



Methodist
Healthcare
Ministries
OF SOUTH TEXAS, INC.

"Serving Humanity to Honor God"

Sí Texas: Social Innovation for a
Healthy South Texas

#MHMSíTexas

Final Evaluation Report: REAL, Inc.



Submitted Date:
March 15, 2019

Prepared by:
Impact Evaluation: Drs. Melissa Valerio, John E. Cornell, Laura Aubree Shay
Implementation Evaluation: Health Resources in Action



Health Resources in Action
Advancing Public Health and Medical Research

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

SIF Final Evaluation Report

Subgrantee: Rural Economic Assistance League (REAL), Inc.

Project Title: TRIP for Salud y Vida (Transportation for Rural Integrated Health Partnership)

Submitted by:

SIF Grantee: Methodist Healthcare Ministries of South Texas, Inc.

Program Name: Sí Texas: Social Innovation for a Healthy South Texas

Prepared by:

Impact Evaluation: Dr. Melissa Valerio, Dr. John E. Cornell and Dr. Laura Aubree Shay

Implementation Evaluation: Health Resources in Action, Inc.

March 2019

Methodist Healthcare Ministries' Sí Texas program is a proud recipient
of the Social Innovation Fund (SIF) program.

This material is based upon work supported by the Corporation for National and Community Service (CNCS) under Social Innovation Fund Grant No. 14SIHTX001. Opinions or points of view expressed in this document are those of the authors and do not necessarily reflect the official position of, or a position that is endorsed by, CNCS.



Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

TABLE OF CONTENTS

EXECUTIVE SUMMARY 1

INTRODUCTION 9

 Program Definition and Background 9

 Overview of Prior Research 11

 Program Components 13

 Overview of Impact Study 19

 Research Questions 20

 Contribution of the Study 21

 Evaluation Plan Updates 22

IMPLEMENTATION STUDY: STUDY APPROACH, METHODS, AND FINDINGS 23

 Implementation Study Design 23

 Implementation Study Findings 26

 Additional Implementation Findings 47

IMPACT STUDY: APPROACH AND METHODS 51

 Overview of Impact Study Design 51

 Impact Study Design and Methods 52

 Study Sample 58

 Study Sample Composition 58

 Study Consumer Flow Description 62

 Sample Recruitment, Retention, and Attrition 63

 Measures 69

 Data Collection Activities 72

IMPACT STUDY: ANALYSIS AND RESULTS 73

 Unit of Analysis and Overview of Analyses Performed 73

 Blood Pressure 78

 Model Selection Process 78

 Findings 79

 Limitations 81

 HbA1c Level 81

 Overview of Analysis 81

 Model Selection Process 82

 Findings 83

 Limitations 83

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Body Mass Index	83
Overview of Analysis	84
Model Selection Process	84
Findings	84
Limitations.....	85
Duke Health Profile	86
Overview of Analysis	86
Model Selection Process	86
Findings	86
Limitations.....	92
Depressive Symptoms.....	92
Overview of Analysis	92
Model Selection Process	92
Findings	92
Limitations.....	94
Dietary Habits	94
Physical Activity Behaviors.....	94
Health Literacy	94
Overview of Analysis	94
Model Selection Process	94
Findings	95
Limitations.....	96
Appointment-keeping.....	97
Influence of Road Type on Health Outcomes	97
Influence of Transportation Utilization on Health Outcomes	97
Model Selection Process	98
Findings	98
Limitations.....	100
CONCLUSION: SUMMARY OF FINDINGS, LESSONS LEARNED AND NEXT STEPS.....	101
Summary of Implementation Findings.....	101
Summary of Outcome/Impact Findings	101
Lessons Learned, Study Limitations, and Next Steps.....	102
OTHER ASPECTS OF STUDY LOGISTICS AND FEASIBILITY	106
Human Subjects Protection	106
Timeline.....	106

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Evaluator/Subgrantee Role and Involvement.....	106
Budget.....	106
REFERENCES.....	107
APPENDICES.....	115
Appendix A. REAL, Inc. Revised Project Timeline.....	116
Appendix B. Program Logic Model.....	117
Appendix C. Sí Texas Mid-Point Implementation Evaluation: Key Informant Interview General Guide.....	118
Appendix D. Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide.....	122
Appendix E. Sí Texas Summative Implementation Evaluation: Focus Group Guide- SPMI Population.....	126
Appendix F: Implementation Evaluation Measures.....	131
Appendix G: Patient-Centered Integrated Behavioral Health Care Checklist.....	141
Appendix H: Patient Health Questionnaire – 9 (PHQ-9).....	143
Appendix I: Duke Health Profile.....	144
Appendix J: TRIP for Salud y Vida Enrollment and Baseline Assessment Form.....	146
Appendix K: TRIP for Salud y Vida Baseline Clinical Assessment Form.....	151
Appendix L: TRIP for Salud y Vida 12-Month Clinical Assessment Form.....	153
Appendix M: TRIP Metrics Assessment Form.....	155
Appendix N: BRIEF Health Literacy Screening Tool (BRIEF).....	161

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

EXECUTIVE SUMMARY

This final report presents the evaluation of the TRIP for Salud y Vida program of Rural Economic Assistance League (REAL), Inc., a subgrantee of SIF Grantee Methodist Healthcare Ministries (MHM) of South Texas, Inc. MHM is a member of the 2014 SIF Cohort. The impact evaluation was conducted by subgrantee evaluator consultant for REAL, Inc., Melissa A. Valerio (PhD, University of Michigan; MPH, University of Michigan School of Public Health), Regional Dean San Antonio Regional Campus and Associate Professor UT School of Public Health at Houston San Antonio Regional Campus. John E. Cornell (PhD and MA, University of Southern Mississippi) is Professor Emeritus with the UT Health San Antonio, Department of Epidemiology and Biostatistics. Laura Aubree Shay (PhD, Virginia Commonwealth University; MSSW, University of Texas in Austin) assisted with the evaluation. Health Resources in Action (HRiA), the external evaluator for the Sí Texas portfolio evaluation, conducted the implementation evaluation.

Program Background

The TRIP for Salud y Vida program was implemented and led by REAL and its partners. The TRIP for Salud y Vida program was designed to expand the current program, Project Salud y Vida, and was developed to respond to a specific need identified by community partners. Its goal is to expand the reach of Project Salud y Vida to improve health outcomes, specifically, blood pressure (primary outcome) through enhanced integrated services and systematic and seamless offering of transportation in the five-county service area receiving care at the 3 intervention clinics. TRIP for Salud y Vida offered eight enhanced integrated services (EIS). These included: (1) assignment of a navigator and case manager; (2) assignment of a consumer attendant (community health worker); (3) home and telephone nurse assessments (as needed); (4) development of an individualized transportation plan; (5) coordination and delivery of transportation services to and from health care appointments; (6) coordination and delivery of transportation services to and from community health and other health care services within the targeted service area; (7) consumer enrollment in a community health worker led diabetes self-management education (DSME); and (8) implementation of community based health and disease management classes tailored to consumer needs (i.e., physical activity, self-management education, food and nutrition education as well as topic specific courses).

The original program (Project Salud y Vida) was designed to provide primary care, substance abuse services, preventative health care and care management/health navigation services to consumers, in a culturally and linguistically “stigma-free” environment. These elements were maintained in the TRIP for Salud y Vida Program with the addition of enhanced integrated services for transportation and disease management. The entire consumer population for Project Salud y Vida and ultimately TRIP for Salud y Vida has a severe mental illness (SMI) diagnosis including severe depression, bipolar, and/or schizophrenia. Eligibility criteria for Project Salud y Vida and TRIP for Salud y Vida included consumers 18 years of age and older, Medicaid eligible or uninsured, SMI diagnosis, and residence within the Coastal Plains Community Center (CPCC) service area.

Prior Research

TRIP for Salud y Vida was developed to respond to a specific need to expand the reach of Project Salud y Vida to improve health outcomes, specifically, blood pressure (primary outcome) through enhanced integrated services and systematic and seamless offering of transportation in the five-county service area. TRIP for Salud y Vida was a combination of two components shown in the literature to be effective. The

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

two components are: collaborative care and transportation assistance (Wagner, 1998; Staten, 2011, Rothman, 2005R; Arcury, 2005). The approach of the TRIP for Salud y Vida program embraces a cross sector approach to address key determinants of health in rural settings and maximize the use and local community resources; integrating elements of the accountable health community framework (Mongeon, 2017).

Two collaborative care strategies were applied. The first collaborative care strategy was accomplished using previously established co-located models adapted for the SMI population (E. H. Wagner, 1998). For persons served in community mental health centers, research has indicated that care management delivered in an integrated primary care setting can result in sustainable improvements in physical health outcomes, patient and provider satisfaction, as well as potential cost savings to health care systems relative to care as usual (i.e., simple referral to a primary care provider). Dependent on the setting and timing of introduction of integrated health; results are often mixed regarding changes within the clinical integration and patient outcomes (Zurovac, 2019; Biel, 2019)

The second collaborative care strategy used was community health workers (promotores). There is a growing body of evidence of the benefits of interventions led by *promotores*, especially in underserved and minority populations. For example, in a quasi-experimental design with pre-post tests and follow-up (N=255), program participants of Pasos Adelante (Spanish for Steps Forward) a lifestyle intervention program targeting chronic disease prevention in Mexican Americans living in a U.S.-Mexico border community in Arizona, demonstrated significant improvements in physiological measures linked to diabetes and CVD risk factors after participating in the 12-week community health worker-led program that combined interactive educational sessions with walking groups (Staten et al., 2011). In African American and Latinos in Detroit, a community health worker driven diabetes management program significantly improved hemoglobin A1c readings at 6-months (Heisler, 2011).

The second component of TRIP for Salud y Vida was transportation assistance. The direct link between transportation, appointment keeping, and hypertension management is supported in the literature. For example, similar to the TRIP for Salud y Vida program, Rothman et al. (2005) implemented a randomized control trial study with the purpose of assessing the efficacy of disease management program to improve cardiovascular risk factors and HbA1c levels in their patient population. As part of their intervention, patients had access to a care coordinator who was trained to address issues related to health behavioral and health education. In addition, as Rothman et al. (2005) indicate, “The coordinator also helped to address barriers to care, including difficulties with transportation, communication, insurance problems, and low health literacy.” At the end of this 12-month study, the researchers found that the intervention group had significantly greater improvements compared to the control group for systolic blood pressure and diabetes knowledge. In addition, there is evidence in the literature that patient compliance with appointment keeping is linked with health outcomes (the more patients keep appointments, the better their health outcomes, and vice versa). A study, reported in Health Services Research, found that patients who often miss appointments were at increased risk for poorer control of blood pressure, blood sugar and cholesterol (M. M. Parker et al., 2012). Rural settings are especially important to understand given the recognized impact in access to care in elderly populations (Nemet, 2000). Place effects in rural settings are known to impact Latino health and access to care that includes reliable and safe transportation (Stone, GA, 2019).

Because the TRIP for Salud y Vida utilized a variety of evidence-based collaborative care components and incorporated a transportation piece, the level of evidence at the start of the program was preliminary with the goal to achieve a moderate level of evidence through this evaluation.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Evaluation Design

The impact evaluation completed used a non-randomized quasi-experimental design (QED) to evaluate the TRIP for Salud y Vida program's impact at three intervention clinics (Alice, Falfurrias and Kingsville clinics) compared to two clinic sites (Beeville and Taft clinics). The QED allows for the identification and control of participant clinical and demographic characteristics that may have influenced impact measures of interest.

TRIP for Salud y Vida's recruitment target was 250 consumers per study arm (e.g., intervention and comparison group) with a realized sample of 425 consumers at 6 months and 364 consumers at 12 months accounting for the estimated 15% attrition at each data collection point and an overall 30% study attrition (recruited 52 consumers over targeted sample at baseline). TRIP for Salud y Vida enrolled 552 consumers, including 302 consumers in the intervention group and 250 consumers in the comparison group. At 6-month follow-up, 213 consumers allocated to the intervention group completed their assessment and 212 consumers allocated to the comparison group completed assessments. At 12-month follow-up, 211 consumers in the intervention group and 153 consumers in the comparison group completed assessments.

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 to the intervention group. Data was collected via key informant interviews and focus groups and record review.

Description of Measures and Instruments

REAL collected data for the Sí Texas shared measures: blood pressure, body mass index (BMI), HbA1c, depression (using the Patient Health Questionnaire [PHQ-9]), and quality of life (using the Duke Health Profile). Other impact measures that were examined for the TRIP for Salud y Vida program included consumer appointment keeping, use of transportation services, and health literacy. The primary impact measure for the TRIP for Salud y Vida program was blood pressure.

Research Questions

Below are the confirmatory and exploratory research questions.

1. Did TRIP for Salud y Vida consumers significantly improve their blood pressure compared to Project Salud y Vida consumers? *The question is confirmatory.*
2. For consumers with a history of and/or diagnosis of diabetes, did TRIP for Salud y Vida consumers significantly improve their HbA1c compared to Project Salud y Vida consumers? *The question is confirmatory.*
3. Did TRIP for Salud y Vida consumers significantly improve their body mass index (BMI) compared to Project Salud y Vida consumers? *This question is exploratory.*
4. Did TRIP for Salud y Vida consumers significantly improve their quality of life (as measured by the Duke Health Profile) compared to Project Salud y Vida consumers? *This question is exploratory.*
5. Did TRIP for Salud y Vida consumers significantly improve their depressive symptoms (as measured by the PHQ-9) compared to Project Salud y Vida consumers? *This question is exploratory.*

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

6. Did TRIP for Salud y Vida consumers experience improved dietary habits compared to Project Salud y Vida consumers? *This question is exploratory. This question is not addressed in this report.*
7. Did TRIP for Salud y Vida consumers experience improved physical activity behaviors compared to Project Salud y Vida consumers? *This question is exploratory. This question is not addressed in this report.*
8. Did TRIP for Salud y Vida consumers experience improved health literacy compared to Project Salud y Vida consumers? *This question is exploratory.*
9. Did TRIP for Salud y Vida consumers experience increased appointment keeping compared to Project Salud y Vida consumers? *This question is exploratory.*
10. Do TRIP for Salud y Vida consumers who live within a rural town have greater percent change in health outcomes compared to TRIP for Salud y Vida consumers traveling from rural farm to market road residents? *This question is exploratory.*
11. Do TRIP for Salud y Vida consumers have different health outcomes based on the amount and type of use of transportation services? For example, do high transportation service users have greater percent change in health outcomes compared to TRIP for Salud y Vida consumers with low use over time? *This question is exploratory.*

Though included in the approved SEP, analyses of questions 6 (dietary habits) and 7 (physical activity) are not included in this final report due to the unavailability of quality data at the clinic sites over the baseline to 12-month follow-up period. In addition, question 10 (rural farm to market road travel) was not analyzed given the transit software coding of routes by the TRIP program.

Implementation Questions

The following evaluation questions examined program implementation.

1. Did the TRIP for Salud y Vida program reach its intended target population?
2. What are the components of the TRIP for Salud y Vida 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 TRIP for Salud y Vida achieve as a result of implementing the program?
 - b. To what extent have providers and program staff adopted the components of the TRIP for Salud y Vida 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 TRIP for Salud y Vida 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 REAL. Inc. and partners implement the TRIP for Salud y Vida model with fidelity?
6. How satisfied are TRIP for Salud y Vida patients with the services they have received? How satisfied are providers with the TRIP for Salud y Vida program?

Impact Analysis

This report presents descriptive statistics, analysis of baseline equivalence and impact across the study groups and time. Analysis was completed using an intent to treat approach. The unit of analysis used was at the individual patient level with the clinic level taken into account in regression models to control

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

for bias introduced by the clinic environment. Bivariate tests were completed comparing baseline demographic, diagnostic, and health status variables between the intervention and comparison group, testing for differences in baseline characteristics. To determine the program's impact, we completed analyses to compare descriptive statistics of patients' sociodemographics and other key covariates between the intervention group and the comparison group. Impact measures were treated as continuous measures (e.g. the primary variable including improvements over time in blood pressure, hemoglobin A1c and BMI) for initial analysis. All analyses are reported by program and comparison group assignment to allow for identification of the validity of the model assumptions and ensure robustness of the primary analysis. Goodness-of-fit analysis of models was performed as well as checking underlying assumptions of the models.

Given the nested structure of individuals within clinic sites and clinic sites within intervention arms, we conducted mixed-effects linear models to assess the effectiveness of TRIP for Salud y Vida on primary and secondary outcomes and account for patient differences. For each consumer (and each outcome), three repeated measures of pre-and-post (from baseline to 6-mo and from baseline to 12-mo) differences were used. A generalized regression analysis was conducted following a modeling sequence from bivariate models to multiple regression models adjusting for demographic and clinical covariates and baseline outcome measures found to be nonequivalent between the groups to control for potential selection bias or based on evidence of potential influence in the literature.

The TRIP for Salud y Vida program impact was evaluated by examining the impact of program services on patients' blood pressure – systolic and diastolic (primary outcome), HbA1c, BMI, depression, quality of life, dietary habits, physical activity, health literacy, and appointment keeping—as measures of overall improvement in these scores and values (exploratory outcomes). Quantitative data related to participation in the approved program activities is also included in this report (see Implementation Evaluation section). There were few deviations in the study design from the approved SEP protocols. Deviations as noted above included the lack of data collection of metrics for impact questions 6, 7 and 10 and non-completion of propensity score matching.

Ongoing assessment of program implementation was completed through data management including the review of 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 (Dilley, 2011).

Key Findings

Implementation and impact evaluation results indicate the TRIP for Salud y Vida program was implemented in alignment with the logic model and program fidelity and achieves a moderate level of implementation fidelity. The program was refined using a Quality Improvement approach during the period of implementation to ensure that any identified challenges to implementation were addressed to allow for greater reach and appropriateness of program strategies for the SMI consumer and rural setting. Major facilitators to implementation included communicating and training including weekly check ins across partners to ensure approaches were systematic and setting of goals were shared. Any review of consumer needs or hard to reach consumers were discussed by the team members and addressed by the appropriate partner. Program staff training and focus across the partner sites was key to ensure implementation of the IBH program, EIS and transportation services. Continuous communication across program elements ensured that any consumer needs were quickly addressed within the scope of the SEP and approved program model.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Updates, Conclusion and Next Steps

Overall, the TRIP for Salud y Vida program was implemented as intended with inputs and outputs completed and a very slight deviation from the original timeline for 6-month assessments. TRIP for Salud y Vida enrollment began in February of 2016 and was completed in September of 2016. Six-month follow-ups began in June of 2016 and were completed in March of 2016 and 12-month follow-ups were completed between February 2017 and September 2017. The timeline is slightly different than that presented and approved in the SEP (see **Appendix A. REAL, Inc. Revised Project Timeline**). One change to the program team was in the loss of a partner in year 1, the subcontractor for the original Salud y Vida program, CACOST clinical partner that subcontracts to the IBH clinic at the Coastal Plains Community Center (CPCC), chose to withdraw as a partner and was removed from the TRIP for Salud y Vida program budget. Given their ongoing work with CPPC and subcontract, these costs were managed by their CPCC services contract and maximized consistent implementation of the programs across clinics.

Changes to the evaluation team were made regarding responsibilities for the final analyses and SIF Final Report. REAL's evaluation consultant team, Drs. Melissa Valerio, John Cornell and Aubree Shay, completed the impact analyses presented in this report per the approved SEP. Drs. Mary Davis and Lisa Wolff from HRIa, MHM's external evaluators for the overall Sí Texas evaluation, conducted the implementation analyses, were responsible for related sections of this report, and supported MHM in ensuring the final report met SIF expectations. Rebecca Adeigbe (Jones), who had been the HRIa lead for REAL's evaluation is no longer with HRIa.

The TRIP for Salud y Vida program achieves a preliminary level of evidence given the findings from the impact and implementation evaluation. Specifically, the program had significant impact on changes of exploratory outcomes and no negative effects on a confirmatory outcome. The Quasi-experimental study showed that the reverse co-located IBH program with transportation and enhanced integrated services (TRIP for Salud y Vida) had a significant improvement in DBP (-3.96 mmHG; 95% CI: -7.48 to -0.45, $p=0.014$, $d=-0.21$) over time when controlling for age, sex and baseline characteristics within the intervention consumers. Differences between the two groups at baseline were found to be significantly different but not by clinical category; covariates were controlled for in analysis. Significant improvements in quality of life (Duke Health Profile) and the PHQ-9 were found within the intervention group and between the intervention and comparison groups at 12-months for Anxiety (-5.83; 95% CI: -9.50 to -2.16, $p < 0.001$, $d = -0.30$) and Pain (-13.44; 95% CI: -24.41 to -2.47, $p = 0.005$, $d = -0.16$) Duke Health Profile domains and PHQ-9 (-2.77; 95% CI: -4.83 to -0.72, $d = 0.18$, $p = 0.001$). Furthermore, the Quasi-Experimental design with nested clinics allowed for the identification of major threats to validity and introduction of bias including selection bias and contamination of the consumer sample across clinics. The program was conducted as planned with major elements completed and achieved over time.

The TRIP for Salud y Vida program expands our understanding of serving a population with severe mental illness through partnered wrap-around services that included evidence-based programs to best address the populations' disproportionate burden of chronic illness. Furthermore, minimal research has been completed to assess not only the impact of integration of primary care services within behavioral health clinical spaces but to assess its impact in rural and transit deprived areas. Oftentimes, transportation is noted as a barrier to access to health care – this is expanded as the rural area requires travel up to 35 miles in each direction. This study allowed for the examination of not only clinical impact but the impact of transportation availability and development and integration of key partners in the design and implementation of the TRIP for Salud y Vida program. REAL plans to expand and scale the program as

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

needed to best serve the rural primarily Hispanic area. The study design has limitations noted in the approved SEP including the use of a QED, but as approved and noted the design was the best research design for the community and clinic setting and allowed for both within and between group comparisons with the designated sample size. The integration of Quality Improvement (QI) activities throughout the implementation of the program allowed for the refinement and implementation of a high-quality study and program.

Lessons learned include: the engagement of the Voices Leadership group allowed for consumer driven changes and much more robust programming, tailoring of the activities to emphasize capacity in the rural area allowed for showcasing of small businesses and local organizational capacity, training and communication that was systematic and part of the ongoing program implementation allowed for addressing the unique needs of the SMI population and engagement during data collection and assistance with navigation of care, EIS classes and transportation on an ongoing basis allowed for greater participation and engagement of consumers over time.

There are several limitations to this study as with most intervention studies. First, the findings indicate trends in clinical outcomes that suggest long term impact, however, we need to examine subgroups that had greater change over time. Additionally, the population resides in rural areas and may not be representative of more urban populations with SMI; however, the clinical partners serve as the mental health authority in the region offering standard protocol based behavioral health services. This limitation however, provides great insight to an often-understudied primarily Hispanic rural population. Finally, the sample is primarily Hispanic of Mexican descent, while important to understand the needs of the population, findings may not be generalizable to a more heterogeneous population of individuals with SMI.

As noted previously, the changes to the SEP were primarily related to collection of select metrics and analyses due to lack of quality data. The questions used to assess food and nutrition as well as physical activity over time were not validated and did not yield appropriate data. Additionally, we did not geocode roads by type of road type given the transportation software platforms used by REAL, Inc. All other analyses were completed as planned per the approved SEP.

Additional analyses to determine subgroup specific population impact will be completed in the next three months and will be used to inform scaling of the TRIP for Salud y Vida program. This will include analyses to examine changes in 1) consumers with a diagnosis of type 2 diabetes in the intervention and comparison group, 2) consumers with a diagnosis of hypertension in the intervention and comparison group, and 3) consumers who are obese in the intervention and comparison group. Results of these analyses are not included in this report as the subgroups were identified by the findings reported.

The TRIP for Salud y Vida program partners continue to work together to identify key areas for program sustainability and partner engagement in coming years. Some current funding opportunities include foundation and state and federal government grant opportunities as well as engagement in identifying changes to reimbursement at the clinic and organizational level. The original CPCC Salud y Vida program is continuing to serve the SMI consumer populations across multiple clinics. The sustainability and management of the TRIP for Salud y Vida program is led by the REAL, Inc. team and is expanding to serve additional consumers. Specifically, the IBH program along with the transportation and EIS which includes access to the CHW are being sustained into year 4 of the program. REAL, Inc. is the local rural transportation service provider and all transit services will remain in place to ensure that the consumers are able to attend appointments. The success of the EIS programming was key to changes in health

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

outcomes within the intervention group and between the intervention and comparison groups. We posit that without the EIS program, the impact on changes of the original Salud y Vida program is stable but not significant over time. We believe the addition of the EIS component was key to changes seen over time within the intervention group and between the intervention and comparison groups.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

INTRODUCTION

This final report reviews the methods implemented to evaluate Rural Economic Assistance League, Inc's program model according to the SEP, notes deviations and/or changes to the SEP, and describes final findings from the impact and implementation evaluations (including baseline data, six-month data, and twelve-month data). This report also provides a description of the reporting timeline discussed in the SEP and revised in **Appendix A. REAL, Inc. Revised Project Timeline**. The intended audience of this report is the Social Innovation Fund (SIF), although excerpts will also be used by Methodist Healthcare Ministries program staff and leadership and internal leadership and staff at Rural Economic Assistance League, Inc. and partners. We will also use findings in peer reviewed journals.

Program Definition and Background

Individuals with severe mental illness (SMI)—including schizophrenia, psychotic disorders, and mood disorders such as major depression and bipolar disorders—are among the most vulnerable populations in the United States. Individuals with SMI have a higher risk of premature death compared to individuals without SMI (Brown, 1997; Harris & Barraclough, 1998; Saha, Chant, & McGrath, 2007). The literature reports that individuals with SMI die an average of one to ten years earlier than persons diagnosed with a “non-major” mental illness (De Hert et al., 2011). Studies attribute disparities in mortality rates among those with SMI to a high prevalence of preventable conditions. These conditions include cardiovascular disease (Scott et al., 2013), diabetes and its complications, respiratory disease such as pneumonia or influenza (Chwastiak et al., 2014), and infectious diseases such as HIV/AIDS (De Hert et al., 2011). Risk factors placing SMI individuals at higher risk of morbidity and mortality include higher rates of antipsychotic medication use, smoking (McClave, McKnight-Eily, Davis, & Dube, 2010), substance abuse (Swendsen et al., 2010), obesity and poor nutrition (Desai, Rosenheck, Druss, & Perlin, 2002), lack of physical activity (Desai et al., 2002), unsafe sexual behavior (Buckingham, Schrage, & Cournos, 2013), exposure to infectious diseases (Himelhoch et al., 2009), homelessness (Fazel, Khosla, Doll, & Geddes, 2008), victimization and trauma (Latalova, Kamaradova, & Prasko, 2014), unemployment (Danziger, Frank, & Meara, 2009), poverty (Kessler et al., 2008), incarceration (Morgan et al., 2012), and social isolation (Cabassa, Nicasio, & Whitley, 2013). Physical activity and engagement has also been found to be correlated to outcomes in health and quality of life (Perez-Cruzado, 2018).

The TRIP for Salud y Vida program examined the impact of an integrated behavioral health program in five counties in the Coastal Bend region for the rural SMI population. The five-county service area included Bee, Brooks, Jim Wells, San Patricio, and Kleberg counties spanning a geographical area over 5,941 square miles, with a population over 93,000. Based on 2013 U.S. Census estimates, 5.4% of the population is 65 years of age or older, and 12.4% of residents live with a disability. The TRIP for Salud y Vida program service area is rural and sparsely populated with ranch and farm land between the various small towns, the three largest towns being Kingsville (26,213), Alice (19,104), and Falfurrias (4,981).

The service area population is estimated to be over 70% Hispanic. The predominantly Mexican American, low income, underserved community has high morbidity and mortality from chronic illness when compared to counties across Texas. The per capita household income in 2010 was lower than that of the state of Texas and up to 23.6% of residents live below the poverty level. Compared to the state overall, the residents in the five-county service area have lower levels of education attainment, lower household incomes and lack access to health care and quality care, which in turn increases their risk for negative health outcomes including high blood pressure and type 2 diabetes.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

SMI patients generally receive fewer preventive services, have lower rates of cardiovascular procedures, and worse hypertension care compared to individuals who do not have SMI. Over one quarter (27%) of the consumers who were eligible for TRIP for Salud y Vida services have been diagnosed with bipolar disorder, 59% have major depressive disorder and 7% have schizophrenia. The percentage of consumers across clinics (intervention and comparison) with hypertension ranged from 47-61%, 32-46% have been diagnosed with diabetes and 58-70% have been diagnosed as obese (CPCC and REAL, Inc., data extracted 07/17/2015 in SEP).

Local reports have indicated that lack of public transit services in this five-county area contribute to patients' challenges in accessing quality behavioral and clinical health care, adoption of healthy lifestyles, and maintaining health over time. Findings from the Regional Public Transportation Coordination Plan for the Coastal Bend Region: Transportation Critical Needs Assessment & Strategic Plan, indicated a high need for public transportation in the region. The need is highest in the south and western portions of the region, particularly in Brooks, Duval, and Kenedy counties. These counties require increased levels of public transportation to serve the higher percentages of the transit dependent segments of the population. Analyzing health demographics revealed similar trends for the region. Jim Wells, Duval, and Aransas Counties are all in the bottom quarter of counties in the state in terms of overall health rankings. Counties with lower health rankings tend to need public transportation, especially for medical purposes.

Project Salud y Vida was designed to provide primary care, substance abuse services, preventative health care and care management/health navigation services to consumers in a culturally and linguistically "stigma-free" environment. The entire consumer population for Project Salud y Vida had a severe mental illness (SMI) diagnosis including severe depression, bipolar or schizophrenia. Eligibility criteria for Project Salud y Vida included 18 years of age and older, Medicaid eligible or uninsured, severe mental illness diagnosis and residing within the Coastal Plains Community Center service area. Eligibility criteria for TRIP for Salud y Vida is described below.

TRIP for Salud y Vida was developed to respond to a specific need identified by community partners to expand the reach of Project Salud y Vida to improve health outcomes, specifically blood pressure (primary outcome), through enhanced integrated services and systematic and seamless offering of transportation in the five-county service area.

The expanded IBH Model, TRIP for Salud y Vida, offered eight enhanced integrated services. The enhanced integrated services included, (1) assignment of a navigator and case manager; (2) assignment of a consumer attendant; (3) home and telephone nurse assessments; (4) development of an individualized transportation plan; (5) coordination and delivery of transportation services to and from health care appointments; (6) coordination and delivery of transportation services to and from community health and other health care services; (7) consumer enrollment in a community-health worker led diabetes self-management education (DSME) for the diabetes subgroup and (8) implementation of community based health and disease management classes tailored to consumer needs (i.e., physical activity, self-management education, food and nutrition education). The enhanced integrated services were designed to improve consumers' self-management, health literacy skills, quality of life, adoption or sustaining of healthy behaviors, such as improved nutrition choices and exercise habits, and appointment keeping.

Eligibility criteria for the TRIP for Salud y Vida program included currently enrolled or eligible for enrollment in the Salud y Vida program, diagnosis of SMI (100% in program sample), 18 years of age and older, reside within the five-county service area, and lack of serious health condition that would preclude

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

ability to use TRIP transportation services and enhanced integrated services. TRIP for Salud y Vida was offered at three intervention clinics (Alice, Falfurrias, Kingsville clinics), and Project Salud y Vida was offered at two comparison clinics (Beeville and Taft clinics).

TRIP for Salud y Vida's recruitment target was 250 consumers per study arm (e.g., intervention and comparison group with an expected 15% attrition per follow-up period) with a realized sample of 552 at baseline, 425 consumers at 6 months and 364 consumers at 12 months accounting for 30% overall study attrition. TRIP for Salud y Vida enrolled 552 consumers, including 302 consumers in the intervention group and 250 consumers in the comparison group.

Overview of Prior Research

TRIP for Salud y Vida was developed to respond to a specific need to expand the reach of Project Salud y Vida to improve health outcomes, specifically blood pressure (primary outcome), through enhanced integrated services and systematic and seamless offering of transportation in the five-county service area. TRIP for Salud y Vida combined two components shown in the literature to be effective: collaborative care and transportation assistance.

TRIP for Salud y Vida built upon the existing Project Salud y Vida, which was informed by key elements of the validated Wagner collaborative-care model for effective chronic illness care. This model features an organized delivery system linked with complementary community resources, sustained by productive interactions between multidisciplinary care teams and "activated" or educated patients and their families (E. H. Wagner, 1998). A meta-analysis conducted by Woltmann et al. (2012) determined that collaborative chronic care models produce "significant effects across disorders and care settings for depression as well as for mental and physical quality of life and social role function."

Two collaborative care strategies were applied. The first collaborative care strategy used previously established co-located models adapted for the SMI population (E. H. Wagner, 1998). For persons served in community mental health centers, research has indicated that care management delivered in an integrated primary care setting can result in sustainable improvements in physical health outcomes, patient and provider satisfaction, as well as potential cost savings to health care systems relative to care as usual (i.e., simple referral to a primary care provider) (Butler et al., 2008; Druss, Rohrbaugh, Levinson, & Rosenheck, 2001; Hutchinson et al., 2006; Shackelford, Sirna, Mangurian, Dilley, & Shumway, 2013). Co-location of primary care services improves access to routine primary care for persons with SMI given that their "primary point of contact with the health care system is through public-sector mental health programs rather than primary medical care" (Druss et al., 2001). A 2001 study involving the integration of primary care services within a mental health clinic treating veterans with mental illness reported that "enrollment in a co-located, integrated clinic was associated with increased primary care use and improved attainment of some cardiovascular risk goals" (Druss et al., 2001). The study found that the veterans who received primary care services co-located within the mental health setting realized "significantly improved goal attainment for blood pressure, low-density lipoprotein cholesterol, triglycerides, and BMI."

