Sí Texas: Social Innovation for a Healthy South Texas

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Final Evaluation Report:

The University of Texas Rio Grande Valley

The University of Texas Rio Grande Valley School of Medicine

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

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LIST OF ABBREVIATIONS

BHC…….. Behavioral Health Consultant

BMI……. Body Mass Index

DHR…… Doctors Hospital at Renaissance

EMR…… Electronic Medical Record

FMR…… Family Medicine Residency

GAD – 7…… Generalized Anxiety Disorder 7

MMC……. McAllen Medical Center

NCDV……. Nuestra Clinica del Valle

PCBH……. Primary Care Behavioral Health

PCP…….. Primary Care Physician

PHQ-9……. Patient Health Questionnaire 9

SEP…… SIF Evaluation Plan

SIF……. Social Innovation Fund

SPMI…… Severe Persistent Mental Illness

TTBH…… Tropical Texas Behavioral Health

UTRGV…… University of Texas Rio Grande Valley

EXECUTIVE SUMMARY

This final report provides an overview of progress and findings for the evaluation of University of Texas Rio Grande Valley (UTRGV) Family Medicine Residency (FMR) program, a subgrantee 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) at family medicine residency clinics in McAllen and Edinburg, TX.

Program Background

The University of Texas Rio Grande Valley (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, 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. The study hypothesized that individuals who participate in the PCBH program would have improved physical health, behavioral health, and quality of life at 12-months.

Prior Research

The UTRGV integration strategy replicated the 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). All three studies involved non-randomized, quasi-experimental designs to study the effectiveness of the PCBH model on a variety of behavioral and other health conditions. The PCBH model is supported by several well-designed quasi-experimental studies, as noted, with an incoming level of evidence of moderate. The evaluation also targeted a moderate level of evidence.

Evaluation Design

UTRGV conducted a non-randomized quasi-experimental design (QED) to evaluate the PCBH model in the two FMR clinics. The QED allows for the identification of and adjustment for participant characteristics that may affect impact the relationship between intervention receipt and outcomes of interest. The use of a comparison group helped mitigate major threats to internal validity. More specifically, use of a comparison group reduced the potential impact of the following threats to internal validity: regression to the mean, history, testing, and expectancy effects. Patients from Tropical Texas Behavioral Health's (TTBH) Weslaco and Brownsville clinics, a population of persons with severe persistent mental illness (SPMI), served as the comparison group for this study. This represents a change from the SEP, which proposed a comparison group from Nuestra Clinical del Valle's Alton and Edcouch clinics. It should be noted that although the intervention group participants are not classified as (SPMI), the baseline PHQ-9 scores indicate that baseline depression among both intervention and comparison groups was equivalent.

UTRGV's recruitment target was 366 participants for the intervention group. UTRGV's final enrollment was 364 for the intervention group. UTRGV's 12-month retention target was 256 for the intervention group, and the final sample was 243.

The comparison group enrolled 262 comparison group participants (167 from Brownsville and 95 from Weslaco) with 205 being eligible for inclusion in UTRGV's analyses based on SPMI diagnosis (see **Figure 2**). This is a deviation from UTRGV's SEP as the comparison group sample size was lower than planned. This is due to the differing enrollment targets for TTBH's study.

The implementation evaluation focused on measuring the level of program services provided and quality of services program participants received relative to what was proposed. In addition, the implementation evaluation assessed the extent to which the comparison groups received program services similar to services received by the intervention group.

Description of Measures and Instruments

The primary impact measure was change in depression symptoms as measured by the Patient Health Questionnaire (PHQ-9). UTRGV also collected data on the following secondary measures: BMI (calculated from height and weight), HbA1C (obtained via blood test), blood pressure (taken by the provider), anxiety (using the Generalized Anxiety Disorder 7-item scale (GAD-7)) and quality of life (using the Duke Health Profile).

Research Questions

The primary impact measure for the PCBH program was improvement in depressive symptoms. Below are the confirmatory and exploratory research questions.

1) Do patients who participate in the PCBH intervention experience improvements in depressive symptoms, as measured by PHQ-9, after 12 months compared to patients who do not participate in the intervention? *This question is confirmatory.*
2) Do patients who participate in the PCBH intervention experience improvements in quality of life, as measured by the Duke Health Profile, after 12 months when compared to patients that do not participate in the intervention? *This question is exploratory.*
3) Do patients who participate in the PCBH intervention experience improvements in anxiety symptoms, as measured by GAD-7, after 12 months compared to patients who do not participate in the intervention? *This question is exploratory.*
4) Do patients who participate in the PCBH intervention experience improvements in blood pressure, when compared to patients that do not participate in the intervention? *This question is exploratory.*
5) Do patients with a history or diagnosis of diabetes who participate in the PCBH intervention experience improvements in HbA1c level after 12 months when compared to patients that do not participate in the intervention? *This question is exploratory.*
6) Do patients who participate in the PCBH intervention experience improvements in BMI after 12 months when compared to patients that do not participate in the intervention? *This question is exploratory.*

Implementation Questions

The following evaluation questions examine program implementation and patient and provider satisfaction.

1) Did the PCBH program reach its intended target population?
2) What are the components of the PCBH program and how do these components work "on the ground" at 6 and 12 months?
    a. Are these components different than what was planned, and why are they different?
3) What level of integrated behavioral health did UTRGV FMR clinics achieve as a result of implementing the program?
    a. To what extent have providers and program staff adopted the components of the PCBH program at 6 and 12 months, and what are the facilitators and barriers to adoption?
    b. To what extend do providers buy-in to the program, and how has that buy-in affected implementation?
4) To what extent did the comparison groups receive program-like components?
5) To what extent did UTRGV FMR clinics implement the PCBH model as outlined?
6) How satisfied are patients with the services they have received? How satisfied are providers with the PCBH model?
7) What barriers to participation do patients experience? Do patients see the cost of the PCP fee as a barrier to participation?

Impact Analysis

This report presents descriptive statistics, analysis of baseline equivalence, and analyses of impact across the study groups. All analyses were conducted based on an intention-to-treat approach. The unit of analysis was the individual patient. Impact measures were treated as continuous variables. Generalized regression analysis results are presented as the final results of the modeling sequence starting with bivariate models and ending with multiple regression models. These multiple regression models adjust for key demographic factors, covariates, and baseline impact measures identified as relevant via review of the scientific literature or found to be non-equivalent at baseline. The possibility of effect modification of the intervention-outcome relationship by patient characteristics was also explored.

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

Key Findings

Evaluation of UTRGV's implementation of the PCBH program indicates that it was implemented in alignment with the logic model and that there was strong fidelity with the PCBH model. Facilitators to program implementation included communication among staff, warm handoffs between primary care and behavioral health providers, staff training on the PCBH model, and flexibility among program staff in adapting workflow and processes. For patients, additional factors that facilitated their participation included patient relationships with their providers and community health workers as well as noticeable improvements in their health status as the program progressed.

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).

Additionally, when controlling for baseline measures and other covariates, intervention participants demonstrated statistically significant smaller decreases at 12 months for the physical health measures of blood pressure (both systolic and diastolic) and BMI when compared to the comparison group participants. On average, the systolic blood pressure of intervention participants was 7.56 mmHg higher than the comparison participants at 12 months, holding all other variables in the model constant (p<0.001). Similarly, on average, the diastolic blood pressure of intervention participants was 2.76 mmHg higher than comparison participants at 12 months, holding all other variables in the model constant (p=0.01). On average, the BMI of participants in the intervention group was 1.12 kg/m^2 higher than comparison participants at 12 months, holding all other variables in the model constant (p=0.005).

Conclusion and Next Steps

This evaluation study achieved a preliminary level of evidence This evaluation study used a QED design with a comparison group which helped mitigate major threats to internal validity. More specifically, the comparison group addressed the following threats to internal validity: regression to the mean, history, testing, and expectancy effects. Further, there was baseline equivalence and no differential attrition between the intervention group and comparison group. This study also meets the criteria for effective evidence for the following reasons: First, the study demonstrates a positive, significant finding for the confirmatory outcome of depression (measured via PHQ-9). Second, the confirmatory outcome of PHQ-9 achieved an effect size (using Cohen's d) of 0.31, which is interpreted as a small to medium effect. Although there was a statistically significant negative intervention effect on BMI, this effect size was not considered to be clinically significant. Finally, while there appeared to be a negative effect on blood pressure within the primary analyses, further analysis identified this as greater improvement in blood pressure among the comparison group rather than worsening blood pressure among the intervention group.

Despite its limitations, this study contributes to our understanding of the implementation of the PCBH model of IBH in an academic primary care setting within a low-income, Hispanic population. Lessons learned include *operational facilitators* such as strong communication, leadership support and staff buy-in, and staff training, *operational barriers* related to staff hiring and retention and data systems, the challenges of conducting population health research, and factors related to sustainability of the PCBH model at UTRGV.
Although there were several challenges with early buy-in to the program, interviewees reported strong support from both the frontline staff and project leadership, as well as positive clinic culture. Feedback from patients was generally very positive as well. Patients were receptive to program services, such as increased time for their appointments with providers, and appreciated the ability to manage their healthcare needs which also included behavioral, emotional, and psychological support. The delivery of care using the PCBH model continues to be strong after the research period. In addition to replicating

PCBH services in an OB/GYN residency program, the PCBH implementation team has partnered with senior UTRGV School of Medicine leaders to present an Integrated Behavioral Health strategic imperative as well as train senior leadership in Integrated Behavioral Health competencies by sending them to clinical leadership training opportunities with high functioning IBH centers. While understanding of and support for IBH has been increasing in the medical field, challenges remain in articulating the value of specific models, such as PCBH, in the larger healthcare environment. The PCBH implementation team continues to advance the case for PCBH within the UTRGV health system, through partnering with a state-level mental health policy institute and developing PCBH as a core strategy for primary care delivery.

INTRODUCTION

This final report reviews the methods implemented to evaluate UTRGV's program model compared to the SEP, notes deviations and/or changes to the SEP, and describes final findings from the impact and implementation evaluations (including baseline data, six-month data, and twelve-month data). This report also provides a description of the reporting timeline discussed in the SEP and revised in **Appendix A: Revised Project Timeline** of this report. The intended audience of this report is the Social Innovation Fund (SIF), although excerpts will also be used by Methodist Healthcare Ministries program staff and leadership and internal leadership at the University of Texas Rio Grande Valley School of Medicine.

Program Definition and Background

Located along the Texas and Mexico border, residents of Hidalgo County suffer from health disparities which likely stem from high poverty, lower levels of educational attainment and inadequate access to basic health care needs. Hidalgo County is also home to *colonias*—unincorporated settlements of land along the Texas-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. In the 19 counties that make up the Rio Grande Valley, there are 1,902 *colonias* of which 943 are located in Hidalgo County (Davila, Rodriguez, Urbina, & Nino, 2014). As identified in numerous region-specific assessments and reports, the scarcity of primary care and behavioral health service providers are key factor influencing higher-than-average disease prevalence and unfavorable disease management.

These cited needs are compounded further by lack of appropriate access to healthcare, especially for residents who are poor and are uninsured. In the Rio Grande Valley, there are only 15.5 family physicians per 100,000 and even fewer behavioral health providers. In 2014, there were 20 psychiatrists and 101 psychologists in Hidalgo County (Center for Health Statistics). Psychiatrists and psychologists often see mental health conditions once they are fully developed or no longer bearable. This is important especially when physical health conditions co-exist with mental health conditions. For example, one community mental health survey found that patients had the following rates of chronic physical health conditions: 33% had chest pain, 29% had high blood pressure, 16% had diabetes and 10% had seizures. In addition, according to the County Health Rankings, 34% of Hidalgo County adults are obese. (University of Wisconsin Population Health Institute, 2015).

Hidalgo County has a population of approximately 860,661 in 2017; 92% of the population is Hispanic/Latino and over 80% (84.3%) of the population 5 years and older indicate they speak a language other than English at home (U.S. Census Bureau, 2018). In addition, as can best be captured by the census, 27% of the population is foreign born, irrespective of citizenship status and 30% of the population is at or below the 200% FPL. This coincides closely with percent of the population with less than a high school education (36%) (U.S. Census Bureau, 2018).

Lack of adequate access to healthcare services and providers, increased health disparities, poverty, and poor resources presents meaningful opportunities to intervene on unmet behavioral health and healthcare needs in Hidalgo County. The health challenges in this county are multi-factorial; the challenge of primary care is to have resources within the clinic to address a range of bio-psycho-socio-cultural problems and develop a culture of working in inter-professional teams to address the vast array of challenges. The health disparities and health-related challenges prevalent in Hidalgo County are not unlike those seen in other underserved and minority-prominent communities across the U.S. What

makes this population unique, however, are the cultural and regional characteristics that require culturally-tailored and culturally-appropriate interventions. Within this context, previous research has supported the use of integrated health services for underserved and minority populations. Integrating mental health services within primary care exists in two dimensions - horizontal and vertical integration (Strosahl, 2001). Horizontal integration emphasizes delivering low-intensity interventions to a high volume of patients. Vertical integration involves targeted, specialized services for a defined subpopulation.

The Primary Care Behavioral Health (PCBH) model is a well-known and widely implemented model. Key elements of Strosahl and Robinson's PCBH horizontal model use Behavioral Health Consultants (BHC) to improve population health, emphasize early identification and prevention; serve a high volume of patients, provide triage and clinical services in a stepped care fashion, use panels instead of a clinical case model, and provide measurement-based care. Ultimately, the PCBH model is conceptually concerned with improving population health, teaching effective behavior change strategies to Primary Care Providers (PCP), and/or identifying challenges or barriers in the delivery care.

Overview of Prior Research

The scientific literature has many examples of interventions targeting improved access to high-quality health care services in low-income populations. 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., 2014; Camacho et al., 2015; Ell et al., 2009). 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., 2012). Several other quasi-experimental studies using behavioral health consultants have also shown positive results (Bryan et al., 2009; Goodie et al., 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).

Additionally, behavioral interventions delivered at point of care by the BHC are evidence-informed treatments for mental and behavioral health conditions. In addition to numerous interventions cited as common behavioral interventions used in primary care setting, Hunter, Goodie, Oordt & Dobemeyer (2017) provide specific intervention strategies for common physical and mental health concerns in primary care. It is also important to note that integrating behavioral health consultants in primary care facilities reduces the cost and inconvenience to patients by eliminating the need to travel to multiple locations to receive behavioral health care.

In the PCBH model, consultative interventions focus on helping patients replace maladaptive behaviors with adaptive ones; providing skill training through psycho-education and patient education strategies; and developing specific behavior change plans to fit the fast work pace of the primary care setting. The following are principles of the PCBH Integration Model (Mountainview Consulting Group, 2013). UTRGV will put these principles into practice through the Activities outlined in the Logic Model.

1. The BHC's role is to identify, treat, triage and manage primary care patients with medical and/or behavioral health problems.
2. The BHC functions as a core member of the primary care team, providing consultative services.

3. The PCBH Model is grounded in a population-based care philosophy that uses a clinic-wide population-based care perspective.
4. The BHC seeks to enhance delivery of behavioral health services at the primary care level and works to support a smooth interface between primary care and specialty services, e.g., mental health and substance abuse.

Based on the evidence available, and the model specifications for the PCBH model, the incoming level of evidence is moderate and aims to advance towards a higher-level of moderate evidence.

Program Components

The Family Medicine Residency clinics in McAllen and Edinburg work together to prepare physicians to serve the surrounding underserved communities with team-based, inter-professional, and integrated care. The PCBH model will reach and address its 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. Use of this model is supported by previous research. For example, as previously mentioned, 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., 2014; Camacho et al., 2015; Ell et al., 2009). In addition, use of PCBH models have shown improvements in global mental health functioning in patients—though not with this particular clinic population (Bryan et al., 2009; Goodie et al., 2009). UTRGV implemented the PCBH model clinic-wide at the McAllen Family Medicine Residency Clinic and the Doctors Hospital at Renaissance Family Medicine Residency Center; the evaluation examines the effect of the PCBH model at both FMR clinics compared to the comparison clinic that does not use the PCBH model. Service provided as part of the intervention and usual care at the comparison clinic are described in the **Impact Study Design and Methods** section of this report.

Theory of change: The FMR clinics' theory of change is that integrated behavioral health services, as implemented through the PCBH model, will lead to improved physical and behavioral health and functioning for an increasing proportion of clients served. The conceptual framework of PCBH clinical work (assessment, interventions, behavioral health case conceptualization) is geared towards addressing most problems observed in primary care. Therefore, to match the needs of primary care without losing the effectiveness of interventions and to support creativity in interventions, PCBH is grounded in ACT[1]. ACT not only enhances patient health outcomes but also focuses on provider and patient satisfaction.

Logic Model Components

The logic model in **Appendix B: Program Logic Model** outlines the inputs, activities, outputs, and outcomes for the FMR clinics' PCBH model.

[1] Acceptance and Commitment Theory (ACT) is an empirically-based psychological intervention that uses acceptance and mindfulness strategies, together with commitment and behavior change strategies, to increase psychological flexibility. Powers, M. B., Zum Vorde Sive Vording, M. B., & Emmelkamp, P. M. G. (2009). Acceptance and commitment therapy: a meta-analytic review. *Psychotherapy and Psychosomatics*, *78*(2), 73–80. http://doi.org/10.1159/000190790

Inputs: The FMR clinics' logic model has inputs that include a number of internal clinic and personnel resources as well as external program partners. Internal personnel who were involved in the planning and implementation of the PCBH model, include:

PCBH Providers

- Four (4) behavioral health consultants (BHC) (e.g. BHCs, including 1 behavioral science faculty) – provide consultation to the primary care team utilizing the PCBH model, including recommendations regarding behavioral interventions to the referring PCP and conduct brief interventions with referred patients on behalf of referring PCP.

PCBH Leadership

- Medical Director/Clinic Site Director – plans and directs the PCBH program at the clinic level and provides administrative supervision of BHCs, including scheduling, productivity, and resolving patient and staff-related issues.
- PCBH Lead – oversees the implementation and ongoing operation of the PCBH program at both FMR clinics.
- PCBH Clinical Supervisor – responsible for system-wide and clinic-specific operation of the PCBH program.

PCBH Support Staff

- One (1) Program Coordinator – will coordinate the program implementation in terms of budget and reporting, including management, coding, and storage of data from both clinics
- One (1) Program Research Assistant – will provide support to the program coordinator and will focus on patient data collection and reporting to the program team.

Primary Care Team: These providers are the focus point of the PCBH model and key to making the model function. They refer patients to the BHC and integrate the BHC into routine daily practice as part of the primary care team.

- Two (2) family medicine programs consisting of seven (7) faculty physicians
- Twenty-four (24) residents
- One (1) Nurse Practitioner (NP)
- One (1) Registered Nurse (RN)
- Eight (8) Medical Assistants (MAs) working under the supervision of an RN or NP, the MA identifies possible referrals to the BHC and also attends to work flow issues.

Resources:

- Two (2) clinics
- Mountainview consulting (IBH consultant) – will provide training and consultation on implementation and evaluation of the PCBH model

Changes in these program inputs that deviate from the SEP include: Three behavioral health consultants were part of the program instead of four. Additional PCBH support staff were hired or had shifts in their roles. These positions included Director of Special Programs, Data and Research Manager, Research Associate, Graduate Research Assistant, and two community health workers. Other primary care team staffing deviations from the SEP included the number and composition of clinical and administrative staff at the FMR clinics. At the Doctors Hospital at Renaissance (DHR) FMR Clinic the primary care team

was comprised of five (5) Faculty Physicians (MD, DO), sixteen (16) Family Medicine Residents, one (1) Pharmacist (PharmD), five (5) Medical Assistants (MAs), four (4) Front Office Specialists (FOS), one (1) Family Medicine Residency Program Coordinator, and three (3) Administrative Personnel. At the McAllen (MMC) FMR Clinic, the primary care team was comprised of four (4) Faculty Physicians (MD, DO), eighteen (18) Family Medicine Residents, three (3) Medical Assistants (MAs), four (4) Front Office Specialists (FOS), two (2) Family Medicine Residency Program Coordinators, four (4) Administrative Personnel, and two (2) Laboratory Specialists.

Activities: UTRGV implemented the PCBH model as outlined in the Primary Care Behavioral Health Toolkit (Mountainview Consulting Group, 2013). The activities section of the logic model provides an overview of FMR clinics' programmatic activities at the clinic level to plan for and implement the PCBH model in both clinics. These activities are based on the principles of the model and include all of the PCBH model elements such that it will be implemented clinic-wide in both FMR clinics. Primary care team, behavioral health providers, and program support staff will engage in the following:

- Develop educational materials
- Provide evidence-based and appropriate training to primary care team regarding PCBH
- Train BHCs in PCBH competencies
- Implement the PCBH model at both clinics
- Establish protocol for BHCs
- Institute practices that increase population health, including behavioral health screening and protocols for immediate access to BHC
- Effectively communicate between patient, provider, and BHC
- Provide BHCs with access to patient registry/EMR used by Primary Care Physicians so that BHC notes can be included in the patient record.

Outputs: through implementation of program activities, expected outputs at the clinic and patient levels include:

Clinic level:

- Recruit 366 participants into each arm of the study (intervention, comparison group)
- Primary care (PC) team trained on PCBH
- Clinic-wide protocol for IBH screening at intake
- Patient EMR access provided to the BHCs
- PC team huddles
- System solutions identified and implemented (team huddles, quarterly meetings, development of pathways for specific conditions and triggers for consults)

Patient level:

- Patient offered behavioral health (BH) services through an integrated BHC
- Patient has measurement-based treatment plan

All activities and outputs identified in the logic model will be evaluated as part of the implementation evaluation and are expected to influence the expected short-, intermediate-, and long-term outcomes.

Short-Term Outcomes: Short-term outcomes are the changes that are expected to occur after 6 months of a participant's enrollment in the program and receiving PCBH services. By implementing the PCBH model and system solutions at the clinic level, patients will be enrolled, screened, and have appropriate treatment plans developed. The expected short-term outcomes are outlined below. These were assessed qualitatively in the study via focus groups and interviews.

Clinic level:

- Systems solutions implemented
- PC team buy-in of PCBH model
- PC team understanding of roles in PCBH model
- Warm hand-offs from PCP to BHCs
- All patient data entered in registry/EMR

Patient level:

- Patients enrolled, screened, baseline measures taken
- Patients have measurement-based treatment plan

Intermediate Outcomes: Intermediate outcomes are the expected changes after 12 months of a participant's enrollment in the program. All intermediate outcomes are outlined below and were measured and reported on during the study.

Clinic level:

- Enhanced effectiveness of PC team
- PCBH model implemented with fidelity
- Improved access to care for integrated services
- Improved integrated clinical service provision
- Patient registry/EMR data reviewed by PC teams and QI recommendations made
- Providers satisfied with PCBH model

Patient level:

- Improved patient attendance and compliance with treatment plan
- Increased control of physical and behavioral health and well-being
- Patients satisfied with PCBH model
- Improved functioning and quality of life

Long-Term Outcomes: Long-term outcomes are the changes that are expected to occur during 18 months of the program. Through complete implementation of the PCBH model in both clinics, patients are expected to experience reduced morbidity and mortality and improved functioning and quality of life. Long-term patient-level outcome measures were not collected or reported in this final report. This is a deviation from the SEP.

Clinical level:

- Adherence to the PCBH model which is outlined in the above Activities section
- Accomplish 100% compliance on instituting population-based practices (regular screenings)

Patient level:

- Reduced morbidity and mortality from physical and behavioral health conditions, including improved BMI, A1c, blood pressure, depression, anxiety, and quality of life

Overview of Impact Study

This study utilized a quasi-experimental design (QED) to compare participants receiving the intervention with a comparison group receiving the usual care. The study was designed to last 12 months and concluded in July 2018. The study hypothesized that individuals who participated in the PCBH program, which provides medical and behavioral health, would improve physical health, behavioral health and quality of life. A QED provides rigorous estimates of the impact of the PCBH model on participant measures of depressive symptoms, anxiety, quality of life, BMI, HbA1c, and blood pressure. This design was appropriate because UTRGV FMR clinics provide the same curriculum to all residents, and to not withhold needed services for patients with low access and high risks, thus within or between clinic randomization was not feasible. Further, the PCBH Model is grounded in a population-based care philosophy that uses a clinic-wide, population-based care perspective. A QED approach can estimate program impacts by comparing the outcomes of program participants (intervention group) to the outcomes of non-participants who are observationally equivalent to program participants (comparison group).

Research Questions

UTRGV's evaluation plan included both implementation and impact research questions, as stated below. These questions have not changed since the approval of the SEP.

Implementation Questions

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

The following evaluation questions examine program implementation and patient and provider satisfaction.

1) Did the PCBH program reach its intended target population?
2) What are the components of the PCBH program and how do these components work "on the ground" at 6 and 12 months?
    a. Are these components different than what was planned, and why are they different?
3) What level of integrated behavioral health did UTRGV FMR clinics achieve as a result of implementing the program?
    a. To what extent have providers and program staff adopted the components of the PCBH program at 6 and 12 months, and what are the facilitators and barriers to adoption?
    b. To what extend do providers buy-in to the program, and how has that buy-in affected implementation?
4) To what extent did the comparison groups receive program-like components?
5) To what extent did UTRGV FMR clinics implement the PCBH model as outlined?
6) How satisfied are patients with the services they have received? How satisfied are providers with the PCBH model?

7) What barriers to participation do patients experience? Do patients see the cost of the PCP fee as a barrier to participation?

Impact Questions

The primary impact measure was the reduction in depression symptoms measured by the PHQ-9. Below are the confirmatory and exploratory research questions. The impact findings are presented in a later section by question.

1) Do patients who participate in the PCBH intervention experience improvements in depressive symptoms, as measured by PHQ-9, after 12 months compared to patients who do not participate in the intervention? *This question is confirmatory.*
2) Do patients who participate in the PCBH intervention experience improvements in quality of life, as measured by the Duke Health Profile, after 12 months when compared to patients that do not participate in the intervention? *This question is exploratory.*
3) Do patients who participate in the PCBH intervention experience improvements in symptoms of anxiety, as measured by GAD-7, after 12 months compared to patients who do not participate in the intervention? *This question is exploratory.*
4) Do patients who participate in the PCBH intervention experience improvements in blood pressure, when compared to patients that do not participate in the intervention? *This question is exploratory.*
5) Do patients with a history or diagnosis of diabetes who participate in the PCBH intervention experience improvements in HbA1c measures after 12 months when compared to patients that do not participate in the intervention? *This question is exploratory.*
6) Do patients who participate in the PCBH intervention experience improvements in BMI after 12 months when compared to patients that do not participate in the intervention? *This question is exploratory.*

Contribution of the Study

UTRGV FMR clinics are replicating the successful 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). UTRGV is implementing the PCBH model with high fidelity in a new setting, expanding the level of evidence for the PCBH model. The evaluation study achieves a preliminary level of evidence.

The evaluation of the PCBH intervention expands the level of evidence related to integrated behavioral health models at FMR clinics serving predominantly low-income, Hispanic communities through using a QED with a comparison group from another site. It is recognized that a QED is not as rigorous as a randomized control trial (RCT). However, a QED can still have strong internal validity, and its threats can be minimized. The QED design helped mitigate major threats to internal validity. More specifically, the comparison group addressed the following threats to internal validity: regression to the mean, history, testing, and expectancy effects. The use of an external clinic (Tropical Texas Behavioral Health's Brownsville and Weslaco clinics) enhanced external validity or generalizability beyond the UTRGV FMR clinics. The use of an external comparison group is appropriate for this evaluation as the PCBH model was implemented clinic-wide at the intervention sites, so randomization to a comparison group was not feasible within the intervention setting.

Further, because the FMR clinics serve a predominantly low-income, Hispanic population, the study design and implementation help the clinics as well as external audiences better understand the PCBH

model's effectiveness in addressing physical and behavioral health concerns of this population. In addition, although the main target of the evaluation is to improve clinical effectiveness, PCBH implementation may also be beneficial to various aspects of the primary care clinics. For example, with a high-fidelity implementation, the providers themselves may feel more capable of responding to patient needs knowing they have an additional team member to consult.

