Sí Texas: Social Innovation for a Healthy South Texas

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Final Evaluation Report:
Hope Family Health Center

Hope
Family Health Center

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

Health Resources in Action
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SIF Final Evaluation Report

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TABLE OF CONTENTS

LIST OF ABBREVIATIONS

AIMS……. Advancing Integrated Mental Health Solutions

BMI……. Body Mass Index

DHR…… Doctors Hospital at Renaissance

EMR…… Electronic Medical Record

GAD – 7…… Generalized Anxiety Disorder 7

HbA1c…….. Hemoglobin A1c

HRiA…….. Health Resources in Action, Inc.

HFHC…….. Hope Family Health Center

IBH…….. Integrated Behavioral Health

MHM…… Methodist Healthcare Ministries of South Texas, Inc.

NEIRB…….. New England Independent Review Board

PCP…….. Primary Care Physician

PHQ-9……. Patient Health Questionnaire 9

RGV……. Rio Grande Valley

SEP…… SIF Evaluation Plan

SIF……. Social Innovation Fund

EXECUTIVE SUMMARY

This final report describes the methods and findings for the evaluation of the Sí Texas Hope program at Hope Family Health Center, (HFHC), 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 HFHC in McAllen, Texas.

Program Background

Community Hope Projects, Inc. doing business as Hope Family Health Center (HFHC), located in McAllen, Texas (Hidalgo County), provides free medical, counseling, and case management services to over 1,800 uninsured individuals annually in the Rio Grande Valley. HFHC began implementing its Sí Texas Hope program, an enhanced integrated behavioral health model, into its practice to improve the health status of uninsured patients living at or below 200% of the federal poverty level in December 2015. The intervention involves moving from HFHC's current collaborative model, where medical and behavioral providers work with each other episodically, to a more fully integrated model with care coordination, shared treatment plans, shared service provision, and shared record keeping. To achieve this enhanced level of integration, HFHC changed its current primary care workflow to include a behavioral health specialist who conducts assessments, provides initial counseling (individual or group), and coordinates referrals to care management and/or community-based health services. The new model of care emphasizes more collaboration between primary care and behavioral health care providers, including enhanced communication. The study hypothesis is that an enhanced level of primary and behavioral health services offered at a charitable clinic will improve control of chronic disease (hypertension, diabetes, and obesity), reduce depression, increase access to behavioral healthcare services, and improve adult functioning and quality of life in the community for patients who are uninsured or living at or below 200% of the poverty line.

Prior Research

The integrated behavioral health (IBH) model on which HFHC based its intervention is the collaborative care model (Sanchez & Watt, 2012; Watt, 2009). The model centers around a mental health care manager and consulting psychiatrist being brought into a primary care facility to more effectively serve clients with mental health needs. The scientific literature has many examples of the effectiveness of collaborative care models including improved clinical and behavioral outcomes, provider engagement, and patient satisfaction. (Rhyne, Livsey, & Becker, 2015; Sanchez & Watt, 2012; Watt, 2009.; Guide to Community Preventive Services, 2010). HFHC's research study builds on this evidence by adapting an integrated services intervention to be culturally-relevant for the unique border community, including bilingual programming and psychoeducation. In addition, the implementation of this model within a free and charitable clinic setting with voluntary providers provides additional information regarding the feasibility of an IBH model within such a setting.

Evaluation Design

This evaluation was designed to achieve a moderate level of evidence based on the growing body of quasi-experimental and experimental evidence supporting the benefit of culturally-relevant, integrated health services (e.g., Sanchez & Watt, 2012). In addition, the implementation of this model within a

clinic setting with voluntary providers will provide additional information regarding the feasibility of an IBH model within a volunteer run clinic setting. The impact evaluation used a randomized control trial (RCT) design to compare participants receiving the enhanced delivery of integrated behavioral care with nonparticipants receiving the usual care provided within a charitable community clinic for uninsured individuals living at or below 200% of the poverty line. Patients who met the following criteria were eligible to participate in the study if they: (1) reside in Cameron, Hidalgo, Willacy, or Starr County, (2) are eligible to receive behavioral health services from HFHC (e.g., uninsured, living at or below 200% of the federal poverty level, residence in HFHC's service area), and (3) have a diagnosis of hypertension (blood pressure of 140/90 mm Hg or higher) and/or obesity (body mass index of 30.0 or higher) and/or poorly controlled diabetes (HbA1c over 6.8%) and/or moderate depression (score of 10 or above on PHQ-9).

The targeted study sample was 283 participants per study arm (i.e., intervention group and control group) with 255 participants providing 6-month follow up assessments accounting for 10% attrition at that time point, and 226 participants per study arm providing 12-month follow-up assessments accounting for 20% attrition. An incentive strategy that includes non-monetary and monetary gift cards of $10 per assessment was developed to increase enrollment, but ultimately was not implemented as planned (a deviation from the amended SEP).

HFHC retained 86.7% of the 6-month target in the intervention group (221 out of 272 returned for a 6-month follow-up assessment, 255 needed to maintain adequate statistical power). Just over three quarters (76.1%) of the 12-month retention target were retained in the intervention group (172 out of 272 returned for a 12-month follow-up assessment, 226 needed to maintain adequate statistical power). The control group reached 74.4% of the 6-month retention target (233 out of 313 returned for a 6-month follow-up assessment, 255 needed to maintain adequate statistical power). The retention target was not met in the control group at 12 months, with HFHC retaining 87.6% of the target (198 out of 313 returned for a 12-month follow-up assessment, 226 needed to maintain adequate statistical power).

The implementation evaluation focused on measuring the level of program services provided and quality of services the intervention group received relative to what was proposed. In addition, the implementation evaluation assessed control group contamination and the extent to which the control group received similar, non-intervention program services.

Description of Measures and Instruments

HFHC collected data for the Sí Texas shared impact measures: Body Mass Index (BMI) (calculated using height and weight), HbA1c (obtained via blood test), blood pressure (taken by provider), depression (using the Patient Health Questionnaire [PHQ-9]) as well as quality of life (using the Duke Health Profile). The primary impact measure is blood pressure.

Research Questions

The primary impact measure for the Sí Texas Hope program is blood pressure. Below are the confirmatory and exploratory research questions for the study:

1) Are patients who receive the enhanced IBH model of care more likely to reduce their blood pressure after 12 months compared to patients who receive the standard of care? *This question is confirmatory.*

2) Are patients with a history or diagnosis of diabetes who receive the enhanced IBH model of care more likely to improve their HbA1c after 12 months compared to patients who receive the standard of care? *This question is exploratory.*
3) Are patients who receive the enhanced IBH model of care more likely to reduce their BMI after 12 months compared to patients who receive the standard of care? *This question is exploratory.*
4) Are patients who receive the enhanced IBH model of care more likely to reduce their depressive symptoms, as measured by the PHQ-9, after 12 months compared to patients who receive the standard of care? *This question is confirmatory.*
5) Are patients who receive the enhanced IBH model of care more likely to improve their quality of life, as measured by the Duke Health Profile, after 12 months compared to patients who receive the standard of care? *This question is exploratory.*

Implementation Questions

The following evaluation questions examine program implementation and potential for replication in other locations.

1) Did HFHC's program reach its intended target population?
2) What are the components of HFHC's program and how do these components work "on the ground" at 6 and 12 months?
    a. Are these components different than what was planned? If so, why?
3) What level of Integrated Behavioral Health did HFHC achieve as a result of implementing the program?
    a. To what extent have providers and program staff adopted the components of HFHC's 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 control groups receive program-like components?
5) To what extent did the HFHC clinic implement the collaborative care model with fidelity?

Impact Analysis

This report presents descriptive statistics, analysis of baseline equivalence, and analyses of impact across the study groups. Analyses were conducted in two ways: an intention-to-treat approach and a per-protocol approach. The per-protocol approach was used to assess the impact of minimal control group contamination on intervention effects. The unit of analysis was the individual patient. Impact measures are treated as continuous variables. Generalized regression analysis results are presented as final results of the modeling sequence starting with bivariate models and ending with multiple regression models. These multiple regression models are adjusted for key demographic factors, covariates, and baseline impact measures identified as relevant via review of the scientific literature or found non-equivalent at baseline. The possibility of effect modification of the intervention-outcome relationship by patients' characteristics was also explored. Specifically, interaction terms of study group and baseline impact measures as well as age were included to understand whether there were differences in intervention effect by these characteristics. Stratified linear regression models were subsequently estimated for any model that found statistically significant effect modification.

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

Key Findings

HFHC was able to implement its IBH model to a high degree of fidelity and in alignment with the program logic model by the mid-point of implementation after modifying its clinic workflow and data collection practices. Key drivers of implementation included team building during program initiation, having initial and continued communication about the program to all staff and providers, knowing in advance what data will need to be collected for the program, having sufficient staffing and training, and building leadership buy-in. Focus group participants described the importance of the HFHC program in enabling them to improve their health. A majority of intervention participants received services from the behavioral health specialist and improved their utilization of behavioral health services compared to control participants.

HFHC's evaluation of program impact utilized a randomized control trial design with strong internal validity. It was not feasible to randomize participants to intervention and control providers due primarily to challenges in scheduling volunteer providers. However, HFHC was able to randomize participants at the individual level, and the intervention and control groups were equivalent at baseline across impact measures and demographic variables. During the study, a small minority of participants in HFHC's control group received intervention services due to challenges in implementation. The impact of contamination was found to be minimal and did not alter the outcome of the study.

When controlling for baseline measures and other covariates, intervention assigned participants did not have statistically significant improvement in either systolic or diastolic blood pressure (the confirmatory outcome) when compared to the control participants at 12 months. However, there was a statistically significant positive effect in the exploratory outcome of depressive symptoms, as measured by PHQ-9 score, in intervention compared to the control group (β= -1.67, p=0.01; d=0.29). Longitudinal analysis demonstrated this same trend in depressive symptoms when the intervention group was compared to the control group. When adjusting for intervention status and time, a significant time/group interaction was detected, 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 PHQ-9 score. Adjusting for the covariates that were selected in the primary model—age, primary language, and employment— did not alter these results. There were no statistically significant effects observed for the other exploratory outcomes (i.e., body mass index, HbA1c, and the Duke Health profile). There were no negative intervention effects on any outcome analyzed in the study.

The study also found evidence of effect modification of PHQ-9 score when stratifying by age. Among those who were the mean study participant age of 51 years or older at baseline, the intervention was significantly associated with a lower PHQ-9 score. On average, for those 51 years or older at baseline, intervention participants had a PHQ-9 score 2.08 points lower than those in the control group (p=0.01); the effect size (using Cohen's d) is 0.34. The intervention was not found to be significantly associated with PHQ-9 score among those who were under 51 years. Based on these impact analyses, the strength of the study design, and implementation with high fidelity, HFHC's study has moved the level of evidence from preliminary to moderate.

Conclusion and Next Steps

The evaluation was implemented as intended except for a deviation to the original timeline which was documented in a SEP amendment in March 2017. The recruitment period was extended to increase enrollment. HFHC conducted enrollment on a rolling basis between December 2015 and February 2017 (13 months). Six-month follow-up ended in October 2017, and 12-month follow-up ended in March 2018. While HFHC did not reach its enrollment target, sufficient sample was recruited and retained in order to detect a small change in PHQ-9 score at 12-months with statistical significance. A detailed timeline of the study can be found in **Figure 3**. HFHC did not have any changes to the budget after their SEP amendment in May 2017. The Sí Texas Study Director departed HFHC a few months before the end of the study, a change to the evaluation team. The Executive Director directed the study for the last few months of implementation.

This evaluation study achieves a moderate level of evidence given that an evidence-based intervention was adapted and evaluated using a study design with strong internal validity. This evaluation study uses an RCT design and mitigated major threats to internal validity such as selection bias. The program was implemented to fidelity, and the evaluation was conducted as intended. Despite some contamination of the control group, sub-analyses demonstrated that contamination was minimal and did not affect the outcome of the study. The study also meets the criteria for effective evidence for the following reasons. The study demonstrates a positive, significant finding for an exploratory outcome (PHQ-9). The study showed that, when controlling for baseline measures and other covariates, the intervention participants had significantly greater improvements in an exploratory outcome (PHQ-9, β=-1.67, p=0.01) at 12 months compared to the control participants, consistent with prior research. This statistically significant outcome achieved a small effect size (Cohen's d=.29). There were no negative intervention effects on confirmatory or exploratory outcomes. Given the internal validity of this study, the fidelity to which the evaluation and program were implemented, the significant results, and the unique and important contribution to the field, this study achieves a moderate level of evidence to improve our understanding of the impact of an integrated behavioral health approach within a free and charitable clinic setting.

The implementation of HFHC's IBH program in a charitable clinic setting has shown that such an approach is feasible and has potential benefits for uninsured patients living at or below 200% of the FPL in a US-Mexico border community. This evaluation contributes to our understanding of the impact of the integration of primary care services and behavioral health services within a free and charitable clinic context. HFHC's RCT is one of the first RCTs examining IBH models in a setting that serves uninsured predominately Hispanics living in poverty at the US-Mexican border. Moreover, this study is the first of its kind in examining IBH implementation in a clinic that exclusively uses volunteer primary care providers. HFHC was not ultimately able to obtain buy-in from volunteer providers but this did not impede implementation of other parts of the program. HFHC's investment in team building during program initiation, prioritizing staff training, and finding appropriate staff to implement the program paid off.

Moving forward, HFHC has sustained its IBH approach and is pursuing funding mechanisms to ensure its future sustainability. While HFHC is a free and charitable clinic, ensuring patients have access to IBH services such as the behavioral health specialist will require consistent funding to ensure access. Sustaining IBH services is made more challenging at HFHC since patients are uninsured and thus HFHC does not have the benefit of insurance reimbursement to defray costs. As HFHC moves ahead in its service implementation after the study, it is planning to continue its IBH model in its facility and to apply

knowledge from this evaluation to obtain additional grant funding and to improve efficiency within the clinic.

INTRODUCTION

This final report describes the methods and findings for the evaluation of the program, Sí Texas HOPE, at Hope Family Health Center (HFHC), 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 at HFHC in McAllen, Texas by the external evaluation contractor, Health Resources in Action (HRiA). The intended audience of this report is the Social Innovation Fund, although excerpts will also be used by Methodist Healthcare Ministries program staff and leadership and internal leadership at HFHC.

Program Definition and Background

Residents of the Rio Grande Valley (RGV) have among the worst health outcomes in the nation. Rates of chronic disease and related mortality among the general population of the RGV exceed those in most other regions of the state and the nation. Based on a study of 2,000 Mexican American adults from 2003 to 2008 called the Cameron County Hispanic Cohort (CCHC), researchers at the University of Texas School of Public Health at Brownsville found that 31% of participants had diabetes and 81% were either obese (49%) or overweight (32%) (Fisher-Hoch et al., 2012). The study also concluded there are a significant number of cases of undiagnosed diabetes in the RGV in comparison, far more than the lower self-reported prevalence rates identified by the Centers for Disease Control's (CDC) 2010 Behavioral Risk Factor Surveillance System (BRFSS).

Poverty is pervasive along the Texas southern border with Mexico, placing border residents at high risk for poor health status. According to the U.S. Census Bureau, based on the 2013-2017 American Community Survey, the McAllen-Edinburg-Mission metropolitan statistical area (MSA) had the lowest per capita personal income of the 381 MSA in the country followed by the Brownsville-Harlingen MSA. With over 27.8% of families living below the poverty level and 15.5% of children uninsured, Hidalgo County is a major site for concentrated effects of poverty. Residents living in high-poverty areas deal with higher rates of crime and other structural deficits along with stressful effects of being poor and marginalized without access to resources. They are also less likely to have completed high school, have higher unemployment, and often live below the poverty line. Border residents are more likely to be exposed to environmental hazards and have higher rates of chronic physical as well as mental health concerns (Cohen et al., 2003; Diez Roux et al., 2001; Quercia & Bates, 2009). For example, in a health survey of Rio Grande Valley/Lower South Texas, 20.4% of respondents reported depressive episodes. These same respondents had an education that was less than high school and 16.7% had an income of less than $25,000 (Davila, Rodriguez, Urbina, & Nino, 2014).

Insufficient access to mental health treatment and services remains one of the most pressing issues facing Texas. The state ranks 49th in state per capita mental health funding, spending $39 per person on mental health, compared with a national average of $121 (Texas State Mental Health Agency). The U.S. Department of Health & Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA) (2014) noted that approximately 62.5% of adults diagnosed with Any Mental Illness (AMI) in Texas did not receive treatment. In low-income areas like the RGV, the needs are compounded by lack of appropriate access to healthcare, especially for residents who are poor and uninsured. In the RGV, there are only 15.5 family physicians per 100,000. There are even fewer behavioral health providers. The ratio for mental health providers to individuals in Texas is 1:1010. In Hidalgo County, it is 1:1,970 (County Health Rankings, 2018).

The lack of public health infrastructure in Hidalgo County further exacerbates challenges in accessing high-quality mental health care as well as primary care. Hidalgo County is home to *colonias*, which are defined as unincorporated settlement of land along 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 Rio Grande Valley/Lower South Texas, there are a total of 1902 *colonias* of which 943 are located in Hidalgo County (Davila et al., 2014). *Colonia* residents rely on an episodic system of care depending on funding and strained social programs with limited capacity. The presence of risk factors stemming from limited access to care, concentration of poverty, and highest concentration of colonias, Hidalgo County presents many opportunities to intervene for several unmet health (physical and behavioral) challenges.

Community Hope Projects, Inc. doing business as Hope Family Health Center (HFHC), located in McAllen, Texas (Hidalgo County), provides free medical, counseling, and case management services to over 1,800 uninsured individuals annually in the RGV. All patients who are provided medical care and mental health counseling at HFHC are 100% uninsured and do not qualify for any government funded medical assistance. The adults and families served at HFHC are low income with a household income less than $14,000 for a family of four compared to the state average of $51,900 (U.S. Census Bureau, 2013).

In the context of an increasingly fragmented behavioral and primary health care system, uninsured individuals living in poverty in the RGV are in need of specialized support to access health care services. Hope Family Health Center's (HFHC) Integrated Behavioral Health Program is aimed at removing barriers between behavioral and primary care by implementing co-location of these services supported by care management. Without effective intervention, it is likely individuals living in HFHC's service area would not receive timely integrated care due to regional healthcare disparities, poverty, and lack of insurance.

HFHC began implementing an enhanced integrated behavioral health (IBH) model into its practice to improve the health status of uninsured patients living at or below 200% of the federal poverty level in December 2015. The intervention involves moving from HFHC's current collaborative model, where medical and behavioral providers work with each other episodically, to a more fully integrated collaborative care model with care coordination, shared treatment plans, shared service provision, and shared record keeping. To achieve this enhanced level of integration, HFHC has changed its current primary care workflow to include a behavioral health specialist who will conduct assessments, provide initial counseling (individual or group), and coordinate referrals to care management and/or community-based health services. The new model of care emphasizes more collaboration between primary care and behavioral health care providers, including enhanced communication. The study hypothesis is that an enhanced level of primary and behavioral health services offered at a charitable clinic will improve control of chronic disease (hypertension, diabetes, and obesity), reduce depression, increase access to behavioral healthcare services, and improve adult functioning and quality of life in the community for patients who are uninsured or living at or below 200% of the poverty line. The evaluation targeted a moderate level of evidence with a randomized control trial design (RCT).

HFHC's recruitment target was 283 participants in each of the two study groups (intervention group and control group) totaling 566 participants. HFHC's program enrolled a total of 585 participants, including 272 in the intervention group and 313 participants in the control group, reaching 103.4% of their enrollment target overall, 96.1% for their intervention group, and 110.6% for their control group.

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 IBH 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., 2009b). In Austin, Texas for example, People's Community Clinic used the IBH model to enable adult clients diagnosed with depression and anxiety to receive psychiatric medication, counseling and education. The clinic had tremendous success with the program, achieving treatment results typically seen only in controlled clinical trials. The studies concluded that the IBH model improved primary care patients' mental health outcomes with a minimal investment of resources (Sanchez & Watt, 2012). Similarly, a study by Bridges et al. (2013) revealed that Latinos who participated in IBH care had significant improvements in symptoms and expressed high satisfaction with integrated health treatment.

The IBH model on which HFHC is basing its intervention is the collaborative care model which has been well described in the literature (e.g., Guide to Community Preventive Services, 2010; Sanchez & Watt, 2012; Watt, 2009; Gilbody et al., 2006). The model centers around a mental health care manager and consulting psychiatrist being brought into a primary care facility to more effectively serve clients with mental health needs. HFHC proposed to replicate the models studied by Sanchez and Watt (2012) and Watt (2009)—though HFHC's proposed intervention is not identical. HFHC planned to utilize a primary care physician, care manager (Master of Social Work level) and consulting psychiatrist, which is similar to the delivery and content of the studied interventions.

Significant evidence does exist for the proposed collaborative care model's effectiveness. Gilbody et al. (2006) conclude, "The evidence base [supporting the collaborative care model] is now sufficient for the emphasis to shift from research to dissemination and implementation." Though no previous evaluation studies have been conducted at HFHC, based on the existing evidence of multiple control trials of similar interventions, there is a preliminary level of evidence to support their intervention.

Appendix A: Prior Research presents an overview of prior research done on integrated behavioral health integration with primary care in predominantly Hispanic communities.

Based on the evidence available, and the model specifications for the HFHC model, the incoming level of evidence was preliminary and aimed to advance towards a moderate level of evidence.

Program Components

HFHC's theory of change was that identifying and removing barriers to full integration of primary and behavioral health care in a charitable care setting would lead to significant improvements in obesity, diabetes, and behavioral health such as depression and anxiety for the poor and uninsured living in the RGV. As mentioned in the Prior Research section, HFHC used a collaborative care model (Sanchez & Watt, 2012; Watt, 2009). The planned activities of the HFHC approach were based on those elements present in the Sanchez and Watt model (2012) including: care management, access to behavioral health specialists, and psychiatric consultations that have been linked to improved health outcomes in the evidence base. HFHC built upon these models by adapting integrated services to be culturally-relevant for the unique border community, including bilingual programming and psychoeducation. In addition, the implementation of this model within a clinic setting with voluntary providers would provide

additional information regarding the feasibility of an IBH model within a volunteer run clinic setting. The logic model in **Appendix C: Logic Model** visually outlines the inputs, activities, outputs, and outcomes for the program, while these elements are discussed narratively below. The roles of the care coordinator and behavioral health specialist in providing warm hand offs is clarified in this report, which was previously not described in the SEP or interim report.