The second collaborative care strategy used community health workers (*promotores*). There is a growing body of evidence of the benefits of interventions led by *promotores* especially in underserved and minority populations. For example, in a quasi-experimental design with pre-post tests and follow-up (N=255), program participants of *Pasos Adelante* (Spanish for Steps Forward) a lifestyle intervention program targeting chronic disease prevention in Mexican Americans living in a U.S.-Mexico border

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

community in Arizona, demonstrated significant improvements in physiological measures linked to diabetes and CVD risk factors after participating in the 12-week community health worker-led program that combined interactive educational sessions with walking groups (Staten et al., 2011). Additionally, one randomized control study conducted to determine the impact of using a diabetes education program led by a community health worker in a community setting for uninsured Mexican Americans found that the intervention group had a significant mean change in their HbA1c over 12 months compared to the control group (Prezio et al., 2013). Another study found similar results when using community health workers for diabetes self-management (Carrasquillo, Patberg, Alonzo, Li, & Kenya, 2014; Walton, Snead, Collinsworth, & Schmidt, 2012) and heart health (Carrasquillo et al., 2014) for Hispanic consumers.

The second component of TRIP for Salud y Vida was transportation assistance. The importance of transportation assistance is supported by Friedman et al.'s findings (2001), based on a national longitudinal study that demonstrated that transportation increased medical utilization among substance abuse patients. Rural residents are more likely to note that they have a usual care provider but report fewer visits to health care providers during a year (Zhang, Tao, & Anderson, 2003). Arcury, Preisser, Gesler, & Powers (2005), which points to the effects of geography and spatial location that have an impact health care utilization in rural regions and points to the need for public policy efforts. Researchers have noted the importance of improved transportation for improved health outcomes. The literature does identify transportation in rural settings as a barrier for care and a contributing factor to worse health outcomes especially so for those the SMI population (Kane & Ennis, 1996; Roberts, Battaglia, & Epstein, 1999).

Further, the incorporation of offering transportation in the five-county service area was designed to create a more comprehensive TRIP for Salud y Vida program to reduce barriers associated with access to and use of health care services for rural SMI patients. The direct link between transportation, appointment keeping, and hypertension management is supported in the literature. For example, similar to the TRIP for Salud y Vida program, Rothman et al. (2005) implemented a randomized control trial to assess the efficacy of a disease management program to improve cardiovascular risk factors and HbA1c levels in their patient population. As part of their intervention, patients had access to a care coordinator who was trained to address issues related to health behavior and health education. In addition, as Rothman et al. (2005) indicate, "The coordinator also helped to address barriers to care, including difficulties with transportation, communication, insurance problems, and low health literacy." At the end of this 12-month study, the researchers found that the intervention group had significantly greater improvements compared to the control group for systolic blood pressure and diabetes knowledge. Furthermore, a systematic review of studies on transportation barriers to health care access focused on identifying: (1) access barriers for ongoing primary care or chronic disease care; (2) assessment of transportation barriers; and (3) completed in the United States. Sixty-one studies were included in the review and the authors concluded that transportation barriers are an important determinant to health care access, particularly for those with lower incomes or the under/uninsured. They also noted that additional research is needed to identify which aspects of transportation limit health care access, to measure the impact of transportation barriers on clinically meaningful health outcomes and to determine the impact of transportation barrier interventions and transportation policy changes (Syed, 2013). The TRIP program was designed to examine these three variables and understanding the impact of transportation on health outcomes.

In addition, there is evidence in the literature that patient compliance with appointment keeping is linked to health outcomes (the more patients keep appointments, the better their health outcomes, and vice versa). A study, reported in *Health Services Research*, found that patients who often miss appointments were at increased risk for poorer control of blood pressure, blood sugar and cholesterol (M. M. Parker et

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

al., 2012). Missed appointments are detrimental for patients because chronic illnesses require vigilant tracking to assess the progression of the disease (J. Wagner, 2012), routine appointments are often needed to fill prescriptions (Gellad, Haas, & Safran, 2007), and a key to chronic disease management is patient education and communication (E. H. Wagner, 2000). The Parker study bears out earlier, broader, evidence that patients who adhere to treatment, even when that treatment is a placebo, have better health outcomes than poorly adherent patients (Horwitz et al., 1993). A study reported in the *Annals of Family Medicine* (Saultz & Lochner, 2005) found a significant association between interpersonal continuity and improved preventive care and reduced hospitalization. (Regular compliance with appointments is a key element of interpersonal continuity.)

Because the TRIP for Salud y Vida utilized a variety of evidence-based collaborative care components and incorporated a transportation piece, the level of evidence at the start of the program was preliminary with the goal to achieve a moderate level of evidence through this evaluation.

Program Components

As described in the SEP, REAL's program theory of change proposed that individuals who participated in TRIP for Salud y Vida would have improved health outcomes as a result of enhanced integrated services and systematic and seamless offering of transportation in the five-county service area.

Inputs: The TRIP for Salud y Vida had five inputs. (Note: This section was updated from the SEP, as was described in the interim report. The Transportation Coordination Network (TCN) was replaced by REAL, Inc. as an input in the logic model. This program change was made given the TCN is a program of REAL, Inc.):

- REAL, Inc.: Transportation coordination, nurse coordination and navigation. Collaborative team coordination, behavioral and clinical education coordination and REDCap database system.
- Coastal Plains Community Center (CPCC): Behavioral health staff, electronic medical record and care coordination
- South Coastal Health Education Center (AHEC): Community education and navigation and
- Consumer Voices Leadership Group: Behavioral health consumers group established and serving as advisory board to TRIP for Salud y Vida Program.

Activities: The TRIP for Salud y Vida included the following programmatic activities at the individual, provider, clinic, and health system levels:

- Assignment of a navigator and case manager (Rothman et al., 2005).
TRIP for Salud y Vida and Program Salud y Vida consumers were assigned a navigator and case manager during enrollment at the clinic site as part of the IBH model. The navigator and case manager were associated with a specific clinic and served enrollees at the specific site. The navigator and case manager were responsible for ensuring the consumer completed all clinic paperwork and scheduled future clinic appointments. The navigator and case manager then sent TRIP for Salud y Vida consumer information to the consumer attendant.
- Assignment of a consumer attendant.
The consumer attendant (certified community health worker (CHW)) was assigned only to consumers enrolled in the TRIP for Salud y Vida Program. The consumer attendant was responsible for developing the consumer's tailored transportation care plans, coordinating enhanced integrated services and training consumers on how to use transportation services and participate in community health and health care services.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- Home and telephone nurse assessments (Rothman et al., 2005).
The home and telephone nurses were responsible for identifying chronic disease management needs and assessment of consumer needs for community educational services. This activity was tied to outcomes related to consumer health literacy (e.g., navigation of the health system), disease management and health outcomes. These visits were limited to consumer requests and not provided to all consumers unless necessary as determined by staff.
- Development of an individualized transportation plan (Rothman et al., 2005).
The consumer attendant developed an individualized transportation plan. This activity was tied to outcomes related to consumer health literacy, disease management, health outcomes and appointment keeping.
- Coordination and delivery of tailored transportation services to behavioral and clinical appointments (Rothman et al., 2005).
The consumer attendant was responsible for coordination and delivery of tailored transportation services to behavioral and clinical appointments. This activity was tied to outcomes related to consumer health literacy, disease management, health outcomes and appointment keeping.
- Coordination and delivery of transportation services to and from community health and other health care services (Rothman et al., 2005).
The consumer attendant was responsible for coordination and delivery of tailored transportation services to behavioral and clinical appointments. This activity was tied to outcomes related to consumer health literacy, disease management, health outcomes and appointment keeping.
- Consumer enrollment in a community-health worker (CHW) led diabetes self-management education (DSME) for the diabetes subgroup (Rothman et al., 2005; Staten et al., 2011).
The CHWs were responsible for leading diabetes self-management education offerings for the diabetes subgroup and all enrolled TRIP consumers. This activity was tied to outcomes related to health literacy, disease management, health outcomes, physical activity, dietary habits, and quality of life. (Note: Providing diabetes self-management education to all TRIP consumers is a deviation from the SEP, which indicated they would be provided only to the diabetic subgroup. This change was made given the high-risk population (high BMI rate and Hispanic population) enrolled in TRIP.)
- Implementation of community-based health and disease management classes tailored to consumer needs (i.e., physical activity, self-management education, food and nutrition education) (Carrasquillo et al., 2014; Staten et al., 2011).
Community Health Workers (CHWs) were responsible for leading community-based health and disease management classes including Walk in the Park, Lunch and Learn and other disease prevention and physical activity promoting programming (each activity described below). This activity was tied to primary and secondary outcomes related to health literacy, disease management, health outcomes, physical activity, dietary habits, and quality of life.

A brief overview of the community-based health and chronic disease management classes follows, each session was tied to primary and secondary outcomes as noted in the logic model (see **Table 1** and **Appendix B. Program Logic Model**). In addition, although the CPCC clinical services use an Electronic Health Record (EHR) system, the Salud y Vida Program did not have direct access to enter or use the EHR data. For the program, we used REDCap to collect all program metrics for the TRIP for Salud y Vida Program. The use of the REDCap program by CPCC staff streamlined communications at the organizational level and allowed the navigators at CPCC to better assess patient needs as part of the IBH program.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Table 1. Enhanced Integrated Services

EIS Offering	Number of Sessions	Participants
Health and Wellness	48-57	Alice, Falfurrias and Kingsville
Introduction to REAL Transit Services	3 per location	Alice, Falfurrias and Kingsville
Art Exploration	26	Alice, Kingsville
La Cocina de TRIP	1 per location	Alice, Falfurrias and Kingsville
Individual Health Education Sessions	As requested with CHW or RN	Alice, Falfurrias and Kingsville
Money Matters	1	Alice, Falfurrias and Kingsville
End of Life Planning	1	Alice, Falfurrias and Kingsville
Fitness Trainer	22	Alice, Falfurrias and Kingsville
In Motion Women's Fitness	14	Alice, Falfurrias and Kingsville
Filo's Total Wellness	3	Alice, Falfurrias and Kingsville
Ztreme Zumba	8	Alice, Falfurrias and Kingsville
Basic Exercise	3	Alice, Falfurrias and Kingsville
Tai chi	20	Alice, Falfurrias and Kingsville
Yoga	33	Alice, Falfurrias and Kingsville
Water Aerobics	43	Alice, Falfurrias and Kingsville
Bowling	2	Alice, Falfurrias and Kingsville
Walk in the Park	35-42	Alice, Falfurrias and Kingsville

Health & Wellness. Group learning presented in a classroom setting led by South Coastal Area Health Education Center (AHEC) Staff. Explores health topics such as Nutrition, Disease Prevention, Stress Relief, group conversation and activities help participants find ways to live healthier lives, feel better, live longer and enjoy life. Classes were led by RN, certified CHW instructors and AHEC staff. Classes were held for one hour weekly in 3 locations (Alice, Falfurrias, and Kingsville) in the TRIP for Salud y Vida service area. Program participants were encouraged to attend the session held in their home area.

Time period: 2016 & 2017

Number of Sessions: 57 Class Sessions held in Alice, 56 Class Sessions held in Falfurrias, 48 Class Sessions held in Kingsville.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Introduction to REAL Transit. Group learning presented in a classroom setting led by REAL Transit Mobility Management staff and/or Consumer Attendants to help educate consumers on what information is required to schedule transportation with REAL transit. Class is targeted for all TRIP program participants to ensure greater understanding of the transportation service covered for program participants, and to ensure that all required information for scheduling a trip is available when consumers call to make a transportation reservation, allow consumers to ask transportation questions and become familiar with transit staff. Class sessions were held for one hour in each of 3 areas throughout the service area (Alice, Falfurrias, and Kingsville) during enrollment phase of the program to ensure understanding of the transportation provided through the program.

Time period: 2016 & 2017

Number of Sessions: 3 Class Sessions held in Alice, 3 Class Sessions held in Falfurrias, 3 Class Sessions held in Kingsville.

Art Exploration. Group learning presented in a classroom setting with the purpose of providing a creative outlet for consumers to express themselves and providing the opportunity for consumers to try something new. Introductions to the Art Exploration Class began with Art basics such as color principles, introduction of different art mediums (i.e. water color, chalk, pencil, paint, sculpture, etc.) so that consumers would gain familiarity with art and feel comfortable exploring different projects. First 4 introductory sessions provided by an instructor with a teaching background in art. The second set of 22 sessions were led by Consumer attendants and were more topic or project focused. A medium was introduced, then an example presented and then the consumer was able to use the art form to create what they wanted. A project example is a plain white paintable mask was presented to each class participant, they were shown examples of masks gathered from different art resources. Supplies were presented to decorate the mask as they saw fit. A suggestion of the project was that the outside of the mask be decorated "how others see you", and the interior of the mask be decorated "how you really feel inside". Consumers then had the ability to paint, attach decorations such as beads, feathers, glitter, sequins, etc. to express themselves and the project was worked on over three separate one-hour sessions.

Time period: 2016 & 2017

Number of Sessions: 26 Class Sessions held available consumers from any location.

La Cocina de TRIP. Group learning, recipe preparation demonstration and instruction with the purpose of providing easy-to-understand nutrition information, healthy- and budget-friendly recipes that are simple to prepare and most importantly taste good. Recipe is prepared on site at class during learning session, and class participants are shown how to prepare recipe, what ingredients are used, discuss the health benefits of the ingredients and leave the class with a handout of recipe, cost per serving, nutrition facts per serving as well as taste test the recipe once it is prepared.

Time period: 2017

Number of Sessions: One class provided in each clinic area (Alice, Falfurrias, and Kingsville) instructed by REAL, Inc. Community Health Worker.

Individual Health Education Sessions. One on one sessions with consumer to discuss a health topic at a setting where the consumer was comfortable. Sessions tailored for those consumers that were not comfortable coming out to a group learning class in the community. In addition, some consumers that did attend group learning also requested one on one sessions to reinforce and support learning and health activity. Sessions used a health assessment tool to ask the consumer health related questions to gain greater understanding of the consumer health concerns and challenges. Based on information gathered, consumer and TRIP program staff discussion then turned to health topics that the consumer would like additional information on such as healthy eating, healthy portion sizes, ways to incorporate physical

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

activity in daily routine, limiting salt consumption, etc. Short video resources and handouts were used using Texas Department of Health resources from Good Food, Good Moves web site. Contact with each enrolled participant in the program was made to attempt for an individual session and were carried out with all those that agreed to the meeting.

Time period: 2016 & 2017

Number of Sessions: As requested

Tailored EIS Learning Sessions

The following EIS learning session topics were identified and session content was developed by the Program Director, Anita Rosas and CHWs to meet the consumer demands and highlight local community capacity.

Money Matters. Group learning presented in a classroom setting led by a REAL, Inc. Community Health Worker to provide basic budgeting and money management skills to consumers.

Time period: 2017

Number of Sessions: One session held, open to all program participants.

End of Life Planning. Group learning presented in a community setting to provide basic end of life planning informational materials and skills to consumers, so that they may plan for the future.

Time period: 2017

Number of Sessions: One session held, open to all program participants.

Tailored Physical Activity Classes

Fitness Trainer. One-hour group workout session conducted in a cross fit training facility, led by a cross fit instructor. The instruction focused on basic movements, increasing balance and physical activity tailored to the individual abilities and comfort level of each class participant.

Time period: 2016 & 2017

Number of Sessions: 22 Class sessions open to all program participants

In Motion Women's Fitness. One-hour group workout session conducted in a women's training facility, led by a fitness instructor. The instruction focused on basic movements, increasing balance and physical activity tailored to the individual abilities and comfort level of each class participant.

Time period: 2016 & 2017

Number of Sessions: 14 Class Sessions held, open to all program participants.

Filo's Total Wellness. One-hour group workout session conducted in a community training facility, led by a fitness instructor. The instruction focused on basic movements, increasing balance and physical activity tailored to the individual abilities and comfort level of each class participant.

Time period: 2017

Number of Sessions: 3 Class Sessions held, open to all program participants.

Ztrema Zumba. One-hour group workout session conducted in a zumba training facility, led by a zumba instructor. The instruction focused on basic dance movements, increasing balance and physical activity tailored to the individual abilities and comfort level of each class participant.

Time period: 2017

Number of Sessions: 8 Class Sessions held, open to all program participants.

Basic Exercise. One-hour group workout session conducted in a community park or meeting facility, led by a REAL, Inc. Community Health Worker. The instruction focused on simple body weight exercises,

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

basic stretching and movements, increasing balance and physical activity tailored to the individual abilities and comfort level of each class participant.

Time period: 2017

Number of Sessions: 3 Class Sessions held, open to all program participants.

Tai Chi. One-hour video-based group workout session conducted in a community park or meeting facility, led by a REAL, Inc. Community Health Worker. The instruction focused on introductory Tai Chi movements and tailored to the individual abilities and comfort level of each class participant.

Time period: 2017

Number of Sessions: 20 Class Sessions held, open to all program participants.

Yoga. One-hour group workout session conducted in a community training facility, led by a yoga instructor. The instruction focused on basic yoga movements, breathing and physical activity tailored to the individual abilities and comfort level of each class participant.

Time period: 2016 & 2017

Number of Sessions: 33 class sessions open to all program participants.

Water Aerobics. One-hour group workout session conducted in a community swimming facility, led by a lifeguard instructor. The instruction took place in a shallow area of the pool facility and focused on basic movements, increasing balance and physical activity tailored to the individual abilities and comfort level of each class participant.

Time period: 2016 & 2017

Number of Sessions: 43 Class sessions open to all program participants

Bowling. One-hour group workout session conducted in a community bowling facility, led by a REAL, Inc. Community Health Worker. The instruction focused on increasing body movement and physical activity in a fun and active environment tailored to the individual abilities and comfort level of each class participant.

Time period: 2017

Number of Sessions: 2 Class Sessions held, open to all program participants.

Walk in the Park. One-hour group walking workout session conducted in a community park, led by a REAL, Inc. Community Health Worker. The instruction focused on easy at your own pace walking workout to increase body movement and physical activity tailored to the individual abilities and comfort level of each class participant.

Time period: 2016 & 2017

Number of Sessions: 42 Class Sessions held in Alice and Kingsville, 35 Class Sessions held in Falfurrias.

The implementation of operational level and health system level activities is described in detail in the Implementation study section and was used to assess the implementation of the TRIP for Salud y Vida program.

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

- Recruitment and enrollment of 500 total consumers to participate in the TRIP for Salud y Vida program (intervention group [n=250] and external comparison group [n=250]).
- Provider and staff training across all partner sites to systematically implement TRIP for Salud y Vida to better address behavioral and clinical needs.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- Increased enrollment and maintenance of enrollment of consumers in services.
- Integration of Voices Leadership Group in planning and implementation of the program.
- Development of tailored consumer transportation care plans.
- Incorporation of transportation scheduling.
- Consumer training and introduction to use of transportation services and scheduling software.
- Consumer referral to and engagement in partner and/or community resources
- Integration of standard measurement protocols, and ongoing quality improvement among partner staff (e.g., weekly reviews of goals and assessment reviews as well as consumer coordination of care and services) to emphasize integration of transportation services and increased communication/collaboration between partners.

All activities and outputs identified in the logic model were assessed as part of the implementation and impact evaluation and were expected to influence the expected **short-, intermediate-, and long-term outcomes**. In this report, we describe implementation evaluation data and present intermediate and long-term outcomes. The implementation of coordinated primary and behavioral health services as well as initial descriptions of provider communication are presented in the Implementation study section of this report.

Outcomes:

Short-Term and Intermediate Outcomes: Short-term and intermediate outcomes are the changes that were expected to occur during the first six months of patients enrolling in the program and receiving TRIP for Salud y Vida services.

REAL's short-term and intermediate outcomes provide information related to the impact of TRIP for Salud y Vida on consumer's self-management, health literacy, physical activity, dietary habits, quality of life, and clinical appointment keeping. An additional outcome is increased use of TRIP Salud y Vida transportation services for health care as measured by number of trips by type (e.g., care appointment, Enhanced Integrated Services – EIS - education). It was expected that changes in these markers would be seen at both the short and intermediate time frame.

Long-Term Outcomes: Long-term outcomes addressed in this report examine the impact of TRIP for Salud y Vida on consumers' health outcomes (i.e., blood pressure, BMI, HbA1c, PHQ-9), and quality of life over a 12-month period.

Overview of Impact Study

REAL's quasi-experimental design (QED) aimed to demonstrate the evidence-based collaborative care components and transportation would achieve a moderate level of evidence supporting the benefit of collaborative care components among the SMI population. This study hypothesized that individuals who participated in TRIP for Salud y Vida would have improved health outcomes as a result of enhanced integrated services (EIS) focused on disease management, educational programming, and systematic and seamless offering of transportation in the five-county service area.

A QED study was designed to provide rigorous estimates of the impact of TRIP for Salud y Vida on participant health measures in the SMI consumer population and specific subgroups. It is recognized that a QED is not as rigorous as a randomized control trial (RCT). A quasi-experimental approach aims to examine program impacts by comparing the outcomes of program participants (intervention group) to

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

the outcomes of non-participants who are observationally equivalent to program participants (comparison group).

Research Questions

REAL's subgrantee evaluation plan included both implementation and impact research questions, as stated below. Three questions were changed since the approval of the SEP: Impact questions 6, 7, and 10 are not included in this final report due to unavailability of data.

Implementation Questions

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

1. Did the TRIP for Salud y Vida program reach its intended target population?
2. What are the components of the TRIP for Salud y Vida 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 TRIP for Salud y Vida achieve as a result of implementing the program?
 - b. To what extent have providers and program staff adopted the components of the TRIP for Salud y Vida 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 TRIP for Salud y Vida 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 REAL, Inc. and partners implement the TRIP for Salud y Vida model with fidelity?
6. How satisfied are TRIP for Salud y Vida patients with the services they have received? How satisfied are providers with the TRIP for Salud y Vida program?

Impact Questions

The primary impact measure for TRIP for Salud y Vida was consumer improvement in blood pressure. Below are the confirmatory and exploratory research questions as presented in the SEP. This final report presents findings labeled by Impact Question.

1. Did TRIP for Salud y Vida consumers significantly improve their blood pressure compared to Project Salud y Vida consumers? *The question is confirmatory.*
2. For consumers with a history of and/or diagnosis of diabetes, did TRIP for Salud y Vida consumers significantly improve their HbA1c compared to Project Salud y Vida consumers? *The question is confirmatory.*
3. Did TRIP for Salud y Vida consumers significantly improve their body mass index (BMI) compared to Project Salud y Vida consumers? *This question is exploratory.*
4. Did TRIP for Salud y Vida consumers significantly improve their quality of life (as measured by the Duke Health Profile) compared to Project Salud y Vida consumers? *This question is exploratory.*

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

5. Did TRIP for Salud y Vida consumers significantly improve their depressive symptoms (as measured by the PHQ-9) compared to Project Salud y Vida consumers? *This question is exploratory.*
6. Did TRIP for Salud y Vida consumers experience improved dietary habits compared to Project Salud y Vida consumers? *This question is exploratory. This question is not addressed in this report.*
7. Did TRIP for Salud y Vida consumers experience improved physical activity behaviors compared to Project Salud y Vida consumers? *This question is exploratory. This question is not addressed in this report.*
8. Did TRIP for Salud y Vida consumers experience improved health literacy compared to Project Salud y Vida consumers? *This question is exploratory.*
9. Did TRIP for Salud y Vida consumers experience increased appointment keeping compared to Project Salud y Vida consumers? *This question is exploratory.*
10. Do TRIP for Salud y Vida consumers who live within a rural town have greater percent change in health outcomes compared to TRIP for Salud y Vida consumers traveling from rural farm to market road residents? *This question is exploratory.*
11. Do TRIP for Salud y Vida consumers have different health outcomes based on the amount and type of use of transportation services? For example, do high transportation service users have greater percent change in health outcomes compared to TRIP for Salud y Vida consumers with low use over time? *This question is exploratory.*

Contribution of the Study

By using a quasi-experimental approach, this evaluation examined the impact of an IBH model on a sample of SMI consumer's blood pressure, (primary confirmatory outcome). We explored the contribution of addressing transportation barriers within the rural community to blood pressure prevention, management and health care access. The TRIP for Salud y Vida project is, therefore, significant because it breaks through reported barriers and provides support for behavioral health management by maximizing the seamless use of transportation and community resources to promote blood pressure management and control. The TRIP for Salud y Vida program also provides evidence related to the effectiveness of integrating CHWs into IBH and improvement of health outcomes in rural communities.

The TRIP for Salud y Vida program was designed to expand the IBH model in place (Project Salud y Vida) and was informed by previous research (Rothman et al., 2005; Staten et al., 2011; E. H. Wagner, 1998). The TRIP for Salud y Vida program resulted in preliminary evidence of impact and informed a greater understanding of best practices based on implementation findings in the delivery of IBH in rural settings. A preliminary level of evidence is most appropriate for the TRIP for Salud y Vida impact evaluation because the program implemented adapted evidence-based integrated care model components within the rural community setting that were most appropriate given the SMI consumer needs, infrastructure and partner capacity; however the baseline differences led to unequal groups (demographic and impact outcomes) the "true" impact of the intervention cannot be disentangled with reported analysis. The TRIP for Salud y Vida population differs from models reported in the literature, TRIP for Salud y Vida modified its approach to best suit the needs of the rural SMI population in partnership with patient advocacy groups. By using a quasi-experimental design (QED) approach with three program clinics and two comparison clinics, the evaluation of TRIP for Salud y Vida expands the level of evidence related to integrated care models for rural SMI consumers in rural communities. It is recognized that a QED is not as rigorous as a randomized control trial (RCT). A true randomized controlled trial design was not possible for the evaluation of the TRIP for Salud y Vida program due to potential contamination within and across the five partner clinic sites given shared provider staff for the existing IBH Salud y Vida program. However, use of a QED helped

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

to minimize threats to internal validity. The QED provided the opportunity to identify and control for participant characteristics that affected impact measures of interest.

Evaluation Plan Updates

Careful planning and coordination to implement the approved SEP implementation and impact evaluation plan as accepted were followed over the 24-months. Areas of changes in the SEP are detailed below. Given feedback at the final SEP approval we focused recruitment in two intervention sites (Alice and Kingsville) with a smaller sample being recruited from the then newly opened IBH clinic in Falfurrias. No changes to the approved recruitment and enrollment procedures at the intervention or comparison were introduced during the study. All SEP and IRB approved protocols were followed, and informed consent processes were implemented as approved. The impact evaluation questions 6, 7 and 10 were eliminated from the analyses due to lack of data to test. The SEP-approved propensity score matching was not completed as it was found to not be appropriate to ensure patient equivalence in evaluation of the program impact. No other modifications to report.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

IMPLEMENTATION STUDY: STUDY APPROACH, METHODS, AND FINDINGS

Implementation Study Design

The Implementation Evaluation study consists of two methods for evaluating the implementation of REAL's program: 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

Health Resources in Action (HRiA) conducted qualitative data collection at two-time points for the implementation study. Across the two-time points, a total of 15 staff were interviewed, and 27 participants were involved in focus groups or group interviews. HRiA worked with REAL staff to identify appropriate interview and focus group participants.

At the mid-point of program implementation (December 2016, approximately six months after the first participant was enrolled), HRiA conducted seven staff interviews and one in-person group interview with three TRIP for Salud y Vida consumer representatives. In late December 2017, approximately five months after the study ended, HRiA interviewed seven staff, including clinic providers (both primary and behavioral care) and other relevant clinical and nonclinical personnel and conducted two focus groups with a total of 24 participants.

The goal of the staff interviews was to assess program fidelity and understand more about the implementation of REAL's program, including the context, facilitators, and challenges within the scope of the project and approved logic model. Program fidelity was assessed with clinic personnel interviewees by asking questions about program implementation from a provider, program, and organizational level:

- **Provider level:** The implementation evaluation measured programmatic implementation including providers' perceptions, attitudes and perceived barriers in care delivery for the target population. Providers were asked about their perceptions regarding the degree to which integration of primary care and behavioral health services has or has not been achieved at the mid- and end-point of the program, and their engagement with each other and aspects of the program.
- **Program and organizational level:** Interviews were also conducted with program managers and staff to obtain information about the operational level workflow and adherence to the original design of the program, and facilitators and barriers to implementation.

The interviews also aimed to capture information on program staff and personnel's perceptions of barriers and facilitators to the adoption of the program's IBH model and activities, perceptions of program successes, challenges and opportunities for improvement, and perceived staff and patient satisfaction. Staff were asked about their experiences with the program and perceptions of patient satisfaction both with the process of participating in the program as well as the outcomes. **Appendix C. Sí Texas Mid-Point Implementation Evaluation: Key Informant Interview General Guide** and **Appendix D. Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide** present the semi-structured interview guides used to conduct the interviews at the mid-point and final data collection periods.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

In addition to the seven semi-structured interviews, HRiA conducted two focus groups with intervention participants (n=24) after study implementation concluded (December 2017, approximately five months after the study ended). The goal of the focus groups was to better understand the influence the program has had on participants' health and wellbeing. **Appendix E. Sí Texas Summative Implementation Evaluation: Focus Group Guide- SPMI Population** presents the semi-structured focus group guide used to conduct the focus groups at the final data collection period. Appendix F presents all implementation program components/activities, outputs, and outcomes that were measured using the qualitative data collection.

A total of 24 participants were involved in the two focus groups, ranging from 10 to 14 participants per focus group. **Table 2** describes participant demographics for the two intervention focus groups. Half of participants lived in Jim Wells County (50.0%), followed by Kleberg (25.0%), Brooks (20.8%), and Duval (4.2%). A majority of participants were female (58.3%) and between the ages of 45 and 54 (54.2%). Participants were predominantly Hispanic or Latino (82.6%) and 'other' or multiple races (54.5%). Most participants spoke English (60.9%) as their primary language and had a high school diploma or less (77.3%). Participants primarily did not have health insurance (39.1%) or had Medicare and/or Medicaid (52.1%). Participants represent the three clinics sites; the Duval participant receives services at the clinic site located in Jim Wells county.

Table 2. Demographic Characteristics of Focus Group Participants Post-Intervention

Measure	REAL (n=24)	
	N	%
County		
Brooks	5	20.8
Duval	1	4.2
Jim Wells	12	50.0
Kleberg	6	25.0
<i>Missing</i>	--	--
Sex		
Male	10	41.7
Female	14	58.3
<i>Missing</i>	--	--
Age		
≤ 34	1	4.2
35-44	2	8.3
45-54	13	54.2
55-64	4	16.7
65+	4	16.7
<i>Missing</i>	--	--
Ethnicity		
Hispanic/Latino	19	82.6
Non-Hispanic/Non-Latino	4	17.4
<i>Missing</i>	--	--

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Measure	REAL (n=24)	
	N	%
Race		
White (Caucasian)	10	45.5
Black or African American	1	4.5
Asian	1	4.5
Other/Multiple:	12	54.5
Hispanic/Latino	10	45.5
No Comment	2	9.1
<i>Missing</i>	2	--
Primary Language		
English	14	60.9
Spanish	3	13.0
English and Spanish	5	21.7
Finnish	1	4.3
<i>Missing</i>	1	--
Education		
Less than a high school diploma	8	36.4
High school degree or equivalent (e.g., GED)	9	40.9
Some college, junior college, or vocational school	4	18.2
College degree or more	1	4.6
<i>Missing</i>	2	--
Health Insurance		
I don't have health insurance	9	39.1
Medicare	6	26.1
Medicaid, Medical Assistance	5	21.7
Medicare and Medicaid	1	4.3
Private	1	4.3
Indigent	1	4.3
<i>Missing</i>	1	--

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

All interviews and focus groups were recorded digitally and transcribed. For the summative interviews and focus groups, two trained team members – who did not conduct the interviews or focus groups - initially reviewed transcripts to develop a mutually-agreed upon codebook using a grounded theory approach. They independently coded each transcript for themes using NVivo qualitative data analysis software and then 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 0.81). 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. Where applicable,

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

key themes that emerged during summative qualitative data collection are compared to key themes that emerged during mid-point qualitative data collection. Unless otherwise noted, implementation data presented in this report is from the summative interviews and focus groups. When a theme is compared to a mid-point finding, it is stated.

Quantitative Data Collection Methods and Analysis

Quantitative implementation data of patient participation in the REAL program were analyzed to examine program use, fidelity, and dose. Data comprised of de-identified patient records from REAL that included information on intervention and comparison participants' behavioral health and primary care visits. For the intervention participants, additional data were collected on transportation plans, trips provided (including mileage and purpose), and number of community-based health and disease management classes attended. Descriptive statistics on this information are provided in this section, discussing the mean, median, and range of number of completed and missed visits related to behavioral health and primary care for both groups as well as data around trips taken and classes attended by the intervention group. This information provides insight into fidelity and dose of the intervention.