SIF Evaluation Plan Updates

The evaluation was implemented as intended except for several deviations, which included the following:

Timeline – UTRGV program enrollment began in July 2016 and continued through May 2017. This is a deviation from the planned timeline in the SEP. Several issues emerged during enrollment, including insufficient staffing to reach all eligible patients, an enrollment stoppage in February 2017 due to delays in IRB renewal, and the political climate creating fear among patients. Ultimately, UTRGV recruited 366 into their intervention group (100% of the target enrollment) (see **Figure 1. Patient Flow Description**). Due to these delays in program enrollment, the timing of interim and final reports was also delayed from what was stated in the SEP. A detailed timeline of the study can be found in **Appendix A: Revised Project Timeline**.

Staffing – UTRGV experienced several changes in staffing that deviate from the SEP. Three behavioral health consultants were part of the program instead of four. Additional PCBH support staff were hired or had shifts in their roles. These positions included Director of Special Programs, Data and Research Manager, Research Associate, Graduate Research Assistant, and two community health workers. Other primary care team staffing deviations from the SEP included the number and composition of clinical and administrative staff at the FMR clinics. At the DHR FMR Clinic the primary care team was comprised of five (5) Faculty Physicians (MD, DO), sixteen (16) Family Medicine Residents, one (1) Pharmacist (PharmD), five (5) Medical Assistants (MAs), four (4) Front Office Specialists (FOS), one (1) Family Medicine Residency Program Coordinator, and three (3) Administrative Personnel. At the McAllen FMR Clinic, the primary care team was comprised of four (4) Faculty Physicians (MD, DO), eighteen (18) Family Medicine Residents, three (3) Medical Assistants (MAs), four (4) Front Office Specialists (FOS), two (2) Family Medicine Residency Program Coordinators, four (4) Administrative Personnel, and two (2) Laboratory Specialists.

Comparison group – The SEP described using Nuestra Clinica del Valle (NCDV) as the comparison group for this study. While data were collected with NCDV comparison group participants, testing for baseline equivalence showed that the intervention group and original NCDV comparison group were significantly different on all seven outcome measures. The imbalances of most concern were between mental health outcomes, with median PHQ-9 and GAD-7 scores between the two groups differing by 10 points. Of the 16 sociodemographic characteristics collected by both UTRGV and NCDV, the groups were only statistically equivalent on four (history of obesity, employment, race, and sex) at baseline. The groups were imbalanced on ethnicity, age, marital status, primary language, additional health history variables (diabetes, hypertension, high cholesterol, depression), physical activity, smoking status, and alcohol consumption.

After careful consideration, it was decided that a different comparison group would serve as a more effective counterfactual for the UTRGV intervention group. Therefore, participants from a different subgrantee's study (TTBH's Weslaco and Brownsville clinics), whose data were collected at the same

time points (baseline starting in January 2016, 6 months, and 12 months ending in May 2017) for comparison in a different subgrantee's study, were used as the comparison group for this study. Of the four health outcomes collected by both UTRGV and TTBH at baseline, the groups were only statistically imbalanced on one measure, HbA1c. The two groups were statistically equivalent at baseline on BMI, blood pressure, and PHQ-9 scores. Of the five sociodemographic characteristics collected by both UTRGV and TTBH, the groups were statistically equivalent on sex, ethnicity, and age category. The groups were nonequivalent on primary language, county, and mean age. Given this, the TTBH comparison group was much more similar at baseline to the UTRGV intervention group than the original NCDV comparison group was. Therefore, after completing all necessary IRB changes and approvals, the study proceeded with the TTBH comparison group for analyses.

Patient satisfaction survey – UTRGV had intended to conduct consistent patient satisfaction surveys for the intervention group at each FMR clinic. However, this was not possible due to operational and logistical challenges. Both residency programs operate as part of independent for-profit hospital systems and patient satisfaction surveys are governed by existing policies and procedures for each hospital. Because PCBH at both sites was only implemented in FMR operated clinics of the hospital system, operational policies and procedures could not be changed to accommodate PCBH specific satisfaction questions. Qualitative patient satisfaction data collected during patient focus groups and staff interviews are presented in this report and discuss patient satisfaction.

Propensity score matching – As proposed in the SEP, only a limited set of covariates were collected among intervention and comparison groups during the study. The inclusion of TTBH as the comparison group further reduced the number of possible covariates to match on to only 4 sociodemographic measures. Given the limitations of a small number of covariates and properties of alternative matching methods, the adjusted regression approach accounting for available covariates with model selection procedure, which have been properly conducted in the analyses, was considered the most appropriate approach to ascertain the intervention effect. Thus, propensity score matching was not conducted as it was not deemed appropriate or feasible (see also Assessment of Baseline Equivalence).

Multivariate analysis of HbA1c - Only a subset of the intervention sample, those with a diagnosis of or suspected of having diabetes, had a measured HbA1c during the study. Due to the small sample size of measured HbA1c at 12 months in the intervention group (n=18), further analyses beyond the bivariate analyses were deemed inappropriate for reporting due to the limitations in interpretation.

Multivariate analysis of GAD-7 – Because TTBH did not assess anxiety symptoms for their study, GAD-7 data were not collected from comparison group participants. As a result, multivariate analyses were not possible comparing the intervention GAD-7 score to a comparison group.

Multivariate analysis of Quality of Life - Because TTBH assessed functioning and quality of life using a different instrument, Duke Health Profile data were not collected from the comparison group participants. As a result, multivariate analyses were not possible comparing the intervention Duke General Health score to a comparison group.

Long-term patient-level outcome measures were not collected or reported in this final report. This was a deviation from the SEP. These measures were collected at 12 months rather than 18 months, as the long-term outcomes stated in the SEP.

IMPLEMENTATION STUDY: STUDY APPROACH, METHODS, AND FINDINGS

Implementation Study Design

The implementation study aimed to understand how UTRGV's program was implemented. As described in the SEP, two methods were used: 1) analysis of qualitative data collected through key informant interviews and focus groups, and 2) analysis of quantitative implementation data (e.g., patient visits, administrative data).

Qualitative Data Collection Methods and Analysis

The program's evaluator, Health Resources in Action (HRiA), conducted qualitative data collection at two time points for the implementation study. Across the two time points, a total of 17 staff members were interviewed, and 22 participants were involved in focus groups.

For the mid-point interviews (April through June 2017), a total of 8 staff were interviewed in-person. Mid-point interviews were intended to be conducted approximately 6 months after initial study enrollment. Due to logistical challenges, these interviews instead were conducted approximately 8 months after initial study enrollment, a deviation from the SEP. After the study concluded, 11 interviews were conducted (in June 2018). Interview participants included clinical providers (both primary care and behavioral health) and other relevant clinical and nonclinical personnel.

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

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

In addition to these semi-structured interviews, HRiA conducted two focus groups with intervention group participants in June 2018, approximately one month after the study ended. The goal of the focus groups was to better understand the influence the program had on participant's health and wellbeing. **Appendix E: Sí Texas Summative Implementation Evaluation: Focus Group Guide** presents the semi-structured focus group guide used to conduct the focus groups at the final data collection period. **Appendix F: Implementation Evaluation Measures** presents all implementation program components/activities, outputs, and outcomes that were measured using the qualitative data collection.

There were 22 intervention participants across the two focus groups, ranging from 10 to 12 participants per group. Prior to the focus groups, participants were asked to voluntarily complete a demographics survey. One participant declined to complete the survey; therefore, demographic data is presented only for 21 participants. **Table 1** describes participant demographics for the two focus groups (n=21). All participants lived in Hidalgo county and most were female (76.2%). A majority of participants were under 45 years (52.4%). Participants were predominantly Hispanic or Latino (95.2%). Most participants spoke Spanish as a primary language (66.7%). Over two fifths of participants had less than a high school diploma (42.9%) and did not have health insurance (42.9%).

Table 1. UTRGV Pre-Focus Group Demographics Survey

Measure	UTRGV (n=21) n	%
County		
Hidalgo	21	100.0
Sex		
Male	5	23.8
Female	16	76.2
Age		
<35	6	28.6
35-44	5	23.8
45-54	5	23.8
55-64	4	19.1
65+	1	4.8
Missing	--	--
Ethnicity		
Hispanic/Latino	20	95.2
Non-Hispanic/Non-Latino	1	4.8
Primary Language		
Spanish	14	66.7
English	7	33.3
Education		
Less than a high school diploma	9	42.9
High school degree or equivalent (e.g., GED)	5	23.8
Some college, junior college, or vocational school	7	33.3

Measure	n	UTRGV (n=21) %
Health Insurance		
None	9	42.9
Private	2	9.5
Medicaid	3	14.3
Medicare	5	23.8
Other	2	9.5

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

All interviews and focus groups were recorded digitally and transcribed. For the summative interviews and focus groups, two trained team members – who did not conduct interviews or focus groups - initially reviewed transcripts to develop a mutually-agreed upon codebook using a grounded theory approach. They then independently coded each transcript for themes using NVivo qualitative data analysis software (NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 12) and met to discuss concordance and discordance between their coding schemes. Differences were reconciled through discussion until a consensus on the first-level of coding was reached (average kappa=0.90) and themes were identified by discussion frequency and intensity. Mid-point interviews were coded using NVivo software by one coder using detailed notes. The mid-point interviews were analyzed with this approach due to the importance of expediency to complete the interim report and to provide findings to the subgrantee quickly for continuous quality improvement. Mid-point data were not re-coded for the summative analysis, but themes from the mid-point and summative data collection were synthesized together, and findings were summarized in narrative descriptions organized by theme with illustrative quotes. If qualitative findings changed from mid-point data collection to summative data collection, it is noted.

Quantitative Data Collection Methods and Analysis

Implementation data of patient participation in the PCBH program were analyzed. These mainly comprised of de-identified patient records from UTRGV's health records system that included information on patient care plans, participants' behavioral health and primary care visits, as well as the number of warm handoffs to behavioral health consultants. Descriptive statistics on these services are provided in Question 5. This information provides insight into fidelity and dose of the intervention.

Implementation Study Findings

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

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

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

As described in the SEP, all UTRGV FMR adult patients were eligible for the intervention if they met one or more of the criteria below:

- Patients who score 5 or greater on PHQ-9
- Patients who score 5 or greater on GAD-7
- 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.

UTRGV enrolled 364 participants into the intervention. Most of the participants enrolled in the intervention were female (69.5%), Hispanic (94.0%), and White (98.9%). Participants lived primarily in Hidalgo County (93.7%). The average intervention participant age was 45.5 years. Over half of participants were not employed (62.8%), were married (53.0%), and spoke English as their primary language (56.0%). All participants met the study eligibility criteria; therefore, the program reached the intended audience. The prevalence of the individual eligibility criteria among the enrolled sample is provided in **Table 2.**

Table 2. Prevalence of Eligibility Criteria in UTRGV Intervention Group Participants

Eligibility Criteria	Prevalence in Enrolled Sample
PHQ-9 ≥ 5	73.1%
GAD-7 ≥ 5	67.3%
PCP Referral Only	22.2%

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

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

The PCBH program's specific components are described in **Appendix B: Program Logic Model** and in the Program Definition section. In summary, the PCBH model, implemented at family medicine residency clinics in McAllen and Edinburg, integrated a behavioral health consultant (BHC) as part of the primary care team and emphasized a behavioral health curriculum. Trained to function as a generalist consultant for the Primary Care Physician (PCP), the BHC addressed lifestyle-based somatic complaints, sub-threshold syndromes, preventive care, and chronic disease. Each participant enrolled in UTRGV's intervention has an individualized care plan that may differ in terms of treatment and recommended services for program participants. Primary care and behavioral health providers met regularly for team huddles to discuss cases, share notes through the medical record, and refer patients to clinic services as needed.

How Components Work "On the Ground"

Focus group and interview participants explored how UTRGV's PCBH program was implemented. When asked about how primary care and behavioral health services were coordinated, interview participants highlighted a flexible workflow, strong communication practices, training, data systems, and co-located services as key components to UTRGV's integrated model.

Workflow

Workflow, or how patients and clinical staff move within the clinical space, was seen as a key component of integration and closely related to communication practices at UTRGV. At the midpoint evaluation, interview participants acknowledged that there were early challenges establishing new workflows that included new roles and processes of the PCBH model. The intake and data collection, as well as referral and scheduling processes challenged the clinics during early implementation of the program. Adjustments, such as a tab label system on the exam room door, templates, and team huddles, allowed the clinics to improve workflow.

During the summative interviews, interviewees shared examples of adapting workflows in order to enhance efficiency throughout the duration of the project. For example, the warm handoff process would vary from a more traditional approach—where primary care would initiate first contact—to a more flexible approach where behavioral health would precede the primary care visit to accommodate the clinic flow. One interviewee explained, *"One of the things we've been able to improve is that while patients are waiting, the BHCs can be involved earlier and better, rather than waiting for the physician [to] trigger the consult.* Another practitioner added, *sometimes the [BHC's] foresee that some patient is going to need their help, so if the doctor is running behind, they jump in first with a particular patient, and that helps the patient flow better."* Focus group participants also noted the flexible workflow at UTRGV, sharing, "*Depending who's available first is who comes into the room. If the doctor's available they'll come right way, but if they're not the health coach (BHC) talks to you first."*

Communication

Similar to findings from the midpoint evaluation, strong communication practices were identified as critical to UTRGV's integration strategy. Focus group and interview participants highlighted the cooperation between disciplines that facilitated integration at UTRGV. One provider shared, *"In terms of the team, we have a really great dynamic. We've been able to accomplish a lot with a very small team initially that has slowly started to grow over time; we communicate very well with each other."* They shared that this collaboration was also closely related to patient satisfaction. Focus group participants observed the collaborative nature of the clinic, with one sharing, *"What I like most is that the two [providers], the life coach [BHC] and medical doctor together, even they communicate with each other about what is happening."* Another participant agreed and added, *"Here they [providers] all work together…they talk to the pharmacist and share opinions with the other doctors. If the problem persists they also have counselors."*

Weekly didactic sessions, team huddles, and hands-on training including shadowing and attending conferences were cited as the most effective mechanisms for program implementation and enhanced communication within the clinics. Interviewees shared that these methods improved interdisciplinary interactions and collaboration. From a project management perspective, several interviewees mentioned that bi-weekly meetings enabled the team to have protected time for communication and process improvement.

Data Systems

In addition to communication practices discussed above, the primary form of electronic communication for the PCBH model was its data systems. Findings from the midpoint evaluation revealed early challenges with data systems that included differing systems across the two clinics and manual data entry for study participants. These issues were also detailed in summative interviews, with several study staff expressing frustration at cumbersome data tracking that involved manual entry. One interviewee shared, *"A challenge that we faced was EMR access; because we are a residency program that is affiliated with different hospitals systems, there may be a lack of communication or support from the hospital systems themselves. Eventually we were able to obtain EMR access for research purposes, but even then, it was limited to the point where we could only view primary care provider visits, and not behavioral health consults."* Interviewees noted that data systems improved throughout the project with the inclusion of additional screening tools added to the system and templates to standardize processes.

Clinic or Physical Space

According to interview and focus group participants, the integration of IBH services at UTRGV was facilitated by the physical integration of the clinics. Specifically, interview participants noted that having the behavioral health consultants stationed in the preceptor room with attending physicians was especially helpful in facilitating integration. One interviewee shared, *"The BHCs sit in the pod where residents come to present their patient's case. So, they're right there front and center sitting by the attending faculty so when they present cases, they present to both of them."* Further, clinic staff used visual cues to facilitate integration. For example, it was noted that the clinics used a flagging system to trigger providers when a patient had a PHQ-9 score of 10 or higher and would likely need a behavioral health coach referral.

Implementation as Planned

Except for the patient satisfaction surveys and some staffing challenges (i.e., turnover and delays in hiring due to contractual agreements that were prolonged by affiliation changes) the UTRGV program was implemented as planned. According to interviewees during the midpoint and summative evaluations, UTRGV implemented the PCBH program with strong fidelity. Participants during the midpoint interviews described early challenges related to staffing such as high turnover for medical assistants and clinic managers at both clinics. These challenges were also reflected in the summative evaluation. For example, one interviewee explained how the high staff turnover required program staff to re-introduce the model multiple times. "*Each time we had a new clinic manager, it was about re-introducing the project from scratch and having to get buy-in from that new person all over again."*

Question 3. What level of Integrated Behavioral Health did UTRGV FMR clinics achieve as a result of implementing the program?

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 (AIM Center, 2011). These principles include: (1) patient-centered care, (2) population-based care, (3) measurement-based treatment to target, (4) evidence-based care, and (5) accountable care. The checklist details core components and tasks for each of these principles that are self-assessed on a scale of "None," "Some," or "Most/all**." Appendix I: Patient-Centered Integrated Behavioral Health Care Checklist** presents the core descriptions of the Patient-Centered Integrated Behavioral Health Care Principles and Tasks Checklist as defined by the AIMS Center.

UTRGV completed the AIMS IBH checklist in March 2016 (pre-intervention implementation) and September 2018 (post-intervention implementation). While the AIMS IBH checklist captures core elements of Integrated Behavioral Health, the AIMS checklist is primarily focused on evaluating the implementation of Collaborative Care Model of integration, where the primary care team includes a behavioral health manager and a consultant psychiatrist. In addition to these specific team members, the collaborative care model uses a target to treat approach, in which a patient registry plays a key role – especially in managing depression over time. Because the UTRGV implementation focused on the PCBH model, some of the categories and definitions do not directly translate to the PCBH operational priorities. For example, while a registry is encouraged, it is not seen as a central component of implementation. While psychiatrists can play a role in advancing psychiatric management in primary care, the PCBH model does not see the psychiatrist involvement as a core component. Separate checklists were completed for each clinic, one for DHR and one for MMC.

Table 3 and **Table 4** present UTRGV's data from the DHR assessment. UTRGV's DHR clinic reported no change in three of the five IBH core principles from baseline to 12 months and a decrease in the number of patients a principle applied to in the remaining two. There was additional change in the IBH core components and tasks with two improving, twelve remaining the same, and twelve decreasing from baseline to 12 months. It should be noted that the principles, components and tasks that were rated lower at 12 months compared to baseline were primarily related to the use of a patient registry. The PCBH model does not see the registry as a core component, and UTRGV used REDCAP rather than a population-based registry for research to track participants. Further, external to the PCBH implementation work and study, the clinic was focused on completing Patient Centered Medical Home Certification, which included the addition of a social worker to the clinic's work flow This change, along with the increased capacity of the integrated team, resulted in expected shifts to the BHCs' role from baseline to 12 months. The BHCs continued tracking and providing appropriate connection services to the patient.

Table 5 and **Table 6** present UTRGV's data from the MMC assessment. UTRGV's MMC clinic reported improvements in four of the five IBH core principles from baseline to 12 months. The clinic saw no change in the fifth core principle. There was additional change in the IBH core components and tasks with twenty showing improvement from baseline to 12 months and six remaining the same over the course of the study.

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

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

• Response at baseline ✓ Response at 12 months

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

We apply this principle in the care of (none, some, most/all) our patients.	None	Some	Most/All
Patient Identification and Diagnosis			
Screen for behavioral health problems using valid instruments			•✓
Diagnose behavioral health problems and related conditions		✓	•
Use valid measurement tools to assess and document baseline symptom severity			•✓
Engagement in Integrated Care Program			
Introduce collaborative care team and engage patient in integrated care program		✓	•
Initiate patient tracking in population-based registry	✓	•	

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

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

• Response at baseline ✓ Response at 12 months

Table 5. MMC Clinic IBH Checklist Baseline to 12 months: Core Principles

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

• Response at baseline ✓ Response at 12 months

Table 6. MMC Clinic IBH Checklist Baseline to 12 months: Core Components and Tasks

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

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

• Response at baseline ✓ Response at 12 months

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

Program Adoption

The program was implemented with fidelity and did not require any major changes to implement successfully. Interview and focus group participants noted what facilitated or hindered program implementation as well as patient participation in the program. Listed below are facilitators and barriers expressed through interviews and focus groups with UTRGV FMR personnel and study participants.

Adoption Facilitators

Communication
Communication was the most frequently mentioned facilitator of program adoption at both the midpoint and summative evaluation points. Participants mentioned various ways in which communication facilitated program adoption; team huddles, didactic sessions, and bi-weekly project meetings were highlighted as especially helpful to enhancing communication practices between disciplines. Interviewees also noted that electronic communications through the EMR facilitated continuity between behavioral and primary care providers by sharing techniques that were used in previous appointments and requests for future follow ups.

Several interviewees discussed early decisions to be intentional about language in order to be sensitive to stigma and cultural perceptions. One project staff member explained, "*The [BHC] goes by 'health coach' just because that's a little bit more culturally accepted than 'behavioral health specialist'. I'm not sure if it's the connotation, but any time you mention 'behavioral', everybody gets a little worried about it."* Another provider explained, *"I use [behavioral health] almost more like a prescription instead of separate services when I talk to patients. It's part of the treatment plan that I discuss with them."*

Warm handoffs

Warm handoffs were cited as a key component to the PCBH model implementation. Interview participants reported the varying levels of definitions of warm handoffs across the field. One shared, *"There's been discussions by national behavioral health groups defining warm handoffs. It's a concept that still lacks a lot of clarity nationally."* According to interviewees, UTRGV's warm handoff process consisted of any process whereby the physician or behavioral health provider would collaborate and staff the case accordingly. As mentioned in preceding sections, the warm handoff process at UTRGV FMR would vary from a more traditional approach—where primary care would initiate first contact—to a more flexible approach where behavioral health would precede the primary care visit to accommodate the clinic flow. In either situation, whether patient contact with BHC was initiated by PCP or vice versa, a conversation occurred between the providers to manage the visit, indicating the completion of a warm handoff. Further, it was noted that warm handoffs improved as the staff capacity for providing integrated care did. For example, a few interviewees explained that efforts were made to train staff around the expanded use of behavioral health coaches for things more than traditional depression or anxiety diagnoses. These efforts, shared interviewees, facilitated more warm handoffs for related morbidities. Even in this context, the key component was that there was communication between primary care team members and BHCs to facilitate the same-day care. One provider summarized, *"Providers are getting a better sense of how to use the BHCs for other things, rather than just for depression or anxiety consults. They're now being [referred] for weight loss, headaches, stress reduction, diabetes, hypertension, all of those things."* Another added, "*clinically we're moving in the direction that we'd hoped. [Primary Care] providers are getting a much better and firmer version of our [PCBH] program and that's part of the behavioral health integration process."*

Additionally, interview participants reported that warm handoffs also facilitated peer learning between disciplines. As one provider shared, *"After getting the patients approval to bring in the health coach, we usually physically go and get her and bring her into the patient room to introduce them. And at that point, they start probing and discussing behavioral concerns. It's eye-opening to the providers because you learn skills that the health coaches have. It's a two-way street."*

Training

The commitment to provider and staff training was a prominent theme in both the midpoint and summative evaluations. Interviewees reported that trainings from external consultants as well as didactic sessions, Topics of the Month, and conferences facilitated integration. Trainings were adapted as needed to meet the needs of clinic staff. For example, findings from the midpoint evaluations found that staff desired more focused training and hands-on training through shadowing providers across disciplines *"Residents have asked us to do a lot more case studies and we also shifted a lot more of our rotation time to be more directly clinical rather than some sort of didactic. We also received feedback to sort of emphasize how PCBH can help the burden of the day-to-day.*" As a result, shared a project staff interviewee, more was done to invest in targeted training from experts in the field of IBH, attending conferences, and visiting clinic sites implementing similar IBH strategies.

Building staff capacity—clinical and non-clinical alike—was a key component to the PCBH model. One interviewee summarized, *"I think the key is education and re-education. When we educated and trained our physicians, we did it through bringing experts in the model here, we've done webinars, and real one-on-one breakdowns like case studies. Our non-clinical team have benefited from these exposures too, because when these people [topic experts] are on the ground, they're able to interact with them and ask them questions about operational workflow and other questions to get a lot of insight."* Lastly, interviewees noted that the ultimate goal of these trainings was to increase the capacity of providers to feel comfortable acting as a behavioral health consultant. In other words, physicians and residents were trained in core behavioral health competencies in order to utilize health coaches effectively and, ultimately, provide behavioral health interventions themselves.

Flexibility

Lastly, flexibility from UTRGV FMR staff was reported as an integral part of successful program implementation. For example, workflows frequently adapted to improve efficiency and roles slightly morphed to meet project and patient needs. Being flexible and adapting, shared project interviewees, facilitated a solution-oriented team that was nimble and willing to modify processes to enhance integration in the clinics. Summarizing, one interviewee shared, *"More than anything, the staff being so flexible has helped a lot because this office, it's constantly, constantly changing. There's always new changes coming in, and not just from the PCBH, but from or, you know, our residents. So, I think everybody has adapted to that idea…that nothing is set in stone and every single day you're going to have changes."*

Adoption Barriers

At the midpoint and summative evaluation points, UTRGV interviewees identified similar challenges to implementing the PCBH model, including participant enrollment, clinic culture that did not yet support the model, and inadequate data systems. According to several interviewees, meeting enrollment targets was challenging early on in implementation due to patient visit fees and limited staffing. Other interviewees highlighted the challenge of previous clinic culture and behaviors that needed to change in order to garner staff and provider buy-in and ownership of the integration process.

Hiring and Staffing

Although focus group and interview participants emphasized the quality of the staff at UTRGV FMR, participants described early challenges to hiring and retaining some staff, including medical assistants (MAs), deans, and clinic administrators. These challenges, shared interviewees, impacted program enrollment in the early phases of implementation. To mitigate these challenges of collecting data for the evaluation study, community health workers were hired to conduct data collection and follow up with patients as a way to mitigate the shortage of staff. It is important to note that the community health worker role was strictly related to the implementation of the evaluation study, not for the delivery of IBH services or patient care at UTRGV. When commenting on the role of the community health worker as it related to the evaluation study, one interviewee explained, "*We realized as time went by that we were one, shorthanded, and two, that it was becoming difficult to get our patients back in for their 6-month data collection. So, we moved forward to hire community health workers to reach out to them specifically. And if the patient could not make it to the clinic, then the data collection visit would happen at their homes."*

Early Buy-In

Findings from the midpoint and summative interviews highlighted early challenges with frontline staff and university system buy-in. As mentioned above, many noted changes in leadership, especially MAs, deans, and clinic managers, that impacted implementation and early buy-in of the program. One interviewee shared, *"We've had three deans in three years. So that's a lot of changes. With the first dean we had worked up a strategy, approached him, had everything in place, and then he stepped down. We had an interim dean, worked a strategy, moved everything, got the meetings, and then he stepped down. Then the third dean came… It's definitely been a hinderance historically because we've just had to refocus and strategize all the time on how to work with the whole process."* Another interviewee commented on buy-in from patients sharing, *"The buy-in has been a challenge because of our affiliation. We have difficulty controlling the charges or the costs that the clinic charges our patients to come in, which deters anybody to come through the front door."*

Workflows

Project staff and providers acknowledged that, at the start of the program, staff had difficulty establishing new workflows that included the new roles and processes of the PCBH model. Interviewees noted that one of the biggest challenges to implementation was minimizing patient wait-times at the clinic. As previously mentioned, clinic workflows were modified early on to improve efficiencies and to adapt to the larger- system in which UTRGV FMR was operating. These modifications included adapting team huddles to be more case-specific which was reported to facilitate deeper engagement between staff—especially among medical assistants and physicians. An interviewee explained, *"Initially we would gather in a room and broadly go through patients with everyone together. When we came back [from training], we ended up pairing each resident with their own MA, and they would go down the list together and say, 'okay, this is the patient, and this is the plan."*

Data Systems

UTRGV's electronic medical record was reported as both a facilitator and barrier to program adoption. While the system provided a communication mechanism for behavioral and primary care to collaborate, several interviewees shared that the EMR was cumbersome for collecting data intended to be used for quality improvement, monitoring, and evaluation related to this study. These challenges were because the two intervention clinics, connected to two different hospital systems, operated under different versions of the Cerner EMR system, which limited the ability for program staff to customize and run reports as necessary. An interviewee summarized, *"The clinics have two different versions of Cerner [EMR] that don't communicate. We can't run any reports or do basic quality improvement research as quickly as we want to."* Further, it was noted that much of the data entry for the study had to be done manually, which was cumbersome and time consuming for project staff. "*All the data we have to report or that we want for our own benefit for implementation has been manually tracked because we can't press a few buttons and look at things like number of referrals, productivity, or number of follows…it has to be done in multiple other ways, which has been very difficult."*

Operating within a University System

Midpoint and summative interviews reveal that systemic challenges related to university affiliations further complicated program implementation. Specifically, the merge of two university systems made it increasingly difficult to finalize contracts, budgets, and decision-making processes. Summarizing, an interviewee shared, "*The leverage points that we [the medical school] have to influence system processes are not the greatest. There are certain things we can do as far as the BHCs are concerned, and that's where the partnership between the university and the hospital is a little unclear…meaning who has a say in what."* Yet these challenges were seen as having small effects on the model's overall fidelity.