Inputs:

The HFHC logic model had six inputs.

- Primary care volunteers: HFHC staffs volunteer primary care providers (all physicians) who see patients by appointment.
- Counseling services: HFHC utilizes counselors (i.e., clinical therapists, master level social workers and master level student interns) who provide behavioral health services to patients by appointment.
- Behavioral health specialist: The behavioral health specialist provided behavioral health interventions (brief therapy), educated medical providers and patients on behavioral health diagnoses and integrated care. The behavioral health specialist also screened patients for counseling services and provided some warm handoffs between primary/preventative and behavioral health care services.
- Care coordinator: The care coordinator was responsible for care coordination and warm handoffs between primary/preventative and behavioral health care services. The care coordinator tracked and monitored patient health, as well as improved preventative care through health promotion and risk reduction training.
- Electronic medical records: HFHC used several data systems during the study period: an EMR (Practice Fusion) for primary health and an MS Access database for behavioral health. Sí Texas data was stored in an MS Access database. In the original SEP, the plan was that data systems would be merged to one EMR for streamlined communication prior to the intervention. This change did not occur until after the study ended.
- Community based chronic disease programs: HFHC referred patients to community based chronic disease programs including *Salud y Vida* (diabetes control), Laughter Yoga, and nutrition education.

Activities:

The activities section of the logic model provides an overview of HFHC's programmatic activities and are outlined below:

- Individual Level: Care plans were tailored and revised to individual patient needs.
- Provider Level: Primary care physicians diagnosed chronic illness and identified patients in need of mental health services based on the clinical interview, physical evaluation, and PHQ-9 scales.
- Clinic Level: Behavioral health staff interviewed patients and screened for level of mental health need and any substance abuse risk or concern. Behavioral health staff provided care as indicated. Care coordinator conducted warm hand offs.
- Health System Level: Patient data was monitored and tracked through streamlined Electronic Medical Record (Practice Fusion).

In addition to clinic-related activities, referrals were made to South Texas Behavioral for psychiatric evaluations and other related needs, based on individualized patient need. The SEP described that HFHC would use a consulting psychiatrist to review cases with the care coordinator and staff counselors. However, HFHC was not able to implement this component of their program due to challenges in finding

an individual to serve in this role. HFHC changed their implementation plan and adapted their model to field conditions. The change to making psychiatry referrals ensured continuity in providing psychiatric services to patients.

Outputs:

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

- Recruit 283 participants into each arm of the study (intervention group and control group)
- Improved adherence to patient care plans
- Increased connections to community resources and chronic disease management programs
- Improved compliance with treatment and attendance follow-up appointments
- Improved provider collaboration and communication

All activities and outputs identified in the logic model were evaluated as part of the implementation evaluation and were expected to influence the expected short-, intermediate-, and long-term outcomes. Short-term and intermediate-term outcomes are presented in this final report.

Short-Term Outcomes:

Short-term outcomes are the changes that are expected to occur during the first nine months of the program. Expected short-term outcomes are outlined below. In the course of enrollment, patients were expected to improve knowledge of self-management and disease prevention. Through participation, it was expected that patients would progressively improve their habits, become more responsive, and thereby establish habits, routines, and schedules for healthy living. Below are the expected short-term outcomes. All short-term outcomes will be measured and reported on during the study.

- Individual Level: improved patient knowledge; adherence to therapy
- Provider Level: improved communication across providers; awareness of IBH best care practices
- Clinic changes: closer collaboration between providers; workflow alignment across primary and behavioral health

Intermediate Outcomes:

Intermediate outcomes are the expected changes during the first 15 months of the program. Below are the expected intermediate outcomes. All intermediate outcomes were measured and reported on during the study unless otherwise noted.

- Increased control of blood pressure, weight, and HBA1c level
- Risk factor reduction through lifestyle modification and clinical intervention (not measured)
- Reduced systolic blood pressure levels, BMI, HbA1c, depressive symptoms
- Increased functioning and quality of life

Long-Term Impact:

Long-term outcomes are the changes that are expected to occur after the first 21 months of the program. Below are the expected long-term impacts. Long-term measures were not collected or reported in the final report because the timeline for achieving these changes fell outside of the study period. This is a change from the SEP which stated that these outcomes would be reported on during the study. Long-term outcomes are outlined below.

- Barriers to access of care significantly reduced as measured by numbers of new patients receiving behavioral care
- Improved population health management
- Reduced disparities in complications from hypertension, obesity, diabetes, and depression

The activities in this logic model represent an adaptation of the collaborative care model (e.g., Guide to Community Preventive Services, 2010; Sanchez & Watt, 2012; Watt, 2009; Gilbody et al., 2006), as noted in the Prior Research section. The HFHC model is similar in the delivery and content of the studied interventions, but with a primary care physician and care coordinator (Master of Social Work level).

Overview of Impact Study

The study conducted a random assignment experimental design, commonly referred to as a randomized control trial (RCT), to compare participants receiving the enhanced delivery of integrated behavioral care with nonparticipants receiving the usual care. The study targeted a moderate level of evidence based on the growing body of quasi-experimental and experimental evidence supporting the benefit of culturally-relevant, integrated health services. Given that the proposed study modified and adapted models to be culturally relevant to the unique border community, the existing level of evidence was preliminary.

Research Questions

HFHC's subgrantee 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 as presented in the subgrantee evaluation plan. The final implementation evaluation included focus groups as well as interviews and assessment of quantitative implementation data.

1) Did HFHC's program reach its intended target population?
2) What are the components of HFHC's program and how do these components work "on the ground" at 6 and 12 months?
    a. Are these components different than what was planned? If so, why?
3) What level of Integrated Behavioral Health did HFHC achieve as a result of implementing the program?
    a. To what extent have providers and program staff adopted the components of HFHC's 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 control group receive program-like components?
5) To what extent did the HFHC clinic implement the collaborative care model with fidelity?

Impact Questions

The primary impact measure for the Sí Texas HOPE program is improvement in blood pressure. Below are the confirmatory and exploratory research questions as presented in the SEP. This final report presents findings labeled by Impact Question.

1) Are patients who receive the enhanced IBH model of care more likely to reduce their blood pressure after 12 months compared to patients who receive the standard of care? *This question is confirmatory.*
2) Are patients with a history or diagnosis of diabetes who receive the enhanced IBH model of care more likely to improve their HbA1c after 12 months compared to patients who receive the standard of care? *This question is exploratory.*
3) Are patients who receive the enhanced IBH model of care more likely to reduce their BMI after 12 months compared to patients who receive the standard of care? *This question is exploratory.*
4) Are patients who receive the enhanced IBH model of care more likely to reduce their depressive symptoms, as measured by the PHQ-9, after 12 months compared to patients who receive the standard of care? *This question is confirmatory.*
5) Are patients who receive the enhanced IBH model of care more likely to improve their quality of life, as measured by the Duke Health Profile, after 12 months compared to patients who receive the standard of care? *This question is exploratory.*

Contribution of the Study

The evaluation contributes to our understanding of IBH services in charitable clinics serving predominantly low-income, Hispanic communities. The evaluation targeted a moderate level of evidence based on the growing body of quasi-experimental and experimental evidence supporting the benefit of culturally-relevant, integrated health services. In addition, the implementation of this model within a clinic setting using voluntary providers will provide information regarding the feasibility of implementing an IBH model within a volunteer run clinic setting.

SIF Evaluation Plan Updates

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

A deviation to the original timeline occurred which was documented in a SEP amendment in March 2017. HFHC conducted enrollment on a rolling basis between December 2015 and February 2017 (13 months) which was 7 months longer than the original SEP. HFHC amended their SEP to include incentives as a mode of boosting enrollment and retention rates. However, HFHC ultimately did not implement this component. Staff misunderstood study procedures and distributed incentives to most study participants well after the study had ended. The implementation evaluation describes incentive procedure implementation challenges in depth.

IMPLEMENTATION STUDY: STUDY APPROACH, METHODS, AND FINDINGS

Implementation Study Design

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

Qualitative Data Collection Methods and Analysis

The program's evaluator, Health Resources in Action (HRiA), conducted qualitative data collection at two points in time for the implementation study. Across the two points in time, a total of 13 staff were interviewed (7 staff participated in both the mid-point and the summative interviews). A total of 18 patient participants were involved in focus groups.

For the mid-point interviews (October 2016) a total of 10 staff interviews were conducted in-person. Mid-point interviews were intended to be conducted approximately 6 months after initial study enrollment. Given logistics challenges, these interviews instead were conducted approximately 10 months after initial study enrollment, a deviation from the SEP. After the study concluded, 13 interviews were conducted (in mid-May 2018, approximately one month after the study ended). Interview participants included clinical providers (both volunteer primary care providers and behavioral care) 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 D: Sí Texas Mid-Point Implementation Evaluation: Key Informant Interview General Guide** and **Appendix E: Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide** 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 participants after study implementation concluded (in mid-May, approximately one month after the study ended). The goal of the focus groups was to better understand the influence the program has had on participant's health and wellbeing. **Appendix F: Sí Texas Summative Implementation Evaluation: Focus Group Guide** presents the semi-structured focus group guide used to conduct the focus groups at the final data collection period. **Appendix G. Implementation Evaluation Measures** presents all implementation program components/activities, outputs and outcomes that were measured using the qualitative data collection.

There was a total of 18 intervention participants in the two focus groups, ranging from 6 to 12 participants per focus group. **Table 1** describes participant demographics from both focus groups who voluntarily completed the survey form. All participants lived in Hidalgo county and most were female (70.6%). A majority of participants were between the ages of 45 and 64 (66.7%). Participants were exclusively Hispanic or Latino. Most participants were White (78.6%) and spoke Spanish as a primary language (52.9%). Most participants had less than a high school diploma (64.7%) and did not have health insurance (94.1%).

Table 1. HFHC Pre-Focus Group Demographics Survey

	HFHC (n=18)	
Measure	N	%
County		
Hidalgo	18	100.0
Missing	--	--
Sex		
Male	5	29.4
Female	12	70.6
Missing	*1*	--
Age		
<35	1	5.6
35-44	4	22.2
45-54	7	38.9
55-64	5	27.8
65+	1	5.6
Missing	--	--
Ethnicity		
Hispanic/Latino	17	100.0
Missing	*1*	--
Primary Language		
Spanish	9	52.9
English	6	35.3
Spanish and English	2	11.8
Missing	*1*	--
Education		

Less than a high school diploma	11	64.7
High school degree or equivalent (e.g., GED)	3	17.7
Some college, junior college, or vocational school	3	17.7
College degree or more	0	0.0
Missing	*1*	--
Health Insurance		
None	17	94.4
Missing	*1*	--

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 both focus groups were bilingual in Spanish and English.

All interviews and focus groups were recorded digitally and transcribed. For the summative interviews and focus groups, two trained team members initially reviewed transcripts to develop a mutually-agreed upon codebook using a grounded theory approach. They then independently coded each transcript for themes using NVivo qualitative data analysis software (NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 12) and met to discuss concordance and discordance between their coding schemes. Differences were reconciled through discussion until a consensus on the first-level of coding was reached (average kappa=0.95), 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.

Implementation Study Findings

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

Question 1. Did HFHC's program reach its intended target population?

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

All HFHC clinic patients were eligible for the intervention study if all of the following criteria were met:

- Resided in Cameron, Hidalgo, Willacy, or Starr County
- Were eligible to receive behavioral health services from HFHC (e.g., uninsured, living at or below 200% of the federal poverty level, residence in HFHC's service area)
- Had a diagnosis of hypertension (blood pressure of 140/90 mm Hg or higher) and/or obesity (body mass index of 30.0 or higher) and/or poorly controlled diabetes (HbA1c over 6.8%) and/or moderate depression (score of 10 or above on PHQ-9).

HFHC's SEP originally stated poorly controlled diabetes would be defined by an 8.0% HbA1c cutoff, but this was an error in the SEP. The 6.8% level is HFHC's clinic established standard for defining poorly controlled diabetes.

HFHC enrolled 585 participants into the intervention (n=272) and control groups (n=313). Participants primary lived in Hidalgo County. Most of the participants enrolled in the study were female (73.7%), Hispanic (82.7%), spoke Spanish as their primary language (88.4%), and were unemployed (98.8%). The average participant age was 50.9 years and just over half of the study population was married (51.1%). Data are presented in **Table 2**. All study participants met the eligibility criteria. The prevalence of the individual eligibility criteria among the enrolled sample is provided in **Table 3**.

Table 2. Participant Demographic Descriptive Statistics

	Full Sample (n=585)		Intervention Group (n=272)		Control Group (n=313)	
Measure	N	%	N	%	N	%
Gender						
Male	154	26.3	71	26.1	83	26.5
Female	431	73.7	201	73.9	230	73.5
Ethnicity						
Hispanic/Latino	484	82.7	217	79.8	267	85.3
Non-Hispanic/Non-Latino	101	17.3	55	20.2	46	14.7
County						
Hidalgo	576	98.5	270	99.3	306	97.8
Other	9	1.5	2	0.7	7	2.2
Age						
≤ 34	41	7.0	16	5.9	25	8.0
35-44	110	18.8	50	18.4	60	19.2
45-54	207	35.4	98	36.0	109	34.8
55-64	194	33.2	95	34.9	99	31.6
65+	33	5.6	13	4.8	20	6.4
Mean	50.9	--	51.3	--	50.6	--
SD	10.6	--	10.4	--	10.7	--
Employment Status						
Employed	7	1.2	2	0.7	5	1.6
Not Employed	578	98.8	270	99.3	308	98.4
Marital Status						
Divorced	49	8.4	21	7.7	28	9.0
Married	299	51.1	137	50.4	162	51.8
Partner	10	1.7	6	2.2	4	1.3
Separated	60	10.3	23	8.5	37	11.8
Single	132	22.6	65	23.9	67	21.4
Widow/Widower	35	6.0	20	7.4	15	4.8
Primary Language						
Spanish-speaking	517	88.4	244	89.7	273	87.2
English-speaking	68	11.6	28	10.3	40	12.8

Table 3. Prevalence of Eligibility Criteria in HFHC Intervention and Control Group Participants

Eligibility Criteria	Prevalence in Enrolled Sample
Cameron, Hidalgo, Willacy, or Starr County	**98.8%**
Cameron	0.3
Hidalgo	98.5
Starr	1.0
Zapata[a]	0.2
Were eligible to receive behavioral health services from HFHC	**100.0%**
Diagnosis of hypertension (blood pressure ≥ 140/90 mmHg) **and/or** obesity (body mass index ≥ 30.0) **and/or** poorly controlled diabetes (HbA1c ≥ 66.5%) **and/or** moderate depression (PHQ-9 score ≥ 10).	**100.0%**
1 diagnosis	54.2
2 diagnoses	32.5
3 diagnoses	12.1
4 diagnoses	1.2

[a]One individual who enrolled in the study indicated he or she was from Zapata, a County outside the service area. This individual did not complete the study and is not included in analytic models.

Question 2. What are the components of HFHC's 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? If so, why?

How Components Work "On the Ground"

Interviews explored how the program was implemented. When asked about how behavioral health and primary care services were coordinated and connected, interview participants highlighted communication practices, data systems, and workflows as the key components of HFHC's integrated model. Data systems and workflows were also mentioned at the mid-point of implementation.

Communication

According to interviewees, communication was a core component of HFHC's integration strategy. Both in-person and electronic communication strategies were mentioned as essential components of clinic integration. Daily morning huddles, weekly integrated team meetings with case reviews, patient chart notes and color-coding were highlighted as key facilitators that improved team-based collaboration and patient care. Interviews noted that these huddles and meetings allowed the whole care team the space and time to discuss individual patients as well as the clinic's integrated systems.

Data Systems

In addition to communication practices discussed above, the primary form of electronic communication for HFHC's IBH model was its data system. HFHC tailored the clinic's existing Access database for the Sí Texas program. Interviewees described how the database facilitated integration by allowing providers to see notes from colleagues from behavioral and primary care. While the Access database was seen as a facilitator to integration, HFHC employed several data systems during the study period that were not

interoperable. As a result, it was necessary for staff to tag Sí Texas patients in both the Access database as well as by their paper charts to ensure that patients were contacted for 6 and 12-month follow-up appointments.

From an operational perspective, staff described challenges adapting to the multiple data collection systems including a scheduling system, a formal electronic medical record (i.e., Practice Fusion), paper charts, and Access. While this clinic-wide challenge was not unique to the Sí Texas program, interviewees described data tracking and monitoring as a cumbersome task that often took time away from serving patients. Participants shared the that the addition of the early-2018 data specialist position mitigated these challenges and was seen as greatly improving the clinic's ability to regularly monitor and track clinic data.

Workflow

Workflow, or how patients and staff move within the clinical space, was seen as a key component of integration and closely tied to HFHC's communication practices and data system. Interview participants acknowledged that, at the start of the program, staff had difficulty establishing a new workflow that included new staff and processes, such as increased data collection. Several staff were described as being resistant and inflexible to new processes, resulting in bottlenecks in the process that exacerbated long wait times for patients. However, according to several clinical and administrative staff interviewees, the Sí Texas program staff took the lead in continuously shifting the workflow to ensure that patients saw all necessary staff in a timelier manner. From the staff perspective, clinical operations adapted in order to implement the IBH model. For example, interviewees described how workflows were modified in order for staff to have sufficient time to make referrals and to coordinate with other providers. Tools such as a clinic-wide clinical checklist facilitated this process and enhanced communication and coordination among staff. As an administrative staff interviewee shared, *"We do have a checklist that we've been doing… We check each patient that is in Sí Texas to see if did they receive all the services, if all the notes are in the system."* From the patient perspective, interview and focus group participants perceived the number of "touches" with providers increased and wait times decreased. This was also supported by several adaptations to the clinical space, in which an additional exam room and a second patient lobby were created to improve workflow and patient experience.

Question 3. What level of integrated behavioral health did HFHC achieve as a result of implementing the HFHC program?

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

Implementation of Integrated Behavioral Health

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

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

HFHC completed the AIMS IBH checklist in November 2015 (pre-intervention implementation) and February 2019 (post-intervention implementation). **Table 4** presents HFHC's AIMS IBH checklist assessment of core principles. HFHC reported a positive change in all four of the IBH core principles that apply to HFHC's model from baseline to 12 months. The fifth principle, accountable care, was evaluated at baseline but later deemed not applicable since HFHC is a free and charitable clinic. Three of the four principles increased from "none" at baseline to "most/all" after the implementation period. The core principle of evidence-based care increased from "some" at baseline to "most/all" at the completion of the project. **Table 5** presents HFHC's evaluation of IBH core components and tasks. Improvement was noted in all seven core components. Most notably, HFHC changed its program oversight and quality improvement from "none" at baseline to "most/all" across all tasks within that component. Only one task within the evidence-based treatment component did not change across all 26 tasks in the checklist: prescribe and manage psychotropic medications as clinically indicated. This task was not a focus of HFHC's intervention.

Table 4. Hope Family Health Center IBH Checklist Baseline to 12 months: Core Principles

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

Accountable Care Providers are accountable and reimbursed for quality care and outcomes.	•		N/A at 12 months

• Response at baseline ✓ Response post-intervention

Table 5. Hope Family Health Center IBH Checklist Baseline to 12 months: Core Components and Tasks

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

We apply this principle in the care of (none, some, most/all) our patients.			
	None	Some	Most/All
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	•	✓	
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 post-intervention

Program Adoption

The majority of program components were implemented and did not require any major changes to implement successfully. Interview and focus group participants were asked 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 HFHC staff members and study participants.

Adoption Facilitators

At the mid-point, interviewees noted several successes to program adoption, including communication and coordination between behavioral health and primary care, new staff, such as the care coordinators, and staff training. During summative interviews and focus group discussions, adoption facilitators included the physical space of the clinic, increased communication, adapted data systems, flexibility of program staff, staff relationships.

Clinic or Physical Space

Interview and focus group participants highlighted that the physical co-location of multiple services (primary care, behavioral health, nutrition, care coordination) facilitated adoption of their Sí Texas program. Behavioral health specialists are located in the middle of the primary and behavioral care sections, which was seen as facilitating communication and workflow for staff as well as normalizing the integration process for patients. Additionally, as previously mentioned, an exam room was repurposed for Sí Texas patients as well as the creation of a small back lobby. An administrative staff interviewee noted that "*before when we were starting, we didn't have that patient lobby in the back. And so now that gives us the flexibility where the provider knows this person needs to see these other providers here."* This adaptation of space was viewed as increasing patient compliance, as they were no longer "*dismissed between providers to wait up front*," resulting in some patients leaving the clinic.

Communication

Communication was the most frequently mentioned facilitator of program adoption from both patients and staff/providers. Patients commented that clinical staff communicating with each other, in-person and electronically, made it easier for patients to get care. Additionally, communication practices between the clinic and patients facilitated their participation. As one focus group participant shared, "*I would get texts and calls saying, 'Are you going to be able to confirm your appointment for tomorrow at whenever time?' That was helpful.*" Administrative and clinical staff also mentioned numerous ways in which communication facilitated the Sí Texas program adoption. The weekly integrated team meetings were highlighted as bringing together the whole team to share information and develop care plans for patients. Interviewees also expressed how provider notes in Access as well as face-to-face encounters provided easy, quick ways to touch base with other staff, allowing them to make efficient adjustments to program implementation. A clinical interviewee explained, "*I think the presence of both [behavioral health and primary care] at the morning huddles has made a difference… There's just so much ease now to talk to each other and to actually communicate and be more assertive about advocating for the patient or for program change."*

Data Systems

Interviewees highlighted how, after numerous adjustments and the hiring of a data specialist, HFHC's Access data system facilitated program implementation. According to staff, using one data system streamlined a process that was previously cumbersome and involved triple data entry. Interviewees described how the data system gave providers and staff access to patient data and provider notes. As one clinical staff interviewee described, "*I'm looking at Access and I'll pull up a patient. I'll see when we last saw her and why we saw her that last time. I'll look at the notes from the doctor, if she had a follow-up, and for what. I can see all of that in Access."*

Flexibility

The flexibility of administrative and clinical staff was noted as assisting with program adoption, especially as staff learned how to implement new integrated practices. For example, one administrative staff interviewee stated, "*There has to be a lot of flexibility. At first, we were so strict, so strict to say, 'ok, first it has to be this person, then this person, then this person.' And we had to realize, it's not going to be the same for every practice or every patient."*

Staff Relationships

Relationships among administrative and clinical support staff were seen as critical to program adoption. According to interviewees, through the communication and coordination that comprises integration,

clinical support staff developed relationships with each other, giving them the knowledge and comfort to work together to provide team-based patient care. As one clinical staff interviewee shared, *"As far as talking to them [primary care providers], they're very friendly. They're very good."* This feeling was echoed by both behavioral health and primary care providers, who expressed mutual appreciation. "*I don't know what I would do without our behavioral health specialist,"* expressed another clinical interviewee.

