standard of care? *(This question is exploratory)*

Impact and Implementation Analysis

This report presents results from a research synthesis utilizing a two-pronged approach: linear regression analysis of pooled individual-level Sí Texas cohort data and conventional meta-analysis. Data presented include descriptive statistics, baseline equivalence, and impact results across subgrantee studies and between pooled study groups.

For the individual-level pooled analyses, an intention-to-treat approach was used, and the unit of analysis was the individual participant. Impact measures were 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 were 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 participants' characteristics was also explored. Specifically, interaction terms of study group and baseline health conditions, age, and sex were included to understand whether there were differences in intervention effect by these characteristics. Stratified linear regression models were also conducted to illuminate any potential differences between the pooled intervention and comparison group within subgroups of the cohort.

For the meta-analysis, conventional procedures in Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRIMSA) were used to conduct a quantitative synthesis of the observed effects across studies (Liberati et al., 2009). Inclusion in the meta-analysis was based on inclusion criteria assessed by a two-reviewer system. Analyses utilized random-effects models to account for the variability of effects across studies.

Program implementation was assessed across the portfolio of subgrantees by analyzing qualitative data using a grounded theory approach from discussions from staff, clinicians, leadership, participants, and partners on program implementation, barriers and facilitators to IBH. Quantitative implementation data from the IBH checklist and enrollment and retention were analyzed comparatively pre- and post-study period.

Key Findings

Implementation Study Findings

Subgrantees implemented their IBH models generally to fidelity but also continually made changes after program implementation to adapt to patient needs or address challenges. Types of changes included adaptations in care coordination, group classes, community outreach, roles and responsibilities of providers, and clinic appointments. This section provides more detail on the changes in each of these areas. Interviewees from five subgrantees (REAL, NCDV, TAMIU, UTHealth, UTRGV) described adaptations to community outreach activities that were part of their IBH programs. They recounted changes to how community engagement and outreach were structured, including transportation services, peer support, and home visits. Adaptations to group classes were discussed among subgrantees from four sites (Mercy,

REAL, NCDV, UTHealth). Subgrantees described changes to how group classes were run or scheduled. Six subgrantees (HFHC, Mercy, NCDV, TAMIU, UTHealth, UTRGV) spoke of adapting the care coordination in their clinics. They discussed changes to how providers connected participants with other providers and services, such as behavioral health and pharmacy. Among six subgrantees (Mercy, NCDV, TAMIU, TTBH, UTHealth, UTRGV), there were adaptations to providers' roles and responsibilities from what was originally planned for their IBH models. As subgrantees described, these shifts were due to hiring of new staff, recognizing that existing staff had skills that went beyond their current role, or building capacity and skills of existing staff. Five subgrantees (HFHC, Mercy, NCDV, TAMIU, UTHealth) spoke about changes in how and when clinic appointments were scheduled. According to subgrantees, most clinics and partners made changes to clinic schedules and hours to accommodate participants and providers.

At the mid-point and end-point of program implementation, communication, use of physical space, and training were identified by all subgrantees as facilitators to implementation. Communication was the primary adoption facilitator discussed during interviews. In-person communication, the most frequently discussed mode, occurred between providers and staff, providers and participants, and subgrantees and their program partners. Subgrantees also detailed communication by phone, data system and other forms of electronic communication (e.g., email, text, instant message) to augment other forms of communication in their setting. The use of electronic medical records (EMRs), or other data systems (e.g., Access or Excel files) was most frequently shared as facilitating communication between staff and providers and integration of services. Although communication was also the most commonly cited adoption facilitator, limited communication was also the primary adoption barrier described across all subgrantees. Communication challenges were discussed related to workflow, program staff/provider roles and responsibilities, and transition to and buy-in for the IBH model. Data system challenges were also a significant communication barrier. These focused on functionality, limited tech support, and communication with providers and partners.

Aside from communication both facilitating and hindering implementation, physical space and its use was also a facilitator to program implementation. Interviewees primarily spoke about physical space in two ways – adaptations to physical space and movement of providers and participants within the physical space. Finally, staff and provider training was an adoption facilitator noted across all subgrantees. According to interviewees, online and in-person training prior to and during implementation facilitated subgrantees' IBH work. A variety of training topics were described, including 1) the IBH model, 2) skills or knowledge specific to staff/provider roles in IBH implementation, 3) specific health topics, 4) communicating with participants, and 5) data systems.

As referenced previously, three subgrantee interventions (REAL, TAMIU, UTHealth) involved a range of external program partners for implementation. In interviews, these subgrantees characterized their partnerships and connectedness with the other IBH program partners. These discussions focused on building or strengthening partnerships, facilitating connectedness of services across organizations, and forming partnerships to fill gaps in services. Although there was regular contact between program staff across agencies, partnership development was primarily described as happening at the leadership level among agencies, at the start of their Sí Texas programs as well as near the end to provide a unified strategic vision for the future of the program and partnership. Finally, while the other five subgrantees (HFHC, Mercy, NCDV, TTBH, UTRGV) did not operate their core IBH model through formal partnerships as part of their IBH programs, several discussed partnerships in the context of communication with and learning from other subgrantees in the Sí Texas cohort, as well as HRiA and MHM.

Impact Study Findings

Results from the pooled individual-level regression analyses indicate that implementing an enhanced level of IBH improved physical and behavioral health. When controlling for baseline measures, individual level characteristics, and contextual covariates, participants in the pooled intervention group had significantly lower PHQ-9 scores (confirmatory variable) compared to those in the pooled comparison group receiving standard of care (which was either standard IBH services or non-integrated services at the project end-point, depending on the subgrantee) (β=-0.39, p=0.03, Cohen's d=0.06). Additionally, when controlling for baseline measures, individual level characteristics, and contextual covariates, the intervention participants had significantly greater improvements in HbA1c, an exploratory outcome (β=-0.14, p=0.02, Cohen's d=0.07) at 12 months compared to the comparison participants. However, compared to those receiving standard of care, those in the pooled intervention group had a higher BMI (β= 0.27, p=0.02, Cohen's d=0.03).

Separate stratified analyses on the pooled individual participant samples showed that among those with diabetes at baseline (β=-0.18, p=0.02, Cohen's d=0.09), higher PHQ-9 scores at baseline (β=-0.21, p=0.02, Cohen's d=0.09), participants with an SPMI diagnosis (β=-0.24, p=0.02, Cohen's d=0.13), older study participants (β=-0.19, p=0.01, Cohen's d=0.10), and female participants (β=-0.21, p=0.004, Cohen's d=0.10), the intervention group within each of these subsamples had a significantly lower HbA1c compared to the comparison group.

The conventional meta-analyses did not detect any significant intervention effect on any of the health outcomes when synthesized across studies.

Conclusion and Next Steps

This evaluation study achieves a moderate level of evidence given that the methods used for the overarching impact study had strong internal validity. The pooled sample of individual-level data and the meta-analysis utilized data from eight strong subgrantee studies, each with an RCT or QED design which mitigated threats to internal validity, particularly selection bias. The main impact analyses of this study pooled individual-level patient data from across the portfolio resulting in a baseline sample of 4,226 participants which provided sufficient power to detect significant differences in outcome measures as well as strong external validity to other border region areas. The pooled analyses controlled for both individual-level and contextual-level variables to adjust for variation across the sample. Overall, interventions were implemented as planned, and the evaluation was conducted to fidelity. The study also meets the criteria for effective evidence. The study demonstrates a positive, significant finding for both the confirmatory outcome (PHQ-9) and an exploratory outcome (HbA1c). The study showed that, when controlling for baseline measures and other covariates, the intervention participants had significantly greater improvements in depressive symptoms (β=-0.39, p=0.03, Cohen's d=0.06) at 12 months compared to the comparison participants, consistent with prior research. Additionally, when controlling for baseline measures and other covariates, the intervention participants had significantly greater improvements in HbA1c (β=-0.14, p=0.02, Cohen's d=0.07) at 12 months compared to the comparison participants, consistent with prior research.

Given the internal validity of this study and large sample size, the fidelity to which the evaluation and programs were implemented, the significant results, and the unique and important contribution to the field, this study achieves a moderate level of evidence to improve our understanding of the impact of integrated behavioral health across the south Texas border region.

There are several limitations to this study, particularly related to the variation of interventions, populations, settings, and data collection processes across subgrantees. The nature of the Sí Texas project is it allowed for subgrantees to identify and adapt evidence-based IBH models. Therefore, there are different intervention models that comprise the "intervention group" of the overarching analysis. Impact findings, thus, do not point to one specific intervention model or set of components that is most effective with this population, but instead is model-agnostic and provides stronger evidence that enhanced integrated care overall in the region has an impact on mental and physical health outcomes.

An additional methodological limitation related to the variation in the overarching sample is that the participants in the comparison group were not uniform in what they received as "standard of care." In some subgrantee studies, standard of care for the comparison group involved very little integration, comprising of a referral for behavioral health services at an external partner with little to no follow-up. In other instances, comparison group participants were already receiving fairly integrated behavioral and primary care services, and the subgrantee study examined the added value of additional, complementary IBH services to their standard IBH care. This variation within the comparison group would lead results more toward the null. Therefore, the fact that there were significant results for PHQ-9 and HbA1c even with this variation within the comparison group provides stronger support for the impact of enhanced IBH.

Despite these limitations, this study contributes to our understanding of the impact and effectiveness of IBH in a range of settings that serve primary low-income Hispanic patients in a border region. It is unique in the field to have findings on this population group. There is a dearth of literature on whether and how IBH can be effective with Hispanic populations in a border region. Additionally, this study leverages the expansiveness and diversity of intervention approaches, in that it does not singularly focus on one IBH model, but, in examining the portfolio as whole, confirms that integration of primary care and behavioral health services within different settings can improve health outcomes across the region. The implementation evaluation for the portfolio study also yields a better understanding of what are the facilitators and barriers common to implementing IBH in the region across different settings and contexts.

INTRODUCTION

This final report describes the methods and findings for the evaluation of the Sí Texas project portfolio. Methodist Healthcare Ministries (MHM) of South Texas, Inc. is an intermediary awardee of the Social Innovation Fund (SIF) from the 2014 SIF cohort. This report describes the Sí Texas project which is comprised of eight subgrantees implementing different integrated behavioral health (IBH) models, the methods used to conduct a portfolio-wide evaluation, any deviations or changes of these methods from the SEP, and final findings from the impact and implementation evaluation. The evaluation was conducted by the external evaluation contractor, Health Resources in Action (HRiA). The intended audience of this report is the Social Innovation Fund, though excerpts will also be used by Methodist Healthcare Ministries program staff and leadership.

Program Definition and Background

South Texas, which covers miles of U.S.-Mexico border and Gulf of Mexico coastline, suffers from high rates of chronic disease. Based on a study of 2,000 Mexican American adults from 2003 to 2008 called the Cameron County Hispanic Cohort (CCHC), researchers at the University of Texas School of Public Health at Brownsville found that 31% of participants had diabetes and 81% were either obese (49%) or overweight (32%) (Fisher-Hoch et al., 2008). The study also concluded there are a significant number of cases of undiagnosed diabetes in the Rio Grande Valley (RGV) in comparison to lower self-reported prevalence rates identified by the Centers for Disease Control's (CDC) 2010 Behavioral Risk Factor Surveillance System (BRFSS).

Poverty is pervasive along the Texas southern border with Mexico, placing border residents at high risk for poor health status. For example, according to the U.S. Census Bureau, in 2017, the McAllen-Edinburg metropolitan statistical area (MSA) had the lowest per capita personal income of the 384 MSAs in the country at $25,617 followed by the Brownsville-Harlingen MSA at $27,741 (U.S. Census, 2017) Residents living in high-poverty areas deal with higher rates of crime and other structural deficits along with stressful effects of being poor and marginalized without access to resources. They are also less likely to have completed high school, have higher unemployment, and often live below the poverty line. Border residents are more likely to be exposed to environmental hazards and have higher rates of chronic physical as well as mental health concerns (Cohen et al., 2003; Diez Roux et al., 2001; Quercia & Bates, 2009). For example, in a health survey of Rio Grande Valley/Lower South Texas, 20.4% of respondents reported depressive episodes. These same respondents had an education that was less than high school and 16.7% had an income of less than $25,000 (Davila, Rodriguez, Urbina, & Nino, 2014).

Insufficient access to mental health treatment and services remains one of the most pressing issues facing Texas. The state ranks 48th in state per capita mental health funding, spending $41 per person on mental health, compared with a national average of $120 (NRI, 2015). The U.S. Department of Health & Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA) (2014) noted that approximately 62.5% of adults diagnosed with Any Mental Illness (AMI) in Texas did not receive treatment. In low-income areas like the Rio Grande Valley and Laredo, the needs are compounded by lack of appropriate access to health care, especially for residents who are poor and uninsured. In the Sí Texas service area, there is an average of 40 primary care physicians per 100,000 individuals, ranging from none in Kenedy County to 47 in Cameron County. For the state of Texas, the ratio is 113.2 primary care physicians per 100,000. Similarly, there are even fewer mental health providers in the region, with an

average of 52 mental health providers for the service area compared to 105.9 per 100,000 for the state of Texas (University of Wisconsin Population Health Institute, 2019; United Health Foundation, 2018).

The lack of public health infrastructure in the region further exacerbates challenges in accessing high-quality mental health care as well as primary care. The region is home to many *colonias*, which are defined as unincorporated settlement of land along the US-Mexico border that may lack some of the most basic living necessities, such as drinking water and sewer systems, electricity, paved roads, and safe and sanitary housing. For example, in the 19 counties that make up Rio Grande Valley/Lower South Texas, there are a total of 1,902 *colonias* (Davila et al., 2014). *Colonia* residents rely on an episodic system of care depending on funding and strained social programs with limited capacity. The presence of risk factors stemming from limited access to care and high concentrations of poverty present opportunities for intervention.

To address the co-occurring conditions of chronic disease and mental health in an area of high need, Methodist Healthcare Ministries of South Texas, Inc. (MHM) launched Sí Texas: Social Innovation for a Healthy South Texas (Sí Texas). The goal of Sí Texas was to stimulate local solutions using evidence-based models to address the co-occurrence of behavioral and physical health conditions in the region. Through the SIF grant, Sí Texas funded eight organizations in the twelve southernmost counties of South Texas.

Project Background and Subgrantees

Sí Texas is a portfolio of eight subgrantee organizations testing different approaches to integrated behavioral health (IBH) to improve the physical and mental health of the unique populations served by their organizations. IBH is a term used to describe team-based, coordinated clinical care for patients' physical and behavioral health needs (Peek & The National Integration Academy Council, 2013). There are many different IBH models being implemented across the country, each with growing evidence to support them. Sí Texas focused on unique models that combined evidence-based IBH practices with innovations adapted for the South Texas population, including incorporation of non-clinical components, such as transportation. The Sí Texas grantees represented a diverse group of organizations from health clinics to academic institutions to a local mental health authority, among others.

Ultimately, the Sí Texas project aimed to improve the identification and treatment of co-occurring behavioral health problems and chronic disease. IBH models implemented across Sí Texas began with at least a preliminary evidence of effectiveness and aimed to advance to a moderate level. (The final levels of evidence achieved varied across subgrantees and are noted in **Table 16** in a subsequent section of this report). Sí Texas was designed to allow for varied IBH models based on community need. As a result, the structures, models, employed strategies, and target populations for each subgrantee project differ based on the unique needs of community systems of care and how their approach is implemented.

Table 2 provides a brief description of each of the eight subgrantees, while the narrative below the table discusses each program in greater depth.

Table 2. Brief Descriptions of Eight Subgrantee Programs within Sí Texas Portfolio

Subgrantee	Organization Type	Program Description	Program Model
Tropical Texas Behavioral Health (TTBH)	Local Mental Health Authority	Tropical Texas Behavioral Health's reverse co-location IBH program, Improving Access to Integrated Care for Rio Grande Valley Residents with Severe & Persistent Mental Illness, serves persons with severe and persistent mental illness by incorporating primary care into a behavioral health setting, which is facilitated by care coordination, warm-handoffs and integrated health teams.	Reverse co-location
Mercy Ministries of Laredo (Mercy)	Faith-based charity clinic	Mercy's Sí Three: Integration of 3-D Health Services program provides collaborative care to low-income patients with patient education, care coordination, and an option for faith-based or standard counseling services. Mercy's program is designed to support the health and wellness of patients' physical, behavioral, and spiritual health.	Collaborative care
Nuestra Clinica del Valle (NCDV)	Federally Qualified Health Center	NCDV's NuCare-Integrated Behavioral Health Reducing Diabetes, Obesity & Depression program is designed to provide Primary Care Behavioral Health services in a Federally Qualified Health Center (FQHC) to low-income diabetic patients. This care is supported through warm-handoffs between clinical services, community health workers working within the clinic, and provision of community-based wellness services.	Primary Care Behavioral Health
The University of Texas Health- Brownsville Campus (UT Health SPH)	University with multiple clinical and community partners	UT Health SPH's Salud y Vida 2.0 program builds off an established community-wide chronic care program, Salud y Vida 1.0, to increase services and support to uncontrolled, low-income diabetic patients in the lower Rio Grande Valley. Key additional services available through Salud y Vida 2.0 include medication therapy management, diabetes friendly cooking classes, and behavioral health services.	Integrated community continuum of care (community chronic care model)
The Rural Economic Assistance League, Inc. (REAL)	Transportation-focused organization with multiple clinical and community partners	REAL's Transportation for Rural Integrated health Partnership (TRIP) for Salud y Vida program addresses the unique challenges of rural patients with severe and persistent mental illness in accessing integrated behavioral healthcare within a five-county service area. This program works in partnership with the Local Mental Health Authority, that provides reverse co-location IBH	Reverse co-location

Subgrantee	Organization Type	Program Description	Program Model
		services, to provide transportation that is customized to meet a patient's medical and health needs, care coordination, and community-based services tailored to increase patient knowledge, self-efficacy, and social support.	
The University of Texas Rio Grande Valley (UTRGV)	University family medicine residency with clinical partners	UTRGV's Primary Care Behavioral Health (PCBH) Implementation program replicates the well-established Primary Care Behavioral Health model, which integrates a behavioral health consultant into a primary care clinic to provide consultation to primary care physicians and brief patient interventions, within two family practice residency clinics that serve low-income patients in the lower Rio Grande Valley.	Primary care behavioral health
Hope Family Health Center (HFHC)	Non-profit charity clinic	HFHC's Sí Texas Hope program provides collaborative primary care and behavioral health services to low-income and uninsured patients living in the lower Rio Grande Valley within a charity care setting utilizing volunteer primary care providers.	Collaborative care
Texas A&M International University (TAMIU)	University with multiple clinical and community partners	TAMIU's Juntos for Better Health Program is a community-wide initiative representing a multi-organizational commitment to improving patient health through system-wide integrated healthcare. Non-compliant, low-income individuals with diabetes living in Webb, Zapata, and Jim Hogg counties receive outreach and screening services, integrated behavioral healthcare, and standardized follow-up to increase treatment compliance. The latter was the focus of their study.	Integrated community continuum of care (integrated network)

The following provides a more detailed description of the subgrantee programs.

Tropical Texas Behavioral Health: (TTBH): Tropical Texas Behavioral Health (TTBH) implemented a reverse co-location IBH model in their Brownsville, Texas (Cameron County) clinic to expand primary care services delivered to adults receiving behavioral health services in their three-county service region (Hidalgo, Willacy, and Cameron). At its core, the intervention featured a team of medical professionals consisting of 1 full-time equivalent (FTE) primary care physician, 1 FTE care coordinator, and other medical support staff. Together, this team delivered co-located, preventative primary care to TTBH clients with co-morbid severe and persistent mental illness (SPMI) and chronic disease (specifically obesity, diabetes, hypercholesteremia, or hypertension) within a community-based outpatient behavioral health setting.

Mercy Ministries of Laredo (Mercy): Mercy Ministries of Laredo implemented the Sí Three: Integration of 3D Health Services program in their clinic setting. The program expanded Mercy's efforts to integrate behavioral health, including providing optional faith-based behavioral health services, and wellness services, such as a nutritionist. The program aimed to improve behavioral health conditions (e.g., depression, anxiety, and addictive behavior) and chronic disease conditions (e.g., hypertension, obesity, and diabetes) through interventions that impact the physical, behavioral, and spiritual health of patients as well as overall quality of life. More specifically, Mercy improved work flow between primary care and behavioral health, increased communication between primary care and behavioral health and improved staff understanding of roles and integrated behavioral health culture. Also, to facilitate the integration of clinic services, a "care coordinator" served as a liaison between patients and clinic staff to promote Sí Three patient program participation with services and follow-ups. Additional personnel included a data entry clerk, nurse practitioners/navigators, a licensed professional counselor, an exercise coach, and a nurse educator.

Nuestra Clinica Del Valle (NCDV): Nuestra Clínica del Valle (NCDV) proposed to fully integrate behavioral health (IBH) and physical health at four of its clinics in the Rio Grande Valley through a multidisciplinary team approach in order to improve the health status of patients with obesity, diabetes, and/or depression. At its core, the NuCare project consisted of: 1) community health worker (CHW) integration into the clinic team through depression screening, clinic navigation, and other patient services, 2) integration of nutritionists into the clinic team to work with patients to set goals and monitor progress, 3) mediated health education meetings led by licensed vocational nurses (LVN); and 4) introduction of a full time Behavioral Health Provider. The clinic added an integrated behavioral health team and includes the warm handoff, in which the primary care provider directly introduces the patient to the behavioral health provider (who operated as the behavioral health consultant) or nutritionist during a medical visit. The behavioral health provider provides a brief behavioral health intervention. This process breaks through the strong local barrier of stigma against behavioral health services and allows the behavioral health provider to develop rapport and encourage patient confidence in the services offered.

University of Texas Health Science Center at Houston School of Public Health (UT Health SPH): The Salud y Vida 2.0 (SyV 2.0) program aimed to enhance UT Health SPH's Chronic Care Model (SyV 1.0) with the addition of evidence-based components that provide a continuum of care for those with diabetes and other chronic disease conditions (e.g., obesity, hypertension, and depression). It was designed to integrate primary and behavioral healthcare with community-based wraparound services provided by community health workers (CHWs) and community partners in Cameron or Willacy counties. Overall, the adapted model included: medication therapy management (MTM) services that utilized pharmacists, peer led support groups (PLSGs) that delivered culturally sensitive experiences, care coordination by a team of providers (e.g., behavioral health care, CHWs, etc), and referrals to community-based lifestyle programs

for healthy eating. The primary goal of this project was to increase the effectiveness of the existing SyV 1.0 program for participants who had not successfully lowered their HbA1c values in their first 6 months of the program by heightening the level of integration and enhancing capacity through the partnerships between UT Health SPH and program partners.

Rural Economic Assistance League, Inc. (REAL): The TRIP for Salud y Vida program examined the impact of an integrated behavioral health program in five counties (Bee, Brooks, Jim Wells, San Patricio, and Kleberg) in the Coastal Bend region for the rural severe mental illness (SPMI) population. The TRIP for Salud y Vida program aimed to expand the current program, Project Salud y Vida, which was designed to provide primary care, substance abuse services, preventative health care and care management/health navigation services in a culturally and linguistically "stigma-free" environment. The population for Project Salud y Vida for this project had a severe mental illness (SMI) diagnosis including severe depression, bipolar or schizophrenia. It was developed to respond to a specific need identified by community partners to expand the reach of Project Salud y Vida to improve health outcomes, specifically, blood pressure through enhanced integrated services and systematic and seamless offering of transportation in the five-county service area. The expanded IBH model offered eight enhanced integrated services. The enhanced integrated services included, (1) assignment of a navigator and case manager; (2) assignment of a consumer attendant; (3) home and telephone nurse assessments; (4) development of an individualized transportation plan; (5) coordination and delivery of transportation services to and from health care appointments; (6) coordination and delivery of transportation services to and from community health and other health care services; (7) consumer enrollment in a community-health worker led diabetes self-management education (DSME) for the diabetes subgroup and (8) implementation of community based health and disease management classes tailored to consumer needs (i.e., physical activity, self-management education, food and nutrition education).

University of Texas Rio Grande Valley (UTRGV): The UTRGV Family Medicine Residency (FMR) program implemented an integration strategy that aimed to replicate the Primary Care Behavioral Health (PCBH) model with training and technical assistance from Mountainview Consulting Group. The PCBH model, implemented at family medicine residency clinics in McAllen and Edinburg (Hidalgo County), aimed to address the patient population with chronic and behavioral health conditions by teaching effective behavior change strategies to primary care physicians (PCPs) to increase their effectiveness and knowledge of disease conditions and health literacy among patients. The model integrated a Behavioral Health Consultant (BHC) as part of the primary care team. Trained to function as a generalist consultant for the Primary Care Physician (PCP), the BHC addresses lifestyle-based somatic complaints, sub-threshold syndromes, preventive care, and chronic disease. The BHC also develops a clear patient care plan for both the patient and the PCP to follow.

Hope Family Health Center (HFHC): HFHC implemented an enhanced IBH model into its practice to improve the health status of uninsured patients living at or below 200% of the federal poverty level. The intervention involved moving from HFHC's past co-located model, where medical and behavioral providers worked with each other episodically, to a more fully integrated model with care coordination, shared treatment plans, shared service provision, and shared record keeping. To achieve this enhanced level of integration, HFHC changed its current primary care workflow to include a behavioral health specialist to conduct assessments, provide initial counseling (individual), coordinate referrals to care management and/or community-based health services and provide warm handoffs between primary/preventative and behavioral health care services. The primary goal of this new model of care was to emphasize more collaboration between primary care and behavioral health care providers, including enhanced communication.

Texas A&M International University (TAMIU): *Juntos for Better Health* is a community partnership of health service providers developing the first fully coordinated, comprehensive health care delivery system among multiple partners in Laredo, Texas. TAMIU and its *Juntos for Better Health* partners focused on the system of health care in Webb, Zapata, and Jim Hogg Counties. TAMIU proposed a system of IBH which provides a continuum of care for those with diabetes, depression, and obesity through prevention as well as a specific focus on compliance. The primary goal of this project was to increase effectiveness of existing services by heightening the level of integration of behavioral health from prevention to community member compliance with their health treatment plans and specifically improving compliance with diabetes care treatment plans among hard-to-reach populations. TAMIU worked with a primary care and behavioral health agency to implement a diabetic patient reminder program to improve patient compliance with treatment plans through attending regularly scheduled appointments. This specific component of their program was the main focus of TAMIU's evaluation for its SIF report. Also, TAMIU worked with these clinics and other community partners to enhance the provider network of care in the community and establish traveling health care teams which included multi-agency staff. These teams traveled to community sites to screen community members for health needs and connect community members with a medical home among the clinics in the community provider care network.

Overview of Prior Research

Across the eight Sí Texas subgrantees, a variety of evidence-based IBH models were being tested. The scientific literature has many examples of interventions targeting improved access to high-quality health care services in low-income populations with the use of coordinated/integrated care. There is a 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., 2014a; Camacho et al., 2015; Ell et al., 2009a).

Tropical Texas Behavioral Health's reverse co-location intervention aimed to accomplish the key elements of the validated Wagner model for effective chronic illness care by adapting it to the SPMI population. The Wagner model features an organized delivery system linked with complementary community resources, sustained by productive interactions between multidisciplinary care teams and "activated" or educated patients and their families (Wagner, 1998). A 2001 study involving the integration of primary care services within a mental health clinic treating veterans with mental illness reported that "enrollment in a co-located, integrated clinic was associated with increased primary care use and improved attainment of some cardiovascular risk goals" (Druss et al., 2001). For persons served in community mental health centers, research has indicated that care management delivered in an integrated primary care setting can result in sustainable improvements in physical health outcomes, patient and provider satisfaction, as well as potential cost savings to health care systems relative to care as usual (i.e., simple referral to a primary care provider) (Druss et al., 2001; Shackelford et al., 2013). Co-location and integration of primary care services within behavioral health settings improves access to routine primary care for persons with SPMI given that their "primary point of contact with the health care system is through public-sector mental health programs rather than primary medical care" (Druss et al., 2001). Co-location also reduces the cost and inconvenience of traveling to multiple locations in order to receive behavioral and physical healthcare (Boardman, 2006; Druss et al., 2001; Shackelford et al., 2013).

Mercy Ministries Sí Three: Integration of 3-D Health Services (Sí Three) model was based on a collaborative care model which focuses on being 1) team-driven, 2) population-focused, 3) measurement-guided, and 4) evidence-based. (Guide to Community Preventive Services, 2010; American Psychiatric Association &

Academy of Psychomatic Medicine, 2016). The Sí Three project combines components of the model studied by Druss, Rohrbaugh, Levinson, & Rosenheck (2001) and faith-based care discussed by Worthington et al. (Worthington, Hook, Davis, & McDaniel, 2011). The Druss model, involving patient education and prevention, nurse practitioners, and increased interaction among the care team, found that patients in the integrated care model were significantly more likely to have received preventive care and had significantly greater improvement in health. Worthington found that religious/spiritual counseling resulted in greater improvements in psychological and spiritual outcomes when compared to secular therapies (Worthington, Hook, Davis, & McDaniel, 2011).

Nuestra Clinica del Valle (NCDV) combined components of the integrated care model studied by Druss et al. (2001), and the collaborative care model studied by Sanchez & Watt (2012). The Druss model involves patient education and prevention and increased interaction among the care team. The Sanchez and Watt (2012) model finds that collaborative care, where structured care involves a greater role of nonmedical specialists to augment primary care, has emerged as an effective intervention to improve quality of primary care and patient outcomes with low-income, Spanish speaking populations. NCDV's implemented model shifted to align more with a primary care and behavioral health (PCBH) approach incorporating warm hand-offs to a behavioral health specialist in a primary care setting. There is strong prior research of quasi-experimental studies that have shown the effectiveness of a PCBH approach in primary care settings to improve well-being, functioning and reduce symptoms of insomnia (Bryan, Morrow, & Appolonio, 2009; Goodie, Isler, Hunter, & Peterson, 2009) and suggest clinical gains were maintained after the final appointment (Ray-Sannerud et al., 2012b)

UT Health SPH implemented Salud y Vida 2.0 which aimed to enhance their current Collaborative Chronic Care Model (CCM) (SyV 1.0) with the addition of two evidence-based models. While the chronic care model can take many different forms, the Centers for Disease Control and Prevention's Task Force on Community Preventive Services defines it as "a multicomponent, healthcare system-level intervention that uses case managers to link primary care providers, patients and mental health specialists." The UT Health SPH intervention built on the key elements of Wagner's model for effective chronic illness care, namely, an organized delivery system linked with complementary community resources, sustained by productive interactions between multidisciplinary care teams and "activated" or educated patients and their families (Wagner, 1998). Preliminary unpublished results showed that participants in SyV 1.0 experience immediate progress in the control of diabetes such that the average HbA1c at baseline of 10.2% has dropped to 9.1% at 3-months. The SyV 2.0 program aimed to enhance Wagner's (1998) Collaborative Chronic Care Model with the addition of evidence-based components including: medication therapy management (MTM), peer led support groups (PLSG), in-clinic behavioral health services, and community-based lifestyle programs for healthy eating (MEND and Cocina Alegre). Individually the MTM and MEND components are evidence-based, however not collectively as proposed for Salud y Vida 2.0.

REAL's intervention built upon the existing Project Salud y Vida, which was informed by key elements of the validated Wagner collaborative-care model for effective chronic illness care (Wagner, 1998). Project Salud y Vida was designed to provide primary care, substance abuse services, preventative health care and care management/health navigation services in a culturally and linguistically "stigma-free" environment. The population for this project had a severe mental illness (SMI) diagnosis including severe depression, bipolar or schizophrenia (Druss et al, 2001). There were two components to the project. The first strategy used previously established co-located models adapted for the SMI population (Wagner, 1998). The second strategy engaged community health workers (*promotores)* to provide diabetes self-management education programs and community-based health and disease management classes. There is a growing body of evidence of the benefits of interventions led by *promotores* especially in underserved

and minority populations. For example, in a quasi-experimental design with pre-post tests and follow-up (N=255), program participants of *Pasos Adelante* (Spanish for Steps Forward) a lifestyle intervention program targeting chronic disease prevention in Mexican Americans living in a U.S.-Mexico border community in Arizona, demonstrated significant improvements in physiological measures linked to diabetes and CVD risk factors after participating in the 12-week community health worker-led program that combined interactive educational sessions with walking groups (Staten et al., 2011). The second component of TRIP for Salud y Vida was coordination and delivery of tailored transportation to behavioral and clinical services and community health and other health care services. The importance of transportation assistance is supported by Friedman et al.'s findings (2001), based on a national longitudinal study that demonstrated that transportation increased medical utilization among substance abuse patients. Rural residents are more likely to note that they have a usual care provider, but report fewer visits to health care providers during a year (Zhang, Tao, & Anderson, 2003). Researchers have noted the importance of improved transportation for improved health outcomes. The literature does identify transportation in rural settings as a barrier for care and a contributing factor to worse health outcomes especially so for those the SMI population (Kane & Ennis, 1996; Roberts, Battaglia, & Epstein, 1999).

UTRGV replicated the primary care and behavioral health (PCBH) model developed by Dr. Kirk Strosahl and Dr. Patricia Robinson of Mountainview Consulting Group and studied by Bryan et al. (2009), Ray-Sannerud et al. (2012), and Goodie et al. (2009), which provides a solid evidence base. A 2012 quasi-experimental study utilizing the PCBH model examined the longitudinal clinical functioning of primary care patients who had received care from BHCs integrated into a large family medicine clinic. Results indicated that patients improved their global mental health functioning during the intervention and sustained improvements through two years of follow up (Ray-Sannerud et al., 2012b). Several other quasi-experimental studies using behavioral health consultants have also shown positive results (Bryan, Morrow, & Appolonio, 2009; Goodie, Isler, Hunter, & Peterson, 2009). Bryan and colleagues conducted a study of 338 primary care patients who were referred to BHCs and participated in brief, behaviorally oriented appointments in primary care. Patients demonstrated simultaneous, clinically meaningful improvements in well-being, symptoms, and functioning in as little as two to three BHC visits (Bryan et al., 2009).

Hope Family Health Center (HFHC) implemented an enhanced collaborative integrated behavioral health (IBH) model into its practice to improve the health status of uninsured patients living at or below 200% of the federal poverty level. The IBH model on which HFHC based its intervention is the collaborative care model which has been well described in the literature (e.g., Guide to Community Preventive Services, 2010; Sanchez & Watt, 2012; Watt, 2009; Gilbody et al., 2006). The model centers around a mental health care manager and consulting psychiatrist being brought into a primary care facility to more effectively serve clients with mental health needs. HFHC proposed to replicate the models studied by Sanchez and Watt (2012) and Watt (2009)—though HFHC's proposed intervention was not identical. HFHC utilized a volunteer primary care physician, care coordinator (Master of Social Work level), and behavioral health specialist, which is similar to the delivery and content of the studied interventions. There is a 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., 2014b; Camacho et al., 2015; Ell et al., 2009b). In Austin, for example, People's Community Clinic used the IBH model to enable adult clients diagnosed with depression and anxiety to receive psychiatric medication, counseling and education. The clinic had tremendous success with the project, achieving treatment results typically seen only in controlled clinical trials. The studies concluded that the IBH model improved primary care patients' mental health outcomes with a minimal investment of resources (Sanchez & Watt, 2012). Similarly, a study by Bridges et al. (Bridges et al., 2013) revealed that Latinos who participated in

integrated behavioral health care had significant improvements in symptoms and expressed high satisfaction with integrated health treatment.

TAMIU implemented a multi-component model, but the focus of the evaluation was on the diabetic patient reminder program to improve patient compliance with treatment plans. 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 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 PCMU 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.

While the Sí Texas project is comprised of eight distinct subgrantees, it aims to improve mental and physical health outcomes collectively for their service populations across the region. There is limited research on similar initiatives within the integrated behavioral health field. A 2013 RAND study of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Primary and Behavioral Health Integration (PBHCI) grant program examined results from 56 programs with a core set of intervention components plus varying optional components (Scharf et al., 2014). The evaluation pooled a smaller sub-set of study participant outcome data to examine differences by the various core features of the interventions. Compared to control participants, participants in the interventions had improvements in some physical health measures (such as diastolic blood pressure, total cholesterol, LDL cholesterol and fasting plasma glucose). Compared with participants served at control sites, participants served through PBHCI showed no benefit in terms of indicators related to behavioral health which included binge drinking, substance use, social connectedness, and self-reported overall health. Additionally, in a 2013 cross-site evaluation of clinical implementation grantees of the Maine Health Access Foundation Integration Initiative, system-level, rather than patient-level data, were aggregated to examine level of organizational change and integration at the clinic setting over the course of the study period ("Maine Health Access Foundation Integration Initiative: Cross-Site Evaluation of Clinical Implementation Grantees," n.d.).

Program Components

Sí Texas aims to improve physical and mental health among a large patient base in the region. The project focuses on advancing the identification and treatment of co-occurring behavioral health problems and chronic disease by using evidenced-based IBH models to determine whether these approaches can be applied to a low-income, predominantly Hispanic population in Southern Texas.

The theory of change behind this approach is that by focusing on the screening and diagnosis of chronic disease and depression and providing greater integration and coordination of services across primary and behavioral health care, residents in this low-income and medically underserved region will have improved physical and behavioral health outcomes and improved overall quality of life.

Logic model components

Appendix A. Program Logic Model provides an illustration of the Sí Texas Project logic model as it relates to the stated theory of change.

Overarching inputs:

- Project personnel. The project personnel are site-specific across the Sí Texas subgrantees. Generally, however, project personnel fall under the following broader categories for the implementation of IBH. Clinic primary care providers, care coordinators, behavioral health specialist, mental health providers, clinic staff, and community health workers/promotoras.

- Project partners. Sí Texas subgrantees are the primary project partners. The overall evaluation of Sí Texas is based on the IBH interventions being implemented across the South Texas region. As reflected in the logic model, the project partners are: Hope Family Health Center (HFHC), Mercy Ministry of Laredo (Mercy), Nuestra Clinica del Valle (NCDV), Rural Economic Assistance League (REAL), Texas A&M International University (TAMIU), Tropical Texas Behavioral Health (Tropical Texas), The University of Texas Health Science Center at Houston School of Public Health (UT Health SPH) and the University of Texas Rio Grande Valley (UTRGV). However, many subgrantees have community organizational partners that are important to their project. A total of 31 additional local organizations were proposed to be involved in the Sí Texas initiative as project partners to the subgrantees.

- Other project partners include Health Resources in Action (HRiA), the external evaluators for Sí Texas and Methodist Healthcare Ministries of South Texas (MHM), who led and funded the Sí Texas project with support from the Corporation for National and Community Service. Valley Baptist Legacy Foundation, the Meadows Foundation, Guadalupe and Lilia Martinez Foundation, Lamar Bruni Vergara Trust, IBC Foundation, Hogg Foundation for Mental Health, Mercy Caritas, Alice Kleberg Reynolds Foundation, The John G. and Marie Stella Kenedy Memorial Foundation, Superior Health Plan, and H.E.B. Foundation also provided funding to Sí Texas subgrantees.

Activities: The activities section of the logic model provides an overview of cross-cutting Sí Texas programmatic activities at the subgrantee clinic levels.

- While each of the Sí Texas subgrantees proposed independent approaches to implementing their programs, many activities were similar. For the Sí Texas overarching evaluation, the following cross-cutting activities were identified and were used in aggregate to evaluate Sí Texas. The project activities were: (1) Implement integrated behavioral health models in Sí Texas subgrantee clinics; (2) Establish and/or ongoing use of care coordination between primary and behavioral healthcare services (coordinated, co-located or integrated); (3) Develop subgrantee level patient database and tracking/monitoring of patient-care plans; (4) Monitor and effectively communicate patient health through the use of patient-care plans w/ clinic staff and patients; (5) Provide care planning and tracking/monitoring of patient health via patient's appointment reminders and use of services.

- At the overarching level, activities related to Collective Impact were proposed. These activities, designated in the Logic Model as activity six (6), were related to the five aspects of Collective Impact: (1) common agenda, (2) shared measures, (3) reinforcing activities, (4) communication and (5) backbone support. While these components were not evaluated in the final study, which was a deviation from the SEP, the Collective Impact framework guided the development of the project.

Outputs: The outputs section of the logic model outlines the expected and corresponding outputs, which include:

- Output one (1) is associated with the first activity. Implementation of integrated behavioral health models at Sí Texas subgrantee clinics is expected to result in (a) provider and clinic staff increased understanding of collaborative/integrated care, (b) provider and staff buy-in to IBH model, (c) primary care (PC) team trained on clinic-wide protocol.

- Outputs two (2) through seven (7) are associated with activity two (2)—Establishment and/or ongoing use of care coordination between primary and behavioral healthcare services. If activity two is implemented as expected across Sí Texas subgrantees, it is expected that there will be an (a) establishment and/or continued use of IBH and clinic protocols, (b) coordinated primary and behavioral health services, (c) ongoing communication about and coordination between primary and behavioral care, (d) provider collaboration and communication about patients receiving both primary and (e) behavioral health care services and ongoing training and clinic-capacity building for primary care, behavioral health and clinical operations (e.g., ERM training, practices policies and protocols).

- Output eight (8) is associated with activity three (3) Development of a patient database and tracking/monitoring system for patient-care plans. It was expected that this activity would assist Sí Texas subgrantees to schedule follow up appointments for primary and behavioral health in addition to more effectively monitoring clinic practices and sharing of patient data. During the project, each subgrantee had their own monitoring system and they shared data with the evaluator.

- Outputs nine (9) through eleven (11) are associated with activity four (4)- Develop, monitor and effectively communicate patient health through the use of patient-care plans with clinic staff and patients. Through the effective implementation of the Sí Texas subgrantee projects, all patients were administered surveys to assess behavioral health (baseline, 6 months and 12 months). Patients were also assessed on physical health measures related to their blood pressure, body mass index, and HbA1c. In addition, activity four (4) will lead to referrals to internal and/or external care services community resources and chronic disease management projects and/or community resources and chronic disease management projects aligned with patient needs.

- Outputs twelve (12) and thirteen (13) are associated with activity five (5) - Care planning and tracking/monitoring of patient health via patients' appointment reminders and use of services. By implementing this activity, it was expected that across Sí Texas projects patients would have improved compliance with treatment and attendance follow up appointments and referrals and written person-centered care plans that cross primary and behavioral health care service boundaries.

- Lastly, outputs fourteen (14) through eighteen (18) are associated with activity six (6) -Activities related to Sí Texas collective impact (common agenda, shared measures, reinforcing activities, communication, and backbone support), each of which aimed to serve as an overarching program output.

Short-term outcomes: Short-term outcomes are the changes that were expected to occur during the first six months of patient enrollment in subgrantee intervention projects. By working with the various project personnel across the subgrantee clinics, the programs aimed for patients to receive IBH services and for clinics to adopt and adhere to the IBH project models.