Interviewees shared how program leaders—alongside the project team and clinic staff—worked diligently to facilitate communication and workflows to support integration.

Participant Facilitators

Focus group and interview participants were asked to reflect specifically on facilitators that patients faced while participating in UTRGV'S PCBH program. The most frequently cited participant facilitators were improved health outcomes, relationships, and cost.

Improved Health Outcomes
Focus group participants frequently discussed improved health outcomes as a facilitator to program participation. Patients mentioned ailments that included chronic diseases like diabetes, obesity, and heart disease. Weight loss was often mentioned as a positive outcome that facilitated participation. One patient shared, *"Since I started with the health coach one year ago, I have lost 65 pounds. The coach has helped me personally and is now helping my children…how do healthy, exercises, and for me it's been a big change."* In terms of mental health, the most frequently cited mental health concern by focus group participants was depression, followed by stress and trouble sleeping. Participants noted that visits with the health coach reduced symptoms for these ailments, with one sharing, *"When I talked to the coach, after the first conversation I had with her I felt more relaxed. Every time I come for my doctor's appointment I try to talk to her if I feel sick or need to vent. She gives you advice, things to practice and it has helped me a lot."*

Relationships
Patients reported that UTRGV FMR staff treated them with courtesy and respect, which was reported as a facilitator to participation. For example, one focus group participant shared, "*They take you into consideration a lot, the doctor has talked to me…asks me how I've been, reminds me to come to appointments. I tell him 'the truth is that I don't have money to come' and he responds that there are free programs that they can help me with. They really take you into account more than anything else."* Apart from strong relationships with providers and health coaches, several interviewees noted the unique role that community health workers played in the PCBH intervention. One interviewee summarized, *"[Patients] feel confident with [the community health worker]…to provide that service to say 'hey you know what, we're here for you, we want to help you, I know that you're not doing better and I want you to get better, so please come back and tell me how can I help you?' And that works very well."* Another interviewee added, *"When patients see a doctor or health coach, they don't see them as part of my family. They say 'oh, they are a doctor. I need to put on my Sunday clothes to see them; they are in a high level. But when they see a community health worker they say, 'hey, she's my friend, she's here to provide me with resources."*

Cost
There were mixed perceptions about cost as a facilitator to program participation. Some focus group participants reported that the cost of the clinic was accessible and used a sliding scale model to maintain affordability. For example, one participant shared, *"They help financially because you pay for the consult depending on your income; for many people who live here they don't have their documents, but I say "go, and get help there, they take care of you very well*." Others indicated that costs—both for clinic services and the transportation to get there—was a barrier to participation. However, it is important to note that these barriers, explained interviewees, are similar to trends across the country related to healthcare access. Summarizing, an interviewee shared: *"Our biggest barriers here are transportation, insurance coverage and then financial hardship, which is sort of the general barriers to healthcare. And I*

think in our way of talking about primary care-behavioral health, what we're really saying is more efficient primary care. We're not here as behavioral health providers to start a separate service, our services are really meant to augment what primary care is already called to do, or already defined to do. So, when we talk about barriers, we're just talking about whatever barriers that exist for the medical system for all of our patients."

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

Interviewees were asked about their support and buy-in for the PCBH program as well as their perceptions of their colleagues' buy-in. Interviewees spoke about strong buy-in from both the frontline staff and project leadership, as well as the positive clinic culture.

Buy-In
Strong buy-in was reported from frontline staff and leadership alike, with interviewees expressing overall satisfaction with the program, citing increased access to care for patients as well as initial positive health outcomes. Several primary care and behavioral health staff shared anecdotes of how the PCBH model has positively impacted patients. One staff member described ways in which patients better advocated for themselves after participating at the clinic. *"We usually have patients who are not insured, but we do not normally have patients that advocate for themselves [in regards to insurance] who feel that strongly about our clinic."* Additionally, interviewees described a strong sense of buy- in from program leadership, which according to staff, modeled a sense of urgency and commitment to implementing IBH strategies. One non-clinical staff person shared, *"They [leadership] are strong believers [in PCBH] and they lead with that example. So, you know everybody else is going fall into place and everybody else is going to follow the leader."* This sentiment was echoed by a behavioral health provider, who shared how critical buy-in was for a large university system: *"Systems that have made the leap to make [IBH] work, it's because their leadership was always willing to say 'this is something that we want to invest in and adopt. And they have... they have paid attention to how to draw the funds for that in multiple ways, rather than say, you know, 'make this work,' without any other infrastructure reworking or changes, so.*

Clinic Culture
In general, interviewees perceived the clinic culture at UTRGV FMR to be a supportive environment for adoption of the PCBH model. Staff indicated that multiple initiatives are implemented at the clinics at any given time, and staff are used to being flexible to accommodate programming. This flexibility, shared clinic staff, facilitated a strong team dynamic of trust and team-work. One interviewee shared an anecdote that summarized a strong clinic culture, where staff at all levels adopted the PCBH model. *"A medical assistant was orientating a new staff member and I remember her telling them, "Now we don't take care of patients the way most clinics do, we take care of them as a whole team". I think that was sort of a testament to the change in attitude of how staff view the program and what the BHC can do."* While most feedback from interviewees about clinic culture was positive, a few mentioned staff turnover due to work environments. One shared, *"We've had a lot of MAs leave, whether it's them being transferred to other departments or other clinics, or because of things we can't necessarily control like their pay, hours, all of those things that are indicative of why they leave."*

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

Patients at TTBH's Brownsville and Weslaco clinics received behavioral health services per individualized care plans. All patients at these clinics are assessed for needs annually which includes assignment of behavioral health services based on acuity determined by the ANSA tool. Services may include but are not limited to psychotherapy, psychiatry, care coordination, and other services designed to support self-care. As persons with severe and persistent mental illness (SPMI) receiving care at a local mental health authority, patients do not receive any primary care services apart from referrals to local primary care. In comparison, the BHCs at the UTRGV FMR clinics provide consultation to the primary care team utilizing the PCBH model, including recommendations to the PCP regarding behavioral interventions and conducting brief interventions with referred patients on behalf of the referring PCP.

Question 5. To what extent did UTRGV FMR clinics implement the PCBH model as outlined?

Below are data describing the number of services provided throughout the study by service type (see **Table 7**). All participants had a care plan created. The Behavioral Health Consultant completed a note in the electronic medical record for every patient seen. This note, entered in as part of the primary care record of the patient included description of the symptoms and problems patient currently presents with, life context, functional assessment and a specific section that outlined the behavioral intervention. The behavioral intervention is an evidence-informed, non-pharmacological intervention and used a SMART (specific, measurable, attainable, relevant, time-bound) format to record in the chart. Every participant received at least one behavioral health visit and all except for 8 participants enrolled received a warm handoff. Including behavioral health, primary care, and warm handoffs, study staff provided 2,605 services to participants over the course of the study. It should be noted that there was no BHC on staff at the MMC clinic for a period of 4 months. While this did affect reach and dose of the intervention, it did not affect fidelity to the PCBH model.

Table 7. Utilization of Services over the Study Period by Intervention Participants

Service Type	Total Services Provided	Mean Visits Per Participant	Median Visits Per Participant	Minimum Visits Per Participant	Maximum Visits Per Participant
Primary Care	1583	4.3	3.0	1.0	20.0
Behavioral Health	538	1.5	1.0	1.0	14.0
Warm Handoff	474	1.3	1.0	0.0	5.0

Question 6. How satisfied are patients with the services they have received? How satisfied are providers with the PCBH model?

Participant Satisfaction

Interviewee and focus group participants indicated that feedback from patients about the program was generally very positive. Patients were receptive to program services, liked the increased time with providers, and were able to better express and manage their feelings. According to interviewees during the midpoint and summative evaluations, participants were satisfied with the timeliness of services at UTRGV FMR as well as the quality of care that was provided at the clinic. This was especially true as it related to patients feeling connected to their providers. One focus-group participant shared, *"They are very attentive they take time with us. The doctors and nurses, everyone will sit and listen to you."* Another patient agreed and added, *"I like that they give you a lot of attention here, not like in many*

places that you're just another patient. Here they look at you and take your pressure and they do all they have to do to keep you on track."

During the midpoint interviews, clinic staff noted that there was some frustration among patients from having to fill out questionnaires (primary care screeners such as PHQ-9, GAD-7) at each visit. However, during summative focus groups, several participants referenced the intake surveys in a positive manner, with some sharing that repeating the same survey gave them a tangible way to track their progress. Others indicated that surveys were a method for providers to flag patients who needed more services. *"They give me that survey every time I come in because they're looking for improvement. I've already done it, but at the end of the survey you add the numbers and I was seeing a change in those numbers…they were less than the start, so that's good."*

Provider Satisfaction

Interviewees participating in the midpoint and summative evaluations reported that provider and staff satisfaction with the program was generally positive. Although implementation of the PCBH model was a culture and practice shift, most staff and primary care providers cited benefiting from the model because behavioral health coaches facilitating more comprehensive care helped the physician better understand how to manage behavioral health concerns. Some primary care providers and residents were seen as being more receptive and satisfied with the program by interview participants, while some of the longer-tenured primary care providers were reported to be more resistant to change during the early stages of the program.

As previously mentioned, training was a key component to successful program implementation, and according to interviewees, closely related to provider satisfaction. One behavioral health staff interviewee shared, *"As a clinician, one of the things that I'm most grateful for that the program has provided has been training. And really, really, investing in their clinicians, whether it's the conferences or having, you know, these site visits, or having consultants come down and helping train us, you know, directly."* Interviewees shared that these investments facilitated more comprehensive, high-quality care. *"I think that [trainings] have caused a ripple effect. Because there's been that emphasis and investment in the clinicians, the quality of care has improved from patients and implementation is more true to the model."*

Question 7. What barriers to participation do patients experience? Do patients see the cost of the PCP fee as a barrier to participation?

Participant Barriers

In addition to barriers experienced by staff and providers adopting the PCBH program, focus group and interview participants were also asked to reflect on barriers that patients faced while participating in the program. Barriers discussed included stigma, the social determinants of health, cost, and staffing.

Stigma
Several patients and program staff suggested that community stigma around mental health was a barrier to program participation. One focus group participant explained cultural influences of valuing privacy may have impacted program participation. *"Unfortunately, we are not very open about coming to people about your problems, especially strangers. Wanting to tell older people 'go and talk' is somewhat difficult."* Several focus group participants agreed and added, "*Yes, it is difficult to open up to*

a stranger. In our culture, we're not very open. But in the two years I've been here, little by little one opens up because they are really patient with me." Despite these cultural influences, focus group participants reported confidence communicating with providers. One participant shared, "*Many people are embarrassed to talk, but since there is a doctor, they give you the confidence that you can talk with them and they won't disclose all your personal things."* Program staff commented on the community stigma around mental health and reported having to be strategic about how behavioral health services were presented because of it. One provider summarized, "*The way providers introduce the behavioral health coaches impacts whether or not they get to go into a room. Because they can say things that are culturally a turn off like saying 'psychiatrist' or 'behavioral health'. We try to limit how much they say about the [BHCs] and instead say something like, 'I have a member of our healthcare team that would like to come in and talk to you about some things you mentioned you're interested in working on."*

Social Determinants of Health

Interviewees stressed that it was especially important to understand the context in which residents in the Rio Grande Valley reside; a region where poverty and uninsured rates exceed that of the rest of the state, many face hardships in their day-to-day that ultimately impact the health of the community. Lack of time to participate in the program because of work or competing family priorities was also reported as barriers to participation. Focus group participants reported that one's own health is secondary to other priorities like caring for elderly parents or children. Further, poverty, transportation, health insurance, and access to affordable, healthy food were reported as barriers by participants. One interviewee summarized, "*If we're aware of the people that we serve and the barriers that they face, we also want to make sure to consider that. We could provide better healthcare, but what happens when they leave? Some will flat out tell us 'I can't afford that' even if it's on the $4 list. Or, I can't afford that in conjunction with some of these other $4 medicines that I also need because I have multiple comorbidities. So, looking at getting their medication, having access to healthy food, working minimum wage jobs and long hours and then trying to get them to exercise on top of that, you know, maybe that's just not realistic or feasible. And if we don't look at the context of the people that we're serving then we're really, I think, doing them a disservice because we're not taking all of that into account."*

Cost

Cost of services were reported as a barrier to participation by focus group and interview participants. Program staff explained that challenges from shifts in policies and payment structures in the for-profit hospital system impacted patient participation, especially changes that required the clinic to collect the copay upfront. Fees varied by clinic, service provided, and insurance coverage. BHC services were not billed for, and professional ($25.00-$219.00), facility ($40.00-$933.00) and lab ($0-$500.00) fees were wide-ranging. (see also Sample Enrollment and Retention)

When discussing how cost barriers impacted no-show rates at the clinic, one staff person shared, *"A lot of our patients come here for the first time and may never come back. I don't know if it's because of the bill that they received, maybe they're afraid that if they come back that they have to pay it all at once, or that they will be denied services."* Several patients noted economic challenges that not only made it difficult to attend the clinic, but to sustain health strategies. One patient noted, "*It's easy [to learn strategies], but at the same difficult because they tell you what you should do, how to do it, but often because of work or more than anything else because of economics, you don't do what you should do."* Another focus group participant agreed and added*, "They help me with certain exercises, but perhaps you can alleviate the pain of the stress momentarily, but the next days come and the thoughts come again."* Difficulties affording medication due to lack of insurance or high deductibles and the inability to pay for transportation were also described as cost barriers to patient participation. One patient shared,

"When I come, I don't have insurance, but the medications that some of us have to take are very costly and it's only 14 pills."

Sociopolitical Environment

Focus group participants and interviewees alike shared that the sociopolitical environment was a barrier for patients receiving care at UTRGV FMR. Specifically, there was a perception from staff that patient participation decreased as a result of participants' fears regarding immigration and customs enforcement. When discussing this fear, one patient shared, *"Everything they talk about on the news…they're going to stop you and ask for your ID and your papers, and if you don't give it, well, they'll arrest you. So many people are afraid to go out."* Several participants agreed with these sentiments and shared stories of loved ones struggling with the fear of navigating the health system as an undocumented resident. These barriers were also discussed by program staff, with one sharing, *"Immigration, and the national conversation around immigration, and whatever is coming out of the White House has definitely affected our patients."*

Staffing

While focus group participants generally reported positive interactions with clinic staff, several commented on the challenging nature of clinics where providers frequently changed. This was especially true, patients shared, when it came to behavioral health services. As one patient shared, "*I like consistency, especially when it comes to a person's health, mental status and everything."* Another patient agreed and added, *"Consistency especially when it's for life coaches. I think that's it's super important that you don't have to backtrack to re-explain, because sometimes, especially when you're stressed out, you feel like nobody's listening when you have to tell it again and again."*

Additional Implementation Findings

Lessons Learned

Overall, interviews with program staff indicated that the implementation of UTRGV's PCBH program has been successful. Several lessons learned and opportunities for improvement emerged regarding workflows, data systems, and system and policy-level change.

Workflows

As mentioned in preceding sections, interviewees noted modifications in workflows that improved efficiency and communication throughout the duration of the project. These changes included restructuring team huddles where providers could interact with medical assistants more closely, adapting the initiation of warm handoffs to be more flexible to the clinic flow, and frequent data monitoring to improve processes. Interviewees detailed the importance of flexibility, frequent in-person communication, and investing in increasing staff capacity as components that facilitate improved workflows.

Data systems

Interview participants emphasized that it would be imperative to have a single, streamlined EMR system at the outset of the program, along with the ability to customize and access the system for reporting. Program staff developed work-arounds for early data system challenges that made it difficult to record and report program data. Throughout the duration of the project, program staff identified opportunities for improvement of existing systems, making necessary adjustments that included manual data entry and creating templates to standardize processes.

System and Policy-Level Change

Many interviewees highlighted the importance of implementing supportive institutional and legislative policies prior to instituting the PCBH model. Several interviewees suggested that the program initially tried to implement the PCBH model without disrupting entrenched institutional policies and procedures. However, this led to weaker buy-in and forcing new systems into existing structures. Reflecting on this experience and thinking ahead to sustainability, a number of program leaders offered that it is critical to make the business case for integrated behavioral health in order to create institutional buy-in and influence policies related to reimbursement. Moving health coaches into an integrated care model requires an integrated payment model, and program leaders look forward to collecting and communicating cost data for the PCBH program at UTRGV in the future.

IMPACT STUDY – APPROACH AND METHODS

Overview of Impact Study Design

The study hypothesized that individuals who participated in the PCBH program, which provides integrated primary and behavioral health care, would improve in physical health, behavioral health, and quality of life. 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., 2014; Camacho et al., 2015; Ell et al., 2009). This QED study provided estimates of the impact of the PCBH model on participant measures of depressive symptoms, anxiety, quality of life, BMI, HbA1c, and blood pressure. A QED study estimates program impacts by comparing the outcomes of program participants (intervention group) to the outcomes of non-participants who are observationally equivalent to program participants (comparison group). This design was appropriate because of UTRGV FMR program's curriculum commitment to training family medicine residents in primary care behavioral medicine and the ethical decision to increase and provide access to a majority underserved, vulnerable population. Randomization was not feasible due to the educational and ethical priorities. Further, the PCBH model is grounded in a population-based care philosophy that uses a clinic-wide population-based care perspective. A 2012 QED 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' global mental health functioning improved during the intervention and improvements were sustained through two years of follow up (Ray-Sannerud et al., 2012). Several other QED studies using BHCs have also shown positive results (Bryan et al., 2009; Goodie et al., 2009).

This evaluation used an external comparison group. An external comparison group allows for the examination of changes in health outcomes in the intervention group as they relate to similar patients not exposed to the intervention through their use of a different clinic, thus enhancing external validity and generalizability beyond the FMR clinics. Patients attending two clinics at NCDV that were providing the comparison group for another SIF subgrantee were originally planned to serve as the comparison for UTRGV's study. However, when data collection was complete, analyses indicated that the comparison group enrolled by these two clinics and UTRGV's intervention group were statistically non-equivalent at baseline on several sociodemographic and health outcome measures, including the confirmatory measure of UTRGV's study.

After careful consideration, it was decided that a different comparison group could represent a more appropriate counterfactual for the UTRGV intervention group. Since the UTRGV study is part of Methodist Healthcare Ministries' larger Sí Texas portfolio of IBH studies, the evaluation team examined baseline equivalence of UTRGV's intervention group with other comparison participants from the other Sí Texas studies. Participants from Tropical Texas Behavioral Health's (TTBH) Weslaco and Brownsville clinics, an SPMI population whose data were collected at the same time points (baseline, 6 and 12 months) for comparison in a different Sí Texas study, were used as the comparison group for this study (see **Figure 3**). The TTBH comparison group and URTGV intervention group were found to be statistically equivalent at baseline on most demographic and health outcome measures collected at both UTRGV and TTBH, including the confirmatory variable of PHQ-9 score, indicating that the TTBH comparison group was more similar to the UTRGV intervention group at baseline than the original NCDV comparison group was. Therefore, the study proceeded with the TTBH comparison group for analyses. Although the intervention group participants were not classified as SPMI, the baseline PHQ-9 scores indicated that

baseline depression among both intervention and comparison groups was equivalent. Because of this comparison group change, there are several deviations from UTRGV's SEP. These deviations are noted throughout the remainder of this report.

Impact Study Design and Methods

Study Design

UTRGV conducted a non-randomized quasi-experimental design (QED) study to evaluate the PCBH model in the two FMR clinics in comparison to participants at TTBH's Weslaco and Brownsville clinics who received the usual care provided within those behavioral health clinics. Participants enrolled in the study were followed for approximately 12 months. Quantitative program implementation data related to participation in the intervention and intervention delivery processes are also reported in this report (see Implementation Evaluation section).

Assessment of Baseline Equivalence

Examining baseline equivalence evaluates whether the two groups are statistically equivalent at that time point. At baseline, sociodemographic characteristics were captured using a standardized set of questions developed by UTRGV and currently being administered to the clinic population. These included gender, ethnicity, race, county, age, employment, marital status, primary language, historical health information, physical activity, smoking, and alcohol consumption. Sociodemographic measures collected in TTBH's study were age, gender, ethnicity, race, primary language, county of residence, problems with employment, and education level. The common measures collected across both studies were age, sex, ethnicity, and primary language (see **Table 8**). The use of TTBH as UTRGV's comparison group was a necessary deviation from the comparisons planned in the SEP to provide UTRGV with a more comparable group for the study and analyses.

Among patient-level demographic characteristics, the intervention and comparison groups were statistically equivalent on sex, ethnicity, and categorical age. The two groups differed on age (mean), primary language, and county of residence.

Table 8. 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	

Measure	Full Sample (n=569)		Intervention (n=364)		Comparison (n=205)		p-value
	N	%	N	%	n	%	
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	

UTRGV's study measured seven health outcome measures: PHQ-9 score, GAD-7 score, Duke General Health score, systolic and diastolic blood pressure, BMI, and HbA1c. However, TTBH did not plan to measure anxiety symptoms, and therefore did not implement the GAD-7 assessment with their participants. Additionally, TTBH utilized an alternative measure to assess functioning and quality of life and therefore Duke Health Profile data were not available for these comparisons. This is a deviation from the SEP which resulted in only bivariate analyses within the intervention group being conducted for these two measures rather than the multivariate linear regression incorporating the comparison group as originally proposed.

For the five impact measures, the intervention and comparison groups were statistically equivalent at baseline on all measures except for HbA1c (see **Table 9**). At the beginning of the study, the intervention group had a higher median HbA1c score than the comparison group.

Table 9. Tests of Baseline Equivalence for Impact Measures

	Full Sample (n=569) Mean (SD)	Intervention (n=364) Mean (SD)	Comparison (n=205) Mean (SD)	p-value
BMI[b]	34.1 (9.0)	33.6 (8.7)	35.0 (9.5)	0.08
Systolic	133.2 (19.1)	133.7 (19.5)	132.2 (18.2)	0.36
Diastolic	79.6 (11.2)	79.2 (11.6)	80.4 (10.5)	0.22
Nonparametric Tests[a]	Median (IQR)	Median (IQR)	Median (IQR)	p-value
HbA1c	**6.1 (2.4)**	**7.8 (4.3)**	**5.8 (1.0)**	**<0.001**
PHQ-9	11.0 (11.0)	11.0 (11.0)	12.0 (9.0)	0.11

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

Because this study used a quasi-experimental design and did not employ randomization to achieve baseline equivalence, adjusted regression analysis was proposed as the main analytic approach in the SEP to assess the intervention effect accounting for potential confounders. Additionally, it was not possible to employ matching in the study design phase since the participants of the originally proposed comparison clinics were also serving as a comparison group to other studies in the Sí Texas portfolio. Therefore, statistical matching at the analysis phase was proposed in the SEP. The proposed matching method to evaluate the robustness of the main results was propensity score matching. In general,

propensity score matching is typically used with a large set of covariates among large samples by matching cases with controls based on covariance of these covariates. It has been shown to reduce selection bias that may be present in observational and quasi-experimental design studies (Rubin and Thomas, 1996). Specifically, propensity score matching identifies close matches and removes participants from the analytic samples that have no appropriate match in the other group. This trade-off of reduced bias and reduced efficiency (due to discarded observations) tends to favor accuracy in large samples with many covariates (e.g., greater than 30 covariates), but can be challenging in terms of reduced precision and decreased statistical power in smaller sample evaluation studies with fewer number of covariates.

Only a limited set of covariates were collected across intervention and comparison groups during the study. The inclusion of TTBH as the comparison group further reduced the number of possible covariates to match on to only 4 sociodemographic measures given the overlap. Therefore, propensity score matching was not appropriate or feasible given the limitations of a small number of covariates. After considering properties of alternative matching methods, the adjusted regression approach accounting for available covariates with model selection procedure, which have been properly conducted in the analyses, was considered to be the most appropriate analytic approach for this study to adjust for potential confounding.

For this study, the PCBH model was implemented with strong fidelity and evaluated using a method with moderate internal validity. This evaluation study used a QED design to address threats to internal validity through including an external comparison group, which minimizes the threat of contamination and mitigates other major threats to internal validity. More specifically, the comparison group addressed the following threats to internal validity: regression to the mean, history, testing, and expectancy effects. This evaluation study targeted a higher moderate level of evidence given the PCBH model's incoming moderate level of evidence, strong fidelity to the PCBH model, internal validity of the study, and the promising results of this study on the primary outcome of PHQ-9.

Intervention and Comparison Group Conditions

Once enrolled in the PCBH program, the behavioral health consultant (BHC) worked with the patient to identify mental and health behavior needs and intervene with behavior change plan. It should be noted that the BHCs at the McAllen FMR clinic left their positions in early summer 2017, and thus the clinic was without these providers for several months. In their absence, the clinic instituted new protocols to address any behavioral health needs of patients who had previously met with a BHC or who were returning for their follow-up time points for the research. In this interim protocol, the clinic ceased screening all non-Sí Texas study clinic patients via the PHQ-9, GAD-7 and Duke Health Profile until a new BHC was hired. Enrolled patients who returned for research follow-ups were re-screened. If these patients indicated that they had suicidal ideation and intent to harm themselves at the time of screening for depressive symptoms via the PHQ-9, they were referred by the research staff and clinic to be evaluated by the Tropical Texas Mobile Crisis Unit. Per protocol, the enrolled patients remained in the study even after referral to the mobile crisis unit. The participants did not receive any additional behavioral health services as part of the intervention during this time. However, they continued to receive regular primary care services at the site.

The external comparison group was comprised of patients from TTBH's Brownsville and Weslaco clinics and received the usual care provided at these facilities. As TTBH's patient population is comprised entirely of individuals with severe persistent mental illness (SPMI), all patients receive behavioral health care through the clinics. The qualifying SPMI diagnoses for TTBH's study were schizophrenia, bipolar,

and major depression. For the comparison with UTRGV's intervention, those participants diagnosed with schizophrenia were excluded. Study participants in the comparison group at TTBH were referred to the nearest federally qualified health center (FQHC) or county health department for their primary care needs. Although the intervention group participants were not classified as having SPMI, the baseline PHQ-9 and GAD-7 scores indicate that the group has high unmet mental health needs and high levels of symptoms of baseline depression. Furthermore, intervention and comparison groups were similar in terms of baseline depression levels. Due to the low access to care in the region, patients with mental health needs seek care from primary care systems, which may or may not address mental health needs. For the study as well as clinical practice, the universal screening for depression and anxiety with PHQ-9 and GAD-7 improved detection and focus of treating such conditions as part of their primary care visit with the integrated behavioral health consultant.

Study Sample

The following section describes the final data on the composition, eligibility, recruitment, enrollment, retention, and attrition of the study sample. Except where explicitly noted in subsections below, there were no deviations from the SEP in the Study Sample section, including no deviations from the SEP related to sample recruitment and retention, assessment and adjustment for non-response bias, or missing data.

Study Sample Composition

As described earlier in the report, **Table 10** presents participant demographics for intervention and comparison groups at baseline. Most of the participants enrolled in these study groups were female (67.0%) and Hispanic (94.6%). Intervention group participants lived primarily in Hidalgo County (93.7%) while the comparison group was mainly from Cameron County (62.4%). The average participant age was 44.5 years. Most participants spoke English as their primary language (61.7%).

