Sí Texas: Social Innovation for a Healthy South Texas

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Final Evaluation Report: Nuestra Clinica del Valle

NCDV
NUESTRA CLINICA DEL VALLE

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Evaluator: Health Resources in Action, Inc.

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EXECUTIVE SUMMARY

This final report describes the methods and findings for the evaluation of the NuCare program at Nuestra Clinica del Valle (NCDV), a subgrantee of the Social Innovation Fund (SIF) Grantee Methodist Healthcare Ministries (MHM) of South Texas, Inc. MHM is a member of the 2014 SIF cohort. The evaluation was conducted by external evaluation contractor Health Resources in Action (HRIA) at the Mission clinic site in Mission, Texas.

Program Background

Nuestra Clínica del Valle (NCDV) proposed to fully integrate behavioral health (IBH) and physical health at four of its clinics in the Rio Grande Valley through a multidisciplinary team approach in order to improve the health status of patients with obesity, diabetes, and/or depression. At its core, the NuCare program consisted of: 1) community health worker (CHW) integration into the clinic team through depression screening and other patient services, 2) integration of nutritionists into the clinic team to work with patients to set goals and monitor progress, 3) mediated health education meetings led by licensed vocational nurses (LVN); and 4) introduction of a full time Behavioral Health Provider. The clinic added an integrated behavioral health team and includes the warm handoff, in which the primary care provider directly introduces the patient to the behavioral health provider (who operates as the behavioral health consultant) during a medical visit. The behavioral health provider provides a brief behavioral health intervention. This process breaks through the strong local barrier of stigma against behavioral health services and allows the behavioral health provider to develop rapport and encourage patient confidence in the services offered. NCDV has found that warm handoffs benefit patients, more of whom receive IBH services, and providers, who save time and reduce their own stress levels through a warm handoff. For the evaluation of NCDV's NuCare program, evaluation activities are in NCDV's Mission Clinic in Mission, Texas. The evaluation targeted a moderate level of evidence with a quasi-experimental design (QED) based on the incoming level of preliminary evidence.

Prior Research

The NCDV NuCare program combined components of the integrated care model studied by Druss et al. (2001), and the collaborative care model studied by Sanchez & Watt (2012). The Druss model involves patient education and prevention and increased interaction among the care team. The Sanchez and Watt (2012) model finds that collaborative care, where structured care involves a greater role of nonmedical specialists to augment primary care, has emerged as an effective intervention to improve quality of primary care and patient outcomes with low-income, Spanish speaking populations. The components of NCDV's intervention are evidence based, and an onsite pre-post test conducted at the clinic furthers that body of evidence. However, given that the proposed NuCare program modified and adapted both models to be culturally-relevant to the unique border community, the incoming level of evidence was preliminary. The evaluation targeted a moderate level of evidence with a quasi-experimental design (QED).

Evaluation Design

The impact evaluation used a non-randomized quasi-experimental design (QED) to evaluate the NuCare program's impact at the Mission Clinic. The QED allowed for the identification and controlling of participant characteristics that may affect impact measures of interest. A comparison group from

NCDV's Edcouch and Alton Clinics was used for the QED. Propensity score matching was explored in the analytic phase to address baseline nonequivalence of the intervention and comparison groups. However, propensity score matching was not applied in the final analyses. Complete case analyses were used instead of propensity score matching due to the loss of sample size and power that resulted from the matching process.

The study aimed to enroll 338 participants per arm (e.g., intervention group and comparison group) totaling 676 participants. The study enrolled a total of 756 participants, 329 in the intervention group and 427 in the comparison group. NCDV's 12-month retention target was 472 participants, with 236 in each study arm. The final 12-month sample totaled 579 participants, with 249 in the intervention group and 330 in the comparison group.

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

Description of Measures and Instruments

NCDV collected data for the Sí Texas shared impact measures: Body Mass Index (BMI) (height/weight), HbA1c (obtained via blood test), blood pressure (taken by manual or automatic blood cuff), depression (using the Patient Health Questionnaire [PHQ-9]) and quality of life (using the Duke Health Profile). The primary impact measure for the NuCare program study was improvement in HbA1c.

Research Questions

The primary impact measure for the NuCare program was HbA1c. Below are the confirmatory and exploratory research questions.

1) Do patients who participate in the NuCare intervention experience improvements in HbA1c measures after 12 months when compared to patients that do not participate in the intervention? *This question is confirmatory.*
2) Do patients who participate in the NuCare intervention experience improvements in BMI after 12 months when compared to patients that do not participate in the intervention? *This question is exploratory.*
3) Do patients who participate in the NuCare intervention experience improvements in depressive symptoms, as measured by PHQ9, after 12 months compared to patients who do not participate in the intervention? *This question is exploratory.*
4) Do patients who participate in the NuCare intervention experience improvements in blood pressure, when compared to patients that do not participate in the intervention? *This question is exploratory.*
5) Do patients who participate in the NuCare intervention experience improvements in quality of life, as measured by the Duke Health Profile, after 12 months when compared to patients that do not participate in the intervention? *This question is exploratory.*

Implementation Questions

The following evaluation questions examined program implementation.

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

Impact Evaluation

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 were found non-equivalent at baseline. The possibility of effect modification of the intervention-outcome relationship by patients' characteristics was also explored. Specifically, interaction terms of study group and baseline impact measures as well as age were included to understand whether there were differences in intervention effect by these characteristics. Stratified linear regression models were subsequently 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

This evaluation study achieves a preliminary level of evidence. This evaluation study uses a QED design with a comparison group which was designed to mitigate major threats to internal validity. More specifically, the comparison group addressed the following threats to internal validity: testing, John Henry, and expectancy effects. The program was implemented to moderate to high fidelity due to a seven-month delay in the implementation of promotora-delivered wellness classes and limited implementation of a warm handoff with brief intervention. The study also meets the criteria for effective evidence because it demonstrates positive, significant findings for an exploratory outcome

(quality of life); there were no negative intervention effects on confirmatory or exploratory outcomes. The exploratory quality of life measure achieved a small effect size (d=0.34).

Significant improvement was demonstrated in the exploratory outcome of quality of life as measured by the Duke Health Profile. Study findings suggest that the NuCare intervention was associated with significantly higher mean values of Duke General Health score at 12 months by 5.36 points ($p<0.001$), Duke Mental Health Score at 12 months by 6.22 points ($p<0.001$) and Duke Social Health Score at 12 months by 6.79 points ($p<0.001$). The Duke General Health score, an exploratory outcome, surpassed the standard threshold for small effect sizes (Cohen's d=0.34) for the analysis comparing intervention participants with the comparison group.

Intervention participants had significantly greater improvements than the comparison group on an additional exploratory outcome measure, PHQ-9. Intervention participants were found to have decreased PHQ-9 scores over time compared to the comparison group (β=-1.39 points, p=<0.001). Stratified analyses, which were conducted to understand the potential influence of the study population's diabetic status on health outcomes, found that those in the intervention group with uncontrolled diabetes at baseline had a statistically significantly lower diastolic blood pressure at 12 months, by 2.38 mmHg, than those in the comparison group with uncontrolled diabetes. While there were no statistically significant changes in blood pressure in the overall study population, this result identified a differential impact of the intervention on diastolic blood pressure by control of diabetes and indicates a need for further research. This result is consistent with the current body of research on the relationship between diabetes and blood pressure; however, additional factors such as medication and adherence to medication were not examined because those data were not available for this study population.

Evaluation of NCDV's implementation of the NuCare program shows that the program was implemented in alignment with the program logic model and that there was moderate to high fidelity in implementation. Facilitators to program implementation included multiple forms of communication among staff, warm handoffs, the establishment of trusting relationships among staff and the flexibility of staff in the roles they played, and creative use of clinic space. For patients, additional factors that facilitated their participation included strong rapport between patients and staff, the no or low cost of services, and the awareness of improved health outcomes.

The evaluation was implemented as intended except for a deviation in the original timeline. NCDV conducted enrollment on a rolling basis between September 2016 and April 2017, a slight deviation from the SEP. NCDV met 97.3% of the enrollment target for the intervention group and exceeded the enrollment target for the comparison group. A detailed timeline of the study can be found in **Appendix A. Revised Project Timeline**.

Conclusion and Next Steps

This evaluation contributes to our understanding of the impact of a multidisciplinary approach to the integration of behavioral health services in a primary care service context. The rationale behind the intervention is that by providing behavioral health within the primary care setting, patients will receive an array of services that will improve their health outcomes, while reducing barriers to treatment and stigma that may be associated with services. These concepts are supported by previous research. For example, as previously mentioned, NCDV adapted evidence-based care models with innovative

components including community health workers. NCDV built upon these models by adapting integrated services to be culturally-relevant for the unique border community, including bilingual programming and psychoeducation. The results of the NuCare evaluation build on this work by examining the impact of a multidisciplinary approach to the integration of behavioral health services in a predominantly Hispanic, low-income population.

Over the course of the study, NCDV improved in level of integration of behavioral health with reported improvement in four of the five IBH core principles from baseline to 12 months. NCDV began the study by applying the fifth core principle (evidence-based care) to most or all patients, a practice that continued through the end of the study. Feedback from patients was generally very positive, with patients citing improvement in health care access, health literacy, and ultimately improved health outcomes as reasons for being satisfied. Apart from improved health outcomes, interviewees and focus group participants reported other improved outcomes, namely improved quality of life, from participation the NuCare program.

The study demonstrated statistically significant improvement in two outcome measures: the exploratory quality of life outcome (as measured by the Duke Health Profile) and the exploratory depression outcome (as measured by the PHQ-9). End-point analysis of quality of life demonstrated that intervention participants increased their Duke Health Profile scores over the scores of comparison group participants. Longitudinal analysis revealed that intervention participants decreased their PHQ-9 scores over time compared to the comparison group. Given the robust execution of the quasi-experimental study design and minimized attrition, there is evidence that the NuCare intervention contributed to the improvements in health outcomes among participants.

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. NCDV created this approach to meet the needs of the clinic patients, who are primarily Hispanic and low income. In the future, researchers might want to consider examining the extent to which other specific populations would benefit from a multidisciplinary approach to integrated behavioral health models. In addition, given the limited implementation of the warm handoff with brief intervention, as NCDV implements and refines their approach, researchers may wish to examine the implementation and outcome effects on this or other populations.

Moving forward post-evaluation, NCDV is using policy and system change strategies to improve buy-in and utilization of the NuCare model. Through the development of a Primary Care-Behavioral Health manual, NCDV administration is regularly reviewing clinical pathways and standing delegation orders to ensure they are functioning to meet the needs of the patients and increase access to the multidisciplinary services that make up NuCare. Team based training is being delivered on a clinic by clinic basis to increase the level of behavioral health integration within each clinic. This work is supported by a perceived growing sense of buy-in from system leadership and administration. Financial resources to maintain the program for all patients poses the greatest challenge for sustainability.

INTRODUCTION

This final report describes the methods and findings for the evaluation of the program, NuCare: Integrated Behavioral Health Reducing Diabetes, Obesity & Depression (NuCare), at Nuestra Clinica del Valle (NCDV), a subgrantee of the Social Innovation Fund (SIF) Grantee Methodist Healthcare Ministries (MHM) of South Texas, Inc. MHM is a member of the 2014 SIF cohort. The evaluation was conducted by the external evaluation contractor, Health Resources in Action (HRiA), at the Mission clinic site in Mission, Texas. The intended audience of this report is the Social Innovation Fund, although excerpts will also be used by Methodist Healthcare Ministries program staff and leadership and internal leadership at NCDV.

Program Definition and Background

Residents of the Rio Grande Valley (RGV) have among the poorest health outcomes in the nation. Rates of chronic disease and related mortality among the general population of the RGV exceed those in most other regions of the state and the nation. Based on a study of 2,000 Mexican American adults from 2003 to 2008 called the Cameron County Hispanic Cohort (CCHC), researchers at the University of Texas School of Public Health at Brownsville found that 31% of participants had diabetes and 81% were either obese (49%) or overweight (32%) (Fisher-Hoch et al., 2008). The study also concluded there are 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).

Poverty is pervasive along the Texas southern border with Mexico, placing border residents at high risk for poor health status. According to the U.S. Census Bureau, from 2011-2013, the McAllen-Edinburg metropolitan statistical area (MSA) had the lowest per capita personal income of the 381 MSA in the country followed by the Brownsville-Harlingen MSA. With over 34% of households living in poverty, 38.6% of children uninsured, Hidalgo County is a major site for concentrated effects of poverty. Residents living in high-poverty areas deal with higher rates of crime and other structural deficits along with stressful effects of being poor and marginalized without access to resources. They are also less likely to have completed high school, have higher unemployment, and often live below the poverty line. Border residents are more likely to be exposed to environmental hazards and have higher rates of chronic physical as well as mental health concerns (Cohen et al., 2003; Diez Roux et al., 2001; Quercia & Bates, 2009). For example, in a health survey of Rio Grande Valley/Lower South Texas, 20.4% of respondents reported depressive episodes. These same respondents had an education that was less than high school and 16.7% had an income of less than $25,000 (Davila, Rodriguez, Urbina, & Nino, 2014).

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

ratio for mental health providers to individuals in Texas is 1:1,757. In Hidalgo County, it is 1:2066 (University of Wisconsin Population Health Institute, 2015).
The lack of public health infrastructure in Hidalgo County further exacerbates challenges in accessing high-quality mental health care as well as primary care. Hidalgo County is home to *colonias*, which are defined as unincorporated settlement of land along Texas-Mexico border that may lack some of the most basic living necessities, such as drinking water and sewer systems, electricity, paved roads, and safe and sanitary housing. In the 19 counties that make up Rio Grande Valley/Lower South Texas, there are a total of 1902 *colonias* of which 943 are located in Hidalgo County (Davila et al., 2014). *Colonia* residents rely on an episodic system of care depending on funding and strained social programs with limited capacity. The presence of risk factors stemming from limited access to care, concentration of poverty, and highest concentration of *colonias*, Hidalgo County presents many opportunities to intervene for several unmet health (physical and behavioral) challenges.

NCDV serves Hidalgo and Starr counties with 11 locations, including two school-based clinics to treat and care for children. NCDV's Mission Clinic, the focus of the evaluation, offers comprehensive medical services to over 5,800 individuals annually in the RGV. Most patients who are provided medical care and mental health counseling at NCDV's Mission Clinic are uninsured and do not qualify for any government-funded medical assistance.

In the context of an increasingly fragmented behavioral and primary health care system, uninsured individuals living in poverty in the RGV are in need of specialized support to access health care services. NCDV's NuCare program is aimed at removing barriers between behavioral and primary care. Without effective intervention, it is likely individuals living in NCDV's service area would not receive timely integrated care due to regional health care disparities, poverty, and lack of insurance.

NCDV implemented the NuCare program, which includes fully integrated behavioral health care in the clinic and an adaption of the collaborative care model (Sanchez & Watt, 2012) to improve the health status of patients with diabetes. The intervention built upon the "warm handoff" approach used at NCDV clinics where primary care providers directly introduce patients to behavioral health providers (who operate as behavioral health consultants), to a more fully integrated model with care coordination, shared treatment plans, shared service provision, and shared record keeping.

This NuCare model emphasized integrated primary care including the following components: promotoras(es)/community health worker integration into the clinic team through depression screening and other patient services, including assistance with clinic navigation, integration of nutritionists into the clinic team to work with patients to set goals and monitor progress, behavioral health consultant integration into the clinic team on a regular, systematic basis, and mediated health education meetings led by licensed vocational nurses (LVNs). The NuCare model focused on low-income adults with diabetes. The study hypothesis was that integrated behavioral health in a primary care setting will improve participants' HbA1c levels and potentially improve participants' BMI, blood pressure, depressive symptoms, and quality of life. The evaluation targeted a moderate level of evidence with a quasi-experimental design (QED). The program deviated from the program logic model as presented in the June 2017 SIF evaluation plan (SEP) in the scope of the health and wellness program activity component which did not begin formal wellness classes until May 2017 and therefore provided fewer wellness class opportunities over the time period of the study. A more detailed description of the program is discussed in the Program Components section on the following page.

NCDV's recruitment target was 338 participants in each of the two study groups (intervention group comparison group) totaling 676 participants. NCDV's program enrolled a total of 756 participants, including 329 in the intervention group and 427 participants in the comparison group, reaching 97.3% of their enrollment target in the intervention group and exceeding their target enrollment in the comparison group.

Overview of Prior Research

The scientific literature has many examples of interventions targeting improved access to high-quality health care services in low-income populations. There is a growing body of evidence that supports the benefits of integrated behavioral health (IBH) with primary care as a way to improve population health in areas demographically similar to South Texas (Bedoya et al., 2014; Camacho et al., 2015; Ell et al., 2009b).

In Austin, for example, People's Community Clinic used an IBH model to enable 329 adult clients diagnosed with depression and anxiety to receive psychiatric medication, counseling, and education. This study sought to (1) evaluate the effectiveness of a collaborative care model with a predominantly Hispanic, low-income population in a primary care setting and (2) examine depression outcomes with a subpopulation of preferentially Spanish-speaking patients compared with non-Hispanic white participants. A mixed methods non-experimental study showed that Spanish-speaking Hispanic patients had significantly greater odds of achieving a clinically meaningful improvement in depression at 3-month follow-up (odds ratio [OR] = 2.45, P = .013) compared to non-Hispanic whites. The finding for greater improvement in the Spanish-speaking population remained after controlling for age, sex, medical comorbidities, prior treatment, and baseline depression scores (Watt, 2009).

The IBH model on which NCDV based its intervention is the collaborative care model (e.g. Sanchez & Watt, 2012; Watt, 2009)—and was supported by evidence on the effectiveness of collaborative care models (Bower, Gilbody, Richards, Fletcher, & Sutton, 2006; Guide to Community Preventive Services, 2010). While the collaborative care model can take many different forms, it is defined as "a multicomponent, healthcare system-level intervention that uses case managers to link primary care providers, patients and mental health specialists." Community health workers (navigators) are integral to the model and perform various functions, such as patient education and patient follow-up to track depression measures and adjustment of treatment plans. The Community Guide review found that collaborative care models produced more favorable results when compared to usual-care models for depression outcomes, including depression symptoms, adherence to treatment, response to treatment, remission/recovery, quality-of-life and functional status, satisfaction with treatment. These results were supported for adults, older adults, women, men, Caucasian, African-American, Latino, and mixed-race populations in a diverse range of organizations and settings. Furthermore, a meta-analysis by Gilbody et al. (2006) support the proposed collaborative care model's effectiveness by noting "the evidence base [supporting the collaborative care model] is now sufficient for the emphasis to shift from research to dissemination and implementation."

The health disparities and health-related challenges prevalent in the RGV are not unlike those seen in other underserved and minority-prominent communities across the U.S. What makes this population unique, however, are the cultural and regional characteristics that require culturally tailored approaches. Salinas and colleagues (2013) and Rosario (2014) highlight the importance of geographic location when it comes to evaluating disease burden in Mexican Americans, in particular, in border

communities. Previous epidemiologic studies demonstrate that Spanish-speaking Hispanics prefer to remain with primary care providers for treatment, the majority of whom use language services (interpreters or bilingual providers), which suggests that Spanish language adaptation of services and cultural competency are critical to facilitating access to care (Vega & Lopez, 2001).

Within this context, NCDV adapted the evidence-based IBH interventions to account for the unique cultural and geographic needs of the RGV, including bilingual programming. An integral part of the NuCare program was the use of *promotoras(es)*, or community health workers (CHWs). 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., 2011).

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

Program Components

NCDV's theory of change is that providing a warm handoff from primary care to behavioral health, health education, and nutrition services in a process that is supported by promotoras(es) will lead to better management of chronic disease, reduce depression, and improve adult functioning and quality of life in the community for patients with chronic disease. The logic model in **Appendix B. Program Logic Model** visually diagrams the inputs, activities, outputs, and outcomes for the NuCare program, while these elements are discussed narratively below.

Through NuCare, NCDV expanded its efforts to more fully integrate behavioral health and primary care initiatives offered in four of its clinics. The Mission Clinic is the focus of the evaluation. The rationale behind the intervention is that by providing behavioral health within the primary care setting, patients will receive an array of services that will improve their health outcomes, while reducing barriers to treatment and stigma that may be associated with services. These concepts are supported by previous research. For example, as previously mentioned, NCDV adapted evidence-based care models with innovative components including community health workers. The activities of the NCDV approach are based on those elements present in the Sanchez and Watt (2012) including: care management, access to behavioral health specialists, and mediated health education meetings that have been linked to improved health outcomes in the evidence base. NCDV built upon these models by adapting integrated services to be culturally-relevant for the unique border community, including bilingual programming and psychoeducation.

Inputs: The NCDV logic model has six inputs including a variety of existing and new internal program personnel.

- Primary care provider: NCDV's Mission Clinic has full time primary care providers who see patients by appointment and occasional walk-ins (e.g., primary care providers, registered nurses registered nurse assistants, study managers).

- Behavioral health consultant: The behavioral health consultant, a Licensed Professional Counselor (LPC), is responsible for providing behavioral health care services.
- Health educators: Health educators, Licensed Vocational Nurses (LVN), provide education and learning opportunities for self-care including insulin administration, checking of blood sugar and fall prevention.
- Nutritionist: The nutritionist assists patients in the development of personalized nutritional goals and a plan for reaching said goals.
- Promotoras(es): These trained individuals assist the behavioral health component of the project by providing peer support, facilitating health and wellness activities, and assistance in navigating the clinic.
- Electronic Medical Records: The NCDV Clinic system uses MicroMD where patient data is monitored and tracked. For the evaluation study, relevant data was exported from the MicroMD into a Wellcentive database. The Wellcentive database was used for managing all data related to the study.

Activities: The activities section of the logic model provides an overview of NCDV's programmatic activities at the patient and clinic level:

- Diagnoses of chronic illness and development of tailored care plans to meet patient need
- Care coordination between primary/preventative and behavioral health care – Primary care physicians diagnose chronic illness and initially identify patients in need of mental health services based on the clinical interview and physical evaluation
- Health promotion and risk reduction training – program staff receive training to improve behavioral-health services provided.
- Tracking and monitoring patient health – Patient data is monitored and tracked through streamlined Electronic Medical Record (MicroMD)
- Health and wellness program delivered in clinic – as part of the coordination of care and preventative health, patients are referred to health and wellness programs.

Outputs: Program outputs are the changes for individuals, communities, organizations, or systems. Below are the expected outputs.

- Recruit 338 participants into each arm of the study (intervention group and comparison group)
- Creation of patient care plan
- Increased connections to behavioral health services, community resources and chronic disease management programs
- Improved compliance with treatment and attendance follow-up appointments
- Improved provider collaboration and communication

Short-Term Outcomes: Short-term outcomes are the changes that are expected to occur after 6 months of the participant's enrollment in NuCare's program model. By working with program staff, patients will improve knowledge of and skills for self-management and disease prevention. These were assessed qualitatively in the study via focus groups and interviews.

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

Intermediate Outcomes: Intermediate outcomes are the changes that are expected to occur after 12 months of the participant's enrollment in program. Intermediate outcome goals are outlined below. All intermediate outcomes were reported on during the study.

- Clinic Level: Improved communication across providers; awareness of IBH best care practices; closer collaboration between providers; workflow alignment across primary and behavioral health
- Patient Level: Reduced BMI, HbA1c, blood pressure levels, depressive symptoms; Increased functioning and quality of life

Long-Term Impact: Long-term outcomes are the changes that are expected to occur during 18 months of the participant's enrollment and are beyond the scope of the planned intervention and evaluation.

The approved SEP indicates that all long-term outcomes will be measured and reported on during the study. To clarify the measurement of long-term outcomes as described in the SEP, the final report includes findings on long-term outcomes at 18 months *at the clinic level only.* Assessment of long-term patient level outcomes will be limited to the first 12 months reported because data collection at the individual level does not include an 18-month measurement point. This is a deviation from the approved SEP.

- Clinic Level: Increased level of IBH integration.
- Patient Level: Reduced BMI, HbA1c, blood pressure levels, depressive symptoms; Increased functioning and quality of life

Overview of Impact Study

The NuCare study conducted a quasi-experimental design (QED) to estimate program impacts by comparing the outcomes of program participants (intervention group) to the outcomes of non-participants who are observationally equivalent to program participants (comparison group). By using a QED, the evaluation of the NuCare program was likely to advance the evidence base related to integrated care models at clinics serving predominantly low-income, Hispanic communities. Given that the proposed NuCare program modified and adapted models to be culturally relevant to the unique border community, the existing level of evidence was preliminary.

Research Questions

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

Implementation Questions

The following evaluation questions examined program implementation as presented in the SEP. The final implementation evaluation included focus groups as well as interviews and assessment of quantitative implementation data.

1) Did the NuCare program reach its intended target population?
2) What are the components of the NuCare program and how do these components work "on the ground" at 6 and 12 months?
    a. Are these components different than what was planned? If so, why?

3) What level of integrated behavioral health did NCDV achieve as a result of implementing the NuCare program?
    b. To what extent have providers and program staff adopted the components of the NuCare program at 6 and 12 months, and what are the facilitators and barriers to adoption?
    c. To what extent do providers and staff buy-in to the NuCare program, and how has that buy-in affected implementation?
4) To what extent did the comparison group receive program-like components?
5) To what extent did NCDV implement the NuCare model with fidelity?
6) How satisfied are NuCare patients with the services they have received? How satisfied are providers with the NuCare program?

Impact Questions

The primary impact measure for the NCDV intervention was HbA1c. Below are the confirmatory and exploratory research questions as presented in the SEP. This final report presents findings labeled by Impact Question.

1) Do patients who participate in the NuCare intervention experience improvements in HbA1c measures after 12 months when compared to patients that do not participate in the intervention? *This question is confirmatory.*
2) Do patients who participate in the NuCare intervention experience improvements in BMI after 12 months when compared to patients that do not participate in the intervention? *This question is exploratory.*
3) Do patients who participate in the NuCare intervention experience improvements in depressive symptoms, as measured by PHQ9, after 12 months compared to patients who do not participate in the intervention? *This question is exploratory.*
4) Do patients who participate in the NuCare intervention experience improvements in blood pressure, when compared to patients that do not participate in the intervention? *This question is exploratory.*
5) Do patients who participate in the NuCare intervention experience improvements in quality of life, as measured by the Duke Health Profile, after 12 months when compared to patients that do not participate in the intervention? *This question is exploratory.*

Contribution of the Study

The NuCare evaluation contributes to the body of evidence associated with the understanding of IBH services in clinics serving predominantly low-income, Hispanic communities. The NuCare program combined components of the integrated care model studied by Druss et al. (2001), and the collaborative care model studied by Sanchez & Watt (2012). The Druss model involves patient education and prevention and increased interaction among the care team. The Sanchez and Watt (2012) model finds that collaborative care, where structured care involves a greater role of nonmedical specialists to augment primary care, has emerged as an effective intervention to improve quality of primary care and patient outcomes with low-income, Spanish speaking populations. The NuCare evaluation targeted a moderate level of evidence by adapting components from available quasi-experimental evidence and adapting these models to ensure they are culturally relevant and appropriate for their population.

With its quasi-experimental design (QED), this study achieves a preliminary level of evidence for NCDV's NuCare program. An RCT was not feasible due to workflow of the clinic and the structure of the intervention. At Mission Clinic, all primary care providers (e.g., physicians and physician assistants) were trained in the NuCare intervention model and services were delivered to all patients eligible for the program. By using a quasi-experimental design, the evaluation of the NuCare program contributes to the evidence base related to integrated care models at clinics serving predominantly low-income, Hispanic communities.

Use of a QED was designed to mitigate major threats to internal validity. The comparison group used for this study was composed of patients from similar clinics (the Alton and Edcouch clinics within the NCDV clinic system). The QED for NCDV identified and controlled for observed participant characteristics that may affect impact measures of interest. The use of a comparison group from an external site aimed to enhance external validity (i.e., generalizability).

The NuCare program was implemented to a moderate to high degree of fidelity, and the evaluation was conducted as intended. The study also meets the criteria for effective evidence. As discussed in the Impact Study section of this report, positive and statistically significant results were demonstrated for the exploratory outcome of quality of life when comparing the intervention group to the comparison group. All statistically significant results achieved small effect sizes (Cohen's $d > 0.2$). There were no negative intervention effects on confirmatory or exploratory outcomes across all outcome analyses. Further, because the NCDV clinic serves a predominantly low-income, Hispanic population, the study design and implementation will help the clinic as well as external audiences better understand the various aspects of the NuCare program in addressing physical and behavioral health concerns of this population.