TRIP for Salud y Vida Program Dosage

All components of the intervention were coordinated and efforts to maintain fidelity were made. Intervention consumer dosage was operationalized as in the original Salud y Vida Program with consumers receiving a minimum of two visits per year. In the TRIP for Salud y Vida program the goal was to increase the number of kept scheduled appointments per year.

Given that all consumers in the program were able to engage in transportation as needed and EIS classes which were of interest a dosage calculation based on the expected percent of use or engagement (e.g., 10 health and wellness classes or 5 lunch and learns) was not appropriate for this program and would not result in a specific dosage assessment given the variance in participation across consumers and varied EIS sessions offered.

The SMI consumer sample engagement in clinic visits was used as a simple dosage for reporting. An EIS based dosage calculation accounting for the EIS participation component will be incorporated in future sub-group analyses to identify the type of evidence-based approach which contributed to greater changes in outcomes and to identify within what type of consumer (demographic and behavioral characteristics) to promote sustainability and maintenance of key EIS offerings for a population with SMI.

Implementation Study Findings

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

Question 1: Did the TRIP for Salud y Vida program reach its intended target population?

TRIP for Salud y Vida's target population included the following.

- Currently enrolled or eligible for enrollment in the Salud y Vida program
- Diagnosis of SMI (100% in program sample)
- 18 years of age and older

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- Reside within the five-county clinic service area (each clinic serves multiple rural counties)
- Lack of serious health condition that would preclude ability to use TRIP transportation services and enhanced integrated services.

A diagnosis of serious mental illness is not presented in **Table 3** below due to consumer confidentiality and the recommendation of the TRIP for Salud y Vida Advisory Voices Leadership group. All participants were confirmed to have an SMI diagnosis by Coastal Plans Community Center; the regional mental health authority.

Table 3. Participant Descriptives

Measure	Full Sample (n=552)		Intervention Group (n=302)		Comparison Group (n=250)	
	n	%	n	%	n	%
Gender						
Male	196	36.0	107	35.9	89	36.2
Female	348	64.0	191	64.1	157	63.8
<i>Missing</i>	8	--	4	--	4	--
Ethnicity						
Hispanic/Latino	388	71.3	256	85.9	132	53.7
Non-Hispanic/ Non-Latino	156	28.7	42	14.1	114	46.3
<i>Missing</i>	8	--	4	--	4	--
Race						
White	521	95.8	290	97.3	231	93.9
Black	20	3.7	8	2.7	12	4.9
Asian	1	0.2	0	0.0	1	0.4
Native American	1	0.2	0	0.0	1	0.4
Other	1	0.2	0	0.0	1	0.4
<i>Missing</i>	8	--	4	--	4	--
County of Residence						
Kenedy	2	0.4	1	0.3	1	0.4
Brooks	48	8.8	48	16.1	0	0.0
Duval	30	5.5	30	10.1	0	0.0
Jim Wells	110	20.2	110	36.9	0	0.0
Kleberg	105	19.3	105	35.2	0	0.0
San Patricio	101	18.6	3	1.0	98	39.8
Bee	107	19.7	1	0.3	106	43.1
Aransas	28	5.1	0	0.0	28	11.4
Live Oak	13	2.4	0	0.0	13	5.3
<i>Missing</i>	8	--	4	--	4	--
County of Service						
Bee	122	22.4	0	0.0	122	49.6
Brooks	55	10.1	55	18.5	0	0.0
Jim Wells	133	24.4	133	44.6	0	0.0
Kleberg	110	20.2	110	36.9	0	0.0
Taft	124	22.8	0	0.0	124	50.4
<i>Missing</i>	8	--	4	--	4	--

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Measure	Full Sample (n=552)		Intervention Group (n=302)		Comparison Group (n=250)	
	n	%	n	%	n	%
Age						
≤ 34	100	18.4	62	20.8	38	15.4
35-44	125	23.0	67	22.5	58	23.6
45-54	200	36.8	106	35.6	94	38.2
55-64	107	19.7	56	18.8	51	20.7
65+	12	2.2	7	2.3	5	2.0
Mean	45.2	--	44.6	--	45.9	--
SD	11.7	--	12.1	--	11.1	--
<i>Missing</i>	8	--	4	--	4	--
Employment Status						
Unemployed	408	77.9	209	74.6	199	81.6
Employed Full-time	115	21.9	70	25.0	45	18.4
Other	1	0.2	1	0.4	0	0.0
<i>Missing</i>	28	--	22	--	6	--
Marital Status						
Married	116	21.9	54	18.6	62	25.9
Single	228	43.1	135	46.6	93	38.9
Divorced	121	22.9	69	23.8	52	21.8
Separated	64	12.1	32	11.0	32	13.4
<i>Missing</i>	23	--	12	--	11	--
Annual Household Income						
Less than \$10,000	383	70.4	214	71.8	169	68.7
\$10,001 - \$20,000	114	21.0	60	20.1	54	22.0
\$20,001 - \$30,000	23	4.2	10	3.4	13	5.3
\$30,001 - \$40,000	11	2.0	6	2.0	5	2.0
\$40,001 - \$50,000	3	0.6	0	0.0	3	1.2
\$50,001 - \$60,000	1	0.2	1	0.3	0	0.0
\$60,001 - \$70,000	1	0.2	1	0.3	0	0.0
Greater than \$70,001	2	0.4	0	0.0	2	0.8
Refusal	6	1.1	6	2.0	0	0.0
<i>Missing</i>	8	--	4	--	4	--
Primary Language						
English	535	98.3	292	98.0	243	98.8
Spanish	9	1.7	6	2.0	3	1.2
<i>Missing</i>	8	--	4	--	4	--
Education						
3 rd Grade	3	0.6	3	1.0	0	0.0
5 th Grade	6	1.2	3	1.0	3	1.3
6 th Grade	2	0.4	2	0.7	0	0.0
7 th Grade	12	2.3	5	1.7	7	3.0
8 th Grade	32	6.1	17	5.9	15	6.4

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Measure	Full Sample (n=552)		Intervention Group (n=302)		Comparison Group (n=250)	
	n	%	n	%	n	%
9 th Grade	50	9.6	25	8.7	25	10.7
10 th Grade	45	8.6	29	10.1	16	6.9
11 th Grade	39	7.5	23	8.0	16	6.9
12 th Grade	88	16.9	50	17.4	38	16.3
GED	102	19.6	65	22.6	37	15.9
Some College	132	25.3	63	21.9	69	29.6
BA/BS	7	1.3	3	1.0	4	1.7
None	3	0.6	0	0.0	3	1.3
<i>Missing</i>	31	--	14	--	17	--
Household Size						
1	299	55.0	161	54.0	138	56.1
2	96	17.6	52	17.4	44	17.9
3	57	10.5	30	10.1	27	11.0
4	52	9.6	27	9.1	25	10.2
5	22	4.0	13	4.4	9	3.7
6	12	2.2	10	3.4	2	0.8
7	4	0.7	4	1.3	0	0.0
8	1	0.2	1	0.3	0	0.0
9	1	0.2	0	0.0	1	0.4
<i>Missing</i>	8	--	4	--	4	--
Veteran Status						
Yes	8	1.5	7	2.3	1	0.4
No	536	98.5	291	97.7	245	99.6
<i>Missing</i>	8	--	4	--	4	--
Health Insurance Status						
Not Insured	397	73.0	210	70.5	187	76.0
Insured	20	3.7	13	4.4	7	2.8
Medicare	34	6.3	20	6.7	14	5.7
Medicaid	91	16.7	53	17.8	38	15.4
Other	2	0.4	2	0.7	0	0.0
<i>Missing</i>	8	--	4	--	4	--

Question 2: What are the components of the TRIP for Salud y Vida 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 TRIP for Salud y Vida program was designed to expand the current IBH program, Project Salud y Vida. TRIP for Salud y Vida was developed to respond to a specific need identified by community partners to expand the reach of Project Salud y Vida to improve health outcomes, through enhanced integrated services and systematic offering of transportation in the five-county service area. The original program (Project Salud y Vida) was designed to provide primary care, substance abuse services, preventative health care and care management/health navigation services to consumers, in a culturally, linguistically and

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

mental health “stigma-free” environment. Its specific components are described in the logic model in **Appendix B. Program Logic Model** and in the Program Definition section.

In summary, TRIP for Salud y Vida offered enhanced integrated services that focused on transportation supports to and from health care appointments, community-based activities, and health and disease management classes (EIS) that were tailored to consumer needs (i.e., physical activity, self-management education, food and nutrition education). The program relied on partnerships across the region to implement the multi-faceted intervention.

How Components Work “On the Ground”

Interviews delved deeper into the how the program was being implemented. When asked about how behavioral health and primary care services were coordinated and connected, interview participants highlighted transportation, staffing, data systems, and communication and coordination as core factors that support integration. Each of the TRIP for Salud y Vida program activities and elements were assessed below.

Transportation

Transportation—which was described as a significant barrier to connecting residents in rural communities with resources—was identified as the primary mechanism used by the TRIP program to connect consumers with primary and behavioral health services including medical appointments, social gatherings, and health literacy classes. As one interview participant shared, *“Our goal is to improve health outcomes for consumers of the Coastal Plains system participating in Salud y Vida integrated behavioral health clinics through a series of enhanced, integrated services with the support of transportation as the access.”* In addition to accessing transportation services, TRIP consumers were provided transportation to free health and wellness classes that included topics such as diabetes management, nutrition, and art, shared interview and focus group participants. Since transportation services were the main mechanism to implement the TRIP program, it is mentioned in several sections of the implementation findings.

Clinic-based Services

Several interview participants noted the significance of Coastal Plains’ experience with integrated behavioral health services, which the clinic implemented several years prior to the Si Texas project. Medical and ancillary services including case management, medication support, and primary and behavioral health were co-located in the clinic and often facilitated by “warm hand offs”. According to TRIP staff, partnering with a clinic with strong knowledge of integrated processes helped prepare and position the TRIP program for success. For example, interview participants indicated that Coastal Plains staff had a keen awareness of wait times between primary and behavioral health visits, which helped inform transportation scheduling. Once a “warm hand off” had been established, shared interview participants, Coastal Plains staff would alert TRIP dispatch that consumers would be ready in approximately 30 minutes.

Staffing

When asked about the integration of staff, focus group and interview participants described close coordination between REAL, Coastal Plains, and community-based partners. Consumers indicated having to interface with multiple staff from partner organizations, including transportation dispatch, consumer navigators, and case managers, among others. Consumer navigators were described by interview participants as a conduit between partner organizations that facilitated coordination and implementation between organizations. Consumers described the services provided by navigators as, *“a one stop shop,”*

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

noting that they were often the first point of contact between primary and behavioral health, community-based activities, and transportation services.

Data Systems

In addition to transportation services, interview participants noted that the REDcap database was used for integration efforts for the TRIP for Salud y Vida program. According to interviewees, Coastal Plains was responsible for collecting clinical health data, while REAL and AHEC were responsible for programmatic and transportation data. These data efforts, shared TRIP staff, were closely aligned with other regional initiatives including the state's 1115 Medicaid waiver projects, which required similar metrics and data tracking. One staff interview participant shared, "The subcontract that REAL shared with [Coastal Plains] was primarily a data provision. A lot of metrics aligned with data for the 1115 waivers we were working towards; now [the data] had to be scrubbed and massaged to match the report formatting for TRIP."

According to interview participants who participated in mid-point and summative interviews, data responsibilities were adapted early on to accommodate a restructuring of TRIP partnerships. Interviewees noted that these changes caused leadership to adapt the original plans for data systems by re-assigning data collection responsibilities to established partners Coastal Plains, the partner organization responsible for data tracking and monitoring, hired two staff members to assist with data transfers and data management. These liaisons were specifically trained to collect survey data and enter it in the REDcap database. According to staff participants, hiring personnel responsible for these responsibilities were key components to facilitating integration between partners

Communication and Coordination

Communication and coordination were identified as critical components to integration of the TRIP program by participants in the mid-point and summative interviews. Both in-person and electronic communication strategies were mentioned as essential components of the TRIP for Salud y Vida program. According to interviewees, TRIP program staff and partners were engaged through frequent meetings and "Pachangas" [quarterly gatherings] to ensure processes were coordinated. While the literal translation of "Pachanga" refers to a celebration, the TRIP staff adopted the term for quarterly project gatherings because it resonated with the unique cultural context of the region. Further, behavioral health consumers established an advisory board for the TRIP program named the Voices Leadership Group. TRIP staff would frequently coordinate with the Voices advisory group to solicit feedback and programmatic suggestions. According to interviewees, this frequent communication allowed for authentic consumer driven feedback that aligned TRIP efforts with the needs of the consumers.

In terms of coordination of services, consumer navigators were viewed as a critical component of integration, with interviewees describing them as a conduit between partner organizations that facilitated coordination between groups. Coordination included: appointment reminders, transportation coordination, and scheduling follow up visits. This coordination was especially important for scheduling clinical appointments and transportation supports in a timely manner, shared interviewees.

Question 3: What level of Integrated Behavioral Health did TRIP for Salud y Vida achieve as a result of implementing the program?

Question 3b. To what extent have providers and program staff adopted the components of the TRIP for Salud y Vida program at 6 and 12 months, and what are the facilitators and barriers to adoption?

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Implementation of Integrated Behavioral Health

REAL, Inc. and partners completed the Integrated Behavioral Health Checklist in July of 2016. The Patient-Centered Integrated Behavioral Health Care Principles & Tasks Tool was used to assess core principles and core components and tasks of IBH care into the clinical settings. A post assessment was not conducted as all IBH core principles of care were met at baseline. Given the original Salud y Vida Program was an existing IBH program our baseline IBH checklist met core principles of care and core components and tasks of effective integrated behavioral health care programs. The IBH Checklist was completed by Coastal Plains Community Center (CPCC, July 2016) as the primary site for the IBH care delivery. The tool items are presented in **Table 4** and **Table 5** below.

Table 4. IBH Checklist - Core Principles

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.

Table 5. IBH Checklist: Core Components and Tasks

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

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

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 skills
Provide evidence-based counseling (e.g., Motivational Interviewing, Behavioral Activation)
Provide evidence-based psychotherapy (e.g., Problem Solving Treatment, Cognitive Behavior Therapy, Interpersonal Therapy)
Prescribe and manage psychotropic medications as clinically indicated
4) Systematic Follow-Up, Treatment Adjustment, and Relapse Prevention
Change or adjust treatments if patients do not meet treatment targets
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
5) Communication and Care Coordination
Coordinate and facilitate effective communication among providers

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

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 referrals
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

Program Adoption

Interview (n=7) and focus group participants (n=24) were asked what facilitated or hindered program implementation as well as patient participation in the program. (Note: Although the research question focuses on providers and program staff, we include focus group participant data here as it is also relevant to this question). The following presents a summary of these facilitators and barriers. The TRIP for Salud y Vida program included multiple program components. Activities are outlined in the **Appendix B. Program Logic Model**.

Adoption Facilitators

In the mid-point interviews, building trust with community and program partners, frequent and intentional messaging, and staff training emerged as key adoption facilitators. During summative interview and focus group discussions, adoption facilitators cited included strong communication and relationships, adapted data systems and physical space, flexibility of program staff, and investments in training and capacity building for staff.

Communication

Communication was the most frequently cited facilitator of program implementation adoption among focus group and interview participants in the summative evaluation. Interview and focus group participants commented on the collaborative approach of TRIP stakeholders, sharing that communication

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

among partner organizations was respectful and solutions-oriented. For example, when describing how partners approached programmatic issues, one interviewee shared, *“We always keep the communication door open and certainly never come at it from a place of ‘Well if you did this’ or ‘Why didn’t you do that?’.* We all knew that we were working hard to do what needed to happen.” Interviewees explained that this strategy was also used when communicating with consumers; TRIP personnel made intentional efforts to collect consumer feedback at multiple touch points in what was described as a *“feedback loop.”* This theme of continuously seeking feedback also emerged in the mid-point interviews. Staff indicated that feedback was collected via focus groups, Pachanga convenings, and the consumer advisory committee, among others. As one interview participant explained, *“There was always that conversation happening with the participants themselves... ‘What can we do better? What do you want to learn?’”*

The emphasis on communication was echoed by focus group participants, who described frequent communication with multiple TRIP staff, including transportation coordination personnel, consumer navigators, and providers. Focus group participants indicated that program information was clearly communicated by staff and was most often done in-person or via telephone. The REAL team developed calendars detailing EIS offerings at quarterly Pachangas allowing for consumers to receive information in writing. These calendars and sign up events allowed consumers to ask questions regarding the sessions. Consumers noted feeling comfortable giving feedback and asking questions of staff, who they described as well-informed, responsive, and non-judgmental. As one focus group participant shared, *“It’s like you go to the doctor and there’s always this level of intimidation and then you never remember what to ask or what they thought. But it’s not the same as these classes...we can ask any kind of stupid question, they’ll find us an answer.”*

Relationships

According to data from interviews conducted at the mid-point and summative timepoints, collaborative and long-standing relationships between partners and consumers facilitated the groundwork for TRIP’s program adoption. One interviewee explained, *“We have been working together for so long that we know the needs of the community, we know the strengths of the community, we know what each of us can do, and we depend on each other to move forward.”* While these prior relationships created a strong foundation for program success, according to interview participants, work still needed to be done in the early stages of program implementation to improve processes. As one interviewee shared, *“We had some communication issues initially, but we got on them and were able to work it out fairly quickly and get the services to our clients.”*

Focus group participants also referenced positive relationships with TRIP staff, often describing the interpersonal connections shared between consumers and personnel *“like family.”* According to focus group participants, these relationships were critical to program adoption. Staff echoed this sentiment and added that positive relationships with consumers helped improve their capacity as providers. More specifically, interview participants noted that working with the SMI population helped demystify many stigmas often associated with persons with mental health diseases in their communities. One interviewee summarized, *“They’ve really impacted our lives as well because many times there’s that stigma with mental health where people think they’re just crazy or they’re never going to learn anything... and it is just so far from the truth.] I mean they’ve worked on a research project!”*

Relationships among consumers were also discussed as a program facilitator. Program staff indicated that relationships among consumers strengthened over time, which was described as an unanticipated positive outcome with program recruiting efforts. Summarizing, *“When they first came, nobody wanted to sit with each other. It was kind of like church, everybody wanted to sit in the back. And now, it’s one big*

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

family. Groups check [with each] other and are like, ‘We missed you at class, what happened? What’s going on?’.”

Staffing

Related to communication and relationships, focus group and interview participants also identified staffing as an integral part of TRIP program adoption. Consumer navigators, consumer attendants, and case managers were noted as integral aspects of program implementation. Findings from mid-point interviews show that the addition of consumer attendants—who served as peer-support staff for consumers in transit—emerged from an unmet need for additional peer engagement and support. Interview and focus group participants described several examples of the importance of new hires in summative interviews. Consumers noted the importance of relationship building with these new staff, sharing that, *“When we have a new staff coming in to meet with us, there’s going to be some time for understanding where we’re coming from and then we start understanding where they’re coming from; it’s a natural flow, learning about each other.”*

Flexibility

Flexibility, particularly being able to stay nimble and adapt, was reported as critical to program adoption. This perception was shared among both TRIP staff and consumers. From the perspective of staff, there was a high degree of flexibility required in service delivery to accommodate the needs of consumers. For example, a provider described education initiatives and stressed the importance of flexibility in one’s teaching approach when working with the SMI population, noting, *“you have to be able to do individual, small group, or large groups; it’s about having lots of ways to reach the individual at their comfort level at different times throughout the program.”* From a consumer perspective, flexibility and patience were key to program adoption for program staff and participants, especially during the early stages of implementation. As one focus group participant shared, *“there’s going to be some issues that have to be discussed with the main office at the very beginning; slowly but surely they’re working on setting things right on the spot.”*

Use of Data and Data Systems

Interviewees highlighted data systems as a facilitator to program adoption, specifically, the use of the REDCap database. Participants described REDCap as a tool that improved communication between primary and behavioral health, sharing, *“being in one EMR system streamlined a process that was very cumbersome for [primary care and behavioral health] providers before.”* It is important to note that while some participants referred to the REDCap database as an electronic health system, the software served as a tool to track study data. Only health care providers at partner clinics had access to patient records through an EMR; TRIP staff did not access medical records, nor did they input data using REDCap database.

Interviewees also reported that TRIP leadership devoted resources to expanding the capacity of staff, especially consumer navigators, for data collection efforts. As discussed in detail in later sections, interviewees indicated that medical providers had minimal time to spend with consumers due to time constraints. According to interview participants, the training and re-training of consumer navigators to collect data facilitated program adoption by leveraging time for medical providers to meet with consumers. According to one interviewee, *“Building the capacity to collect data from the navigator standpoint worked really well. [We] created training manuals and worked with them every Friday to build that capacity.”*

Interview participants reported a high degree of engagement with programmatic data that was facilitated by regular data monitoring meetings between TRIP leadership and partners. As one participant shared,

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

“REAL has shown us from day one where we were [with the data] at baseline...year 1, then Year 2. [We] see all the different outcomes.” Focus group participants also exhibited high engagement with data discussions, with several participants indicating being engaged in discussions about quantitative and qualitative data at Pachanga convenings.

Physical Space

The physical proximity of primary and behavioral health services was described as a facilitator to integration by TRIP staff. Interview participants explained that *“warm handoffs”* were frequently used between primary and behavioral providers and often occurred during the same visit. One participant explained that, *“[Services] are down the hall from each other and [we] try to run them simultaneously. We try to put their appointments back to back so that the warm handoff is definitely there whenever there are care issues that cross over the two paradigms.”*

Training, Education, and Staff Capacity

Findings from the summative interviews show that building staff and consumer capacity, particularly via training, was reported as a key facilitator of program adoption, especially during early stages of implementation. These findings were also prevalent in mid-point interviews conducted in December 2016. Interview participants noted that all TRIP staff participated in trainings to clarify roles and responsibilities before and during project implementation. As one participant summarized, *“During the enrollment period, it was really training and retraining to reinforce what the goals [of the project] were.”* Further, interviewees indicated that all TRIP staff participated in mental health first aid training, which was described as a critical resource for building staff capacity to work with the SMI population, especially for drivers and consumer navigators. As previously mentioned, consumer navigators were trained for data collection efforts on a weekly basis to ensure data collection processes were carried out to standard; this was reported as a mechanism to increase time among consumers and health providers.

Education and training were also described as useful for managing expectations among consumers and staff. According to TRIP staff, consumers were requesting services outside of the project scope such as rides to the grocery store or visiting family early on. One participant shared, *“We needed to educate consumers in the whole process of how to get in and out of services in a way that meets the needs of the passenger as well as the coordination of the schedules on our end.”* Staff would initially try and meet these additional requests when possible, but quickly discovered it was hindering efficient work flows, shared interviewees. As one interview participant explained, *“We had to educate the drivers and the consumers through different sessions about how things worked and the different policies we were implementing to iron things out.”* Interviewees noted that drivers were trained to manage these expectations by establishing consistent procedures and messaging.

Adoption Barriers

At the mid-point, interviewees briefly noted several challenges to program adoption, including contracts and reimbursement processes as well as communicating the importance of a rigorous evaluation to partners and consumers. During the summative interviews and focus group discussions, barriers were discussed more in depth. These barriers, discussed in-depth below, included hiring and retaining staff, communication, data systems, and environmental context factors.

Hiring and Retaining Staff

Hiring and staff retention was described as an adoption barrier by both interview and focus group participants; participants indicated limited access to non-medical staff, especially drivers, consumer navigators, and mental health practitioners. Several interviewees explained that challenges retaining and

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

recruiting staff was not limited to the TRIP program, detailing long-time struggles with provider shortages in the area. One interview participant shared, *“Here in South Texas as a whole there is a real shortage of providers, midlevel of all types of providers...mental health providers especially. That’s a real challenge in our area.”*

Focus group participants specified the need for backup staff, noting, *“We need backup, like when we’re ready and the bus driver gets sick, or something happens, we need a backup, so they can come and pick us up, because we’re ready to go.”* Staff echoed this sentiment, explaining that hiring more staff would have alleviated several challenges they faced including the limited scheduling of education classes and backup drivers. Summarizing, an interview participant shared, *“We have certain times of the day where we already have long standing reservations where our capacity is limited for the transportation services that we provide. We just don’t have enough vehicles, and we don’t have enough drivers to increase our capacity.”*

Communication

Communication barriers were mentioned by several interview and focus group participants, who most frequently mentioned transportation logistics as a barrier. Focus group participants reported instances of miscommunication with the main office and dispatch system, explaining, *“sometimes they call us and sometimes they forget [about trip reminders].”* Other focus group participants agreed elaborating that, *“in the very beginning there were certain miscommunications with us and the main office. I’m an individual you have to call and remind, because I don’t remember [on my own].”*

Further, interviewees spoke of the importance of clarifying consumer expectations early on. For example, focus group participants perceived that program expectations had changed, explaining that many assumed travel to specialty care in larger cities would be included in services. However, offering transportation to larger cities was never intended as part of the TRIP program. As such, it was important for staff to communicate in multiple formats with participants to re-iterate what was available through the TRIP program and what requests would need to be referred out.

Interview participants observed that communication needed to be addressed from a consumer perspective as well. As an example, consumers would often cancel trips without advance notification in the beginning of the implementation period, which exacerbated wait times and affected work flows. Program staff, especially navigators and case managers, also described challenges sustaining communication with a highly mobile, hard to reach population. As one interview participant shared, *“This population is especially difficult to keep in one place, much more than I think we thought initially. Finding them throughout the program and following up was harder than we expected.”*

From an organizational perspective, interviewees noted early communication challenges among partners regarding program logistics such as timelines for data transfers and scheduling. These challenges, explained interview participants, were expected when two entities collaborate: *“It’s about different work cultures and basic things that occur when two organizations come together; you know, they have their ideas and we have ours.”* Despite these early challenges, participants indicated that strong relationships facilitated the partners to find solutions by clarifying roles and expectations on a regular basis. Some partners reported meeting more often than others, noting the desire for more frequent opportunities to collaborate, explaining, *“I think we met quarterly just to see kind of where we were at, but it would have been nice just to have more interaction with each other.”*

Data Systems

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Although the electronic health record was described as an asset, interviewees also expressed limitations of the data system. Most notably, several participants perceived that the REDCap database used for TRIP was designed for behavioral health care, and it often limited user interface with tracking primary care outcomes. One interview participant noted, *“the software platform isn’t as amenable to primary care as others, but we’ve managed to find workarounds so that we have a single repository of information, which we felt was critical.”*

In terms of scheduling transportation, several interviewees commented on challenges that arose from the automatic dispatch system. As one interview participant shared, *“when computers started taking over the scheduling, people didn’t know what the schedule looked like because the machines were handling it.”* Focus group participants echoed these sentiments and indicated that transportation reservations were sometimes done by phone, in-person, or through the automatic system, which they reported caused confusion.

Environmental Context

Environmental barriers were reported by several participants, most notably Hurricane Harvey and limited health care access in rural communities. Interviewees explained that the impact of the hurricane varied across the region, affecting some partner organizations more than others. As one interviewee shared, *“our [partner] was on a completely different path because their clinics were closed, and that population’s psyche was impacted in ways it wasn’t here.”* These barriers affected program implementation and work flows, according to interview participants, who explained that routes and resources had to be redirected to account for the closed facilities.

It is important to note that while some expressed concern regarding the impact of the hurricane on study implementation, quantitative implementation data verify that less than 10 observations were impacted during this time. It is likely that the Hurricane was top of mind for some interviewees because of the close timing of the summative implementation interviews preceding the storm.

Further, several interview participants expressed that accessing health care in rural communities was a challenge. One interview participant shared, *“There is very limited availability of physicians and specialty care. That presents challenges for everyone in rural communities...the sheer distance you have to travel to get care.”* This was echoed by other staff participants who reported challenges scheduling efficient trip routes because of the distance between service areas. Despite these environmental challenges, interviewees described the resiliency of the population, noting that *“no matter what, they stood up, shook the dirt off their feet and moved forward. Some of them lost everything but they did not lose their pride and stamina to move forward.”*

Participant Facilitators

In addition to facilitators experienced by staff and providers adopting the TRIP program, focus group and interview participants were also asked to reflect specifically on what facilitated consumer participation in the program. Facilitators that were most frequently mentioned included transportation services, peer relationships, cost, and improved health outcomes.

Transportation Services

Participants described transportation services as a mechanism to enhance access to services that were previously out of reach. Focus group and interview participants indicated that prior to TRIP, consumers had to rely on transportation methods that were cumbersome and unreliable through private companies. One consumer concisely summarized, *“[TRIP] has given us the freedom to move.”* Interview providers

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

echoed this sentiment, adding, *“I can’t emphasize how liberating it is to a person with a mental illness to be able to move. It’s one thing to know the care is out there, but if you can’t get there it doesn’t do any good.”*

Peer Relationships

In addition to patient-staff relationships helping with program adoption, patient relationships with each other were described by focus group participants as facilitating their participation in the program. When consumers were asked what they enjoyed most about TRIP, friendship and camaraderie—between staff and consumers—were the most frequently cited. Focus group participants described enjoying being able to engage with residents in other cities at events like Pachanga convenings. These relationships, shared consumers, reduced social isolation and empowered consumers to live healthier lives. Many noted the importance of camaraderie as it related to health, with one consumer sharing, *“Being able to be among this many people, especially knowing that we all have shared our problems, our disabilities, our needs. It has given me the confidence to start living again.”*

Cost

Focus group and interview participants indicated that TRIP services were free of cost, which was described as a participant facilitator. As one interviewee shared, *“Rather than looking at how many times they can afford to go to the clinic, they can look to their peer groups for support without having to look at their budget to see if it’s feasible for them to make it till the end of the month.”*

Improved Health Outcomes

Consumers noted that improved health outcomes enabled them to participate in various program services including health literacy classes and primary care appointments. The most frequent improved health outcome focus group participants described were depression and weight loss. One focus group participant shared, *“Not only did this program help me understand that my medication is a daily thing I need for the rest of my life, but they also got me off my feet moving. I was constantly in pain...but with the exercise I got I’m mobile again and I can actually move and participate.”*

Participant Barriers

In addition to barriers experienced by staff and providers adopting the TRIP program, focus group and interview participants were also asked to reflect specifically on barriers that consumers experienced to participate in the program. Barriers discussed included transportation services, relationships, cost, patients’ health, and wait times.

Transportation Services

While transportation services were reported as the most highly valued program component of TRIP for Salud y Vida, consumers described challenges related to these services. The most frequently cited barrier included the need for more drivers and vans, especially to account for staff absences due to illness. Staff interviewees indicated that these issues were exacerbated by the rural nature of the region, sharing that, *“So one of our biggest barriers for treatment is obviously transportation because of the rural area we are in and the lack of resources we’re constantly dealing with. We have hired some transporters and peer specialists to help but it is never, never enough.”*

Interview participants expressed that expectations for transportation services were miscommunicated in the early stages of implementation, explaining that many consumers believed TRIP would function as a door-to-door service. As one participant shared, *“The expectation was created that if you have an appointment at 9am, we’ll pick you up at 8:45 and you’d be there five minutes...that’s not the case. [TRIP]*

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

isn't a taxi cab service, it's more like a bus route where you need 5-6 people to gain critical mass to make it work." Further, a few consumers indicated being confused about the roll-out of the automatic scheduling system, noting that there were instances of miscommunication around reminders and scheduling.

Peer Relationships

It was also mentioned by interview and focus group participants that interpersonal relationships between consumers could cause barriers to program participation in addition to facilitating participation. Though this sentiment was not shared by the majority of the group, some consumers explained that it would be important to monitor interpersonal dynamics between participants that could impact program participation. When discussing interpersonal challenges, one consumer explained, *"At the beginning we heard a lot of 'Oh, I don't want to go on the TRIP because so-and-so will be there. It was being able to get around that and understand that everyone will be in each other's space if you want a ride."*

Patients' Health

Patients' health sometimes presented a barrier to participation, according to both consumers and staff. As one focus group participant explained, *"I mean I couldn't get to the doctor a lot of the time. "My arthritis is real bad sometimes, and I get panic attacks, so I can't go to the specialist all the way in Corpus."* Similarly, interviewees shared that patients' physical or mental health prevented them from coming to enhanced integrated services or Pachanga celebrations at times.

Wait Times

Wait times were noted as a participant barrier, specifically as it related to coordinating transportation and medical care. Focus group participants expressed that wait times for transportation can be a disincentive to participation. TRIP consumers explained that pick-up times varied, and drivers would be late or get lost in early stages of the project. According to participants, these issues were largely in part due to unreliable GPS services; participants noted that once drivers were familiar with residential locations and did not have to rely on the GPS, wait-times improved.

Having to wait for peer consumers at their homes when they were unresponsive was also a point of frustration for focus group participants. Focus group participants described waiting long hours at medical appointments, which would then be followed by long transportation routes home. One interviewee explained, *"When you factor in transportation and integrated care, it ameliorates the [wait-time] problem. Because first you're going to see the navigator, then the case manager, then the psychiatrist, then you're taken back to the waiting room to wait another 20 minutes for the primary care doctor. It's a long, long day."*

Question 3c. To what extent do providers and staff buy-in to the TRIP for Salud y Vida program, and how has that buy-in affected implementation?