Adoption Barriers

At the mid-point, interviewees noted several challenges to program adoption, including enrollment procedures, the organizational culture of a charitable clinic with volunteer providers, as well as program staffing. During summative interviews and focus group discussions, barriers to adoption mentioned were communication practices, data systems, and hiring and staffing.

Communication

While communication was generally viewed as a facilitator of implementation, there were several instances highlighted in which there were communication challenges for the Sí Texas team. Early on it was noted that weekly integrated team meetings were not held consistently, although these have been implemented routinely since the mid-point of the program. Additionally, given the increase in staffing and the shifting of existing staff, several interviewees expressed a lack of communication regarding program roles and responsibilities at the outset of the program. Limited communication to the volunteer providers was noted as particularly difficult in getting their buy-in to the program. "*When you think about it … you recently found out there were some assumption as to who knew what and what they thought their role was going to be,"* explained one administrative staff interviewee.

Data Systems

HFHC's data system was both a facilitator and barrier to Sí Texas program adoption. While the system provided a communication mechanism for providers, several administrative staff interviewees shared that *"it isn't as accessible or usable as it could be. It's tedious."* Thus, interviewees expressed that the data system had limited functionality. Despite these challenges, an administrative staff shared that they found *"workarounds so that we had a single database of information."* At the time of study closure, HFHC was working to select a new electronic medical record system at their clinic.

Hiring and Staffing

Interview participants noted that due to the Sí Texas program, there was a lot of growth and hiring in the early phase of program implementation. Staff shared that a challenge during this period of growth was retaining staff and onboarding new staff to existing clinic norms. With the HFHC staff growing from 7 to 20 with the Sí Texas program, previous culture and behaviors were difficult to change, such as providers being accustomed to referring externally instead of internally within the clinic. Despite the growth in staff, retention was challenging for the first year of program implementation due to turnover in several critical roles. For example, interviewees shared that changes in the Care Coordinator position left an unbalanced workload for other staff, which was noted to impact staff buy-in during the early phases of the project. Toward the end of the study period, another significant staffing change was the program director's departure, which created a staffing shortage. Interviewees shared that given the short timeline for implementing the Sí Texas program, staffing challenges were magnified as positions needed to be filled immediately to keep the program moving forward.

Participant Facilitators

In addition to facilitators experienced by staff adopting the Sí Texas program, focus group and interview participants were also asked to reflect specifically on facilitators that patients experienced while participating in the program. Facilitators mentioned included cost and relationships with staff and providers.

Cost

Patients complimented HFHC for being very affordable and only accepting of donations and not payment for services. According to focus group participants, this low cost (donation only) allows patients to seek and receive care more readily than they were able to outside of HFHC. For example, one patient explained, *"I've been here at the clinic for the past five years. I used to go to [external clinic name] and when you are there if you have $100 to start with, you don't have anything after you leave. You're here and [cost of care] it's nothing. You give as a donation for all the services you get in exchange at this clinic."* Focus group participants shared that at other clinics, each service (primary care, behavioral health, nutrition) would cost separate fees, and they were appreciative of receiving all these services at HFHC for free. Additionally, several patients spoke of receiving financial assistance from HFHC to pay for medication.

Relationships

Patients in the focus groups recognized that relationships among staff enabled program adoption but also that relationships between staff and patients supported patient participation. As one clinical interviewee shared, "*The foundation of what they [patients] tell me why they like to come to the clinic, is the clinic itself. They like it here… a lot of them really like our providers."* Further, as one focus group participant described, *"You notice that they care about their clients. They worry about you. They help you with whatever they can. They're all very caring."* Patients in focus groups shared their appreciation for the many provider and staff interactions at HFHC. "*Here it's a lot of one-on-one. They look at you in the eye, and you feel that's the important thing."*

Participant Barriers

In addition to barriers experienced by staff and providers implementing the Sí Texas program, focus group and interview participants were also asked to reflect on barriers that patients faced while participating in the program. Barriers discussed included cost, the sociopolitical environment, transportation, and wait times.

Cost

While most focus group participants spoke of the minimal costs to participate in the Sí Texas program at HFHC, they noted cost as a barrier to care outside of HFHC. Diagnostic (e.g. x-rays) and specialty services (e.g. ENT) to which patients are referred were specifically highlighted as being prohibitively expensive. "*If you have services here, it's affordable*. *But, the moment you have to go elsewhere, that's when it gets bad,"* explained one focus group participant. Additionally, as discussed below, patients experienced the financial burden of getting to and from appointments.

Sociopolitical Environment

Focus group participants and interviewees alike shared that the sociopolitical environment was a barrier for patients receiving care at HFHC. Specifically, there was a perception that patient participation decreased as a result of resident fears regarding lack of documentation. As one administrative staff interviewee shared that, *"Because of the scare of immigration, of them being deported, we had a whole*

summer where patients were not showing up. It made a difference. We were having cancellations left and right. I mean, they weren't even calling, they weren't showing up. They didn't want to leave their homes or the area." Patients in focus group reinforced this, but also acknowledged that they feel HFHC is a safe place. *"A lot of people are afraid to come over because they think that they're going to ask them for things they don't have, that they going to ask for documents and that's not true, they don't ask you for anything here [at HFHC]."* It should be noted that concerns about documentation status are the norm at HFHC and are something that the clinic anticipates and addresses as part of its overall operation.

Transportation
While several patients and administrative staff reported that HFHC did provide some financial support for transportation services in the form of the study incentive gift card, most interviewees and focus group participants still highlighted transportation as the biggest barrier to care. Both the limited transportation options and the cost of transportation (gasoline, bus fare) hindered patients' ability to get to and from HFHC. As one administrative interviewee described, "*Transportation has always been an issue with our patients and that's so unfortunate that it's the transportation that holds them back from getting the care they need. So, we may not see them for months because they can't get to the clinic, or they ride a bike and it's 104 degrees outside."*

Wait Times
Participants expressed that wait times while at the clinic were a disincentive to participation at times. For example, as one patient who received multiple services at HFHC shared, *"I spent three hours after I get out of my appointment. No, they sent me to a room and then the counselor comes in and then he goes out and somebody else comes in afterwards, but they make you wait a lot longer."* Focus group participants agreed that wait times were long given the many different staff and providers they needed to see. However, focus group and interview participants alike reported that wait times improved as the Sí Texas program progressed.

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

Clinical and administrative staff members were asked about their support and buy-in for the Sí Texas program as well as their perceptions of their colleagues' buy-in. Interviewees spoke about the culture of the clinic, as well as buy-in and satisfaction of both frontline clinical staff as well as leadership and administration. However, the volunteer primary care providers were not considered "bought-in" to the Si Texas program due to the episodic nature of their role, as will be discussed in this section.

Clinic Culture
A few interview participants spoke of working through some initial tension around roles, responsibilities and expectations for integration, as well as specific challenges with creating a supportive clinic culture. However, as the study period concluded, interviewees perceived the clinic culture to be a helpful environment for integrated care. *"We have everyone on board now. Everyone is back on, on their flow… we have more of that integration that we're going for in terms of the program"* shared one clinical staff interviewee. Program leadership *"helped to develop a culture that was collaborative and collegial"* highlighted another administrative staff interviewee. Despite rapid growth in staff due to the Sí Texas program, the small size of HFHC was also seen as contributing to the successful development of a culture of integration.

Frontline Clinical Staff

Frontline clinic staff satisfaction with the program has been mixed, according to interviewees. Staff interviews commented that volunteer primary care providers had limited buy-in for the integrated care model and its benefits because they do not see the full scope of IBH services offered in the clinic. The majority of primary care providers spent only a few hours at HFHC per week. HFHC leadership noted that specific training and orientation was challenging to incorporate into the program at the beginning and did not take place. Additionally, a few clinical support staff interviewees reported some dissatisfaction with the increased workload as they implemented new data collection and workflows throughout the study period of both implementing a new program model and adhering to study protocols. The difference between these could not be disentangled from the data. However, frontline clinical support staff expressed overall satisfaction with the program as it concluded, citing increased access to care for their patients as well as initial positive health outcomes. *"I think medical providers are also benefiting in the way their patients' care is managed. For example, Jane Doe was referred to behavioral health, and now she's more receptive and compliant,"* explained one administrative staff. Despite the aforementioned concerns, the overall sentiment among staff was one of pride and satisfaction as the study concluded.

Leadership and Administration

Staff interviewees commented on the strong engagement and commitment from the executive director to adopt the IBH model at HFHC. An example of this commitment was the financial investment to move forward with integrated care as the study concluded, shared interviewees. One administrative staff interviewee explained, *"We have a strong leader but also a shared mode of leadership with a team-based approach … and it's working, it's working again. We've got everyone on board."*

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

HFHC did not collect data from the control group about program-like components they may have received outside of HFHC during the study period. All study participants, regardless of group assignment, were eligible to participate in programs available to all HFHC patients. For diabetic patients, this included the Salud y Vida program. Services available through Salud y Vida included home visits, transportation to medical appointments, nutrition assessments and courses, assistance with medical supplies such as glucose strips, and intensive case management to control diabetes. Since these services were accessible to both intervention and control group participants, and the evaluation design was randomized, no further assessment of Salud y Vida was conducted for the impact analysis.

During the course of summative interviews, there was evidence that the control group may have been contaminated during the course of the study. Initial analysis of interviews with program staff included mention of confusion about which patients were in the control group, and some staff reported that control group patients may have received intervention services. The evaluation team from Health Resources in Action conducted a site visit in July 2018 to review all study documentation, including the Access database. Initial review of HFHC's Access database identified 85 potential cases that may have been contaminated. HFHC program staff completed a chart audit of those records to determine whether those patients received intervention services. The audit revealed that 35 control group participants received at least one intervention service during the study period. This finding was the basis for adding a per-protocol analysis to the impact analysis.

Further discussion with HFHC identified operational challenges as the primary driver of contamination. Specifically, there was some confusion among providers about which patients were eligible for Sí Texas intervention services and referrals may have been made inappropriately. There was also potential miscommunication about the meaning of the patient medical chart colors that were used by staff to distinguish Sí Texas intervention and control group participants.

Question 5. To what extent did the HFHC clinic implement the collaborative care model with fidelity?

Except for some challenges to enrollment procedures and minor changes to data collection practices and workflows, the HFHC program was implemented as planned with the exception of the psychiatrist consultant which had been intended to benefit the intervention group. As described in the Program Logic Model section of this report, the position was not filled due to challenges in finding a qualified candidate. Based on analysis of all interviews conducting during the mid-point and summative evaluations, HFHC implemented their IBH program with high fidelity. Summarizing, an administrative staff interviewee said, *"I think it didn't happened the way that it was originally set to have happened, but I think that patients did get, for example, behavioral health services, or care coordination, or transitional nursing, that they were supposed to get, but they didn't get it in the way that we originally thought it was going to happen."* The minor challenges faced early on were seen as having small effects on the model's overall fidelity. Interviewees shared how leadership worked diligently to facilitate communication systems, workflows, and data systems to support integration.

There were two main challenges to implementing the study design: contamination and failure to distribute incentives as planned. It should be noted that interviewees did not report either of these issues as impeding implementation of the actual IBH program. HFHC's implementation of the evaluation itself and the potential effect of evaluation implementation challenges is discussed in the impact analysis section.

Below are data describing the number of services provided over the course of the study period including the total number of visits provided by type and study group as well as the average, median, minimum, and maximum number of visits provided to participants.

Table 6. Number of Visits Received by Study Group and Service Type

Service Type	Intervention					Control					Total				
	Total	Mean	Median	Min	Max	Total	Mean	Median	Min	Max	Total	Mean	Median	Min	Max
Care Coordination	860	3.9	3.0	1.0	21.0	157	1.8	1.0	1.0	7.0	1017	3.3	2.0	1.0	21.0
Behavioral Health	568	2.4	2.0	1.0	8.0	19	1.3	1.0	1.0	5.0	587	2.3	2.0	1.0	8.0
Primary Care	1595	5.9	5.0	1.0	22.0	1647	5.3	4.0	1.0	22.0	3242	5.9	20.5	1.0	22.0
Case Management	203	2.1	1.0	1.0	14.0	908	3.5	2.0	1.0	14.0	1111	3.1	2.0	1.0	14.0
Transitional Nursing	598	2.5	2.0	1.0	10.0	164	1.4	1.0	1.0	5.0	762	2.2	2.0	1.0	10.0
Total	3824	14.2	13.0	2.0	46.0	2895	9.3	8.0	1.0	31.0	6719	11.6	10.0	1.0	46.0

Below are data describing which participants in each study group received or did not receive the various services offered at HFHC. For the purposes of the analysis described in this report, "care coordination"

was considered the service type that defined whether a participant actually received the intervention. Care coordination indicates receipt of services from the behavioral health specialist, the minimum dose of the intervention and critical factor theorized in the program logic model to improve outcomes. Among the intervention group, 45 participants did not receive the intervention; however, 38 control participants received care coordination and thus were contaminated. In the impact analysis presented later in this report, this information was used to construct an analytic sample for per-protocol analysis to assess the potential impact of control group contamination on the effect of the intervention on outcomes of interest.

Table 7. Number of Participants Receiving and Not Receiving Services by Group and Service Type

Service Type	Intervention (n=272)		Control (n=313)	
	Received Service	Did Not Receive Service	Received Service	Did Not Receive Service
Care Coordination	227	45	38	275
Behavioral Health	241	31	15	298
Primary Care	269	3	311	2
Case Management	99	173	257	56
Transitional Nursing	238	34	116	197

Additional Implementation Findings

In addition to data to answer the *a priori* implementation questions presented in the SEP, the qualitative implementation evaluation also yielded additional findings related to participant satisfaction, perceived success and impacts, sustainability, and lessons learned. Presented here are key themes that emerged during the key information interviews and focus groups not directly asked by the implementation research questions outlined above but that are still valuable to provide context for HFHC's program.

Participant Satisfaction

Participants in focus groups were overwhelmingly satisfied with the Sí Texas program, citing improvements in services, relationships with staff, and ultimately health outcomes as reasons for being satisfied. All quotes in this section are from intervention group participants.

Services Provided

Patients spoke highly about the quantity and quality of services received as part of the Sí Texas program, including behavioral health, nutrition services, and care coordination. In addition to clinical services, several focus group participants highlighted the diabetes management Salud y Vida program, "*They teach you how to take pills, how to eat healthy portions. They teach you about what affects your eyes, your kidneys. I mean, they have everything there."* Interviewees noted that there was some initial frustration among patients because of the long wait times to receive all the services, but workflow changes significantly decreased the amount of time patients had to spend at HFHC.

Relationships

In addition to the services provided as part of the Sí Texas program, participants spoke about the relationships they developed and strengthened with HFHC staff and providers. Patients feel comfortable at the clinic and feel like they are being heard. *"They give you a lot of attention here. They make you feel important,"* one patient shared. According to focus group participants, these relationships made them

happy to come to the clinic and more receptive to care. For example, one patient said, *"Everybody's helping me. No matter who I go to [at HFHC], everybody knows my story."* As a result of these relationships, patients felt like they could *"talk to the staff and be heard."*

Improved Outcomes
According to focus group participants, the additional services provided, as well as improved health literacy, led to perceived improvement in health outcomes for both chronic disease and mental health. For example, one patient said, "*Ever since I've been here everything is under control.*" Others emphasized how they were satisfied with the program because it improved their quality of life as well as their health. As one focus group participant expressed, *"I had headaches all the time, and I didn't know what it was. I would just take pills. But they solved my blood pressure issues. I came over here and I've been really happy so far."* Staff interviewees also perceived patient satisfaction due to improved outcomes, citing many examples of patients who were happy with the program because they lost weight or controlled their diabetes.

Program Successes and Impact
Program participants (intervention group) and staff were asked to speak about their perceived successes and the impacts of the Sí Texas program at HFHC. Both groups identified the program's impact on integration of care and its effects on patients' health literacy, chronic disease and mental health.

Integration of care
According to interviewees and focus group participants, one of the successes of the Sí Texas program was that it integrated physical, behavioral, and emotional care to treat patients holistically. As one clinical interviewee stated, "*Patients like that it targets all of their needs."* Interviewees shared that this internal program impact was achieved through the reorganization of workspace and staff within the clinic, use of the clinical checklist, and the provision of many complementary services as part of the Sí Texas program.

Health Literacy
According to several interview and focus group participants, the Sí Texas program was perceived as increasing health literacy of patients. From sessions with the nutritionist to visits with the behavioral health specialist, patients shared that they *"were taught so many things that we didn't know before,"* such as how to do healthy meal planning and how to quit smoking. Program participants and clinical staff explained that this education helped patients build a basic understanding of their health conditions to more effectively manage them over time. As one patient explained, *"I feel like I've been educated here, especially about my diabetes problem. Now it's under control"*

Chronic Diseases
Patients and clinical staff alike discussed how the increased services in addition to health literacy also resulted in improved chronic disease management and outcomes for patients. Many interviewees and focus group participants shared success stories of patients learning about and managing their diabetes, losing weight, and lowering their blood pressure and cholesterol. *"They helped me with my sugar and my blood pressure."* described one patient.

Mental Health
Program participants, as well as HFHC staff, spoke of the program's perceived impact on patients' mental health, which included improvements to quality of life. Focus group participants explained that

they saw benefits to their mental health and quality of life. For example, one patient shared, *"The advice they gave me helped me a lot to overcome my depression. I didn't eat, I didn't sleep, but they helped me a lot here and now I do."* Clinical staff also noted changes in patients' mental health as a result of physical health improvements: *"I think the patients who are involved in the program have really benefited from understanding and seeing that it's more than just their blood sugar. It's affects everything. They get their sugar down and they're feeling better overall."*

Sustainability and Lessons Learned

Overall, interviews with HFHC staff as well as focus groups with patients indicated that implementation of HFHC's Sí Texas program has been successful. Several lessons learned and opportunities for improvement emerged. At the mid-point, lessons learned related to collaboration and team-building, data systems/evaluation, communication, leadership buy-in, staffing and training. During the summative interviews and focus groups, lessons learned and opportunities for improvement focused on the same themes with the additions of funding and program replication and scalability. Below we discuss four major themes that came up consistently during interviews related to sustainability and learnings.

Funding

Most interviewees acknowledged that providing evidence of the team-based integrated care model's effectiveness will be key to securing the funding necessary to expand the program at HFHC. *"We are trying to prove that the program has given us good outcomes and secure funding to continue,"* a clinical staff interviewee shared. Another reinforced that, "*we see that it [integrated care] is working. It's just the financial side that's limiting the scope of what we can provide."* Interviewees highlighted the realities of needing funding to sustain IBH implementation and reported that the Sí Texas evaluation is a vehicle to demonstrate the value of their program to local stakeholders who can assist with sustaining future IBH work at HFHC. Funding from medical billing was also mentioned by one interviewee as a potential strategy to sustain an integrated model of care.

Program Replication and Scalability

The integrated care model at HFHC represents a wide array of services and staff that were not available before the Sí Texas program was implemented. Interviewees shared hopes that the integrated services would be offered to the clinic's entire patient population. As the Sí Texas study ended, "*While the research portion is over, we are just to continue the [integrated] flow of things. That's what we're aiming to do… if the need is there, now we have the flexibility of saying, 'we have all these other services that we can offer you as well,'"* shared one clinical staff interviewee. HFHC leadership confirmed that the plan is to focus integrated care on patients who have depression, diabetes, hypertension and obesity, but all clinic patients will have the option of integrated care.

Staffing

There were numerous lessons learned and opportunities for improvement around staffing, according to interview and focus group participants. From the staff perspective, several interviewees stated that the clinic's patient volume increased dramatically upon implementing the Sí Texas program because the clinic was recruiting more and promoting services. Given this increased volume, administrative and clinical staff suggested that it would have been helpful to have more full-time primary care and behavioral health providers to better meet the needs of patients. Additionally, one administrative staff interviewee advised that at the start of the program it would have been beneficial to take into account how the program would impact the roles of various staff people. Challenges with changing job roles and staff retention, such as the receptionist, care coordinator, and program supervisor leaving necessitated

conversations about supporting remaining program staff as well as program sustainability. Looking back, staff recommended that HFHC would consider utilizing social work interns and medical students moving forward.

Training

While training, both online and in person, was seen as an early success, interviewees had numerous suggestions for improvement. In terms of timing of training, several interviewees suggested that participating in training before implementation would have facilitated program readiness. In particular, early training for frontline administrative staff as well as providers may have helped their buy-in to the program. Regarding training topics, interviewees recommended all-staff training on the administrative aspects of the program as well as roles and responsibilities as they related to the integration model.

"We received trainings on integration, evaluation. But sometimes the clinical side doesn't have time for administrative tasks, so more training on that end would help."

IMPACT STUDY – APPROACH AND METHODS

Overview of Impact Study Design

Hope Family Health Center (HFHC) implemented a collaborative care model (e.g., Guide to Community Preventive Services, 2010; Sanchez & Watt, 2012; Watt, 2009; Gilbody et al., 2006) aimed at identifying and removing barriers to full integration of primary and behavioral health care in a charitable care setting with the ultimate goal of significantly improving obesity, diabetes, and behavioral health such as depression, anxiety, and substance abuse for the poor and uninsured living in the RGV. The activities of the HFHC approach were based on those elements present in the Sanchez and Watt model (2012) including: care management, and access to behavioral health specialists that have been linked to improved health outcomes in the evidence base. This program built upon these models by adapting integrated services to be culturally-relevant for the unique border community, including bilingual programming and psychoeducation. In addition, the study sought to garner information about the feasibility of implementing an IBH model within a free and charitable clinic setting that utilizes volunteers to provide medical services (e.g., primary care providers).

This study utilized a randomized control trial design (RCT) to compare outcomes of intervention participants receiving the enhanced delivery of integrated behavioral care with control participants receiving usual care. Use of an RCT research design was preferred because it minimized threats to internal validity by better controlling for patient and clinic level characteristics. The RCT design allowed for the presumption that any differences observed in outcomes between the intervention and control groups were likely caused by participation (or lack of participation) in HFHC's IBH program. The study hypothesized that an enhanced level of primary and behavioral health services offered at a charitable clinic would improve participants' blood pressure and related health measures. The study targeted a moderate level of evidence based on the feasibility of implementing the intervention in HFHC's current practice setting.