SIF Evaluation Plan Updates

In December 2017, the Interim Report submitted for NuCare provided a snapshot of the study as of September 2017. Preliminary findings indicated that the program appeared to be implemented with fidelity with the exception of a seven-month delay in the implementation of promotora-delivered wellness classes. Program implementation appears to have improved as NCDV staff have become more comfortable and experienced with program components and the new workflow. Other deviations from the approved SEP reported in the Interim Report include clarifying limitations on data available for measuring long-term outcomes and the timing of the interim and final report. No changes in the study design occurred since the interim report. Analyses described in the SEP were also slightly modified in response to field conditions, and the Principal Investigator was replaced during the period between the interim and final report. Analytic plan changes are presented in the impact analysis section.

IMPLEMENTATION STUDY: STUDY APPROACH, METHODS, AND FINDINGS

Implementation Study Design

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

Qualitative Data Collection Methods and Analysis

The program's evaluator, Health Resources in Action (HRiA), conducted qualitative data collection at two points in time for the implementation study. Across the two points in time, a total of 19 staff were interviewed (8 staff participated in both the interim and summative interviews), and 18 patient participants were involved in focus groups.

For the mid-point interviews (April 2017) a total of 14 staff interviews were conducted in-person. Mid-point interviews were intended to be conducted approximately 6 months after initial study enrollment. Given logistics challenges, these interviews instead were conducted approximately seven months after initial study enrollment, a deviation from the SEP. After the study concluded, 13 interviews were conducted (in mid-May 2018, approximately one month after the study ended). Interview participants included clinical providers (both 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** presents the

semi-structured interview guides used to conduct the interviews at the mid-point and final data collection periods.

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

There were 18 intervention participants in the three focus groups, ranging from 4 to 9 participants per focus group. **Table 1** describes participant demographics for the three focus groups. All participants resided in Hidalgo county and self-identified their ethnicity as Hispanic or Latino. Approximately three-fourths of participants self-identified as female (76.5%) and White (76.5%). A majority of participants were between the ages of 45 and 64 (83.3%) and spoke Spanish as a primary language (72.2%). Around half of participants had less than a high school diploma (56.3%) and did not have health insurance (50.0%).

Table 1. NCDV Pre-Focus Group Demographics Survey

	NCDV (n=18)	
Measure	N	%
County		
Hidalgo	18	100.0
Missing	--	--
Sex		
Male	4	23.5
Female	13	76.5
Missing	*1*	--
Age		
<35	0	0.0
35-44	2	11.1
45-54	6	33.3
55-64	9	50.0
65+	1	5.6
Missing	--	--
Ethnicity		
Hispanic/Latino	18	100.0
Missing	--	--
Primary Language		
Spanish	13	72.2
English	4	22.2
Spanish and English	1	5.6
Missing	--	--
Education		

Less than a high school diploma	9	56.3
High school degree or equivalent (e.g., GED)	4	25.0
Some college, junior college, or vocational school	1	6.3
College degree or more	2	12.5
Missing	*2*	--
Health Insurance		
None	9	50.0
Private	7	38.9
Other	2	11.1
Missing	--	--

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 and one focus group were conducted in English and two focus groups were conducted in Spanish to match the primary language spoken at home by the majority of participants.

All interviews and focus groups were recorded digitally and transcribed. For the summative interviews and focus groups, two trained team members 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=0.82). 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 together, and findings were summarized in narrative descriptions organized by theme with illustrative quotes. If qualitative findings changed from mid-point data collection to summative data collection, it is noted.

Implementation Study Findings

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

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

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

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

- 18 years of age or older
- Lives in Hidalgo or Starr Counties
- (Diabetes) A1C ≥ 6.5%

NCDV enrolled 756 participants into the intervention (n=329) and comparison groups (n=427). Participants were primarily female (70.5%) and Hispanic (99.3%) whose primary language was Spanish (80.7%). The mean age of participants at enrollment was 54 years, a majority (61.5%) reported being not employed, and the majority (62.7%) reported being married. Almost all participants reported Hidalgo County as their residence (99.2%). Data are presented in **Table 2**. All participants met the study eligibility criteria. The prevalence of the individual eligibility criteria among the enrolled sample is provided in **Table 3.**

Table 2. Participant Demographic Descriptive Statistics

	Full Sample (n=756)		Intervention (n=329)		Comparison (n=427) p value	
Variables	N	%	N	%	N	%
Sex						
Male	223	29.5	89	27.1	134	31.4
Female	533	70.5	240	73.0	293	68.6
Missing	--	--	--	--	--	--
Ethnicity						
Hispanic/Latino	751	99.3	326	99.1	2	0.5
Non-Hispanic/Non-Latino	5	0.7	3	0.9	2	0.5
Missing	--	--	--	--	--	--
Race						
White	755	99.9	328	43.4	427	56.7
Other	1	0.1	1	0.3	0	0.0
Missing	--	--	--	--	--	--
County						
Hidalgo	750	99.2	325	98.8	425	99.5
Starr	6	0.8	4	1.2	2	0.5
Missing	--	--	--	--	--	--
Age						
Mean	54.1	--	55.9	--	52.7	--
SD	10.6	--	10.2	--	10.7	--
<35	26	3.4	9	2.7	17	4.0
35-44	105	13.9	31	9.4	74	17.3
45-54	241	31.9	93	28.3	148	34.4
55-64	295	39.0	148	45.0	147	34.4
65+	89	11.8	48	14.6	41	9.6
Missing	--	--	--	--	--	--
Employment						
Not Employed	465	61.5	199	60.5	266	62.3
Employed	286	37.8	126	38.3	160	37.5
Migrant Farm Worker	4	0.5	3	0.9	1	0.2
Student	1	0.1	1	0.3	0	0.0
Missing	--	--	--	--	--	--
Marital Status						

	Full Sample (n=756)		Intervention (n=329)		Comparison (n=427) p value	
Variables	N	%	N	%	N	%
Divorced	44	5.9	28	8.6	16	3.8
Married	471	62.7	193	59.4	193	59.4
Separated	68	9.1	24	7.4	44	10.3
Single	110	14.7	53	16.3	57	13.4
Widowed	58	7.7	27	8.3	31	7.3
Missing	5	--	4	--	1	--
Primary Language						
English	144	19.2	61	18.9	83	19.4
Samar-Leyte	0.1	0.0	0	0.0	1	0.2
Spanish	605	80.7	262	81.1	343	80.3
Missing	6	--	6	--	0	--
History of Diabetes						
No	111	14.7	27	8.2	84	19.7
Yes	645	85.3	302	91.8	343	80.3
Missing	--	--	--	--	--	--
History of Hypertension						
No	324	42.9	148	45.0	176	54.3
Yes	432	57.1	181	55.0	251	58.8
Missing	--	--	--	--	--	--
History of Obesity						
No	301	39.8	131	39.8	170	39.8
Yes	455	60.2	198	60.2	257	60.2
Missing	--	--	--	--	--	--
History of High Cholesterol						
No	164	21.7	55	16.7	109	25.5
Yes	592	78.3	274	83.3	318	74.5
Missing	--	--	--	--	--	--
History of Depression						
No	703	93.0	305	92.7	398	93.2
Yes	53	7.0	24	7.3	29	6.8
Missing	--	--	--	--	--	--
Level of Physical Activity						
Never	310	41.0	119	36.2	191	44.7
1-2 times/week	157	20.8	82	24.9	75	17.6
3-4 times/week	107	14.2	50	15.5	56	13.1
5-6 times/week	54	7.4	16	4.9	38	8.9
Daily	128	16.9	61	18.5	67	15.7
Missing	--	--	--	--	--	--
Smoking Status[a]						
Current Every Day Smoker	35	4.6	20	6.1	15	3.5
Current Some Day Smoker	18	2.4	6	1.8	12	2.8

	Full Sample (n=756)		Intervention (n=329)		Comparison (n=427) p value	
Variables	N	%	N	%	N	%
Former Smoker	121	16.0	39	11.9	82	19.2
Never Smoker	582	77.0	264	80.2	318	74.5
Missing	--	--	--	--	--	--
Alcohol Consumption						
Never	588	77.8	248	75.4	340	79.6
Monthly or Less	96	12.7	50	15.2	46	10.8
2-4 per/month	50	6.6	21	6.4	29	6.8
2-3 per/week	14	1.9	7	2.1	7	1.6
4+ per/week	8	1.1	3	0.9	5	1.2
Missing	--	--	--	--	--	--
Insurance Status						
Insured	198	26.2	101	30.7	97	22.7
Uninsured	558	73.8	228	69.3	330	77.3
Missing	--	--	--	--	--	--

Table 3. Prevalence of Eligibility Criteria in NuCare Intervention and Comparison Group Participants

Eligibility Criteria	**Prevalence in Enrolled Sample**
Age (≥18 years)	**100.0%**
<34 years	3.4%
35-44 years	13.9%
45-54 years	31.9%
55-64 years	39.0%
≥65 years	11.8%
Diabetes (HbA1c ≥6.5%)	**100.0%**
HbA1c 6.5%-7.9%	45.6%
HbA1c ≥8.0%	54.4%
Hidalgo or Starr County	**100.0%**
Hidalgo	99.2%
Starr	0.8%

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

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

The NuCare program's specific components are described in **Appendix B. Program Logic Model** and in the Program Definition section. In summary, the program aimed to enhance integration through a multidisciplinary team approach in order to improve the health status of patients with obesity, diabetes, and/or depression. At its core, the NuCare project consisted of: 1) community health worker (CHW) integration into the clinic team through depression screening and other patient services, 2) integration of nutritionists into the clinic team to work with patients to set goals and monitor progress, 3) mediated

health education meetings led by licensed vocational nurses (LVN); and 4) introduction of a full time Behavioral Health Provider.

How Components Work "On the Ground"

Interview and focus groups explored how the NuCare program was implemented. When asked about how primary care and behavioral health services were coordinated or connected, interview participants highlighted communication practices, clinic space, workflows, and data systems as the key components to NCDVS's integrated model. At the mid-point evaluation, interviewees identified staff understanding of the NuCare program, data systems, and workflows as critical to IBH integration.

Communication
According to interview participants in the mid-point and summative evaluations, communication practices were among the core components of the NuCare integration strategy. In-person communication was reported as the most effective mechanism for program implementation and relationship building. For example, staff explained that brief and informal conversations with primary care doctors was often a more efficient way to communicate programmatic changes or requests. A few participants also indicated that emails helped facilitate integration between disciplines, especially as it related to warm handoffs. One participant shared, *"She [behavioral health provider] will email me if she feels that I need to pay special attention to a patient before an appointment."* Staff reported that collaborative communication between primary and behavioral health improved at NCDV throughout the duration of the NuCare program. Participants noted this improvement was facilitated by cross-departmental meetings, team huddles, Performance Improvement Committee (PIC) meetings, and informal consults between primary and behavioral health. When describing the monthly provider meeting, one interview shared, *"In provider meetings we talk about how we [behavioral health and primary care] could combine forces to make things a little better for us all*."

Clinic or Physical Space for Co-Location
According to focus group and interview participants, the physical integration of the NuCare model was facilitated by the creative use of clinic space. Specifically, participants noted co-locating nutrition with primary care and hosting health education classes in the lobby as examples of visibly integrating services at NCDV. Having co-located services has been central to providing comprehensive and integrated care, according to both interview and focus group participants. One interviewee shared, *"We were having problems with patients leaving the room and not ending up with the nutrition or counselor…a lot of things happen from room to room."* Another participant added, *"Our sessions are short but to the point and the patients don't have to be routed to nutrition and wait another 30 minutes or an hour. What I've heard from patients is, 'I like when you come into the rooms because we don't have to wait…we don't have to go to you, you come to us.'"*

Data Systems
In addition to the communication practices discussed above, the primary form of electronic communication for NCDV's model was its data system, which had been in place prior to the start of the Sí Texas program. Interview participants noted that the electronic medical record, MicroMD, facilitated integration of primary and behavioral health by allowing providers to view patient notes and to flag key areas to address. One participant shared, *"Mostly everything happens through the EMR; doctors will send orders through the system and that's how we do the warm handoff."* While mostly reported as a facilitator to integration, a few participants noted the limitations of the NCDV's data systems, most

notably the challenge of developing customized reports in the electrical medical record. One interviewee shared, *"The reporting system is very limited. If you want a specific report that you can do through the [MicroMD] EMR you have to reach out to another company. You tell them what you want and then a week or more later you get a report and it wasn't what we wanted."*

Workflow
Workflow, or how patients and clinical staff move within the clinical space, was seen as a key component of integration and closely related to NCDV's communication practices. NuCare staff indicated that a critical component to implementation was being intentional about adapting to the system in which the program was operating. Adapting behavioral health and ancillary services to the existing flow as to not interrupt or delay care was described as essential for provider buy-in. One participant explained, "*We don't want to interrupt the flow of the doctor. The fact that they [providers] have easy access and can find us whenever they need us is important."*

Implementation as Planned

The NuCare program was implemented as planned except for the brief intervention component of warm handoffs, a delay with the start of the wellness classes, and some staff turnover. Interview participants involved in the mid-point and summative evaluations indicated that NCDV implemented their program to a moderate to high level of fidelity. As noted above, co-location and in-person communication supported the building of relationships among members of the NuCare team. As program implementation progressed, staff became more comfortable with the NuCare model and leadership reviewed barriers and facilitators to identify strategies to strengthen implementation.

NCDV's approach to warm handoffs for the NuCare program called for a departure from the traditional warm handoff approach—where the primary care provider would introduce the patient to the behavioral health provider and a future appointment would be set up—to a "brief intervention" approach—where the behavioral health provider would initiate a 15-20 minute intervention upon request from the primary care provider (in person or via internal email). This update to the traditional warm handoff approach was a response to the changing needs of the population served by NCDV. For example, interviewees explained that brief interventions facilitated connections to behavioral health in a non-stigmatizing way. One interviewee summarized, *"I think it's been very beneficial for [patients] because a lot of this population is hesitant to go to a counselor. They say they're not crazy so introducing ourselves in a different light and talking about behavior changes has really helped them and then their time [constraints] also."* NCDV intended to implement the brief intervention version of the warm handoff. After the midpoint in the study, NuCare leadership became aware that warm handoffs did not consistently include the brief intervention component. NuCare leadership acted to increase buy-in and utilization of the warm handoff with brief intervention approach by adjusting clinical pathways and standing delegation orders. However, these changes did not occur until April 2018 toward the end of the study.

In terms of the wellness classes, scheduling delays were due to institutional changes that were out of the control of NuCare staff. Staff interviewees explained that wellness classes were delayed for several months during the early stages of program implementation and were "revamped" to be more structured and led by community health workers beginning May 2017[1]. Lastly, staff turnover—both

[1] Wellness classes began in May 2017. Classes delivered between May 2017 and April 2018 included: Walking Group, Physical Activity, Chair Yoga, Cooking Demonstrations, Health and Wellness, Support Group

frontline staff and administration—caused NCDV to modify staff roles and responsibilities. Despite these adaptations, NCDV implemented the NuCare IBH model to a moderate to high degree of fidelity by working diligently to facilitate communication and workflows to support integration.

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

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

Implementation of Integrated Behavioral Health

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

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

NCDV completed the AIMS IBH checklist October 2016 (pre-intervention implementation) and August 2018 (post-intervention implementation). **Table 4** and **Table 5** present NCDV's data from these assessments. NCDV reported improvement in four of the five IBH core principles from baseline to 12 months. NCDV began the study by applying the fifth core principle (evidence-based care) to most or all patients, a practice that continued through the end of the study. There was additional change in the IBH core components and tasks with nineteen showing improvement and nine remaining the same from baseline to 12 months (five of which were applied to the care of "most/all" patients at baseline). Two components showed a decrease in how they were applied in patient care: "Facilitate and track referrals to specialty care, social services, and community-based resources" and "Use valid measurement tools to assess and document baseline symptom severity." When asked about this decrease, respondents noted an increased knowledge of the providers and program staff in the implementation of IBH that led to a stronger understanding of the implementation of the core principles.

Table 4. 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.		• ✓	

Table 5. IBH Checklist Baseline to 12 months: Core Components and Tasks

We apply this principle in the care of (none, some, most/all) our patients.			
	None	**Some**	**Most/All**
Patient Identification and Diagnosis			
Screen for behavioral health problems using valid instruments			• ✓
Diagnose behavioral health problems and related conditions			• ✓
Use valid measurement tools to assess and document baseline symptom severity		✓	•
Engagement in Integrated Care Program			
Introduce collaborative care team and engage patient in integrated care program		•	✓
Initiate patient tracking in population-based registry	•		✓
Evidence-Based Treatment			
Develop and regularly update a biopsychosocial treatment plan		• ✓	
Provide patient and family education about symptoms, treatments, and self-management skills		•	✓

We apply this principle in the care of (none, some, most/all) our patients.			
	None	Some	Most/All
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	•	✓	
Program Oversight and Quality Improvement			
Provide administrative support and supervision for program		• ✓	
Provide clinical support and supervision for program	•	✓	

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

NCDV's NuCare program was implemented to a moderate to high degree of fidelity due to the modifications mentioned above that include inconsistent implementation of the brief intervention component of the warm handoff, the delay of wellness classes, and some staff turnover. Focus group and interview participants were asked what facilitated or hindered program implementation as well as patient participation in NuCare. The section below lists facilitators and barriers expressed by staff interviews and focus group participants.

Adoption Facilitators

At the mid-point evaluation, interviewees noted several successes to program adoption, including increased communication and coordination between behavioral health and primary care, improved patient access, and staff training. During the summative interviews and focus groups discussions, adoption facilitators included increased communication, warm handoffs, staff relationships, the physical space of the clinic, trainings, and flexibility.

Communication

Communication was the most frequently mentioned facilitator of program adoption according to NCDV staff interviews. Participants mentioned various ways in which communication facilitated program adoption; team huddles, PIC meetings, and cross-departmental meetings were often described as mechanisms to collaboration across the NCDV system. Provider meetings—where behavioral health and primary care would meet monthly—were highlighted as bringing together the two disciplines to share information and collaborate on treatment plans for patients. Interviewees also noted that electronic communications like automated email messaging through the EMR facilitated program implementation by providing quick ways to collaborate across departments.

Warm Handoffs

The adoption of warm handoffs was frequently described as a program strength. While the original design of the NuCare warm handoff was to include a 15 to 20-minute brief intervention, summative data collection and case notes document that implementation of the brief intervention component was not implemented as part of the warm handoff consistently until April 2018 when the study was largely over. This adaptation, according to staff, was facilitated by behavioral health providers proactively seeking patients before a traditional referral from primary care, and by the creation of clinical pathway templates and supporting materials (see **Appendix H: Clinical Pathway Templates and Supporting Materials**) to "guide" primary care staff like medical assistants to the appropriate behavioral health referral. Regarding the modification of the warm handoff, one interviewee explained, *"[Behavioral health] has been a very reactive model, but now it's more proactive. They [behavioral health] look at the list of patients coming in, look at their diagnoses and current complaints, and they may initiate a contact or encounter before the [primary care] provider sees them."* Regarding clinical pathway templates,

interviewees shared, "*We have created clinical pathways to establish when [primary care] should handoff to behavioral. So, if the patient has an A1C or depression score over 9 it should be an automatic referral or warm handoff to the behavioral health consultant*."

Staff Relationships
Relationships between primary care, behavioral health, and ancillary staff were seen as critical to program adoption. NuCare project staff explained that there were early challenges with buy-in across the organization due to a clinic culture that was historically slow to adopt change. To change this, shared interviewees, project staff created intentional opportunities to strengthen personal connections among staff. This was done by increasing opportunities to collaborate cross-departmentally, attending agency-wide trainings, and more informal interactions that connected staff on a personal level. One interviewee shared, *"I do attempt to communicate with the doctors, saying good morning, and sometimes do a little bit of side talk. I want them to be comfortable with me, so they'll be able to say 'Okay, I know them, we have a relationship.'"* NuCare staff added that relationships with other Sí Texas subgrantees, partner evaluators, and funders were also important to program implementation.

Clinic or Physical Space
As discussed in the preceding section, interview participants frequently mentioned the creative use of clinic space that facilitated integration of primary and behavioral health services. For example, community health workers led health education presentations in the lobby of the clinic, which was reported as a critical component to increasing patient participation in program services. One interviewee shared that these highly-visible services helped destigmatize behavioral health, saying, "*Patients were very hesitant to understand [behavioral] services for a while but with the increased activities of things like the lobby presentations, that's really helped a lot."* The co-location of nutrition and ancillary services were also described as integration facilitators. Providers indicated that having quick and easy access to project staff reinforced the idea of an integrated team. One provider shared, *"The communication is better because [behavioral health]* is *easily accessible…she's here, physically here, so I don't have to send patients to San Juan."*

Trainings
Trainings, both internal and external, were described as facilitators to program implementation. Specifically mentioned were trainings conducted by an external consultant on integrated behavioral health that were offered clinic-wide. Internal trainings, according to interviewees, were geared to reinforce NuCare's programmatic goals and purpose, as well increasing staff capacity to implement wellness classes and ancillary services. In terms of reinforcing programmatic goals, one interviewee shared, *"It took a lot of different types of trainings specifically geared towards primary [care staff] to work because [primary and behavioral health] were very separate…they were two different entities we needed to combine."* According to staff interviews, it was important for trainings to be geared towards primary care to enhance staff competencies and improve buy-in around behavioral health, which according to participants, was less common in the area. Related to building staff capacity, participants in the mid-point and summative evaluations indicated that trainings that focused on specific topics like diabetes management, medication adherence, and motivational interviewing were most helpful.

Flexibility
Lastly, flexibility from NCDV staff was reported as an integral part of successful program implementation. For example, staff roles morphed throughout the projects to meet the needs of the project and patient needs. Community health workers, shared participants, went from focusing on

recruitment efforts to leading components of health education and outreach. Behavioral health staff and ancillary services were flexible about timeframes for providing services to convenience primary care providers. In addition, it was reported that there were several changes in staffing that resulted in restructuring of program components and increased responsibilities for junior level staff. Interview participants shared that being flexible was critical to ensuring that the NuCare project was nimble and adaptable.

Adoption Barriers

Several challenges to program adoption including reaching enrollment targets, leadership and provider buy-in, and staffing were mentioned during the mid-point interviews. During summative focus group and interview discussions barriers to adoption mentioned included early communication and buy-in, hiring and staffing, clinic space, and data systems.

Early Communication and Buy-In

Communication between primary and behavioral health was reported as fragmented in the early stages of project implementation. Mid-point interviewees described early challenges related to workflows and staffing, with many indicating that early communication surrounding these issues was lacking. These findings were also prevalent in the summative evaluation, with multiple interviewees reporting minimal communication between project staff, primary care, and clinic leadership. One interviewee shared that, *"There were times during this process that there was no communication between the medical and the behavioral side where the medical department was basically at times, blind-sided because they didn't know what was happening."* Interviewees attributed these early communication issues to multiple changes in leadership and program staff; yet these challenges were perceived as having a minimal effect on the model's overall fidelity. Interviewees shared how project and administrative staff worked diligently to facilitate and adapt workflows, communication, and staffing to support integration. Examples of these strategies to improve communication and buy-in included attending internal meetings to explain the project goal and purpose, adjusting workflows and appointment times to decrease wait times, and encouraging staff to attend internal and external trainings related to IBH.

Hiring and Staffing

As mentioned above, interviewees in the summative evaluation reported early challenges with hiring and retaining of staff, both in terms of frontline providers and leadership/administration. This finding was also prominent in the mid-point evaluation. Interviewees explained that there was a high level of staff turnover at the clinic. According to participants, these frequent changes of staff—especially clinic leadership—made it challenging to realize NuCare's vision, goals, and fully understand roles and responsibilities. One interviewee shared, *"We had some changes in medical directors and turnover with some of the staff. I think that slowed our progress because you're having to re-educate, retrain, basically having to communicate the whole program again."* It was also reported that there was a limited number of behavioral health staff, which impacted the ability to successful execute a warm handoff. For example, an interview explained, *"One of the challenges I've seen is that providers will give the warm handoffs to the LPC, but then the LPC is not available because she also does appointments and she can't do anything about it because she's in a consultation with another patient."* Another interviewee added, "*The providers want it, they really really want it [behavioral health]. But we have to have realistic expectations because we're understaffed…, So, you do what you can do but we can't give them the expectation that anytime you [providers] need help it's going to come. Being understaffed is hard."*

Workflows

As previously mentioned, NuCare workflows were modified early on to improve efficiencies and to adapt to the NCDV system in which it was operating. It was important, shared participants, that NuCare worked seamlessly with primary care as to not disturb the pre-established clinic flow or culture. However, participants noted that there were early challenges to the NuCare workflow that included patient delays or instances of behavioral health not being available for a warm handoff when a primary care initiated an encounter. One participant summarized*, "The [problems] are more of the logistics of not interrupting patient flows and the other is the availability of the LPCs when they need them."* These challenges led the NCDV team to adapt workflows to improve processes and productivity levels. An example of one these workflow modifications, shared participants, was adapting the warm handoff from a traditional model (primary care provider introduces patient to behavioral health provider and a future appointment with the behavioral health provider is scheduled) to more of a brief intervention approach. According to interviewees reflecting at the summative phase of the evaluation, this workflow and service adjustment significantly improved patient wait times and facilitated communication between disciplines by freeing up time for providers to collaborate on cases. However, documentation indicates that the brief intervention component of the warm handoff was not consistently implemented until the end of the study. Another example of workflow modifications was the creation of clinical pathway templates that assisted frontline providers such as medical assistants to initiate encounters with behavioral health. In turn, these workflow enhancements improved buy-in from primary care providers who were initially resistant to program implementation because of the perception that it would impact a smooth clinic flow.

Clinic or Physical Space

While most interviewees who discussed clinic space spoke positively about the physical integration of services, a few interviewees mentioned that NCDV's Mission layout was large and could be confusing to patients. For example, interviewees explained that when warm handoffs could not happen in the same room, it was more likely that patients would not follow through with additional services like medication management, case management, and nutrition. Staff interviewees explained that having participants stay in one room was important because it was more likely that patients would leave the clinic if they were redirected to services in different parts of the building. Further, interviewees reported that changes were recently made to move ancillary services to a different part of the clinic building; this meant that select services such as nutrition and the LPC were no longer co-located with primary care services. These changes, shared participants, created barriers to easily collaborative across departments. As one participant explained, "*The nutritionist used to be in the same building which was great because we could write a general referral and she's just next door to me. I'm not sure why she was moved to [another part of the clinic building]."*

Data Systems

As previously mentioned, NCDV's electronic medical record was mentioned as both a facilitator and barrier to adoption. While the system facilitated integration between providers, share participants in both the mid-point and summative evaluations, administrative staff interviewees explained that customizing data reports for internal and external reporting was challenging.

Participant Facilitators

Focus group and interview participants were asked to reflect specifically on facilitators that patients faced while participating in the NuCare program. The most frequently cited participant facilitators were relationships with clinic staff, cost, and improved health outcomes.

Relationships
Focus group participants reported strong relationships with clinic staff, especially the community health workers with the NuCare project. Patients reported that NCDV staff treated them with courtesy and respect, which was reported as a facilitator to participation. Focus group participants indicated having high-levels of trust with staff like community health workers, with one sharing, *"For me if the promotoras are calling you for something that will benefit you, well, you should take advantage of it."* Others noted how relationships with clinic staff improved their quality of life by being able to connect with someone who cared. One interviewee shared, "*Well, in general, the program has helped me feel important to someone. When the nutritionist tells me I've improved I feel it because sometimes my morale is all over the place because there are so many problems but when I come here and see everybody's smiling face I feel better."*

Cost
Focus group and interview participants indicated that services that were free of cost facilitated program participation. Interviewees mentioned that the no-cost services were critical to improving access of integrated health services in low-income communities. One interviewee shared, "*The [wellness] classes have been a life changing experience, not only for participants but for [staff]. Services that they can't get anywhere else because they're free. So, for us to offer them these services that's been something they've needed has really been something."* Focus group participants highlighted that other services within usual care at the clinic such as medication assistance was especially helpful, with one patient noting, "*It's really good to come here because they give you medication for 3 months."* Another added, *"Me and my husband have really been struggling and there's nobody who can cover that [medication] need, so any help from the clinic is a lot."* Further, a couple of focus group participants indicated that incentives were helpful to offset the costs of travel and facilitated participation in the NuCare program.

Improved Health Outcomes
Several focus group participants discussed improved health outcomes that in turn, facilitated participation in the NuCare program. The most frequently mentioned health improvements by focus group participants included weight loss, better control of diabetes, a reduction of prescription medications, and healthier eating. One patient shared, *"I used to weigh a lot and I felt really heavy. Now I have participated in several [classes] and feel better."* Staff interviewees also reflected on patients' improved health outcomes. One shared, *"Just last week I was at an event and a participant came over to me to say that she went from taking fourteen medications to only taking two."* When asked what prompted these improved health outcomes, another provider shared, *"You have your emotions under control, you're feeling better, you're exercising, you've changed your diet, you've lost weight. It's everything."*

Participant Barriers
In addition to barriers experienced by staff and providers adopting the NuCare program, focus group and interview participants were also asked to reflect on barriers that patients faced while participating in the program. Barriers discussed included transportation, outreach, stigma, costs, time, wait times, and the sociopolitical environment.

