Sí Texas: Social Innovation for a Healthy South Texas

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Final Evaluation Report:

UT Health

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The University of Texas
Health Science Center at Houston

School of Public Health
Brownsville Regional Campus

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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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EXECUTIVE SUMMARY

This final report describes the methods and findings for the evaluation of the program Salud y Vida 2.0 at The University of Texas Health Science Center at Houston (UT Health SPH), a subgrantee of 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); study subjects were recruited from two clinic sites: Rio Grande State Center and Su Clinica.

Program Background

In September 2016, UT Health SPH and partners implemented an enhanced version of the free of charge, evidence-based chronic care management program (Salud y Vida 1.0 [SyV 1.0]) designed to integrate primary and behavioral healthcare with home and community-based wraparound services provided by community health workers (CHWs) and community partners. Individuals with uncontrolled HbA1c results (HbA1c ≥ 8%) are referred to SyV 1.0 by their clinic provider or are identified through community outreach events. Individuals are voluntarily enrolled in SyV 1.0 and assigned a community health worker (CHW) who conducts follow up home visits and phone calls for the duration of 15-months[1] to provide education and social support. SyV 1.0 participants are also enrolled in a 6-week long course on diabetes self-management education.

The Salud y Vida 2.0 (SyV 2.0) program aimed to enhance UT Health SPH's current Chronic Care Model (Wagner et al., 1998) with the addition of evidence-based components that provided a continuum of care for those with diabetes and other chronic disease conditions (e.g., obesity, hypertension, and depression). Overall, the adapted model included: medication therapy management (MTM) services that utilized pharmacists, peer led support groups (PLSG) that delivered culturally sensitive experiences, care coordination by a team of providers (e.g., behavioral health care, CHWs, etc.), and referrals to community-based lifestyle programs that promote healthy eating. The study eligibility criteria for the SyV 2.0 program included SyV 1.0 participants residing in Cameron or Willacy counties with an HbA1c ≥ 9.0% at any point during 6 and 36 months of SyV 1.0 services and an HbA1c ≥ 8.0% at study enrollment, and who were patients at Rio Grande State Center or Su Clinica. The study hypothesis was that an enhanced level of primary and behavioral health services offered through an integrated health care delivery network will improve control of chronic disease (diabetes, hypertension, and obesity), reduce depression, increase access to behavioral healthcare services, and improve adult functioning and quality of life for current SyV 1.0 participants.

Prior Research

The UT Health SPH intervention built on the key elements of Wagner's model for effective chronic illness care, namely, an organized delivery system linked with complementary community resources, sustained by productive interactions between multidisciplinary care teams and "activated" or educated patients and their families (Wagner, 1998). Preliminary unpublished results showed that participants in SyV 1.0 experience immediate progress in the control of diabetes such that the average HbA1c at baseline of

[1] SyV 1.0 was initially designed for participants to actively participate in the program for approximately 12 months followed by a monitoring period. As the program has evolved to better meet participant needs, the intensive phase of the program has been extended to 15 months. All participants are then monitored by the team for an additional 12 months.

10.2% has dropped to 9.1% at 3-months. The SyV 2.0 program aimed to enhance Wagner's (1998) Collaborative Chronic Care Model with the addition of evidence-based components including: medication therapy management (MTM), peer led support groups (PLSG), behavioral health care coordination, and community-based lifestyle programs. Given that the proposed intervention had multiple prongs that were adaptations of various tested models with innovative additions, the incoming level of evidence was preliminary, and the proposed evaluation targeted a moderate level of evidence.

Evaluation Design

The evaluation targeted a moderate level of evidence with a randomized control trial design (RCT) based on the incoming level of preliminary evidence. The impact evaluation study used an RCT design to evaluate the SyV 2.0 program's impact. The RCT allows for the comparison of (a) intervention participants receiving the delivery of enhanced integrated behavioral health (SyV 2.0) with (b) control group participants receiving the usual care (services provided by SyV 1.0). Study inclusion criteria required individuals to be patients at Rio Grande State Center or Su Clinica and have an HbA1c greater than or equal to (1) 9.0% at any point during 6 and 36 months of SyV 1.0 services and (2) 8.0% at 2.0 baseline enrollment. A standardized difference of means greater than 0.25 was used to determine if propensity score matching was needed (Rosenbaum & Rubin, 2012; Rubin, 2001).

The study aimed to enroll 350 participants (175 participants per study arm). The study enrolled a total of353 participants, 176 intervention participants and 177 control participants. UT Health SPH's 12-month retention target was 244 participants, with 122 in each study arm. The final 12-month sample totaled 292 participants, with 147 in the intervention and 145 in the control group.

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

Description of Measures and Instruments

UT Health SPH collected data for the Sí Texas shared measures: BMI (weight/height^2), HbA1c (obtained via blood test by a reference lab), blood pressure (taken by Research Assistant), depression (using the Patient Health Questionnaire [PHQ-9]), and quality of life (using the Duke Health Profile). Other impact measures included cholesterol (obtained via blood test by a reference lab), medication adherence (using the Diabetes Medication Adherence Questionnaire) and disease management self-efficacy (Diabetes Self-Efficacy Scale). The primary impact measure was improvement in HbA1c.

Research Questions

The primary impact measure for SyV 2.0 was glycated hemoglobin (HbA1c). Below are the confirmatory and exploratory research questions.

1) Are participants who receive SyV 2.0 more likely to reduce HbA1c after 12 months compared to participants who receive SyV 1.0 (the standard of care)? *This question is confirmatory.*
2) Are participants who receive SyV 2.0 more likely to improve their blood pressure after 12 months compared to participants who receive SyV 1.0? *This question is exploratory.*

3) Are participants who receive SyV 2.0 more likely to reduce their BMI after 12 months compared to overweight or obese participants who receive SyV 1.0? *This question is exploratory.*
4) Are participants who receive SyV 2.0 more likely to reduce their depressive symptoms, as measured by the PHQ-9, after 12 months compared to participants who receive SyV 1.0? *This question is exploratory.*
5) Are participants who receive SyV 2.0 more likely to improve their quality of life, as measured by the Duke Health Profile, after 12 months compared to participants who receive SyV 1.0? *This question is exploratory.*
6) Are participants who receive SyV 2.0 more likely to normalize their total cholesterol after 12 months compared to participants who receive SyV 1.0? *This question is exploratory.*
7) Are participants who receive SyV 2.0 more likely to have improved medication adherence, as measured by the Diabetes Medication Adherence Questionnaire, after 12 months compared to participants who receive SyV 1.0? *This question is exploratory.*
8) Are participants who receive SyV 2.0 more likely to have improved self-efficacy, as measured by the Diabetes Self-Efficacy Scale, after 12 months compared to participants who receive SyV 1.0? *This question is exploratory.*

Implementation Questions

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

1) Did the SyV 2.0 program reach its intended target population?
2) What are the components of SyV 2.0 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 are they different?
3) What level of integrated behavioral health did UT Health SPH achieve as a result of implementing SyV 2.0?
    a. To what extent have providers and staff adopted the components of the SyV 2.0 program at 6 and 12 months? What are the facilitators and barriers to adoption?
    b. To what extent do providers and staff buy in to the SyV 2.0 program, and how has buy-in affected implementation?
4) To what extent did the control group receive program-like components?
5) To what extent did the UT Health SPH implement the SyV 2.0 model with fidelity?
6) How satisfied are SyV 2.0 patients with the services they have received? How satisfied are providers with the SyV 2.0 program?

Impact Analysis

This report presents descriptive statistics, analysis of baseline equivalence, and analyses of impact across the study groups. All analyses were conducted based on an intention-to-treat approach. The unit of analysis was the individual patient. Impact measures are treated as continuous. Generalized regression analysis results are presented as the final results of the modeling sequence starting with bivariate models and ending with multiple regression models. These multiple regression models are adjusted for covariates and baseline impact measures identified as relevant via review of the scientific literature or statistical model selection. The possibility of effect modification of the intervention-outcome relationship by patients' characteristics was also explored. Specifically, interaction terms of

study group and baseline HbA1c, education, insurance status, gender, age, and time in SyV 1.0 were included to understand whether there were differences in intervention effect by these characteristics. Stratified linear regression models were subsequently performed for any model that found statistically significant effect modification.

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

Key Findings

Evaluation of the implementation of the SyV 2.0 program shows the program was implemented in alignment with the program logic model to fidelity after the early implementation period. Due to delays in providing services, participants did not receive a full twelve months of the intervention. Findings from the implementation evaluation reveal there were several facilitators and challenges to implementation. Major facilitators to implementation included: increased communication via promotores, Chronic Care Management (CCM) meetings, and physical space (i.e., co-location of staff). Common adoption barriers identified included data systems, hiring and staffing, and the location of services which limited accessibility for participants.

For the impact evaluation, the SyV 2.0 RCT utilized a robust design that produced strong internal validity. When controlling for baseline measures and other covariates, intervention assigned participants did not have statistically significant improvement in the HbA1c confirmatory outcome when compared to the control participants at 12 months. However, bivariate results within intervention and control groups showed improvements in HbA1c, PHQ-9, Duke General Health score, total cholesterol, medication adherence score, and diabetes self-efficacy. There is also evidence of effect modification of PHQ-9 score when stratifying by time enrolled in the SyV 1.0 program. The intervention was not found to be significantly associated with lower PHQ-9 score among those who spent less than the median tenure (21.5 months) in SyV 1.0, but there was a positive effect among those intervention participants who spent more than the median tenure in SyV 1.0 (β= -1.28, p=0.01; d=0.36). There were no negative intervention effects on the confirmatory outcome; however, the intervention had negative effects on diastolic blood pressure for select subpopulations. For example, among those who spent less than the median tenure (21.5 months) in SyV 1.0, the intervention was associated with a significantly higher mean diastolic blood pressure (β= 4.68, p=0.004; d=0.44).

Conclusion and Next Steps

The evaluation was implemented as intended except for a deviation to the original timeline. Recruitment was extended by two months to meet the enrollment target of 350 participants. UT Health SPH revised its study eligibility criteria because the criteria were originally too narrow to recruit a sufficient sample size over the specified time period. A detailed timeline of the study can be found in **Appendix A: Revised Project Timeline**.

While the evidence-based interventions were adapted and evaluated using a method with strong internal validity, results do not indicate a change in the preliminary level of evidence assignment at this time. This evaluation study uses an RCT design and has mitigated major threats to internal validity such as selection bias. The program was implemented to fidelity after the early implementation period, and

the evaluation was conducted as intended. However, due to delays in providing services, participants did not receive a full twelve months of the intervention. After 12 months in the program, intervention participants were not more likely than control participants to see significant improvements in their HbA1c levels, when controlling for age, sex, and baseline characteristics. However, bivariate results within intervention and control groups showed improvements in HbA1c, PHQ-9, Duke General Health score, total cholesterol, medication adherence score, and diabetes self-efficacy. This could indicate that SyV 1.0 (usual care) was effective at improving health outcomes; therefore, no statistically significant differences were observed between intervention and control. Alternatively, given that most intervention participants did not receive the minimum dose of services, the level of exposure may have been too low to detect the effect of the intervention. While the RCT impact study did not show significant association with physical health improvements among intervention participants overall, models were stratified to examine whether outcomes differed for important subpopulations. As previously mentioned, the intervention was not found to be significantly associated with lower PHQ-9 score among those who spent less than the median tenure (21.5 months) in SyV 1.0, but there was a positive effect among those intervention participants who spent more than the median tenure in SyV 1.0 (β= -1.28, p=0.01, d=0.36). The intervention was also associated with a significantly higher mean diastolic blood pressure among those participants with lower than median tenure in SyV 1.0 (β= 4.68, p=0.004; d=0.44). Among participants referred to MTM, those participants who received the minimum dose of MTM had a significantly higher diastolic blood pressure than those who did not receive minimum dose (β= 6.65, p=0.0.03). Finally, among those referred to La Cocina Alegre, those who received the minimum dose of La Cocina classes had a significantly higher self-efficacy compared to those who did not receive minimum dose (β= 0.69 p=0.002).

Despite its findings, this study contributes to our understanding of the implementation of an enhanced chronic care model in a community-based setting within a low-income, Hispanic population. Lessons learned included *adoption facilitators* such as increased communication, physical clinic space, data systems, staff relationships, staffing, and training; *adoption barriers* related to physical space for community-based programs, data systems, and hiring and staffing.

UT Health SPH is reviewing findings from this study to improve the implementation of SyV 2.0. Since the study, UT Health SPH has expanded access to 2.0 services (MTM, BH, and La Cocina Alegre) to all participants in SyV in the region and is working to improve workflows. UT Health SPH is planning to continue the Chronic Care Model but is examining these findings and their operational plans to determine how to modify the model so it is financially sustainable.

Subgrantee: University of Texas Health Science Center at Houston School of Public Health
Project Title: Salud y Vida 2.0

INTRODUCTION

This final report describes the methods implemented to evaluate the Salud y Vida 2.0 program of The University of Texas Health Science Center at Houston (UT Health SPH), according to the Standard Evaluation Plan (SEP), notes deviations and/or changes to the SEP, and describes final findings from the impact and implementation evaluations (including baseline data, six-month data, and twelve-month data). This report also provides a description of the reporting timeline discussed in the SEP and revised in the **Appendix A: Revised Project Timeline.** UT Health SPH was a subgrantee of SIF Grantee Methodist Healthcare Ministries (MHM) of South Texas, Inc., a member of the 2014 SIF Cohort. The evaluation was conducted by external evaluation contractor, Health Resources in Action (HRiA); study subjects were recruited from two clinic sites: Rio Grande State Center and Su Clinica. The intended audience of this report is the Social Innovation Fund, although excerpts will also be used by MHM staff and leadership and internal leadership at UT Health SPH.

Program Definition and Background

The Rio Grande Valley (RGV), located on the northern bank of the Rio Grande River that separates the United States from Mexico, is home to more than 1.2 million residents, representing about 5% of Texas' general population (U.S. Census Bureau, 2011). The Salud y Vida 2.0 (SyV 2.0) program focuses on the system of health care in the lower RGV, comprised of a predominantly Mexican American, low-income, underserved community with chronic disease rates and related mortality that 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 results also pointed to the existence of a significant number of cases of undiagnosed diabetes in the RGV in comparison to lower self-reported prevalence rates identified by the Centers for Disease Control's (CDC) 2010 Behavioral Risk Factor Surveillance System (BRFSS). Residents in this region suffer from disproportionate health disparities which stem from extreme poverty, lower levels of educational attainment, and inadequate access to basic health care needs.

As identified in numerous region-specific assessments and reports, the scarcity of primary care and behavioral health service providers is one of the factors influencing underreporting of disease prevalence and poor health outcomes. The lower RGV and the surrounding communities continue to see increasing behavioral health related cases (including mental health problems, substance abuse, and domestic violence) with limited personnel and service-based resources that are insufficient to match the need. The ratio of mental health providers to individuals in Texas is 1:1,757. However, in the Lower Rio Grande Valley, the average of the four-county area is 1:15,549 (University of Wisconsin Population Health Institute, 2015) .

The lack of public health infrastructure in the lower RGV further exacerbates challenges in accessing high-quality mental health care as well as primary care. The Lower Rio Grande Valley has the highest concentration of *colonias* in Texas, 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* in Texas, the lower RGV presents many opportunities to intervene for several unmet health (physical and behavioral) challenges. Outreach to Salud y Vida participants includes *colonia* residents in Cameron and Hidalgo counties.

UT Health SPH and its partners implemented SyV 2.0 in September 2016. The free of charge, evidence-based chronic care management SyV 2.0 program aimed to expand the current SyV 1.0 program. The original program (SyV 1.0), which is considered standard of care, was designed to assist individuals with uncontrolled diabetes (HbA1c ≥ 8%) by working closely with health care providers to address the needs of the patient which go beyond basic primary care needs such as referral to behavioral health, counseling, financial support, and other ancillary services. Those without a primary care provider were connected to a partner clinic for ongoing care.

At the time of this evaluation study, SyV 1.0 participants were referred to the program by their clinic provider or identified through community outreach events. Individuals were voluntarily enrolled in the program by highly trained staff who include registered nurses, licensed vocational nurses (LVNs) or research assistants and were assigned a community health worker (CHW) who conducts follow up home visits and phone calls for the duration of 15-months[2] to provide education and social support. Participants were also enrolled in a 6-week long course on diabetes self-management education.

Participants' HbA1c results were obtained every 3 months. The case management team reviewed any cases that demonstrated a 1.5% increase at any time point. Participants were eligible to graduate from the program if their HbA1c result was reduced to below 9% by 12 or 15 months but were followed up to 24 months.

The SyV 1.0 program has yielded tremendous success since its inception, with over half of the 3,000 participants gaining control of their diabetes (HbA1c < 9.0) within 12 months. Some participants, however, still struggled with the disease due to behavioral health, primary health care access issues, and other social and environmental barriers to making lifestyle changes. For this reason, UT Health SPH aimed to enhance the current SyV 1.0 program to expand services for participants who were not able to control their diabetes within 6 months of enrolling in the program, resulting in SyV 2.0. The program was enhanced through four major initiatives:

1) Medication Therapy Management (MTM) for participants with low levels of medication adherence;
2) Care coordination which includes behavioral health services (BHS) for participants who do not qualify for services with the mental health authority, but need behavioral health support;
3) Peer led support groups (PLSG) for participants and their loved ones; and
4) Access to community-based Lifestyle Programs (CBLP) across the Rio Grande Valley for the participants and their loved ones which include capacity building cooking classes, and an obesity treatment program.

[2] SyV 1.0 was initially designed for participants to actively participate in the program for approximately 12 months followed by a monitoring period. As the program has evolved to better meet participant needs, the intensive phase of the program has been extended to 15 months. All participants are then monitored by the team for an additional 12 months.

The healthy food choices customized smart phone application was removed from the fourth program component (access to CBLP) because it was never intended to be part of the evaluation. This change represents a deviation from the SEP.

SyV 2.0 aims to improve access to crucial care, data sharing across institutions, cost effective primary and behavioral health services and other programs that support lifestyle changes and help participants better control diabetes. SyV 2.0 uses technology hosted at the Rio Grande Valley Health Information Exchange (RGVHIE) to integrate clinical, behavioral health and program information from separate facilities into a participant's aggregate health record. Comprehensive patient data increases efficiency of care management, reduces unnecessary tests, and improves communication and care coordination across facilities.

Overview of Prior Research

SyV 2.0 built upon the existing SyV 1.0 program, which was informed by key elements of the validated Wagner model for effective chronic illness care. This Collaborative Chronic Care Model features an organized delivery system linked with complementary community resources, sustained by productive interactions between multidisciplinary care teams and "activated" or educated patients and their families (Wagner, 1998). A meta-analysis conducted by Woltmann et al., (2012) determined that collaborative chronic care models produce "significant effects across disorders and care settings for depression as well as for mental and physical quality of life and social role function." The SyV 1.0 program implements the model articulated by Woltmann et al. with fidelity to all six criteria identified: 1) Delivery system redesign (changes in the organization of care delivery, inclusion of behavioral health screening and referral); 2) Self-management support strategies; 3) Decision supports; 4) Information systems (changes to facilitate use of information about participants, their care and their outcomes, shared data); 5) Community linkages; and 6) Health system supports.

The SyV 1.0 program has adapted models supported in the evidence base to account for the unique cultural and geographic needs of the RGV. Preliminary results (not yet published) showed that participants in SyV 1.0 experience immediate progress in the control of diabetes such that the average HbA1c at baseline (n=1,986) of 10.23% has dropped to 9.08% at 3-months (n=1,102). There are fluctuations thereafter, with an average HbA1c of 9.24% at 6-months (n=783) and 9.3% at 9-months (n=494). Enrollment in this program is ongoing; the results reported are based on the maximum number of people that have reached that time point. Despite slight increases in the overall average after 3-months, data for those who have completed their HbA1c tests show that more than 60% are reducing their HbA1c at each time point.

An integral part of the SyV 2.0 program was the use of *promotores*, or community health workers (CHW). There is a growing body of evidence of the benefits of interventions led by CHWs, especially in underserved and minority populations. For example, in a quasi-experimental design with pre-post tests and follow-up (N=255), program participants of *Pasos Adelante* (Spanish for Steps Forward) a lifestyle intervention program targeting chronic disease prevention in Mexican Americans living in a U.S.-Mexico border community in Arizona, demonstrated significant improvements in physiological measures linked to diabetes and CVD risk factors after participating in the 12-week CHW-led program that combined interactive educational sessions with walking groups (Staten et al., 2012).

SyV 2.0 aimed to incorporate additional evidence-based components into their intervention. These components included: Medication Therapy Management (MTM), Community-based lifestyle programs (CBLP), care coordination (including behavioral health), and peer led support groups (PLSGs). In a quasi-experimental, five-year longitudinal cohort study of diabetics enrolled in a community-based MTM program, it was found that more than 50% (n=85) of patients who received community-based pharmaceutical care services (i.e., education by certified diabetes educators, long-term community pharmacist follow-up using scheduled consultations, clinical assessment, goal setting, monitoring, and collaborative drug therapy management with physicians) significantly improved or maintained HbA1c levels, had higher satisfaction with pharmacy services, and decreased medical utilization costs over time (Cranor et al., 2003). Similarly, CBLPs and PLSGs have shown to be effective in areas demographically similar to South Texas. For example, results from a mixed methods study utilizing a randomized design to provide CBLPs and PLSGs to elderly Mexican-American diabetics using Bridges Diabetes Peer Support Groups resulted in significant reductions in HbA1c levels among the intervention group at four and six-month follow ups (n=42) (Haltiwanger & Brutus, 2012).

Because resources are limited in the lower RGV and among the SyV 1.0 participant population, the SyV 2.0 program combines multiple approaches to offer as many resources as possible to participants. Through the addition of new program components and the enhancement of existing services, UT Health SPH aims to more efficiently and effectively care for its participants' health needs. Given that the proposed intervention has multiple components that are adaptations of various tested models with innovative additions, the incoming level of evidence is preliminary. The evaluation targeted a moderate level of evidence.

Based on the evidence available, and the model specifications for SyV 2.0, the incoming level of evidence was preliminary and aimed to advance towards a moderate level of evidence.

Program Components

Through SyV 2.0*,* UT Health SPH and its partners aimed to implement a system of integrated health care that provides a continuum of care for those with diabetes. The theoretical frameworks used to guide this intervention include elements of the Transtheoretical Model (Prochaska & Velicer, 1997) and Social Cognitive Theory (Bandura, 1986). The Transtheoretical Model operates on the assumption that people do not change behaviors quickly and decisively. Rather, change in behavior, especially habitual behavior, occurs continuously through a cyclical process. Social Cognitive Theory considers the unique way in which individuals acquire and maintain behavior, while also considering the social environment in which individuals perform the behavior. The SyV 2.0 theory of change is based on these theoretical models of behavior, with particular emphasis on changing individual's readiness for change and self-efficacy towards adopting health-promoting behaviors. The Salud y Vida 2.0 program theory of change is that comprehensive and coordinated community services (e.g., cooking classes, peer-led support groups, and programs to address family obesity) and clinical care services (i.e., MTM and behavioral health) delivered to adults with uncontrolled diabetes will lead to improved physical and mental health outcomes for an increasing proportion of the participants served.

The logic model in **Appendix B: Program Logic Model** outlines the inputs, activities, and outcomes for the SyV 2.0 program.

Inputs: The UT Health SPH logic model has four inputs.

- Program Personnel
    - Community Health Workers (CHWs): Provide home-based wraparound services, screening and motivational interviewing
    - Diabetes Self-Management Educators: Teach diabetes self-management classes
    - Transition Specialists (RN, LVN, Research Assistant): Enroll SyV 1.0 participants in the program and provide referral information and resources
    - Pharmacists/Technicians: Provide Medication Therapy Management (MTM) at clinics and off-site locations (via floating pharmacists)
    - Primary care clinicians (e.g., RN, PA): Screen and refer enrolled participants to services
    - Peer leaders: Facilitate peer led support groups
    - Behavioral health counselors: Provide behavioral health services
    - UT Health SPH Program Staff: Oversee intervention implementation and evaluation
    - Chronic care management (CCM) team: Reviews SyV 1.0 participant progress, recommends referral to SyV 2.0, and designs a SyV 2.0 care plan for each participant. Specific personnel include:
        - RNs/LVNs, Case Managers, and Executive Directors from Su Clinica and RGSC who serve as liaisons between patients and healthcare providers and help reconcile the recommended action plans developed at the Chronic Care Management Case Review Meeting (Case Review).
        - CHW Supervisors serve as liaisons between patients and healthcare providers and help reconcile the recommended action plans developed at Case Review.
        - Case Manager/Outpatient Coordinator serves as a liaison for behavioral health referrals appropriate for TTBH.
        - Clinical Quality Specialist, Data Quality Analyst and Application Support Analyst provide database support and serve as liaisons between patient's medical homes and the Wellcentive database.
        - UT Health SPH Program Managers supervise, implement and manage interventions to ensure project goals are achieved as well as assist in Case Presentation, recording of Action Items and notes, and provide SyV program expertise.
        - UT Health SPH Program Coordinators and Quality Improvement Coordinator coordinate the Case Review process, meetings, and documentation as well as facilitate referrals to MTM and BH services.
        - UT Health SPH Social Workers serve as liaisons between different institutions to assist patients and collaborate with their healthcare providers to ensure patient wellness by directing patients to community resources.

- Program partners, to and from whom participants may potentially be referred, include:
    - Brownsville Wellness Coalition: Delivers the Happy Kitchen healthy cooking program
    - Infant and Family Nutrition Agency: Delivers the MEND program and provides peer-led support groups for women
    - Proyecto Juan Diego: Provides peer-led support groups for individuals with diabetes
    - Tropical Texas Behavioral Health: Provides peer-led support groups for individuals with diabetes
    - UTRGV/UT Austin College of Pharmacy Cooperative Pharmacy Program: Coordinates educational needs associated with medication therapy management (MTM) program

  - Rio Grande State Center: Provides behavioral health services through master-level trained counselor, medication therapy management services, and participants were recruited from this clinic.
  - Su Clinica: Provides behavioral health services through master-level trained counselor, medication therapy management services, and participants were recruited from this clinic.
  - Referrals are created by CHWs and forwarded to a clinic representative to verify and update for presentation at a Case Review meeting. Documentation of approval or denial is documented in REDCap or Wellcentive. Approved recommendations are then sent to the clinic behavioral health contact to schedule an appointment.

- Program Funders
  - Methodist Healthcare Ministries: Provides funds to carry out the SyV 2.0 program. In addition, Methodist Healthcare Ministries provides oversight of intervention implementation and evaluation activities for the SyV 2.0 program.
  - Valley Baptist Legacy Foundation: Provides matching funds to carry out the SyV 2.0 program.

- External Community Resources
  - Valley Baptist Health Systems: Was to provide an in-kind donation of a mobile clinic unit for the purpose of enhancing care coordination for participants without a primary care physician.
  - Rio Grande Valley Health Information Exchange: Provides a community platform for health information aggregation, normalization, and analytics as well as provides program management, technical, clinical analyst, and administrative support for the SyV 2.0 program.
  - Wellcentive: Serves as a cloud-based database that liaises between community health and clinic EMRs by making demographics, appointment information, labs, and other information available to community health workers.
  - MTMPath: Serves as a database used by pharmacists to assist them in administering and tracking MTM services. RGVHIE facilitated linking data from Wellcentive to MTMPath so pharmacists had current patient medical information when building their action plan for the MTM service appointment. MTMPath is not connected to clinic EMRs, requiring manual entry of data relevant to a patient's MTM visit.
  - REDCap: Serves as a research database that captures study data via Case Review Forms (CRFs) created in Microsoft Word. REDCap does not interface with clinic EMRs, Wellcentive, or MTMPath. It is a mature, secure web application for designing, building, and managing clinical and research databases (Harris et al., 2009).
  - Le Fleur transportation company provided transportation services via a contract with UTHealth until July 31, 2017. On February 23, 2018, UTHealth contracted with Gracious Transportation to provide transportation services. Transportation is available to all Salud y Vida participants (1.0 and 2.0) to all services. During the time between the end of Le Fleur's contract, and the beginning of Gracious' contract, transportation was provided to study participants by qualified UTHealth Si Texas staff using UTHealth vehicles.

Changes in these program inputs that deviate from the SEP include: "Healthy Communities Brownsville: Will develop and promote a healthy food application for mobile devices" is no longer an input because it was never intended to be part of the evaluation. The delivery of MEND changed from Infant and Family Nutrition Agency (IFNA) to UT Health SPH in year 3 due to capacity issues. Valley Baptist Health Systems was to provide an in-kind donation of a mobile clinic unit for the purpose of enhancing care coordination

for participants without a primary care physician but is also no longer an input. Valley Baptist Health Systems and UT Health were unable to come to an agreement about the donation or purchase of the mobile clinic unit. Instead, the PA and medical assistant are providing medical services in selected community locations and therefore provide increased access to Salud y Vida participants.

Activities: The activities section of the logic model provides an overview of UT Health SPH's programmatic activities and are outlined below:

- Medication Therapy Management (MTM)
  - Pharmacists trained and certified in MTM
  - Establish MTM services for individuals with low medication adherence
- Behavioral Health Counseling
  - Master-level trained counselors provides behavioral health services
- Community-based lifestyle programs
  - Offer *Cocina Alegre* 6-week course on healthy meal planning and preparation
  - Establish relationships with restaurants to have "diabetes friendly" meals
  - Offer MEND! 10-week family-based programs obesity prevention program
- Care Coordination
  - Chronic care management (CCM) team develops individual health plans for participants
  - Bi-monthly case review meetings
  - Provide partners with requested resources
  - Enhance clinic services and workflows to include connection and referral of Salud y Vida participants by CHWs and Care Teams
- Peer Led Support Groups
  - Train CHWs on IBH and motivational interviewing strategies
  - Establish face-to face and phone-based PLSGs

Changes in these program activities that deviate from the SEP include: "Establish relationships with restaurants to have "diabetes friendly" meals" is no longer an activity because it corresponds to the healthy food application input, which was never intended to be part of the evaluation.

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

- Recruit 175 participants into each arm of the study (intervention and control group)
- Health education protocols developed
- Referral protocols developed
- Participants engaged in health care system and enrolled in study through program partners and UT Health SPH
- Agreements among program partners
- New resources for partner capacity development

Short-term and intermediate outcomes in bold, italicized font are those that were measured via the evaluation and reported during the study. These were assessed qualitatively through focus groups and interviews and through analysis of quantitative implementation data. Other outcomes will not be measured because they are the result of usual care (SyV 1.0) activities and do not directly measure the impact of enhanced services being provided by SyV 2.0.

Short-Term Outcomes: Short-term outcomes are the changes that are expected to occur during the first six months of the program. Expected short-term outcomes are outlined below.

- ***Eligible participants enrolled, screened, and baseline measures obtained***
- ***Participants received care plan***
- Implementation and improvement of health education protocols
- ***Implementation and improvement of referral protocols***
- Increased number of participants engaged in health care system
- Increased capacity among program personnel and partners
- ***Increased confidence in performing diabetes self-care practices***
- Increased awareness of services

Intermediate Outcomes: Intermediate outcomes are the changes that are expected to occur during the first 12 months of the program. Below are the expected intermediate outcomes.

- Increased patient understanding of obesity, diabetes, and depression
- ***Increased patient self-efficacy for disease management***
- ***Increased patient compliance with treatment plans***
- ***High patient satisfaction with SyV 2.0***
- Risk factor reduction through lifestyle modification and clinical intervention
- ***Reduced HbA1c, blood pressure, BMI, cholesterol, and depressive df***
- Increased control of HBA1c level, blood pressure, weight and cholesterol
- ***Increased functioning and quality of life***

Long-Term Outcomes: Long-term outcomes are the changes that are expected to occur after 18 months of the participant's enrollment and are beyond the scope of the planned intervention and evaluation. Long-term outcomes are outlined below. Long-term measures will not be collected or reported in the final report. This is a change from the SEP which stated that these outcomes would be reported on during the study.

- Improved HbA1c, depression, blood pressure, BMI, and quality of life
- Reduced morbidity due to physical and behavioral health conditions
- Improved integration between program partners
- Reduced disparities in complications from hypertension, obesity, diabetes, and depression

The activities and pathways represent an adaptation of the collaborative chronic care model (e.g., Wagner, 1998), as noted in the Prior Research section. The UTHealth SPH model is similar in the delivery and content of the studied interventions, but with culturally-relevant adaptations including community health workers and bilingual programming.

Overview of Impact Study

This study used a randomized control trial (RCT) design to compare intervention participants receiving the enhanced delivery of integrated behavioral care with control participants receiving usual care. Participants enrolled in the study were followed through 12 months. The study hypothesis was that an enhanced level of primary and behavioral health services offered through the SyV 2.0 program will improve participants' HbA1c levels and related health measures.

Use of an RCT research design was preferred because it minimizes threats to internal validity by better controlling for patient and clinic level characteristics. Using an RCT design allowed for the presumption

that any differences observed in program impact between the intervention and control groups were potentially caused by participation (or lack of participation) in the SyV 2.0 program.

Research Questions

UT Health SPH's subgrantee evaluation plan includes 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 SEP. The final implementation evaluation included focus groups, interviews and assessment of quantitative implementation data.

1) Did the SyV 2.0 program reach its intended target population?
2) What are the components of SyV 2.0 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 are they different?
3) What level of integrated behavioral health did UT Health SPH achieve as a result of implementing SyV 2.0?
    a. To what extent have providers and staff adopted the components of the SyV 2.0 program at 6 and 12 months? What are the facilitators and barriers to adoption?
    b. To what extent do providers and staff buy in to the SyV 2.0 program, and how has buy-in affected implementation?
4) To what extent did the control group receive program-like components?
5) To what extent did UT Health SPH implement the SyV 2.0 model with fidelity?
6) How satisfied are SyV 2.0 patients with the services they have received? How satisfied are providers with the SyV 2.0 program?

Impact Questions

The primary impact measure for SyV 2.0 was plasma glucose level (HbA1c). Below are the confirmatory and exploratory research questions. The impact findings are presented later by Impact Question.

1) Are participants who receive SyV 2.0 more likely to reduce HbA1c after 12 months compared to participants who receive SyV 1.0 (the standard of care)? *This question is confirmatory.*
2) Are participants who receive SyV 2.0 care more likely to improve their blood pressure after 12 months compared to participants who receive SyV 1.0? *This question is exploratory.*
3) Are participants who receive SyV 2.0 more likely to reduce their BMI after 12 months compared to overweight or obese participants who receive SyV 1.0? *This question is exploratory.*
4) Are participants who receive SyV 2.0 more likely to reduce their depressive symptoms, as measured by the PHQ-9, after 12 months compared to participants who receive SyV 1.0? *This question is exploratory.*
5) Are participants who receive SyV 2.0 more likely to improve their quality of life, as measured by the Duke Health Profile, after 12 months compared to participants who receive SyV 1.0? *This question is exploratory.*

6) Are participants who receive SyV 2.0 more likely to normalize their total cholesterol after 12 months compared to participants who receive SyV 1.0? *This question is exploratory.*
7) Are participants who receive SyV 2.0 more likely to have improved medication adherence, as measured by the Diabetes Medication Adherence Questionnaire, after 12 months compared to participants who receive SyV 1.0? *This question is exploratory.*
8) Are participants who receive SyV 2.0 more likely to have improved self-efficacy, as measured by the Diabetes Self-Efficacy Scale, after 12 months compared to participants who receive SyV 1.0? *This question is exploratory.*

Contribution of the Study

The SyV 2.0 evaluation contributes to the body of evidence regarding integrated behavioral health services in a community-based setting within a low-income, Hispanic population. The SyV 2.0 evaluation targeted a moderate level of evidence by incorporating additional evidence-based components into their intervention. Prior evidence for these additional evidence-based components include a quasi-experimental study which found that diabetic patients who received MTM services significantly improved or maintained HbA1c levels (Cranor et al, 2003) and an RCT providing CBLPs and PLSGs to diabetics which resulted in significant reductions in HbA1c levels among the intervention group (Haltiwanger & Brutus, 2012). UT Health SPH built upon this work by combining multiple evidence-based components to more efficiently and effectively care for participants' health needs in a low resource setting and examined the effects of the intervention through an RCT.