Impact Study Design and Methods

Study Design

The study's impact evaluation used data from the RCT designed study to evaluate HFHC's IBH program's impact by comparing intervention participants to control participants. Participants enrolled in the study were followed for approximately 12 months. Quantitative program implementation data related to participation in intervention components is also reported herein (see Implementation Evaluation section).

Randomization Procedure

After a patient provided voluntary consent, he or she was entered into the randomization process. Random assignments were created by a computer-generated calculator to account for the project's sample size, printed, and placed in individual unmarked envelopes. The program assistant who assessed eligibility and obtained informed consent then asked participants to choose an envelope to determine the participant's assignment to either the intervention or control group. The program assistant verified the assignment by checking the number in the envelope against the master list of computer-generated random numbers. Those participants randomized to the intervention group received enhanced integrated care, and those participants randomized to the control group received HFHC's usual care services. Due to limited clinic capacity, simple random assignment was utilized. HFHC generated a pool

of numbers that exceeded their total enrollment target, which resulted in a slight imbalance between the control and intervention groups as noted later in this report.

Assessment of Baseline Equivalence

Examining baseline equivalence evaluates whether the intervention and control groups are statistically equivalent in regard to a specified set of characteristics at study enrollment. At baseline, a series of sociodemographic characteristics were captured for all participants using a standardized set of questions developed by HFHC, including age, gender, ethnicity, primary language, county of residence, employment status, and marital status. These sociodemographic characteristics were selected because they are routinely collected by HFHC and captured in their EMR and represent potentially important covariates.

There were no statistically significant differences detected between the intervention and control groups on any of the demographic characteristics presented in **Table 8**.

Table 8. Tests of Baseline Equivalence for Demographic Measures

Measure	Full Sample (n=582)		Intervention Group (n=270)		Control Group (n=312)		p-value
	N	%	N	%	N	%	
Gender							
Male	154	26.5	71	26.3	83	26.6	0.93
Female	428	73.5	199	73.7	229	73.4	
Ethnicity							
Hispanic/Latino	484	83.2	217	80.4	267	85.6	0.09
Non-Hispanic/Non-Latino	98	16.8	53	19.6	45	14.4	
County							
Hidalgo	573	98.5	268	99.3	305	97.8	0.19
Other	9	1.6	2	0.7	7	2.2	
Age							
≤ 34	41	7.0	16	5.9	25	8.0	0.65
35-44	110	18.9	50	18.5	60	19.2	
45-54	206	35.4	98	36.3	108	34.6	
55-64	193	33.2	94	34.8	99	31.7	
65+	32	5.5	12	4.4	20	6.4	
Mean	50.9	--	51.2	--	50.6	--	0.51
SD	10.6	--	10.3	--	10.7	--	
Employment Status							
Employed	7	1.2	2	0.7	5	1.6	0.34
Not Employed	575	98.8	268	99.3	307	98.4	
Marital Status							
Married	296	50.9	135	50.0	161	51.6	0.46
Single	132	22.7	65	24.1	67	21.5	
Separated	60	10.3	23	8.5	37	11.9	
Divorced	49	8.4	21	7.8	28	9.0	
Widow/Widower	35	6.0	20	7.4	15	4.8	

Partner	10	1.7	6	2.2	4	1.3	
Primary Language							
Spanish-speaking	514	88.3	242	89.6	272	87.2	0.36
English-speaking	68	11.7	28	10.4	40	12.8	

For the six impact measures analyzed, there was a statistically significant difference in median PHQ-9 score between the two groups at baseline. There were no statistically significant differences detected between the intervention and control groups on any of the other baseline impact measures presented in **Table 9**.

Table 9. Tests of Baseline Equivalence for Impact Measures

	Full Sample (n=582)[a] Mean (SD)	Intervention (n=270)[a] Mean (SD)	Control (n=312)[a] Mean (SD)	p-value
Systolic	134.0 (20.3)	133.4 (21.3)	134.5 (19.4)	0.48
Diastolic	81.5 (9.4)	81.0 (9.6)	82.0 (9.2)	0.17
BMI[b]	33.7 (7.0)	33.9 (7.5)	33.6 (6.6)	0.85
Nonparametric Tests[c]	Median (IQR)	Median (IQR)	Median (IQR)	
HbA1c	7.0 (3.6)	7.4 (4.2)	6.8 (2.9)	0.24
PHQ-9	**4.0 (10.0)**	**5.0 (12.0)**	**2.0 (8.0)**	**0.001**

Note: Bold denotes statistical significance (p-value < 0.05).). [a] Sample sizes vary by measure due to missing data. [b] The Wilcoxon rank sum test was used to examine non-normally distributed data. [c] A log transformation was used.

Propensity score matching was considered as an option in the analytic phase for this final report in case baseline equivalence was not established. However, due to the RCT design and simple randomization assignment procedures, matching strategies were not required. Participants were statistically equivalent on all baseline sociodemographic measures. Additionally, all except one impact measure were balanced between the groups at baseline. There is no evidence that randomization was implemented improperly as all procedures were followed and documented. As noted previously, there was a slight difference in the number of participants enrolled in the two study groups. This was due to generation of a pool of random numbers that was larger than the original targeted sample size. More control group numbers were drawn than intervention at the time recruitment was discontinued. If there were problems with the randomization, we would expect to find some imbalance in the demographic or impact measures, which was not the case in our assessment.

Intervention and Control Group Conditions

Participants randomized to the intervention group received the enhanced integrated primary care program in addition to behavioral health services they were eligible to receive if indicated in their patient care plan. Originally, HFHC intended that intervention participants receive care from only HFHC primary care providers participating in the Sí Texas program. Some of HFHC volunteer providers would serve as "intervention only" providers and be part of HFHC's IBH team. The remaining HFHC volunteer providers would treat the control group. In practice, providers saw both intervention and control participants due primarily to capacity and HFHC's priority to ensure patient care continuity. Field conditions prohibited this plan from being implemented. Volunteer providers did not have set schedules

making it difficult for staff to ensure the intervention and control groups saw specific providers. Moreover, HFHC had difficulty obtaining buy-in from volunteer providers about the IBH program.

At study enrollment, intervention participants were first seen by a nurse manager to complete baseline assessment for the study, including the administration of the PHQ-9 and Duke Health Profile. Next the participant was seen by a medical assistant to assess vitals including height, weight, and blood pressure. The participant was then seen by a HFHC primary care provider.

As part of the intervention, participants had a person-centered care plan developed which included services available to all HFHC patients (e.g., standard, uncoordinated behavioral health services) or intervention-specific services (e.g., behavioral health specialist or dietician services). In addition, each participant received an individualized safety plan, referrals to specialty care, and when applicable referrals to community-based programs and, participants discussed goals and treatment planning with the behavioral specialist and/or counselor at every visit. Once these plans were developed, participants in the intervention group received coordinated care, meaning the care coordinator provided the participants with a warm-handoff to either the behavioral health specialist, dietician and/or member from pharmacy services. The behavioral health specialist would also make warm hand offs as appropriate (e.g., the dietician, behavioral health services, etc.).

A clinic administrator made follow-up appointments for the participants depending on their care plan. Intervention group participants, whenever possible, had primary care appointments scheduled immediately following mental health appointments to minimize missed appointments. Clinic care coordinators prompted participants with telephone reminders and rescheduled appointments that were missed

Participants randomized to the control group received standard primary care from any HFHC provider available at the clinic on the day of service. As noted above, the intention of HFHC was to have control group participants see providers that were not part of the intervention which was not feasible. HFHC's volunteer providers saw both intervention and control group participants. Participants were first seen by a nurse manager to complete baseline assessment for the study, including the administration of the PHQ-9 and Duke Health Profile. Next participants were seen by a medical assistant to assess vitals including height, weight, and blood pressure. Participants were then seen by a primary care provider who provided HFHC's usual standard of care.

Similar to the intervention group, control group participants received a person-centered care plan, safety plan, referrals to specialty care and when applicable referrals to community-based programs. Once these plans were developed, participants in the control group did not receive coordinated care or warm-handoffs. They were only provided with referrals to services. Control group participants did not have access to dietician services. All patients at HFHC have access to limited pharmacy services.

Study Sample

The following section describes 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 related to sample recruitment and retention, assessment and adjustment for non-response bias, or missing data.

Study Sample Composition

Table 10 presents participant demographics for intervention and control groups at baseline. Intervention and control group participants primary lived in Hidalgo County. Most of the participants enrolled in the study were female (73.7%), Hispanic (82.7%), spoke Spanish as their primary language (88.4%), and were unemployed (98.8%). The average participant age was 50.9 years and just over half of the study population was married (51.1%).

Table 10. Participant Demographic Measures for Full Sample and by Intervention Group

Measure	Full Sample (n=582)		Intervention Group (n=270)		Control Group (n=312)	
	N	%	N	%	N	%
Gender						
Male	154	26.5	71	26.3	83	26.6
Female	428	73.5	199	73.7	229	73.4
Ethnicity						
Hispanic/Latino	484	83.2	217	80.4	267	85.6
Non-Hispanic/Non-Latino	98	16.8	53	19.6	45	14.4
County						
Hidalgo	573	98.5	268	99.3	305	97.8
Other	9	1.6	2	0.7	7	2.2
Age						
≤ 34	41	7.0	16	5.9	25	8.0
35-44	110	18.9	50	18.5	60	19.2
45-54	206	35.4	98	36.3	108	34.6
55-64	193	33.2	94	34.8	99	31.7
65+	32	5.5	12	4.4	20	6.4
Mean	50.9	--	51.2	--	50.6	--
SD	10.6	--	10.3	--	10.7	--
Employment Status						
Employed	7	1.2	2	0.7	5	1.6
Not Employed	575	98.8	268	99.3	307	98.4
Marital Status						
Divorced	296	50.9	135	50.0	161	51.6
Married	132	22.7	65	24.1	67	21.5
Partner	60	10.3	23	8.5	37	11.9
Separated	49	8.4	21	7.8	28	9.0
Single	35	6.0	20	7.4	15	4.8
Widow/Widower	10	1.7	6	2.2	4	1.3
Primary Language						
Spanish-speaking	514	88.3	242	89.6	272	87.2
English-speaking	68	11.7	28	10.4	40	12.8

Table 11 describes participant impact measures at baseline for the intervention and control groups. As previously presented in the assessment of baseline equivalence section, the intervention and control groups were found to be statistically equivalent on all baseline impact measures other than PHQ-9 score. The median PHQ-9 score was higher in the intervention than in the control at baseline.

Table 11. Descriptive Statistics for Baseline Impact Measures

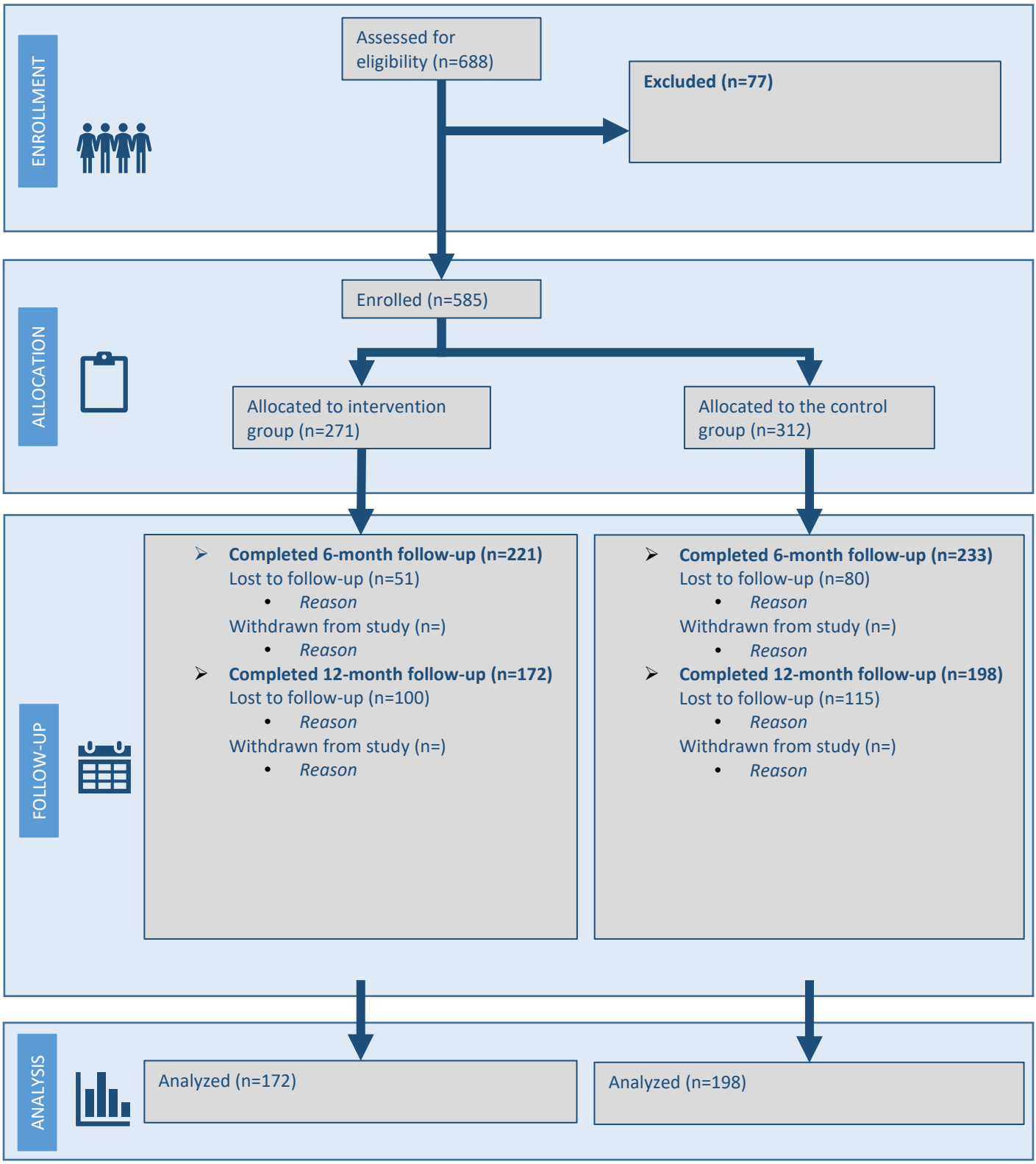
	Full Sample (n=582)[a] Mean (SD)	Intervention (n=270)[a] Mean (SD)	Control (n=312)[a] Mean (SD)
Systolic	134.0 (20.3)	133.4 (21.3)	134.5 (19.4)
Diastolic	81.5 (9.4)	81.0 (9.6)	82.0 (9.2)
BMI[b]	33.7 (7.0)	33.9 (7.5)	33.6 (6.6)
Nonparametric Tests[c]	Median (IQR)	Median (IQR)	Median (IQR)
HbA1c	7.0 (3.6)	7.4 (4.2)	6.8 (2.9)
PHQ-9	**4.0 (10.0)**	**5.0 (12.0)**	**2.0 (8.0)**

Note: Bold denotes statistical significance (p-value < 0.05).). [a] Sample sizes vary by measure due to missing data. [b] The Wilcoxon rank sum test was used to examine non-normally distributed data. [c] A log transformation was used.

Patient Flow Description

A patient flow diagram following the CONSORT structure (Schulz et al., 2010) is presented in **Figure 1** on the following page. This diagram depicts the study process from assessment of eligibility, to enrollment and group selection, ending with retention and analysis. Sample sizes are provided throughout to show timing of participant attrition. Qualitative reasons for any ineligibility, withdrawal, or lost-to-follow-up are provided where applicable. In the "enrollment" stage, 77 participants who were excluded did not meet one or more of the eligibility criteria and could not be allowed to participate. In the "follow-up" stage, those participants categorized as "lost to follow-up" did not complete an assessment at that time point but did not formally withdraw from the study. Due to the lack of official withdrawal from the study, those who were lost to follow-up at 6 months remained in the study and were still eligible to complete a 12-month assessment.

Figure 1. Patient Flow Description



Sample Recruitment, Retention, and Attrition

Participant Eligibility and Recruitment

IBH program participants were recruited from HFHC patients receiving behavioral health services. Patients who meet the following criteria were eligible to participate in the study:

- Reside in Cameron, Hidalgo, Willacy, or Starr County
- Eligible to receive behavioral health services from HFHC (e.g., uninsured, living at or below 200% of the federal poverty level, residence in HFHC's service area)
- A diagnosis of one or more chronic conditions:
    - Hypertension (blood pressure of 140/90 mm Hg or higher)
    - Obesity (body mass index of 30.0 or higher)
    - Poorly controlled diabetes (HbA1c over 6.8%)[1]
    - Moderate depression (score of 10 or above on PHQ-9)

Patients who expressed suicide ideation upon intake were not approached for enrollment but may have been enrolled during the study recruitment period if stabilized. If a potential participant or participant was found to be suicidal at any time during the study, HFHC followed its well-established protocol for treating suicidal patients. Severe cases were referred to the local mental health authority, Tropical Texas Behavioral Health. Other exclusion criteria included enrollment in another research study and patients who did not speak English nor Spanish.

Sample Enrollment and Retention

Participant enrollment began in December 2015 and continued through February 2017. HFHC amended their SEP in March 2017 to extend the original 9-month enrollment period (ending in August 2016) to a 13-month period to allow sufficient time for recruitment of the target sample size. The final timeline is presented in **Appendix B. Revised Project Timeline**. The enrollment target was 283 participants each for the intervention and control groups; a total of 272 participants were enrolled into the intervention and 313 participants in the control groups (see **Figure 2**), meeting the enrollment target for the control group and enrolling 96% of the intervention group target. As previously mentioned, HFHC generated a pool of random numbers larger than the target sample size which inadvertently resulted in selection of a higher number of control group numbers than intervention group numbers by the end of the recruitment period.

[1] HbA1C test was only recommended by the clinician and subsequently collected among patients who had shown symptoms and other clinical indicators that met clinician's diagnostic need for patient's HbA1C test results. Therefore, only a portion of enrolled patients had HbA1C data available. Comparative analysis to evaluate the intervention effect on the outcome of HbA1C was based on a partial sample, instead of the full sample of enrolled patients. The limited availability of HbA1C data at HFHC could potentially result in insufficient sample size to detect significant intervention effect (i.e., type II error).

Figure 2. Cumulative Baseline Enrollment by Month, Overall and by Group

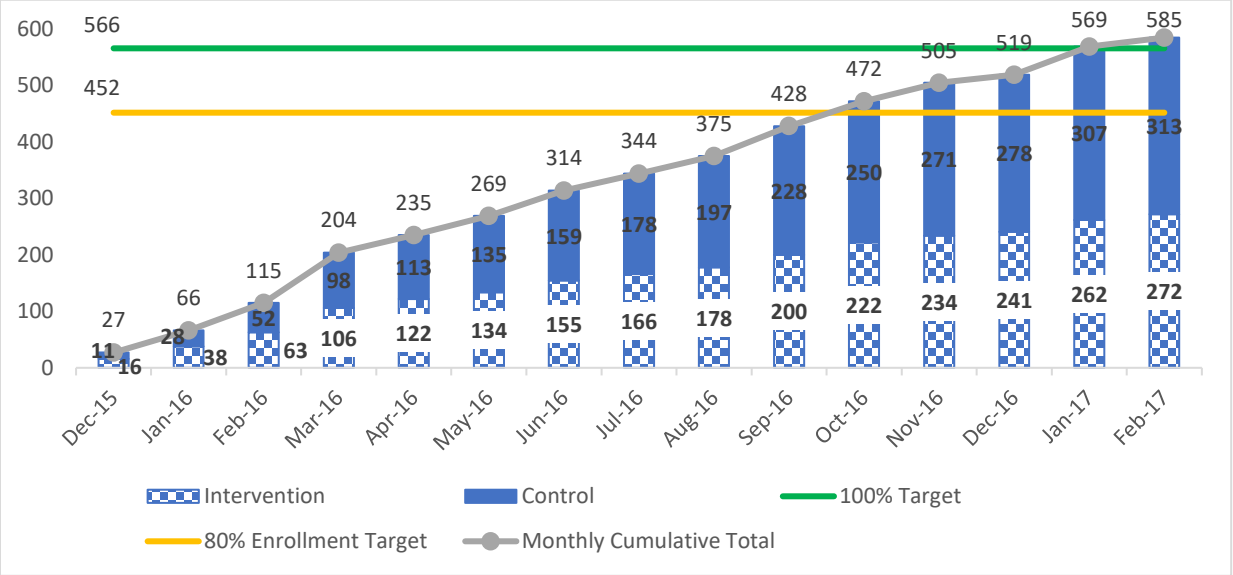


Table 12 presents subgrantee-reported information on the number of participants who returned for 6-month and 12-month follow-up through October 2017 and March 2018 respectively, by study arm. HFHC retained 86.7% of the 6-month target in the intervention group (221 out of 272 returned for a 6-month follow-up assessment, with 255 needed to maintain adequate statistical power). Just over three quarters (76.1%) of the 12-month retention target were retained in the intervention group (172 out of 272 returned for a 12-month follow-up assessment, with 226 needed to maintain adequate statistical power). The control group reached 74.4% of the 6-month retention target (233 out of 313 returned for a 6-month follow-up assessment, with 255 needed to maintain adequate statistical power). The retention target was not met in the control group at 12 months, with HFHC retaining 87.6% of the target (198 out of 313 returned for a 12-month follow-up assessment, with 226 needed to maintain adequate statistical power).

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

Group	Number Enrolled	Retention Target[a]	Number Retained[b]	Percent Retained of the Enrolled Sample	Percent Retained of Retention Target
6-month Retention					
Intervention Group	272	255	221	81.3%	86.7%
Control Group	313	255	233	74.4%	74.4%
12-month Retention					
Intervention Group	272	226	172	63.2%	76.1%
Control Group	313	226	198	63.2%	87.6%

[a]These targets anticipate 10% attrition at 6 months and 20% at 12 months. [b]These data are the number that completed an assessment at 6 and 12-month follow-ups.

Sample Attrition Analyses

The study anticipated 80% retention of the sample at 12 months. At 12 months, the study retained 63% of both the intervention and control groups. To assess if differential attrition existed between

intervention and control groups, a chi-square test was performed comparing the proportion of participants who were lost to follow-up in the intervention to those who were lost to follow-up in the control group. The results of this analysis were not statistically significant at the 0.05 level (p=0.99). Given these results, we conclude that the two study groups did not have significantly differing attrition rates at 12 months of follow-up.