Transportation
According to participants, transportation was among the most challenging barrier to program participation. Participants indicated that many patients at NCDV depended on family or friends for transportation, which limited their ability to either make it to the clinic for an appointment or stay

additional time for ancillary services. One focus group participant noted, "*Since I don't drive they have to drive me all the way over here, so it requires a lot of patience from my son and daughter in law."* Others agreed and added*, "Getting here is hard because my daughter works, and it gets late so I have to go home instead of going here to the health thing."* Interview participants explained how transportation challenges exacerbate the financial limitations faced by patients, with one sharing, *"Sometimes patients lack transportation and they have to pay someone to bring them but then they're not able to pay at the clinic. So, it's either they get here or get their medication."* Interview participants indicated that it was important to be mindful of transportation challenges among the population by scheduling patients at convenient times and ensuring their appointments were not too long.

Outreach

Focus group participants reported that there was limited community knowledge regarding the NuCare program, which may have impacted program participation. Most participants reported being told about the program in-person at the clinic, and a few were told about the program by a family or friend. Still, participants noted that outreach efforts could be expanded to promote services at NCDV. One participant who had attended NCDV for many years shared, *"Lots of people don't realize the program exists. My mom is diabetic, and she hasn't noticed these [services]."*

Stigma

Several staff and patients suggested that community stigma around mental health was a barrier for patients coming to NCDV. Interview participants reported having to be strategic about how behavioral health services were presented as to not imply that patients were "crazy." One interviewee explained, *"Stigmatization is obviously huge. So, we talk about presenting services in a way that you're not implying that they're mentally ill.*" This stigma, shared interviewees, was not specific to behavioral health services. Staff interviewees explained that this approach of de-stigmatization was important for NuCare wellness classes as well, which covered a plethora of health issues including sexual health and coping strategies. One participant shared, *"There's a lack of education around HIV and its different stages because of the strong stigma behind in. We work to explain how to see these different stages and the dangers we might encounter and reduce the stigma behind it so we can clear them as well."*

Cost

Focus group and interview participants indicated that costs vary for clinic services, which can pose as a barrier to participation. While most participants spoke of minimal costs to participate in the NuCare program, they noted cost as a barrier to care outside of NCDV. As mentioned in the preceding section, participants indicated financial barriers associated with transportation to the clinic, which limited their ability to pay for medication, and as a result, were labeled as uncompliant by their providers. Specialty service and lab work to which patients were referred were specifically highlighted as being prohibitively expensive. Additionally, staff members discussed the pay structure of behavioral health services prior to the NuCare program and realized that payment for behavioral health services was not sustainable. One interviewee explained, "*The clinic at the time ran a very co-located style, behavioral health would receive the referrals and patients would come into see us. But unfortunately, what started happening is that you realized that the patients don't come in because there is a fee, there's a cost, and then there's transportation."*

Time

Lack of time because of work or competing family priorities were reported as barriers to participation. Focus group participants indicated that many work for hourly pay, and when time is taken off to attend

to one's health, it further burdens the financial pressures of community members. Others noted that clinic services were not conveniently scheduled for those who work, especially the wellness classes. Focus group participants also noted the many responsibilities—caring for older loved ones and children; working multiple jobs to make ends meet; navigating being undocumented, or lacking transportation—these multiple stressors were reported as competing with the limited time patients had to focus on their health.

Wait Times

Participants expressed that wait times at the clinic vary and can be a disincentive to participate in services. Focus group participants did note that wait times have improved in recent months, but more could be done to reduce the amount of time patients spent at the clinic. "*They give me an appointment at 9:30 am but I don't get on in until 11. Sometimes, by the time I leave here it's already 4pm."* It was reported that long waits were especially difficult for the diabetic population who had to monitor their blood levels and needed to eat regularly. Patients indicated that in order to visit the clinic "*you have to be psychologically prepared to wait and have patience."* Focus group participants also indicated that it would be helpful to give realistic expectations of how long they will wait. One participant explained, "*With my work schedule, sometimes I have to go in at 9 or 10. If my meeting is here at 8:30 am, I plan to work because I think I'll go in and get out. But nope, didn't happen and I had to leave."*

Sociopolitical Environment

Lastly, participants also noted that there was fear among the undocumented community, who were mentioned as having a large presence in the area. This stigma, shared interviewees, impacted participation in behavioral health and ancillary services like wellness classes. One participant shared, *"Right now at this moment, for political reasons, immigration [and customs enforcement] (ICE) is causing a lot of fear and sometimes people don't come because they're scared."* Others agreed and explained that undocumented residents may avoid areas where they are asked personal questions for fear of deportation. Further, staff interviewees indicated that following up with patients at the 6-month and 12-month time points was a challenge due to unanswered calls, changes in phone numbers, or addresses, which several attributed to the sociopolitical environment. One staff interviewee explained how this impacted engagement with the comparison group, sharing, "*One of the problems in the comparison group for retention was not a lot of people were picking up their phones. A lot of people were very skeptical about what the actual study was about or what having them go to the clinic was about, the information that they were giving me and how it would be used. And it was all because of this atmosphere of this past election and the mentality of America as a whole over immigrants and as you know, most of our population is immigrants."*

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

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

Clinic Culture

In general, interviewees perceived the clinic culture at NCDV to be a supportive environment for adoption of the NuCare program. Staff indicated that multiple programs are implemented as NCDV, and staff are used to being flexible to accommodate programming. One interviewee shared, "*We implement*

a lot of programs here, so this is not the first to happen. We're kind of used to it already, all of these new programs. So, staff are pretty positive about new programs because it's more services for patients." However, a few noted that the clinic culture was historically slow to adopting major changes, and that some were resistant to new initiatives. Part of this resistance, shared interviewees, was because of fragmented communication regarding program expectations that confused and frustrated staff. One participant shared, *"We have to get the people who are going to be involved in the project on board from day one. There needs to be open lines of communication regarding what the program is all about what the goals are, how the staff are going to redesign some processes. There were times when there was no communication and that creates additional challenges when we don't have everyone on the same page."* Interview participants noted that clinic culture began to adapt to the NuCare project after intentional efforts to educate staff about programmatic goals and expectations. One interviewee explained, "*They did presentations to the medical providers, gave them a summary of the program, basically what we were charged with as far as the program was concerned. So, the physicians and the medical providers were all on board and said 'okay, now we understand what to do here.'"*

Buy-In

Findings from the mid-point and summative interviews highlighted early challenges with frontline staff, leadership and administrative buy-in. It was reported that these challenges were present from the very onset of the project. For example, interview participants explained how the project grant was written by an external colleague of NCDV administration. While the opportunity was enthusiastically welcomed by NCDV, participants noted that it siloed early communication with frontline staff. One explained, "*This program was started by someone outside of the clinic. They had the drive and the idea, but then it was passed down to [clinic administrator] who left and thrown [to junior staff] without any guidance from administration." Another added, "One of the major problems was that someone had an idea, but that idea wasn't communicated in the best way, so we came across all these other problems."* Many noted changes in leadership that impacted implementation. Specifically, interviewees mentioned multiple staff changes among NuCare administration that "muddled" the vision of the project. One participant shared, *"Leadership was leaving and then this person would communicate with this person when they left, who communicated to another person and, but it felt like things were getting lost every time that happened."* Interviewees explained that early communication challenges impacted buy-in and an understanding of the program model. One participant explained how these misunderstandings impacted implementation, sharing, "*We really weren't doing the warm handoffs as the [original] IBH model stated and that was because of the lack of provider-buy in, cooperation, and just overall agency-wide communication."* These barriers improved, shared participants, when a new Chief Medical Officer (CMO) joined the clinic. Interviewees reported that the CMO was a strong supporter of IBH services and reinforced the importance of staff utilizing behavioral health services. One interviewee shared, *"It was communicated by the CMO that [warm handoffs] were a problem. [They were] able to communicate to the other providers to take these PHQ9s seriously and encouraged them that, even if they feel the [patient] needs a small intervention, to not be afraid and bring in the LPC."*

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

The comparison group was assigned to receive usual care at the Edcouch and Alton clinics including standard visits with a primary care provider and formal referrals to behavioral health care. Edcouch Clinic usual care for behavioral health entails referring patients with a PHQ-9 score ≥ 10 or when the PCP observes behavioral health distress to a NCDV clinic with a behavioral health provider. The nurse calls the Behavioral Health Care Manager to schedule an appointment to be seen by an LPC at the NCDV San

Juan or Mercedes clinic, dependent on the patient's discretion. In addition, if desired, the patient can call the care manager to set up an appointment to be seen by the LPC. If the patient shows suicidal ideation with a plan to hurt themselves or others, a call is made to the mental health authority, Tropical Texas Behavioral Health. Usual care regarding primary care involves a visit with the medical doctor.

Alton Clinic usual care for behavioral health entails referring patients with a PHQ-9 score ≥ 10 or when the PCP observes behavioral health distress, to outside services with an in-clinic visit with an LPC. The LPC is only at the Alton Clinic for one day every two weeks. Patients can call the care manager to set up an appointment to be seen by the LPC. If scheduling with the LPC at the Alton Clinic is inconvenient, the patient is given the option to set up an appointment with an LPC at the NCDV San Juan clinic or NCDV Mercedes clinic. If the patient shows suicidal ideation with a plan to hurt themselves or others, a call is made to the mental health authority, Tropical Texas Behavioral Health. Usual care regarding primary care involves a visit with the medical doctor.

During the course of the study, no comparison group participants received a warm handoff to an LPC within the NCDV system.

In September 2017, due to a change in NCDV system-wide policy, nutrition education services (review of American Diabetes Association informational sheet) were expected to be integrated into regular encounters. Patients had a brief educational encounter where they reviewed a handout from the American Diabetic Association with a provider. This was considered usual care within the NCDV system during the study. Intervention participants received more tailored care in meeting with a nutritionist to create a set of nutritional goals, a plan to achieve those goals, and to monitor their progress. For these reasons, this overlap in provided services was evaluated to have minimal impact on the study results.

Question 5. To what extent did NCDV implement the NuCare model with fidelity?

NCDV implemented the NuCare IBH model with a moderate to high degree of fidelity. Most components were implemented as planned, except for the limited implementation of the warm handoff with brief intervention, the delay of the wellness classes, and staffing changes. According to findings from the mid-point and summative evaluations, NCDV implemented their IBH program to a moderate to high degree of fidelity. Participants during the mid-point interviews described early challenges such as high staff turnover, service delays, and early workflow issues, and these themes were also prevalent in summative interviewees.

The expected dose participants were to receive was defined as at least one warm handoff encounter and one related regular encounter for the service related to the warm handoff (either nutrition services or behavioral health.) Of the intervention participants receiving nutrition services over the course of the study, a majority (73%) met minimum dose. For behavioral health services, 25% received the minimum dose (see **Table 6**).

Table 6. Number of Participants by Categories of Services Received

Dose Category	**Nutrition Services** (n=320)	**Behavioral Health Services** (n=138)
Participants with ONLY 1 Warm Handoff and no Regular Encounter	30	62

Participants with no Warm Handoff and ≥1 Regular Encounter	4	8
Participants with ≥1 Warm Handoff and ≥1 Regular Encounter	233	34
Participants with ≥2 Warm Handoffs and no Regular Encounters	53	34

In **Table 7**, data on utilization of services, for participants in the intervention group, through the full study period are presented. A total of 964 warm handoffs and 2,224 regular encounters were provided to participants across the different service types.

Table 7. Service Utilization Data by Number of Services Provided

Service Type	**Total Warm Handoffs**	**Total Regular Encounters**
Behavioral Health	202	105
Nutrition	762	422
Health Education/Nursing	--	894
Clinic Navigator	--	662
Peer Support Activities	--	141
Walking Group	--	39
Physical Activity	--	21
Chair Yoga	--	28
Cooking Demonstration	--	16
Health and Wellness	--	33
Support Group	--	4
Total (overall study)	964	2224

Of the 320 participants who received some type of nutrition services, 65% (n=209) received at least one warm handoffs before their first regular encounter. About half of participants receiving nutrition services had 3 warm handoffs before their first nutrition encounter (52%). For the 138 participants receiving some type of behavioral health services, 22% (n=30) had at least one warm handoff before a regular encounter indicating most first warm handoffs occurred after at least one behavioral health encounter. **Table 8** presents these results.

Table 8. Participants' Number of Warm Handoffs by Service Type

NUTRITION SERVICES		
Number of Warm Handoffs	Before 1st Encounter (n=237)	Over full study period (n=320)
0	28	4
1	146	49
2	63	95
3	0	165
4	0	7
BEHAVIORAL HEALTH SERVICES		
Number of Warm Handoffs	Before 1st Encounter (n=42)	Over full study period (n=138)
0	12	8
1	21	75
2	9	43
3	0	10
4	0	1
7	0	1

Of the 320 participants receiving some type of nutrition services, 74% received a regular encounter. Among the 138 participants receiving some type of behavioral health services, 30% received a regular encounter. **Table 9** presents these data.

Table 9. Participants' Number of Regular Encounters by Service Type

Number of Regular Encounters	Nutrition (n=237)	Behavioral Health (n=42)
1	111	22
2	85	9
3	27	5
4	14	6

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

Similar to findings at the mid-point evaluation, feedback from patients was generally very positive, with patients citing improvement in health care access, health literacy, and ultimately improved health outcomes as reasons for being satisfied. Interviewees indicated that patients were very receptive to the NuCare program and felt like they were being heard, and thus, took a more active role in their health. Focus group participants cited exercise classes and nutrition services among the services they enjoyed most. In the mid-point and summative interviews, participants noted that there used to be more frustration among patients because of long wait times, but workflow changes in the clinic decreased the amount of time patients spent at NCDV to get multiple services.

Services Provided
Patients spoke highly about the quality of services received as part of the NuCare program. Participants most frequently cited primary and behavioral health services, nutrition resources, followed by medication assistance and exercise classes as especially helpful. In terms of counseling services, participants reported learning strategies about things like grief and bereavement, and stress reduction techniques. One participant shared, *"I had depression because of infidelity problem. I was confused and would blame myself. [Then] I came to see the advisor and I felt really good, I felt encouraged and before I didn't feel that."* When discussing their satisfaction with nutrition services, one participant shared, *"I learned a lot in nutrition because they explain how to eat and explain how to make food. They remind you of what to avoid and what could jeopardize your [health]. That's why I like coming here."*

Health Literacy
Program services, specifically the nutrition services and behavioral health services were seen as increasing health knowledge and were cited as a significant reason why patients were satisfied with the NuCare program. As one patient shared, *"I used to take my diabetes so lightly but now that they've explained to me the consequences I have begun to be more concerned but before I wasn't, I never thought anything was going to happen to me."* Another focus group participant shared, *"Everything they explain to me [about diabetes] has been useful and now I understand this is something I should worry about. They explain to you the consequences and I have begun to be concerned when before I wasn't."*

Improved Health Outcomes
Apart from improved health outcomes, interviewees and focus group participants reported other improved outcomes, namely improved quality of life, from participation the NuCare program. When asked about the impact the program had in their lives, participants noted improvements in symptoms related to stress and family issues. Many focus group participants also indicated a reduction in chronic issues such as elevated A1C, hypertension, and depression. One shared, *"I felt depressed and didn't want to talk to anybody, but then they got me in this Sí Texas class. My A1C has gone down and I lost some weight and feel happier about myself."* Focus group participants also commented on the satisfaction with the wellness classes, sharing, "*I really like the idea of the exercise classes. It's built a community and has had a positive, overall outcome with those who participate."*

Provider Satisfaction
Provider and staff satisfaction with the program has been mixed, according to interviewees. Some providers have been resistant to change how they work, while others have been more receptive to the resources and staff allocated to their clinic. Interviewees did note some dissatisfaction due to limited

administrative support, which was perceived as creating barriers to the implementation of program components in a timely manner. Those who were generally satisfied with the program cited increased integration, access to care for their patients, and positive health outcomes as reasons. According to several interviewees at both the mid-point and summative evaluations, there was some dissatisfaction and hesitation from NCDV clinic staff during the early stages of program implementation.

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 overall understanding of the NuCare program, and sustainability and lessons learned.

Perception of Program Goals
When asked about the goals and purpose of the NuCare program, interviewees demonstrated varied understandings. Staff tended to report that the overall goal of the NuCare program was to improve chronic disease health outcomes, whereas patients reported that the NuCare program was intended to improve quality of life "*in many aspects in one's life*." While some interviewees had a view of the program based solely on lowering patients' A1c level or BMI, others shared a more holistic view of integrating primary care and behavioral health services overall.

Staff interviewees most frequently cited improved health outcomes as the primary goal of the NuCare program. Specifically, staff participants identified reducing A1c, PHQ9, BMI, hypertension, and improving quality of life as primary goals facilitated by warm handoffs. As one interviewee explained, "*We wanted to see if [we] added the warm handoffs and the added services such as the behavioral health consultant and the LVN and the promotoras, the patient should have overall decreased our measures, lower their A1C, lower their blood pressure, lower hypertension, lower depression rates, and increase their quality of life, and lower their BMI as well."*

Others mentioned that a primary goal of the NuCare program was to better integrate primary and behavioral health. As one staff participant shared, "*One of the major goals was to try to get the integration of the behavioral health and your primary care model basically to enhance it and to continue improving the integration going from the initial level that we were at."* Secondary goals reported by interviewees included increased health literacy/education, improved health care access, and lifestyle changes.

A few clinic staff who were less involved in the NuCare program reported a lack of clarity around the program goals and specific roles, noting, "*it's interesting because it's one of those things where I've heard multiple providers say, "What is Sí Texas, what are they doing?" and there's never really been an answer given to us in a clear, concise way."*

Sustainability and Lessons Learned

Leadership Buy-In
Several interviewees noted that having the NCDV administration involved early in the process would have helped get their buy-in and ensure the clinic was ready to implement the program at the start. Being able to identify and address administrators' and providers' concerns early could have made

implementation smoother. According to interviewees, initial program success would include all staff being on the same page about the program, its benefits, and operations.

Information Sharing
Having initial and continued communication about the program to all staff and providers, was seen as critical to program success. According to interviewees, increased communication between administration, clinic providers and staff, as well as training on the IBH model and its evaluation, would be helpful to make staff feel heard and included in efforts moving forward. Further, NuCare staff shared the importance of peer-to-peer support among the Sí Texas cohort, and technical assistance provided by the external evaluator and funder.

Data and Information Sharing
Interview participants highlighted the importance of knowing in advance what data will need to be collected for the program. Participants emphasized that it would be imperative to have a customizable EMR system at the onset of the program, along with training for all staff on how to use it. Interviewees acknowledged that evaluation planning was difficult since customizing data reports from MicroMD was challenging. Participants shared that moving forward it would be important to build data reporting capacities in-house for efficiency and to improve communication and information sharing for the success of similar interventions similar to NuCare.

Staffing
There were numerous lessons learned and opportunities for improvement around staffing, according to interview participants. Several interviewees stated that the clinic's patient volume has increased upon implementing the NuCare program because the clinic is recruiting more and promoting services. Given this increased volume, one interviewee suggested that it would have been helpful to have more behavioral health providers and nutritionists on staff at the Mission clinic to better meet the needs of patients and the clinic as a whole.

Program Replication and Scalability
Participants were asked what advice they would give to another clinic replicating the program. The most common suggestion was related to communication and change management. One participant summarized, "*I think the best advice that I would be able to give would be for staff to be really open about the idea and that change is really difficult, but it's not to make everyone's lives difficult, it's to improve patient care. So, I know that was one of the biggest barriers that I encountered was that people don't like change and it's not fun and they're really complacent or they're comfortable where they're at. That idea of change can be pretty difficult for people."*

IMPACT STUDY – APPROACH AND METHODS

Overview of Impact Study Design

For the evaluation, NCDV implemented its NuCare program in the Mission Clinic. This program consists of four components: community health workers, nutritionists and dieticians, mediated health education, and a full time behavioral health provider. This program includes the use of warm handoffs from the primary care provider to the other program providers and services. The NuCare program is based on a combination of components of the integrated care model studied by Druss et al. (2001), and the collaborative care model studied by Sanchez & Watt (2012). The Druss model involves patient education and prevention and increased interaction among the care team. The Sanchez and Watt (2012) model finds that collaborative care, where structured care involves a greater role of nonmedical specialists to augment primary care, has emerged as an effective intervention to improve quality of primary care and patient outcomes with low-income, Spanish speaking populations.

An RCT was not feasible due to workflow of the clinic and the structure of the intervention. However, use of a non-randomized quasi-experimental design (QED) helped to minimize threats to internal validity. A comparison group was used for this study. The comparison group was composed of patients from similar clinics (the Alton and Edcouch clinics in the NCDV clinic system) who met the same eligibility as participants in the intervention group, adults living in Hidalgo or Starr Counties, with an HbA1c of 6.5 or higher. The use of a comparison group from an external site enhanced external validity (i.e., generalizability). The study targets a moderate level of evidence and aims to remove barriers between behavioral and primary care particularly among a predominantly low-income, Hispanic population.

Impact Study Design and Methods

Study Design

The impact evaluation will use a non-randomized QED to evaluate the NuCare program's impact at the Mission Clinic by comparing Mission participants to those from the Alton and Edcouch comparison clinics. This design allowed for the identification and controlling of participant characteristics that may have affected impact measures of interest. Participants enrolled in the study were followed for approximately 12 months. Quantitative program implementation data related to participation in intervention components is also reported in this report (see Implementation Evaluation section).

Assessment of Baseline Equivalence

At baseline, sociodemographic characteristics were captured using a standardized set of questions developed by NCDV and currently being administered to the clinic population. These included characteristics such as gender, ethnicity, race, county, age, employment, marital status, primary language, historical health information, physical activity, smoking, and alcohol consumption. Baseline sociodemographic data were captured for all program participants; however, for marital status and primary language responses of "unknown" were recoded as missing, as noted in **Table 11**.

Baseline equivalence was assessed for chronic disease status using the study impact measures (HbA1c, BMI, PHQ-9, systolic blood pressure, diastolic blood pressure, and Duke General Health) as noted in **Table 10**. Equivalence was assessed using t tests for continuous variables and Chi-square tests for categorical variables. For PHQ-9, Duke General Health, and HbA1c measures, nonparametric tests were

employed due to non-normal distributions. The log transformation for BMI was used with the parametric test.

Examining baseline equivalence evaluates whether the two groups are statistically equivalent at that time point. For the six impact measures in NCDV's study, the intervention and comparison groups were statistically nonequivalent on three measures (PHQ-9, BMI, and diastolic blood pressure). At the beginning of the study, the intervention group had a lower mean diastolic blood pressure and BMI and a higher median PHQ-9 score than the comparison group.

Among patient-level demographic characteristics, the intervention and comparison groups were statistically equivalent on many measures; however, there were some statistically significant differences. The two groups differed on age, marital status, histories of diabetes and high cholesterol, as well as on behavior related measures of physical activity and smoking.

Table 10. Tests of Baseline Equivalence for Impact Measures

	Full Sample (n=756) Mean (SD)	Intervention (n=329) Mean (SD)	Comparison (n=427) Mean (SD)	p value
BMI[b]	**33.9 (7.0)**	**33.3 (6.4)**	**34.4 (7.4)**	**0.047**
Systolic	132.9 (19.3)	133.2 (20.3)	132.7 (18.5)	0.720
Diastolic	**78.6 (9.2)**	**77.0 (8.5)**	**79.8 (9.4)**	**<0.001**
Nonparametric Tests[a]	Median (SD)	Median (SD)	Median (SD)	
PHQ-9	**2.5 (18.7)**	**4.0 (23.8)**	**1.0 (12.6)**	**<0.001**
General Health	83.3 (265.3)	76.7 (286.2)	83.3. (265.3)	<0.001
HbA1c	8.1 (2.8)	8.1 (2.7)	8.2 (2.9)	0.800

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

Table 11. Tests of Baseline Equivalence for Demographic Measures

	Full Sample (n=756)		Intervention (n=329)		Comparison (n=427)		p value
Variables	N	%	N	%	N	%	
Sex							
Male	223	29.5	89	27.1	134	31.4	
Female	533	70.5	240	73.0	293	68.6	0.20
Missing	--	--	--	--	--	--	
Ethnicity							
Hispanic/Latino	751	99.3	326	99.1	2	0.5	
Non-Hispanic/Non-Latino	5	0.7	3	0.9	2	0.5	0.66
Missing	--	--	--	--	--	--	
Race							
White	755	99.9	328	43.4	427	56.7	
Other	1	0.1	1	0.3	0	0.0	0.44
Missing	--	--	--	--	--	--	
County							

	Full Sample (n=756)		Intervention (n=329)		Comparison (n=427)		p value
Variables	N	%	N	%	N	%	
Hidalgo	750	99.2	325	98.8	425	99.5	
Starr	6	0.8	4	1.2	2	0.5	0.10
Missing	--	--	--	--	--	--	
Age							
Mean	54.1	--	55.9	--	52.7	--	**<0.001**
SD	10.6	--	10.2	--	10.7	--	
<35	26	3.4	9	2.7	17	4.0	
35-44	105	13.9	31	9.4	74	17.3	
45-54	241	31.9	93	28.3	148	34.4	**<0.001**
55-64	295	39.0	148	45.0	147	34.4	
65+	89	11.8	48	14.6	41	9.6	
Missing	--	--	--	--	--	--	
Employment							
Not Employed	465	61.5	199	60.5	266	62.3	
Employed	286	37.8	126	38.3	160	37.5	
Migrant Farm Worker	4	0.5	3	0.9	1	0.2	0.39
Student	1	0.1	1	0.3	0	0.0	
Missing	--	--	--	--	--	--	
Marital Status							
Divorced	44	5.9	28	8.6	16	3.8	
Married	471	62.7	193	59.4	193	59.4	
Separated	68	9.1	24	7.4	44	10.3	**0.02**
Single	110	14.7	53	16.3	57	13.4	
Widowed	58	7.7	27	8.3	31	7.3	
Missing	5	--	4	--	1	--	
Primary Language							
English	144	19.2	61	18.9	83	19.4	
Samar-Leyte	0.1	0.0	0	0.0	1	0.2	0.92
Spanish	605	80.7	262	81.1	343	80.3	
Missing	6	--	6	--	0	--	
History of Diabetes							
No	111	14.7	27	8.2	84	19.7	
Yes	645	85.3	302	91.8	343	80.3	**<0.001**
Missing	--	--	--	--	--	--	
History of Hypertension							
No	324	42.9	148	45.0	176	54.3	
Yes	432	57.1	181	55.0	251	58.8	0.30
Missing	--	--	--	--	--	--	
History of Obesity							
No	301	39.8	131	39.8	170	39.8	0.99
Yes	455	60.2	198	60.2	257	60.2	

	Full Sample (n=756)		Intervention (n=329)		Comparison (n=427)		p value
Variables	N	%	N	%	N	%	
Missing	--	--	--	--	--	--	
History of High Cholesterol							
No	164	21.7	55	16.7	109	25.5	
Yes	592	78.3	274	83.3	318	74.5	**0.004**
Missing	--	--	--	--	--	--	
History of Depression							
No	703	93.0	305	92.7	398	93.2	
Yes	53	7.0	24	7.3	29	6.8	0.79
Missing	--	--	--	--	--	--	
Level of Physical Activity							
Never	310	41.0	119	36.2	191	44.7	
1-2 times/week	157	20.8	82	24.9	75	17.6	
3-4 times/week	107	14.2	50	15.5	56	13.1	
5-6 times/week	54	7.4	16	4.9	38	8.9	**0.01**
Daily	128	16.9	61	18.5	67	15.7	
Missing	--	--	--	--	--	--	
Smoking Status[a]							
Current Every Day Smoker	35	4.6	20	6.1	15	3.5	
Current Some Day Smoker	18	2.4	6	1.8	12	2.8	
Former Smoker	121	16.0	39	11.9	82	19.2	**0.01**
Never Smoker	582	77.0	264	80.2	318	74.5	
Missing	--	--	--	--	--	--	
Alcohol Consumption							
Never	588	77.8	248	75.4	340	79.6	
Monthly or Less	96	12.7	50	15.2	46	10.8	
2-4 per/month	50	6.6	21	6.4	29	6.8	
2-3 per/week	14	1.9	7	2.1	7	1.6	0.45
4+ per/week	8	1.1	3	0.9	5	1.2	
Missing	--	--	--	--	--	--	
Insurance Status							
Insured	198	26.2	101	30.7	97	22.7	
Uninsured	558	73.8	228	69.3	330	77.3	0.01
Missing	--	--	--	--	--	--	

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

Because this study used a quasi-experimental design and did not employ randomization to achieve baseline equivalence, adjusted regression analyses was proposed as the main analytic approach in the SEP to analyze the intervention effect accounting for potential confounders. Additionally, it was not possible to employ matching in the study design phase since the NCDV participants were also serving as a comparison group to another study in the Sí Texas portfolio. Therefore, statistical matching at the analysis phase was proposed in the SEP. The proposed matching method to enhance the robustness of

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

As proposed in the SEP, only a limited set of covariates were collected among intervention and comparison groups during the NuCare study. The optimal matching algorithm within the nearest neighbor matching method was conducted and found that the propensity score matching reduced the total sample by 304 participants or 40.5% of the comparison group analysis sample. Discarding over a third of the study sample who completed an assessment at 12 months reduced statistical power. This is in part due to a limited set of covariates and the inherent differences between the intervention group and comparison group. Other matching methods (i.e., weighting, full matching, and sub-classification) require additional assumptions and weight assignment (either implicit or explicit), which are generally not as preferable as the optimal matching based on nearest neighbor method (Stuart 2010). An adjusted regression approach accounting for available covariates with model selection was appropriately applied to ascertain the intervention effect. This approach was chosen due to the limitations of 1. reduced available analytic sample, 2. a small number of covariates, and 3. properties of alternative matching methods.