This evaluation study executed a robust RCT design, mitigating major threats to internal validity such as selection bias. The program was implemented to fidelity after the early implementation phase, and the evaluation was conducted as intended; however, due to delays in providing services participants did not receive a full twelve months of the intervention. The most significant threat to internal validity was differential attrition, but analyses of participants in the study compared to those lost to follow-up revealed there were no significant differences in health measures among these participants. There is no evidence that other threats to internal validity—history, instrumentation, etc.—were challenges in this study.

The evaluation of SyV 2.0 program advances the evidence base related to enhanced chronic care models in a community-based setting serving predominantly low-income, Hispanic communities. While the evidence-based interventions were adapted and evaluated using a method with strong internal validity, results do not indicate a change in the preliminary level of evidence assignment at this time. As discussed in the Impact Study section of this report, when controlling for baseline measures and other covariates, intervention assigned participants did not have statistically significant improvement in the HbA1c confirmatory outcome when compared to the control participants at 12 months. However, bivariate results within intervention and control groups showed improvements in HbA1c, PHQ-9, Duke General Health score, total cholesterol, medication adherence score, and diabetes self-efficacy. There is also evidence of effect modification of PHQ-9 score when stratifying by time enrolled in the SyV 1.0 program. The intervention was not found to be significantly associated with lower PHQ-9 score among those who spent less than the median tenure (21.5 months) SyV 1.0, but there was a positive effect among those intervention participants who spent more than the median tenure in SyV 1.0 (β= -1.28, p=0.01). This stratified analysis achieved an effect size of 0.36 (using Cohen's d), which may be interpreted as "small to moderate" based on Cohen's rule of thumb for interpretation of effect sizes (Cohen, 1988). There were no negative intervention effects on the confirmatory outcome; however, the

intervention had negative effects on diastolic blood pressure for select subpopulations. For example, among those who spent less than the median tenure (21.5 months) in SyV 1.0, the intervention was associated with a significantly higher mean diastolic blood pressure (β= 4.68, p=0.004; d=0.44). Among participants referred to MTM, those participants who received the minimum dose of MTM had a significantly higher diastolic blood pressure than those who did not receive minimum dose (β= 6.65, p=0.0.03). Finally, among those referred to La Cocina Alegre, those who received the minimum dose of La Cocina classes had a significantly higher self-efficacy compared to those who did not receive minimum dose (β= 0.69 p=0.002). Despite its findings, this study contributes to our understanding of the implementation of an enhanced chronic care model in a community-based setting within a low-income, Hispanic population.

SIF Evaluation Plan Updates

The evaluation plan was updated as follows.

- Recruitment was extended for two months to meet the enrollment target of 350 participants.
- Study eligibility criteria was revised because the criteria were originally too narrow to recruit a sufficient sample size over the specified time period.
- The SEP logic model included the following components which were removed or revised: "Healthy Communities Brownsville: Will develop and promote a healthy food application for mobile devices" is no longer an input because it was never intended to be part of the evaluation. The delivery of MEND changed from IFNA to UT Health SPH in year 3 due to capacity issues. Valley Baptist Health Systems was to provide an in-kind donation of a mobile clinic unit for the purpose of enhancing care coordination for participants without a primary care physician but is also no longer an input. Valley Baptist Health Systems and UT Health were unable to come to an agreement about the donation or purchase of the mobile clinic unit. Instead, the PA and medical assistant are providing medical services in selected community locations and therefore provide increased access to Salud y Vida participants. "Establish relationships with restaurants to have "diabetes friendly" meals" is no longer an activity because it corresponds to the healthy food application input, which was never intended to be part of the evaluation.
- The program manager ascertained if participants met inclusion criteria rather than the CCM team.
- Participant data was collected via paper forms and then entered into REDCap, rather than entered directly into REDCap.

IMPLEMENTATION STUDY - STUDY APPROACH, METHODS, AND FINDINGS

Implementation Study Design

The implementation study aimed to understand how SyV 2.0 was implemented. As described in the SEP, two main methods were used: 1) qualitative data collection via key informant interviews and focus groups, and 2) analysis of quantitative implementation data (e.g., patient visits, administrative data).

Qualitative Data Collection Methods and Analysis
The program's evaluator, Health Resources in Action (HRiA), conducted qualitative data collection at two time points for the implementation study. Across the two time points, a total of 22 staff members were interviewed, and 19 program participants were involved in focus groups.

For the mid-point interviews (April 2017), a total of 16 semi-structured interviews were conducted with 18 individuals who performed a range of roles at UT Health SPH and its partner organizations, including administrative, programmatic, and executive roles. Twelve interviews were conducted by telephone and 4 interviews were conducted in-person. Mid-point interviews were conducted approximately 6 months after initial study enrollment. In June 2018, when the study ended, 16 summative interviews with 22 staff members were conducted. Interview participants included clinical providers (both primary 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 C: Sí Texas Mid-Point Implementation Evaluation: Key Informant Interview General Guide** and **Appendix D: Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide** present the semi-structured interview guides used to conduct the interviews at the mid-point and final data collection periods.

In addition to these semi-structured interviews, HRiA conducted two focus groups with intervention group participants after study implementation concluded (in June 2018). The goal of the focus groups was to better understand the influence the program has had on participants' health and wellbeing. Focus group participants were recruited from those who had participated in at least two services. Of the 34 participants who met these criteria, the majority participated in MTM and La Cocina Alegre. **Appendix E: Sí Texas Summative Implementation Evaluation: Focus Group Guide** presents the semi-structured focus group guide used to conduct the focus groups at the final data collection period. **Appendix F: Implementation Evaluation Measures** presents all implementation program components/activities, outputs, and outcomes that were measured using qualitative methods.

There were a total of 19 intervention participants in UT Health SPH's summative focus groups. One focus group had 15 participants and the other had 4 participants. **Table 1** describes participant demographics for the two focus groups (n=19). All participants lived in Cameron County and most were female (68.4%). A majority of participants were 55 or older (63.2%). All participants were Hispanic or Latino (100.0%). Most participants were White (77.8%) and spoke Spanish as a primary language (73.7%). Over half of participants had less than a high school diploma (52.9%) and did not have health insurance (55.6%).

Table 1. Demographic Characteristics of Salud y Vida 2.0 Focus Group Participants

	UT Health SPH Focus Group Participants (n=19)	
Measure	n	%
County		
Cameron	19	100.0
Sex		
Male	6	31.6
Female	13	68.4
Age		
<35	0	0.0
35-44	1	5.3
45-54	6	31.6
55-64	11	57.9
65+	1	5.3
Ethnicity		
Hispanic/Latino	17	100.0
Non-Hispanic/Non-Latino	0	0.0
Missing	*2*	--
Primary Language		
Spanish	14	73.7
English	5	26.3
Education		
Less than a high school diploma	9	52.9
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	2	11.8
Missing	*2*	--

	UT Health SPH Focus Group Participants (n=19)	
Measure	n	%
Health Insurance		
None	10	55.6
Private	1	5.6
Medicaid	2	11.1
Medicare	3	16.7
Other	2	11.1
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, one focus group was conducted in Spanish (n=4), and one focus group was conducted in English and Spanish (n=15, bilingual focus group).

All interviews and focus groups were recorded digitally and transcribed. For the summative interviews and focus groups, two trained team members – who did not conduct the interviews or focus groups - initially reviewed transcripts to develop a mutually-agreed upon codebook using a grounded theory approach. They then independently coded each transcript for themes using NVivo qualitative data analysis software (NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 12) and met to discuss concordance and discordance between their coding schemes. Differences were reconciled through discussion until a consensus on the first-level of coding was reached (average kappa=0.98). Differences were reconciled through discussion, and themes were identified by discussion frequency and intensity. Mid-point interviews were coded using NVivo software by one coder using detailed notes. 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, and findings were summarized in narrative descriptions organized by theme with illustrative quotes. If qualitative findings changed from mid-point data collection to summative data collection, it is noted.

Quantitative Data Collection Methods and Analysis

Implementation data of patient participation in the SyV 2.0 were analyzed. These mainly comprised of de-identified patient records from SyV 2.0 REDCap database that included information on intervention and control group participants' clinic and community-based services received. Descriptive statistics on these services are provided in this section, including the mean, median, and range of number of completed and missed visits related to behavioral health and MTM, as well as Cocina Alegre, MEND, and PLSG sessions. This information provides insight into fidelity and dose of the intervention.

Implementation Study Findings

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

Subgrantee: University of Texas Health Science Center at Houston School of Public Health
Project Title: Salud y Vida 2.0

Question 1. Did the SyV 2.0 program reach its intended target population?

All patients who met eligibility criteria and voluntarily consented to participate in the SyV 2.0 program were offered the opportunity to participate in the intervention research study at the time of baseline data collection.

As described in the SEP, all SyV 1.0 participants were eligible for the intervention study after they had been enrolled in SyV 1.0 for a minimum of 6 months and a maximum of 36 months. Participants recruited for SyV 2.0 were also required to:

- Be a patient of Su Clinica or Rio Grande State Center;
- Reside in Cameron or Willacy Counties;
- Have an HbA1c $\geq$ 9.0% at any point between 6 and 36 months of SyV 1.0 services; and
- Have an HbA1c $\geq$ 8.0% at 2.0 baseline enrollment.

UT Health SPH enrolled a total of 353 participants into the intervention (n=176) and control groups (n=177). Intervention and control group study participants lived primarily in Cameron County. Most of the participants enrolled in the study were female (70.5%), Hispanic (92.1%), and spoke Spanish as their primary language (67.7%). The average participant age was 51.5 years. Almost all participants met the study eligibility criteria (3 participants were outside of the range for enrollment in SyV 1.0 services between 6 and 36 months); therefore, the program reached the intended audience. The prevalence of the individual eligibility criteria among the enrolled sample is provided in **Table 2**. The 0.8% of participants who are noted as not meeting the SyV 1.0 eligibility criteria were just outside the cutoffs (e.g. partially through their 5th month in SyV 1.0) and were allowed to participate in the study. The demographic characteristics of the study sample can be found in **Table 20** later in the report.

Table 2.Prevalence of Eligibility Criteria in Salud y Vida 2.0 Intervention and Control Group Participants

Eligibility Criteria	Prevalence in Enrolled Sample
Reside in Cameron or Willacy Counties	100.0%
Patient at Su Clinica or Rio Grande State Center	100.0%
Enrollment in the SyV 1.0 services for a minimum of 6 months to a maximum of 36 months	99.2%
An HbA1c $\geq$9.0% at any point between 6 and 36 months of SyV 1.0 service	100.0%
An HbA1c $\geq$8.0% at baseline enrollment	100.0%

Question 2. What are the components of SyV 2.0 and how do these components work "on the ground" at 6 and 12 months?

UT Health SPH program staff and clinic staff interviewees were asked to describe the components of SyV 2.0 and how these components were implemented. According to interviewees, SyV 2.0 components included programs such as community health workers/promotores and peer-led support groups; clinic-based interventions such as behavioral health consultations and medication therapy management; Chronic Care Management meetings which brought together clinic and UT Health SPH program staff; and community-based programs including Cocina Alegre and MEND.

Community Health Workers/Promotores
According to UT Health SPH and clinic staff interviewees, promotores were central to care coordination and participants' involvement in the aspects of SyV 2.0 for which they were eligible (based on diabetes and behavioral health status). Promotores' activities that emerged in the interviews included: conducting phone-based outreach and home visits with participants, building relationships with participants by maintaining regular contact, discussing stressors and concerns that participants navigated, working with participants to mitigate stressors and barriers that may affect health (e.g., transportation barriers), coordinating care by scheduling participant appointments, recommending participation in community-based programs, collecting evaluation data, and accompanying participants to lab visits. Program participants characterized promotoras as being *"very involved"* in participants' day-to-day lives, often working with participants to address the social determinants of health and coordinating care. As one participant explained, *"The promotoras, like the one that I had … I liked her because they were really helpful, like telling us what you need."* Promotoras were also central to the CCM meetings (described below).

Peer-Led Support Groups (PLSGs)
According to UT Health SPH staff interviewees, PLSGs offered a space for participants to discuss stressors, healthy eating, physical activity, and sustaining lifestyle behavior changes related to improving behavioral and physical health. As one UT Health SPH program staff interviewee explained, "*In the meetings, we talk about the challenges we have, what things are working better … sharing experiences … We always try to make some different activities with them."* Another UT Health SPH program staff interviewee noted that participant priorities shape the PLSG content: "*The participants in each peer-led support group kind of guide where the conversation goes."* One UT Health SPH program staff interviewee explained that PLSGs are structured to strengthen leadership capacity amongst participants: *"[We] identify people who can be facilitators, and she trains them … to guide the support group and …[to] learn more about other diseases that the participants are asking them for information about."* Most UT Health SPH program staff interviewees discussed PLSGs as in-person support groups, while they noted that one PLSG was facilitated online (i.e. Facebook). In several cases, UT Health SPH program staff interviewees noted that PLSGs incorporated physical activity into the group activities. Additionally, UT Health SPH program staff interviewees noted that PLSG facilitators connected participants with social and economic resources (e.g., clothing) when needed. As a UT Health SPH program staff interviewee described, "*And also, we are helping them [participants] in other ways. There's people with high needs. Or many needs. We have low-income people."*

Behavioral Health Consultations
UT Health SPH program and clinic staff interviewees explained that when providers identified participants as having high PHQ-9 scores, they referred participants internally for a behavioral health consultation. At one implementation site, staff interviewees noted that behavioral health consultations took place immediately following the provider assessment. At the other implementation site, staff interviewees explained that program staff scheduled a separate behavioral health consultation. One clinical staff interviewee described behavioral health consultations as a brief discussion about managing behavioral health concerns: *"[I] go ahead and have a consult with them where we basically address those symptoms [physical symptoms of behavioral health issues]. So it's not a counseling relationship, but it's a consultation to address the symptoms of depression or anxiety or anything that might arise from that … From there, I basically am part of that network of referring them [participants] to additional services if they need it."* Clinical staff interviewees noted that behavioral health staff referred participants for psychiatric evaluation, psychotherapy, or counseling as needed.

Medication Therapy Management
According to clinic staff and UT Health SPH program staff interviewees, pharmacists conducted medication therapy management (MTM), which involved discussions about medication therapy plans with patients and providers. Interviewees explained that pharmacists used information from EMRs and discussions with participants and providers to inform the development of MTM action plans. Clinical staff interviewees noted that pharmacists and participants often discussed the details of the multiple medications (prescriptions and over-the-counter medications) that participants were taking, medication side-effects, lifestyle factors (e.g., smoking status, vaccine recommendations), and the importance of continuous medication therapy. Additionally, clinical staff interviewees noted that pharmacists made medication management recommendations to providers, which sometimes involved multiple exchanges before finalizing MTM action plans. As one clinical staff interviewee explained, *"We get a new recommendation, that's great, we then need to get the medication into the patient's body and to do that we need to make sure we go the extra step so that the pharmacy has what we need to lawfully process that order and to further communicate with the patient to come pick up their drug, add the counseling on top of that, [to] make sure that they understand what's going on with their care and moving forward to, in this case, lowering their A1c value."*

According to clinic staff and UT Health SPH program staff interviewees, to address scheduling and transportation barriers, pharmacists temporarily implemented a floating pharmacist model. In this model, staff interviewees noted that pharmacists attempted to meet patients at their home to deliver the medication therapy management services.

Cocina Alegre
UT Health SPH program staff interviewees explained that Cocina Alegre delivered healthy eating education in the form of cooking classes that provided diabetes-friendly recipes. This program also provided groceries, so participants could replicate the recipes at home. UT Health SPH program staff interviewees and community-based partner interviewees noted that these cooking classes were regularly held in community-based settings, and family members of SyV 2.0 participants were also invited to participate.

According to a couple of UT Health SPH program staff interviewees, the strict Cocina Alegre participation requirements initially limited SyV 2.0 participants' participation in Cocina Alegre (i.e., if a participant missed the first two sessions they were unable to participate). After consultation with SyV 2.0 program administrators, staff interviewees noted that Cocina Alegre attendance requirements were adjusted to be more flexible for SyV 2.0 participants. For example, one UT Health SPH program staff interviewee explained, "*"So … after several discussions with the Brownsville Wellness Coalition, [we] convinced them to modify the design of La Cocina Alegre to allow …our 2.0 people in after the second class."*

Some UT Health SPH program staff and community-based provider interviewees noted that they revised several Cocina Alegre recipes to align with dietary needs of persons with diabetes. As one UT Health SPH program staff interviewee explained, *"So I think those classes work well. … We had to work with that organization to really tailor it to a population with diabetes, so it was going to be the most effective."*

MEND
According to UT Health SPH interviewees, MEND was a 10-week program designed for SyV 2.0 families to engage in and discuss physical activity twice per week. Recruitment challenges (described in the sections that follow) contributed to MEND not getting off the ground.

Integration of Care
Several UT Health SPH program staff and clinic staff interviewees perceived bi-weekly Chronic Care Management (CCM) meetings as a critical component of care coordination. According to staff interviewees, CCM meetings included promotores, other program staff, program partners, pharmacists, and representatives from each clinic. Staff interviewees explained that during CCM meetings, UT Health SPH program staff and clinic staff discussed updates about participants whom promotores identified as having HbA1c levels that increased. According to one clinical staff interviewee, *"We discuss either different strategies or more recommendations to help this participant improve … We kind of discuss what we can do to help this participant and that could be referring them to a service that they weren't initially approved [for] from the beginning of enrollment."*

Interviews also examined how the SyV 2.0 program was implemented. When asked about how primary care, behavioral health, and community-based programs were coordinated and connected, at both midpoint and summative interviews, UT Health SPH program staff and clinic staff interviewees discussed communication, workflows, and data systems as critical to the SyV 2.0 program. During the summative evaluation, staff interviewees highlighted the importance of physical space. Web-based and on-site training was also mentioned during mid-point interviews.

Communication
According to several clinic staff and UT Health SPH program staff interviewees, communication was a core component to implementing the SyV 2.0 program. Bi-weekly Chronic Care Management meetings, morning huddles with clinic staff, and partnership meetings were identified as critical elements of clinical and program communication and coordination. Chronic Care Management meetings leveraged promotores' assessments and updates of participants' health, SyV 2.0 data systems, and the perspectives of clinical providers and UT Health SPH program staff to discuss and revise case management plans for participants whose HbA1c levels had increased. According to some clinical staff interviewees, morning huddles with behavioral health and primary care clinic staff at the nurses' station enabled a careful review of incoming participants, coordination of contact with participants, and reminders about SyV 2.0 services to facilitate the integration of clinical services and referrals to community-based programs. One clinical staff interviewee emphasized the importance of morning huddles: *"So, when you talk about it [SyV 2.0] the first thing that morning and they [clinic staff] start … as soon as that huddle is done. [T]hey're off doing and focusing on those things that they were just told. That, I think works really well as far as communication for the clinic."*

Staff interviewees explained that shared physical space for clinic-based and program partners (at one implementation site), as well as regular communication strategies (e.g., CCM meetings, monthly program coordination meetings) facilitated the integration of services and programs. One UT Health SPH program staff interviewee emphasized that co-located clinic space, shared office space for program partners, and SyV 2.0 funding facilitated the opportunity to *"have these conversations and to start building the system."* According to UT Health SPH program staff interviewees, monthly in-person

meetings and regular email communication between SyV 2.0 partners facilitated communication across partners and was characterized as a strength.

Workflow
Clinic staff interviewees perceived workflow, or how participants and clinical staff move within a clinical space, to be another important element of integration. According to clinic staff interviewees, warm handoffs from primary care facilitated participant engagement with primary care, MTM, and behavioral health counselors. Additionally, staff interviewees shared that MTM pharmacists modified their workflow to better connect with participants by tracking primary care visits and coordinating with primary care providers to deliver MTM consultations during scheduled visits.

Data Systems
According to clinic staff interviewees, two clinical systems – Wellcentive and MTM Path – were implemented to integrate primary care, medication management, and behavioral health. Clinic staff interviewees shared that EMRs facilitated integration of services when the participant was in the clinic. As one clinical staff interviewee explained: *"[T]he consult, the findings and so forth is in our EMR and the providers are all aware."*

During mid-point and summative interviews, staff interviewees explained that community-based partners did not have a streamlined data system to collect and share data. During summative interviews, program staff interviewees explained that program staff used Excel databases to enter program data, which in turn needed to be manually entered into the REDCap database. Staff interviewees perceived that these multiple data systems challenged partners to implement collaborative systems and is discussed further in the adoption barriers section.

Physical Space for Integration
According to clinical staff interviewees, primary care, behavioral health, pharmacy, and social welfare services (distinct from community-based services) were available at each clinic site. Of note, primary care providers and behavioral health counselors were co-located at one clinic site, in which behavioral health counselors worked in the primary care unit. By contract, at the second clinic site primary care and behavioral health services were located in the same clinic, but in different areas. According to clinic staff interviewees, the co-location of primary care providers and behavioral health counselors at one site facilitated warm-handoffs: *"If they flagged that this particular person might need behavioral health services, then [participants] immediately get a warm hand off … Before the end of the PCP visit, there will be a warm hand off to the counselor on site at that clinic."* According to a couple of clinic staff interviewees, at the site where providers were not co-located, staff walked participants with high PHQ-9 scores over to behavioral health care providers when possible or participants received electronic referrals. In the latter situation, according to one UT Health SPH program staff interviewee, based upon EMR data, program staff would call participants after their clinic visit to schedule a behavioral health visit.

Additionally, some community-based partners and promotores shared office space at UT Health SPH. According to UT Health SPH program staff interviewees, this co-location fostered opportunities to build relationships and communicate across programs. As one community-based provider explained, *"We have great communication … We're housed right there with them [promotores] so we're always kind of meeting and seeing each other."*

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

Implementation as Planned
According to interviewees, overall the SyV 2.0 program was implemented as planned, particularly with respect to the delivery of integrated clinical services. As one UT Health SPH program staff interviewee explained: *"Well it is definitely helping to build structure or workflows with our partners, like specifically with the clinics."* According to staff interviewees, some adaptations were made to strengthen the integration of services. For example, according to some clinic staff and UT Health SPH program staff interviewees, to address participant scheduling and transportation barriers, staff temporarily implemented a floating pharmacist model. In this model, staff interviewees explained that MTM pharmacists attempted to meet participants at their home or in other community-based settings to deliver MTM services. Due to several challenges in connecting with participants (e.g., no-shows), the floating pharmacist model was only temporarily implemented (Note: Clinic pharmacists continued to provide MTM consultations when floating pharmacists were not available. The temporary implementation of the floating pharmacist model did not constitute a gap in service delivery).

UT Health SPH program staff interviewees described low participation rates in MEND, which they attributed to limited alignment between the eligibility criteria and participant population. Specifically, according to interviewees, MEND was designed for adults and children in a given household. However, UT Health SPH program staff interviewees explained that the enrollment population primarily included older adults who often did not have young children. According to one UT Health SPH program staff interviewee, MEND did not get off the ground due to these low participation rates. As one UT Health SPH program staff interviewee described: "*I don't think we had a clear sense of who [did] and who didn't have eligible children in their household … after some investigation there was only … somewhere in the teens of people who were actually eligible and out of that pool there was like virtually no interest."*

According to staff interviewees, several other minor implementation revisions were made: staff extended clinic hours to some evenings and two weekends per month; recipes for Cocina Alegre were tailored to align with the dietary needs of persons with diabetes; and there was a brief delay in implementation of PLSGs due to the need for additional staff. Furthermore, in addition to in-person PLSGs, according to one UT Health SPH program staff interviewee, one ongoing PLSG was offered through Facebook due to limited participation in phone-based support groups. Otherwise, according to staff interviewees the SyV 2.0 program was implemented with fidelity.

At mid-point, staff interviewees identified delays in hiring clinic and UT Health SPH program staff with appropriate technical expertise as roadblocks to early implementation. During mid-point and summative interviews, staff interviewees recalled some delays in enrollment during the early phase of SyV 2.0. Staff interviewees attributed this delay in part to tight enrollment timelines, narrow inclusion criteria that made it challenging to meet enrollment targets, and challenges of re-contacting and re-engaging with eligible patients who participated in previous programs. During the early phase of implementation, this contributed to some confusion and delays in providing services. UT Health SPH met the enrollment target in May 2017.

Question 3. What level of Integrated Behavioral Health did UT Health SPH achieve as a result of implementing SyV 2.0?

Question 3a. To what extent have providers and staff adopted the components of the SyV 2.0 program at 6 and 12 months? 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. 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 H: 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, 2011.

UT Health SPH partner clinics completed the AIMS IBH checklist September 2016 (pre-intervention implementation) and August 2018 (post-intervention implementation). Additional details for each clinic site is provided below.

Table 3 and **Table 4** present data from the assessments completed by Rio Grande State Center (RGSC). Results were the same at both time points for all Core Principles. They responded as applying the Core Principles in the care of "Most/All" patients, except for "Accountable Care" principle, which they did not apply at baseline or 12 months. There was no change reported for any of the Core Components and Tasks at baseline or 12 months. RGSC is a state-run free clinic that provides evidence-based, patient-centered care. Through SyV 2.0, UT Health SPH added new evidence-based options for RGSC to implement into their clinic workflow, which built upon an existing high level of IBH. The "Accountable Care" principle is not applied because clinic staff are employed by the State of Texas and it is unlikely Texas will change its provider payment structure in the near future.

Table 5 and **Table 6** present Su Clinica's data from these assessments. Su Clinica reported improvement in four of the five Core Principles from baseline to 12 months. Su Clinica began the study by applying the Evidence-Based Care Core Principle to "Most/All" patients, a practice that continued through the end of the study. There was additional change in the Core Components and Tasks, with twelve indicating improvement and thirteen remaining the same from baseline to 12 months (twelve of which were applied to the care of "Most/All" patients at baseline). One component indicated a decrease in how it was applied in patient care: "Create and support relapse prevention plan when patients are substantially improved."

Rio Grande State Center IBH Checklist Results

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

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

• Response at baseline ✓ Response at 12 months

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

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

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

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

• Response at baseline ✓ Response at 12 months

Su Clinica IBH Checklist Results

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

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

• Response at baseline ✓ Response at 12 months

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

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

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

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

• Response at baseline ✓ Response at 12 months

Program Adoption

Staff interviewees and program participants were asked about factors that facilitated or hindered program implementation and participant participation in the program. Presented in the following section are adoption facilitators and barriers that emerged from interviews with staff and partners and from focus groups with program participants.

Adoption Facilitators

At mid-point, staff interviewees cited several successes to early program implementation, including: participant access to services through community and clinical partners; communication within the SyV 2.0 team and between clinic staff and UT Health SPH program staff; and web-based and online training regarding the Sí Texas evaluation, group facilitation, and motivational interviewing. During summative interviews and focus groups, adoption facilitators included increased communication, physical space, data systems, staff relationships, staffing, and training.

Communication

Communication was the most frequently mentioned facilitator from the perspective of clinic staff interviewees, UT Health SPH program staff interviewees, and program participants. According to program participants and staff interviewees, promotores played a key role in ensuring continuous communication with participants and facilitating or encouraging program participants' engagement with recommended program and clinic resources. Program participants and staff interviewees perceived that phone calls, texts, home visits, and brief meetings with promotoras during community-based classes or groups enabled participants to communicate with staff about their HbA1c levels and psychosocial factors (e.g., family-related stressors, financial stressors, depression, and anxiety) that affected diabetes control. As one program staff interviewee described*: "They're [promotores] in constant communication with [participants], whether it's in a home visit, or by text or at a class, or at their clinic appointment. Their role is really to manage all of the services that are being offered to the participant, to motivate the participants, refer out and address barriers."* According to program participants, staff communication with participants, such as reminder phone calls and texts also made it easier to receive care. Clinical staff interviewees identified several ways in which in-person and email communication facilitated implementation of SyV 2.0. Clinic staff and UT Health SPH program staff interviewees described how the Chronic Care Management meetings brought together primary care providers, behavioral health providers, and promotores to facilitate discussion and development of care plans for participants in a timely manner. As one UT Health SPH program staff interviewee described, *"Having them in the same*

room, talking about the same patients worked." According to staff interviewees, morning huddles among primary care clinic staff, the Salud y Vida patient navigator and behavioral health counselors provided an opportunity to remind clinical staff about SyV 2.0 components and to address workflow considerations. Case Review meetings provided another opportunity for a multi-disciplinary team to staff the cases of participants who struggle. Staff interviewees shared that monthly program coordination meetings strengthened relationships across UT Health SPH program staff with community-based and clinic partners.

According to clinical staff and UT Health SPH program staff interviewees, in-person communication, co-located clinical spaces, and office space for program partners that are co-located with each other offered opportunities to communicate about participant needs and different programs, and to strengthen relationships among UT Health SPH program staff and community-based partners. As one UT Health SPH program staff interviewee mentioned: *"I started going to all of the promotoras meetings, [I] really establish[ed] a friendly rapport with all of the promotoras."* One program staff interviewee emphasized that space and funding facilitated the opportunity to *"have these conversations and to start building the system."*

Physical Space

Some clinic staff interviewees described the co-location of primary care providers, behavioral health counselors, and pharmacists as factors that facilitated the integration of clinical services. One UT Health SPH program staff interviewee described how co-locating behavioral and primary care services facilitated the integration of care at one clinic site: *"That counselor is found on the same floor, on the same area that the PCP visits occur, so it's very convenient."* One clinical staff interviewee highlighted how they leveraged their co-location in the clinic building and access to scheduling information to reach patients during clinic wait times: *"[When] the patient was just waiting for the doctor we would just slip into the room and sort of do the MTM interview in the examination room while they were waiting for the doctor."*

Data Systems

Some clinic staff interviewees highlighted that the data systems (e.g., MTM Path, EMRs) facilitated communication between clinical staff. According to clinic staff interviewees, MTM Path enhanced communication between pharmacists and providers. Additionally, some clinic staff interviewees shared that MTM pharmacists used the schedule function in the EMR to identify when participants would be at the clinic and to coordinate delivery of MTM during the visit. Some clinic staff interviewees noted that behavioral health counselors used EMRs to communicate with primary care providers and participants about the participant's clinical schedule and clinical assessments. As one clinical staff interviewee explained, *"So, the consult, the findings and so forth is in our EMR and the providers are all aware, [the behavioral health provider], … the primary care provider for the patient is aware. And it's all right here for the patient."*

Staffing

Some clinic staff and UT Health SPH program staff interviewees attributed the skilled management of program leaders overseeing the implementation of SyV 2.0, communication across clinic staff and UT Health SPH program staff and with participants, and/or technical expertise (e.g., program coordinators, data manager, counselors) of staff as important facilitators of program adoption. Pharmacists also highlighted the hiring of two pharmacists and data entry support as important facilitators of timely MTM and data entry. One UT Health SPH program staff interviewee characterized the different staff roles and

coordination as important strengths: *"Working together as a team to bring the different skills that we all have, the different types of experience that we have with the participants within the program."*

Trainings

Clinic staff and UT Health SPH program staff interviewees cited the training in data collection and management (e.g., program participation, participant measurements), refreshers regarding diabetes and medication therapy management, and evidence-based MTM training as important facilitators of program implementation. A couple of clinic staff interviewees described trainings in REDCap, MTM Path, and Wellcentive databases as helpful. During mid-point and summative interviews, UT Health SPH program staff interviewees highlighted the importance of group facilitation and motivational interview trainings. In summative interviews, some UT Health SPH program staff interviewees characterized the trainings on how to administer assessments of health outcomes as helpful.

Adoption Barriers

At the mid-point, staff interviewee participants described several adoption barriers, including initial staffing challenges and meeting enrollment targets. During summative interviews, barriers to adoption included physical space for community-based programs, data systems and collection of evaluation data, and hiring and staffing.

Physical Space

Given significant transportation barriers that participants encounter, some clinic staff interviewees identified the limited locations of community-based programs as an important barrier to participant participation, which is discussed further in the participant barriers section. One UT Health SPH program staff interviewee member wished for *"accessibility to offer participants more choices of locations and places for them to [attend] these classes."* Additionally, some community-based classes were briefly offered at the Brownsville Community Networking Center run by the police department, which promotoras mentioned might have inhibited participation given the current sociopolitical context. Due to these concerns, this community-based class was relocated.

Data Systems

According to interviewees, Wellcentive, and MTM Path were facilitators and barriers to program implementation. Similarly, interviewees shared that REDCap served as a facilitator and barrier to program evaluation. Several clinical staff and UT Health SPH program staff interviewees cited the need to strengthen training in REDCap, Wellcentive, and MTM Path prior to program implementation, and to enhance IT support for the data systems. Though REDCap supported tracking of participants for the evaluation, according to interviewees REDCap was not available to all staff and was not always up to date. As one UT Health SPH program staff interviewee described, *"The [data] I would get would eventually go into REDCap, but I would have to get it first from the partner or the promotoras. It was really difficult to coordinate."* According to staff interviewees, one challenge early in the implementation process was determining when participants were assigned to the intervention or control group, a challenge that was partially linked to data systems. Additionally, during mid-point and summative interviews, UT Health SPH program staff interviewees noted that community-based staff used spreadsheets for data entry. Some clinical staff interviewees characterized MTM Path as challenging to learn and described the functionality as limited (e.g., data were lost, it was difficult to edit recommendations). One staff interviewee explained: *"MTM Path was probably the most challenging platform to work …it still came with issues that they had to work through that we are still working through today."* According to clinical staff interviewees, the hiring of additional MTM technicians and clerks facilitated data entry and communication via MTM Path. Some program participants mentioned

that while they preferred or expected paper reports, they did not receive paper copies of their HbA1c levels from providers, though pharmacists provided HbA1c levels (drawn from EMRs) to participants when coordinating medication management.