Although differential attrition between groups is not a concern for the end-point analyses, the overall attrition rate was higher than anticipated in both groups. Bivariate analyses were conducted to examine whether participants lost to follow-up were significantly different than those who remained in the study across demographic characteristics and baseline health measures, for the entire sample and within each study arm. T-tests were used for continuous measures and chi-square tests for categorical data. Fisher's Exact Test was utilized if the expected cell counts were less than 5 and nonparametric tests were performed on non-normally distributed data. **Appendix H. Loss to Follow-Up/Attrition Tables** presents the results from these analyses.

Regarding demographic measures, there were statistically significant differences in ethnicity and language within the intervention group; a higher proportion of non-Hispanic and Spanish-speaking participants did not complete the study. There was a statistically significant difference in gender within the control group; a higher proportion of males in the control group did not complete the study.

There were no statistically significant differences in health measures at baseline between those who were lost to follow-up and those who remained in the study at 12 months within the intervention group. Within the control group, however, there was a statistically significant difference in baseline diastolic blood pressure between those who completed the study and those who did not. Those who dropped out of the study had a slightly higher mean diastolic blood pressure than those who remained through their 12-month assessment.

A multivariate logistic regression model was then utilized to understand the independent influence of these significant differences identified in predicting a participant's likelihood to drop out of the study. In this model, intervention status did not have a statistically significant influence on the likelihood of being lost to follow-up (p=0.87), but gender was found to be a significant independent predictor of the probability of a participant not completing the study (p=0.002). This statistically significant difference in loss to follow up by gender should be considered in the interpretation of the final analyses.

Sample Retention Strategies

Sample attrition was mitigated by using a variety of retention strategies. Study participants are asked to provide their current contact information during the enrollment process.

The first strategy HFHC applied to counter sample attrition was to collect varied participant contact information to allow for as many contact methods as possible from the study participant during the enrollment process. The second strategy for minimizing attrition was to manage follow-up via care management. The care coordinator kept in touch with study participants on a monthly basis using the participant's preferred mode of communication. The care coordination staff utilized all means of communication to reach the participant, including telephone, text, voicemail, or mail. Email was excluded as a mode of patient communication to prevent disclosure of the participant's participation in the study. The care coordinator utilized his or her relationships with participants 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.

Apart from non-monetary incentives such as a pill box and lunch box, HFHC planned to give participants a $10 HEB (supermarket) gift card upon completion of 3, 6, 9, and 12-month appointments (two assessments for the evaluation and two interim appointments for services). However, incentive implementation did not take place as planned. HFHC did not implement the amended informed consent form due to procedural miscommunication with study staff. HFHC did attempt to provide incentives to all participants for compliance purposes using multiple contacts, but these contacts occurred after the study had ended and most of these participants could not be reached. We have incomplete evidence that study participants were influenced by incentives, either by promise of incentive or receipt of an incentive. In reviewing incentive distribution logs kept by HFHC staff, 81% of study participants had any incentive documentation, indicating either that they had or had not received an incentive. Among those study participants with incentive documentation (n=475), 53% of study participants received incentives overall and 86% of those incentives were financial (e.g., not the pill box or lunch box). HFHC estimates that almost all of the study participants received their incentives after their 12-month assessment; however, the evaluation was unable to independently verify this estimate with quantitative data.

We alerted the New England Independent Review Board (NEIRB) that the amended consent form was never implemented, completed a deviation protocol form for the IRB review, and were informed by the IRB that no further action was needed. This was also reported to the Corporation for National and Community Service (CNCS) program officer.

Non-Response Bias and Missing Data

All data collected for the HFHC evaluation were entered and recorded in HFHC's Access database rather than the Patient Fusion electronic medical record system identified in the SEP. In order to minimize missing and inaccurate data in the HFHC Access database, HFHC provided training to data entry staff. However, HFHC did not conduct audits of the data as originally planned. In addition, a large majority of Duke Health Profiles, at baseline and follow-up, were never entered into Access due to staff capacity and could not be used for analysis. As a result, the Duke Health Profile data were not analyzed for the study.

Missing data on covariates is a potential issue that could lead to biased results. The data collection team made all efforts to minimize missing data through training and use of standard practice measures within the clinic settings captured by the Access database. In the SEP, imputation approaches were considered as an option to address missing data on important covariates (Rubin, 1996). For HFHC's study, a multiple imputation approach was used to fill in the missing data in the primary end-point analyses of blood pressure, body mass index, and depressive symptoms at 12 months for participants who had returned for a 12-month follow-up (i.e. participants who had some 12-month outcome measured, but missing data for other outcomes). These datasets, 10 in total generated using PROC MI, were then used to conduct analyses with standard procedures. SAS PROC MIANALYZE was used to analyze the imputed datasets and reduced potential bias in effect estimates that can arise when incomplete cases differed systematically from the rest (Little and Rubin, 1987; Rubin, 1996). Because HbA1c level was not universally collected from participants, multiple imputation was not applied to the primary model of this outcome.

All participants enrolled had complete baseline sociodemographic data collected. There were missing minimal data at baseline for both blood pressure measures and BMI with 6 (1%) and 10 (2%) participants missing these measures respectively. There were also missing data for these measures at 12 months, with 39 participants (11%) missing both blood pressure measures and 44 (12%) missing BMI. There was more substantial missing data for PHQ-9 score, with 123 participants (21%) missing scores at baseline and 71 (19%) missing scores at 12 months. Due to the amount of missing data for these four measures at baseline and/or 12 months, multiple imputation methods were utilized for the primary models of the intervention effect on these outcome measures. 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. The imputed datasets were not used for longitudinal analyses; these were completed with a complete case analysis approach.

Measures

The impact measures assessed for the HFHC program were blood pressure, HbA1c, Body Mass Index (BMI), and depression. Quality of life data was collected via the Duke Health Profile but is not included in this report due to data availability and quality considerations described above, which is a deviation from the measures listed in the SEP. Information on the number of respondents and tests of normality are provided here (see **Table 13**). PROC UNIVARIATE in SAS was used to describe the distributions of these measures at baseline. Q-Q plots and histograms were used to determine if the measure should be treated as normal, be transformed, or treated as non-normal data. Descriptive statistics for each of these measures, including number of participants with or without the impact measures, are included in this final report.

Table 13. Impact Measure Sample Size at Baseline and Follow-up Assessments

Measure	Sample Size		
	Baseline	6-month	12-month
Systolic Blood Pressure	579	422	331
Diastolic Blood Pressure	579	422	331
HbA1c	328	266	219
BMI	575	418	326
PHQ-9	462	312	299

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

Blood pressure was measured by the primary care provider manually using a Manometer and following clinically-established practice guidelines (National Guidelines Clearinghouse, 2011). Patients with a blood pressure greater than or equal to 140/90 mm Hg were considered hypertensive. In addition, the primary care provider determined the need for and appropriateness of medication.

For blood pressure, there were 579 respondents with complete data at baseline, 422 respondents at 6 months, and 331 respondents at 12 months for the intervention and control groups. The distributions of

responses for systolic and diastolic at baseline were determined to both be normal and therefore parametric tests were used for bivariate analyses.

HbA1c: HbA1c levels are routinely measured in the monitoring of people with diabetes. HbA1c levels depend on the blood glucose concentration. That is, the higher the glucose concentration in blood, the higher the level of HbA1c. Levels of HbA1c are not influenced by daily fluctuations in the blood glucose concentration but reflect the average glucose levels over the prior six to eight weeks. Therefore, HbA1c is a useful indicator of how well the blood glucose level has been controlled in the recent past (over two to three months) and may be used to monitor the effects of diet, exercise, and drug therapy on blood glucose in people with diabetes (American Diabetes Association, 2014).

HbA1c was measured by the primary care provider for patients suspected to be diabetic based on: (1) known/self-reported to be diabetic, (2) an elevated blood glucose at time of clinic visit or suspected to be diabetic. The primary care provider may have suspected a patient to be diabetic based on body weight and/or Acanthosis nigricans. Patients with an HbA1c greater than or equal to 6.8% were considered as eligible for the study based on local clinical procedures in identifying poorly controlled diabetes. In addition, the primary care provider determined the need for and appropriateness of medication.

For HbA1c, there were 328 respondents with complete data at baseline, 266 respondents at 6 months, and 219 respondents at 12 months for the intervention and control groups. The distribution of responses for HbA1c at baseline was determined to be non-normal. The log transformation was examined but did not normalize the distribution of HbA1c; therefore, nonparametric tests were used in bivariate analyses.

Body Mass Index (BMI): BMI is generally used as an indicator of body fat. Specific ranges of BMI are accepted in the literature to indicate overweight and obesity, conditions that may lead to health problems. However, BMI itself is not diagnostic of the body fat or health of an individual (National Guideline Clearinghouse, 2014).

The primary care provider collected BMI data using a clinical weight scale and height measurement instrument following clinically-established practice guidelines (National Guideline Clearinghouse, 2014). BMI was calculated based on height and weight analytically for the impact evaluation.

For BMI, there were 575 respondents with complete data at baseline, 418 respondents at 6 months, and 326 respondents at 12 months for the intervention and control groups. The distribution of responses for BMI at baseline was determined to be slightly skewed in the sample. The log transformation was found to normalize the distribution of BMI. Therefore, parametric tests on the log transformation were used in bivariate analyses.

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

depression is the result of an unhealthy behavior or whether depression causes the behavior (American Psychiatric Association, 1994).

- **Administration method:** Depression was measured through provider interview administration of the PHQ-9 assessment tool. The PHQ-9 is a multipurpose instrument for screening, diagnosing, monitoring and measuring the severity of depression.
- **Administration time:** The assessment tool was given to participants to review as part of their intake process and completed verbally with a provider or clinical support staff person.
- **Intended respondent:** The PHQ-9 was completed by a provider or clinical support staff with participants.
- **Potential score/response range:** The PHQ-9 total possible score of 27. The PHQ-9 scoring criteria is categorized as minimal (0-4), mild (5-9), moderate (10-14), moderately severe (15-19) and severe (20-27) depression. Patients with a score of 10 or higher were referred for behavioral health services.

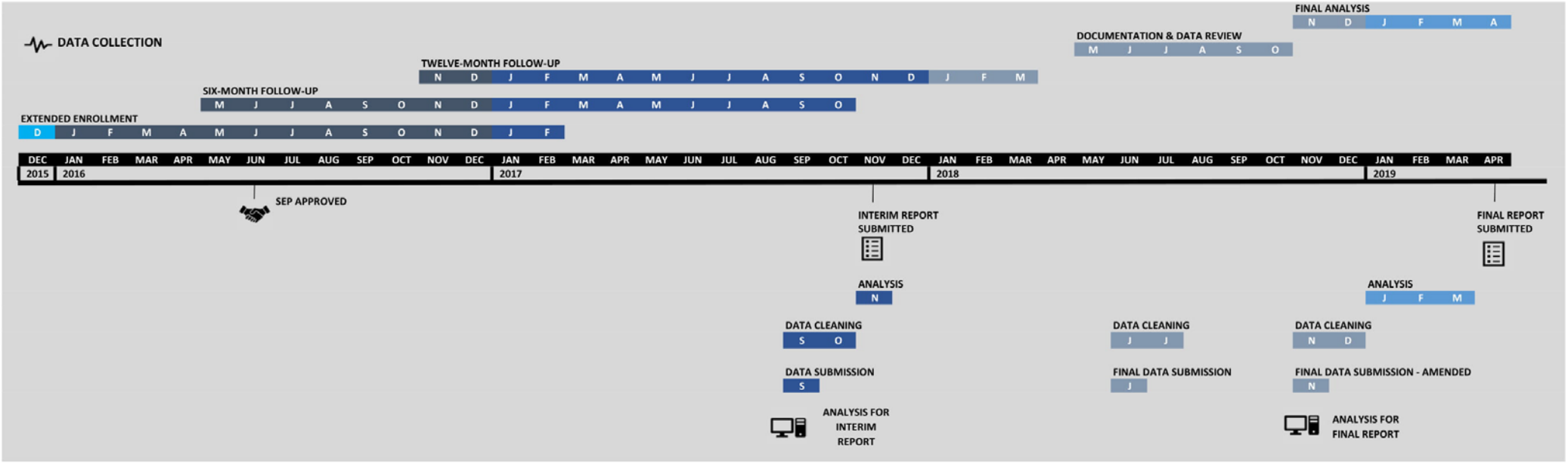
See **Appendix J: Patient Health Questionnaire – 9 (PHQ-9**) to view the PHQ-9 assessment tool (available in English and Spanish).

For PHQ-9 score, there were 462 respondents with complete data at baseline, 312 respondents at 6 months, and 299 respondents at 12 months for the intervention and control groups. The distribution of responses for PHQ-9 at baseline was determined to be non-normal. The log transformation was examined but did not normalize the distribution of PHQ-9. Therefore, nonparametric tests were used in bivariate analyses.

Data Collection Activities

HFHC collected data starting in December 2015 and extended enrollment by six months from August 2016 to February 2017 to meet the enrollment target of 566 participants. As previously noted, this is a deviation from the planned timeline in the SEP. **Figure 3** depicts the data collection timeline as it relates to SEP approval and analyses completed for this final report. Six-month follow-up began in May 2016 and continued through October 2017.Twelve-month follow-up began in November 2016 and ended in March 2018.

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

Descriptive statistics for complete data are presented in this final report for the intervention and control groups. These statistics summarize patients' demographics and other key covariates. These covariates were examined to assist in identifying potential factors that may result in nonequivalence between the two groups. To examine baseline equivalence, Chi-square tests and Fisher's Exact Tests, when necessary based on cell counts, were used for categorical data while two sample t-tests were used for normally distributed continuous data, and the Wilcoxon Signed Rank test was used for non-normally distributed data. Because an RCT design was used for the study, intent-to-treat analyses were conducted for the final analysis. In addition, due to concerns about possible contamination based on analysis of implementation data that revealed 38 control group participants received care coordination, per protocol analyses were conducted with a subset of the sample (n=285). Receipt of the intervention was operationally defined as having any evidence in the medical record of care coordination. This subset removed control participants who were reported as having received intervention services (n=38) and intervention participants who were reported as not having received the expected intervention services at all (n=45). The results of the per protocol analysis are similar to the results of in the intent to treat analysis, lending confidence in the interpretation of the intent-to-treat analyses in that the influence of contamination was minimal. Therefore, the findings section of this report presents the intent to treat analysis, while results of the per protocol analysis can be found in **Appendix K: Per-protocol analyses**.

While this study was balanced on most health and demographic measures at baseline, adjustment for some covariates was performed to account for imbalance of those measures not equivalent at baseline as well as to increase the precision of study results. 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 (Cary, NC). PROC GLM was utilized for the primary linear regression models. To confirm this was an appropriate approach given the non-normal distributions for some outcomes, the distribution of errors was examined for each outcome. The residual errors were determined to be normally distributed for all outcome measures and therefore the use of linear regression as our primary approach was suitable. Differences were considered statistically significant at $p<0.05$.

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

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

Unit of Analysis and Overview of Analyses Performed

The unit of analysis was the individual patient. An end-point analysis was our primary analytic approach. This end-point analysis approach is a conventional approach to analyze clinical trial data collected from individuals with both baseline data and end-point data of primary interest (Liebschutz, et al., 2017). We employed generalized regression analysis following a modeling sequence from bivariate models to multiple regression models adjusting for baseline levels of outcome measures and covariates that were assessed as relevant based on nonequivalence at baseline and review of the scientific literature. The parameter of interest was the dichotomous variable that differentiates the treatment status (i.e., intervention vs. control). Between-group comparison of baseline and single follow-up outcomes were assessed by end-point analyses that accounted for the baseline level of impact measures. Additionally, because multiple follow-up impact measures form individual trajectories, we conducted longitudinal analyses assessing whether the impact measure trajectories differed by intervention status (Fitzmaurice et al., 2004). A time measure was developed and applied to denote baseline, 6-month, and 12-month follow-up measures.

In addition to adjusting for key covariates, we also assessed potential collinearity and its impact on the standard error estimates for the covariates in the model by examining the variance inflation factor when necessary. We stated in the SEP that in areas where multiple comparisons are necessary, we would employ adjustment of the p-value to account for multiple comparisons, such as the Bonferroni correction. This step was ultimately 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 outcome measure on intervention status (intervention vs. control) followed by the estimation of an adjusted model accounting for the baseline measure of interest and further adjustment for key covariates. Parametric two sample t-tests were used for bivariate analysis of confirmatory and exploratory study outcomes (blood pressure and BMI). The other exploratory outcomes (HbA1c and PHQ-9) were found to be non-normally distributed. In these bivariate analyses, nonparametric Wilcoxon Rank Sum tests were conducted due to the increased sensitivity to detect a difference in non-normally distributed data. The nonparametric results are presented throughout this report; however, additional parametric t-tests were performed for these measures to align with linear regression methods for the final analyses. Though the bivariate parametric results are not presented, both the nonparametric and parametric bivariate analyses produced consistent results.

Following bivariate comparisons, multivariate and longitudinal analyses were performed separately to answer each research question. Due to the amount of missing data, multiple imputation was utilized for the primary linear regression analysis of blood pressure, BMI, and PHQ-9 score. It was determined propensity score matching methodology was not necessary as randomization successfully led to statistically equivalent groups at baseline. The primary adjusted multivariate analysis models the outcome of interest on intervention status with relevant covariates included. The longitudinal analysis evaluates whether the impact measure trajectories differ by intervention status across the 12-month study. Effect modification of the intervention-outcome relationships were also examined by including interactions terms between sample characteristics and intervention group status in the regression models. Possible effect modification of baseline health condition was explored for the corresponding impact measure (e.g. baseline depression as an effect modifier for impact on PHQ-9 score at 12 months.) Age was considered as a potential effect modifier for each model; age was divided into under

51 years and 51 years or older based on the average age in the full study population. The potential for effect modification by sex, male and female, was also assessed.

The SEP indicated a set of planned covariates for adjustment in the models. Of those listed, age, sex, ethnicity, language, marital status, employment, and time were included in one or more of the analyses. Categorical age was operationally defined by the following categories: 18-34 years, 35-44 years, 45-54 years, 55-64 years, and those who are 65 years or older. Age was included as a continuous variable in all regression models for parsimony. Marital status was considered a dichotomous variable with categories of "married", including only those who indicated they were married, and "not married", which includes all other categories for the marital status variable. Employment was also recoded to a dichotomous variable of "employed" and "unemployed". Baseline PHQ-9 score was included as a covariate for possible selection in models for all outcomes to adjust for the non-equivalence found at baseline.

A backward elimination modeling selection procedure was employed for the end-point analysis approach where covariates with a p-value larger than 0.15 were excluded from the final model for parsimony. To accommodate our stepwise approach in the context of multiply imputed data, we chose to include variables in our final models for blood pressure, BMI, and PHQ-9 score based on the number of times a covariate was selected across the ten imputed datasets (Wood et al., 2008). We selected to include covariates that were selected in analyses of 5 or more of the imputed datasets.

A priori selection was considered, particularly for age and sex due to the known biological influence of these characteristics on health outcomes. However, in response to the baseline equivalence on all demographic measures it was decided a priori selection was not appropriate. The variables were still included for possible selection in the model based on the p-value of 0.15.

Per-Protocol Analysis

For all studied outcome measures, both the per-protocol and intent-to-treat complete case analysis yielded similar results. Due to the alignment of these results, any potential bias due to contamination was determined to have minimal impact on the intervention effect on all outcomes. Therefore, the primary analyses presented are intent-to-treat analyses. The per-protocol analyses are presented in **Appendix K: Per-protocol analyses.**

Blood Pressure

Question 1. **Are patients who receive the enhanced IBH model of care more likely to reduce their blood pressure after 12 months compared to patients who receive the standard of care? <u>This question is confirmatory</u>.**

Overview of Analysis

To answer this confirmatory question about intervention impact on blood pressure, data were collected on patient systolic and diastolic blood pressure levels. HFHC submitted all blood pressure data collected within the study timeframe for each participant, including the date of collection. The participant enrollment date was then used to create ideal 6- and 12-month dates based on the allowed analytic windows (-60/+90 days for 6-month and -60/+60 days for 12-month). Both blood pressure measurements were selected from all collected values for baseline, 6-, and 12-month time points based on the alignment of the collection dates with the enrollment and ideal follow-up dates.

For the bivariate analyses, the total sample size was 331. With the use of multiple imputation, the total sample size for the primary linear analyses was 370 participants. For the longitudinal analysis, the sample size was 455 participants. The analytic sample for longitudinal assessment includes all participants who had a baseline visit and at least one follow-up assessment (at either 6 or 12 months) at which blood pressure data were collected.

Descriptive Statistics and Bivariate Comparisons

At the end of this section **Table 25** presents the mean systolic and diastolic blood pressure values in each study period for the overall sample as well as the intervention and control groups. The overall study sample had a mean blood pressure of 134.0/81.5 at baseline. For those who returned for a follow-up assessment, mean blood pressure was 129.2/78.8 at 6-months and 129.3/78.6 at 12-month follow-up. The intervention group began the study with a mean blood pressure of 133.4/81.0. For those participants in the intervention group who returned for a follow-up, mean blood pressure reduced to 127.7/78.5 at 6-month follow-up and 128.4/78.1 at 12-month follow-up. The control group began the study with a mean blood pressure of 134.5/82.0. For those participants in the control group who returned for follow-up, mean blood pressure decreased to 130.6/79.1 at 6-months and 130.0/79.0 at 12-months. As previously noted in **Table 9**, the intervention and control groups were statistically equivalent on systolic and diastolic blood pressure at baseline.

Bivariate analyses were performed within each study group, testing the statistical significance of the change in impact measures from baseline to 12-month follow-up without controlling for any additional covariates (**Table 23**). The decreases observed within diastolic blood pressure from baseline to 12-month follow-up were statistically significant within both the intervention and control groups. The decrease in systolic blood pressure within the intervention group from baseline to 12 months was also statistically significant; however, this was not the case for systolic blood pressure within the control group.