Staff Buy-In

Program staff and administrative leadership were asked about their support and buy-in for the program as well as their perceptions of their colleagues' buy-in. Interviewees spoke about a culture of empowerment and strong, trusted partnerships that facilitated staff buy-in. While staff indicated a strong buy-in for the program itself, some noted challenges of collecting data from the comparison group.

Interview participants indicated a high degree of staff buy-in from both frontline providers and leadership. In interviews, staff expressed strong support for the program and frequently indicated that it increased

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

access to resources for consumers, which ultimately led to positive health outcomes. Many interview participants in the mid-point and summative evaluations described their work as meaningful and necessary to the community. TRIP staff described having a strong commitment to their work, noting that normal inconveniences such as long commutes between services areas, were worth the reward. Focus group participants echoed this sentiment, reporting that staff genuinely cared about their well-being. Both staff and consumers noted that many interpersonal connections had been established between TRIP staff and consumers, often described as familial. These relationships, shared participants, were established in places like Pachanga celebrations and advisory meetings.

Interviewees also noted a strong level of trust between TRIP partners, expressing confidence that issues could be easily resolved because *“they were determined to make things work no matter what.”* This determination was echoed by frontline staff and leadership alike, who expressed a strong level of buy-in, citing the desire to sustain and scale the efforts. A culture of empowerment was described by many staff participants. One interview participant summarized it sharing, *“What I appreciated about the program is that there is an underlying philosophy that is implemented every day in what we do. The mechanics of that implementation are different in every situation but the energy and the emphasis and that drive stems from the same understanding that we are here to serve and that consumers really do have the ability to change their lives in their own way in reaching their targeted goals.”*

Lastly, interview participants reported challenges collecting data on comparison group patients, expressing concerns about the time burden it took to complete surveys, noting, *“we had several navigators who got very frustrated and had to get really creative in having these individuals participate because they weren’t getting transportation services, they were just filling out assessments and surveys. And our clients, who are schizophrenic, bipolar, and depressed, cannot sit there for an hour and a half and be calm and then be told you’re just part of a survey, you’re not going to get it but thank you for the information.”*

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

The consumers in the comparison group at the Salud y Vida program clinics received usual care as did the consumers assigned to the intervention clinics. This is detailed in **Table 6** and was approved in the original SEP as part of the program. The number of participants impacted by a midpoint program introduction with similar elements at 6-months was reported and adjustments to account for comparison site consumers enrolling in this other program were made. Consumers choosing to enroll in the new program were deemed ineligible for the TRIP for Salud y Vida program (n=15) and were withdrawn.

Table 6. Practices and services the program clinics and external comparison clinic consumers receive as proposed in the SEP

	Intervention Clinics ^a	Usual Care Clinics ^b
	TRIP for Salud y Vida	Project Salud y Vida
Timeline for Collecting Impact Measures		
Baseline	•	•
6 months	•	•
12 months	•	•

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

	Intervention Clinics ^a	Usual Care Clinics ^b
	TRIP for Salud y Vida	Project Salud y Vida
Impact Measures Being Collected		
Blood Pressure	•	•
BMI	•	•
HbA1c	•	•
PHQ-9	•	•
Duke Health Profile	•	•
IBH Components		
Assignment of a navigator and case manager	•	•
Assignment of a consumer attendant	•	--
Home and telephone nurse assessments	•	--
Development of an individualized transportation plan	•	--
Coordination and delivery of transportation services to and from health care appointments	•	--
Delivery (no coordination) of transportation services to and from health care appointments ^c	--	•
Coordination and delivery of transportation services to and from community health and other health care services	•	--
Consumer enrollment in a community-health worker led diabetes self-management education (DSME) for the diabetes subgroup	•	--
Implementation of community based health and disease management classes tailored to consumer needs (i.e., physical activity, self-management education, food and nutrition education)	•	--
^a Alice, Falfurrias and Kingsville clinic sites were the intervention clinics.		
^b Taft and Beeville clinic sites were the comparison clinics.		

In January 2017 MHM provided a grant to Coastal Plains Community Center (CPCC, the IBH clinic overseer and partner for TRIP) to add primary care services at their Rockport and Aransas clinics. These clinics were not part of the SEP approved evaluation; however, the new services led to a change in practice and invitations to Salud y Vida program participants of comparison clinic participants to receive services at these two clinics instead of at their current site (comparison enrollment site). Of those invited, seven participants from the Taft clinic enrolled in the new program.

Question 5: To what extent did REAL, Inc. and partners implement the TRIP for Salud y Vida model with fidelity?

REAL, Inc. and partners implemented the TRIP for Salud y Vida model with a moderate level of fidelity. No show rates for both intervention and comparison group consumers decreased from pre-program levels (25% to 7.5% among intervention consumers and 5.7% among comparison group consumers). Transportation to EIS classes was the primary use of transportation among intervention consumers. Interviewees reported that adjustments to program implementation were made primarily during early program implementation to address intervention consumer needs.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Table 7 presents the number and percent of scheduled and unscheduled visits by consumers in each study group. The show rate for appointments for both the intervention and comparison groups was approximately the same percent, 75.4% for intervention consumers and 76.5% for comparison consumers. Intervention consumers had a higher percentage of walk in and seen visits and no-show visits when compared with comparison consumers.

Consumers at the intervention clinics had a total of 1685 appointments for the TRIP for Salud y Vida program reported. Reasons for not keeping appointments included cancelled by client (8.7%) and cancelled by employee (5.4%). Reasons for cancelled by client included other family demands and timing of appointments conflicting with schedules. Reasons for cancelled by employee included, lack of provider availability and service rescheduling at clinic site. Consumers at the comparison clinics had a total of 1080 appointments for the Salud y Vida program reported. Reasons for comparison group participants not keeping appointments included cancelled by client (10.8%) and cancelled by employee (5.5%). Reasons for cancelled by client across both intervention and comparison clinics included other family demands and timing of appointments conflicting with schedules. Reasons for cancelled by employee included, lack of provider availability (specifically Falfurrias site – intervention clinic) and service rescheduling at clinic site.

The reported missed appointment rate due to no-shows at the start of the program was over 25% at the clinics, the changes indicate a positive trend in improvement of appointment attendance.

Table 7. Number of scheduled and unscheduled visits completed by group

Appointment Outcome	Total		Intervention		Comparison	
	Count	Percent	Count	Percent	Count	Percent
Scheduled and Seen	2350	76%	1270	75.4%	1080	76.5%
Walk in and Seen	72	2.3%	51	3.0%	21	1.5%
Cancelled by Client	299	9.6%	146	8.7%	153	10.8%
No Show	210	6.7%	127	7.5%	83	5.7%
Cancelled by Employee	168	5.4%	91	5.4%	77	5.5%
TOTAL APPOINTMENTS	3099		1685		1414	

Table 8 provides the transportation utilization by purpose of the transportation for the intervention group consumers. The highest percentage of trips were for education (51.1%) and medical purposes (26.3%). Additional transportation purposes included shopping, work, and adult day care.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Table 8. Transportation Utilization by Purpose in the Intervention Group

Purpose	Number of Trips % (N)	Total Miles	Median Miles per Trip	Interquartile Range	Minimum	Maximum
Education	51.12% (8158)	104470	6	2 to 28	0	111
Medical	26.35% (4205)	54532	6	2 to 23	0	84
Shopping	1.32% (210)	1206	1	1 to 3	0	75
Work	5.22% (833)	21607	38	3 to 38	0	163
Adult Day Care	0.04 % (6)	81	5	0 to 35	0	36
Business	0.73% (117)	1168	2	1 to 9	0	80
Home	8.87% (1415)	21733	8	2 to 30	1	76
Visiting	0.10% (16)	225	2	1 to 35	0	41
Bank	0.04% (7)	133	1	1 to 36	1	80
Other	6.21% (991)	18937	23	2 to 32	1	73

For purposes of the TRIP for Salud y Vida program each transportation request and trip was recorded in the Shah Transportation Manager software. For each trip, the purpose of the transportation request was recorded to better identify the types of trips needed to examine sustainability. Trips at REAL, Inc. are defined as one-way transportation to an event; therefore, round-trip transportation is counted as two trips with return to home. TRIP transportation was defined as presented in **Table 9**.

Table 9. Purpose and Definition of TRIP transportation

Purpose	Definition
Education	Attendance at TRIP for Salud y Vida EIS sessions.
Medical	Integrated behavioral health appointments or other doctor appointments.
Shopping	Grocery shopping or other shopping related needs.
Work	Employment related trips.
Adult day care	Attendance at adult day care services.
Business	Needs related to personal business needs including insurance, social security or other office visits.
Home	Usually one-way transport from a specific location and not coded as round-trip requests.
Visiting	Family and other relative time including visits to hospitals or other locations.
Bank	Personal banking needs.
Other	Range of personal related transit needs.

Program Fidelity

Participants were asked to describe the extent to which program services changed or stayed the same from what was originally planned. According to interviewees, the TRIP program was implemented to a moderate degree of fidelity, with adaptations being considered and implemented based on patient and provider feedback. As one TRIP staff person shared, *“There were minor issues that we kind of adapted based on feedback as we went along, because there was always a feedback loop with the participants themselves.”* At the mid-point interviews, an example of these slight modifications included the addition of Pachangas [quarterly gatherings] and consumer attendants that emerged from a need for more peer

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

support and engagement. In the summative interviews, structural adaptations mentioned included adjusting work flows to account for long wait times and re-routing trips that were not time efficient.

Interview participants also reported adaptations to the enhanced service component of the program. The most cited adaptations included modifying class topics and frequency to meet the demands of consumers, schedule and location adjustments to facilitate maximum participation, and varied teaching methods to account for the needs of the SMI population. For example, interviewees indicated that class times were originally scheduled early mornings, which made it difficult for consumers to attend. Based on consumer feedback, TRIP staff adjusted class times to later in the afternoon to maximize participation. It was also noted in both the mid-point and summative interviews that consumers wanted time to network and attend classes in neighboring towns, which led to slight schedule adjustments and restructuring.

These adaptations were reported as mostly positive by focus group and interview participants. While focus group participants agreed that adapting was an important component to program success, they also emphasized the importance of consistency, sharing that, *“My main thing is consistency...I know we have to try different things to see what works for everyone, but what works, you should leave alone.”* This sentiment was reported for both the structure of the program and the staffing, with participants noting changes in TRIP staff and providers.

Question 6: How satisfied are TRIP for Salud y Vida patients with the services they have received? How satisfied are providers with the TRIP for Salud y Vida program? [Note: health care providers were not interviewed in the summative evaluation interviews. As such, provider satisfaction is discussed in response to question 3c, but through the lens of administrative leadership.]

Participant Satisfaction

Focus group and interview participants were asked about their overall satisfaction with the TRIP for Salud y Vida program. Consumers who participated in focus groups in the mid-point and summative evaluation were overwhelmingly satisfied with the TRIP program, citing improvements in accessing resources, health literacy, relationships and ultimately health outcomes, as factors that contributed to their satisfaction. According to participants, there were little to no community-based opportunities to engage the SMI population prior to the TRIP program. Having the opportunity to socialize in community settings without being stigmatized, shared participants, were major components to participant satisfaction.

Services Provided

TRIP consumers spoke highly of the quality and quantity of integrated services provided through TRIP, specifically citing nutrition classes, social activities, chronic disease management classes, and intramural sports, as especially beneficial. Apart from health-related programming, consumers appreciated opportunities to socialize, identifying events such as bowling, art, and Pachanga convenings. In terms of service improvement, consumers indicated the desire for more provider options sharing, *“I’d like to see a choice of doctors, both psychiatrists and medical doctors. I would like to be able to actually go to the medical doctor, rather than the nurse practitioner and have a choice.”*

In terms of enhanced community-based services, focus group participants reported a high-degree of satisfaction with the quality of services offered. Focus group participants indicated that classes were engaging and allowed time for community building amongst participants. It was also noted that having classes across geographic locations and at local colleges added an additional level of relationship-building and legitimacy, which consumers valued. As one staff participant shared, *“Having the classes at local colleges, on actual college campuses, was very empowering [for consumers].”* Both interview and focus

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

group participants mentioned a “*graduation ceremony*” that was hosted at the local college, as a meaningful experience for both program staff and consumers.

Health Literacy

Enhanced IBH services were seen as increasing health literacy and being a significant contributor to consumer satisfaction. Focus group participants indicated having a deeper understanding of managing chronic diseases such as diabetes because of these services and spoke often about the importance of healthy eating and exercise. One patient shared, “*With their instruction, we’ve learned about our bodies and what affects us, what one can or cannot do. We know how to improve what to ask and how to read your own medical charts and blood tests.*” Further, focus group and interview participants described several instances where peers would assist with explaining health-related materials and demonstrating exercises. One staff summarized, “*they have really been promoters of their own health.*” Apart from health literacy, focus group participants described an understanding of evaluation and research, mentioning participating in classes that focused on data collection and analysis.

Improved Health Outcomes

Participants identified perceived improvements in health outcomes as a reason for program satisfaction. According to focus group participants, the enhanced integrative services, as well as the improved health literacy, led to perceived improvement in health outcomes, both chronic disease and mental health. More specifically, interview and focus group participants observed improved health outcomes in the form of weight loss, improved A1C and blood pressure, personal appearance and hygiene, and pain management. For example, one patient said, “*before [TRIP], I couldn’t move, was constantly in pain, couldn’t kneel, couldn’t sit on the floor...the program changed that for me. The exercises like water aerobics got me mobile and moving again.*” Others indicated improved adherence to medication and treatment plans, which consumers explained lowered the likelihood of hospitalizations and emergency room utilization.

Staff

In terms of staff, consumers reported a high-degree of satisfaction with TRIP personnel, noting that providers were well-informed and nonjudgmental, with many consumers reporting that they felt comfortable asking questions. Participants explained that TRIP services were less intimidating than going to a doctor, sharing, “*You go to the doctor and there’s always this level, it feels like a level of intimidation, and then you never remember what to ask or what they thought.*” However, some focus group participants indicated being less satisfied with medical providers, citing a need to improve culturally-relevant care between behavioral health providers and consumers. Consumers also noted that they would like more variety in providers, so they would have greater provider choice, when possible.

Additional Implementation Findings

In addition to answering the a priori implementation questions presented in the SEP, the qualitative implementation evaluation yielded findings related to perceived success and impacts, sustainability, and lessons learned from the TRIP program. The following outlines key themes that emerged during the interviews and focus groups not directly examined by the implementation research questions outlined above but that are still valuable to provide context for the program.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Perceived Program Successes and Impact

Focus group and interview participants were asked about their perceptions of program success. Both groups identified the program's impact on consumers' mental health, health literacy, and chronic disease management. Interview participants also shared successes related to building staff capacity.

Mental Health

Focus group participants, as well as program staff and providers, spoke of the program's perceived impact related to patients' mental health, which included improvements to quality of life and socialization. Focus group participants in the mid-point and summative evaluations described increased motivation and independence, with many sharing examples of how the TRIP program helped empower them to take control of their health. As one focus group participant shared, *"When your motivation is higher than it was at the beginning, then you go more and more and more. You get comfortable, and you feel better on the inside, and it shows on the outside."*

Improved socialization was reported as a perceived program success. As previously mentioned, TRIP consumers reported highly valuing the friendships and camaraderie that were facilitated by the program. Interview and focus group participants described examples of peers motivating and learning from each other. One interviewee explained, *"We have seen them [consumers] grow and continue to grow into this well-rounded person because they interact, and they feel for each other."* Another interviewee added, *"It's been a total turnaround since we've begun the program...I've definitely noticed an improvement in the consumer's health, their attitudes, and their willingness to socialize with one another."*

Health Literacy

As discussed related to participant satisfaction, the TRIP program—specifically the educational classes—were perceived as increasing health literacy of consumers. Focus group participants indicated a deeper understanding of managing chronic diseases such as diabetes and spoke often about the importance of healthy eating and exercise. One patient shared, *"I've been borderline diabetic since I started going to the doctor in '99, but nobody ever explained to me what that meant. Yet with [TRIP's] instruction, we've learned about our bodies and what affects us, what one can or cannot do."*

Chronic Disease

Consumers and staff alike discussed how the enhanced integrated services, in addition to health literacy, also resulted in improved chronic disease management and outcomes for consumers. Many interview and focus group participants shared success stories of consumers learning about and managing their diabetes, losing weight, and lowering their blood pressure and cholesterol. As one focus group participant detailed, *"I was on insulin, and now I'm not. I lost over 30 pounds and I went from a size 16/18 to a size 9/10."*

Staff Capacity

Staff described increased confidence and motivation working with the SMI population in the mid-point and summative interviews. According to interviewees, one of the successes of the TRIP program was that it built capacity among staff to implement integrated behavioral health as well as engage with the SMI effectively. Interviewees shared that staff learned new information and skills, such as mental health first aid and different teaching approaches. One interviewee shared, *"I think [the staff's] personal growth...I've been really impressed because you have navigators who have been there a long time and new navigators and they learned different things from data collection to communicating with consumers differently. They've all learned a lot and really grown."*

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Sustainability and Lessons Learned

Overall, interviews with TRIP staff as well as consumer focus groups, indicated that implementation of the TRIP program has been successful. Several lessons learned and opportunities for improvement emerged and focused on funding, program replication and scalability, the policy environment, and staffing.

Funding

When asked about sustainability and lessons learned, funding was top of mind for many interview participants. TRIP staff described how the funding landscape presented challenges to providing medical care, especially for the indigent and mentally ill. In both the mid-point and summative findings, interviewees highlighted the realities of needing funding to sustain IBH implementation, which according to TRIP staff, was even more challenging due to the rural nature of the region. As one interview participant explained, *“There is no strong philanthropy giving privately in these rural areas...we live in a funding desert.”*

In terms of clinical care, TRIP partners explained that funding constraints minimized the amount of time providers could engage with consumers, citing pressures to schedule upwards of twenty-five appointments each day. As one interviewee shared, *“We can only really afford to give the smallest increment of care because we are uncompensated for 70% of the care we give.”* According to interviewees, this meant that consumers generally spent less than 15 minutes per visit with their provider, making it difficult to establish patient-provider rapport. Focus group participants echoed these sentiments and indicated having a stronger rapport with ancillary staff, including case managers and navigators, who could spend more time with consumers to coordinate care and fact-find. For these reasons, interview participants suggested expanding ancillary services when possible.

Program Replicability

Interview and focus group participants shared hopes for scaling and replicating the TRIP program in other rural communities. According to focus group participants, consumers would benefit from more integrated health classes and schedule adjustments that included offering services in the evenings and on weekends. Suggestions were also made to include more outdoor activities, including gardening and golfing. Consumers shared technical suggestions to improve transportation services moving forward that included: expanding seat size for larger consumers, reducing noise level for consumers who are noise-sensitive, working air conditioners, and proper equipment for lifting wheel chairs into vehicles.

TRIP staff acknowledged that the Sí Texas program could be leveraged to scale and fund sustainability efforts in the future. Specifically, interview participants suggested using TRIP data for grant proposals that could sustain efforts moving forward. One interviewee shared, *“I think there’s an opportunity to take the information and the data and look at it from different ways...from transportation, to the different education offerings, to the program itself.”* Interview participants stressed that scaling and replication efforts should be consumer-driven and culturally relevant.

Referencing the funding constraints described previously, interviewees stressed the importance of collaboration and partnership to extend limited resources in scaling and sustainability efforts. When asked what advice they would share with someone attempting to scale the program, one interviewee shared, *“I would try to get as many individuals in the community, stakeholders, as possible to assist with the program to help stretch that dollar as far as you can.”*

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Cost

While the TRIP program and transportation services were free of charge, participants noted a desire for other subsidized services that were not available as part of the program; most notably, participants mentioned the need for affordable transportation options to get to larger cities like Corpus Christi or McAllen. Several explained that a longstanding challenge in rural communities has been accessing specialty care in larger cities. Participants mentioned that while some resources were available to travel longer distances to specialty care, they were expensive, which often made these services inaccessible. One interviewee shared, *“The horrible burden that we ended up having to say ‘gosh we don’t have funding to take you to your specialist, this isn’t covered through this program. We weren’t expecting that.’”* Though this need was not intended to be addressed through the TRIP program, it was suggested that future efforts could consider expanding TRIP’S service area to improve access to specialty care.

Health Care Policy Environment

When asked about sustaining IBH efforts in the area, interview participants frequently explained that the health care policy environment was closely tied to funding. According to interview participants, Texas did not expand Medicaid, which has affected reimbursement structures and restricted the ability to sustain integrated services. Interviewees commented on the challenging nature of providing care for the indigent and mentally ill in the state of Texas, despite compelling evidence of cost-savings programs. As one interview participant summarized, *“Probably nowhere else is the 1115 waiver so important in terms of indigent care as in the state of Texas because of a lack of an expansion of Medicaid. That speaks to issues in terms of sustainability because, if this money goes, the whole ballgame goes, which is sad because we’ve [demonstrated] how well this care can keep people out of the ER.”*

It was also noted that the state invests minimal funding in preventative measures; interviewees explained that mental health centers across the state are only allowed to treat the chronically and persistently ill. One interviewee described, *“Consumers have to be chronically and persistently ill before we can see them, with no preventative piece in mind.”*

Staffing

Focus group and interview participants shared numerous lessons learned and opportunities for improvement around staffing. Hiring more staff to meet demand—specifically drivers, consumer navigators, consumer attendants and case managers—was among the most frequently cited staffing suggestion. Another suggestion included re-structuring staffing assignments to employ contract peer specialists on a full-time basis. These additional personnel, shared interviewees, should reflect the community and share common experiences with consumers. As one interviewee described, *“Who better to have than people who have been in recovery, who teach classes, who are clients themselves but have gone through the recovery process and are stable.”* While interviewees mentioned that it was helpful to have specific staff responsible for coordinating care, it would also be beneficial to have more regular engagement between partners, providers, and frontline staff of community-based services.

Interviewees noted that these staffing issues were especially problematic in rural communities, which were described as provider shortage areas. The problem was exacerbated, shared interviewees, by stringent protocols to hire licensed employees. One interview participant explained, *“The [state] has made it to where we can’t employ para-professionals. The only person who can bill is a licensed, bachelor’s level individual.”* The suggestion to consider para-professionals (e.g., low- to mid-level providers) for coordination roles was mentioned to alleviate this limitation.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

IMPACT STUDY: APPROACH AND METHODS

Overview of Impact Study Design

The TRIP for Salud y Vida evaluation aimed to target a moderate level of evidence based on quasi-experimental evidence supporting the benefit of collaborative care components among the SMI population. The study hypothesized that individuals who participated in TRIP for Salud y Vida would have improved health outcomes (e.g. primary outcome: high blood pressure) as a result of enhanced integrated services and systematic and seamless offering of transportation as part of the IBH model in the five-county rural service area. No significant changes to the approved SEP were made. However, we did not have quality data metrics to assess questions 6 and 7 of the approved SEP.

TRIP for Salud y Vida built upon the existing IBH Project Salud y Vida, which was informed by key elements of the validated Wagner collaborative-care model for effective chronic illness care. This model features an organized delivery system linked with complementary community resources, sustained by productive interactions between multidisciplinary care teams and “activated” or educated patients and their families (E. H. Wagner, 1998). A meta-analysis conducted by Woltmann et al. (2012) determined that collaborative chronic care models produce “significant effects across disorders and care settings for depression as well as for mental and physical quality of life and social role function.” The TRIP program added key components built to activate patient engagement and promote health outcomes.

A QED study was chosen as it provides rigorous estimates of the impact of TRIP for Salud y Vida on participant health measures in the SMI consumer population and specific subgroups. It is recognized that a QED is not as rigorous as a randomized control trial (RCT). A quasi-experimental approach can estimate program impacts by comparing the outcomes of consumers who received the intervention to the outcomes of consumers who did not receive the intervention and are observationally equivalent to those who do. While the controlled, experimental design is the ideal, statistically, when an experiment is not possible or practical, the best approach is to eliminate threats to validity through the implementation of a quasi-experimental approach (Gall, Borg, & Gall, 1996). This evaluation used an external comparison group. An external comparison group allows for the examination of observed improvements in the intervention group as they relate to patients who use a different clinic with similar demographics and disease characteristics. The QED did not sufficiently account for threats to internal and external validity to support the targeted moderate level of evidence; a preliminary level of evidence is determined with key changes within the intervention group (diastolic blood pressure and Duke Health Profile) and between the intervention and treatment groups at 12-months (PHQ-9 and multiple Duke Health Profile domains).

A true randomized controlled trial design was not possible for the evaluation of the TRIP for Salud y Vida program due to the clinic practices, the community/patient advocacy group suggestions and the implementation of the TRIP for Salud y Vida program clinic wide at the three intervention clinics. In addition, the TRIP for Salud y Vida partners managed both intervention and comparison site clinics. The intervention and comparison site clinics were chosen purposely to ensure the assessment of the TRIP for Salud y Vida program was compared to the existing Project Salud y Vida program only (containment of threats to validity and bias within the intervention clinics).

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Impact Study Design and Methods

Study Design – QED

A quasi-experimental design (QED) was used to estimate the impact of Trip for Salud y Vida on the participant measures described below. A QED approach can estimate program impacts by comparing the outcomes of program participants (intervention group clinics in the TRIP program) to the outcomes of non-participants who are observationally equivalent to program participants (comparison group clinics). Consumers enrolled in the study completed baseline, 6-month and 12-month assessments. All efforts to collect assessments during the time frames to ensure appropriate time across groups. This report also describes how the sample recruited for the study reflects the original Salud y Vida program population presented in the approved SEP.

The TRIP for Salud y Vida program impact was evaluated by examining the impact of program services on patients' blood pressure – systolic and diastolic (primary confirmatory outcome), HbA1c, BMI, depression, quality of life, dietary habits, physical activity, health literacy, and appointment keeping—as measures of overall improvement in these scores and values (exploratory outcomes). Quantitative data related to participation in the approved program activities is also reported in this report (see Implementation Evaluation section). There were no deviations in the study design from the approved SEP protocols other than metrics for impact questions 6, 7 and 10 were not collected.

Assessment of Baseline Equivalence

At baseline, sociodemographic characteristics of current Project Salud y Vida consumers by clinic were analyzed for both intervention and comparison clinics using a standardized set of questions used by the CPCC program. **Table 10** presents tests of baseline equivalence for demographic measures of the intervention and comparison groups. These demographic questions were used to create a REDCap based demographic questionnaire (see **Appendix J: TRIP for Salud y Vida Enrollment and Baseline Assessment Form**). To assess baseline equivalence between the intervention and comparison groups we analyzed sex, age, ethnicity/race, insurance status, household income and education level. Baseline sociodemographic data were collected for all program participants at enrollment. The CPCC codes the type of SMI, however, as a program the TRIP partners did not approve the coding of the individual level consumer primary SMI condition (e.g., schizophrenia, major depressive disorder or bipolar disorder); 100% of the population has a diagnosed SMI which was confirmed by the study team through review of electronic health record coding (see approved SEP).

Table 10. Tests of Baseline Equivalence for Demographic Measures: Intervention and Comparison Groups

Measure	Full Sample (n=552)		Intervention (n=302)		Comparison (n=250)		p-value
	N	%	N	%	N	%	
Gender							
Male	196	36.0	107	35.9	89	36.2	0.95
Female	348	64.0	191	64.1	157	63.8	
Missing	8	--	4	--	4	--	

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Measure	Full Sample (n=552)		Intervention (n=302)		Comparison (n=250)		p-value
	N	%	N	%	N	%	
Ethnicity							
Hispanic	388	71.3	256	85.9	132	53.7	<0.001
Non-Hispanic	156	28.7	42	14.1	114	46.3	
Missing	8	--	4	--	4	--	
Race^a							
White	521	95.8	290	97.3	231	93.9	0.23
Black	20	3.7	8	2.7	12	4.9	
Asian	1	0.2	0	0.0	1	0.4	
Native American	1	0.2	0	0.0	1	0.4	
Other	1	0.2	0	0.0	1	0.4	
Missing	8	--	4	--	4	--	
County of Residence^a							
Kenedy	2	0.4	1	0.3	1	0.4	<0.001
Brooks	48	8.8	48	16.1	0	0.0	
Duval	30	5.5	30	10.1	0	0.0	
Jim Wells	110	20.2	110	36.9	0	0.0	
Kleberg	105	19.3	105	35.2	0	0.0	
San Patricio	101	18.6	3	1.0	98	39.8	
Bee	107	19.7	1	0.3	106	43.1	
Aransas	28	5.1	0	0.0	28	11.4	
Live Oak	13	2.4	0	0.0	13	5.3	
Missing	8	--	4	--	4	--	
County of Service							
Bee	122	22.4	0	0.0	122	49.6	<0.001
Brooks	55	10.1	55	18.5	0	0.0	
Jim Wells	133	24.4	133	44.6	0	0.0	
Kleberg	110	20.2	110	36.9	0	0.0	
Taft	124	22.8	0	0.0	124	50.4	
Missing	8	--	4	--	4	--	
Age							
≤ 34	100	18.4	62	20.8	38	15.4	0.60
35-44	125	23.0	67	22.5	58	23.6	
45-54	200	36.8	106	35.6	94	38.2	
55-64	107	19.7	56	18.8	51	20.7	
65+	12	2.2	7	2.3	5	2.0	
Mean	45.2	--	44.6	--	45.9	--	
SD	11.7	--	12.1	--	11.1	--	
Missing	8	--	4	--	4	--	

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Measure	Full Sample (n=552)		Intervention (n=302)		Comparison (n=250)		p-value
	N	%	N	%	N	%	
Employment Status^a							
Unemployed		77.9		74.6		81.6	0.12
Employed Full-time		21.9		25.0		18.4	
Other		0.2		0.4		0.0	
Missing		28		22		6	
Marital Status							
Married	116	21.9	54	18.6	62	25.9	0.12
Single	228	43.1	135	46.6	93	38.9	
Divorced	121	22.9	69	23.8	52	21.8	
Separated	64	12.1	32	11.0	32	13.4	
Missing	23	--	12	--	11	--	
Annual Household Income^a							
Less than \$10,000	383	70.4	214	71.8	169	68.7	0.08
\$10,001 - \$20,000	114	21.0	60	20.1	54	22.0	
\$20,001 - \$30,000	23	4.2	10	3.4	13	5.3	
\$30,001 - \$40,000	11	2.0	6	2.0	5	2.0	
\$40,001 - \$50,000	3	0.6	0	0.0	3	1.2	
\$50,001 - \$60,000	1	0.2	1	0.3	0	0.0	
\$60,001 - \$70,000	1	0.2	1	0.3	0	0.0	
Greater than \$70,001	2	0.4	0	0.0	2	0.8	
Refusal	6	1.1	6	2.0	0	0.0	
Missing	8	--	4	--	4	--	
Primary Language							
English	535	98.3	292	98.0	243	98.8	0.47
Spanish	9	1.7	6	2.0	3	1.2	
Missing	8	--	4	--	4	--	
Education^a							
3 rd Grade	3	0.6	3	1.0	0	0.0	0.13
5 th Grade	6	1.2	3	1.0	3	1.3	
6 th Grade	2	0.4	2	0.7	0	0.0	
7 th Grade	12	2.3	5	1.7	7	3.0	
8 th Grade	32	6.1	17	5.9	15	6.4	
9 th Grade	50	9.6	25	8.7	25	10.7	
10 th Grade	45	8.6	29	10.1	16	6.9	
11 th Grade	39	7.5	23	8.0	16	6.9	
12 th Grade	88	16.9	50	17.4	38	16.3	
GED	102	19.6	63	22.6	69	15.9	
Some College	132	25.3	63	21.9	69	29.6	
BA/BS	7	1.3	3	1.0	4	1.7	
None	3	0.6	0	0.0	3	1.3	
Missing	31	--	14	--	17	--	

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Measure	Full Sample (n=552)		Intervention (n=302)		Comparison (n=250)		p-value
	N	%	N	%	N	%	
Household Size^a							
1	299	55.0	161	54.0	138	56.1	0.28
2	96	17.6	52	17.4	44	17.9	
3	57	10.5	30	10.1	27	11.0	
4	52	9.6	27	9.1	25	10.2	
5	22	4.0	13	4.4	9	3.7	
6	12	2.2	10	3.4	2	0.8	
7	4	0.7	4	1.3	0	0.0	
8	1	0.2	1	0.3	0	0.0	
9	1	0.2	0	0.0	1	0.4	
Missing	8	--	4	--	4	--	
Veteran Status^a							
Yes	8	1.5	7	2.3	1	0.4	0.06
No	536	98.5	291	97.7	245	99.6	
Missing	8	--	4	--	4	--	
Health Insurance Status^a							
Not Insured	397	73.0	210	70.5	187	76.0	0.44
Insured	20	3.7	13	4.4	7	2.8	
Medicare	34	6.3	20	6.7	14	5.7	
Medicaid	91	16.7	53	17.8	38	15.4	
Other	2	0.4	2	0.7	0	0.0	
Missing	8	--	4	--	4	--	

Note: ^aCells have expected count less than 5

As noted, statistically significant differences between the intervention and comparison sites were found in the following variables. County of service and county of residence were found to be statistically different between the intervention and comparison sites. Given the rural service area, the clinic settings serve clients from various counties; for example, the Jim Wells (Alice clinic) serves clients from Duval and other areas; the differences do not represent selection but rather are random between the two groups given the designated service areas. Specifically, clinic sites are designated service providers to specific counties, therefore the chance of any contamination between the groups remains minimal as this is the practice across all of the CPCC clinics. In addition, the large rural service area does not allow for clinical services at each county. Given that some categorical variables had levels with very low frequency counts: e.g., see income distribution in the tables above. We made preliminary judgments about collapsing and recoding these categorical variables for our analyses.