Some staff interviewees characterized the collection and entry of evaluation data as burdensome. UT Health SPH program staff interviewees perceived REDCap as a source of duplicated data entry because promotores also used Wellcentive. As one UT Health SPH program staff interviewee explained, *"In the case of the study, they were having to document everything into two databases, you know REDCap for the study elements and then Wellcentive for the program element. So that's very tedious."*

Hiring and Staffing
During mid-point and summative interviews, staff interviewees noted that significant delays in hiring staff challenged early implementation of SyV 2.0 and meeting of enrollment targets. According to staff interviewees, delays in hiring initially burdened some clinic and UT Health SPH program staff with additional roles. One UT Health SPH program staff interviewee explained: *"Salud y Vida [had] to hire someone to fill my empty position, so the job duties kind of fell on others' backs who already had their own jobs on their plates."* Communication challenges between SyV 1.0 and 2.0 UT Health SPH program staff, which were seen as a result of different workloads between the two groups of staff, emerged in both mid-point and summative interviews. At follow-up, some UT Health SPH program staff interviewees perceived these tensions had diminished over time. During mid-point and summative interviews, staff interviewees identified the need for additional staffing, including a PLSG facilitator, promotores, and administrative support. Of note, several staff interviewees were not familiar with all of the referral mechanisms by which participants were connected with recommended services, nor all the roles of SyV 2.0 staff, which is described in greater detail in Section 3b.

Communication
Staff interviewees participants recommended building upon and improving information-sharing among clinic and community-based program staff, particularly as it relates to participant cases, staff roles in the SyV 2.0 program, and coordination of programs. One staff interviewee explained: *"Keep those regular meetings with the clinic for sure. Integrating 2.0 into the CCM the way we have it is a huge plus. I think I would also try to establish regular communication with the PCPs at each clinic."* Staff interviewees also recommended enhancing information-sharing to better coordinate MTM services and case check-ins during Chronic Care Management meetings and improving the workflow.

Staff interviewees emphasized the importance of discussing the goal of the SyV 2.0 program and each staff member or partner's role in the program. One UT Health SPH program staff interviewee shared: *"The key is the communication. Making sure that we all are clear and know what's our mission as a whole, not just as you as being a community partner."* One clinic staff interviewee emphasized the importance of staff understanding each staff members' roles as they relate to the overarching goals for SyV 2.0: *"I would definitely say that these are my goals, these are the individuals that we're going to target for this service, and it would have been a little bit more clear cut."* Some staff also noted that improved communication might reduce confusion about differences in workloads between SyV 1.0 and 2.0 staff.

Relatedly, some staff interviewees suggested that enhancing each staff and partner's understanding of how their activities are connected would spill over to help participants to see the SyV 2.0 services as integrated. One staff interviewee noted, *"If we have partners communicating with each other and*

collaborating with each other, at least understanding what one another is doing, that will translate to the promotoras understanding and hopefully that will translate to the participants understand[ing]." As one staff interviewee observed, *"Participants don't necessarily see the inter-relationships between all of the services that they're receiving. I think they see them just as discrete services that they are receiving."* Similarly, program participants tended to describe the clinical services in list-like fashions and did not explicitly characterize these as integrated within the clinical setting or explicitly connected to community-based programs.

Participant Facilitators

In addition to facilitators to program adoption experienced by staff, program participants and staff interviewees were asked to identify factors that supported participation in SyV 2.0. Facilitators included: participant-staff relationships, participant-participant relationships, and family support.

Participant-Staff Relationships

Participant-staff relationships were the most common facilitator mentioned by program participants. Several program participants cited the attention from clinic staff and UT Health SPH program staff as important sources of program communication. One program participant explained, "*They're all kind and they talk to you, they ask you [things], a nurse who calls me asks me about every two weeks, apart from the outreach worker."* According to several program participants, promotores genuinely took interest in their lives and health and connected them to important services. Several program participants highlighted the importance of being able to confide in non-family members. One program participant explained, *"[Having] someone outside your family listening to you, I think you feel very relieved. At least I always give thanks because there's someone who helps you, there's someone who listens to you."* Staff interviewees echoed the importance of participant-promotores relationships. Additionally, several program participants shared that because of the stigma of talking about mental health and stressors, they appreciated that they could talk to promotores about their concerns. As one UT Health SPH program staff interviewee highlighted: *"They're [promotores] the front line … they're in the homes literally of people and have multiple conversations with them, do lots of assessment, so they know a lot about their participants."*

Participant-Participant Relationships

A couple of UT Health SPH program staff interviewees noted that through community-based programs, participants developed and strengthened relationships with other participants. One UT Health SPH program staff interviewee explained: *"And they build their own friendships. They met there [at peer-led support groups] and … they've become friends, they actually call each other."* One program participant echoed the importance of their relationship with other participants and the social support they may draw from these new friendships: *"We need each other sometimes. That's why we have this group here for a reason, to get to know each other, help each other however we can."*

Family Support

Some UT Health SPH program staff interviewees identified family support as important motivators to program participation. Recognizing the importance of family in improving health outcomes and adopting lifestyle changes, several UT Health SPH program staff interviewees noted that family members are invited to attend community-based programs. As one UT Health SPH program staff interviewee explained, *"What we do to motivate the person is look for what will motivate him: his family, his children, his health."*

Participant Barriers

In addition to barriers experienced by UT Health SPH program staff and clinic staff when adopting the SyV 2.0 program, program participants and staff interviewees were asked to discuss barriers that participants faced while participating in the program. Barriers that emerged included transportation, participant health and health literacy, and stigma.

Transportation

Some staff interviewees described temporary transportation services arranged through the clinic as a factor that facilitated program participation. However, given that this program was not implemented until the end of the program, participant transportation to clinical and community-based services was the most common participant barrier that emerged in focus groups and interviews. As one program participant explained, *"It was very difficult for me to attend the talks, the classes, and everything … but thank God now, well, with the transportation it's going very well."* According to staff interviewees, advanced chronic conditions prevented some participants from being able to drive. Additionally, staff interviewees and program participants described the significant travel times and difficulty scheduling a ride from family members as important barriers to participation. Staff interviewees identified the co-location of clinical services as an important strategy for reducing the effect of transportation barriers on program participation.

Participant Health and Health Literacy

UT Health SPH program staff interviewees highlighted that participants' physical or mental health or a family member's illness prevented some participants from participating in community-based programs. As one UT Health SPH program staff interviewee explained, *"They're fatigued, tired, and they don't have the spirit to do it because of tiredness."* Staff interviewees described several health literacy challenges, including participants' limited knowledge of diabetes, particularly HbA1c levels and that diabetes is a chronic condition. In response, staff provided diagrams and bilingual materials to convey health and lifestyle concepts.

Stigma

Program participants explained that diabetes-related stigma is a barrier to program participation. One participant explained: *"They don't want anybody else to know [they] have diabetes, and they are maybe embarrassed*." According to UT Health SPH program staff and clinic staff interviewees described stigma around mental health as a barrier to participant engagement with behavioral health counselors. One clinic staff interviewee explained, *"Because of the culture where the people are not used to seeing behavioral health or mental health as a positive thing, they don't even want to mention that they're having issues."*

Question 3b. To what extent do providers and staff buy in to the SyV 2.0 program, and how has buy-in affected implementation?

Clinic staff and UT Health SPH program staff interviewees were asked about their support and buy-in for the SyV 2.0 program, as well as their perceptions of their colleagues' buy-in. Staff interviewees described the role of the clinic's organizational culture towards adopting IBH and buy-in from frontline staff and administration and leadership.

Organizational Culture Towards Adopting IBH

In general, staff interviewees characterized the clinic's the organizational cultures as receptive to integrating primary care and behavioral health. According to one clinical staff interviewee, *"Our providers are very open to it [integration]."* Another clinical staff interviewee identified room for improvement so that providers better integrate behavioral and primary care services within the participant visit, noting that they could *"teach [participants] how to manage these things on their own and not just become dependent on the medication part."* Additionally, another clinical staff interviewee perceived an increase in provider acceptance of MTM recommendations. The small number of participants at one clinic implementation site was perceived by clinical staff interviewees as a facilitator of integration.

Frontline Staff

Overall, frontline staff interviewees expressed satisfaction with the program, highlighting that participants have access to important clinical and community-based services. However, some staff interviewees perceived that other staff members did not fully understand their colleagues' role, which might have hindered program participation or integration across clinical and community-based services. As one staff interviewee described: *"I don't think that like Cocina Alegre understands their relationship to behavioral health. And the behavioral health doesn't understand the relationship to peer-led support groups."* Additionally, some UT Health SPH program staff interviewees perceived that promotores did not fully promote community-based programs when talking with participants, while others observed that *"[promotores are] the main source of actually kind of selling the services to the participant, motivating them to go and even following up."*

Leadership and Administration

Staff interviewees characterized leadership and administration as generally very supportive. However, several UT Health SPH program staff interviewees identified several areas of program implementation that could be strengthened by leadership and administration. These recommendations included: ensuring that all staff know the details of the SyV 2.0 program and components, clarifying staff roles and the distribution of program responsibilities, outlining evaluation expectations (e.g. timing of data collection, goals), and providing additional time for program implementation.

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

According to two clinical staff interviewees, shifts in the clinic culture to enhance communication between providers and pharmacists contributed to some non-SyV 2.0 participants benefiting from clinic-level organizational changes. As one clinical staff interviewee explained: "*The successes we're seeing [are] spilling over into other areas of patients that are not Si Texas. … Ya'll are not seeing that because they're not part of your cohort. But what we're seeing on our end is providers sending us referrals for MTM consults for patients that are not part of your group. Some of those patients they're coming in, we're seeing them get healthier."*

Another program staff interviewee explained that in some cases, staff referred control group participants to behavioral health providers. This interviewee explained: *"We did have some instances where a doctor or somebody else would mention this person really, really needs behavioral health services. [S]o in that instance that control participant would receive that service because you know it's more important for them to receive care that they need."*

According to one program staff interviewee, during the early phase of implementation, some non-SyV 2.0 participants at Su Clinica and Rio Grande State Center received components of SyV 2.0. According to this program staff interviewee, program staff worked diligently to identify those individuals who received SyV 2.0 services, but were not part of the intervention group, and to refine recruitment/scheduling processes: *"I do have long reports documenting that because I know it was definitely something that was alarming, and we had long conversations about what we should do for those people and what was the negotiation between the clinic and our organization."* As noted in Section 3, according to staff interviewees, earlier in the implementation process there were some delays in identifying whether participants were assigned to the intervention or control group.

While qualitative data indicated some control participants may have received MTM, behavioral health, and PLSG services, which are components of the SyV 2.0 program, the receipt of these services was not considered to be contamination by program-like components. Because SyV 2.0 is an enhancement of the SyV 1.0 program, and both aim to manage diabetes, there were some commonalities between the types of service provided by the two versions of the program. Any similar services received by the control group were services provided through the SyV 1.0 program.

During the study period, staff learned that some participants (n=23) from both study clinics were participating in an additional program while in the SyV 2.0 study. The intent of the Integrated Health Improvement & Prevention grant was to promote patient health improvement and more in-depth tracking of outcomes. Partners of this grant served a panel of underserved patients, each with two or more co-morbidities including diabetes, hypertension, obesity management & prevention, and depression, with a focus on improving health outcomes. The panel services available included primary care, behavioral health, psychiatry, care coordination, and diabetic and nutrition counseling. While there are similarities between the panel services and those offered through SyV 2.0, it was determined, through statistical analyses, that the exposure of both intervention and control participants to this external event did not affect impact results presented later in the report.

Question 5. To what extent did the UT Health SPH implement the SyV 2.0 model with fidelity?

Evaluation of the implementation of the SyV 2.0 program shows the program was implemented in alignment with the program logic model to fidelity after the early implementation period. However, due to delays in providing services, participants did not receive a full twelve months of the intervention.

According to interviewees, UT Health SPH implemented the SyV 2.0 model with fidelity. UT Health SPH program and clinic staff interviewees identified some delays in hiring and some strain on clinic and program staff roles during the early phase of implementation. Yet, according to staff interviewees, these challenges had minimal effects on the model's overall fidelity and qualified staff were hired.

According to staff interviewees, clinic staff and UT Health SPH program staff worked diligently to facilitate communication and workflows, citing for example shifts in pharmacist workflow to deliver MTM services during primary care visits. One clinic staff interviewee described how pharmacists leveraged EMR scheduling information to coordinate MTM visits around scheduled appointments: *"We had access to the scheduler in the EMR, so we'd know when a patient was scheduled to come see their physician. And, of course, we had permission from the physician to speak to the patient either before or immediately after their appointment was complete."* Additionally, a couple of clinic staff interviewees described how MTM technicians leveraged EMR scheduling information to ensure that MTM Path was

up to date by the next primary care appointment. UT Health SPH program staff interviewees identified CCM meetings as an example of the SyV 2.0 model being implemented with high fidelity. For example, one UT Health SPH program staff interviewee highlighted the coordination and communication across primary care and behavioral health providers, who applied a social determinants of health lens to case management discussions: *"It's a moment where we dedicate that time to review all of the social determinants that are not helping this participant control their diabetes. It's a good time where the clinic side and the community talk together and review each case."*

Quantitative implementation data show the program was implemented in alignment with the program logic model to fidelity after the early implementation period. Almost all participants enrolled in the intervention met study eligibility criteria and were referred to services, as appropriate; however, there were delays in providing services. Consequently, a majority of those who remained in the study for the 12 months did not receive a minimum dose of the intervention.

Of the 123 participants referred to MTM services and the 98 referred participants who received MTM services, referral and service date data were available for almost all participants. **Table 7** describes the time between different points of program implementation for MTM services. It took, on average, 31.8 days from date of randomization for a participant to be referred to MTM services. From that date of referral, there was an average of 170.4 days before a participant received their first MTM service. From randomization date (baseline date for this study) to first MTM service, the average time elapsed was 205.2 days.

Table 7. MTM Service Time Windows, in Days

Time Windows	N	Mean	SD	Median	Minimum	Maximum
Screening to Enrollment	353	0.7	4.9	0.0	-6	69
Enrollment to Randomization	353	24.2	19.1	20.0	0	75
Randomization to MTM Referral Approval	121[a]	31.8	19.8	28.0	3	91
MTM Referral Approval to Initial MTM Service	93[ab]	170.4	79.3	152.0	7	369
Enrollment to Initial MTM Service	95[b]	229.7	84.8	209.0	65	485
Randomization to Initial MTM Service	95[b]	205.2	82.7	189.0	40	440

[a]2 participants are missing referral dates, windows could not be calculated [b]3 participants are missing a service date, windows could not be calculated

Of the 65 participants referred to BH services and the 21 referred participants who received BH services, referral and service date data were available for almost all participants. **Table 8** describes the time between different points of program implementation for behavioral health services. It took, on average, 31.3 days from date of randomization for a participant to be referred to behavioral health services. From that date of referral, there was an average of 76.9 days before a participant received their first behavioral health service. From randomization date (baseline date for this study) to first behavioral health service, the average time elapsed was 111.6 days.

Table 8. Behavioral Health Service Time Windows, in Days

Time Windows	N	Mean	SD	Median	Minimum	Maximum
Screening to Enrollment	353	0.7	4.9	0.0	-6	69
Enrollment to Randomization	353	24.2	19.1	20.0	0	75
Randomization to BH Referral Approval	64[a]	31.3	19.9	24.0	3	86
BH Referral Approval to Initial BH Service	20[b]	76.9	55.9	72.5	-3	186
Enrollment to Initial BH Service	20[b]	131.9	56.6	117.5	57	267
Randomization to Initial BH Service	20[b]	111.6	56.1	100.0	42	215

[a]1 participant is missing referral date, window could not be calculated [b]1 participant is missing a service date, window could not be calculated

Of the 173 participants referred to PLSGs and the 8 referred participants who received PLSGs, referral and service date data were available for all participants. **Table 9** describes the time between different points of program implementation for PLSGs. It took, on average, 30.1 days from date of randomization for a participant to be referred to peer-led support groups. From that date of referral, there was an average of 204.3 days before a participant attended their first peer-led support group. From randomization date (baseline date for this study) to first peer-led support group, the average time elapsed was 234.4 days.

Table 9. Peer-Led Support Groups Time Windows, in Days

Time Windows	N	Mean	SD	Median	Minimum	Maximum
Screening to Enrollment	353	0.7	4.9	0.0	-6	69
Enrollment to Randomization	353	24.2	19.1	20.0	0	75
Randomization to PLSG Referral Approval	173	30.1	19.4	28.0	3	91
PLSG Referral Approval to Initial PLSG Service	8	204.3	160.0	175.0	-49	413
Enrollment to Initial PLSG Service	8	252.4	148.9	219.0	37	448
Randomization to Initial PLSG Service	8	234.4	158.9	205.0	0	443

Of the 174 participants referred to La Cocina Alegre services and the 56 referred participants who received La Cocina Alegre services, referral and service date data were available for all participants. **Table 10** describes the time between different points of program implementation for La Cocina Alegre services. It took, on average, 22.2 days from date of randomization for a participant to be referred to La Cocina Alegre services. From that date of referral, there was an average of 236.7 days before a participant attended their first La Cocina Alegre class. From randomization date (baseline date for this study) to first La Cocina Alegre class, the average time elapsed was 266.6 days.

Table 10. La Cocina Alegre Services Time Windows, in Days

Time Windows	N	Mean	SD	Median	Minimum	Maximum
Screening to Enrollment	353	0.7	4.9	0.0	-6	69
Enrollment to Randomization	353	24.2	19.1	20.0	0	75
Randomization to CA Referral Approval	174	30.6	22.2	28.0	-17	167
CA Referral Approval to Initial CA Service	56	236.7	110.0	260.0	11	405
Enrollment to Initial CA Service	56	287.1	111.2	314.0	53	447
Randomization to Initial CA Service	56	266.6	112.1	285.5	25	442

Service utilization data for the study's intervention participants is presented in **Table 11**. Almost all intervention participants were referred to La Cocina Alegre services during the study (98.9%). A total of 467 visits were expected for these 174 participants and 224 of those were completed. For those who completed a La Cocina Alegre visit, the average number of visits was 4.0 visits per participant and ranged from 1.0 visit to 10.0 visits per participant. Most intervention participants also were referred to the peer-led support groups (98.3%). There were 462 PLSG visits expected and 34 completed visits among those referred to the service. For those who attended a PLSG, the average number of visits was 4.3 visits per participant, ranging from 1.0 visit to 20.0 visits per participant. A referral to MTM services was given to 69.3% of intervention participants. There were 335 MTM visits expected and 163 completed. For those who completed a MTM visit, the average number of visits was 1.7 visits per person, ranging from 1.0 visit to 3.0 visits. About one third of intervention participants were referred to BHS over the course of the study (36.4%). There were 179 BHS visits expected and 40 visits completed for those referred to the service. For those who completed a BHS visit, the average number of visits was 1.0 visit per participant, ranging from 1.0 visit to 7.0 visits per participant. One third of intervention participants were referred to MEND! services (33.0%); however, no services were expected or completed.

Table 11. Utilization Data for Salud y Vida 2.0 Services Among Intervention Participants

Program Service	Number of Approved Referrals	Number of Expected Visits[a]	Number of Completed Visits[b]	Average Number of Visits per Participant[c]	Median Number of Visits per Participant[c]	Minimum Number of Visits per Participant[c]	Maximum Number of Visits per Participant[c]
La Cocina Alegre	174	467	224	4.0	4.0	1.0	10.0
Medication Therapy Management	123	340	164	1.7	2.0	1.0	3.0
Behavioral Health	65	185	40	1.9	1.0	1.0	7.0
Peer-Led Support Groups	173	462	34	4.3	2.0	1.0	20.0
MEND! Family Obesity Program	58	--	--	--	--	--	--

[a] definition includes any visit noted as "complete", "incomplete", or "unverified" in the implementation data;
[b] definition includes all visits noted as "complete" in the implementation data; [c] these statistics are calculated among those who were referred to and completed at least one visit of the service type

A standard for completion of each individual program in the SyV 2.0 program was defined in the SEP (see **Table 12**).

Table 12. Standard for Completion of Each Individual Program

Program Service	Proposed number of services	Minimum number of services
La Cocina Alegre	6 classes	4 classes
Medication Therapy Management	Usually 2 visits (patient dependent)	2 visits (initial + follow-up)
Behavioral Health	Max. 6 visits (patient dependent)	2 visits (patient dependent)
MEND! Family Obesity Program	10 classes (2-5 yo)/20 classes (6-13 yo) (dependent upon age of children)	2 classes (2-5 yo)/5 classes (6-13 yo (dependent upon age of children)
Peer-Led Support Groups	Weekly	2 sessions

Table 13 presents the number of referred participants meeting the minimum dose criteria by type of service. Because no MEND! services were provided, that service is not included in the table. Of those referred to La Cocina Alegre services, 19.0% of participants attended the minimum 4 classes. For MTM services, nearly half (49.0%) of referred participants had 2 MTM visits. Five participants referred to BHS services received the minimum 2 visits (7.8%). Of those referred to PLSG, 5 attended the minimum 2 sessions (2.9%).

Table 13.Number of Referred Participants Receiving Minimum Program Dose

	Number of Participants Over Full Study Period[a]	**Number of Participants with 12-month Assessment[b]**
La Cocina Alegre	*n=174*	*n=146*
Did not meet criteria	141	114
Met criteria	33	32
Exceeded criteria	0	0
Medication Therapy Management	*n=123*	*n=105*
Did not meet criteria	63	50
Met criteria	60	55
Exceeded criteria	0	0
Behavioral Health	*n=65*	*n=54*
Did not meet criteria	60	51
Met criteria	5	3
Exceeded criteria	0	0
Peer-Led Support Groups	*n=173*	*n=145*
Did not meet criteria	168	140
Met criteria	5	5
Exceeded criteria	0	0

[a]these data include all intervention participants (whether they completed a 12-month assessment or not) [b]these data include only intervention participants who completed 12-month data collection

Question 6. How satisfied are SyV 2.0 patients with the services they have received? How satisfied are providers with the SyV 2.0 program?

A portion of participants completed satisfaction surveys concerning the services they received, at two points during the study.

Of the 12 participants who completed a satisfaction survey about behavioral health counseling services at the study midpoint, 83.3% were very satisfied with behavioral health counseling services overall, interactions with and helpfulness of the counselor and clinic staff, and the time to get an appointment. Fewer participants answering the survey responded with "very satisfied" regarding the helpfulness of these services on managing their diabetes (66.7%). At the endpoint, 95.7% of the 23 participants responding to the survey were "very satisfied" for all service components (see **Table 14**).

Table 14. Satisfaction Survey Results for Behavioral Health Services, Midpoint and Endpoint

How satisfied are you with…	Midpoint[a]		Endpoint[b]	
	Participants Responding "Very Satisfied"		Participants Responding "Very Satisfied"	
	N	%	N	%
The behavioral health counseling services you received?	10	83.3	22	95.7
The help from the counselor and clinic staff?	10	83.3	22	95.7
How much the service helped you better manage your diabetes?	8	66.7	22	95.7
The overall way you were treated by the counselor and the clinic staff?	10	83.3	22	95.7
The time it took to get an appointment with the counselor?	10	83.3	22	95.7

[a] sample size for survey was 12 participants [b] sample size for survey was 23 participants

Of the 18 participants who completed a satisfaction survey about *La Cocina Alegre* services at the study midpoint the majority noted being "very satisfied" with each of the components of *La Cocina Alegre* services. For those who completed a survey at endpoint (n=55), the majority also noted being very satisfied with all components of this service (see **Table 15**).

Table 15. Satisfaction Survey Results for La Cocina Alegre Services, Midpoint and Endpoint

How satisfied are you with…	Midpoint[a]		Endpoint[b]	
	Participants Responding "Very Satisfied"		Participants Responding "Very Satisfied"	
	N	%	N	%
The *Cocina Alegre* services you received?	17	94.4	49	87.5
The help from the *Cocina Alegre* staff?	17	94.4	50	89.3
How much the service helped you better manage your diabetes?	16	88.9	48	85.7
The overall way you were treated by the *Cocina Alegre* staff?	17	94.4	49	87.5
The time it took for *Cocina Alegre* to start?	17	94.4	51	91.1

[a] sample size for survey was 18 participants [b] sample size for survey was 55 participants

Of the 35 participants who completed a satisfaction survey about MTM services at the study midpoint the majority noted being "very satisfied" with each of the components of MTM services. For those who completed a survey at endpoint (n=87), the majority also noted being very satisfied with all components of this service (see **Table 16**).

Table 16. Satisfaction Survey Results for MTM Services, Midpoint and Endpoint

How satisfied are you with…	Midpoint[a]		Endpoint[b]	
	Participants Responding "Very Satisfied"		Participants Responding "Very Satisfied"	
	N	%	N	%
The pharmacy services you received?	31	88.6	82	94.3
The help from the pharmacist and clinic staff?	31	88.6	81	93.1
How much the service helped you better manage your diabetes?	29	82.9	80	92.0
The overall way you were treated by the pharmacist and the clinic staff?	32	91.4	83	95.4
The time it took to get an appointment with the pharmacist?	30	85.7	81	93.1

[a] sample size for survey was 35 participants [b] sample size for survey was 87 participants

Of the 15 participants who completed a satisfaction survey about PLSG services at the study midpoint, most were very satisfied with PLSG services overall, interactions with and helpfulness of the PLSG staff, and the time it took for a group to start. Fewer participants answering the survey responded with "very satisfied" regarding the helpfulness of these services on managing their diabetes (60.0%). At the endpoint, 90.0% of participants responding to the survey were "very satisfied" for all service components (see **Table 17**).

Table 17. Satisfaction Survey Results for PLSG Services, Midpoint and Endpoint

How satisfied are you with…	Midpoint[a]		Endpoint[b]	
	Participants Responding "Very Satisfied"		Participants Responding "Very Satisfied"	
	N	%	N	%
The peer-led support group services you received?	11	73.3	8	80.0
The help from the peer-led support group staff?	12	80.0	9	90.0
How much the service helped you better manage your diabetes?	9	60.0	9	90.0
The overall way you were treated by the peer-led support group staff?	13	86.7	9	90.0
The time it took for the peer-led support group services to start?	12	80.0	9	90.0

[a] sample size for survey was 15 participants [b] sample size for survey was 10 participants

According to focus group discussions, program participants indicated that they were very satisfied with the SyV 2.0 program, citing relationships with UT Health SPH program staff and peers, improved health knowledge and health behaviors, and improved health outcomes as reasons for being satisfied. Clinic staff and UT Health SPH program staff interviewees also highlighted these themes as areas of participant satisfaction with the program. Provider satisfaction is addressed in Section 3b regarding provider buy-in for adopting the IBH model.

Relationships

Program participants cited their relationships with UT Health SPH program staff and peers from their peer-led support group as reasons why they were satisfied with SyV 2.0. One focus group participant emphasized the importance of their close relationship with promotores and PLSG facilitators: *"They are keeping an eye on us, our health, and they are very kind."* Another program participant shared: *"It's a very excellent program. It's a program with a lot of human warmth."* UT Health SPH program staff interviewees cited participants' comfort talking with and confiding in UT Health SPH program staff and support from peers as important indicators of participant satisfaction. As one UT Health SPH program staff interviewee described: *"They're comfortable with us, talking, any issues or problems they have in life."*

Health Knowledge and Health Behaviors

Program participants highlighted community-based programs, particularly cooking classes, nutrition education, physical activity discussions, and diabetes education as valuable forms of health information, which program participants explained helped them to control their diabetes. Several program participants perceived that these programs enhanced their health literacy and supported them in controlling their diabetes. One program participant described their satisfaction with several health education programs: *"They teach you a lot about how to cook and how to prepare your meal, your plate, what your [healthy] plate is. And that you have to exercise as well because it's necessary for the body, and also to lower your [blood] sugar."* Another program participant explained: *"I have had diabetes for 24 years, I was always 500 and up and now with Salud y Vida … they taught me about small portions, how to nourish myself well, how to do exercises, and thank God now my sugar doesn't get above 200."*

Participants also reported that they invited family members to community-based programs and/or shared health education information with neighbors and family members. According to clinic staff and UT Health SPH program staff interviewees, participants expressed satisfaction with MTM and health education discussions that focused on improving dietary practices and managing stress.

Improved Outcomes
Several program participants cited improved health outcomes as shaping their satisfaction with the SyV 2.0 program. When asked about what they like about the program, one program participant shared, *"I started with 10 and 11 A1c and got it all the way down to a 6.5*." Indeed, several program participants described reductions in their HbA1c levels during the SyV 2.0 program. Promotores described reductions in participants' HbA1c levels and improved health behaviors as sources of participant satisfaction. One UT Health SPH program staff interviewee participant explained: *"We see that their health is improving, the A1c, or they stopped drinking soda or eating more fruits and vegetables, they started walking a little, they started taking more medicine. More [important] than anything else, is when the program participant tells us 'thanks to you I have been doing this.'"* Another UT Health SPH program staff interviewee shared: *"The people that I spoke with really gave me glowing reviews on how it's helped them lower their A1cs, how they feel better now, how they feel encouraged to improve."*

Additional Implementation Findings

In addition to data to answer the *a priori* implementation questions presented in the SEP, the qualitative implementation evaluation also yielded additional findings related to perceived successes and impacts, information-sharing, program replication/scalability, funding, and additional or complementary activities. Presented here are key themes that emerged during the interviews and focus groups not directly asked by the implementation research questions outlined above but that still provide context for the SyV 2.0 program.

Perceived Program Successes and Impact

Program participants and staff interviewees were asked to speak about their perceived successes and impacts of the SyV 2.0 program. Both groups perceived that the program enhanced health literacy, supported participants in managing chronic disease, improved behavioral health, and facilitated the integration of community-based programs. Successes identified at the midpoint included: increased participant access to health education, support groups, and behavioral health services through community and clinic partners; communication between clinic staff and UT Health SPH program staff, and between UT Health SPH program staff and partner agencies; and web-based and on-site trainings regarding the SyV 2.0 evaluation, group facilitation, and motivational interviewing.

Health Literacy
As discussed regarding participation satisfaction, the SyV 2.0 program was perceived to improve health literacy among program participants. From nutrition education classes to discussions with promotores and PLSGs, program participants shared that they learned new skills, including how to assess which foods are healthy, eat in moderation, and cook healthy foods. Additionally, some program participants and staff interviewees highlighted discussions about the importance of physical activity, the etiology of diabetes, and lifestyle-based strategies to control diabetes as helpful for understanding diabetes as a chronic condition that participants can manage over time. One program participant explained, *"Yes, I*

would recommend it, because you learn about, a lot about your disease, diabetes, the control of it. The more you learn, the better equipped you are to fight it."

Chronic Diseases
Program participants and clinic and UT Health SPH program staff interviewees described how program activities, including cooking classes, PLSGs, promotores model, and discussions with pharmacists and behavioral health providers strengthened participant health knowledge and in turn helped participants to better manage their diabetes and experience improvements in chronic disease. One focus group participant explained, *"I learned to portion my food, eat less breads, which I was very attached to, and less sweets, because I loved my chocolate and my apple pie. I cut those out, and thanks to the diet I followed, I went from 210 to now 191. It helped me physically."* Another program participant shared, *"I have had diabetes for 25 years. Before I felt tired, fatigued. [If] I did any little thing in the house, then I had to sit down, and now no, I walk … with the dogs, I walk everywhere, I don't stop and the guys tell me that I injected myself because I'm active and I tell my kids "no, it's that I now have the diabetes controlled."*

Behavioral Health
Program participants and staff interviewees perceived that the SyV 2.0 program improved participants' behavioral health, particularly their quality of life, which they attributed to diabetes management and better physical health. Several program participants mentioned that their improved mood and energy enabled them to be more active with their family and to engage in other social activities. As one program participant shared, *"I always felt tired and everything. I have three boys, teenagers, so they always require my attention. So now I'm able to go walking with them, play ball or whatever they want to go do."* Another program participant described: *"Yeah, [I'm] getting a little bit more energy, with more interest in doing other things, getting involved in different things."* One UT Health SPH program staff interviewee described how a participant's improved physical health and good experience in cooking classes inspired him to open a restaurant: *"[He] lost over 100 pounds since he's been in the program. It started when he was in 1.0 but it kind of continued on because obviously he qualified for 2.0 because he wasn't quite there in 1.0. But he continued to lose weight, he lowered his A1c, he loved Cocina Alegre and was kind of dreaming of opening a restaurant based on what he learned there."*

Integration
According to program participants, one of the successes of the SyV 2.0 program was the integration of community-based programs, which they perceived was facilitated by promotores. As one program participant shared: *"The outreach workers, the classes, Cocina Alegre, so everything goes hand-in-hand and everything helps us, everything."* Another program participant described how promotores were critical to ensuring integration: *"I love the way the promoters just completely get involved in your life. And they go all out to make sure you get the services that you [need], well, at least mine does."*

Sustainability and Lessons Learned

Overall, results from interviews with SyV 2.0 staff as well as focus group discussions with SyV 2.0 participants indicated that implementation of UT Health SPH's Sí Texas program has been successful. Several lessons learned and opportunities for improvement emerged. At the mid-point, lessons learned related to addressing participant barriers to care, including the sociopolitical environment, limited transportation options, and stigma around behavioral health services; enhancing internal and external communication; and hiring additional staff. During the summative interviews and focus groups, lessons

learned and opportunities for improvement focused on information-sharing, program replication and scalability, funding, and additional or complementary activities. Presented below are themes that emerged from interviews and focus groups.

Program Replication and Scalability
Though the SyV 2.0 program represents an enhanced version of the Salud y Vida model already in place, staff interviewees and program participants expressed hopes that the SyV 2.0 program would be scaled up and replicated. Several program participants characterized the region as having a sizable population with diabetes and noted that many of their family members have diabetes or are at risk for diabetes. Several program participants and clinic and UT Health SPH program staff interviewees expressed hope that the SyV 2.0 program would be available to the broader population and also focus on preventing diabetes. One program participant shared, *"I think they should reach out a lot, also not only to the people that are diabetic, but the people that are healthy still, and you know, advise them."* Echoed one program participant: *"There are prediabetic people who should be in this program because they're in time to prevent it. They're already predisposed, so they can be alerted to how to stop or prevent it."*

During the summative interviews, some staff interviewees noted that plans were underway to expand SyV 2.0 to the broader Salud y Vida participant population. One clinic staff interviewee shared: *"I did hear that we were going to integrate and open up the extra services to the larger Salud y Vida population."* Specifically, staff interviewees perceived that plans were underway to expand the MTM, Cocina Alegre, and behavioral health components of SyV 2.0 to the Salud y Vida population. One UT Health SPH program staff interviewee expressed uncertainty about plans for the PLSGs: *"The peer led support group has been the most challenging intervention to provide for a number of reasons, whether it's finding a facilitator to help facilitate the support groups or just getting people in. … We are looking at [it] to see if we can sustain peer led support groups moving forward."*

Funding
Clinic and UT Health SPH program staff Interviewees emphasized the importance of sustaining the SyV 2.0 program and discussed several strategies that are underway to secure funding for the program. Several staff interviewees shared that some programs may be easier to fund and sustain than others. One UT Health SPH program staff interviewee described plans for the pending 1115 waiver DSRIP funding: *"It's changed a little bit and it's focused more on clinic patients only, so unfortunately we are not able to reach those people who are not clinic patients already and there's a lot of those folks who don't have access."*

Several UT Health SPH program staff interviewees perceived that grant funding would be the most sustainable funding mechanism. Some staff interviewees identified the need for health care policy change so that SyV 2.0 services can be billed. For example, one UT Health SPH program staff interviewee shared their vision: *"I think the more that we can support community health workers being billable services and community-based services being made billable, that's going to be a good thing."* One UT Health SPH program staff interviewee highlighted the challenges of sustaining insurance-based funding for the low-income SyV 2.0 participant population*: "It sounds really good to figure out a billable way, a business model, you know make it sustainable, but the reality is there is not money to be made off of people who have no payer source."* One UT Health SPH program staff interviewee hoped that shifts towards outcomes-focused billing structures would incentivize the investment in programs like SyV 2.0.