Intervention and Comparison Group Conditions

Patients who consented to participate in the intervention were seen for their physical exam appointment and received warm handoff referrals to other needed services. These participants were offered appropriate health education and behavioral health services according to needs identified through physical and behavioral health assessments. If the patient showed suicidal ideation with a plan to hurt themselves or a plan to hurt others, a call was made to the mental health authority, Tropical Texas Behavioral Health Center.

The comparison group was comprised of patients from the Edcouch and Alton clinics and received the usual care provided at these facilities. Edcouch Clinic usual care for behavioral health entails referring patients with a PHQ-9 score ≥ 10 or when the PCP observes behavioral health distress to a NCDV clinic with a behavioral health provider. The nurse calls the Behavioral Health Care Manager to schedule an appointment to be seen by an LPC at the NCDV San Juan or Mercedes clinic, dependent on the patient's discretion. In addition, if desired, the patient can call the care manager to set up an appointment to be seen by the LPC. If the patient shows suicidal ideation with a plan to hurt themselves or others, a call is made to the mental health authority, Tropical Texas Behavioral Health. Usual care regarding primary care involves a visit with the medical doctor.

Alton Clinic usual care for behavioral health entails referring patients with a PHQ-9 score ≥ 10 or when the PCP observes behavioral health distress, to outside services with an in-clinic visit with an LPC. The LPC is only at the Alton Clinic for one day every two weeks. Patients can call the care manager to set up an appointment to be seen by the LPC. If scheduling with the LPC at the Alton Clinic is inconvenient, the patient is given the option to set up an appointment with an LPC at the NCDV San Juan clinic or NCDV

Mercedes clinic. If the patient shows suicidal ideation with a plan to hurt themselves or others, a call is made to the mental health authority, Tropical Texas Behavioral Health. Usual care regarding primary care involves a visit with the medical doctor.

Study Sample

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

Study Sample Composition

As described earlier in the report, **Table 12** presents participant demographics for intervention and comparison groups at baseline. Intervention and comparison group study participants lived primarily in Hidalgo County. Most of the participants enrolled in these study groups were female (70.5%), Hispanic (99.3%), and spoke Spanish as their primary language (80.7%). The average participant age was 54.1 years. Well over half of participants were not employed (61.5%), married (62.7%), and uninsured (73.8%). The majority of participants reported they had never smoked (77.0%), that they did not consume alcohol (77.8%), and that they had done some physical activity at least 1-2 times per week (59.0%).

Table 12. Participant Demographic Descriptive Statistics

	Full Sample (n=756)		Intervention (n=329)		Comparison (n=427) p value	
Variables	N	%	N	%	N	%
Sex						
Male	223	29.5	89	27.1	134	31.4
Female	533	70.5	240	73.0	293	68.6
Missing	--	--	--	--	--	--
Ethnicity						
Hispanic/Latino	751	99.3	326	99.1	2	0.5
Non-Hispanic/Non-Latino	5	0.7	3	0.9	2	0.5
Missing	--	--	--	--	--	--
Race						
White	755	99.9	328	43.4	427	56.7
Other	1	0.1	1	0.3	0	0.0
Missing	--	--	--	--	--	--
County						
Hidalgo	750	99.2	325	98.8	425	99.5
Starr	6	0.8	4	1.2	2	0.5
Missing	--	--	--	--	--	--
Age						
Mean	54.1	--	55.9	--	52.7	--

	Full Sample (n=756)		Intervention (n=329)		Comparison (n=427) p value	
Variables	N	%	N	%	N	%
SD	10.6	--	10.2	--	10.7	--
<35	26	3.4	9	2.7	17	4.0
35-44	105	13.9	31	9.4	74	17.3
45-54	241	31.9	93	28.3	148	34.4
55-64	295	39.0	148	45.0	147	34.4
65+	89	11.8	48	14.6	41	9.6
Missing	--	--	--	--	--	--
Employment						
Not Employed	465	61.5	199	60.5	266	62.3
Employed	286	37.8	126	38.3	160	37.5
Migrant Farm Worker	4	0.5	3	0.9	1	0.2
Student	1	0.1	1	0.3	0	0.0
Missing	--	--	--	--	--	--
Marital Status						
Divorced	44	5.9	28	8.6	16	3.8
Married	471	62.7	193	59.4	193	59.4
Separated	68	9.1	24	7.4	44	10.3
Single	110	14.7	53	16.3	57	13.4
Widowed	58	7.7	27	8.3	31	7.3
Missing	5	--	4	--	1	--
Primary Language						
English	144	19.2	61	18.9	83	19.4
Samar-Leyte	0.1	0.0	0	0.0	1	0.2
Spanish	605	80.7	262	81.1	343	80.3
Missing	6	--	6	--	0	--
History of Diabetes						
No	111	14.7	27	8.2	84	19.7
Yes	645	85.3	302	91.8	343	80.3
Missing	--	--	--	--	--	--
History of Hypertension						
No	324	42.9	148	45.0	176	54.3
Yes	432	57.1	181	55.0	251	58.8
Missing	--	--	--	--	--	--
History of Obesity						
No	301	39.8	131	39.8	170	39.8
Yes	455	60.2	198	60.2	257	60.2
Missing	--	--	--	--	--	--
History of High Cholesterol						
No	164	21.7	55	16.7	109	25.5
Yes	592	78.3	274	83.3	318	74.5
Missing	--	--	--	--	--	--

	Full Sample (n=756)		Intervention (n=329)		Comparison (n=427) p value	
Variables	N	%	N	%	N	%
History of Depression						
No	703	93.0	305	92.7	398	93.2
Yes	53	7.0	24	7.3	29	6.8
Missing	--	--	--	--	--	--
Level of Physical Activity						
Never	310	41.0	119	36.2	191	44.7
1-2 times/week	157	20.8	82	24.9	75	17.6
3-4 times/week	107	14.2	50	15.5	56	13.1
5-6 times/week	54	7.4	16	4.9	38	8.9
Daily	128	16.9	61	18.5	67	15.7
Missing	--	--	--	--	--	--
Smoking Status						
Current Every Day Smoker	35	4.6	20	6.1	15	3.5
Current Some Day Smoker	18	2.4	6	1.8	12	2.8
Former Smoker	121	16.0	39	11.9	82	19.2
Never Smoker	582	77.0	264	80.2	318	74.5
Missing	--	--	--	--	--	--
Alcohol Consumption						
Never	588	77.8	248	75.4	340	79.6
Monthly or Less	96	12.7	50	15.2	46	10.8
2-4 per/month	50	6.6	21	6.4	29	6.8
2-3 per/week	14	1.9	7	2.1	7	1.6
4+ per/week	8	1.1	3	0.9	5	1.2
Missing	--	--	--	--	--	--
Insurance Status						
Insured	198	26.2	101	30.7	97	22.7
Uninsured	558	73.8	228	69.3	330	77.3
Missing	--	--	--	--	--	--

Table 13 describes participant impact measures at baseline for the intervention and comparison groups. The intervention group began the study with lower mean BMI and diastolic blood pressure, but slightly higher mean systolic blood pressure. The median PHQ-9 score was higher in the intervention while the median Duke score was lower in this group. The intervention participants had a slightly lower median HbA1c at baseline, though the difference in values was not statistically significant. As previously mentioned, in the assessment of baseline equivalence, there was a statistically significant difference between the study groups for median PHQ-9 and mean diastolic blood pressure.

Table 13. Baseline Primary Impact Measures

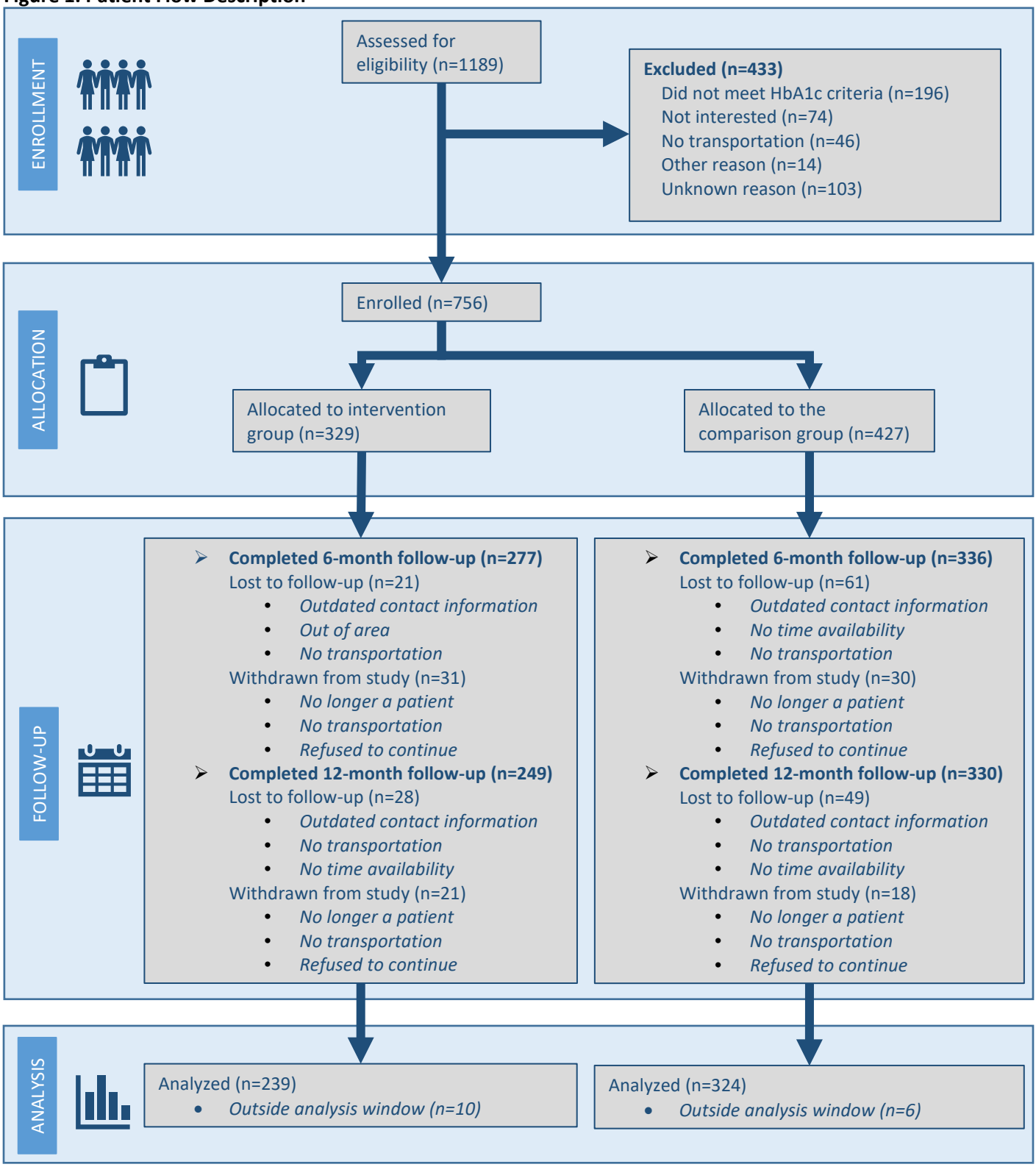
	Full Sample (n=756) Mean (SD)	Intervention (n=329) Mean (SD)	Comparison (n=427) Mean (SD)
BMI[b]	**33.9 (7.0)**	**33.3 (6.4)**	**34.4 (7.4)**
Systolic	132.9 (19.3)	133.2 (20.3)	132.7 (18.5)
Diastolic	**78.6 (9.2)**	**77.0 (8.5)**	**79.8 (9.4)**
Nonparametric Tests[a]	Median (SD)	Median (SD)	Median (SD)
PHQ-9	**2.5 (18.7)**	**4.0 (23.8)**	**1.0 (12.6)**
General Health	83.3 (265.3)	76.7 (286.2)	83.3. (265.3)
HbA1c	8.1 (2.8)	8.1 (2.7)	8.2 (2.9)

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

Patient Flow Description

A patient flow diagram following the CONSORT structure (Schulz et al., 2010) is presented in **Figure 1** on the following page. This diagram depicts the study process from assessment of eligibility, to enrollment and group selection, ending with retention and analysis. Sample sizes are provided throughout to show timing of participant attrition. Qualitative reasons for any ineligibility, withdrawal, or lost-to-follow-up are provided where applicable. In the "enrollment" stage, 196 participants who were excluded did not meet one or more of the eligibility criteria and could not be allowed to participate. An additional 237 participants were assessed for eligibility but did not enroll for other reasons. In the "follow-up" stage, those participants categorized as "lost to follow-up" did not complete an assessment at that time point but did not formally withdraw from the study. Due to the lack of official withdrawal from the study, those who were lost to follow-up at 6 months remained in the study and were still eligible to complete a 12-month assessment. While the total number of participants who returned and completed an assessment at each follow-up point is reported in the follow-up stage, some participants' 12-month assessment dates fell outside the allotted analytic windows. In the analysis stage, the number of participants where this was the case is noted from each study group. These participants were not included in the final analyses.

Figure 1. Patient Flow Description



Sample Recruitment, Retention, and Attrition

Participant Eligibility and Recruitment

Patients for the intervention group were recruited from new and existing patients at NCDV's Mission clinic. Patients at Mission learned about the study through contact with the promotora(es) at the beginning of the patient visit. The recruitment process used at the Mission Clinic was comprised of a data manager who reviewed patient records for those patients who were scheduled for appointments in the next week. The data manager reviewed patient's health information retrospectively for the 90 days. As part of this review, the data manager looked to see if the patient met the eligibility criteria; if it was determined that the patient did meet the eligibility criteria, their record was flagged, and the patient was called in advance of their appointment to remind them of their appointment and inform them of the study. Potential study participants were asked to arrive for their appointment 15 minutes early to learn about the study and undergo informed consent procedures. Patients who meet all the following criteria were eligible to participate in the study:

- Over 18 years old
- Lives in Hidalgo or Starr Counties
- HbA1c ≥ 6.5%[2]

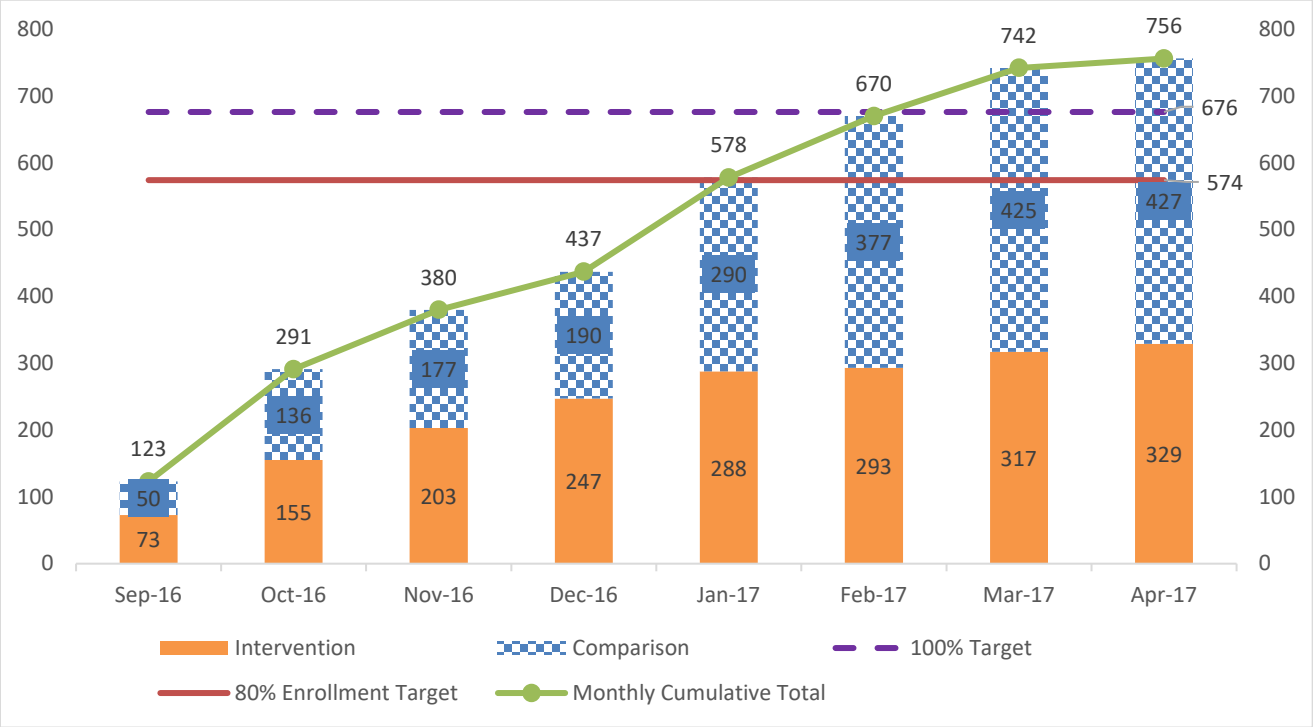
If a patient was deemed eligible, at the time of the patient's appointment, the promotora(es) spoke to the potential study participant at the beginning of their visit. At this time, s/he explained the purpose of the study and answered any questions the patient might have had regarding their participation.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

Sample Enrollment and Retention

Participant enrollment began in September 2016 and continued through April 2017. This was a deviation from the planned timeline in the SEP, which presented an initial enrollment end date of November 2016. This change was to provide additional time to achieve initial enrollment targets. The final timeline is presented in **Appendix A. Revised Project Timeline.** The enrollment target was 338 participants each for the intervention and comparison groups; a total of 329 participants were enrolled into the intervention and 427 participants in the comparison groups (see **Figure 2**), representing 97.3% of the enrollment target for the intervention group and exceeding the enrollment target for the comparison group.

[2] If a patient is flagged as eligible because they have an HbA1c ≥ 6.5 in the previous 90 days but their reading is over 30 days old their A1c will be captured and recorded as their baseline measure. If the patient record reveals that the patient has an HbA1c reading completed within last 30 days, that value will be used as their baseline measure.

Figure 2. Cumulative Baseline Enrollment, Overall and by Group



For 6-month follow-up data collection, NCDV collected data starting from 60 days before a participant's 6-month enrollment anniversary date through 90 days after the anniversary date. For 12-month, NCDV used a window of 60 days before and 60 days after the 12-month anniversary date. The extended follow-up period for the 6-month assessments was in response to guidance distributed by MHM in April 2017. This guidance encouraged subgrantees to continue to aim for a 6-month follow-up within the originally set time frame of 60 days before and after a participant's anniversary. It further informed the study teams that, if participants were unable to return in this window, they could complete 6-month assessments through 90 days after the 6-month anniversary date. The goal of this adjustment was to allow collection of as many mid-point assessments as possible to strengthen study analyses. NCDV began assessing participants for their 6-month follow-up assessments in March 2017 and completed the follow-up assessments in December 2017. Twelve-month follow-up assessments were collected between August 2017 and March 2018.

Table 14 presents subgrantee-reported information on the number of participants who returned for 6-month and 12-month follow-up through December 2017 and March 2018 respectively, by study arm. NCDV retained 97% of the 6-month target in the intervention group (277 out of 329 returned for a 6-month follow-up assessment, 287 needed to maintain adequate statistical power). The retention rate in the intervention exceeded the 12-month retention target (239 out of 329 returned for a 12-month follow-up assessment, 236 needed to maintain adequate statistical power). The comparison group reached 116% of the 6-month retention target (334 out of 427 returned for a 6-month follow-up assessment, 287 needed to maintain adequate statistical power). The retention target was also exceeded in the comparison group at 12 months, with NCDV retaining 137% of the 12-month target (324 out of 427 returned for a 12-month follow-up assessment, 236 needed to maintain adequate statistical power).

Table 14. Final Assessment of Follow-up Retention at 6 and 12 Months

Group	Number Enrolled	Retention Target (assumes 15% and 30% attrition from enrollment)	Number Retained (i.e., completed assessment at 6 or 12 months)	Percent of Retention of the Enrolled Sample	Percent of Retention Target
6-month Retention					
Intervention Group	329	287	277	84%	97%
Comparison Group	427	287	334	78%	116%
12-month Retention					
Intervention Group	329	236	239	73%	101%
Comparison Group	427	236	324	76%	137%

Sample Attrition Analyses

The study anticipated 70% retention of the sample at 12 months. At 12 months, the overall study sample had 74% retention (472 of 756), with 73% retention in the intervention group and 76% retention in the comparison group. These numbers reflect the sample analyzed at 12 months and do not include participants who came in outside of the allowed window for this follow-up point. Using this analytic sample, NCDV met the set targets for each group. To examine whether this 3% difference in attrition was statistically significant, a chi-square test was performed comparing the proportion of participants who were lost to follow-up in the intervention to those who were lost to follow-up in the comparison group. The results of this analysis were not statistically significant at the 0.05 level. Given these results, the two study groups did not have significantly differing attrition rates overall at 12 months of follow-up.

Although differential attrition, in regard to the proportion lost to follow-up in each study group, is not a concern for the end-point analyses, bivariate analyses were conducted to examine whether participants who were lost to follow-up were significantly different than those who remained in the study, for the entire sample and within each study arm across demographic characteristics and baseline health measures. T-tests were used for continuous measures and chi-square tests for categorical data. Fisher's Exact Test was utilized if the expected cell counts were less than 5 and nonparametric tests were performed on non-normally distributed data. **Appendix G. Loss to Follow-Up/Attrition Tables** presents 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 either intervention or comparison group. When looking at the full study sample however, there was a small but statistically significant difference in baseline Duke General Health score between those who completed the study and those who did not. Those who dropped out of the study had a slightly lower score than those who remained through their 12-month assessment, which is consistent with the expected potential effects of a lower quality of life score on a person.

Regarding demographic measures, there were no differences between attrition groups within the comparison group. There were statistically significant differences in gender, marital status, and primary language within the intervention group; those who did not complete the study were more likely to be male, speak English, and not be married. In the overall sample there were similar statistically significant differences in gender and marital status and those who did not complete the study were also more likely to be current every day smokers.

A multivariate logistic regression model was then utilized to understand the independent influence of each significant difference 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, but baseline Duke General Health score and gender were found to significantly predict the probability of a participant not completing the study, with p values less than or equal to 0.05. Marital status, smoking, and primary language were not statistically significant at the 0.05 level. It is important to note that intervention status did not influence a participant's likelihood of dropping out of the study. These statistically significant differences in baseline Duke General Health score and gender should be considered in the interpretation of the final analyses, particularly for the quality of life impact measure; however, because no statistically significant differences were found in Duke General Health score between attrition groups when examining the intervention and comparison groups separately, the concern for potential bias is lessened.

Sample Retention Strategies

NCDV reported challenges in retaining study subjects at the 6-month data collection point, which began in March 2017 and continued through January 2018. Six-month data collection was slowed early on as study managers worked to develop a voucher system that allowed study participants presenting with an elevated blood pressure to be seen by the provider without incurring additional costs to the patient. This voucher system ensured that cost of these services was not a barrier to participation which allowed for. Similar to the enrollment phase, whenever possible, data collection was scheduled to coincide with an existing appointment. All study subjects were offered a progressive incentive for completing each of the three assessments, which enticed participants to follow through. Study subjects received a $10 Walmart gift card for completing the baseline assessment, a $15 Walmart gift card for completing the 6-month assessment, and a $25 Walmart card for completing the 12-month assessment.

Non-Response Bias and Missing Data

All data collected for the NCDV evaluation were recorded in NCDV's Wellcentive system. Clinical data taken during the vitalization process was entered by the clinician directly into a patient's electronic medical record in MicroMD then exported to Wellcentive for the purpose of the study. The Duke Health Profile and PHQ-9 questionnaires were integrated into the Wellcentive system as electronic data entry forms with built-in validation checks for out-of-range values.

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

Regarding the five study impact measures for the primary end-point analysis, complete baseline data were collected for all participants for each measure except for BMI. There were 6 participants missing BMI at baseline. There were no missing impact measures at 12 months for those who returned for a follow-up. There was minimal missing demographic data. All demographic measures had complete data collected at baseline except for marital status (n=5) and primary language (n=6). Both the missing data points for marital status primary language were reported as "unknown" and recoded to missing.

Measures

The measures for the impact analysis aligned with the measures presented are depicted in **Appendix B. Program Logic Model.** The impact measures assessed for the NuCare program were HbA1c, BMI, blood pressure, depression score, and quality of life. There were no changes to the measures described in NCDV's SEP and interim report. Information on the number of respondents and tests of normality are provided here (see **Table 15**). PROC UNIVARIATE in SAS was used to understand the distributions of these measures at baseline. Q-Q plots and histograms were used to determine if the measure should be treated as normal, be transformed, or treated as non-normal data. Descriptive statistics for each of these measures, including number of participants with or without the impact measures, are included in this final report.

Table 15. Impact Measure Sample Size by Follow-up Period

Measure	Sample Size		
	Baseline	6-month	12-month
HbA1c	756	613	563
BMI	750	612	563
PHQ-9	756	613	563
Systolic Blood Pressure	756	613	563
Diastolic Blood Pressure	756	613	563
Duke Health Profile	756	613	563

HbA1c: HbA1c levels are routinely measured in the monitoring of people with diabetes. HbA1c levels depend on the blood glucose concentration. That is, the higher the glucose concentration in blood, the higher the level of HbA1c. Levels of HbA1c are not influenced by daily fluctuations in the blood glucose concentration but reflect the average glucose levels over the prior six to eight weeks. Therefore, HbA1c is a useful indicator of recent blood glucose control 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).

Because only patients with diabetes (HbA1c of 6.5% or higher) were eligible for the study, HbA1c was collected from all participants. The primary care provider determined the need and/or appropriateness of medication.

HbA1c level is the confirmatory outcome in this study. There were 756 respondents with complete data at baseline, 613 respondents at 6 months, and 563 respondents at 12 months for the intervention and comparison group. The distribution of responses for HbA1c at baseline was determined to be non-normally distributed. The log transformation was examined but did not normalize the distribution of HbA1c; therefore, nonparametric tests were used in bivariate analyses.

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

The primary care provider calculated BMI using a clinical weight scale and height measurement instrument following clinically-established practice guidelines (National Guideline Clearinghouse, 2014). Patients with a BMI greater than or equal to 30 were referred to the health educator and nutritionist.

For BMI, there were 750 respondents with complete data at baseline, 612 respondents at 6 months, and 563 respondents at 12 months for the intervention and comparison groups. The distribution of responses for BMI at baseline was determined to be slightly skewed in the sample. Using the log transformation of the BMI data for bivariate analyses led to a more normal distribution and therefore the parametric test was used.

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

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

For blood pressure, there were 756 respondents with complete data at baseline, 613 respondents at 6 months, and 563 respondents at 12 months for the intervention and comparison group. The distribution of responses for systolic and diastolic at baseline were determined to both be normally distributed and therefore parametric tests were used.

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 chronic, the burden of depression is further increased as depression appears to be associated with behaviors linked to other chronic diseases. In many 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). See **Appendix J: Patient Health Questionnaire – 9 (PHQ-9)** to view the PHQ-9 assessment tool (available in English and Spanish).

- **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 conducted with participants as part of their intake process.
- **Intended respondent:** The PHQ-9 was completed with participants.
- **Potential score/response range:** The PHQ-9 has a total possible score of 27. The PHQ-9 scoring criteria is categorized as minimal (0-4), mild (5-9), moderate (10-14), moderately severe (15-19) and severe (20-27) depression. Patients with a score of 5 or higher were referred for behavioral health services.

For PHQ-9 score, there were 756 respondents with complete data at baseline, 613 respondents at 6 months, and 563 respondents at 12 months for the intervention and comparison group. The distribution of responses for PHQ-9 at baseline was determined to be non-normally distributed. The log transformation was examined but did not normalize the distribution of PHQ-9. Therefore, nonparametric tests were used in bivariate analyses. Comparisons between parametric and nonparametric results were confirmed prior to implementing multivariate linear regression 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). See **Appendix K: Duke Health Profile** to view the Duke Health Profile assessment tool (available in English and Spanish).