Bivariate analyses were also performed between the intervention and control groups comparing systolic and diastolic blood pressure at 12-month follow-up, without controlling for any additional covariates (**Table 24**). Based on a p-value greater than 0.05 for both systolic and diastolic blood pressure when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. Systolic and diastolic blood pressure were not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcomes, systolic and diastolic blood pressure. Covariates were removed from the model if their p-value was found to be greater than 0.15. The initial covariates that were input into the models for systolic and diastolic blood pressure were age, sex, primary language, ethnicity, marital status, employment, baseline systolic blood pressure, baseline diastolic blood pressure, baseline comorbidities, and baseline PHQ-9 score. Age was modeled as a continuous variable for parsimony.

$$Y_{(SBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 Ethnicity + \beta_6 MaritalStatus + \beta_7 Employment + \beta_8 BL\_SBP + \beta_9 BL\_DBP + \beta_{10} BL\_Comorbidities + \beta_{11} BL\_PHQ9 + \varepsilon$$

$$Y_{(DBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 Ethnicity + \beta_6 MaritalStatus + \beta_7 Employment + \beta_8 BL\_SBP + \beta_9 BL\_DBP + \beta_{10} BL\_ Comorbidities + \beta_{11} BL\_PHQ9 + \varepsilon$$

The covariates that were selected for inclusion in the final model based on our threshold of model inclusion within analyses of 5 or more of the imputed datasets for systolic blood pressure were age, sex, marital status, baseline systolic blood pressure, and baseline PHQ-9 score.

$$Y_{(SBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 MaritalStatus + \beta_5 BL\_SBP + \beta_6 BL\_PHQ9 + \varepsilon$$

The covariates that were selected in analyses of 5 or more of the imputed datasets for diastolic blood pressure were marital status, baseline diastolic blood pressure, and baseline comorbidities.

$$Y_{(DBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 MaritalStatus + \beta_3 BL\_DBP + \beta_4 BL\_ Comorbidities + \varepsilon$$

Findings

Estimates for the final models of systolic and diastolic blood pressure are presented in **Table 14**.

Mean systolic blood pressure at 12 months did not differ significantly by intervention status (p=0.15); the effect size (using Cohen's d) is 0.13.

$$Y_{(SBP)}=43.65 + -2.47(Intervention) + 0.24(Age) + -3.16(Female) + 4.94(Married) + 0.55(BL\_SBP) + 0.27(BL\_PHQ9) + \varepsilon$$

Mean diastolic blood pressure at 12 months did not differ significantly by intervention status (p=0.22); the effect size (using Cohen's d) is 0.12.

$$Y_{(DBP)}=42.71 + -0.93(Intervention) + 1.03(Married) + 0.41(BL\_DBP) + 1.53(BL\_Comorbidities) + \varepsilon$$

Table 14. Effect of IBH Intervention on Twelve Month Systolic and Diastolic Blood Pressure, Full HFHC Sample

Variable	Systolic Blood Pressure (n=370)		
	Estimate (β)	Standard Error	p-value
Intervention	-2.47	1.70	0.15
Control (ref)	--	--	--
Age (continuous)	0.24	0.10	0.01
Female	-3.27	2.07	0.11
Male (ref)	--	--	--
Married	4.94	1.74	0.005
Not married (ref)	--	--	--
Baseline SBP	0.55	0.04	<0.001
Baseline PHQ-9	0.27	0.16	0.10
Variable	Diastolic Blood Pressure (n=370)		

	Estimate (β)	Standard Error	p-value
Intervention	-0.93	0.75	0.22
Control (ref)	--	--	--
Married	1.0303	0.72	0.15
Not married (ref)	--	--	--
Baseline DBP	0.341	0.04	<0.001
Baseline Comorbidities	1.53	0.50	0.002

Note: "ref" indicates the reference category used to calculate the estimate for a covariate

Additional Analyses

When examining effect modification between intervention participation and select participant characteristics at baseline on systolic blood pressure, significant effect modification was identified by sex. However, when stratifying, the intervention was not found to have a statistically significant effect on systolic blood pressure for either sex. Similarly, when examining effect modification between intervention participation and select participant characteristics at baseline on diastolic blood pressure, significant effect modification was identified by sex. However, when stratifying, the intervention was not found to have a statistically significant effect on diastolic blood pressure for either sex.

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

For systolic blood pressure, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.28, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for systolic blood pressure (see **Table 15**). Adjusting for the covariates that were selected in the primary model— age, sex, marital status, baseline systolic blood pressure, and baseline PHQ-9 score — did not alter these results (not shown).

For diastolic blood pressure, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.71, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for diastolic blood pressure (see **Table 15**). Adjusting for the covariates that were selected in the primary model— marital status, baseline diastolic blood pressure, and baseline comorbidities — did not alter these results (not shown).

Table 15. Effect of IBH Intervention on Trajectory of Systolic and Diastolic Blood Pressure Across Twelve Month Study, Full HFHC Sample

Variable	Systolic Blood Pressure (n=455)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	-1.99	1.84	0.28
Time*Control (ref)	--	--	--
Time	-3.80	1.26	0.003
Intervention	-1.66	1.65	0.32
Control (ref)	--	--	--

Variable	Diastolic Blood Pressure (n=455)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	-0.32	0.86	0.71
Time*Control (ref)	--	--	--
Time	-2.64	0.59	<0.001
Intervention	-1.09	0.76	0.16
Control (ref)	--	--	--

Note: "ref" indicates the reference category used to calculate the estimate for a covariate

Limitations

A limitation to the diastolic blood pressure result is, within the control group, more participants with a higher diastolic blood pressure at baseline did not complete the study. In other words, the control participants who remained in the study were healthier. This could potentially be a contributing factor to the non-significant results for diastolic blood pressure. There are no limitations to note for systolic blood pressure.

HbA1C Level

Question 2. **Are patients with a history or diagnosis of diabetes who receive the enhanced IBH model of care more likely to improve their HbA1c after 12 months compared to patients who receive the standard of care? <u>This question is exploratory</u>.**

Overview of Analysis

To answer this exploratory question about intervention impact on HbA1c, data were collected on patient HbA1c level from those with a history, diagnosis, or suspected diagnosis of diabetes. HFHC submitted all HbA1c data collected within the study timeframe for each participant, including the date of collection. The participant enrollment date was then used to create ideal 6- and 12-month dates based on the allowed analytic windows (-60/+90 days for 6-month and -60/+60 days for 12-month). HbA1c measurements were selected, from all collected values, for baseline, 6-, and 12-month time points based on the alignment of the collection dates with the enrollment and ideal follow-up dates.

For the bivariate analyses, the total sample size was 219. The total sample size for the primary linear analysis was 146 participants. For the longitudinal analysis, the sample size was 214 participants. The analytic sample for longitudinal assessment includes all participants who had a baseline visit and at least one follow-up assessment (at either 6 or 12 months) at which HbA1c data were collected.

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 25** presents the mean HbA1c level data in each study period for the overall sample as well as the intervention and control groups. The overall study sample had a mean HbA1c of 7.8% at baseline and both follow-up points. The intervention had a mean HbA1c of 8.0% throughout the study. The control group participants began the study with a baseline HbA1c of 7.6%. For those participants in the control group who returned for a follow-up visit, the mean HbA1c was also 7.6% and those who returned at 12 months had an average HbA1c of 7.7%. As previously noted in **Table 9**, the intervention and control groups were statistically equivalent on HbA1c level at baseline.

Bivariate analyses were performed within each study group, testing the statistical significance of the change in impact measures from baseline to 12-month follow-up without controlling for any additional covariates (**Table 23**). There were no statistically significant differences for HbA1c level detected from baseline to 12-month follow-up for neither the intervention nor control group.

Bivariate analyses were also performed between the intervention and control groups comparing HbA1c levels at 12-month follow-up, without controlling for any additional covariates (**Table 24**). Based on a p-value greater than 0.05 for HbA1c when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. The HbA1c level was not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, HbA1c level. Covariates were removed from the model if their p-value was found to be greater than 0.15. The initial covariates that were input into the models for HbA1c level were age, sex, primary language, ethnicity, marital status, employment, baseline HbA1c level, and baseline comorbidities. Age was modeled as a continuous variable for parsimony. Baseline PHQ-9 score was not included in this model due to the large amount of missing data and inability to utilize multiple imputation.

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

As previously stated, multiple imputation was considered but not performed due to the fact that this measure was not collected universally at HFHC.

The covariate selected based on a p-value of 0.15 or less was baseline HbA1c level. The final model specification was:

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

Findings

Estimates for the final model of HbA1c level are presented in **Table 16**.

Mean HbA1c level at 12 months did not differ significantly by intervention status (p=0.67).

$$Y_{(HbA1c)} = 3.43 + -0.11(Intervention) + 0.53(BL\_HbA1c) + \varepsilon$$

Table 16. Effect of IBH Intervention on Twelve Month HbA1c Value, Full HFHC Sample

Variable	HbA1c (n=146)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.11	0.24	0.67
Control (ref)	--	--	--
Baseline HbA1c	0.53	0.05	<0.001

Note: "ref" indicates the reference category used to calculate the estimate for a covariate

Additional Analyses

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

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differed by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For HbA1c level, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.33, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for HbA1c level (see **Table 17**).

Table 17. Effect of IBH Intervention on Trajectory of HbA1c Value Across Twelve Month Study, Full HFHC Sample

Variable	HbA1c (n=214)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	-0.24	0.25	0.33
Time*Control (ref)	--	--	--
Time	-0.33	0.17	0.06
Intervention	0.48	0.22	0.03
Control (ref)	--	--	--

Note: "ref" indicates the reference category used to calculate the estimate for a covariate

Limitations

Because this health measure was not collected universally due to standard practice at HFHC, the sample sizes for these analyses were smaller than other measures. This could have led to reduced power to detect a statistically significant result.

Body Mass Index

Question 3. **Are patients who receive the enhanced IBH model of care more likely to reduce their BMI after 12 months compared to patients who receive the standard of care? <u>This question is exploratory</u>.**

Overview of Analysis

To answer this exploratory question about intervention impact on BMI data were collected on patient BMI level. HFHC submitted all BMI data collected within the study timeframe for each participant, including the date of collection. The participant enrollment date was then used to create ideal 6- and 12-month dates based on the allowed analytic windows (-60/+90 days for 6-month and -60/+60 days for 12-month). BMI measurements were selected, from all collected values, for baseline, 6-, and 12-month time points based on the alignment of the collection dates with the enrollment and ideal follow-up dates.

For the bivariate analyses, the total sample size was 326. With the use of multiple imputation, the total sample size for the primary linear analyses was 370 participants. For the longitudinal analysis, the

sample size was 450 participants. The analytic sample for longitudinal assessment includes all participants who had a baseline visit and at least one follow-up assessment (at either 6 or 12 months) at which BMI data were collected.

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 25** presents the mean body mass index values in each study period for the overall sample as well as the intervention and control groups. The overall study sample had a mean body mass index of 33.7 at baseline. For those who returned for a follow-up assessment, mean body mass index was 33.6 at 6-month follow-up and 33.7 at 12-month follow-up. The intervention group began the study with a mean body mass index of 33.9. For those participants in the intervention group who returned for a follow-up, mean body mass index was 34.1 at 6-month follow-up and 34.3 at 12-month follow-up. The control group began the study at mean body mass index of 33.6. For those participants in the control group who returned for follow-up, mean body mass index was 33.0 at 6-months, and 33.1 at 12-months. As previously noted in **Table 9**, the intervention and control groups were statistically equivalent on body mass index at baseline.

Bivariate analyses were performed within each study group, testing the statistical significance of the change in impact measures from baseline to 12-month follow-up without controlling for any additional covariates (**Table 23**). The slight changes observed within body mass index from baseline to 12-month follow-up were not statistically significant within both the intervention and control groups.

Bivariate analyses were also performed between the intervention and control groups comparing body mass index at 12-month follow-up, without controlling for any additional covariates (**Table 24**). Based on a p-value greater than 0.05 for body mass index when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. Body mass index was not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, BMI. 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 model for BMI were age, sex, primary language, ethnicity, marital status, employment, baseline BMI, number of comorbidities at baseline, and baseline PHQ-9 score. Age was modeled as a continuous variable for parsimony.

$$Y_{(BMI)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 Ethnicity + \beta_6 MaritalStatus + \beta_7 Employment + \beta_8 BL\_BMI + \beta_9 BL\_ Comorbidities + \beta_{10} BL\_PHQ9 + \varepsilon$$

The covariates that were selected for inclusion in the final model based on our threshold of model inclusion within analyses of 5 or more of the imputed datasets for BMI were baseline BMI and baseline PHQ-9 score.

$$Y_{(BMI)}=\beta_0 + \beta_1 StudyArm + \beta_2 BL\_BMI + \beta_3 BL\_ PHQ9 + \varepsilon$$

Findings

Estimates for the final model of BMI level are presented in **Table 18**.

Mean BMI level at 12 months did not differ significantly by intervention status (p=0.52).

$$Y_{(BMI)}=0.48 + 0.14(\text{Intervention}) + 0.99(\text{BL\_BMI}) + -0.04(\text{BL\_ PHQ9}) + \varepsilon$$

Table 18. Effect of IBH Intervention on Twelve Month BMI, Full HFHC Sample

Variable	BMI (n=370)		
	Estimate (β)	Standard Error	p-value
Intervention	0.14	0.22	0.52
Control (ref)	--	--	--
Baseline BMI	0.99	0.01	<0.001
Baseline PHQ9	-0.04	0.02	0.05

Note: "ref" indicates the reference category used to calculate the estimate for a covariate

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 to examine time as an independent variable, assessing whether the outcome trajectories differed by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For BMI, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.87, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for BMI (see **Table 19**). Adjusting for baseline PHQ-9 score, selected in the primary model did not alter these results (not shown).

Table 19. Effect of IBH Intervention on Trajectory of BMI Across Twelve Month Study, Full HFHC Sample

Variable	BMI (n=450)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	-0.04	0.22	0.87
Time*Control (ref)	--	--	--
Time	-0.03	0.15	0.84
Intervention	0.37	0.59	0.53
Control (ref)	--	--	--

Note: "ref" indicates the reference category used to calculate the estimate for a covariate

Limitations

There are no limitations specific to this analysis to note.

Depressive Symptoms

Question 4. **Are patients who receive the enhanced IBH model of care more likely to reduce their depressive symptoms, as measured by the PHQ-9, after 12 months compared to patients who receive the standard of care? <u>This question is exploratory</u>.**

Overview of Analysis

To answer this exploratory question about intervention impact on PHQ-9 score, data were collected on patient PHQ-9 score. HFHC submitted all PHQ-9 score data collected within the study timeframe for each participant, including the date of collection. The participant enrollment date was then used to create ideal 6- and 12-month dates based on the allowed analytic windows (-60/+90 days for 6-month and -60/+60 days for 12-month). PHQ-9 score measurements were selected, from all collected values, for baseline, 6-, and 12-month time points based on the alignment of the collection dates with the enrollment and ideal follow-up dates.

For the bivariate analyses, the total sample size was 299. With the use of multiple imputation, the total sample size for the primary linear analyses was 370 participants. For the longitudinal analysis, the sample size was 312 participants. The analytic sample for longitudinal assessment includes all participants who had a baseline visit and at least one follow-up assessment (at either 6 or 12 months) at which PHQ-9 score data were collected.

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 25** presents the mean PHQ-9 values in each study period for the overall sample as well as the intervention and control groups. The overall study sample had a mean PHQ-9 score of 6.0 at baseline. For those who returned for a follow-up assessment, mean PHQ-9 was 4.7 at 6-month follow-up and 5.0 at 12-month follow-up. The intervention group began the study with a mean PHQ-9 of 7.1. For those participants in the intervention group who returned for a follow-up, mean PHQ-was 5.0 at 6-month follow up and 4.6 at 12-month follow-up. The control group began the study at mean PHQ-9 of 5.0. For those participants in the control group who returned for follow-up, mean PHQ-9 was 4.4 at 6-month follow-up and 5.3 at 12-month follow-up. As previously noted in **Table 9**, the intervention and control groups were not statistically equivalent on baseline PHQ-9, thus baseline PHQ-9 was included within modeling of intervention effectiveness for outcome measures to account for this imbalance.

Bivariate analyses were performed within each study group, testing the statistical significance of the change in impact measures from baseline to 12-month follow-up without controlling for any additional covariates (**Table 23**). The reductions observed within PHQ-9 from baseline to 12-month follow-up were statistically significant within both the intervention and control groups (p=0.01).

Bivariate analyses were also performed between the intervention and control groups comparing PHQ-9 at 12-month follow-up, without controlling for any additional covariates (**Table 24**). Based on a p value greater than 0.05 for PHQ-9 score when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. PHQ-9 score was not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, PHQ-9 score. Covariates were removed from the model if their p-value was found to be greater than 0.15. The initial covariates that were input into the model for PHQ-9 score were age, sex, primary language, ethnicity, marital status, employment, baseline PHQ-9 score, and baseline comorbidities. Age was modeled as a continuous variable for parsimony.

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

The covariates that were selected for inclusion in the final model based on our threshold of model inclusion within analyses of 5 or more of the imputed datasets for PHQ-9 score were age, primary language, employment, and baseline PHQ-9 score.

$$Y_{(PHQ9)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Language + \beta_4 Employment + \beta_5 BL\_PHQ9 + \varepsilon$$

Findings

Estimates for the final model of PHQ-9 score are presented in **Table 20**.

On average, the PHQ-9 score of intervention participants was 1.67 points lower than the control participants, holding all other variables in the model constant (p=0.01); the effect size (using Cohen's d) was 0.29.

$$Y_{(PHQ9)}=5.00 + -1.67(Intervention) + -0.04(Age) + 1.61(English) + -3.79(Employed) + 0.45(BL\_PHQ9) + \varepsilon$$

Table 20. Effect of IBH Intervention on Twelve Month PHQ-9 Score, Full HFHC Sample

Variable	PHQ-9 (n=370)		
	Estimate (β)	Standard Error	p-value
Intervention	**-1.67**	**0.66**	**0.01**
Control (ref)	--	--	--
Age (continuous)	-0.04	0.03	0.18
English-speaking	1.61	0.86	0.06
Spanish-speaking (ref)	--	--	--
Employed	-3.79	3.12	0.23
Unemployed (ref)	--	--	--
Baseline PHQ-9	0.45	0.06	<0.001

Notes: Bold denotes statistical significance (p-value < 0.05); "ref" indicates the reference category used to calculate the estimate for a covariate.

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 category (<51 years versus ≥51 years). However, when stratifying, the intervention was not found to have a statistically significant effect on PHQ-9 among participants under 51 years (see

Table 21). Among participants who were 51 years or older at baseline, the intervention was significantly associated with a lower PHQ-9 score. On average, for those 51 years or older at baseline, intervention participants had a PHQ-9 score 2.08 points lower than those in the control group (p=0.01); the effect size (using Cohen's d) was 0.34.

Table 21. Effect of IBH Intervention on Twelve Month PHQ-9 Score, Stratified by Age Category

	Under 51 Years			51 Years or Older		
Variable	PHQ-9 (n=164)			PHQ-9 (n=206)		
	Estimate (β)	Standard Error	p-value	Estimate (β)	Standard Error	p-value
Intervention	-1.34	0.88	0.13	**-2.08**	**0.81**	**0.01**
Control (ref)	--	--	--	--	--	--
Baseline PHQ-9	0.35	0.09	0.001	0.49	0.06	<0.001

Notes: Bold denotes statistical significance (p-value < 0.05); "ref" indicates the reference category used to calculate the estimate for a covariate

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differed by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For PHQ-9 score, only adjusting for intervention status and time, a significant time/group interaction was detected, 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 PHQ-9 score (see **Table 22**). Adjusting for the covariates that were selected in the primary model— age, primary language, and employment — did not alter these results (not shown).

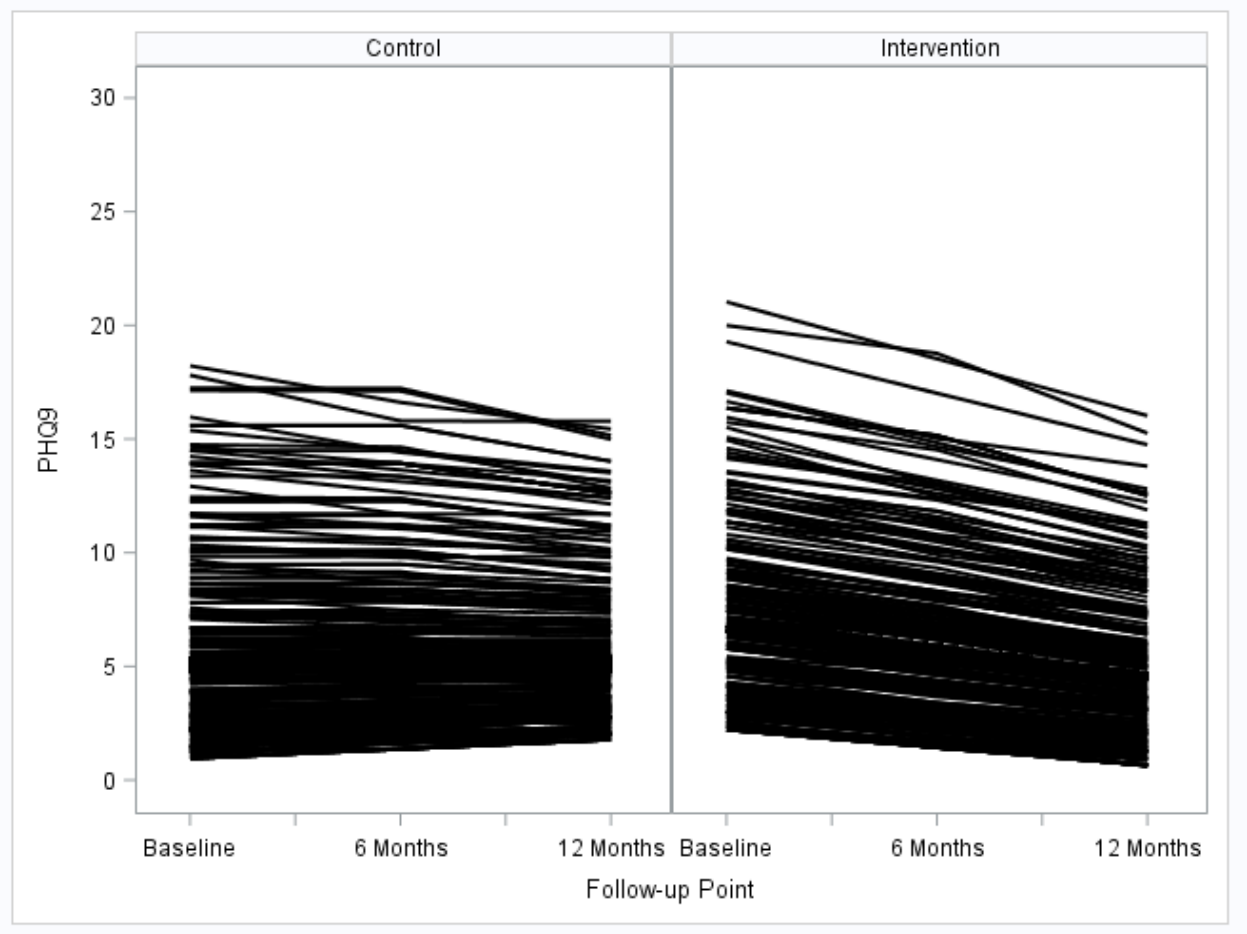
Table 22.Effect of IBH Intervention on Trajectory of PHQ-9 Score Across Twelve Month Study, Full HFHC Sample

Variable	PHQ-9 (n=312)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	**-2.42**	**0.70**	**0.001**
Time*Control (ref)	--	--	--
Time	0.07	0.49	0.88
Intervention	1.73	0.588	0.004
Control (ref)	--	--	--

Notes: Bold denotes statistical significance (p-value < 0.05); "ref" indicates the reference category used to calculate the estimate for a covariate.