Table 10. Participant Demographic Descriptive Statistics

Measure	Full Sample (n=569)		Intervention (n=364)		Comparison (n=205)	
	N	%	N	%	n	%
Sex						
Male	188	33.0	111	30.5	77	37.6
Female	381	67.0	253	69.5	128	62.4
Ethnicity						
Hispanic/Latino	538	94.6	342	94.0	196	95.6
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
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)	

Measure	Full Sample (n=569)		Intervention (n=364)		Comparison (n=205)	
	N	%	N	%	n	%
Primary Language						
English	351	61.7	204	56.0	147	71.7
Spanish	218	38.3	160	44.0	58	28.3
County						
Cameron County	136	23.9	8	2.2	128	62.4
Hidalgo County	418	73.5	341	93.7	77	37.6
Other Counties[a]	15	2.6	15	4.1	0	0.0

[a] includes Brooks, Kleberg, Starr, and other counties

Table 11 describes participant impact measures at baseline for the intervention and comparison groups. As previously mentioned, in the assessment of baseline equivalence, the groups were statistically equivalent on all measures apart from HbA1c. Mean BMI was 34.1 kg/m^2. Mean blood pressure was 133.2/79.6 mm Hg. Median PHQ-9 was 11.0. By intervention group, median HbA1c was 7.8% in the intervention group compared to 5.8% in the comparison group.

Table 11. Baseline Primary Impact Measures

	Full Sample (n=569) Mean (SD)	Intervention (n=364) Mean (SD)	Comparison (n=205) Mean (SD)
BMI	34.1 (9.0)	33.6 (8.7)	35.0 (9.5)
Systolic	133.2 (19.1)	133.7 (19.5)	132.2 (18.2)
Diastolic	79.6 (11.2)	79.2 (11.6)	80.4 (10.5)
	Median (IQR)	Median (IQR)	Median (IQR)
HbA1c	6.1 (2.4)	7.8 (4.3)	5.8 (1.0)
PHQ-9	11.0 (11.0)	11.0 (11.0)	12.0 (9.0)

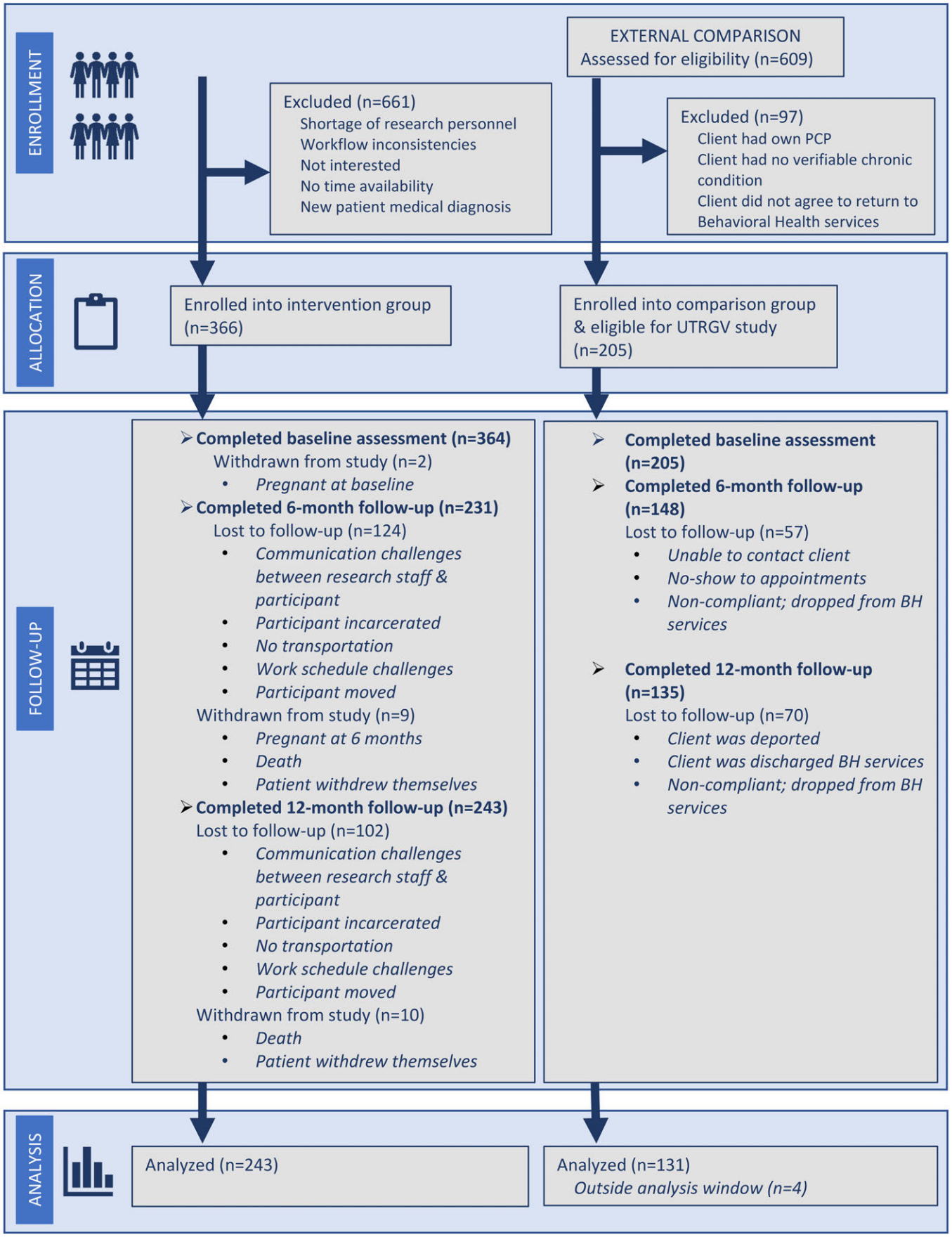
Patient Flow Description

A patient flow diagram, following the CONSORT structure, is presented in **Figure 1** (Schulz et al., 2010). This diagram depicts the study process from assessment of eligibility, to enrollment, ending with retention and analysis. Sample sizes are provided throughout to show where there was participant attrition. Qualitative reasons for any ineligibility, withdrawal, or lost-to-follow-up are provided where applicable.

Intervention group: 661 patients were excluded during enrollment activities at FMR clinics, with reasons for exclusion described. Research personnel challenges included insufficient personnel and longer hiring processes which made it difficult to manage enrollment across two clinical sites and led to additional research staff being hired after enrollment began. Workflow inconsistencies comprised of errors in clinic workflow at both FMR sites. These errors sometimes caused eligible participants to leave the clinic without meeting with research staff for project recruitment or to return to the research staff again after seeing the BHC. This led to more consults, but lower enrollment. The study staff also noted some non-enrollment information related to patient preferences including personal time constraints, a lack of general interest in participating in the project, or receipt of a diagnosis that would interfere with long-term participation (e.g., pregnancy, cancer, gastric surgery, etc.).

Comparison group: 97 patients were excluded during enrollment at TTBH's clinics. An additional 58 participants from the TTBH sample were excluded from the analytic sample for UTRGV's study based on a diagnosis of schizophrenia. Lastly, the 249 participants enrolled in TTBH's intervention group were not included as possible members of the comparison group for UTRGV's study, resulting in a comparison group of 205 participants.

The number of patients excluded for each reason was not available for the intervention group. 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 withdraw from the study. Due to the lack of official withdrawal from the study, those who were lost to follow-up at 6 months remained in the study and were still eligible to complete a 12-month assessment. For this study's intervention group, a total of 366 participants were enrolled, however it was discovered 2 participants were pregnant at that time and were therefore deemed ineligible. The total intervention sample size used throughout this report is 364 as noted in the follow-up stage of the number who completed a baseline assessment. The patient flow diagram is presented on the following page.


ENROLLMENT
EXTERNAL COMPARISON
Assessed for eligibility (n=609)
Excluded (n=661)
Shortage of research personnel
Workflow inconsistencies
Not interested
No time availability
New patient medical diagnosis
Excluded (n=97)
Client had own PCP
Client had no verifiable chronic condition
Client did not agree to return to Behavioral Health services
ALLOCATION
Enrolled into intervention group (n=366)
Enrolled into comparison group & eligible for UTRGV study (n=205)
FOLLOW-UP
Completed baseline assessment (n=364)
Withdrawn from study (n=2)
Pregnant at baseline
Completed 6-month follow-up (n=231)
Lost to follow-up (n=124)
Communication challenges between research staff & participant
Participant incarcerated
No transportation
Work schedule challenges
Participant moved
Withdrawn from study (n=9)
Pregnant at 6 months
Death
Patient withdrew themselves
Completed 12-month follow-up (n=243)
Lost to follow-up (n=102)
Communication challenges between research staff & participant
Participant incarcerated
No transportation
Work schedule challenges
Participant moved
Withdrawn from study (n=10)
Death
Patient withdrew themselves
Completed baseline assessment (n=205)
Completed 6-month follow-up (n=148)
Lost to follow-up (n=57)
Unable to contact client
No-show to appointments
Non-compliant; dropped from BH services
Completed 12-month follow-up (n=135)
Lost to follow-up (n=70)
Client was deported
Client was discharged BH services
Non-compliant; dropped from BH services
ANALYSIS
Analyzed (n=243)
Analyzed (n=131)
Outside analysis window (n=4)

Sample Recruitment, Retention, and Attrition

Participant Eligibility and Recruitment

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.

All UTRGV FMR clinic adult patients were eligible for the intervention if they met one or more of the criteria below.

- Scored 5 or greater on PHQ-9, indicating moderate, moderately severe, or severe depression
- Scored 5 or greater on GAD-7, indicating mild, moderate, or severe anxiety
- Judged by the PCP to need behavioral health services according to PCBH model protocols which included meeting score thresholds on the PHQ-9 and/or GAD-7 or presenting with any type of behavioral health issue.

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. Eligibility criteria, which did not deviate from TTBH's SEP, included:

- Reside in Cameron, Hidalgo, or Willacy County

- Have a severe, persistent mental illness as diagnosed by a licensed behavioral health care provider including schizophrenia, bipolar, or major depression. For the comparison with UTRGV those diagnosed with schizophrenia were excluded from the analytic sample.
- Be eligible to receive behavioral health services from TTBH
- Must not be receiving any primary care outside of TTBH (as ascertained via patient self-report)
- Have a diagnosis of one or more chronic conditions:
    - Hypertension (blood pressure of 140/90 mmHg or higher)
    - Obesity (body mass index of 30.0 or higher)
    - Poorly controlled diabetes (HbA1c over 8.5%)
    - Hypercholesterolemia (Total cholesterol level above 200)

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.

Sample Enrollment and Retention

Intervention group: Program enrollment for the intervention group began in July 2016 and continued through May 2017. This was a deviation from the planned timeline in the SEP. Several issues emerged during enrollment, including insufficient staffing to reach all eligible patients, an enrollment stoppage in February 2017 due to delays in IRB renewal, and the political climate creating fear among patients. The final timeline is presented in **Appendix A: Revised Project Timeline.** Ultimately, UTRGV recruited 364 into their intervention group (99.5% of the target enrollment).

In the spring of 2017, UTRGV collected 6-month follow-up data starting 30 days before the 6-month anniversary enrollment date through 90 days post-enrollment six-month anniversary. For 12-month

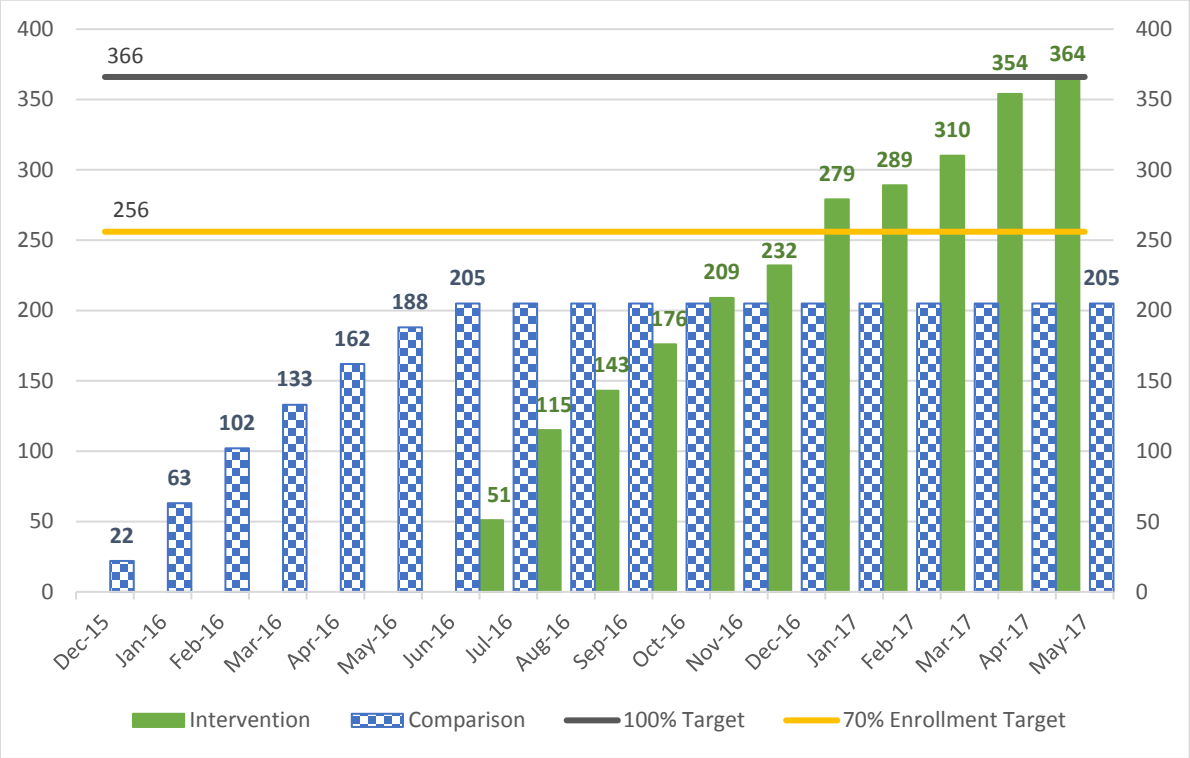
follow-up, UTRGV used a window of 60 days before and 60 days after the 12-month anniversary date. This extended follow-up period was in response to several challenges, including one FMR clinic requiring payment up front, which resulted in an increase in the no-show rate. This occurred for only one month during the study and was addressed after the overall clinic no-show rate was impacted negatively. Additionally, for a short period of time, due to a misunderstanding, one FMR clinic had the perception that the patient was required to pay a copay for each BHC visit, even when no PCP visit was occurring. **Table 12** presents subgrantee reported information on the number of intervention participants who returned for 6-month and 12-month follow-up through February 2018 and May 2018 respectively.

UTRGV began assessing participants for their 6-month follow-ups in December 2016 and completed follow-ups at the end of February 2018. As of the end of 6-month follow-up, UTRGV did not meet their retention goal at 6 months. UTRGV retained 74.3% of the 6-month target in the intervention group (231 out of 364 returned for a 6-month follow-up assessment with 311 needed to maintain power). At 12 months, UTRGV retained 94.9% of the intervention group target (243 out of 364 returned for a 12-month follow-up assessment, 256 needed to maintain power).

Comparison group: The comparison group began enrollment in November 2015 and ended in June 2016 with 262 comparison group participants (167 from Brownsville and 95 from Weslaco) with 205 being eligible for inclusion in UTRGV's analyses based on SPMI diagnosis (see **Figure 2**). This is a deviation from UTRGV's SEP as the comparison group sample size was lower than planned. This is due to the differing enrollment targets for TTBH's study.

For 6-month follow-up data collection, TTBH collected data starting from 60 days before a participant's 6-month enrollment anniversary date up through 90 days after the anniversary date. For 12-month, TTBH used a window of 60 days before and 60 days after the 12-month anniversary date. TTBH began assessing participants for their 6-month follow-up assessments in May 2016 and completed the follow-up assessments in December 2016. Twelve-month follow-up assessments were collected between December 2016 and June 2017. **Table 12** presents subgrantee reported information on the number of comparison participants who returned for 6-month and 12-month follow-up. The comparison retained 72.2% at 6 months (148 of 205 returned for follow-up assessment) and 63.9% at 12 months (131 of 205 returned for follow-up assessment). The final sample for all groups was 569 participants.

Figure 2. Cumulative Baseline Enrollment



Note: included 100% and 70% targets are based on UTRGV's study design and do not apply to the external comparison group

Table 12. Final Assessment of Follow-up Retention at 6 and 12 Months

Group	Number Enrolled	Retention Target (assumes 15% attrition at 6 months and-30% attrition at 12 months)	Number Retained (i.e., completed assessment at 6 or 12 months)	Percent of Retention of the Enrolled Sample	Percent of Retention Target
6-month Retention					
Intervention Group	364	311	231	63.5%	74.3%
External Comparison Group	205	--	148	72.2%	--
Total Sample	569	--	379	66.6%	--
12-month Retention					
Intervention Group	364	256	243	66.8%	94.9%
External Comparison Group	205	--	131	63.9%	--
Total Sample	569	--	374	65.7%	--

Sample Retention Strategies

Intervention group: UTRGV monitored any issues that arose in retaining the study sample through monitoring patient enrollment and conducting quality improvement cycles to counter any enrollment and retention challenges. Attrition was countered using a variety of retention strategies validated in the scientific literature for use with similar populations. For example, UTRGV research staff collected

multiple patient contacts from the study participant during the enrollment process. In addition, patients were reminded of upcoming appointments via telephone calls to reduce the number of missed appointments. Appointments for study follow-up were made for the same day as scheduled primary care or behavioral health care appointments to minimize the number of return trips to the clinic for study participants. If the appointment for follow-up data collection was not able to be scheduled at the time of another clinic visit, the participant was then seen through a follow-up "research visit" where data was collected at no cost to the participant.

UTRGV also provided incentives to intervention participants at baseline ($10), 6 months ($15), and 12 months ($25) as a strategy for recruiting and retaining an adequate number of participants for data collection. The amount of the incentive increased over time to offset the greater likelihood of attrition at later data collection dates (Grady, 2005) and to offset patient fees.

Comparison group: TTBH countered sample attrition by collecting as many contact methods as possible from the study participant during the enrollment process. Study participants were asked to provide their current contact information. To minimize attrition, TTBH oversaw follow-up via care management. The care manager kept in touch with study participants, aiming for a monthly basis using the participant's preferred mode of communication. The care management staff exhausted all means of communication to reach the participant, including telephone, voicemail, or mail. Email was excluded as a mode of patient communication to prevent disclosure of the participant's participation in the study. Care managers utilized their relationships with participants and their family and friends to locate and remind participants of their follow-up appointments. Appointments for study follow-up were made for the same day as scheduled primary care or behavioral health care appointments to minimize the number of return trips to the clinic for study participants. Finally, TTBH offered financial incentives to study participants for the intervention and control group. The scientific literature provides evidence that financial incentives improve adherence to medication among the severely mentally ill during clinical trials (Priebe et al., 2013). All study subjects were offered a progressive incentive for completing each of the three assessments. Study subjects 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

Sample Attrition Analysis

The study anticipated 70% retention of the sample at 12 months. At 12 months, the study had 66.8% retention in the intervention group and 63.9% retention in the comparison group. These numbers reflect the sample analyzed at 12 months. Eleven participants were removed from the intervention group and four from the comparison group prior to analysis because their data were collected outside the specified analytic window. To examine whether this 3% 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-value 0.49). Given these results, the two study groups did not have significantly differing attrition rates after 12 months of follow-up.

Although there is no evidence of differential attrition between the intervention and comparison groups, the overall attrition rate for the study was higher than anticipated in both groups.

To explore the potential influence this may have had on results, bivariate analyses were conducted to examine whether participants who were lost to follow-up were significantly different than those who remained in the study, for the entire sample and within each study arm across demographic characteristics and baseline health measures. T-tests were used for continuous measures and chi-square

tests for categorical data. Fisher's Exact Test was utilized if the expected cell counts were less than 5 and nonparametric tests were performed on non-normally distributed data. **Appendix G: Loss to Follow-Up/Attrition Tables** presents all the results from these analyses. There were no statistically significant differences in baseline health measures between those who were lost to follow-up and those who remained in the study at 12 months within the full study sample, intervention, or comparison group.

Regarding demographic measures, there were no differences in attrition within the intervention group. Within the comparison group, there were statistically significant differences in attrition by sex and ethnicity. Those who did not complete the study were more likely to be male. Larger proportions of the non-Hispanic and multiple ethnicities categories did not complete the study. However, the total number of participants in these categories with the comparison group was small, with 95.6% being Hispanic. This difference in category size should be considered in the interpretation of this attrition analysis.

A logistic regression model was then utilized to understand the influence of these differences in estimating a participant's odds of dropping out of the study. In this model of the full study sample, intervention status (p=0.67) and ethnicity (p=0.19) did not have a statistically significant influence on the likelihood of being lost to follow-up. Within the full sample, sex was found to predict the probability of a participant not completing the study (p=0.03); however, within each study group, sex did not significantly predict study completion within the intervention group (p=0.32) but did in the comparison group (p=0.03). Females had reduced odds of dropping out of the study. This result should be considered in the generalizability of the final model results regarding participant sex.

Missing Data

Data collected for intervention participants during "research visits" that did not entail a visit with a provider were entered into UTRGV's Research Electronic Data Capture (REDCap), a secure web application for building and managing online surveys and databases. For visits that involved a provider, data were extracted from the clinics' respective electronic medical record system and entered into REDCap.

All data collected for comparison group were recorded in TTBH's Cerner/Anasazi electronic medical record system. To minimize missing and inaccurate data in the TTBH EMR, TTBH provided ongoing training and technical support for all staff members who perform data entry and conducted regular audits of the data to ensure the completeness.

Missing data on covariates is a potential problem that could lead to biased results. The UTRGV data collection team made all efforts to minimize missing data through training and use of standard practice measures within the clinic settings captured by the EMR. However, where there were missing data on important covariates, we used imputation approaches (Rubin, 1996). Specifically, a multiple imputation approach was used to fill in the missing data by generating 10 imputed complete datasets. Demographic variables were used as predictors to create these imputed datasets. Linear regression analyses were then performed within each imputed dataset using PROC GLMSELECT. Once results were produced for each imputation, PROC MIANALYZE was used to pool results from all imputed datasets to produce one overall result evaluating the intervention effect on an outcome of interest. Using this approach reduced the likelihood of bias in effect estimates that can arise in complete case analyses where incomplete cases differ systematically from the rest (Little and Rubin, 1987; Rubin, 1996).

There were no missing data for the sociodemographic variables collected for both study groups. Regarding the five study impact measures collected for both the intervention and comparison groups, there were missing data at baseline and at 12 months (see **Table 13**). Among the intervention group at baseline, 15 were missing PHQ-9 scores and 4 were missing BMI, systolic and diastolic blood pressure scores. Among the comparison group members at baseline, 6 participants were missing both blood pressure measures and BMI. There were no missing data for PHQ-9 score at baseline in the comparison group. HbA1c data were collected only for intervention participants with known or suspected diabetes, therefore missingness was not assessed for this variable in either group.

At 12 months, in the intervention group, there were 18 participants missing PHQ-9 scores, 4 missing systolic blood pressure scores, 3 missing diastolic blood pressure scores, and 2 missing BMI scores. Among the comparison group at 12 months, 35 participants were missing PHQ-9 score, with no other missing data for impact variables. Because of the greater magnitude of missing data for PHQ-9 score, 14% of the final 12-month sample, multiple imputation methods were implemented in the analysis of this confirmatory outcome. However, this adjustment was not necessary for the physical health measures.

There were missing data on two other measures collected for the intervention group only, Duke General Health and GAD-7 scores. However, because these measures were not assessed for the comparison group analyses of the intervention effect compared to the comparison could not be conducted; therefore, multiple imputation was not necessary for these measures.

Table 13. Missing Data for Full Study Sample for Baseline and 12-month Follow-up

Measure	Intervention		Comparison	
	Baseline (n=364)	12-month (n=243)	Baseline (n=205)	12-month (n=131)
PHQ-9	15	18	0	35
Systolic Blood Pressure	4	4	6	0
Diastolic Blood Pressure	4	3	6	0
HbA1c	--	--	7	0
BMI	4	2	6	0
Duke General Health	22	31	--	--
GAD-7	12	14	--	--

Six-month data were not imputed because these data were not used to complete the end-point analysis, which used the 12-month data as the end-point. Additionally, longitudinal analyses utilized the complete case data for both 6- and 12-month follow-up, further supporting the decision to not impute 6-month data. Because HbA1c level was not universally collected from all participants, multiple imputation was not appropriate for this outcome.

Measures

The measures for the impact analysis are depicted in **Appendix B: Program Logic Model** with some exceptions. The impact measures collected for the PCBH program were depression, quality of life, anxiety, blood pressure, HbA1c, and Body Mass Index (BMI). There were no changes to the measures described in UTRGV's SEP and interim report. However, due to the use of TTBH participants as the comparison group, multivariate linear analyses of the quality of life and anxiety outcomes compared to

the comparison group were not possible. This is a deviation from the SEP that was the result of incomplete available data for both groups.

Information on the number of respondents and tests of normality are provided here where appropriate (see **Table 14**). PROC UNIVARIATE in SAS was used to understand the distributions of these measures at baseline. QQ plots and histograms were used to determine if the measure should be treated as normal, be transformed, or treated as non-normal data. Descriptive statistics for each of these measures, including number of participants with or without the impact measures, are included in this final report.

Table 14. Impact Measure Sample Size by Follow-up

Measure	Sample Size		
	Baseline	6-month	12-month
PHQ-9	554	326	325
Systolic Blood Pressure	559	378	374
Diastolic Blood Pressure	559	378	375
HbA1c	302	170	153
BMI	559	376	375
Duke General Health[a]	342	186	212
GAD-7[a]	352	201	229

[a] *sample sizes presented are for the intervention group only*

Sociodemographic characteristics: Sociodemographic characteristics were captured using a standardized set of questions developed by UTRGV and administered to the clinic population. These include age, gender, ethnicity, county, and primary language. Although the sociodemographic characteristics are not program impact measures, they are potential covariates and were captured for all program participants.

Depressive symptoms: Depressive symptoms are 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).

- **Administration method:** Depression was measured using the self-administered PHQ-9 assessment tool at UTRGV for the intervention participants. For the comparison participants, the PHQ-9 assessment was completed via provider interview. The PHQ-9 is a multipurpose instrument for screening, diagnosing, monitoring and measuring the severity of depression.
- **Administration time:** The PHQ-9 was given to patients at UTRGV as part of their assessment and at TTBH as part of their intake process and at follow-up.
- **Intended respondent:** The PHQ-9 was administered to all adult patients who visited the clinics.
- **Potential score/response range:** 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). Patients at the UTRGV clinics with a score of 10 or higher were referred to the behavioral health consultant.

PHQ-9 score is the confirmatory outcome in this study. For PHQ-9 score, there were 554 respondents with complete data at baseline, 326 respondents at 6 months, and 325 respondents at 12 months for the intervention and comparison group. The distributions of responses for PHQ-9 at baseline and 12 months were determined to be non-normally distributed. The log transformation was examined but did not normalize the distribution of PHQ-9. Therefore, nonparametric tests were used in bivariate analyses.

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

- **Administration method:** Quality of life was measured via the self-administered Duke Health Profile. The Duke Health Profile instrument contains six health measures (physical, mental, social, general, perceived health, and self-esteem), and five dysfunction measures (anxiety, depression, anxiety-depression, pain, and disability) (Parkerson, Broadhead, & Tse, 1990).
- **Administration time:** The Duke Health Profile assessment tool was given to the patient as part of their assessment.
- **Intended respondent:** The Duke Health Profile assessment tool was administered to all adult patients who visited the UTRGV clinics.
- **Potential score/response range:** The Duke Health profile has 11 domain 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. Greater levels of dysfunction are represented by lower scores on the function domains and higher scores on the dysfunction domains.