- As a result of the Sí Texas cross-cutting activities and outputs, it was expected that throughout participating clinics, the following short-term outcomes would be observed at the patient level. Given variation in subgrantee data collection, not all short-term outcomes were measured across all subgrantees and were unavailable for analysis. Limitations in data collection are discussed in the results section.
    1. Patients who were eligible for Sí Texas intervention projects were enrolled, screened, baseline measures obtained *(measured across all subgrantees)*
    2. Patients enrolled in Sí Texas intervention projects received their care plans *(not measured across all subgrantees)*
    3. Patients would take an active role in adhering to their care plans (as measured by follow-up with referrals and appointments) *(measured across all subgrantees)*

- Similarly, at the clinic level, it was expected that across the Sí Texas subgrantees the following outcomes would be observed. These outcomes were captured via qualitative data or administrative data in the implementation evaluation.
    4. Primary care team buy-in of IBH model and clinic staff understanding of roles in IBH model
    5. Adherence to model policies & procedures
    6. Closer collaboration between providers and behavioral health staff
    7. Increase in warm-handoffs and referral processes
    8. All intervention patient data entered in patient database or electronic medical record (EMR) for tracking and monitoring patient use of services
    9. Scheduling of follow-up appointments with in-house or community resources

Overarching intermediate outcomes: Intermediate outcomes were the expected changes during the first year of subgrantee patient enrollment in the various interventions and receiving of Sí Texas project services. Through participation in the Sí Texas projects, it was expected that patients would progressively improve their physical and behavioral health and report increased quality of life and physical functioning. In addition, at the clinic level, improved adherence to the IBH model and improved clinic operations would be reported.

- As a result of the Sí Texas cross-cutting activities and outputs, it was expected that throughout participating clinics, the following intermediate-term outcomes would be observed at the patient level: Given variation in subgrantee data collection, not all intermediate outcomes were measured across all subgrantees and were unavailable for analysis. Limitations in data collection are discussed in the results section.
    1. Improved patient attendance and compliance with treatment plan *(not measured across all subgrantees)*
    2. Increased functioning and/or quality of life
    3. Reduced HbA1c, blood pressure levels, BMI and/or depressive symptoms
    4. Patients participate in and are satisfied with in-house or community resources, behavioral health and primary care services

- Similarly, at the clinic level it was expected that across Sí Texas subgrantees the following outcomes would be observed. Most of the concepts were captured through the qualitative data in the implementation evaluation.
    5. Improved workflow alignment across providers and services
    6. Improved rate of successful referrals and use of behavioral-health services *(not measured across all subgrantees)*

7. Ongoing follow-up assessments and monitoring of patients
8. Improved integrated clinical service provision/Improved clinic efficiency
9. Patient data reviewed by primary care teams and recommendations made

Overarching long-term outcomes: Long-term outcomes are the expected changes in patient and clinic impact beyond the 12-month data collection period of the Sí Texas project and are not captured as part of this evaluation. It is expected that through participation in the Sí Texas projects, patients will have progressively improved their physical and behavioral health and report increased quality of life and physical functioning.

- As a result of the Sí Texas cross-cutting activities and outputs, it is expected that throughout participating clinics, the following long-term outcomes will be achieved:
    1. Improved quality of life (as measured by the Duke Health Profile) and physical functioning among all Sí Texas intervention participants
    2. Reduced chronic disease (as measured by blood pressure, HbA1c, and BMI) and depressive symptoms (as measured by the PHQ-9) prevalence among all Sí Texas intervention participants
    3. Improvement of integration of primary care and behavioral health services at subgrantee sites
    4. Implementation of IBH best practices sustained over time

Overview of Impact Study

The Sí Texas overarching evaluation aims to examine the effectiveness of enhanced IBH on improving patient health outcomes on measures of depressive symptoms, quality of life, BMI, HbA1c, and blood pressure compared to participants engaged in standard of care. To achieve this, the overarching evaluation utilizes a research synthesis approach to 1) conduct an individual-level pooled QED approach to take into account individual-level differences among participants and 2) conduct a meta-analysis to examine study-level effects across the portfolio from the randomized control trials (four subgrantees) or quasi-experimental designs (four subgrantees) among the subgrantee-level studies The implementation evaluation gathered data to understand fidelity, facilitators, and barriers to implementation of IBH across the portfolio.

Research Questions

The SEP included both implementation and impact research questions, as stated below.

Implementation Questions

The following evaluation questions examined program implementation of the Sí Texas models. The final implementation evaluation included interviews, focus groups, and assessment of quantitative implementation data. Most of these questions have not changed since the approval of the SEP, although the methods to answer these questions have changed since SEP approval. In a few instances, some questions were not answered in the final evaluation. A description of these are presented in the SIF Evaluation Updates section.

The implementation evaluation questions in the SEP were:

1. To what extent did the Sí Texas subgrantees reach their intended target population?

2. To what extent did the Sí Texas subgrantees implement their projects to fidelity?
    a. What were the facilitators and barriers to adoption?

3. To what extent did the Sí Texas subgrantee sites improve their level of integrated behavioral health during the period of the Sí Texas initiative?
    a. What components of integrated behavioral health were most successfully achieved, and which were not?

4. How have organizational partnerships and connectedness changed over the Sí Texas period between subgrantees and community partners?

5. What system-level changes around integrated behavioral health have been implemented across the region? And, are sub-regional (e.g., Lower Rio Grande Valley, Alice, TX, and Laredo, TX) differences seen? *(This question is not answered in this report. Please see SIF Evaluation Update section for more information.)*

6. In what way were the components of the Collective Impact framework (common agenda, development of shared measures, mutually reinforcing activities, continuous communication, and backbone organization) integrated in and contributed to overall Sí Texas project? *(This question is not answered in this report. Please see SIF Evaluation Update section for more information.)*

Impact Questions

The impact questions focused on understanding the effectiveness of various IBH models implemented in a predominantly low-income and minority population in South Texas. The primary impact measure for the overall impact evaluation was PHQ-9. Below are the confirmatory and exploratory research questions. In the SEP, question 3 discussing the outcome of HbA1c was defined as only focusing on diabetic patients. Given the opportunity to analyze HbA1c data across a range of participants, including those who are pre-diabetic, this question was changed to remove the restriction among diabetics only. All other questions have not changed since the approval of the SEP.

The sub-research questions aimed to explore the potential differences of intervention impact on health outcomes among specific sub-populations. The original sub-populations described in the SEP for stratified analyses were: the severe and persistent mentally ill (SPMI), 200% below FPL, and general population. Given data collection challenges, participant income was not able to be collected among all subgrantee. Additionally, it was decided that biological conditions such as baseline health conditions e.g., diabetes, hypertension, depression, etc.), gender, and age were more appropriate for stratified analyses given the likelihood that these groups might potentially experience a differential intervention effect.

1. Did intervention participants who participated in a Sí Texas intervention significantly reduce their depressive symptoms after 12 months compared to participants who receive the standard of care? *(This question is confirmatory)* Did the impact vary based on the population served? *(This question is exploratory)*

2. Did intervention participants who participated in a Sí Texas intervention obtain significantly improved blood pressure readings after 12 months compared to participants who receive the

standard of care? *(This question is exploratory)* Did the impact vary based on the population served? *(This question is exploratory)*

3. Did intervention participants who participated in a Sí Texas intervention obtain significantly improved HbA1c readings after 12 months compared to participants who received the standard of care? *(This question is exploratory)* Did the impact vary based on the population served? *(This question is exploratory)*

4. Did intervention participants who participated in a Sí Texas intervention obtain significantly improved BMI scores after 12 months compared to participants who received the standard of care? *(This question is exploratory)* Did the impact vary based on the population served? *(This question is exploratory)*

5. Did Sí Texas intervention participants report significant improvements in their quality of life after 12 months compared to participants who receive the standard of care? *(This question is exploratory)*

6. What type of integrated behavioral health model improves participants' physical and mental health outcomes controlling for sociodemographic and patient population characteristics? *(This question is exploratory)*

Contribution of the Study

This study builds on a substantial body of evidence in the literature for the effectiveness of various IBH models. With subgrantee-level studies using an experimental or quasi-experimental design, the overarching evaluation will advance our understanding of the effect of evidence-based IBH models on specific mental health and physical health outcomes among mainly low income, Hispanic patient populations. Analyses also examine whether there are differential effects of the intervention on different sub-populations (e.g., by baseline health conditions such as diabetes or depression). Additionally, the implementation evaluation discusses implementation fidelity, the barriers and facilitators to implementation, and key program changes that have moved subgrantees closer to integrated behavioral health.

In addition, by using a research synthesis approach, we are able to use empirical research for the purpose of generalizations to the larger South Texas population and other similar populations (Cooper & Hedges, 2009). The meta-analysis in our study allows us to investigate study level attributes such as study design, trends over time, the impact of covariate adjustment, study quality, and the identification of research gaps that require new primary studies. The pooled individual-level approach provides a large sample to be able to stratify by specific sub-populations and identify whether there are differential intervention effects by group.

The target level of evidence for the impact evaluation was moderate. The intervention models implemented across subgrantees are adaptations of existing evidence-based programs. Per the design, each subgrantee-level study, which is the basis for the overarching Sí Texas evaluation, was a randomized control trial (RCT) or quasi-experimental design (QED). By analyzing these data via pooled individual-level regression and meta-analysis the overarching evaluation contributes to the field by assessing both the site-level and individual-level impacts of this portfolio of IBH programs.

SIF Evaluation Plan Updates

The overarching Sí Texas evaluation study experienced several deviations from the SIF Evaluation Plan (SEP). First, the original impact analyses in the SEP described the meta-analysis as the primary impact analysis, and the pooled individual-level regression as a secondary analysis. However, given the richness of the individual-level patient data and the limited number of studies for the meta-analysis (seven was the maximum that met inclusion criteria), our analytic focus shifted for the pooled individual-level regression to be the primary analysis for the impact study so that the large sample size for analyses across the portfolio and by sub-populations of interest (e.g., those with chronic conditions) could be leveraged.

Additionally, there was a research question and proposed methods of a subgrantee survey and interviews to examine how the principles of Collective Impact were operationalized. As noted earlier, the SEP discussed conducting multiple evaluation activities to examine the operationalization of the Collective Impact framework in this project. Data collection methods were proposed to identify the change in and extent to which the components of the Collective Impact framework (common agenda, development of shared measures, mutually reinforcing activities, continuous communication, and backbone organization) had contributed to the overall impact of Sí Texas. MHM decided not to conduct those evaluation activities so that resources could be focused on evaluation efforts that would provide more action-oriented data for next steps of the project. Therefore, the Collective Impact-related evaluation activities were not conducted which was a deviation from the SEP.

Another implementation research question that was not ultimately a focus of the evaluation was around identifying system-level changes related to IBH that have been implemented across the region and by sub-region. As interventions were implemented, it became clearer that many of the interventions were site-specific and varied dramatically by setting and context, and thus were not necessarily engaging with other institutions across the larger region to achieve systems changes. Therefore, this question was not formally part of the data collection process so that efforts could focus more on understanding the site-specific practice changes and IBH implementation barriers and facilitators.

Another major deviation from the SEP was a change in methods to examine organizational connectedness among subgrantees and partners within the Sí Texas project. The SEP proposed the administration of a survey among subgrantees in order to conduct a social network analysis (SNA). The methods and social network analysis were not conducted as part of the evaluation. Since the SEP was not approved until one year into the program, it was not possible to collect data to capture a true baseline to answer this question. Additionally, there has been significant staff turnover across all the subgrantees. Also, the time to complete a survey to produce a SNA would be a large participant burden and was not expected to provide actionable results to MHM or subgrantees. Given these reasons, and that the organizational partnership and connectedness question was not a focus of the implementation evaluation, MHM and HRiA decided to eliminate the survey and SNA from the implementation evaluation and instead will garner perceptions of organizational connectedness through summative qualitative interviews.

As previously noted, the sub-research impact questions aimed to explore the potential differences of intervention impact on health outcomes among specific sub-populations. The original sub-populations described in the SEP for stratified analyses were: the severe and persistent mentally ill (SPMI), 200% below FPL, and general population. Given data collection challenges, participant income was not able to be collected among all subgrantee. Additionally, it was decided that biological conditions such as baseline health conditions (e.g., diabetes, hypertension, depression, etc.), gender, and age were more appropriate

for stratified analyses given the likelihood that these groups might potentially experience a differential intervention effect.

Lastly, the final question proposed in the impact section—What type of integrated behavioral health model improves participants' physical and mental health outcomes controlling for sociodemographic and patient population characteristics? — is not answered in this report using the regression analyses as proposed. The original expectation was for analyses to pool study samples together of similar interventions to better understand the effectiveness of specific components. However, the standard of care received by comparison group participants varied dramatically. In some instances, comparison group participants received very little integrated care, while in other studies, the comparison group was receiving a high level of integrated care and was utilized to better understand if additional components could impact health outcomes. This variation occurred within studies that utilized similar IBH models, so that pooling smaller study samples together would not be able to appropriately answer the question of what type of IBH model improved participant health outcomes. Instead the response to this question includes a summary of each subgrantee-level study discussing the type of IBH model utilized and specific results found.

There are smaller, more administrative changes in planned activities for the evaluation. These minor deviations are noted throughout this report.

IMPLEMENTATION STUDY: STUDY APPROACH, METHODS, AND FINDINGS

Implementation Study Design

The implementation evaluation design aimed to understand to what extent the Sí Texas interventions were implemented and what the barriers and facilitators were to implementation. Qualitative methods of key informant interviews and focus groups were the primary methods used for the implementation evaluation and was supplemented with analysis of administrative participant data and self-reported questionnaires on practice level changes.

As previously noted, the implementation study research questions answered in this report are:

1. To what extent did the Sí Texas subgrantees reach their intended target population?
2. To what extent did the Sí Texas subgrantees implement their projects to fidelity?
    a. What were the facilitators and barriers to adoption?
3. To what extent did the Sí Texas subgrantee sites improve their level of integrated behavioral health during the period of the Sí Texas initiative?
    a. What components of integrated behavioral health were most successfully achieved, and which were not?
4. How have organizational partnerships and connectedness changed over the Sí Texas period between subgrantees and community partners?

The SEP also included a research question around the extent to which the principles of the Collective Impact framework were implemented in the project. As noted previously, these evaluation activities were not conducted, which is a deviation from the SEP.

Qualitative Implementation Data Collection Methods and Analysis

The program's evaluator, HRiA, conducted qualitative data collection with each subgrantee at two time points for the implementation study. Across the two time points, a total of 182 subgrantee clinicians, staff members, leaders, and partners were interviewed, and 184 program participants were involved in 18 focus groups. The primary focus of the interviews and focus groups was to inform each subgrantees' specific evaluation study. These data were then pooled to be analyzed for the overarching implementation evaluation.

For the mid-point interviews, a total of 91 staff from all eight subgrantees were interviewed between September 2016 through April 2017. From November 2017 through September 2018, summative interviews were conducted also with 91 staff from all eight subgrantees. **Table 3** provides the number of interviews conducted for each subgrantee. While in many cases the same individual was interviewed at both time points, in other instances different individuals were part of the summative discussions due to staff turnover or the need to gather a different perspective (e.g., clinician, community health worker) that might have been missing from the mid-point interviews. Interviews were conducted by telephone and in-person. Participants included clinic providers (both primary and behavioral care) and other relevant clinical and nonclinical personnel, ranging from case managers to community health workers to subgrantee leadership.

Table 3. Key Informant Interview Participants by Subgrantee and Timepoint

	Mid-point		Summative	
Subgrantee	# of interviews (n=91)	% of interviews	# of interviews (n=91)	% of interviews
Hope	10	11.0%	13	14.3%
Mercy	8	8.8%	8	8.8%
NCDV	14	15.4%	13	14.3%
REAL	7	7.7%	7	7.7%
TAMIU	11	12.1%	13	14.3%
Tropical	17	18.7%	10	11.0%
UTHealth	16	17.6%	16	17.6%
UTRGV	8	8.8%	11	12.1%

The goal of these interviews was to assess program fidelity and understand the context of integration of care and implementation of subgrantees' programs. Program fidelity was assessed with clinic personnel interviewees by asking questions about program implementation from a provider, program and organizational level:

- ***Provider level:*** The implementation evaluation measures programmatic implementation including providers' perceptions, attitudes and perceived barriers in care delivery for the target population. Providers were asked about their perceptions regarding the degree to which integration of primary care and behavioral health services has or has not been achieved at the mid- and end-point of the program, and their engagement with each other and aspects of the program.

- ***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 semi-structured interviews also aimed to capture information on each subgrantee's program staff and personnel's perceptions of barriers and facilitators to the adoption of their program's IBH model, perceptions of program successes, challenges and opportunities for improvement, and perceived staff and patient satisfaction. Staff 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 D: Sí Texas Mid-Point Implementation Evaluation: Key Informant Interview General Guide** and **Appendix E: Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide** present the semi-structured interview guide used to conduct the interviews at the mid-point and final data collection periods.

All interviews were conducted by experienced and trained qualitative researchers from the HRiA evaluation team. A lead moderator conducted the interviews and a research assistant took detailed notes. All interviews were recorded digitally to check the accuracy of notes; summative interviews were transcribed. The interviews were conducted in English and Spanish.

In addition to these semi-structured interviews, HRiA conducted 18 focus groups with 184 study participants after the individual subgrantee studies had ended. The goal of these summative focus groups

was to better understand the influence the program had on participant's health and wellbeing. **Appendix F: 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.

There were 184 participants in 18 focus group across the 8 subgrantees. Each subgrantee study had 2-3 focus groups each (**Table 4**). Prior to the focus groups, participants were asked to voluntarily complete a demographics survey. **Table 5** describes the demographic characteristics for the focus group participants. Participants were from a range of counties, but were predominantly from Cameron, Hidalgo, and Webb Counties. Nearly all participants were Hispanic or Latino (97.2%), and nearly half spoke Spanish as a primary language (49.2%). More than half had less than a high school diploma (52.9%) and did not have health insurance (58.9%).

Table 4. Number and Distribution of Summative Participant Focus Groups across Subgrantees

Subgrantee	Number of Focus Groups (n=18)	% of Total Groups
Hope	2	11.1%
Mercy Ministries of Laredo	2	11.1%
Nuestra Clinica del Valle	3	16.7%
REAL	2	11.1%
TAMIU	2	11.1%
Tropical Texas Behavioral Health	3	16.7%
UTHealth	2	11.1%
UTRGV	2	11.1%

Table 5. Focus Group Participant Summary

	N=184	%
County		
Brooks	5	2.7%
Cameron	59	32.4%
Duval	1	0.5%
Hidalgo	57	31.3%
Jim Hogg	0	0.0%
Jim Wells	13	7.1%
Kenedy	0	0.0%
Kleberg	6	3.3%
Starr	0	0.0%
Webb	40	22.0%
Willacy	1	0.5%
Zapata	0	0.0%
Missing	2	-
Sex		
Male	56	30.9%
Female	125	69.1%

Missing	3	-
Age		
18-34	22	12.1%
35-44	28	15.4%
45-54	65	35.7%
55-64	51	28.0%
65+	16	8.8%
Missing	2	-
Ethnicity		
Hispanic/Latino	174	97.2%
Non-Hispanic/Non-Latino	5	2.8%
Missing	5	
Primary Language		
English	77	43.5%
Spanish	87	49.2%
English and Spanish	11	6.2%
Other	2	1.1%
Missing	7	-
Education		
Less than a high school diploma	92	52.9%
High school degree or equivalent (e.g., GED)	37	21.3%
Some college, junior college, or vocational school	32	18.4%
College degree or more	13	7.5%
Missing	10	
Health Insurance		
None	103	58.9%
Medicare	23	13.1%
Medicaid, Medical Assistance	22	12.6%
Private	12	6.9%
Medicare and Medicaid	1	0.6%
Indigent	1	0.6%
Other	13	7.4%
Missing	9	

**One participant declined to complete the voluntary survey but did participate in the focus group session.*

As noted, the primary focus of the interviews and focus groups was to inform each subgrantees' specific evaluation study. Qualitative data analysis for each subgrantee study used a grounded theory approach. For the summative interviews, two trained team members – who did not conduct the interviews – initially reviewed transcripts for each individual subgrantee study to develop a mutually-agreed upon codebook for that study. They then independently coded each transcript for themes specific to that subgrantee

study 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 (kappa scores ranged in subgrantee studies from 0.62 to 0.98, with a mean kappa of 0.87). Differences were reconciled through discussion, and themes were identified by discussion frequency and intensity.

Mid-point interviews were coded using NVivo software by one coder using detailed notes, a slight deviation from the SEP. 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.

This overarching implementation evaluation utilizes the pooled qualitative dataset conducted for each subgrantee study. Given the focus on adoption facilitators and barriers in this report, most of the findings discussed here derive from the interview data. For this overarching report, coding from subgrantee-level analyses was used to identify the cross-cutting themes that were prominent among most or all subgrantees and would warrant further coding. One team member – who did not conduct the interviews – initially reviewed individual subgrantee final reports to develop a preliminary overarching codebook. Selected codes were those where four or more subgrantees were represented. These codes included communication, clinic or physical space, and training as adoption facilitators; communication and data systems as adoption barriers; and services added or adapted for program fidelity. When examining partnerships and organizational connectedness, this threshold was relaxed because only three subgrantees included partners as part of their IBH models. Once the codebook was finalized, two trained team members independently coded summative qualitative data for themes using NVivo qualitative data analysis software; examined and adjudicated coding discrepancies; revised the codebook as necessary; and addressed any coding discrepancies until consensus on the second-level of coding was reached (average kappa=0.94). Differences were reconciled through discussion, and themes were identified by discussion frequency and intensity.

Mid-point data, in the form of interview notes, was incorporated into the overarching report as themes from the summative data collection were synthesized. If qualitative findings changed from mid-point data collection to summative data collection, it is noted. In this report, findings are summarized in narrative descriptions organized by theme with illustrative quotes.

Quantitative Data Collection Methods and Analysis

Implementation data of participant recruitment and practice changes were analyzed. These consist of administrative data related to participant eligibility and recruitment, as well as subgrantee self-reported responses from the Advancing Integrated Mental Health Solutions (AIMS) IBH checklist to assess five core principles of collaborative care (AIM Center, 2011). Since IBH intervention components across the portfolio were different and there was great variation in the implementation data collected across subgrantees, it was not possible to pool more specific implementation data across all eight subgrantees.

As noted earlier in the report, there is one significant deviation from the SEP in the methods used to answer the implementation question #5 about organizational connectedness. In the SEP, the evaluation included a survey with subgrantees in order to conduct a social network analysis (SNA) to answer the implementation question: “How have organizational partnerships and connectedness changed over the Sí Texas period between subgrantees and community partners?” The methods and social network analysis

were not conducted as part of the evaluation. Since the SEP was not approved until one year into the program, it was not possible to collect data to capture a true baseline to answer this question. Additionally, there was significant staff turnover across all the subgrantees. Also, the time to complete a survey to produce a SNA would be a large participant burden and was not expected to provide actionable results to MHM or subgrantees. Given these reasons and that the organizational partnership and connectedness question was not a focus of the implementation evaluation, MHM and HRiA decided to eliminate the survey and SNA from the implementation evaluation and instead garnered perceptions of organizational connectedness through summative qualitative interviews. Findings from those interviews are presented in this section.

Implementation Study Findings

The following section discusses the implementation study findings by research question as presented in the SEP.

1. To what extent did the Sí Texas subgrantees reach their intended target population?

Subgrantees had a range of eligibility criteria for their own studies. Any participant who met eligibility criteria and was included in their specific subgrantee evaluation was included in the overarching evaluation. **Table 6** provides a description of the most common eligibility criteria that were consistent across subgrantee sites.

Table 6. Common Eligibility Criteria for Subgrantee Studies

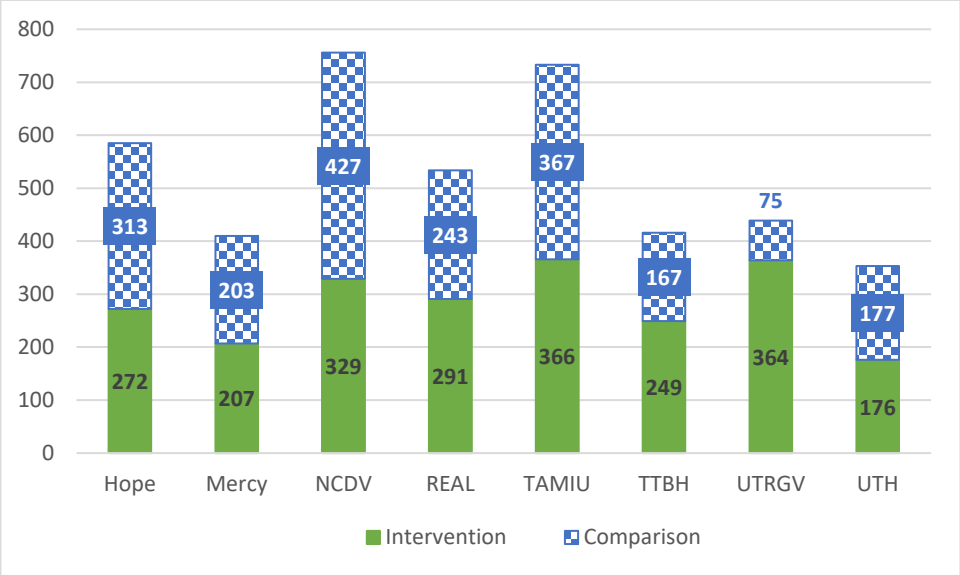
Criterion	Hope	Mercy	NCDV	REAL	TAMIU	TTBH	UTHealth	UTRGV
At least 18 years old	●	●	●	●	●	●	●	●
County								
Cameron	●					●	●	
Hidalgo	●		●			●		
Jim Hogg					●			
Starr	●		●					
Webb					●			
Willacy	●					●	●	
Zapata					●			
Coastal Plains Community Center service area				●				
Have a SPMI/SMI as diagnosed by a licensed behavioral health care provider				●		●		
Have diabetes (HbA1c ≥ 6.5%)			●		●			
Have a diagnosis of one or more chronic conditions:								
Hypertension (Blood Pressure ≥ 140/90)	●	●				●		
Obesity (BMI ≥ 30)	●	●				●		
Poorly controlled diabetes	●[a]	●[b]				●[c]	●[d]	

Hypercholesterolemia (Total cholesterol level ≥200)						●		
Depression	●[e]	●[f]						●[f g]
Anxiety (GAD-7 ≥ 5)		●						●[g]
Medicaid eligible or uninsured	●			●				

[a] HbA1c ≥6.8% [b] HbA1c ≥7.0% [c] HbA1c ≥8.5% [d] HbA1c ≥8.0% [e] PHQ-9 ≥10 [f] PHQ-9 ≥5 [g] This also applies to patients who are judged by the PCP to need behavioral health services according to PCBH model protocols which include meeting score thresholds on the PHQ-9 and/or GAD-7 or presenting with any type of behavioral health issue

Across all studies, 6,458 patients were assessed for eligibility. A total of 2,271 participants were excluded from participation due to not meeting eligibility criteria or ultimately chose not to participate for other reasons. Participant enrollment began at the first subgrantee in November 2015 and ended in April 2017 when the last subgrantee enrolled its final participant. Enrollment totals, by study group, for each subgrantee are presented in **Figure 2**. A total of 4,226 participants comprised the pooled cohort sample, with 2,254 in the intervention group and 1,972 in the comparison, resulting in a sample that aligned with the target population.

Figure 2. Baseline Enrollment by Subgrantee



Note: UTRGV used a comparison group (n=205) that was originally recruited by and partially shared by TTBH. OF those 205 comparison group participants in the URTGV study, 130 of them were also comparison participants in TTBH's study. In the figure above those 130 participants are represented within the TTBH enrollment numbers. The 75 comparison group participants for UTRGV represent those used in UTRGV's study that were not included in TTBH's study.

2. To what extent did the Sí Texas subgrantees implement their projects to fidelity?

a. What were the facilitators and barriers to adoption?

Fidelity to Intended Program

> *"Not major changes, I think more than anything there were adaptations that needed to be based on reality versus theory."* – interviewee, REAL

Overall, subgrantees implemented most of the program components that they originally proposed. However, there were changes along the way due to identified needs of participants or challenges in implementation. Specific programmatic changes to each of the individual subgrantee programs are detailed in the subgrantee's final SIF report. This report discusses the overall themes that were common across the portfolio of subgrantees. Related to fidelity, all eight subgrantees reported making some changes to program services after program initiation, primarily, adding or adapting services during the course of implementation or shifting how staff engage with participants. Types of changes included adaptations in care coordination, group classes, community outreach, roles and responsibilities of providers, and clinic appointments. This section provides more detail on the changes in each of these areas.

In-clinic Care Coordination

> *"I think it [care coordination] didn't happen the way that it was originally set to have happened, but I think that patients did get, for example, behavioral health, or care coordination, or transitional nursing. They just didn't get it in the way that we originally thought it was going to happen, or how it's happening now."* – interviewee, HFHC

Six subgrantees (HFHC, Mercy, NCDV, TAMIU, UTHealth, UTRGV) spoke of adapting how care was coordinated in their setting during the program period. They discussed making changes to the way providers connected participants with other providers and services, such as with behavioral health and pharmacy. With the dynamic nature of health care in general, and the addition of new IBH services, subgrantees shared that they frequently adapted their coordination and workflow to meet the needs of participants and providers. Several subgrantees reported that they had started the program with a vision for participant flow (i.e. routing or mapping) and tools to help staff and providers move participants through, such as a checklist. However, many adaptations were needed in the clinic when an appointment took longer than planned, a participant had a new diagnosis, or needed to see additional providers. As one interviewee explained an adaptation, "*We ended up pairing, having each resident have their own MA, and from there they would kind of go down the [check]list and have more communication with them and say, 'ok, this is this patient, this is the plan. When you go in there, ask this patient this.' Or, a little bit before the visit, the physician would go in to kind of to prepare a little bit more. What we noticed that as there was more communication with the MA, they were kind of more involved, coordinated, and they would assist the patient and the physician to kind of make the clinic flow run better"* (UTRGV interviewee). Workflows were continually being re-evaluated during the program period to try to have better care coordination, especially in settings where the IBH changes were dramatically different than subgrantees' standard of care.

Group Classes

> *"You know our struggle with our support groups, and I think you know we've tried a lot of different things, and I think they're very different, in some ways, from what we had envisioned."* – interviewee, UTHealth

Adaptations to group classes were discussed among subgrantees from four sites (Mercy, REAL, NCDV, UTHealth). Subgrantees described changes to how group classes were run or scheduled. For example, several subgrantees shared that the timing of classes shifted to accommodate participants. As one explained, "*Well they started offering classes at night. If they needed, she [the instructor] would stay late or come early depending on the patient's needs*" (Mercy). Scheduling was also discussed about the timing

of classes in relation to each other. For example, if participants were part of multiple classes, changes were made to schedule classes consecutively, which was helpful to facilitate participation. Additionally, subgrantees illustrated other classes or topics that were added after initial program implementation. One subgrantee shared that they solicited feedback after each class and adjusted future topics based on how participants were doing clinically and what they would benefit most from learning going forward.

Activities related to Participant and Community Engagement

> *"I think that the ability to be individual, small group, or large group. Having lots of ways to reach the individual and it really was on their comfort level at different times throughout the life of being in the program. We saw some people that really are not comfortable to be in a large group. They are just simply not going to do it. So, shifting and still being able to reach out to them with some health information by having an individual meeting."* – interviewee, REAL

Five subgrantees (REAL, NCDV, TAMIU, UTHealth, UTRGV) described adaptations to community outreach activities that were part of their IBH programs. They recounted changes to how community engagement and outreach were structured, including transportation services, peer support, and home visits. For adaptations to transportation services, one subgrantee spoke about changing drivers, routes and pick-up locations to better reach and meet the needs of participants in the program (REAL interviewee). Regarding participant engagement, several subgrantees detailed shifting the roles and responsibilities of promotoras or community health workers to better suit the needs of participants. As one subgrantee explained, "*I think at the beginning they were more like clinic navigators. So, they would go with the patient and walk them through their day, their clinic appointments. But that just wasn't going to be functional at all, so I know there was a shift in that away from clinic navigator toward more peer support. And, now a lot of their role is doing outreach, making patients aware of the services*" (NCDV interviewee). Another subgrantee shared that community health worker roles shifted to home visiting to expand the capacity and reach of the services provided in the clinical settings. Further, one program described "floating" pharmacists who collaborated with promotoras to reach participants. "*We did of course, you know, try to adapt our tactics based on what the participant needed like when I started we didn't have a transportation company that we were contracting with to help provide transportation to our participants so they could get to the clinic so we developed a strategy of doing floating pharmacist home visits so we had the floating pharmacists work with the promotoras to try and facilitate these home visits in participants home. And once we were able to find a transportation company to contract with we started to shift it back so now we can offer transportation instead of utilizing the floating pharmacist home visits"* (UTHealth interviewee).

Roles and Responsibilities of Providers

> *"Well, one of the biggest changes was we didn't end up using those community resources anywhere near the extent that we thought we would be because of [name] and her unique credentials. And the fact that we had a psychologist who was also a pastoral counselor and also a hospital chaplain. She has credentials in all three areas."* – interviewee, Mercy

Among six subgrantees (Mercy, NCDV, TAMIU, TTBH, UTHealth, UTRGV), there were adaptations to providers' roles and responsibilities from what was originally planned for their IBH models. As subgrantees described, these shifts were due to hiring of new staff, building skills and capacity of existing staff, or recognizing that staff already had skills that went beyond their current role. For example, one subgrantee detailed shifting nutrition education responsibilities from a case manager to a nutritionist. While the case

manager had been providing some basic nutrition information, participants in the Sí Texas program also visited a nutritionist. Conversations between these two staff resulted in switching all nutrition-related counseling to the nutritionist who had greater expertise related to nutrition, while the case manager took on more counseling related to exercise. Another subgrantee shared that an LPC (licensed professional counselor) had a unique skill set that obviated a need for another provider. The subgrantee had planned on referring out to community resources and providers for behavioral health care, but the existing LPC was trained in psychology, as well as pastoral counseling and hospital chaplaincy, thus filling the needs of the clinic internally.

Clinic Appointments

> *"So, another thing that we changed to do in conjunction with the home visits was to extend the clinic hours so that participants had more opportunity to come into the clinic."*
> – interviewee, UTHealth

Five subgrantees (HFHC, Mercy, NCDV, TAMIU, UTHealth) described changes in how and when clinic appointments were scheduled. According to subgrantees, most clinics and partners made changes to clinic schedules and hours to accommodate participants coming in for services. For example, a main tenet of several programs was to be a "one-stop shop" for care. With this integration of services, appointments across different providers were more intentionally scheduled in relation to each other. A result was that participants often had multiple appointments on the same day with different providers, explained subgrantees. Other subgrantees revised their scheduling practices to a different format, depending on the preference of participants. In some instances, subgrantees extended clinic hours or provided weekend appointments. As one interviewee noted, "*Some patients were working and wanted to be seen either before normal working hours or after normal working hours. We did all of that. So those that wanted to be seen before or after normal hours, we saw. We accommodated those. So, I'd like to say that we really bent over backwards to see those who wanted to be seen*" (UTHealth interviewee).

One subgrantee highlighted their realization of the need to change their scheduling practices, "*Initially we thought it would be so easy to get patients to come in and see everybody. Every appointment they're going to see everybody, no matter what. But then we would see that on the days that we are very busy, or we have a physician that comes in and sees 40 patients, it's impossible for those patients to get seen by all of those because we don't have the rooms, we don't have the facilities, we don't have the capacity. And so, we've had to make adjustments in that sense"* (HFHC interviewee). In this instance, the subgrantee made adjustments to start conducting brief therapy check-ins in addition to phone follow-ups to accommodate physicians' and participants' busy schedules.

Adoption Facilitators

At the mid-point of the program, interviewees cited several adoption facilitators, including staff and provider training, participant access to multiple services, communication and coordination, and clinic space. Many of these remained the same at the end of the program, as interviewees described communication and coordination and clinic space as key factors that helped support their success. Additionally, in the end-point discussions, interviewees also noted that staff training was an important factor that facilitated implementation. This section provides more detail on each of these.

Communication

Across all subgrantees, communication was the primary adoption facilitator discussed during interviews. Several modes of communication were described, including in-person, leadership meetings, phone, data systems, and other forms of electronic communication.

In-person Communication
In-person communication, noted as a key adoption facilitator, was important across multiple parties, including between 1) providers and staff, 2) providers and participants, and 3) subgrantees and their program partners.

In-Person Provider-Staff Communication
Among providers and staff, in-person communication facilitated program adoption and happened through huddles and provider and staff meetings.

Huddles

> *"What are some of the things that have really helped make it [communication] work? I think the presence of [the providers from] counseling during the medical huddles in the mornings … that's really made a difference. There's just so much ease now to talk to each other and actually communicate."* – interviewee, HFHC

Four subgrantees (HFHC, NCDV, UTHealth, UTRGV) spoke of team huddles as impromptu or regularly scheduled opportunities to discuss and review participant cases and integration of services. According to interviewees, huddles occurred once or twice per day or week, and consisted of a less formal gathering of staff and providers compared to team meetings. Huddles focused on coordinating operations and discussing specific participants. Subgrantees shared that huddles allowed administrative staff and providers from both primary care and behavioral health the opportunity to interact together in order to get a holistic picture of a participant (i.e., the current status of a participant's health and treatment plan as well as administrative data on scheduling and referrals). While the previous examples discuss huddles as mainly consisting of clinical staff, one subgrantee (NCDV interviewee) specifically highlighted frequent, brief implementation team huddles that consisted of non-clinical staff, the purpose of which was to strategize on workflow.

Staff and Provider Meetings

> *"I think what worked really well was involving the doctors that were providing these services, with behavioral health, and the pharmacy. Having them in the same room, talking about the same patients, worked."* – interviewee, UTHealth

> "*I think convening of the advisory work group on a regular basis assisted in staying clear and adhering to the implementation as it's envisioned. It really served as the sounding board of what staff were seeing out in the community."* – interviewee, REAL

All subgrantees discussed staff and provider meetings as a form of communication that facilitated program implementation. Similar to huddles discussed previously among subgrantees at clinical sites (NCDV, UTRGV, TTBH, Mercy, HFHC), these staff-provider meetings were described as more formal and were regularly scheduled weekly or monthly gatherings of staff and providers to develop, discuss and/or

revise care plans for participants, work through implementation challenges, and discuss performance improvement. As one subgrantee explained, *"There are the clinical staffings that we've implemented involving staff and the clinicians from the two different disciplines [primary care and behavioral health]. Those are at least monthly where they get together, and they discuss cases and share information about treatment approaches so that they can tailor their treatment or customize their treatment to address the whole person"* (TTBH interviewee). Several subgrantees talked about using provider and staff meetings to review participant lists for the week to discuss the needs of each participant and coordinate care across providers. Others shared that having initial weekly meetings to talk about early program implementation challenges and brainstorm solutions helped refine implementation, "*especially at the beginning because the implementation was a lot of coordination with a lot of different people and departments and sites*" (UTRGV interviewee).

<u>In-Person Provider-Participant Communication</u>

> *"What worked well running the program? I guess the communication with the patients, meeting them, involving them in participating because I love talking to them and I missed that. Just talking to the patients, having that one to one with them, and just emphasizing the importance of them taking care of themselves, of them attending to the appointments that they had."* – interviewee, Mercy

Interviewees from all eight subgrantees (HFHC, Mercy, NCDV, REAL, TAMIU, TTBH, UTHealth, UTRGV) described in-person communication between providers and participants as greatly supporting program adoption. Provider-participant in-person communication was viewed as a key factor in helping providers to a) explain the IBH program to participants, b) communicate how participants should orient themselves within the clinic space, c) deliver primary care and/or behavioral health, and d) provide referrals or warm hand-offs.

Having providers explain the IBH program to the participants was perceived as facilitating the provider-participant relationship as well as participant buy-in and compliance with the program. As one interviewee explained, *"The program was explained well to the patient from the beginning. That they know they're in this program and they know they're gonna see all of us providers."* (HFHC interviewee) Another interviewee shared a participant encounter, stating, *"And, you know, one of the things, these last couple of times that I've seen him, even if I go in just to say hello to see how he's doing without actually having a formal consult, you know he just cannot say enough good things about how much he enjoys coming to the clinic." (*UTRGV interviewee)

Subgrantees also talked about provider-participant communication as helping the participant know where to go in the clinic to receive IBH services. For example, one interviewee shared "*I'm telling a patient, 'Somebody else needs to speak to you. Ok, do you mind staying here in the room, or do you mind staying over here in the little lobby while they come get you.' Whereas before we would just dismiss the patient to the front, and we wouldn't get a chance to even view where the patient was, and some of them would just leave*." (HFHC interviewee)

In-person communication between providers and participants was also described as a critical facilitator for delivering care. For example, one interviewee explained that because of a participant's relationship and open communication with her provider "*She was also able to speak to the doctor regarding her drinking, how it was gonna affect her health, how it was affecting her health*." (TTBH interviewee). Another interviewee emphasized this, "*My rapport and communication with the clients has helped me out*

a bit because I feel that some of them may feel more comfortable with me so they're a bit more receptive coming into group session" (UTHealth interviewee).

Finally, provider-participant interactions were also seen as facilitating referrals, both internally (e.g., warm hand-offs) and externally to community providers and programs. *"So, you know the MD can now go and ask for assistance. They can ask for help with a patient and make the introduction. They will introduce the behavioral health person to the patient and say, 'okay ma'am, so and so is going to talk to you."* (NCDV interviewee)

In-Person Subgrantee-Program Partner Communication

> *"We're improving communication among agencies, community agencies, because through this program now, even though we've worked with all of these agencies in the past, now, because we're meeting and because of this partnership, we've been able to identify the individuals in the specific agencies that I can always just pick up the phone or they can stop by and see me."* – interviewee, TAMIU
>
> *"Having these meetings be face to face, so being able to see the person that you're working with and emailing with, really helps the relationship and it also I think, it like encouraged brainstorming on how to tackle the different challenges that would pop up. So, I think those meetings were super important and super helpful.* – interviewee, UTHealth

Three subgrantee interventions (TAMIU, UTHealth, REAL) involved a range of program partners for implementation. In interviews, these subgrantees and their partners talked of the importance of having frequent in-person interactions throughout the course of program implementation. The structure and content of meetings looked somewhat different for these subgrantees who had external program partners. Partnership or advisory group meetings were held on a regular basis to discuss overall program updates, check in on implementation progress, and share information about programs and services. These three subgrantees explained that partner meetings were an opportunity to "*discuss the challenges they face and troubleshoot any issues that they're having."* Two subgrantees (TAMIU, REAL) also spoke of holding partner meetings to plan for events or to debrief after an event occurred in order to improve their collaboration moving forward.

Communication at the start of the programs was noted as critical as partners sought to understand the programs' goals and all parties' roles and responsibilities for implementation. Interviewees acknowledged that partner organizations were all at different phases of understanding IBH as well as different levels of capacity to implement an IBH model. Thus, weekly or monthly partner meetings to *"really work on creating connections amongst the agencies"* supported the creation and maintenance of strong partnerships. Partners also discussed how in-person communication was critical when implementation challenges arose. Meeting face-to-face *"when there were roadblocks was key. They all came together, discussed [the challenges] and said, 'This is important for our community. We have to find a way to do it together.'"* (TAMIU interviewee). According to subgrantees, in-person communication also helped solidify connections between program partners, which would help with sustainability after program implementation concluded. For example, one subgrantee talked about facilitating conversations to build a relationship between two programs, but then stepping back toward the end of program implementation, allowing the two programs to build on the trust that had been established.