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 control group trajectory in the left panel and the intervention group trajectory in the right panel. The trajectory figure visually displays the differences identified in the longitudinal statistical model, showing the intervention group's higher baseline PHQ-9 score and steeper decrease in PHQ-9 score from baseline to 12 months compared to the control group.

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



Limitations

There are no limitations specific to this measure to note.

Functioning and Quality of Life

Question 5. **Are patients who receive the enhanced IBH model of care more likely to improve their quality of life, as measured by the Duke Health Profile, after 12 months compared to patients who receive the standard of care? <u>This question is exploratory</u>.**

During the course of the study, procedures to collect the Duke Health Profile data were implemented inconsistently or not at all in some cases. An evaluation of the data revealed significant missing data at all three time points. At baseline only 35% of profiles were completed within the study window. At 6-month follow-up 45% of assessments were completed. Just under half of 12-month assessments were completed (48%). On this basis, the proposed impact analyses were not performed for this measure.

Table 23. Within Group Bivariate Analyses Comparing Impact Measures from Baseline to 12 Months, by Intervention Group

	INTERVENTION GROUP (n=172)[a]			
	12-Month Mean (SD)	Baseline Mean (SD)	12-month (–) Baseline Mean Difference (SD)	*P*
Systolic	**128.4 (18.3)**	**134.1 (21.7)**	**-4.5 (16.8)**	**0.001**
Diastolic	**78.1 (7.1)**	**80.9 (9.2)**	**-2.4 (7.7)**	**<0.001**
BMI[b]	34.3 (7.7)	34.2 (7.8)	0.03 (1.9)	0.83
Nonparametric Tests[c]	12-Month Median (SD)	Baseline Median (SD)		*P*
HbA1c	7.7 (2.9)	7.4 (4.2)		0.47
PHQ-9	**3.0 (8.0)**	**5.0 (12.0)**		**0.01**
	CONTROL GROUP (n=198) [a]			
	12-Month Mean (SD)	Baseline Mean (SD)	12-month (–) Baseline Mean Difference (SD)	*PP*
Systolic	130.0 (20.3)	133.7 (18.9)	-2.6 (18.3)	0.06
Diastolic	**79.0 (8.5)**	**81.0 (8.6)**	**-1.9 (8.7)**	**0.01**
BMI[b]	33.1 (6.9)	33.3 (6.8)	-0.02 (1.9)	0.87
Nonparametric Tests[c]	12-Month Median (SD)	Baseline Median (SD)		*P*
HbA1c	7.4 (2.9)	7.0 (3.1)		0.47
PHQ-9	**3.0 (8.0)**	**2.5 (8.0)**		**0.01**

Note: Bold denotes statistical significance (p-value < 0.05) [a] Sample sizes vary by measure due to missing data [b] A log transformation was used [c] The Wilcoxon rank sum test was used to examine non-normally distributed data

Table 24. Between Group Bivariate Analyses Comparing Intervention to Control at 12-Month Follow-Up

	Full Sample (n=370)[a] Mean (SD)	Intervention (n=172) [a] Mean (SD)	Control (n=198) [a] Mean (SD)	p-value
Systolic	129.3 (19.4)	128.4 (18.3)	130.0 (20.3)	0.46
Diastolic	78.6 (7.9)	78.1 (7.1)	79.0 (8.5)	0.31
BMI[b]	33.7 (7.3)	34.3 (7.7)	33.1 (6.9)	0.15
Nonparametric Tests[c]	Median (IQR)	Median (IQR)	Median (IQR)	p-value
HbA1c	7.6 (3.0)	7.7 (2.9)	7.4 (2.9)	0.20
PHQ-9	3.0 (8.0)	3.0 (8.0)	3.0 (8.0)	0.36

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

Table 25. Impact Measures by Study Arm and Follow-up Period, Overall and by Study Group

	Full Sample			Intervention			Control		
	Baseline n=582	6-Mo n=454	12-Mo n=370	Baseline n=270	6-Mo n=221	12-Mo n=172	Baseline n=312	6-Mo n=233	12-Mo n=198
Measure		Mean (SD)			Mean (SD)			Mean (SD)	
Blood pressure									
Systolic	134.0 (20.3)	129.2 (19.5)	129.3 (19.4)	133.4 (21.3)	127.7 (18.2)	128.4 (18.3)	134.5 (19.4)	130.6 (20.6)	130.0 (20.3)
Diastolic	81.5 (9.4)	78.8 (9.0)	78.6 (7.9)	81.0 (9.6)	78.5 (9.1)	78.1 (7.1)	82.0 (9.2)	79.1 (8.9)	79.0 (8.5)
Missing	3	32	39	1	6	18	2	26	21
HbA1c									
HbA1c	7.8 (2.4)	7.8 (2.1)	7.8 (1.9)	8.0 (2.5)	8.0 (2.1)	8.0 (1.9)	7.6 (2.3)	7.6 (2.1)	7.7 (1.9)
Missing	254	188	151	115	89	66	139	99	85
BMI									
BMI	33.7 (7.0)	33.6 (7.3)	33.7 (7.3)	33.9 (7.5)	34.1 (7.8)	34.3 (7.7)	33.6 (6.6)	33.0 (6.7)	33.1 (6.9)
Missing	7	36	44	4	9	20	3	27	24
PHQ-9									
PHQ-9 Score	6.0 (6.7)	4.7 (6.2)	5.0 (5.8)	7.1 (5.0)	5.0 (6.0)	4.6 (5.4)	5.0 (6.3)	4.4 (6.4)	5.3 (6.2)
Missing	120	142	71	49	65	29	71	77	42

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

Summary of Findings

This final report provides an overview of findings for the evaluation of the Sí Texas HOPE program at Hope Family Health Center. HFHC implemented an adaptation of the collaborative care model which has been well described in the literature (e.g., Guide to Community Preventive Services, 2010; Sanchez & Watt, 2012; Watt, 2009; Gilbody et al., 2006). HFHC's intervention was designed to improve physical and mental health outcomes and included care management and access to behavioral health specialists. To evaluate the impact of their program, HFHC conducted an RCT to compare intervention participants receiving the delivery of IBH services with control group participants receiving usual care available to all HFHC patients.

HFHC's evaluation of program impact utilized a randomized control trial design with strong internal validity. There were two major threats to internal validity: attrition and contamination. First, analysis of participants in the study compared to those lost to follow-up revealed that there were no significant differences in health measures among these participants; however, men were significantly more likely to be lost to follow up. We accounted for differential attrition by including sex in all models. Second, during the study a small minority of participants in HFHC's control group received intervention services due to challenges in implementation. The impact of contamination was found to be minimal and did not alter the outcome of the study. Finally, the RCT's original design called for provider-level randomization. It was not feasible to randomize participants to intervention and control providers due primarily to challenges in scheduling volunteer providers. However, HFHC was able to randomize participants at the individual level, and the intervention and control groups were equivalent at baseline across impact measures and demographic variables.

This evaluation study achieves a moderate level of evidence given that an evidence-based intervention was adapted and evaluated using a study design with strong internal validity. This evaluation study uses an RCT design and mitigated major threats to internal validity such as selection bias. The program was implemented to fidelity, and the evaluation was conducted as intended. Despite some contamination of the control group, sub-analyses demonstrated that contamination was minimal and did not affect the outcome of the study. The study also meets the criteria for effective evidence for the following reasons. The study demonstrates a positive, significant finding for an exploratory outcome (PHQ-9). The study showed that, when controlling for baseline measures and other covariates, the intervention participants had significantly greater improvements in depressive symptoms, an exploratory outcome (PHQ-9, β=-1.67, p=0.01) at 12 months compared to the control participants, consistent with prior research. This statistically significant outcome achieved a small effect size (Cohen's d=.29). There were no negative intervention effects on confirmatory or exploratory outcomes. Given the internal validity of this study, the fidelity to which the evaluation and program were implemented, the significant results, and the unique and important contribution to the field, this study achieves a moderate level of evidence to improve our understanding of the impact of an integrated behavioral health approach within a free and charitable clinic setting.

The evaluation was implemented as intended except for two areas 1) a deviation to the original timeline which was documented in a SEP amendment in March 2017, and 2) adoption of a consulting psychiatrist due to not being able to fill the position. The recruitment period was extended to increase enrollment. HFHC conducted enrollment on a rolling basis between December 2015 and February 2017 (13 months).

Six-month follow-up ended in October 2017, and 12-month follow-up ended in March 2018. While HFHC did not reach its enrollment target, sufficient sample was recruited and retained in order to detect a small change in depressive symptoms, as measured by PHQ-9 score, at 12-months with statistical significance. A detailed timeline of the study can be found in **Figure 3**. HFHC did not have any changes to the budget after their SEP amendment. Their Executive Director directed the study after the departure of the Sí Texas Study Director during the last few months of the study.

This study contributes to our understanding of the implementation of IBH programs in free and charitable clinic settings. The implementation of HFHC's IBH program demonstrates that such an approach is feasible and has potential benefits for the mental health of uninsured patients living at or below 200% of the FPL in a US-Mexico border community. Key facilitators included communication and coordination between behavioral health and primary care, new staff such as the care coordinators, physical space of the clinic, increased communication, adapted data systems, flexibility of program staff, staff relationships, and staff training. Barriers were hiring and staff retention, challenges in data system implementation, and volunteer provider engagement.

Summary of Implementation Findings

The implementation evaluation examined fidelity to HFHC's program logic model by conducting focus groups and interviews and examining patient visit data. HFHC was able to implement its IBH model to a high degree of fidelity and in alignment with the program logic model by the mid-point of implementation after modifying its clinic workflow and data collection practices. Key drivers of implementation included team building during program initiation, having initial and continued communication about the program to all staff and providers, knowing in advance what data will need to be collected for the program, having sufficient staffing and training, and building leadership buy-in. Focus group participants described the importance of the HFHC program in enabling them to improve their health. A majority of intervention participants received services from the behavioral health specialist and improved their utilization of behavioral health services compared to control participants.

While fidelity to the program was high, findings from the focus groups and interviews in the implementation study revealed facilitators and challenges to implementation. Major facilitators to implementation and lessons learned from the program include: prioritizing staff team building and buy-in at the beginning of implementation, adapting data systems to align with clinic workflow in support of integrated activities, and consistent leadership support and buy-in for integration activities. Engaging volunteer providers was challenging during implementation but did not turn out to be essential for program implementation success.

Summary of Impact Findings

All impact analyses were conducted as proposed in the amended SEP. Impact analyses indicate that HFHC's study has moved the level of evidence from preliminary to moderate. When controlling for baseline measures and other covariates, intervention assigned participants did not have statistically significant improvement in either systolic or diastolic blood pressure (the confirmatory outcome) when compared to the control participants at 12 months. However, there was a statistically significant positive effect in the exploratory outcome of depressive symptoms, measured through PHQ-9 score, in intervention compared to the control group (β= -1.67, p=0.01; d=0.29). Longitudinal analysis demonstrated this same trend in depressive symptoms improvement over study follow-up in the

intervention compared to controls. When adjusting for intervention status and time, a significant time/group interaction was detected, 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 PHQ-9 score. Adjusting for the covariates that were selected in the primary model— age, primary language, and employment — did not alter these results. There were no statistically significant effects observed for the other exploratory outcomes (i.e., body mass index, HbA1c, and the Duke Health profile). There were no negative intervention effects on any outcome analyzed in the study.

The study also found evidence of effect modification of PHQ-9 score when stratifying by age. Among those who were the mean study participant age of 51 years or older at baseline, the intervention was significantly associated with a lower PHQ-9 score. On average, for those 51 years or older at baseline, intervention participants had a PHQ-9 score 2.08 points lower than those in the control group (p=0.01); the effect size (using Cohen's d) is 0.34. The intervention was not found to be significantly associated with PHQ-9 score among those who were under 51 years.

Lessons Learned, Study Limitations, and Implications for Future Research

This evaluation contributes to our understanding of the impact of the integration of behavioral health services with primary care via improve coordination and a behavioral health specialist intervention. This study builds on this previous work by examining the impact of an adaptation to prior studied models of collaborative care with predominantly Hispanic population living under 200% of the FPL without health insurance. Further, this is the first study to examine this model implemented in a free and charitable clinic study that exclusively utilizes volunteers to provide clinical services.

HFHC's RCT is one of the first RCTs examining IBH models in a setting that serves uninsured predominately Hispanics living in poverty at the US-Mexican border. Moreover, this study is the first of its kind in examining IBH implementation in a clinic that exclusively uses volunteer primary care providers. HFHC was not ultimately able to obtain buy-in from volunteer primary care providers but this did not impede implementation of other parts of the program. HFHC's investment in team building during program initiation, prioritizing staff training, and finding appropriate staff to implement the program paid off.

Lessons Learned

While the intervention was implemented with high fidelity, many lessons emerged that could inform other organizations interested in implementing IBH strategies within a free and charitable clinic setting. The primary area of learning is the impact of HFHC's volunteer-based operational model on program implementation. HFHC's setting is unique in that primary care services are provided by volunteers who work a range of hours: from just a few hours to a day or two or more per week. Volunteer providers may or may not be fully integrated into clinic operations to accommodate their donation of time around their needs. Most volunteer providers who donate time to HFHC's primary care clinic also work at or run their own private practices. As a result, a majority of the volunteer providers were not engaged in the clinic's integration efforts as planned or anticipated. While this lack of engagement and buy-in did not impede implementation of the program itself in the long run, it is possible that integration may have been increased or optimized with more focused effort on volunteer engagement. Further, the design of HFHC's model emphasized integration at the clinical support staff level, with warm handoffs primarily being performed by care coordinators. This program feature allowed HFHC to bypass more direct

participation in integration activities by providers, and may be a design element that other free and charitable clinics may wish to consider in the design of their own programs.

On the evaluation side, the volunteer-based structure of HFHC's program resulted in two major challenges that ultimately did not harm the trial. First, HFHC was unable to randomize at the provider level, a failure which was driven by scheduling needs of the individual providers. HFHC overcame this challenge by randomizing at the individual level. With this challenge came an additional obstacle of minimizing contamination. As shown in the analyses presented, control group contamination did occur. It is possible that inappropriate volunteer provider referrals to Si Texas intervention services played a role in contaminating the trial. While there is no objective evidence that this occurred, it is an area that should be noted for clinics with similar operational models. As a strategy for mitigation, clinics that employ volunteers that are also implementing research trials may wish to develop an orientation for each provider to ensure that they understand study procedures and their role in ensuring those procedures are implemented appropriately.

Going forward, HFHC is working to better involve their providers into their integration efforts around their availability. Other free and charitable clinics utilizing volunteer clinicians may wish to prioritize buy-in of their providers to optimize potential benefits of their integration efforts. Alternatively, other free and charitable clinics may wish to build IBH programs that require minimal buy-in from providers when it is not feasible to integrate them more fully into clinic operations.

Study Limitations and Implications for Future Research

It is important to note the limitations of this study. HFC evaluation findings show that intervention participants were more likely than control participants to see significant improvements in their depressive symptoms but there were no statistically significant improvements in physical health or quality of life. It is possible that changes to physical and quality of life outcomes require a longer term (e.g., more than a year) to develop into meaningful changes. Older patients (over 50) were more likely to reduce their depressive symptoms compared to younger patients.

HFHC experienced several challenges in implementing their evaluation. Despite not being able to randomize at the provider level, HFHC was able to randomize patients at the individual level. HFHC had never implemented a study at their clinic previously and works within a free and charitable clinic context, making the implementation of an RCT a tremendous accomplishment and potential model for other clinics working in similar conditions to implement research. HFHC also experienced contamination in their study despite implementing strategies to limit control group exposure to the intervention. Given HFHC's limited physical space and limited buy-in from volunteer providers, it is not surprising that some contamination occurred. Volunteer engagement and buy-in of the evaluation (in addition to the program itself) may have mitigated contamination and prevented referrals of control group patients to behavioral health specialists. Finally, HFHC never implemented the incentive protocol to fidelity which presented a challenge to the implementation of the study. Improved staff training on study procedures may have enabled implementation of the incentive protocol.

It is also important to note that HFHC made some changes to their implementation approach based on field conditions that prevented implementation to plan. This is normal in any program implementation, but worthy of discussion because of HFHC's setting and its implications for future adoption of their model. Integrated, collaborative care models typically include psychiatric consultation. HFHC had

planned to hire a consulting psychiatrist to review cases with the care manager and staff counselors. However, HFHC was not able to fill this position due to lack of available psychiatrists in the area. This outcome is not surprising, as HFHC's service area is a designated professional shortage area. In the end, HFHC changed their implementation plan and adapted their model by making referrals to external psychiatric services. What is remarkable about the absence of this program component is that there was still an intervention effect on depressive symptoms. This study demonstrated that the psychiatric consultation component may not be necessary to improve depressive symptoms in a charitable clinic setting. Given that professional shortages are a common theme in areas served by free and charitable clinics, more research is needed to validate this finding and to provide valuable information to other clinics working to design integrated behavioral health programs.

Next Steps

Moving forward, HFHC has sustained its IBH approach and made it available to all their patients. HFHC is also pursuing funding mechanisms to ensure its future sustainability. While HFHC is a free and charitable clinic, ensuring patients have access to IBH services such as the behavioral health specialist will require consistent funding to ensure access. HFHC has made an investment in implementing an EMR system post-study implementation, a step toward sustaining their new IBH-focused operational model. Sustaining IBH services is made more challenging at HFHC since patients are uninsured and thus HFHC does not have the benefit of insurance reimbursement to defray costs. As HFHC moves ahead in its service implementation after the study, it is planning to continue its IBH model in its facility and to apply knowledge from this evaluation to obtain additional grant funding and to improve efficiency within the clinic.

OTHER ASPECTS OF STUDY LOGISTICS AND FEASIBILITY

Human Subjects Protection

HFHC submitted its initial research protocol in September 2015 to the New England Independent Review Board (NEIRB) for their determination of risk and approval of study procedures. NEIRB approved HFHC's initial research protocol on November 23, 2015 (protocol reference number #120160447, formerly #15-410). HFHC submitted an amendment on November 2, 2016 and received approval for that amendment on November 8, 2016. No enrollment took place while the amendment was being reviewed by NEIRB. HFHC did not encounter any problems securing approval from NEIRB and received approval according to the planned study timeline. In accordance with NEIRB procedures, HFHC has submitted two annual continuing review reports to the NEIRB. Both reports were approved.

In May 2018, the Principal Investigator became aware of administrative challenges in implementing the NEIRB-approved procedures. These challenges were reported to NEIRB through a Promptly Reportable Information report on September 21, 2018 after an on-site assessment was undertaken from July 31 through August 1, 2018 with support of the funder, Methodist Healthcare Ministries of South Texas, Inc. On October 17, 2018, after review of the report, NEIRB determined the corrective and preventative action plan undertaken by HRiA and HFHC was adequate and required no further action.

Timeline

SIF Conditional approval to begin data collection was received in September 2015. HFHC began their enrollment in December 2015 after IRB approval was secured. Due to enrollment challenges, HFHC amended their SEP to extend their enrollment period from 6 months to a year (excluding their December 2015 period due to start up challenges) and to add financial incentives. Assessment periods were adjusted to reflect the extended enrollment period. The dates for the interim and final reports were revised accordingly. In a deviation from the SEP, the interim report was submitted November 2017. This final report was delayed to April 2019 due to the challenges reported above and until the team received NEIRB approval to continue. No other major changes to the timeline occurred. An updated timeline is presented in **Appendix B. Revised Project Timeline** below.

Evaluator/Subgrantee Role and Involvement

Over the course of the study, HFHC experienced one staff leadership change. In April 2018, the HFHC Sí Texas Project Director left the organization and the Executive Director took on the responsibilities of that role. HFHC's clinical staff and leadership conducted all on-site enrollment and data collection activities. The Principal Investigator of record for the study under the IRB protocol is Karen Errichetti.

Budget

Financial incentives were introduced during the study period; however, these changes were budget neutral. No changes were made to the budget during the project period to-date. SIF approved these changes in an amendment dated June 8, 2017.