For Duke General Health score, data were only collected for the intervention group. There were 342 respondents with complete data at baseline, 186 respondents at 6 months, and 212 respondents at 12 months for the intervention group.

Anxiety: Anxiety disorders are characterized by excessive and unrealistic worry about everyday tasks or events or may be specific to certain objects or rituals. In addition to being helped by pharmacotherapies, anxiety disorders are often treated by behavioral approaches (Sadock & Sadock, 2007).

- **Administration method:** Anxiety was measured via the self-administered GAD-7 assessment tool. The GAD-7 is a valid and efficient tool for screening for anxiety and assessing its severity in clinical practice and research (Sadock & Sadock, 2007).
- **Administration time:** The assessment was given to the patient as part of their assessment.
- **Intended respondent:** The GAD-7 was administered to all adult patients who visited the UTRGV clinics.
- **Potential score/response range:** For the GAD 7, of a possible total point value of 21, anxiety is measured as mild (5-9), moderate (10-14) or severe (15 or above) (Spitzer, Kroenke, Williams, & Löwe, 2006); Kroenke & Spitzer, 2002) Patients with a score of five (5) or higher were referred for behavioral health services provider.

For GAD-7 score, data were only collected for the intervention group. There were 352 respondents with complete data at baseline, 201 respondents at 6 months, and 229 respondents at 12 months for the intervention group.

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).

For both the intervention and comparison groups, the health care provider measured blood pressure manually using a Manometer and following clinically established practice guidelines (National Guidelines Clearinghouse, 2011).

Clinical guidelines for management of prehypertension and hypertension differed at the intervention clinics compared to the comparison clinics. At UTRGV, patients with a blood pressure of 120/80 mmHg were considered prehypertensive; a blood pressure of 140/90 mmHg indicated hypertension. Patients with a blood pressure of 135/70 mmHg or above were considered as high-risk, identified as prehypertensive or hypertensive (depending on their results), and would be referred to appropriate services. The primary care provider determined the need/appropriateness of lifestyle and behavior modification. At TTBH, patients with a blood pressure greater than or equal to 140/90 mmHg were considered hypertensive. Hypertensive study participants in the comparison group at TTBH were referred to the nearest federally qualified health center (FQHC) or county health department for their primary care needs.

For systolic blood pressure, there were 559 respondents with complete data at baseline, 378 respondents at 6 months, and 374 respondents at 12 months for the intervention and comparison groups. For diastolic blood pressure, there were 559 respondents with complete data at baseline, 378 respondents at 6 months, and 375 respondents at 12 months for the intervention and comparison group. The distribution of responses for systolic and diastolic blood pressure at baseline and 12 months were determined to both be normally distributed and therefore parametric tests were used for bivariate analyses.

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).

For the intervention group, HbA1c was ordered by the PCP for patients who were: (1) known/self-reported to be diabetic, (2) had an elevated blood glucose at time of clinic visit or were suspected to be diabetic through other signs and symptoms. Patients with an HbA1c greater than or equal to 7.0% were referred to the provider for services. In addition, the primary care provider determined the need/appropriateness of medication and any patient receiving the PCBH model received a behavior change plan and skills to improve their physical health according to protocols.

UTRGV only collected HbA1c data for diabetic patients or patients with signs and symptoms of diabetes. The MMC clinic had an onsite lab. For those patients needing an HbA1c test, the lab work was done as part of the baseline visit. Patients at the DHR clinic needing an HbA1c test had the test conducted at a nearby hospital shortly after the baseline data collection visit.

There were 302 respondents with complete data at baseline, 170 respondents at 6 months, and 153 respondents at 12 months for the intervention and comparison groups. It is important to note that, of these complete sample sizes, in the intervention group there were 104 participants with complete HbA1c data at baseline, 22 at 6 months, and 18 at 12 months. The distribution of responses for HbA1c at baseline and 12-months were determined to be non-normally distributed. The log transformation was examined but did not normalize the distribution of HbA1c. Therefore, nonparametric tests were used in bivariate analyses.

Body Mass Index (BMI): BMI is generally used as an indicator of body fat. BMI can be used to screen for weight categories that may lead to health problems but it is not diagnostic of the body fat or health of an individual (National Guideline Clearinghouse, 2014).

For both intervention and comparison groups, the health care provider calculated BMI using a clinical weight scale and height measurement instrument following clinically established practice guidelines (National Guideline Clearinghouse, 2014). Patients with a BMI greater than or equal to 30 were considered to be obese.

For BMI, there were 559 respondents with complete data at baseline, 376 respondents at 6 months, and 375 respondents at 12 months for the intervention and comparison group. The distribution of responses for BMI at baseline and 12-months were determined to be slightly skewed in the intervention and comparison sample. Using the log transformation of the BMI data for bivariate analyses led to a more normal distribution and therefore the parametric test was used.

Data Collection Activities

UTRGV provided services at its FMR clinics in McAllen, TX and Edinburg, TX. Medical Assistants (MAs) assessed vitals for all patients receiving care at the clinics. Vitals included measures of height, weight and blood pressure as well as observation for signs of diabetes such as Acanthosis Nigricans. Patients with signs of diabetes or having already been diagnosed with diabetes had a blood draw to check HbA1c levels at their baseline clinic visit. At the time of check-in, clinic patients completed primary care screens for quality of life, depression, and anxiety. Patients new to the FMR clinics also provided blood samples for a standard panel of laboratory screens such as CBC, lipid panels, and glucose. Existing patients received their vitals/physical exams and provided blood samples on an annual basis for similar laboratory screens. Patients with elevated blood glucose levels on initial laboratory panels were screened for HbA1c levels.

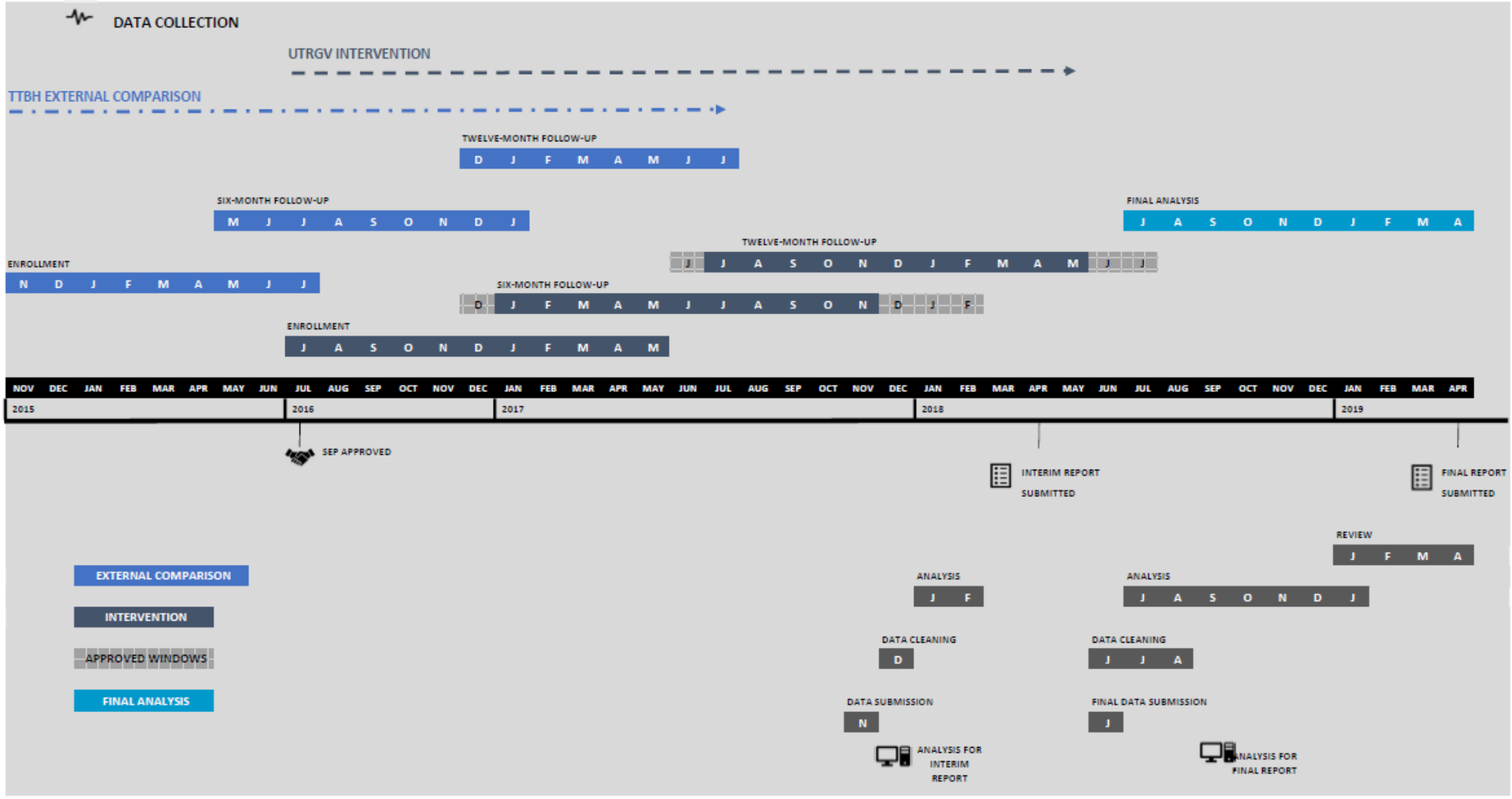
At the UTRGV clinics, there were no deviations from the SEP related to the data collection process, but there were deviations to the timeline. Several issues emerged during enrollment that shifted the timeline, including insufficient staffing to reach all eligible patients, an enrollment stoppage in February 2017 due to delays in IRB renewal, and the political climate creating fear among patients. An additional deviation to the data collection process was the use of TTBH as the external comparison group as an alternative group due to challenges related to baseline equivalence with the proposed comparison group from NCDV. A limitation related to this change is that TTBH's data collection period does not align with the data collection at UTRGV. The data collection timeline is described in the paragraph below.

Baseline data collection for the intervention group and comparison group occurred at the first visit when participants were enrolled in the study. Within the intervention group FMR clinics, the registration staff distributed and collected the behavioral health assessments (PHQ-9, GAD-7, and Duke Profile), and the medical assistants collected physical health measures on intervention participants.

At TTBH, clinical data taken during the vitalization process (e.g., blood pressure, height, weight) were entered by a nurse into a laptop computer directly into the patient's health record. Blood tests for HbA1c were done on-site and results were input to the EMR by technicians with roles to run blood tests. The PHQ-9 questionnaire was completed via clinician interview and input into TTBH's EMR system. The clinician conducting the interview for PHQ-9 directly entered participant responses into the data entry form in the EMR. The data entry form had built-in validation checks for out-of-range answers. Clinic staff asked participants in which language they would prefer to complete the surveys.

Figure 3 depicts the data collection and analysis timeline for this final report. UTRGV enrollment occurred from July 2016 through May 2017. Mid-point follow-up assessments occurred from December 2016 and continued through February 2018. End-point follow-up began for UTRGV in June 2017 and was completed in May 2018. TTBH enrollment occurred from November 2015 through June 2016. Mid-point follow-up assessments occurred from May 2016 and continued through January 2017. End-point follow-up began for TTBH in November 2016 and was completed in June 2017. Data from the study were submitted on a quarterly basis to HRiA by UTRGV and TTBH and then cleaned and assessed for quality.

Figure 3. Timeline for Data Collection and Analyses for the Final Report



IMPACT STUDY –ANALYSIS AND RESULTS

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

Descriptive statistics for complete data are examined in this final report for the intervention and comparison group. These statistics include patients' 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. Because a nonequivalent comparison group design is employed in the study, an intent-to-treat analysis was conducted with adjustment for potential nonequivalence of covariates and baseline outcome measure. The decision was made not to perform secondary power calculations as prior research indicated that these tests are not necessarily helpful in the interpretation of observed results (Goodman and Berlin, 1994).

All descriptive, baseline equivalence, bivariate, multivariate, and longitudinal analyses reported in this final report were performed with SAS version 9.4. PROC GLM was utilized for the primary linear regression models. For impact measures that were assessed to be non-normal, both the PROC GLM and PROC GENMOD were performed in order to assess any possible bias deriving from the non-normality. For linear regression models, using normal linear regression methods (e.g., PROC GLM) produced results consistent with those produced with methods accounting for the non-normality of these data (e.g., PROC GENMOD).

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. The parameter of interest was the dichotomous variable differentiating 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. Additionally, because multiple follow-up impact measures form individual trajectories over the study period, longitudinal analyses were used to assess whether the impact measure trajectories differ by intervention status (Fitzmaurice et al., 2004). A time measure was developed and applied to denote baseline, 6 and 12-month follow-up measures.

In addition to adjusting for key covariates, we also assessed potential collinearity and its impact on the standard error estimates for the covariates in the model by examining variance inflation factor when necessary. We stated in the SEP that in areas where multiple comparisons were necessary, we would employ adjustment of the p-value to account for multiple comparisons, such as the Bonferroni

correction. This step was ultimately unnecessary for the executed analyses since we did not need to account for multiple comparisons.

To evaluate the intervention effect, a multiple linear regression model approach was used following a sequence of models. The analysis sequence began by developing a bivariate model regressing the follow-up 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 an exploratory outcome (PHQ-9 and HbA1c) 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 and longitudinal analyses were performed separately to answer each research question. As previously mentioned, multiple imputation methods were used for all measures to account for missing covariate data. Propensity score matching was explored but was not included in the outcome analyses for the reasons described previously in the Methods section of this report. Instead, covariates were adjusted for in the models. The primary adjusted multivariate analysis models the outcome of interest on intervention status with relevant covariates included. The longitudinal analysis evaluates whether the impact measure trajectories differ by intervention status across the 12-month study. Effect modification of the intervention-outcome relationships was also examined by including interaction terms with intervention group in the outcome models. Possible effect modification by baseline health condition was explored for the corresponding impact measure (e.g. baseline depression as an effect modifier for impact on PHQ-9 score at 12 months). Age was also considered as an effect modifier for each model; age was divided into under 45 years and 45 years or older based on the average age of the full study population. The effect modification of sex, male and female, was also assessed.

The SEP indicated a set of planned covariates for adjustment in the models. Of those listed, the following variables were included in the model building phase: age (continuous), sex, ethnicity, language, number of comorbidities, and time. Of these, the following variables were selected or included into one or more models: age (continuous), sex, and time.

We employed a backward elimination modeling selection procedure for our end-point analysis approach where covariates with a p-value larger than 0.15 were excluded from the final model for parsimony, as is the standard threshold used in model selection. In some cases, age and sex were selected for inclusion in statistical models a priori due to the known biological influence of these characteristics on health outcomes; this is noted where relevant under each research question.

Depressive Symptoms

***Question 1*. Do patients who participate in the PCBH intervention experience improvements in depressive symptoms, as measured by PHQ-9, after 12 months compared to patients who do not participate in the intervention? <u>This question is confirmatory.</u>**

Overview of Analysis

To answer this confirmatory question about depressive symptoms, data were collected using the PHQ-9 assessment tool. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for the PHQ-9 score. The sample sizes for the presented analyses of PHQ-9 score are as follows: bivariate analyses (n=325), primary linear regression analyses with multiple imputation methods applied (n=374), and longitudinal analyses (n=394).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 24** presents the mean PHQ-9 score data in each study period for the overall sample as well as the intervention and comparison groups. The overall sample had a mean PHQ-9 score of 11.7 at baseline. For participants who returned for follow-up the mean PHQ-9 score was 9.5 at 6 months and 8.8 at 12 months. The intervention group began the study with a mean PHQ-9 score of 11.3 at baseline compared to the comparison group's mean PHQ-9 score of 12.3 at baseline. Those who returned for follow-up within the intervention group had a mean PHQ-9 score of 8.8 at 6 months and 8.2 at 12 months. Those who returned for follow-up within the comparison group had a mean PHQ-9 score of 10.7 at 6 months and 10.2 at 12 months. As previously noted in **Table 9**, the intervention and comparison groups were statistically equivalent on PHQ-9 score 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. These bivariate analyses did not control for any additional covariates (**Table 25**). The change in PHQ-9 score from baseline to 12-month follow-up within both the intervention and comparison group was statistically significant.

Bivariate analyses also were performed between the intervention and comparison group comparing mean impact measures at 12-month follow-up (**Table 26**). Based on a p-value less than 0.05 for PHQ-9 score when comparing the intervention and comparison group at 12 months, we can reject the null hypothesis. The mean PHQ-9 score was significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, the difference in PHQ-9 score from baseline to 12 months. Due to the need for multiple imputations due to missing data, the process for this outcome differs slightly from models without imputation. The initial covariates that were input into the models for PHQ-9 score were: sex, age, ethnicity, language, baseline PHQ-9 score, and number of qualifying comorbidities at baseline.

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

Inclusion in the final model was based on the number of times a covariate was selected across the ten imputations, at $p<0.15$ threshold (Wood et al., 2008). The covariate that was selected in all ten models was baseline PHQ-9 score. Age and sex were maintained based on a priori selection. Age was modeled as a continuous variable for parsimony based on similar adjusted R-square results across the two models. The final model specification was:

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

Findings

Estimates by covariate for the final model of PHQ-9 score are presented in **Table 15**.

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) is 0.31.

$$Y_{(PHQ9)} = 3.57 + -1.94(\text{Intervention}) + 0.01(\text{Age}) + -0.23(\text{Sex}) + 0.54(\text{BL\_PHQ9}) + \varepsilon$$

Table 15. Effect of IBH Intervention on PHQ-9 Score, Full UTRGV Sample

Variable	PHQ-9 (n=374)		
	Estimate (β)	Standard Error	p-value
Intervention	**-1.94**	**0.60**	**0.001**
Comparison (ref)	--	--	--
Age[a]	0.01	0.02	0.60
Female[a]	-0.23	0.60	0.70
Male (ref)	--	--	--
Baseline PHQ-9	0.54	0.04	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and comparison groups (p-value<0.05). [a] Included in the model a priori despite not having met the stepwise inclusion criteria.

Additional Analyses

When examining effect modification between intervention participation and select participant characteristics at baseline on PHQ-9 score, using the imputed dataset, significant effect modification was identified by age group. When stratifying by age, the intervention was not found to be significantly associated with PHQ-9 score among those who were 45 years or older at baseline (see **Table 16**). Among those who were younger than 45 at baseline, the intervention was significantly associated with a lower PHQ-9 score. On average, for those under the age of 45 at baseline, intervention participants had a PHQ-9 score 2.65 points lower than those in the comparison group (p=0.01); the effect size (using Cohen's d) is 0.44.

Table 16. Effect of IBH Intervention on Twelve Month PHQ-9 Score, Stratified by Age

	Under 45 Year			45 Years or Older		
Variable	PHQ-9 (n=188)			PHQ-9 (n=186)		
	Estimate (β)	Standard Error	p-value	Estimate (β)	Standard Error	p-value
Intervention	**-2.65**	**0.98**	**0.01**	-1.40	0.92	0.13
Comparison (ref)	--	--	--	--	--	--
Female	0.40	0.91	0.66	-0.44	0.86	0.61
Male (ref)	--	--	--	--	--	--
Baseline PHQ-9	0.43	0.07	<0.001	0.63	0.06	<0.001

We conducted longitudinal analyses examining time as an independent variable. In the model, we utilized the PROC MIXED procedure in SAS. For PHQ-9, only adjusting for intervention status and time, there was a significant time/group interaction with a p-value of 0.01, indicating that the trajectories from baseline to 6 months, and then to 12 months were different between the two study arms for PHQ-9 score (see **Table 17**). Adjusting for the covariates that were selected in the primary model – age and sex – did not alter these results.

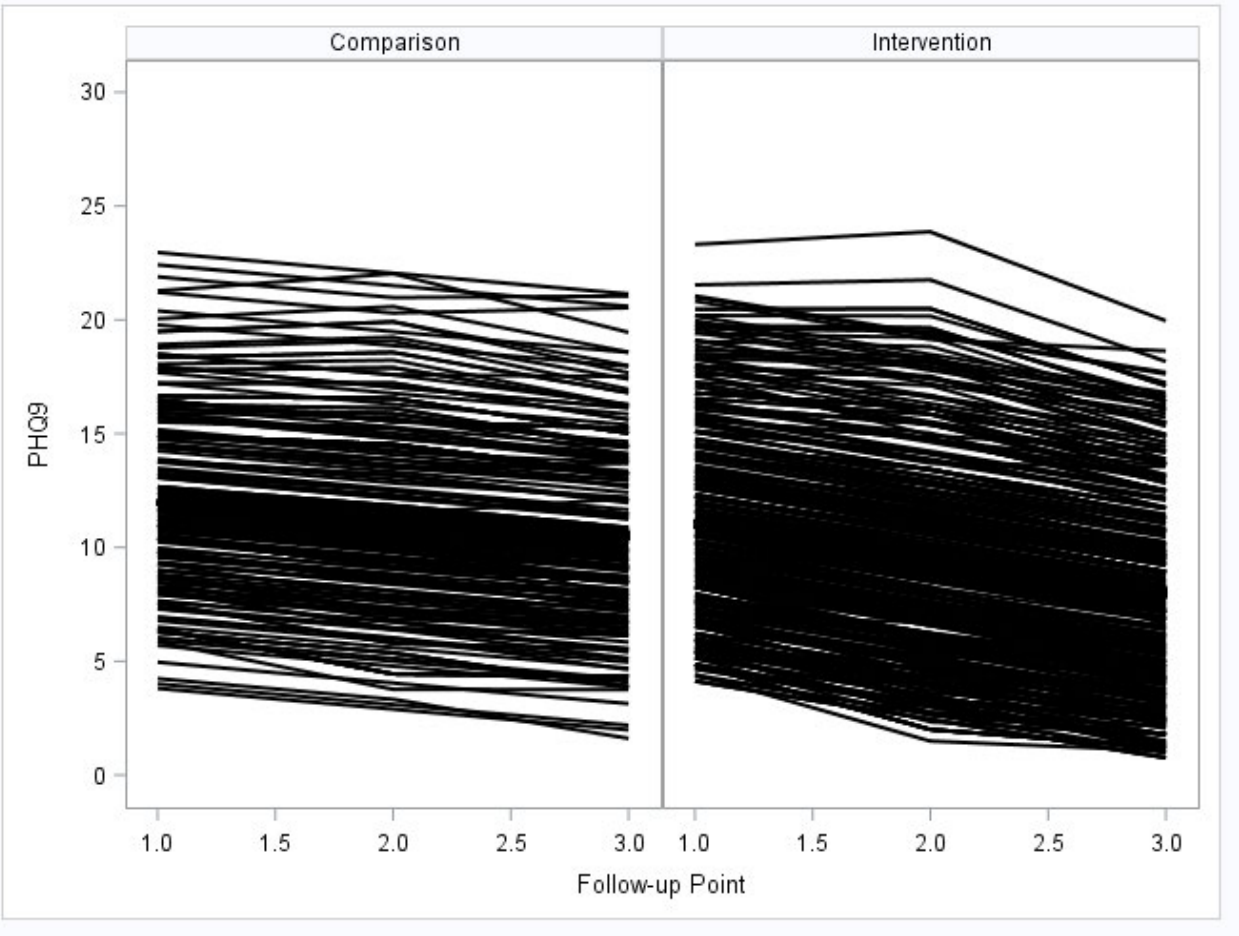
Table 17. Effect of IBH Intervention on Trajectory of PHQ-9 Score Across Twelve Month Study, Full UTRGV Sample

Variable	PHQ-9 (n=394)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	**-1.70**	**0.68**	**0.01**
Time*Comparison (ref)	--	--	--
Time	-1.67	0.56	0.003
Intervention	-0.98	0.59	0.10
Comparison (ref)	--	--	--

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

To visualize the longitudinal effect of the intervention on PHQ-9 score, we produced a two-panel spaghetti plot using PROC SGPANEL. **Figure 4** displays the comparison group trajectory in the left panel and the intervention group trajectory in the right panel. The x-axis of the graph shows the study follow-up points with 1.0 representing study baseline, 2.0 the 6-month follow-up, and 3.0 the 12-month end-point. The trajectory figure visually displays the differences identified in the longitudinal statistical model, illustrating the decreasing PHQ-9 score in both groups and the intervention group's steeper decrease in PHQ-9 score from baseline to 12 months compared to the comparison group.

Figure 4. Individual Trajectories of PHQ-9 Across 12-Month Study Period by IBH Intervention and Comparison Group



Limitations
There are no limitations specific to this measure to note.

Functioning and Quality of Life

Question 2. **Do patients who participate in the PCBH intervention experience improvements in quality of life, as measured by the Duke Health Profile, after 12 months when compared to patients that do not participate in the intervention? <u>This question is exploratory.</u>**

Overview of Analysis
Because of the study deviation to utilize an alternative comparison group, the multivariate analyses of Duke Health Profile data comparing outcomes between the intervention and comparison groups were not possible. TTBH employed a different measure to answer their study question about functioning and quality of life and therefore comparisons could not be made between UTRGV and TTBH for this question. In this section, we present the change over time in Duke Health Profile for the intervention group only.

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 24** presents the mean Duke General Health data in each study period for the intervention group. The intervention group participants had a mean Duke General Health score of 50.2 at baseline, 56.8 at 6 months, and 56.6 at 12 months.

A bivariate analysis was performed within the intervention group, testing the statistical significance of the change in impact measure from baseline to 12-month follow-up. This analysis did not control for any additional covariates (see **Table 25**). The change from baseline to 12-month follow-up for Duke General Health score was statistically significant within the intervention group ($p<0.001$). The median Duke General Health score at 12 months was 6.7 points higher than the median score at baseline within the intervention group, without adjusting for any other factors.

Limitations
Because TTBH assessed functioning and quality of life using a different measure, Duke Health Profile data were not collected from the comparison group participants. As a result, multivariate analyses were not possible comparing the intervention Duke General Health score to a comparison group.

Anxiety Symptoms

Question 3. **Do patients who participate in the PCBH intervention experience improvements in anxiety symptoms, as measured by GAD-7, after 12 months compared to patients who do not participate in the intervention? <u>This question is exploratory.</u>**

Overview of Analysis
Because of the study deviation to utilize an alternative comparison group, the analyses of GAD-7 data are not possible. TTBH did not have a study question concerning anxiety symptoms and did not collect data on GAD-7 assessments during their study. Therefore, comparisons could not be made between UTRGV and TTBH for this question. In this section we present the change over time in GAD-7 for the intervention group only.

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 24** presents the mean GAD-7 score data in each study period for the intervention group. The intervention group participants had a mean GAD-7 score of 10.0 at baseline, 7.8 at 6 months, and 7.7 at 12 months.

A bivariate analysis was performed within the intervention, testing the statistical significance of the change in impact measure from baseline to 12-month follow-up. This analysis did not control for any additional covariates (see **Table 25**). The change from baseline to 12-month follow-up for GAD-7 score was statistically significant within the intervention group ($p<0.001$). The median GAD-7 score at 12 months was 4.0 points lower than at baseline within the intervention group, without adjusting for any other factors.

Limitations
Because TTBH did not assess anxiety symptoms for their study, GAD-7 data were not collected from comparison group participants. As a result, multivariate analyses were not possible comparing the intervention GAD-7 score to a comparison group.

Blood Pressure

Question 4. **Do patients who participate in the PCBH intervention experience improvements in blood pressure, when compared to patients that do not participate in the intervention? <u>This question is exploratory.</u>**

Overview of Analysis

To answer this exploratory question, patient systolic and diastolic blood pressure data were collected and analyzed. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for blood pressure. The sample sizes for the presented analyses of systolic blood pressure are as follows: bivariate analyses (n=374), primary linear regression analyses (n=366), and longitudinal analyses (n=437). The sample sizes for the presented analyses of diastolic blood pressure are as follows: bivariate analyses (n=375), primary linear regression analyses (n=367), and longitudinal analyses (n=438).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 24** presents the mean systolic and diastolic blood pressure data in each study period for the overall sample as well as the intervention and comparison groups. The overall sample had a mean blood pressure of 133.2/79.6 mmHg at baseline. For those who returned for a follow-up assessment, the mean blood pressure was 129.4/77.2 mmHg at 6-month follow-up and 128.8/77.6 mmHg at 12-month follow-up. The intervention group began the study with a mean blood pressure of 133.7/79.2 mmHg at baseline while the comparison group had a mean blood pressure of 132.2/80.4 mmHg at baseline. In the intervention group, for those who returned for a follow-up assessment, the mean blood pressure was 131.6/77.3 mmHg at 6 months and 131.8/78.3 mmHg at 12 months. In the comparison group, for those who returned for a follow-up, the 6-month mean blood pressure was 126.0/77.0 mmHg and 123.2/76.1 mmHg at the 12-month follow-up. As previously noted in **Table 9**, the intervention and comparison groups were statistically equivalent on systolic blood pressure 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. These bivariate analyses did not control for any additional covariates (**Table 25**). The decrease from baseline to 12-month follow-up for blood pressure in the comparison group was statistically significant, but the decrease in the intervention group was not statistically significant.