Leadership Communication to Providers and Staff

> *"We have a strong leader who also a shared mode of leadership with a team-based approach … and it's working, it's working again. We've got everyone on board."* – interviewee, HFHC

In addition to regular meetings between program staff and providers, various forms of leadership communication to staff and providers, including leadership meetings, were seen as facilitating program implementation among six subgrantees (Mercy, TAMIU, UTRGV, HFHC, TTBH, REAL). Leadership communication early in implementation was critically important, according to subgrantees. An "open-door" leadership style was noted as especially helpful for implementation. As staff learned about IBH and took on new roles and responsibilities, they appreciated strong and consistent communication from their administrative and clinical leadership.

> "*I think that [leadership communication] was very important for the staff, and I think the same thing occurred there, presentations were made so that the staff understood the integration, the program. And I think that was a contributing factor to the success of implementing it,"* explained one subgrantee (NCDV).

Leadership communication with providers was specifically emphasized as facilitating provider buy-in to the IBH program. A primary form of leadership communication was meetings, particularly with providers. These meetings were in-person gatherings involving providers as well as program staff and organizational leadership and focused on program implementation and integration of services. As one subgrantee explained, "*She [program leader] did a lot of that, working with the staff and allowing them to ask questions and any clarifications. She gave presentations to our board as well"* (Mercy). To reinforce in-person leadership meetings, interviewees also discussed leadership communication via email as being helpful to further communicate about program updates and administrative issues.

Telephone Communication with Participants

> *"The patient would get texts and calls saying, 'Are you going to be able to confirm your appointment for tomorrow at whenever time?' That was helpful."* – interviewee, HFHC

Four subgrantees (HFHC, UTHealth, TAMIU, REAL) shared that communication with participants via telephone – both calling and texting – facilitated implementation of their IBH programs. Telephone calls were specifically mentioned both in the recruitment phase as well as retention. For subgrantees whose IBH interventions involved multiple services and/or multiple partners, scheduling and reminder calls and texts to participants were important for coordination.

For one subgrantee (TAMIU), participant compliance was a primary goal of their IBH work, and phone calls were a critical component of the intervention from the implementation side as well as important for the participant to feel that they were connected to care. "*So, we were essentially conducting reminder phone calls, not just for primary care appointments but also for other appointments that they would have, which is challenging because there are some individuals who have more appointments than others and we had to really think about how to sort of approach that in a way where we were going beyond the normal, you get a phone call forty-eight hours before or twenty-four hours before your appointment by some automated system or something like that, and really give the client or the patient the sense that somebody*

is looking out for their treatment and sort of giving them that extra reminder to say, 'You have some stuff coming up and we're here to remind you about that.'"

Electronic communication

> *"They started to really talk to each other and understand that they could communicate with each other twenty-four hours a day if they needed to… The doctors could IM each other, you know."* – interviewee, TTBH

> "*I try to make it a point to email them [program partner] pretty regularly to make sure everything is on track."* – interviewee, UTHealth

Six subgrantees (NCDV, TTBH, HFHC, UTHealth, REAL, Mercy) indicated that electronic communication facilitated program adoption. These forms of communication included email and instant messaging between providers and staff. While data systems, e.g., EMRs, represent a form of electronic communication, they are discussed more extensively below. The mode of preferred electronic communication varied by subgrantee, depending on the timing of communication and the technological capacity of the site. Emails were used for less time-sensitive communication to do advanced planning and to have communication in writing, according to subgrantees. For example, after seeing a participant, one provider might email another to communicate that a referral was made and to convey critical participant information more directly than only entering it into the participant's EMR. As one interviewee explained, "*She [behavioral health provider] will email me if she feels that I need to pay special attention to a patient before an appointment.*" (NCDV interviewee) Additionally, subgrantees with program partners (UTHealth, REAL) indicated that they communicated regularly via email in order to have written documentation of the process. Email was also as a primary communication mechanism with external partners, as subgrantees and partners were not necessarily on the same internal communication system (E.g., such as intraoffice instant messaging). Texting and instant messaging (IM) were also mentioned as frequent modes of electronic communication between staff, most often used for impromptu requests and questions between staff and providers. Subgrantees described this mode of communication as "*quick and very convenient during our busy days*." For example, if a primary care provider is seeing a participant who needs immediate behavioral health care, the provider may send a text or IM to the behavioral health provider to come see the participant. One subgrantee (TTBH interviewee) also shared that they would use IM with their finance department to follow up on participants' administrative or financial issues.

Data Systems as a Communication Mechanism

> *"We put alerts in [the EMR] and they'll reroute and say, 'I've got a client that you'll want to see,' and then they'll come get him or we'll bring him over. I think that interaction is really good."* – interviewee, TTBH

> *"I'm looking at [our database] and I'll pull up a patient. I'll see when we last saw her and why we saw her that last time. I'll look at the notes from the doctor, if she had a follow-up, and for what. I can see all of that in Access."* – interviewee, HFHC

Interviewees from all eight subgrantees spoke about how the use of electronic medical records (EMRs) or other data systems (e.g., Access or Excel files) facilitated communication between staff/providers so that they could more effectively coordinate services. Examples of data systems as a communication mechanism included viewing participant notes from other members of the care team, identifying or

flagging areas to address with participants, and/or using the electronic scheduling function to coordinate services. Interviewees described how their data systems gave providers and staff access to participant data alongside provider notes, which streamlined their work. Having a data system also provided better continuity of care, according to subgrantees, as several shared that one provider could leave a note for another to follow up on. This was seen as a critical facilitator of coordination, as both primary care and behavioral health were using one integrated system, and thus able to communicate effectively with each other. As one interviewee explained, "*The doctor will send the orders and I go in and talk to the patient about this. Mostly all of that goes through the EMR."* (NCDV interviewee) Several subgrantees also had data systems with electronic scheduling functions, which allowed not only for improved communication between providers but also better coordination of services. For example, providers and staff could see when participants were scheduled to be in the clinic and could cluster appointments.

Subgrantees with external program partners described a different use for their data systems – monitoring and tracking program performance among partners. "*We had monthly reports that we put together that they submitted to us where they reported their performance – the number of visits, the number of clients they were seeing, how many of them were unduplicated, how well they were doing with their six-month and twelve-month follow-up," explained one subgrantee* (TAMIU interviewee).

Workflow and Use of Physical Space

All eight subgrantees described physical space and how was used as a facilitator to program implementation. Interviewees primarily spoke about physical space in two ways – adaptations to physical space and workflow and movement of providers and participants within the physical space. These facets of physical space supported effective implementation of IBH programs as well as participant engagement. As one interviewee summarized, *"And it's better to keep them [patients] in one place cause if you're sending them out, they're not gonna go, they're, they're not gonna go see their doctor out there. It's better to send them here, just walk them over and there it is"* (TTBH interviewee).

Adaptations to Physical Space

> "*Part of our integrated behavioral health program, part of what we are very adamant about is that we do not segregate behavioral health from all the primary care. [Behavioral health provider] sits along the same hall where all the other providers and all the exam rooms are, [behavioral health provider] sits right there*" – interviewee, UTHealth

Interviewees across five subgrantees (HFHC, Mercy, NCDV, TAMIU, UTHealth) described additions or modifications to the physical space that facilitated integration of services and communication. Examples included co-location of program offices, staff and providers, or creation of new clinic spaces. Interviewees highlighted that the physical co-location of multiple services (primary care, behavioral health, nutrition, care coordination) facilitated adoption of their Sí Texas programs. For example, for several subgrantees, behavioral health providers were located adjacent to or within the primary care section of the clinic, which was seen as facilitating communication and workflow for staff as well as normalizing the integration process for participants. As one interviewee explained, *"One of the things [that changed] that I think helped a lot was my office relocation. I was moved at the beginning of the program to a new area to accommodate the new coworkers since we hired more coworkers on the program. Now I'm next to the clinical area, very near to where the providers are, the primary care providers. I think that was one of the*

major advantages now to be near the providers, they see me more, they ask more questions and I think it is better, much better" (Mercy interviewee).

Additionally, subgrantees talked of making changes to the physical space to better integrate primary care and behavioral health services as well as to provide non-clinical components (e.g. physical activity or nutrition classes) of their Sí Texas programs. For example, at one subgrantee's site, an exam room was repurposed for Sí Texas participants and a small back lobby was created as well. An interviewee explained that "*before when we were starting, we didn't have that patient lobby in the back. And so now that gives us the flexibility where the provider knows this person [in the lobby] needs to see these other providers here"* (HFHC interviewee).

Subgrantees with external program partners (TAMIU, UTHealth) discussed adaptations to physical space between partners. As an example, one partner spoke of shifting services to a different partner's location one day per week to support collaboration between the two partners and facilitate participants' access to services.

Workflow within the Physical Space

> "*We don't want to interrupt the flow of the doctor. The fact that they [providers such as licensed professional counselors (LPCs)] have easy access and can find us whenever they need us is important."* – interviewee, NCDV

Similar to the physical setup of the clinic space, interviewees talked about how providers and staff moved within the physical space of the clinic, i.e., workflow. Interviewees indicated that a critical component to program implementation was being intentional about adapting workflows to the space and systems within which the programs were operating. For example, several subgrantees (NCDV, Mercy, HFHC, UTRGV) discussed the process for the warm handoff, a workflow practice in which a primary care provider directly connects the participant with a behavioral health provider, pharmacist, nutritionist or other service when appropriate. While significant changes to workflow were identified to be implemented at the outset of their Sí Texas programs, subgrantees modified their workflow processes throughout the program implementation period to continuously improve quality and efficiency. As one interviewee explained, "*And so we have five rooms here, and the six they use for a hub to house SiTX [patients]. But what had to happen was that we had to figure out who's gonna see which patient when and where. There has had to be a lot of flexibility [in workflow]. It's not going to be the same for every patient*" (HFHC interviewee). An example of one these workflow modifications was adapting the warm handoff from a traditional model (primary care provider introduces participant to behavioral health provider for a longer counseling visit) to more of a brief intervention approach (10-15-minute intervention with potential for longer follow-up). This occurred in two subgrantee sites. According to interviewees, this workflow and service adjustment significantly improved participant wait times and facilitated communication between disciplines (primary care and behavioral health) by freeing up time for providers to collaborate on cases. Another example of a workflow modification was the creation of clinical pathway templates (e.g., a tool to define, standardize, and sequence what happens to a participant who meets a certain cutoff for A1c or PHQ9 score) that assisted frontline providers such as medical assistants to initiate encounters with behavioral health or other service providers. In turn, these workflow enhancements were noted as improving buy-in among providers as clinic flow was made more efficient.

The subgrantees with external program partners (UTHealth, REAL, TAMIU) spoke about workflow both within their partner clinics as well as between agencies. Within the partner clinics of these subgrantees,

warm handoffs and general clinical workflow was described as similar to the other subgrantees above. However, workflow was also discussed relative to collaborating between clinical and non-clinical agencies. Because the intervention was comprised of services across multiple organizations and sites, subgrantee partners explained that workflow adjustments sometimes meant shifting or sharing staff across agencies or referring participants to services within program partners.

Staff/Provider Training

Among all eight subgrantees, staff/provider training prior to and during implementation facilitated subgrantees' IBH work. A variety of training topics were described, including 1) the IBH model and its implementation, 2) skills or knowledge specific to staff/provider roles in IBH implementation, 3) specific health topics, 4) communicating with participants, and 5) data systems.

Training on IBH Model and Implementation

> *"I think during the initial period there were a few things and it was really training and retraining and kind of reinforcing what the goals were."* – interviewee, REAL

> "*So, we had some speakers and some training that came to us, but also sent some of the providers out [to training]. And I was part of that group. And it was an eye-opening experience… because we saw how a well-oiled machine works."* – interviewee, UTRGV

Subgrantees from all eight sites most often described training on their site's IBH model helping to support implementation of the model itself. In-person training was primarily conducted prior to and during early implementation, according to subgrantees. These in-person trainings took several forms, including lectures and interactive role plays and simulations. Subgrantees shared that didactic trainings were common and helpful for providing an overview of the IBH model, including program goals, as well as announcements about program updates, such as staffing changes. One interviewee described pre-implementation role play to practice the new clinical workflow that would be part of their IBH implementation: "*Simulation, yes. We had all of the staff here in the clinical area and we followed the new workflow. This is what is going to happen when the patient is here. This is who is going to be involved in the patient's care and what their patient is going to be doing, how we do the introduction when the primary care sees them, what the needs of the behavioral health provider there. So, we did that actually before we implemented the program so everybody was aware of what was coming and how we were going to do it*" (Mercy interviewee). This type of role play was noted by five subgrantees (Mercy, Hope, NCDV, TTBH, UTRGV) as assisting implementation teams with adjusting existing processes and learning new workflows, as well as building staff cohesion. In general, in-person trainings before and during early implementation were critical for staff and provider buy-in. Virtual trainings were more likely to occur as implementation moved into its later stages. Several subgrantees mentioned participating in webinars or online trainings for continuing education on IBH.

Interviewees also specifically highlighted training that occurred off-site at other clinics and health systems implementing similar IBH models. This "on-the-ground" training and observation was considered helpful in allowing interviewees to see how other clinical sites implement IBH and how it could be applied in the subgrantees' specific settings. "*I think the trainings have helped us, or at least for me it has helped me really connect to where we are now, and really think about sort of the models or the molds that we are*

copying from other sites where these key experts, and having them directly input ideas and trainings for us has been very helpful" (UTRGV interviewee).

Training on Roles and Responsibilities for IBH Implementation

> *"Especially my superiors, they've been the ones that have guided me, instructed me, showed me, this is what might work for my role."* – interviewee, HFHC

> *"Yes, all the outreach workers received training [on] their role, how to make the visits, how to document, how to talk to the person, how to make a home visit, how to do the examinations, how to take the blood pressure, the waist so that we all are doing it uniformly. Generally, we all do the same thing and we do the same thing with everyone. Everyone has received training."* – interviewee, UTHealth

Similar to training on the IBH model and its implementation, six subgrantees (HFHC, NCDV, REAL, UTHealth, TAMIU, UTRGV) also talked of training prior to or during implementation that they perceived as strengthening their skills, knowledge and/or capacity to carry out their IBH roles. Topics mentioned included clarifying responsibilities related to their role, for example conducting home visits or executing warm handoffs. Clarification of roles was particularly important if staff had been on board before the IBH program and were transitioning to have different responsibilities as part of the program. For example, one interviewee recalled training for primary care providers to help them make better use of behavioral health providers: "*I guess the real meat and potatoes of it is the actual clinic training, the on, hands-on training, when they have the opportunity to shadow… where they sit in and actively follow the BHCs into a room to learn how to use them*" (UTRGV interviewee). Training on IBH roles was primarily delivered in-person in a group setting or one-on-one trainings between a supervisor and supervisee, according to subgrantees.

Trainings on Communicating with Participants

> *"Yes, a lot of trainings. Especially for the promotora trainings, those have been very helpful for me because like I stated before, I'm not really good at public speaking so that has actually gotten me out of my comfort zone and it has actually helped me communicate and be more open with my participants, so I think that has been one of the biggest things with the trainings."* – interviewee, NCDV

While subgrantees reported learning new content to discuss with participants, they also received training on how to communicate with participants. Five subgrantees (REAL, NCDV, TAMIU, UTHealth, UTRGV) shared that they participated in in-person (group and individual) training that built and supported their skills and capacity to communicate with participants in their IBH programs. One topic specified was communicating with participants about IBH and its benefits. Interviewees also mentioned training on tailoring communication styles and content for participant comfort, needs, and health status; for example, how to speak to a participant with SPMI. As an interviewee explained, "*This next topic that were going to be talking about is how the BHC and the primary care provider along with the nursing staff can deal with a patient who has complex or resistant medical decisions*" (NCDV interviewee). Finally, subgrantees described training on the process of motivational interviewing, which helped them meet participants where they were and "*get a better response out of the patient*." The trainings *"have taught us to key in on the different ways patients express themselves and for us to think differently to help them"* (UTRGV interviewee).

Trainings on Specific Health Topics

> *"Many of the outreach workers also lack a great deal of information about diabetes, we need refresher training, to receive training in what diabetes is, the latest. And provide information to patients based on studies that have been proven to benefit the people. Yes, we all go through a series of- every year, in general, we have refresher training."* – interviewee, UTHealth

In addition to training on the IBH model and how to implement it, interviewees from four subgrantees (NCDV, TAMIU, UTHealth, UTRGV) also discussed training that they perceived as strengthening their skills, knowledge and/or capacity to discuss health topics with participants. Interviewees discussed online and in-person training on a variety of health topics, including upstream social determinants of health as well as downstream health outcomes. As one interviewee shared, "*They've helped a lot. Mental health, diabetes, Zika, things that patients need to know, medication, anything that has to do with health. Even the exercise focus area, health issues, dieticians. Yeah everything, we've received several trainings*" (NCDV interviewee). Several interviewees with behavioral health roles talked about receiving training on primary care topics and, similarly, primary care providers receiving behavioral health training. As one interviewee explained, "*I took a lot of different types of trainings specifically geared towards primary care because, as I've said before, it was very separate, they were two different entities so kind of combining them. Myself, learning about different medical conditions, being aware of that, and how we can make behavior changes has really helped me in my role because otherwise I wouldn't feel confident to say hey we need to make behavior changes about diabetes and this is what it is and this is how we change it because I wouldn't feel confident enough but the trainings have really helped be able to talk about them* (NCDV interviewee). According to interviewees, this increased knowledge not only facilitated provider and staff communication with participants but also increased integration across the two disciplines as they each learned more about the expertise of the other.

Trainings on Data Systems

> *"I think that worked really well was training them on the data tools, training them with what's happening with data sharing, building that capacity. Even understanding that these are the things that you use, we created training manuals and all that. And I think that really helped."* – interviewee, REAL

Four subgrantees (REAL, NCDV, TAMIU, UTHealth), primarily those with program partners, described trainings related to their IBH data systems, which they believed helped in their program implementation. Data system-related training topics included data entry, navigation of an integrated system, data sharing or transfer between partner agencies, and using program data for quality improvement. As one interviewee explained, "*Well they always also give us training on the database. We put the information in the database. They run the analysis. They look at these results; if they don't agree, we want to check what's happening - are we not collecting all the information or not in the right way? So then comes more training to say,' let's see how we are doing that, should it be done in such-and-such a way,' and they go about finding little things that are not being done very well, to see what we are going to improve"* (UTHealth interviewee).

Adoption Barriers

At the mid-point and end-point of program implementation, interviewees across subgrantees cited several adoption challenges, which mainly focused around issues with communication and challenges with data systems. This section provides a deeper dive into the different dimensions of these challenges.

Communication

Although communication was also the most commonly discussed adoption facilitators, across all subgrantees, limited communication was the primary adoption barrier discussed. Communication was discussed related to transitioning to the IBH model, workflow, and program staff/provider roles and responsibilities.

Communication about Transitioning to the IBH Model

> *"We learned that we have to get the people that are going to be involved in the program, need to be brought on board from day 1. There need to be open lines of communication regarding what the program is all about, what our goals are, how the staff are going to have to make some changes. You're going to have to redesign some of your processes. It's going to be a work in progress."* – interviewee, NCDV

All eight subgrantees described communication barriers related to transitioning to their IBH model. Communication was described as critical to helping the subgrantees develop buy-in for their IBH programs (i.e., embracing new practices and culture, and integrating behavioral health and primary care components of the IBH model). For example, one interviewee shared, "*It's very hard to do something in the clinic and not have everyone understanding what's happening and why. There is nothing worse than 'you all made a change, but you didn't tell us'"* (Mercy interviewee). Interviewees talked about how staffing played into this. With new staff coming on board and existing staff transitioning to new roles and responsibilities, subgrantees noted that limited communication around their shared goals created some tension between staff that impeded implementation. For example, several subgrantees spoke about the entrenched traditions of operating in siloes in which some staff and providers did not want to adopt integrated care. There was a need for consistent communication early and often to reinforce the purpose of IBH and how each team member contributed. As one interviewee explained, "*Because they were viewing themselves like, we're behavioral health, y'all are primary care. You know, you [primary care] are on that side of the building, we [behavioral health] are on this side of the building. So, you know, physically you're separated so mentally you're feeling like I don't belong over there, I don't have to think about that part. And so, it started to be apparent that we needed to do something"* (TTBH interviewee). Interviewees noted that having clearer communication among all parties involved early on would have helped garner more support for the program at the beginning and facilitated implementation roll-out.

Communication related to Workflow Changes

> *"What I'm really talking about is some lack of communication at the beginning where it just didn't seem as connected or as seamless as it should be for the participant. One of the struggles that we had at the beginning, I would say, was communicating about the flow."* – interviewee, UTHealth

Interviewees from all eight subgrantees discussed communication challenges related to workflow as a challenge to implementing their IBH program. While some subgrantees shared that they needed more

communication during early implementation as they learned new workflows, others described challenges related to communication even when the program was underway. Sometimes workflow changes were made mid-way through implementation, but these were not always communicated to all necessary staff and providers. For example, many subgrantees' programs involved new ways in which staff, providers, and participants moved within the clinic: "*[It was] challenging trying to educate different staff in the clinic about the different change in movement because it had to change radically… whether it was incorporating us and calling patients and incorporating us into their flow and medical records*" (NCDV interviewee).

Subgrantees with external program partners spoke about increased communication challenges related to workflow. Issues related to coordination, communication, and workflow were challenging to address within subgrantee sites; addressing these with their external partners was an even a greater challenge. One subgrantee explained, *"The whole process has had challenges and accomplishments. It took a long time to iron out workflow with all the clinics, etc. It can be difficult to work with so many different partners … every partner plays a different role. There has also been a delay in providing services"* (UTHealth interviewee). Another interviewee reinforced this saying, *"We have had to work quite a bit with the entities [partners] to ensure that they're more coordinated, not only amongst the different partners, but also within their organization. We have found that patients get lost quite often in our two largest entities, and I really think it just has to do with that they're so large, and they continue to grow. It's difficult for them to maintain that constant communication"* (TAMIU interviewee).

Communication about Roles and Responsibilities

> *"The first behavioral specialist was here, and he was doing a great job. Then he was moved to another position and [name] came in. They weren't communicating that well, and so she didn't know what her role actually was."* – interviewee, HFHC

Seven subgrantees (HFHC, Mercy, NCDV, TAMIU, TTBH, UTHealth, UTRGV) shared that limited communication from program and clinic leadership regarding staff and provider roles and responsibilities hindered implementation at the program outset as well as throughout the implementation period. Some staff and providers stayed in the same roles prior to and during IBH program implementation, but their responsibilities changed, while others were new to the program and their role. Several subgrantees noted that these changes were not as clearly communicated as they should have been, given the new context within which they were working. As one interviewee explained, "*Communication was a little hard because if you don't know what the left hand is doing, the right hand doesn't know what is going on. So, communication about the new program provided a big challenge at the clinic. Just getting it organized, you know communicating the roles and communicating between the providers.*" (Mercy interviewee).

Staffing changes – hiring and retention – were also discussed, with several subgrantees sharing that it was difficult to keep up with the coming and going of staff, and how that affected others' responsibilities. Overall, interviewees indicated that the lack of clear communication around roles and responsibilities was symptomatic of a larger issue of leadership not communicating the goals of the IBH program. As a subgrantee described, "*No, just introducing the program and having an understanding of the program. I think that was a big challenge because we didn't have that. It was that people were having a little bit of a hard time understanding what it was that we were trying to do."* Among subgrantees with external program partners (TAMIU, UTHealth), interviewees noted the challenges of ensuring all partners knew what their roles were in the program, what other partners were doing, and how they all fit together under one IBH program.

Data Systems

In addition to communication barriers, data systems were a primary challenge discussed across all subgrantees. Data system challenges related to functionality, limited tech support, and communication with providers and partners.

Functionality of Data Systems

> "*There's a complicated set up, the way we had it. It's just the person that built it from the ground up, there's all these queries but there's no descriptions of what the queries are for. In my experience it's just a lot of browsing through them and trying to figure out what's where.*" – interviewee, HFHC

All eight subgrantees described limited functionality of their existing data systems as hampering program implementation. Specific challenges were mentioned related to data entry and sharing, navigating within data systems, and customizing data reports. Regarding data entry and sharing, subgrantees with program partners (REAL, TAMIU, UTHealth) reported not having efficient or effective ways to enter data into one system or to share data across systems. As one interviewee shared, "*There were challenges in the sense of everyone's electronic medical record is different, to say the least. Some programs have electronic medical records that have staff for data entry, and some have electronic medical records that facilitated the extraction of data much easier than others*" (TAMIU interviewee). Navigating data systems was also a perceived challenge. For example, subgrantees spoke of difficulty in finding the notes left by other providers or communicating with other providers through the EMR, particularly between behavioral health and primary care. As one interviewee explained, "*[The data system] is not designed as an integrated product, it actually was designed as a behavioral product. And so, it doesn't have all the typical bells and whistles that a medical EHR would have*" (TTBH interviewee). Interviewees also discussed challenges with their data systems that prevented the creation, generation, or customization of data reports. "*So, they're able to chart in there [data system]. We do have some queries where we can pull results and pull out data, but we don't have the ability to run complex reports. A lot of it is exporting data to Excel and then making the reports there and whatever. It's a little difficult*" (HFHC interviewee). Additionally, one subgrantee was affiliated with several hospitals that designed and controlled their data system. Because the locus of control was above the clinic level, the implementation team had difficulty creating customized data reports. "*At least the clinic I'm in, we can't run any reports, we can't run checks and other things, so that way we're sort of behind. I can't do basic quality improvement work as quickly as I want to*" (UTRGV interviewee).

Limited Tech Support

> *"Not every clinic is going to have that skill set. They might have an IT department, they might have a support person for their EMR, but not necessarily."* – interviewee, UTHealth

Seven subgrantees (HFHC, Mercy, REAL, NCDV, TAMIU, UTHealth, UTRGV) reported having limited technical assistance in implementation or use of their data systems. For most subgrantee sites, there was a new data system, or a new component of a system developed for their IBH implementation. As one interviewee explained, *"I do see a need for support for this new system. When we ask staff to run a report or pull data to make sure they understand what they are pulling and why and the right parameters and that sort of thing. I can't say specifically but I remember once seeing some data and thinking that doesn't*

look right. How did they pull it? What were they pulling? That kind of thing" (NCDV interviewee). Technological capacity varied widely among subgrantees. While some had data system experts on their teams, other subgrantees had to work on building competency among existing administrative and clinical staff. Across most subgrantees, however, interviewees spoke of limited tech support and a steep learning curve at the outset of implementation and throughout their programs. "*I would say that [specific data system named] was probably the most challenging platform to work with because it was new to the pharmacist, there was some lag time in getting them up to speed to use the program but it still came with issues that they had to work through that we are still working through today*" (UTHealth interviewee).

Health Information Sharing

> *"For example, say you come in as a patient and I want to know if you saw the behavioral specialist. I would have to be searching in Epic to see if that person has attended the sessions with behavioral health… Sometimes I would have to search to see what the last time this patient came in was."* – interviewee, Mercy

Four subgrantees (Mercy, REAL, TAMIU, UTHealth) talked of their existing data systems creating barriers to communication with other providers and partners. For example, within a clinical setting, several interviewees told of challenges finding information on whether a participant saw another provider or partner. For the subgrantees who had external program partners (REAL, TAMIU, UTHealth), there were unique challenges that impeded communication. Because these subgrantees had both clinical and non-clinical partners, multiple data systems had to be used and navigated. As one interviewee described, *"We need that health information sharing portal to access the medical record quicker and more efficiently to treat the person better. That was one of the original plans, and we couldn't get it off the ground for many reasons"* (TAMIU interviewee). The existence of a shared data system would have helped partners track participants, their referrals, and services received, according to subgrantees.

3. To what extent did the Sí Texas subgrantee sites improve their level of integrated behavioral health during the period of the Sí Texas initiative?
   a. What components of integrated behavioral health were most successfully achieved, and which were not?

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." For analytic purposes, those marked "None," were coded with a value of 0, those marked "Some," were coded with a value of 1, and those marked "Most/all" were coded with a value of 2. The values were then averaged across all of the clinics.

Subgrantees completed the AIMS IBH checklist prior to implementing their program and then after study completion. Each subgrantee completed one AIMS IBH checklist per site. Therefore, those subgrantees with multiple settings or clinics had each setting or clinic complete its own checklist. Data are self-reported. **Table 7** and **Table 8** present subgrantees' pooled data from these assessments. None of the differences between baseline and follow-up are statistically significant, which is not necessarily surprising given the small sample size. However, ratings on all principles, core components, and tasks increased from baseline to follow-up.

Principles related to Evidence Based Care and Patient-Centered Care had the highest averages at 12 months, but also had high ratings at baseline. When looking at improvements over time, those principles with a large increase from baseline to follow-up and the smallest p-values (p=.13) were related to Population-Based Care and Measurement-Based Treatment to Target. The principle around Accountable Care (providers are accountable and reimbursed for quality care and outcomes) continues to be related the lowest among subgrantees.

Several core principles and components were rated as being applied to most or all of patients by nearly all of the clinics at twelve months and had an average score greater than 1.90. The core principles that were the highest on average were patient-centered care (1.91) and evidence-based care (2.00). These principles were also ranked the highest on average at baseline. Two patient identification and diagnosis components ("screen for behavioral health problems using valid instruments" and "use valid measurement tools to assess and document baseline symptom severity") had an average score of 1.91, though they started with a 1.80 average score at baseline. One of the engagements in integrated care program components ("introduce collaborative care team and engage patient in integrated care program") had an average score of 1.91 at twelve months, starting with a score of 1.70 at baseline. One of the evidence-based treatment components ("provide patient and family education about symptoms, treatments, and self-management skills") also had an average score of 1.91, starting at 1.40 at baseline. Lastly, one of the program oversight and quality improvement components ("provide clinical support and supervision") had an average score of 1.91, starting at an average score of 1.30 at baseline.

For core components and tasks, providing clinical support and supervision for program under the Program Oversight and Quality Improvement domain was the component that had the biggest improvement from baseline (1.30 to follow-up (1.91) which was marginally significant (p=0.06), indicating that this component was reported as being implemented among most/all subgrantee program participants. Several other components and tasks were rated highly at follow-up—noting that they were completed with most/all patients. However, these also were rated high at baseline. These highly rated components included: screen for behavioral health problems using valid instruments; use valid measurement tools to assess and document baseline symptom severity; introduce collaborative care team and engage patient in integrated care program; and provide patient and family education about symptoms, treatments, and self-management skills.

Other components that saw somewhat of a change from baseline to follow-up (p=0.13) of being implemented during the program period were develop and regularly update a biopsychosocial treatment plan, provide patient and family education about symptoms, treatments, and self-management skills, and monitor treatment response at each contact with valid outcome measures.

Table 7. Aggregate Clinic IBH Checklist Baseline to 12 months: Core Principles

We apply this principle in the care of (none, some, most/all) of our patients.	Baseline N=10 Mean	Twelve Month N=11 Mean	p-value
Patient-Centered Care Primary care and behavioral health providers collaborate effectively using shared care plans.	1.50	1.91	0.27
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.	0.80	1.36	0.13
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.	1.10	1.73	0.13
Evidence-Based Care Patients are offered treatments for which there is credible research evidence to support their efficacy in treating the target condition.	1.70	2.00	0.25
Accountable Care Providers are accountable and reimbursed for quality care and outcomes.	0.80	1.00	0.25

Note: The Wilcoxon Signed Rank test was used to examine non-normally distributed data

Table 8. Aggregate 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.	Baseline N=10 Mean	Twelve Month N=11 Mean	p-value
Patient Identification and Diagnosis			
Screen for behavioral health problems using valid instruments	1.80	1.91	0.99
Diagnose behavioral health problems and related conditions	1.60	1.64	0.99
Use valid measurement tools to assess and document baseline symptom severity	1.80	1.91	0.99
Engagement in Integrated Care Program			
Introduce collaborative care team and engage patient in integrated care program	1.70	1.91	0.63
Initiate patient tracking in population-based registry	1.30	1.45	0.50

We apply this principle in the care of (none, some, most/all) our patients.			
	Baseline N=10 Mean	Twelve Month N=11 Mean	p-value
Evidence-Based Treatment			
Develop and regularly update a biopsychosocial treatment plan	1.00	1.64	0.13
Provide patient and family education about symptoms, treatments, and self-management skills	1.40	1.91	0.13
Provide evidence-based counseling (e.g., Motivational Interviewing, Behavioral Activation)	1.40	1.64	0.50
Provide evidence-based psychotherapy (e.g., Problem Solving Treatment, Cognitive Behavior Therapy, Interpersonal Therapy)	1.40	1.55	0.75
Prescribe and manage psychotropic medications as clinically indicated	1.20	1.36	0.99
Change or adjust treatments if patients do not meet treatment targets	1.30	1.73	0.31
Systematic Follow-up, Treatment Adjustment, and Relapse Prevention			
Use population-based registry to systematically follow all patients	1.10	1.36	0.31
Proactively reach out to patients who do not follow-up	1.40	1.55	0.99
Monitor treatment response at each contact with valid outcome measures	1.10	1.64	0.13
Monitor treatment side effects and complications	1.40	1.73	0.50
Identify patients who are not improving to target them for psychiatric consultation and treatment adjustment	1.40	1.73	0.25
Create and support relapse prevention plan when patients are substantially improved	1.30	1.55	0.63
Communication and Care Coordination			
Coordinate and facilitate effective communication among providers	0.70	1.09	0.13
Engage and support family and significant others as clinically appropriate	1.30	1.82	0.25
Facilitate and track referrals to specialty care, social services, and community-based resources	0.80	1.55	0.99
Systematic Psychiatric Case Review and Consultation			
Conduct regular (e.g., weekly) psychiatric caseload review on patients who are not improving	0.70	1.09	0.25
Provide specific recommendations for additional diagnostic work-up, treatment changes, or referrals	1.30	1.82	0.25

We apply this principle in the care of (none, some, most/all) our patients.			
	Baseline N=10 Mean	Twelve Month N=11 Mean	p-value
Provide psychiatric assessments for challenging patients in-person or via telemedicine	0.80	1.55	0.06
Program Oversight and Quality Improvement			
Provide administrative support and supervision for program	1.40	1.82	0.25
Provide clinical support and supervision for program	1.30	1.91	0.06
Routinely examine provider- and program-level outcomes (e.g., clinical outcomes, quality of care, patient satisfaction) and use this information for quality improvement	1.30	1.73	0.38

Note: The Wilcoxon Signed Rank test was used to examine non-normally distributed data

4. How have organizational partnerships and connectedness changed over the Sí Texas period between subgrantees and community partners?

Partnerships and Organizational Connectedness

Three subgrantee interventions (REAL, TAMIU, UTHealth) involved a range of program partners for implementation. In interviews, these subgrantees characterized their partnerships and connectedness with the other IBH program partners. These discussions focused on building or strengthening partnerships, facilitating connectedness of services across organizations, and forming partnerships to fill gaps in services. While other subgrantees did not have formal partnerships as part of their IBH programs, several discussed partnerships in the context of communication with and learning from other subgrantees in the Sí Texas cohort.

Building or Strengthening Partnerships

> *"Partnership is the way to go. That's how most of the grants are out there. That's what most of these people want who are offering these grants, they're looking for partnerships. It helps sustains when the grant is over, it makes sense."* – interviewee, REAL

> *"It was a good model presented by TAMIU proposing it because we were already partners, some more than others — with all the three main partners: SCAN, Gateway Community Health, and Border Region—we've always worked with them. This just formalized a way of partnering which we already did informally and set the groundwork for the future."* – interviewee, TAMIU

Several subgrantees (REAL, TAMIU, UTHealth) discussed partnerships across organizations that were built or strengthened through their involvement in the Sí Texas program. As discussed previously (see Adoption Facilitators - Communication), these subgrantees described building and strengthening of their partnerships through frequent communication as well as through program staff, such as program

managers or navigators, who would act as liaisons to connect directly on the day-to-day activities of program implementation. Although there was regular contact between program staff across agencies, partnership development was primarily described as happening at the leadership level among agencies, particularly at the start of their Sí Texas programs, as well as near the end to provide a unified strategic vision for the future of the program and partnership. One subgrantee described the future for its partnership. "*For the future, what I would encourage them to do is jump in with both feet and just do it. You'll work it out. The main thing is just to make sure whoever your partner is has the same arrows that you do and they're all in the same direction*." (REAL interviewee). Another interviewee described how its Sí Texas partnership has strengthened its agency and the community and created opportunities for sustainability: "*I think Juntos has facilitated the opportunity to implement better behavioral health services and given us the opportunity to discuss options for sustainability, which we've integrated for us. Not only do we use the Juntos resources that allow us to go out and outreach and make sure that persons who aren't in the healthcare system get in, but for our regular [non-Sí Texas] patients, we're using other resources to implement behavioral health"* (TAMIU interviewee).

In addition to sustaining their partnerships, these three subgrantees spoke about partnership development in order to sustain shared initiatives. Capacity-building across agencies, shared resources, and leadership and staff relationships were seen as critical components for sustainability after the Sí Texas program, according to subgrantees. Regarding capacity-building, for example, one subgrantee explained that secondary goals of their Sí Texas program were development of infrastructure and capacity among its partners and clients through engagement efforts (e.g., advisory work group) and training throughout the life of the program. Another subgrantee described sharing resources as a sustainability strategy. "*We'll just do it – we'll move one of our clinic's [staff] once a week to your place so we can make sure that the patients you're seeing are getting the… care they need. Again, this increased the relationship, formalized it a little bit better"* (TAMIU interviewee).

Aside from the three subgrantees with formal program partners, several other subgrantees recounted building and strengthening partnerships with other subgrantees, HRiA, and MHM through networking, information-sharing, and building capacity at the Evaluation Learning Collaboratives. As one interviewee shared, "*I would say that in terms of the objective of the Sí Texas project to not just affect these clinical outcomes but to also impact the competencies of the subgrantees, the skillsets, the capacity of the subgrantees going forward to continue to do this work, it's been very, very effective. There's been a lot of teaching that's gone on. I also think that it has been effective in that it will sort of yield benefits outside of the Si Texas project in terms of collaborations and partnerships going forward*" (TTBH interviewee). Subgrantees shared that they built relationships with each other that allowed them to email or pick up the phone to brainstorm about challenges and share advice or lessons learned.

Facilitating Connectedness of Services Across Organizations

> "*And our program has really worked to raise that awareness of integrated health as it 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."* – interviewee, TAMIU

In addition to talking about how partnerships were built and strengthened for the future, several subgrantees spoke about the more technical aspects of facilitating connectedness across their partner organizations. One strategy for connecting partners and services was having staff whose specific role was to liaise between partners. As one subgrantee shared, "*I think having the personnel to be able to kind of*

focus on certain areas was helpful. You know normally we're all kind of having to do everything so having that person who supposed to be really focused on the clinic integration, the clinic partnerships, and then someone who is focused on the community partnerships and all of that. So that's been really helpful for connecting with all the partners" (UTHealth interviewee).

According to subgrantees, formal or informal liaisons or program staff would share information with partner agencies through one-on-one meetings or presentations. Partners also mentioned attending presentations at other agencies to enhance their knowledge about what services were offered and potential opportunities for connecting at organizational and/or programmatic levels. Information was then brought back to the other agencies and shared with staff and participants. While programmatic data were often discussed during these presentations, subgrantees also outlined the use of databases or other reporting mechanisms to share information about participants with partners in order to coordinate services. Because these subgrantees had both clinical and non-clinical partners, multiple data systems had to be used and navigated. While the existence of a shared data system would have helped partners track participants, their referrals, and services received, according to subgrantees, staffing and communication workarounds were employed.

In addition to staffing and data systems to facilitate connectedness of services, having shared systems and procedures was discussed among subgrantees. For example, one subgrantee shared that they have worked to come up with a standardized follow-up and referral system across all their partner agencies. "*There is now a system where the case worker is following up saying, 'I saw you here today. Now you need to come back for follow-up here or there and continue to stay in care.*" (TAMIU interviewee)

Forming Partnerships to Fill Gaps in Services

> "*I think it's the fact that we have these different agencies. I think having them as a partner is really important, so we can fill gaps and get assistance faster. Having all these partnerships, it's good because you're aware – 'OK, I can't help them with this, but they can.'"* – interviewee, TAMIU

Building on the partnerships developed as part of Sí Texas, two subgrantees described partnering with other organizations that offer services to fill a gap in or complement existing Sí Texas services. For example, one subgrantee discussed partnering with an organization outside the Sí Texas partnership to train navigators in providing enhanced health education services beyond the scope and timeline of the Sí Texas program. Another subgrantee spoke about identifying a need for oral health care services among program participants, which were not available within the Sí Texas partnership organizations. "*We have all of it, but we don't have dental. So, we keep working within our agency with other departments but also with the agencies outside of us to make sure that these services are available for ours and their clients too*" (TAMIU interviewee).

5. What system-level changes around integrated behavioral health have been implemented across the region? And, are sub-regional (e.g., Lower Rio Grande Valley, Alice, TX, and Laredo, TX) differences seen?

This question is not answered in this report. Please see SIF Evaluation Update section for more information.

6. In what way were the components of the Collective Impact framework (common agenda, development of shared measures, mutually reinforcing activities, continuous communication, and backbone organization) integrated in and contributed to overall Sí Texas project?

This question is not answered in this report. Please see SIF Evaluation Update section for more information.

IMPACT STUDY – APPROACH AND METHODS

Overview of Impact Study

This impact evaluation utilized a research synthesis approach at both the study- and individual-level to understand the effectiveness of various IBH models implemented in predominantly low-income, Hispanic populations in South Texas. The approach included a pooled analysis of all study participants from the eight subgrantee studies together for each impact measure and a meta-analyses of the end-point results of the separate subgrantee studies. In the SEP, the meta-analysis was the original focus of the overarching evaluation. However, given the small number of studies for the meta-analysis and the large dataset at the individual-level, the pooled individual-level analysis is presented as the primary study for the overarching evaluation in this report.

The combination of both approaches (pooled individual-level analyses and meta-analysis) provide a robust and powerful evaluation of the overall impact of Sí Texas. The target level of evidence for the overarching evaluation is moderate. The primary aim of the research synthesis was to examine the effectiveness of the Sí Texas portfolio of integrated behavioral health (IBH) models in improving physical and mental health needs among low-income and predominantly Hispanic populations. The subgrantee-specific aims of their respective studies aligned with the research synthesis aim but differed in that PHQ-9 was the primary impact measure of interest. The research synthesis provided a rigorous approach to examining the common effects across subgrantee patient profiles and allowed for examination of the inherent heterogeneity across subgrantees to further identify any key study-level characteristics that may influence the common effect.

With a focus on a low-income, low-resourced, and predominantly Hispanic population in south Texas, these analyses and results add to the substantial body of evidence in the literature for the effectiveness of various IBH models. With subgrantee-level studies all having used either an experimental or quasi-experimental design, the overarching evaluation advances our understanding of the effect of evidence-based IBH models on specific mental health and physical health outcomes among mainly low income, Hispanic populations. Analyses also examined whether there are differential effects of the intervention among different sub-populations (e.g., severely mentally ill, those with chronic health conditions).