Although demographic differences were found between the intervention and control groups these were statistically significant differences associated to: 1) location and clinic service area designations for patient care services and 2) rural setting. Given the findings from tests of equivalence at baseline all impact analyses were conducted controlling for demographic and clinical covariates.

When using continuous variables, we see that the intervention and internal comparison groups were statistically different at baseline for variables except for BMI, HbA1c and BRIEF Health Literacy Measures.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Intervention group consumers had statistically significantly higher diastolic and systolic blood pressure readings at baseline, 2017 Guidelines for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults (Whelton et al., 2018). Although differences in the continuous diastolic blood pressure variable were found to be statistically significant, these differences are not clinically different. In other words, intervention and comparison group consumers were both in the same clinical diagnostic category for systolic and diastolic blood pressure. For PHQ-9, intervention group consumers had statistically significantly, but not clinically different lower scores; and, for Quality of Life measure of general health, intervention group consumers had statistically significantly higher, but not clinically different (same levels of risk across both groups), scores than comparison group consumers (**Table 11**).

Table 11. Tests of Baseline Equivalence for Impact Measures: Intervention and Comparison Groups

	Full Sample	Intervention v. Comparison		
	Mean (SD)	Mean (SD)	Mean (SD)	p-value
BMI	34.1 (8.8)	34.3 (9.4)	33.9 (8.0)	0.54
BP -Systolic	129.6 (18.9)	131.9 (17.3)	127.0 (20.5)	0.004
BP -Diastolic	80.6 (12.0)	82.3 (11.2)	78.6 (12.5)	<0.001
PHQ-9	14.2 (6.6)	13.5 (6.5)	14.9 (6.6)	0.01
Duke Health Profile	40.8 (19.9)	43.1 (20.3)	38.0 (19.0)	0.003
Non-Parametric Tests ^a		Median (Variance)	Median (Variance)	
HbA1c	5.8 (4.1)	5.8 (3.9)	5.8 (4.4)	0.14
BRIEF Health Literacy	13.0 (21.8)	14.0 (21.2)	12.0 (22.7)	0.35

Note: Bold denotes significance of p-value ≤ 0.05 with 95% confidence

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

Tests of Equivalence at 12-months

There were significantly more Hispanics enrolled at the intervention sites at baseline: 85.9% (250/291) for the intervention sites compared to 54.3% (134/247) for the control sites. In addition, consumers at the intervention sites were more likely to have at least some high school or high school/GED degree than participants enrolled at the intervention sites (overall p-value = 0.021). Both of these demographic differences were expected given the population and region and are consistent with the baseline demographic differences reported above.

Table 12. Logistic model comparing sociodemographic and clinical characteristics

	OR	STD. ERR.	Z	P>Z	[95% CI]	
Age at Enrollment	1.00	0.01	-0.26	0.793	0.97	1.02
Household Size	1.15	0.10	1.56	0.118	0.97	1.37
Female	1.04	0.28	0.14	0.887	0.61	1.77
Hispanic	4.29	1.27	4.91	0.000	2.40	7.67
Education						
Some HS	1.74	0.71	1.37	0.169	0.79	3.86
High School/GED	1.52	0.51	1.25	0.212	0.79	2.95
Some College or Higher	1.18	0.41	0.47	0.640	0.59	2.33
\$10,001-\$20,000	0.97	0.32	-0.09	0.928	0.51	1.84
over \$20,000	0.54	0.28	-1.18	0.237	0.20	1.49
Uninsured	0.42	0.18	-2.05	0.041	0.18	0.96
Medicaid	0.53	0.28	-1.21	0.227	0.19	1.48

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

	OR	STD. ERR.	Z	P>Z	[95% CI]	
Employed	1.61	0.51	1.49	0.136	0.86	3.00
Diabetic	0.71	0.19	-1.27	0.203	0.41	1.21
BMI	1.00	0.01	0.24	0.810	0.98	1.03
Systolic Blood Pressure	1.01	0.01	1.11	0.267	0.99	1.03
Diastolic Blood Pressure	1.00	0.01	-0.26	0.792	0.97	1.02

We used logistic regression to compare sociodemographic and clinical characteristics between intervention and control sites to account for the correlations among the measures and the type I error rate for the collection of comparisons (**Table 12**). We had complete data for all variables to compare sociodemographic and clinical characteristics between intervention and control sites on $N = 322$ consumers at 12-month follow-up. There were significantly more Hispanics enrolled at the intervention sites at 12 months: 87.2% (184/221) for the intervention sites compared to 57.6% (70/165) for the control sites. The relative proportions at 12 months were similar to those at baseline. While participants at the intervention site continued to appear to have more education than those at the control sites, the difference was not statistically different at the 12-month assessment. Although the participants at the intervention sites appear less likely to be uninsured than in the 12-month sample. The overall effect for insurance was not statistically significant ($p = 0.227$)

Propensity Score Matching. Propensity score matching was added following the SIF evaluation feedback and approved for use in the SEP, however, given the use of intervention and comparison clinics, the original Salud y Vida program inclusion criteria and the 100% SMI population we did not complete the suggested propensity score matching from our SEP review for these analyses (Cepeda, Boston, Farrar and Strom, 2003). Although propensity score matching is suggested for large population studies, the quasi-experimental design as well as the inclusion of the 100% SMI population and the variation on demographics due to the rural area served by the intervention and comparison group clinics were not appropriate for completing the method (King, 2019). Therefore, we opted to include the critical sociodemographic and clinical variables in our mixed-effect models recognizing that the demographic and clinical differences between the groups at baseline would diminish our ability to disentangle the impact of the intervention. To account for the baseline differences we also modeled baseline as a dependent variable to account for baseline differences rather than a covariate to provide a more robust assessment of the impact of the intervention. This is the most widely recommended approach in current practice.

Intervention & Comparison Group Conditions

Intervention group participants at the intervention group clinic sites (Alice, Falfurrias and Kingsville) received the expanded IBH Model, TRIP for Salud y Vida, which includes the following eight enhanced integrated services, (1) assignment of a navigator and case manager; (2) assignment of a consumer attendant; (3) home and telephone nurse assessments; (4) development of an individualized transportation plan; (5) coordination and delivery of transportation services to and from health care appointments; (6) coordination and delivery of transportation services to and from community health and other health care services; (7) consumer enrollment in a community-health worker led diabetes self-management education (DSME) for the diabetes subgroup and (8) implementation of community based health and disease management classes tailored to consumer needs (i.e., physical activity, self-management education, food and nutrition education). The enhanced integrated services were designed to improve consumers' self-management, health literacy skills, quality of life, adoption or sustaining of healthy behaviors, such as improved nutrition choices and exercise habits and appointment keeping.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Consumers at the comparison clinics (Beeville and Taft) received usual clinic care and IBH components that are part of the current Project Salud y Vida. If a consumer consented to participate in the study, data was collected, and the patient continued with their regular clinic visit. Comparison group consumers received usual care as provided at the clinics and had the opportunity to participate in Project Salud y Vida (if they are not already participating). Aside from visits with a primary care provider, the comparison clinics offers, as part of Project Salud y Vida, in-clinic diabetes education. It should be noted that at the consumer request, Project Salud y Vida consumers at the two comparison clinics can receive coordination and delivery of transportation services to and from health care appointments only. As discussed in the logic-model section, the services provided as part of TRIP for Salud y Vida are unique to TRIP for Salud y Vida consumers except for the assignment of a case navigator and a case manager—both TRIP for Salud y Vida (intervention) and Project Salud y Vida (comparison) consumers are provided with this service as part of the original Salud y Vida program.

Of utmost importance is the fact that 100% of the sample at both the intervention and comparison sites will have a diagnosis of serious mental illness (SMI). No changes to the approved SEP were made. The clinics ran parallel systems that include shared programming and EMRs. The comparison clinic site selection process and clinic demographics for current Project Salud y Vida consumers were maintained as approved.

Study Sample

The following section describes the final data on enrollment and retention, composition of the study characteristics, and baseline equivalence of the intervention group and the comparison group. 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. A patient flow description is presented in **Figure 1. Patient Flow Diagram** below.

Study Sample Composition

As described earlier in the report in **Table 10** and the following **Table 13**, the overall 100% SMI consumer population enrolled in the TRIP for Salud y Vida Program varied by county of service and county of residence. Again, as noted above, given the rural area several counties are served by one clinic service site. These are not differences in the population but due to the rural community context and service locations. Additional differences were found by ethnicity and clinic measures.

Table 13. Participant Demographic Descriptive Statistics: Intervention and Comparison

Measure	Full Sample (n=552)		Intervention (n=302)		Comparison (n=250)		p-value
	N	%	N	%	N	%	
Gender							
Male	196	36.0	107	35.9	89	36.2	0.95
Female	348	64.0	191	64.1	157	63.8	
Missing	8	--	4	--	4	--	
Ethnicity							
Hispanic	388	71.3	256	85.9	132	53.7	<0.001
Non-Hispanic	156	28.7	42	14.1	114	46.3	
Missing	8	--	4	--	4	--	

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Measure	Full Sample (n=552)		Intervention (n=302)		Comparison (n=250)		p-value
	N	%	N	%	N	%	
Race^a							
White	521	95.8	290	97.3	231	93.9	0.23
Black	20	3.7	8	2.7	12	4.9	
Asian	1	0.2	0	0.0	1	0.4	
Native American	1	0.2	0	0.0	1	0.4	
Other	1	0.2	0	0.0	1	0.4	
Missing	8	--	4	--	4	--	
County of Residence^a							
Kenedy	2	0.4	1	0.3	1	0.4	<0.001
Brooks	48	8.8	48	16.1	0	0.0	
Duval	30	5.5	30	10.1	0	0.0	
Jim Wells	110	20.2	110	36.9	0	0.0	
Kleberg	105	19.3	105	35.2	0	0.0	
San Patricio	101	18.6	3	1.0	98	39.8	
Bee	107	19.7	1	0.3	106	43.1	
Aransas	28	5.1	0	0.0	28	11.4	
Live Oak	13	2.4	0	0.0	13	5.3	
Missing	8	--	4	--	4	--	
County of Service							
Bee	122	22.4	0	0.0	122	49.6	<0.001
Brooks	55	10.1	55	18.5	0	0.0	
Jim Wells	133	24.4	133	44.6	0	0.0	
Kleberg	110	20.2	110	36.9	0	0.0	
Taft	124	22.8	0	0.0	124	50.4	
Missing	8	--	4	--	4	--	
Age							
≤ 34	100	18.4	62	20.8	38	15.4	0.60
35-44	125	23.0	67	22.5	58	23.6	
45-54	200	36.8	106	35.6	94	38.2	
55-64	107	19.7	56	18.8	51	20.7	
65+	12	2.2	7	2.3	5	2.0	
Mean	45.2	--	44.6	--	45.9	--	
SD	11.7	--	12.1	--	11.1	--	
Missing	8	--	4	--	4	--	
Employment Status^a							
Unemployed		77.9		74.6		81.6	0.12
Employed Full-time		21.9		25.0		18.4	
Other		0.2		0.4		0.0	
Missing		28		22		6	

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Measure	Full Sample (n=552)		Intervention (n=302)		Comparison (n=250)		p-value
	N	%	N	%	N	%	
Marital Status							
Married	116	21.9	54	18.6	62	25.9	0.12
Single	228	43.1	135	46.6	93	38.9	
Divorced	121	22.9	69	23.8	52	21.8	
Separated	64	12.1	32	11.0	32	13.4	
Missing	23	--	12	--	11	--	
Annual Household Income^a							
Less than \$10,000	383	70.4	214	71.8	169	68.7	0.08
\$10,001 - \$20,000	114	21.0	60	20.1	54	22.0	
\$20,001 - \$30,000	23	4.2	10	3.4	13	5.3	
\$30,001 - \$40,000	11	2.0	6	2.0	5	2.0	
\$40,001 - \$50,000	3	0.6	0	0.0	3	1.2	
\$50,001 - \$60,000	1	0.2	1	0.3	0	0.0	
\$60,001 - \$70,000	1	0.2	1	0.3	0	0.0	
Greater than \$70,001	2	0.4	0	0.0	2	0.8	
Refusal	6	1.1	6	2.0	0	0.0	
Missing	8	--	4	--	4	--	
Primary Language							
English	535	98.3	292	98.0	243	98.8	0.47
Spanish	9	1.7	6	2.0	3	1.2	
Missing	8	--	4	--	4	--	
Education^a							
3 rd Grade	3	0.6	3	1.0	0	0.0	0.13
5 th Grade	6	1.2	3	1.0	3	1.3	
6 th Grade	2	0.4	2	0.7	0	0.0	
7 th Grade	12	2.3	5	1.7	7	3.0	
8 th Grade	32	6.1	17	5.9	15	6.4	
9 th Grade	50	9.6	25	8.7	25	10.7	
10 th Grade	45	8.6	29	10.1	16	6.9	
11 th Grade	39	7.5	23	8.0	16	6.9	
12 th Grade	88	16.9	50	17.4	38	16.3	
GED	102	19.6	63	22.6	69	15.9	
Some College	132	25.3	63	21.9	69	29.6	
BA/BS	7	1.3	3	1.0	4	1.7	
None	3	0.6	0	0.0	3	1.3	
Missing	31	--	14	--	17	--	

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Measure	Full Sample (n=552)		Intervention (n=302)		Comparison (n=250)		p-value
	N	%	N	%	N	%	
Household Size^a							
1	299	55.0	161	54.0	138	56.1	0.28
2	96	17.6	52	17.4	44	17.9	
3	57	10.5	30	10.1	27	11.0	
4	52	9.6	27	9.1	25	10.2	
5	22	4.0	13	4.4	9	3.7	
6	12	2.2	10	3.4	2	0.8	
7	4	0.7	4	1.3	0	0.0	
8	1	0.2	1	0.3	0	0.0	
9	1	0.2	0	0.0	1	0.4	
Missing	8	--	4	--	4	--	
Veteran Status^a							
Yes	8	1.5	7	2.3	1	0.4	0.06
No	536	98.5	291	97.7	245	99.6	
Missing	8	--	4	--	4	--	
Health Insurance Status^a							
Not Insured	397	73.0	210	70.5	187	76.0	0.44
Insured	20	3.7	13	4.4	7	2.8	
Medicare	34	6.3	20	6.7	14	5.7	
Medicaid	91	16.7	53	17.8	38	15.4	
Other	2	0.4	2	0.7	0	0.0	
Missing	8	--	4	--	4	--	

Note: ^aCells have expected count less than 5

Table 14. Baseline Primary Impact Measures: Intervention and Comparison

	Full Sample	Intervention v. Comparison		p-value
	Mean (SD)	Mean (SD)	Mean (SD)	
BMI	34.1 (8.8)	34.3 (9.4)	33.9 (8.0)	0.54
BP -Systolic	129.6 (18.9)	131.9 (17.3)	127.0 (20.5)	0.004
BP -Diastolic	80.6 (12.0)	82.3 (11.2)	78.6 (12.5)	<0.001
PHQ-9	14.2 (6.6)	13.5 (6.5)	14.9 (6.6)	0.01
Duke Health Profile	40.8 (19.9)	43.1 (20.3)	38.0 (19.0)	0.003
Non-Parametric Tests^a		Median (Variance)	Median (Variance)	
HbA1c	5.8 (4.1)	5.8 (3.9)	5.8 (4.4)	0.14
BRIEF Health Literacy	13.0 (21.8)	14.0 (21.2)	12.0 (22.7)	0.35

Note: Bold denotes significance of p-value ≤ 0.05 with 95% confidence

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

As described earlier, the intervention and internal comparison groups were statistically different at baseline for variables except for BMI, HbA1c and BRIEF Health Literacy Measures. Intervention group consumers had statistically significantly higher diastolic and systolic blood pressures. Although differences in the continuous diastolic blood pressure variable were found to be statistically significant, these

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

differences are not clinically different. In other words, intervention and comparison group consumers were both in the same category of systolic blood pressure. For PHQ-9, intervention group consumers had statistically significantly, but not clinically different lower scores; and, for Quality of Life measure of general health, intervention group consumers had statistically significantly higher, but not clinically different, scores than comparison group consumers (**Table 14**).

Study Consumer Flow Description

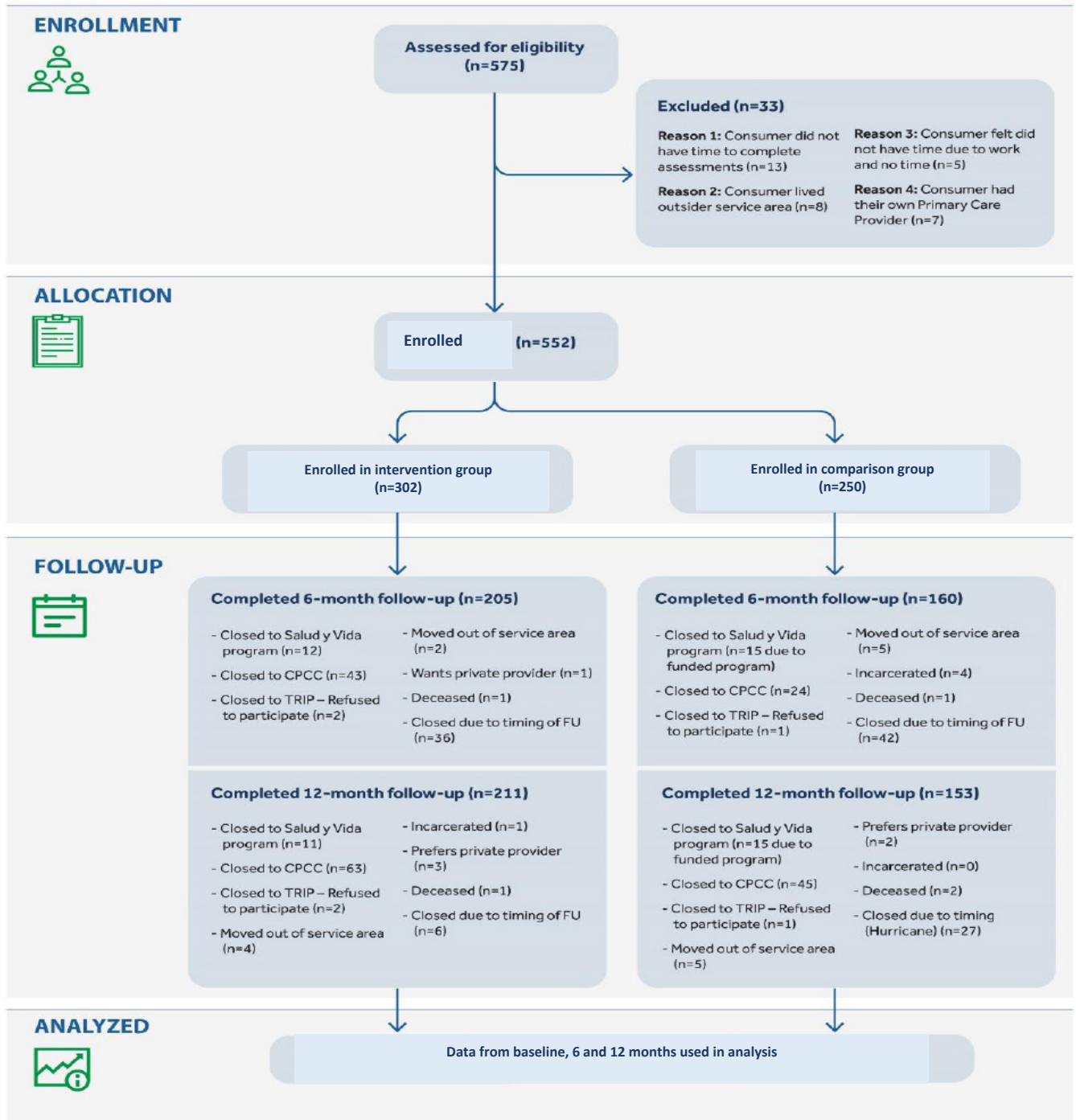
The consumer flow diagram for the QE study is presented using the CONSORT 2010 structure in **Figure 1** (Schulz et al., 2010). The diagram illustrates the study design and accounts for the number of consumers assessed for eligibility, the number allocated to the intervention and the comparison groups as assigned to a clinic (3 clinics intervention and 2 comparison) and the number of consumers completing the study assessments at baseline, 6- and 12-month interviews. At baseline, 33 consumers did not meet study eligibility or did not choose to enroll in the TRIP for Salud y Vida program; all consumers remained eligible to participate in the original Salud y Vida program and received services at the clinic. Once consumers enrolled in the study and completed their informed consent, we began tracking participant and coded all reasons for non-completion of assessments at 6- and 12-months.

At 6- and 12-month assessments, the reasons for non-completion including withdrawal or ineligibility are reported with specific reasons for non-completion of assessments. We used the American Association for Public Opinion Research (AAPOR) standard definitions to track and assign final disposition codes (e.g., interviewed, cannot locate, death, incarceration and study specific eligibility changes or clinic program changes) (AAPOR, Standard Definitions 2016). We specifically report on changes in eligibility, withdrawal or lost to follow-up at each assessment point. Consumers who did not complete their assessment at 6-months remained eligible to complete a 12-month assessment unless the consumer withdrew or was no longer eligible to participate in the study.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Figure 1. Patient Flow Diagram



Sample Recruitment, Retention, and Attrition

Participant Eligibility & Recruitment

Recruitment occurred within the consumer population that was enrolled or eligible for the Project Salud y Vida at each specific clinic site, either of the intervention clinic sites and the comparison clinic sites.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Eligibility criteria for the study included the following.

- Currently enrolled or eligible for enrollment in the Salud y Vida program
- Diagnosis of SMI (100% in program sample)
- 18 years of age and older
- Reside within the five-county clinic service area (each clinic serves multiple rural counties)
- Lack of serious health condition that would preclude ability to use TRIP transportation services and enhanced integrated services.

Exclusion criteria included: (1) serious health conditions, e.g. terminal cancer, active tuberculosis, HIV/AIDS; (2) suicidality and (3) live outside the five-county program area. Pregnant women and individuals who reported that they can never be contacted by phone were also excluded. The TRIP for Salud y Vida program was offered at three intervention clinics (Alice, Falfurrias, Kingsville clinics) and Project Salud y Vida was offered at two comparison clinics (Beeville and clinics).

The TRIP for Salud y Vida program used a rolling recruitment process. Recruitment of the consumer population that is currently enrolled or eligible for enrollment in Project Salud y Vida at either of the three intervention clinic sites were approached to participate by the program navigators. We estimated that 60-80% of the current Project Salud y Vida consumers would agree to enroll in the TRIP for Salud y Vida program. Once a consumer indicated a wish to enroll in the program they were taken through the informed consent process. Consumers who chose not to participate (opt-out) of the TRIP for Salud y Vida program were assured that no disruption or changes will be made to their current care. Navigator weekly meeting reports indicated that 80% (8 of 10 approached to participate agreed to participate in the program). All consumers with an appointment during the enrollment period were approached.

Consumers who qualified for the study were asked to voluntarily sign the informed consent. This included volunteering to take all baseline and follow-up surveys, volunteering to have vitals (e.g., blood pressure, height, weight) and bloodwork (to assess HbA1c and total cholesterol) taken during the study, and understanding that they were part of a research study. Those consumers who did not consent to the study or who were unable to consent to the study were referred to other REAL usual care services. Enrollment was conducted on a rolling basis between February 2016 and July 2016. The UTHHealth Houston Institutional Review Board (IRB) reviewed all study protocols prior to the enrollment and collection of TRIP program evaluation data (HSC-SPH-15-0583). Renewals for the TRIP for Salud y Vida IRB review were submitted and granted by the UTHHealth Houston IRB at the University of Texas Health Science Center Houston (UTHSC-H); continuing reviews were granted on 08/22/16, 06/11/17, 03/19/18 and 03/01/19.

Completed Submissions

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

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

As noted in the SEP, obtaining meaningful informed consent from individuals diagnosed with SMI presents unique ethical challenges due to cognitive impairment. For the TRIP for Salud y Vida program,

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

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

Per Institutional Review the study personnel were trained to read the consent form aloud to the prospective participants and ensure the prospective participant has an understanding of what the research participation entails and their rights as participants. Study personnel emphasized the commitment required for participation. Caution was exercised to not obtain consent from potential participants if they were sedated or too emotionally distraught to give informed consent at the time of intake. Following the informed consent process, the consumer was assigned a community health worker to navigate program activities as outlined in the logic model.

Sample Enrollment and Retention

As outlined in the SEP, program enrollment began in February 2016 and continued through July 2016 for the intervention and comparison groups.

This was not a deviation from the SEP, the rolling recruitment process was planned at each of the clinic sites. The recruitment of consumers at the comparison sites began later 30 days after enrollment at the intervention clinics. The goal for REAL's overall sample (without attrition) was $n=500$ in total, or $n=250$ per study arm (i.e., intervention group and comparison group). Accounting for 70% retention at 12 months, the effective sample size goal was $n=180$ per study arm. REAL consented and enrolled 302 consumers into the intervention group and 250 into the comparison group (see **Figure 1**). The anticipated number of participants to be recruited for the study was 250 per arm (e.g., intervention and comparison groups) with realized sample of 425 at 6 months and 360 at 12 months accounting for 15% attrition at each time period.

Enrollment in the intervention and comparison groups met enrollment targets needed to conduct analyses with sufficient power. The TRIP for Salud y Vida Program partners set enrollment goals and used a quality improvement process to review goals weekly and set specific targets for recruitment and noted any specific issues with reaching consumers to ensure retention goals were met to achieve sufficient study power (see next section).

For 6-month follow-up data collection, TRIP scheduled data collection using the baseline data completion date to calculate the date for release of a consumer; usually releasing the consumer for data collection at 30 days prior to the follow-up due date and collected data up to 45 days post 6-month date. This allowed for IBH visit scheduling and coordination within the clinic setting. Twelve-month follow-ups began in February 2017 and concluded in September of 2017. **Table 15** presents the number of 6-month data collected and 12-month follow-up data collection by study arm. Efforts to minimize attrition were made including reminder calls, emails and communication that included home visits by community health workers to maximize program participation as well as data collection. We tailored and used techniques successfully used by Drs. Valerio and Cornell to maximize follow-up participation and trained partners and staff at partner locations including the case managers and navigators to promote the TRIP for Salud y Vida program participation and data collection activities.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

TRIP did not achieve its retention goal at 6-months follow-up (96% for the intervention group and 75% for the comparison group) as we used a strict close out date and did not seek to track additional consumers following the 45 days post 6-month date. At 12-months, the original goals for retention were achieved for the intervention group; the intervention group ended the study with a total of 211 consumers in the intervention group (>100% retention) and 153 (85% of target) in the comparison group. Our goals had been 180 per group at the 12-month data collection point. At 12 months, we completed a total of 363 follow-ups (See **Table 15**). The retention rate was calculated to allow for a 15% attrition at each follow-up period from the total at the follow-up point.

Table 15. Final Assessment of Follow-up Retention at 6 and 12 months

Study Arm	Baseline Sample Target	Actual at Baseline	6-month Target (15% attrition)	Actual at 6 months	12-month Target (15% attrition)	Actual at 12 months	Percent of Retention of the Enrolled Sample	Percent of Retention Target
Intervention	250	302	213	205	180	211	69.8%	117%
Comparison	250	250	212	160	180	153	61.2%	85%
Total	500	552	425	365	360	364	72.5%	101%

As described in the SEP, loss of participants during a research trial follow-up can introduce bias and reduce power which affects the internal validity and generalizability of study results. REAL's study design called for baseline and two follow-up assessments at 6 and 12 months. However, the SMI population, due to the nature of the mental health conditions involved, is an elusive population to retain in a health care setting, much less a research study. Studies have demonstrated that SMI patients are frequently lost to follow-up in studies without strategies to address attrition (Kim, Hickman, Gali, Orozco, & Prochaska, 2014). Sample losses of over 20% among severely mentally ill study participants are not uncommon, even with appropriate planning to retain participants.

Based on the previous experience of the REAL evaluation team as well as the partners, various methods were carefully integrated to retain consumers in the program and avoid differential loss between the intervention and comparison groups. Examples include integrating the Voices Leadership Group in the design of the program, hiring local staff as community health workers, training transportation specialists to arrange attendance, rescheduling testing so that it is convenient and reminder phone calls and emails. Strategies used to ensure loss of consumers (attrition) was kept to the project 15% per data collection point included:

- At enrollment, updating and collecting all contact information at the clinic. At each follow-up visit each consumer updated contact information and identified two emergency contacts.
- Rural sampling area – tracking using contact information was made easier for in person visits as needed.
- Original Salud y Vida Program procedures at organizational level allowed for contract at clinical visits only if needed. Data collection was coordinated with case managers to ensure capturing data on same day as clinical visit. Navigators checked scheduling of clinical appointments to coordinate and ensure less burden for data collection given already scheduled to travel. (The majority of the clinical outcome impact evaluation data was collected from electronic health records maintained by the partner site, CPCC and the transportation related metrics are collected through REAL data base.)
- Those enrolled in EIS or using transportation services were reminded of data collection.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- Transportation identified consumers as needed and provided consumers reminders regarding clinical and data collection appointments.

We worked with partner clinic staff to address attrition over time and track any loss to follow-up. Consumers participated in multiple activities related to their behavioral and clinical care; we monitored all appointments through the transportation plan. A weekly report was generated to identify upcoming appointments and detect low retention and follow-up for behavioral, clinical and self-management related activities. Attempts to contact individuals for their care as part of their treatment occurred. All missed appointments were noted at the CPCC EMR and scheduled activities in the REAL, Inc. database. As part of the Salud y Vida program, community health workers provided reminder calls and navigators to contact participants about behavioral and clinical appointments as well as self-management activities. Attrition was also monitored at the comparison clinics on a weekly basis.

Further, financial incentives for participation in the TRIP for Salud y Vida program were considered as a method of retaining study participants; however, after consideration, the REAL partnership team chose not to offer monetary incentives as a sample retention strategy. While the scientific literature provides evidence that financial incentives improve adherence to medication among the severely mentally ill during clinical trials (e.g., Priebe et al., 2013), there is less evidence that these incentives improve rates of follow-up for medical appointments. There is also concern that financial incentives would promote coercion in the SMI population and jeopardize the validity of informed consent and overall impact of the TRIP for Salud y Vida results given incentives are not part of usual care and would not be available post-evaluation. Given the no to low-cost transportation services offered across the sites we did not expect the lack of incentives to be a barrier to participation in the sample.

Sample Attrition Analyses

The TRIP for Salud y Vida program expected attrition for both the intervention and the control on a conservative estimate of a 15% attrition rate in intervention and comparison sites per data collection point and clinic capacity, **Table 16** presents the number of participants per site to be recruited to ensure sufficient sample size at 12-month follow-up accounting for expected and unexpected attrition. Given the final assessments from baseline to 12-month follow-up the study was sufficiently powered for blood pressure.

Although the overall attrition rate from baseline to 6-month follow-up was slightly higher than expected (15% at each time point and actual rate 31%) we achieved a 69.8% retention at 6-months in the intervention group and 61% retention in the comparison group. Given the differential attrition we completed bivariate analyses to examine whether participants who were lost to follow-up were significantly different in key demographic and clinical characteristics across and within the groups.

Non-Response Bias and Missing Data

Data collected for the TRIP Salud y Vida program were entered into a REDCap system.

At the start of the program it was determined that the data were not able to be extracted from the CPCC electronic health record or the contracted health provider electronic health record for the existing Salud y Vida program. Ongoing training of all TRIP data collectors, CPCC navigators, was incorporated into the study protocols to focus on minimizing missing and inaccurate data entry. Feedback on quality of data were provided bi-weekly to program team members. Navigators entered data into REDCap, all data received for the evaluation was entered into the system. At baseline, we discovered that HbA1c measures were primarily available only for consumers with a diagnosis or high

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

risk of type 2 diabetes. Therefore, the data missing at baseline on HbA1c were primarily due to organizational clinic protocol to not schedule and collect HbA1c. Given the challenge REAL, Inc. and CPCC worked to promote readings for all TRIP Salud y Vida consumers. Data at 12-months was much more complete. **Table 16** presents missing data at each time point for the intervention and comparison groups.