Additional or Complementary Activities

During summative interviews and focus groups, program participants and UT Health SPH program and clinic staff interviewees had several recommendations for additional or complementary activities that Salud y Vida could provide to participants with diabetes. Given that transportation emerged as a significant barrier to program participation, program participants and UT Health SPH program staff and clinic staff interviewees emphasized the importance of providing transportation services to appointments and programs. One clinic staff interviewee explained: *"Transportation is one issue. If finances were available, [I] wonder what kind of change it would do if we were actually able to go pick up patients or have resources for them to come to their appointments."* Additionally, program participants cited a need to integrate dental and vision care into the SyV program. Program participants explained that many people with advanced diabetes also suffer from dental and vision issues and health insurance coverage for these services is limited. Some UT Health SPH program staff interviewees recommended strengthening connections between the community-based programs, such as integrating cooking classes and peer-led support groups. One clinic staff interviewee recommended offering MTM in schools and other community-based settings.

IMPACT STUDY – APPROACH AND METHODS

Overview of Impact Study Design

For this study, UT Health SPH implemented an enhanced version of the free of charge, evidence-based chronic care management program (Salud y Vida 1.0 [SyV 1.0]). The original program (SyV 1.0), which is considered standard of care, was designed to assist individuals with uncontrolled diabetes (HbA1c ≥ 8%) by working closely with health care providers to address the needs of the patient which go beyond basic primary care needs such as referral to behavioral health, counseling, financial support, and other ancillary services. The Salud y Vida 2.0 (SyV 2.0) program aimed to enhance UT Health SPH's current Chronic Care Model (Wagner et al., 1998) with the addition of evidence-based components to provide a continuum of care for those with diabetes who also may have other additional chronic disease conditions (e.g., obesity, hypertension, and depression); however SyV 2.0 focused on diabetes and is not intended to address additional chronic disease conditions. Overall, the model was adapted to include: medication therapy management (MTM) services that utilize pharmacists, peer led support groups (PLSG) that deliver culturally sensitive experiences, care coordination by a team of providers (e.g., behavioral health care, CHWs, etc.), and referrals to community-based lifestyle programs that promote healthy eating. The intervention built on key elements of Wagner's model for effective chronic illness care, namely, an organized delivery system linked with complementary community resources, sustained by productive interactions between multidisciplinary care teams and "activated" or educated patients and their families. Preliminary unpublished results showed that participants in SyV 1.0 experienced immediate progress in the control of diabetes including a reduction in average HbA1c from 10.2% at baseline to 9.1% at 3-months. The SyV 2.0 program aimed to enhance Wagner's Collaborative Chronic Care Model with the addition of the aforementioned evidence-based components.

This study utilized a randomized control trial design (RCT) to compare 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 potentially caused by participation (or lack of participation) in the SyV 2.0 program. The study hypothesized that an enhanced level of primary and behavioral health services offered through an integrated health care delivery network would improve control of chronic disease (diabetes, hypertension, and obesity), reduce depression, increase access to behavioral healthcare services, and improve adult functioning and quality of life for current SyV 1.0 participants. The evaluation targeted a moderate level of evidence with a RCT based on the incoming level of preliminary evidence.

Impact Study Design and Methods

Study Design

The study's impact evaluation used data from the RCT designed study to evaluate the SyV 2.0 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
Eligible participants were enrolled and randomized to the intervention or control group. A computerized minimization randomization schedule based on dynamic random allocation algorithm for minimization of unbalanced intervention assignment was used. Minimization randomization is one of the adaptive randomization procedures (Han et al., 2009; Pocock and Simon, 1975) that allocates participants to study arms based on similar characteristics already randomized to best balance the study arms across all stratification variables. A minimization randomization algorithm requires recalculation of assignment and it works based on the probability of group assignment which changes according to assigned group of participants already in the study, whereas ordinary randomization algorithm can be determined prior to the onset of the study.

Each time a new participant was enrolled in the study the algorithm was run to decide which arm he/she was to be assigned based on the data distribution of demographic information from the previously enrolled participants. Since the minimization randomization algorithm works based on the distribution of demographic information from the previously enrolled participants, the first 5-10% of enrolled participants were randomized with equal chance of assignment. Minimization algorithm was programmed using R (R Core Team 2013) to balance the two study arms with respect to participants' demographics, specifically age and sex. Minimization randomization takes potential covariates into consideration at randomization to reduce imbalances between groups and does not suffer from some of stratification's limitations (e.g. increased probability of group imbalance when stratifying across several characteristics). A random allocation of p = 0.67-0.80 was used in the minimization algorithm. Implementation of the computerized minimization/randomization schedule was continuously monitored by two statisticians to ensure balance.

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 UT Health SPH, including age, gender, ethnicity, race, primary language, county of residence, education level, employment status, marital status, household income, and insurance status. These sociodemographic characteristics were selected because they are potential covariates routinely collected by UT Health SPH and captured in their existing web-based data capture system (Wellcentive).

There were no statistically significant differences detected between the intervention and control groups on any of the demographic characteristics presented in **Table 18**. In addition to sociodemographic characteristics, the number of months spent in SyV 1.0, and number of visits received over the course of the study (not included below, presented in **Table 11** in the implementation section) were also captured for each participant, as these exposures were considered potential confounding variables.

Table 18. Tests of Baseline Equivalence for Demographic Measures

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

Monthly Household Income							
$0	47	13.6	26	15.3	21	12.1	0.83
$1 - $500	89	25.9	44	28.9	45	25.9	
$501 - $1,000	119	34.6	56	32.9	63	36.2	
$1, 001 - $2,000	62	18.0	29	17.1	33	19.0	
≥ $2,001	27	7.9	15	8.8	12	6.9	
Missing	*9*	--	*6*	--	*3*	--	
Health Insurance Status							
Medicaid	23	7.3	13	8.2	10	6.3	0.54
Medicare	14	4.4	8	5.0	6	3.8	
Medicaid and Medicare	6	1.9	4	2.5	2	1.3	
Private	38	12.0	17	10.7	21	13.3	
Indigent	16	5.1	5	3.1	11	7.0	
No insurance	220	69.4	112	70.4	108	68.4	
Missing	*36*	--	*17*	--	*19*	--	
Time in Salud y Vida 1.0							
Mean (SD), in months	20.6 (9.5)		21.2 (9.5)		19.9 (9.5)		0.24

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

For the nine impact measures in UT Health SPH's study, the intervention and control groups were statistically equivalent on all except for two measures (PHQ-9 and Duke General Health). At the beginning of the study, the intervention group had a lower median PHQ-9 score and a higher median Duke General Health score than the control group (see **Table 19**).

Table 19. Tests of Baseline Equivalence for Impact Measures

	Full Sample (n=353)	Intervention (n=176)	Control (n=177)	*p*
	Mean (SD)	Mean (SD)	Mean (SD)	
Systolic	136.1 (19.8)	136.3 (19.7)	135.9 (20.0)	0.83
Diastolic	79.8 (12.8)	80.0 (12.4)	79.5 (13.1)	0.74
Total Cholesterol	194.3 (50.0)	195.6 (51.5)	193.1 (48.6)	0.64
Nonparametric Tests[a]	Median (IQR)	Median (IQR)	Median (IQR)	p
HbA1c	10.3 (2.0)	10.2 (2.1)	10.4 (2.0)	0.33
PHQ-9[b]	**4.0 (5.0)**	**3.0 (6.0)**	**4.0 (6.0)**	**0.01**
BMI[c]	31.6 (9.0)	31.4 (9.5)	31.6 (8.9)	0.93
General Health[d]	**70.0 (23.3)**	**73.4 (23.4)**	**66.7 (26.6)**	**0.01**
Medication Adherence[e]	6.0 (2.3)	6.0 (2.3)	6.0 (2.5)	0.66
Self-efficacy	7.8 (2.4)	7.8 (2.5)	7.6 (2.3)	0.75

Note: Bold denotes statistical significance (p-value < 0.05); [a] The Wilcoxon rank sum *test was used to examine non-normally distributed data; [b] Sample size in intervention group is 175 due to missing data for this measure; [c] Sample size in control group is 176 due to missing data for this measure; [d] Sample size for this measure is 348, intervention= 174 control=174, due to missing data for this measure; [e] Sample size for this measure is 329, intervention=166 control=163, due to non-applicability to participants not currently being treated with medication.*

Propensity score matching was considered as an option in the analytic phase for this final report in case baseline equivalence was not established. However, due to the RCT design and application of the minimization randomization procedure, matching strategies were not needed. Participants were statistically equivalent on the randomized characteristics of age and sex. Additionally, all except two health outcomes were balanced between the groups at baseline (Altman, 1985; Senn, 1994). There is no evidence that randomization was done improperly as all procedures were followed and documented. If there were problems with the randomization, we would expect to find imbalance in the randomization characteristics, which was not the case in our assessment. While there is no need to make any adjustments to the analytical approach regarding the randomized study design, the imbalance between PHQ-9 and Duke General Health scores at baseline was adjusted for in the final analyses presented.

Intervention and Control Group Conditions
Participants randomized to the intervention group received the SyV 2.0 program, which in addition to SyV 1.0 services, included medication therapy management (MTM) services comprised of individual sessions with a pharmacist to review and refine medications, behavioral health counseling sessions coordinated with primary care providers, and/or referrals to community-based lifestyle programs, as determined by their tailored care plan. The community-based lifestyle programs could have included a series of hands-on cooking classes, peer-led support groups, and behavioral lifestyle change programs focused on healthy eating and physical activity for the whole family. These additional 2.0 services provided increased access to educational and behavior change support content and were delivered after the participant had received at least 6 months of SyV 1.0 services.

Participants randomized to the usual care group continued to participate in the SyV 1.0 program. All participants in the SyV 1.0 program were individuals with uncontrolled diabetes when they began the program. To achieve control the SyV 1.0 coalition of providers blended coordinated care options in the clinic, community and home. These participants were voluntarily enrolled in the program by a registered nurse, LVN, or a research assistant and assigned a community health worker (CHW) who conducted follow up home visits and phone calls for the duration of the intervention. The CHW provided ongoing support to the individual through home visits and ensured they were enrolled in a 6-week long diabetes self-management course. The participants also may have received referrals to the mental health authority agency if necessary (i.e., expressed suicidal ideation via administration of the PHQ-9) and quarterly home visits including feedback on HbA1c levels. During the home visits CHWs worked with the participant to set goals and identify strategies of change using motivational interviewing techniques. The program worked closely with health care providers to address the needs of the patient and in some cases include providing brief financial support for items such as medications. Those without a primary care provider were connected to a partner clinic for ongoing care. SyV 1.0 participants also received an information session as per their treatment plan, and/or a onetime mailing of information about the importance of following their treatment plan.

The usual care group was comprised of SyV 1.0 participants who met the eligibility criteria, chose to participate in the program and were randomized into the control group.

Both intervention and control participants were first seen by UT Health SPH evaluation staff or a CHW to complete baseline assessment for the study, including administration of the PHQ-9, Duke Health Profile, Diabetes Medication Adherence Questionnaire, and Diabetes Self-Efficacy Scale, as well as measurement of vitals including height, weight, and blood pressure. Cholesterol and HbA1c were assessed via blood draw at a community reference lab. A care plan was developed by the 1.0 and 2.0

CHWs and included information on additional services provided by UT Health SPH such as, but not limited to, behavioral health services or pharmacy services. The CCM team would then review, modify and approve the care plan as deemed appropriate. Each participant received an individualized care plan, referrals to specialty care when needed (e.g. allergists, orthopedics, cardiologists), and referrals to community-based programs when applicable. UT Health SPH evaluation staff and CHWs assisted with making follow-up appointments for the patient depending on their care plan.

Study Sample

The following section describes 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 described 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 20 presents participant demographics for intervention and control groups at baseline. Intervention and control group study participants lived primarily in Cameron County. Most of the participants enrolled in the study were female (70.5%), Hispanic (92.1%), and spoke Spanish as their primary language (67.7%). The average participant age was 51.5 years. Over half of study participants were unemployed (61.4%), uninsured (69.4%), and made $1,000 or less a month in their household (74.1%). Over half of participants were married (53.2%) and did not graduate from high school (59.1%). The average time participants spent in SyV 1.0 prior to enrolling in the study was 20.6 months.

Table 20. Participant Demographic Measures for Full Sample and by Intervention Group

	Full Sample (n=353)		Intervention (n=176)		Control (n=177)	
Measure	N	%	N	%	N	%
Sex						
Male	104	29.5	53	30.1	51	28.8
Female	249	70.5	123	69.9	126	71.2
Ethnicity						
Hispanic/Latino	325	92.1	162	92.1	163	92.1
Non-Hispanic/Non-Latino	28	7.9	14	8.0	14	7.9
Race						
White (Caucasian)	332	96.5	163	95.3	169	97.7
Other	12	3.5	8	4.7	4	2.3
Missing	9	--	5	--	4	--
County of Residence						
Cameron County	352	99.7	176	100.0	176	99.4
Willacy County	1	0.3	0	0.0	1	0.6
Age						
≤ 34	16	4.5	9	5.1	7	4.0
35-44	61	17.3	30	17.1	31	17.5
45-54	136	38.5	67	38.1	69	39.0
55-64	124	35.1	63	35.8	61	34.5
65+	16	4.5	7	4.0	9	5.1

	Full Sample (n=353)		Intervention (n=176)		Control (n=177)	
Mean (SD)	51.5 (9.1)		51.4 (9.0)		51.7 (9.2)	
Employment Status						
Employed	42	12.1	16	9.3	26	14.9
Unemployed	213	61.4	105	60.7	108	62.1
Other	92	26.5	52	30.1	40	23.0
Marital Status						
Married	185	53.2	86	50.0	99	56.3
Unmarried	163	46.8	86	50.0	77	43.8
Missing	5	--	4	--	1	--
Education						
Less than high school	207	59.1	103	58.9	104	59.34
High school graduate/GED or higher	143	40.9	72	41.1	71	40.6
Missing	*3*	--	*1*	--	*2*	--
Primary Language						
English	114	32.3	60	34.1	54	30.5
Spanish	239	67.7	116	65.9	123	69.5
Monthly Household Income						
$0	47	13.6	26	15.3	21	12.1
$1 - $500	89	25.9	44	28.9	45	25.9
$501 - $1,000	119	34.6	56	32.9	63	36.2
$1, 001 - $2,000	62	18.0	29	17.1	33	19.0
≥ $2,001	27	7.9	15	8.8	12	6.9
Missing	*9*	--	*6*	--	*3*	--
Health Insurance Status						
Medicaid	23	7.3	13	8.2	10	6.3
Medicare	14	4.4	8	5.0	6	3.8
Medicaid and Medicare	6	1.9	4	2.5	2	1.3
Private	38	12.0	17	10.7	21	13.3
Indigent	16	5.1	5	3.1	11	7.0
No insurance	220	69.4	112	70.4	108	68.4
Missing	*36*	--	*17*	--	*19*	--
Time in Salud y Vida 1.0						
Mean (SD), in months	20.6 (9.5)		21.2 (9.5)		19.9 (9.5)	

Table 21 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 differ significantly on PHQ-9 and General Health at baseline, with PHQ-9 significantly higher in the control group and General Health significantly higher within the intervention group. Average values of all other impact values presented below were similar across intervention groups.

Table 21. Descriptive Statistics for Baseline Impact Measures

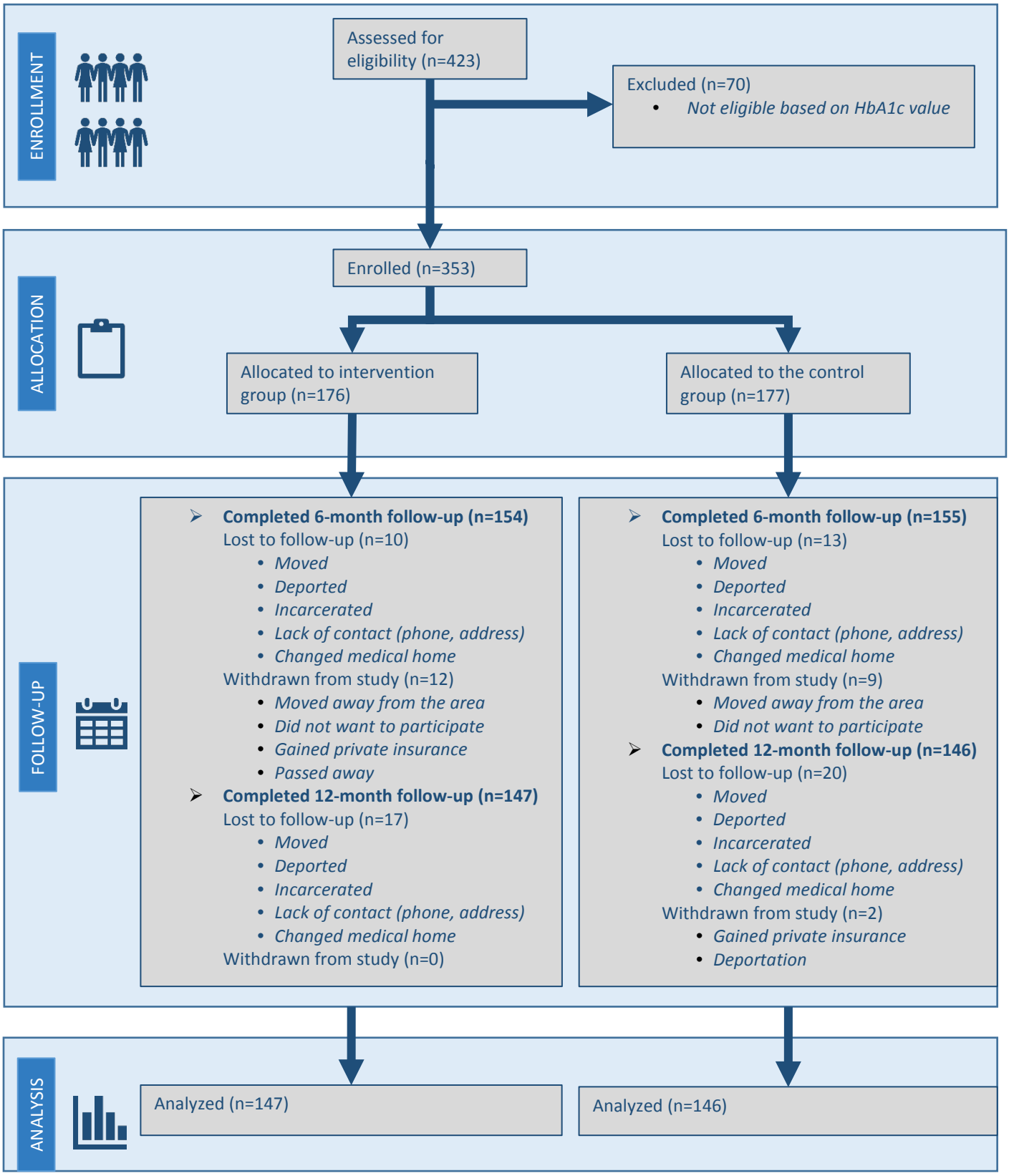
	Full Sample (n=353)	Intervention (n=176)	Control (n=177)
	Mean (SD)	Mean (SD)	Mean (SD)
Systolic	136.1 (19.8)	136.3 (19.7)	135.9 (20.0)
Diastolic	79.8 (12.8)	80.0 (12.4)	79.5 (13.1)
Total Cholesterol	194.3 (50.0)	195.6 (51.5)	193.1 (48.6)
	Median (IQR)	Median (IQR)	Median (IQR)
HbA1c	10.3 (2.0)	10.2 (2.1)	10.4 (2.0)
PHQ-9[a]	**4.0 (5.0)**	**3.0 (6.0)**	**4.0 (6.0)**
BMI[b]	31.6 (9.0)	31.4 (9.5)	31.6 (8.9)
General Health[c]	**70.0 (23.3)**	**73.4 (23.4)**	**66.7 (26.6)**
Medication Adherence[d]	6.0 (2.3)	6.0 (2.3)	6.0 (2.5)
Self-efficacy	7.8 (2.4)	7.8 (2.5)	7.6 (2.3)

[a] Sample size in intervention group is 175 due to missing data for this measure;
[b] Sample size in control group is 176 due to missing data for this measure; [c] Sample size for this measure is 348, Intervention= 174 control=174, due to missing data for this measure; [d] Sample size for this measure is 329, intervention=166 control=163, due to non-applicability to participants not taking medication.

Patient Flow Description

A patient flow diagram following the CONSORT structure (Schulz et al., 2010) is presented in **Figure 1**. 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, 70 participants who were excluded did not meet one or more of the eligibility criteria, mainly based on HbA1c at baseline, 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

SyV 2.0 participants were recruited after they had participated in SyV 1.0.[3] Participants who met the following criteria were eligible to participate in the study:

- Reside in Cameron or Willacy Counties
- a patient at Su Clinica or Rio Grande State Center
- Enrollment in the SyV 1.0 services for a minimum of 6 months to a maximum of 36 months
- An HbA1c ≥9.0% at any point between 6 and 36 months of SyV 1.0 participation
- An HbA1c ≥8.0% at baseline enrollment

Participants who expressed suicide ideation upon intake were not approached for enrollment but may have been enrolled during the study recruitment period if stabilized. If a potential participant or participant was found to be suicidal at any time during the study, UT Health SPH followed its well-established protocol for treating suicidal participants. Severe cases were referred to the local mental health authority, Tropical Texas Behavioral Health.

At the time the study began, there were approximately 1,200 active SyV 1.0 participants in the Lower Valley, of which about 500 (~42%) were eligible to participate in SyV 2.0. Nearly 70% of the SyV 1.0 participants were female and over 60% were over the age of 50. Over 70% were uninsured Hispanics whose preferred language was Spanish. To have been eligible for SyV1.0 an individual must have been 18 years of age or older, had uncontrolled diabetes (HbA1c of 8 or greater) and lived in Regional Healthcare Partnership 5[4]. While not a requirement, it was also preferred that the individual had been uninsured, receiving Medicaid or Medicare, or of low-income status (200% below poverty level) given that these are priority populations. Exclusion criteria for SyV 1.0 included: a diagnosis of Type 1 diabetes, home address outside of RHP 5 area, history of violent behavior towards others, substance abuse, dialysis recipient, cancer diagnosis, open chronic wounds, untreated bipolar or personality disorders (determined by asking about conditions and any current care), and pregnancy. Individuals were voluntarily enrolled in SyV 1.0

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

Once deemed eligible for the study, the UT Health SPH evaluation staff or a CHW assigned to the participant arranged special contact to meet with and consent the participant. If a participant consented to be a part of SyV 2.0, baseline data were collected by a UT Health SPH staff during a scheduled

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

[4] Regional Healthcare Partnerships are locally-developed confederations that fund the state share of all waiver payments in a partnership. The four-county region consists of Hidalgo, Cameron, Willacy, and Starr counties.

appointment at a community reference lab. After baseline data was collected, the participant was entered into the randomization process. The evaluation staff or community health worker who obtained informed consent used the minimization randomization algorithm to determine the participant's assignment to either the intervention or control group.

Sample Enrollment and Retention

Participant enrollment began in September 2016 and continued through May 2017. This is a deviation from the planned timeline in the SEP in that the plan was to end enrollment in March 2017. Recruitment was extended by two months to meet the enrollment target of 350 participants. In December 2016, UT Health SPH determined that its eligibility criteria were too narrow to recruit a sufficient sample size over the specified time period. In January 2017, UT Health SPH submitted a SEP amendment to SIF and received approval to revise study eligibility criteria to include participants enrolled in SyV 1.0 for a maximum of 36 months (vs. 12 months) with a baseline HbA1c of 8.0% (vs. 9.0%). The final timeline is presented in **Appendix A: Revised Project Timeline**... The enrollment target was 175 participants each for the intervention and control groups; a total of 176 participants were enrolled into the intervention and 177 participants in the control groups (see **Figure 2**), meeting the enrollment target for both the intervention and control groups.

Figure 2. Cumulative Enrollment Overall and by Intervention and Control Group, Sep 2016 – May 2017

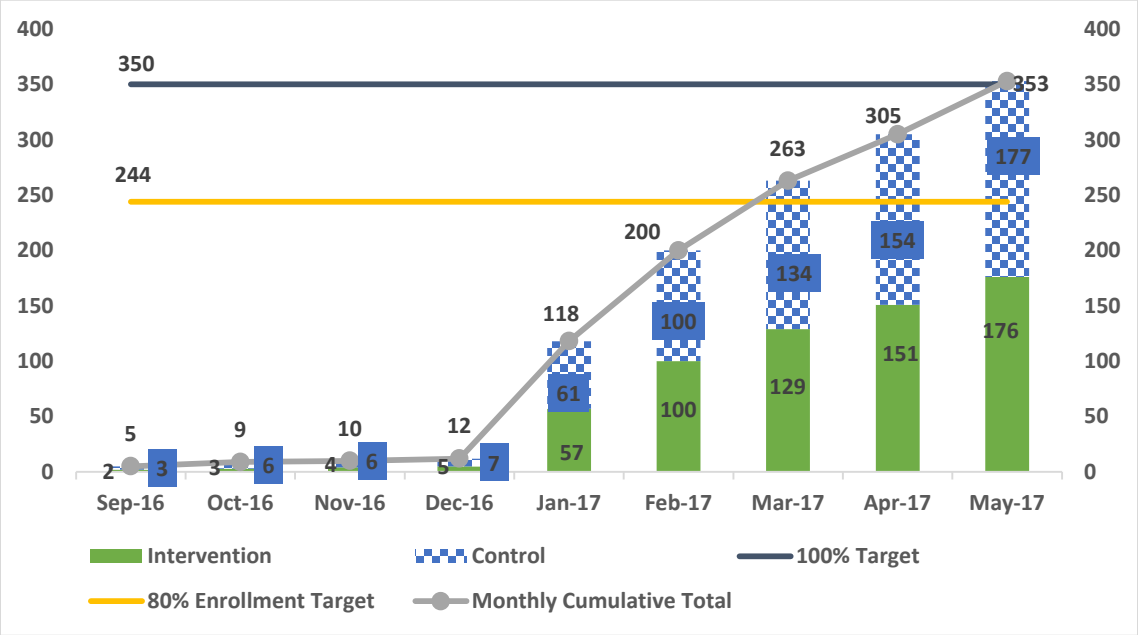


Table 22 presents subgrantee-reported information on the number of participants who returned for 6-month and 12-month follow-up through December 2017 and June 2018 respectively, by study arm. UT Health SPH retained 103% of the 6-month target in the intervention group (154 out of 176 returned for a 6-month follow-up assessment, 149 needed to maintain adequate statistical power). The retention rate in the intervention also exceeded the 12-month retention target by 20.5% (147 out of 176 returned for a 12-month follow-up assessment, 122 needed to maintain adequate statistical power). The control group reached 102% of the 6-month retention target (152 out of 177 returned for a 6-month follow-up assessment, 149 needed to maintain adequate statistical power). The retention target was also exceeded in the control group at 12 months, with UT Health SPH retaining 119% of the 12-month target

(145 out of 177 returned for a 12-month follow-up assessment, 122 needed to maintain adequate statistical power).

Table 22. Study Retention at 6 and 12 Months by Intervention Group

Group	Number Enrolled	Retention Target[a]	Number Retained[b]	Percent Retention of the Enrolled Sample	Percent of Retention Target
6-month Retention					
Intervention Group	176	149	154	87.5%	103.4%
Control Group	177	149	152	85.9%	102.0%
12-month Retention					
Intervention Group	176	122	147	83.5%	120.5%
Control Group	177	122	145	81.9%	118.9%

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

Sample Attrition Analyses

The study anticipated 70% retention of the sample at 12 months. At 12 months, the study retained 84% of the intervention group and 82% of the comparison group. UT Health SPH exceeded the set targets for each group. To examine whether the 2% difference in attrition between intervention and control groups was statistically significant, a chi-square test was performed comparing the proportion of participants who were lost to follow-up in the intervention to those who were lost to follow-up in the control group. The results of this analysis were not statistically significant at the 0.05 level (p=0.59). Given these results, we conclude that the two study groups did not have significantly differing attrition rates at 12 months of follow-up.

Bivariate analyses were conducted to examine whether participants lost to follow-up were significantly different 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 G: Loss to Follow-Up/Attrition Tables** presents the results from these analyses.

There were no statistically significant differences in health measures at baseline between those who were lost to follow-up and those who remained in the study at 12 months within the intervention group. Within the control group, however, there was a statistically significant difference in baseline HbA1c level between those who completed the study and those who did not. Those who dropped out of the study had a slightly higher median HbA1c level than those who remained through their 12-month assessment. Regarding demographic measures, there were no differences between attrition groups within the intervention group. 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.

A multivariate logistic regression model was then utilized to understand the independent influence of these two 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=0.69), but baseline HbA1c and gender were found to be significant independent predictors of the probability of a participant not completing the study, with p values less than or equal to 0.05. These statistically significant differences in baseline HbA1c and gender should be considered in the interpretation of the final analyses.

Sample Retention Strategies

UT Health SPH monitored issues that arose in retaining the study sample through review of patient enrollment and quality improvement cycles to counter any enrollment and retention challenges. Sample attrition was mitigated by using a variety of retention strategies for use with similar populations in RCTs. The first strategy UT Health SPH used to counter sample attrition was to collect as many contact methods as possible from the study participant during the enrollment process. Study participants were asked to provide their current contact information, including telephone number and mailing address.

The second strategy for minimizing attrition that UT Health SPH used was to manage follow-up via care management. UT Health SPH evaluation staff and an assigned community health worker kept in touch with study participants on at least a bi-monthly basis using the participant's preferred mode of communication. The staff utilized telephone, text, voicemail, or mail to reach the participant; email was excluded as a mode of patient communication to prevent disclosure of the participant's participation in the study. Staff utilized their relationships with participants to locate and remind participants of their follow-up appointments. Staff strived to make appointments for study follow-up 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. Staff also visited the participants home to streamline access to the study.

Finally, UT Health SPH offered incremental financial incentives of a total value of $80 to SyV 2.0 intervention and control group participants at baseline, 6, and 12 months as a strategy for recruiting and retaining an adequate sample size. Participants received a $25 grocery store gift card after completion of the baseline and 6-month follow up assessment, respectively. A $30 grocery store gift card was given to participants who completed the 12-month assessment.

Non-Response Bias and Missing Data

All data for this study were collected by the UT Health SPH evaluation staff or assigned CHWs. These staff entered participants' clinical data taken during the initial assessment process (e.g., blood pressure, height, weight, PHQ-9, (which were all routinely collected) on to the Case Report Forms (CRFs) using paper forms. After data were collected onto the CRFs it was then filed in the participant record and entered into the REDCap database within 24 hours of collection. This is a deviation from the SEP which stated participant data would be entered directly into REDCap. While this was the goal, often CRFs was the only way data could be collected due to technological challenges (e.g., laptop was not working properly, internet was unavailable).

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

Regarding the eight study impact measures for the primary end-point analysis, complete baseline data were collected from all participants for blood pressure, total cholesterol, HbA1c, and self-efficacy. There was 1 intervention participant missing baseline PHQ-9 score and one control participant missing BMI. A total of 5 participants were missing Duke General Health score at baseline: 2 intervention participants and 3 control participants. Complete data were collected for participants who completed a 12-month follow-up on each measure except for BMI for which 1 participant was missing data. Medication adherence data was only collected at baseline and follow-up for whom it was applicable.

There were missing sociodemographic data for some characteristics. At baseline, 9 participants did not report a race or had a race of "unknown", 5 participants were missing marital status, 3 did not report their education level, 9 were missing their monthly household income, and 36 were missing their health insurance status.

Measures

The impact measures assessed for the SyV 2.0 program were HbA1c, blood pressure, BMI, total cholesterol, depression, quality of life, medication adherence, and self-efficacy. There were no changes to the measures described in UT Health SPH's amended SEP and interim report. Information on the number of respondents and tests of normality are provided here (see **Table 23**). 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 23. Impact Measure Sample Size by Follow-up

Measure	Sample Size		
	Baseline	6-month	12-month
HbA1c	353	306	292
Systolic Blood Pressure	353	306	292
Diastolic Blood Pressure	353	306	292
BMI	352	305	291
PHQ-9	352	306	292
Duke Health Profile	348	305	292
Total Cholesterol	353	306	292
Medication Adherence	329	302	288
Self-efficacy	353	306	292

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 recent average glucose levels. 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 UT Health SPH evaluation staff or assigned CHW for all participants because prior diagnosis of diabetes was required eligibility criteria for the study. Participants with an HbA1c greater than or equal to 8.0% at baseline were considered eligible for the study based on local clinical

procedures in identifying poorly controlled diabetes. In addition, the UT Health SPH staff determined the need/ appropriateness of medication.

For HbA1c, there were 353 respondents with complete data at baseline, 306 respondents at 6 months, and 292 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.

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 manually by the UT Health SPH staff using a Manometer and following clinically-established practice guidelines (National Guidelines Clearinghouse, 2011). Participants with a blood pressure greater than or equal to 140/90 mm Hg were considered hypertensive.

For blood pressure, there were 353 respondents with complete data at baseline, 306 respondents at 6 months, and 292 respondents at 12 months for the intervention and control groups. The distributions of responses for systolic and diastolic at baseline were determined to both be normal and therefore parametric tests were used for bivariate analyses.

Body Mass Index (BMI): BMI is generally used as an indicator of body fat. Specific ranges of BMI are accepted in the literature to indicate overweight (BMI between 25.0 and 29.9) and obesity (BMI $\geq$30), 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 UT Health SPH staff calculated BMI using a clinical weight scale and height measurement instrument following clinically-established practice guidelines (National Guideline Clearinghouse, 2014). Participants were referred to a community-based lifestyle program (e.g., exercise classes, cooking classes, etc.) as deemed appropriate (i.e., not based on BMI threshold).

For BMI, there were 352 respondents with complete data at baseline, 305 respondents at 6 months, and 291 respondents at 12 months for the intervention and control groups. The distribution of responses for BMI at baseline was determined to be slightly skewed in the sample. The log transformation was examined but did not normalize the distribution of BMI. Therefore, nonparametric tests were used in bivariate analyses.

Total Cholesterol: Cholesterol is a fatty substance that is present in all the cells in the body. Total cholesterol is measured through a blood test called lipid profile or panel and is typically expressed in milligrams per deciliter (mg/dL) (Birtcher & Ballantyne, 2004). Total cholesterol is made up of LDL cholesterol, HDL cholesterol, and VLDL cholesterol. A desirable level of total cholesterol is less than 200. The scientific literature shows that elevated levels of LDL cholesterol are associated with an increased risk of developing blockages in the coronary arteries, whereas elevated levels of HDL cholesterol reduce that risk.