Selection of Studies for Inclusion

Pooled Individual-Level Analysis Study Selection

The sample for the pooled regression analyses was created by combining all participants included in the primary end-point analyses in each of the eight subgrantee studies. These participants had to have complete data on at least one health outcome at 12 months. Additionally, their data had to be collected within the allowed analytic window of 60 days before or after their one-year date (based on date of baseline data collection).

Meta-Analysis Study Selection

The meta-analyses for examining the impact of the portfolio of Sí Texas programs adapted conventional procedures in Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) to conduct a quantitative synthesis of the observed effects across these studies (Liberati et al., 2009). To ensure internal and external validity, as it specifically relates to the use of meta-analytical methods, the following factors were considered:

- Specificity of research synthesis research questions
- Systematic method for study inclusion criteria appraisal
- Assessment of subgrantee study similarities and quality measures (assessment of subgrantee internal and external validity)

To provide a valid assessment of the overall impact at the portfolio level, inclusion criteria of subgrantees and their studies to the meta-analysis were based on key study-level factors with respect to design, quality, patient profiles, and similarity of IBH involved in the studies. We adopted general approaches in systematic review and research synthesis used in prior literature with respect to collaborative care and chronic care model, which were then applied to the assessment of study similarities and quality measures across subgrantee studies (Gilbody, Bower, Fletcher, Richards, & Sutton, 2006; Stellefson, Dipnarine, & Stopka, 2013). Specifically, the inclusion of studies required the following key considerations of study similarities and quality measures:

- Studies should have adequate scientific rigor with respect to study design (e.g., at least in the form of quasi-experimental design or randomized control trial) that has moderate to strong internal validity.
- Studies should have 12-month follow-up data points with an overall retention rate of at least 60%, with no significant differential attrition by study arm detected within the individual subgrantee study.
- Studies must have data on at least one of the primary outcomes at the study end-point (i.e. 12 months).
- Studies should have a clear scope and focus on improving both physical and mental health and have distinct components to be considered as part of the integrated behavioral health program in their intervention design.
- Studies should have similar patient populations. Patient populations may include one or more of the following:
    - Diabetic
    - Hypertensive
    - Obese
    - Depressed
    - Severe and Persistent Mentally Ill (SPMI)
    - Low income (< 200% FPL)
    - Uninsured
    - Urban/rural county of residence
- Confirmatory and exploratory impact measures in each study should employ proven valid and reliable instrument and measures.
- Studies should have strong evaluation of program implementation to ensure the exposure of the intervention components by the targeted patients.
- Studies should utilize a linear regression approach for end-point analyses.

The above criteria are the same as described in the SEP with two exceptions. First, an initial retention threshold of 70% was set in the SEP. However, this was revised to 60% with the additional criterion that there be no differential attrition by study arm within the subgrantee study. This lack of differential attrition was decided to be more critical to maintaining internal validity than achieving a higher retention rate. Second, a criterion around the type of end-point analyses conducted was added. So that outcome

analyses could be synthesized together, it was important that all studies utilized the same type of analysis. This criterion aims to reduce the heterogeneity of the results synthesized for the overarching results.

Using these criteria, HRiA determined which subgrantee studies would be included in the meta-analyses. Two reviewers, the overall PI and data analyst across the project, conducted the extraction and coding of study-related data from all subgrantee evaluation studies. While the two reviewers were not directly involved in any one specific subgrantee evaluation (e.g., as a subgrantee evaluation pair or lead), as the principal investigator and analyst on the project they were involved in the overall evaluation of the Si Texas project and were involved equally across subgrantee studies. This choice prevented bias in data extraction from those involved in specific studies. Selecting reviewers familiar with the evaluation project that were "external" to each specific subgrantee study allowed for independent study inclusion appraisal. On areas where any coding disagreements arose, the two reviewers assessed the areas of disagreement. Through this process they ensured a systematic, objective, and transparent appraisal process.

Through this process, consensus was that seven of the eight subgrantee studies were eligible for inclusion in the meta-analyses for depressive symptoms, blood pressure, and BMI. The exclusion of one study was based on the criterion for type of end-point analyses conducted for these outcomes. For HbA1c level, only six studies met the criteria, with two studies being excluded since they did not have end-point analyses for this specific outcome measure. Lastly, for the quality of life measure, four studies were excluded from the meta -analysis, due to either the type of end-point analysis or a lack of end-point analysis for this outcome.

It was proposed in the SEP that, if a study was excluded due to failure to meet the eligibility criteria, sensitivity analyses were to be conducted with multiple meta-analyses to evaluate the robustness of the results with and without the specific study site. However, because the excluded studies were not included based on a lack of appropriate data and results, these sensitivity analyses could not be completed; this is a deviation from the SEP.

Analytic Methods for Primary Study: Pooled Individual-Level Analysis

Given the robust dataset of individual-level data from the eight subgrantee studies, the individual-level pooled analysis was the primary approach to analyses for the impact study. Analyses were conducted to compare those who were in the intervention group, and thus received some level of enhanced IBH care, to those who received the standard of care. It is important to note that standard of care varied across the subgrantee studies. The sample for these analyses was comprised of individual-level data pooled together from all eight subgrantee studies. The sample was comprised of all participants who were included in their respective subgrantee studies. A simple pooling approach was used without weighting.

The pooled individual-level patient data across all sites substantially increased the sample size therefore enhanced statistical power and enabled more robust estimates in evaluating the overall impact of the intervention on patient-level outcomes. An additional advantage of the large pooled sample was the enhanced statistical power to conduct stratified analyses examining the effect of IBH within sub-populations (e.g., those with chronic health conditions, by age group) due to increased sample sizes. Stratified analysis also enabled an improved understanding of which sub-populations are most affected by an integrated behavioral health approach.

Assessment of Baseline Equivalence

Examining baseline equivalence evaluates whether the intervention and comparison groups are statistically equivalent regarding a specified set of characteristics at study enrollment. At baseline, for each individual subgrantee study, sociodemographic characteristics were collected for study participants to assess baseline equivalence within an individual study (see **Appendix G: Subgrantee Baseline Equivalence Tables**). Many collected covariates were unique to the specific subgrantee; however, age, sex, ethnicity, primary language, and county were collected consistently across all eight studies with largely complete data for each variable. For the pooled analysis, baseline equivalence of the combined intervention and comparison group samples from all eight studies was assessed on these five common measures (see **Table 9**).

The pooled intervention and comparison groups were equivalent on age and sex; the groups were non-equivalent on ethnicity, primary language spoken, and county of residence. While there was a greater difference in proportion of language spoken, the vast majority in both groups identified as Hispanic.

Table 9. Tests of Baseline Equivalence for Demographic Measures

	Total Sample (n = 4226)	Pooled Intervention Group (n = 2254)	Pooled Comparison Group (n = 1972)	p-value
Demographic Characteristics				
Age	%	%	%	
18-35	12.4	13.7	11.0	
35-44	20.9	20.8	21.0	
45-54	31.2	30.5	31.9	0.07
55-64	27.6	26.8	28.5	
65+	8.0	8.2	7.6	
Mean (SD)	49.2 (12.2)	48.9 (12.6)	49.5 (11.8)	0.10
Missing	*6*	*4*	*2*	
Sex				
Male	30.2	30.2	30.2	
Female	69.8	69.8	69.8	0.99
Missing	*7*	*4*	*3*	
Ethnicity				
Hispanic	91.5	92.6	90.3	
Non-Hispanic	8.1	7.0	9.5	**0.01**
Other	0.4	0.4	0.3	
Missing	*12*	*5*	*7*	
Language				
English	37.5	40.1	34.5	
Spanish	61.3	58.5	64.6	**<0.001**
Other	1.2	1.5	0.9	
Missing	*22*	*17*	*5*	
County				
Hidalgo	43.2	43.6	42.6	
Cameron	19.1	19.9	18.2	
Webb	23.4	21.8	25.3	
Starr	0.5	0.7	0.4	
Zapata	0.4	0.4	0.4	
Jim Hogg	0.3	0.2	0.4	
Bee	2.9	0.0	6.2	**<0.001**
Brooks	1.4	2.6	0.0	
Jim Wells	3.2	6.1	0.0	
Kleberg	2.5	4.8	0.0	
San Patricio	3.1	0.0	6.6	
Willacy	0.02	0.0	0.1	
Missing	*177*	*98*	*79*	

For the impact measures, the intervention and comparison groups were statistically equivalent on all physical health measures at baseline. There were statistically significant differences in the two behavioral health measures, PHQ-9 and Duke General Health scores, with the comparison group having statistically better health scores at baseline (see **Table 10**).

Table 10. Tests of Baseline Equivalence for Impact Measures

	Total Sample (n=4226)	Pooled Intervention Group (n=2254)	Pooled Comparison Group (n=1972)	*p*
	Mean (SD)	Mean (SD)	Mean (SD)	
BMI[a]	33.5 (7.5)	33.6 (7.8)	33.5 (7.3)	0.78
Systolic blood pressure	131.9 (19.5)	132.0 (19.7)	131.8 (19.2)	0.67
Diastolic blood pressure	79.0 (10.8)	79.0 (10.8)	79.0 (10.8)	0.94
Non-Parametric Tests[b]	Median (IQR)	Median (IQR)	Median (IQR)	*P*
HbA1c	7.7 (3.4)	7.6 (3.7)	7.7 (3.2)	0.11
PHQ-9	**6.0 (11.0)**	**7.0 (12.0)**	**5.0 (10.0)**	**<0.001**
Duke (General)[c]	**66.7 (36.6)**	**63.3 (36.6)**	**70.0 (36.6)**	**<0.001**

Note: Bold denotes significance of p < 0.05 [a] the log transformation was used to conduct statistical testing [b] the Wilcoxon Signed Rank test was used to examine non-normally distributed data [c] TTBH did not collect data using the Duke Health Profile & data collected from Hope not included in analyses

Intervention and Comparison Group Conditions

Conditions in both the intervention and comparison groups varied across subgrantee studies. Universally, those enrolled in the intervention group received some additional or enhanced form of IBH compared to comparison group participants, who received standard of care from the subgrantee and/or its partners. This additional or enhanced form of IBH could include a combination of primary health care, behavioral health care, care coordination, health education (e.g. diabetic, nutritional), peer support, community health workers, community services, transportation services, and warm handoffs between services among other components.

Because some subgrantees were already implementing some level of IBH care, comparison group participants in this pooled sample may have received some of these components. For example, the comparison groups in TAMIU, REAL, and UTHealth received a coordinated range of IBH services; however, they did not receive the additional services provided to the intervention group such as transportation or nutrition classes. In many cases, standard of care did not include components such as warm handoffs, additional community services or education, or enhanced coordination and had little coordination or integration involved in service delivery.

Study Sample Composition

The following section describes the final data on the composition, eligibility, recruitment, enrollment, retention, and attrition of the pooled sample.

Table 11 presents participant demographic characteristics for the intervention and comparison groups at baseline. In the pooled sample, most participants were female (69.8%) and Hispanic (91.5%). The average age was just under 50 years old (49.2) with most participants being 45 years or older (66.8%). The most common primary language spoken was Spanish (61.3%), and most participants lived in either Hidalgo, Cameron, or Webb counties (85.7%).

Table 11. Pooled Participant Demographic Measures for Full Sample and by Intervention Group

	Total Sample (n = 4226)	Pooled Intervention Group (n = 2254)	Pooled Comparison Group (n = 1972)
Demographic Characteristics			
Age	%	%	%
18-35	12.4	13.7	11.0
35-44	20.9	20.8	21.0
45-54	31.2	30.5	31.9
55-64	27.6	26.8	28.5
65+	8.0	8.2	7.6
Mean (SD)	49.2 (12.2)	48.9 (12.6)	49.5 (11.8)
Missing	*6*	*4*	*2*
Sex			
Male	30.2	30.2	30.2
Female	69.8	69.8	69.8
Missing	*7*	*4*	*3*
Ethnicity			
Hispanic	91.5	92.6	90.3
Non-Hispanic	8.1	7.0	9.5
Other	0.4	0.4	0.3
Missing	*12*	*5*	*7*
Language			
English	37.5	40.1	34.5
Spanish	61.3	58.5	64.6
Other	1.2	1.5	0.9
Missing	*22*	*17*	*5*
County			
Hidalgo	43.2	43.6	42.6
Cameron	19.1	19.9	18.2
Webb	23.4	21.8	25.3
Starr	0.5	0.7	0.4
Zapata	0.4	0.4	0.4
Jim Hogg	0.3	0.2	0.4
Bee	2.9	0.0	6.2
Brooks	1.4	2.6	0.0
Jim Wells	3.2	6.1	0.0
Kleberg	2.5	4.8	0.0
San Patricio	3.1	0.0	6.6
Willacy	0.02	0.0	0.1
Missing	*177*	*98*	*79*

Table 12 presents participant impact measures at baseline for the pooled cohort. The two groups had similar physical health measures, however the comparison group was healthier via lower mean depressive symptoms [PHQ-9] and higher mean Duke General Health scores.

Table 12. Descriptive Statistics for Baseline Impact Measures

	Total Sample (n=4226)	Pooled Intervention Group (n=2254)	Pooled Comparison Group (n=1972)
	Mean (SD)	Mean (SD)	Mean (SD)
BMI[a]	33.5 (7.5)	33.6 (7.8)	33.5 (7.3)
Systolic blood pressure	131.9 (19.5)	132.0 (19.7)	131.8 (19.2)
Diastolic blood pressure	79.0 (10.8)	79.0 (10.8)	79.0 (10.8)
Non-Parametric Tests[b]	Median (IQR)	Median (IQR)	Median (IQR)
HbA1c	7.7 (3.4)	7.6 (3.7)	7.7 (3.2)
PHQ-9	**6.0 (11.0)**	**7.0 (12.0)**	**5.0 (10.0)**
Duke (General)[c]	**66.7 (36.6)**	**63.3 (36.6)**	**70.0 (36.6)**

Patient Flow Description

Patient flow diagrams following the CONSORT structure (Schulz et al., 2010) for each subgrantee are presented in **Appendix H: Subgrantee Patient Flow Diagrams.** These diagrams depict 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 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 subgrantee study and were still eligible to complete a 12-month assessment.

Across all studies, 6,458 patients were assessed for eligibility. A total of 2,271 participants were excluded from participation due to not meeting eligibility criteria or ultimately choosing not to participate for other reasons. See **Appendix I** for subgrantee-specific information on how intervention and comparison groups were formed in each of the QED studies.

Sample Enrollment, Retention, and Attrition

Participant Eligibility and Recruitment

This overarching study sample is comprised of participants who met the eligibility criteria for the specific subgrantee study in which they were enrolled. **Table 13** presents the various eligibility criteria for the subgrantee specific studies, particularly those that apply to more than one study. A few studies included some eligibility criteria that were only related to their own study. These are not included in the table below but were: not receiving primary care for a reverse co-location intervention (TTBH), a certain HbA1c level while participating in a program in place at the subgrantee clinics (UTHealth), non-compliance with clinic visits (TAMIU), addiction symptoms (Mercy), and waist circumference criteria (Mercy). Across all studies, participants were 18 years or older and resided in one of the following counties in southern Texas: Hidalgo, Cameron, Webb, Starr, Zapata, Jim Hogg, Bee, Brooks, Jim Wells, Kleberg, San Patricio, Willacy. In the SEP, Bee and San Patricio counties were not listed as part of the Sí Texas project; however, these counties are part of the service area of one subgrantee, so were included as a comparison sites and considered eligible for analyses. See **Appendix J** for more detailed information on recruitment in each subgrantee study.

Table 13. Eligibility Criteria for Subgrantee Studies

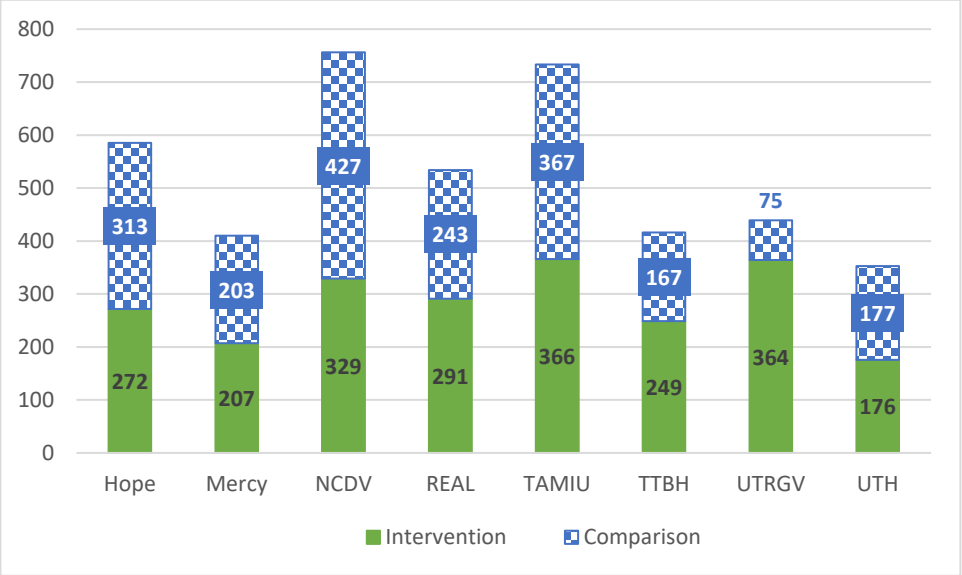
Criterion	Hope	Mercy	NCDV	REAL	TAMIU	TTBH	UTHealth	UTRGV
At least 18 years old	●	●	●	●	●	●	●	●
County								
Cameron	●					●	●	
Hidalgo	●		●			●		
Jim Hogg					●			
Starr	●		●					
Webb					●			
Willacy	●					●	●	
Zapata					●			
Coastal Plains Community Center service area				●				
Have a SPMI/SMI as diagnosed by a licensed behavioral health care provider				●		●		
Have diabetes (HbA1c ≥ 6.5%)			●		●			
Have a diagnosis of one or more chronic conditions:								
Hypertension (Blood Pressure ≥ 140/90)	●	●				●		
Obesity (BMI ≥ 30)	●	●				●		
Poorly controlled diabetes	●[a]	●[b]				●[c]	●[d]	
Hypercholesterolemia (Total cholesterol level ≥200)						●		
Depression	●[e]	●[f]						●[f g]
Anxiety (GAD-7 ≥ 5)		●						●[g]
Medicaid eligible or uninsured	●			●				

[a] HbA1c ≥6.8% [b] HbA1c ≥7.0% [c] HbA1c ≥8.5% [d] HbA1c ≥8.0% [e] PHQ-9 ≥10 [f] PHQ-9 ≥5 [g] This also applies to patients who are judged by the PCP to need behavioral health services according to PCBH model protocols which include meeting score thresholds on the PHQ-9 and/or GAD-7 or presenting with any type of behavioral health issue

Sample Enrollment and Retention

Participant enrollment began at the first subgrantee in November 2015 and ended in April 2017 when the last subgrantee enrolled its final participant. Enrollment totals, by study group, for each subgrantee are presented in **Figure 3**. A total of 4,226 participants comprised the pooled cohort sample, with 2,254 in the intervention group and 1,972 in the comparison.

Figure 3. Baseline Enrollment by Subgrantee



Note: UTRGV used a comparison group (n=205) that was originally recruited by and partially shared by TTBH. OF those 205 comparison group participants in the URTGV study, 130 of them were also comparison participants in TTBH's study. In the figure above those 130 participants are represented within the TTBH enrollment numbers. The 75 comparison group participants for UTRGV represent those used in UTRGV's study that were not included in TTBH's study.

Table 14 presents retention information by subgrantee. All subgrantees reached a 12-month retention of 60% or higher, with a pooled cohort retention rate of 70%. The range of overall retention rates were 60% to 83%. An analytic window was used to produce the final endpoint dataset for each subgrantee. This window allowed a 12-month assessment to be completed within 60 days before or 60 days after a participant's 12-month anniversary date, based on their enrollment date.

Table 14. Final Assessment of Follow-up Retention at 6 and 12 Months of Participants in the Individual-Level Pooled Sample, by Subgrantee and Study Arm

			6-month Retention				12-month Retention			
Subgrantee	**Study Arm**	**Enrollment Total**	**6-month Target**	**Completed 6-month Follow-ups**	**% of Participants Enrolled**	**% of 6-month Target**	**12-month Target**	**Completed 12-month Follow-ups**	**% of Participants Enrolled**	**% of 12-month Target**
Tropical	Intervention	249	164	175	70%	107%	145	155	62%	107%
	Control	167	164	120	72%	73%	145	116	69%	80%
	Overall	***416***	***328***	***295***	***71%***	***90%***	***290***	***271***	***65%***	***93%***
Mercy	Intervention	207	184	169	82%	92%	164	142	69%	87%
	Comparison	203	184	143	70%	78%	164	151	74%	92%
	Overall	***410***	***368***	***312***	***76%***	***85%***	***328***	***293***	***71%***	***89%***
REAL[d]	Intervention	291	213	152	52%	71%	180	186	64%	103%
	Comparison	243	212	102	42%	48%	180	132	54%	73%
	Overall	***534***	***425***	***254***	***48%***	***60%***	***360***	***318***	***60%***	***88%***
Hope	Intervention	272	255	221	81%	87%	226	172	63%	76%
	Control	313	255	233	74%	91%	226	198	63%	88%
	Overall	***585***	***510***	***454***	***78%***	***89%***	***452***	***370***	***63%***	***82%***
UTRGV	Intervention	366	311	231	63%	74%	256	243	66%	95%
TAMIU	Intervention	366	311	297	81%	96%	255	275	75%	108%
	Control	367	311	285	78%	92%	255	286	78%	112%
	Overall	***733***	***622***	***582***	***80%***	***94%***	***510***	***561***	***77%***	***110%***
UTSPH	Intervention	176	149	154	88%	103%	122	147	84%	120%
	Control	177	149	152	86%	102%	122	145	82%	119%
	Overall	***353***	***298***	***306***	***87%***	***103%***	***244***	***292***	***83%***	***120%***
NCDV	Intervention	329	287	277	84%	97%	236	239	73%	101%
	Comparison	427	287	334	78%	116%	236	324	76%	137%
	Overall	***756***	***574***	***611***	***81%***	***106%***	***472***	***563***	***74%***	***119%***
SiTX Pooled Dataset	Intervention	2254	1874	1676	74%	89%	1584	1559	69%	98%
	Comparison	1972[a]	1562	1421[b]	72%	91%	1328	1396[c]	71%	105%
	Overall	***4226***[a]	***3436***	***3097***[b]	***73%***	***90%***	***2912***	***2955***[c]	***70%***	***101%***

[a] These totals include an additional 75 participants that were enrolled in TTBH's secondary comparison group. This group was not used for TTBH's study and is therefore not included in the totals for TTBH in this table; however, these 75 were used in the comparison sample for UTRGV alongside 130 from TTBH's primary control group. [b] These totals include an additional 52 participants from TTBH's secondary comparison group that were used as part of UTRGV's comparison. [c] These totals include an additional 44 participants

from TTBH's secondary comparison group that were used as part of UTRGV's comparison. [d] REAL's dataset for this overarching report uses the 60-day window, which is a slightly different window than the window used in REAL's subgrantee study report. Because of this, the enrollment and retention data presented in this report may differ from the final REAL SIF report.

Sample Attrition Analyses

Each subgrantee study anticipated a 12-month retention rate of 70-80%. At 12 months, the pooled cohort had a retention rate of 70% in the intervention group and 72% in the comparison group. To examine whether this 2% difference in attrition 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 comparison group. The results of this analysis were not statistically significant at the 0.05 level (p=0.27). Given these results, the two study groups did not have significantly differing attrition rates after 12 months of follow-up.

Additional analyses examining whether there was significant differential attrition by other characteristics can be found in Appendix K: Additional Analyses - Differential Attrition**: Additional Analyses - Differential Attrition**. These analyses were conducted within the full pooled sample as well as within the pooled intervention and pooled comparison groups separately.

For demographic variables, there were significant differences in attrition by sex, ethnicity, language, and age for those who dropped out of the study compared to those who remained in the full pooled sample as well as within each study group separately. However, this was not different by study arm as the patterns were consistent within both groups. A higher proportion of males, those who were non-Hispanic, and spoke English as their primary language did not complete the study and these participants also had a younger mean age.

There were significant attrition differences found when looking at the health outcome measures of diastolic blood pressure, but only for those in the pooled comparison group, and for HbA1c, PHQ-9 score, and Duke General Health score in the full pooled sample as well as in each study group separately. For both the intervention and comparison groups, those who dropped out had higher diastolic blood pressure, lower HbA1c, higher PHQ-9 scores, and lower General Health scores. These results indicate that while there were differences between those who remained in the study and those who did not, these differences occurred consistently across the two study groups, alleviating concern for biases that could influence interpretation of the study results.

Lastly, logistic regression analyses were conducted to understand if any of these differences contributed to a participant's likelihood of not completing the study. Within the full pooled sample as well as the two study groups separately, only sex and baseline Duke General Health scores significantly influenced the likelihood of not completing the study. While these results are helpful in interpreting the final results of the overarching study, they also indicate that any possible bias due to attrition is minimal given there was no differential attrition rate overall by study arm.

Sample Retention Strategies

Each subgrantee employed various strategies to recruit and retain their study participants. These included provision of monetary and/or non-monetary incentives, collection of comprehensive contact information, clinical team communication, and utilization of a care coordinator, manager, and/or navigator.

Non-Response Bias Missing Data

Data collected for intervention and comparison group participants during research follow-up visits were collected through subgrantee data collection systems, including databases and electronic medical records by research study and clinical staff.

Missing data on covariates is a potential issue that could lead to biased results. The subgrantee research teams made all efforts to minimize missing data through training and use of standard practice measures within the clinic settings. In the SEP, a multiple imputation approach to address possible bias due to missing data was proposed (MacKinnon, 1993; Short, 1994; Little, 1987). However, based on the amount of missing data for those who completed a 12-month assessment across all eight studies, this adjustment was ultimately not necessary.

At baseline, there were few participants missing data on the common sociodemographic measures apart from county. For age, sex, ethnicity, and primary language spoken no more than 1% of participants were missing data. A larger number were missing county of residence, but still only 4% of the total sample. In the final 12-month sample, 96 participants (3%) were missing county. This presented a challenge in applying county level contextual covariates to the individual participants (e.g. rate of uninsured in the county they reside). A comparison was made of the proportion of participants missing county between the intervention and comparison groups and no significant difference was found (p=0.27). Because of this lack of difference, these 96 participants were removed from final analyses without concern of bias.

For health measures, there were also missing data (see **Table 15**). At baseline, for blood pressure and BMI, no more than 1% of participants were missing values for these measures. Only 3% of participants were missing a value for their PHQ-9 score. For HbA1c, a high number of participants were missing data; however, this is because HbA1c was not universally collected from all patients based on clinical practice of the specific subgrantee. Therefore, missing data should not be imputed for those participants. For Duke General Health score, there were also a high number of missing; however, this is due to these data not being available from multiple subgrantees. Therefore, these data should also not be imputed.

For participants who completed a 12-month assessment, no more than 3% were missing blood pressure or BMI values. A higher proportion were missing PHQ-9 score at baseline (7%); however, there were no significant differences in missingness of PHQ-9 by study arm. At 12 months, there were larger amounts of missing data for HbA1c and Duke General Health as was at baseline. For reasons discussed in the previous paragraph, these data were not imputed.

Table 15. Number of Participants Missing Data, by Measure and Time Point

Measure	Missing Data	
	Baseline n (%)	12-month n (%)
PHQ-9	147 (3%)	194 (7%)
Systolic Blood Pressure	36 (1%)	64 (2%)
Diastolic Blood Pressure	36 (1%)	63 (2%)
HbA1c[a]	882 (21%)	534 (18%)
BMI	39 (1%)	71 (2%)
Duke Health Profile[b]	1117 (26%)	743 (25%)

[a] not universally collected from all patients based on clinical practice of the specific subgrantee
[b] data not available from some subgrantees

Analytic Approach for the Secondary Study: Meta-Analysis

Description of Studies

A total of eight studies of 4,226 individuals were part of the Sí Texas project. **Table 16** describes key aspects of all eight studies. The table below describes each of the Sí Texas subgrantee studies, their samples, study design, and level of evidence achieved.

Table 16. Description of Sí Texas Studies

Subgrantee	Sample Size	Study Design	Retention Rate	Sample Description	Level of Evidence Achieved: Designated by CNCS
TTBH	Total: n=416 Intervention: n=249 Control: n=167	RCT	Total: 65% Intervention: 62% Control: 69%	SPMI Have a physical chronic condition Eligible to receive behavioral health services	Moderate
Mercy	Total: n=410 Intervention: n=207 Comparison: n=203	QED	Total: 71.4% Intervention: 68.6% Comparison: 74.4%	At least one eligible physical or behavioral health condition	Preliminary
REAL	Total: n=552 Intervention: n=302 Comparison: n=250	QED	Total: 65.9% Intervention: 69.8% Comparison: 61.2%	SPMI Enrolled in or eligible for Salud y Vida Lack a serious health condition that would preclude use of TRIP transportation	Preliminary
Hope	Total: n=585 Intervention: n=272 Control: n=313	RCT	Total: 63.2% Intervention: 63.2% Control: 63.2%	Eligible to receive behavioral health services Diagnosis of at least one eligible health condition	Moderate
UTRGV	Total n=569 Intervention n=364 Comparison n=205	QED	Total: 65.7% Intervention: 66.8% Comparison: 63.9%	Eligible for behavioral health services either by screening test criteria or by PCP recommendation	Preliminary
TAMIU	Total n=733 Intervention n=366 Control n=367	RCT	Total: 76.5% Intervention: 75.1% Control: 77.9%	Diagnosed with diabetes Non-compliant with treatment plan	Preliminary
UTHealth	Total n=353 Intervention n=176 Control n=177	RCT	Total: 82.7% Intervention: 83.5% Control: 81.9%	Have an HbA1c $\geq$ 9.0% at any point between 6 and 36 months of SyV 1.0 services; and Have an HbA1c $\geq$ 8.0% at 2.0 baseline enrollment.	Preliminary

Subgrantee	Sample Size	Study Design	Retention Rate	Sample Description	Level of Evidence Achieved: Designated by CNCS
NCDV	Total n=756 Intervention n=329 Comparison n=427	QED	Total: 74.5% Intervention: 73% Comparison: 76%	Diagnosis of diabetes	Preliminary

Of the eight studies included as part of the Sí Texas cohort, four utilized RCT study designs, and the other four were QEDs. Seven studies met the eligibility criteria for inclusion in the meta-analyses of PHQ-9 score, blood pressure, and BMI. A total of six studies were included in the meta-analysis of HbA1c based on the criteria. Half of the Sí Texas cohort studies (n=4) were included in the meta-analysis of Duke General Health score results. **Table 17** describes the analyses conducted for each outcome in each subgrantee study.

Table 17. Description of Analyses for Outcomes, by Subgrantee

Subgrantee	Method Used in Subgrantee Study	Covariates included in analyses[a]					
		PHQ-9	*BMI*	*Duke General Health*	*HbA1c*	*Systolic Blood Pressure*	*Diastolic Blood Pressure*
Tropical	Multiple linear regression models with multiple imputation on PHQ-9	Baseline comorbidities Major Depression Baseline PHQ-9 Baseline Life Function Age Sex	Sex Age Baseline BMI	N/A	Sex Education Age group Baseline HbA1c	Sex Age Baseline SBP Baseline DBP Baseline comorbidities	Sex Age Ethnicity Baseline DBP Baseline comorbidities
Mercy	Multiple linear regression models	Age Sex Language Smoking status Baseline PHQ-9 Baseline Duke General Health Baseline GAD-7 Baseline BMI	Age Sex Language Baseline BMI Baseline Comorbidities	Age Sex Baseline Duke General Health Baseline PHQ-9 Baseline BMI	Age Sex Alcohol Status Baseline HbA1c	Age Sex Language Marital status Smoking status Alcohol status Employment status Baseline SBP Baseline DBP Baseline comorbidities Baseline PHQ-9	Age Sex Language Marital status Smoking status Alcohol status Employment status Baseline DBP Baseline SBP Baseline comorbidities Baseline PHQ-9
NCDV[b]	Multiple linear regression models	Age Sex Married Smoking Status Alcohol Status Baseline PHQ-9 Baseline General Health Baseline comorbidities	Age Sex Baseline BMI Baseline comorbidities	Age Sex Language Marital status Insurance status Smoking status Alcohol status Baseline General Health Baseline PHQ-9	Age Sex Language Smoking status Baseline HbA1c	Age Sex Marital status Employment status Alcohol status Baseline SBP	Age Sex Smoking status Baseline DBP Baseline SBP Baseline comorbidities

Subgrantee	Method Used in Subgrantee Study	Covariates included in analyses[a]					
		PHQ-9	*BMI*	*Duke General Health*	*HbA1c*	*Systolic Blood Pressure*	*Diastolic Blood Pressure*
UT Health SPH	Multiple linear regression models	Age Language Baseline PHQ-9 Baseline Comorbid	Ethnicity Baseline comorbid Baseline BMI	Sex Marital Status Education Baseline General Health	Age Ethnicity Baseline HbA1c	Age SyV1.0 Baseline SBP Baseline DBP	Age SyV1.0 Baseline SBP Baseline DBP
REAL[c]	Mixed-effect linear models with random effects	Age Sex	Age Ethnicity Education Diabetic	N/A	Age Sex Ethnicity Education	Age Sex Ethnicity Education Diabetic BMI	Age Sex Ethnicity Education Diabetic BMI
UTRGV	Multiple linear regression models with multiple imputation for PHQ-9	Age Sex Baseline PHQ-9	Sex Age Baseline BMI	N/A	N/A	Age Sex Baseline SBP	Age Sex Baseline DBP
Hope	Multiple linear regression models with multiple imputation on PHQ-9, blood pressure, and BMI	Age Language Employment status Baseline PHQ-9	Baseline BMI Baseline PHQ-9	N/A	Baseline HbA1c	Age Sex Marital status Baseline SBP Baseline PHQ-9	Marital Status Baseline DBP Baseline comorbidities
TAMIU	Multiple linear regression models	Age Clinic PHQ-9	Age Sex Language BMI	Education Clinic Duke General Health	Age Sex Clinic HbA1c	Age Sex Systolic blood pressure Diastolic blood pressure Number of comorbidities	Age Diastolic blood pressure Number of comorbidities

[a] These covariates were selected using a backward selection approach with a p=0.15 threshold [b] This study also analyzed the component scores of the Duke General Health score: physical health, mental health, and social health c REAL did not analyze the composite General Health score, their analyses examined the Duke Depression, Anxiety/Depression, Pain, and Disability scores

Measures

The measures collected for the impact analysis aligned with the planned set of measures outlined in the overarching SEP**.** The impact measures assessed were depressive symptoms (via the PHQ-9 assessment tool), blood pressure, HbA1c, BMI, and quality of life (via the Duke Health Profile tool). For some subgrantees HbA1c was only collected on a subset of participants, please see each subgrantee's final report for full details regarding impact analyses for this measure.

Information on the number of respondents (**Table 18**) and tests of normality are provided. 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 be 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 18. Impact Measure Sample Size by Measure and Time Point

Measure	Sample Size	
	Baseline	12-month
PHQ-9	4079	2761
Systolic Blood Pressure	4190	2891
Diastolic Blood Pressure	4190	2892
HbA1c	3344	2421
BMI	4187	2884
Duke Health Profile	3109	2212

HbA1c: HbA1c levels are routinely measured in the monitoring of people with diabetes. HbA1c levels depend on the blood glucose concentration. 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, 2014).

HbA1c was captured by Sí Texas subgrantee clinic staff. All HbA1c data was reported by Sí Texas subgrantees to the external evaluator as a continuous variable. For the overarching Sí Texas evaluation, patients with an HbA1c greater than or equal to 6.5% were classified as diabetic when this variable was dichotomized, based on the American Diabetes Association recommendation (American Diabetes Association, 2018). This is a deviation from the SEP which stated a threshold of 7.0% for diabetes; however, 6.5% is the clinically accepted threshold and is what was used for many of the subgrantees.

At baseline and 12-month follow-up, the distribution of responses for HbA1c were 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.

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, age, and disease states (American Heart Association, 2015).

Blood pressure was captured by Sí Texas clinic staff following clinically-established practice guidelines (National Guidelines Clearinghouse, 2011). All blood pressure data was reported by Sí Texas subgrantees to the external evaluator as a continuous variable. For the overarching Sí Texas evaluation, study participants with a blood pressure greater than or equal to 140/90 mmHg were classified as hypertensive when this variable was dichotomized. This threshold is different than the current guidelines, but was the standard clinical guideline at the start of the Sí Texas project (American Heart Association, 2015).

At baseline and 12-month follow-up, the distributions of responses for systolic and diastolic blood pressure were determined to both be normal and therefore parametric tests were used for bivariate analyses.

Obesity: Excessive abdominal fat 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. Obesity will be captured using body mass index (BMI), a calculation of the ratio of height and weight.

Height and weight for the calculation of BMI were captured by Sí Texas clinic staff. Height, weight, and/or BMI data was reported by Sí Texas subgrantees to the external evaluator as continuous variables. For the overarching Sí Texas evaluation, patients with a BMI greater than or equal to 30 were classified as obese when this variable was dichotomized.

At baseline and 12-month follow-up, the distribution of responses for BMI were 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.

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 (American Psychiatric Association, 1994).

Depression was measured using the PHQ-9 assessment tool. The PHQ-9 is a multipurpose instrument for screening, diagnosing, monitoring and measuring the severity of depression. The PHQ-9 has a total possible score of 27. The PHQ-9 scoring criteria are categorized as minimal (0-4), mild (5-9), moderate (10-14), moderately severe (15-19) and severe (20-27) depression (Kroenke & Spitzer, 2002). PHQ-9 data was reported by Sí Texas subgrantees to the external evaluator as a numerical score. A patient's severity of depression was determined based on Kroenke & Spitzer categorization. For the overarching Sí Texas evaluation, patients with a PHQ-9 score greater than or equal to 5 were classified as depressed when this variable was dichotomized.

See Appendix M: Patient Health Questionnaire – 9 (PHQ-9) *to view the PHQ-9 assessment tool (available in English and Spanish).*

At baseline and 12-month follow-up, the distribution of responses for PHQ-9 were 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: Quality of life 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).

Quality of life was measured via the self-administered Duke Health Profile in seven of the subgrantee sites. 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. The higher the score, the more functional or dysfunctional the person being evaluated. For the Duke General Health score, a higher score indicates better quality of life.

Patient's quality of life score was assessed using the pre-identified scoring criteria. Similarly, these data were reported by Sí Texas subgrantees as a numerical score. It should be noted TTBH did not use the Duke Health Profile; they instead collected life functioning data using the Adult Needs and Strengths Assessment (ANSA) tool. This decision was based on existing practice at TTBH. Because of this, TTBH participants are not included in any analyses of the Duke General Health score. A pooled analysis of the ANSA data was not possible as only TTBH collected this measure.

See Appendix N: Duke Health Profile to view the Duke Health Profile assessment tool (available in English and Spanish).

At baseline and 12-month follow-up, the distribution of responses for Duke General Health score were 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.

Data Collection Activities

Appendix C: Project Timeline – Subgrantee Activities depicts the data collection timeline as it relates to SEP approval and analyses completed for this final report. Data collection started for the first subgrantee in November 2015 and ended in October 2018 when the last end-point assessment was completed. Data collection procedures are detailed in individual subgrantee reports.

IMPACT STUDY – ANALYSIS AND RESULTS

Overview

Final impact study results for the intervention and comparison group are presented for both the meta-analyses and individual-level patient data pooled regression. This section 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 Sí Texas cohort. All descriptive, baseline equivalence, bivariate, and multivariate analyses reported in this final report were performed with SAS version 9.4.

The primary analysis, individual-level pooled regression of each outcome, results are presented first by research question. The secondary analysis, meta-analyses of each outcome, results follow the primary results.

Pooled Individual-Level Analyses Results

As the primary approach to the overarching impact study, the individual-level pooled analysis leverages the large sample size on common measures across the portfolio. Final impact study results comparing the pooled intervention to comparison participants are presented by research question for these analyses. Descriptive statistics for complete data among the intervention and comparison group are examined in this final report. These statistics include participants' sociodemographics and other key covariates. These covariates were examined to assist in identifying potential factors that may result in nonequivalence between the two groups. Chi-square tests and Fisher's Exact Tests, when necessary based on cell counts, were used for categorical data to examine baseline equivalence. Two sample t-tests were used for continuous data that were normally distributed, and the Wilcoxon Signed Rank test was used for non-normally distributed data. These analyses take an in intent-to-treat approach with adjustment of potential nonequivalence of covariates and baseline outcome measure. The decision was made not to perform secondary power calculations as the overall retention rate was as expected and prior research indicated that these tests are not necessarily helpful in the interpretation of observed results (Goodman and Berlin, 1994).

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 specific 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 the 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). Generalized regression analysis was used following a modeling sequence from bivariate models to multiple regression models adjusting for baseline levels of outcome measures and covariates assessed to be relevant based on review of the scientific literature or found to be unbalanced between the two groups at baseline. Additional contextual covariates, based on county level data, were also included to adjust for potential differences across individuals from different studies on a county level. The parameter of interest was the dichotomous variable that differentiates the treatment status (i.e., intervention vs. comparison group). 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. In addition to adjusting for key covariates, we assessed potential collinearity and its impact of the standard error estimates for the covariates in the model by examining Pearson correlation coefficients and variance inflation factor when necessary.

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 impact measure on intervention status (intervention vs. comparison group) 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 (BMI and blood pressure). The confirmatory variable and exploratory outcomes (PHQ-9, HbA1c, 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 parametric results are not presented, both the nonparametric and parametric bivariate analyses produced consistent results.

Following bivariate comparisons, multivariate analyses were performed to answer each research question. As previously mentioned, multiple imputation methods were considered, but ultimately deemed unnecessary. The primary adjusted multivariate analyses model the outcome of interest on intervention status with relevant covariates included.

Additionally, understanding the intervention effect within subgroups was an important question to answer. This was examined in two ways: 1) conducting analyses for effect modification of the intervention-outcome relationship by including an interaction term of characteristic of interest by interventions status and 2) stratifying the linear regression analyses by sub-population. The effect modification analyses which used an interaction term looked at whether the intervention effect significantly differed by subgroup examined. Stratified analyses were also conducted to assess the intervention effect within subgroups. These subgroups were identified *a priori* based on biological and/or clinical relevance on health outcomes and knowledge of the subgrantee study populations. Characteristics of interest included: known SPMI diagnosis, age (under 49 years and 49 years or older based on the mean age in the pooled study population), sex (male/female) and known chronic condition at baseline (i.e. depression, hypertension, obesity, diabetes).