- **Administration method:** Physical functioning and quality of life was measured by the Duke Health Profile and captured through provider interview. 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 reference window.
- **Administration time:** The assessment was conducted with 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 domains, five of which measure function (physical health, mental health, social health, general health, perceived health, self-esteem) and six 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.

For the Duke General Health score, there were 756 respondents with complete data at baseline, 613 respondents at 6 months, and 563 respondents at 12 months for the intervention and comparison group. The distribution of responses for the Duke General Health score at baseline was determined to be non-normally distributed. The log transformation was examined but did not normalize the distribution of Duke General Health. Therefore, nonparametric tests were used in bivariate analyses. Comparisons between parametric and nonparametric results were confirmed prior to implementing multivariate linear regression analyses.

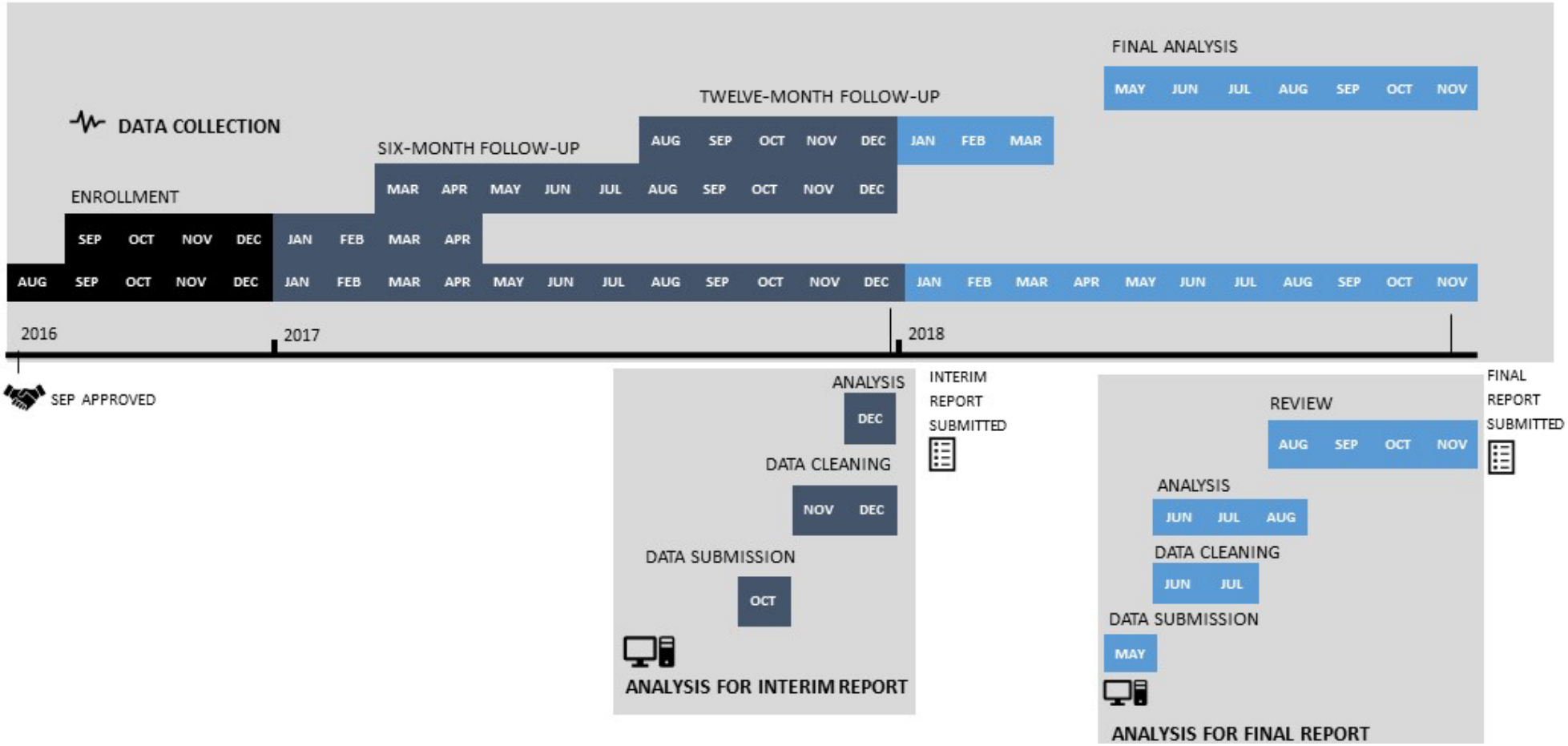
Data Collection Activities

Planned data collection activities were executed as described in the SEP with the exception of the timeline utilized. Baseline data collection for the intervention and comparison group occurred at study enrollment.

Figure 3 depicts the data collection timeline as it relates to SEP approval and analyses completed for this final report. Participant enrollment began in September 2016 and continued through April 2017. As previously noted, this was a deviation from the planned timeline in the SEP. This change was to provide additional time to achieve initial enrollment targets. NCDV began assessing participants for their 6-

month follow-ups in March 2017 and completed follow-ups in December 2017. Twelve-month follow-ups began in August 2017 and concluded in March 2018. Data from the study were submitted on a quarterly basis to HRiA by NCDV for data cleaning and quality assessment.

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



IMPACT STUDY – ANALYSIS AND RESULTS

Final impact study results for the intervention and comparison group 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 NCDV study.

Descriptive statistics for complete data are examined in this final report for the intervention and comparison group. These statistics include 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. Chi-square tests and Fisher's Exact Tests, when necessary based on cell counts, were used for categorical data to examine baseline equivalence. Two sample t-tests were used for continuous data that were normally distributed, and the Wilcoxon Signed Rank test was used for non-normally distributed data. Because a nonequivalent comparison group design is employed in the study, an intent-to-treat analysis was conducted with adjustment for potential nonequivalence of covariates and baseline outcome measure. The decision was made not to perform secondary power calculations as the final sample size was just shy of 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. For impact measures that were assessed to be non-normally distributed, analyses were conducted using both PROC GLM and PROC GENMOD in order to assess any possible bias deriving from the non-normality. For linear regression models, using normal linear regression methods (e.g., PROC GLM) produced results consistent with those produced with methods accounting for the non-normality of these data (e.g., PROC GENMOD). Differences were considered statistically significant at $p<0.05$. Effect size was 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 analysis was conducted at the individual patient level. 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 or found to be unbalanced between the two groups at baseline. The parameter of interest was the dichotomous variable that differentiates the treatment status (i.e., intervention vs. comparison). 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 differ by intervention status (Fitzmaurice et al., 2004). A time measure was developed and applied to denote baseline, 6 and 12-month follow-up measures.

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

To evaluate the intervention effect, a multiple linear regression model approach was used following a sequence of models. The analysis sequence began by developing a bivariate model regressing the follow-up outcome measure on intervention status (intervention vs. comparison) followed by the estimation of an adjusted model accounting for the baseline measure of interest and further adjustment for key covariates. Parametric two sample t-tests were used for bivariate analysis of exploratory study outcomes (BMI and blood pressure). The confirmatory variables and two exploratory outcomes (HbA1c, PHQ-9, and Duke General Health) were found to be non-normally distributed. In these bivariate analyses, nonparametric Wilcoxon Rank Sum tests were conducted due to the increased sensitivity to detect a difference in non-normally distributed data. The nonparametric results are presented throughout this report; however, additional parametric t-tests were performed for these measures to align with linear regression methods for the final analyses. Though the 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 necessary due to the complete nature of the submitted data; it was also decided to forgo propensity score matching methodology due to the loss of sample size and statistical power that would have resulted from that process. 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. Because the NCDV study focused on patients with diabetes, there was interest in understanding if and how a patient's controlled or uncontrolled diabetes affected the intervention impact. Models were estimated to explore whether having controlled diabetes (HbA1c between 6.5-7.9%) versus uncontrolled diabetes (HbA1c greater than 8.0%) at study baseline modified the intervention effect. Additionally, based on knowledge of both the study and overall clinic population, models were estimated to assess for effect modification by age using a dichotomous variable of under 54 years versus 54 years and older, based on the mean age of the study population.

The SEP indicated a set of planned covariates for adjustment in the models. Of those listed, age (continuous and categorical), sex, employment, number of comorbidities, and time were included in one or more of the analyses. Categorical age was operationally defined by the following categories: 18-34-year-olds, 35-44-year-olds, 45-54-year-olds, 55-64-year-olds, and those who are 65 years or older. Employment was included as a dichotomized variable with categories of "employed", including employed and migrant farmer worker participants, and "not employed", including unemployed and student participants. As anticipated, the study population was fairly homogeneous on ethnicity and thus

this was not included in the final models. Additional data on characteristics of the study population including primary language, smoking, alcohol consumption, insurance status, and marital status were included for possible selection in one or more of the analyses. 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. Additional models were examined among only intervention participants, with the aim of understanding if exposure to certain intervention components had varying influence on the relationship between the intervention and outcomes of interest. Dichotomous covariates, representing receipt of specific intervention component or not, were included as the exposure of interest in these models. However, no results are presented in this report due to the lack of statistical significance.

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. In some cases, age and sex were selected for inclusion in statistical models a priori due to the known biological influence of these characteristics on health outcomes; this is noted where relevant under each research question. For some research questions, predictor variables were included that could be correlated with the outcome of interest. Where relevant, the variation inflation factor (VIF) is reported in the model selection process. Using PROC CORR, the range of correlation between the predictors included in the model and the outcomes of interest is -0.48, the Pearson coefficient for baseline Duke General Health score and 12-month PHQ-9 score, to 0.95, the Pearson coefficient for baseline BMI and 12-month BMI.

HbA1c Level

Question 1. **Do patients who participate in the NuCare intervention experience improvements in HbA1c measures after 12 months when compared to patients that do not participate in the intervention? <u>This question is confirmatory</u>.**

Overview of Analysis

To answer this confirmatory question about intervention impact on HbA1c level, data were collected on patient HbA1c levels. As previously stated, eligibility for participation in the study required an HbA1c of 6.5% or more 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=563), primary linear regression analyses (n=559), and longitudinal analyses (n=634).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 31** presents the mean HbA1c level data in each study period for the overall sample as well as the intervention and comparison groups. The overall study sample had a mean HbA1c of 8.6% at baseline. For those who returned for a follow-up assessment, this decreased to 8.4% at 6-month follow-up and 8.3% at 12-month follow-up. Both the intervention and comparison groups began the study with the same mean HbA1c (8.6%) at baseline. For participants who returned for a follow-up visit, the intervention group mean HbA1c decreased at 6-month follow-up to 8.4% and again at 12 months (8.2%). For those participants in the comparison group who returned for a follow-up visit, the mean HbA1c decreased at 6 months to 8.4% and increased to 8.5% at 12 months. As previously

noted in **Table 10**, the intervention and comparison groups were statistically equivalent on HbA1c level at baseline.

Bivariate analyses were performed within each study group, testing the statistical significance of the change in impact measures from baseline to 12-month follow-up without controlling for any additional covariates (**Table 32**). The decrease observed in HbA1c level from baseline to 12-month follow-up was statistically significant within the intervention group but was not statistically significant within the comparison group.

Bivariate analyses were also performed between the intervention and comparison groups comparing mean HbA1c levels at 12-month follow-up, without controlling for any additional covariates (**Table 33**). Based on a p value greater than 0.05 for HbA1c when comparing the intervention and comparison groups at 12 months, the null hypothesis cannot be rejected. The mean 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. Age and sex were selected a priori for inclusion due to the known biological influence of age and sex on health outcomes. Other covariates were removed from the model if their p value was found to be greater than 0.15. The initial covariates that were input into the models for HbA1c level were: age, sex, primary language, marital status, employment, insurance status, smoking, alcohol consumption, level of physical activity, baseline HbA1c level, and the number of comorbidities at baseline.

$$Y_{(HbA1c)} = \beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 MaritalStatus + \beta_6 Employment + \beta_7 InsuranceStatus + \beta_8 Smoke + \beta_9 Alcohol + \beta_9 PhysicalActivity + \beta_{10} BL\_HbA1c + \beta_{11} BL\_Comorbidities + \varepsilon$$

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 HbA1c level included those covariates with p value of 0.15 or less: age, sex, primary language, smoking status, 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:

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

Findings

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

Mean HbA1c level at 12 months did not differ significantly by intervention status (p= 0.13); the effect size (using Cohen's d) is 0.11.

$Y_{(HbA1c)}$ = 4.66 + -0.20(Intervention) + -0.02(Age) + 0.25(Male) + -0.31(English) + -0.30(Current Every Day Smoker) + 0.89(Current Some Day Smoker) + 0.18(Former Smoker) + 0.54(BL_HbA1c) + ε

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

Variable Selected	HbA1c (n=559)		
	Estimate (β)	Standard Error	P value
Intervention	-0.20	0.13	0.13
Comparison (ref)	--	--	--
Age (continuous)	-0.02	0.01	0.01
Male	0.25	0.15	0.10
Female (ref)	--	--	--
English	-0.31	0.17	0.07
Spanish (ref)	--	--	--
Current smoker (everyday)	-0.30	0.37	0.43
Current smoker (some days)	0.89	0.42	0.03
Former smoker	0.18	0.18	0.32
Never smoker (ref)	--	--	--
Baseline HbA1c	0.54	0.04	<0.001

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

There were no statistically significant effect modifications for HbA1c level (not shown). The models estimated included interaction terms of study group and baseline HbA1c level categories and age.

Additional Analyses

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 HbA1c level, only adjusting for intervention status and time, there was no significant time/group interaction with a p value of 0.08, indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for HbA1c level (see **Table 17**). Adjusting for the covariates that were selected in the primary model—age, sex, smoking status, and language —did not alter these results (p=0.07).

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

Variable	HbA1c (n=634)		
	Estimate (β)	Standard Error	p value
Time*Intervention	-0.24	0.14	0.08
Time*Comparison (ref)	--	--	--
Time	-0.12	0.09	0.17
Intervention	0.01	0.13	0.92
Comparison (ref)	--	--	--

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

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

Body Mass Index

Question 2. **Do patients who participate in the NuCare intervention experience improvements in BMI after 12 months when compared to patients that do not participate in the intervention? <u>This question is exploratory</u>.**

Overview of Analysis
To answer this exploratory question on intervention impact on BMI, patient BMI data were collected and analyzed. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for BMI. The sample sizes for the presented analyses of BMI are as follows: bivariate analyses (n=563), primary linear regression analyses (n=559), and longitudinal analyses (n=634).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 31** presents the mean BMI in each study period for the overall sample as well as the intervention and comparison groups. The overall sample had a mean BMI of 33.9 kg/m^2 at baseline. This increased to 34.0 kg/m^2 for those who returned at 6-month follow-up with a subsequent decrease at 12 months for those who completed a follow-up (33.9 kg/m^2). The intervention group began the study with a lower mean BMI of 33.3 kg/m^2 at baseline while the comparison group had a significantly higher mean BMI of 34.4 kg/m^2 at baseline. For those who completed an assessment at follow-up, the intervention group mean BMI decreased to 33.2 kg/m^2 at 6-month follow-up and increased again back to 33.3 kg/m^2 at 12 months. In the comparison group, the mean BMI increased from baseline to 6 months to 34.7 kg/m^2 and decreased at 12 months for those who completed a follow-up assessment (34.3 kg/m^2). As previously noted in **Table 10**, the intervention and comparison groups were not statistically equivalent on BMI at baseline. The inclusion of baseline BMI score in the final model controlled for the statistical imbalance between intervention and comparison groups 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 32**). The decrease from baseline to 12-month follow-up within the comparison group for BMI was not statistically significant.

Bivariate analyses were also performed between the intervention and comparison groups comparing mean BMI at 12-month follow-up without controlling for any additional covariates (**Table 33**). Based on a p value greater than 0.05 for BMI when comparing the intervention and comparison group at 12 months, the null hypothesis cannot be rejected. The mean BMI measure was not significantly different between the two groups when not adjusting for any additional covariates.

Model Selection Process
A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, BMI. Age and sex were selected a priori for inclusion due to the known biological influence of age and sex on health outcomes. Other 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 BMI were: age, sex, primary language, marital status, employment, insurance status,

smoking, alcohol consumption, level of physical activity, baseline BMI, and the number of comorbidities at baseline.

$$Y_{(BMI)} = \beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 MaritalStatus + \beta_6 Employment + \beta_7 InsuranceStatus + \beta_8 Smoke + \beta_9 Alcohol + \beta_9 PhysicalActivity + \beta_{10} BL\_BMI + \beta_{11} BL\_Comorbidities + \varepsilon$$

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 completeness of the evaluated data.

The final model of BMI included those covariates with p value of 0.15 or less: baseline BMI and the number of comorbidities at baseline. Age and sex were maintained based on a priori selection. 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:

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

Findings

Estimates by covariate for the final model of BMI are presented in **Table 18**. Mean BMI at 12-months did not differ significantly by intervention status (p= 0.92).

$$Y_{(BMI)} = 1.09 + -0.02(Intervention) + -0.001(Age) + -0.11(Male) + 0.98(BL\_BMI) + -0.18(BL\_Comorbidities) + \varepsilon$$

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

Variable Selected	BMI (n=559)		
	Estimate (β)	Standard Error	p value
Intervention	-0.02	0.17	0.92
Comparison (ref)	--	--	--
Age (continuous)[a]	-0.001	0.01	0.96
Male [a]	-0.11	0.19	0.58
Female (ref)	--	--	--
BL_BMI	0.98	0.01	<0.001
Number of comorbidities at baseline	-0.18	0.11	0.12

Note: "ref" indicates the reference category used to calculate the estimate for a covariate; [a] Selected a priori for model inclusion

There were no statistically significant effect modifications for BMI (not shown). The models estimated included interaction terms of study group and baseline HbA1c level categories and age.

Additional Analyses

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 BMI, only adjusting for intervention status and time, there was no significant time/group interaction with a p value of 0.45, indicating that the trajectories from baseline to

6 months, and then to 12 months were not different between the two study arms for BMI (see **Table 19**). Adjusting for the covariates that were selected in the primary model—age, sex, and number of comorbidities at baseline—did not alter these results.

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

Variable	BMI (n=634)		
	Estimate (β)	Standard Error	p value
Time*Intervention	-0.13	0.17	0.45
Time* Comparison (ref)	--	--	--
Time	-0.12	0.11	0.30
Intervention	-1.18	0.52	0.02
Comparison (ref)	--	--	--

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

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

Depressive Symptoms

Question 3. **Do patients who participate in the NuCare intervention experience improvements in depressive symptoms, as measured by PHQ-9, after 12 months compared to patients who do not participate in the intervention? <u>This question is exploratory</u>.**

Overview of Analysis
To answer this exploratory question about intervention impact on depressive symptoms, data were analyzed from the PHQ-9 assessment tool. While systematic checks for outliers were performed and questions sent to study site staff for verification on a quarterly basis, there were no unique data cleaning processes needed for PHQ-9 score. The sample sizes for the presented analyses of PHQ-9 score are as follows: bivariate analyses (n=563), primary linear regression analyses (n=559), and longitudinal analyses (n=635).

Descriptive Statistics and Bivariate Comparisons
At the end of this section, **Table 31** presents the mean PHQ-9 score data in each study period for the overall sample as well as the intervention and comparison groups. The overall sample had a mean PHQ-9 score of 3.8 at baseline. This decreased to 3.3 for participants who returned at 6-month follow-up and again to 2.8 for those who returned at 12-month follow-up. The intervention group began the study with a higher mean PHQ-9 score of 5.2 at baseline while the comparison group had a lower mean PHQ-9 score of 2.9 at baseline. Aligning with the overall sample trend, for participants who completed a follow-up assessment, the intervention group mean PHQ-9 score decreased at both 6 and 12-month follow-up to 4.3 and 3.4 respectively. The comparison group also followed this trend with the mean PHQ-9 score for those who completed a follow-up decreasing over time to 2.6 at 6 months and 2.5 at 12 months. As previously noted in **Table 10**, the intervention and comparison groups were not statistically equivalent on PHQ-9 score at baseline. This imbalance was controlled for in the final models.

Bivariate analyses were performed within each study group, testing the statistical significance of the change in PHQ-9 from baseline to 12-month follow-up without controlling for any additional covariates (**Table 32**). The decrease observed in PHQ-9 score from baseline to 12-month follow-up was statistically significant within the intervention group but was not statistically significant within the comparison group.

Bivariate analyses also were performed between the intervention and comparison groups comparing mean PHQ-9 at 12-month follow-up without controlling for any additional covariates (**Table 33**). Based on a p value less than 0.05 for PHQ-9 score when comparing the intervention and comparison groups at 12 months, we can reject the null hypothesis. The mean PHQ-9 score was significantly different between the two groups at 12-months when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify a parsimonious model with covariates that contributed to the outcome, PHQ-9 score. Age and sex were selected a priori for inclusion due to the known biological influence of age and sex on health outcomes. Other covariates were removed from the model if their p value was found to be greater than 0.15. The initial covariates that were input into the models for PHQ-9 score were: age, sex, primary language, marital status, employment, insurance status, smoking, alcohol consumption, level of physical activity, baseline PHQ-9 score, baseline Duke General Health score, and the number of comorbidities at baseline. The inclusion of baseline PHQ-9 score controlled for the statistical imbalance between intervention and comparison groups at baseline.

$$Y_{(PHQ9)} = \beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 MaritalStatus + \beta_6 Employment + \beta_7 InsuranceStatus + \beta_8 Smoke + \beta_9 Alcohol + \beta_9 PhysicalActivity + \beta_{10} BL\_PHQ9 + \beta_{11} BL\_General + \beta_{12} BL\_Comorbidities + \varepsilon$$

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

The final model of PHQ-9 score included those covariates with p value of 0.15 or less: marital status, smoking, alcohol consumption, baseline PHQ-9 score, baseline Duke General Health score, and the number of comorbidities at baseline. Age and sex were maintained based on a priori selection. 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:

$$Y_{(PHQ9)} = \beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 MaritalStatus + \beta_5 Smoke + \beta_6 Alcohol + \beta_7 BL\_PHQ9 + \beta_8 BL\_General + \beta_9 BL\_Comorbidities + \varepsilon$$

Because the baseline quality of life measure was selected for inclusion into the final model of depressive symptoms, and quality of life and depressive symptoms are known to be related, we conducted an additional test to quantify any multicollinearity between the Duke General Health score and PHQ-9 scores. The variance inflation factor of Duke General Health score in the PHQ-9 score model was 1.9, below the commonly accepted cutoff of 5 indicating minimal influence on the variance from the correlation of these variables (Belsley et al., 1980; O'Brien, 2007; Lasser, et al. 2017).

Findings

Estimates by covariate for the final model of PHQ-9 score are presented in **Table 20**.
Mean PHQ-9 score at 12 months did not differ significantly by intervention status (p= 0.56).

$Y_{(PHQ9)}$ = 3.47 + -0.16(Intervention) + 0.03(Age) + 0.17(Male) + -0.71(Married) + 1.01(Current Every Day Smoker) + 1.32(Current Some Day Smoker) + 0.72(Former Smoker) + -0.14(Drink Monthly or Less) + -1.28(Drink 2-4 Times/Month) + -1.72(Drink 2-3 Times/Week) + -0.01(Drink 4+ Times/Week) + 0.27(BL_PHQ9) + -0.06(BL_General) + 0.26(BL_Comorbidities) + ε

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

Variable Selected	PHQ-9 (n=559)		
	Estimate (β)	Standard Error	p value
Intervention	-0.16	0.28	0.56
Comparison (ref)	--	--	--
Age (continuous)[a]	0.03	0.01	0.01
Male[a]	0.17	0.33	0.62
Female (ref)	--	--	--
Married	-0.71	0.28	0.01
Unmarried (ref)	--	--	--
Current smoker (every day)	1.01	0.77	0.19
Current smoker (some days)	1.32	0.86	0.12
Former smoker	0.72	0.38	0.05
Never smoker (ref)	--	--	--
Drink Monthly or Less	-0.14	0.41	0.73
Drink 2-4 Times/Month	-1.28	0.57	0.03
Drink 2-3 Times/Week	-1.72	1.00	0.09
Drink 4+ Times/Week	-0.01	1.17	0.99
No Alcohol Use (ref)	--	--	--
BL_PHQ9	0.27	0.05	<0.001
BL_General	-0.06	0.01	<0.001
Number of comorbidities at baseline	0.26	0.18	0.14

Note: "ref" indicates the reference category used to calculate the estimate for a covariate; [a] Selected a priori for model inclusion

There were no statistically significant effect modifications for PHQ-9 score (not shown). The models estimated included interaction terms of study group and baseline HbA1c level categories and age.

Additional Analyses

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differ by intervention status. To estimate the linear mixed model, we utilized the PROC MIXED procedure in SAS. For PHQ-9 score, only adjusting for intervention status and time, there was a significant time/group interaction with a p value of <0.001, indicating that the trajectories from baseline to 6 months, and then to 12 months were different between the two study arms for PHQ-9 score (see **Table 21**). Adjusting for the covariates that were selected in the primary model—age, sex,

marital status, smoking, alcohol consumption, baseline Duke General Health score, and number of comorbidities at baseline—did not alter these results.

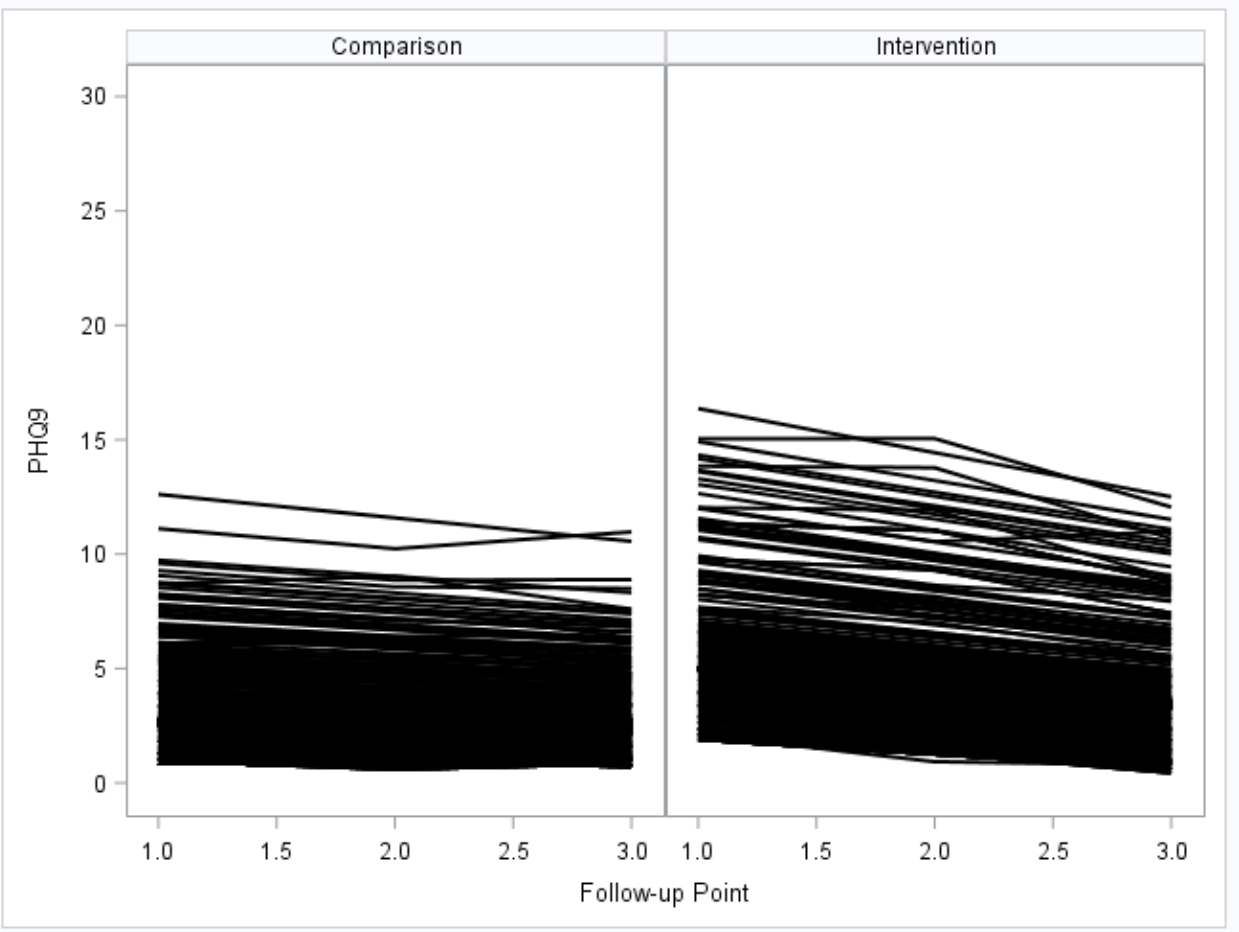
Table 21. Effect of IBH Intervention on Trajectory of PHQ-9 Score Across Twelve Month Study, Full NCDV Sample

Variable	PHQ9 (n=635)		
	Estimate (β)	Standard Error	p value
Time*Intervention	**-1.39**	**0.32**	**<0.001**
Time*Comparison (ref)	--	--	--
Time	-0.41	0.21	0.05
Intervention	2.27	0.32	<0.001
Comparison (ref)	--	--	--

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

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

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



Limitations
There are no limitations specific to this measure to note. Administration of this data collection tool was consistent at the intervention and comparison clinics utilizing provider interview methods.