Table 16. Missing data at each time point and the number of subjects contributing data to our the Mixed-effects models in our primary analyses

Variable	Number of Observations Included			Missing at Baseline	Missing at 6 Months	Missing at 12 Months
	Total	Intervention	Comparison			
Blood Pressure						
Systolic	483	250	233	98	10	13
Diastolic	483	250	233	97	10	13
BMI	486	253	233	95	10	13
Brief Health Literacy	490	257	233	36	24	9
PHQ-9 Depression	479	246	233	36	24	9
Duke Health Profile						
Physical Health	485	256	229	51	29	12
Mental Health	482	255	227	56	33	13
Social Health	488	257	231	48	27	19
General Health	477	254	233	79	40	25
Perceived Health	480	257	233	36	24	9
Self-esteem	485	257	228	50	28	17
Anxiety	483	255	228	55	32	17
Depression	473	244	229	52	32	16
Duke AD	471	243	229	58	36	16
Pain	489	257	232	39	25	9
Disability	488	256	232	38	24	10

Other variables had minimal missing data for completed questionnaires. In the approved SEP, we noted that multiple imputation for important missing covariates would be completed to fill in the missing data for final analyses and reporting. We carefully reviewed and data missing and if missingness was high or required imputation. Eleven participants at the intervention sites and two participants at the comparison sites lacked data on the key sociodemographic variables included in our analyses. We used Stata 15 for our analyses. Since we used mixed-effect models with baseline, 6-month, and 12-month assessment as repeated measures; the numbers include in each analysis was based on all the information available across the repeated assessments, rather than restricting the analyses to complete cases only. This is the most efficient way to deal with missing data in an analysis based on longitudinal data. Multiple Imputation would be appropriate for missing covariates. We had reasonably complete ascertainment for the covariates we included in the models. In this context, multiple imputation would yield little. We also noted that some cases, like HbA1c, were clearly not missing at random. In this case multiple imputation is not appropriate. We plan to conduct some further sensitivity analyses including the use of multiple imputation in future analyses but suspect that the impact would be minimal.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Measures

The measures for the impact analysis closely track the measures presented in the logic model depicted in **Appendix B. Program Logic Model**. The impact measures assessed for the REAL program are HbA1c, blood pressure, Body Mass Index (BMI), depression, quality of life and health literacy. There are no changes to the measures described in REAL's SEP. Descriptive statistics for each of these measures, including number of consumers with or without the impact measures, are provided in this report.

Clinical measures for program impact: Five clinical impact measures were measured during this study. For Type 2 diabetes mellitus, the primary impact measure was HbA1c. For hypertension, the primary impact measure was blood pressure. For obesity, the primary impact measure was BMI. For depression, the primary impact measure was score on the PHQ-9 instrument. For life functioning, the primary impact measure was score on the Duke Quality of Life instrument. Differences between groups among those consumers who have moved from poorly controlled to controlled were be examined. A more detailed description of each variable is presented below.

Sociodemographic characteristics: Sociodemographic characteristics were captured using a standardized set of questions adapted by CPCC and administered to the clinic population. These include characteristics such as, age, gender, race, ethnicity, primary language, income, employment status, and access to transportation. In addition, participant's length of time enrolled in Project Salud y Vida was noted in the consumer's file for both intervention and comparison group consumers. This allows the evaluation to account for any differences between intervention and comparison consumers during analysis. (Note: This section has been updated from the SEP, which stated that the characteristic "social support" would be captured. Social support is not included in the sociodemographic characteristics captured for this study.)

Blood Pressure: Blood pressure is usually expressed in terms of the systolic pressure over diastolic pressure and is measured in millimeters of mercury (mm Hg). Blood pressure varies depending on situation, activity, age, and disease states (American Heart Association, 2015).

Blood pressure was measured by a health provider manually using a Stethoscope and Sphygmomanometer and following clinically-established practice guidelines (National Guidelines Clearinghouse, 2011). TRIP for Salud y Vida consumers with a blood pressure greater than or equal to 150/90 mm Hg were referred to the consumer attendant and received the home and telephone nurse assessments to determine available community programming for hypertension. The current IBH Model, Project Salud y Vida program health provider provided usual care.

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

HbA1c was measured by the primary care provider for patients suspected to be diabetic based on: (1) known/self-reported to be diabetic, or (2) have an elevated blood glucose at time of clinic visit or are suspected to be diabetic. The primary care provider may have suspected a patient to be diabetic based on body weight and/or Acanthosis nigricans or other symptoms or family history. In addition, the primary care provider determined the need/appropriateness of medication. For the purposes of this study, an

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

attempt to collect HbA1c readings was made for any enrolled participant. (Note: This section has been updated from the SEP, which incorrectly indicated that HbA1c of 7.0 was an eligibility criterion for referral to enhanced integrated services. All consumers in the intervention group are referred to enhanced integrated services.)

Obesity: BMI (Body Mass Index) is generally used as an indicator of body fat (National Guideline Clearinghouse, 2014). The health provider recorded the patient's height and weight and the electronic medical record (EMR) system will calculate patient's BMI.

The current IBH Model, Project Salud y Vida program health provider provided usual care. (Note: This section has been updated from the SEP, which indicated that consumers with a BMI of 30 or greater would receive specific health education through TRIP for Salud y Vida enhanced integrated services. All consumers in the intervention group are referred to enhanced integrated services.

Depression: Depression is characterized by depressed or sad mood, diminished interest in activities which used to be pleasurable, weight gain or loss, psychomotor agitation or retardation, fatigue, inappropriate guilt, difficulties concentrating, as well as recurrent thoughts of death. Diagnostic criteria established by the American Psychiatric Association dictate that five or more of the above symptoms must be present for a continuous period of at least two weeks. In addition to being a chronic disease in its own right, the burden of depression is further increased as depression appears to be associated with behaviors linked to other chronic diseases (American Psychiatric Association, 1994).

- **Administration method:** Depression was measured using the self-administered PHQ-9 assessment tool. The PHQ-9 is a multipurpose instrument for screening, diagnosing, monitoring and measuring the severity of depression.
- **Administration time:** The PHQ-9 was being administered at baseline, 6 months and 12 months.
- **Intended respondent:** The PHQ-9 was being administered to all TRIP for Salud y Vida and Project Salud y Vida consumers who visited the clinic.
- **Potential score/response range:** The PHQ-9 has a total possible score of 27. The PHQ-9 scoring criteria are categorized as minimal (0-4), mild (5-9), moderate (10-14), moderately severe (15-19) and severe (20-27) depression (Kroenke & Spitzer, 2002). Patients with a score of 5 or higher were referred for behavioral health services provider.

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

- **Administration method:** Quality of life was measured via the self-administered Duke Health Profile. The Duke Health Profile instrument containing six health measures (physical, mental, social, general, perceived health, and self-esteem), and four dysfunction measures (anxiety, depression, pain, and disability) (Parkerson, Broadhead, & Tse, 1990). Assessments were administered by the nurse or caseworkers as needed based on literacy.
- **Administration time:** The Duke Health Profile assessment tool was administered at baseline, 6 months and 12 months.
- **Intended respondent:** The Duke Health Profile assessment tool was administered to all TRIP for Salud y Vida and Project Salud y Vida consumers who visited the clinic.
- **Potential score/response range:** The Duke Health Profile has 11 scales, five of which measure function (physical health, mental health, social health, general health, perceived health, self-

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

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. For the purposes of this report, data analysis includes general health, physical health, and social health scales.

Health literacy: Health literacy is a complex construct that encompasses multiple dimensions (functional, critical, and interactive) and skills (print, oral, and Internet-based information seeking). As such no single measure captures its complexity. Two instruments were utilized in an attempt to capture the multiple dimensions of health literacy and to assess changes in health literacy related skills over time. The BRIEF Literacy Screener (BRIEF), and electronic Health Literacy Scale (eHEALS) instruments were used to capture health literacy. (Note: This section has been updated from the SEP. The Shortened Test of Functional Health Literacy Assessment, S-TOFHLA, was not used to capture health literacy).

- **Administration method:** The BRIEF and eHEALS were administered by the nurse or caseworkers and entered into the TRIP for Salud y Vida REDCap system at CPCC.
- **Administration time:** Instruments were administered at baseline and 12 months.
- **Intended respondent:** Instruments were administered to all TRIP for Salud y Vida and Project Salud y Vida consumers who visited the clinic.
- **Potential score/response range:**
 - BRIEF scoring is based on a sum of the four nonweighted items and ranges from 4-20. BRIEF levels of health literacy are inadequate (4-12), marginal (13-16) and adequate (17-20) (Chew et al. 2004, Chew et al. 2008, Wallace et al. 2006).
 - eHEALS is based on an eight items and summed to range from 8 to 40, with higher scores representing higher self-perceived eHealth literacy (van der Vaart et al., 2011).

Dietary Habits: We intended to assess participant dietary habits based on questions from the Fruits and Vegetables section in the Behavioral Risk Factor Surveillance Survey (BRFSS). Due to unavailability of quality data for this measure, dietary habits were not assessed. This is a change to the SEP.

Physical Activity: We intended to assess participant engagement in physical activity based on questions from the Exercise section in the Behavioral Risk Factor Surveillance Survey (BRFSS). Due to unavailability of quality data for this measure, physical activity was not assessed. This is a change to the SEP.

Appointment keeping and transportation data and use: REAL tracked the use and type of transit request and increased its tracking to ensure that the consumer's use and type of services is captured. This tracking allowed for the monitoring of number of appointments kept, type of follow-up care visit, and attendance and participation in self-management education by type and location across the community. In addition, we used vehicle odometer readings to measure distance traveled by the individual per trip allowing us to assess transportation use by type of trip and distance. We determined usage and impact of community services as well as reach across the rural communities at a level that has not been previously detailed. The same approach for tracking appointment keeping and transportation use was used for consumers enrolled in Project Salud y Vida.

- **Administration method:** The data was collected and entered at CPCC as part of the consumer treatment and REAL, Inc.
- **Administration time:** Collected at each program consumer use of transit services throughout the duration of the program. Comparison consumer use of transportation services was also tracked.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Data Collection Activities

Planned data collection activities were executed as described in the SEP with minor deviations. Clinical data taken during the vitalization process (e.g., blood pressure, height, weight) were entered by a CPCC staff member or nurse into a laptop computer directly into the patient’s health record. As consumers came into the clinic their high blood pressure and BMI assessments were completed. Clinicians ordered HbA1c tests as appropriate with CPCC patients with a diagnosis of type 2 diabetes receiving HbA1c tests done on site and results received from the lab entered into the consumer’s electronic record by nurses or technicians. The Duke Health Profile, PHQ-9 and all other behavioral metrics were collected by the Salud y Vida navigators at the clinic site. Once collected data was entered into REDCap system for use and analysis. The REDCap system was designed with data entry checks and validation checks for appropriate ranges for data entry. All data was collected in English. Clinic staff asked consumers in which language they would prefer to complete the surveys. Very few patients indicated they were unable to complete forms due to illiteracy; in cases of illiteracy or visual impairment, a clinic staff member administered forms orally.

REAL began collecting data in February 2016. **Figure 2** depicts the data collection timeline as it relates to SEP approval and analyses completed for report. Six-month follow-up began in August 2016 and ended in February 2017. Twelve-month follow-up began in February 2017 and ended in October 2017.

Data was submitted as requested to HRiA using ProtonMail and cleaning and data management was completed by the TRIP for Salud y Vida team as well as the HRiA as appropriate. As data were received by HRiA, they were reviewed by a research assistant and any questions were submitted to the TRIP team. Data cleaning errors were identified and quality checks between partners, REAL, Inc. and data collectors were discussed and resolved for the final analyses. At 12-month follow-up we closed data collection at the two comparison sites following the impact of Hurricane Harvey and closing of the clinic sites due to damage and community wide impact.

Figure 2. Timeline for Data Collection and Analyses for the Final Report



Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

IMPACT STUDY: ANALYSIS AND RESULTS

The TRIP for Salud y Vida program targeted a moderate level of evidence because the TRIP for Salud y Vida population differs from models reported in the literature, TRIP for Salud y Vida modified its approach to best suit the needs of the rural SMI population. The TRIP for Salud y Vida program used a quasi-experimental design (QED) approach, the evaluation of TRIP for Salud y Vida expands the level of evidence related to integrated care models for rural SMI consumers. While it is recognized that a QED is not as rigorous as a randomized control trial (RCT), a true randomized controlled trial design was not possible for the evaluation of the TRIP for Salud y Vida program due to potential contamination across the five partner clinic sites given shared provider staff for the existing IBH Salud y Vida program. The use of a QED helped to minimize threats to internal validity and to identify and control for participant characteristics that may affect impact measures of interest. Deviations from the SEP included assessment of SBP/DBP controlling for transportation and other variates. We will complete this analysis in the future. Analysis of drop outs was random and was not included in this report; all models accounted for the covariates of interest as well as a variable for time.

Unit of Analysis and Overview of Analyses Performed

Final impact analyses are presented by research question. This section also notes the statistical method used, deviations from the SEP and findings for data collected for the TRIP for Salud y Vida program. Descriptive statistics are examined for both the intervention and comparison group. Consumer sociodemographics and other key covariates are presented throughout the report. We specifically included key covariates associated with findings in the literature and to allow us to examine nonequivalence between the two groups. Chi-square tests, and Fisher's Exact Tests were used for categorical data. Each question notes the exact tests used to examine the data and determine distribution. We used an overall intent-to treat analysis to examine changes in outcomes over time. We have not implemented multiple imputation to deal with missing data at this point.

The sample sizes in the final 12-month analyses were sufficient per our SEP sample power calculations. We used SAS to perform all analyses presented in the report.

The unit of analysis was at the individual patient level within the clinic site. The 12-month data collection point was used to assess impact on behavioral and clinical outcomes. This analysis approach is the most often used approach to assess outcomes over time. As noted in the SEP, the basic model(s) used for the TRIP impact models. We adjusted all models for key covariates and assessed between group differences from baseline to 12-month follow-up. Given the longitudinal aspect of the project, we looked at the consumer trajectories over time to identify any differences by group. A time measure was included in the analysis for each question.

We fit mixed-effect linear models with random effects for site and subject. We need to account for variation due to site in our analyses, one could control for site either as a fixed-effect in the model or as a random-effect. Fixed-effects for site is a less efficient and costly approach (in terms of loss of degrees of freedom for the error term), and our overall sample size is too small to offset the loss of degrees of freedom. The random effect approach is commonly used to deal with variation due to site in this context. Ideally, we should have a large number of sites, randomly assigned to the intervention and control group, but this ideal is seldom satisfied in practice. Intervention group, time-point for the assessments (0, 6 and 12 months), and an intervention X time-point interaction were modeled as fixed effects, along with

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

participant's age, gender, Hispanic origin, education (Some High School, High School/GED, and Some College or Higher), diabetes, and BMI. The covariates were selected based on the SEP indicated planned covariates for adjustment in the models. Systolic and Diastolic blood pressure were also considered for some of the models. It would need to be modeled as a time-varying covariate. Since missing data on any covariate at any time-point would exclude an entire observation from an analysis, this would impact the number of observations available for our analyses. So, we decided to exclude blood pressure as a covariate for our primary and secondary analyses. The multilevel independent variables for time-point, Hispanic Origin and education were dummy coded in the model. We also fitted models with a random-slope for time-point, but these models provided no better fit than the random-intercept models.

Let y_{ij} represent our outcome(s) of interest for individual $i = 1, \dots, n$ at each time $j = 1, \dots, J$ and x_{ijk} represent a participant's score at each time for each of the $k = 1, \dots, K$ independent variables. We'll let u_i represent the random error associated with site, s_i the random error associated with participant, and ε_{ij} be the overall error term for the fixed-effects model. The basic mixed-effects model with random effects for site and participant is

$$y_{ij} = \beta_0 + \sum_{k=1}^K \beta_k x_{ijk} + u_i + s_i + \varepsilon_{ij}$$

Standardized effect sizes (d) were computed based on the adjusted marginal mean differences estimated from the model divided by the pooled standard error time the square root of the sample size.

Table 17, **Table 18**, and **Table 19** present findings on the mean and standard deviation for baseline, and 12 month scores for intervention and comparison groups on the outcomes of interest.

Sí Texas Subgrantee: Rural Economic Assistance League (REAL), Inc.

Program Title: TRIP for Salud y Vida (Transportation for Rural Integrated Health Partnership)

Table 17. Health Impact Measures by Study Arm and Follow-up Period (SBP, DBP, BMI, HbA21c, BRIEF Health Literacy Questionnaire, PHQ-9)

Parametric Comparisons ^{a, b}											
Measure	Group	Baseline			12 Months			Within-groups Comparisons 12 Months - Baseline			
		N	Mean	SD	N	Mean	SD	N	Mean Change	SD	P value
Brief	Intervention	269	13.0	4.7	206	12.7	4.9	185	-0.156	3.394	0.531
	Control	244	12.6	4.8	163	13.2	5.1	159	0.604	4.039	0.061
	Total	513	12.8	4.7	369	12.9	5.0				
Between-groups at 12-months p-value = 0.363											
PHQ-9	Intervention	269	13.6	6.5	206	11.6	6.4	185	-1.422	6.371	0.003
	Control	244	14.9	6.6	163	14.2	6.6	159	-0.522	6.396	0.305
	Total	513	14.2	6.6	369	12.8	6.6				
Between-groups at 12-months p-value = 0.001											
Non-parametric Comparisons ^{c, d}											
Measure	Group	N	Median	IQR (Q ₂₅ , Q ₇₅)	N	Median	IQR (Q ₂₅ , Q ₇₅)	P value			
SBP	Intervention	251	131.0	18.5 (121.5, 140.0)	204	128.0	19.0 (118.0, 137.0)	0.010			
	Control	200	126.0	28.0 (112.0, 140.0)	161	127.0	22.0 (116.0, 138.0)	0.824			
	Total	451			365						
Between-groups at 12-months p-value = 0.569											
DBP	Intervention	252	83.0	14.0 (76.0, 90.0)	204	78.0	18.0 (70.0, 88.0)	0.002			
	Control	200	80.0	15.5 (71.0, 86.5)	161	79.0	14.0 (71.0, 85.0)	0.948			
	Total	452			365						
Between-groups at 12-months p-value = 0.734											
BMI	Intervention	254	32.5	13.7 (26.5, 40.2)	204	38.8	12.6 (27.9, 40.5)	0.077			
	Control	200	32.7	10.2 (28.2, 38.4)	161	33.3	9.2 (29.9, 38.1)	0.648			
	Total	454			365						
Between-groups at 12-months p-value = 0.524											
HbA1c	Intervention	79	6.5	2.5 (5.7, 8.2)	201	5.9	1.7 (5.4, 71.1)	0.329			
	Control	34	7.4	5.0 (6, 11)	157	5.9	1.4 (5.5, 6.9)	0.935			
	Total	113			358						
Between-groups at 12-months p-value = 0.472											

^a Paired t tests used to test within-groups comparisons for the Brief Health Literacy Questionnaire and the PHQ-9 Depression Score

^b Independent samples t test with equal variances used to test between-groups comparisons for the Brief Health Literacy Questionnaire and the PHQ-9 Depression Score

^c Wilcoxon signed-rank test used to test within-groups comparisons for all clinical measures

^d Wilcoxon rank-sum test used to test between-groups comparisons for all clinical measures

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Table 18. Health Impact Measures by Study Arm and Follow-up Period (Duke Health Profile Health Status Measures)

Parametric Comparisons ^{a,b}											
Measure	Group	Baseline			12 Months			Within-groups Comparisons			
		N	Mean	SD	N	Mean	SD	N	12 Months - Baseline Mean Change	SD	P value
Physical Health	Intervention	263	36.1	26.7	205	38.3	28.8	181	3.425	22.444	0.042
	Control	235	30.2	24.7	161	29	25.5	152	1.053	20.816	0.534
	Total	498	33.3	25.9	366	34.1	27.7				
Between-groups at 12-months p-value = 0.001											
Mental Health	Intervention	261	49.5	15.2	202	54.6	16.2	176	4.205	17.581	0.002
	Control	232	51.2	16.2	163	50.4	15.4	155	-0.774	17.114	0.5741
	Total	493	50.3	15.6	365	52.7	16				
Between-groups at 12-months p-value = 0.011											
Social Health	Intervention	263	54.5	14.5	200	53.4	15.4	174	-1.667	18.749	0.243
	Control	238	55.3	14.6	159	54.7	14.2	151	-0.397	16.728	0.771
	Total	501	54.9	14.5	359	54	14.9				
Between-groups at 12-months p-value = 0.381											
General Health	Intervention	251	46.7	12.2	196	48.8	14	162	2.037	11.465	0.025
	Control	219	45.5	12.3	157	44.5	12.7	140	0.000	11.274	1.000
	Total	470	46.2	12.3	353	46.8	13.6				
Between-groups at 12-months p-value = 0.003											
Perceived Health	Intervention	269	42.9	40.4	206	55.8	42.9	185	10.811	49.088	0.003
	Control	244	37.9	38.9	163	43.3	39.5	159	10.692	43.707	0.001
	Total	513	40.5	39.7	369	50.3	41.9				
Between-groups at 12-months p-value = 0.003											

^a Paired t tests used to test within-groups comparisons for all the Health Impact Measures

^b Independent samples t test with equal variances used to test between-groups comparisons for all the Health Impact Measures

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Table 19. Health Impact Measures by Study Arm and Follow-up Period (Duke Health Profile Mental Health, Pain and Disability measures)

Parametric Comparisons ^{a,b}											
Measure	Group	Baseline			12 Months			Within-groups Comparisons			
		N	Mean	SD	N	Mean	SD	N	12 Months - Baseline Mean Change	SD	P value
Self-esteem	Intervention	266	53.3	17.9	201	53.4	16.5	178	-1.011	17.437	0.440
	Control	233	51	16.3	160	50.8	16.7	152	-0.197	17.670	0.891
	Total	499	52.2	17.2	361	52.2	16.6				
Between-groups at 12-months p-value = 0.146											
Anxiety	Intervention	262	60.1	16.2	202	57.4	18	177	-2.166	15.539	0.065
	Control	232	60.7	17.2	159	61.1	16.9	149	-0.895	16.977	0.521
	Total	494	60.4	16.6	361	59	17.6				
Between-groups at 12-months p-value = 0.041											
Depression	Intervention	261	58.2	14.7	201	53.7	17.9	175	-3.829	16.106	0.002
	Control	236	56.5	16.5	161	57.1	16	154	-0.325	16.703	0.810
	Total	497	57.4	15.6	362	55.2	17.2				
Between-groups at 12-months p-value = 0.056											
Anxiety/Depression	Intervention	259	60.5	15.3	201	55	18.8	174	-5.460	15.044	0.001
	Control	232	60.4	16.6	161	60.7	16.8	151	-0.851	15.756	0.508
	Total	491	60.4	15.9	362	57.5	18.2				
Between-groups at 12-months p-value = 0.002											
Pain	Intervention	268	69	15.3	206	64.1	40.1	185	-7.027	34.416	0.016
	Control	242	78.3	31.5	163	77.9	33.4	158	-2.532	31.822	0.319
	Total	510	73.4	34.5	369	70.2	37.8				
Between-groups at 12-months p-value = 0.003											
Disability	Intervention	268	45.3	43.6	205	32.7	41.8	184	-13.859	52.122	0.001
	Control	243	63	40.2	163	55.8	42.8	159	-10.692	48.184	0.006
	Total	511	53.7	42.9	368	42.9	43.7				
Between-groups at 12-months p-value = 0.001											

^a Paired t tests used to test within-groups comparisons for Health Impact Measures

^b Independent samples t test with equal variances used to test between-groups comparisons for all the Health Impact Measures

Blood Pressure

Question 1. Did TRIP for Salud y Vida consumers significantly improve their blood pressure compared to Project Salud y Vida consumers? This question is confirmatory.

Overview of Analysis

Both systolic and diastolic blood pressures were collected to assess the program's impact on changes in blood pressure between the TRIP for Salud y Vida consumers (intervention) and the Project Salud y Vida consumers (comparison). Data checks were performed and accounted for as appropriate. Any outliers were checked for verification and no unique data cleaning processes were needed. At baseline the mean blood pressure was 129.6/80.6 mmHg with the intervention group having slightly higher blood pressure, 131.9/82.3 than the comparison site 127.0/78.6 mmHg.

Model Selection Process

We fit mixed-effect linear models with random effects for site and subject. Intervention group, time-point for the assessments (0, 6 and 12 months), and an intervention X time-point interaction were modeled as fixed effects, along with participant's age, gender, Hispanic origin, education (Some High School, High School/GED, and Some College or Higher), diabetes, and BMI. The multilevel independent variables for time-point, Hispanic Origin and education were dummy coded in the model. We also fitted models with a random-slope for time-point, but these models provided no better fit than the random-intercept models.

Let y_{ij} represent our outcome(s) of interest for individual $i = 1, \dots, n$ at each time $j = 1, \dots, J$ and x_{ijk} represent a participant's score at each time for each of the $k = 1, \dots, K$ independent variables. We'll let u_i represent the random error associated with site, s_i the random error associated with participant, and ε_{ij} be the overall error term for the fixed-effects model. The basic mixed-effects model with random effects for site and participant is

$$y_{ij} = \beta_0 + \sum_{k=1}^K \beta_k x_{ijk} + u_i + s_i + \varepsilon_{ij}$$

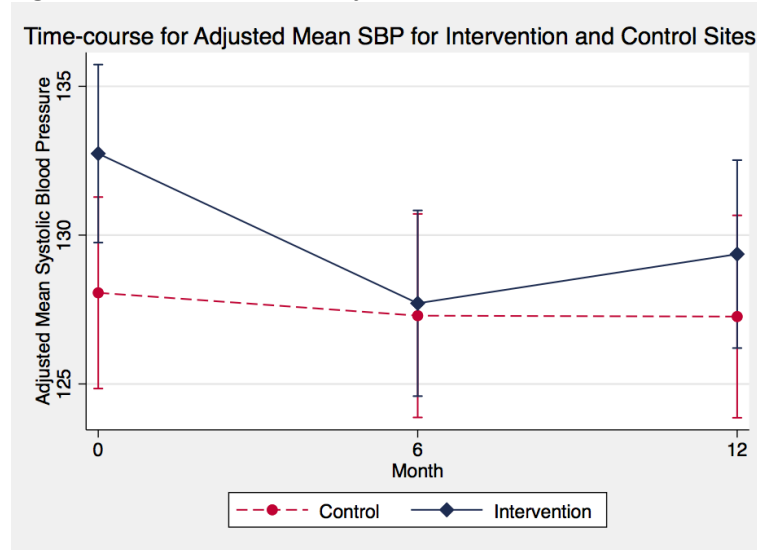
Mixed-effect Model Analysis for Systolic and Diastolic Blood Pressure

The Likelihood ratio test for the mixed-effect vs. a linear model without the random-effects was statistically significant ($p < 0.001$) suggesting that the random-effects model with random-effects for site and participant provide the better fit to the data. We also ran a mixed-effect model with two random intercepts and a random slope for time, but it was not statistically different from the model that included only random effects for site and participant. Participants at the intervention sites had significantly higher mean SBP than participants at the control sites ($p = 0.040$). **Figure 3** presents time-course adjusted mean SBP.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Figure 3. Time-course for Adjusted Mean SBP for Intervention and Control Sites



The Intervention x time interaction is the test for the effect of the intervention on systolic blood pressure. The SEP indicated a set of planned covariates for adjustment in the models, the final model controls for age, sex, race, education, diabetes and BMI.

Findings

Table 20 presents results for SBP over time. The joint test for change in SBP over time effect is statistically significant ($p = 0.021$), due to the significant reduction in SBP over time in the intervention arm ($p = 0.04$). The test for the change in SBP over time for the comparison sites was not statistically significant ($p = 0.860$). The joint test is essentially an *a posteriori* test for rate of change (slope) in SBP averaged across the intervention and comparison groups over time. We used the Bonferroni procedure to control for multiple testing bias in all our *a posteriori* statistical tests. Bonferroni adjusted pairwise contrasts show a statistically significant reduction from baseline in SBP for the intervention arm of -4.97 mmHg (95% CI: -9.48 to -0.45 , $d = -0.20$) at 6 months ($p = 0.019$). The change in SBP for the intervention group of -3.32 mmHg (95% CI: -7.89 to 1.25 , $d = -0.13$) at 12 months was not statistically significant ($p = 0.498$).

Table 17. Mixed-effect model for systolic blood pressure (SBP) with random intercepts for site and individual

	COEF.	STD. ERR.	Z	P>Z	[95% CI]	
INTERVENTION	4.68	2.28	2.05	0.040	0.21	9.14
TIME						
6-MONTH	-0.77	1.63	-0.47	0.637	-3.96	2.42
12-MONTH	-0.80	1.61	-0.49	0.621	-3.96	2.37
INTERVENTION*TIME						
INTERVENTION*6-MO	-4.26	2.23	-1.91	0.057	-8.64	0.12
INTERVENTION*12-MO	-2.58	2.24	-1.15	0.250	-6.97	1.81
AGE AT ENROLLMENT	0.27	0.06	4.36	0.000	0.15	0.39

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

FEMALE	-5.57	1.46	-3.8	0.000	-8.44	-2.70
HISPANIC	0.08	1.69	0.05	0.963	-3.24	3.40
SOME HS	3.29	2.27	1.45	0.148	-1.16	7.74
HIGH SCHOOL/GED	-2.25	1.90	-1.18	0.236	-5.97	1.47
SOME COLLEGE OR HIGHER	0.54	1.99	0.27	0.785	-3.35	4.44
DIABETES	2.83	1.39	2.03	0.042	0.10	5.56
BMI	0.03	0.01	2.55	0.011	0.01	0.05

The Likelihood ratio test for the mixed-effect vs. a linear model without the random-effects was statistically significant ($p < 0.001$) suggesting that the random-effects model with random-effects for site and participant provide the better fit to the data. We also ran a mixed-effect model with two random intercepts and a random slope for time, but it was not statistically different from the model that included only random effects for site and participant.

Participants at the intervention sites tend to have significantly higher DBP at time 0 ($p = 0.040$). **Figure 4** presents time course for DPB over the intervention and control sites.

Figure 4. Time-course for mean DBP for the Intervention and Control Sites

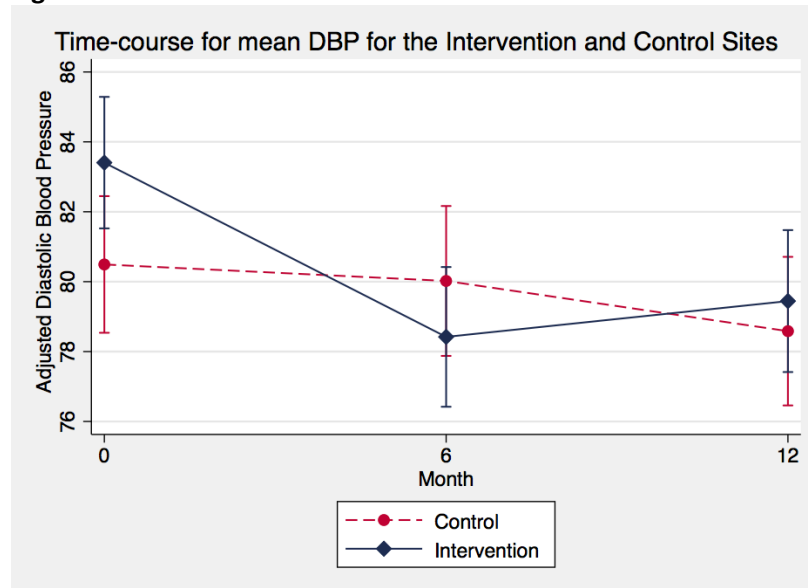


Table 21 presents the mixed-effect model for DBP.

The joint test for change in DBP over time effect is statistically significant ($p = 0.001$) due to the significant **reduction in DBP over time in the intervention arm** ($p < 0.001$). The test for the change in DBP over time **(at 12 months)** for the comparison sites was not statistically significant ($p = 0.265$). The joint test is essentially an *a posteriori* test for rate of change (slope) in SBP averaged across the intervention and comparison groups over time. We used the Bonferroni procedure to control for multiple testing bias in all our *a posteriori* statistical tests. The Bonferroni adjusted pairwise contrasts show a statistically significant **reduction from baseline in DBP for the intervention arm** of -5.00 mmHg (95% CI: -8.47 to -1.54, $d = -0.27$) at 6 months ($p < 0.001$) and -3.96 mmHg (95% CI: -7.48 to -0.45, $d = -0.21$) at 12 months ($p = 0.014$). **The statistically significant reductions over time were found between the intervention and comparison sites at 6-months and maintained differences were found within the intervention arm only at 12-months.**

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Table 18. Mixed-effect model for diastolic blood pressure (DBP) with random intercepts for site and individual

	COEF.	STD. ERR.	Z	P>Z	[95% CI]	
Intervention	2.91	1.42	2.06	0.040	0.14	5.69
Time						
6-month	-0.47	1.25	-0.38	0.706	-2.92	1.98
12-month	-1.91	1.24	-1.54	0.124	-4.34	0.52
Intervention*Time						
Intervention*6-mo	-4.51	1.72	-2.63	0.009	-7.88	-1.15
Intervention*12-mo	-2.05	1.72	-1.19	0.233	-5.43	1.32
Age at enrollment	-0.01	0.05	-0.13	0.898	-0.10	0.08
Female						
	-3.70	1.09	-3.40	0.001	-5.84	-1.57
Hispanic						
Some HS	-0.75	1.25	-0.60	0.547	-3.19	1.69
High School/GED						
Some College or Higher						
	0.81	1.69	0.48	0.634	-2.51	4.12
Diabetic	-1.47	1.41	-1.04	0.300	-4.24	1.30
	2.00	1.48	1.36	0.175	-0.89	4.90
BMI	0.01	0.01	1.69	0.092	0.00	0.03

Limitations

The trend in changes within the intervention group is statistically significant for the intervention group as a whole and does not account for varied participation within the EIS and transportation. Further examination regarding differences and impact in change over time between the intervention group adjusting for EIS participation may yield significant differences between the two groups. The subgroup analysis is planned but not included in this report.