Adjustment was made based on covariates collected across eight subgrantees: age, sex, ethnicity, primary language spoken, and number of comorbidities at baseline. Additional variables were also included to account for possible contextual level differences in the sample: rate of uninsured at the county level and prevalence of obesity at the county level. Other contextual level covariates were considered for the analysis, including region, rate of unemployment at the county level, and prevalence of diabetes at the county level. The region variable was highly correlated with the rate of uninsured residents (coeff=-0.91). Prevalence of diabetes was highly correlated with prevalence of obesity (coeff=-0.69). Lastly, rate of unemployment was highly correlated with prevalence of obesity (coeff=-0.72) Based on the high correlation between these covariates and others included in the model, these three—region, county-level employment rate, and county-level diabetes prevalence—were removed from the final models. All variables assessed to be appropriate were included in all models without a selection process as concerns around parsimony of the model were mitigated by the large sample size.

Depressive Symptoms

Question 1. **Did intervention participants who participated in a Sí Texas intervention significantly reduce their depressive symptoms after 12 months compared to participants who receive the standard of care? This question is confirmatory. Did the impact vary based on the population served? This question is exploratory.**

Overview of Analysis

To answer these questions about intervention impact on depressive symptoms, data were collected using the PHQ-9. This measure was collected for all eight subgrantee studies. The sample sizes for the presented analyses of PHQ-9 score in the pooled cohort sample are as follows: bivariate analyses (n=2761) and primary linear regression analyses (n=2574).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 40** presents the mean PHQ-9 values in each study period for the overall sample as well as the intervention and comparison groups. The overall study sample had a mean PHQ-9 score of 7.7 at baseline. For those who returned for a follow-up assessment, mean PHQ-9 was 5.9 at 6-month follow up and 5.5 at 12-month follow-up. The intervention group began the study with a mean PHQ-9 of 8.4. For those participants in the intervention group who returned for a follow-up, mean PHQ-9 was 6.3 at 6-month follow up and 5.8 at 12-month follow-up. The comparison group began the study at mean PHQ-9 of 7.0. For those participants in the comparison group who returned for follow-up, mean PHQ-9 was 5.4 at 6-month follow-up and 5.2 at 12-month follow-up. As previously noted in **Table 10**, the intervention and comparison groups were not statistically equivalent on baseline PHQ-9 score. This imbalance was considered in the final analyses presented.

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 38**). For PHQ-9 score, the differences from baseline to 12-month follow-up were statistically significant within the intervention ($p<0.001$) and the comparison ($p<0.001$).

Bivariate analyses were also performed between the intervention and comparison groups comparing PHQ-9 at 12-month follow-up, without controlling for any additional covariates (**Table 39**). Based on a p-value less than 0.05 for PHQ-9 score when comparing the intervention and comparison groups at 12

months, the null hypothesis can be rejected (p=0.01). PHQ-9 score was significantly different between the two groups when not adjusting for any additional covariates.

Model Building Process

All relevant covariates deemed appropriate (i.e. not collinear with other included covariates) were included in the model. These covariates included: age, sex, ethnicity, primary language, number of comorbidities at baseline, baseline PHQ-9 score, rate of uninsured at the county level, and prevalence of obesity at the county level. The final model specification is below.

$$Y_{(PHQ9)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Ethnicity + \beta_5 Language + \beta_6 BL\_Comorbidities + \beta_7 BL\_PHQ9 + \beta_8 UninsuredRate + \beta_9 Obesity + \varepsilon$$

As previously stated, multiple imputation approach was considered but not performed due to the small amount of missing data at end-point.

Findings

Estimates for the final model of depressive symptoms at 12 months are presented in **Table 19**.

Mean PHQ-9 score at 12 months differed significantly by intervention status (p=0.03) when analyzing the full cohort sample; the effect size (using Cohen's d) is 0.06. On average, the PHQ-9 score of those receiving enhanced IBH care was 0.39 points lower than those receiving standard of care, adjusting for the included covariates.

$$Y_{(PHQ9)}= 12.81 + -0.39(Intervention) + -0.004(Age) + -0.17(Female) + 0.79(Non\text{-}Hispanic) + 2.30(Other\ Eth) + 1.08(English) + 2.43(Other\ Lang) + -0.30(BL\_Comorbidities) + 0.56(BL\_PHQ9) + -0.19(UninsuredRate) + -0.16(Obesity) + \varepsilon$$

Table 19. Effect of IBH Intervention on Twelve Month PHQ-9 score, Full Sí Texas Sample

Variable	PHQ-9 (n=2574)		
	Estimate (β)	Standard Error	p-value
Intervention	**-0.39**	**0.18**	**0.03**
Comparison (ref)	--	--	--
Age	-0.004	0.01	0.59
Female	-0.17	0.20	0.38
Male (ref)	--	--	--
Non-Hispanic	0.79	0.37	0.03
Other Ethnicity	2.30	2.21	0.30
Hispanic (ref)	--	--	--
English	1.08	0.22	<0.001
Other language	2.43	0.85	0.004
Spanish (ref)	--	--	--
Number of Comorbidities	-0.30	0.09	0.001
Baseline PHQ-9	0.56	0.02	<0.001
County Rate of Uninsured	-0.19	0.03	<0.001

County Obesity Prevalence	-0.16	0.06	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).

Additional Analyses

Effect modification of the intervention effect on PHQ-9 was explored for baseline health conditions (depression, hypertension, obesity, and diabetes), age, sex, and known SPMI diagnosis. The interaction terms of group and depression (p=0.74), hypertension (p=0.80), obesity (p=0.97), diabetes (p=0.76), age (p=0.63), sex (p=0.79), and known SPMI diagnosis (p=0.10) were not significant, indicating the intervention effect did not differ significantly based on these characteristics.

To answer the exploratory question of if the impact varied based on the population served, stratified analyses were conducted looking at those with and without each baseline condition, older and younger participants, males and females, and those with and without a known SPMI diagnosis separately. These groupings were selected a priori. When stratifying by these characteristics, there were no statistically significant differences found between the intervention and comparison groups within subgroups (results not shown). This indicates that the intervention effect was only significant when not stratifying.

Limitations

It should be noted that PHQ-9 scores were not balanced at baseline, with those in the intervention group having higher average scores than those in the comparison group at the start of the study. Additionally, participants who did not complete the study in both groups were more likely to have higher average PHQ-9 scores; however, this attrition pattern was consistent across both the intervention and comparison groups. It is possible that these differences may have led to the intervention having higher PHQ-9 scores throughout the study, although baseline scores were adjusted for in the model. However, analyses were still able to detect a significant difference between the intervention and comparison group at 12 months, adjusting for baseline PHQ-9, indicating lower scores in the intervention group. However, these limitations may explain the lack of significant effects found in the stratified analyses when sample sizes are smaller

Blood Pressure

Question 2. **Did intervention participants who participated in a Sí Texas intervention obtain significantly improved blood pressure readings after 12 months compared to participants who receive the standard of care? Did the impact vary based on the population served?** ***These questions are exploratory.***

Overview of Analysis

To answer these questions about intervention impact on blood pressure, systolic and diastolic blood pressure data were collected. These measures were collected for all eight subgrantee studies. The sample sizes for the presented analyses of blood pressure in the pooled cohort sample are as follows: bivariate analyses (n=2891 for systolic, n=2892 for diastolic) and primary linear regression analyses (n=2775 for systolic, n=2776 for diastolic).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 40** presents the mean systolic and diastolic blood pressure values in each study period for the overall sample as well as the intervention and comparison groups. The overall study sample had a mean blood pressure of 131.9/79.0 mmHg at baseline. For those who returned for a follow-up assessment, mean blood pressure was 128.9/77.4 mmHg at 6-months and 128.3/77.0 mmHg at 12-month follow-up. The intervention group began the study with a mean blood pressure of 132.0/79.0 mmHg. For those participants in the intervention group who returned for a follow-up, mean blood

pressure was 128.9/77.1 mmHg at 6-month follow-up and 128.8/76.8 mmHg at 12-month follow-up. The comparison group began the study with a mean blood pressure of 131.8/79.0 mmHg. For those participants in the comparison group who returned for follow-up, mean blood pressure was 129.0/77.6 mmHg at 6-months and 127.8/77.2 mmHg at 12-months. As previously noted in **Table 10**, the intervention and comparison 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 38**). The decreases observed within systolic and diastolic blood pressure from baseline to 12-month follow-up were statistically significant within both the intervention ($p<0.001$) and comparison groups ($p<0.001$).

Bivariate analyses were also performed between the intervention and comparison groups comparing systolic and diastolic blood pressure at 12-month follow-up, without controlling for any additional covariates (**Table 39**). Based on a p-value greater than 0.05 for both systolic and diastolic blood pressure when comparing the intervention and comparison 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 Building Process

All relevant covariates deemed appropriate (i.e. not collinear with other included covariates) were included in the model. These covariates included: age, sex, ethnicity, primary language, number of comorbidities at baseline, baseline blood pressure, rate of uninsured at the county level, and prevalence of obesity at the county level. The final model specifications are below.

$$Y_{(SBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Ethincity + \beta_5 Language + \beta_6 BL\_Comorbidities + \beta_7 BL\_SBP + \beta_8 Uninsured + \beta_9 Obesity + \varepsilon$$

$$Y_{(DBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Ethincity + \beta_5 Language + \beta_6 BL\_Comorbidities + \beta_7 BL\_DBP + \beta_8 Uninsured + \beta_9 Obesity + \varepsilon$$

As previously stated, multiple imputation was considered but not performed due to the small amount of missing data at end-point.

Findings

Estimates for the final model of blood pressure at 12 months are presented in **Table 20**.

Mean systolic blood pressure at 12 months did not differ significantly by intervention status ($p=0.70$) when analyzing the full cohort sample.

$$Y_{(SBP)}= 72.35 + 0.23(Intervention) + 0.24(Age) + -2.65(Female) + 3.44(Non\text{-}Hispanic) + -18.74(Other\ Eth) + -0.23(English) + -4.76(Other\ Lang) + 1.25(BL\_Comorbidities) + 0.40(BL\_SBP) + 0.02(UninsuredRate) + -0.36(Obesity) + \varepsilon$$

Mean diastolic blood pressure at 12 months did not differ significantly by intervention status ($p=0.08$) when analyzing the full cohort sample.

$$Y_{(DBP)}= 51.21 + -0.62(Intervention) + -0.03(Age) + -0.90(Female) + 1.47(Non\text{-}Hispanic) +$$

-13.35(Other Eth) + 0.17(English) + -0.18(Other Lang) + 0.58(BL_Comorbidities) + 0.37(BL_DBP) + 0.04(UninsuredRate) + -0.13(Obesity) + ε

Table 20. Effect of IBH Intervention on Twelve Month Blood Pressure, Full Sí Texas Sample

Variable	Systolic Blood Pressure (n=2775)		
	Estimate (β)	Standard Error	p-value
Intervention	0.23	0.60	0.70
Comparison (ref)	--	--	--
Age	0.24	0.03	<0.001
Female	-2.65	0.67	<0.001
Male (ref)	--	--	--
Non-Hispanic	3.44	1.21	0.005
Other Ethnicity	-18.74	6.98	0.01
Hispanic (ref)	--	--	--
English	-0.23	0.73	0.76
Other language	-4.76	2.99	0.11
Spanish (ref)	--	--	--
Baseline Systolic Blood Pressure	0.40	0.02	<0.001
Number of Comorbidities	1.25	0.32	<0.001
County Rate of Uninsured	0.02	0.09	0.79
County Obesity Prevalence	-0.36	0.21	0.08
Variable	Diastolic Blood Pressure (n=2776)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.62	0.35	0.08
Comparison (ref)	--	--	--
Age	-0.03	0.02	0.05
Female	-0.90	0.40	0.02
Male (ref)	--	--	--
Non-Hispanic	1.47	0.71	0.04
Other Ethnicity	-13.35	4.09	0.01
Hispanic (ref)	--	--	--
English	0.17	0.43	0.70
Other language	-0.18	1.76	0.92
Spanish (ref)	--	--	--
Baseline Diastolic Blood Pressure	0.37	0.02	<0.001
Number of Comorbidities	0.58	0.18	0.001
County Rate of Uninsured	0.04	0.05	0.44
County Obesity Prevalence	-0.13	0.12	0.29

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

Effect modification of the intervention effect on systolic blood pressure was explored for baseline health conditions (depression, hypertension, obesity, and diabetes), age, sex, and known SPMI diagnosis. The interaction terms of group and depression (p=0.91), hypertension (p=0.58), obesity (p=0.26), diabetes (p=0.37), age (p=0.11), sex (p=0.79), and known SPMI diagnosis (p=0.05) were not significant, indicating the intervention effect did not differ significantly based on these characteristics.

To answer the exploratory question of if the impact varied based on the population served, stratified analyses were conducted looking at those with and without each baseline condition, older and younger participants, males and females, and those with and without a known SPMI diagnosis separately. These groupings were selected a priori. When stratifying by these characteristics, there were statistically significant differences found between the intervention and comparison groups based on age. For those in the older age group, there were no significant differences between the intervention and comparison groups. Among the younger population, on average, those in the intervention group had a higher systolic blood pressure than those in the comparison group (see **Table 21**); the effect size (using Cohen's d) is 0.10.

Table 21. Effect of IBH Intervention on Twelve Month Systolic Blood Pressure, Under 49 Years

Variable	Systolic Blood Pressure (n=1186)		
	Estimate (β)	Standard Error	p-value
Intervention	**1.73**	**0.85**	**0.04**
Comparison (ref)	--	--	--
Female	-5.30	0.94	<0.001
Male (ref)	--	--	--
Non-Hispanic	3.30	1.67	0.05
Other Ethnicity	-12.46	8.24	0.13
Hispanic (ref)	--	--	--
English	-1.72	0.95	0.07
Other language	-10.07	4.82	0.04
Spanish (ref)	--	--	--
Baseline Systolic Blood Pressure	0.45	0.03	<0.001
Number of Comorbidities	0.78	0.43	0.07
County Rate of Uninsured	-0.18	0.12	0.12
County Obesity Prevalence	0.12	0.28	0.68

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).

Effect modification of the intervention effect on diastolic blood pressure was explored for baseline health conditions (depression, hypertension, obesity, and diabetes), age, sex, and known SPMI diagnosis. The interaction terms of group and depression (p=0.97), hypertension (p=0.68), obesity (p=0.67), age (p=0.35), sex (p=0.18), and known SPMI diagnosis (p=0.07) were not significant, indicating the intervention effect did not differ significantly based on these characteristics. The interaction between group and diabetes was significant (p=0.03), indicating the intervention effect on diastolic blood pressure was significantly different for those with diabetes compared to those without diabetes.

To answer the exploratory question of if the impact varied based on the population served, stratified analyses were conducted looking at those with and without each baseline condition, older and younger participants, males and females, and those with and without a known SPMI diagnosis separately. These groupings were selected a priori. When stratifying by these covariates, significant differences were found between the intervention and comparison group by sex, age, and diabetes. There was no significant difference between the intervention and comparison groups for diastolic blood pressure within the younger age group. On average, intervention participants in the older age group had lower diastolic blood pressure than older comparison participants (see **Table 22**); the effect size (using Cohen's d) is 0.10.

Table 22. Effect of IBH Intervention on Twelve Month Diastolic Blood Pressure, 49 Years and Older

Variable	Diastolic Blood Pressure (n=1589)		
	Estimate (β)	Standard Error	p-value
Intervention	**-0.94**	**0.46**	**0.04**
Comparison (ref)	--	--	--
Female	0.36	0.52	0.49
Male (ref)	--	--	--
Non-Hispanic	1.87	0.94	0.05
Other Ethnicity	-7.52	6.37	0.24
Hispanic (ref)	--	--	--
English	0.78	0.59	0.18
Other language	0.66	2.10	0.75
Spanish (ref)	--	--	--
Baseline Diastolic Blood Pressure	0.34	0.02	<0.001
Number of Comorbidities	0.55	0.23	0.02
County Rate of Uninsured	0.09	0.08	0.22
County Obesity Prevalence	-0.10	0.16	0.53

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).

There was no significant difference between the intervention and comparison groups for diastolic blood pressure for males. On average, female intervention participants had a lower diastolic blood pressure than female comparison participants (see **Table 23**); the effect size (using Cohen's d) is 0.09.

Table 23. Effect of IBH Intervention on Twelve Month Diastolic Blood Pressure, Females

Variable	Diastolic Blood Pressure (n=2020)		
	Estimate (β)	Standard Error	p-value
Intervention	**-0.88**	**0.40**	**0.03**
Comparison (ref)	--	--	--
Age	0.01	0.02	0.72
Non-Hispanic	1.67	0.82	0.04
Other Ethnicity	-15.64	6.27	0.01
Hispanic (ref)	--	--	--

English	0.01	0.50	0.98
Other language	-0.16	2.32	0.95
Spanish (ref)	--	--	--
Baseline Diastolic Blood Pressure	0.37	0.02	<0.001
Number of Comorbidities	0.47	0.20	0.02
County Rate of Uninsured	0.05	0.06	0.47
County Obesity Prevalence	-0.09	0.14	0.51

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

There are no limitations specific to systolic blood pressure to note. For diastolic blood pressure, participants from both groups who did not complete the study were more likely to have higher diastolic blood pressure measures. The influence of these participants could be a contributing factor in the lack of significance detected in the overall pooled sample.

HbA1c Level

Question 3. **Did intervention participants with diabetes who participated in a Sí Texas intervention obtain significantly improved HbA1c readings after 12 months compared to diabetic participants who received the standard of care? Did the impact vary based on the population served?** ***These questions are exploratory.***

Overview of Analysis

To answer these questions about intervention impact on HbA1c level, HbA1c readings data were collected. This measure was collected universally for four subgrantee studies (NCDV, TAMIU, TTBH, and UTHealth SPH). The four other studies collected HbA1c for a subset of their study population based on clinic procedures (Hope, Mercy, REAL, and UTRGV). The sample sizes for the presented analyses of HbA1c in the pooled cohort sample are as follows: bivariate analyses (n=2421) and primary linear regression analyses (n=2174).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 40** presents the mean HbA1c level data in each study period for the overall sample as well as the intervention and comparison groups. The overall study sample had a mean HbA1c of 8.1% at baseline. For those who returned for a follow-up assessment, mean HbA1c was 7.8% at 6-month follow-up and 7.9% at 12-month for follow-up. The intervention group began with mean HbA1c of 8.1%. For those participants in the intervention group who returned for a follow-up visit, mean HbA1c was 7.8% at 6-month and 12-month follow-ups. The comparison group participants began the study with a baseline HbA1c of 8.1%. For those participants in the control group who returned for a follow-up visit, the mean HbA1c was 7.8% at 6 months and 8.0% at 12 months. As previously noted in **Table 10**, the intervention and comparison groups were statistically equivalent on HbA1c level 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 38**). The change observed in HbA1c level from baseline to 12-month follow-up was statistically significant within both the intervention (p<0.001) and comparison (p<0.001) groups.

Bivariate analyses were also performed between the intervention and comparison groups comparing HbA1c levels at 12-month follow-up, without controlling for any additional covariates (**Table 39**). Based on a p value less than 0.05 for HbA1c when comparing the intervention and comparison groups at 12 months, the null hypothesis can be rejected (p=0.01). The HbA1c level was significantly different between the two groups when not adjusting for any additional covariates.

Model Building Process

All relevant covariates deemed appropriate (i.e. not colinear with other included covariates) were included in the model. These covariates included: age, sex, ethnicity, primary language, number of comorbidities at baseline, baseline HbA1c level, rate of uninsured at the county level, and prevalence of obesity at the county level. The final model specifications are below.

$$Y_{(HbA1c)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Ethincity + \beta_5 Language + \beta_6 BL\_Comorbidities + \beta_7 BL\_HbA1c + \beta_8 Uninsured + \beta_9 Obesity + \varepsilon$$

As previously stated, multiple imputation approach was considered but not performed due to the small amount of missing data at end-point.

Findings

Estimates for the final model of HbA1c level at 12 months are presented in **Table 24**.

Mean HbA1c level at 12 months differed significantly by intervention status (p=0.02) when analyzing the full cohort sample; the effect size (using Cohen's d) is 0.07. On average, the HbA1c level of those receiving enhanced IBH care was 0.14 percentage points lower than those receiving standard of care, adjusting for the included covariates.

$$Y_{(HbA1c)}= 2.85 + -0.14(Intervention) + -0.001(Age) + -0.01(Female) + -0.08(Non\text{-}Hispanic) + -0.31(Other\ Eth) + -0.25(English) + -0.37(Other\ Lang) + 0.05(BL\_Comorbidities) + 0.72(BL\_HbA1c) + 0.001(UninsuredRate) + -0.03(Obesity) + \varepsilon$$

Table 24. Effect of IBH Intervention on Twelve Month HbA1c, Full Sí Texas Sample

Variable	HbA1c (n=2174)		
	Estimate (β)	Standard Error	p-value
Intervention	**-0.14**	**0.06**	**0.02**
Comparison (ref)	--	--	--
Age	-0.001	0.003	0.65
Female	-0.01	0.07	0.89
Male (ref)	--	--	--
Non-Hispanic	-0.08	0.13	0.52
Other Ethnicity	-0.31	0.64	0.63
Hispanic (ref)	--	--	--
English	-0.25	0.08	0.001
Other language	-0.37	0.28	0.18
Spanish (ref)	--	--	--
Baseline HbA1c	0.72	0.02	<0.001

Number of Comorbidities	0.05	0.03	0.12
County Rate of Uninsured	0.001	0.01	0.94
-0.03	-0.03	0.02	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).

Additional Analyses

Effect modification of the intervention effect on HbA1c was explored for baseline health conditions (depression, hypertension, obesity, and diabetes), age, sex, and known SPMI diagnosis. The interaction terms of group and depression (p=0.29), hypertension (p=0.97), obesity (p=0.35), diabetes (p=0.12), age (p=0.37), sex (p=0.06), and known SPMI diagnosis (p=0.35) were not significant, indicating the intervention effect did not differ significantly based on these characteristics.

To answer the exploratory question of if the impact varied based on the population served, stratified analyses were conducted looking at those with and without each baseline condition, older and younger participants, males and females, and those with and without a known SPMI diagnosis separately. These groupings were selected a priori. When stratifying by these covariates, there were significant differences between the intervention and comparison groups based on diabetes, depression, age, sex, and known SPMI diagnosis. For those without diabetes, there was no difference between the intervention and comparison group for HbA1c. On average, intervention participants with diabetes at baseline had a lower HbA1c than comparison group participants with diabetes at 12 months (see **Table 25**); the effect size (using Cohen's d) is 0.09.

Table 25. Effect of IBH Intervention on Twelve Month HbA1c, Participants with Diabetes

Variable	HbA1c (n=1681)		
	Estimate (β)	Standard Error	p-value
Intervention	**-0.18**	**0.08**	**0.02**
Comparison (ref)	--	--	--
Age	-0.01	0.004	<0.001
Female	-0.003	0.08	0.97
Male (ref)	--	--	--
Non-Hispanic	0.04	0.19	0.82
Hispanic (ref)	--	--	--
English	-0.16	0.10	0.10
Other language	-0.47	0.30	0.13
Spanish (ref)	--	--	--
Baseline HbA1c	0.61	0.02	<0.001
Number of Comorbidities	0.003	0.04	0.93
County Rate of Uninsured	-0.02	0.01	0.14
County Obesity Prevalence	-0.04	0.03	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 those without depression, there was no difference between the intervention and comparison group for HbA1c. On average, intervention participants with depression at baseline had a lower HbA1c than

comparison group participants with depression at 12 months (see **Table 26**); the effect size (using Cohen's d) is 0.09.

Table 26. Effect of IBH Intervention on Twelve Month HbA1c, Participants with Depression

Variable	HbA1c (n=1135)		
	Estimate (β)	Standard Error	p-value
Intervention	**-0.21**	**0.09**	**0.02**
Comparison (ref)	--	--	--
Age	-0.0002	0.004	0.96
Female	0.05	0.10	0.58
Male (ref)	--	--	--
Non-Hispanic	-0.05	0.17	0.76
Other Ethnicity	-0.09	0.73	0.90
Hispanic (ref)	--	--	--
English	-0.27	0.11	0.01
Other language	-0.65	0.37	0.08
Spanish (ref)	--	--	--
Baseline HbA1c	0.72	0.02	<0.001
Number of Comorbidities	0.16	0.05	0.001
County Rate of Uninsured	-0.01	0.01	0.45
County Obesity Prevalence	-0.06	0.03	0.02

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 younger participants, there was no difference between the intervention and comparison group for HbA1c. On average, intervention participants in the older age group had a lower HbA1c than older comparison group participants at 12 months (see **Table 27**); the effect size (using Cohen's d) is 0.10.

Table 27. Effect of IBH Intervention on Twelve Month HbA1c, 49 Years and Older

Variable	HbA1c (n=1315)		
	Estimate (β)	Standard Error	p-value
Intervention	**-0.19**	**0.08**	**0.01**
Comparison (ref)	--	--	--
Female	0.03	0.09	0.76
Male (ref)	--	--	--
Non-Hispanic	-0.08	0.17	0.65
Other Ethnicity	-0.12	1.01	0.91
Hispanic (ref)	--	--	--
English	-0.05	0.10	0.62
Other language	-0.66	0.34	0.05
Spanish (ref)	--	--	--

Baseline HbA1c	0.68	0.02	<0.001
Number of Comorbidities	0.10	0.04	0.02
County Rate of Uninsured	0.01	0.01	0.51
County Obesity Prevalence	-0.02	0.03	0.40

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 males, there was no difference between the intervention and comparison group for HbA1c. On average, female intervention participants had a lower HbA1c than female comparison group participants at 12 months (see **Table 28**); the effect size (using Cohen's d) is 0.10.

Table 28. Effect of IBH Intervention on Twelve Month HbA1c, Females

Variable	HbA1c (n=1542)		
	Estimate (β)	Standard Error	p-value
Intervention	**-0.21**	**0.07**	**0.004**
Comparison (ref)	--	--	--
Age	<0.001	0.003	0.93
Non-Hispanic	0.04	0.16	0.80
Other Ethnicity	-0.60	1.00	0.54
Hispanic (ref)	--	--	--
English	-0.23	0.09	0.01
Other language	-0.44	0.38	0.25
Spanish (ref)	--	--	--
Baseline HbA1c	0.72	0.02	<0.001
Number of Comorbidities	0.07	0.04	0.07
County Rate of Uninsured	0.003	0.01	0.79
County Obesity Prevalence	-0.01	0.02	0.69

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 those without a known SPMI diagnosis, there was no difference between the intervention and comparison group for HbA1c. On average, intervention participants with a known SPMI diagnosis had a lower HbA1c than comparison group participants with a known SPMI diagnosis at 12 months (see **Table 29**); the effect size (using Cohen's d) is 0.13.

Table 29. Effect of IBH Intervention on Twelve Month HbA1c, Participants with SPMI diagnosis

Variable	HbA1c (n=596)		
	Estimate (β)	Standard Error	p-value
Intervention	**-0.24**	**0.11**	**0.02**
Comparison (ref)	--	--	--
Age	0.01	0.004	0.05
Female	-0.11	0.10	0.29

Male (ref)	--	--	--
Non-Hispanic	-0.36	0.17	0.03
Other Ethnicity	0.02	0.54	0.97
Hispanic (ref)	--	--	--
English	0.05	0.14	0.72
Other language	-0.57	0.38	0.13
Spanish (ref)	--	--	--
Baseline HbA1c	0.69	0.03	<0.001
Number of Comorbidities	0.08	0.06	0.19
County Rate of Uninsured	-0.02	0.01	0.12
County Obesity Prevalence	-0.05	0.03	0.11

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

Participants in both groups who did not complete the study were more likely to have lower HbA1c levels; which was consistent in both the intervention and comparison groups. This could have led to the groups becoming more similar at the end of the study. However, the study was able to detect a significant difference in the overall sample as well as several subgroups with the intervention having lower HbA1c levels.

Body Mass Index

Question 4. **Did intervention participants who participated in a Sí Texas intervention obtain significantly improved BMI scores after 12 months compared to participants who received the standard of care? Did the impact vary based on the population served? These questions are exploratory.**

Overview of Analysis

To answer these questions about intervention impact on BMI, height, weight, and/or BMI data were collected. This measure was collected for all eight subgrantee studies. The sample sizes for the presented analyses of BMI in the pooled cohort sample are as follows: bivariate analyses (n=2884) and primary linear regression analyses (n=2772).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 40** presents the mean body mass index values in each study period for the overall sample as well as the intervention and comparison groups. The overall study sample had a mean body mass index of 33.5 kg/m^2 at baseline. For those who returned for a follow-up assessment, mean body mass index was 33.7 kg/m^2 at 6-month follow-up and 33.9 kg/m^2 at 12-month follow-up. The intervention group began the study with a mean body mass index of 33.6 kg/m^2. For those participants in the intervention group who returned for a follow-up, mean body mass index was 33.8 kg/m^2 at 6-month follow-up and 34.0 kg/m^2 at 12-month follow-up. The comparison group began the study at mean body mass index of 33.5 kg/m^2. For those participants in the comparison group who returned for follow-up, mean body mass index was 33.6 kg/m^2 at 6- and 12-month follow-ups. As previously noted in **Table 10**, the intervention and comparison 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 38**). The slight change observed within body mass index from baseline to 12-month follow-up was not statistically significant within the comparison group but was significant in the intervention (p=0.01).

Bivariate analyses were also performed between the intervention and comparison groups comparing body mass index at 12-month follow-up, without controlling for any additional covariates (**Table 39**). Based on a p-value greater than 0.05 for body mass index when comparing the intervention and comparison 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 Building Process

All relevant covariates deemed appropriate (i.e. not collinear with other included covariates) were included in the model. These covariates included: age, sex, ethnicity, primary language, number of comorbidities at baseline, baseline BMI, rate of uninsured at the county level, and prevalence of obesity at the county level. The final model specifications are below.

$$Y_{(BMI)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Ethincity + \beta_5 Language + \beta_6 BL\_Comorbidities + \beta_7 BL\_BMI + \beta_8 Uninsured + \beta_9 Obesity + \varepsilon$$

As previously stated, multiple imputation approach was considered but not performed due to the small amount of missing data at end-point.

Findings

Estimates for the final model of BMI at 12 months are presented in **Table 30**.

Mean BMI at 12 months differed significantly by intervention status (p=0.02) when analyzing the full cohort sample; the effect size (using Cohen's d) is 0.03. On average, the BMI of those receiving enhanced IBH care was 0.27 kg/m^2 higher than those receiving standard of care, adjusting for the included covariates.

$$Y_{(BMI)}= 2.90 + 0.27(Intervention) + -0.01(Age) + 0.13(Female) + -0.18(Non\text{-}Hispanic) + 0.20(Other\ Eth) + 0.17(English) + -0.03(Other\ Lang) + -0.08(BL\_Comorbidities) + 0.96(BL\_BMI) + -0.01(UninsuredRate) + -0.01(Obesity) + \varepsilon$$

Table 30. Effect of IBH Intervention on Twelve Month BMI, Full Sí Texas Sample

Variable	BMI (n=2772)		
	Estimate (β)	Standard Error	p-value
Intervention	**0.27**	**0.11**	**0.02**
Comparison (ref)	--	--	--
Age	-0.01	0.005	0.005
Female	0.13	0.13	0.29
Male (ref)	--	--	--
Non-Hispanic	-0.18	0.23	0.42
Other Ethnicity	0.20	1.30	0.88
Hispanic (ref)	--	--	--

English	0.17	0.14	0.22
Other language	-0.03	0.56	0.95
Spanish (ref)	--	--	--
Baseline BMI	0.96	0.01	<0.001
Number of Comorbidities	-0.08	0.06	0.17
County Rate of Uninsured	-0.01	0.02	0.47
County Obesity Prevalence	-0.01	0.04	0.79

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

Effect modification of the intervention effect on BMI was explored for baseline health conditions (depression, hypertension, obesity, and diabetes), age, sex, and known SPMI diagnosis. The interaction terms of group and depression (p=0.59), hypertension (p=0.35), diabetes (p=0.85), age (p=0.58), sex (p=0.52), and known SPMI diagnosis (p=0.55) were not significant, indicating the intervention effect did not differ significantly based on these characteristics. The interaction term of group and obesity was significant (p=0.02), indicating the intervention effect on BMI was significantly different for participants who were obese compared to participants who were not.

To answer the exploratory question of if the impact varied based on the population served, stratified analyses were conducted looking at those with and without each baseline condition, older and younger participants, males and females, and those with and without a known SPMI diagnosis separately. These groupings were selected a priori. When stratifying by these covariates, there were significant differences between the intervention and comparison groups based on hypertension, diabetes, age, sex, and known SPMI diagnosis. For those without hypertension, there was no difference between the intervention and comparison group for BMI. On average, intervention participants with hypertension have a higher BMI than comparison participants with hypertension at 12 months (see **Table 31**); the effect size (using Cohen's d) is 0.05.

Table 31. Effect of IBH Intervention on Twelve Month BMI, Participants with Hypertension

Variable	BMI (n=962)		
	Estimate (β)	Standard Error	p-value
Intervention	**0.41**	**0.20**	**0.04**
Comparison (ref)	--	--	--
Age	-0.02	0.01	0.02
Female	0.18	0.21	0.39
Male (ref)	--	--	--
Non-Hispanic	0.06	0.41	0.88
Other Ethnicity	-0.23	2.16	0.92
Hispanic (ref)	--	--	--
English	0.25	0.24	0.32
Other language	-0.22	0.87	0.80
Spanish (ref)	--	--	--
Baseline BMI	0.97	0.01	<0.001

Number of Comorbidities	-0.10	0.12	0.41
County Rate of Uninsured	-0.01	0.03	0.82
County Obesity Prevalence	-0.03	0.07	0.68

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 those with diabetes, there was no difference between the intervention and comparison group for BMI. On average, intervention participants without diabetes have a higher BMI than comparison participants without diabetes at 12 months (see **Table 32**); the effect size (using Cohen's d) is 0.09.

Table 32. Effect of IBH Intervention on Twelve Month BMI, Participants without Diabetes

Variable	BMI (n=557)		
	Estimate (β)	Standard Error	p-value
Intervention	**0.78**	**0.29**	**0.01**
Comparison (ref)	--	--	--
Age	-0.02	0.01	0.06
Female	0.13	0.30	0.65
Male (ref)	--	--	--
Non-Hispanic	0.24	0.46	0.60
Other Ethnicity	0.16	1.47	0.92
Hispanic (ref)	--	--	--
English	-0.26	0.35	0.45
Spanish (ref)	--	--	--
Baseline BMI	0.97	0.02	<0.001
Number of Comorbidities	0.16	0.16	0.34
County Rate of Uninsured	-0.06	0.03	0.10
County Obesity Prevalence	-0.10	0.09	0.27

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 younger participants, there was no difference between the intervention and comparison group for BMI. On average, intervention participants in the older age group have a higher BMI than older comparison participants at 12 months (see **Table 33**); the effect size (using Cohen's d) is 0.05.

Table 33. Effect of IBH Intervention on Twelve Month BMI, 49 Years or Older

Variable	BMI (n=1587)		
	Estimate (β)	Standard Error	p-value
Intervention	**0.32**	**0.14**	**0.02**
Comparison (ref)	--	--	--
Female	0.11	0.16	0.51
Male (ref)	--	--	--
Non-Hispanic	-0.18	0.29	0.53

Other Ethnicity	-0.41	1.97	0.84
Hispanic (ref)	--	--	--
English	0.05	0.18	0.80
Other language	-0.13	0.65	0.84
Spanish (ref)	--	--	--
Baseline BMI	0.95	0.01	<0.001
Number of Comorbidities	-0.04	0.07	0.58
County Rate of Uninsured	-0.01	0.02	0.60
County Obesity Prevalence	-0.03	0.05	0.56

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 females, there was no difference between the intervention and comparison group for BMI. On average, male intervention participants have a higher BMI than male comparison participants at 12 months (see **Table 34**); the effect size (using Cohen's d) is 0.06.

Table 34. Effect of IBH Intervention on Twelve Month BMI, Males

Variable	BMI (n=756)		
	Estimate (β)	Standard Error	p-value
Intervention	**0.44**	**0.21**	**0.03**
Comparison (ref)	--	--	--
Age	-0.01	0.01	0.25
Non-Hispanic	-0.67	0.40	0.09
Other Ethnicity	-0.77	1.60	0.63
Hispanic (ref)	--	--	--
English	0.15	0.24	0.54
Other language	-0.05	0.79	0.95
Spanish (ref)	--	--	--
Baseline BMI	0.96	0.02	<0.001
Number of Comorbidities	-0.23	0.11	0.03
County Rate of Uninsured	-0.02	0.03	0.53
County Obesity Prevalence	0.01	0.07	0.91

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 those with a known SPMI diagnosis, there was no difference between the intervention and comparison group for BMI. On average, intervention participants with no known SPMI diagnosis have a higher BMI than non-SPMI comparison participants at 12 months (see **Table 35**); the effect size (using Cohen's d) is 0.03.

Table 35. Effect of IBH Intervention on Twelve Month BMI, Participants without SPMI diagnosis

Variable	BMI (n=2133)		
	Estimate (β)	Standard Error	p-value
Intervention	**0.25**	**0.11**	**0.03**
Comparison (ref)	--	--	--
Age	-0.01	0.01	0.01
Female	0.05	0.13	0.70
Male (ref)	--	--	--
Non-Hispanic	-0.66	0.27	0,01
Hispanic (ref)	--	--	--
English	0.13	0.14	0.36
Other Language	0.42	0.64	0.51
Spanish (ref)	--	--	--
Baseline BMI	0.96	0.01	<0.001
Number of Comorbidities	-0.10	0.06	0.08
County Rate of Uninsured	-0.11	0.06	0.09
County Obesity Prevalence	-0.17	0.09	0.07

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

There are no limitations specific to this measure to note.

Quality of Life

Question 5. **Did Sí Texas intervention participants report significant improvements in their quality of life (or physical functioning) after 12 months compared to participants who receive the standard of care? Did the impact vary based on the population served? These questions are exploratory.**

Overview of Analysis

To answer these questions about intervention impact on quality of life, data were collected using the Duke Health Profile tool. Quality of life data for these analyses are comprised of six subgrantees' data. This measure was collected for all but one of the subgrantee studies (TTBH) due to clinic procedures. Among the seven that collected data on the measure, one (Hope) did not include it as part of their final subgrantee study analyses and therefore those data are not included in this overarching analysis. The sample sizes for the presented analyses of Duke General Health score in the pooled cohort sample are as follows: bivariate analyses (n=2212) and primary linear regression analyses (n=2083).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 40** 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 63.5 at baseline. For those who returned for a follow-up assessment, mean General Health score was 70.2 at 6-month follow-up and 71.5 at 12-month follow-up. The intervention group began the study with a mean Duke General Health score of 61.2. For those participants

in the intervention group who returned for a follow-up, mean Duke General Health score was 68.5 at 6-month follow up and 69.6 at 12-month follow-up. The comparison group began the study with a mean Duke General Health score of 66.2 For those participants in the comparison group who returned for follow-up, mean Duke General Health score was 72.3 at 6-month follow-up and 73.8 at 12-month follow-up. As previously noted in **Table 10**, the intervention and control groups were not statistically equivalent on Duke General Health score at baseline. This imbalance was considered in final analyses presented.

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 38**). The changes observed within Duke General Health score from baseline to 12-month follow-up were statistically significant within both the intervention and comparison groups ($p<0.001$).

Bivariate analyses were also performed between the intervention and comparison groups comparing body mass index at 12-month follow-up, without controlling for any additional covariates (**Table 39**). Based on a p value less than 0.05 for Duke General Health score when comparing the intervention and comparison groups at 12 months, the null hypothesis can be rejected ($p<0.001$). Duke General Health score was significantly different between the two groups when not adjusting for any additional covariates.

Model Building Process

All relevant covariates deemed appropriate (i.e. not colinear with other included covariates) were included in the model. These covariates included: age, sex, ethnicity, primary language, number of comorbidities at baseline, baseline Duke General Health score, rate of uninsured at the county level, and prevalence of obesity at the county level. The final model specifications are below.

$$Y_{(General)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Ethincity + \beta_5 Language + \beta_6 BL\_Comorbidities + \beta_7 BL\_General + \beta_8 Uninsured + \beta_9 Obesity + \varepsilon$$

As previously stated, multiple imputation approach was considered but not performed due to the small amount of missing data at end-point.

Findings

Estimates for the final model of Duke General Health score at 12 months are presented in **Table 36**.

Mean Duke General Health score at 12 months did not differ significantly by intervention status ($p=0.54$) when analyzing the full cohort sample.

$$Y_{(General)}= 3.92 + -0.43(Intervention) + -0.01(Age) + 1.08(Female) + -1.08(Non\text{-}Hispanic) + -4.16(English) + -8.37(Other\ Lang) + -1.50(BL\_Comorbidities) + 0.46(BL\_General) + 0.31(UninsuredRate) + 1.09(Obesity) + \varepsilon$$

Table 36. Effect of IBH Intervention on Twelve Month Duke General Health score, Full Sí Texas Sample

Variable	Duke General Health (n=2083)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.43	0.69	0.54
Comparison (ref)	--	--	--
Age	-0.01	0.03	0.78

Female	1/08	0.77	0.16
Male (ref)	--	--	--
Non-Hispanic	-1.08	1.51	0.48
Hispanic (ref)	--	--	--
English	-4.16	0.89	<0.001
Other language	-8.37	3.01	0.01
Spanish (ref)	--	--	--
Baseline Duke General Health	0.46	0.02	<0.001
Number of Comorbidities	-1.50	0.36	<0.001
County Rate of Uninsured	0.31	0.11	0.003
County Obesity Prevalence	1.09	0.21	<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

Effect modification of the intervention effect on Duke General Health score was explored for baseline health conditions (depression, hypertension, obesity, and diabetes), age, sex, and known SPMI diagnosis. The interaction terms of group and depression (p=0.68), hypertension (p=0.12), obesity (p=0.78), diabetes (p=0.32), age (p=0.36), and sex (p=0.78) were not significant, indicating the intervention effect did not differ significantly based on these characteristics. The interaction between group and known SPMI diagnosis was significant (p=0.03), indicating that the intervention effect on Duke General Health differed for those with a known SPMI diagnosis compared to those without.

To answer the exploratory question of if the impact varied based on the population served, stratified analyses were conducted looking at those with and without each baseline condition, older and younger participants, males and females, and those with and without a known SPMI diagnosis separately. These groupings were selected a priori. When stratifying by these covariates, significant differences were found between the intervention and comparison groups based on depression.

On average, intervention participants without depression had a higher Duke General Health score than comparison participants without depression at 12 months (see **Table 37**); the effect size (using Cohen's d) is 0.10.

Table 37. Effect of IBH Intervention on Twelve Month Duke General Health score, Participants without Depression

Variable	Duke General Health (n=1015)		
	Estimate (β)	Standard Error	p-value
Intervention	**1.53**	**0.71**	**0.03**
Comparison (ref)	--	--	--
Age	-0.07	0.03	0.03
Female	0.05	0.80	0.95
Male (ref)	--	--	--
Non-Hispanic	0.09	2.29	0.97
Hispanic (ref)	--	--	--

English	-1.51	0.95	0.11
Other language	-0.07	3.79	0.98
Spanish (ref)	--	--	--
Baseline Duke General Health	0.54	0.03	<0.001
Number of Comorbidities	0.36	0.44	0.41
County Rate of Uninsured	3.06	0.20	<0.001
County Obesity Prevalence	4.43	0.33	<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).