Bivariate analyses also were performed between the intervention and external comparison groups comparing mean impact measures at 12-month follow-up (**Table 26**). Based on a p-value less than 0.05 for systolic blood pressure, when comparing the intervention and comparison group at 12 months and without controlling for any additional covariates, the null hypothesis can be rejected. The mean systolic blood pressure measure is significantly different between the two study groups when not adjusting for any additional covariates. Based on a p-value greater than 0.05 for diastolic blood pressure, when comparing the intervention and comparison group at 12 months, the null hypotheses cannot be rejected. The mean diastolic blood pressure measure is not significantly different between the two study groups when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcomes of the differences from baseline to 12 months in systolic

and diastolic blood pressure scores. Covariates were removed from the model if their p value was found to be greater than 0.15. The initial covariates that were input into the models for systolic and diastolic blood pressure scores were: sex, age, ethnicity, language, baseline systolic and diastolic blood pressure, and number of qualifying comorbidities at baseline. Baseline systolic and diastolic were not included in each other's models because there is a strong and statistically significant correlation ($r=0.64$; $p<0.001$). As previously stated, a multiple imputation approach was considered but not performed due to the near completeness of the evaluated data.

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

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

The final model for systolic blood pressure included those covariates with p-values of 0.15 or less: age, sex, and baseline systolic blood pressure.

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

The final model for diastolic blood pressure included those covariates with p-values of 0.15 or less: sex and baseline diastolic blood pressure. Age was selected a priori for inclusion due to the known biological influence of age and sex on health outcomes.

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

Findings
Estimates for the final models of systolic and diastolic blood pressure are presented in **Table 18**.

On average, the systolic blood pressure of intervention participants at 12 months was 7.56 mmHg higher than the comparison participants, holding all other variables in the model constant ($p<0.001$); the effect size (using Cohen's d) is 0.39.

$$Y_{(SBP)} = 55.23 + 7.56(Intervention) + 0.20(Age) + -6.11(Female) + 0.48(BL\_SBP) + \varepsilon$$

On average, the diastolic blood pressure of intervention participants at 12 months was 2.76 mmHg higher than the comparison participants, holding all other variables in the model constant ($p=0.01$); the effect size (using Cohen's d) is 0.24.

$$Y_{(DBP)} = 38.87 + 2.76(Intervention) + 0.01(Age) + -3.01(Female) + 0.49(BL\_DBP) + \varepsilon$$

Table 18. Effect of IBH Intervention on Systolic and Diastolic Blood Pressure Values, Full UTRGV Sample

Variable	Systolic Blood Pressure (n=366)		
	Estimate (β)	Standard Error	p-value
Intervention	**7.56**	**1.77**	**<0.001**
Comparison (ref)	--	--	--
Age (continuous)	0.20	0.06	0.003
Female	-6.11	1.87	0.001
Male (ref)	--	--	--
Baseline SBP	0.48	0.05	<0.001
Variable	Diastolic Blood Pressure (n=367)		
	Estimate (β)	Standard Error	p-value
Intervention	**2.76**	**1.07**	**0.01**
Comparison (ref)	--	--	--
Age (continuous)[a]	0.01	0.04	0.82
Female	-3.01	1.14	0.01
Male (ref)	--	--	--
Baseline DBP	0.49	0.05	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and comparison groups (p-value<0.05). [a] Included in the model a priori despite not having met the stepwise inclusion criteria.

Additional Analyses

For systolic blood pressure, significant effect modification was identified by sex. When stratifying by sex, the intervention was not found to be significantly associated with systolic blood pressure among males (see **Table 19**). Among females, the intervention was significantly associated with a higher systolic blood pressure. On average, females in the intervention group had a systolic blood pressure 9.54 mmHg higher than females in the comparison group (p<0.001); the effect size (using Cohen's d) is 0.50.

Table 19. Effect of IBH Intervention on Twelve Month Systolic Blood Pressure, Stratified by Sex

	Female			Male		
Variable	Systolic Blood Pressure (n=258)			Systolic Blood Pressure (n=108)		
	Estimate (β)	Standard Error	p-value	Estimate (β)	Standard Error	p-value
Intervention	**9.54**	**2.13**	**<0.001**	4.33	3.13	0.17
Comparison (ref)	--	--	--	--	--	--
Age	0.36	0.08	<0.001	-0.06	0.11	0.57
English	3.78	2.15	0.08	--	--	--
Spanish (ref)	--	--	--	--	--	--
Baseline SBP	0.45	0.05	<0.001	0.49	0.09	<0.001

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

In order to understand whether baseline chronic condition status differentially influenced the relationship between intervention group and 12-month outcome, we considered examining the potential of effect modification of baseline hypertension status for blood pressure outcomes; however, due to some differences in protocols at the intervention and comparison clinics, this was not considered appropriate. Instead, potential effect modification by baseline chronic condition status was assessed using the variable indicating whether a participant met the threshold for referral to services based on blood pressure. These referrals were not to intervention related services, but to clinical services specific to addressing hypertension.

For diastolic blood pressure, significant effect modification was identified by referral to services for hypertension at baseline. When stratifying by referral to these services, the intervention was not found to be significantly associated with diastolic blood pressure among those who had a referral to services at baseline (see **Table 20**). Among those who were not referred to services at baseline, the intervention was significantly associated with a lower diastolic blood pressure. On average, among those who were not referred to services for hypertension at baseline, intervention participants had a diastolic blood pressure 4.00 mmHg lower than in the comparison group (p=0.04); the effect size (using Cohen's d) is 0.41.

Table 20. Effect of IBH Intervention on Twelve Month Diastolic Blood Pressure, Stratified by Referral to Service at Baseline

	Not Referred to Service at Baseline			Referred to Service at Baseline		
Variable	Diastolic Blood Pressure (n=118)			Diastolic Blood Pressure (n=249)		
	Estimate (β)	Standard Error	p-value	Estimate (β)	Standard Error	p-value
Intervention	**-4.00**	**1.92**	**0.04**	0.72	1.77	0.68
Comparison (ref)	--	--	--	--	--	--
Female	-3.70	2.12	0.08	-3.70	1.49	0.01
Male (ref)	--	--	--	--	--	--
English	--	--	--	2.43	1.45	0.09
Spanish (ref)	--	--	--	--	--	--

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

We conducted longitudinal analyses to examine time as an independent variable and whether the outcome trajectories differ by intervention status. To estimate the model, we utilized the PROC MIXED procedure in SAS. For systolic blood pressure, only adjusting for intervention status and time, there was a significant time/group interaction with a p-value of <0.001, indicating that the trajectories from baseline to 6 months, and then to 12 months differed between the two study arms for systolic blood pressure (see **Table 21**). Adjusting for the covariates that were selected in the primary model – age and sex – did not alter these results.

For diastolic blood pressure, only adjusting for intervention status and time, there was a significant time/group interaction with a p-value of 0.005, indicating that the trajectories from baseline to 6 months, and then to 12 months differed between the two study arms for diastolic blood pressure (see **Table 21**). Adjusting for the covariates that were selected in the primary model – age and sex – did not alter these results.

Table 21. Effect of IBH Intervention on Trajectory of Systolic and Diastolic Blood Pressure Values Across Twelve Month Study, Full UTRGV Sample

Variable	Systolic Blood Pressure (n=437)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	**6.95**	**1.94**	**<0.001**
Time*Comparison (ref)	--	--	--
Time	-8.49	1.55	<0.001
Intervention	2.06	1.64	0.21
Comparison (ref)	--	--	--
Variable	Diastolic Blood Pressure (n=438)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	**3.32**	**1.17**	**0.005**
Time*Comparison (ref)	--	--	--
Time	-4.04	0.94	<0.001
Intervention	-1.10	0.99	0.26
Comparison (ref)	--	--	--

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

To visualize the longitudinal effect of the intervention on blood pressure, we produced two-panel spaghetti plots using PROC SGPANEL. **Figure 5** displays the comparison group trajectory in the left panel and the intervention group trajectory in the right panel for systolic blood pressure. The x-axis of the graph shows the study follow-up points with 1.0 representing study baseline, 2.0 the 6-month follow-up, and 3.0 the 12-month end-point. The trajectory figure visually displays the differences identified in the longitudinal statistical model, showing the comparison group's steep decrease in systolic blood pressure from baseline to 12 months compared to the intervention group's more steady measures over time.

Figure 5. Individual Trajectories of Systolic Blood Pressure Across 12-Month Study Period by IBH Intervention and Comparison Group

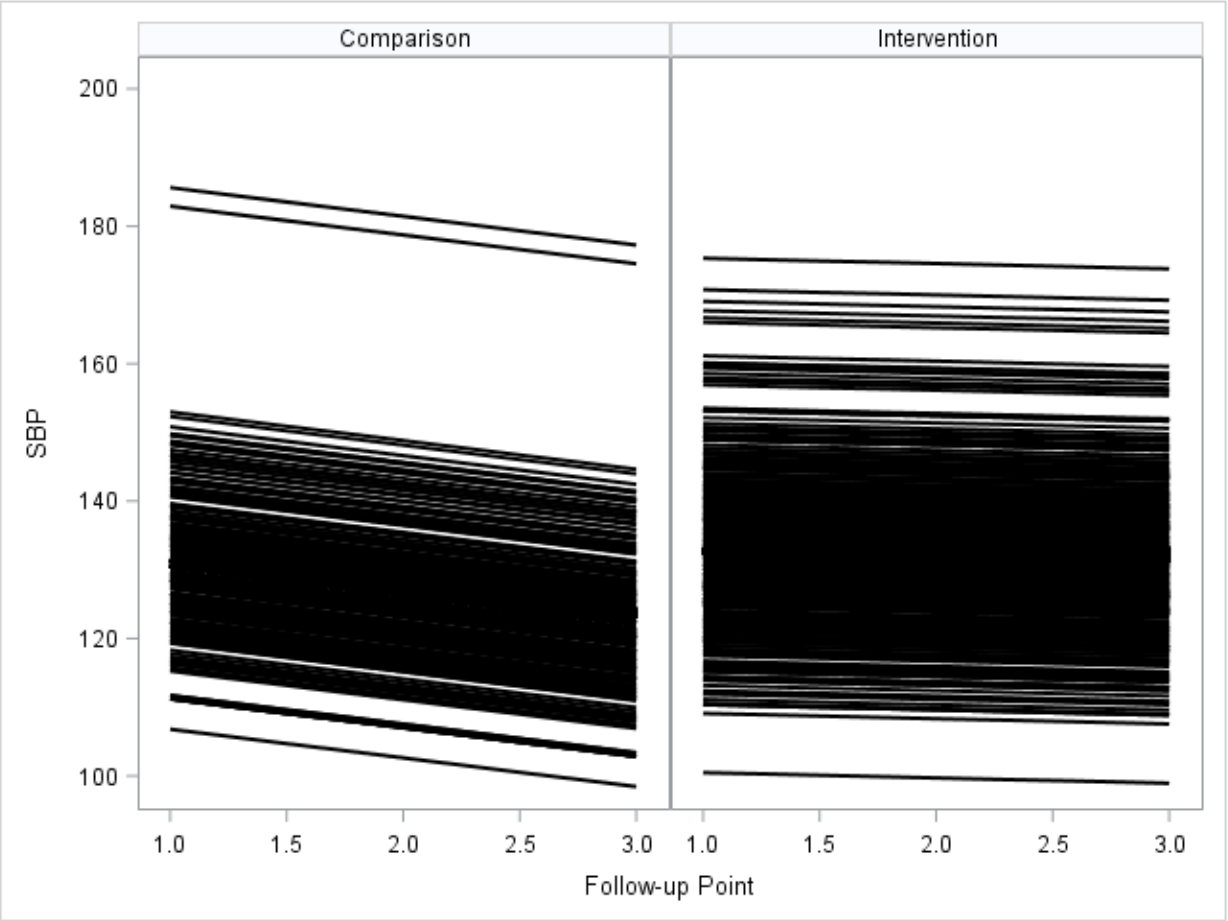
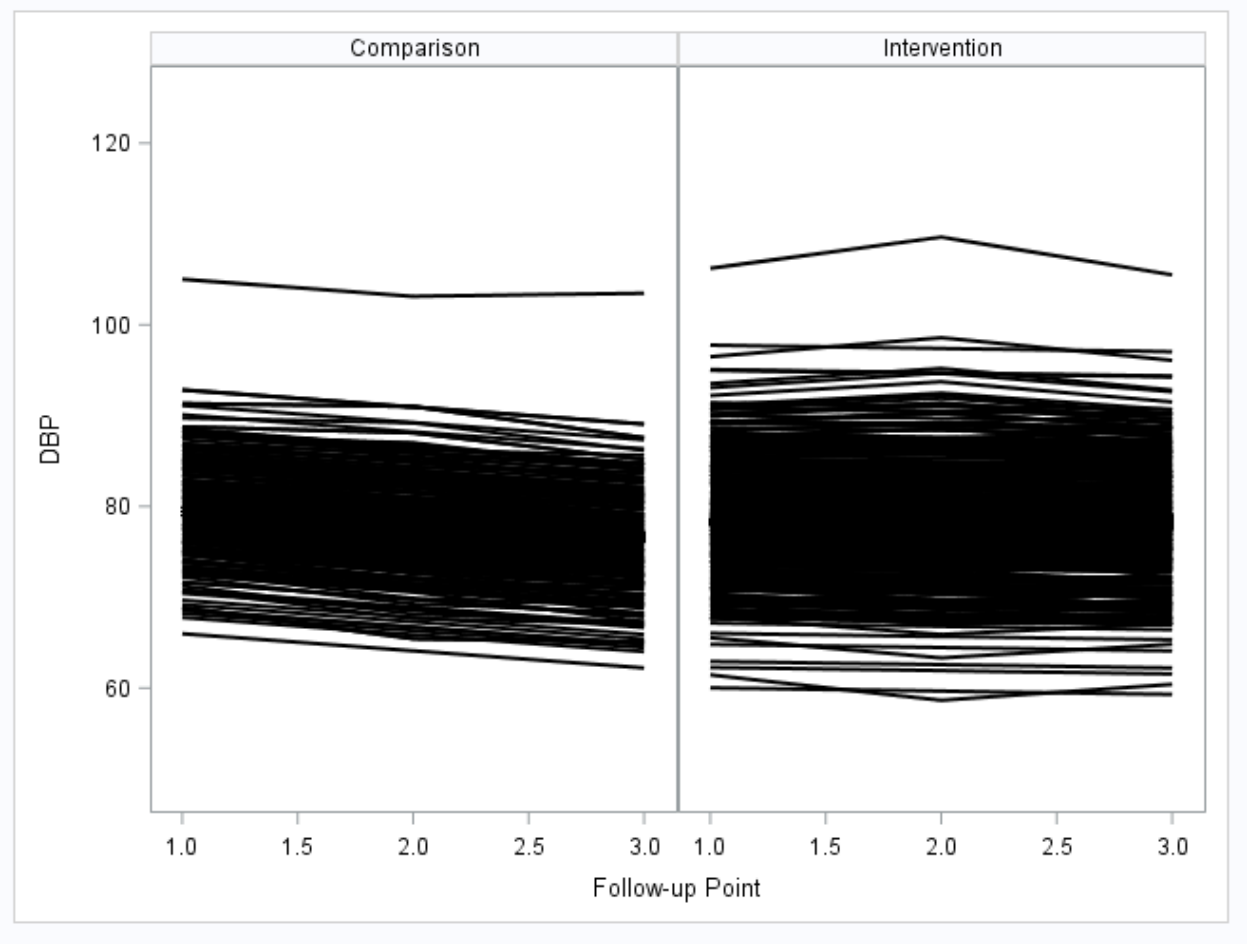


Figure 6 displays the comparison group trajectory in the left panel and the intervention group trajectory in the right panel for diastolic blood pressure. The x-axis of the graph shows the study follow-up points with 1.0 representing study baseline, 2.0 the 6-month follow-up, and 3.0 the 12-month end-point. The trajectory figure visually displays the differences identified in the longitudinal statistical model, showing the comparison group's decrease in diastolic blood pressure from baseline to 12 months compared to the intervention group's more steady measures over time.

Figure 6. Individual Trajectories of Diastolic Blood Pressure Across 12-Month Study Period by IBH Intervention and Comparison Group



Limitations

A limitation of this measure is the differing thresholds used to indicate a high-risk patient across study groups. Within the UTRGV sample, this cutoff was 135/70 mmHg, including pre-hypertensive and hypertensive patients. In TTBH's sample this referral cutoff was 140/90 mmHg, including only hypertensive patients.

HbA1c Level

Question 5. **Do patients with a history or diagnosis of diabetes who participate in the PCBH intervention experience improvements in HbA1c measures after 12 months when compared to patients that do not participate in the intervention? <u>This question is exploratory.</u>**

Overview of Analysis

To answer this exploratory question, patient HbA1c data were collected and analyzed. Systematic checks for outliers by looking at data ranges were performed and questions about potential data entry errors were sent to study site staff for verification on a quarterly basis. There were no additional data cleaning processes needed for HbA1c. Only a subset of the intervention sample, those with a diagnosis of or suspected of having diabetes, had a measured HbA1c during the study. Due to the small sample size at 12 months in the intervention group (n=18), further analyses beyond the bivariate analyses were deemed inappropriate for reporting due to the limitations in interpretation. The sample size for the presented bivariate analysis of HbA1c, including the comparison group, is 152 participants.

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 24** 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 7.1% at baseline. For those who returned for a follow-up assessment, the mean HbA1c was 6.7% at 6-month follow-up and 6.8% at 12-month follow-up. The intervention group had a mean of 8.4% at baseline while the comparison group had a mean of 6.4% at baseline. For participants who returned for a follow-up visit, the intervention group mean HbA1c was 8.3% at 6 and 12 months. For those participants in the comparison group who returned for a follow-up visit, the mean HbA1c was 6.4% at 6 months and 6.6% at 12 months. As previously noted in **Table 9**, the intervention and comparison groups were not statistically balanced on HbA1c 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. These bivariate analyses did not control for any additional covariates (**Table 25**). The change from baseline to 12-month follow-up for HbA1c was not statistically significant within the comparison group ($p=0.99$) or the intervention group ($p=0.09$).

Bivariate analyses were also performed between the intervention and external comparison groups comparing mean impact measures at 12-month follow-up (**Table 26**). The median HbA1c score among the comparison group was lower than the score in the intervention group ($p<0.001$).

Limitations

As mentioned earlier, due to the small sample size at 12 months in the intervention group (n=18), further analyses beyond the bivariate analyses were deemed inappropriate for reporting due to the limitations in interpretation. The bivariate analyses presented are also limited by this sample size and additionally do not adjust for the baseline difference between the intervention and comparison groups.

Body Mass Index

Question 6. **Do patients who participate in the PCBH intervention experience improvements in BMI after 12 months when compared to patients that do not participate in the intervention? <u>This question is exploratory.</u>**

Overview of Analysis

To answer this exploratory question, patient BMI data were collected and analyzed. Initially, an end-point analysis was run per the plan laid out in the SEP. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for BMI. The sample sizes for the presented analyses of BMI are as follows: bivariate analyses (n=376), primary linear regression analyses (n=370), and longitudinal analyses (n=439).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 24** presents the mean BMI data in each study period for the overall sample as well as the intervention and comparison groups. The overall sample had a mean BMI of 34.1 kg/m^2 at baseline. The mean BMI for those who completed a follow-up assessment was 34.9 kg/m^2 at 6 and 12-month follow-up. The intervention group began the study with a mean BMI of 33.6 kg/m^2 at baseline compared to the comparison group's mean of 35.0 kg/m^2 at baseline. For those who completed an assessment at follow-up, the intervention group mean BMI was 34.6 kg/m^2 at 6 and 12-month follow-up. In the comparison group, the mean BMI was 35.3 kg/m^2 at 6 months and 35.1 kg/m^2 at 12 months. As previously noted in **Table 9**, the intervention and comparison groups were statistically equivalent on BMI 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. These bivariate analyses did not control for any additional covariates (**Table 25**). The increase from baseline to 12-month follow-up was statistically significant within the intervention group (p=0.002) but the decrease was not statistically significant within the comparison group (p=0.17).

Bivariate analyses were also performed between the intervention and external comparison groups comparing mean impact measures at 12-month follow-up (**Table 26**). Based on a p-value greater than 0.05 for BMI when comparing the intervention and comparison group at 12 months, the null hypothesis cannot be rejected. The mean BMI measure was not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome of the difference from baseline to 12 months in BMI. Covariates were removed from the model if their p-values were found to be greater than 0.15. The initial covariates that were input into the BMI model were: sex, age, ethnicity, language, baseline BMI, and the number of qualifying comorbidities at baseline.

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

The final model for BMI included those covariates with p-values of 0.15 or less: sex, and baseline BMI. Age was selected a priori for inclusion due to the known biological influence of age and sex on health outcomes.

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

Findings

Estimates for the final models of BMI are presented in **Table 22**.

On average, the BMI of intervention participants at 12 months was 1.12 kg/m^2 higher than the comparison participants, holding all other variables in the model constant (p=0.005); the effect size (using Cohen's d) is 0.12.

$$Y_{(BMI)} = 0.89 + 1.12(\text{Intervention}) + 0.68(\text{Female}) + -0.02(\text{Age}) + 0.97(\text{BL\_BMI}) + \varepsilon$$

Table 22. Effect of IBH Intervention on BMI, Full UTRGV Sample

Variable	BMI (n=370)		
	Estimate (β)	Standard Error	p-value
Intervention	**1.12**	**0.40**	**0.005**
Comparison (ref)	--	--	--
Age[a]	-0.02	0.01	0.23
Female	0.68	0.41	0.10
Male (ref)	--	--	--
Baseline BMI	0.97	0.02	<0.001

Notes: "ref" indicates the reference category used to calculate the estimate for a covariate. Bold denotes statistically significant difference between intervention and comparison groups (p-value<0.05). [a] Included in the model a priori despite not having met the stepwise inclusion criteria.

Additional Analyses

When examining effect modification between intervention participation and select participant characteristics at baseline on BMI, no significant effect modification was identified.

We conducted longitudinal analyses examining time as an independent variable. In the model, we utilized the PROC MIXED procedure in SAS. For BMI, only adjusting for intervention status and time, there was a significant time/group interaction with a p-value of 0.005, indicating that the trajectories from baseline to 6 months, and then to 12 months were different between the two study arms for BMI score (see **Table 23**). Adjusting for the covariates that were selected in the primary model – age and sex – did not alter these results.

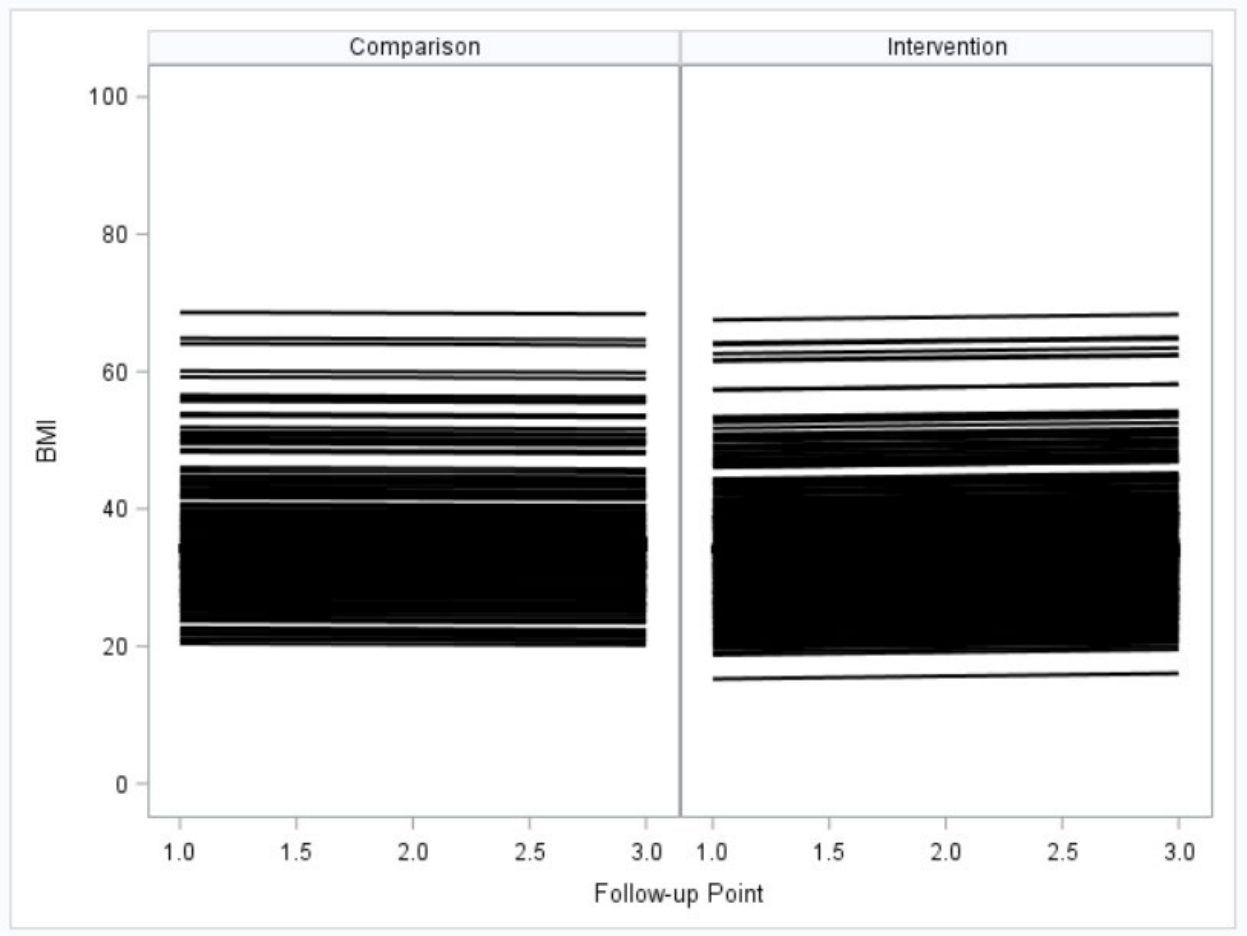
Table 23. Effect of IBH Intervention on Trajectory of BMI Across Twelve-Month Study, Full UTRGV Sample

Variable	BMI (n=439)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	**1.07**	**0.38**	**0.005**
Time* Comparison (ref)	--	--	--
Time	-0.26	0.30	0.40
Intervention	-1.34	0.81	0.10
Comparison (ref)	--	--	--

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

Figure 7 displays the comparison group trajectory in the left panel and the intervention group trajectory in the right panel for BMI. The x-axis of the graph shows the study follow-up points with 1.0 representing study baseline, 2.0 the 6-month follow-up, and 3.0 the 12-month end-point. The trajectory figure visually displays the differences identified in the longitudinal statistical model, showing the comparison group's steady BMI from baseline to 12 months compared to the intervention group's slightly increasing measures over time.

Figure 7. Individual Trajectories of BMI Across 12-Month Study Period by IBH Intervention and Comparison Group



Limitations

There are no limitations specific to this measure to note.