Total cholesterol was measured following clinically-established practice guidelines. Participants with an elevated total cholesterol reading were considered to have hypercholesterolemia. The primary care provider determined the need/appropriateness of medication.

For total cholesterol, there were 353 respondents with complete data at baseline, 306 respondents at 6 months, and 292 respondents at 12 months for the intervention and control groups. The distribution of responses for total cholesterol at baseline was determined to be normal and therefore a parametric test was used for 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 was given to participants as part of their intake process.
- **Intended respondent:** The PHQ-9 was completed by a provider interviewing 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. Participants with a score of 5 or higher were referred for behavioral health services.

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

For PHQ-9 score, there were 352 respondents with complete data at baseline, 306 respondents at 6 months, and 292 respondents at 12 months for the intervention and control groups. The distribution of responses for PHQ-9 at baseline was determined to be non-normal. The log transformation was examined but did not normalize the distribution of PHQ-9. Therefore, nonparametric tests were used in bivariate analyses.

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

- **Administration method:** Physical functioning and quality of life were measured through provider interview by the Duke Health Profile. The Duke Health Profile is a 17-item generic questionnaire instrument designed to measure adult self-reported functional health status quantitatively during a one-week time window.
- **Administration time:** The assessment was given to participants as part of their intake process.

- **Intended respondent:** The Duke Health Profile was completed by a provider interviewing participants.
- **Potential score/response range:** The Duke Health profile has 11 scales, six of which measure function (physical health, mental health, social health, general health, perceived health, self-esteem) and five of which measure dysfunction (anxiety, depression, anxiety-depression, pain, disability). Scores range from 0 to 100. For scales measuring function, the higher the score, the more functional the person being evaluated. For scales measuring dysfunction, the higher the score, the more dysfunctional the person being evaluated. The general health domain score, a composite of the physical health, mental health and social health domain scores, was utilized as the primary quality of life indicator in our analyses.

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

For the Duke General Health score, there were 348 respondents with complete data at baseline, 305 respondents at 6 months, and 292 respondents at 12 months for the intervention and control groups. The distribution of responses for the Duke General Health score at baseline was determined to be non-normal. The log transformation was examined but did not normalize the distribution of Duke General Health. Therefore, nonparametric tests were used in bivariate analyses.

Medication Adherence: Patient non-adherence to prescribed treatment is one factor contributing to poor control of diabetes. Adherence to (or compliance with) a medication regimen is generally defined as the extent to which participants take medications as prescribed by their health care provider.

- **Administration method:** Adherence to taking medication was measured through provider interview by the Diabetes Medication Adherence Questionnaire. The Diabetes Medication Adherence Questionnaire is a 12-item generic questionnaire instrument designed to measure adult self-reported medication intake schedule fulfillment and identifies barriers to nonadherence of taking medication.
- **Administration time:** The assessment was given to participants as part of their intake process.
- **Intended respondent:** The Diabetes Medication Adherence Questionnaire was completed by a provider interviewing participants.
- **Potential score/response range:** The Diabetes Medication Adherence Questionnaire consists of 12 questions, including the Morisky Medication Adherence Scale (MMAS-8) (questions 8 to 12). The proposed questionnaire also has initial items regarding access to medications. Each participant's score on the Morisky scale was used to identify their medication adherence level. Scores range from 0 to 8. The higher the score, the higher the adherence to medication. For those participants randomized to the SyV 2.0 intervention arm of the study, their medication adherence score was reviewed and taken into consideration in their care planning for SyV 2.0 services.

See **Appendix L: Medication Adherence Questionnaire** *to view the Medication Adherence Questionnaire (available in English and Spanish).*

For medication adherence, there were 329 respondents with complete data at baseline, 302 respondents at 6 months, and 288 respondents at 12 months for the intervention and control groups. The distribution of responses for medication adherence at baseline was determined to be non-normal.

The log transformation was examined but did not normalize the distribution of medication adherence. Therefore, nonparametric tests were used in bivariate analyses.

Self-efficacy: The concept of self-efficacy originates from social cognitive theory and posits that participants' confidence in their ability to perform health behaviors influences which behaviors they will engage in. The concept of self-efficacy is relevant for improving diabetes self-management because behavioral, personal, and environmental factors affect daily performance of recommended activities.

- **Administration method:** Participant self-efficacy was measured through provider interview using the Diabetes Self-Efficacy Scale. The Diabetes Self-Efficacy Scale is an 8-item generic questionnaire instrument that is self-reported and designed to measure adult patient perception in regard to performing self-care tasks related to diabetes.
- **Administration time:** The assessment was given to participants as part of their intake process.
- **Intended respondent:** The Diabetes Self-Efficacy Scale was completed by a provider interviewing participants.
- **Potential score/response range:** The Diabetes Self-Efficacy Scale has 8 items. Scores range from 0 to 10. The lower the score, the lower the self-efficacy of the person being evaluated.

See **Appendix M: Diabetes Self-Efficacy Scale** *to view the Diabetes Self-Efficacy Scale (available in English and Spanish).*

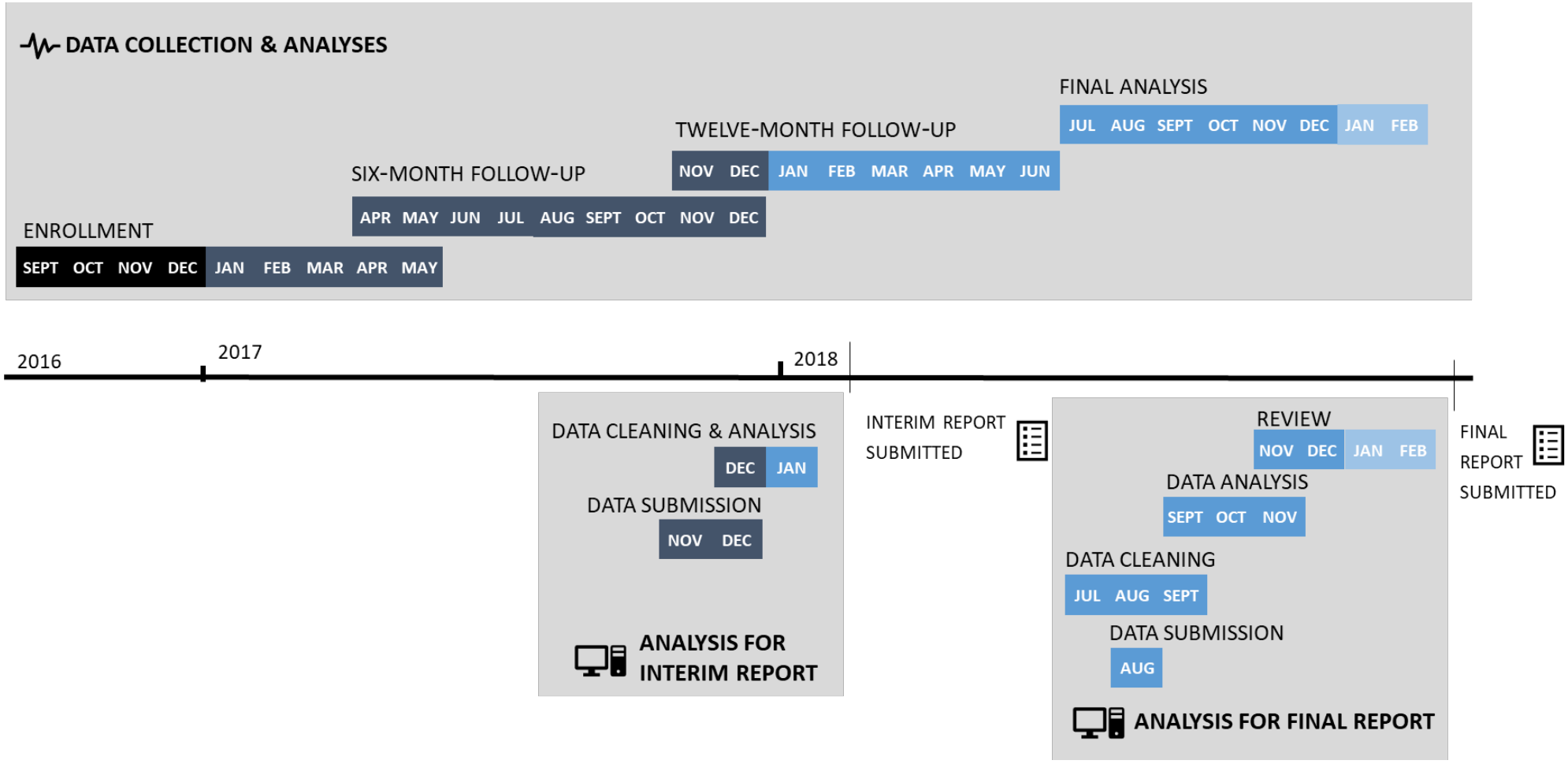
For self-efficacy, there were 353 respondents with complete data at baseline, 306 respondents at 6 months, and 292 respondents at 12 months for the intervention and control groups. The distribution of responses for self-efficacy at baseline was determined to be non-normal. The log transformation was examined but did not normalize the distribution of self-efficacy. Therefore, nonparametric tests were used in bivariate analyses.

Data Collection Activities

UT Health SPH collected data starting in September 2016 and extended enrollment from March 2016 to May 2016. 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. Recruitment was extended by two months to meet the enrollment target of 350 participants. In December 2016, UT Health SPH determined that its eligibility criteria were too narrow to recruit sufficient sample size. In January 2017, UT Health SPH submitted to SIF and received approval for a SEP amendment to revise study eligibility criteria. Six-month follow-up began in April 2017 and continued through December 2017. Twelve-month follow-up began in November 2017 and ended in June 2018.

Subgrantee: University of Texas Health Science Center at Houston School of Public Health
Project Title: Salud y Vida 2.0

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 UT Health SPH study.

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

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

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

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

Unit of Analysis and Overview of Analyses Performed

The unit of analysis was the individual patient. An end-point analysis was our primary analytic approach. This end-point analysis approach is a conventional approach to analyze clinical trial data collected from individuals with both baseline data and end-point data of primary interest (Liebschutz, et al., 2017). We employed generalized regression analysis following a modeling sequence from bivariate models to multiple regression models adjusting for baseline levels of outcome measures and covariates that were assessed to be relevant based on review of the scientific literature. The parameter of interest was the dichotomous variable that differentiates the treatment status (i.e., intervention vs. control). Between-

group comparison of baseline and single follow-up outcomes were assessed by end-point analyses that accounted for the baseline level of impact measures. Additionally, because multiple follow-up impact measures form individual trajectories, we conducted longitudinal analyses assessing whether the impact measure trajectories differed by intervention status (Fitzmaurice et al., 2004). A time measure was developed and applied to denote baseline, 6-month, and 12-month follow-up measures.

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

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

Following bivariate comparisons, multivariate and longitudinal analyses were performed separately to answer each research question. As previously mentioned, multiple imputation methods were not needed due to the complete nature of the submitted data. It was also decided propensity score matching methodology was not necessary as randomization successfully led to statistically equivalent groups at baseline. The primary adjusted multivariate analysis models the outcome of interest on intervention status with relevant covariates included. The longitudinal analysis evaluates whether the impact measure trajectories differ by intervention status across the 12-month study. Effect modification of the intervention-outcome relationships were also examined by including interactions terms between sample characteristics and intervention group status in the regression models. In alignment with the SEP, modification by the baseline confirmatory variable, HbA1c, was explored. Because of the study's eligibility requirements, all participants were diabetic and therefore modification by diabetic status was not possible. Instead, participants were grouped as having a baseline HbA1c under 10.0% or 10.0% or higher based on the median of the sample. To assess whether there was a difference in effect related to participation in SyV 1.0, participants were grouped as having spent less than 21.5 months (median tenure) or 21.5 months or longer in the initial program based on the median number of months spent in SyV 1.0. Additional effect modification was explored around demographics assessed to be potentially influential by program staff who are knowledgeable about this population. The characteristics considered were education (less than high school compared to high school or higher), insurance status (uninsured compared to insured), age (under 51 years compared to 51 years or older, based on the mean age in the sample), and gender (male compared to female).

The SEP indicated a set of planned covariates for adjustment in the models. Of those listed, age (continuous), sex, ethnicity, language, marital status, education, number of months in SyV 1.0, 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. 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. Education was also recoded to a dichotomous variable of "less than high school" and "high school or higher". Baseline PHQ-9 score was included as a covariate for possible selection in models for all outcomes except for Duke General Health Score. The correlation between baseline Duke General Health Score and baseline PHQ-9 was high and therefore PHQ-9 could not be included in the model that was adjusting for baseline measure of interest. The inclusion of baseline PHQ-9 aimed to adjust for the imbalance of that measure at the start of the study.

An additional set of analyses were considered to understand the potential effect of a participant having received particular services they were referred to on the outcomes of interest compared to those who did not receive a needed service. We compared those who reached minimum dose compared to those who did not among those who were referred to a service (see **Table 13**). Given the sample sizes at 12 months, we explored the possible effect of the La Cocina Alegre and MTM components of the intervention on 12-month outcomes. We determined the sample sizes of those completing BHS and PLSGs to be insufficient for analyses. Results are presented in this section by research question as applicable.

Other demographic measures collected included race, employment, insurance, and household income. Race was not included in any of the models as ethnicity was included and is a more representative characteristic for the study population. Employment was recoded as a dichotomized variable with categories of "employed", including participants indicating clerical, professional/managerial, sale, or skilled labor work and "not employed", including participants indicating they were unemployed, disabled, retired, or a homemaker. There were two types of responses recoded to "missing" for employment, those providing no answer or those indicating other, but not specifying any type of work. Insurance status was coded into one categorical variable from multiple dichotomous "yes/no" variables. The categories were "Medicaid only", "Medicare only", "Medicaid and Medicare", "private", "indigent", and "not insured". Those who did not select "yes" on any of the dichotomous variables were coded as "missing". Because of the number of participants categorized as missing for employment and insurance, these variables were not included in any models to avoid sample size reduction.

A backward elimination modeling selection procedure was employed for the end-point analysis approach where covariates with a p-value larger than 0.15 were excluded from the final model for parsimony. A priori selection was considered, particularly for age and sex due to the known biological influence of these characteristics on health outcomes. However, in response to the baseline equivalence on all demographic measures, including age and sex, 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. When testing for effect modification, interaction terms between intervention group and variables of interest were included in the model for possible selection using the same criteria of a p-value $\leq$0.15. Additional, more conservative criteria of p-value $\leq$0.25, were applied if the interaction term was not selected using this cutoff p-value.

HbA1c Level

Question 1. **Are participants who receive SyV 2.0 more likely to reduce HbA1c after 12 months compared to participants who receive SyV 1.0 (the standard of care)? This question is confirmatory.**

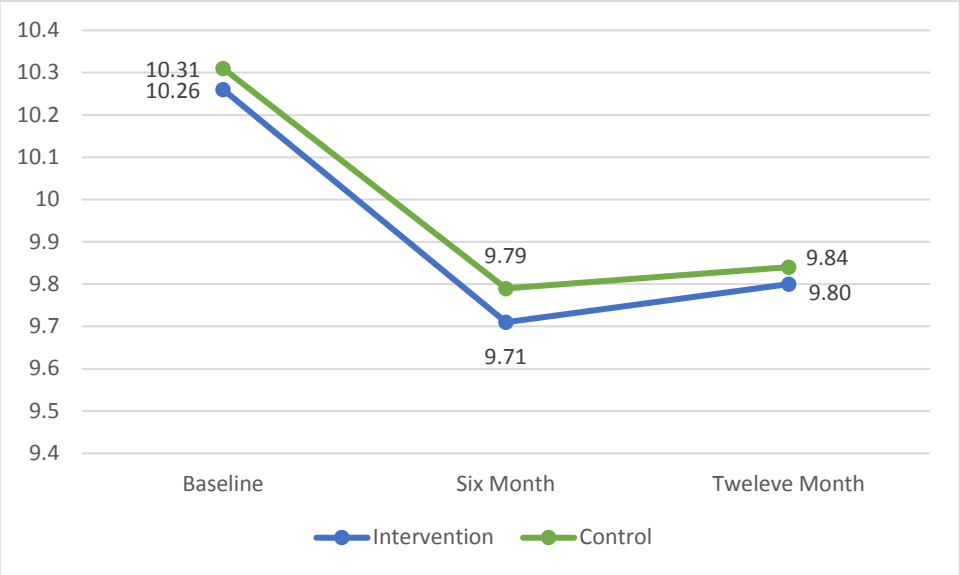
Overview of Analysis
To answer this confirmatory question about intervention impact on HbA1c level, data were collected on patient HbA1c levels. As previously stated, eligibility for participation in the study required an HbA1c of 8.0% or more at baseline and HbA1c data were collected for all participants at all time points. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for HbA1c level. The sample sizes for the presented analyses of HbA1c are as follows: bivariate analyses (n=292), primary linear regression analyses (n=284), and longitudinal analyses (n=317).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 50** 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 10.4% at baseline. For those who returned for a follow-up assessment, this decreased to 9.8% at 6-month follow-up and remained the same for those who returned at 12-month for follow-up. The intervention group began with a slightly lower HbA1c at baseline (10.3%). For those participants in the intervention group who returned for a follow-up visit, mean HbA1c decreased at 6-month follow-up to 9.7% and increased slightly at 12 months (9.8%). The control group participants began the study with a baseline HbA1c of 10.5%. For those participants in the control group who returned for a follow-up visit, the mean HbA1c decreased at 6 months to 9.9% and to 9.8% at 12 months. As previously noted in **Table 19**, 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 48**). The decrease observed in HbA1c level from baseline to 12-month follow-up was statistically significant within both the intervention and control groups.

Figure 4 presents the mean HbA1c level at each time point for those who completed a 12-month assessment in the intervention and control groups. On average, both the intervention and control group participants who completed the study saw improvement in their HbA1c from baseline to 6 months and a slight increase from 6 months to the study endpoint. The average in both groups at the end of the study was lower than the average at the start of the study.

Figure 4. Mean HbA1c Among Participants Completing 12-month Follow-up, by Time Point and Participant 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 49**). 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, time in SyV 1.0, primary language, ethnicity, marital status, education, baseline HbA1c level, number of comorbidities at baseline, and baseline PHQ-9.

$$Y_{(HbA1c)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 SyV1.0 + \beta_5 Language + \beta_6 Ethnicity + \beta_7 MaritalStatus + \beta_8 Education + \beta_9 BL\_HbA1c + \beta_{10} BL\_Comorbidities + \beta_{11} BL\_PHQ9 + \varepsilon$$

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

The final model of HbA1c level included those covariates with p-value of 0.15 or less: age, ethnicity, and baseline HbA1c level. Age was modelled as a continuous variable for parsimony based on similar adjusted R-square results across the two models. The final model specification was:

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

Findings
Estimates for the final model of HbA1c level are presented in **Table 24**.

Mean HbA1c level at 12 months did not differ significantly by intervention status (p=0.98); the effect size (using Cohen's d) is 0.002.

$$Y_{(HbA1c)}=4.46 + 0.004(\text{Intervention}) + -0.02(\text{Age}) + 1.08(\text{Non-Hispanic}) + 0.63(\text{BL\_HbA1c})$$

Table 24. Effect of IBH Intervention on Twelve Month HbA1c Value, Full UT Health SPH Sample

Variable	HbA1c n=284		
	Estimate (β)	Standard Error	p-value
Intervention	0.004	0.18	0.98
Control (ref)	--	--	--
Age (continuous)	-0.02	0.01	0.02
Non-Hispanic	1.08	0.35	0.002
Hispanic (ref)	--	--	--
Baseline HbA1c	0.63	0.07	<0.001

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

Additional Analyses
When examining effect modification between intervention participation and select participant characteristics at baseline for the confirmatory outcome of HbA1c, significant effect modification was identified by education, using conservative criteria of p-value ≤ 0.25 (interaction term p=0.23). However, in analyses of intervention effect stratified by education, the intervention was not found to be significantly associated with HbA1c in either group (results not shown).

Analyses exploring the possible effect of receiving minimum dose of La Cocina Alegre or MTM services on HbA1c among those in the intervention group who were referred to a service did not detect statistically significant results (results not shown).

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 0.79, 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 25**). Adjusting for the covariates that were selected in the primary model—age and ethnicity —did not alter these results.

Table 25. Effect of IBH Intervention on Trajectory of HbA1c Value Across Twelve Month Study, Full UT Health SPH Sample

Variable	HbA1c (n=317)		
	Estimate (β)	Standard Error	p value
Time*Intervention	0.05	0.19	0.79
Time*Control (ref)	--	--	--
Time	-0.56	0.13	<0.001
Intervention	-0.18	0.17	0.30
Control (ref)	--	--	--

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

Limitations

The distribution of this outcome was found to be non-normal and a nonparametric approach was taken for bivariate analyses. However, the use of linear regression methods for the endpoint analyses was not a concern. The distribution of errors for the linear regression model was assessed to be normal, likely due to the large sample size available for these analyses. Regarding the stratified analyses conducted, the lack of statistically significant differences could be due to limitations of sample size and power to detect a difference after stratification.

Blood Pressure

Question 2. **Are participants who receive SyV 2.0 more likely to improve their blood pressure after 12 months compared to participants who receive SyV 1.0? <u>This question is exploratory</u>.**

Overview of Analysis

To answer this exploratory question about intervention impact on blood pressure, data were collected on patient systolic and diastolic blood pressure levels. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for blood pressure. The sample sizes for the presented analyses of blood pressure are as follows: bivariate analyses (n=292), primary linear regression analyses (n=284), and longitudinal analyses (n=317).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 50** 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 136.1/79.8 at baseline. For those who returned for a follow-up assessment, mean blood pressure was 132.5/78.0 at 6-months and 133.7/78.4 at 12-month follow-up. The intervention group began the study with a mean blood pressure of 136.3/80.0. For those participants in the intervention group who returned for a follow-up, mean blood pressure reduced slightly to 133.7/78.6 at 6-month follow-up and 133.3/78.7 at 12-month follow-up. The control group began the study with a mean blood pressure of 135.9/79.5. For those participants in the control group who returned for follow-up, mean blood pressure decreased to 131.3/77.4 at 6-months, and increased slightly to 134.2/78.0 at 12-months. As previously noted in **Table 19**, 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 48**). The slight decreases observed within systolic and diastolic blood pressure 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 systolic and diastolic blood pressure at 12-month follow-up, without controlling for any additional covariates (**Table 49**). 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, time in SyV 1.0, primary language, ethnicity, marital status, education, baseline systolic blood pressure, baseline diastolic blood pressure, number of comorbidities at baseline, and baseline PHQ-9.

$$Y_{(SBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 SyV1.0 + \beta_5 Language + \beta_6 Ethnicity + \beta_7 MaritalStatus + \beta_8 Education + \beta_9 BL\_SBP + \beta_{10} BL\_DBP + \beta_{11} BL\_Comorb + \beta_{12} BL\_PHQ9 + \varepsilon$$

$$Y_{(DBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 SyV1.0 + \beta_5 Language + \beta_6 Ethnicity + \beta_7 MaritalStatus + \beta_8 Education + \beta_9 BL\_SBP + \beta_{10} BL\_DBP + \beta_{11} BL\_Comorb + \beta_{12} BL\_PHQ9 + \varepsilon$$

Two variations of the model were run to assess the best fit model: one including age as a continuous predictor and another utilizing categorical age. As previously stated, multiple imputation approach was considered but not performed due to the near completeness of the evaluated data.

The final model of systolic blood pressure included those covariates with a p-value of 0.15 or less: age, sex, time in SyV 1.0, baseline systolic blood pressure and baseline diastolic blood pressure. Age was modelled as a continuous variable for parsimony based on similar adjusted R-square results across the two models. The final model specification was:

$$Y_{(SBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 SyV1.0 + \beta_5 BL\_SBP + \beta_6 BL\_DBP + \varepsilon$$

The final model of diastolic blood pressure included those covariates with a p-value of 0.15 or less: age, education, time in SyV 1.0, baseline systolic blood pressure and baseline diastolic blood pressure. Age was modelled as a continuous variable for parsimony based on similar adjusted R-square results across the two models. The final model specification was:

$$Y_{(DBP)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Education + \beta_4 SyV1.0 + \beta_5 BL\_SBP + \beta_6 BL\_DBP + \varepsilon$$

Findings
Estimates for the final models of systolic and diastolic blood pressure are presented in **Table 26**.

Mean systolic blood pressure at 12 months did not differ significantly by intervention status (p=0.73).

$Y_{(SBP)}$=67.46 + -0.59(Intervention) + 0.23(Age) + 4.69 (Male) + -0.19(SyV1.0) +0.59(BL_SBP) + -0.29(BL_DBP)

Mean diastolic blood pressure at 12 months did not differ significantly by intervention status (p=0.51).

$Y_{(DBP)}$=62.44 + 0.74(Intervention) + -0.20(Age) + 2.40(HighSchoolEd+) + -0.16(SyV1.0) +0.10(BL_SBP) + 0.19(BL_DBP)

Table 26. Effect of IBH Intervention on Twelve Month Systolic and Diastolic Blood Pressure, Full UT Health SPH Sample

Variable	Systolic Blood Pressure (n=284)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.59	1.69	0.73
Control (ref)	--	--	--
Age (continuous)	0.23	0.10	0.02
Male	4.69	2.00	0.02
Female (ref)	--	--	--
Time in SyV1.0 Program	-0.19	0.09	0.03
Baseline systolic blood pressure	0.59	0.06	<0.001
Baseline diastolic blood pressure	-0.29	0.09	0.002
Variable	Diastolic Blood Pressure (n=284)		
	Estimate (β)	Standard Error	p-value
Intervention	0.74	1.13	0.51
Control (ref)	--	--	--
Age (continuous)	-0.20	0.07	0.003
Education: high school +	2.40	1.17	0.04
Education: <high school (ref)	--	--	--
Time in SyV1.0 Program	-0.16	0.06	0.01
Baseline diastolic blood pressure	0.19	0.06	0.001
Baseline systolic blood pressure	0.10	0.04	0.02

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 age, time in SyV 1.0, and HbA1c level, using conservative criteria of p-value ≤ 0.25. For age, the interaction term p-value was 0.15. For time in SyV 1.0, the interaction term p-value was 0.10. For HbA1c level, the interaction term p-value was 0.21. When stratifying by age, time in SyV 1.0, or HbA1c groups,

the intervention was not found to be significantly associated with systolic blood pressure within any subgroup (results not shown).

When examining effect modification between intervention participation and select participant characteristics at baseline on diastolic blood pressure, significant effect modification was identified by age, time in SyV 1.0, and gender, using conservative criteria of p-value ≤ 0.25. For age, the interaction term p-value was 0.23. When stratifying by age, the intervention was not found to be significantly associated with diastolic blood pressure in either group (results not shown).

For time in SyV 1.0, the interaction term p-value was 0.001. When stratifying by time in SyV 1.0, the intervention was not found to be significantly associated with diastolic blood pressure among those who spent the median tenure or longer in SyV 1.0 (see **Table 27**). Among those who spent less than the median tenure in SyV 1.0, the intervention was associated with a significantly higher mean diastolic blood pressure (see **Table 31**). On average, among those who spent less than the median tenure in SyV 1.0, intervention participants had a blood pressure 4.68 mmHg higher than those in the control group (p=0.004); the effect size (using Cohen's d) is 0.44.

Table 27. Effect of IBH Intervention on Twelve Month Diastolic Blood Pressure, Stratified by Time in SyV 1.0

	Less than Median Tenure in SyV 1.0			Median Tenure or Longer in SyV 1.0		
Variable	Diastolic Blood Pressure (n=143)			Diastolic Blood Pressure (n=141)		
	Estimate (β)	Standard Error	p-value	Estimate (β)	Standard Error	p-value
Intervention	**4.68**	**1.58**	**0.004**	-2.74	1.57	0.08
Control (ref)	--	--	--	--	--	--
Age	-0.28	0.09	0.003	-0.17	0.09	0.08
English	--	--	--	-4.05	1.87	0.03
Spanish (ref)	--	--	--	--	--	--
High school or more	--	--	--	4.94	1.77	0.01
Less than high school (ref)	--	--	--	--	--	--
Baseline diastolic BP	0.20	0.08	0.01	0.26	0.06	<0.001
Baseline systolic BP	0.14	0.05	0.01	--	--	--

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

For gender, the interaction term p-value was 0.08. When stratifying by gender, the intervention was not found to be significantly associated with diastolic blood pressure among females (see **Table 28**). Among males, those in the intervention had a significantly higher diastolic blood pressure (see **Table 28**).

Table 28. Effect of IBH Intervention on Twelve Month Diastolic Blood Pressure, Stratified by Gender

	Males			Females		
Variable	Diastolic Blood Pressure (n=74)			Diastolic Blood Pressure (n=210)		
	Estimate (β)	Standard Error	p-value	Estimate (β)	Standard Error	p-value
Intervention	**5.41**	**2.51**	**0.03**	-0.26	1.23	0.83
Control (ref)	--	--	--	--	--	--
Time in SyV 1.0	--	--	--	-0.12	0.07	0.08
Age	-0.41	0.14	0.004	-0.22	0.08	0.01
English	--	--	--	-2.30	1.57	0.14
Spanish (ref)	--	--	--	--	--	--
High school or more	--	--	--	3.59	1.47	0.02
Less than high school (ref)	--	--	--	--	--	--
Baseline diastolic BP	--	--	--	0.19	0.06	0.003
Baseline systolic BP	0.14	0.07	0.06	0.12	0.04	0.01
Number of baseline comorbidities	-3.18	1.54	0.04	--	--	--
Baseline PHQ-9	--	--	--	0.23	0.11	0.03

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

Analyses exploring the possible effect of receiving minimum dose of La Cocina Alegre or MTM services on systolic blood pressure among those in the intervention group who were referred to a service detected an effect that was statistically significant. Those who completed at least 2 MTM services had a higher systolic blood pressure than those with less than 2 MTM visits (see **Table 33**). Analyses exploring the possible effect of receiving minimum dose of La Cocina Alegre or MTM services on diastolic blood pressure among those in the intervention group who were referred to a service did not detect statistically significant results (results not shown).

Table 29. Effect of Receiving Minimum Dose for MTM Services, Intervention Participants

Variable	Systolic Blood Pressure (n=101)		
	Estimate (β)	Standard Error	p-value
Received minimum dose	**6.65**	**3.05**	**0.03**
Did not receive minimum dose (ref)	--	--	--
Male	6.76	3.61	0.06
Female (ref)	--	--	--
Non-Hispanic	-8.33	5.58	0.14
Hispanic (ref)	--	--	--
Time in SyV1.0 Program	-0.28	0.15	0.07
Baseline systolic blood pressure	0.46	0.11	<0.001
Baseline diastolic blood pressure	-0.26	0.17	0.14
Baseline comorbidities	3.28	1.63	0.05

Note: 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 differ by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS.

For systolic blood pressure, only adjusting for intervention status and time, there was no significant time/group interaction with a p value of 0.42, 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 30).** Adjusting for the covariates that were selected in the primary model— age, sex, time in SyV1.0, and baseline diastolic blood pressure – did not alter these results.

For diastolic blood pressure, only adjusting for intervention status and time, there was no significant time/group interaction with a p value of 0.99, 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 30).** Adjusting for the covariates that were selected in the primary model— age, education, time in SyV1.0, and baseline systolic blood pressure – did not alter these results.

Table 30. Effect of IBH Intervention on Trajectory of Systolic and Diastolic Blood Pressure Across Twelve Month Study, Full UTHealth SPH Sample

Variable	Systolic Blood Pressure (n=317)		
	Estimate (β)	Standard Error	p value
Time*Intervention	-1.60	1.99	0.42
Time*Control (ref)	--	--	--
Time	-1.03	1.41	0.47
Intervention	1.29	2.01	0.52
Control (ref)	--	--	--
Variable	Diastolic Blood Pressure (n=317)		
	Estimate (β)	Standard Error	p value
Time*Intervention	-0.02	1.47	0.99
Time*Control (ref)	--	--	--
Time	-1.17	1.04	0.26
Intervention	0.60	1.31	0.65
Control (ref)	--	--	--

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

Limitations

Regarding the stratified analyses conducted for both systolic and diastolic blood pressure, the lack of statistically significant differences in some analyses could be due to limitations of sample size and power to detect a difference after stratification.

Body Mass Index

Question 3. **Are participants who receive SyV 2.0 more likely to reduce their BMI after 12 months compared to participants who receive SyV 1.0? <u>This question is exploratory</u>.**

Overview of Analysis
To answer this exploratory question about intervention impact on body mass index, data were collected on patient weight and height, from which body mass index was calculated. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for weight or height. The sample sizes for the presented analyses of body mass index are as follows: bivariate analyses (n=291), primary linear regression analyses (n=283), and longitudinal analyses (n=316).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 50** 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 33.3 at baseline. For those who returned for a follow-up assessment, mean body mass index was 33.4 at 6-month follow-up and 33.5 at 12-month follow-up. The intervention group began the study with a mean body mass index of 33.4. For those participants in the intervention group who returned for a follow-up, mean body mass index was 33.3 at 6-month follow-up and 33.6 at 12-month follow-up. The control group began the study at mean body mass index of 33.2. For those participants in the control group who returned for follow-up, mean body mass index was 33.6 at 6-months, and 33.3 at 12-months. As previously noted in **Table 19**, 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 48**). 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 49**). Based on a p-value greater than 0.05 for body mass index when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. Body mass index was not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process
A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, body mass index. Covariates were removed from the model if their p-value was found to be greater than 0.15. The initial covariates that were input into the models for body mass index were: age, sex, time in SyV 1.0, primary language, ethnicity, marital status, education, baseline body mass index, number of comorbidities, and PHQ-9 score at baseline.

$$Y_{(BMI)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 SyV1.0 + \beta_5 Language + \beta_6 Ethnicity + \beta_7 MaritalStatus + \beta_8 Education + \beta_9 BL\_BMI + \beta_{10} BL\_Comorb + \beta_{11} BL\_PHQ\text{-}9 + \varepsilon$$

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

The final model of body mass index included those covariates with p-value of 0.15 or less: ethnicity, baseline comorbidities, and baseline body mass index:

$$Y_{(BMI)}=\beta_0 + \beta_1 StudyArm + \beta_2 Ethnicity + \beta 3 BL\_Comorb + \beta_4 BL\_BMI + \varepsilon$$

Findings
Estimates for the final model of body mass index are presented in **Table 31**.

Mean body mass index at 12 months did not differ significantly by intervention status (p=0.58).

$$Y_{(BMI)}=2.79 + -0.15(Intervention) + -1.48(NotHispanic) + -0.21(BL\_Comorb) + 0.95(BL\_BMI)$$

Table 31. Effect of IBH Intervention on Twelve Month BMI, Full UT Health SPH Sample

Variable	BMI (n=283)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.15	0.27	0.58
Control (ref)	--	--	--
Non-Hispanic	-1.48	0.50	0.003
Hispanic (ref)	--	--	--
Baseline Comorbidities	-0.21	0.14	0.14
Baseline BMI	0.95	0.02	<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 for BMI, significant effect modification was identified by HbA1c level at baseline, using conservative criteria of p-value ≤ 0.25 (interaction term p=0.14). However, in analyses of intervention effect stratified by HbA1c level, the intervention was not found to be significantly associated with BMI in either group (results not shown).