Limitations

There was imbalance at baseline for Duke General Health score with those in the intervention having lower average scores than those in the comparison. Additionally, participants who did not complete the study in both groups were more likely to have lower average scores; indicating consistent patterns across the groups. These could be contributing factors in the nonsignificant results detected in the overall pooled sample.

Question 6. **What type of integrated behavioral health model improves participants' physical and mental health outcomes controlling for sociodemographic and patient population characteristics?** ***(This question is exploratory)***

The following section describes the integrated behavioral health model implemented by each subgrantee, the specific setting and context for each, and the key findings from the subgrantee-specific evaluation study.

Tropical Texas Behavioral Health

This intervention at a local mental health authority used an RCT design to examine the reverse co-location of primary care services within a behavioral health service organization. The impact evaluation study used a randomized control trial (RCT) design to compare intervention participants receiving the delivery of integrated behavioral health with comparison participants receiving the usual care provided within a behavioral health clinic for patients with SPMI. The program was implemented to fidelity, and the evaluation was conducted as intended. The study showed that, when controlling for baseline measures and other covariates, the intervention participants had significantly greater improvements in the confirmatory outcome (reduced systolic blood pressure, β=-3.86, p=0.04) and an additional outcome identified in the logic model (reduced HbA1c, β=-0.36, p=0.001) at 12 months compared to the control participants, consistent with prior research.

Mercy Ministries of Laredo

In their Sí Three program, this faith-based charity clinic combined components of the integrated care model studied by Druss et al. (2001) with faith-based care discussed by Worthington et al. (2011) The implementation of Mercy's Sí Three program showed that the program was implemented in alignment with the program logical model and that there was strong fidelity in implementation. Using a quasi-experimental design, study results indicate that the Sí Three program improved behavioral health among intervention participants. More specifically, the study showed that, when controlling for baseline measures and other covariates, the intervention participants had significantly greater improvements when compared with the primary comparison group participants in the depression outcome over time

(reduced depression as measured through PHQ-9 over the study period which includes baseline, 6-month and 12-month, β=-1.76, p=0.001).

Nuestra Clinica del Valle

In this federally qualified health center, the NCDV NuCare program incorporated a primary care behavioral health (PCBH) approach focusing on low-income diabetic patients. The NuCare program supported warm-handoffs between clinical services, community health workers working within the clinic, and provision of community-based wellness services. Using a quasi-experimental design, study findings show a significant improvement was demonstrated in the exploratory outcome of quality of life as measured by the Duke Health Profile. Study findings suggest that the NuCare intervention was associated with significantly higher mean values of Duke General Health score at 12 months by 5.36 points ($p<0.001$), Duke Mental Health Score at 12 months by 6.22 points ($p<0.001$) and Duke Social Health Score at 12 months by 6.79 points ($p<0.001$). The Duke General Health score, an exploratory outcome, surpassed the standard threshold for small effect sizes (Cohen's d=0.34) for the analysis comparing intervention participants with the comparison group.

UT Health SPH

In a university-affiliated setting with multiple clinical and community partners, UT Health SPH's Salud y Vida 2.0 program used an integrated community continuum of care approach. The model builds off an established community-wide chronic care program, Salud y Vida 1.0, to increase services and support to uncontrolled, low-income diabetic patients in the lower Rio Grande Valley. Key additional services available through Salud y Vida 2.0 include medication therapy management, diabetes friendly cooking classes, and behavioral health services. The RCT study compared intervention participants receiving the delivery of enhanced integrated behavioral health (SyV 2.0) with control group participants already receiving the usual integrated care (services provided by SyV 1.0). When controlling for baseline measures and other covariates, intervention assigned participants did not have statistically significant improvement in the HbA1c confirmatory outcome when compared to the control participants at 12 months. However, bivariate results within intervention and control groups showed improvements in HbA1c, PHQ-9, Duke General Health score, total cholesterol, medication adherence score, and diabetes self-efficacy. There is also evidence of effect modification of PHQ-9 score when stratifying by time enrolled in the SyV 1.0 program. The intervention was not found to be significantly associated with lower PHQ-9 score among those who spent less than the median tenure (21.5 months) in SyV 1.0, but there was a positive effect among those intervention participants who spent more than the median tenure in SyV 1.0 (β= -1.28, p=0.01; d=0.36).

UTRGV

Within two university-affiliated family medicine residency clinics, UTRGV implemented a PCBH program integrating a behavioral health consultant into a primary care clinic to provide consultation to primary care physicians and brief patient interventions to low-income patients in the lower Rio Grande Valley. In their QED study, results found that, on average, the PHQ-9 score of intervention participants at 12 months was 1.94 points lower than the comparison participants, holding all other variables in the model constant (p=0.001); the effect size (using Cohen's d) was 0.31. Consistent with this finding, the study results also suggested that the intervention group experienced a statistically significant increased decline in depression trajectory compared to the external comparison group (β=-1.70, p=.01). Significant effect modification in intervention effect was identified by age group, with greater gains observed in PHQ-9 score among participants younger than 45 years old compared to participants aged 45 and above. On average, for participants under age 45 at baseline, intervention participants had a PHQ-9 score 2.65 points lower at 12 months than those in the comparison group (p=0.01).

REAL, Inc.

REAL is a transportation-focused organization with multiple clinical and community partners. TRIP for Salud y Vida focused on an SPMI population using a reverse co-location model. The program worked in partnership with the Local Mental Health Authority, which offered reverse co-location IBH services, and provided transportation that was customized to meet a patient's medical and health needs, care coordination, and community-based services tailored to increase patient knowledge, self-efficacy, and social support. The quasi-experimental study showed that the reverse co-located IBH program with transportation (TRIP for Salud y Vida) had a significant improvement in DBP (-3.96 mmHG; 95% CI: -7.48 to – 0.45, *p*=0.014, *d=-0.21)* over time when controlling for age, sex and baseline characteristics within the intervention consumers. Significant improvements in quality of life (Duke Health Profile) and the PHQ-9 were found within the intervention group and between the intervention and comparison groups at 12-months for Anxiety (-5.83; 95% CI: -9.50 to -2.16, p < 0.001, *d* = -0.30) and Pain (-13.44; 95% CI: -24.41 to -2.47, p = 0.005, *d* = -0.16) Duke Health Profile domains and PHQ-9 (-2.77; 95% CI: -4.83 to -0.72, *d* = 0.18, *p* = 0.001).

Hope

Hope, a non-profit charity clinic utilizing volunteer primary care providers, implemented a collaborative care model of IBH (Sanchez & Watt, 2012; Watt, 2009) at its site. The impact evaluation used a randomized control trial (RCT) design to compare participants receiving the enhanced delivery of integrated behavioral care with nonparticipants receiving the usual care provided within a charitable community clinic for uninsured individuals living at or below 200% of the poverty line. When controlling for baseline measures and other covariates, there was a statistically significant positive effect in the exploratory outcome of depressive symptoms, as measured by PHQ-9 score, in intervention compared to the control group (β= -1.67, p=0.01; d=0.29). The study also found evidence of effect modification of PHQ-9 score when stratifying by age. Among those who were the mean study participant age of 51 years or older at baseline, the intervention was significantly associated with a lower PHQ-9 score. On average, for those 51 years or older at baseline, intervention participants had a PHQ-9 score 2.08 points lower than those in the control group (p=0.01); the effect size (using Cohen's d) is 0.34. The intervention was not found to be significantly associated with PHQ-9 score among those who were under 51 years.

TAMIU

With its multitude of clinical and community partners, TAMIU, a university-affiliated subgrantee, implemented a model based on an integrated community continuum of care approach. This model 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 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. The RCT study found that when controlling for baseline measures and other covariates, intervention participants did not have statistically significant improvement in any of the outcomes of interest when compared to control participants at 12 months. However, 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.

Table 38. Within Group Bivariate Analyses Comparing Impact Measures from Baseline to 12 Months, by Intervention Group

POOLED INTERVENTION GROUP				
	12-Month (n=1564) Mean (SD)	Baseline (n=2254) Mean (SD)	12-month (–) Baseline Mean Difference (SD)	p-value
BMI[a]	**33.9 (8.0)**	**33.7 (7.8)**	**0.2**	**0.01**
Systolic blood pressure	**128.8 (18.6)**	**132.3 (19.6)**	**-3.5**	**<0.001**
Diastolic blood pressure	**76.8 (10.4)**	**79.0 (10.7)**	**-2.0**	**<0.001**
Non-Parametric Tests[b]	12-Month Median (IQR)		Baseline Median (IQR)	p-value
HbA1c	**7.4 (2.9)**		**7.7 (3.5)**	**<0.001**
PHQ-9	**4.0 (8.0)**		**6.0 (11.0**	**<0.001**
Duke (General)[c]	**73.3 (30.0)**		**66.7 (33.3)**	**<0.001**
POOLED COMPARISON GROUP				
	12-Month (n=1399) Mean (SD)	Baseline (n=1972) Mean (SD)	12-month (–) Baseline Mean Difference (SD)	p-value
BMI[a]	33.6 (7.5)	33.6 (7.3)	0.0 (0.1)	0.58
Systolic blood pressure	**127.8 (17.9)**	**131.6 (18.8)**	**-3.8 (18.4)**	**<0.001**
Diastolic blood pressure	**77.2 (10.0)**	**78.6 (10.5)**	**-1.5 (11.0)**	**<0.001**
Non-Parametric Tests[b]	12-Month Median (IQR)		Baseline Median (IQR)	p-value
HbA1c	**7.6 (3.0)**		**7.8 (3.0)**	**<0.001**
PHQ-9	**3.0 (8.0)**		**4.0 (9.0)**	**<0.001**
Duke (General)[c]	**76.7 (30.0)**		**73.3 (33.3)**	**<0.001**

Note: Bold denotes significance of p < 0.05 [a] the log transformation was used to conduct statistical testing [b] the Wilcoxon Signed Rank test was used to examine non-normally distributed data [c] TTBH did not collect data using the Duke Health Profile & data collected from Hope not included in analyses

Table 39. Between Group Bivariate Analyses Comparing Intervention to Comparison at 12-Month Follow-Up

	Total Sample (n=2963)	Pooled Intervention Group (n=1564)	Pooled Comparison Group (n=1399)	*p*
	Mean (SD)	Mean (SD)	Mean (SD)	
BMI[a]	33.8 (7.8)	33.9 (8.0)	33.6 (7.5)	0.43
Systolic blood pressure	128.3 (18.3)	128.8 (18.6)	127.8 (17.9)	0.13
Diastolic blood pressure	77.0 (10.2)	76.8 (10.4)	77.2 (10.0)	0.39
Non-Parametric Tests[b]	Median (IQR)	Median (IQR)	Median (IQR)	*p*
HbA1c	**7.5 (3.0)**	**7.4 (2.9)**	**7.6 (3.0)**	**0.01**
PHQ-9	**3.0 (8.0)**	**4.0 (8.0)**	**3.0 (8.0)**	**0.01**
Duke (General)[c]	**73.4 (26.7)**	**73.3 (30.0)**	**76.7 (30.0)**	**<0.001**

Note: Bold denotes significance of p < 0.05 [a] the log transformation was used to conduct statistical testing [b] the Wilcoxon Signed Rank test was used to examine non-normally distributed data [c] TTBH did not collect data using the Duke Health Profile & data collected from Hope not included in analyses

Table 40. Impact Measures by Study Arm and Follow-up Period, Overall and by Study Group

	Total Sample			Pooled Intervention Group			Pooled Comparison Group		
	Baseline	6-Mo	12-Mo	Baseline	6-Mo	12-Mo	Baseline	6-Mo	12-Mo
	n=4226	n=3097	n=2955	n=2254	n=1676	n=1559	n=1972	n=1421	n=1396
Measure		Mean (SD)			Mean (SD)			Mean (SD)	
Blood pressure									
Systolic	131.9 (19.5)	128.9 (18.5)	128.3 (18.3)	132.0 (19.7)	128.9 (18.6)	128.8 (18.6)	131.8 (19.2)	129.0 (18.4)	127.8 (17.9)
Missing	36	49	64	22	18	35	14	31	29
Diastolic	79.0 (10.8)	77.4 (10.4)	77.0 (10.2)	79.0 (10.8)	77.1 (10.5)	76.8 (10.4)	79.0 (10.8)	77.6 (10.3)	77.2 (10.0)
Missing	36	48	63	22	18	34	14	30	29
HbA1c[a]	N=3344	N=2542	N=2421	N=1712	N=1295	N=1191	N=1632	N=1247	N=1230
HbA1c	8.1 (2.2)	7.8 (2.4)	7.9 (2.1)	8.1 (2.3)	7.8 (2.4)	7.8 (2.1)	8.1 (2.2)	7.8 (2.4)	8.0 (2.2)
Missing	--	--	--	--	--	--	--	--	--
BMI									
BMI	33.5 (7.5)	33.7 (7.6)	33.8 (7.8)	33.6 (7.8)	33.8 (7.8)	33.9 (8.0)	33.5 (7.3)	33.6 (7.3)	33.6 (7.5)
Missing	39	59	71	24	22	38	15	37	33
PHQ-9									
PHQ-9 Score	7.7 (7.0)	5.9 (6.4)	5.5 (6.1)	8.4 (7.0)	6.3 (6.5)	5.8 (6.3)	7.0 (6.9)	5.4 (6.2)	5.2 (6.0)
Missing	147	265	194	72	134	98	75	131	96
DUKE Health[a]	N=3109	N=2447	N=2212	N=1703	N=1332	N=1184	N=1406	N=1115	N=1028
General Health	63.5 (23.0)	70.2 (21.6)	71.5 (19.9)	61.2 (22.7)	68.5 (21.2)	69.6 (20.8)	66.2 (23.2)	72.3 (21.9)	73.8 (18.5)
Missing	--	--	--	--	--	--	--	--	--

[a] *Because this measure was not universally collected at all subgrantees, the N presented is the number of participants for which data were collected. It cannot be determined if those without data reported are missing data or data were not collected based on clinical practice*.

Meta-Analysis Results

For the conventional meta-analyses, random effects models (DerSimonian & Laird, 1986) were used to address heterogeneity across studies. Because we did not include effect sizes for multiple health outcomes in one regression analysis, there was no need to adjust for clustering.

There were some deviations from the proposed analyses in the SEP. Several analyses originally described in the SEP aimed to further dive deeper into the effect of IBH across studies by examining results by different intervention type or other characteristics. However, given the small number of studies available for the meta-analysis and the availability of individual-level patient data for the pooled regression, it was decided that deeper dive examinations into the potential effect of IBH and its differential impact would be better represented through the individual-level regression rather than the meta-analysis. Therefore, in this section, one simple random effects meta-analysis is presented for each of the health outcomes.

Studies had variation in results regarding significance and effect direction. The adjusted mean differences are present in **Table 41**.

For PHQ-9 score, of the seven studies included, two detected statistically significant positive effects in the intervention group compared to the comparison group, in that the mean difference was negative and thus showed a significant decrease in PHQ-9 score associated with the intervention. One study resulted in a significant negative effect of PHQ-9 in the intervention compared to the comparison, a result that appears to be mediated by number of behavioral health visits. The remaining four studies did not detect a statistically significant difference in PHQ-9 score between the intervention and comparison groups. The estimates produced from the linear regression models in these four studies were in the direction of improvement despite the lack of statistical significance in the final multivariate model.

For systolic blood pressure, of the seven studies, one detected a significant positive effect in the intervention group compared to the control group. Another study detected a statistically significant negative effect on systolic blood pressure in the intervention group compared to the comparison group. The other five studies did not detect a significant effect of the intervention on systolic blood pressure; three of which produced estimates in the direction of improvement despite the lack of significance for the final multivariate model. For diastolic blood pressure, of the seven studies, one detected a statistically significant negative effect on diastolic blood pressure for the intervention group compared to the comparison group. The other six studies did not detect a statistically significant difference on diastolic blood pressure between the intervention and comparison groups; four of which produced estimates in the direction of improvement despite the lack of statistical significance in the final model.

For HbA1c, of the six studies, one study detected a statistically significant positive effect on HbA1c for the intervention group compared to the control group. The other five studies did not detect a statistically significant difference between the intervention and comparison groups on HbA1c; three of which produced estimates in the direction of improvement despite lack of statistical significance in the final model.

For BMI, of the seven studies, one detected a significant negative effect on BMI in the intervention compared to the comparison group indicating increased BMI in the intervention group, an unexpected direction for this relationship. The other six studies did not detect a statistically significant difference between the intervention and comparison groups; three studies produced estimated in the direction of improvement despite the lack of significance in the final model.

For Duke General Health score, of the four studies, two detected significant positive effects on Duke General Health score in the intervention compared to the comparison groups. The other two studies did not detect a statistically significant difference between the intervention and comparison groups; one produced an estimate in the direction of improvement despite the lack of significance in the final model.

Table 41. End-Point Results from Sí Texas Studies included in Meta-Analyses

Subgrantee	PHQ-9 Score		Systolic BP		Diastolic BP		HbA1c		BMI		Duke General Health	
	Adjusted Mean Difference	p-value	Adjusted Mean Difference	p-value	Adjusted Mean Difference	p-value	Adjusted Mean Difference	p-value	Adjusted Mean Difference	p-value	Adjusted Mean Difference	p-value
Tropical	-0.39	0.60	**-3.86**	**0.04**	-2.05	0.08	**-0.36**	**0.001**	0.70	0.05	N/A	--
Mercy	-0.81	0.06	-0.71	0.63	-0.60	0.56	-0.09	0.60	0.03	0.87	**4.01**	**0.02**
Hope	**-1.67**	**0.01**	-2.47	0.15	-0.93	0.22	-0.11	0.67	0.14	0.52	N/A	--
UTRGV	**-1.94**	**0.001**	**7.56**	**<0.001**	**2.76**	**0.01**	N/A	--	**1.12**	**0.005**	N/A	--
TAMIU	**0.76**	**0.03**	2.51	0.05	0.82	0.27	0.11	0.38	-0.03	0.93	-0.28	0.80
UTSPH	-0.44	0.21	-0.59	0.73	0.74	0.52	0.00	0.98	-0.15	0.58	1.25	0.38
NCDV	-0.1	0.56	1.99	0.14	-0.86	0.24	-0.20	0.13	-0.02	0.92	**5.36**	**<0.001**

Prior to conducting the meta-analysis, analyses were conducted to test for heterogeneity across studies. For PHQ-9 outcome, the Cochran Q was significant ($Q=22.7$, $df=6$, $p<0.05$), suggesting heterogeneity across the effects of the intervention on PHQ-9 among the seven sites. Similarly, the Cochran Q was also significant for the intervention effects on SBP ($Q=28.6$, $def=6$, $p<0.05$), DBP ($Q=14.7$, $df=6$, $p<0.05$), and Duke Health score ($Q=14.6$, $df=3$, $p<0.05$). However, despite significant heterogeneity detected among the four outcomes, there was no significant heterogeneity among the interventions effects on two other outcomes including BMI or HbA1c across the study sites. It is known in the literature that Cochran Q has limited statistical power to detect true underlying heterogeneity across studies when the number of included studies is small (Alexander et al, 1989). Given there are multiple outcomes across study sites where significant heterogeneity of the intervention effects were detected, a random-effects models meta-analysis was determined as the approach most suitable for the study-level meta-analysis (DerSimonian and Laird, 1986). Random-effects model meta-analysis is also suitable for the findings to be generalizable to potentially wider population of studies (Hedges and Vevea, 1998; Field, 2001).

Meta-Analysis Results

Overall estimates for the difference in health outcomes between intervention and comparison groups are presented in **Table 42**. There were no statistically significant differences detected when synthesizing the average effects across the included studies.

Table 42. Meta-Analyses Results, by Outcome

Outcome	Average Mean Difference	SE	*p*
PHQ-9 Score	-0.56	0.34	0.15
Systolic Blood Pressure	0.65	1.42	0.66
Diastolic Blood Pressure	-0.03	0.57	0.96
HbA1c	-0.12	0.16	0.48
BMI	0.17	0.40	0.40
Duke General Health Score	2.58	1.31	0.14

Limitations

Limitations of these meta-analyses include the small number of studies available, considerable heterogeneity across the interventions and their implementation, measured and unmeasured site-level and patient-level difference, and the mixture of study design with various rigor related to internal validity at the individual study level. Stratified meta-analyses would result in even smaller number of studies to be included and limit generalizability of the results.

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

OVERALL SUMMARY

This final report describes the findings from the evaluation of the entire Sí Texas project portfolio, comprised of eight subgrantees implementing different IBH models in south Texas. Four of the subgrantees employed an RCT design and the other four used a QED for their subgrantee-level studies. They also conducted implementation evaluation studies with extensive qualitative data collection using focus groups and interviews. This overarching evaluation examines these findings within the context of the larger portfolio. For the overarching impact study, individual-level patient data were pooled across all eight subgrantees to examine the impact on five mental and physical health outcomes of participants in a Sí Texas IBH program for 12 months compared to participants receiving standard of care. The impact study also included a meta-analysis of subgrantee-level study results. This overarching implementation evaluation analyzed a large dataset of qualitative data pooled across subgrantees to understand the common facilitators and barriers to implementing various IBH programs across settings and contexts in south Texas.

This evaluation study achieves a moderate level of evidence given that the methods used for the overarching impact study had strong internal validity. The pooled sample of individual-level data and the meta-analysis utilized data from eight subgrantee studies, each with an RCT or QED design which mitigated threats to internal validity, particularly selection bias. The main impact analyses of this study pooled individual-level patient data from across the portfolio resulting in a baseline sample of 4,226 participants which provided sufficient power to detect significant differences in outcome measures as well as strong external validity to other border region areas. The pooled analyses controlled for both individual-level and contextual-level variables to adjust for variation across the sample. Overall, interventions were implemented as planned, and the evaluation was conducted to fidelity. The study also meets the criteria for effective evidence. The study demonstrates a positive, significant finding for both the confirmatory outcome (PHQ-9) and an exploratory outcome (HbA1c). The study showed that, when controlling for baseline measures and other covariates, the intervention participants had significantly greater improvements in depressive symptoms (β=-0.39, p=0.03, Cohen's d=0.06) at 12 months compared to the comparison participants. Additionally, when controlling for baseline measures and other covariates, the intervention participants had significantly greater improvements in HbA1c (β=-0.14, p=0.02, Cohen's d=0.07)) at 12 months compared to the comparison participants.

Given the internal validity of this study and large sample size, the fidelity to which the evaluation and programs were implemented, the significant results, and the unique and important contribution to the field, this study achieves a moderate level of evidence to improve our understanding of the impact of integrated behavioral health across the south Texas border region.

This study contributes to our understanding of the impact and effectiveness of IBH in a range of settings that serve primary low-income Hispanic patients in a border region. It is unique in the field to have findings on this population group. There is a dearth of literature on whether and how IBH can be effective with Hispanic populations in a border region. Additionally, this study leverages the expansiveness and diversity of intervention approaches, in that it does not singularly focus on one IBH model, but, in examining the portfolio as whole, confirms that integration of primary care and behavioral health services within different settings can improve health outcomes across the region. The implementation evaluation for the

portfolio study also yields a better understanding of what are the facilitators and barriers common to implementing IBH in the region across different settings and contexts.

Summary of Implementation Findings

Subgrantees implemented their IBH models generally to fidelity but also continually made changes after program implementation to adapt to patient needs or address challenges. Types of changes included adaptations in care coordination, group classes, community outreach, roles and responsibilities of providers, and clinic appointments. This section provides more detail on the changes in each of these areas. Five subgrantees (REAL, NCDV, TAMIU, UTHealth, UTRGV) described adaptations to community outreach activities that were part of their IBH programs. They recounted changes to how community engagement and outreach were structured, including transportation services, peer support, and home visits. Adaptations to group classes were discussed among subgrantees from four sites (Mercy, REAL, NCDV, UTHealth). Subgrantees described changes to how group classes were run or scheduled. Six subgrantees (HFHC, Mercy, NCDV, TAMIU, UTHealth, UTRGV) spoke of adapting the care coordination in their clinics. They discussed changes to how providers connected participants with other providers and services, such as behavioral health and pharmacy. Among six subgrantees (Mercy, NCDV, TAMIU, TTBH, UTHealth, UTRGV), there were adaptations to providers' roles and responsibilities from what was originally planned for their IBH models. As subgrantees described, these shifts were due to hiring of new staff, recognizing that existing staff had skills that went beyond their current role, or building capacity and skills of existing staff. Five subgrantees (HFHC, Mercy, NCDV, TAMIU, UTHealth) spoke about changes in how and when clinic appointments were scheduled. According to subgrantees, most clinics and partners made changes to clinic schedules and hours to accommodate participants and providers.

At the mid-point and end-point of program implementation, communication, use of physical space, and training were identified by all subgrantees as facilitators to implementation. Communication was the primary adoption facilitator discussed during interviews. In-person communication, the most frequently discussed mode, occurred between providers and staff, providers and participants, and subgrantees and their program partners. To support in-person communication, subgrantees detailed communication by phone, data system and other forms of electronic communication (e.g., email, text, instant message). The use of electronic medical records (EMRs), or other data systems (e.g., Access or Excel files) was most frequently shared as facilitating communication between staff and providers and integration of services. Examples included viewing participant notes from other members of the care team, identifying or flagging areas to address with participants, and using the electronic scheduling function to coordinate services. Although communication was also the most commonly cited adoption facilitator, limited communication was also the primary adoption barrier described across all subgrantees. Communication challenges were discussed related to workflow, program staff/provider roles and responsibilities, and transition to and buy-in for the IBH model. While some subgrantees shared that they needed more communication during early implementation as they learned new workflows, others described how changes were made throughout implementation but not always communicated to all necessary staff and providers. Data system challenges were also a significant communication barrier. These focused on functionality, limited tech support, and communication with providers and partners. Specific challenges with functionality were mentioned related to data entry and sharing, navigating within data systems, and health information sharing. These issues were challenging to address within subgrantee sites; addressing these with their external partners was an even a greater challenge, according to the three subgrantees with external program partners.

Aside from communication both facilitating and hindering implementation, physical space and its use was also a facilitator to program implementation. Interviewees primarily spoke about physical space in two ways – adaptations to physical space and movement of providers and participants within the physical space. These facets of physical space supported effective implementation of IBH programs as well as participant engagement. Finally, staff and provider training was an adoption facilitator noted across all subgrantees. According to interviewees, online and in-person training prior to and during implementation facilitated subgrantees' IBH work. A variety of training topics were described, including 1) the IBH model, 2) skills or knowledge specific to staff/provider roles in IBH implementation, 3) specific health topics, 4) communicating with participants, and 5) data systems.

As referenced previously, three subgrantee interventions (REAL, TAMIU, UTHealth) involved a range of external program partners for implementation. In interviews, these subgrantees characterized their partnerships and connectedness with the other IBH program partners. These discussions focused on building or strengthening partnerships, facilitating connectedness of services across organizations, and forming partnerships to fill gaps in services. Although there was regular contact between program staff across agencies, partnership development was primarily described as happening at the leadership level among agencies, at the start of their Sí Texas programs as well as near the end to provide a unified strategic vision for the future of the program and partnership. In addition to talking about how partnerships were built and strengthened for the future, several subgrantees spoke about the more technical aspects of facilitating connectedness across their partner organizations through staff and data systems. Building on the partnerships developed as part of Sí Texas, several subgrantees described partnering with other organizations that offer services to fill a gap in or complement existing Sí Texas services. Finally, while the other five subgrantees (HFHC, Mercy, NCDV, TTBH, UTRGV) did not have formal partnerships as part of their IBH programs, several discussed partnerships in the context of communication with and learning from other subgrantees in the Sí Texas cohort, as well as HRiA and MHM.

Summary of Impact Findings

Results from the pooled individual-level regression analyses indicate that implementing an enhanced level of IBH improved physical and behavioral health. When controlling for baseline measures, individual level characteristics, and contextual covariates, participants in the pooled intervention group had significantly lower PHQ-9 scores (confirmatory variable) compared to those in the pooled comparison group receiving standard of care (which was either standard IBH services or non-integrated services at the project end-point, depending on the subgrantee) (β=-0.39, p=0.03, Cohen's d=0.06). Additionally, when controlling for baseline measures, individual level characteristics, and contextual covariates, the intervention participants had significantly greater improvements in HbA1c, an exploratory outcome (β=-0.14, p=0.02, Cohen's d=0.07) at 12 months compared to the comparison participants. However, compared to those receiving standard of care, those in the pooled intervention group had a higher BMI (β= 0.27, p=0.02, Cohen's d=0.03). There were no statistically significant differences detected in blood pressure or quality of life measures in the full pooled sample. Stratified analyses did find, for those under 49 years, participants in the intervention group had significantly higher average systolic blood pressure compared to the comparison participants at 12 months (β= 1.73, p=0.04, Cohen's d=0.10). Additional stratified analyses indicated, for those 49 years or older, that those in the intervention group had a lower average diastolic blood pressure than comparison participants at 12 months (β=-0.94, p=0.04, Cohen's d=0.10). Further research in this area could help clarify whether these differences are clinically meaningful or whether engagement in integrated services may affect blood pressure differently in patients of different ages and identify potential reasons.

Separate stratified analyses on the pooled individual participant samples showed that among those with diabetes at baseline (β=-0.18, p=0.02, Cohen's d=0.09), higher PHQ-9 scores at baseline (β=-0.21, p=0.02, Cohen's d=0.09), participants with a known SPMI diagnosis at baseline (β=-0.24, p=0.02, Cohen's d=0.13), older study participants (β=-0.19, p=0.01, Cohen's d=0.10), and female participants (β=-0.21, p=0.004, Cohen's d=0.10), the intervention group within each of these subsamples had a significantly lower HbA1c compared to the comparison group.

The conventional meta-analyses did not detect any significant intervention effect on any of the health outcomes when synthesized across studies.

Lessons Learned

This evaluation contributes to our understanding of the impact of the integration of primary care and behavioral health services in the south Texas region. Sí Texas was set up to allow subgrantees to identify locally-tailored IBH models for their patient populations and settings. The implementation evaluation identified that regardless of model, setting, or context, some key factors were challenges in implementing IBH. Communication and buy-in were two important issues that facilitated success if done well and challenged implementation if limited. One lesson learned across subgrantees was that engagement of staff across offices, leadership, and partners at the beginning of the project was critical. Subgrantees without that buy-in early on had a harder time with roll-out and implementation. This was coupled with the importance of explaining roles and responsibilities clearly, especially as workflows and positions changed. Investing in a data system that is appropriate for the setting and providing training on that system across positions was another lesson learned in implementation.

In addition to lessons learned on IBH implementation, there were also several lessons learned on conducting an overarching evaluation across eight subgrantees that were also implementing their own program-specific evaluations. There was a constant balance between tailoring evaluation activities to subgrantee-specific populations, settings, and contexts, while also aiming to have consistency for the overarching portfolio evaluation. Decision-making conversations focused on whether there was a cascading effect across the portfolio if changes were made to one subgrantee study. For example, if a decision was made related to one grantee-specific evaluation—such as relaxing the time window for follow-up data collection—it needed to be discussed whether this decision then applied to all grantees.

Communication and engagement among all parties were key elements for the evaluation. Regular telephone and in-person meetings were held throughout the study period to discuss evaluation updates, facilitators and challenges, and technical assistance needs. Additionally, an intensive capacity building effort was undertaken with subgrantees to ensure they were equal partners in the evaluation efforts. Individualized technical assistance was provided throughout the study period, and quarterly daylong in-person evaluation learning collaborative sessions with presentations, peer-sharing, role-playing, and other interactive activities were utilized to engage subgrantees in complex evaluation topics. This helped build capacity as well as strengthened trust between subgrantees and the external evaluator. Additionally, recognizing subgrantees as experts in their evaluations was critical. For example, as the evaluations moved to the data analysis phase, several guided conversations among the intermediary funder, the evaluator, and grantees were held to ensure that grantee wishes and needs for participating in and informing data analyses were incorporated into data analysis plans. The approach resulted in more in-depth grantee capacity building on data analysis methods, a collaborative relationship towards data analysis, and multiple discussions on interpreting results that took into account and respected the range of expertise —analytical, clinical, and practice-focused.

Study Limitations and Implications for Future Research

It is important to note the limitations of this study. Given that the overarching evaluation utilizes data from subgrantee studies and there is inconsistency and variation across these studies, the lack of precision for the overarching evaluation is a consideration. Throughout the Sí Texas project, there was a constant balance—and tension—between tailoring the program-specific evaluation studies to the context, setting, and population of the grantees and having enough consistency across the portfolio to be able to examine the larger Sí Texas project. In this balance, it was decided early on that the needs of the grantee-specific evaluation studies would guide more of the decision-making processes around the evaluation. For example, there was slight variation in data collection processes across the subgrantees. To minimize grantee burden, several processes followed existing clinic practice—even if it varied across subgrantees—so that workflow was not disrupted and to facilitate data collection at the subgrantee level. For example, the PHQ-9 questionnaire for depression was administered slightly differently across grantees, with some grantees having it orally administered by a clinic staff member, while others had patients take the written questionnaire on their own. However, both methods have been validated in the literature (Kroenke, Spitzer, & Williams, 2001). While this resulted in some potential inconsistent instrumentation challenges for the overarching evaluation, it allowed flexibility for grantees to use their existing clinic practices which reduced grantee burden and likely resulted in meeting enrollment and retention targets.

The nature of the Sí Texas project is it allowed for subgrantees to identify and adapt evidence-based IBH models to their setting, context, and population group. Therefore, not only is there variation within the sample, but there are different intervention models that comprise the "intervention group" of the overarching analysis. Therefore, impact findings do not point to one specific intervention model or set of components that is most effective with this population, but instead are model-agnostic and provide stronger evidence that enhanced integrated care overall in the region has an impact on mental and physical health outcomes.

An additional methodological limitation related to the variation in the overarching sample is that the participants in the comparison group were not uniform in what they received as "standard of care." In some subgrantee studies, standard of care for the comparison group involved very little integration, comprising of a referral for behavioral health services at an external partner with little to no follow-up. In other instances, comparison group participants were already receiving fairly integrated behavioral and primary care services, and the subgrantee study examined the added value of additional, complementary IBH services to their standard IBH care. This variation within the comparison group would lead results more toward the null. Therefore, the fact that there were significant results for PHQ-9 score and HbA1c even with this variation within the comparison group provides stronger support for the impact of enhanced IBH.

One result of the study that was not as expected was that, after 12 months, intervention participants were more likely than comparison group participants to experience increases in BMI over time. When looking at the BMI within the intervention group, the changes are small over the study period (33.7 mean BMI at baseline and 33.9 mean BMI at follow-up) and may not be clinically relevant. It is also possible that the statistical significance of this change is an artifact of the large sample of the pooled dataset. Additionally, the period of observation being only 12 months limits the ability to see long term effects of increased protective and positive factors gained from behavioral health services, such as active coping with depression, which often leads to more activity, improved mood, appropriate appetite, improved sleep, and less isolation. It is possible that these physical outcomes require a longer term (e.g., more than a year) to manifest into meaningful changes. Observing these outcomes with a longer follow-up period may yield

different results. Additionally, this study did not assess medication as a covariate or effect modifier. For example, the study was unable to account for medications that can cause weight gain (e.g. medications for diabetes, antidepressants, etc.).

Next Steps

Subgrantees are in various stages of continuing to implement their Sí Texas IBH program. Some have fully integrated all components into their existing workflows, while others have integrated a few components—those that have had the most effectiveness, patient compliance, and ease of implementation. Some subgrantees are considering various funding options for greatest sustainability so that they can maintain their interventions.

MHM and subgrantees are actively engaged in disseminating their evaluation results to the larger IBH field of practitioners and researchers. Many subgrantees have presented their evaluation findings at national conferences such as AcademyHealth, Collaborative Family Healthcare Association, and the Association for Community Health Improvement. Every subgrantee is also working on papers of their own evaluation findings to be published in a scholarly or practice-based journal. This will be an opportunity to share their important results on how integrated services can work in a border community and/or within their type of clinical or community setting to advance the field and build the evidence base around IBH.

OTHER ASPECTS OF STUDY LOGISTICS AND FEASIBILITY

Human Subjects Protection

For the overarching Sí Texas Project, the proposed research involves no risk to Sí Texas Project participants. The overarching Sí Texas Project used de-identified and disaggregated data for assessing project impact, reported from each of the eight Sí Texas subgrantees. For the qualitative interviews and focus groups, individual identities were kept confidential.

All patient-level data received by or collected by the evaluators (HRiA) did not contain any personal health information (PHI) or personally identifiable information (PII)—except for potentially zip code and county. Implementation-related data sent by subgrantees or collected by HRiA (e.g., staff focus group, key informant interview, staff surveys, etc.) included names when collected in some cases, but were de-identified when reported out.

All subgrantee evaluation studies were reviewed by institutional review boards in 2015 or 2016 for their determination of risk and approval of study procedures. All subgrantees submitted required amendments and continuing review applications as appropriate to their respective IRB. The overarching SEP was approved nearly one year after subgrantee programs completed their IRBs and began enrollment. The overarching evaluation analyses were conducted with de-identified data collected by subgrantees. Analyses were conducted after the completion of data collection. Given that data collection at the subgrantee level was well underway before the overarching SEP was approved, the portfolio evaluators were advised that IRB approval for the overarching study was not needed. At the time of analysis for the overarching study, the data no longer constituted human subjects data in that: 1) data collection was complete, and 2) all data was de-identified. Subgrantees shared complete data with HRiA via data sharing agreements approved by the sponsor, MHM. Qualitative data collection was reviewed and determined to be exempt from IRB review by the New England Independent Review Board.

In regard to data storage, all data were stored on a password-protected, internal server that uses FIPS 140-2 compliant software. All computer workstations and laptops at HRiA had full disc encryption that uses FIPS 140-2 compliant software, and HRiA employs strong security controls for password creation, automatic screen timeout, intrusion detection, and anti-virus processes. All transmissions of electronic PID outside the secure internal network (e.g., emails, website access, and file transfer) were encrypted using software which was compliant with FIPS 140-2. Data stored on portable devices were required to also be password protected and encrypted. Data provided to HRiA were only be accessible to HRiA staff and contracted consultants directly working on the project, which included evaluation leads (4), evaluation managers (4), program biostatisticians and analysts (3), and qualitative analysts (3).

Timeline

The overarching Sí Texas timeline is categorized in three primary section. (1) Planning and program administration, (2) program implementation and (3) data analysis and reporting. A detailed timeline can be found in **Appendix B. Revised Project Timeline - Overarching.**

Planning and Program Administration

As reflected in the timeline, eight Sí Texas subgrantees implemented IBH models. Six of these were awarded in May 2015 and two in August 2015. Individual subgrantee SIF evaluation plans (SEPs) were approved by November 2016 and the Overarching Evaluation SEP was approved December 2016. During the SEP development and approval timeframe, subgrantees simultaneously worked on protocol development and training as well as IRB applications. During this phase, subgrantees worked closely with HRiA for SEP development and ongoing technical assistance, as needed.

Program Implementation

Subgrantee program recruitment and enrollment started in November 2015. The majority of subgrantees used a rolling recruitment, which ensures that the majority of 12-month data collection is completed by November 2018. Due to challenges in recruitment, TAMIU had to temporarily stop and begin another phase of recruitment in April 2017. An overview of the timeline is provided in **Appendix C: Project Timeline – Subgrantee Activities.**

Data analysis and reporting

Data for the subgrantee-specific evaluations was shared with HRiA on a quarterly basis between October 2016 and January 2019. HRiA performed data quality checks quarterly with subgrantee data to ensure the data were accurate. Larger program reporting data analysis occurred between October and December 2016 to accommodate the generation of interim reports for each subgrantee (January 2016-November 2017).

Evaluator/Subgrantee Role and Involvement

No major changes were made to the evaluator listed in the SEP during the project period; however, there were some personnel changes on the HRiA evaluation team, including changes in project manager and additional data analyst staff being hired.

There were several personnel changes across the specific subgrantee studies, but no significant changes to subgrantee evaluation leads within HRiA.

NCDV: In November 2017, NCDV changed the Principal Investigator of record for the study from Dr. Erica Bonura to Ms. Veronica Gonzalez. Dr. Bonura's role with NCDV had changed and she was unable to provide adequate day-to-day oversight of the study. NCDV appointed Ms. Gonzalez as PI for the Study. This change was submitted to the NEIRB on November 28, 2017 and approved on December 6, 2017.

REAL: REAL's evaluation consultant team, Drs. Melissa Valerio, John Cornell and Aubree Shay, completed the impact analyses presented in REAL's final SIF report per the approved SEP. Drs. Mary Davis and Lisa Wolff from HRiA, external evaluators for the overall Sí Texas evaluation, conducted the implementation analyses and were responsible for related sections of REAL's report.

HFHC: Over the course of the study, HFHC experienced one staff leadership change. In April 2018, the HFHC Sí Texas Project Director left the organization and the Executive Director took on the responsibilities of that role. HFHC's clinical staff and leadership conducted all on-site enrollment and data collection activities.

Budget

No changes were made to the budget during the project period.