HbA1c Level

Question 2: For consumers with a history of and/or diagnosis of diabetes, did TRIP for Salud y Vida consumers significantly improve their HbA1c compared to Project Salud y Vida consumers? *The question is confirmatory.*

Overview of Analysis

Linear models for the HbA1c outcome. HbA1c was missing for the majority of participants at baseline. HbA1c was missing for 223 of the 302 participants in the intervention group and for 215 participants at the comparison sites. Administrative and/or medical decisions at CPCC about whether to order HbA1c labs was the primary reason for the missing data, so the data cannot be assumed to be missing at random. The majority of HbA1c at baseline were for known diabetic patients: 67.6% (23/34) of participants enrolled at the control sites and 51.9% (41/79) at the intervention sites. All efforts to identify data for HbA1c at baseline were completed. Multiple efforts to identify in the electronic health record by CPCC staff were completed.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Several readings were identified but sufficient data was not found at baseline. Once identified as an issue, we took steps to assist the sites to improve HbA1c consumer readings were made.

As a result, insufficient data to fit a full longitudinal model were available. Upon review of the available data, the best models we can fit are cross-sectional models at 12-months with a diabetic by HbA1c interaction. We will complete subgroup analysis with available data to further examine the impact of the EIS classes on changes over time in those with a diagnosis of type 2 diabetes.

Model Selection Process

The models that included a random-effect for site were not statistically significantly different from the normal regression ($p = 1.000$), therefore the random effect was dropped from the models. We fit a multivariable linear model to HbA1c at the 12-month follow-up. We included an intervention X diabetic interaction term in the model to evaluate whether the effects varied with diabetic diagnosis. Intervention group, and an intervention X diabetic interaction were modeled as fixed effects, along with participant's age, gender, Hispanic origin, education (Some High School, High School/GED, and Some College or Higher), diabetes, BMI, and the HbA1c measure at 6 month as covariates. The HbA1c value at 6 months was center about the mean in fitting the model. Categorical independent variables for diabetes diagnosis, gender, Hispanic Origin and education were dummy coded in the model.

Let y_i represent our outcome(s) of interest and x_{ij} represent a participant's score for each of our $j = 1, \dots, J$ independent variables. We'll let ε_{ij} be the overall error term for the multivariable regression model. The basic multivariable regression model is

$$y_i = \beta_0 + \sum_{j=1}^J \beta_j x_{ik} + \varepsilon_{ij}$$

Table 22 and **Table 23** present the summary statistics and multivariable linear regression models for HbA1c.

Table 19. Summary statistics for HbA1c stratified by intervention and follow-up

Follow-up	Intervention			Control		
	N	Mean	Std Dev	N	Mean	Std Dev
Baseline						
HbA1c	79	7.50	2.41	34	8.21	2.52
6 Months						
HbA1c	150	6.74	1.90	104	6.69	1.76
Change in HbA1c	41	0.22	0.78	15	-0.26	1.27
12 Months						
HbA1c	201	6.62	1.94	158	6.76	2.12
Change in HbA1c	63	-0.05	1.40	22	-0.04	1.33

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Findings

Table 20. Multivariable linear regression model for HbA1c at 12-month follow-up with the 6-month value centered about its mean as a covariate (N = 204)

	COEF.	STD. ERR.	Z	P>Z	[95% CI]	
Intervention	-0.21	0.21	-1.02	0.310	-0.63	0.20
Diabetic	0.00	0.26	0.00	0.997	-0.51	0.51
InterventionxDiabetic	0.30	0.32	0.94	0.347	-0.32	0.92
Age at enrollment	0.00	0.01	0.14	0.892	-0.01	0.02
Female	-0.13	0.17	-0.75	0.457	-0.46	0.21
Hispanic	0.22	0.19	1.18	0.241	-0.15	0.58
Education						
Some HS	0.23	0.24	0.94	0.347	-0.25	0.70
High School/GED	-0.12	0.21	-0.57	0.571	-0.54	0.30
Some College or Higher	0.38	0.22	1.70	0.090	-0.06	0.81
bmi	0.01	0.01	1.61	0.109	0.00	0.03
HbA1c (at 6 months)	0.88	0.05	18.03	0.000	0.78	0.97

This analysis is at best exploratory and provisional. It is based on a complete case analysis conducted at the last follow-up. The results are disappointing but should not be taken very seriously. We noted in a number of our analyses that significant changes in our clinical measures appear at the 6-month point. Without sufficient baseline information, it is impossible to draw inferences about either the effectiveness or ineffectiveness of the intervention based on this analysis. If we ignore the 6-month HbA1c altogether and run a complete case end-point analysis, we observe a significant effect for intervention ($p = 0.002$), diabetic diagnosis ($p < 0.001$), and the intervention X diabetic diagnosis interaction ($p = 0.050$). Bonferroni adjusted paired comparisons between the intervention and control group for diabetics showed essentially no difference -0.002 mg/dL (95% CI: -0.86 mg/dL to 0.86 mg/dL, $p = 1.000$). There was a significant effect for HbA1c among nondiabetics in this analysis. Participants enrolled at the intervention sites had significantly lower average HbA1c at 12 months of -0.80 mg/dL (95% CI: -1.46 mg/dL to -0.13 mg/dL, $p = 0.010$) relative to participants enrolled at the intervention sites.

Without reliable HbA1c at baseline, however, it is impossible to say whether these differences merely reflect baseline differences or are a function of the intervention.

Limitations

The problems we encountered with the HbA1c measures at baseline limit our ability to assess the impact of the intervention, even in an exploratory way.

Body Mass Index

Question 3: Did TRIP for Salud y Vida consumers significantly improve their body mass index (BMI) compared to Project Salud y Vida consumers? *This question is exploratory.*

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Overview of Analysis

Consumer BMI was collected to assess the program's impact on changes in weight and BMI status between the TRIP for Salud y Vida consumers (intervention) and the Project Salud y Vida consumers (comparison). Data checks were performed and accounted for as appropriate. Any outliers were checked for verification and no unique data cleaning processes were needed. At baseline the mean BMI was 34.1 (SD = 8.8), indicating a majority of the TRIP consumers were categorized as obese. The intervention group had slightly higher mean BMI 34.3 (SD=9.4) than the comparison group mean BMI 33.9 (SD=8.0). The difference was not statistically significant ($p = 0.710$).

Model Selection Process

We fit mixed-effect linear models with random effects for site and subject. Intervention group, time-point for the assessments (0, 6 and 12 months), and an intervention X time-point interaction were modeled as fixed effects, along with participant's age, gender, Hispanic origin, education (Some High School, High School/GED, and Some College or Higher) and diabetes. The multilevel independent variables for time-point, Hispanic Origin and education were dummy coded in the model. We also fitted models with a random-slope for time-point, but these models provided no better fit than the random-intercept models.

Let y_{ij} represent our outcome(s) of interest for individual $i = 1, \dots, n$ at each time $j = 1, \dots, J$ and x_{ijk} represent a participant's score at each time for each of the $k = 1, \dots, K$ independent variables. We'll let u_i represent the random error associated with site, s_i the random error associated with participant, and ε_{ij} be the overall error term for the fixed-effects model. The basic mixed-effects model with random effects for site and participant is

$$y_{ij} = \beta_0 + \sum_{k=1}^K \beta_k x_{ijk} + u_i + s_i + \varepsilon_{ij}$$

The Likelihood ratio test for the mixed-effect vs. a linear model was statistically significant, suggesting that the random-effects are necessary ($p < 0.001$). Participants at the intervention sites had slightly lower mean BMI at time 0 than participants at the intervention sites, but the difference was not statistically significant ($p = 0.710$).

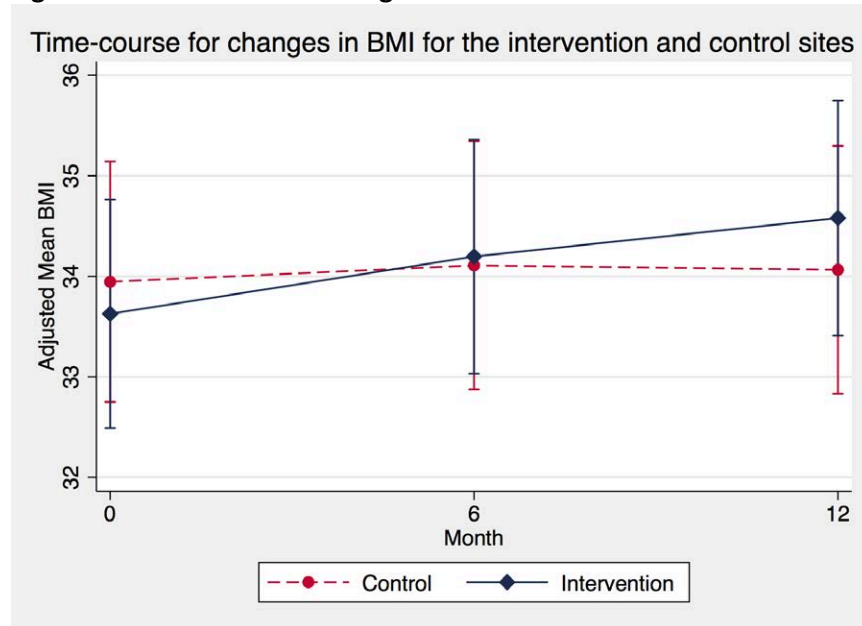
Findings

The Intervention x time interaction is the test for the effect of the intervention on BMI. The joint test for change over time between intervention and control site effects is not statistically significant ($p = 0.152$). See **Figure 5** for time course change in BMI and **Table 24** for BMI mixed effect model results for the intervention and comparison sites.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Figure 5. Time-course for changes in BMI for the intervention and control sites



No significant change in BMI was found within or between the intervention and comparison groups.

Table 21. Mixed-effect model for Body-mass Index (BMI) with random intercepts for site and individual

	COEF.	STD. ERR.	Z	P>Z	[95% CI]
Intervention	-0.32	0.87	-0.370	0.71	-2.02 1.38
Time					
6-month	0.16	0.40	0.410	0.68	-0.61 0.94
12-month	0.12	0.39	0.300	0.76	-0.65 0.89
Intervention*Time					
Intervention*6-mo	0.41	0.54	0.750	0.45	-0.65 1.47
Intervention*12-mo	0.83	0.54	1.540	0.12	-0.23 1.90
Age at enrollment	-0.08	0.03	-2.400	0.02	-0.15 -0.01
Female	3.00	0.81	3.700	0.00	1.41 4.59
Hispanic	-0.11	0.93	-0.120	0.90	-1.93 1.70
Some HS	1.19	1.26	0.940	0.35	-1.28 3.67
High School/GED	0.66	1.05	0.620	0.53	-1.41 2.72
Some College or Higher	-0.04	1.10	-0.030	0.97	-2.20 2.12
Diabetic	1.39	0.49	2.850	0.00	0.44 2.35

Limitations

The changes seen in individuals may have been maxed with the inclusion of all consumers in the intervention group and not only those that participated in a specific number of EIS classes at the mid or high level – indicating uptake and change in physical activity. Given the higher BMI in the consumer population and the risk factor of overweight in the SMI population we will continue to examine changes in

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

weight and BMI. Further examination regarding differences and impact in change over time within the intervention group adjusting for EIS participation may yield significant differences between the two groups. The subgroup analysis is planned.

Duke Health Profile

Question 4: Did TRIP for Salud y Vida consumers significantly improve their quality of life (as measured by the Duke Health Profile) compared to Project Salud y Vida consumers? *This question is exploratory.*

Overview of Analysis

Consumer quality of life was assessed to examine the program's impact on changes in multiple domains of quality of life between the TRIP for Salud y Vida consumers (intervention) and the Project Salud y Vida consumers (comparison). Data checks were performed and accounted for as appropriate. Any outliers were checked for verification and no unique data cleaning processes were needed. At baseline the mean Duke Health Profile (DHP) score was 40.8 (SD=19.9) the intervention group had slightly higher mean Duke Health Profile score at 43.1 (SD=20.3) than the comparison group with a mean score of 38.0 (SD=19.0). The difference was statistically significant ($p=0.003$) at baseline. Given the importance of each domain of the Duke Health Profile we completed domain specific analyses to report changes over time in key areas addressed by the EIS TRIP program.

Model Selection Process

We fit mixed-effect linear models with random effects for site and subject. Intervention group, time-point for the assessments (0, 6 and 12 months), and an intervention X time-point interaction were modeled as fixed effects, along with participant's age, gender, Hispanic origin, education (Some High School, High School/GED, and Some College or Higher), diabetes and BMI. The multilevel independent variables for time-point, Hispanic Origin and education were dummy coded in the model. We also fitted models with a random-slope for time-point, but these models provided no better fit than the random-intercept models.

Let y_{ij} represent our outcome(s) of interest for individual $i = 1, \dots, n$ at each time $j = 1, \dots, J$ and x_{ijk} represent a participant's score at each time for each of the $k = 1, \dots, K$ independent variables. We'll let u_i represent the random error associated with site, s_i the random error associated with participant, and ε_{ij} be the overall error term for the fixed-effects model. The basic mixed-effects model with random effects for site and participant is

$$y_{ij} = \beta_0 + \sum_{k=1}^K \beta_k x_{ijk} + u_i + s_i + \varepsilon_{ij}$$

Findings

Duke Health Profile Depression Scores

The Likelihood ratio test for the mixed-effect vs. a linear model was statistically significant, suggesting that the random-effects are necessary ($p < 0.001$). The Intervention x time interaction is the test for the effect of the intervention on DHP Depression scores was statistically significant. The joint test for change over time between intervention and control site effects were statistically significant ($p < 0.004$), due to the significant reduction in Depression scores over time in the intervention arm ($p < 0.001$). The test for the change in depression score over time for the comparison sites was not statistically significant ($p = 0.565$). The joint test is essentially an *a posteriori* test for rate of change (slope) in depression score averaged across the intervention and comparison groups over time. We used the Bonferroni procedure to control for multiple testing bias in all our *a posteriori* statistical tests. See **Figure 6** for DHP time-course depression

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

scores and **Table 25** for mixed effect models for DHP depression scores for intervention and comparison sites.

Figure 6. Time-course of DHP Depression Scores for intervention and control sites

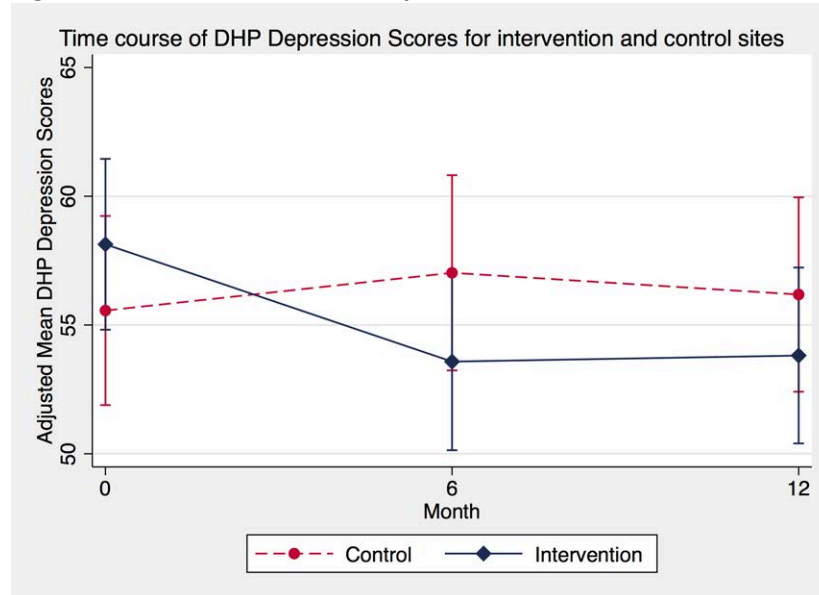


Table 22. Mixed-effect model for DHP Depression Scores with random intercepts for site and individual

	COEF.	STD. ERR.	Z	P>Z	[95% CI]	
Intervention	2.57	2.55	1.01	0.313	-2.43	7.57
Time						
6-month	1.47	1.38	1.07	0.287	-1.23	4.17
12-month	0.62	1.36	0.46	0.648	-2.05	3.30
Intervention*Time						
Intervention*6-mo	-6.02	1.94	-3.10	0.002	-9.83	-2.21
Intervention*12-mo	-4.94	1.92	-2.57	0.010	-8.71	-1.17
Age at enrollment	0.14	0.06	2.55	0.011	0.03	0.25
Female	1.99	1.33	1.49	0.136	-0.62	4.59
Hispanic	-1.47	1.55	-0.95	0.342	-4.50	1.56
Some HS	-1.62	2.07	-0.78	0.433	-5.67	2.43
High School/GED	-1.91	1.74	-1.10	0.271	-5.31	1.49
Some College or Higher	0.18	1.81	0.10	0.923	-3.38	3.73
Diabetic	1.04	1.26	0.83	0.409	-1.43	3.51
BMI	-0.01	0.01	-0.69	0.491	-0.02	0.01

Although depression scores tended to slightly worsen for participants at the control sites, the scores improved over time for participants enrolled at the intervention sites. The adjusted mean depression declined (improved) by -4.56 (95% CI: -8.59 to -0.52, Bonferroni adjusted $p = 0.014$, $d = -0.21$) at 6 months and remained fairly stable at -4.32 (95% CI: -8.30 to -0.34, Bonferroni adjusted $p = 0.022$, $d = -0.20$) lower than baseline at 12 months.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Duke Health Profile Anxiety/Depression Scores

The Likelihood ratio test for the mixed-effect vs. a linear model was statistically significant, suggesting that the random-effects are necessary ($p < 0.001$). The Intervention x time interaction is the test for the effect of the intervention on Duke Anxiety/Depression scores was statistically significant. The joint test for change over time between intervention and control site effects were statistically significant ($p < 0.001$), due to the significant reduction in Anxiety/Depression scores over time in the intervention arm ($p < 0.001$). The test for the change in Anxiety/Depression over time for the comparison sites was not statistically significant ($p = 0.6830$). The joint test is essentially an *a posteriori* test for rate of change (slope) in Anxiety/Depression averaged across the intervention and comparison groups over time. We used the Bonferroni procedure to control for multiple testing bias in all our *a posteriori* statistical tests. See **Figure 7** for time course of Duke Anxiety/Depression scores and **Table 26** for the mixed effect model of Duke Anxiety/Depression scores for intervention and comparison sites.

Figure 7. Time-course of Duke Anxiety/Depression for intervention and control sites

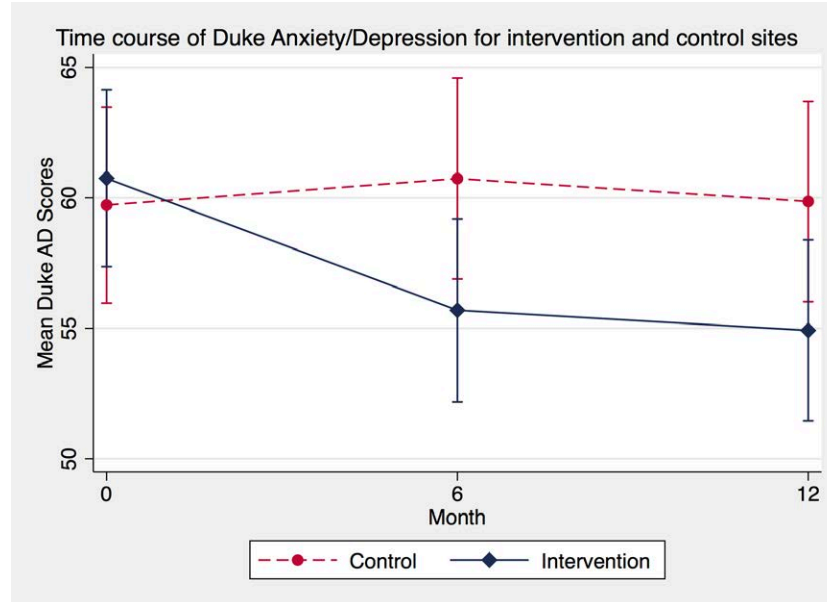


Table 23. Mixed-effect model for Duke Anxiety/Depression (AD) Scores with random intercepts for site and individual

	COEF.	STD. ERR.	Z	P>Z	[95% CI]	
Intervention	1.03	2.61	0.39	0.694	-4.09	6.14
Time						
6-month	1.02	1.27	0.80	0.423	-1.47	3.50
12-month	0.14	1.26	0.11	0.913	-2.33	2.60
Intervention*Time						
Intervention*6-mo	-6.08	1.80	-3.38	0.001	-9.60	-2.56
Intervention*12-mo	-5.97	1.77	-3.37	0.001	-9.44	-2.50
Age at enrollment	0.17	0.06	2.77	0.006	0.05	0.28
Female	3.90	1.42	2.75	0.006	1.13	6.68
Hispanic	-1.59	1.65	-0.96	0.335	-4.81	1.64

	COEF.	STD. ERR.	Z	P>Z	[95% CI]	
Some HS	-1.84	2.21	-0.83	0.405	-6.17	2.49
High School/GED	-4.21	1.85	-2.28	0.023	-7.83	-0.59
Some College or Higher	-2.27	1.93	-1.17	0.241	-6.06	1.52
Diabetic	1.44	1.27	1.14	0.256	-1.04	3.93
BMI	-0.01	0.01	-0.75	0.450	-0.02	0.01

Although Duke AD scores tended to worsen for participants at the comparison sites, the scores significantly declined (improved) over time for participants enrolled at the intervention sites. The adjusted mean Duke AD score declined by -5.06 (95% CI: -8.80 to -1.32, Bonferroni adjusted $p = 0.001$, $d = -0.26$) at 6 months and continued to decline to -5.83 (95% CI: -9.50 to -2.16, Bonferroni adjusted $p < 0.001$, $d = -0.30$) lower than baseline at 12 months.

Duke Health Profile Pain Scores

The Likelihood ratio test for the mixed-effect vs. a linear model was statistically significant, suggesting that the random-effects are necessary ($p < 0.001$). The Intervention x time interaction is the test for the effect of the intervention on DHP Pain scores was statistically significant. The joint test for change over time between intervention and control site effects were statistically significant ($p < 0.043$), due to the significant reduction in SBP over time in the intervention arm ($p < 0.011$). The test for the change in SBP over time for the comparison sites was not statistically significant ($p = 0.632$). The joint test is essentially an *a posteriori* test for rate of change (slope) in SBP averaged across the intervention and comparison groups over time. We used the Bonferroni procedure to control for multiple testing bias in all our *a posteriori* statistical tests. See **Figure 8** for time course of DHP pain scores and **Table 27** for mixed effect models of DHP pain scores.

Figure 8. Time course of DHP Pain for intervention and control sites

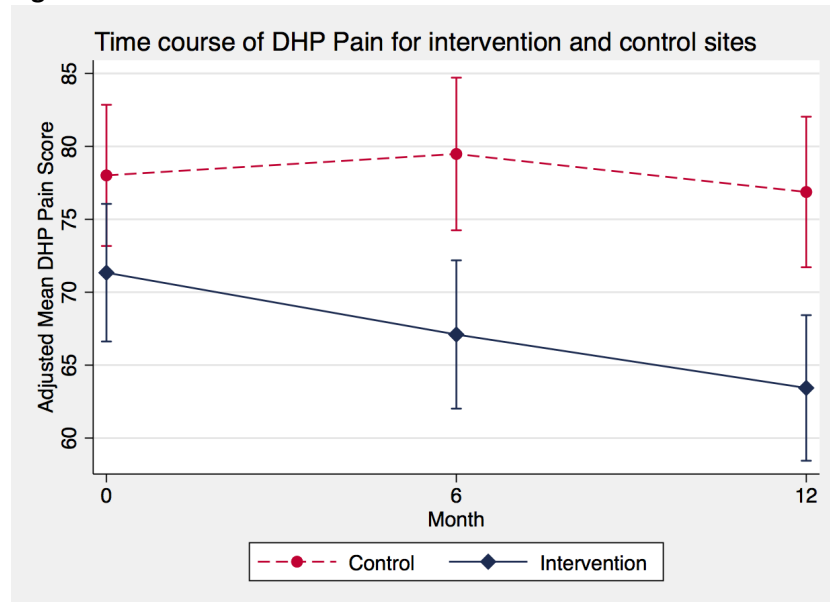


Table 24. Mixed-effect model for DHP Pain Scores with random intercepts for site and individual

	COEF.	STD. ERR.	Z	P>Z	[95% CI]	
Intervention	-6.67	3.54	-1.89	0.059	-13.61	0.26
Time						
6-month	1.47	2.73	0.54	0.591	-3.88	6.82
12-month	-1.14	2.70	-0.42	0.673	-6.43	4.15
Intervention*Time						
Intervention*6-mo	-5.71	3.83	-1.49	0.136	-13.20	1.79
Intervention*12-mo	-6.77	3.78	-1.79	0.073	-14.17	0.64
Age at enrollment	0.49	0.12	4.01	0.000	0.25	0.74
Female	10.45	2.92	3.58	0.000	4.73	16.17
Hispanic	-4.85	3.33	-1.46	0.145	-11.37	1.67
Some HS	2.93	4.53	0.65	0.518	-5.95	11.80
High School/GED	-7.50	3.80	-1.98	0.048	-14.93	-0.06
Some College or Higher	-6.63	3.95	-1.68	0.093	-14.37	1.11
Diabetic	8.14	2.65	3.07	0.002	2.95	13.33
BMI	0.01	0.02	0.76	0.446	-0.02	0.05

DHP Pain scores tended to be stable over time for participants at the control sites, the scores significantly improved over time for participants enrolled at the intervention sites. The adjusted mean DHP pain score for participants enrolled at the intervention sites decreased (improved) by -7.91 (95% CI: -15.67 to -0.14, Bonferroni adjusted $p = 0.042$, $d = -0.19$) between baseline and 12 months. While there was no difference in DHP Pain scores between the intervention and control sites at baseline ($p = 0.890$), mean pain scores were statistically significantly lower for participants enrolled at the intervention sites at 6 and 12 months. The mean pain scores for participants enrolled at the intervention sites at 6 months were lower by -12.38 (95% CI: -23.51 to -1.25, $p = 0.016$, $d = -0.15$) and -13.44 (95% CI: -24.41 to -2.47, $p = 0.005$, $d = -0.16$) at 12 months.

DHP Disability Score

The Likelihood ratio test for the mixed-effect vs. a linear model was statistically significant, suggesting that the random-effects are necessary ($p < 0.001$). The interaction term was not statistically significant. DHP Disability scores tended to decrease between baseline and 12 months in both groups. DHP Disability scores were higher for participants enrolled at the comparison sites at each time-point. However, contrast between the two groups at baseline was not statistically significant ($p = 0.197$). The contrasts between the two groups were statistically significant at 6 and 12 months. The intervention group had significantly lower mean DHP Disability scores of -26.75 (95% CI: -52.51 to -1.00, Bonferroni adjusted $p = 0.034$) at 6 months and -29.31 (95% CI: -54.98 to -3.63, $p = 0.012$). These differences reflect initial differences in baseline DHP Disability scores and cannot be attributed to the effects of the intervention. See **Figure 9** for time course of DHP disability scores and **Table 28** for mixed effect models of DHP disability scores.

Figure 9. Time course of DHP Disability for intervention and control sites

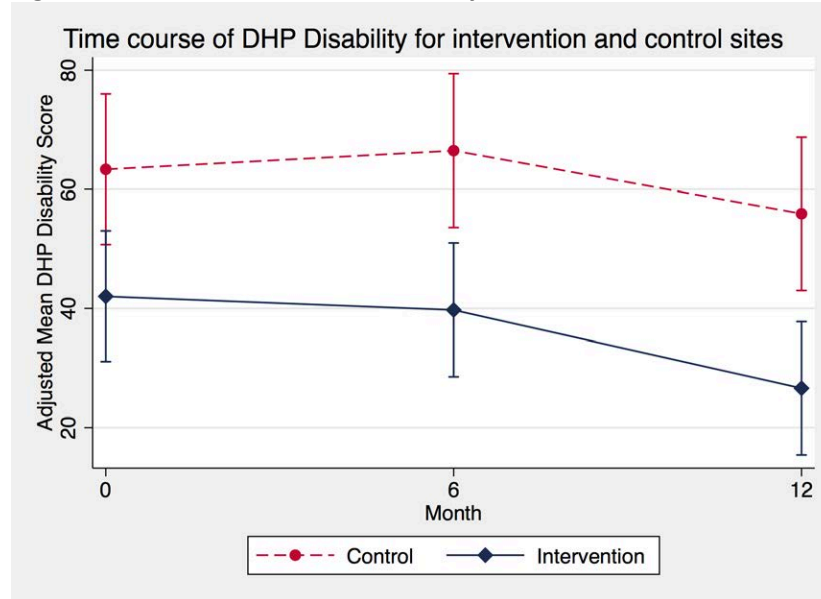


Table 25. Mixed-effect model for DHP Disability Scores with random intercepts for site and individual

	COEF.	STD. ERR.	Z	P>Z	[95% CI]	
Intervention	-21.31	8.59	-2.48	0.013	-38.15	-4.47
Time						
6-month	3.15	3.75	0.84	0.402	-4.21	10.51
12-month	-7.45	3.71	-2.01	0.044	-14.71	-0.18
Intervention*Time						
Intervention*6-mo	-5.44	5.25	-1.04	0.300	-15.74	4.85
Intervention*12-mo	-8.00	5.19	-1.54	0.124	-18.17	2.18
Age at enrollment						
Female	0.11	0.14	0.76	0.448	-0.17	0.38
Hispanic	2.86	3.27	0.88	0.381	-3.54	9.26
Some HS	11.98	3.80	3.15	0.002	4.53	19.43
High School/GED						
Some College or Higher	-9.25	5.04	-1.84	0.066	-19.12	0.62
Diabetic	-3.42	4.24	-0.80	0.421	-11.73	4.90
BMI	-2.76	4.44	-0.62	0.533	-11.46	5.93

DHP Disability scores tended to be stable over time for participants at the control sites, the scores significantly improved over time for participants enrolled at the intervention sites. The p values for the adjusted mean differences between baseline and the 6- and 12-month points were $p = 1.00$ and $p = 0.667$, respectively. The adjusted mean DHP Disability score for participants enrolled at the intervention sites did significantly decrease (improved) by an average -15.45 (95% CI: -26.13 to -4.76, Bonferroni adjusted $p < 0.001$, $d = -0.27$) at 12 months.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Limitations

Overall changes in DHP domain scores were significant within the intervention group and statistically lower than those of the consumers at the comparison clinics. The impact of the program on the DHP Depression Scores between the intervention and comparison sites is quite promising. Further examination regarding differences and impact in change over time between the intervention group adjusting for EIS participation may yield significant differences between the two groups. The subgroup analysis is planned.

Depressive Symptoms

Question 5: Did TRIP for Salud y Vida consumers significantly improve their depressive symptoms (as measured by the PHQ-9) compared to Project Salud y Vida consumers? *This question is exploratory.*

Overview of Analysis

We used the PHQ-9 to assess the impact of the TRIP for Salud y Vida program on depressive symptoms between the TRIP for Salud y Vida consumers (intervention) and the Project Salud y Vida consumers (comparison). Data checks were performed and accounted for as appropriate. Any outliers were checked for verification and no unique data cleaning processes were needed. At baseline the mean PHQ-9 score was 14.2 (SD=6.6) the intervention group had slightly higher mean PHQ-9 was 13.5 (SD=6.5) while the comparison group had a mean score of 14.9 (SD=6.6). The difference was statistically significant ($p=0.01$) at baseline.

Model Selection Process

We fit mixed-effect linear models with random effects for site and subject. Intervention group, time-point for the assessments (0, 6 and 12 months), and an intervention X time-point interaction were modeled as fixed effects, along with participant's age, gender, Hispanic origin, education (Some High School, High School/GED, and Some College or Higher), diabetes and BMI. The multilevel independent variables for time-point, Hispanic Origin and education were dummy coded in the model. We also fitted models with a random-slope for time-point, but these models provided no better fit than the random-intercept models.

Let y_{ij} represent our outcome(s) of interest for individual $i = 1, \dots, n$ at each time $j = 1, \dots, J$ and x_{ijk} represent a participant's score at each time for each of the $k = 1, \dots, K$ independent variables. We'll let u_i represent the random error associated with site, s_i the random error associated with participant, and ε_{ij} be the overall error term for the fixed-effects model. The basic mixed-effects model with random effects for site and participant is

$$y_{ij} = \beta_0 + \sum_{k=1}^K \beta_k x_{ijk} + u_i + s_i + \varepsilon_{ij}$$

Findings

The Likelihood ratio test for the mixed-effect vs. a linear model was statistically significant, suggesting that the random-effects are necessary ($p < 0.001$). The Intervention x time interaction is the test for the effect of the intervention on PHQ-9 Depression scores. The joint test for change over time between intervention and control site effects was statistically significant ($p = 0.003$), due to the significant reduction in depressive symptoms over time in the intervention arm ($p < 0.001$). The test for the change in SBP over time for the comparison sites was not statistically significant ($p = 0.449$). The joint test is essentially an *a posteriori* test for rate of change (slope) in SBP averaged across the intervention and comparison groups over time. We used the Bonferroni procedure to control for multiple testing bias in all our *a posteriori* statistical tests. See

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Figure 10 for time course of PHQ-9 depression scores and **Table 29** for mixed effect models of PHQ-9 depression scores.