Blood Pressure

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

Overview of Analysis
To answer this exploratory question about blood pressure, data were collected and analyzed for both systolic and diastolic blood pressure. 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 systolic or diastolic blood pressure. The sample sizes for the presented analyses of systolic and diastolic blood pressure are as follows: bivariate analyses (n=563), primary linear regression analyses (n=559), and longitudinal analyses (n=634).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 31** presents the mean systolic and diastolic blood pressure data in each study period for the overall sample as well as the intervention and comparison groups. The overall sample had a mean blood pressure of 132.9/78.6 mmHg at baseline. For those who returned for a follow-up assessment, this decreased to 131.0/77.8 mmHg at 6-month follow-up and decreased again at 12-month follow-up (130.0/77.0 mmHg). The intervention group began the study with a mean blood pressure, 133.2/77.0 mmHg at baseline while the comparison group had a mean blood pressure of 132.7/79.8 mmHg at baseline. In the intervention group, for those who returned for a follow-up assessment, the mean blood pressure decreased at both 6 and 12 months to 132.0/76.7 mmHg and 131.9/75.8 mmHg respectively. In the comparison group, the 6-month mean blood pressure decreased to 130.2/78.7 mmHg and then again to 128.6/78.0 mmHg at the 12-month follow-up. As previously noted in **Table 10**, the intervention and comparison groups were statistically equivalent on systolic blood pressure, but not diastolic blood pressure at baseline. This imbalance was controlled for in the final models.

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 32**). The observed decreases in mean systolic and diastolic blood pressures within the intervention group were not statistically significant, but the changes in mean systolic and diastolic blood pressures within the comparison group were statistically significant.

Bivariate analyses also were performed between the intervention and comparison groups, testing the statistical significance of the difference in mean impact measures at 12-month follow-up without controlling for any additional covariates (**Table 33**). Based on a p value less than 0.05 for systolic blood pressure, when comparing the intervention and comparison group at 12 months and without controlling for any additional covariates, the null hypotheses can be rejected. The mean systolic blood pressure measure is significantly different between the two study groups when not adjusting for any additional covariates. Based on a p value less than 0.05 for diastolic blood pressure, when comparing the intervention and comparison group at 12 months and without controlling for any additional covariates, the null hypotheses can be rejected. The mean diastolic blood pressure measure is significantly different between the two study groups when not adjusting for any additional covariates.

Model Selection Process

A backward elimination model selection approach was used to identify parsimonious models with covariates that contributed to the outcomes of systolic and diastolic blood pressure. Age and sex were selected a priori for inclusion due to the known biological influence of age and sex on health outcomes. Other 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 both systolic and diastolic blood pressure were: age, sex, primary language, marital status, employment, insurance status, smoking, alcohol consumption, level of physical activity, baseline systolic blood pressure, baseline diastolic blood pressure, and the number of comorbidities at baseline. The inclusion of baseline diastolic blood pressure controlled for the statistical imbalance between intervention and comparison groups at baseline in diastolic blood pressure.

$$Y_{(SBP)} = \beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 MaritalStatus + \beta_6 Employment + \beta_7 InsuranceStatus + \beta_8 Smoke + \beta_9 Alcohol + \beta_9 PhysicalActivity + \beta_{10} BL\_SBP + \beta_{11} BL\_DBP + \beta_{12} BL\_Comorbidities + \varepsilon$$

$$Y_{(DBP)} = \beta_0 + \beta_1 StudyArm + \beta_2 Age + \beta_3 Sex + \beta_4 Language + \beta_5 MaritalStatus + \beta_6 Employment + \beta_7 InsuranceStatus + \beta_8 Smoke + \beta_9 Alcohol + \beta_9 PhysicalActivity + \beta_{10} BL\_DBP + \beta_{11} BL\_SBP + \beta_{12} BL\_Comorbidities + \varepsilon$$

Two variations of each model were run to assess the best fit model: one including age as a continuous predictor and another utilizing categorical age. 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 systolic blood pressure included those covariates with p value of 0.15 or less: age, marital status, employment status, alcohol consumption, and baseline systolic blood pressure. Sex was maintained based on a priori selection. 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:

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

The final model of diastolic blood pressure included those covariates with p value of 0.15 or less: smoking, baseline systolic blood pressure, baseline diastolic blood pressure, and the number of comorbidities at baseline. Age and sex were maintained based on a priori selection. 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:

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

Because systolic blood pressure was selected for inclusion into the final model of diastolic blood pressure, and systolic and diastolic blood pressure are known to be related, we conducted an additional test to quantify any multicollinearity between systolic and diastolic blood pressure. The variance inflation factor of systolic blood pressure in the diastolic blood pressure model was 1.7, below the accepted cutoff of 5 representing a minimal influence on the variance from the correlation of these two variables (Belsley et al., 1980; O'Brien, 2007; Lasser, et al. 2017).

Findings
Estimates for the final models of systolic and diastolic blood pressure are presented in **Table 22**.

No difference in systolic blood pressure at 12 months was identified for participants in the intervention group compared to those in the comparison group (p=0.14), holding all other variables in the model constant.

$$Y_{(SBP)} = 48.55 + 1.99(Intervention) + 0.41(Age) + 1.41(Male) + 2.88(Married) + 2.60(Employed) + -5.27(Drink\ Monthly\ or\ Less) + -2.78(Drink\ 2\text{-}4\ Times/Month) + -2.64(Drink\ 2\text{-}3\ Times/Week) + -1.70(Drink\ 4+\ Times/Week) + 0.43(BL\_SBP) + \varepsilon$$

No difference in diastolic blood pressure at 12 months was identified for participants in the intervention group compared to those in the comparison group (p=0.24), holding all other variables in the model constant.

$Y_{(DBP)}$ = 59.11 + -0.86(Intervention) + -0.08(Age) + 0.11(Male) + -4.10(Current Every Day Smoker) + -3.63(Current Some Day Smoker) + -0.43(Former Smoker) + 0.37(BL_DBP) + -0.06(BL_SBP) + 0.75(BL_Comorbidities) + ε

Table 22. Effect of IBH Intervention on Twelve Month Systolic and Diastolic Blood Pressure, Full NCDV Sample

Variable Selected	Systolic Blood Pressure (n=559)		
	Estimate (β)	Standard Error	p value
Intervention	1.99	1.34	0.14
Comparison (ref)	--	--	--
Age (continuous)[a]	0.41	0.07	<0.001
Male [a]	1.41	1.64	0.39
Female (ref)	--	--	--
Married	2.88	1.39	0.04
Unmarried (ref)	--	--	--
Employed	2.60	1.37	0.06
Unemployed (ref)	--	--	--
Drink Monthly or Less	-5.27	2.07	0.01
Drink 2-4 Times/Month	-2.78	2.86	0.33
Drink 2-3 Times/Week	-2.64	5.04	0.60
Drink 4+ Times/Week	-1.70	5.93	0.77
No Alcohol Use (ref)	--	--	--
Baseline systolic blood pressure	0.43	0.04	<0.001
Variable Selected	Diastolic Blood Pressure (n=559)		
	Estimate (β)	Standard Error	p value
Intervention	-0.86	0.73	0.24
Comparison (ref)	--	--	--
Age (continuous)[a]	-0.08	0.04	0.04
Male[a]	0.11	0.84	0.90
Female (ref)	--	--	--
Current smoker (every day)	-4.10	2.03	0.04
Current smoker (some days)	-3.63	2.26	0.11
Former smoker	-0.43	1.00	0.67
Never smoker (ref)	--	--	--
Baseline diastolic blood pressure	0.37	0.05	<0.001
Baseline systolic blood pressure	-0.06	0.02	0.01
Number of comorbidities at baseline	0.75	0.47	0.11

Note: "ref" indicates the reference category used to calculate the estimate for a covariate; [a] Selected a priori for model inclusion

There were no statistically significant effect modifications for systolic blood pressure (not shown). The models estimated included interaction terms of study group and baseline HbA1c level categories and age. For diastolic blood pressure, no effect modification was identified by age (not shown); however, there was effect modification by HbA1c level category. Below is the model selected when including an interaction term of the study group by uncontrolled diabetes at baseline (see **Table 23**).

$Y_{(DBP)}$ = 57.50 + 0.91(Intervention) + 1.88(BL_UncontrolledDiabetes) + -3.03(BL_UncontrolledDiabetes*Intervention) + -0.08(Age) + 0.21(Male) + -4.03(Current Every Day Smoker) + -4.22(Current Some Day Smoker) + -0.39(Former Smoker) + 0.39(BL_DBP) + -0.05(BL_SBP) + ε

Table 23. Twelve-Month Diastolic Blood Pressure Effect Modification Model of Study Group by Uncontrolled Diabetes Status, Full NCDV Sample

Variable Selected	Diastolic Blood Pressure (n=559)		
	Estimate (β)	Standard Error	p value
Intervention	0.91	1.03	0.38
Comparison (ref)	--	--	--
Baseline Uncontrolled Diabetes	1.88	0.92	0.04
Baseline Uncontrolled Diabetes*intervention	**-3.03**	**1.41**	**0.03**
Baseline Uncontrolled Diabetes*comparison (ref)	--	--	--
Age (continuous)	-0.08	0.04	0.03
Male	-0.21	0.83	0.80
Female (ref)	--	--	--
Current smoker (every day)	-4.03	2.03	0.05
Current smoker (some days)	-4.22	2.27	0.06
Former smoker	-0.39	1.00	0.69
Never smoker (ref)	--	--	--
Baseline diastolic blood pressure	0.39	0.05	<0.001
Baseline systolic blood pressure	-0.05	0.02	0.03

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

When the diastolic blood pressure model was stratified by baseline uncontrolled diabetes, the intervention effect was statistically significant among those with uncontrolled diabetes (p=0.02), but not among those with controlled diabetes (p=0.40; see **Table 24**). Among the subpopulation of participants with uncontrolled diabetes at baseline, on average, for those in the intervention group, there is a significant 2.38 mmHg decrease in diastolic blood pressure at 12 months compared to participants in the comparison group, holding all other variables in the selected model constant (p=0.02).

Uncontrolled diabetes:

$Y_{(DBP)}$ = 64.80 + -2.38(Intervention) + -0.08(Age) + 1.90 (Male) + -5.05(Current Every Day Smoker) + -7.15(Current Some Day Smoker) + -1.54(Former Smoker) + 0.31(BL_DBP) + -0.07(BL_SBP) + 1.34(BL_Comorbidities) + ε

Controlled diabetes:

$Y_{(DBP)} = 47.00 + 0.85(\text{Intervention}) + -0.05(\text{Age}) + -2.41(\text{Male}) + 2.24(\text{English}) + 1.77(\text{Married}) + 0.40(\text{BL\_DBP}) + \varepsilon$

Table 24. Effect of IBH Intervention on Twelve-Month Diastolic Blood Pressure Results, Stratified Analyses for Controlled vs. Uncontrolled Diabetes

	Uncontrolled Diabetes			Controlled Diabetes		
Variable Selected	Diastolic Blood Pressure (n=264)			Diastolic Blood Pressure (n=294)		
	Estimate (β)	Standard Error	p value	Estimate (β)	Standard Error	p value
Intervention	**-2.38**	**1.02**	**0.02**	0.85	1.02	0.40
Comparison (ref)	--	--	--	--	--	--
Age (continuous)	-0.08	0.05	0.12	-0.05	0.05	0.35
Male[a]	1.90	1.19	0.11	-2.41	1.17	0.04
Female (ref)	--	--	--	--	--	--
English	--	--	--	2.24	1.37	0.10
Spanish (ref)	--	--	--	--	--	--
Married	--	--	--	1.77	1.03	0.09
Unmarried (ref)	--	--	--	--	--	--
Current smoker (every day)	-5.05	2.57	0.05	--	--	--
Current smoker (some days)	-7.15	2.89	0.01	--	--	--
Former smoker	-1.54	1.35	0.25	--	--	--
Never smoker (ref)	--	--	--	--	--	--
Baseline diastolic blood pressure	0.31	0.07	<0.001	0.40	0.06	<0.001
Baseline systolic blood pressure	-0.07	0.03	0.04	--	--	--
Number of comorbidities at baseline	1.34	0.68	0.05	--	--	--

Note: Bold denotes statistical significance (p value < 0.05)

Additional Analyses

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. No significant time/group interaction was identified for systolic blood pressure, adjusting for intervention status and time (p=0.09; not shown), 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. Adjusting for the covariates that were selected in the primary model—age, sex, marital status, employment, and alcohol consumption —did not alter these results (p=0.08; see **Table 25**).

No significant time/group interaction was identified for diastolic blood pressure, adjusting for intervention status and time (p=0.42; not shown), indicating that the trajectories from baseline to 6 months, and then to 12 months were not different between the two study arms for diastolic blood pressure. Adjusting for the covariates that were selected in the primary model—age, sex, smoking, baseline systolic blood pressure, and number of comorbidities at baseline—did not alter these results (p=0.44; see **Table 25)**.

Table 25. Effect of IBH Intervention on Trajectory of Systolic and Diastolic Blood Pressure Across Twelve Month Study, Full NCDV Sample

Variable	Systolic Blood Pressure (n=634)		
	Estimate (β)	Standard Error	p value
Time*Intervention	2.71	1.56	0.08
Time*Comparison (ref)	--	--	--
Time	-3.79	1.02	<0.001
Intervention	0.34	1.37	0.80
Comparison (ref)	--	--	--
Variable	Diastolic Blood Pressure (n=634)		
	Estimate (β)	Standard Error	p value
Time*Intervention	0.63	0.82	0.44
Time*Comparison (ref)	--	--	--
Time	-1.67	0.53	0.002
Intervention	-2.69	0.65	<0.001
Comparison (ref)	--	--	--

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

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

Functioning and Quality of Life

Question 5. **Do patients who participate in the NuCare intervention experience improvements in quality of life, as measured by the Duke Health Profile, after 12 months when compared to patients that do not participate in the intervention? <u>This question is exploratory</u>.**

Overview of Analysis
To answer this exploratory question about intervention impact on functioning and quality of life, data were analyzed from the Duke Health Profile, specifically the General Health domain. 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. Analyses were

also conducted separately for each of the Duke Health Profile subdomains that comprise the General Health domain: Physical Health and Mental Health. The sample sizes for the presented analyses of the Duke General Health score are as follows: bivariate analyses (n=563), primary linear regression analyses (n=559), and longitudinal analyses (n=635).

Descriptive Statistics and Bivariate Comparisons

At the end of this section, **Table 31** presents the mean Duke General Health score at each study period for the overall sample as well as the intervention and comparison groups. The overall sample had a mean Duke General Health score of 75.5 at baseline. This increased to 81.0 for participants who returned at 6-month follow-up and subsequently decreased to 79.2 for those who returned at 12-month follow-up. The intervention group began the study with a lower mean Duke General Health score of 71.9 at baseline while the comparison group had a higher mean Duke General Health score of 78.2 at baseline; however, this difference was not statistically significant (**Table 10**). For participants who completed a follow-up assessment, the intervention group mean Duke General Health score increased at both 6 and 12-month follow-up to 77.0 and 79.6 respectively. The comparison group also followed the overall sample trend with the mean Duke General Health score for those who completed a follow-up increasing at 6 months to 84.4 and subsequently decreasing at 12 months to 78.9.

Bivariate analyses were performed within each study group, testing the statistical significance of the change in median Duke General Health score from baseline to 12-month follow-up without controlling for any additional covariates (**Table 32**). The increases observed in median Duke General Health score from baseline to 12-month follow-up was statistically significant within the intervention group but was not statistically significant within the comparison group.

Bivariate analyses were also performed between the intervention and comparison groups comparing mean Duke General Health score at 12-month follow-up (**Table 33**). Based on a p value greater than 0.05 for median Duke General Health score when comparing the intervention and comparison group at 12 months, we cannot reject the null hypothesis. The median 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. Age and sex were selected a priori for inclusion due to the known biological influence of age and sex on health outcomes. Other covariates were removed from the model if their p value was found to be greater than 0.15. The initial covariates that were input into the models for Duke General Health score were: age, sex, primary language, marital status, employment, insurance status, smoking, alcohol consumption, level of physical activity, baseline Duke General Health score, baseline PHQ-9 score, and the number of comorbidities at baseline.

$$Y_{(\text{Duke General})} = \beta_0 + \beta_1 \text{StudyArm} + \beta_2 \text{Age} + \beta_3 \text{Sex} + \beta_4 \text{Language} + \beta_5 \text{MaritalStatus} + \beta_6 \text{Employment} + \beta_7 \text{InsuranceStatus} + \beta_8 \text{Smoke} + \beta_9 \text{Alcohol} + \beta_9 \text{PhysicalActivity} + \beta_{10} \text{BL\_General} + \beta_{11} \text{BL\_PHQ9} + \beta_{12} \text{BL\_Comorbidities} + \varepsilon$$

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, a 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 p value of 0.15 or less: age, primary language, marital status, insurance status, smoking, alcohol consumption, baseline Duke General Health score, and baseline PHQ-9 score. Sex was maintained based on a priori selection. 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:

$$Y_{(\text{Duke General})} = \beta_0 + \beta_1 \text{StudyArm} + \beta_2 \text{Age} + \beta_3 \text{Sex} + \beta_4 \text{Language} + \beta_5 \text{MaritalStatus} + \beta_6 \text{InsuranceStatus} + \beta_7 \text{Smoke} + \beta_8 \text{Alcohol} + \beta_9 \text{BL\_General} + \beta_{10} \text{BL\_PHQ9} + \varepsilon$$

Because the baseline depression measure was selected for inclusion into the final model of quality of life, and depression and quality of life are known to be related, we conducted an additional test to quantify any multicollinearity between the PHQ-9 and Duke General Health scores. The variance inflation factor of PHQ-9 score in the Duke General Health score model was 2.0, below the commonly accepted cutoff of 5 indicating minimal influence on the variance from the correlation of these variables (Belsley et al., 1980; O'Brien, 2007; Lasser, et al. 2017).

Findings

Estimates by covariate for the final model of Duke General Health score are presented in **Table 26**.

On average, for participants in the intervention group, there is a statistically significant 5.36-point increase in Duke General Health at 12 months compared to those in the comparison group, holding all other variables in the model constant ($p < 0.001$); the effect size (using Cohen's d) is 0.34.

$$Y_{(\text{Duke General})} = 49.54 + 5.36(\text{Intervention}) + -0.22(\text{Age}) + -0.31(\text{Male}) + -2.17(\text{English}) + 1.81(\text{Married}) + 2.47(\text{Insured}) + -4.12(\text{Current Every Day Smoker}) + -3.32(\text{Current Some Day Smoker}) + -4.12(\text{Former Smoker}) + 0.95(\text{Drink Monthly or Less}) + 2.75(\text{Drink 2-4 Times/Month}) + 9.37(\text{Drink 2-3 Times/Week}) + -4.02(\text{Drink 4+ Times/Week}) + 0.44(\text{BL\_General}) + -0.87(\text{BL\_PHQ9}) + \varepsilon$$

Table 26. Effect of IBH Intervention on Twelve Month Duke General Health Score, Full NCDV Sample

Variable Selected	Duke General Health (n=559)		
	Estimate (β)	Standard Error	p value
Intervention	**5.36**	**1.09**	**<0.001**
Comparison (ref)	--	--	--
Age (continuous)	-0.22	0.05	<0.001
Male[a]	-0.31	1.32	0.81
Female (ref)	--	--	--
English	-2.17	1.40	0.12
Spanish (ref)	--	--	--
Married	1.81	1.12	0.11
Unmarried (ref)	--	--	--
Insured	2.47	1.20	0.04
Uninsured (ref)	--	--	--

Current smoker (every day)	-4.12	3.02	0.17
Current smoker (some days)	-3.32	3.35	0.32
Former smoker	-4.12	1.48	0.01
Never smoker (ref)	--	--	--
Drink Monthly or Less	0.95	1.63	0.56
Drink 2-4 Times/Month	2.75	2.23	0.22
Drink 2-3 Times/Week	9.37	3.94	0.02
Drink 4+ Times/Week	-4.02	4.60	0.38
No Alcohol Use (ref)	--	--	--
Baseline Duke General Health	0.44	0.04	<0.001
Baseline PHQ9	-0.87	0.17	<0.001

Note: "ref" indicates the reference category used to calculate the estimate for a covariate; Bold denotes statistical significance (p value < 0.05); [a] Selected a priori for model inclusion

There were no statistically significant effect modifications for Duke General Health Score (not shown). The models estimated included interaction terms of study group and baseline HbA1c level categories and age.

As previously noted, models were created to examine the two subdomains of the composite Duke General Health score. These analyses aimed to further understand the statistically significant improvement in quality of life in the intervention group. The two models of the component scores began with the same possible model for selection as the General Health score, substituting the corresponding baseline Duke Health Profile score for the baseline General Health score.

The final model for the Duke Physical Health score using the backward selection approach included those covariates with p value of 0.15 or less: age, primary language, insurance status, alcohol consumption, baseline Physical Health score, baseline PHQ-9 score, and number of comorbidities at baseline. Sex was maintained based on a priori selection. Estimates by covariate for the final model of Duke Physical Health score are presented in **Table 27**.

No significant intervention effect was identified for Duke Physical Health score at 12 months compared to those in the comparison group, holding all other variables in the model constant (p=0.11).

$$Y_{(\text{DUKE Physical})} = 63.76 + 2.92(\text{Intervention}) + -0.36(\text{Age}) + 0.73(\text{Male}) + -4.69(\text{English}) + 3.79(\text{Insured}) + 4.09(\text{Drink Monthly or Less}) + 4.52(\text{Drink 2-4 Times/Month}) + 18.62(\text{Drink 2-3 Times/Week}) + -7.34\ (\text{Drink 4+ Times/Week}) + 0.45(\text{BL\_Physical}) + -0.94(\text{BL\_PHQ9}) + -2.19(\text{BL\_Comorbidities}) + \varepsilon$$

Table 27. Effect of IBH Intervention on Twelve Month Duke Physical Health Score, Full NCDV Sample

Variable Selected	Duke Physical Health (n=559)		
	Estimate (β)	Standard Error	P value
Intervention	2.92	1.84	0.11
Comparison (ref)	--	--	--
Age (continuous)	-0.36	0.09	<0.001

Male[a]	0.73	2.13	0.73
Female (ref)	--	--	--
English	-4.69	2.30	0.04
Spanish (ref)	--	--	--
Insured	3.79	2.01	0.06
Uninsured (ref)	--	--	--
Drink Monthly or Less	4.09	2.70	0.13
Drink 2-4 Times/Month	4.52	3.72	0.23
Drink 2-3 Times/Week	18.62	6.63	0.01
Drink 4+ Times/Week	-7.34	7.74	0.34
No Alcohol Use (ref)	--	--	--
Baseline Physical Health	0.45	0.04	<0.001
Baseline PHQ-9 score	-0.94	0.27	0.001
Number of comorbidities at baseline	-2.19	1.17	0.06

Note: "ref" indicates the reference category used to calculate the estimate for a covariate; [a] Selected a priori for model inclusion

The final model for the Duke Mental Health score using the backward selection approach included those covariates with p value of 0.15 or less: age, primary language, smoking, baseline Mental Health score, and baseline PHQ9 score. Sex was maintained based on a priori selection. Estimates by covariate for the final model of Duke Mental Health score are presented in **Table 28**.

On average, for participants in the intervention group, there is a 6.22-point statistically significant increase in Duke Mental Health at 12 months compared to those in the comparison group, holding all other variables in the model constant (p<0.001).

$$Y_{(DUKE\ Mental)} = 69.65 + 6.22(Intervention) + -0.22(Age) + 1.03(Male) + -3.08\ (English) + -4.50(Current\ Every\ Day\ Smoker) + -0.96(Current\ Some\ Day\ Smoker) + -4.35(Former\ Smoker) + 0.37(BL\_Mental) + -1.19(BL\_PHQ9) + \varepsilon$$

Table 28. Effect of IBH Intervention on Twelve Month Duke Mental Health Score, Full NCDV Sample

Variable Selected	Duke Mental Health (n=559)		
	Estimate (β)	Standard Error	P value
Intervention	**6.22**	**1.35**	**<0.001**
Comparison (ref)	--	--	--
Age (continuous)[a]	-0.22	0.06	0.001
Male[a]	1.03	1.50	0.49
Female (ref)	--	--	--
English	-3.08	1.66	0.06
Spanish (ref)	--	--	--
Current smoker (every day)	-4.50	3.62	0.21
Current smoker (some days)	-0.96	4.02	0.81
Former smoker	-4.35	1.78	0.02
Never smoker (ref)	--	--	--

Baseline Mental Health	0.37	0.04	<0.001
Baseline PHQ9	-1.19	0.20	<0.001

Note: "ref" indicates the reference category used to calculate the estimate for a covariate; [a] Selected a priori for model inclusion

The final model for the Duke Social Health score using the backward selection approach included those covariates with p value of 0.15 or less: marital status, smoking, baseline Social Health score, and baseline PHQ9 score. Age and sex were maintained based on a priori selection. Estimates by covariate for the final model of Duke Mental Health score are presented in **Table 29**.

On average, for participants in the intervention group, there is a 6.79-point statistically significant increase in Duke Social Health at 12 months constant compared to those in the comparison group, holding all other variables in the model constant (p<0.001).

$$Y_{(DUKE\ Social)} = 65.59 + 6.79\ (Intervention) + -0.08(Age) + -1.92(Male) + 2.82\ (Married) + -2.59(Current\ Every\ Day\ Smoker) + -7.07(Current\ Some\ Day\ Smoker) + -4.46(Former\ Smoker) + 0.29(BL\_Social) + -0.79(BL\_PHQ9) + \varepsilon$$

Table 29. Effect of IBH Intervention on Twelve Month Duke Social Health Score, Full NCDV Sample

Variable Selected	Duke Social Health (n=557)		
	Estimate (β)	Standard Error	P value
Intervention	**6.79**	**1.29**	**<0.001**
Comparison (ref)	--	--	--
Age (continuous)[a]	-0.08	0.06	0.16
Male[a]	-1.92	1.43	0.18
Female (ref)	--	--	--
Married	2.82	1.27	0.03
Unmarried (ref)	--	--	--
Current smoker (every day)	-2.59	3.48	0.46
Current smoker (some days)	-7.07	3.88	0.07
Former smoker	-4.46	1.72	0.01
Never smoker (ref)	--	--	--
Baseline Social Health	0.29	0.03	<0.001
Baseline PHQ9	-0.79	0.15	<0.001

Note: "ref" indicates the reference category used to calculate the estimate for a covariate; [a] Selected a priori for model inclusion

Additional Analyses

We conducted longitudinal analyses to examine time as an independent variable, assessing whether the outcome trajectories differ by intervention status. To estimate a 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 a significant time/group interaction with a p value of <0.001, indicating that the trajectories from baseline to 6 months, and then to 12 months were different between the two study arms for Duke General Health score (not shown). Adjusting for the covariates that were selected in the primary model—age, sex, primary language, marital status, insurance status, smoking, alcohol consumption, and baseline PHQ-9 score—did not alter these results (p<0.001; see **Table 30**).