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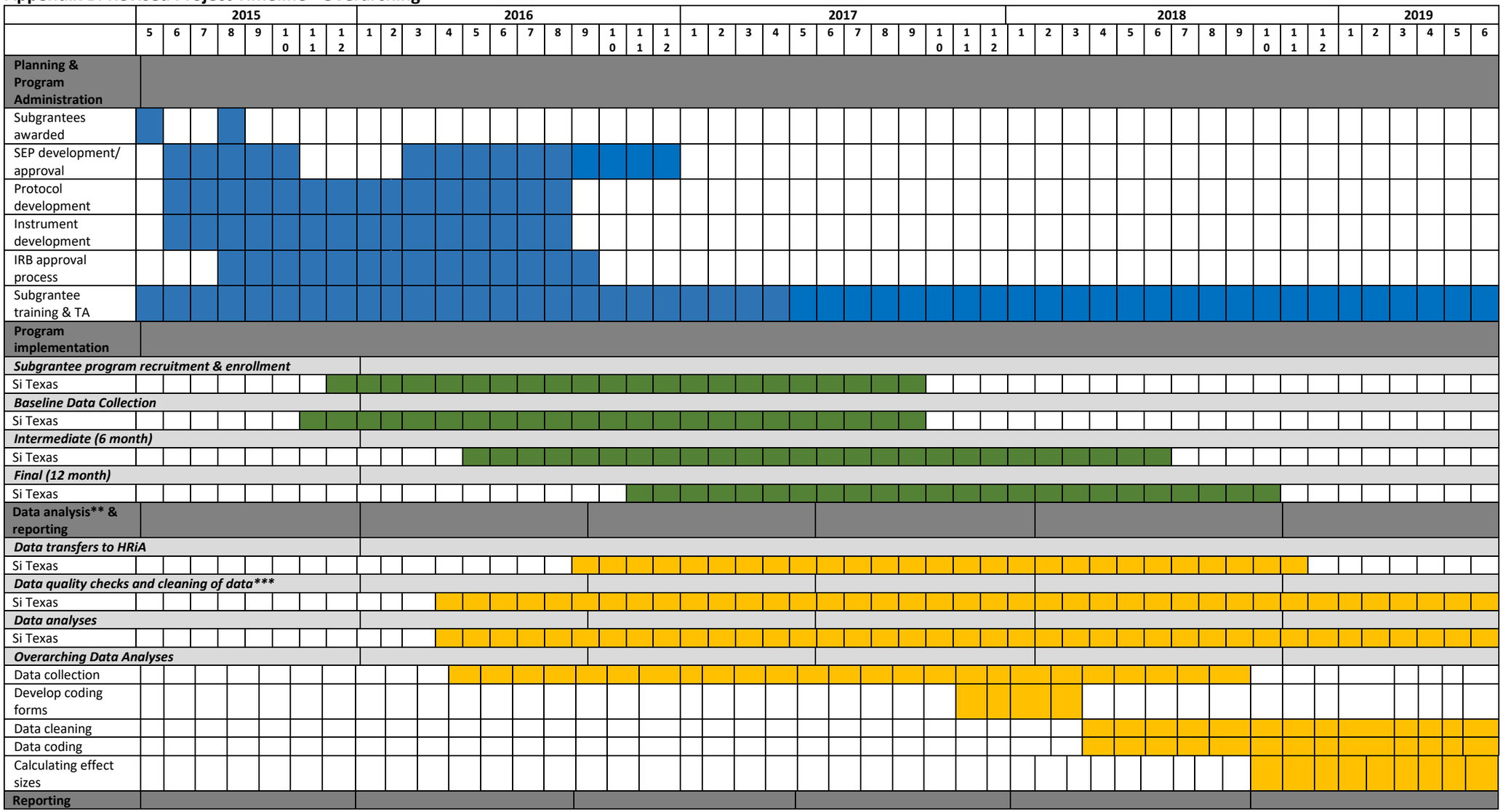
APPENDICES

Grantee: Methodist Healthcare Ministries of South Texas, Inc.
Project: Sí Texas: Social Innovation for a Healthy South Texas

Appendix A. Program Logic Model

			Outcomes		
Inputs/Resources	**Activities**	**Outputs**	**Short**	**Intermediate**	**Long**
Project personnel: Clinic primary care providers, care coordinators, behavioral health specialist, mental health providers, clinic staff and community health workers/promotoras. **Project partners:** Sí Texas Project subgrantees o UTSPH o TAMIU o Nuestra Clinica o UTHSCSA/UTRGV o REAL o TTBH o HFHC o Mercy Ministries HRiA, external evaluators MHM, program funders and overall Sí Texas Project managers	1. Implementation of integrated behavioral health models among eight Sí Texas subgrantees 2. Establish and/or augment ongoing use of care coordination between primary and behavioral healthcare services (coordinated, co-located, or integrated) 3. Develop patient database and tracking/monitoring of patient-care plans 4. Develop, monitor, and effectively communicate patient health through the use of patient-care plans w/ clinic staff and patients 5. Care planning and tracking/monitoring of patient health via patients' appointment reminders and use of services 6. Activities related to Sí Texas collective impact	1. Provider and clinic staff increased understanding of integration, provider and staff buy-in to model, PC team trained on clinic-wide protocol and improved provider collaboration and communication. 2. Establishment and/or continued use of IBH and clinic protocols 3. Coordinated primary and behavioral health services 4. Ongoing communication about and coordination between primary and behavioral care 5. Provider collaboration and communication about patients receiving both primary and behavioral health care services 6. Ongoing quality improvement among clinic staff 7. Ongoing training and clinic-capacity building for primary care, behavioral health and clinical operations (e.g., ERM training, practices policies and protocols) 8. Scheduling of follow up appointments for primary and behavioral health 9. Administer surveys to assess behavioral health baseline, 6 months and 12 months) 10. Diagnosis of depression, diabetes, hypertension and/or obesity 11. Referral to internal and/or external care services community resources and chronic disease management projects (exercise coach, behavioral coach, dietician, faith-based counselor) and/or community resources and chronic disease management projects aligned with patient needs 12. Improved compliance with treatment and attendance follow up appointments and referrals 13. Written person-centered care plans that cross primary and behavioral health care service boundaries/Development of a patient care plan (including behavioral and spiritual health treatment plans) 14. Agreeance on a common agenda 15. Consensus workshop on shared measures 16. Reinforcing program activities 17. Continued communication across subgrantees 18. Presence of a backbone support organization	1. Patients who are eligible for Sí Texas intervention projects are enrolled, screened, baseline measures obtained 2. Patients enrolled in Sí Texas intervention project receive their care plans 3. Patients take an active role in adhering to their care plans (as measured by follow-up with referrals and appointments) 4. PC team buy-in of IBH model and clinic staff understanding of roles in IBH model 5. Adherence to model policies & procedures 6. Closer collaboration between providers and behavioral-health staff 7. Increase in warm-handoffs and referral processes 8. All intervention patient data entered in patient database/EMR for and tracking and monitoring patient use of services 9. Scheduling of follow-up appointments with in-house or community resources	1. Improved patient attendance and compliance with treatment plan 2. Increased functioning and/or quality of life 3. Reduced HbA1c, blood pressure levels, BMI and/or depressive symptoms 4. Patients participate in and are satisfied with in-house or community resources behavioral health and primary care services (as measured qualitatively) 5. Improved workflow alignment across providers and services 6. Improved rate of successful referrals and use of behavioral-health services 7. Ongoing follow-up assessments and monitoring of patients 8. Improved integrated clinical service provision/Improved clinic efficiency 9. Patient database reviewed by PC teams and recommendations made	1. Improved quality of life and physical functioning among all Sí Texas intervention participants 2. Reduced chronic disease and depressive symptoms prevalence among all Sí Texas intervention participants 3. Providers and staff involved with integrated services will advance to their proposed level of integration 4. Barriers to access of care significantly reduced as measured by number of patients receiving integrated behavioral care 5. Awareness of best care practices and improved communication across providers is achieved and the IBH model is implemented for sustainability 6. Overall assessment of the Sí Texas collective impact and social network analysis.

Appendix B. Revised Project Timeline - Overarching



Grantee: Methodist Healthcare Ministries of South Texas, Inc.
Project: Sí Texas: Social Innovation for a Healthy South Texas

	2015								2016												2017												2018												2019					
	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6
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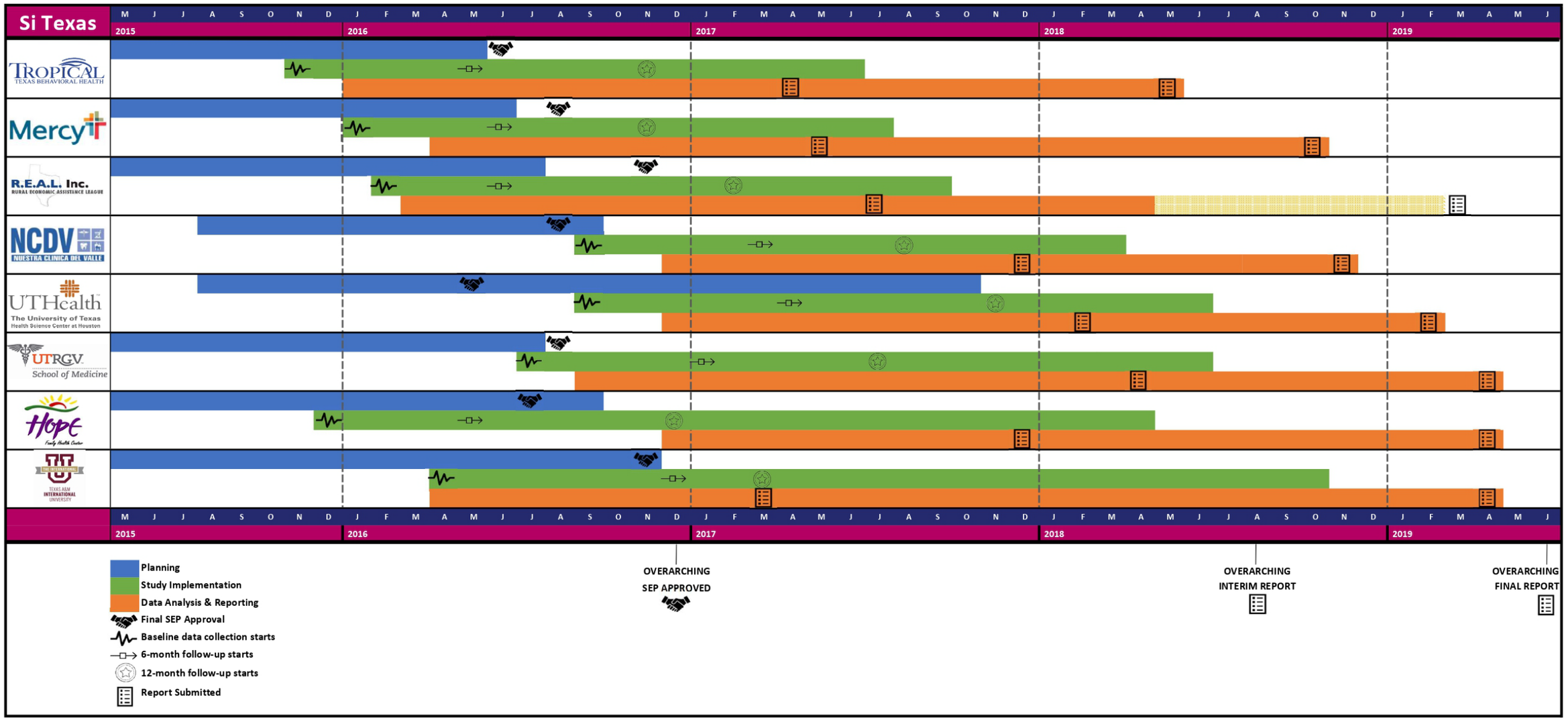
**HRiA was contracted by MHM as the Sí Texas project evaluator. All data analyses and reporting were done on a collaborative basis with the subgrantee
*** collection/cleaning/coding of raw or subgrantee data

Appendix C: Project Timeline – Subgrantee Activities



Appendix D: 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.

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 handoffs between providers a component of the services participants receive? How do those handoffs 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 E: 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 handoffs work? Since the program started, have any changes been made to how warm handoffs 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 F: Sí Texas Summative Implementation Evaluation: Focus Group Guide

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

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 like least 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 easier 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 harder 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 G: Subgrantee Baseline Equivalence Tables

Table 43. Tropical Texas Behavioral Health - Tests of Baseline Equivalence for Demographic Measures

	Full Sample (n=416)		Brownsville Intervention (n=249)		Brownsville Control (n=167)		p-value
Measure	N	%	N	%	N	%	
Sex							
Male	186	44.7	112	45.0	74	44.3	
Female	230	55.3	137	55.0	93	55.7	0.89
Missing	--	--	--	--	--	--	
Race[a]							
White	389	93.5	231	92.8	158	94.6	
Native Hawaiian/Pacific Islander	1	0.2	0	0.0	1	0.6	
Other	22	5.3	16	6.4	6	3.6	0.35
Unknown	4	1.0	2	0.8	2	1.2	
Missing	--	--	--	--	--	--	
Ethnicity							
Hispanic	385	92.5	226	90.8	159	95.2	
White	13	3.1	9	3.6	4	2.4	0.21
Non-Hispanic	18	4.3	14	5.6	4	2.4	
Missing	--	--	--	--	--	--	
Age							
Mean	40.9	--	41.0	--	40.7	--	0.82
(SD)	(12.9)	--	(12.5)	--	(13.4)	--	
18-24	48	11.5	30	12.0	18	10.8	
25-34	94	22.6	49	19.7	45	26.9	
35-44	112	26.9	69	27.7	43	25.7	
45-54	95	22.8	61	24.5	34	20.4	0.27
55-64	54	13.0	35	14.1	19	11.4	
65+	13	3.1	5	2.0	8	4.8	
Missing	--	--	--	--	--	--	
Education[a]							
Below High School	77	19.1	41	16.9	36	22.2	
Some High School	158	39.1	100	41.3	58	35.8	
GED/HS Grad/Some College	141	34.9	86	35.5	55	34.0	0.66
Associates/Bachelor Degree	23	5.7	13	5.4	10	6.2	
Special Education	5	1.2	2	0.8	3	1.9	
Missing	12	--	7	--	5	--	
Employment Status							
No Evidence of Problems	52	12.5	32	12.9	20	12.0	
History of Problems, Mild	11	2.7	6	2.4	5	3.0	0.58
Moderate Problems	14	3.4	11	4.4	3	1.8	
Severe Problems	243	58.6	146	58.9	97	58.1	
N/A	95	22.9	53	21.4	42	25.1	

	Full Sample (n=416)		Brownsville Intervention (n=249)		Brownsville Control (n=167)		p-value
Measure	N	%	N	%	N	%	
Missing	1	--	1	--	--	--	
Primary Language[a]							
English	284	68.4	173	69.8	111	66.5	
Spanish	131	31.6	75	30.2	56	33.5	0.71
Missing	1	--	1	--	--	--	
County of Residence[a]							
Cameron County	410	98.6	245	98.4	165	98.8	
Hidalgo County	6	1.4	4	1.6	2	1.2	0.99
Missing	--	--	--	--	--	--	
SPMI Diagnosis							
Bipolar Disorder	129	31.0	78	31.3	51	30.5	
Major Depression	191	45.9	112	45.0	79	47.3	
Schizophrenia	81	19.5	53	21.3	28	16.8	0.30
Schizophrenia and Major Depression	15	3.6	6	2.4	9	5.4	
Missing	--	--	--	--	--	--	

[a]Fisher's Exact test was used due to cells having expected count less than 5

Table 44. Mercy Ministries of Laredo - Tests of Baseline Equivalence for Demographic Measures: Intervention and Primary Comparison Groups

	Full Sample (n=410)		Intervention Group (n=207)		Primary Comparison Group (n=203)		p-value
Variables	N	%	N	%	N	%	
Sex							
Male	52	12.7	27	13.0	25	12.3	0.82
Female	359	87.3	180	87.0	178	87.7	
Ethnicity							
Hispanic	409	99.8	206	99.5	203	100.0	0.99
Non-Hispanic	1	0.2	1	0.5	0	0.0	
Age							
Mean	44.1	--	43.8	--	44.3	--	0.62
SD	10.8	--	11.3	--	10.3	--	
18-24	16	3.9	9	4.3	7	3.5	0.63
25-34	55	13.4	29	14.0	26	12.8	
35-44	147	35.9	75	36.2	72	35.5	
45-54	120	29.3	61	29.5	59	29.1	
55-64	67	16.3	29	14.0	38	18.7	
65+	5	1.2	4	1.9	1	0.5	
Employment Status[a]							
Employed	95	23.2	36	17.4	59	29.1	**0.03**
Not Employed	213	52.0	117	56.5	96	47.3	
Self Employed	99	24.2	53	25.6	46	22.7	
Student	3	0.7	1	0.5	2	1.0	
Marital Status							
Divorced	24	5.9	11	5.3	13	6.4	0.86
Legally Separated	26	6.4	11	5.3	15	7.4	
Married	218	53.3	113	54.6	105	51.7	
Significant Other	42	10.3	19	9.2	23	11.3	
Single	82	20.1	44	21.3	38	18.7	
Widowed	17	4.2	8	3.9	9	4.4	
Missing	1	--	1	--	--	--	
Primary Language							
English	50	12.2	26	12.6	24	11.8	0.82
Spanish	360	87.8	181	87.4	179	88.2	
County of Residence							
Webb County	410	100.0	207	100.0	203	100.0	--
Missing	--	--	--	--	--	--	
Smoking Status							
Current Smoker	38	9.2	23	11.1	15	7.4	0.43
Former Smoker	14	3.4	7	3.4	7	3.4	
Never Smoked	358	87.3	177	85.5	181	89.2	

	Full Sample (n=410)		Intervention Group (n=207)		Primary Comparison Group (n=203)		p-value
Variables	N	%	N	%	N	%	
Alcohol Consumption							
Yes	83	20.7	43	21.4	40	20.0	
No	318	79.3	158	78.6	160	80.0	0.73
Missing	9	--	6	--	3	--	
Spirituality Index							
Mean	48.9	--	47.6	--	50.2	--	**0.004**
SD	12.1	--	11.9	--	12.1	--	
Perceived Spiritual Strength							
Weak	--	--	16	10.6	--	--	
Moderate	--	--	37	24.5	--	--	--
Strong	--	--	98	64.9	--	--	
Missing	--	--	56	--	--	--	

Note: Bold denotes statistical significance (p-value < 0.05).
[a] Fisher's Exact test was used due to cells having expected count less than 5

Table 45. Nuestra Clinica del Valle - Tests of Baseline Equivalence for Demographic Measures

	Full Sample (n=756)		Intervention (n=329)		Comparison (n=427)		p value
Variables	N	%	N	%	N	%	
Sex							
Male	223	29.5	89	27.1	134	31.4	
Female	533	70.5	240	73.0	293	68.6	0.20
Missing	--	--	--	--	--	--	
Ethnicity							
Hispanic/Latino	751	99.3	326	99.1	2	0.5	
Non-Hispanic/Non-Latino	5	0.7	3	0.9	2	0.5	0.66
Missing	--	--	--	--	--	--	
Race							
White	755	99.9	328	43.4	427	56.7	
Other	1	0.1	1	0.3	0	0.0	0.44
Missing	--	--	--	--	--	--	
County							
Hidalgo	750	99.2	325	98.8	425	99.5	
Starr	6	0.8	4	1.2	2	0.5	0.10
Missing	--	--	--	--	--	--	
Age							
Mean	54.1	--	55.9	--	52.7	--	**<0.001**
SD	10.6	--	10.2	--	10.7	--	
<35	26	3.4	9	2.7	17	4.0	
35-44	105	13.9	31	9.4	74	17.3	
45-54	241	31.9	93	28.3	148	34.4	**<0.001**
55-64	295	39.0	148	45.0	147	34.4	
65+	89	11.8	48	14.6	41	9.6	
Missing	--	--	--	--	--	--	
Employment							
Not Employed	465	61.5	199	60.5	266	62.3	
Employed	286	37.8	126	38.3	160	37.5	
Migrant Farm Worker	4	0.5	3	0.9	1	0.2	0.39
Student	1	0.1	1	0.3	0	0.0	
Missing	--	--	--	--	--	--	
Marital Status							
Divorced	44	5.9	28	8.6	16	3.8	
Married	471	62.7	193	59.4	193	59.4	
Separated	68	9.1	24	7.4	44	10.3	
Single	110	14.7	53	16.3	57	13.4	**0.02**
Widowed	58	7.7	27	8.3	31	7.3	
Missing	5	--	4	--	1	--	
Primary Language							

	Full Sample (n=756)		Intervention (n=329)		Comparison (n=427)		p value
Variables	N	%	N	%	N	%	
English	144	19.2	61	18.9	83	19.4	0.92
Samar-Leyte	0.1	0.0	0	0.0	1	0.2	
Spanish	605	80.7	262	81.1	343	80.3	
Missing	6	--	6	--	0	--	
History of Diabetes							
No	111	14.7	27	8.2	84	19.7	**<0.001**
Yes	645	85.3	302	91.8	343	80.3	
Missing	--	--	--	--	--	--	
History of Hypertension							
No	324	42.9	148	45.0	176	54.3	0.30
Yes	432	57.1	181	55.0	251	58.8	
Missing	--	--	--	--	--	--	
History of Obesity							
No	301	39.8	131	39.8	170	39.8	0.99
Yes	455	60.2	198	60.2	257	60.2	
Missing	--	--	--	--	--	--	
History of High Cholesterol							
No	164	21.7	55	16.7	109	25.5	**0.004**
Yes	592	78.3	274	83.3	318	74.5	
Missing	--	--	--	--	--	--	
History of Depression							
No	703	93.0	305	92.7	398	93.2	0.79
Yes	53	7.0	24	7.3	29	6.8	
Missing	--	--	--	--	--	--	
Level of Physical Activity							
Never	310	41.0	119	36.2	191	44.7	**0.01**
1-2 times/week	157	20.8	82	24.9	75	17.6	
3-4 times/week	107	14.2	50	15.5	56	13.1	
5-6 times/week	54	7.4	16	4.9	38	8.9	
Daily	128	16.9	61	18.5	67	15.7	
Missing	--	--	--	--	--	--	
Smoking Status[a]							
Current Every Day Smoker	35	4.6	20	6.1	15	3.5	**0.01**
Current Some Day Smoker	18	2.4	6	1.8	12	2.8	
Former Smoker	121	16.0	39	11.9	82	19.2	
Never Smoker	582	77.0	264	80.2	318	74.5	
Missing	--	--	--	--	--	--	
Alcohol Consumption							
Never	588	77.8	248	75.4	340	79.6	0.45
Monthly or Less	96	12.7	50	15.2	46	10.8	

	Full Sample (n=756)		Intervention (n=329)		Comparison (n=427)		p value
Variables	N	%	N	%	N	%	
2-4 per/month	50	6.6	21	6.4	29	6.8	
2-3 per/week	14	1.9	7	2.1	7	1.6	
4+ per/week	8	1.1	3	0.9	5	1.2	
Missing	--	--	--	--	--	--	
Insurance Status							
Insured	198	26.2	101	30.7	97	22.7	
Uninsured	558	73.8	228	69.3	330	77.3	0.01
Missing	--	--	--	--	--	--	

[a]Fisher's Exact test was used due to cells having expected count less than 5

Table 46. University of Texas Health Science Center at Houston School of Public Health Tests of Baseline Equivalence for Demographic Measures

Measure	Full Sample (n=353)		Intervention (n=176)		Control (n=177)		p-value
	n	%	n	%	n	%	
Sex							
Male	104	29.5	53	30.1	51	28.8	0.79
Female	249	70.5	123	69.9	126	71.2	
Ethnicity							
Hispanic/Latino	325	92.1	162	92.1	163	92.1	0.99
Non-Hispanic/Non-Latino	28	7.9	14	8.0	14	7.9	
Race[a]							
White (Caucasian)	332	96.5	163	95.3	169	97.7	0.26
Other	12	3.5	8	4.7	4	2.3	
Missing	*9*	--	*5*	--	*4*	--	
County[a]							
Cameron County	352	99.7	176	100.0	176	99.4	0.99
Willacy County	1	0.3	0	0.0	1	0.6	
Age							
≤ 34	16	4.5	9	5.1	7	4.0	0.97
35-44	61	17.3	30	17.1	31	17.5	
45-54	136	38.5	67	38.1	69	39.0	
55-64	124	35.1	63	35.8	61	34.5	
65+	16	4.5	7	4.0	9	5.1	
Mean (SD)	51.5 (9.1)		51.4 (9.0)		51.7 (9.2)		0.80
Employment Status							
Employed	42	12.1	16	9.3	26	14.9	0.14
Unemployed	213	61.4	105	60.7	108	62.1	
Other	92	26.5	52	30.1	40	23.0	
Missing	*6*	--	*3*	--	*3*	--	
Marital Status[b]							
Married	185	53.2	86	50.0	99	56.3	0.24
Unmarried	163	46.8	86	50.0	77	43.8	
Missing	*5*	--	*4*	--	*1*	--	
Education[b]							
Less than high school	207	59.1	103	58.9	104	59.34	0.91
High school graduate/GED or higher	143	40.9	72	41.1	71	40.6	
Missing	*3*	--	*1*	--	*2*	--	
Primary Language							
English	114	32.3	60	34.1	54	30.5	0.47
Spanish	239	67.7	116	65.9	123	69.5	
Monthly Household Income							
$0	47	13.6	26	15.3	21	12.1	0.83

$1 - $500	89	25.9	44	28.9	45	25.9	
$501 - $1,000	119	34.6	56	32.9	63	36.2	
$1, 001 - $2,000	62	18.0	29	17.1	33	19.0	
≥ $2,001	27	7.9	15	8.8	12	6.9	
Missing	*9*	--	*6*	--	*3*	--	
Health Insurance Status							
Medicaid	23	7.3	13	8.2	10	6.3	0.54
Medicare	14	4.4	8	5.0	6	3.8	
Medicaid and Medicare	6	1.9	4	2.5	2	1.3	
Private	38	12.0	17	10.7	21	13.3	
Indigent	16	5.1	5	3.1	11	7.0	
No insurance	220	69.4	112	70.4	108	68.4	
Missing	*36*	--	*17*	--	*19*	--	
Time in Salud y Vida 1.0							
Mean (SD), in months	20.6 (9.5)		21.2 (9.5)		19.9 (9.5)		0.24

Note: missing data were not included in the calculations of proportions across categories. [a]Due to cell counts less than 5, Fisher's exact test was used

Table 47. Rural Economic Assistance League, Inc - Tests of Baseline Equivalence for Demographic Measures: Intervention and Comparison Groups

	Full Sample (n=552)		Intervention (n=302)		Comparison (n=250)		p-value
Measure	N	%	N	%	N	%	
Gender							
Male	196	36.0	107	35.9	89	36.2	
Female	348	64.0	191	64.1	157	63.8	0.95
Missing	8	--	4	--	4	--	
Ethnicity							
Hispanic	388	71.3	256	85.9	132	53.7	
Non-Hispanic	156	28.7	42	14.1	114	46.3	**<0.001**
Missing	8	--	4	--	4	--	
Race[a]							
White	521	95.8	290	97.3	231	93.9	
Black	20	3.7	8	2.7	12	4.9	
Asian	1	0.2	0	0.0	1	0.4	0.23
Native American	1	0.2	0	0.0	1	0.4	
Other	1	0.2	0	0.0	1	0.4	
Missing	8	--	4	--	4	--	
County of Residence[a]							
Kenedy	2	0.4	1	0.3	1	0.4	
Brooks	48	8.8	48	16.1	0	0.0	
Duval	30	5.5	30	10.1	0	0.0	
Jim Wells	110	20.2	110	36.9	0	0.0	
Kleberg	105	19.3	105	35.2	0	0.0	**<0.001**
San Patricio	101	18.6	3	1.0	98	39.8	
Bee	107	19.7	1	0.3	106	43.1	
Aransas	28	5.1	0	0.0	28	11.4	
Live Oak	13	2.4	0	0.0	13	5.3	
Missing	8	--	4	--	4	--	
County of Service							
Bee	122	22.4	0	0.0	122	49.6	
Brooks	55	10.1	55	18.5	0	0.0	
Jim Wells	133	24.4	133	44.6	0	0.0	**<0.001**
Kleberg	110	20.2	110	36.9	0	0.0	
Taft	124	22.8	0	0.0	124	50.4	
Missing	8	--	4	--	4	--	
Age							
≤ 34	100	18.4	62	20.8	38	15.4	
35-44	125	23.0	67	22.5	58	23.6	
45-54	200	36.8	106	35.6	94	38.2	0.60
55-64	107	19.7	56	18.8	51	20.7	
65+	12	2.2	7	2.3	5	2.0	

	Full Sample (n=552)		Intervention (n=302)		Comparison (n=250)		p-value
Measure	N	%	N	%	N	%	
Mean	45.2	--	44.6	--	45.9	--	
SD	11.7	--	12.1	--	11.1	--	
Missing	8	--	4	--	4	--	
Employment Status[a]							
Unemployed		77.9		74.6		81.6	0.12
Employed Full-time		21.9		25.0		18.4	
Other		0.2		0.4		0.0	
Missing		28		22		6	
Marital Status							
Married	116	21.9	54	18.6	62	25.9	0.12
Single	228	43.1	135	46.6	93	38.9	
Divorced	121	22.9	69	23.8	52	21.8	
Separated	64	12.1	32	11.0	32	13.4	
Missing	23	--	12	--	11	--	
Annual Household Income[a]							
Less than $10,000	383	70.4	214	71.8	169	68.7	0.08
$10,001 - $20,000	114	21.0	60	20.1	54	22.0	
$20,001 - $30,000	23	4.2	10	3.4	13	5.3	
$30,001 - $40,000	11	2.0	6	2.0	5	2.0	
$40,001 - $50,000	3	0.6	0	0.0	3	1.2	
$50,001 - $60,000	1	0.2	1	0.3	0	0.0	
$60,001 - $70,000	1	0.2	1	0.3	0	0.0	
Greater than $70,001	2	0.4	0	0.0	2	0.8	
Refusal	6	1.1	6	2.0	0	0.0	
Missing	8	--	4	--	4	--	
Primary Language							
English	535	98.3	292	98.0	243	98.8	0.47
Spanish	9	1.7	6	2.0	3	1.2	
Missing	8	--	4	--	4	--	
Education[a]							
3rd Grade	3	0.6	3	1.0	0	0.0	0.13
5th Grade	6	1.2	3	1.0	3	1.3	
6th Grade	2	0.4	2	0.7	0	0.0	
7th Grade	12	2.3	5	1.7	7	3.0	
8th Grade	32	6.1	17	5.9	15	6.4	
9th Grade	50	9.6	25	8.7	25	10.7	
10th Grade	45	8.6	29	10.1	16	6.9	
11th Grade	39	7.5	23	8.0	16	6.9	

	Full Sample (n=552)		Intervention (n=302)		Comparison (n=250)		p-value
Measure	N	%	N	%	N	%	
12th Grade	88	16.9	50	17.4	38	16.3	
GED	102	19.6	63	22.6	69	15.9	
Some College	132	25.3	63	21.9	69	29.6	
BA/BS	7	1.3	3	1.0	4	1.7	
None	3	0.6	0	0.0	3	1.3	
Missing	31	--	14	--	17	--	
Household Size[a]							
1	299	55.0	161	54.0	138	56.1	0.28
2	96	17.6	52	17.4	44	17.9	
3	57	10.5	30	10.1	27	11.0	
4	52	9.6	27	9.1	25	10.2	
5	22	4.0	13	4.4	9	3.7	
6	12	2.2	10	3.4	2	0.8	
7	4	0.7	4	1.3	0	0.0	
8	1	0.2	1	0.3	0	0.0	
9	1	0.2	0	0.0	1	0.4	
Missing	8	--	4	--	4	--	
Veteran Status[a]							
Yes	8	1.5	7	2.3	1	0.4	0.06
No	536	98.5	291	97.7	245	99.6	
Missing	8	--	4	--	4	--	
Health Insurance Status[a]							
Not Insured	397	73.0	210	70.5	187	76.0	0.44
Insured	20	3.7	13	4.4	7	2.8	
Medicare	34	6.3	20	6.7	14	5.7	
Medicaid	91	16.7	53	17.8	38	15.4	
Other	2	0.4	2	0.7	0	0.0	
Missing	8	--	4	--	4	--	

Note: [a]Cells have expected count less than 5

Table 48. University of Texas Rio Grande Valley - Tests of Baseline Equivalence for Demographic Measures

Measure	Full Sample (n=569)		Intervention (n=364)		Comparison (n=205)		p-value
	N	%	N	%	n	%	
Sex							
Male	188	33.0	111	30.5	77	37.6	0.09
Female	381	67.0	253	69.5	128	62.4	
Ethnicity							
Hispanic/Latino	538	94.6	342	94.0	196	95.6	0.08
Non-Hispanic/Non-Latino	27	4.8	21	5.8	6	2.9	
Other	4	0.7	1	0.3	3	1.5	
Age							
≤ 34	151	26.5	88	24.2	63	30.7	0.16
35-44	149	26.2	94	25.8	55	26.8	
45-54	136	23.9	92	25.3	44	21.5	
55-64	92	16.2	58	15.9	34	16.6	
65+	41	7.2	32	8.8	9	4.4	
Mean (SD)	44.5 (13.5)		45.5 (13.7)		42.7 (13.2)		**0.02**
Primary Language							
English	351	61.7	204	56.0	147	71.7	**<0.001**
Spanish	218	38.3	160	44.0	58	28.3	
County							
Cameron County	136	23.9	8	2.2	128	62.4	**<0.001**
Hidalgo County	418	73.5	341	93.7	77	37.6	
Other Counties	15	2.6	15	4.1	0	0.0	

Table 49. Hope Family Health Center - Tests of Baseline Equivalence for Demographic Measures

Measure	Full Sample (n=585)		Intervention Group (n=272)		Control Group (n=313)		p-value
	N	%	N	%	N	%	
Gender							
Male	154	26.3	71	26.1	83	26.5	0.91
Female	431	73.7	201	73.9	230	73.5	
Ethnicity							
Hispanic/Latino	484	82.7	217	79.8	267	85.3	0.08
Non-Hispanic/Non-Latino	101	17.3	55	20.2	46	14.7	
County							
Hidalgo	573	98.0	269	98.9	304	97.1	0.24
Other	12	2.1	3	1.1	9	2.9	
Age							
≤ 34	41	7.0	16	5.9	25	8.0	0.70
35-44	110	18.8	50	18.4	60	19.2	
45-54	207	35.4	98	36.0	109	34.8	
55-64	194	33.2	95	34.9	99	31.6	
65+	33	5.6	13	4.8	20	6.4	
Mean	50.9	--	51.3	--	50.6	--	0.46
SD	10.6	--	10.4	--	10.7	--	
Employment Status							
Employed	7	1.2	2	0.7	5	1.6	0.34
Not Employed	578	98.8	270	99.3	308	98.4	
Marital Status							
Married	299	51.1	137	50.4	162	51.8	0.46
Single	132	22.6	65	23.9	67	21.4	
Separated	60	10.3	23	8.5	37	11.8	
Divorced	49	8.4	21	7.7	28	9.0	
Widow/Widower	35	6.0	20	7.4	15	4.8	
Partner	10	1.7	6	2.2	4	1.3	
Primary Language							
Spanish-speaking	517	88.4	244	89.7	273	87.2	0.35
English-speaking	68	11.6	28	10.3	40	12.8	

Table 50. Texas A&M International University - 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	

Appendix H: Subgrantee Patient Flow Diagrams

Figure 4. Tropical Texas Behavioral Health - Patient Flow Diagram

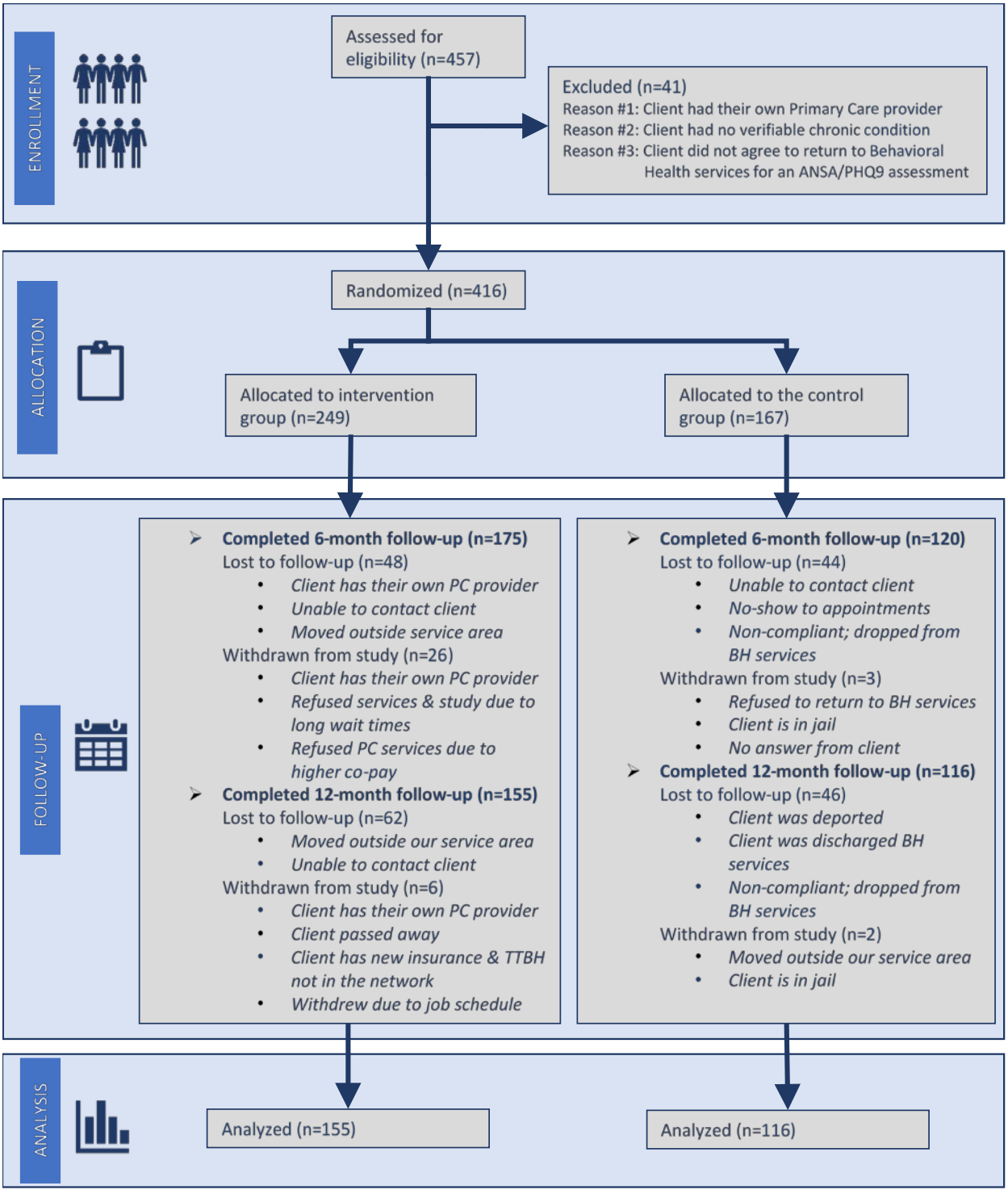


Figure 5. Mercy Ministries of Laredo - Patient Flow Diagram, Intervention and Primary Comparison

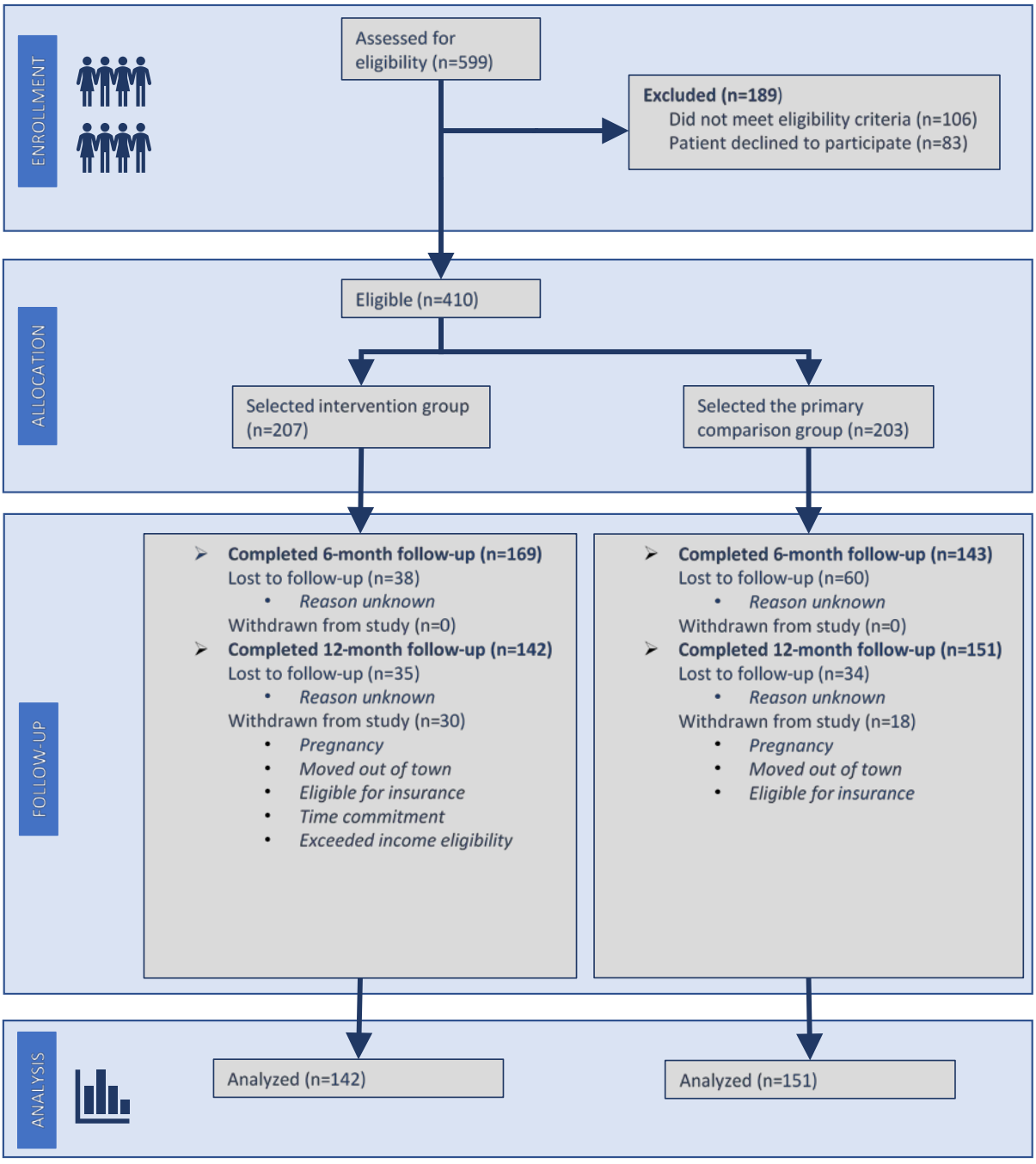


Figure 6. Nuestra Clinica del Valle - Patient Flow Diagram

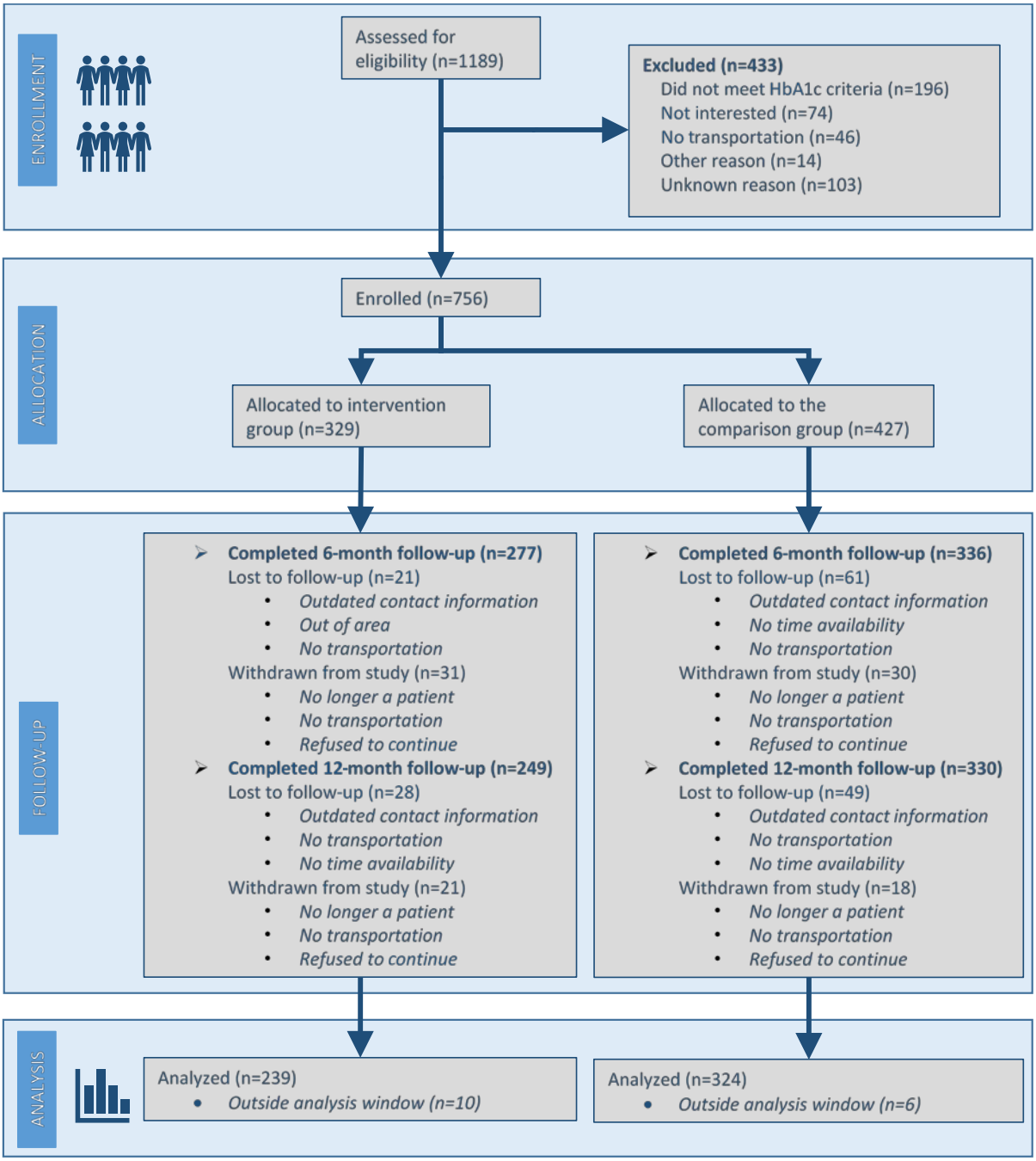


Figure 7. University of Texas Health Science Center at Houston School of Public Health - Patient Flow Diagram