Analyses exploring the possible effect of receiving minimum dose of La Cocina Alegre or MTM services on BMI among those in the intervention group who were referred to a service did not detect statistically significant results (results not shown).

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differed by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For body mass index, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.60, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for body mass index (see **Table 32**). Adjusting for the covariates that were selected in the primary model—ethnicity and baseline comorbidities - did not alter these results.

Table 32. Effect of IBH Intervention on Trajectory of Body Mass Index Across Twelve Month, Full UT Health SPH Sample

Variable	BMI (n=316)		
	Estimate (β)	Standard Error	p value
Time*Intervention	-0.15	0.29	0.60
Time*Control (ref)	--	--	--
Time	0.23	0.20	0.26
Intervention	0.09	0.77	0.91
Control (ref)	--	--	--

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

Limitations
The distribution of this outcome was found to be non-normal and a log transformation was used for bivariate analyses. However, the use of linear regression methods for the endpoint analyses was not a concern. The distribution of errors for the linear regression model was assessed to be normal, likely due to the large sample size available for these analyses. Regarding the stratified analyses conducted, the lack of statistically significant differences could be due to limitations of sample size and power to detect a difference after stratification.

Depressive Symptoms

Question 4. **Are participants who receive SyV 2.0 more likely to reduce their depressive symptoms, as measured by the PHQ-9, after 12 months compared to participants who receive SyV 1.0? <u>This question is exploratory</u>.**

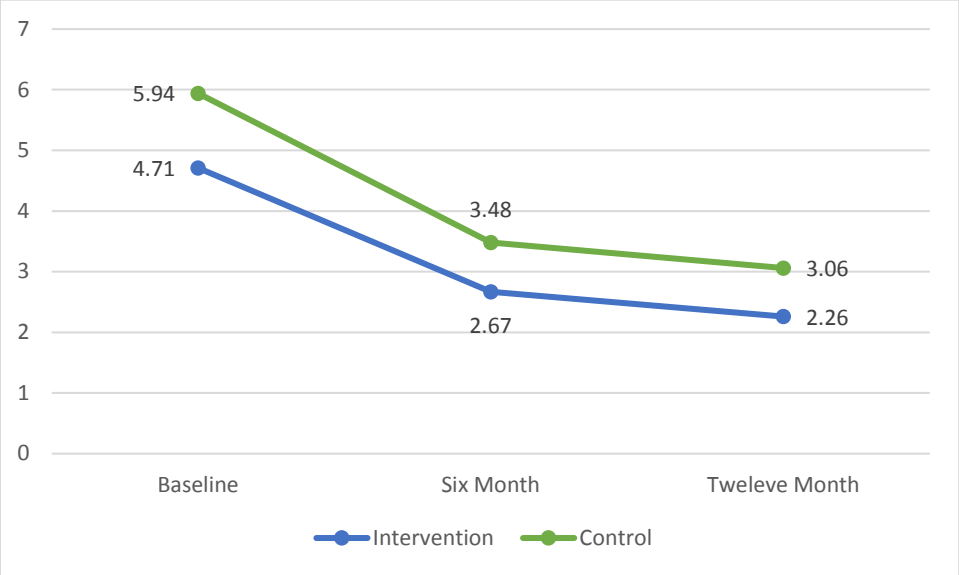
Overview of Analysis
To answer this exploratory question about intervention impact on depressive symptoms, data were collected using the PHQ-9. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for the PHQ-9 scale. The sample sizes for the presented analyses of depressive symptoms are as follows: bivariate analyses (n=292), primary linear regression analyses (n=284), and longitudinal analyses (n=316).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 49** 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 5.5 at baseline. For those who returned for a follow-up assessment, mean PHQ-9 decreased to 3.1 at 6-month follow up and 2.7 at 12-month follow-up. The intervention group began the study with a mean PHQ-9 of 4.8. For those participants in the intervention group who returned for a follow-up, mean PHQ-9 decreased to 2.7 at 6-month follow up and to 2.3 at 12-month follow-up. The control group began the study at mean PHQ-9 of 6.1. For those participants in the control group who returned for follow-up, mean PHQ-9 decreased to 3.5 at 6-month follow-up and to 3.1 at 12-month follow-up. As previously noted in **Table 19**, the intervention and control groups were not statistically equivalent on baseline PHQ-9, thus baseline PHQ-9 was included within subsequent modeling of intervention effectiveness.

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 48**). The reductions observed within PHQ-9 from baseline to 12-month follow-up were statistically significant within both the intervention and control groups ($p < 0.001$).

Figure 5 presents the mean PHQ-9 score at each time point for those who completed a 12-month assessment in the intervention and control groups. On average, both the intervention and control group participants who completed the study saw improvement in their PHQ-9 score from baseline to 6 months and from 6 months to the study endpoint. The average in both groups at the end of the study was lower than the average at the start of the study.

Figure 5. Mean PHQ-9 Score Among Participants Completing 12-month Follow-up, by Time Point and Participant Group



Bivariate analyses were also performed between the intervention and control groups comparing PHQ-9 at 12-month follow-up, without controlling for any additional covariates (**Table 49**). Based on a p value greater than 0.05 for PHQ-9 score when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. PHQ-9 score was not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, PHQ-9. Covariates were removed from the model if their p-value was found to be greater than 0.15. The initial covariates that were input into the models for PHQ-9 score were: age, sex, time in SyV 1.0, primary language, ethnicity, marital status, education, baseline PHQ-9, and number of comorbidities at baseline.

$$Y_{(BMI)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 SyV1.0 + \beta_5 Language + \beta_6 Ethnicity + \beta_7 MaritalStatus + \beta_8 Education + \beta_9 BL\_PHQ9 + \beta_{10} BL\_Comorb + \varepsilon$$

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

The final model of PHQ-9 included those covariates with a p-value of 0.15 or less: age, primary language, baseline PHQ-9 score, and baseline comorbidities:

$$Y_{(PHQ\text{-}9I)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Language + \beta_4 BL\_PHQ\text{-}9 + \beta_5 BL\_Comorb + \varepsilon$$

Findings
Estimates for the final model of depressive symptoms are presented in **Table 33**.

Mean PHQ-9 score at 12 months did not differ significantly by intervention status (p=0.21).

$$Y_{(BMI)}=1.93 + -0.44(Intervention) + -0.03(Age) + 1.00(PrimaryLanguage\_English) + -0.25(BL\_PHQ\text{-}9) + 0.34(BL\_Comorb)$$

Table 33. Effect of IBH Intervention on Twelve Month PHQ-9 score, Full UT Health SPH Sample

Variable	PHQ-9 (n=284)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.44	0.35	0.21
Control (ref)	--	--	--
Age (continuous)	-0.03	0.02	0.08
Primary language English	1.00	0.38	0.01
Primary language Spanish (ref)	--	--	--
Baseline PHQ-9	0.25	0.04	<0.001
Baseline Comorbidities	0.34	0.19	0.08

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 for PHQ-9, significant effect modification was identified by time in SyV 1.0 (interaction term p=0.04). When stratifying by time in SyV1.0, the intervention was not found to be significantly associated with PHQ-9 score among those who spent less than the median tenure in SyV 1.0 (see **Table 34**). Among those who spent the median tenure or longer in SyV 1.0, the intervention was associated with a significantly lower mean PHQ-9 score (see **Table 34**). On average, among those who spent the median tenure or longer in SyV 1.0, intervention participants had a PHQ-9 score 1.28 points lower than those in the control group (p=0.01); the effect size (using Cohen's d) is 0.36.

Table 34. Effect of IBH Intervention on Twelve Month PHQ-9 Score, Stratified by Time in SyV 1.0

	Less than Median Tenure in SyV 1.0			Median Tenure or Longer in SyV 1.0		
Variable	PHQ-9 (n=143)			PHQ-9 (n=141)		
	Estimate (β)	Standard Error	p-value	Estimate (β)	Standard Error	p-value
Intervention	0.29	0.50	0.56	**-1.28**	**0.50**	**0.01**
Control (ref)	--	--	--	--	--	--
Age	-0.04	0.03	0.09	-0.05	0.03	0.09
Male	--	--	--	1.63	0.60	0.01
Female (ref)	--	--	--	--	--	--
English	--	--	--	1.47	0.60	0.02
Spanish (ref)	--	--	--	--	--	--
High school or more	--	--	--	-1.03	0.56	0.07
Less than high school (ref)	--	--	--	--	--	--
Baseline PHQ-9	0.30	0.04	<0.001	0.29	0.04	<0.001

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

Analyses exploring the possible effect of receiving minimum dose of La Cocina Alegre or MTM services on PHQ-9 score among those in the intervention group who were referred to a service did not detect statistically significant results (results not shown).

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differ by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For PHQ-9 score, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.29, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for PHQ-9 score (see **Table 35**). Adjusting for the covariates that were selected in the primary model— age, language, and baseline comorbidities - did not alter these results.

Table 35. Effect of IBH Intervention on Trajectory of PHQ-9 Score across Twelve-Month Study, Full UT Health SPH Sample

Variable	PHQ-9 (n=317)		
	Estimate (β)	Standard Error	p value
Time*Intervention	0.58	0.55	0.29
Time*Control (ref)	--	--	--
Time	-3.10	0.39	<0.001
Intervention	-1.30	0.58	0.03
Control (ref)	--	--	--

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

Limitations
The distribution of this outcome was found to be non-normal and a nonparametric approach was taken for bivariate analyses. However, the use of linear regression methods for the endpoint analyses was not a concern. The distribution of errors for the linear regression model was assessed to be normal, likely due to the large sample size available for these analyses. Regarding the stratified analyses conducted, the lack of statistically significant differences for some analyses could be due to limitations of sample size and power to detect a difference after stratification.

Functioning and Quality of Life

Question 5. **Are participants who receive SyV 2.0 more likely to improve their quality of life, as measured by the Duke Health Profile, after 12 months compared to participants who receive SyV 1.0? This question is exploratory.**

Overview of Analysis
To answer this exploratory question about intervention impact on quality of life, data were collected using the Duke Health Profile. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for the Duke Health Profile scale. The sample sizes for the presented analyses of depressive symptoms are as follows: bivariate analyses (n=292), primary linear regression analyses (n=281), and longitudinal analyses (n=312).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 50** presents the mean Duke General Health index values in each study period for the overall sample as well as the intervention and control groups. The overall study sample had a mean General Health score of 67.3 at baseline. For those who returned for a follow-up assessment, mean General Health score increased to 71.7 at 6-month follow-up and to 73.3 at 12-month follow-up. The intervention group began the study with a mean Duke General Health score of 69.5. For those participants in the intervention group who returned for a follow-up, mean Duke General Health score increased to 73.7 at 6-month follow up, and to 75.1 at 12-month follow-up. The control group began the study with a mean Duke General Health score of 65.2. For those participants in the control group who returned for follow-up, mean Duke General Health score increased to 69.7 at 6-month follow-up and to 71.5 at 12-month follow-up. As previously noted in **Table 19**, the intervention and control groups were not statistically equivalent on Duke General Health score at baseline, thus baseline general health was included within subsequent modeling of intervention effectiveness.

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

Bivariate analyses were also performed between the intervention and control groups comparing body mass index at 12-month follow-up, without controlling for any additional covariates (**Table 49**). Based on a p value greater than 0.05 for Duke General Health score when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. Duke General Health score was not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process
A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, Duke General Health score. Covariates were removed from the model if their p-value was found to be greater than 0.15. The initial covariates that were input into the models for Duke General Health score were: age, sex, time in SyV 1.0, primary language, ethnicity, marital status, education, baseline Duke General Health score, and number of comorbidities at baseline.

$$Y_{(BMI)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 SyV1.0 + \beta_5 Language + \beta_6 Ethnicity + \beta_7 MaritalStatus + \beta_8 Education + \beta_9 BL\_GenHlth + \beta_{10} BL\_Comorb + \varepsilon$$

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

The final model of Duke General Health score included those covariates with a p-value of 0.15 or less: sex, marital status, education, and baseline Duke General Health score:

$$Y_{(GenHlth)}=\beta_0 + \beta_1 StudyArm + \beta_2 Sex + \beta_3 MaritalStatus + \beta_4 Education + \beta_5 BL\_GenHlth + \varepsilon$$

Findings
Estimates for the final model of quality of life are presented in **Table 36**.

Mean Duke General Health score at 12 months did not differ significantly by intervention status (p=0.38).

$$Y_{(GenHlth)}=31.26 + 1.25(Intervention) + -2.54(Male) + -2.53(Married) + 2.18(HighSchoolEd+) + 0.63(BL\_GenHlth)$$

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

Variable	Duke General Health (n=281)		
	Estimate (β)	Standard Error	p-value
Intervention	1.25	1.43	0.38
Control (ref)	--	--	--
Male	-2.54	1.65	0.12
Female (ref)	--	--	--
Married	-2.53	1.43	0.08
Not married (ref)	--	--	--
High school +	2.18	1.47	0.14
<High school (ref)	--	--	--
Baseline General Health	0.63	0.04	<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 for Duke General Health score, there was only effect modification by gender, based on the wider 0.25 p-value criteria (interaction term p=0.24). However, in analyses of intervention effect stratified by gender, the intervention was not found to be significantly associated with Duke General Health in either group (results not shown).

Analyses exploring the possible effect of receiving minimum dose of La Cocina Alegre or MTM services on Duke General Health score among those in the intervention group who were referred to a service did not detect statistically significant results (results not shown).

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differed by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For Duke General Health score, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.62, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for Duke General Health score (see **Table 37**). Adjusting for the covariates that were selected in the primary model— sex, marital status, and education - did not alter these results.

Table 37. Effect of IBH Intervention on Trajectory of Duke General Health Score across Twelve-Month Study, Full UT Health SPH Sample

Variable	Duke General Health (n=312)		
	Estimate (β)	Standard Error	p-value
Time*Intervention	-0.79	1.61	0.62
Time*Control (ref)	--	--	--
Time	6.34	1.14	<0.001
Intervention	4.07	1.98	0.04
Control (ref)	--	--	--

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

Limitations
The distribution of this outcome was found to be non-normal and a nonparametric approach was taken for bivariate analyses. However, the use of linear regression methods for the endpoint analyses was not a concern. The distribution of errors for the linear regression model was assessed to be normal, likely due to the large sample size available for these analyses. Regarding the stratified analyses conducted, the lack of statistically significant differences could be due to limitations of sample size and power to detect a difference after stratification.

Total Cholesterol

Question 6. **Are participants who receive SyV 2.0 more likely to normalize their total cholesterol after 12 months compared to participants who receive SyV 1.0? <u>This question is exploratory</u>.**

Overview of Analysis
To answer this exploratory question about intervention impact on total cholesterol, data were collected on total cholesterol. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for total cholesterol. The sample sizes for the presented analyses of total cholesterol are as follows: bivariate analyses (n=292), primary linear regression analyses (n=284), and longitudinal analyses (n=317).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 50** presents the mean total cholesterol values in each study period for the overall sample as well as the intervention and control groups. The overall study sample had a mean total cholesterol value of 194.3 at baseline. For those who returned for a follow-up assessment, mean total cholesterol was 185.6 at 6-month follow up and 188.4 at 12-month follow-up. The intervention group began the study with a mean total cholesterol value of 195.6. For those participants in the intervention group who returned for a follow-up, mean total cholesterol decreased to 184.2 at 6-month follow-up and increased slightly to 185.6 at 12-month follow-up. The control group began the study at mean total cholesterol value of 193.1. For those participants in the control group who returned for follow-up, mean total cholesterol decreased to 187.1 at 6-months and increased to 191.3 at 12-months. As previously noted in **Table 19**, the intervention and control groups were statistically equivalent on total cholesterol 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 48**). The decreases observed in total cholesterol from baseline to 12-month follow-up were statistically significant within the intervention group (p=0.01) but were not statistically significant within the control group (p=0.52).

Bivariate analyses were also performed between the intervention and control groups comparing total cholesterol at 12-month follow-up, without controlling for any additional covariates (**Table 49**). Based on a p-value greater than 0.05 for total cholesterol when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. Total cholesterol 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, total cholesterol. 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 total cholesterol were: age, sex, time in SyV 1.0, primary language, ethnicity, marital status, education, baseline total cholesterol, number of comorbidities at baseline, and baseline PHQ-9 score.

$$Y_{(TotCholesterol)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 SyV1.0 + \beta_5 Language + \beta_6 Ethnicity + \beta_7 MaritalStatus + \beta_8 Education + \beta_9 BL\_TotCholesterol + \beta_{10} BL\_Comorb + \beta_{11} BL\_PHQ9 + \varepsilon$$

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

The final model of total cholesterol included those covariates with a p-value of 0.15 or less, baseline comorbidities and baseline total cholesterol:

$$Y_{(TotCholesterol)}=\beta_0 + \beta_1 StudyArm + \beta_2 BL\_Comorbities + \beta_3 BL\_TotCholesterol + \varepsilon$$

Findings
Estimates for the final model of total cholesterol are presented in **Table 38**.

Mean total cholesterol at 12 months did not differ significantly by intervention status (p=0.25).

$$Y_{(TotCholesterol)}=83.11 + -6.25(Intervention) + 5.52(BL\_Comorbities) + 0.49(BL\_TotCholesterol)$$

Table 38. Effect of IBH Intervention on Twelve Month Total Cholesterol, Full UT Health SPH Sample

Variable	Total Cholesterol (n=284)		
	Estimate (β)	Standard Error	p-value
Intervention	-6.25	5.37	0.25
Control (ref)	--	--	--
Baseline Comorbidities	5.52	2.88	0.06
Baseline Total Cholesterol	0.48	0.06	<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 for total cholesterol, significant effect modification was identified by insurance status (p=0.09), gender (p=0.08), and HbA1c level (p=0.07), using the more conservative criteria of p-value ≤ 0.25. However, in analyses of intervention effect stratified by insurance status, gender, or baseline HbA1c level, the intervention was not found to be significantly associated with total cholesterol in either group (results not shown).

Analyses exploring the possible effect of receiving minimum dose of La Cocina Alegre or MTM services on total cholesterol among those in the intervention group who were referred to a service did not detect statistically significant results (results not shown).

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 total cholesterol, only adjusting for intervention status and time, there was no significant time/group interaction with a p-value of 0.09, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for total cholesterol (see **Table 39**). Adjusting for the covariates that were selected in the primary model—baseline comorbidities - did not alter these results.

Table 39. Effect of IBH Intervention on Trajectory of Total Cholesterol across Twelve-Month Study, Full UT Health SPH Sample

Variable	Total Cholesterol (n=317)		
	Estimate (β)	Standard Error	p value
Time*Intervention	-10.10	5.82	0.09
Time*Control (ref)	--	--	--
Time	-0.62	4.13	0.88
Intervention	1.62	5.11	0.75
Control (ref)	--	--	--

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

Limitations
Regarding the stratified analyses conducted, the lack of statistically significant differences could be due to limitations of sample size and power to detect a difference after stratification.

Medication Adherence

Question 7. **Are participants who receive SyV 2.0 more likely to have improved medication adherence, as measured by the Diabetes Medication Adherence Questionnaire, after 12 months compared to participants who receive SyV 1.0? <u>This question is exploratory</u>.**

Overview of Analysis
To answer this exploratory question about intervention impact on medication adherence, data were collected using the Diabetes Medication Adherence Questionnaire. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for the Diabetes Medication Adherence scale. Not all patients were on diabetes-related medication, thus, the sample sizes for the presented analyses of medication adherence are as follows: bivariate analyses (n=288), primary linear regression analyses (n=267), and longitudinal analyses (n=299).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 50** presents the mean medication adherence score in each study period for the overall sample as well as the intervention and control groups. The overall study sample had a mean medication adherence score of 5.8 at baseline. For those who returned for a follow-up assessment, mean medication adherence score was 5.9 at 6-month follow up and 6.4 at 12-month follow-up. The intervention group began the study with a mean medication adherence score of 5.9. For those participants in the intervention group who returned for a follow-up; mean medication adherence was 6.0 at 6-month follow-up and 6.4 at 12-month follow-up. The control group began the study at mean medication adherence score of 5.7. For those participants in the control group who returned for follow-up, mean medication adherence was 5.8 at 6-months and 6.4 at 12-months. As previously noted in **Table 19**, the intervention and control groups were statistically equivalent on medication adherence 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 48**). The changes observed in median medication adherence score from baseline to 12-month follow-up were statistically significant within both the intervention group (p=0.003) and the control group (p<0.001).

Bivariate analyses were also performed between the intervention and control groups comparing median medication adherence score at 12-month follow-up, without controlling for any additional covariates (**Table 49**). Based on a p-value greater than 0.05 for medication adherence score when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. Medication adherence 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, medication adherence. 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 medication adherence were: age, sex, time in SyV 1.0, primary language, ethnicity, marital status, education, baseline medication adherence, number of comorbidities at baseline, and baseline PHQ-9 score.

$$Y_{(MedAdh)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 SyV1.0 + \beta_5 Language + \beta_6 Ethnicity + \beta_7 MaritalStatus + \beta_8 Education + \beta_9 BL\_MedAdh + \beta_{10} BL\_Comorb + \beta_{11} BL\_PHQ9 + \varepsilon$$

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

The final model of medication adherence included those covariates with a p-value of 0.15 or less: primary language, baseline medication adherence, and baseline PHQ-9 score:

$$Y_{(MedAdh)}=\beta_0 + \beta_1 StudyArm + \beta_2 Language + \beta_3 BL\_MedAdh + \beta_4 BL\_PHQ\text{-}9 + \varepsilon$$

Findings
Estimates for the final model of medication adherence are presented in **Table 40**.

Mean medication adherence at 12 months did not differ significantly by intervention status (p=0.42).

$$Y_{(MedAdh)}=5.13 + -0.12(Intervention) + -0.44(PrimLang{:}English) + 0.29(BL\_MedAdh) + -0.04(BL\_PHQ\text{-}9)$$

Table 40. Effect of IBH Intervention on Twelve Month Medication Adherence, Full UT Health SPH Sample

Variable	Medication Adherence (n=267)		
	Estimate (β)	Standard Error	p-value
Intervention	-0.12	0.14	0.42
Control (ref)	--	--	--
Primary Language: English	-0.44	0.15	0.01
Primary Language: Spanish (ref)	--	--	--
Baseline Medication Adherence	0.29	0.04	<0.001
Baseline PHQ-9	-0.04	0.01	0.004

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 for medication adherence, significant effect modification was identified by education and age, using conservative criteria of p-value ≤ 0.25. For age, the interaction term p-value was 0.21. However, in analyses of intervention effect stratified by age group, the intervention was not found to be significantly associated with medication adherence in either group (results not shown).

For education, the interaction term p-value was 0.004. In analyses of intervention effect stratified by education, the intervention was not found to be significantly associated with medication adherence among those who had not completed high school (see **Table 41**). Among those who had completed high school or higher, those in the intervention group had significantly lower mean medication adherence score (**Table 41**), indicating lower adherence.

Table 41. Effect of IBH Intervention on Twelve Month Medication Adherence, Stratified by Education

	High school or higher			Less than high school		
Variable	Medication Adherence (n=109)			Medication Adherence (n=158)		
	Estimate (β)	Standard Error	p-value	Estimate (β)	Standard Error	p-value
Intervention	**-0.60**	**0.23**	**0.01**	0.23	0.19	0.21
Control (ref)	--	--	--	--	--	--
English	-0.42	0.24	0.08	-0.52	0.26	0.05
Spanish (ref)	--	--	--	--	--	--
Baseline medication adherence	0.30	0.07	<0.001	0.27	0.05	<0.001
Baseline PHQ-9	-0.04	0.02	0.05	-0.05	0.02	0.02

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

Analyses exploring the possible effect of receiving minimum dose of La Cocina Alegre or MTM services on medication adherence among those in the intervention group who were referred to a service did not detect statistically significant results (results not shown).

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differ by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For medication adherence, only adjusting for intervention status and time, there was no significant time/group interaction with a p value of 0.41, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for medication adherence (see **Table 42**). Adjusting for the covariates that were selected in the primary model— language and baseline PHQ-9 – did not alter these results.

Table 42. Effect of IBH Intervention on Trajectory of Medication Adherence across Twelve-Month Study, Full UTHealth SPH Sample

Variable	Medication Adherence (n=298)		
	Estimate (β)	Standard Error	p value
Time*Intervention	-0.16	0.20	0.41
Time*Control (ref)	--	--	--
Time	0.69	0.14	<0.001
Intervention	0.19	0.20	0.35
Control (ref)	--	--	--

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

Limitations
The distribution of this outcome was found to be non-normal and a nonparametric approach was taken for bivariate analyses. However, the use of linear regression methods for the endpoint analyses was not a concern. The distribution of errors for the linear regression model was assessed to be normal, likely due to the large sample size available for these analyses. Regarding the stratified analyses conducted, the lack of statistically significant differences for some analyses could be due to limitations of sample size and power to detect a difference after stratification.

Self-efficacy

Question 8. **Are participants who receive SyV 2.0 more likely to have improved self-efficacy, as measured by the Diabetes Self-Efficacy Scale, after 12 months compared to participants who receive SyV 1.0? <u>This question is exploratory</u>.**

Overview of Analysis
To answer this exploratory question about intervention impact on diabetes-related self-efficacy, data were collected using the Diabetes Self-Efficacy Scale. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for the Diabetes Self-Efficacy Scale. The sample sizes for the presented analyses of self-efficacy are as follows: bivariate analyses (n=292), primary linear regression analyses (n=284), and longitudinal analyses (n=317).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 50** presents the mean diabetes-related self-efficacy values in each study period for the overall sample as well as the intervention and control groups. The overall study sample

had a mean diabetes-related self-efficacy score of 7.5 at baseline. For those who returned for a follow-up assessment, mean self-efficacy increased to 8.1 at 6-month follow up and again to 8.3 at 12-month follow-up. The intervention group began the study with a mean diabetes-related self-efficacy score of 7.5. For those participants in the intervention group who returned for a follow-up, mean self-efficacy score increased to 8.1 at 6-month follow-up and again to 8.3 at 12-month follow-up. The control group began the study at mean diabetes-related self-efficacy score 7.4. For those participants in the control group who returned for follow-up, mean self-efficacy score increased to 8.0 at 6-months and again to 8.2 at 12-months. As previously noted in **Table 19**, the intervention and control groups were statistically equivalent on diabetes-related self-efficacy 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 48**). The increases observed in diabetes-related self-efficacy from baseline to 12-month follow-up were statistically significant within both the intervention and control groups ($p<0.001$).

Bivariate analyses were also performed between the intervention and control groups comparing diabetes-related self-efficacy at 12-month follow-up, without controlling for any additional covariates (**Table 49**). Based on a p-value greater than 0.05 for diabetes-related self-efficacy when comparing the intervention and control groups at 12 months, the null hypothesis cannot be rejected. Diabetes-related self-efficacy 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, diabetes-related self-efficacy. 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 diabetes-related self-efficacy were: age, sex, time in SyV-1.0, primary language, ethnicity, marital status, education, baseline diabetes-related self-efficacy, number of comorbidities at baseline, and baseline PHQ-9 score.

$$Y_{(SelfEfficacy)}=\beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 SyV1.0 + \beta_5 Language + \beta_6 Ethnicity + \beta_7 MaritalStatus + \beta_8 Education + \beta_9 BL\_SelfEfficacy + \beta_{10} BL\_Comorb + \beta_{11} BL\_PHQ9 + \varepsilon$$

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

The final model of diabetes-related self-efficacy included those covariates with a p-value of 0.15 or less: ethnicity, baseline self-efficacy, and baseline PHQ-9 score:

$$Y_{(SelfEfficacy)}=\beta_0 + \beta_1 StudyArm + \beta_2 Ethnicity + \beta_3 BL\_SelfEfficacy + \beta_4 BL\_PHQ\text{-}9 + \varepsilon$$

Findings
Estimates for the final model of diabetes-related self-efficacy is presented in **Table 43**.

Mean diabetes-related self-efficacy at 12 months did not differ significantly by intervention status ($p=0.95$).

$Y_{(SelfEfficacy)}$=5.55 + 0.01(Intervention) + 0.40(NotHispanic) + 0.39(BL_SelfEfficacy) + -0.05(BL_PHQ-9)

Table 43. Effect of IBH Intervention on Twelve Month Diabetes-related Self-efficacy, Full UT Health SPH Sample

Variable	Self-efficacy (n=284)		
	Estimate (β)	Standard Error	p-value
Intervention	0.01	0.14	0.95
Control (ref)	--	--	--
Non-Hispanic	0.40	0.25	0.11
Hispanic (ref)	--	--	--
Baseline Self-efficacy	039	0.04	<0.001
Baseline PHQ-9	-0.05	0.01	<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 for self-efficacy, significant effect modification was identified by education, age, and gender, using conservative criteria of p-value ≤ 0.25. For age, the interaction term p-value was 0.24. However, in analyses of intervention effect stratified by age group, the intervention was not found to be significantly associated with self-efficacy in either group (results not shown).

For education, the interaction term p-value was 0.01. In analyses of intervention effect stratified by education, the intervention was not found to be significantly associated with self-efficacy among those who had not completed high school (see **Table 44**). Among those who had completed high school or higher, those in the intervention had significantly lower self-efficacy (see **Table 44**).

Table 44. Effect of IBH Intervention on Twelve Month Diabetes-related Self-efficacy, Stratified by Education

	High school or higher			Less than high school		
Variable	Self-efficacy (n=114)			Self-efficacy (n=170)		
	Estimate (β)	Standard Error	p-value	Estimate (β)	Standard Error	p-value
Intervention	**-0.42**	**0.20**	**0.04**	0.29	0.19	0.12
Control (ref)	--	--	--	--	--	--
Baseline self-efficacy	0.41	0.07	<0.001	0.38	0.06	<0.001
Baseline PHQ-9	-0.05	0.02	0.002	-0.04	0.02	0.03

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

For gender, the interaction term p-value was 0.02. In analyses of intervention effect stratified by gender, the intervention was not found to be significantly associated with self-efficacy among females (see **Table 49**). Among males, those in the intervention had significantly higher self-efficacy (β= 0.53, p=0.045).

Table 45. Effect of IBH Intervention on Twelve Month Diabetes-related Self-efficacy, Stratified by Gender

Variable	Male			Female		
	Self-efficacy (n=74)			Self-efficacy (n=210)		
	Estimate (β)	Standard Error	p-value	Estimate (β)	Standard Error	p-value
Intervention	**0.53**	**0.26**	**0.045**	-0.17	0.16	0.29
Control (ref)	--	--	--	--	--	--
Time in SyV 1.0	0.03	0.01	0.04	--	--	--
Baseline self-efficacy	0.31	0.08	<0.001	0.44	0.05	<0.001
Baseline PHQ-9	-0.09	0.03	0.002	-0.04	0.01	0.01

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

Analyses exploring the possible effect of receiving La Cocina Alegre or MTM services on self-efficacy among those in the intervention group who were referred to a service detected an effect that was statistically significant. Those who completed at least 4 La Cocina Alegre classes had a higher self-efficacy score than those who attended less than 4 classes (see **Table 46**).

Table 46. Effect of Receiving Minimum Dose for La Cocina Alegre Services, Intervention Participants

Variable	Self-efficacy (n=141)		
	Estimate (β)	Standard Error	p-value
Received minimum dose	**0.69**	**0.22**	**0.002**
Did not receive minimum dose (ref)	--	--	--
Male	0.55	0.21	0.01
Female (ref)	--	--	--
English	-0.36	0.21	0.09
Spanish (ref)	--	--	--
High school education or higher	-0.34	0.21	0.10
Less than high school education (ref)	--	--	--
Baseline self-efficacy	0.43	0.06	<0.001
Baseline PHQ-9	-0.04	0.02	0.04

Note: 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 differ by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For diabetes-related self-efficacy, only adjusting for intervention status and time, there was no significant time/group interaction with a p value of 0.96, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for diabetes-related self-efficacy score at our established threshold for statistical significance (see **Table 47**). Adjusting for the covariates that were selected in the primary model— language and baseline PHQ-9 - did not alter these results.

Table 47. Effect of IBH Intervention on Trajectory of Diabetes-related Self-efficacy across Twelve-Month Study, Full UTHealth SPH Sample

Variable	Self-efficacy (n=317)		
	Estimate (β)	Standard Error	p value
Time*Intervention	-0.01	0.17	0.96
Time*Control (ref)	--	--	--
Time	0.78	0.12	<0.001
Intervention	0.07	0.17	0.70
Control (ref)	--	--	--

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

Limitations

The distribution of this outcome was found to be non-normal and a nonparametric approach was taken for bivariate analyses. However, the use of linear regression methods for the endpoint analyses was not a concern. The distribution of errors for the linear regression model was assessed to be normal, likely due to the large sample size available for these analyses. Regarding the stratified analyses conducted, the lack of statistically significant differences for some analyses could be due to limitations of sample size and power to detect a difference after stratification.

Table 48. Within Group Bivariate Analyses Comparing Impact Measures from Baseline to 12 Months, by Intervention Group

INTERVENTION GROUP (n=176)				
	12-Month	Baseline	12-month (–) Baseline	*p*
	Mean (SD)	Mean (SD)	Mean Difference (SD)	
Systolic	133.0 (18.9)	135.4 (20.0)	-2.4 (19.2)	0.13
Diastolic	78.7 (10.7)	79.6 (12.8)	-0.83 (13.5)	0.47
Total Cholesterol	**185.1 (53.1)**	**195.5 (52.0)**	**-10.4 (47.5)**	**0.01**
Nonparametric Tests[a]	12-Month	Baseline	*p*	
	Median (SD)	Median (SD)		
HbA1c	**9.7 (1.9)**	**10.1 (1.3)**	**0.01**	
PHQ-9[b]	**1.0 (2.7)**	**3.0 (5.2)**	**<0.001**	
BMI	32.2 (7.2)	31.5 (7.5)	0.60	
General Health[d]	**76.7 (15.5)**	**73.4 (18.9)**	**<0.001**	
Medication Adherence[e]	**7.0 (1.4)**	**6.0 (1.7)**	**0.003**	
Self-efficacy	**8.8 (1.4)**	**8.0 (1.7)**	**<0.001**	
CONTROL GROUP (n=177)				
	12-Month	Baseline	12-month (–) Baseline	*p*
	Mean (SD)	Mean (SD)	Mean Difference (SD)	
Systolic	133.7 (16.0)	134.3 (19.0)	-0.55 (15.1)	0.67
Diastolic	77.9 (10.4)	78.8 (12.9)	-0.87 (12.8)	0.43
Total Cholesterol	189.0 (45.0)	191.5 (47.3)	-2.5 (45.4)	0.52
Nonparametric Tests[a]	12-Month	Baseline	*p*	
	Median (SD)	Median (SD)		
HbA1c	**9.9 (1.7)**	**10.2 (1.3)**	**0.003**	
PHQ-9	**2.0 (3.9)**	**4.0 (5.8)**	**<0.001**	
BMI[c]	31.6 (7.0)	31.5 (7.2)	0.08	
General Health[d]	**73.4 (17.3)**	**68.4 (18.5)**	**<0.001**	
Medication Adherence[e]	**7.0 (1.4)**	**6.0 (1.8)**	**<0.001**	
Self-efficacy	**8.5 (1.3)**	**7.9 (1.6)**	**<0.001**	

Note: Bold denotes statistical significance (p-value < 0.05) [a] The Wilcoxon Signed Rank test was used to examine non-normally distributed data; [b] Sample size in is 175 due to missing data for this measure ;[c] Sample size is 176 due to missing data for this measure; [d] Sample size for this measure is 348, Intervention= 174 control=174, due to missing data for this measure; [e] Sample size for this measure is 329, intervention=166 control=163, due to non-applicability to participants not taking medication.