Table 24. Health Impact Measures by Study Arm and Follow-up Period

	Full Sample			Intervention			Comparison		
	Baseline	6-Mo	12-Mo	Baseline	6-Mo	12-Mo	Baseline	6-Mo	12-Mo
	n=569	n=379	n=378	n=364	n=231	n=243	n=205	n=148	n=131
Measure		Mean (SD)			Mean (SD)			Mean (SD)	
Blood pressure									
Systolic	133.2 (19.1)	129.4 (18.9)	128.8 (19.6)	133.7 (19.5)	131.6 (18.0)	131.8 (20.5)	132.2 (18.2)	126.0 (19.8)	123.2 (16.8)
Missing	*10*	*1*	*4*	*4*	*1*	*4*	*6*	*0*	*0*
Diastolic	79.6 (11.2)	77.2 (11.4)	77.6 (11.5)	79.2 (11.6)	77.3 (11.6)	78.3 (12.1)	80.4 (10.5)	77.0 (11.1)	76.1 (10.1)
Missing	*10*	*1*	*3*	*4*	*1*	*3*	*6*	*0*	*0*
HbA1c	N=302	N=170	N=153	N=104	N=22	N=18	N=198	N=148	N=131
HbA1c	7.1 (2.2)	6.7 (1.9)	6.8 (2.1)	8.4 (2.6)	8.3 (2.2)	8.3 (2.3)	6.4 (1.7)	6.4 (1.8)	6.6 (2.0)
BMI									
BMI	34.1 (9.0)	34.9 (9.1)	34.9 (9.6)	33.6 (8.7)	34.6 (9.2)	34.6 (9.4)	35.0 (9.5)	35.3 (9.0)	35.1 (9.9)
Missing	*10*	*3*	*2*	*4*	*3*	*2*	*6*	*0*	*0*
PHQ-9									
PHQ-9 Score	11.7 (7.0)	9.5 (6.7)	8.8 (6.4)	11.3 (7.4)	8.8 (7.1)	8.2 (6.5)	12.3 (6.4)	10.7 (5.9)	10.2 (5.9)
Missing	*15*	*53*	*53*	*15*	*28*	*18*	*0*	*25*	*35*
Duke Health Profile									
General Health Score	--	--	--	50.2 (22.0)	56.8 (20.2)	56.6 (19.3)	--	--	--
Missing	--	--	--	*22*	*45*	*31*	--	--	--
GAD-7									
GAD-7 Score	--	--	--	10.0 (7.0)	7.8 (6.6)	7.7 (6.3)	--	--	--
Missing	--	--	--	*12*	*30*	*14*	--	--	--

Table 25. Within Group Bivariate Analyses at 12 Months

	12-Month Mean (SD)	Baseline Mean (SD)	12-month (–) Baseline Mean Difference (SD)	p-value
INTERVENTION GROUP (n=243)				
BMI[b]	**34.6 (9.4)**	**33.6 (8.7)**	**0.8 (3.9)**	**0.002**
Systolic Blood Pressure	131.8 (20.5)	133.7 (19.5)	-1.5 (19.7)	0.25
Diastolic Blood Pressure	78.3 (12.1)	79.2 (11.6)	-0.6 (11.4)	0.42
Nonparametric Tests[a]	12-Month Median (IQR)	Baseline Median (IQR)		p-value
HbA1c	7.8 (3.9)	7.8 (4.3)		0.09
PHQ-9	**7.0 (9.0)**	**11.0 (11.0)**		**<0.001**
General Health	**56.7 (26.7)**	**50.0 (30.0)**		**<0.001**
GAD-7	**6.0 (11.0)**	**10.0 (12.0)**		**<0.001**
COMPARISON GROUP (n=131)				
BMI[b]	35.1 (9.9)	35.5 (9.7)	-0.4 (3.0)	0.17
Systolic Blood Pressure	**123.2 (16.8)**	**131.4 (17.7)**	**-8.2 (18.7)**	**<0.001**
Diastolic Blood Pressure	**76.0 (10.1)**	**79.6 (10.7)**	**-3.5 (11.2)**	**<0.001**
Nonparametric Tests[a]	12-Month Median (IQR)	Baseline Median (IQR)		p-value
HbA1c	5.8 (1.3)	5.9 (1.1)		0.99
PHQ-9	**8.5 (8.0)**	**11.0 (9.0)**		**0.01**

Note: Bold denotes statistical significance of p-value < 0.05

[a] The Wilcoxon Signed Rank test was used to examine non-normally distributed data

Table 26. Between Group Bivariate Analyses: Intervention vs. Comparison at 12 Months

	Full Sample (n=378) Mean (SD)	Intervention (n=243) Mean (SD)	Comparison (n=131) Mean (SD)	p value
BMI[b]	34.9 (9.6)	34.6 (9.4)	35.1 (9.9)	0.60
Systolic	**128.8 (19.6)**	**131.8 (20.5)**	**123.2 (16.8)**	**<0.001**
Diastolic	77.6 (11.5)	78.3 (12.1)	76.1 (10.1)	0.06
Nonparametric Tests[a]	Median (IQR)	Median (IQR)	Median (IQR)	
HbA1c	**5.8 (2.1)**	**7.8 (3.9)**	**5.8 (1.3)**	**<0.001**
PHQ-9	**8.0 (9.0)**	**7.0 (9.0)**	**8.5 (8.0)**	**0.004**

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

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

This final report provides an overview of findings for the evaluation of the UTRGV PCBH program. UTRGV implemented the PCBH model in two family medicine residency (FMR) clinics in McAllen and Edinburg. UTRGV implemented a QED study to compare intervention participants receiving the PCBH model with an external comparison group who received usual clinic care at Tropical Texas Behavioral Health (TTBH) Brownsville and Weslaco clinics.

This evaluation study achieved a preliminary level of evidence. This evaluation study used a QED design with a comparison group which helped mitigate major threats to internal validity. More specifically, the comparison group addressed the following threats to internal validity: regression to the mean, history, testing, and expectancy effects. Further, there was baseline equivalence and no differential attrition between the intervention group and comparison group. This study also meets the criteria for effective evidence for the following reasons. First, the study demonstrates a positive, significant finding for the confirmatory outcome (PHQ-9). Second, this confirmatory PHQ-9 achieved an effect size (using Cohen's d) of 0.31, which is interpreted as a small to medium effect. Finally, although there was a statistically significant negative intervention effect on BMI, this was not considered clinically significant. Also, while there appears to be a negative effect on blood pressure within the primary analyses, upon further analysis this was understood to be due to greater improvement in blood pressure among the comparison group rather than worsening blood pressure among the intervention group.

Despite its limitations, this study contributes to our understanding of the implementation of the PCBH model of IBH in an academic primary care setting within a low-income, Hispanic population. Lessons learned include *operational facilitators* such as strong communication, leadership support and staff buy-in, and staff training, *operational barriers* related to staff hiring and retention and data systems, the challenges of conducting population health research, and factors related to sustainability of the PCBH model at UTRGV.

Summary of Implementation Findings

The implementation evaluation examined fidelity to UTRGV's program model by conducting focus groups and interviews and examining patient visit data. The evaluation was implemented as intended except for several deviations, which included the following: UTRGV program enrollment began in July 2016 and continued through May 2017. This is a deviation from the planned timeline in the SEP. Ultimately, UTRGV recruited 366 into their intervention group (100% of the target enrollment). Due to these delays in program enrollment, the timing of interim and final reports were also delayed from what was stated in the SEP. A detailed timeline of the study can be found in **Appendix A: Revised Project Timeline**. Additional implementation deviations from the approved SEP include a change in the comparison group, changes in program staffing (see logic model components), not conducting a patient satisfaction survey (see implementation study findings), and several changes to planned analyses given the change in comparison group.

Evaluation of the implementation of UTRGV's program shows that overall the program was implemented in alignment with the program logic model and that the program was implemented with strong fidelity. UTRGV met the enrollment target for the study and 67% of their overall 12-month retention target (final sample was 243 total participants compared to a target of 256 participants.) All participants enrolled in the intervention met study eligibility criteria, and all who remained in the study

for the 12 months received the intervention as designed including physical and behavioral health services. Intervention participants received one or more visits with a behavioral health consultant while external comparison group participants received usual clinic care.

Separate AIMS checklists were completed for each clinic, one for DHR and one for MMC. UTRGV's DHR clinic reported no change in three of the five IBH core principles from baseline to 12 months and a decrease in the number of patients a principle applied to in the remaining two. There was additional change in the IBH core components and tasks with two improving, twelve remaining the same, and twelve decreasing from baseline to 12 months. UTRGV's MMC clinic reported improvements in four of the five IBH core principles from baseline to 12 months. The clinic saw no change in the fifth core principle. There was additional change in the IBH core components and tasks with twenty showing improvement from baseline to 12 months and six remaining the same over the course of the study. While the AIMS checklist provides an overall direction to check for elements of integration, the AIMS checklist is particularly designed to evaluate implementation the Collaborative Care Model of integration. The Collaborative Care Model, spearheaded by the University of Washington, is a population-based integrated behavioral health model that includes a psychiatrist, a behavioral health care manager, and the use of a structured population registry to manage depression through the use of PHQ-9. The registry, an independent data tracking system separate from the electronic medical record of the primary care team, tracks patient related changes in PHQ-9 score. The implementation of the Collaborative Care Model therefore includes specific training for staff and have assigned roles to manage the registry as well as have a psychiatric consultant working collaboratively with the behavioral health manager. The items that decreased at 12 months from baseline reflect the lack of a structured registry system, but the attempt to create one at the beginning for improved tracking of services.

Facilitators to program implementation included communication among staff, warm handoffs between primary care and behavioral health providers, staff training on the PCBH model, and flexibility among program staff in adapting workflow and processes. For patients, additional factors that facilitated their participation included satisfying patient-provider (both physician and behavioral health consultant) relationships and involvement of the community health worker as well as improvements in their health status motivating participation as the program progressed. Despite challenges with early buy-in to the program, interviewees reported strong support from both the frontline staff and project leadership, as well as positive clinic culture. Feedback from patients was generally very positive as well. Patients were receptive to program services, such as increased time for their appointments with both providers and appreciated the ability to manage their healthcare needs which also included behavioral, emotional, and psychological support.

UTRGV interviewees identified several challenges to implementing the PCBH model, including participant enrollment, a clinic culture that delayed fully learning competencies required to support the model, and inadequate data systems. Specific to the clinic culture, interviewees noted variability in provider and staff understanding of the PCBH model and delays in adopting integrated process as routine part of the clinic's process. Initial delays and failure to establish ownership of integration of behavioral health consultant was visible in processes like scheduling, completion of universal screening, and staff involvement in transitioning patients to the BHC and vice versa. According to several interviewees, meeting enrollment targets was challenging early on in implementation due to patient visit fees and limited staffing. For patients, barriers discussed included stigma, the social determinants of health, time constraints, cost, and staffing.

Summary of Impact Findings

SEP Deviations - The QED impact study and its related analyses were conducted as proposed in the SEP with several exceptions:

Comparison group – The SEP described using Nuestra Clinica del Valle (NCDV) as the comparison group for this study. While data were collected with NCDV comparison group participants, testing for baseline equivalence showed that the intervention group and original NCDV comparison group were significantly different on all outcome measures. Of the seven health outcomes collected by both UTRGV and NCDV, the groups were statistically nonequivalent on all outcomes. The imbalances of most concern were between mental health outcomes, with median PHQ-9 and GAD-7 scores between the two groups differing by 10 points. Of the 16 sociodemographic characteristics collected by both UTRGV and NCDV, the groups were only statistically equivalent on four (history of obesity, employment, race, and sex) at baseline. The groups were imbalanced on ethnicity, age, marital status, primary language, additional health history variables (diabetes, hypertension, high cholesterol, depression), physical activity, smoking status, and alcohol consumption.

After careful consideration, it was decided that a different comparison group would serve as a more effective counterfactual for the UTRGV intervention group. Therefore, participants from TTBH's Weslaco and Brownsville clinics, whose data were collected at the same time points for comparison in a different Sí Texas study, were used as the comparison group for this study. Of the five health outcomes collected by both UTRGV and TTBH at baseline, the groups were only statistically imbalanced on one measure, HbA1c. The two groups were statistically equivalent at baseline on BMI, blood pressure, and PHQ-9 scores. Of the five sociodemographic characteristics collected by both UTRGV and TTBH, the groups were statistically equivalent on sex, ethnicity, and age category. The groups were nonequivalent on primary language, county, and age. Given this, the TTBH comparison group was much more similar at baseline to the UTRGV intervention group than the original NCDV comparison group was. Therefore, the study proceeded with the TTBH comparison group for analyses.

Propensity score matching – As proposed in the SEP, only a limited set of covariates were collected among intervention and comparison groups during the study. The inclusion of TTBH as the comparison group further reduced the number of possible covariates to match on to only 4 sociodemographic measures. Given the limitations of a small number of covariates and properties of alternative matching methods, the adjusted regression approach accounting for available covariates with model selection procedure, which have been properly conducted in the analyses, should be the most appropriate approach to ascertain the intervention effect. Thus, propensity score matching was not conducted as it was not appropriate or feasible.

Multivariate analysis of HbA1c - Only a subset of the intervention sample, those with a diagnosis of or suspected of having diabetes, had a measured HbA1c during the study. Due to the small sample size at 12 months in the intervention group (n=18), further analyses beyond the bivariate analyses were deemed inappropriate for reporting due to the limitations in interpretation.

Multivariate analysis of GAD-7 – Because TTBH did not assess anxiety symptoms for their study, GAD-7 data were not collected from comparison group participants. As a result, multivariate analyses were not possible comparing the intervention GAD-7 score to a comparison group.

Multivariate analysis of Quality of Life - Because TTBH assessed functioning and quality of life using a different measure, Duke Health Profile data was not collected from the comparison group participants. As a result, multivariate analyses were not possible comparing the intervention Duke General Health score to a comparison group.

The confirmatory variable for this study was depressive symptoms as measured through the PHQ-9. 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 also showed that there is some evidence to suggest that the intervention group had a statistically significant greater trajectory of improvement in depression over time compared to the external comparison group (β=-1.70, p=.01). When stratifying by age, the intervention was significantly associated with a lower PHQ-9 score among those participants who were younger than 45 years old. On average, for those under the age of 45 at baseline, intervention participants had a PHQ-9 score 2.65 points lower than those in the comparison group (p=0.01). While multivariate analyses were not conducted for GAD-7, within group results indicated that the intervention group experienced a statistically significant improvement in anxiety symptoms, from an average score of 10.0 at baseline to 6.0 at 12 months.

Additionally, the study showed that when controlling for baseline measures and other covariates, the intervention participants demonstrated statistically significant smaller decreases when compared to the external comparison group participants for blood pressure (both systolic and diastolic) and a greater increase in BMI. On average, the systolic blood pressure of intervention participants was 7.56 mmHg higher than the comparison participants, holding all other variables in the model constant (p<0.001). Similarly, on average, the diastolic blood pressure of intervention participants was 2.76 mmHg higher than comparison participants, holding all other variables in the model constant (p=0.01). While these data represent statistically significant findings, they are not clinically significant as there was no within group decrease in blood pressure and there was no change in diagnostic category. Although this appears to be a negative intervention effect, upon further examination this was understood to be due to greater improvement in blood pressure among the comparison group rather than the intervention group worsening. Looking at within group analyses showed that both systolic and diastolic blood pressure decreased slightly among intervention patients during the study period. Finally, on average, the BMI of participants in the intervention group was a 1.12 kg/m^2 higher at 12 months than comparison participants, holding all other variables in the model constant (p=0.005). This increase in BMI among the intervention group is slightly more than would be expected clinically, given that American adults on average gain one or more pounds per year (Mozaffarian D, et al., 2011).

Lessons Learned

While the intervention and evaluation were implemented with strong fidelity, many lessons emerged that could inform other organizations interested in implementing the PCBH model.

Operational Facilitators and Barriers

As detailed in findings from the implementation evaluation, there were a number of critical elements from an operational perspective that facilitated and hindered UTRGV's implementation of the PCBH model. As a relatively new healthcare enterprise in the Rio Grande Valley, UTRGV School of Medicine's operations began in September of 2015, around the start of the PCBH implementation project.

Therefore, the greatest strength and challenge in implementing a high fidelity PCBH model has been the "newness" of the institution.

Leadership: In terms of facilitators, the combined funding mechanisms from federal, local, and private sources provided the project with momentum to collaborate directly with evolving leadership at the School of Medicine. From the beginning, the UTRGV implementation team focused on learning to articulate the PCBH initiative as a bigger strategy rather than a siloed program. Even though there were three major shifts in senior leadership during the first three years of implementation of behavioral health integration, being strategically aligned with University and School of Medicine's vision helped to elevate PCBH as a broader strategy of integration.

Technical assistance: Another facilitator was the technical assistance provided over the course of the project to orient, train, and implement the PCBH model. Relationships with the PCBH model developers helped the implementation team move in the right direction of integration. Each visit for technical assistance not only trained BHCs with a high degree of supervision and skills-based training but also reached all clinical members of the primary care team. This team included the group of faculty physicians, medical residents, medical students, and staff from each of the two FMR sites (DHR and MMC). In addition to on-the-ground technical assistance from the PCBH developers, a primary care team also had the opportunity to visit Central Washington Community Health Center to learn about its PCBH integration process. Through observation of expert modeling, this allowed UTRGV team members to develop an informed, experiential perspective on all aspects of implementation to better understand their roles and responsibilities and develop shared mental models for workflow and communication patterns.

Several operational barriers also hindered implementation for UTRGV. These ranged from hiring and retention to larger systemic disconnections such as operational and financial methods to link PCBH integration.

Staffing: As a designated healthcare professional shortage area, especially in mental health, attracting, training, and maintaining BHCs have been a struggle. Over the course of implementation three of UTRGV's trained BHC providers have either moved away from the region or have pursued other opportunities that are more in line with traditional mental health practices. Therefore, the workforce shortage has impacted growth of PCBH as well as proved to be an expensive process to retrain and get providers ready for the world of primary care behavioral health services. From a clinical point of view, the lag between hiring, training, and approximately reaching competent practice patterns has been a barrier.

Hospital affiliations: UTRGV School of Medicine's affiliations with two for-profit hospitals limited the PCBH implementation team's control over administrative services and costs to patients. With early focus on clinical skills, competencies of BHCs, and consultation process, the implementation team did not proportionately focus on operational aspects such as workflow, scheduling, full EMR integration, entire staff training, linking BHC involvement to quality metrics and other aspects of clinic operations. The implementation team delayed in their articulation of financial aspects of integration, thereby delaying overall integration of PCBH as a core strategy for the system than just a program.

Evaluation Lessons

UTRGV's success with the evaluation study can be attributed to several factors. Prior to implementing the intervention, UTRGV participated in site visits and staff training with the PCBH model developers. These activities allowed UTRGV to identify challenges with clinic flow and needs for additional staff training. However, while these preemptive strategies identified potential threats to continuous enrollment and data gathering, the larger nature of uncoordinated EMR systems between hospital systems and disproportionate technical support and access for the research team became significant barriers in data collection.

To overcome these barriers, the PCBH implementation team designed various processes to stave off system limitations. These included undergraduate student volunteers and hiring additional project staff to focus on data collection and longitudinal follow-up. Manual processes of data collection methods such as chart reviews, creation of a superbill to collect basic data for billing and research purposes, and a community health worker to follow up with patients for 6 and 12-month data collection visits were additional methods used to overcome barriers to research.

While academic medical center clinics are accustomed to conducting research, most research studies tend to be strictly controlled experiments with clear inclusion and exclusion criteria and managed patient complexity. Conducting research in a real-world primary care training setting with multiple partnerships and affiliation agreements presented significant barriers to service design and the implementation of services and data collection. As mentioned previously, because UTRGV School of Medicine's operations are fairly new, the "newness" was helpful in molding the process for PCBH implementation while at the same time posed significant challenges due to lack of infrastructure and coordination between and within systems.

Study Limitations and Implications for Future Research

It is important to note the limitations of this study. UTRGV evaluation findings show that there was evidence to suggest that the intervention group had a greater decrease in PHQ-9 and greater trajectory of improvement in depression over time compared to the comparison group. However, after 12 months in the program intervention participants were more likely than comparison group participants to experience increases in BMI over time, and the intervention participants demonstrated statistically significant smaller decreases in both systolic and diastolic blood pressure when compared to the external comparison group participants. When looking at the physical health outcomes (BMI, blood pressure) within the intervention group, the changes are small over the study period. The period of observation being only 12 months limits the ability to see long term effects of increased protective and positive factors gained from visits with BHC, 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 and 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.).

As previously discussed, the PCBH program was evaluated using a QED evaluation design with an external comparison group to minimize threats to internal validity. The comparison group was comprised of patients from TTBH's Brownsville and Weslaco clinics and received the usual care provided

at these facilities. As TTBH's patient population is SPMI, all patients received behavioral health care through the clinics. The qualifying SPMI diagnoses for TTBH's study were schizophrenia, bipolar, and major depression. For the comparison with UTRGV's intervention, those participants diagnosed with schizophrenia were excluded. Study participants in the comparison group at TTBH were referred to the nearest federally qualified health center (FQHC) or county health department for their primary care needs. Although the intervention group participants are not classified as SPMI, the baseline PHQ-9 and GAD-7 scores indicate that the group has high unmet mental health needs and baseline depression among both intervention and comparison groups was equivalent. Additionally, within the full sample, sex was found to predict the probability of a participant not completing the study; however, within each study group, sex did not significantly predict study completion within the intervention group but did in the comparison group. Females had reduced odds of dropping out of the study. This should be considered in future research and explore the barriers that men face in participating in similar studies. While the two groups' mental health may appear equivalent at baseline, more research is needed into how their mental health needs have been addressed prior to this study. For example, because TTBH is a mental health authority, their patients have existing behavioral health diagnoses and may be in more of a steady state than the UTRGV patients who may have been receiving their first behavioral health services as part of the PCBH model. Thus, the intervention group may have greater potential for change. Future research could explore how the brief intervention of BHCs can impact patients with newly diagnosed behavioral health needs.

Next Steps

The delivery of care with BHC integration continues to be strong after the research period. In addition to shifting PCBH services to OB/GYN residency program, the PCBH implementation team has partnered with senior UTRGV School of Medicine leaders to present an Integrated Behavioral Health Strategic imperative as well as train senior leadership in Integrated Behavioral Health competencies by sending them to clinical leadership training opportunities with high functioning IBH centers like Cherokee Health Systems in Tennessee and Central Washington Community Health Centers' Family Medicine Residency program.

Despite the effectiveness IBH can have on patient health, a number of persistent challenges continue to create barriers to IBH implementation. At the forefront of these concerns is deciding how to best support consumers with complex, co-morbid needs to address patient health and be financially sustainable. This program was funded by a grant from Methodist Healthcare Ministries of South Texas, Inc. through the Social Innovation Fund (and matching funds from The Valley Baptist Legacy Foundation). While understanding of and support for IBH has been increasing in the medical field, challenges remain in articulating the value of specific models, such as PCBH, in the larger healthcare environment.

To overcome these challenges, through educating, training, and raising awareness of the value of PCBH for good healthcare delivery, the PCBH implementation team has been systematically advancing the case for PCBH with the above-mentioned strategic plan, partnering with a state-level mental health policy institute, and developing PCBH as the core strategy for primary care delivery within the UTRGV health system. UTRGV has plans to expand PCBH services to other residency clinics, new UT-based primary care clinics, and work with local healthcare systems to strengthen behavioral health integration in the Rio Grande Valley.

OTHER ASPECTS OF STUDY LOGISTICS AND FEASIBILITY

Human Subjects Protection

UTRGV received Institutional Review Board approval from UTRGV for a duration of 12 months beginning February 7, 2016. In accordance with UTRGV IRB procedures, UTRGV submitted Continuing Review Forms in January 2017 and January 2018, both of which were approved for a duration of one year. No deviations in research protocol have occurred to date.

Timeline

Intervention group: SIF conditional approval to begin data collection at was received in May 2016, with final approval in August 2016. Program recruitment and baseline data collection began in July 2016 and enrollment concluded May 2017; this program had a 6-month enrollment period and utilized a rolling recruitment. 12-month follow up occurred between June 2017 and July 2018. Participant de-identified data was sent quarterly to HRiA (November 2016 – June 2018). Follow-up was completed in June 2018.

Comparison group: SIF conditional approval to begin data collection was received in November 2015. TTBH conducted enrollment on a rolling basis between November 2015 and June 2016. Six-month follow-up began in May 2016 and ended in January 2017. Twelve-month follow-up began in November 2016 and ended in June 2017.

Evaluator/Subgrantee Role and Involvement

No major changes were made to the evaluator listed in the subgrantee evaluation plan during the project period; however, there were several subgrantee personnel changes, including additional research staff, community health workers, and behavioral health consultants. The Principal Investigator of record for the study under the IRB protocol is Dr. Deepu George.

Budget

No changes were made to the evaluation budget.