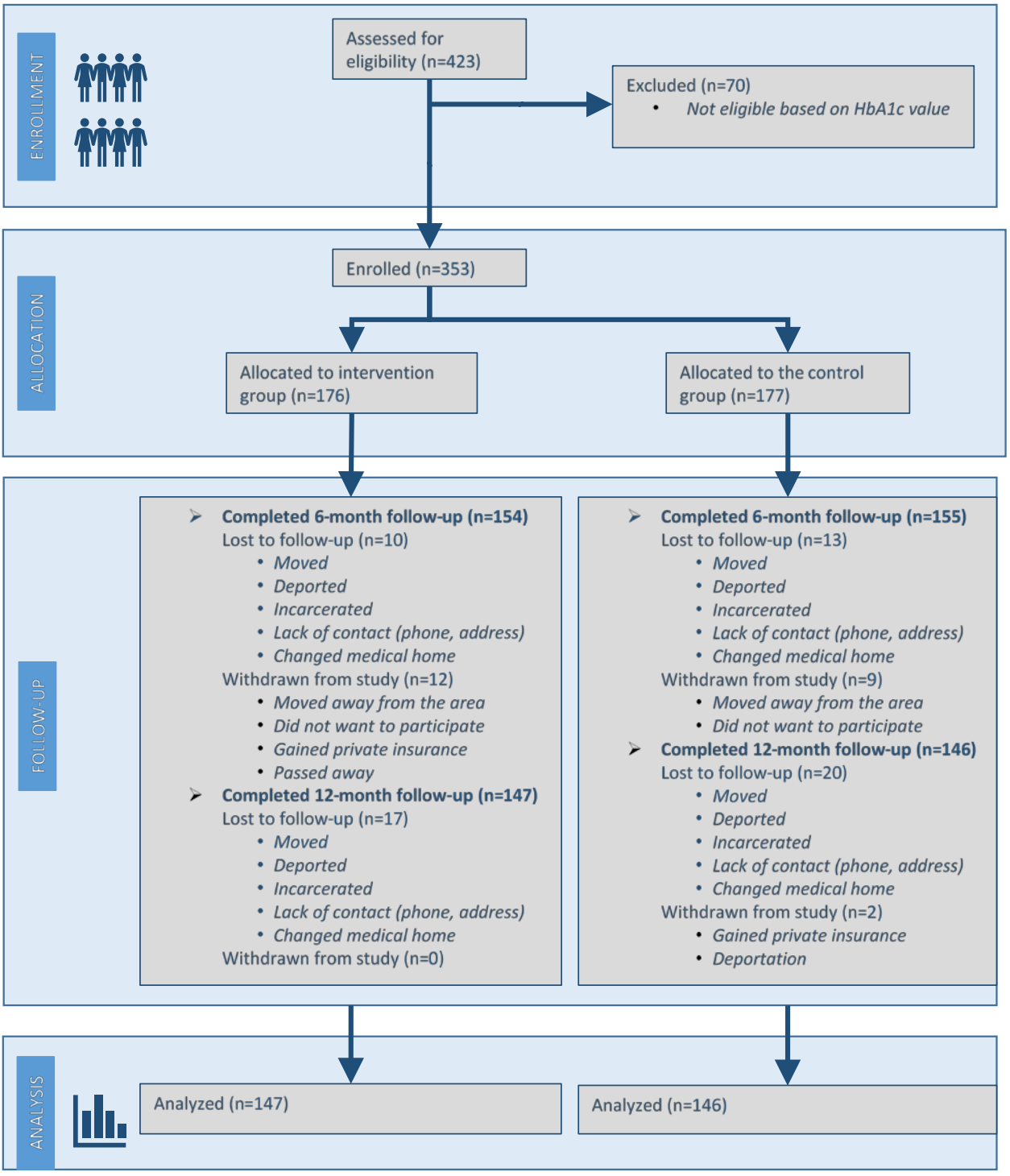


Figure 8. Rural Economic Assistance League, Inc - Patient Flow Diagram

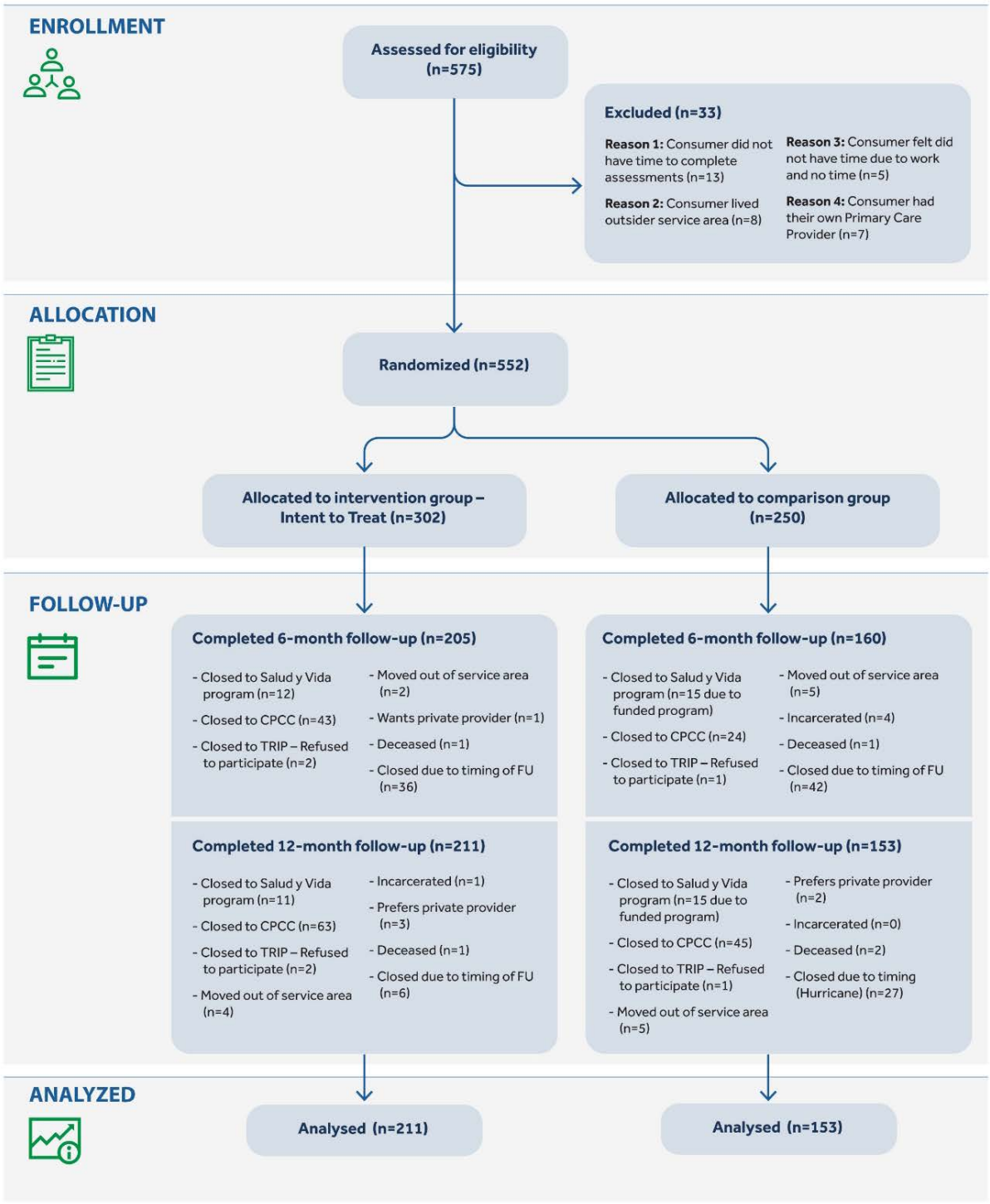


Figure 9. University of Texas Rio Grande Valley - Patient Flow Diagram

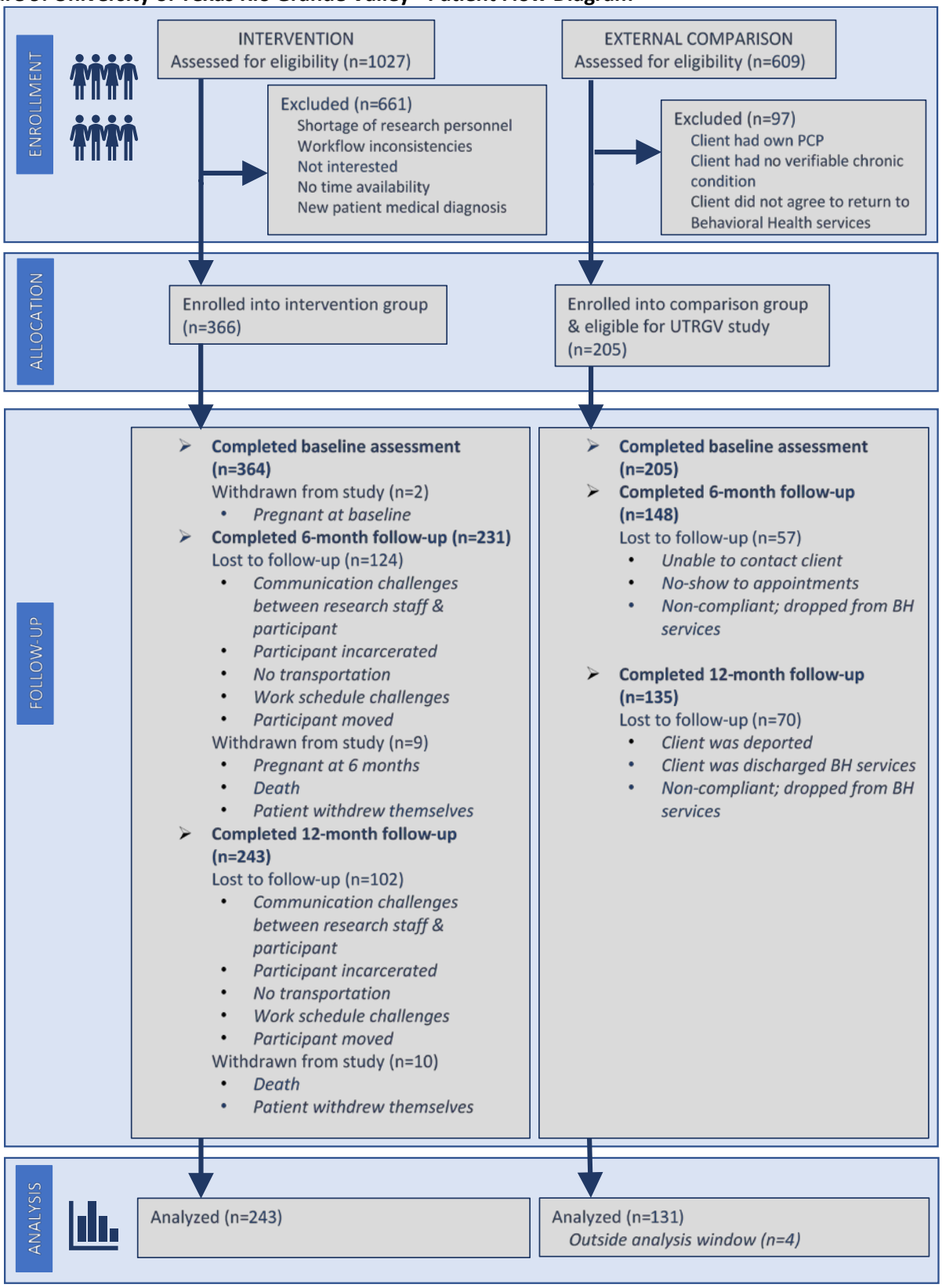


Figure 10. Hope Family Health Center - Patient Flow Diagram

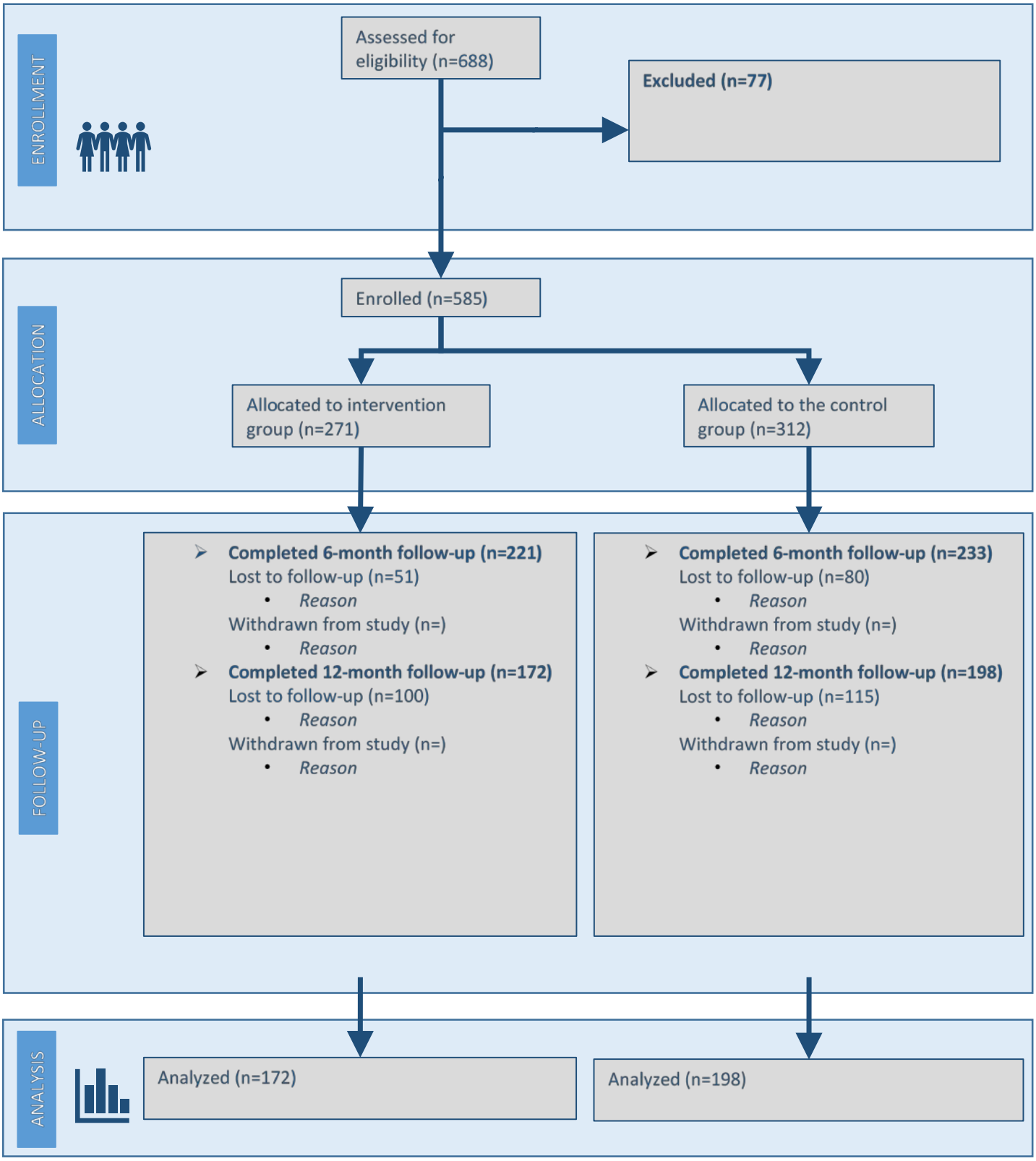
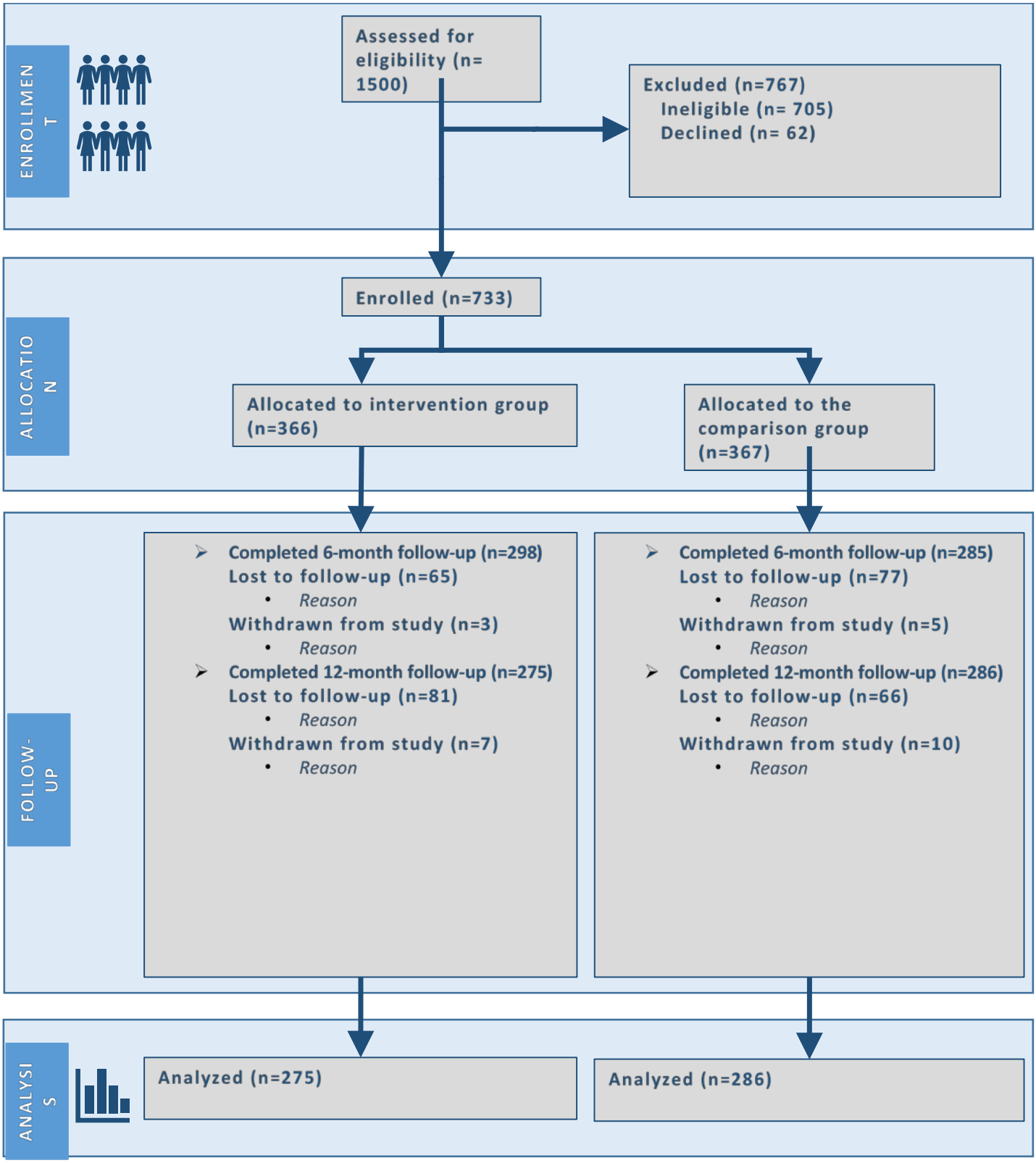


Figure 11. Texas A&M International University - Patient Flow Diagram



Appendix I. Non-Randomized QED Intervention and Comparison Group Assignment

Table 51. **Intervention and Comparison Group Assignment for QED Subgrantee Studies**

Subgrantee	Intervention Group	Comparison Group
Mercy Ministries of Laredo	Eligible patients who elected to participate in the Sí Three program recruited from Mercy's clinic population and enrolled in the study	A primary clinic comparison group of eligible and potentially similar patients who chose not to participate in the Sí Three program recruited from Mercy's clinic population and enrolled in the study
Nuestra Clinica del Valle	Eligible patients at NCDV's Mission Clinic who elected to participate in the NuCare program and enroll in the study	Eligible patients at NCDV's Alton or Edcouch Clinics who enrolled in the study
REAL	Patients who were currently enrolled or eligible for enrollment in the Salud y Vida program at one of three intervention clinics (Alice, Falfurrias, Kingsville clinics), who elected to participate in the TRIP for Salud y Vida program and enroll in the study	Patients who were currently enrolled or eligible for enrollment in the Salud y Vida program at one of two comparison clinics (Beeville and Taft clinics) and enrolled in the study
UTRGV	Eligible patients at UTRGV's two FMR clinics that used the PCBH model who enrolled in the study	Eligible patients at TTBH's Weslaco and Brownsville clinics who received the usual care provided within those behavioral health clinics who enrolled in the study

Appendix J. Subgrantee Participant Recruitment

Tropical Texas Behavioral Health

TTBH recruited existing patients who presented at the Brownsville clinic for scheduled behavioral health services. When a patient potentially eligible for the study entered the clinic, he or she was required to complete a behavioral health care service eligibility screening and assessment. The assessment was performed by a behavioral health care assistant. Potential participants were asked a series of eligibility questions.

If the patient qualified for the study, the patient was then asked to review and voluntarily sign the informed consent. This included consenting to the randomization process, volunteering to take all baseline and follow-up surveys, volunteering to have vitals (e.g., blood pressure, height, weight) and blood work (to assess HbA1c and total cholesterol) taken during the study, and understanding that they were part of a research study. Those participants who did not consent to the study or who were unable to consent to the study were referred to other TTBH usual care behavioral health services. Enrollment was conducted on a rolling basis between November 2015 and June 2016.

Mercy Ministries of Laredo

Patients for the Sí Three program were recruited from new and existing patients through Mercy's clinic and mobile van sites. At the time of the patient's clinic visit, the medical office assistant (MOA) took vital signs (height, weight, BP, waist circumference), and the care coordinator presented the surveys to the patient and patient self-administered the Sí Three surveys (instruments that measure depression, anxiety, quality of life, spirituality, and addiction). Patients at the mobile van site were given the surveys by the promotora, seen by the nurse practitioner, and referred to the clinic care coordinator for enrollment. Patients were then handed off from the care coordinator (with their assessments) to the program manager (navigator/NP) to discuss eligibility for the program. During the enrollment period, Mercy screened all adult patients for hypertension, obesity, diabetes, depression, anxiety, quality of life and/or addiction. Patients who met the eligibility criteria were informed of the Sí Three program and offered an opportunity to participate in the program.

If the eligible patient chose to participate, the program manager conducted the informed consent process. Consent procedures included explanation of the study and answering all questions that the participant had at the time of enrollment. The navigator read the consent form aloud to prospective participants, making sure they understood what participation entailed and their rights as participants.

Nuestra Clinica del Valle

Patients for the intervention group were recruited from new and existing patients at NCDV's Mission clinic. Patients at Mission learned about the study through contact with the promotora(es) at the beginning of the patient visit. The recruitment process used at the Mission Clinic was comprised of a data manager who reviewed patient records for those patients who were scheduled for appointments in the next week. The data manager reviewed patient's health information retrospectively for the 90 days. As part of this review, the data manager looked to see if the patient met the eligibility criteria; if it was determined that the patient did meet the eligibility criteria, their record was flagged, and the patient was called in advance of their appointment to remind them of their appointment and inform them of

the study. Potential study participants were asked to arrive for their appointment 15 minutes early to learn about the study and undergo informed consent procedures.

If a patient was deemed eligible, at the time of the patient's appointment, the promotora(es) spoke to the potential study participant at the beginning of their visit. At this time, s/he explained the purpose of the study and answered any questions the patient might have had regarding their participation. The promotora(es) read the consent form aloud to prospective participants, making sure they understood participation was voluntary and to ensure they understood what participation entails, including that their health information may be used for a study, and their rights as participants. The promotora(es) explained that the patient's involvement would consist of the patient consenting to the clinic using their health information—which is part of their standard medical record—and completing the Duke Health Profile and PHQ-9. If the patient consented to allowing the clinic to the use of their health information, they would receive a $10 gift card as compensation for their baseline study visit, $15 for their 6-month follow-up and $25 for their 12-month follow-up; compensation was provided after data were collected. If a patient declined to participate, they did not receive any type of compensation, declination was noted in medical record and the patient was not asked to participate again at any other time. This same recruitment process was followed in the Alton and Edcouch clinics for recruitment of the comparison group.

University of Texas Health Science Center at Houston School of Public Health

SyV 2.0 participants were recruited after they had participated in SyV 1.0.[1] Participants 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, UT Health SPH followed its well-established protocol for treating suicidal participants. Severe cases were referred to the local mental health authority, Tropical Texas Behavioral Health.

The program manager identified participants who met SyV 2.0 criteria by running weekly reports to assess eligibility criteria. This is a deviation from the SEP which originally proposed that the program manager would identify participants on a monthly basis and recommend participant review to the Chronic Care Management (CCM) Team. Therefore, the program manager initially ascertained if participants met inclusion criteria (HbA1c level greater than or equal to 9.0% at any point during 6 and 36 months of SyV 1.0 services, must speak either English or Spanish, and cannot participate if immediate household family member is in SyV 2.0 program) rather than the CCM team.

Once deemed eligible for the study, the UT Health SPH evaluation staff or a CHW assigned to the participant arranged special contact to meet with and consent the participant. If a participant consented to be a part of SyV 2.0, baseline data were collected by a UT Health SPH staff during a scheduled appointment at a community reference lab. After baseline data was collected, the participant was entered into the randomization process. The evaluation staff or community health worker who obtained informed consent used the minimization randomization algorithm to determine the participant's assignment to either the intervention or control group.

[1] SyV 1.0 participants are individuals with uncontrolled diabetes (HbA1c ≥ 8%) who are referred to the program by their clinic provider or are identified through community outreach events.

Rural Economic Assistance League, Inc

Recruitment occurred within the consumer population that was enrolled or eligible for the Project Salud y Vida at each specific clinic site, either of the intervention clinic sites and the comparison clinic sites. The TRIP for Salud y Vida program was offered at three intervention clinics (Alice, Falfurrias, Kingsville clinics) and Project Salud y Vida was offered at two comparison clinics (Beeville and clinics).

The TRIP for Salud y Vida program used a rolling recruitment process. Consumers that were currently enrolled or eligible for enrollment in Project Salud y Vida at either of the three intervention clinic sites were approached to participate by the program navigators. It was estimated that 60-80% of the current Project Salud y Vida consumers would agree to enroll in the TRIP for Salud y Vida program. Once a consumer indicated a wish to enroll in the program, they were taken through the informed consent process. Consumers who chose not to participate (opt-out) of the TRIP for Salud y Vida program were assured that no disruption or changes would be made to their current care. Navigator weekly meeting reports indicated that 80% of those who were approached to participate agreed to participate in the program. All consumers with an appointment during the enrollment period were approached. Consumers who qualified for the study were asked to voluntarily sign the informed consent. This included volunteering to take all baseline and follow-up surveys, volunteering to have vitals (e.g., blood pressure, height, weight) and bloodwork (to assess HbA1c and total cholesterol) taken during the study, and understanding that they were part of a research study. Those consumers who did not consent to the study or who were unable to consent to the study were referred to other REAL usual care services. Enrollment was conducted on a rolling basis between February 2016 and July 2016.

Completed Submissions

Study Status:	Active - No Continuing Review
Principal Investigator:	**Valerio, Melissa**
Study Title:	TRIP for Salud y Vida Program Evaluation for REAL, Inc.

Reference Number	Request Type	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received
125962	Initial Review Submission Form						
	Initial Review Submission Form	Committee for the Protection of Human Subjects		Returned for Corrections			07/16/2015 07:02:18 AM CDT
	Submission Correction for Initial Review Submission Form	Committee for the Protection of Human Subjects IRB #2		Expedite	12/18/2015	Approved	11/24/2015 12:46:50 PM CST
141785	IRB - Continuing Review Form						
	IRB - Continuing Review Form	Committee for the Protection of Human Subjects IRB #2		Expedite	09/16/2016	Approved	08/22/2016 08:45:04 AM CDT
154073	IRB - Continuing Review Form						
	IRB - Continuing Review Form	Committee for the Protection of Human Subjects IRB #2		Expedite	06/16/2017	Approved	06/11/2017 12:11:34 PM CDT
168498	IRB - Continuing Review Form						
	IRB - Continuing Review Form	Committee for the Protection of Human Subjects IRB #2		Expedite	04/20/2018	Approved	03/19/2018 10:31:11 AM CDT
184982	IRB - Continuing Review Form						
	IRB - Continuing Review Form	Committee for the Protection of Human Subjects IRB #2		Expedite	03/15/2019	Approved	03/01/2019 06:17:33 AM CST

Obtaining meaningful informed consent from individuals diagnosed with SMI presents unique ethical challenges due to cognitive impairment. For the TRIP for Salud y Vida program, informed consent was considered valid when the following criteria were met: 1) verbal information sharing about the study (each section of the informed consent form was read to the consumer), 2) an assessment of the decisional capacity of the participant, and 3) an assessment of the capacity for the participant to voluntarily participate in the evaluation. All three of these elements were assessed by the navigator to meet ethical standards. The TRIP for Salud y Vida program team navigators/case managers did not enroll participants where any one of these elements was in question.

The study personnel were trained to read the consent form aloud to the prospective participants and ensure the prospective participant had an understanding of what the research participation entails and their rights as participants. Study personnel emphasized the commitment required for participation. Caution was exercised to not obtain consent from potential participants if they were sedated or too emotionally distraught to give informed consent at the time of intake. Following the informed consent

process, the consumer was assigned a community health worker to navigate program activities as outlined in the logic model.

University of Texas Rio Grande Valley

Intervention group: Potential intervention group participants were recruited from UTRGV using the following procedures: All patients receiving care at UTRGV clinics during the enrollment period were requested to complete standard intake documents which included behavioral health screening measures (PHQ-9, GAD-7, Duke) at check-in for their appointment. Each patient then had health history questions and vital physical measures taken (height, weight, blood pressure) upon intake into the clinical area. The patients then received standard care from their physician (resident and preceptor) and/or allied health professionals. During some appointments, if recommended by the provider, a warm handoff to a BHC (to receive integrated behavioral health services) would occur. After completion of the standard check-out process, UTRGV study-eligible patients met with a research staff member who provided them with an informed consent packet to discuss the study, assess their eligibility, and invite them to participate if eligible. All patients receiving primary care services at both FMR clinics were eligible for the behavioral health services as part of the PCBH program. The criteria for a referral to behavioral health services is based on mood questionnaires (PHQ-9 and GAD-7) and/or recommendation of the PCP. For the purpose of this study, screening criteria were receipt of both primary care and behavioral health services. Patients who met the additional eligibility criteria for the study (shown below) were then offered an opportunity to give consent to join the study at the end of their visit. Participants enrolled in the study were responsible for payment of any clinical services that were billed. Behavioral health services were provided to all enrolled patients at no cost.

The informed consent was placed at the end of the visit to prevent any undue influence on patient's primary reason for the healthcare visit. The patient gave consent to use health information which is part of their standard medical record. The research staff were available for any questions, translations, as well as to provide the compensation. If the patient consented to allowing study staff to use their health information, they received a $10 gift card as compensation for their baseline study visit, $15 for their 6-month follow-up, and $25 for their 12-month follow-up. By giving consent at either FMR Clinic, the patient agreed to allow access to medical records, from their visits, for clinical data measures as available. This procedure has been approved by the UTRGV IRB.

Comparison group: Potential comparison group participants were recruited from TTBH using the following procedures: All existing patients who presented at the Brownsville and Weslaco clinics for scheduled behavioral health services were requested to complete a behavioral health care service eligibility screening and assessment. The assessment was performed by a behavioral health care assistant. Potential participants were asked a series of eligibility questions.

As noted above, the comparison group for these analyses was selected after UTRGV's study had ended. The original comparison group from Nuestra Clinica del Valle (NCDV), selected during study design, ultimately was not appropriate for analyses due to substantial nonequivalence at baseline. This was likely due to the fact that the NCDV group was recruited for multiple studies and therefore the eligibility requirements could not be matched exactly to UTRGV's study. While the TTBH comparison group was also recruited using different eligibility requirements, the group was found to be statistically equivalent at baseline on more sociodemographic and health impact measures, particularly UTRGV's confirmatory variable of PHQ-9 score. To mitigate threats to internal validity that may exist due to the TTBH comparison group being comprised of patients with SPMI, those with a diagnosis of schizophrenia were

removed from the TTBH analytic sample used as a comparison for UTRGV. Patients with major depression and bipolar are frequently treated and managed by a PCP, whereas patients with schizophrenia often have more active symptoms that need to be treated by a behavioral health provider. Additionally, medications for schizophrenia can create metabolic syndrome. Thus, by removing patients with schizophrenia from the comparison group, the sample is more comparable to a primary care sample.

If the patient qualified for the study, the patient was then asked to review and voluntarily sign the informed consent. This included volunteering to take all baseline and follow-up surveys, volunteering to have vitals (e.g., blood pressure, height, weight) and blood work (to assess HbA1c and total cholesterol [for TTBH's study]) taken during the study and understanding that they were part of a research study. TTBH offered financial incentives to comparison group participants. They were offered a progressive incentive for completing each of the three assessments. Comparison group participants received a $10 Walmart or HEB gift card for completing the baseline assessment, a $20 Walmart or HEB gift card for completing the 6-month assessment, and a $30 Walmart or HEB gift card for completing the 12-month assessment. Those participants who did not consent to the study or who were unable to consent to the study were referred to TTBH usual care behavioral health services.

Hope Family Health Center

IBH program participants were recruited from HFHC patients receiving behavioral health services. Patients who met the eligibility criteria were given the option to participate in the study.

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, HFHC followed its well-established protocol for treating suicidal patients. Severe cases were referred to the local mental health authority, Tropical Texas Behavioral Health.

Texas A&M International University

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

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.

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. 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.

Appendix K: Additional Analyses - Differential Attrition

Table 52. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Demographic Characteristics among the Intervention and Comparison

	Completed the Study (n = 2955)	Did Not Complete the Study (n = 1271)	p-value
Demographic Characteristics			
Age	%	%	
Mean (SD)	50.0 (11.5)	47.4 (13.6)	**<0.001**
Missing	*2*	*4*	
Sex			
Male	27.3	36.9	**<0.001**
Female	72.7	63.1	
Missing	*3*	*4*	
Ethnicity			
Hispanic	6.8	11.2	**<0.001**
Non-Hispanic	93.0	88.1	
Other	0.2	0.7	
Missing	*6*	*6*	
Language			
English	34.2	45.1	**<0.001**
Spanish	64.7	53.5	
Other	1.1	1.4	
Missing	*11*	*11*	

Table 53. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Demographic Characteristics among the Intervention

	Completed the Study (n = 1559)	Did Not Complete the Study (n = 695)	p-value
Demographic Characteristics			
Age	%	%	
Mean (SD)	49.9 (11.7)	46.7 (14.2)	**<0.001**
Missing	*2*	*2*	
Sex			
Male	27.8	35.5	
Female	72.2	64.5	**<0.001**
Missing	*2*	*2*	
Ethnicity			
Hispanic	93.5	90.5	
Non-Hispanic	6.2	8.8	**0.03**
Other	0.3	0.7	
Missing	*2*	*3*	
Language			
English	36.8	47.4	
Spanish	61.9	50.9	**<0.001**
Other	1.4	1.7	
Missing	*10*	*7*	

Table 54. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Demographic Characteristics among the Comparison

	Completed the Study (n = 1396)	Did Not Complete the Study (n = 576)	p-value
Demographic Characteristics			
Age	%	%	
Mean (SD)	50.1 (11.4)	48.1 (12.7)	**<0.001**
Missing	*0*	*2*	
Sex			
Male	26.7	38.7	
Female	73.3	61.3	**<0.001**
Missing	*0*	*3*	
Ethnicity			
Hispanic	92.4	85.2	
Non-Hispanic	7.5	14.1	**<0.001**
Other	0.1	0.7	
Missing	*4*	*3*	
Language			
English	31.3	42.3	
Spanish	67.8	56.6	**<0.001**
Other	0.9	1.1	
Missing	*1*	*4*	

Table 55. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Health Impact Measures among the Intervention and Comparison Groups

	Completed the Study (n=2955)	Did Not Complete the Study (n=1271)	*p*
	Mean (SD)	Mean (SD)	
BMI[a]	33.7 (7.5)	33.3 (7.5)	0.08
Systolic blood pressure	132.0 (19.2)	131. (20.1)	0.66
Diastolic blood pressure	78.8 (10.6)	79.5 (11.3)	0.08
Non-Parametric Tests[b]	Median (IQR)	Median (IQR)	*p*
HbA1c	7.7 (3.2)	7.4 (3.8)	**<0.001**
PHQ-9	5.0 (10.0)	7.0 (13.0)	**<0.001**
Duke (General)[c]	70.0 (33.3)	63.3 (40.0)	**<0.001**

Note: Bold denotes significance of p < 0.05 [a] the log transformation was used to conduct statistical testing [b] the Wilcoxon Signed Rank test was used to examine non-normally distributed data [c] TTBH did not collect data using the Duke Health Profile & data collected from Hope not included in analyses

Table 56. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Health Impact Measures among the Intervention Group

	Completed the Study (n = 1559)	Did Not Complete the Study (n = 695)	*p*
	Mean (SD)	Mean (SD)	
BMI[a]	33.7 (7.8)	33.3 (7.7)	0.19
Systolic blood pressure	132.3 (19.6)	131.4 (19.9)	0.29
Diastolic blood pressure	79.0 (10.7)	79.2 (11.1)	0.64
Non-Parametric Tests[b]	Median (IQR)	Median (IQR)	*p*
HbA1c	7.7 (3.4)	7.4 (4.1)	**0.08**
PHQ-9	6.0 (11.0)	8.0 (12.0)	**<0.001**
Duke (General)[c]	66.7 (33.3)	60.0 (36.7)	**<0.001**

Note: Bold denotes significance of p < 0.05 [a] the log transformation was used to conduct statistical testing [b] the Wilcoxon Signed Rank test was used to examine non-normally distributed data [c] TTBH did not collect data using the Duke Health Profile & data collected from Hope not included in analyses

Table 57. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Health Impact Measures among the Comparison Group

	Completed the Study (n = 1396)	Did Not Complete the Study (n = 576)	*p*
	Mean (SD)	Mean (SD)	
BMI[a]	33.6 (7.3)	33.3 (7.3)	0.25
Systolic blood pressure	131.6 (18.8)	132.1 (20.2)	0.62
Diastolic blood pressure	78.7 (10.5)	79.8 (11.5)	**0.04**
Non-Parametric Tests[b]	Median (IQR)	Median (IQR)	*p*
HbA1c	7.8 (3.0)	7.4 (3.5)	**<0.001**
PHQ-9	4.0 (9.0)	6.0 (12.0)	**<0.001**
Duke (General)[c]	73.3 (33.3)	66.7 (40.0)	**<0.001**

Note: Bold denotes significance of p < 0.05 [a] the log transformation was used to conduct statistical testing [b] the Wilcoxon Signed Rank test was used to examine non-normally distributed data [c] TTBH did not collect data using the Duke Health Profile & data collected from Hope not included in analyses

Appendix L: 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 ...		
	None	Some of our patients	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.	☐	☐	☐

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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 of our patients receive this service	Some of our patients receive this service	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 M: 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

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CUESTIONARIO SOBRE LA SALUD DEL PACIENTE-9 (PHQ-9)

Durante las <u>últimas 2 semanas</u>, ¿qué tan seguido ha tenido molestias debido a los siguientes problemas? *(Marque con un "□" para indicar su respuesta)*	**Ningún día**	**Varios días**	**Más de la mitad de los días**	**Casi todos los días**
1. Poco interés o placer en hacer cosas	0	1	2	3
2. Se ha sentido decaído(a), deprimido(a) o sin esperanzas	0	1	2	3
3. Ha tenido dificultad para quedarse o permanecer dormido(a), o ha dormido demasiado	0	1	2	3
4. Se ha sentido cansado(a) o con poca energía	0	1	2	3
5. Sin apetito o ha comido en exceso	0	1	2	3
6. Se ha sentido mal con usted mismo(a) – o que es un fracaso o que ha quedado mal con usted mismo(a) o con su familia	0	1	2	3
7. Ha tenido dificultad para concentrarse en ciertas actividades, tales como leer el periódico o ver la televisión	0	1	2	3
8. ¿Se ha movido o hablado tan lento que otras personas podrían haberlo notado? o lo contrario – muy inquieto(a) o agitado(a) que ha estado moviéndose mucho más de lo normal	0	1	2	3
9. Pensamientos de que estaría mejor muerto(a) o de lastimarse de alguna manera	0	1	2	3

FOR OFFICE CODING *0* + _____ + _____ + _____

=Total Score: _____

Si marcó <u>cualquiera</u> de los problemas, ¿qué tanta <u>dificultad</u> le han dado estos problemas para hacer su trabajo, encargarse de las tareas del hogar, o llevarse bien con otras personas?

No ha sido difícil	**Un poco difícil**	**Muy difícil**	**Extremadamente difícil**
☐	☐	☐	☐

Appendix N: 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

PHYSICAL HEALTH SCORE

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

MENTAL HEALTH SCORE

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

SOCIAL HEALTH SCORE

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

GENERAL HEALTH SCORE

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

PERCEIVED HEALTH SCORE

Item	Raw Score*
3 =	_____ x 50 =

SELF-ESTEEM SCORE

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

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.

ANXIETY SCORE

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

DEPRESSION SCORE

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

ANXIETY-DEPRESSION (DUKE-AD) SCORE

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

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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