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APPENDICES

Appendix A	Prior Research Supplement
Appendix B	Revised Project Timeline
Appendix C	Program Logic Model
Appendix D	Sí Texas Mid-Point Implementation Evaluation: Key Informant Interview General Guide
Appendix E	Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide
Appendix F	Sí Texas Summative Implementation Evaluation: Focus Group Guide
Appendix G	Implementation Evaluation Measures
Appendix H	Loss to Follow-Up/Attrition Tables
Appendix I	Patient-Centered Integrated Behavioral Health Care Checklist
Appendix J	Patient Health Questionnaire – 9 (PHQ-9)
Appendix K	Per-protocol analyses
Appendix L	Duke Health Profile

Appendix A: Prior Research

Study	Peer Review	Date of Data Collection	Study Type	Sample Size	Sample Description	Outcome Measures	Key Study Results	Similarity to Proposed Program
Sanchez & Watt, 2012	Yes	2006-2009	Retrospective Evaluation	269	Predominantly Hispanic, low-income, preferentially Spanish-speaking	Spanish-speaking patients had significantly greater odds of achieving meaningful improvement in depression at 3-month follow-up	Attention to patient preferences in primary care is essential to improve quality of depression treatment	High degree of fidelity
Gilbody et al. 2006	Yes	NA	Meta-analysis	12,355	37 randomized studies of patients with depression receiving primary care	Depression outcomes were improved at 6 months and benefits of longer-term benefit found for up to 5 years	Collaborative care is more effective than standard care in improving depression outcomes in the short and long terms	NA

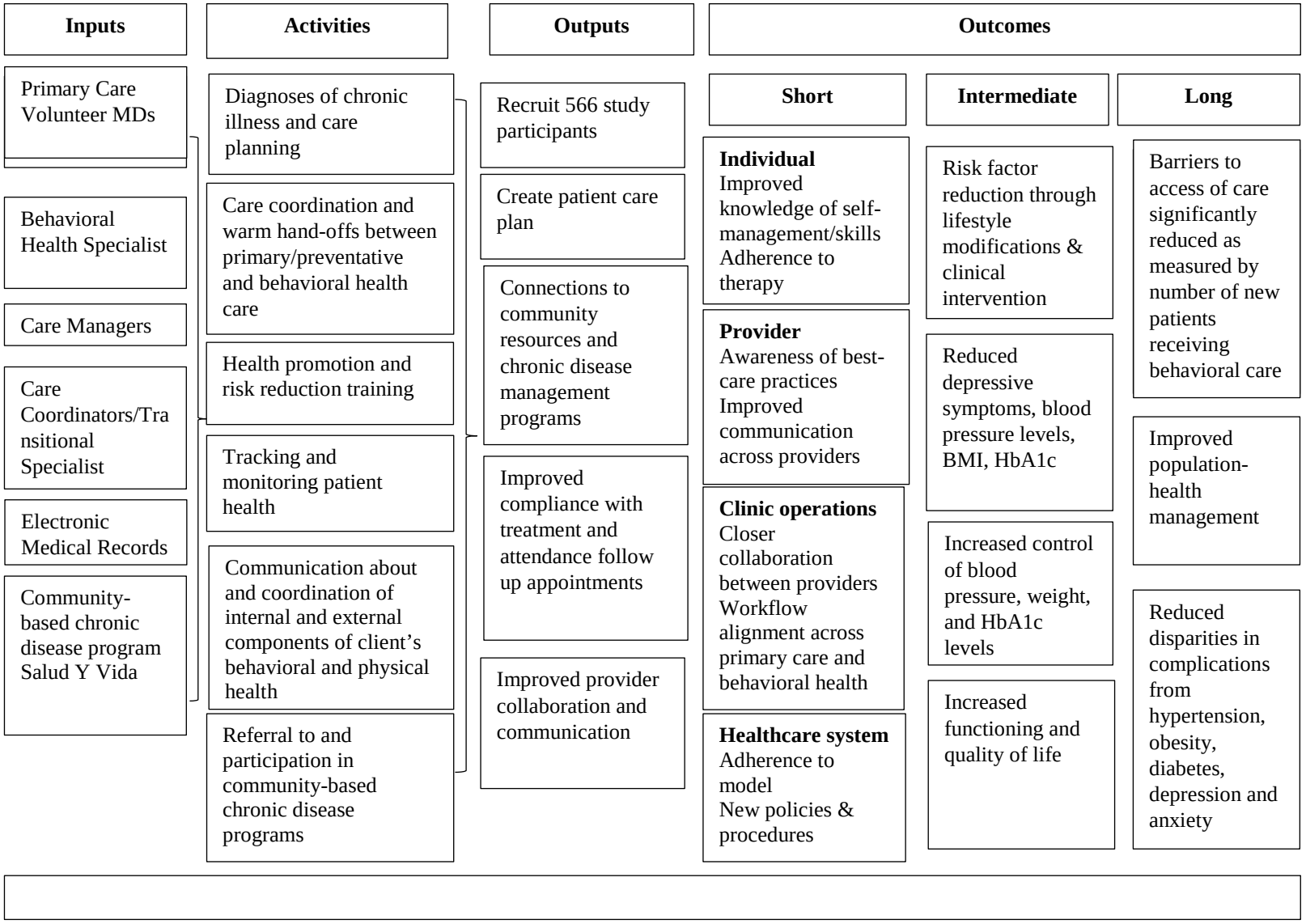
Sí Texas Subgrantee: Hope Family Health Center
Program Title: Sí Texas HOPE

Appendix B. Revised Project Timeline

	2015								2016												2017												2018												2019			
	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4
Planning & Program Administration																																															
Program awarded																																															
SEP development & approval																																															
Protocol development																																															
Instrument development																																															
IRB approval process																																															
Staff training																																															
Program start																																															
Program implementation [1]																																															
Program recruitment & enrollment																																															
Data Collection																																															
Baseline (0-6 months)																																															
Intermediate (6-9 month)																																															
Final (12 month)																																															
Data analysis* & reporting																																															
HRiA (quarterly reporting)																																															
Data cleaning & analysis[2,3]																																															
Report writing & editing[2, 3]																																															
Report to CNCS[2,3]																																															
Reports to partners/stakeholders[2,3]																																															
Reports to general public/scientific com. [2,3]																																															

*HRiA has been contracted by MHM as the Sí Texas program evaluator. All data analyses and reporting will be done on a collaborative basis with the subgrantee; [1] Lighter color designates extension of program enrollment to 6 months if needed, [2]Annual; [3] Final

Appendix C: Logic Model



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

INTERVIEW GOALS

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

INTRODUCTION/INFORMED CONSENT

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

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

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

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

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

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

INTERVIEW QUESTIONS

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

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

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

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

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

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

6. Operations (Choose Clinic or Community as appropriate)

Clinic-based Operations

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

Community-based Operations

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

7. Patient and Provider Satisfaction

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

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

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

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

10. Closing

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

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

Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide

CORE INTERVIEW GOALS

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

INTRODUCTION/INFORMED CONSENT (2 MIN)

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

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

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

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

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

INTERVIEW QUESTIONS

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

Key Informant Background (3 MIN)

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

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

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

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

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

Adoption Facilitators and Barriers (15 MIN)

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

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

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

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

Provider and Patient Satisfaction (5 MIN)

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

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

Program Impact (5 MIN)

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

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

Sustainability and Lessons Learned (10 MIN)

12. Lastly, I'd like to talk about the future of [name of subgrantee Sí Texas program]. As the Sí Texas project draws to a close, what is the plan for [name of subgrantee Sí Texas program]? [PROBE ON PROGRAM CONTINUATION, REPLICATION, SCALING UP]
    a. Moving forward, how does [subgrantee] plan to improve or enhance the integration of primary care and behavioral health services?

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

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

Closing (2 MIN)

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

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

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

CORE FOCUS GROUP GOALS

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

INTRODUCTION (5 MIN)

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

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

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

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

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

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

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

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

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

INTRODUCTION AND WARM-UP (5 MIN)

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

PROGRAM RECRUITMENT (10 MIN)

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

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

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

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

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

i. In what ways has the program/service/study met your needs?
ii. What was helpful to you?

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

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

PROGRAM VALUE/IMPACT (10-15 MIN)

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

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

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

CLOSING/INCENTIVE DISTRIBUTION (2 MIN)

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

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

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

Appendix G. Implementation Evaluation Measures

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
REACH: Did the HFHC's program reach its intended target population?				
	Demographic characteristics of participants	Eligibility criteria data	• How would you describe the population that your program is serving? • What are they like in terms of demographics generally? • Is this the population it intended to serve?	None
FIDELITY: What are the components of HFHC's program and how do these components work "on the ground" at 6 and 12 months? Are these components different than what was planned? If so, why? To what extent did the Mercy clinic implement the HFHC model with fidelity?				
What are the resources of the program?	Input: Primary care volunteers	--	What is your current role?	Yes/No
What are the resources of the program?	Input: Behavioral health specialist	--	What is your current role?	Yes/No
What are the resources of the program?	Input: Care manager	--	What is your current role?	Yes/No
What are the resources of the program?	Input: Electronic medical records	--	• To what extent have information/data systems/your EMR been changed to support the program? • Have you added any information/data systems for the project?	Yes/No

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
What are the resources of the program?	Input: Community based chronic disease programs	Record of referral to medical specialists (community based programs for chronic diseases)	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
What are the program activities and how have they been operationalized?	Activity: Diagnoses of chronic illness and care planning	• Percentage of patients who complete their care plan • Number of patients receiving treatment plan • Number of patients with all intake forms and assessments completed (e.g., PHQ-9, Duke Health Profile, etc.)	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

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
What are the program activities and how have they been operationalized?	Activity: Care coordination between primary/preventative and behavioral health care	• Record of referral to medical specialists (community based programs for chronic diseases) • Record of receipt of care outside of HFHC after referral (appointment dates & treatment results/ dates?) • Show rate for primary care services • Show rate for behavioral health services	• Probe: Are warm hand offs between providers a component of the services participants receive? How do those hand offs work? • 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/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
		• Number of referrals created • Number of referrals completed • Percentage of patients who complete their care plan		
What are the program activities and how have they been operationalized?	Activity: Health promotion and risk reduction training	• Show rate for behavioral health services	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Evidence of specific health promotion and risk reduction training
What are the program activities and how have they been operationalized?	Activity: Tracking and monitoring patient health	• Record of vitalization of blood pressure, height, weight • Record of blood test results for HbA1c	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

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
		• Number of patients with all intake forms and assessments completed (e.g., PHQ-9, Duke Health Profile, etc.) • Percentage of patients who complete their care plan • Number of patients lost to follow-up		
What are the program activities and how have they been operationalized?	Activity: Communication about and coordination of internal and external components of client's behavioral and physical health	• Number of referrals created • Number of referrals completed	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?	Other evidence of communication and coordination
What are the program activities and how have	Activity: Referral to and participation in	Record of referral to medical	Since beginning enrollment, to what extent has the program been able to	Participation in community-based

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
they been operationalized?	community-based chronic disease programs	specialists (community based programs for chronic diseases)	deliver all the program services that had been planned as part of the program intervention?	chronic disease programs
Are the components different than what was planned? If so, why?	Output: Recruit 283 participants into each arm of the study	• Number of target participants—intervention and internal comparison groups • 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	--	None

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
		participate in the study • Number of patients enrolled in the program – intervention and internal comparison groups • Number of patients excluded from study after enrollment (pregnant, suicidal)		
Are the components different than what was planned? If so, why?	Output: Improved adherence to patient care plans	• Percentage of patients who complete their care plan	--	None

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
Are the components different than what was planned? If so, why?	Output: Increased connections to community resources and chronic disease management programs	• Record of referral to medical specialists (community based programs for chronic diseases)	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?	Show rate/usage of community resources and chronic disease management programs
Are the components different than what was planned? If so, why?	Output: Improved compliance with treatment and attendance follow-up appointments	• Percentage of patients who complete their care plan • Show rate for primary care services • Show rate for behavioral health services • Number of referrals created	--	None

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
		• Number of referrals completed • Number of patients lost to follow-up		
Are the components different than what was planned? If so, why?	Output: Improved provider collaboration and communication	--	• 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? • Probe: Are warm hand offs between providers a component of the services participants receive? How do those hand offs work? • Now that the program has been implemented, to what extent are primary care and behavioral health services connected, coordinated, combined, if at all?	Provider satisfaction survey; evidence of collaboration and communication
INTEGRATION: What level of Integrated Behavioral Health did HFHC achieve as a result of implementing the program?				

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

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
To what extend do providers buy-in to the program, and how has that buy-in affected implementation?	--	--	• Have you heard any feedback from providers about program implementation? • What are some of the general themes from their feedback been?	Staff satisfaction surveys
To what extent did the comparison groups receive program-like components?				
--	--	--	• When a participant is randomized/enrolled in the control/comparison group of your program, what can they expect to receive or participate in terms of services or activities? • Since the program started, has anything changed about the services that control group participants received or activities they have access to at your clinic? In what way? • What do you see as the impact of this workflow change, if any? • Have these changes had any effects on patient care for those participants not enrolled in the study? In what way?	• Number of patients in internal comparison group that receive 1 program-like component • Number of patients in internal comparison group that receive more than 1 program-like component

Appendix H. Loss to Follow-Up/Attrition Tables

Table 26. Comparison of Demographic Characteristics between Participants Who Completed the Study Compared to Participants Lost to Follow-up among All Study Participants (Intervention and Control Groups)

	Full Sample (n=582)		Completed Study (n=370)		Did Not Complete Study (n=212)		p-value
Measure	N	%	N	%	N	%	
Gender							
Male	154	26.5	80	21.6	74	34.9	**<0.001**
Female	428	73.5	290	78.4	138	65.1	
Ethnicity							
Hispanic/Latino	484	83.2	316	85.4	168	79.3	0.06
Non-Hispanic/Non-Latino	98	16.8	54	14.6	44	20.8	
County							
Hidalgo	573	98.5	366	98.9	207	97.6	0.23
Other	9	1.6	4	1.1	5	2.4	
Age							
≤ 34	41	7.0	23	6.2	18	8.5	0.16
35-44	110	18.9	66	17.8	44	20.8	
45-54	206	35.4	132	35.7	74	34.9	
55-64	193	33.2	133	36.0	60	28.3	
65+	32	5.5	16	4.3	17	7.6	
Mean	50.9	--	51.3	--	50.2	--	0.23
SD	10.6	--	9.9	--	11.6	--	
Employment Status							
Employed	7	1.2	4	1.1	3	1.4	0.72
Not Employed	575	98.8	366	98.9	209	98.6	
Marital Status							
Married	296	50.9	194	52.4	102	48.1	0.32
Not Married	286	49.1	176	47.6	110	51.9	
Primary Language							
English-speaking	68	11.7	48	13.0	20	9.4	0.20
Not English-speaking	514	88.3	322	87.0	192	90.6	

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

	Full Intervention Group (n=270)		Completed Study (n=172)		Did Not Complete Study (n=98)		p-value
Measure	N	%	N	%	N	%	
Gender							
Male	71	26.3	40	23.3	31	31.6	0.13
Female	199	73.7	132	76.7	67	68.4	
Ethnicity							
Hispanic/Latino	217	80.4	144	83.7	73	74.5	0.06
Non-Hispanic/Non-Latino	53	19.6	28	16.3	25	25.5	
County							
Hidalgo	268	99.3	172	100.0	96	98.0	0.06
Other	2	0.7	0	0.0	2	2.0	
Age							
≤ 34	16	5.9	7	4.1	9	9.2	0.13
35-44	50	18.5	30	17.4	20	20.4	
45-54	98	36.3	65	37.8	33	33.7	
55-64	94	34.8	65	37.8	29	29.6	
65+	12	4.4	5	2.9	7	7.1	
Mean	51.2	--	51.8	--	50.2	--	0.25
SD	10.3	--	9.3	--	11.9	--	
Employment Status							
Employed	2	0.7	2	1.2	0	0.0	0.28
Not Employed	268	99.3	170	98.8	98	100.0	
Marital Status							
Married	135	50.0	85	49.4	50	51.0	0.80
Not Married	135	50.0	87	50.6	48	49.0	
Primary Language							
English-speaking	28	10.4	25	14.5	3	3.1	**0.003**
Not English-speaking	242	89.6	147	85.5	95	96.9	

Table 28. Comparison of Demographic Characteristics between Participants Who Completed the Study Compared to Participants Lost to Follow-up among the Control Group

	Full Control Group (n=312)		Completed Study (n=198)		Did Not Complete Study (n=114)		p-value
Measure	N	%	N	%	N	%	
Gender							
Male	83	26.6	40	20.20	43	37.7	**<0.001**
Female	229	73.4	158	79.8	71	62.3	
Ethnicity							
Hispanic/Latino	267	85.6	172	86.9	95	83.3	0.39
Non-Hispanic/Non-Latino	45	14.4	26	13.1	19	16.7	
County							
Hidalgo	305	97.8	194	98.0	111	97.4	0.73
Other	7	2.2	4	2.0	3	2.6	
Age							
≤ 34	25	8.0	16	8.1	9	7.9	0.70
35-44	60	19.2	36	18.2	24	21.1	
45-54	108	34.6	67	33.8	41	36.0	
55-64	99	31.7	68	34.3	31	27.2	
65+	20	6.4	11	5.6	9	7.9	
Mean	50.6	--	50.9	--	50.2	--	0.62
SD	10.7	--	10.4	--	11.3	--	
Employment Status							
Employed	5	1.6	2	1.0	3	2.6	0.27
Not Employed	307	98.4	196	99.0	111	97.4	
Marital Status							
Married	161	51.6	109	55.1	52	45.6	0.11
Not Married	151	48.4	89	45.0	62	54.4	
Primary Language							
English-speaking	40	12.8	23	11.6	17	14.9	0.40
Not English-speaking	272	87.2	175	88.4	97	85.1	

Table 29. Comparison of Health Impact Measures at Baseline between Participants Who Completed the Study Compared to Participants Lost to Follow-up among All Study Participants (Intervention and Control Groups)

	Full Sample (n=582)[a] Mean (SD)	Completed Study (n=370)[a] Mean (SD)	Did Not Complete Study (n=212)[a] Mean (SD)	p-value
Systolic	134.0 (20.3)	133.9 (20.3)	134.2 (20.4)	0.83
Diastolic	81.5 (9.4)	81.0 (8.9)	82.5 (10.2)	0.06
BMI[b]	33.7 (7.0)	33.7 (7.3)	33.7 (6.5)	0.75
Nonparametric Tests[c]	Median (IQR)	Median (IQR)	Median (IQR)	
HbA1c	7.0 (3.6)	7.3 (3.3)	6.7 (3.8)	0.10
PHQ-9	4.0 (10.0)	4.0 (10.0)	3.0 (10.0)	0.40

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

Table 30. Comparison of Health Impact Measures at Baseline between Participants Who Completed the Study Compared to Participants Lost to Follow-up among the Intervention Group

	Full Intervention (n=270)[a] Mean (SD)	Completed Study (n=172)[a] Mean (SD)	Did Not Complete Study (n=98)[a] Mean (SD)	p-value
Systolic	133.4 (21.3)	134.1 (21.7)	132.1 (20.5)	0.46
Diastolic	81.0 (9.6)	80.9 (9.2)	81.0 (10.2)	0.95
BMI[b]	33.9 (7.5)	34.2 (7.8)	33.3 (6.9)	0.40
Nonparametric Tests[c]	Median (IQR)	Median (IQR)	Median (IQR)	
HbA1c	7.4 (4.2)	7.4 (4.2)	7.2 (4.3)	0.52
PHQ-9	5.0 (12.0)	5.0 (12.0)	5.5 (13.0)	0.88

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

Table 31. Comparison of Health Impact Measures at Baseline between Participants Who Completed the Study Compared to Participants Lost to Follow-up among the Control Group

	Control (n=312)[a] Mean (SD)	Completed Study (n=198)[a] Mean (SD)	Did Not Complete Study (n=114)[a] Mean (SD)	p-value
Systolic	134.5 (19.4)	133.7 (18.9)	136.1 (20.2)	0.30
Diastolic	82.0 (9.2)	81.0 (8.6)	83.8 (10.0)	**0.01**
BMI[b]	33.6 (6.6)	33.3 (6.8)	34.1 (6.2)	0.18
Nonparametric Tests[c]	Median (IQR)	Median (IQR)	Median (IQR)	
HbA1c	6.8 (2.9)	7.0 (3.1)	6.3 (2.8)	0.09
PHQ-9	2.0 (8.0)	2.5 (8.0)	2.0 (8.0)	0.40

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

Appendix I: Patient-Centered Integrated Behavioral Health Care Checklist

Patient-Centered Integrated Behavioral Health Care Principles & Tasks

AIMS CENTER
Advancing Integrated Mental Health Solutions

About This Tool

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

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

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

Page 2

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

Core Components & Tasks	None 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 J: Patient Health Questionnaire – 9 (PHQ-9)

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

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

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

=Total Score: _____

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

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

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

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

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

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

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

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

Appendix K: Per-protocol analyses

Table 32. Effect of IBH Intervention on Twelve Month Systolic and Diastolic Blood Pressure, Per Protocol

Variable	Systolic Blood Pressure (n=285)		
	Estimate (β)	Standard Error	p-value
Intervention	-1.11	1.87	0.55
Control (ref)	--	--	--
Age (continuous)	0.22	0.10	0.03
Married	4.70	1.86	0.01
Not married (ref)	--	--	--
Baseline SBP	0.53	0.05	<0.001
Baseline Comorbidities	1.88	1.22	0.13
Variable	Diastolic Blood Pressure (n=285)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.77	0.79	0.33
Control (ref)	--	--	--
Age (continuous)	-0.06	0.04	0.14
Baseline DBP	0.8	0.05	<0.001
Baseline Comorbidities	1.73	0.51	0.001

Notes: Bold denotes statistical significance (p-value < 0.05); "ref" indicates the reference category used to calculate the estimate for a covariate

Table 33. Effect of IBH Intervention on Twelve Month HbA1c Value, Per Protocol

Variable	HbA1c (n=102)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.23	0.28	0.42
Control (ref)	--	--	--
Baseline HbA1c	0.52	0.06	<0.001

Notes: Bold denotes statistical significance (p-value < 0.05); "ref" indicates the reference category used to calculate the estimate for a covariate

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

Variable	BMI (n=281)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.01	0.23	0.97
Control (ref)	--	--	--
Baseline BMI	0.98	0.02	<0.001

Notes: Bold denotes statistical significance (p-value < 0.05); "ref" indicates the reference category used to calculate the estimate for a covariate

Table 35. Effect of IBH Intervention on Twelve Month PHQ-9 Score, Per Protocol

Variable	PHQ-9 (n=188)		
	Estimate (β)	Standard Error	p-value
Intervention	**-1.64**	**0.74**	**0.04**
Control (ref)	--	--	--
Baseline PHQ-9	0.49	0.05	<0.001

Notes: Bold denotes statistical significance (p-value < 0.05); "ref" indicates the reference category used to calculate the estimate for a covariate

Appendix L: Duke Health Profile

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

DUKE HEALTH PROFILE (The DUKE)

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

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

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

TODAY would you have any physical trouble or difficulty:

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

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

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

DURING THE PAST WEEK: How often did you:

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

DURING THE PAST WEEK: How often did you:

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

MANUAL SCORING FOR THE DUKE HEALTH PROFILE

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

PHYSICAL HEALTH SCORE ☐

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

MENTAL HEALTH SCORE ☐

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

SOCIAL HEALTH SCORE ☐

GENERAL HEALTH SCORE

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

☐

PERCEIVED HEALTH SCORE

Item		Raw Score*
3	=	_____ x 50 =

☐

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

SELF-ESTEEM SCORE ☐

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

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

ANXIETY SCORE ☐

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

DEPRESSION SCORE ☐

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

ANXIETY-DEPRESSION (DUKE-AD) SCORE ☐

PAIN SCORE

Item		Raw Score*	Revised
11	=	_____	_____

x 50 = ☐

DISABILITY SCORE

Item		Raw Score*	Revised
17	=	_____	_____

x 50 = ☐

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

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

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

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

PERFIL DE SALUD DE DUKE (El Duke)

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

Fecha de nacimiento: _____ Sexo: Femenino ☐ Masculino ☐

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

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

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

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

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

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

173