Table 49. Between Group Bivariate Analyses Comparing Intervention to Control at 12-Month Follow-Up

	Full Sample (n=292)	Intervention (n=147)	Control (n=145)	*p*
	Mean (SD)	Mean (SD)	Mean (SD)	
Systolic	133.7 (17.8)	133.3 (18.6)	134.2 (16.9)	0.68
Diastolic	78.4 (10.5)	78.7 (10.7)	78.0 (10.4)	0.57
Total Cholesterol	188.4 (51.8)	185.6 (51.9)	191.3 (51.7)	0.34
Nonparametric Tests[a]	Median (SD)	Median (SD)	Median (SD)	*p*
HbA1c	9.8 (1.8)	9.7 (1.9)	9.9 (1.8)	0.88
PHQ-9	1.0 (3.5)	1.0 (3.0)	2.0 (3.9)	0.06
BMI[b]	32.0 (7.1)	32.2 (7.3)	31.7 (7.0)	0.67
General Health	75.1 (16.8)	76.7 (15.8)	73.4 (17.5)	0.06
Medication Adherence[e]	7.0 (1.4)	7.0 (1.4)	7.0 (1.4)	0.74
Self-efficacy	8.6 (1.4)	8.8 (1.4)	8.5 (1.4)	0.49

Note: Bold denotes statistical significance (p-value < 0.05); [a] The Wilcoxon rank sum test was used to examine non-normally distributed data; [b] Sample size in control group is 144 due to missing data for this measure; [c] Sample size for this measure is 288, intervention=145 control=143, due to non-applicability to participants not currently being treated with medication

Table 50. Impact Measures by Study Arm and Follow-up Period, Overall and by Intervention Group

	Full Sample			Intervention			Control		
	Baseline	6-Mo	12-Mo	Baseline	6-Mo	12-Mo	Baseline	6-Mo	12-Mo
	n=353	n=306	n=292	n=176	n=154	n=147	n=177	n=152	n=145
Measure		Mean (SD)			Mean (SD)			Mean (SD)	
HbA1c									
HbA1c	10.4 (1.4)	9.8 (1.7)	9.8 (1.8)	10.3 (1.3)	9.7 (1.8)	9.8 (1.9)	10.5 (1.4)	9.9 (1.6)	9.8 (1.8)
Missing	--	--	--	--	--	--	--	--	--
Blood pressure									
Systolic	136.1 (19.8)	132.5 (18.1)	133.7 (17.8)	136.3 (19.7)	133.7 (18.8)	133.3 (18.6)	135.9 (20.0)	131.3 (17.4)	134.2 (16.9)
Diastolic	79.8 (12.8)	78.0 (11.3)	78.4 (10.5)	80.0 (12.4)	78.6 (12.3)	78.7 (10.7)	79.5 (13.1)	77.4 (10.2)	78.0 (10.4)
Missing	--	--	--	--	--	--	--	--	--
BMI									
BMI	33.3 (7.3)	33.4 (7.1)	33.5 (7.1)	33.4 (7.4)	33.3 (7.2)	33.6 (7.3)	33.2 (7.1)	33.6 (7.0)	33.3 (7.0)
Missing	1	1	1	--	--	--	1	1	1
PHQ-9									
PHQ-9 Score	5.5 (5.6)	3.1 (4.2)	2.7 (3.5)	4.8 (5.3)	2.7 (4.0)	2.3 (3.0)	6.1 (5.9)	3.5 (4.3)	3.1 (3.9)
Missing	1	--	--	1	--	--	--	--	--
Duke Health Profile									
General Health	67.3 (18.7)	71.7 (18.4)	73.3 (16.8)	69.5 (18.8)	73.7 (18.0)	75.1 (15.8)	65.2 (18.4)	69.7 (18.7)	71.5 (17.5)
Mental Health	78.5 (23.0)	80.7 (22.5)	79.9 (20.4)	81.5 (21.7)	83.6 (21.0)	82.7 (19.0)	75.4 (23.9)	77.7 (23.6)	77.1 (21.4)
Physical Health	55.2 (28.9)	63.1 (27.6)	68.4 (26.8)	58.3 (28.8)	66.0 (27.9)	69.5 (26.0)	53.2 (29.0)	60.2 (27.1)	67.3 (27.5)
Social Health	68.5 (20.0)	71.3 (21.1)	71.7 (19.8)	70.2 (19.7)	71.4 (22.2)	73.4 (18.7)	66.9 (20.3)	71.2 (20.0)	70.0 (20.8)
Missing	5	1	--	2	--	--	3	1	--

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	Full Sample			Intervention			Control		
	Baseline	6-Mo	12-Mo	Baseline	6-Mo	12-Mo	Baseline	6-Mo	12-Mo
	n=353	n=306	n=292	n=176	n=154	n=147	n=177	n=152	n=145
Measure		Mean (SD)			Mean (SD)			Mean (SD)	
Total Cholesterol									
Total Cholesterol	194.3 (50.0)	185.6 (47.0)	188.4 (51.8)	195.6 (51.5)	184.2 (46.0)	185.6 (51.9)	193.1 (48.6)	187.1 (46.0)	191.3 (51.7)
Missing	--	--	--	--	--	--	--	--	--
Medication Adherence[a]									
Medication Adherence Score	5.8 (1.8)	5.9 (1.7)	6.4 (1.4)	5.9 (1.8)	6.0 (1.7)	6.4 (1.4)	5.7 (1.9)	5.8 (1.7)	6.4 (1.4)
Missing	--	--	--	--	--	--	--	--	--
Self-efficacy									
Self-efficacy score	7.5 (1.7)	8.1 (1.6)	8.3 (1.4)	7.5 (1.7)	8.1 (1.7)	8.3 (1.4)	7.4 (1.6)	8.0 (1.5)	8.2 (1.4)
Missing	--	--	--	--	--	--	--	--	--

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

Summary of Findings

This final report provides an overview of findings for the evaluation of UT Health SPH's SyV 2.0 program. UT Health SPH implemented an enhanced version of the CCM program (SyV 1.0) for participants who had not successfully lowered their HbA1c values in their first 6 months of their engagement with the program. This enhanced offering was designed to integrate primary and behavioral healthcare by adding the following evidence-based components to existing SyV 1.0 services: medication therapy management (MTM) services, peer led support groups (PLSGs), in clinic behavioral health services), and community-based life style programs (CBLP). UT Health SPH conducted an RCT to compare intervention participants receiving the delivery of enhanced integrated behavioral health (SyV 2.0) with control group participants receiving the usual care (services provided by SyV 1.0).

This evaluation study executed a robust RCT design, mitigating major threats to internal validity such as selection bias. The program was implemented to fidelity after the early implementation period and the evaluation was conducted as intended; however, due to delays in providing services participants did not receive a full twelve months of the intervention. The most significant threat to internal validity was differential attrition, but analyses of participants in the study compared to those lost to follow-up revealed there were no significant differences in health measures among these participants. There is no evidence that other threats to internal validity—history, instrumentation, etc.—were challenges in this study.

While the evidence-based interventions were adapted and evaluated using a method with strong internal validity, results do not indicate a change in the preliminary level of evidence assignment at this time. When controlling for baseline measures and other covariates, intervention assigned participants did not have statistically significant improvement in the HbA1c confirmatory outcome when compared to the control participants at 12 months. However, bivariate results within intervention and control groups showed improvements in HbA1c, PHQ-9, Duke General Health score, total cholesterol, medication adherence score, and diabetes self-efficacy. There is also evidence of effect modification of PHQ-9 score when stratifying by time enrolled in the SyV 1.0 program. The intervention was not found to be significantly associated with lower PHQ-9 score among those who spent less than the median tenure (21.5 months) SyV 1.0, but there was a positive effect among those intervention participants who spent more than the median tenure in SyV 1.0 (β= -1.28, p=0.01). This stratified analysis achieved an effect size of 0.36 (using Cohen's d), which may be interpreted as "small to moderate" based on Cohen's rule of thumb for interpretation of effect sizes (Cohen, 1988). There were no negative intervention effects on the confirmatory outcome; however, the intervention had negative effects on diastolic blood pressure for select subpopulations. For example, among those who spent less than the median tenure (21.5 months) in SyV 1.0, the intervention was associated with a significantly higher mean diastolic blood pressure (β= 4.68, p=0.004; d=0.44).

Despite its findings, this study contributes to our understanding of the implementation of an enhanced chronic care model in a community-based setting within a low-income, Hispanic population. Lessons learned included *adoption facilitators* such as increased communication, physical clinic space, data systems, staff relationships, staffing, and training; *adoption barriers* related to physical space for community-based programs, data systems, and hiring and staffing.

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Summary of Implementation Findings

The implementation evaluation examined fidelity to UT Health SPH's program model by examining participant referral and visit data as well as conducting focus groups and interviews. Evaluation of the implementation of the SyV 2.0 program shows the program was implemented in alignment with the program logic model to fidelity after the early implementation period. UT Health SPH exceeded their enrollment and retention targets for the study. Almost all participants enrolled in the intervention met study eligibility criteria and were referred to services, as appropriate; however, there was an overall delay in providing services. On average, participants were referred to services within a month of their randomization date (baseline date for this study). The average window of time for participants to receive services was 6-8 months from date of referral, except for behavioral health services, for which the average window of time for participants to receive services was within two months of their referral date (See Tables 1-4). Due to these delays, participants did not receive a full twelve months of the intervention. Additionally, while most participants were referred to La Cocina Alegre (98.9%), peer-led supports groups (98.3%), and MTM services (69.3%), and over a third of participants were referred to behavioral health services (36.4%), less than half of scheduled visits were completed. Consequently, a majority of those who remained in the study for the 12 months did not receive a minimum dose of the intervention (See Tables 5-8). Of those referred to La Cocina Alegre services, 19.0% of participants attended the minimum 4 classes (Table 4). For MTM services, nearly half (49.0%) of referred participants had 2 MTM visits. Five participants referred to BHS services received the minimum 2 visits (7.8%). Of those referred to PLSGs, five attended the minimum 2 sessions (2.9%). No participants received MEND! services because few participants met eligibility criteria. MEND was designed for adults and children in a given household. However, the enrollment population primarily included older adults who often did not have young children.

A delayed timeline in enrollment was the main deviation from the SEP; recruitment was extended by two months to meet the enrollment target of 350 participants. UT Health SPH revised its study eligibility criteria because the criteria were originally too narrow to recruit a sufficient sample size over the specified time period. A detailed timeline of the study can be found in Appendix A.

Additional implementation deviations from the approved SEP included changes in program inputs (see logic model components), having the program manager ascertain if participants met inclusion criteria rather than the CCM team, and collecting participant data via paper forms and then entering data into REDCap, rather than entering data directly into REDCap.

Findings from staff interviews and participant focus groups in the implementation study revealed facilitators and barriers to program adoption. Primary perceived facilitators to program implementation included: increased communication via promotores, Chronic Care Management (CCM) meetings, and physical space (i.e., co-location of staff). According to program participants and staff interviewees, promotores played a key role in ensuring continuous communication with participants and facilitating program participants' engagement with recommended services via phone calls, texts, home visits, and other interactions. CCM meetings were described as facilitating discussion among primary care providers, behavioral health providers, and promotores when developing care plans for participants. According to staff interviewees, co-located clinic space for providers and office space for program partners offered opportunities to communicate about participant needs and services and served to strengthen relationships among UT Health SPH program staff and community-based partners.

Common adoption barriers identified included data systems, hiring and staffing, and the location of services which limited accessibility for participants. While data systems (i.e., REDCap, Wellcentive, and MTM Path) were described as facilitating implementation, several clinical staff and UT Health SPH program staff interviewees cited the need to strengthen training in REDCap, Wellcentive, and MTM Path prior to program implementation, and to enhance IT support for data systems. Staff interviewees also noted that significant delays in hiring staff challenged early implementation of SyV 2.0 by burdening staff with multiple roles. Similarly, staff interviewees identified the need for additional staffing, including a PLSG facilitator, promotores, and administrative support.

Limited transportation to clinic and community-based services was the most common participant barrier that emerged in focus groups and interviews, including significant travel times and difficulty scheduling a ride from family members. Despite early implementation challenges UT Health SPH implemented the SyV 2.0 to fidelity by the midpoint of the project by working diligently to facilitate communication and workflows to support integration. However, it is important to note that due to delays in providing services participants did not receive a full twelve months of the intervention.

Summary of Impact Findings

The main impact study and its related analyses were conducted as proposed in the SEP. This RCT impact study did not show that the enhanced version of the CCM program had a significant association with health outcomes among intervention participants with in the 12-month study period when compared to control participants; however, there were statistically significant improvements in health outcomes within each group.

The confirmatory variable for this study was diabetes as measured through HbA1c level. After 12 months in the program, intervention participants were not more likely than control participants to see significant improvements in their HbA1c levels, when controlling for age, sex, and baseline characteristics. However, bivariate results within intervention and control groups showed improvements in HbA1c, PHQ-9, Duke General Health score, total cholesterol, medication adherence score, and diabetes self-efficacy. This could indicate that SyV 1.0 (usual care) was effective at improving health outcomes; therefore, no statistically significant differences were observed between intervention and control. Alternatively, given that most intervention participants did not receive the minimum dose of services, the level of exposure to the additional program components may have been too low to detect the effect of the intervention, and only detected the standard program effect.

While the RCT impact study did not show statistically significant differences in physical health improvements between intervention and control participants overall, models were stratified to examine whether outcomes differed for important subpopulations. As previously mentioned, the intervention was not found to be significantly associated with lower PHQ-9 score among those who spent less than the median tenure (21.5 months) SyV 1.0, but there was a positive effect among those intervention participants who spent more than the median tenure in SyV 1.0 (β= -1.28, p=0.01, d=0.36). The intervention was also associated with a significantly higher mean diastolic blood pressure among those participants with lower than median tenure in SyV 1.0 (β= 4.68, p=0.004). Among participants referred to MTM, those participants who received the minimum dose of MTM had a significantly higher diastolic blood pressure than those who did not receive minimum dose (β= 6.65, p=0.0.03). Finally, among those referred to La Cocina Alegre, those who received the minimum dose of La Cocina classes had a

significantly higher self-efficacy compared to those who did not receive minimum dose (β= 0.69 p=0.002).

Lessons Learned, Study Limitations, and Next Steps

This evaluation contributes to our understanding of the implementation and impact of an enhanced CCM program. The rationale behind the intervention is that comprehensive and coordinated community services (e.g., cooking classes, peer-led support groups, and programs to address family obesity) and clinical care services (i.e., MTM and behavioral health) delivered to adults with uncontrolled diabetes will lead to improved physical and mental health outcomes. UT Health SPH incorporated additional evidence-based components into their intervention. Prior evidence for these additional evidence-based components include a quasi-experimental study which found that diabetic patients who received MTM services significantly improved or maintained HbA1c levels (Cranor et al, 2003) and an RCT providing CBLPs and PLSGs to diabetics which resulted in significant reductions in HbA1c levels among the intervention group (Haltiwanger & Brutus, 2012). UT Health SPH built upon this work by combining multiple evidence-based components to more efficiently and effectively care for participants' health needs in a low resource setting. The following summary outlines key lessons learned, study limitations, and next steps.

Lessons Learned
While significant findings were limited, several lessons emerged that could inform other organizations interested in implementing a similar model.

Operational Facilitators
As described in findings from the implementation evaluation, there were three primary elements that facilitated success. First, promotores were central to coordination of participant care. Key activities of promotores included: conducting phone-based outreach and home visits with participants, building relationships with participants by maintaining regular contact, discussing stressors and concerns navigated by participants, working with participants to mitigate stressors and barriers that may affect health (e.g., transportation barriers), and coordinating care by scheduling participant appointments. Second, bi-weekly CCM meetings were a critical component of care coordination. Promotores were also central to CCM meetings, which included other program staff, program partners, pharmacists, and representatives from each clinic. CCM meetings leveraged promotoras' assessments and updates of participants' health, data systems, and the perspectives of clinical providers and UT Health SPH program staff to discuss and revise case management plans for participants whose HbA1c levels had increased. Lastly, co-location of primary care and behavioral health providers as well as community-based partners and promotores, fostered opportunities to build relationships and communicate across services.

Study Limitations and Implications for Future Research

It is important to note the limitations of this study. SyV 2.0 evaluation findings show that while there were improved health outcomes within the intervention and control groups, intervention participants were not more likely than control participants to see significant improvements in these outcomes. It is possible these physical and mental health outcomes require a longer term (e.g., more than a year) to manifest into meaningful changes and observing these outcomes with a longer follow-up period may yield different results.

The study timeline required simultaneous implementation of the evaluation and intervention. Study recruitment and enrollment were occurring while UT Health SPH was adapting workflows in coordination with several partners to provide new services. As a result, there was a delay in providing services to intervention participants. As previously mentioned, the average window of time for participants to receive services was 6-8 months from date of referral, except for behavioral health services, for which the average window of time for participants to receive services was within two months of their referral date. Due to these delays, participants did not receive a full twelve months of the intervention. Additionally, because the target population for the study was comprised of participants who had been enrolled in SyV 1.0 for 6 to 36 months with uncontrolled diabetes (HbA1c ≥ 8%), it is possible these participants were less likely to access the additional services available through the intervention.

Defining SyV 1.0 as usual care does not reflect the standard of care among the target population for this study and may have reduced the ability to detect the effect of SyV 2.0. Given that statistically significant improvements in confirmatory and exploratory measures were observed within the control and intervention group -- including HbA1c, PHQ-9, Duke General Health score, medication adherence score, and diabetes self-efficacy – SyV 1.0 may have been effective at improving health outcomes. Using a control group that receives a standard of care distinct from SyV 1.0, could better demonstrate the effect of the additional services provided by SyV 2.0. Alternatively, given that most intervention participants did not receive the minimum dose of services, the level of exposure may have been too low to detect the effect of the intervention.

This study examined the effectiveness of the intervention as a whole and was not designed to evaluate the effectiveness of each specific component of the intervention. Future research might want to consider examining the effect of MTM and BHS alone, for example, without the inclusion of CBLPs. Given sustainability challenges ahead, future research may also want to examine different doses of the intervention to identify what is the minimum amount that achieves impact across the study population.

Next Steps

UT Health SPH is reviewing findings from this study to improve the implementation of SyV 2.0. Since the study, UT Health SPH has expanded access to 2.0 clinic services (MTM and BH) and La Cocina Alegre to all participants in SyV in the region. Collaborations with two new clinic partners has been initiated to be able to offer MTM and BH at their facilities as well. Two additional floating pharmacists have been hired to assist in the delivery of MTM in the region. A new workflow is being developed for the UT Health SPH Patient Navigators that are housed in our partner clinics to be able to refer newly enrolled SyV participants to MTM and BH services. A collaboration with Tropical Texas Behavioral Health is being initiated to include provision of BH services to SyV participants that do not want to receive them at their respective clinic.

UT Health SPH is also working to improve workflows. For example, access to patient data in MTMPath is necessary to maximize the usefulness of this data system. Establishing the dataflow of patient data from the clinic's EMR into MTM Path was a long and complicated process. However, once this dataflow was fully established, it made the provision of MTM services much easier. The plan is to immediately establish a similar dataflow for any new clinic collaborations. Individualized standing meetings with all partners to provide progress updates and discuss any areas of improvement was found to be helpful in expediting the referral process. The plan is to hold more frequent standing meetings with any new

collaborators to help establish workflows and dataflows quickly to avoid any delays. Additionally, a strategy that was deemed helpful in scheduling referral appointments during the study is currently being piloted with control participants. Specifically, during home visits the promotores are scheduling MTM or BH appointments on behalf of control participants. If this process continues to show positive results (i.e., appointment is scheduled, and the participant attends the appointment), this strategy will be employed for all participants.

UT Health SPH is planning to continue the Chronic Care Model but is examining these findings and their operational plans to determine how to modify the model so it is financially sustainable. For example, peer-led support groups are no longer being offered due to low attendance. UT Health SPH is also participating in capacity building around financial sustainability and conducting further data analysis to examine the effects of SyV 1.0, including a cost-savings analysis. These efforts will help market the program and model to potential partners, such as health systems, managed care providers and other funders.

OTHER ASPECTS OF STUDY LOGISTICS AND FEASIBILITY

Human Subjects Protection

UT Health SPH submitted its initial research protocol on January 20, 2016 to the University of Texas Health Science Center at Houston Committee for the Protection of Human Subjects (the Committee) for their determination of risk and approval of study procedures. The Committee approved UT Health SPH's initial research protocol on March 16, 2016 (protocol reference number HSC-SPH-16-0044). UT Health SPH submitted an amendment on September 13, 2016 and received approval for that amendment on September 23, 2016. No enrollment took place while the amendment was being reviewed by the Committee. UT Health SPH did not encounter any problems securing approval from the Committee and received approval according to the planned study timeline. In accordance with IRB procedures, UT Health SPH submitted continuing review reports to the Committee which were approved on November 16, 2016, September 19, 2017, and August 16, 2018. No deviations in research protocol have occurred to-date.

Timeline

Program recruitment and baseline data collection began September 2016 and concluded May 2017; this program had an 8-month enrollment period and utilized a rolling recruitment. This is a deviation from the planned timeline in the SEP in that the plan was to end enrollment in March 2017 Recruitment was extended by two months to meet the enrollment target of 350 participants. In December 2016, UT Health SPH determined that its eligibility criteria were too narrow to recruit sufficient sample size. In January 2017, UT Health SPH submitted to SIF and received approval for a SEP amendment to revise study eligibility criteria. Twelve-month follow up occurred between November 2017 and June 2018. Participant de-identified data was sent quarterly to HRiA (September 2016 – May 2018) with a final data submission in August 2018. The dates for the interim and final reports were revised accordingly. This final report was generated by HRiA and sent to SIF/CNCS for review and approval in February 2019.

Evaluator/Subgrantee Role and Involvement

No major changes were made to the evaluator and subgrantee personnel listed in the subgrantee evaluation plan during the project period. The Principal Investigator of record for the study under the IRB protocol is Belinda Reininger.

Budget

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

REFERENCES

Altman DG. Comparability of randomised groups. Statistician. 1985;34:125–136.

American Diabetes Association. (2014). Standards of medical care in diabetes--2014. *Diabetes Care*, *37 Suppl 1*, S14–80. http://doi.org/10.2337/dc14-S014

American Heart Association. (2015). Understanding Blood Pressure Readings. Retrieved July 22, 2015, from http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/AboutHighBloodPressure/Understanding-Blood-Pressure-Readings_UCM_301764_Article.jsp

American Psychiatric Association. (1994). *Quick Reference to the Diagnostic Criteria from DSM-IV*. Washington, DC: Press, Inc.

Bandura, A. (1986). Social foundations of thought and action: a social cognitive theory. Englewood Cliffs, NJ: Prentice-Hall.

Birtcher, K. K., & Ballantyne, C. M. (2004). Cardiology patient page. Measurement of cholesterol: a patient perspective. *Circulation*, *110*(11), e296–7.

CDC. (2011). Health Related Quality of Life. Retrieved July 22, 2015, from http://www.cdc.gov/hrqol/concept.htm

Cohen, D.J., Balasubramanian, B.A., Davis, M., Hall, J., Gunn, R., Stange, K.C. Miller, B.F. (2015). Understanding Care Integration from the Ground Up: Five Organizing Constructs that Shape Integrated Practices. *Journal Of The American Board Of Family Medicine: JABFM, 28 Suppl 1,* S7-S20 https://doi.org/10.3122/jabfm.2015.S1.150050

Cranor, C. W., Bunting, B. A., & Christensen, D. B. (2003). The Asheville Program: long-term clinical and economic outcomes of a community pharmacy diabetes care program. JAPHA-WASHINGTON-, 43(2), 173-184.

Davila, V., Rodriguez, D., Urbina, L., & Nino, A. (2014). *Regional Needs Assessment: Region XI (Regional No. 2). Pharr, TX: Behavioral Health Solutions of South Texas*.

Fisher-Hoch, S. P., Vatcheva, K. P., Laing, S. T., Hossain, M. M., Rahbar, M. H., Hanis, C. L., … McCormick, J. B. (2012). Missed opportunities for diagnosis and treatment of diabetes, hypertension, and hypercholesterolemia in a Mexican American population, Cameron County Hispanic Cohort, 2003-2008. *Preventing Chronic Disease*, *9*, 110298. http://doi.org/10.5888/pcd9.110298

Fitzmaurice, G. M., Laird, N. M., & Ware, J. H. (2004). *Applied longitudinal analysis*. Hoboken, N.J: Wiley-Interscience.

Goodman, S.N., & Berlin, J.A. (1994). The Use of Predicted Confidence Intervals When Planning Experiments and the Misuse of Power When Interpreting Results. *Ann Intern Med, 121, 200-206.* Retrieved from: https://dirnagl.files.wordpress.com/2014/07/goodman-the-use-of-predicted-confidence-intervals-when-planning-experiments-and-the-misuse-of-power-when-interpreting-results-ann-intmed-1994.pdf

Haltiwanger, E. P., & Brutus, H. (2012). A Culturally Sensitive Diabetes Peer Support for Older Mexican-Americans. Occupational therapy international,19(2), 67-75.

Han, B., Enas, N.H., McEntegart, D. (2009) Randomization by minimization for unbalanced treatment allocation. *Statist. Med*.; 28:3329–3346

Harris, P. A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., & Conde, J. G. (2009). Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J. Biomed. Inform*., 42, 377-381.

Liebschutz JM**,** Xuan Z, Shanahan CW, LaRochelle M, Keosaian J, Beers D, Guara G, O''Connor K, Alford DP, Parker V, Weiss RD, Samet JH, Crosson J, Cushman PA, Lasser KE. (2017) Improving Adherence

to Long-term Opioid Therapy Guidelines to Reduce Opioid Misuse in Primary Care: A Cluster-Randomized Clinical Trial. *JAMA Intern Med*. 2017 Sep 01; 177(9):1265-1272

National Guideline Clearinghouse. (2014). Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. Rockville MD: Agency for Healthcare Research and Quality (AHRQ). Retrieved from http://www.guideline.gov/content.aspx?id=48872&search=waist+circumference

National Guidelines Clearinghouse. (2011). Hypertension. Clinical management of primary hypertension in adults. Rockville MD: Agency for Healthcare Research and Quality (AHRQ). Retrieved from http://www.guideline.gov/content.aspx?id=34824

Pocock, S.J., Simon, R. (1975) Sequential Treatment Assignment with Balancing for Prognostic Factors in the Controlled Clinical Trial. *Biometrics*, Vol. 31, No. 1, 103-115.

Prochaska, J. & Velicer, W. (1997). The transtheoretical model of health behavior change. *American Journal of Health Promotion:* 12(1), 38-48.

R Core Team (2013). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0, URL http://www.R-program.org/

Rosenbaum, P. R., & Rubin, D. B. (2012). Constructing a Control Group Using Multivariate Matched Sampling Methods That Incorporate the Propensity Score. *The American Statistician*. Retrieved from http://amstat.tandfonline.com/doi/abs/10.1080/00031305.1985.10479383#.VgxA4vlViko

Rubin DB and Thomas N. Matching using estimated propensity scores: relating theory to practice, 1996, BIOMETRICS , 52, 249-264.

Rubin, D. B. (2001). Using Propensity Scores to Help Design Observational Studies: Application to the Tobacco Litigation. *Health Services and Outcomes Research Methodology*, *2*(3-4), 169–188. http://doi.org/10.1023/A:1020363010465

Senn S. Testing for baseline balance in clinical trials. Stat Med. 1994;13:1715–1726.

Staten, L., Cutshaw, C., Davidson, C., Reinschmidt, K. Steward, R., Roe, D., (2012). Effectiveness of the Pasos Adelante chronic disease prevention and control program in a US-Mexico Border Community, 2005-2008. Preventing Chronic Disease 2012; 9: 100301

Stuart, E. A. (2008). Developing practical recommendations for the use of propensity scores: discussion of "A critical appraisal of propensity score matching in the medical literature between 1996 and 2003" by Peter Austin, Statistics in Medicine. *Statistics in Medicine*, *27*(12), 2062–5; discussion 2066–9. http://doi.org/10.1002/sim.3207

Sumlin, L. L., Garcia, T. J., Brown, S. A., Winter, M. A., García, A. A., Brown, A., & Cuevas, H. E. (2014). Depression and adherence to lifestyle changes in type 2 diabetes: a systematic review. *The Diabetes Educator*, *40*(6), 731–44. http://doi.org/10.1177/0145721714538925

U.S. Census Bureau. (2013). 2013 American Community Survey 5-Year Estimates. Retrieved from http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_13_5YR_S0501&prodType=table

University of Wisconsin Population Health Institute. (2015). County Health Rankings 2015. Retrieved June 26, 2015, from http://www.countyhealthrankings.org/sites/default/files/state/downloads/2015 County Health Rankings Texas Data - v1_0.xls

Wagner, E. H. (1998). Chronic disease management: what will it take to improve care for chronic illness? *Effective Clinical Practice: ECP*, *1*(1), 2–4. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/10345255

Woltmann, E., Grogan-Kaylor, A., Perron, B., Georges, H., Kilbourne, A. M., Bauer, M. S. Comparative effectiveness of collaborative chronic care models for mental health conditions across primary,

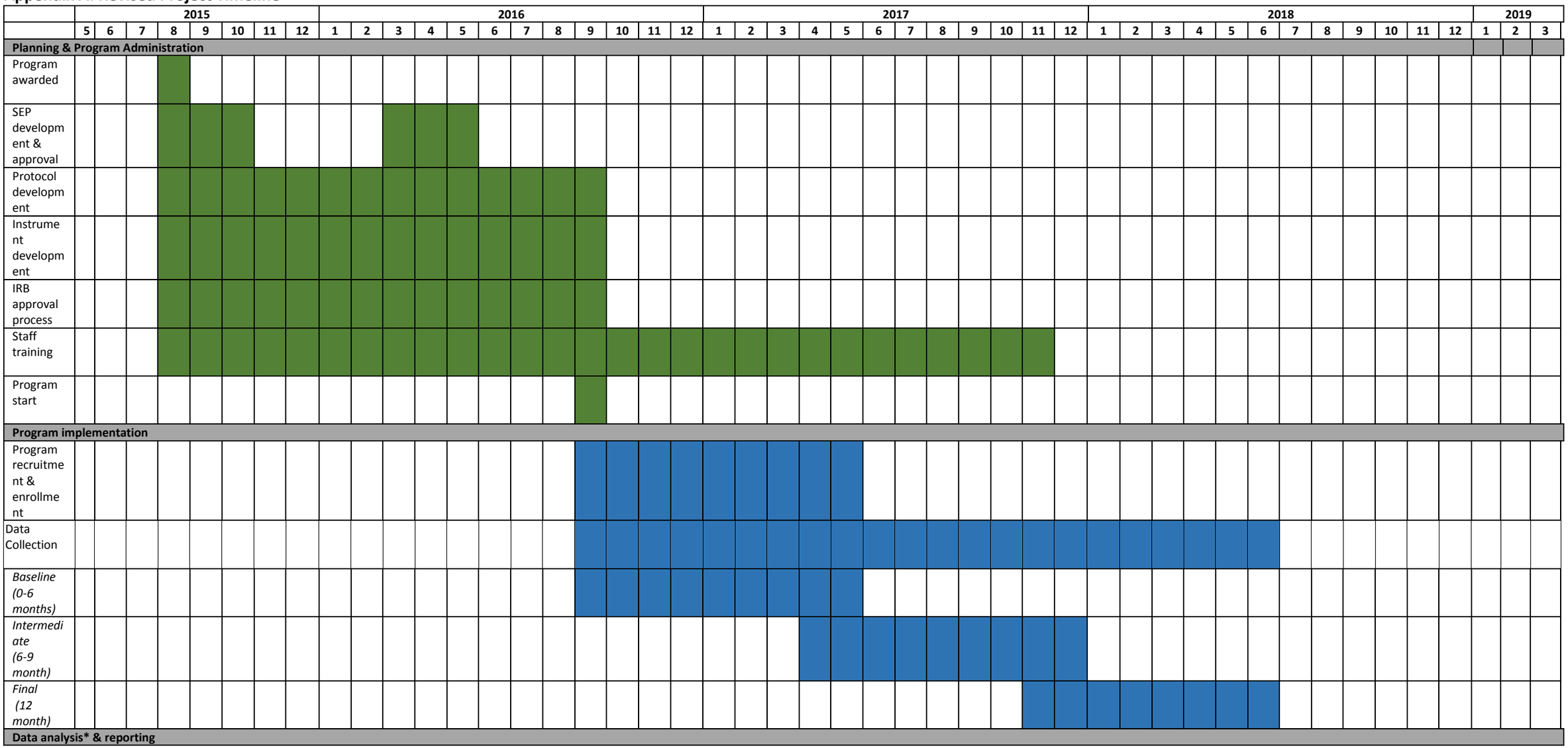
specialty, and behavioral health care settings: systematic review and meta-analysis (2012). Am J Psychiatry. 2012 Aug;169(8):790-804. doi: 10.1176/appi.ajp.2012.11111616

World Health Organization definition of integrated care. (2008). Retrieved from http://www.who.int/healthsystems/service_delivery_techbrief1.pdf

APPENDICES

Subgrantee: University of Texas Health Science Center at Houston School of Public Health
Project Title: Salud y Vida 2.0

Appendix A: Revised Project Timeline



Subgrantee: University of Texas Health Science Center at Houston School of Public Health
Project Title: Salud y Vida 2.0

	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
HRiA (quarterly reporting)																																														
Data cleaning & analysis[1,2]																																														
Report writing & editing[1,2]																																														
Report to CNCS[1,2]																																														
Reports to partners/ stakeholders[1,2]																																														
Reports to public/scientific com. [1,2]																																														

*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] Annual; [2] Final

Subgrantee: University of Texas Health Science Center at Houston School of Public Health
Project Title: Salud y Vida 2.0

Appendix B: Program Logic Model

			Outcomes*		
Inputs	**Activities**	**Outputs**	**Short-term**	**Intermediate**	**Long-term**
Program personnel: • CHW • DSME • TS • Pharm/tech • Primary care clinicians (e.g., RN, PA) • Peer leaders • Behavioral health counselors • UTSPH Program staff • Chronic Care Management (CCM) **Program partners:** • Brownsville Wellness Coalition • Infant and Family Nutrition Agency • Proyecto Juan Diego • Tropical Texas Behavioral Health • UTRGV/UT Austin College of Pharmacy Cooperative Pharmacy Program • Rio Grande State Center • Su Clinica **Program funders:** • Methodist Healthcare Ministries • Valley Baptist Legacy Foundation **Other resources:** • Valley Baptist Health Systems • RGV Health Information Exchange • Wellcentive • MTMPath • REDCap	**Behavioral health counseling** • Behavioral health counselors provide services **Medication Therapy Management** • Pharmacists trained and certified in MTM • Establish MTM services for individuals with low medication adherence **Community-based lifestyle programs** • Offer Cocina Alegre 6-week course • Offer MEND! 10-week obesity program **Care Coordination** • CCM develops individual health plans • Bi-monthly case review meetings • Provide partners with requested resources **Peer Led Support Groups** • Train peer leaders • Establish face-to face and phone-based PLSGS	• Recruit 175 participants into each arm of the study (intervention and control groups) • Health education protocols developed • Referral protocols developed • Participants engaged in health care system and enrolled in study through program partners and UTSPH • Agreements among program partners • New resources for partner capacity development	• ***Eligible participants enrolled, screened, and baseline measures obtained*** • ***Participants receive care plan*** • Implementation and improvement of health education protocols • ***Implementation and improvement of referral protocols*** • Increased number of participants engaged in health care system • Increased capacity among program personnel and partners • ***Increased confidence in performing diabetes self-care practices*** • Increased awareness of services	• Increased patient understanding of obesity, diabetes, and depression • ***Increased patient self-efficacy for disease management*** • ***Increased patient compliance with treatment plans*** • ***High patient satisfaction*** • Risk factor reduction through lifestyle modification and clinical intervention • ***Reduced blood pressure levels, BMI, HbA1c, cholesterol, and depressive symptoms*** • Increased control of blood pressure, weight, cholesterol, and HBA1c level • ***Increased functioning and quality of life***	• Improved depression, cholesterol, blood pressure, diabetes, BMI, and quality of life • Reduced morbidity due to physical and behavioral health conditions • Improved integration between program partners • Reduced disparities in complications from hypertension, obesity, diabetes, and depression

- ***Bold, italicized*** text indicates outcomes measured via evaluation

Subgrantee: University of Texas Health Science Center at Houston School of Public Health
Project Title: Salud y Vida 2.0

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

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

INTRODUCTION/INFORMED CONSENT

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

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

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

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

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

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

Subgrantee: University of Texas Health Science Center at Houston School of Public Health
Project Title: Salud y Vida 2.0

INTERVIEW QUESTIONS

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

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

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

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

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

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

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

6. Operations (Choose Clinic or Community as appropriate)

Clinic-based Operations

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

Community-based Operations

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

7. Patient and Provider Satisfaction

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

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

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

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

10. Closing

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

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

Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide

CORE INTERVIEW GOALS

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

INTRODUCTION/INFORMED CONSENT (2 MIN)

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

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

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

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

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

Subgrantee: University of Texas Health Science Center at Houston School of Public Health
Project Title: Salud y Vida 2.0

INTERVIEW QUESTIONS

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

Key Informant Background (3 MIN)

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

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

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

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

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

Adoption Facilitators and Barriers (15 MIN)

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

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

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

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

Provider and Patient Satisfaction (5 MIN)

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

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

Program Impact (5 MIN)

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

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

Sustainability and Lessons Learned (10 MIN)

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

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

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

Closing (2 MIN)

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

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

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

NEIRB 120170278
#96104.0

CORE FOCUS GROUP GOALS

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

INTRODUCTION (5 MIN)

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

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

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

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

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

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

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

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

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

INTRODUCTION AND WARM-UP (5 MIN)

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

PROGRAM RECRUITMENT (10 MIN)

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

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

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

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

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

   i. In what ways has the program/service/study met your needs?
   ii. What was helpful to you?
b. What did you like least about the program/service/study?
c. What could have made your experience better?