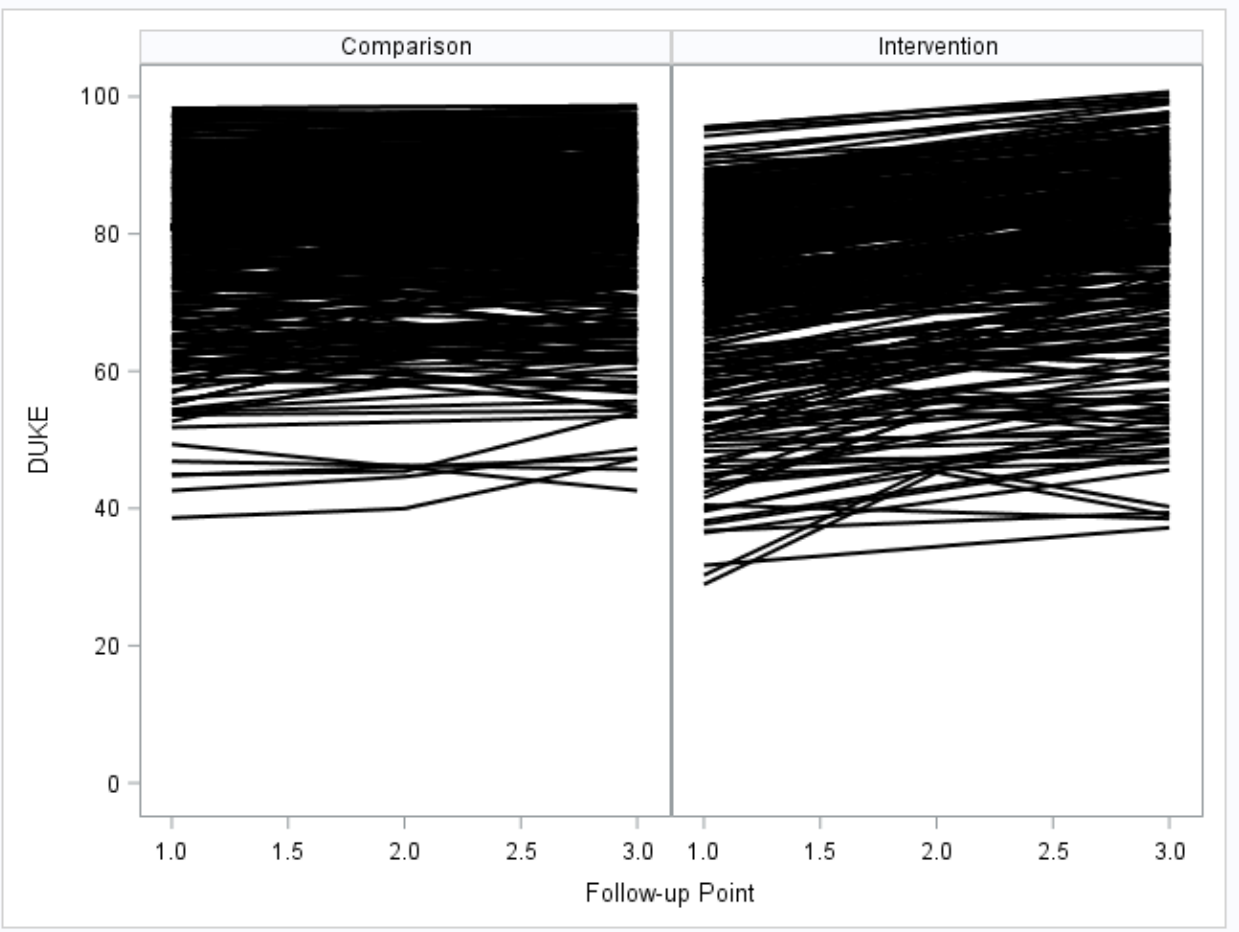
Table 30. Effect of IBH Intervention on Trajectory of Duke General Health Score Across Twelve Month Study, Full NCDV Sample

Variable	Duke General Health (n=635)		
	Estimate (β)	Standard Error	p value
Time*Intervention	**6.59**	**1.16**	**<0.001**
Time*Comparison (ref)	--	--	--
Time	0.68	0.76	0.37
Intervention	-7.88	1.14	<0.001
Comparison (ref)	--	--	--

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

To visualize the longitudinal effect of the intervention on Duke General Health score, we produced a two-panel spaghetti plot using PROC SGPANEL. **Figure 5** displays the comparison group trajectory in the left panel and the intervention group trajectory in the right panel. The x-axis of the graph shows the study follow-up points with 1.0 representing baseline, 2.0 is the 6-month point, and 3.0 is the 12-month end-point. Looking at the trajectories, the two groups clearly differ from one another. The trajectory figure visually displays the differences identified in the longitudinal statistical model, identifying the intervention group's lower Duke General Health score measurements and steeper increase from baseline to 12 months compared to the comparison group.

Figure 5. Individual Trajectories of DUKE General Health Score Across Twelve Month Study Period for IBH Intervention and Comparison Groups



Limitations

As mentioned, those who did not complete the study were more likely to have lower Duke General Health scores than those who completed the study and that Duke General Health score statistically significantly contributed to the likelihood of a participant not completing the study. Results also showed that this difference in General Health score between attrition groups was not detected when analyzing the intervention and comparison group separately. This difference in the full sample indicates a potential limitation related to internal validity on this measure. However, because of the strength of the significant end-point analysis results for this measure and that this difference was not detected when comparing attrition within the intervention and comparison groups separately, the concern for potential bias is lessened. *(Note: The Duke Spanish language surveys used in the Sí Texas study had been validated in the literature and HRiA conducted focus groups in the study area to ensure that the survey language was regionally appropriate. Administration of this data collection tool was consistent at the intervention and comparison with all clinics utilizing provider interview methods)*.

Table 31. Impact Measures by Study Arm and Follow-up Period, Overall and by Study Group

	Full Sample			Intervention			Comparison		
	Baseline	6-Mo	12-Mo	Baseline	6-Mo	12-Mo	Baseline	6-Mo	12-Mo
	n=756	n=611	n=563	n=329	n=277	n=239	n=427	n=334	n=324
Measure		Mean (SD)			Mean (SD)			Mean (SD)	
Blood pressure									
Systolic	132.9 (19.3)	131.0 (17.3)	130.0 (18.2)	133.2 (20.3)	132.0 (17.5)	131.9 (18.3)	132.7 (18.5)	130.2 (17.1)	128.6 (18.0)
Diastolic	78.6 (9.2)	77.8 (8.7)	77.0 (8.8)	77.0 (8.5)	76.7 (8.6)	75.8 (7.5)	79.8 (9.4)	78.7 (8.7)	78.0 (9.6)
Missing	--	--	--	--	--	--	--	--	--
HbA1c									
HbA1c	8.6 (1.7)	8.4 (1.7)	8.3 (1.8)	8.6 (1.6)	8.4 (1.8)	8.2 (1.7)	8.6 (1.7)	8.4 (1.7)	8.5 (1.8)
Missing	--	1	--	--	1	--	--	0	--
BMI									
BMI	33.9 (7.0)	34. 0 (7.1)	33.9 (7.1)	33.3 (6.4)	33.2 (6.6)	33.3 (6.6)	34.4 (7.4)	34.7 (7.5)	34.3 (7.4)
Missing	6	--	--	6	--	--	0	--	--
PHQ-9									
PHQ-9 Score	3.8 (4.3)	3.3 (4.3)	2.8 (3.7)	5.2 (4.9)	4.3 (4.7)	3.4 (4.4)	2.9 (3.6)	2.6 (3.7)	2.5 (3.0)
Missing	--	--	--	--	--	--	--	--	--
Duke Health									
General Health	75.5 (16.9)	81.0 (16.2)	79.2 915.9)	71.9 (16.9)	77.0 (16.6)	79.6 (16.2)	78.2 (16.3)	84.4 (15.1)	78.9 (15.8)
Mental Health	82.8 (20.2)	86.3 (19.4)	85.4 (18.5)	82.2 (20.4)	85.6 (19.7)	86.9 (19.6)	83.3 (20.0)	86.8 (19.2)	84.3 (17.7)
Physical Health	64.0 (25.2)	68.2 (25.0)	67.5 (25.3)	60.4 (24.8)	61.2 (25.6)	65.9 (26.2)	66.7 (25.3)	74.0 (23.0)	68.7 (24.6)
Social Health	79.7 (19.8)	88.1 (16.0)	84.8 (15.9)	73.5 (19.7)	84.0 (17.3)	85.9 (16.1)	84.5 (18.5)	91.5 (14.1)	83.9 (15.7)
Missing	--	--	--	--	--	--	--	--	--

Table 32. Within Group Bivariate Analyses Comparing Baseline to 12 Months

	12-Month Mean (SD)	Baseline Mean (SD)	12-month (–) Baseline Mean Difference (SD)	p value
INTERVENTION GROUP (n=239)				
BMI[a]	33.3 (6.6)	33.5 (6.4)	0.02 (0.06)	0.10
Systolic Blood Pressure	131.9 (18.3)	132.6 (19.6)	-0.68 (20.7)	0.61
Diastolic Blood Pressure	75.8 (7.5)	76.6 (8.5)	-0.87 (9.1)	0.14
Nonparametric Tests[a]	12-Month Median (SD)		Baseline Median (SD)	p value
PHQ-9	**2.0 (4.4)**		**4.0 (4.9)**	**<0.001**
General Health	**83.3 (16.2)**		**76.7 (16.0)**	**<0.001**
HbA1c	**7.8 (1.7)**		**8.0 (1.6)**	**0.001**
	12-Month Mean (SD)	Baseline Mean (SD)	12-month (–) Baseline Mean Difference (SD)	p value
COMPARISON GROUP (n=324)				
BMI[a]	34.3 (7.4)	34.5 (7.5)	0.2 (0.06)	0.22
Systolic Blood Pressure	**128.6 (18.0)**	**132.1 (17.7)**	**-3.5 (17.4)**	**<0.001**
Diastolic Blood Pressure	**78.0 (9.6)**	**79.5 (9.2)**	**-1.6 (10.7)**	**0.01**
Nonparametric Tests[a]	12-Month Median (SD)		Baseline Median (SD)	p value
PHQ-9	1.0 (3.0)		1.0 (3.5)	0.17
General Health	83.3 (15.8)		83.3 (16.5)	0.75
HbA1c	8.0 (1.8)		8.2 (1.6)	0.10

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

Table 33. Between Group Bivariate Analyses at 12 Months

	Full Sample n=563 Mean (SD)	Intervention n=239 Mean (SD)	Comparison n=324 Mean (SD)	p value
BMI[a]	33.9 (7.1)	33.3 (6.6)	34.3 (7.4)	0.10
Systolic Blood Pressure	**130.0 (18.2)**	**131.9 (18.3)**	**128.6 (18.0)**	**0.03**
Diastolic Blood Pressure	**77.0 (8.8)**	**75.8 (7.5)**	**78.0 (9.6)**	**0.003**
Nonparametric Tests[b]	Median (SD)	Median (SD)	Median (SD)	p value
PHQ-9	**2.0 (3.7)**	**2.0 (4.4)**	**1.0 (3.0)**	**0.047**
General Health	83.3 (15.9)	83.3 (16.2)	83.3 (15.8)	0.44
HbA1c	7.9 (1.8)	7.8 (1.7)	8.0 (3.4)	0.07

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

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

Summary of Findings

This final report provides an overview of findings for the evaluation of Nuestra Clinica del Valle's NuCare program conducted at their clinic in Mission, Texas. NCDV implemented a QED study to compare intervention participants receiving the delivery of IBH and other services with a comparison group who received usual care at NCDV's Edcouch and Alton clinics.

At its core, the NuCare project consisted of: 1) community health worker (CHW) integration into the clinic team through depression screening and other patient services, 2) integration of nutritionists into the clinic team to work with patients to set goals and monitor progress, 3) mediated health education meetings led by licensed vocational nurses (LVN); and 4) introduction of a full time Behavioral Health Provider. The clinic added an integrated behavioral health team and included the warm handoff, in which the primary care provider directly introduces the patient to the behavioral health provider and an immediate, brief intervention is delivered.

The evaluation study achieves a preliminary level of evidence given the evidence-based interventions were adapted and evaluated using methods with moderate internal validity. The internal validity of this study was maintained through multiple factors including the use of a similar comparison group recruited from clinics within the same system as the intervention clinic. Specifically, the comparison group addressed the following threats to internal validity: testing, John Henry, and expectancy effects. This QED, with similar clinics, allowed for the identification of and controlling for differences in participant characteristics at baseline that may affect impact measures of interest. Additionally, while the attrition rate was slightly higher in the intervention group, there was no statistically significant differential attrition detected comparing the proportion of participants who did not complete the study between the intervention and comparison groups, further preserving internal validity. A comparison group allowed for the examination of observed improvements in the intervention group as they relate to patients who use a different clinic (factors related to being part of a different population in the same region).

The study showed, when controlling for baseline measures and other covariates, intervention participants did not have a significantly greater improvement in the HbA1c confirmatory outcome over time when compared to the comparison group participants ($p=0.13$). Significant improvement was demonstrated in the exploratory outcome of quality of life as measured by the Duke Health Profile. Our findings suggest that the intervention was associated with significantly higher mean values of Duke General Health score at 12 months by 5.36 points ($p<0.001$), Duke Mental Health Score at 12 months by 6.22 points ($p<0.001$) and Duke Social Health Score at 12 months by 6.79 points ($p<0.001$).

NCDV serves a border region with high rates of diabetes and limited access to services. NCDV's multidisciplinary team approach aimed to improve the health status of patients by improving access to services in an area where access remains one of the most pressing issues. The study population reflects this with 54.6% of participants with an HbA1c$\geq$8.0% and the remaining with an HbA1c 6.5%- 7.9%, and 61.5% of participants unemployed. Findings from the implementation evaluation support the significant findings of improved functionality and quality of life for participants experiencing NCDV's multidisciplinary approach. Further, because the NCDV clinic serves a predominantly low-income, Hispanic population, the study design and implementation will help the clinic as well as external

audiences better understand the various aspects of the NuCare program in addressing physical and behavioral health concerns of this population.

Given the fidelity to which the evaluation and program were implemented, the significant results, the contribution to the field, and the limit to internal validity presented by the lack of a matched comparison group, this study achieves a preliminary level of evidence to improve our understanding of the impact of the multidisciplinary team care model.

Summary of Implementation Findings

The implementation evaluation examined fidelity to NCDV's NuCare program model by conducting focus groups and interviews and examining patient visit and administrative data. Mid-point interviews with a total of 14 staff interviews were conducted in-person. Mid-point interviews were intended to be conducted approximately 6 months after initial study enrollment. Interview participants included clinical providers (both primary and behavioral care) and other relevant clinical and nonclinical personnel. Given logistics challenges, these interviews instead were conducted approximately seven months after initial study enrollment, a deviation from the SEP. After the study concluded, 13 interviews with staff and 3 focus groups with a total of 18 intervention participants were conducted approximately one month after the study ended.

Evaluation of the implementation of NuCare program shows that the program was implemented in alignment with the program logic model and that the program was implemented with moderate to high degree of fidelity. NCDV's program enrolled a total of 756 participants, including 329 in the intervention group and 427 participants in the comparison group, reaching 97.3% of their enrollment target in the intervention group and exceeding their enrollment target in the comparison group. The final 12-month sample totaled 579 participants, with 239 in the intervention group exceeding the target of 236 and keeping a 72.6% retention rate.

Except for inconsistent implementation of the brief intervention component of the warm handoff process, a delay with the start of the wellness classes, and some staff turnover, the NuCare program was implemented as planned. Interview participants involved in the mid-point and summative evaluations indicated that NCDV implemented their program to a moderate to high level of fidelity. Expanding the warm handoff approach from a more traditional approach—where primary care would introduce the patient to the behavioral health provider and a future appointment would be set up—to a more "brief intervention" approach—where behavioral health would initiate 15-20 min interventions upon request (in person or via internal email) from the primary care provider —was a result of the need to adapt to the needs of the population. Staff turnover—both frontline staff and administration—caused NCDV to modify staff roles and responsibilities. Despite these adaptations, NCDV implemented the NuCare multidisciplinary model to a moderate to high degree of fidelity by working diligently to facilitate communication and workflows to support integration.

All participants enrolled in the intervention met study eligibility criteria, and all who remained in the study for the 12 months received the intervention as designed including physical and behavioral health services. Intervention participants received guidance and support from community health workers, nutrition education services, health education services, and behavioral health services as appropriate. Intervention participants received a total of 964 warm handoffs and 2,224 regular encounters across the different survey types. Of the 320 participants who received some type of nutrition services, 65%

(n=209) received at least one warm handoff before their first regular encounter. About half of participants receiving nutrition services had 3 warm handoffs before their first nutrition encounter (52%). For the 138 participants receiving some type of behavioral health services, 22% (n=30) had at least one warm handoff before a regular encounter indicating most first warm handoffs occurred after at least one behavioral health encounter.

Over the course of the study, NCDV improved in level of integration of behavioral health with reported improvement in four of the five IBH core principles from baseline to 12 months. NCDV began the study by applying the fifth core principle (evidence-based care) to most or all patients, a practice that continued through the end of the study. There was additional change in the IBH core components and tasks with nineteen showing improvement and nine remaining the same from baseline to 12 months (five of which were applied to the care of "most/all" patients at baseline). Two components showed a decrease in how they were applied in patient care: "Facilitate and track referrals to specialty care, social services, and community-based resources" and "Use valid measurement tools to assess and document baseline symptom severity." This change may be attributed to a change in the level of awareness of the implementation of these components.

Facilitators to program implementation included multiple forms of communication among staff, warm handoffs, the establishment of trusting relationships among staff and the flexibility of staff in the roles they played, and creative use of clinic space. For patients, additional factors that facilitated their participation included strong rapport between patients and staff, the no or low cost of services, and the awareness of improved health outcomes. Feedback from patients was generally very positive, with patients citing improvement in health care access, health literacy, and ultimately improved health outcomes as reasons for being satisfied. Apart from improved health outcomes, interviewees and focus group participants reported other improved outcomes, namely improved quality of life, from participation the NuCare program. One shared, *"I felt depressed and didn't want to talk to anybody, but then they got me in this Sí Texas class. My A1C has gone down and I lost some weight and feel happier about myself."* Focus group participants also commented on the satisfaction with the wellness classes, sharing, "*I really like the idea of the exercise classes. It's built a community and has had a positive, overall outcome with those who participate."*

Interviewees indicated that patients were very receptive to the NuCare program and felt like they were being heard, and thus, took a more active role in their health. Patients reported that the NuCare program was intended to improve quality of life "*in many aspects in one's life*." In the mid-point and summative interviews, participants noted that there used to be more frustration among patients because of long wait times, but workflow changes in the clinic decreased the amount of time patients spent at NCDV to get multiple services.

Adoption barriers included a lack of buy-in from providers early in the program implementation due to challenges in communication, workflow changes within the clinic layout, and limitations within the data systems for internal and external report development. For patients, stigma, the cost of services, and transportation to services were challenges. An additional barrier was the socio-political environment which heightened anxiety and deterred patients from seeking services.

Summary of Impact Findings

The impact evaluation used a non-randomized QED to evaluate the NuCare program's impact at the Mission Clinic by comparing Mission participants to those from the Alton and Edcouch comparison clinics. This design allowed for the identification and controlling of participant characteristics that may have affected impact measures of interest. Participants enrolled in the study were followed for 12 months.

The study also meets the criteria for effective evidence for the following reasons. First, the study demonstrates a positive, significant finding for an exploratory outcome (quality of life). Second, there were no negative intervention effects on confirmatory or exploratory outcomes. Finally, the exploratory quality of life measure achieved an effect size of 0.34 (using Cohen's d). This value may be interpreted as exceeding the minimum standard for a small effect size (d=0.2) based on Cohen's rule of thumb for interpretation of effect sizes (Cohen, 1988).

Significant improvement was demonstrated in the exploratory outcome of quality of life as measured by the Duke Health Profile. Our findings suggest that the intervention was associated with significantly higher mean values of Duke General Health score at 12 months by 5.36 points ($p<0.001$), Duke Mental Health Score at 12 months by 6.22 points ($p<0.001$) and Duke Social Health Score at 12 months by 6.79 points ($p<0.001$). Additional analyses found increased Duke General Health score over time for the intervention group ($\beta=6.59$ points, $p=<0.001$). This finding is further supported by comments from focus group participants who noted improved quality of life as the goal of the program and later cited improved overall health as one of the motivators to keep participating.

Intervention participants had significantly greater improvements than the comparison group on an additional exploratory outcome measure, PHQ-9. Intervention participants were found to have decreased PHQ-9 scores over time compared to the comparison group ($\beta=-1.39$ points, $p=<0.001$). Stratified analyses, which were conducted to understand the potential influence of the study population's diabetic status on health outcomes, found that those in the intervention group with uncontrolled diabetes at baseline had a statistically significantly lower diastolic blood pressure at 12 months, by 2.38 mmHg, than those in the comparison group with uncontrolled diabetes. While there were no statistically significant changes in blood pressure in the overall study population, this result identified a differential impact of the intervention on diastolic blood pressure by control of diabetes and indicates a need for further research. This result is consistent with the current body of research on the relationship between diabetes and blood pressure; however, additional factors such as medication and adherence to medication were not examined because those data were not available for this study population.

Lessons Learned

This evaluation contributes to our understanding of the impact of a multidisciplinary approach to the integration of behavioral health services in a primary care service context. The rationale behind the intervention is that by providing behavioral health within the primary care setting, patients will receive an array of services that will improve their health outcomes, while reducing barriers to treatment and stigma that may be associated with services. These concepts are supported by previous research. For example, as previously mentioned, NCDV adapted evidence-based care models with innovative components including community health workers. The activities of the NCDV approach are based on those elements present in the Sanchez and Watt (2012) including: care management, access to behavioral health specialists, and mediated health education meetings that have been linked to

improved health outcomes in the evidence base. NCDV built upon these models by adapting integrated services to be culturally-relevant for the unique border community, including bilingual programming and psychoeducation. The results of the NuCare evaluation build on this work by examining the impact of a multidisciplinary approach to the integration of behavioral health services in a predominantly Hispanic, low-income population.

While significant findings were limited to improvements in quality of life, several lessons emerged that could inform other organizations interested in implementing a similar model.

Operational Facilitators
As reviewed in findings from the implementation evaluation, three primary areas facilitated success in NCDV that have implications for other clinics. The first major factor is gaining leadership or administrative buy-in. This buy-in early on ensures the clinic and the system in which it functions is ready to implement the program at the start. Being able to identify and address administrators' and providers' concerns early supports initial program success ensures all staff being on the same page about the program, its benefits, and operations.

Second, data system(s) should support the needs of the providers for patient care, documentation, and communication among providers to coordinate patient care. When possible, the data system should be customizable to allow for internal and external reporting, when appropriate. Learnings from the evaluation led to increased buy in from providers and administration as shown in the workflow modifications. These modifications led to the creation of clinical pathway templates that assisted frontline providers such as medical assistants to initiate encounters with behavioral health. In turn, these workflow enhancements improved buy-in from primary care providers who were initially resistant to program implementation because of the perception that it would impact a smooth clinic flow.

The final facilitator is clear communication for the implementation of the program and development of a trusting, coordinated team of service providers. Providers understand their role in the team and the capacities of other team members. This increases the likelihood that patients will access the services they need to improve their health.

When all three of these facilitators were in place, the NuCare program influenced both provider and patient satisfaction. Services were better coordinated in a timely manner leading to improved health outcomes.

Study Limitations and Implications for Future Research

It is important to note the limitations of this study. NuCare evaluation findings show that intervention participants were more likely than comparison group participants to experience significant improvements in their quality of life and depression, but there were no statistically significant improvements observed in blood pressure, obesity, or diabetes. When considering the effect of the study population's diabetic status on health outcomes, intervention group participants with uncontrolled diabetes were more likely than comparison group participants with uncontrolled diabetes to experience lower diastolic bold pressure at 12 months.

As previously discussed, the NuCare program was evaluated using a QED evaluation design with a comparison group to minimize threats to internal validity. The comparison group was included to

examine observed improvements in the intervention group as they relate to patients who use a different clinic (factors related to being part of a larger population). These participants were significantly different from the intervention group three impact and six demographic and behavior measures at baseline. For the six impact measures in NCDV's study, the intervention and comparison groups were statistically nonequivalent on three measures (PHQ-9, BMI, and diastolic blood pressure). In addition, the two groups differed on age, marital status, histories of diabetes and high cholesterol, as well as on behavior related measures of physical activity and smoking. Although propensity score matching was not used because of an insufficient number of variables to match on, the complete case analyses sufficiently controlled for these baseline differences.

Because this study used a quasi-experimental design and did not employ randomization to achieve baseline equivalence, adjusted regression analyses was proposed as the main analytic approach in the SEP to analyze the intervention effect accounting for potential confounders. Additionally, it was not possible to employ matching in the study design phase since the NCDV participants were also serving as a comparison group to another study in the Sí Texas portfolio. Therefore, statistical matching at the analysis phase was proposed in the SEP. The proposed matching method to evaluate the robustness of the main results was propensity score matching. In general, propensity score matching is typically used with a large set of covariates among large samples by matching cases with controls based on covariance of these covariates. It has been shown to reduce selection bias that may be present in observational and quasi-experimental design studies (Rubin and Thomas, 1996). Specifically, propensity score matching identifies close matches and removes participants from the analytic samples that have no appropriate match in the other group. This trade-off of reduced bias and reduced efficiency (due to discarded observations) tends to favor accuracy in large samples with many covariates (e.g., greater than 30 covariates), but can be challenging in terms of reduced precision and decreased statistical power in smaller sample evaluation studies with fewer number of covariates.

As proposed in the SEP, only a limited set of covariates were collected among intervention and comparison groups during the NuCare study. The optimal matching algorithm within the nearest neighbor matching method was conducted and found that the propensity score matching reduced the total sample by 304 participants or 40.5% of the comparison group analysis sample. Discarding over a third of the study sample who completed an assessment at 12 months reduced statistical power. This is in part due to a limited set of covariates and the inherent differences between the intervention group and comparison group. Other matching methods (i.e., weighting, full matching, and sub-classification) require additional assumptions and weight assignment (either implicit or explicit), which are generally not as preferable as the optimal matching based on nearest neighbor method (Stuart 2010). An adjusted regression approach accounting for available covariates with model selection was appropriately applied to ascertain the intervention effect. This approach was chosen due the limitations of 1. reduced available analytic sample, 2. a small number of covariates, and 3. properties of alternative matching methods.

No limitations specific to any of the five impact measures were noted. Patients and staff did not report any difficulties with the administration and completion of the Duke Quality of Life survey or the PHQ9. Both data collection tools were administered consistently at the intervention and comparison clinics with all clinics utilizing provider interview methods.

As mentioned, those who did not complete the study were more likely to have lower Duke General Health scores than those who completed the study and that Duke General Health score statistically

significantly contributed to the likelihood of a participant not completing the study. Results also showed that this difference in General Health score between attrition groups was not detected when analyzing the intervention and comparison group separately. This difference in the full sample indicates a potential limitation related to internal validity on this measure. However, because of the strength of the significant end-point analysis results for this measure and that this difference was not detected when comparing attrition within the intervention and comparison groups separately, the concern for potential bias is lessened.

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. NCDV created this approach to meet the needs of the clinic patients, who are primarily Hispanic and low income. In the future, researchers might want to consider examining the extent to which other specific populations would benefit from a multidisciplinary approach to integrated behavioral health models. In addition, given the limited implementation of the warm handoff with brief intervention, as NCDV implements and refines their approach, researchers may wish to examine the implementation and outcome effects on this or other populations. Given the implementation of clinical pathways and standard delegation orders for PHQ-9, researchers may wish to examine the impacts of policy and systems change on implementation and health outcome measures.

Next Steps

NCDV is reviewing findings from this study to improve the implementation of the NuCare model across four other clinics in the NCDV system. NCDV is using policy and system change strategies to improve buy-in and utilization of the NuCare model. Through the development of a Primary Care-Behavioral Health manual, NCDV administration routinely reviews and adjusts clinical pathways and standing delegation orders to ensure they are functioning to meet the needs of the patients and increase access to the multidisciplinary services that make up NuCare. -Team based training is being delivered on a clinic by clinic basis to increase the level of behavioral health integration within each clinic. This work is supported by a perceived growing sense of buy-in from system leadership and administration. Financial resources to maintain the program for all patients poses the greatest challenge for sustainability.

OTHER ASPECTS OF STUDY LOGISTICS AND FEASIBILITY

Human Subjects Protection

NCDV submitted its initial research protocol in December 2015 to the New England Independent Review Board (NEIRB) for their determination of risk and approval of study procedures. The NEIRB granted NCDV conditional approval on January 19, 2016 (protocol reference number 120160473, formerly IRB# 16-012). After conditional approval of the SEP from SIF was received in July 2016, the amended protocol and revised consent forms and scripts were submitted to NEIRB. Full approval was received from NEIRB on August 2, 2016. Enrollment began in September 2016.

In April 2017, NCDV submitted an amendment to revise target numbers for enrollment and retention to account for an increased attrition rate and an extension in the baseline enrollment period through April 2017. The amendment was approved by NEIRB on April 13, 2017. A change in principal investigator form was filed with NEIRB on November 28, 2017 and approved on December 6, 2017.

NCDV did not encounter any problems securing approval from NEIRB. In accordance with NEIRB procedures, NCDV has submitted an annual continuing review report to NEIRB which was approved. No deviations in research protocols have occurred to-date.

Timeline

SIF final approval to begin data collection was received in August 2016. NCDV began their enrollment in September 2016 after IRB approval was secured. Enrollment continued through the beginning of April 2017. In a deviation from the SEP, the dates for the interim and final reports were revised accordingly with the interim report due in December 2017 and the final report in late fall 2018. No other major changes to the timeline occurred. An updated timeline is presented in **Appendix A. Revised Project Timeline** below.