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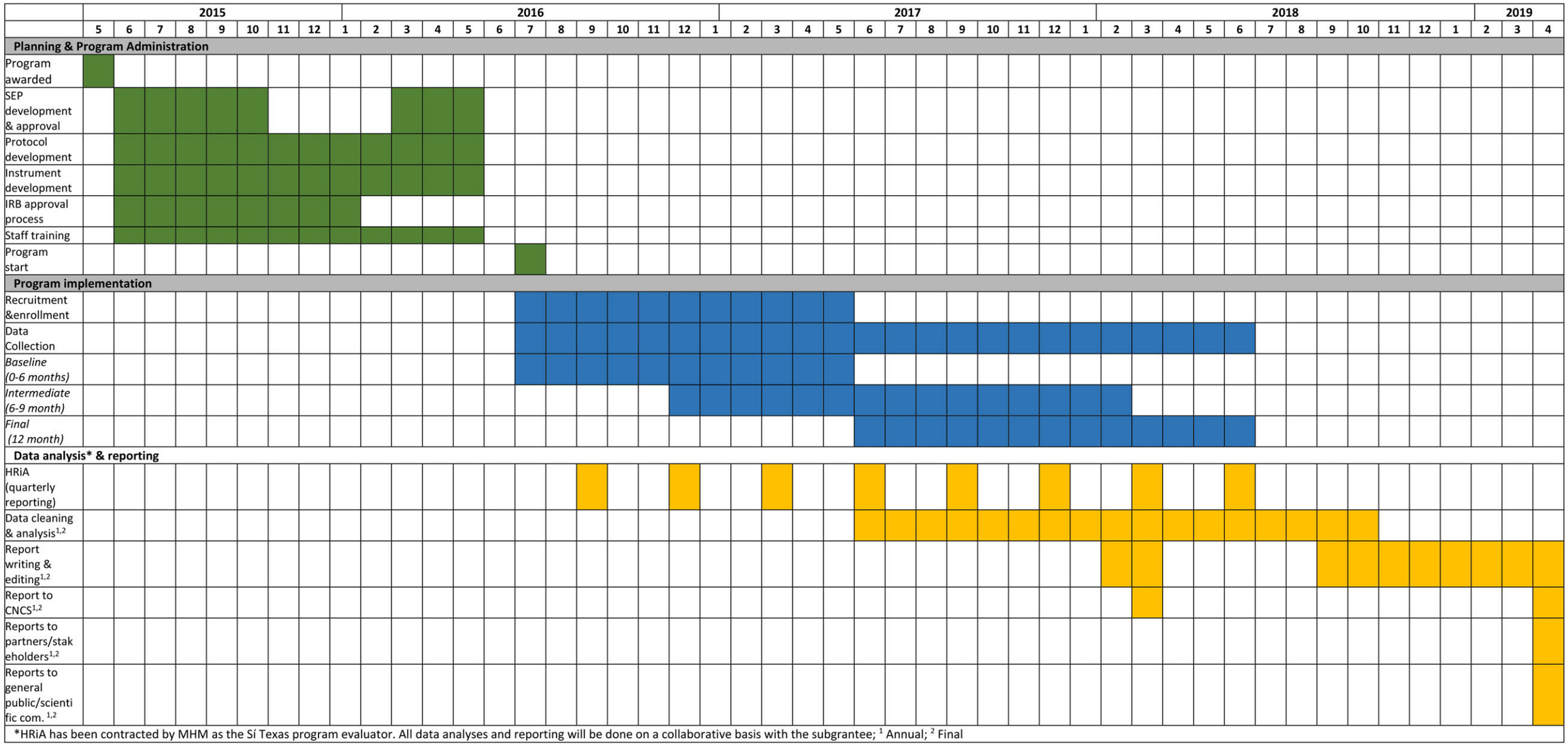
APPENDICES

Sí Texas Subgrantee: University of Texas Rio Grande Valley
Program Title: Primary Care Behavioral Health (PCBH) Implementation

Appendix A: Revised Project Timeline



Appendix B: Program Logic Model

			Outcomes		
Inputs/Resources	**Activities**	**Outputs**	**Short**	**Intermediate**	**Long**
Program personnel: • PCBH Providers (4 BHCs (1 behavioral science faculty) • PCBH leadership (medical director/ clinic manager, PCBH lead, PCBH supervisor) • Primary care team (2 family medicine programs -7 faculty, 24 residents, 5 MAs, 1 RN, 1 NP) • 1 Program Coordinator • 1 Program research assistant **Resources:** • 2 clinics • Mountainview consulting	**Clinic level:** • Develop educational materials • Provide evidence-based and appropriate training to PC team regarding PCBH • Train BHCs in PCBH competencies • Establish protocols for BHCs • Implement the PCBH model clinic-wide at both clinics • Develop group-based treatment for chronic conditions via regular review of implementation progress • Develop patient registry/EMR • Institute practices that increase population health, including BH screening and protocols for immediate access to BHC • Effectively communicate between patient, provider, and BHC	**Clinic level**: • Recruit 366 participants into each arm of the study • PC team trained on PCBH • Clinic-wide protocol for IBH screening at intake • Patient registry developed • PC team huddles • Quarterly PC team meetings to make data-driven decisions • System solutions identified and implemented **Patient level**: • Patient offered BH services through PCBH • Patient has measurement-based treatment plans	**Clinic level**: • Systems solutions implemented • PC team buy-in of PCBH model • PC team understanding of roles in PCBH model • PCP/BHC integrated visits (e.g., warm handoffs, collaborative visits) • All patient data entered in registry/EMR **Patient level**: • Patients enrolled, screened, baseline measures taken • Patients have treatment plan	**Clinic level**: • Enhanced effectiveness of PC team • PCBH model implemented with fidelity • Improved access to care for integrated services • Improved integrated clinical service provision • Patient registry data reviewed by PC teams and QI recommendations made • Providers satisfied with PCBH model **Patient level**: • Improved patient attendance and compliance with treatment plan • Increased control of physical and behavioral health and well-being • Patients satisfied with PCBH model • Improved functioning and quality of life	**Clinic level**: • 100% compliance on implementing PCBH model • 100% compliance on instituting population-based practices (regular screenings) **Patient level**: • Reduced morbidity and mortality from physical and behavioral health conditions, including Improved BMI, A1c, blood pressure, depression, anxiety, and quality of life

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

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

INTRODUCTION/INFORMED CONSENT

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

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

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

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

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

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

INTERVIEW QUESTIONS

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

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

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

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

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

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

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

6. Operations (Choose Clinic or Community as appropriate)

Clinic-based Operations

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

Community-based Operations

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

7. Patient and Provider Satisfaction

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

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

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

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

10. Closing

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

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

Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide

CORE INTERVIEW GOALS

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

INTRODUCTION/INFORMED CONSENT (2 MIN)

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

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

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

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

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

INTERVIEW QUESTIONS

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

Key Informant Background (3 MIN)

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

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

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

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

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

Adoption Facilitators and Barriers (15 MIN)

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

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

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

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

Provider and Patient Satisfaction (5 MIN)

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

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

Program Impact (5 MIN)

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

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

Sustainability and Lessons Learned (10 MIN)

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

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

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

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

Closing (2 MIN)

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

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

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

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CORE FOCUS GROUP GOALS

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

INTRODUCTION (5 MIN)

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

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

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

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

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

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

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

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

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

INTRODUCTION AND WARM-UP (5 MIN)

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

PROGRAM RECRUITMENT (10 MIN)

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

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

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

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

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

ii. What was helpful to you?

b. What did you 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 F: Implementation Evaluation Measures

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative or Quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
REACH: Did the PCBH program reach its intended target population?				
--	Demographic characteristics of participants	Eligibility criteria data	• How would you describe the population that your program is serving? • What are they like in terms of demographics generally? • Is this the population it intended to serve?	None
FIDELITY: What are the components of the PCBH program and how do these components work "on the ground" at 6 and 12 months? Are these components different than what was planned? If so, why? To what extent did the UTRGV FMR clinic implement the PCBH model with fidelity?				
What are the resources of the program?	Input: PCBH Providers	--	What is your current role?	Yes/No
What are the resources of the program?	Input: PCBH Leadership (medical director, PCBH lead, PCBH Clinical Supervisor)	--	What is your current role?	Yes/No
What are the resources of the program?	Input: Support Staff (Program Coordinator, Program Research Assistant)	--	What is your current role?	Yes/No
What are the resources of the program?	Input: Primary Care Team (faculty physicians, residents, NP, RN, Mas)	--	What is your current role?	Yes/No
What are the resources of the program?	Input: Two FMR Clinics	--		Yes/No

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative or Quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
What are the resources of the program?	Mountainview IBH consultants			Yes/No
What are the resources of the program?	Input: Methodist Healthcare Ministries	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the program activities and how have they been operationalized?	Activity: Implement the PCBH Model in two clinics	• Clinic staff educational Materials • Training logs and evaluations • PCBH clinic protocols	Since beginning the program, to what extent has the program been able to implement the PCBH program with fidelity?	Record of communication with patient
What are the program activities and how have they been operationalized?	Activity: Develop patient registry/EMR	• Operational patient registry/EMR	Since beginning the program, to what extent has the program been able to establish data systems to support the program?	
What are the program activities and how have they been operationalized?	Activity: Implement PCBH model in 2 FMR clinics	• Record of vitalization of blood pressure, height, weight, and waist circumference • Record of blood test results for HbA1c • Record of patient treatment plan created • Number of patients with all intake forms and assessments completed (e.g., PHQ-9, Duke Health Profile, etc.)	Since the beginning of the program to what extent has the program been able to implement study procedures?	None

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative or Quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
What are the program activities and how have they been operationalized?	Activity: Track, monitor, and remind patients of appointments	• Number of patients lost to follow-up • Number of patients whose eligibility status for the study changed after enrollment (e.g., pregnant, suicidal) • Show rate for primary care services • Show rate for behavioral health services • Number of clinic visits/follow-up visits received (total and by type of service)	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.	None
What are the program activities and how have they been operationalized?	Activity: Diagnosis of diabetes, obesity and hypertension by the MA.	• Record of vitalization of blood pressure, height, weight, and waist circumference • Record of blood test results for HbA1c • Record of patient treatment plan created	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.	Record of actual diagnosis

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative or Quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
Are the components different than what was planned? If so, why?	Output: Recruit 366 participants into the intervention group	• Number of target participants—intervention group • Number of patients screened for participation in the study • Number of patients consented to participate in the study • Number of patients who choose not to participate in the study • Number of patients enrolled in the program	--	None
Are the components different than what was planned? If so, why?	Output: Development of a patient care plan (including behavioral health treatment plans)	• Record of patient treatment plan created	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?	None
Are the components different than what was planned? If so, why?	Output: PCP referral for BHC services	• Number of warm-handoffs to BHCs • Number of patients who completed BHC treatment plan	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?	None

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative or Quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
INTEGRATION: What level of Integrated Behavioral Health did UTRGV FMR achieve as a result of implementing the program?				
What level of Integrated Behavioral Health did the two FMR clinics achieve as a result of implementing the program?	IBH Level	Score (measured by IBH Checklist)	--	None
To what extent have providers and program staff adopted the components of the PCBH program at 6 and 12 months?	Output: Increased understanding of integration	• Number of warm hand-offs to BHCs • Number of BHC consults requested • Number of BHC consults completed • Average number of BHC encounters/day • Percent of clinic population seen by BHCs annually • Ratio of return to initial patient visits • Percent of patients with 4 or more BHC visits	• Now that the program has been implemented, to what extent are primary care and behavioral health services connected, coordinated, combined, if at all?	None

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative or Quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
What are the facilitators and barriers to adoption?	Output: Ongoing quality improvement among clinic staff Activity: Continued clinic educational activities	--	• Please describe any barriers you or your organization has experienced in implementing the program. • In what ways did these barriers affect program implementation? In what ways have you been able to address these barriers? • Please describe anything that has helped your organization implement the program. • Probes: Is the staff, the facilities, the data systems, outside partners, or other things?	Staff/Administration satisfaction surveys
To what extend do providers buy-in to the program, and how has that buy-in affected implementation?	Activity: Administer staff satisfaction surveys Output: Provider and staff buy-in to model	--	• Have you heard any feedback from providers about program implementation? • What are some of the general themes from their feedback been?	Staff satisfaction surveys

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative or Quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
To what extent did the comparison groups received program-like components? (N/A)				
How satisfied are patients with the services they have received? How satisfied are providers with the PCBH program?				
--	--	• Patient satisfaction with program (by type of service)	• 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?	None

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative or Quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
What percent of patients were seen by primary care providers for diabetes, obesity, and/or hypertension complete standardized assessments (depression, anxiety, addiction, quality of life, and spiritual well-being) on their initial visit?				
--	--	• Number of patients with all intake forms and assessments completed (e.g., PHQ-9, Duke Health Profile, etc.) • Record of vitalization of blood pressure, height, and weight circumference • Record of blood test results for HbA1c	--	None
What percent of completed assessment results were recorded according to protocol? Were all staff able to implement standard measurement protocols?				
Are the components different than what was planned? If so, why?	Output: Use of standard measurement protocols	--	--	Percentage of participant assessments that were done using standard measurement protocols

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative or Quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
What percent of patients with depression, anxiety, and addiction were referred to the appropriate behavioral health provider?				
--	--	• Number of referrals created • Show rate for referral appointments (total and by type of service) • Number of patients receiving appropriate intervention (as determined by assessments)	--	None
What percent of patients were assessed for depression, anxiety, quality of life, and addiction on a semi-annual basis?				
--	--	Number of patients with all intake forms and assessments completed (e.g., PHQ-9, Duke Health Profile, etc.)	--	Is there record of the number of times these assessments were completed? Dates?

Appendix G: Loss to Follow-Up/Attrition Tables

Table 27. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Demographic Characteristics among the Intervention and Comparison

	Full Sample (n=730)		Completed Study (n=500)		Did Not Complete Study (n=230)		p-value
Variables	N	%	N	%	N	%	
Sex							
Male	215	29.4	134	26.8	81	35.2	**0.02**
Female	515	70.6	366	73.2	149	64.8	
Ethnicity[a]							
Hispanic/Latino	706	96.7	481	96.2	225	97.8	
Non-Hispanic/Non-Latino	23	3.2	18	3.6	5	2.2	0.57
Multiple	1	0.1	1	0.2	0	0.0	
Race[a]							
White	726	99.5	497	99.4	229	99.6	
Other	4	0.6	3	0.6	1	0.4	0.99
County							
Hidalgo	706	96.7	487	97.4	219	95.2	0.12
Other	24	3.3	13	2.6	11	7.8	
Age							
Mean	47.8	--	47.8	--	47.8	--	0.97
SD	12.9	--	12.2	--	14.3	--	
<35	118	16.2	74	14.8	44	19.1	
35-44	177	24.3	127	25.4	50	21.7	
45-54	211	28.9	147	29.4	64	27.8	0.06
55-64	164	22.5	119	23.8	45	19.6	
65+	60	8.2	33	6.6	27	11.7	
Employment							
Not Employed	444	63.3	311	64.4	133	60.7	
Employed	258	36.8	172	35.6	86	39.3	0.35
Missing	28	--	17	--	11	--	
Marital Status							
Not Married	314	43.7	210	42.6	104	46.0	
Married	405	56.3	283	57.4	122	54.0	0.39
Missing	11	--	7	--	4	--	
Primary Language[a]							
English	304	41.6	203	40.6	101	43.9	
Samar-Leyte	1	0.1	0	0.0	1	0.4	0.20
Spanish	425	58.2	297	59.4	128	55.7	
History of Diabetes							
No	430	58.9	284	56.8	146	63.5	0.09
Yes	300	41.0	216	43.2	84	36.5	

	Full Sample (n=730)		Completed Study (n=500)		Did Not Complete Study (n=230)		p-value
Variables	N	%	N	%	N	%	
History of Hypertension							
No	321	44.0	214	42.8	107	46.5	0.35
Yes	409	56.0	286	57.2	123	53.5	
History of Obesity							
No	288	39.5	187	37.4	101	43.9	0.09
Yes	442	60.6	313	62.6	129	56.1	
History of Cholesterol							
No	445	61.0	302	60.4	143	62.2	0.65
Yes	285	39.0	198	39.6	87	37.8	
History of Depression							
No	631	86.4	427	85.1	204	88.7	0.23
Yes	99	13.6	73	14.6	26	11.3	
Level of Physical Activity							
Never	330	53.0	218	51.5	112	56.0	**0.03**
1-2 times/week	86	13.8	60	14.2	26	13.0	
3-4 times/week	87	14.0	64	15.1	23	11.5	
5-6 times/week	48	7.7	40	9.5	8	4.0	
Daily	72	11.6	41	9.7	31	15.5	
Missing	107	--	77	--	30	--	
Smoking Status							
Not Current	627	85.9	433	86.6	194	84.4	0.42
Current	103	14.1	67	13.4	36	15.7	
Alcohol Consumption							
Not Current	539	74.1	371	74.2	168	74.0	0.96
Current	188	25.9	129	25.8	59	26.0	
Missing	3	--	0	--	3	--	

[a]Over 80% of cells have expected count less than 5 and Fisher's exact test was used

Table 28. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Demographic Characteristics among the Intervention

	Full Sample (n=364)		Completed Study (n=243)		Did Not Complete Study (n=121)		p-value
Variables	N	%	N	%	N	%	
Sex							
Male	111	30.5	70	28.8	41	33.9	0.32
Female	253	69.5	173	71.2	80	66.1	
Ethnicity[a]							
Hispanic/Latino	342	94.0	225	92.6	117	96.7	0.31
Non-Hispanic/Non-Latino	21	5.8	17	7.0	4	3.3	
Multiple	1	0.3	1	0.4	0	0.0	
Race[a]							
White	360	98.9	240	98.8	120	99.2	0.99
Other	4	1.1	3	1.2	1	0.8	
County							
Hidalgo	341	93.7	231	95.1	110	90.9	0.13
Other	23	6.3	12	4.9	11	9.1	
Age							
Mean	45.5	--	45.9	--	44.7	--	0.44
SD	13.7	--	12.9	--	15.0	--	
<35	88	24.2	53	21.8	35	28.9	0.41
35-44	94	25.8	66	27.2	28	23.1	
45-54	92	25.3	63	25.9	63	25.9	
55-64	58	15.9	42	17.3	16	13.2	
65+	32	8.8	19	7.8	13	10.7	
Employment							
Not Employed	211	62.8	143	63.3	68	61.8	0.80
Employed	125	37.2	83	36.7	42	38.2	
Missing	28	--	17	--	11	--	
Marital Status							
Not Married	188	53.0	122	51.5	66	55.9	0.43
Married	167	47.0	115	48.5	52	44.1	
Missing	9	--	6	--	3	--	
Primary Language							
English	204	56.0	132	54.3	72	59.5	0.35
Spanish	160	44.0	111	45.7	49	40.5	
History of Diabetes							
No	255	70.1	167	68.7	88	72.7	0.43
Yes	109	30.0	76	31.3	33	33.2	
History of Hypertension							
No	216	59.3	141	58.0	75	62.0	0.47
Yes	148	40.7	102	42.0	46	38.0	

	Full Sample (n=364)		Completed Study (n=243)		Did Not Complete Study (n=121)		p-value
History of Obesity							
No	136	37.4	91	37.5	45	37.2	0.96
Yes	228	62.6	152	62.6	76	62.8	
History of Cholesterol							
No	314	86.3	211	86.8	103	85.1	0.66
Yes	50	13.7	32	13.2	18	14.9	
History of Depression							
No	280	76.9	184	75.7	96	79.3	0.44
Yes	84	23.1	59	24.3	25	20.7	
Level of Physical Activity							
Never	147	57.2	94	56.6	53	58.2	0.09
1-2 times/week	35	13.6	20	12.1	15	16.5	
3-4 times/week	27	10.5	21	12.7	6	6.6	
5-6 times/week	12	4.7	11	6.6	1	1.1	
Daily	36	14.0	20	12.1	16	17.6	
Missing	107	--	77	--	30	--	
Smoking Status							
Not Current	285	78.3	188	77.4	97	80.2	0.54
Current	79	21.7	55	22.6	24	19.8	
Alcohol Consumption							
Not Current	250	69.3	165	67.9	85	72.0	0.42
Current	111	30.8	78	32.1	33	28.0	
Missing	3	--	0	--	3	--	

[a]Over 80% of cells have expected count less than 5 and Fisher's exact test was used

Table 29. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Demographic Characteristics among the Comparison

	Full Sample (n=366)		Completed Study (n=257)		Did Not Complete Study (n=109)		p-value
Variables	N	%	N	%	N	%	
Sex							
Male	104	28.4	64	24.9	40	36.7	**0.02**
Female	262	71.6	193	75.1	69	63.3	
Ethnicity[a]							
Hispanic/Latino	364	99.5	256	99.6	108	99.1	0.51
Non-Hispanic/Non-Latino	2	0.6	1	0.4	1	0.9	
Multiple	0	0.0	0	0.0	0	0.0	
Race							
White	366	100.0	257	100.0	109	100.0	--
Other	0	0.0	0	0.0	0	0.0	
County							
Hidalgo	365	99.7	256	99.6	109	100.0	0.99
Other	1	0.3	1	0.4	0	0.0	
Age							
Mean	50.1	--	49.6	--	51.2	--	0.24
SD	11.6	--	11.1	--	12.7	--	
<35	30	8.2	21	8.2	9	8.3	0.18
35-44	83	22.7	61	23.7	22	20.2	
45-54	119	32.5	84	32.7	35	32.1	
55-64	106	29.0	77	30.0	29	26.6	
65+	28	7.7	14	5.5	14	12.8	
Employment							
Not Employed	233	63.7	168	65.4	65	59.6	0.30
Employed	133	36.3	89	34.6	44	40.4	
Marital Status							
Not Married	126	34.6	88	34.4	38	35.2	0.88
Married	238	65.4	168	65.6	70	64.8	
Missing	2	--	1	--	1	--	
Primary Language[a]							
English	100	27.3	71	27.6	29	26.6	0.44
Samar-Leyte	1	0.3	0	0.0	1	1.0	
Spanish	265	72.4	186	72.4	79	72.5	
History of Diabetes							
No	175	47.8	117	45.5	58	53.2	0.18
Yes	191	52.2	140	54.5	51	46.8	
History of Hypertension							
No	105	28.7	73	28.4	32	29.4	0.85
Yes	261	71.3	184	71.6	77	70.6	

	Full Sample (n=366)		Completed Study (n=257)		Did Not Complete Study (n=109)		p-value
History of Obesity							
No	152	41.5	96	37.4	56	51.4	**0.01**
Yes	214	58.5	161	62.7	53	48.6	
History of Cholesterol							
No	131	35.8	91	35.4	40	36.7	0.81
Yes	235	64.2	166	64.6	69	63.3	
History of Depression[a]							
No	351	95.9	243	94.6	108	99.1	**0.05**
Yes	15	4.1	14	5.5	1	5.5	
Level of Physical Activity							
Never	183	50.0	124	48.3	59	54.1	0.16
1-2 times/week	51	13.9	40	15.6	11	10.1	
3-4 times/week	60	16.4	43	16.7	17	15.6	
5-6 times/week	36	9.8	29	11.3	7	6.4	
Daily	36	9.8	21	8.2	15	13.8	
Smoking Status							
Not Current	342	93.4	245	95.3	97	89.0	**0.03**
Current	24	6.6	12	4.7	12	11.0	
Alcohol Consumption							
Not Current	289	79.0	206	80.2	83	76.2	0.39
Current	77	21.0	51	19.8	26	23.9	

[a]Over 80% of cells have expected count less than 5 and Fisher's exact test was used

Table 30. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Health Impact Measures among the Intervention and Comparison

	Full Sample (n=730) Mean (SD)	Completed Study (n=500) Mean (SD)	Did Not Complete Study (n=230) Mean (SD)	p-value
BMI [a]	34.5 (8.2)	34.7 (8.1)	34.1 (8.4)	0.25
Systolic [a]	132.2 (19.3)	132.2 (19.0)	132.3 (19.9)	0.98
Diastolic	80.2 (10.9)	80.3 (10.9)	80.1 (11.1)	0.78
Nonparametric Tests[b]	Median (SD)	Median (SD)	Median (SD)	
PHQ-9	4.0 (7.1)	4.0 (7.1)	4.0 (7.3)	0.94
General Health	70.0 (24.5)	70.0 (24.5)	66.7 (24.7)	0.26
GAD-7	3.0 (6.7)	3.0 (6.6)	3.0 (6.8)	0.70
HbA1c	7.1 (2.2)	7.1 (2.0)	6.9 (2.5)	0.48

[a] *A log transformation was used*
[b] *The* Wilcoxon rank sum *test was used to examine non-normally distributed data*

Table 31. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Health Impact Measures among the Intervention

	Intervention (n=364)	Completed Study (n=243)	Did Not Complete Study (n=121)	p-value
	Mean (SD)	Mean (SD)	Mean (SD)	
BMI [a]	33.6 (8.7)	33.8 (8.7)	33.1 (8.7)	0.42
Systolic [a]	133.7 (19.5)	133.2 (19.6)	134.7 (19.3)	0.48
Diastolic	79.2 (11.6)	79.0 (11.5)	79.4 (11.8)	0.80
Nonparametric Tests[b]	Median (SD)	Median (SD)	Median (SD)	
PHQ-9	11.0 (7.4)	12.0 (7.3)	11.0 (7.5)	0.71
General Health	50.0 (22.0)	50.0 (21.7)	50.0 (22.6)	0.75
GAD-7	10.0 (7.0)	10.0 (7.2)	10.0 (6.9)	0.89
HbA1c	7.8 (2.6)	7.6 (2.4)	8.2 (2.9)	0.78

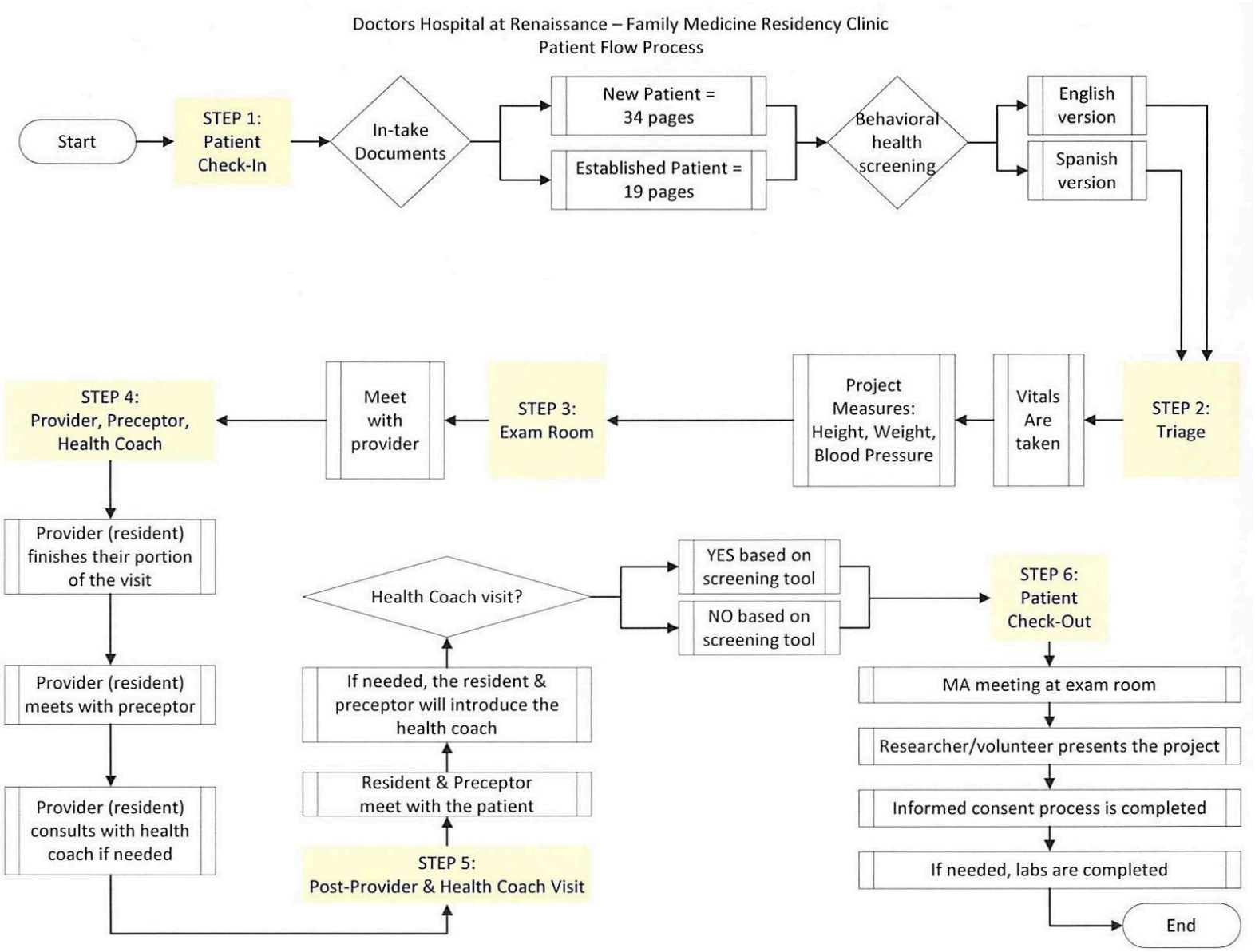
[a] *A log transformation was used*
[b] *The* Wilcoxon rank sum *test was used to examine non-normally distributed data*

Table 32. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Health Impact Measures among the Comparison

	Full Sample (n=366)	Completed Study (n=257)	Did Not Complete Study (n=109)	p-value
	Mean (SD)	Mean (SD)	Mean (SD)	
BMI [a]	35.4 (7.6)	35.5 (7.5)	35.1 (7.8)	0.53
Systolic [a]	130.8 (18.9)	131.3 (18.3)	129.7 (20.4)	0.37
Diastolic	81.3 (10.2)	81.5 (10.1)	81.1 (14.0)	0.59
Nonparametric Tests[b]	Median (SD)	Median (SD)	Median (SD)	
PHQ-9	1.0 (2.5)	1.0 (2.6)	1.0 (2.3)	0.61
General Health	86.7 (15.4)	86.7 (16.0)	83.3 (14.0)	0.30
GAD-7	0.0 (2.2)	0.0 (2.3)	0.0 (1.9)	0.83
HbA1c	6.8 (2.0)	7.0 (1.9)	6.4 (2.3)	0.33

[a] *A log transformation was used*
[a] *The* Wilcoxon rank sum *test was used to examine non-normally distributed data*

Appendix H: PCBH Patient-Flow Process



Appendix J: Patient-Centered Integrated Behavioral Health Care Checklist

Patient-Centered Integrated Behavioral Health Care Principles & Tasks

AIMS CENTER
Advancing Integrated Mental Health Solutions

About This Tool

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

The core principles

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

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

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

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

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

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

=Total Score: _____

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

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

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

Appendix L: GAD – 7

Generalized Anxiety Disorder 7-item (GAD-7) scale

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all sure	Several days	Over half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
Add the score for each column	+	+	+	
Total Score *(add your column scores)* =				

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

Not difficult at all _____
Somewhat difficult _____
Very difficult _____
Extremely difficult _____

Source: Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. *Arch Inern Med.* 2006;166:1092-1097.

Appendix M: 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.