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

PROGRAM VALUE/IMPACT (10-15 MIN)

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

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

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

CLOSING/INCENTIVE DISTRIBUTION (2 MIN)

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

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

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

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Project Title: Salud y Vida 2.0

Appendix F: Implementation Evaluation Measures

Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
REACH: Did the SyV 2.0 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 SyV 2.0 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 UTSPH implement the SyV 2.0 model with fidelity?				
What are the resources of the program?	Input: CHW	--	What is your current role?	Yes/No
What are the resources of the program?	Input: DSME	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
What are the resources of the program?	Input: TS	--	What is your current role?	Yes/No
What are the resources of the program?	Input: Pharm/tech	--	What is your current role?	Yes/No
What are the resources of the program?	Input: Primary care clinicians (e.g., RN, PA)	--	What is your current role?	Yes/No

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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: Peer leaders	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
What are the resources of the program?	Input: Behavioral health counselors	--	What is your current role?	Yes/No
What are the resources of the program?	Input: UTSPH Program staff	--	What is your current role?	Yes/No
What are the resources of the program?	Input: Chronic Care Management (CCM)	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
What are the resources of the program?	Input: Brownsville Wellness Coalition	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Healthy Communities Brownsville	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Infant and Family Nutrition Agency	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No

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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: Proyecto Juan Diego	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Tropical Texas Behavioral Health	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: UTRGV/UT Austin College of Pharmacy Cooperative Pharmacy Program	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Rio Grande State Center	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Su Clinica	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Methodist Healthcare Ministries	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Valley Baptist Legacy Foundation	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No

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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: Valley Baptist Health Systems	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: RGV Health Information Exchange	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the program activities and how have they been operationalized?	Activity: Pharmacists trained and certified in MTM	--	--	Yes/No
What are the program activities and how have they been operationalized?	Activity: Establish MTM services for individuals with low medication adherence	• Type of clinic services delivered/follow-up care visit o Number of medication therapy management visits • Diabetes medication adherence score (Diabetes Medication Adherence Questionnaire) • Frequency of adjusting referrals/treatments if participants do not participate in care plan • Number of participants receiving appropriate intervention (as determined by assessments)	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	None (possibly adherence to other medication other than diabetes if that is not covered in one of the other bullet points)

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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: Offer Cocina Alegre 6-week course	• Number of community-based lifestyle classes/sessions received o Number of Cocina Alegre classes	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?	Number of Cocina Alegre classes offered
What are the program activities and how have they been operationalized?	Activity: Establish relationships with restaurants to have "diabetes friendly" meals	--	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: Offer MEND! 10-week obesity program	• Number of community-based lifestyle classes/sessions received o Number of MEND! Family Obesity Program classes	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?	Number of MEND! classes offered
What are the program activities and how have they been operationalized?	Activity: CCM develops individual health plans	• Number of participants receiving care plan • Number of participants receiving appropriate intervention (as determined by assessments) • Receipt of intervention by review of participant care plans	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	None

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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: Bi-monthly case review meetings	• Frequency of adjusting referrals/treatments if participants do not participate in care plan	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No (the bullet point is only for participants who do not participate in care plans, case reviews may include other participants)
What are the program activities and how have they been operationalized?	Activity: Provide partners with requested resources	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
What are the program activities and how have they been operationalized?	Activity: Train peer leaders	--	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: Establish face-to face and phone-based PLSGS	• Number of community-based lifestyle classes/sessions received o Number of peer-led support group sessions	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?	Number of PLSGS offered

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Project Title: Salud y Vida 2.0

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: Recruit 175 participants into each arm of the study (intervention and control groups)	• Number of target participants • Number of participants screened for participation in the study • Number of participants consented to participate in the study • Number of participants who refused to participate in the study • Number of participants enrolled in the program	--	None
Are the components different than what was planned? If so, why?	Output: Health education protocols developed	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
Are the components different than what was planned? If so, why?	Output: Referral protocols developed	• Number of 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?	Yes/No protocols developed

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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: Participants engaged in health care system and enrolled in study through program partners and UTSPH	• Number of visits completed • Receipt of intervention by review of participant care plans • Receipt of intervention by review of participant attendance • Overall treatment participation or show rate • Percentage of participants who complete their care plan • Participant encounters by provider and CHW • Number of clinic visits/Follow-up care visits received	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
Are the components different than what was planned? If so, why?	Output: Agreements among program partners	--	How would you describe your partnership(s) with external organizations related to this program? What role have these partnerships played in early implementation?	Yes/No
Are the components different than what was planned? If so, why?	Output: New resources for partner capacity development	--	How would you describe your partnership(s) with external organizations related to this program? What role have these partnerships played in early implementation?	Yes/No, count of resources

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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?*
INTEGRATION: What level of Integrated Behavioral Health did SyV 2.0 achieve as a result of implementing the program?				
What level of Integrated Behavioral Health did SyV 2.0 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 SyV 2.0 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?	
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?	

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Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
To what extent 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?	
To what extent did the control 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 control group that receive 1 program-like component

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Research question/subquestions	**Logic Model Elements/Components** *What are we measuring to answer this research question?*	**Quantitative Indicator(s) Captured** *What data is being collected by subgrantee that we could use to capture this?*	**Qualitative Data** *What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?*	**Qualitative/quantitative Indicator(s) Needed** *If gap, what quantitative data do we need?*
How satisfied are SyV 2.0 patients with the services they have received? How satisfied are providers with the SyV 2.0 program?				
--	--	Participant satisfaction with Salud y Vida 2.0	• What do you think participants in general would say about the program? Would you mind sharing any general themes from feedback you have heard from participants about the program? • Have you heard any feedback from providers about program implementation? What are some of the general themes from their feedback been? • To what extent have there been challenges to retaining primary care, behavioral health, or community-based staff during the course of the [name of subgrantee program]? Why do you think there have been challenges, and what has been done to address those challenges?	None

Appendix G: Loss to Follow-Up/Attrition Tables

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

	Full Sample (n=353)		Completed Study (n=293)		Did Not Complete Study (n=60)		p value
Variables	N	%	N	%	N	%	
Sex							
Male	104	29.5	77	26.3	27	45.0	**0.004**
Female	249	70.5	216	73.7	33	55.0	
Missing	--	--	--	--	--	--	
Ethnicity[a]							
Hispanic/Latino	325	92.1	271	92.5	54	90.0	0.60
Non-Hispanic/Non-Latino	88	7.9	22	7.5	6	10.0	
Missing	--	--	--	--	--	--	
County[a]							
Cameron	352	99.7	292	99.7	60	100.0	0.99
Willacy	1	0.3	1	0.3	0	0.0	
Missing	--	--	--	--	--	--	
Age							
<35	16	4.5	14	7.8	2	3.3	0.55
35-44	61	17.3	50	17.1	11	18.3	
45-54	136	38.5	108	36.9	28	46.7	
55-64	124	35.1	108	36.9	16	26.7	
65+	16	4.5	13	4.4	3	5.0	
Mean (SD)	51.5 (9.1)		51.6 (9.1)		51.5 (9.4)		0.97
Employment Status							
Employed	42	12.1	35	12.2	7	11.9	0.36
Not employed	213	61.4	181	62.9	32	54.2	
Other	92	26.5	72	25.0	20	33.9	
Missing	*6*	--	5	--	1	--	
Marital Status							
Married	163	46.8	151	52.3	34	57.6	0.45
Unmarried	185	53.2	138	47.8	25	42.4	
Missing	5	--		--		--	
Education							
Less than high school	207	59.1	174	60.0	33	55.0	0.47
High school graduate/GED or higher	143	40.9	116	40.0	27	45.0	
Missing	*3*	--	3	--	--	--	
Primary Language							
English	114	32.3	96	32.8	18	30.0	0.68
Spanish	239	67.7	197	67.2	42	70.0	

	Full Sample (n=353)		Completed Study (n=293)		Did Not Complete Study (n=60)		p value
Variables	N	%	N	%	N	%	
Monthly Household Income							
$0	47	13.6	40	14.0	7	11.9	0.68
$1 - $500	89	25.9	75	26.3	14	23.7	
$501 - $1,000	119	34.6	98	34.4	21	35.6	
$1, 001 - $2,000	62	18.0	48	16.8	14	23.7	
≥ $2,001	27	7.9	24	8.4	3	5.1	
Missing	*9*	--	9	--	--	--	
Insurance Status							
Insured	97	30.6	80	30.4	17	31.5	0.88
Not insured	220	69.4	183	69.6	37	68.5	
Missing	36	--	30	--	--	--	
Time In Salud y Vida 1.0							
Mean (SD), in months	20.6 (9.5)		20.4 (9.4)		21.3 (9.8)		0.50

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

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

	Full Intervention Group (n=176)		Completed Study (n=148)		Did Not Complete Study (n=28)		p-value
Variables	N	%	N	%	N	%	
Sex							
Male	53	30.1	42	28.4	11	39.3	0.25
Female	123	69.9	106	71.6	17	60.7	
Ethnicity[a]							
Hispanic/Latino	162	92.1	137	92.6	25	89.3	0.47
Non-Hispanic/Non-Latino	14	8.0	11	7.4	3	10.7	
County							
Cameron County	176	100.0	148	100.0	28	100.0	--
Willacy County	0	0.0	0	0.0	0	0.0	
Age							
≤ 34	9	5.1	8	5.4	1	3.6	0.74
35-44	30	17.1	27	18.2	3	10.7	
45-54	67	38.1	55	37.2	12	42.9	
55-64	63	35.8	53	35.8	10	35.7	
65+	7	4.0	5	3.4	2	7.1	
Mean (SD)	51.4 (9.0)		51.0 (9.0)		53.5 (9.1)		0.19
Employment Status							
Employed	16	9.3	14	9.7	2	7.1	0.27
Unemployed	105	60.7	91	62.8	14	50.0	
Other	52	30.1	40	27.6	12	42.9	
Missing	*3*	--	*3*	--	--	--	
Marital Status							
Married	86	50.0	74	51.0	12	44.4	0.53
Unmarried	86	50.0	71	49.0	15	55.6	
Missing	*4*	--	*3*	--	*1*	--	
Education							
Less than high school	103	58.9	89	60.5	14	50.0	0.30
High school graduate/GED or higher	72	41.1	58	39.5	14	50.0	
Missing	*1*	--	*1*	--	--	--	
Primary Language							
English	60	34.1	51	34.5	9	32.1	0.81
Spanish	116	65.9	97	65.5	19	67.9	

	Full Intervention Group (n=176)		Completed Study (n=148)		Did Not Complete Study (n=28)		p-value
Monthly Household Income							
$0	26	15.3	23	16.2	3	10.7	0.91
$1 - $500	44	28.9	37	26.1	7	25.0	
$501 - $1,000	56	32.9	46	32.3	10	35.7	
$1, 001 - $2,000	29	17.1	23	16.2	6	21.4	
≥ $2,001	15	8.8	13	9.2	2	7.1	
Missing	*6*	--	*6*	--	--	--	
Health Insurance Status							
Insured	47	29.6	39	29.6	8	29.6	0.99
Not insured	112	70.4	93	70.5	19	70.4	
Missing	*17*	--	*16*	--	*1*	--	
Time In Salud y Vida 1.0							
Mean (SD), in months	21.2 (9.5)		20.9 (9.4)		23.0 (9.8)		0.29

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

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

Measure	Full Control Group (n=177)		Completed Study (n=145)		Did Not Complete Study (n=32)		p-value
	N	%	N	%	N	%	
Sex							
Male	51	28.8	35	24.1	16	50.0	**0.004**
Female	126	71.2	110	75.9	16	50.0	
Ethnicity[a]							
Hispanic/Latino	163	92.1	134	92.4	29	90.6	0.72
Non-Hispanic/Non-Latino	14	7.9	11	7.6	3	9.4	
County[a]							
Cameron County	176	99.4	144	99.3	32	100.0	0.99
Willacy County	1	0.6	1	0.7	0	0.0	
Age							
≤ 34	7	4.0	6	4.1	1	3.1	0.23
35-44	31	17.5	23	15.9	8	25.0	
45-54	69	39.0	53	36.6	16	50.0	
55-64	61	34.5	55	37.9	6	18.8	
65+	9	5.1	8	5.5	1	3.1	
Mean (SD)	51.7 (9.2)		52.1 (9.2)		49.8 (9.5)		0.20
Employment Status							
Employed	26	14.9	21	14.7	5	16.1	0.88
Unemployed	108	62.1	90	62.9	18	58.1	
Other	40	23.0	32	22.4	8	25.8	
Missing	*3*	--	*2*	--	*1*	--	
Marital Status							
Married	99	56.3	77	53.5	22	68.8	0.12
Unmarried	77	43.8	67	46.5	10	31.3	
Missing	*1*	--	*1*	--	--	--	
Education							
Less than high school	104	59.4	85	59.4	19	59.4	0.99
High school graduate/GED or higher	71	40.6	58	40.6	13	40.6	
Missing	*2*	--	*2*	--	--	--	
Primary Language							
English	54	30.5	45	31.0	9	28.1	0.75
Spanish	123	69.5	100	69.0	23	71.9	

Measure	Full Control Group (n=177)		Completed Study (n=145)		Did Not Complete Study (n=32)		p-value
Monthly Household Income							
$0	21	12.1	17	11.9	4	12.9	0.76
$1 - $500	45	25.9	38	26.6	7	22.6	
$501 - $1,000	63	36.2	52	36.4	11	35.5	
$1, 001 - $2,000	33	19.0	25	17.5	8	25.8	
≥ $2,001	12	6.9	11	7.7	1	3.2	
Missing	*3*	--	*2*	--	*1*	--	
Health Insurance Status							
Insured	50	31.6	41	31.3	9	33.3	0.84
Not insured	108	68.4	90	68.7	18	66.7	
Missing	*19*	--	*14*	--	*5*	--	
Time In Salud y Vida 1.0							
Mean (SD), in months	19.9 (9.5)		19.9 (9.5)		19.8 (9.8)		0.98

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

	Full Sample (n=353)	Completed Study (n=293)	Did Not Complete Study (n=60)	*p*
	Mean (SD)	Mean (SD)	Mean (SD)	
Systolic	**136.1 (19.8)**	**134.9 (19.5)**	**142.0 (20.4)**	**0.01**
Diastolic	79.8 (12.8)	79.2 (12.3)	82.6 (13.2)	0.06
Total Cholesterol	194.3 (50.0)	193.4 (49.1)	198.9 (54.3)	0.44
Nonparametric Tests[a]	Median (IQR)	Median (IQR)	Median (IQR)	p
HbA1c	**10.3 (2.0)**	**10.2 (2.0)**	**10.7 (2.0)**	**0.01**
PHQ-9[b]	4.0 (5.0)	4.0 (5.0)	5.0 (6.0)	0.21
BMI[b]	31.6 (9.0)	31.5 (8.7)	32.6 (10.2)	0.79
General Health[c]	70.0 (23.3)	70.0 (23.3)	70.0 (20.0)	0.98
Medication Adherence[d]	6.0 (2.3)	6.0 (2.3)	6.0 (3.3)	0.97
Self-efficacy	7.8 (2.4)	7.9 (2.4)	7.1 (2.6)	0.06

Note: Bold denotes statistical significance (p-value < 0.05); [a] The Wilcoxon rank sum *test was used to examine non-normally distributed data; [b] Sample size is 292 due to missing data for this measure;*
[c] Sample size for this measure is 348 due to missing data for this measure; [d] Sample size for this measure is 329 due to non-applicability to participants not currently being treated with medication.

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

	Full Intervention Group (n=176)	Completed Study (n=148)	Did Not Complete Study (n=28)	*p*
	Mean (SD)	Mean (SD)	Mean (SD)	
Systolic	136.3 (19.7)	135.3 (19.7)	141.9 (18.7)	0.10
Diastolic	80.0 (12.4)	79.5 (12.5)	82.6 (11.9)	0.22
Total Cholesterol	195.6 (51.5)	195.1 (50.5)	198.0 (57.4)	0.78
Nonparametric Tests[a]	Median (IQR)	Median (IQR)	Median (IQR)	p
HbA1c	10.2 (2.1)	10.2 (2.2)	10.5 (1.4)	0.41
PHQ-9[b]	3.0 (6.0)	3.0 (5.0)	4.0 (6.0)	0.45
BMI[c]	31.4 (9.4)	31.5 (9.5)	30.7 (9.2)	0.76
General Health[d]	73.4 (23.4)	73.4 (23.4)	76.7 (20.0)	0.86
Medication Adherence[e]	6.0 (2.3)	6.0 (2.3)	5.3 (2.5)	0.47
Self-efficacy	7.8 (2.5)	8.0 (2.5)	7.1 (2.9)	0.10

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

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

	Full Control Group (n=177)	Completed Study (n=145)	Did Not Complete Study (n=32)	*p*
	Mean (SD)	Mean (SD)	Mean (SD)	
Systolic	135.9 (20.0)	134.5 (19.3)	142.0 (22.1)	0.05
Diastolic	79.5 (13.1)	78.9 (12.8)	82.6 (14.4)	0.14
Total Cholesterol	193.1 (48.6)	191.6 (47.8)	199.7 (52.4)	0.40
Nonparametric Tests[a]	Median (IQR)	Median (IQR)	Median (IQR)	p
HbA1c	**10.4 (2.0)**	**10.2 (1.9)**	**11.3 (2.2)**	**0.003**
PHQ-9	4.0 (6.0)	4.0 (6.0)	6.0 (6.5)	0.33
BMI	31.6 (8.9)	31.5 (8.1)	34.4 (10.6)	0.46
General Health	66.7 (26.6)	66.7 (26.6)	66.7 (20.0)	0.74
Medication Adherence	6.0 (2.5)	6.0 (2.5)	6.8 (3.5)	0.50
Self-efficacy	7.6 (2.3)	7.8 (2.1)	7.2 (2.4)	0.29

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

Appendix H: Patient-Centered Integrated Behavioral Health Care Checklist

Patient-Centered Integrated Behavioral Health Care Principles & Tasks

AIMS CENTER
Advancing Integrated Mental Health Solutions

About This Tool

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

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

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

Core components and tasks

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

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

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

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

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

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

Appendix J: Duke Health Profile

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

DUKE HEALTH PROFILE (The DUKE)

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

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

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

TODAY would you have any physical trouble or difficulty:

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

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

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

DURING THE PAST WEEK: How often did you:

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

DURING THE PAST WEEK: How often did you:

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

MANUAL SCORING FOR THE DUKE HEALTH PROFILE

PHYSICAL HEALTH SCORE

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

MENTAL HEALTH SCORE

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

SOCIAL HEALTH SCORE

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

GENERAL HEALTH SCORE

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

PERCEIVED HEALTH SCORE

Item	Raw Score*
3 =	_____ x 50 = ☐

SELF-ESTEEM SCORE

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

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

ANXIETY SCORE

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

DEPRESSION SCORE

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

ANXIETY-DEPRESSION (DUKE-AD) SCORE

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

PAIN SCORE

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

DISABILITY SCORE

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

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

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

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

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

PERFIL DE SALUD DE DUKE (El Duke)

Fecha de hoy:_____ Nombre: _____ Número de identificación: _____

Fecha de nacimiento: _____ Sexo: Femenino ☐ Masculino ☐

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

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

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

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

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

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

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Appendix K: Health Literacy Screening Tool

Health Literacy Measure

1. How often do you have someone help you read hospital materials?
(a) All the time
(b) Most of the time
(c) Some of the time
(d) A little of the time
(e) None of the time
(f) Refused

2. How often do you have problems learning about your medical condition because of difficulty understanding written information?
(a) All the time
(b) Most of the time
(c) Some of the time
(d) A little of the time
(e) None of the time
(f) Refused

3. How confident are you filling out medical forms by yourself?
(a) Not at all
(b) A little bit
(c) Somewhat
(d) Quite a bit
(e) Extremely
(f) Refused

4. How often do you have a problem understanding what is told to you about your medical condition?
(a) All the time
(b) Most of the time
(c) Some of the time
(d) A little of the time
(e) None of the time
(f) Refused

5. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?"
(a) All the time
(b) Most of the time
(c) Some of the time
(d) A little of the time
(e) None of the time
(f) Refused

Encuesta de la comprensión de información sobre la salud

1.¿Qué tan seguido tiene a alguien que le ayude leer los materiales del hospital?
(a) Todo el tiempo
(b) Mayoría de tiempo
(c) Algo de tiempo
(d) Un poco de tiempo
(e) Ninguna vez
(f) No respuesta (espacio en blanco)

2.¿Qué tan seguido tiene problemas aprendiendo acerca de su condición médica por causa de la dificultad a entender la información escrita?
(a) Todo el tiempo
(b) Mayoría de tiempo
(c) Algo de tiempo
(d) Un poco de tiempo
(e) Ninguna vez
(f) No respuesta (espacio en blanco)

3. ¿Qué tan seguro(a) se siente al tener que llenar formularios médicos por usted mismo(a)?
(a) Para Nada
(b) Un poco seguro(a)
(c) Algo seguro(a)
(d) Muy seguro(a)
(e) Extremadamente seguro(a)
(f) No respuesta (espacio en blanco)

4.¿Qué tan seguido tiene problemas para entender sobre su condición médica?
(a) Todo el tiempo
(b) Mayoría de tiempo
(c) Algo de tiempo
(d) Un poco de tiempo
(e) Ninguna vez
(f) No respuesta (espacio en blanco)

5.¿Qué tan seguido necesita a alguien que le ayude leer instrucciones, folletos, u otros materiales escritos de su médico o farmacia?
(a) Todo el tiempo
(b) Mayoría de tiempo
(c) Algo de tiempo
(d) Un poco de tiempo
(e) Ninguna vez
(f) No respuesta (espacio en blanco)

Appendix L: Medication Adherence Questionnaire

Enrollment site: _____ Participant ID: _____ Date: _____

Prepared by: _____ Participant DOB: _____

DIABETES MEDICATION ADHERENCE QUESTIONNAIRE

1- Have you ever been prescribed medication(s) for your diabetes?
(¿Alguna vez le han recetado medicamento(s) para su diabetes?)
☐ Yes ☐ No
If No -> do NOT administer the questionnaire (Si No -> no administrar el cuestionario)
If Yes -> administer the questionnaire – go on to question 2 (En caso afirmativo -> pase a la pregunta 2)

2- Have you ever picked up your diabetes medication(s) (pharmacy, clinic, free sample)?
(¿Alguna vez ha recogido su medicamento(s) (farmacia, clínica, muestra gratis)?)
☐ Yes ☐ No
If No -> adherence level = 0 – STOP Questionnaire (Si No -> nivel de adherencia = 0)
If Yes -> go on to question 3 (En caso afirmativo -> pase a la pregunta 3)

3- Are you currently taking medication(s) for your diabetes?
(¿Está tomando medicamento(s) para su diabetes?)
☐ Yes ☐ No
If No -> adherence level = 0 – STOP Questionnaire (Si No -> nivel de adherencia = 0)
If Yes -> go on to question 4 (En caso afirmativo -> pase a la pregunta 4)

You indicated that you are taking medication(s) for your diabetes. Individuals have identified several issues regarding their medication-taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your diabetes medication.
(Usted ha indicado que ha estado tomando su medicamento(s) para su diabetes. Las personas han identificado varios problemas relacionados con su comportamiento de la toma de medicamentos y nos interesa conocer su experiencia al respecto. No hay respuestas correctas ni incorrectas. Por favor conteste cada una de las preguntas de acuerdo con su experiencia personal con el diabetes.)

4- Have you ever cut back or stopped taking your diabetes medication(s) without telling your doctor, because you couldn't afford it? *(¿Alguna vez has recortado o dejado de tomar su medicamento(s) para la diabetes sin antes hablar con su médico, porque no podía pagarla?)*	**Yes**	**No**

MMAS-8 item		
5- Do you sometimes forget to take your diabetes pills? *(¿A veces se le olvida tomar sus tabletas para la diabetes?)*	**Yes=0**	**No=1**
6- People sometimes miss taking their medication(s) for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your diabetes medicine? *(La gente a veces no toma su medicamento(s) por otras razones que no implican el haber olvidado tomar el medicamento. Pensando en las últimas dos semanas, ¿hubo algunos días que no tomó su medicamento para la diabetes?)*	**Yes=0**	**No=1**
7- Have you ever cut back or stopped taking your diabetes medication(s) without telling your doctor, because you felt worse when you took it? *(¿Alguna vez redujo la dosis o dejó de tomar su medicamento(s) para la diabetes sin decirle a su doctor porque se sentía peor cuando se lo tomaba?)*	**Yes=0**	**No=1**

Enrollment site: _____ Participant ID: _____ Date: _____

Prepared by: _____ Participant DOB: _____

8- When you travel or leave home, do you sometimes forget to bring along your diabetes medication(s)? *(Cuando viaja o sale de casa, ¿a veces olvida llevar su medicamento(s) para la diabetes?)*	**Yes=0**	**No=1**
9- Did you take your diabetes medicine(s) yesterday? *(¿Tomó su medicamento(s) para la diabetes ayer?)*	**Yes=1**	**No=0**
10- When you feel like your diabetes is under control, do you sometimes stop taking your medicine(s)? *(Cuando siente que su diabetes está bajo control, ¿a veces deja de tomar su medicamento(s)?)*	**Yes=0**	**No=1**
11- Taking medication every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your diabetes treatment plan? *(El tomar medicamento para la diabetes todos los días resulta muy inconveniente para algunas personas. ¿Alguna vez se ha sentido fastidiado acerca de seguir a su plan del tratamiento para la diabetes?)*	**Yes=0**	**No=1**
12- How often do you have difficulty remembering to take all your diabetes medication(s)? *(¿Qué tan a menudo se le dificulta recordar el tomar todos sus medicamento(s) para la diabetes?)* **(Please circle your response /** Por favor marque su respuesta) **Never/Rarely** *(Nunca/Rara vez)*.....1 **Once in a while** *(De vez en cuando)*.....0.75 **Sometimes** *(A veces)*.....0.5 **Usually** *(A menudo)*.....0.25 **All the time** *(Todo el tiempo)*.....0		

Score (0-8)	**Adherence Level (Please circle your response)**	**HbA1c**
	Low – Medium – High	
Coding Instructions for the ©Morisky Medication Adherence Scale (8-Item): questions 5-12 - Add 1 point for each "No" except for questions 9 and 12 - Question 9: reverse the code response in a positive direction: Yes=1 and No=0 - Question 12: circle score matching with answer	**Adherence Level** Low adherence (=5 or <5) Medium Adherence (>5 or <8) High Adherence (= 8)	**At enrollment visit**

Appendix M: Diabetes Self-Efficacy Scale

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Self-Efficacy for Diabetes

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?

2. How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?

3. How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)?

4. How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?

5. How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?

6. How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?

7. How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?

8. How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?

not at all confident | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | totally confident

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the six items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.

Characteristics

Tested on 186 subjects with diabetes.

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No. of items	Observed Range	Mean	Standard Deviation	Internal Consistency Reliability	Test-Retest Reliability
8	1-10	6.87	1.76	.828	NA

Source of Psychometric Data

Stanford English Diabetes Self-Management study. Study reported in Lorig K, Ritter PL, Villa FJ, Armas J. Community-Based Peer-Led Diabetes Self-Management: A Randomized Trial. The Diabetes Educator 2009; Jul-Aug;35(4):641-51.

Comments

This 8-item scale was originally developed and tested in Spanish for the Diabetes Self-Management study. For internet studies, we add radio buttons below each number. There is another way that we use to format these items, which takes up less space on a questionnaire, shown also in the PDF document. This scale is available in Spanish.

References

Unpublished.

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Funded by the National Institute of Nursing Research (NINR)

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Spanish Diabetes Self-Efficacy

En las siguientes preguntas nos gustaría saber qué piensa Ud. de sus habilidades para controlar su enfermedad. Por favor marque el número que mejor corresponda a su nivel de seguridad de que puede realizar en este momento las siguientes tareas.

1. ¿Qué tan seguro(a) se siente Ud. de poder comer sus alimentos cada 4 ó 5 horas todos los días. Esto incluye tomar desayuno todos los días?

2. ¿Que´ tan seguro(a) se siente Ud. de continuar su dieta cuando tiene que preparar o compartir alimentos con personas que no tienen diabetes?

3. ¿Qué tan seguro(a) se siente Ud. de poder escoger los alimentos apropiados para comer cuando tiene hambre (por ejemplo, bocadillos)?

4. ¿Qué tan seguro(a) se siente Ud. de poder hacer ejercicios de 15 a 30 minutos, unas 4 o 5 veces por semana?

5. ¿Qué tan seguro(a) se siente Ud. de poder hacer algo para prevenir que su nivel de azúcar en la sangre disminuya cuando hace ejercicios?

6. ¿Qué tan seguro(a) se siente Ud. de poder saber qué hacer cuando su nivel de azúcar en la sangre sube o baja más de lo normal para usted?

7. ¿Qué tan seguro(a) se siente Ud. de poder evaluar cuando los cambios en su enfermedad significan que usted debe visitar a su médico?

muy inseguro(a) 1 2 3 4 5 6 7 8 9 10 muy seguro(a)

8. ¿Qué tan seguro(a) se siente Ud. de poder controlar su diabetes para que no interfiera con las cosas que quiere hacer?

muy inseguro(a)	1	2	3	4	5	6	7	8	9	10 muy seguro(a)

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the eight items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.

Characteristics

Tested on 189 Spanish-speaking subjects with type 2 diabetes.

No. of items	Observed Range	Mean	Standard Deviation	Internal Consistency Reliability	Test-Retest Reliability
8	1.13-10	6.46	2.07	.854	NA

Source of Psychometric Data

Spanish Diabetes Self-Management (Programa de Manejo Personal de la Diabetes) Study. Study reported in Lorig KR, Ritter PL, Gonzalez VM. Hispanic chronic disease self-management: a randomized community-based outcome trial. Nurs Res. 2003; Nov-Dec;52(6):361-9.

Comments

This 8-item scale was developed and tested in Spanish for the Diabetes Self-Management study, and has been translated into English. There are 2 ways to format these items. We use the format above, because it takes up less room on the questionnaire. The other is shown on the web page.

References

Unpublished at this time.

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Appendix N: Patient Satisfaction Survey

Salud y Vida 2.0: Enhancing Integrated Behavioral Health for Individuals with Diabetes in the Rio Grande Valley/
Salud y Vida 2.0: Mejorando la salud de comportamiento integrado para personas con diabetes en el Valle del Rio Grande

Evaluation Form/ Forma de evaluación

Please help us improve! Your input is important to us. It helps us improve the quality and effectiveness of the Salud y Vida 2.0./ Por favor ayúdenos mejorar! Sus opiniones son muy importantes para nosotros. Nos ayuda mejorar la calidad y eficaz del estudio Salud y Vida 2.0.

Please check the box that represents your level of satisfaction with the following services:
Por favor marque con una palomita el cuadrito que represente su nivel de satisfacción con los siguientes servicios:

	Not at all satisfied/ Nada satisfecho	Somewhat satisfied/ Un poquito satisfecho	Satisfied/ Satisfecho	Very Satisfied/ Muy satisfecho	This Service was not part of my care plan/ Este servicio no fue parte de mi plan de cuidados
Medication Therapy Management/ el manejo de terapia de medicamentos					
Behavioral Health Services/ servicios de salud de comportamiento					
Peer-led Support Groups/ grupo de apoyo					
La Cocina Alegre Cooking Course/ La Cocina Alegre clases de cocinar					
MEND program- programa familiar para reducir la obesidad					

What did you like **best** about Salud y Vida 2.0?/ ¿Qué fue lo que **más** le gusto del estudio, Salud y Vida 2.0?

_____
_____
_____

What did you like **least** about Salud y Vida 2.0?/ ¿Qué fue lo que **menos** le gusto del estudio, Salud y Vida 2.0?

_____
_____
_____