Evaluator/Subgrantee Role and Involvement

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

Budget

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

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APPENDICES

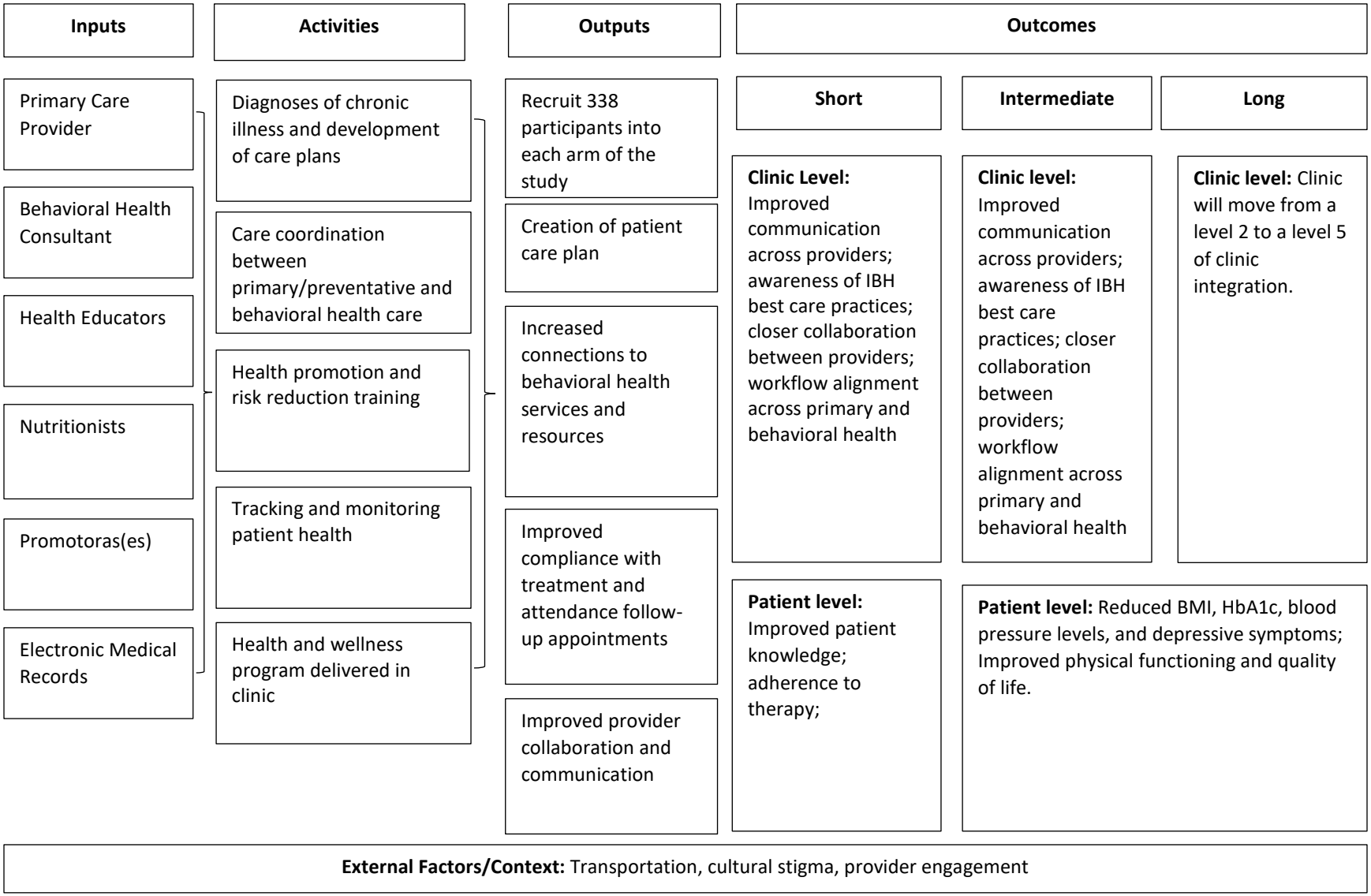
Sí Texas Subgrantee: Nuestra Clinica del Valle (NuCare)
Program Title: Integrated Behavioral Health Reducing Diabetes, Obesity & Depression

Appendix A. Revised Project Timeline

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

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

Appendix B. Program Logic Model



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

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

INTRODUCTION/INFORMED CONSENT

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

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

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

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

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

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

INTERVIEW QUESTIONS

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

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

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

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

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

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

6. Operations (Choose Clinic or Community as appropriate)

Clinic-based Operations

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

Community-based Operations

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

7. Patient and Provider Satisfaction

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

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

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

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

10. Closing

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

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

Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide

CORE INTERVIEW GOALS

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

INTRODUCTION/INFORMED CONSENT (2 MIN)

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

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

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

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

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

INTERVIEW QUESTIONS

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

Key Informant Background (3 MIN)

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

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

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

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

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

Adoption Facilitators and Barriers (15 MIN)

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

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

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

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

Provider and Patient Satisfaction (5 MIN)

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

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

Program Impact (5 MIN)

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

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

Sustainability and Lessons Learned (10 MIN)

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

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

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

Closing (2 MIN)

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

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

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#96104.0

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

CORE FOCUS GROUP GOALS

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

INTRODUCTION (5 MIN)

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

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

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

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

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

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

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

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

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

INTRODUCTION AND WARM-UP (5 MIN)

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

PROGRAM RECRUITMENT (10 MIN)

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

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

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

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

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

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

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

PROGRAM VALUE/IMPACT (10-15 MIN)

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

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

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

CLOSING/INCENTIVE DISTRIBUTION (2 MIN)

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

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

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

Appendix F. Implementation Evaluation Measures

Research question/sub-questions	**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 NuCare program reach its intended target population?				
	Demographic characteristics of participants	Eligibility criteria data	• How would you describe the population that your program is serving? • What are they like in terms of demographics generally? • Is this the population it intended to serve?	None
FIDELITY: What are the components of the NuCare 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 NCDV implement the NuCare model with fidelity?				
What are the resources of the program?	Input: Primary Care Provider	--	What is your current role?	Yes/No
What are the resources of the program?	Input: Behavioral Health Consultant	Encounters with behavioral health provider (LPC)	What is your current role?	None
What are the resources of the program?	Input: Health Educators	Encounters with health educator	What is your current role?	None
What are the resources of the program?	Input: Nutritionists	Evidence of warm handoff to Nutrition	What is your current role?	None
What are the resources of the program?	Input: Promotoras(es)	--	What is your current role?	Yes/No
What are the resources of the program?	Input: Electronic Medical Records	--	• To what extent have information/data	Yes/No

Research question/sub-questions	**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?*
			systems/your EMR been changed to support the program? • Have you added any information/data systems for the project?	
What are the program activities and how have they been operationalized?	Activity: Diagnoses of chronic illness and development of care plans	--	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.	Yes/No
What are the program activities and how have they been operationalized?	Activity: Care coordination between primary/preventative and behavioral health care	• Evidence of warm handoff to behavioral health • Evidence of warm handoff to health education • Evidence of warm handoff to Nutrition • Evidence of handoff/contact with clinic navigator	• Probe: Are warm handoffs between providers a component of the services participants receive? How do those handoffs work? • Now that the program has been implemented, to what extent are primary care and behavioral health services connected, coordinated, combined, if at all?	None

Research question/sub-questions	**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: Health promotion and risk reduction training	• Encounters with behavioral health provider (LPC) • Encounters with health educator	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
What are the program activities and how have they been operationalized?	Activity: Tracking and monitoring patient health	• Encounters with clinic navigator	When a participant enrolls in the program, what happens to them next? Take me through the services and activities that an enrollee receives in the program.	Patient records; follow-up call counts
What are the program activities and how have they been operationalized?	Activity: Health and wellness program delivered in clinic	--	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: Recruit 295 participants into each arm of the study	• Eligible for study based on demographic diagnoses • Screened for Study participation (does not receive services from other SiTX	--	None

Research question/sub-questions	**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?*
		programs, does not participate in other studies) • Consent/Refused to participate in study • Reasons for declining • Suicidality at time of screening • Incentive Receipt • Study ID		
Are the components different than what was planned? If so, why?	Output: Creation of patient care plan	• Encounters with clinic navigator	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.	Yes/No
Are the components different than what was planned? If so, why?	Output: Increased connections to behavioral health services and resources	• Evidence of warm handoff to behavioral health • Evidence of warm handoff to health education	• 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	None

Research question/sub-questions	**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?*
		• Evidence of warm handoff to Nutrition • Evidence of handoff/contact with clinic navigator • Encounters with peer support	connected/coordinated/combined, if at all? • Probe: Are warm handoffs between providers a component of the services participants receive? How do those handoffs work? • Now that the program has been implemented, to what extent are primary care and behavioral health services connected, coordinated, combined, if at all?	
Are the components different than what was planned? If so, why?	Output: Improved compliance with treatment and attendance follow-up appointments	• Referral to behavioral health • Encounters with behavioral health	--	Participant referral and attendance counts
Are the components different than what was planned? If so, why?	Output: Improved provider collaboration and communication	• Evidence of warm handoff to behavioral health • Evidence of warm handoff to health education	• 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	None

Research question/sub-questions	**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?*
		• Evidence of warm handoff to Nutrition • Evidence of handoff/contact with clinic navigator • Evidence of handoff/contact with peer support	connected/coordinated/combined, if at all? • Probe: Are warm handoffs between providers a component of the services participants receive? How do those handoffs work? • Now that the program has been implemented, to what extent are primary care and behavioral health services connected, coordinated, combined, if at all?	
INTEGRATION: What level of Integrated Behavioral Health did NuCare achieve as a result of implementing the program?				
What level of Integrated Behavioral Health did NCDV 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 NCDV's program at 6 and 12 months?	--	--	• Now that the program has been implemented, to what extent are primary care and behavioral health services connected, coordinated, combined, if at all?	Staff satisfaction/knowledge survey

Research question/sub-questions	**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 facilitators and barriers to adoption?	--	--	• Please describe any barriers you or your organization has experienced in implementing the program. • In what ways did these barriers affect program implementation? In what ways have you been able to address these barriers? • Please describe anything that has helped your organization implement the program. • Probes: Is the staff, the facilities, the data systems, outside partners, or other things?	Staff/Administration satisfaction surveys
To what extent do providers buy into the program, and how has that buy-in affected implementation?	--	--	• Have you heard any feedback from providers about program implementation? • What are some of the general themes from their feedback been?	Staff satisfaction surveys
To what extent did the comparison groups receive program-like components?				
--	--	--	• When a participant is randomized/enrolled in the control/comparison group of your program, what can they expect to receive or participate in terms of services or activities?	• Number of patients in comparison group that receive 1 program-like component

Research question/sub-questions	**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?*
			• 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 comparison group that receive more than 1 program-like component
How satisfied are NuCare patients with the services they have received? How satisfied are providers with the NuCare program?				
--	--	--	• What do you think participants in general would say about the program? Would you mind sharing any general themes from feedback you have heard from participants about the program? • Have you heard any feedback from providers about program implementation? What are some of the general themes from their feedback been?	Provider and participant satisfaction with NuCare

			• 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?	

Appendix G. Loss to Follow-Up/Attrition Tables

Table 34. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Demographic Characteristics among the Intervention and Comparison

	Full Sample (n=756)		Completed Study (n=563)		Did Not Complete Study (n=193)		p value
Variables	N	%	N	%	N	%	
Sex							
Male	223	29.5	151	26.8	72	37.3	
Female	533	70.5	412	73.2	121	62.7	**0.01**
Missing	--	--	--	--	--	--	
Ethnicity[a]							
Hispanic/Latino	751	99.3	558	99.1	193	100.0	
Non-Hispanic/Non-Latino	5	0.7	5	0.9	0	0.0	0.34
Missing	--	--	--	--	--	--	
Race[a]							
White	755	99.9	563	100.0	193	99.5	
Other	1	0.1	0	0.0	1	0.5	0.26
Missing	--	--	--	--	--	--	
County[a]							
Cameron	1	0.1	1	0.2	0	0.0	
Hidalgo	749	99.1	560	99.5	189	97.9	**0.04**
Starr	6	0.8	2	0.4	4	2.1	
Missing	--	--	--	--	--	--	
Age							
Mean	54.1	--	53.8	--	54.9	--	0.25
SD	10.6	--	10.2	--	11.8	--	
<35	26	3.4	17	3.0	9	4.7	
35-44	105	13.9	77	13.7	28	14.5	
45-54	241	31.9	190	33.8	51	26.4	0.15
55-64	295	39.0	220	39.1	75	38.9	
65+	89	11.8	59	10.5	30	15.5	
Missing	--	--	--	--	--	--	
Employment							
Not Employed	466	61.6	338	60.0	128	66.3	
Employed	290	38.4	225	40.0	65	33.7	0.12
Missing	--	--	--	--	--	--	
Marital Status							
Unmarried	280	37.3	197	35.2	83	43.5	
Married	471	62.7	363	64.8	108	56.5	**0.04**
Missing	5	--	3	--	2	--	
Primary Language[a]							
English	144	19.2	102	18.2	42	22.3	0.08
Spanish	605	80.7	460	81.9	145	77.1	

	Full Sample (n=756)		Completed Study (n=563)		Did Not Complete Study (n=193)		p value
Variables	N	%	N	%	N	%	
Samar-Leyte	0.1	0.0	0	0.0	1	0.5	
Missing	6	--	1	--	5	--	
Level of Physical Activity							
Never	310	41.0	221	39.3	89	46.1	0.42
1-2 times/week	157	20.8	122	21.7	35	18.1	
3-4 times/week	107	14.2	78	13.9	29	15.0	
5-6 times/week	54	7.4	42	7.5	12	6.2	
Daily	128	16.9	100	17.8	28	14.5	
Missing	--	--	--	--	--	--	
Smoking Status[a]							
Current Every Day Smoker	35	4.6	17	3.0	18	9.3	**0.003**
Current Some Day Smoker	18	2.4	14	2.5	4	2.1	
Former Smoker	121	16.0	88	15.6	33	17.1	
Never Smoker	582	77.0	444	78.9	138	71.5	
Missing	--	--	--	--	--	--	
Alcohol Consumption							
Never	588	77.8	445	79.0	143	74.1	0.49
Monthly or Less	96	12.7	66	11.7	30	15.5	
2-4 per/month	50	6.6	35	6.2	15	7.8	
2-3 per/week	14	1.9	10	1.8	4	2.1	
4+ per/week	8	1.1	7	1.2	1	0.5	
Missing	--	--	--	--	--	--	

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

Table 35. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Demographic Characteristics among the Intervention

	Full Sample (n=329)		Completed Study (n=239)		Did Not Complete Study (n=90)		p value
Variables	N	N	N	%	N	%	
Sex							
Male	89	27.1	54	22.6	35	38.9	
Female	240	73.0	185	77.4	55	61.1	**0.003**
Missing	--	--	--	--	--	--	
Ethnicity[a]							
Hispanic/Latino	326	99.1	236	98.7	90	100.0	
Non-Hispanic/Non-Latino	3	0.9	3	1.3	0	0.0	0.56
Missing	--	--	--	--	--	--	
Race[a]							
White	328	99.7	239	100.0	89	98.9	
Other	1	0.3	0	0.0	1	1.1	0.27
Missing	--	--	--	--	--	--	
County[a]							
Cameron	0	0.0	0	0.0	0	0.0	
Hidalgo	325	98.8	238	99.6	87	96.7	0.06
Starr	4	1.2	1	0.4	3	3.3	
Missing	--	--	--	--	--	--	
Age							
Mean	55.9	--	55.7	--	56.4	--	0.61
SD	10.2	--	9.5	--	11.9	--	
<35	9	2.7	4	1.7	5	5.6	
35-44	31	9.4	21	8.8	10	11.1	
45-54	93	28.3	74	31.0	19	21.1	0.10
55-64	148	45.0	109	45.6	39	43.3	
65+	48	14.6	31	13.0	17	18.9	
Missing	--	--	--	--	--	--	
Employment							
Not Employed	200	60.8	141	59.0	59	65.6	
Employed	129	39.2	98	41.0	31	34.4	0.28
Missing	--	--	--	--	--	--	
Marital Status							
Unmarried	132	40.6	88	37.3	44	49.4	
Married	193	59.4	148	62.7	45	50.6	0.05
Missing	4	--	3	--	1	--	
Primary Language							
English	61	18.9	36	15.1	25	29.4	
Samar-Leyte	0	0.0	0	0.0	0	0.0	
Spanish	262	81.1	202	84.9	60	70.6	**0.004**
Missing	6	--	1	--	5	--	

	Full Sample (n=329)		Completed Study (n=239)		Did Not Complete Study (n=90)		p value
Variables	N	N	N	%	N	%	
Level of Physical Activity							
Never	119	36.2	80	33.5	39	43.3	0.23
1-2 times/week	82	24.9	60	25.1	22	24.4	
3-4 times/week	51	15.5	36	15.1	15	16.7	
5-6 times/week	16	4.9	12	5.0	4	4.4	
Daily	61	18.5	51	21.3	10	11.1	
Missing	--	--	--	--	--	--	
Smoking Status[a]							
Current Every Day Smoker	20	6.1	10	4.2	10	11.1	0.13
Current Some Day Smoker	6	1.8	5	2.1	1	1.1	
Former Smoker	39	11.9	28	11.7	11	12.2	
Never Smoker	264	80.2	196	82.0	68	75.6	
Missing	--	--	--	--	--	--	
Alcohol Consumption[a]							
Never	248	75.4	188	78.7	60	66.7	0.07
Monthly or Less	50	15.2	29	12.1	21	23.3	
2-4 per/month	21	6.4	15	6.3	6	6.7	
2-3 per/week	7	2.1	4	1.7	3	3.3	
4+ per/week	3	0.9	3	1.3	0	0.0	
Missing	--	--	--	--	--	--	

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

Table 36. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Demographic Characteristics among the Comparison

	Full Sample (n=427)		Completed Study (n=324)		Did Not Complete Study (n=103)		p value
Variables	N	N	N	%	N	%	
Sex							
Male	134	31.4	97	29.9	37	35.9	
Female	293	68.6	227	70.1	66	64.1	0.25
Missing	--	--	--	--	--	--	
Ethnicity							
Hispanic/Latino	425	99.5	322	99.4	103	100.0	
Non-Hispanic/Non-Latino	2	0.5	2	0.6	0	0.0	0.42
Missing	--	--	--	--	--	--	
Race							
White	427	100.0	324	100.0	103	100.0	
Other	0	0.0	0	0.0	0	0.0	--
Missing	--	--	--	--	--	--	
County[a]							
Cameron	1	0.2	1	0.3	0	0.0	
Hidalgo	424	99.3	322	99.4	102	99.0	0.56
Starr	2	0.5	1	0.3	1	1.0	
Missing	--	--	--	--	--	--	
Age							
Mean	52.7	--	52.4	--	53.6	--	0.34
SD	10.7	--	10.4	--	11.6	--	
<35	17	4.0	13	4.0	4	3.9	
35-44	74	17.3	56	17.3	18	117.5	
45-54	148	34.7	116	35.8	32	31.1	0.77
55-64	147	34.4	111	34.3	36	35.0	
65+	41	9.6	28	8.6	13	12.6	
Missing	--	--	--	--	--	--	
Employment							
Not Employed	266	62.3	197	60.8	69	67.0	
Employed	161	37.7	127	39.2	34	33.0	0.26
Missing	--	--	--	--	--	--	
Marital Status							
Unmarried	148	34.7	109	33.6	39	38.2	
Married	278	65.3	215	66.4	63	31.8	0.40
Missing	1	--	0	--	1	--	
Primary Language[a]							
English	83	19.4	66	20.4	17	16.5	
Samar-Leyte	1	0.2	0	0.0	1	1.0	0.18
Spanish	343	80.3	258	79.6	85	82.5	
Missing	0	0		--		--	

	Full Sample (n=427)		Completed Study (n=324)		Did Not Complete Study (n=103)		p value
Variables	N	N	N	%	N	%	
Level of Physical Activity							
Never	191	44.7	141	43.5	50	48.5	0.59
1-2 times/week	75	17.6	62	19.1	13	12.6	
3-4 times/week	56	13.1	42	13.0	14	13.6	
5-6 times/week	38	8.9	30	9.3	8	7.8	
Daily	67	15.7	49	15.1	18	17.5	
Missing	--	--	--	--	--	--	
Smoking Status[a]							
Current Every Day Smoker	15	3.5	7	2.2	8	7.8	0.05
Current Some Day Smoker	12	2.8	9	2.8	3	3.0	
Former Smoker	82	19.2	60	18.5	22	21.4	
Never Smoker	318	74.5	248	76.5	70	68.0	
Missing	--	--	--	--	--	--	
Alcohol Consumption[a]							
Never	340	79.6	257	79.3	83	80.6	0.83
Monthly or Less	46	10.8	37	11.4	9	8.7	
2-4 per/month	29	6.8	20	6.2	9	8.7	
2-3 per/week	7	1.6	6	1.9	1	1.0	
4+ per/week	5	1.2	4	1.2	1	1.0	
Missing	--	--	--	--	--	--	

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

Table 37. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Health Impact Measures among the Intervention and Comparison Groups

	Full Sample (n=756) Mean (SD)	Completed Study (n=563) Mean (SD)	Did Not Complete Study (n=193) Mean (SD)	p value
BMI	33.9 (7.0)	34.1 (7.1)	33.5 (6.9)	0.33
Systolic	132.9 (19.3)	132.3 (18.5)	134.7 (21.4)	0.18
Diastolic	78.6 (9.2)	78.3 (9.0)	79.3 (9.5)	0.18
Nonparametric Tests[a]	Median (SD)	Median (SD)	Median (SD)	
PHQ-9	2.5 (18.7)	2.0 (4.3)	3.0 (4.3)	0.74
General Health	**83.3 (265.3)**	**80.0 (16.5)**	**76.7 (17.6)**	**0.02**
HbA1c	8.1 (2.8)	8.1 (1.6)	8.4 (1.8)	0.12

Note: Bold denotes statistical significance (p value < 0.05)

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

Table 38. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Health Impact Measures among the Intervention Group

	Intervention (n=329) Mean (SD)	Completed Study (n=239) Mean (SD)	Did Not Complete Study (n=90) Mean (SD)	p value
BMI	33.3 (6.4)	33.5 (6.4)	32.7 (6.5)	0.33
Systolic	133.2 (20.3)	132.6 (19.6)	134.9 (22.0)	0.37
Diastolic	77.0 (8.5)	76.6 (8.5)	77.8 (8.7)	0.26
Nonparametric Tests[a]	Median (SD)	Median (SD)	Median (SD)	
PHQ-9	4.0 (23.8)	4.0 (4.9)	4.0 (4.7)	0.68
General Health	76.7 (286.2)	76.7 (16.0)	73.3 (18.9)	0.19
HbA1c	8.1 (2.7)	8.0 (1.6)	8.7 (1.7)	0.09

Note: Bold denotes statistical significance (p value < 0.05)

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

Table 39. Analysis of Participants Who Completed the Study Compared to Lost to Follow-up on Health Impact Measures among the Comparison Group

	Full Sample (n=427) Mean (SD)	Completed Study (n=324) Mean (SD)	Did Not Complete Study (n=103) Mean (SD)	p value
BMI	34.4 (7.4)	34.5 (7.5)	31.2 (7.3)	0.69
Systolic	132.7 (18.5)	132.1 (17.7)	134.5 (20.9)	0.31
Diastolic	79.8 (9.4)	79.5 (9.3)	80.6 (10.0)	0.33
Nonparametric Tests[a]	Median (SD)	Median (SD)	Median (SD)	
PHQ-9	1.0 (12.6)	1.0 (3.5)	2.0 (3.8)	0.66
General Health	83.3. (265.3)	83.3 (16.5)	80.0 (15.7)	0.09
HbA1c	8.2 (2.9)	8.2 (1.6)	8.2 (1.9)	0.57

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: Clinical Pathway Templates and Supporting Materials

August 7, 2018

NCDV Policy and Procedures: Adolescent and Adult Depression Screening and Follow-up

Rationale: Standardize the screening and follow-up of NCDV Adolescent and Adult patients with major depression.
Target Population: All NCDV patients age 12 years of age and older with a PHQ9 ≥ 10
Screening and Follow-up tool: PHQ9 in native language (Spanish or English)
Procedure:

1. All NCDV patients 12 years of age and older will be screened once per year according to the Standing Delegation Order by the nursing staff during routine clinic visits.
2. The medical assistant (nursing staff) who performs the initial PHQ9 ≥10 will enter the patient in the specific clinic PHQ9 group
3. The date of the first PHQ9 result ≥ 10 captured in the Behavioral Health Form will be set as time 0 for follow-up with serial PHQ9 measurements.
4. Each clinic will have an assigned Licensed Professional Counselor by the Director of Behavioral Health. Due to staffing limitations, outlying clinics will not have an LPC on site.
5. All PHQ9 results will be entered in the correct form in the Behavioral Health section of the MicroMD EMR.
6. Any routine screening PHQ9 ≥ 10 will be automatically referred to Behavioral Health, and an onsite LPC if present will see the patient for warm handoff and brief intervention.
7. The LPC assigned to each clinic will arrange follow-up directly with the LPC or during visits to the clinic for other reasons.
8. Using the EMR report capacity, the Behavioral Health Care Coordinator will capture all screening PHQ9 results once per month
9. The Behavioral Health Care Coordinator and LPC will maintain a log of all patients in the above group for a minimum of 12 months
10. The Behavioral Health Care Coordinator and LPC assigned to each clinic will be responsible for obtaining the following points
11. PHQ9 Follow-up time points from time 0 will be obtained by either face to face encounters in the NCDV clinics (preferable) or by telephone at times 1 month to determine response to therapy, 6 months, and 11-13 months to determine if in remission
12. If the patient has a PHQ9 < 5 (adequate response to treatment) at the 6 and 12-month period, they will be removed from the patient group.

Section 2 Standing Delegation Orders

SDO: 12 All patients 12 years and older

SDO: Depression Screen (PHQ-9)

Purpose: To standardize the screening and follow up of NCDV adolescent and adult patients with major depression.

Procedure:

Nursing Staff will review Medical Records Preventive Medicine Flow Sheet with each visit for **Depression Screening**. If not performed, Nurse will initiate the PHQ-9 questionnaire by verbally asking the patient the first two questions, "." if the patient scores 3 or more on the first two questions, complete the rest of the questionnaire. If the final score is ≥ 10, nursing staff will enter the patient in the specific clinic PHQ9 group. Nursing staff will initiate a warm handoff to behavior department, or a referral if no behavior department personnel available at the time. The date for this result will be set up as time "0" for follow up with serial PHQ9 measurements. Nursing staff will enter all PHQ9 results in the correct form under the Behavioral Health section of the MicroMD EMR. Nursing staff will also verbally communicate the results to their provider. **For Adolescents use the PHQ-9 for Adolescents**

	Signature	Date
A, M.D.		
B, M.D.		
C, M.D.		
D, M.D.		
E, M.D.		
F, M.D.		

Diabetes Clinical Pathway for BHC

1. Identification of Patients for Diabetes Pathway

    a. Criteria for inclusion into diabetes clinical pathway: Patients meeting the following criteria should be asked to attend an BHC appointment as part of their standard evidence-based team healthcare:
        1.Patients newly diagnosed with diabetes
        2.Patients with poor glucose control (defined as an HbA1c of 9 or greater)
        3.Diabetic patients with comorbid depression
        4.Diabetic patients with comorbid hyperlipidemia, hypertension, or obesity

    b. Process for identification: Multiple methods should be used to identify diabetic patients for referral to the BHC.
        1.Screening of PCP daily patient charts by BHC
        2.Identification of patient by nurse/tech during screening for PCP appointment
        3.Identification of patient by PCP during PCP appointment

2. Methods of linking identified patients with BHC

    a. During a PCP appointment with a patient who meets any of the inclusion criteria, the PCP, nurse, and/or other designated team member ensures the patient receives a same-day appointment with BHC (warm handoff).
    b. If patient refuses to see the BHC, the PCP, nurse, or medical assistant may ask the BHC to review the available medical record and information from the PCP and then document recommendations for care based on available medical data.

Appendix I: Patient-Centered Integrated Behavioral Health Care Checklist

Patient-Centered Integrated Behavioral Health Care Principles & Tasks

AIMS CENTER
Advancing Integrated Mental Health Solutions

About This Tool

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

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

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

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

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

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

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

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

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

=Total Score: _____

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

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

Appendix K: 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)?	160	151	152
16. Participó en actividades sociales, religiosas, o recreativas (por ejemplo, reuniones, iglesia, cine, deportes, fiestas)?	160	161	162

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

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