Figure 10. Time-course for PHQ-9 Depression scores for intervention and control sites

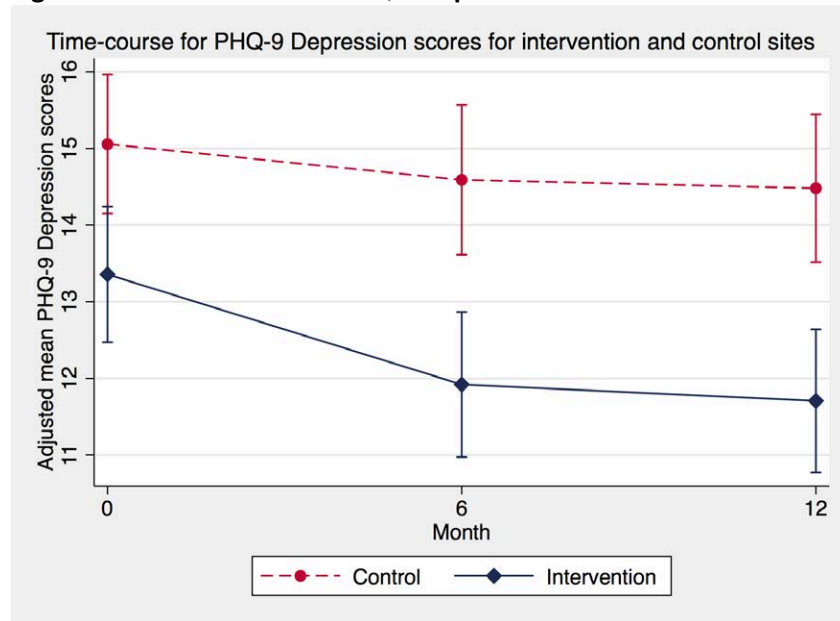


Table 26. Mixed-effect model for PHQ-9 Depression Scores with random intercepts for site and individual

	COEF.	STD. ERR.	Z	P>Z	[95% CI]
Intervention	-1.70	0.66	-2.56	0.010	-3.00 -0.40
Time					
6-month	-0.47	0.49	-0.96	0.338	-1.42 0.49
12-month	-0.58	0.48	-1.20	0.231	-1.52 0.37
Intervention*Time					
Intervention*6-mo	-0.97	0.68	-1.42	0.155	-2.31 0.37
Intervention*12-mo	-1.07	0.68	-1.59	0.112	-2.40 0.25
Age at enrollment	0.00	0.02	0.08	0.940	-0.04 0.05
Female	0.59	0.56	1.06	0.291	-0.51 1.69
Hispanic	1.35	0.64	2.12	0.034	0.10 2.60
Some HS	-0.09	0.87	-0.10	0.919	-1.79 1.62
High School/GED	-1.50	0.73	-2.06	0.039	-2.93 -0.08
Some College or Higher	-2.04	0.76	-2.69	0.007	-3.52 -0.55
Diabetic	-0.51	0.49	-1.05	0.296	-1.48 0.45

Bonferroni adjusted pairwise contrasts showed no statistically significant difference in depression at baseline between the intervention and control sites ($p = 0.156$). Depression scores decreased over time for participants at the intervention sites. Participants at the intervention sites showed decreases in depression at 6 and 12 months relative to baseline of -1.44 (95% CI: -2.84 to -0.03 , $d = 0.19$, $p = 0.040$) and -1.65 (95% CI: -3.04 to -0.26 , $d = -0.22$, $p = 0.007$), respectively.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Participants at the intervention sites also had significantly ($p=0.002$ and $p=0.001$) lower depression scores than participants at the control sites at 6 and 12 months. The difference at 6 months was -2.67 (95% CI: -4.75 to -0.59, $d = 0.17$, $p = 0.002$) points, and the difference at 12 months was -2.77 (95% CI: -4.83 to -0.72, $d = 0.18$, $p = 0.001$) points.

Limitations

The impact of the program on depression is significant and promising, indicating the inclusion of EIS and transportation positively impacts depression over time within and IBH program. Further examination regarding differences and impact in change over time between the intervention group adjusting for EIS participation may yield significant differences within and between the two groups. The subgroup analysis is planned.

Dietary Habits

Question 6: Did TRIP for Salud y Vida consumers experience improved dietary habits compared to Project Salud y Vida consumers? *This question is exploratory. This question is not addressed in this report.*

As noted earlier, the exploratory question was not assessed due to availability of quality data within the original Salud y Vida program.

Physical Activity Behaviors

Question 7: Did TRIP for Salud y Vida consumers experience improved physical activity behaviors compared to Project Salud y Vida consumers? *This question is exploratory. This question is not addressed in this report.*

As noted earlier, the exploratory question was not assessed due to availability of quality data within the original Salud y Vida program.

Health Literacy

Question 8: Did TRIP for Salud y Vida consumers experience improved health literacy compared to Project Salud y Vida consumers? *This question is exploratory.*

Overview of Analysis

We used the BRIEF Health Literacy assessment to explore the impact of the TRIP for Salud y Vida program on health literacy between the TRIP for Salud y Vida consumers (intervention) and the Project Salud y Vida consumers (comparison). Data checks were performed and accounted for as appropriate. Any outliers were checked for verification and no unique data cleaning processes were needed. At baseline the mean BRIEF score was 13.0 (SD=21.8) the intervention group had slightly better health literacy with a mean score of 14.0 (marginal) while the comparison group had a mean score of 12.0 (inadequate). The difference was not statistically significant at baseline. The BRIEF Health Literacy assessment has not been used to assess changes over time, this is an exploratory assessment of changes in health literacy.

Model Selection Process

We fit mixed-effect linear models with random effects for site and subject. Intervention group, time-point for the assessments (0, 6 and 12 months), and an intervention X time-point interaction were modeled as fixed effects, along with participant's age, gender, Hispanic origin, education (Some High School, High School/GED, and Some College or Higher), diabetes and BMI. The multilevel independent variables for time-

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

point, Hispanic Origin and education were dummy coded in the model. We also fitted models with a random-slope for time-point, but these models provided no better fit than the random-intercept models.

Let y_{ij} represent our outcome(s) of interest for individual $i = 1, \dots, n$ at each time $j = 1, \dots, J$ and x_{ijk} represent a participant's score at each time for each of the $k = 1, \dots, K$ independent variables. We'll let u_i represent the random error associated with site, s_i the random error associated with participant, and ε_{ij} be the overall error term for the fixed-effects model. The basic mixed-effects model with random effects for site and participant is

$$y_{ij} = \beta_0 + \sum_{k=1}^K \beta_k x_{ijk} + u_i + s_i + \varepsilon_{ij}$$

We ran both a mixed-effects linear model on the continuous health literacy scores and a mixed-effect ordinal logistic model on the health literacy categories. Both produced similar patterns of results, so we report only the results for the continuous health literacy scores. The Likelihood ratio test for the mixed-effect vs. a linear model was statistically significant, suggesting that the random-effects are necessary ($p < 0.001$).

Findings

Participants at the intervention sites had a statistically significantly higher mean Health Literacy score at baseline. The intervention by time-point interaction term was statistically significant ($p = 0.003$). Bonferroni adjusted multiple comparison tests were conducted on the components of the interaction. The mean difference in adjusted Health Literacy between the intervention and comparison sites was 1.52 (95% CI: 0.65 to 2.38, Bonferroni adjusted $p = 0.009$) points higher at baseline than participants at the comparison sites. Health Literacy remained fairly stable over time for the intervention group ($p = 0.431$), but significantly increased within the comparison group ($p = 0.003$). The difference in mean Health Literacy scores was no long statistically significant at 6 and 12 months, Bonferroni adjusted $p = 1.000$ for both comparisons.

The joint test for change in health literacy over time was statistically significant ($p = 0.009$), due mainly to a significant increase in health literacy for participants enrolled at the comparison sites ($p = 0.009$). Health Literacy remained fairly stable for the intervention group over time ($p = 0.431$). Participants at the control sites showed increases in health literacy at 6 and 12 months. Their health literacy scores at 12 months were statistically significantly higher than at baseline by a mean of 0.91 (95% CI: 0.06 to 1.76, $p = 0.027$) points. However, as noted above the between group differences were not statistically different at either the 6- or 12- month points. See **Figure 11** for time course of Brief Health Literacy scores and **Table 30** for mixed effect models of Brief Health Literacy scores.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Figure 11. Time-course for Brief Health Literacy for intervention and control sites

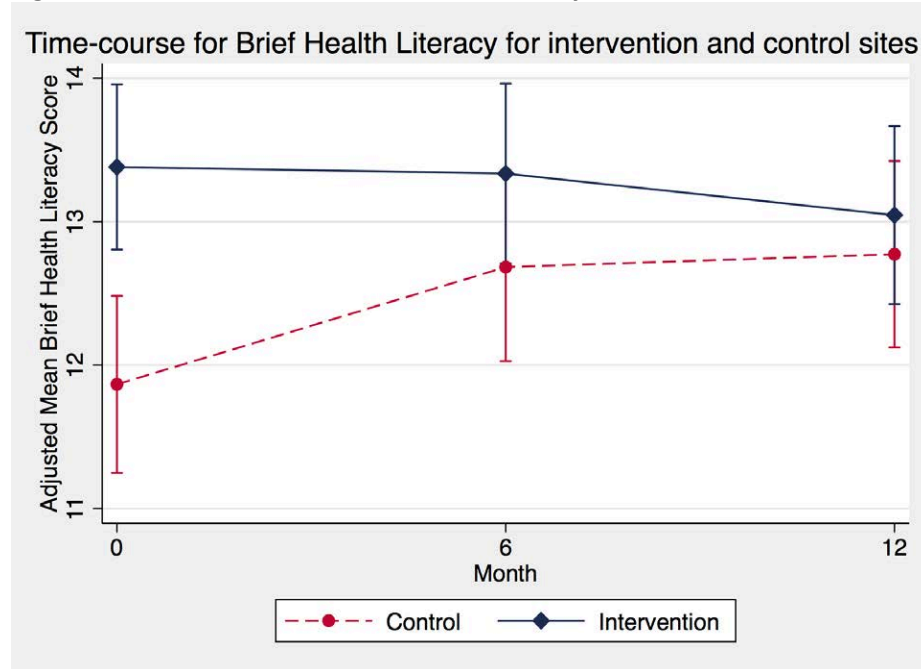


Table 27. Mixed-effect model for BRIEF Health Literacy with random intercepts for site and individual

	COEF.	STD. ERR.	Z	P>Z	[95% CI]
Intervention	1.52	0.44	3.43	0.001	0.65 2.38
Time					
6-month	0.82	0.29	2.79	0.005	0.24 1.39
12-month	0.91	0.29	3.12	0.002	0.34 1.48
Intervention*Time					
Intervention*6-mo	-0.86	0.41	-2.13	0.033	-1.66 -0.07
Intervention*12-mo	-1.24	0.40	-3.10	0.002	-2.03 -0.46
Age at enrollment	-0.04	0.02	-2.29	0.022	-0.07 -0.01
Female	1.46	0.39	3.71	0.000	0.69 2.23
Hispanic					
Some HS	0.10	0.61	0.16	0.869	-1.10 1.30
High School/GED	2.02	0.51	3.95	0.000	1.02 3.02
Some College or Higher	4.26	0.53	8.00	0.000	3.22 5.30
Diabetic	-0.05	0.32	-0.16	0.876	-0.68 0.58

Limitations

Given the BRIEF Health Literacy assessment is most often used as a covariate in models to adjust for the potential influence of inadequate health literacy on health outcomes, the analysis was exploratory to determine if an EIS program could influence health literacy over time. Overall changes in health literacy were seen in the comparison group but not the intervention. We posit that the intervention group through the EIS sessions learned about their “true” needs related to functional health literacy skills over time and the lower health literacy scores at 12-months may be due to an educational influence and more accurate

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

assessment of health literacy. It is important to note that health literacy in both groups at 12-months was similar. Similarly, the comparison group may have benefited from educational impact of the survey questions over time. Further examination regarding differences and impact in change over time between the intervention group adjusting for EIS participation may yield significant differences between the two groups. The subgroup analysis are planned.

Appointment-keeping

Question 9: Did TRIP for Salud y Vida consumers experience increased appointment keeping compared to Project Salud y Vida consumers? *This question is exploratory.*

The reported missed appointment rate due to no-shows at the start of the program was over 28% at the clinics, the changes indicate a positive trend in improvement of appointment attendance.

Influence of Road Type on Health Outcomes

Question 10: Do TRIP for Salud y Vida consumers who live within a rural town have greater percent change in health outcomes compared to TRIP for Salud y Vida consumers traveling from rural farm to market road residents? *This question is exploratory.*

The data for this question are not available, as the coding for the type of road was not indicated in the data base. The number of trips across the rural region were collected and reported as part of the analysis for question 11.

Influence of Transportation Utilization on Health Outcomes

Question 11: Do TRIP for Salud y Vida consumers have different health outcomes based on the amount and type of use of transportation services? For example, do high transportation service users have greater percent change in health outcomes compared to TRIP for Salud y Vida consumers with low use over time? *This question is exploratory.*

Effect of Transportation Service Utilization on Primary and Secondary Outcomes

Measures of Utilization. We stratified usage of Transportation Services on the total number of trips. Quantiles were computed for those participants in the intervention group who utilized the Transportation Services. Specifically, the interquartile ranges were used as natural ranges for use – defined as number of trips. The low users has a range of trips from 1-6, moderate from 7-32, high from 33-125 and very high users had 126-528 trips (shown as 143-528). The interquartile range allows for a best practice approach to classify categories taking into account the full dataset.

Only 69.3% of the participants who completed the 12-month assessment utilized the transportation service during the course of our year-long trial. See **Table 31** for utilization metrics.

Table 28. Summary of utilization metrics stratified by individual level of utilization

Level of Utilization	Measure	N	Mdn	Interquartile Range		Range	
Low Users	Number of Trips	46	2	2	4	1	6
	Total Miles	46	15	7	57	1	239
Moderate Users	Number of Trips	42	18.5	11	25	7	32
	Total Miles	42	133.5	64	292	15	1002

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Level of Utilization	Measure	N	Mdn	Interquartile Range		Range	
High Users	Number of Trips	46	75.5	51	96	33	125
	Total Miles	46	753	364	1267	102	3053
Very High Users	Number of Trips	43	241	181	316	143	528
	Total Miles	43	2806	1768	4377	473	18307
Total	Number of Trips	177	33	6	124	1	528
	Total Miles	177	345	61	1506	1	18307

Effect of Utilization on Systolic and Diastolic Blood Pressure (primary outcome)

Model Selection Process

We fit mixed-effect linear models with random effects for site and subject, along with a random slope for time. Level of utilization, time-point for the assessments was modeled as a continuous variable, and level of utilization X time-point interaction were modeled as fixed effects, along with participant’s age, gender, Hispanic origin, education (Some High School, High School/GED, and Some College or Higher), diabetes, and BMI. The multilevel independent variables for level of utilization, Hispanic Origin and education were dummy coded in the model. Models fitted models with a random-slope for time-point provided the best fit for these analyses. AIC and BIC were used determine the model that provided the best fit.

Let y_{ij} represent our outcome(s) of interest for individual $i = 1, \dots, n$ at each time $j = 1, \dots, J$ and x_{ijk} represent a participant’s score at each time for each of the $k = 1, \dots, K$ independent variables. We’ll let u_i represent the random error associated with site, s_i the random error associated with participant, and ε_{ij} be the overall error term for the fixed-effects model. The basic mixed-effects model with random effects for site, participant and time is

$$y_{ij} = \beta_0 + \sum_{k=1}^K \beta_k x_{ijk} + u_i + s_i + s_i time_{ij} + \varepsilon_{ij}$$

Findings

Systolic Blood Pressure

The *utilization* × *time* interaction term was not statistically significant ($p = 0.301$), but the main effect for level of utilization was statistically significant ($p = 0.047$). **Table 32** shows the adjusted mean contrasts for SBP between levels of utilization among those who used transportation services and those who did not use the service were significantly different.

Table 29. Adjusted Mean differences in systolic blood pressure for those who used the transportation service compared to those who did not (N = 250)

Level of Utilization	Coefficient	Standard Error	z	p-value	95% CI
Low	0.01	2.96	0.00	1.00	-5.79 to 5.81
Moderate	-2.89	3.13	-0.93	0.36	-9.02 to 3.24
High	-7.46	2.90	-2.57	0.01	-13.15 to -1.78
Very High	-6.49	3.09	-2.10	0.04	-12.54 to -0.44

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Mean systolic blood pressure appears to decrease with increasing utilization. The largest and statistically different contrasts are for High and Very High levels of utilization. Participants who were High users of the transportation service had a mean SBP that was -7.46 (95% CI: -13.15 to -1.78) mmHg lower than those who did not use the transportation service. Very High users had a mean SBP that was -6.49 (95% CI: -12.54 to -0.44) mmHg lower than those who did not use the transportation service.

Diastolic Blood Pressure.

Neither the *utilization* × *time* interaction term nor the marginal effect for level of utilization was statistically significant for diastolic blood pressure ($p < 0.133$). **Table 33** displays the adjusted mean contrasts for DBP between levels of utilization among those who used the transportation service and those who did not use the service.

Table 30. Adjusted Mean differences in diastolic blood pressure for those who used the transportation service compared to those who did not (N = 251)

Level of Utilization	Coefficient	Standard Error	z	p-value	95% CI
Low	-0.53	2.14	-0.25	0.803	--4.72 to 3.66
Moderate	-3.25	2.26	-1.44	0.150	-7.68 to 1.17
High	-3.31	2.09	-1.58	0.115	-7.41 to 0.80
Very High	-2.09	2.22	-0.94	0.347	-6.45 to 2.27

Exploratory Outcomes

Neither the *utilization* × *time* interaction term nor the marginal effect for level of *utilization* was statistically significant for any of our exploratory outcomes. The exception is the Brief Health Literacy Questionnaire, exploratory measure. These results are summarized in **Table 34**.

Table 31. Summary of results for the marginal effect of level of utilization for our exploratory outcomes

Exploratory Outcome	N	p-value
BMI	253	0.353
Brief Health Literacy	256	0.005
PHQ-9 Depression	256	0.924
Duke Health Profile		
DHP Physical Health	255	0.992
DHP Mental Health	254	0.713
DHP Social Health	256	0.696
DHP General Health	253	0.841
DHP Perceived Health	256	0.092
DHP Self-esteem	256	0.206
DHP Anxiety	254	0.463
DHP Depression	254	0.782
DHP Duke AD (Anxiety/Depression)	253	0.662
DHP Pain	256	0.152
DHP Disability	255	0.439

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Health Literacy was the one exploratory outcome that showed a significant effect for *utilization* ($p = 0.005$). The adjusted mean differences between levels of utilization among those who used the transportation service and those who did not use the service are shown in **Table 35**.

The results for the Brief Health Literacy Questionnaire are unexpected. The health literacy scores for those who utilized transportation services appear lower than for those who did not use the service. This is likely due to the fact that those with lower or inadequate health literacy will need additional assistance in navigating their daily activities as well as health services including accessing medical and basic needs. This finding may be due to the Transportation plans, the Transportation EIS informational session and the assistance of CHWs may have benefited those with lower health literacy and assisted them in scheduling and use of greater number of transportation services.

Table 32. Adjusted mean differences in health literacy between levels of utilization among those who used the transportation service and those who did not use the service

Level of Utilization	Coefficient	Standard Error	z	p-value	95% CI
Low	-0.23	0.67	-0.35	0.729	--1.54 to 1.08
Moderate	-0.66	0.71	-0.93	0.353	-2.04 to 0.73
High	-2.23	0.67	-3.31	0.001	-3.55 to -0.91
Very High	-2.18	0.69	-3.18	0.001	-3.52 to -0.83

Limitations

The range and use of transportation services by consumers in the intervention group varied greatly. The finding related to a decrease in mean systolic blood pressure with increased utilization likely is related to EIS participation. The subgroup analysis are planned.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

CONCLUSION: SUMMARY OF FINDINGS, LESSONS LEARNED AND NEXT STEPS

Summary of Implementation Findings

The implementation evaluation examined fidelity to REAL's program by conducting focus groups and interviews and examining consumer visit data. A slightly delayed timeline in data collection was the main deviation from the SEP; mid-point interviews were conducted 10 months post-enrollment rather than 6 months, and final interviews and focus groups were conducted 4 months after study conclusion rather than immediately after.

Evaluation of the implementation of REAL's program shows that the program was implemented in alignment with their program logic model and that there was moderate fidelity in implementation. All participants enrolled in the intervention met study eligibility criteria. REAL exceeded the enrollment target for the study and retained 69.8% of intervention participants and 61.2% of comparison participants at 12-months. Of the five core principles in the AIMS IBH checklist (patient-centered care, population-based care, measurement-based treatment to target, evidence-based care, and accountable care), CPCC implemented these to all consumers at baseline.

While fidelity to the program was moderate, findings from the focus groups and interviews in the implementation study revealed facilitators and challenges to implementation. Major facilitators to implementation and lessons learned from the program include: strong communication and relationships, adapted data systems and physical space, flexibility of program staff, and investments in training and capacity building for staff. Adoption barriers included hiring and retaining staff, communication, data systems, and environmental context factors, including health care policy and natural disasters.

Several lessons learned and opportunities for improvement emerged and focused on funding, program replication and scalability, the health care policy environment, and staffing. Funding and program scalability are tied to the health care policy environment which provides minimal resources for behavioral health in predominantly rural areas. Additional staffing is greatly needed to address the considerable demand for the Trip for Salud y Vida services.

Summary of Outcome/Impact Findings

The quasi-experimental design used for the TRIP for Salud y Vida program can estimate program impacts by comparing the outcomes of program participants (intervention group clinics in the TRIP program) to the outcomes of non-participants who are observationally equivalent to program participants (comparison group clinics). Consumers enrolled in the study completed baseline, 6-month and 12-month assessments. All efforts to collect assessments during the time frames to ensure appropriate time across groups. This report also describes how the sample recruited for the study reflects the five-clinic site population presented in the approved SEP.

The TRIP for Salud y Vida program outcomes were evaluated by examining the impact of program services on patients' blood pressure – systolic and diastolic (primary confirmatory outcome), HbA1c (confirmatory outcome), BMI, depression, quality of life, dietary habits, physical activity, health literacy, and appointment keeping—as measures of overall improvement in these scores and values (exploratory outcomes). Quantitative data related to participation in the approved program activities is also reported in this report (see Implementation Evaluation section). There were no deviations in the study design from the approved SEP protocols other than metrics for impact questions 6, 7 and 10 were not collected.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Impact Evaluation

The main impact study and related analyses were conducted as proposed in the SEP. Any deviations were identified and justified. The questions for which no data was available are noted (questions, 6, 7 and 10). Any deviations from the analysis were also reported.

The TRIP for Salud y Vida program achieves a preliminary level of evidence given the findings from the impact and a moderate level of fidelity in the implementation evaluation. Specifically, the program resulted in significant impact on changes of exploratory outcomes and no negative effects on a confirmatory outcome; however the baseline differences in the intervention and treatment groups and analysis performed do not allow us to determine the true impact of the intervention on impact outcomes. The Quasi-experimental study showed that the reverse co-located IBH program with transportation (TRIP for Salud y Vida) resulted in significant improvements in DBP (-3.96 mmHG; 95% CI: -7.48 to -0.45, $p=0.014$, $d=-0.21$) over time when controlling for age, sex and baseline characteristics within the intervention consumers. Baseline equivalence was significantly different but not clinically significant (hypertension risk was equal per clinical categories). Significant improvements in quality of life (Duke Health Profile) and the PHQ-9 were found within the intervention group and between the intervention and comparison groups at 12-months for Anxiety (-5.83; 95% CI: -9.50 to -2.16, $p < 0.001$, $d = -0.30$) and Pain (-13.44; 95% CI: -24.41 to -2.47, $p = 0.005$, $d = -0.16$) Duke Health Profile domains and PHQ-9 (-2.77; 95% CI: -4.83 to -0.72, $d = 0.18$, $p = 0.001$). Furthermore, the Quasi-Experimental design with nested clinics allowed for the identification of major threats to validity and introduction of bias including selection bias and contamination of the consumer sample across clinics. The program was conducted as planned with major elements completed and achieved over time. Given the unequal demographic and clinical characteristics between the treatment and intervention groups we cannot designate the study to have resulted in a moderate level of evidence.

The impact of the program on depression is significant and promising, indicating the inclusion of EIS and transportation positively impacts depression over time as part of an IBH program for populations with SMI in rural communities. Further examination regarding differences and impact in change over time between the intervention groups adjusting for EIS participation may yield significant differences within and between the intervention and comparison groups. The subgroup analysis is being completed and will be used to inform manuscripts and reports to the community. Given the strengths of the study design, there is evidence that the intervention contributed to the positive changes in health outcomes observed over time within and between the groups. However, we did not observe any changes in exploratory outcomes including hemoglobin A1c, BMI or health literacy.

Lessons Learned, Study Limitations, and Next Steps

Overall, the study contributes to our understanding of the impact of IBH within a behavioral health clinical setting in rural areas. It is important to note that the unique aspect of this study is the addition of transportation services that address a determinant of health, specifically, adherence to care. The findings expand our understanding of the impact of a co-located clinic on changes to disease adherence, chronic disease management and integration of transit services. To our knowledge, this is one of the few quasi-experimental clinic-based studies to examine the impact of IBH and enhanced integrated services to impact disease management in a predominately Hispanic SMI population. A better understanding of the population and the unique aspects of chronic disease management were examined more thoroughly as the study integrated the Voices Leadership Group, consumer driven components and aspects of activities yielded greater reach, retention efforts and integration of feedback into organizational level activities.

Additional analyses to determine subgroup specific population impact will be completed in the next three months. This will include analyses to examine changes in 1) consumers with a diagnosis of type 2 diabetes

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

in the intervention and comparison group, 2) consumers with a diagnosis of hypertension in the intervention and comparison group, and 3) consumers who are obese in the intervention and comparison group. These analyses are planned and will be completed within the next three months. Results of these analyses are not included in this report.

The findings from this study point to key aspects of reach and impact that promoted behavioral and clinical outcome changes consistent with the literature (Scharf, et al. 2014). However, the TRIP for Salud y Vida program also points to the impact of transportation services to adherence and integration of care in rural settings. We do not believe the TRIP program would have been as successful without the facilitation of transportation services.

Lessons Learned

While all attempts to implement the intervention and evaluation with fidelity were made, several lessons learned will inform future research and programming by the TRIP partners and others interested in addressing the unique disease management needs of an SMI population within rural settings.

Evaluation Lessons

The quasi-experimental study implemented for this evaluation was the first for REAL, Inc. and partners that required assignment of clinic settings as either intervention or comparison sites. Careful planning and integration of unique data collection as well as tracking systems was necessary. For example, the tracking of each EIS activity was important to estimate the participation in key intervention programming as well as to better understand who participated in the intervention. As part of the TRIP program, careful tracking of transit use was integrated through software at the REAL, Inc. site. The software allowed for tracking of mileage, purpose of the trip as well as no-shows for transportation services. Data from both the Access CHW access tracking database and the transportation database were used to identify key points for quality improvement. Partners carefully worked together to meet recruitment goals and retention goals at each follow-up data collection point. The ability to partner allowed for the identification of methods and processes to promote quality of care (HbA1c testing changes at CPCC) and sharing of important data across the IBH program. Several strategies were used to promote retention as well as attendance to EIS classes, these included reminder calls from the navigators and CHWs and frequent check-ins and reminders of upcoming data collection activities (implementation and impact). Partner communication and planning allowed for the identification of program needs as well as training and addressing of data collection and retention needs that promoted clear processes and protocols as well as quality communication.

Study Limitations and Implications for Future Research

Additional analyses to determine subgroup specific population impact will be completed in the next three months. This will include analyses to examine changes in 1) consumers with a diagnosis of type 2 diabetes in the intervention and comparison group, 2) consumers with a diagnosis of hypertension in the intervention and comparison group, and 3) consumers who are obese in the intervention and comparison group. These analyses are planned and will be completed within the next three months.

We will also complete analysis to determine the impact of participating in specific educational sessions. This will include assessing changes between the intervention and comparison groups over time for specific populations and by EIS session type. We posit that other confirmatory and exploratory variables of interest to TRIP will be found to have greater changes once we explore for specific levels of participation in the EIS and transportation services.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

There are several limitations to this study as with most intervention studies. First, the findings indicate trends in clinical outcomes that suggest long term impact, however, we need to examine subgroups that had greater change. Specifically, did changes vary by intervention clinic site or other environmental level factor that can be identified and used to promote health outcomes across the CPCC IBH clinic sites and points to specific intervention components that may be most effective in the SMI population. The study sample includes males and females with SMI however, we did not examine varied changes in the population by time since diagnosis – this would be a small subgroup analysis but could yield potential benefits to greater understanding of population level needs. Additionally, the population resides in rural areas and may not be representative of more urban populations with SMI. This limitation however, provides great insight to an often-understudied rural population. Finally, the sample is primarily Hispanic of Mexican descent, while important to understand the needs of the population, findings may not be generalizable to a more heterogeneous population of individuals with SMI.

As noted previously, the changes to the SEP were primarily related to data collection and analyses due to lack of quality data. The questions used to assess the food and nutrition as well as physical activity over time were not validated and did not yield appropriate data. Additionally, we did not geocode roads by type of road type. All other analyses were completed as planned and approved in the approved SEP.

Studies have pointed to gaps in access to care and management of chronic illness due to transportation services. The TRIP for Salud y Vida program evaluation findings point to integration of rural transit services will increase reach, participation and improve health outcomes over time. Ongoing programming to promote sustainability of key programs targeting depression, anxiety and hypertension and type 2 diabetes prevention and control across the TRIP partners are planned.

While limitations to the use of a quasi-experimental design are important to note, the larger sample size, use of multiple clinic sites and set usual care model (comparing the original Salud y Vida program to the TRIP for Salud y Vida program) improved our ability to examine changes over time across two programs. The examination of key chronic disease indicators in a co-morbid population with severe mental illness (SMI) will improve our understanding of the relationship between chronic diseases such as hypertension, type 2 diabetes and obesity and SMI. Given the rural population, the generalizability of study findings may not represent the overall population with SMI, however we believe that the population's enthusiasm, response to the EIS and participation rates point to engagement and activation of a population with SMI that often receives set protocol-based treatment within a clinic setting. A limitation of quality and systematic data collection for key variables such as HbA1c points to needs for yearly examination of risk in populations with SMI. Changes in delivery of care to improve reach and quality of care informed by best practices is key. Quality improvement opportunities including changes in physician care practices in collaboration with psychiatric and behavioral health specialists will be key for long term care management improvements.

Future directions point to better understanding of the risk and impact of changes over time in populations with a diagnosis of hypertension or type 2 diabetes. While the TRIP for Salud y Vida population primarily represented a high-risk population, Hispanic and overweight, the population included individuals with and without a diagnosis of hypertension and type 2 diabetes.

We posit that the use and integration of community health workers in the delivery of a systematic intervention in rural and clinical settings points to an opportunity to design and effectively reach high risk populations. The SMI population is often times isolated within both urban and rural settings; a behavioral health approach that improves access through set transportation services appears to improve health and

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

outcomes over time. The CHWs were carefully trained and certified to best serve and address the needs of the SMI populations. The use of local resources to deliver EIS was a value to both the community and the consumers enrolled in the TRIP for Salud y Vida program. Focusing on local resources will result in 1) building a sense of community, 2) decreasing social isolation and stigma in the SMI population and 3) improved behavioral and health outcomes over time. The sustainability of programs such as TRIP benefits from integration of multiple partners.

Planning for maintaining capacity and sustaining the TRIP program are in place. Ongoing efforts for integration of services across the partners is planned.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

OTHER ASPECTS OF STUDY LOGISTICS AND FEASIBILITY

Human Subjects Protection

The UTHealth System awarded 12-month approval with Dr. Melissa Valerio as contact on 12/14/15 date. Mr. Martin Ornelas is listed on the IRB for REAL, Inc. Several members of the TRIP partner organizations completed and received CITI certification as part of the program's capacity building within partner organizations. Continuation of IRB approval for one year was awarded on 8/24/16, 6/13/2017, 03/19/18 and 03/01/19. No amendments or changes to the approved protocols were submitted.

Timeline

From the final approved SEP, the only deviation in the timeline is in the timing for data analysis and reporting. Data cleaning and analysis were delayed due to delays in SEP approval and data submission. This also resulted in delays for report submission. Please see the attached table for an updated timeline.

Evaluator/Subgrantee Role and Involvement

Changes to the evaluation team were made regarding responsibilities for the final analyses and SIF Final Report. REAL's evaluation consultant team, Drs. Melissa Valerio, John Cornell and Aubree Shay, completed the impact analyses presented in this report per the approved SEP. Drs. Mary Davis and Lisa Wolff from HRiA, MHM's external evaluators for the overall Sí Texas evaluation, conducted the implementation analyses, were responsible for related sections of this report, and supported MHM in ensuring the final report met SIF expectations. Rebecca Adeigbe (Jones), who had been the HRiA lead for REAL's evaluation is no longer working at HRiA.

Budget

No changes have been made to the evaluation budget to date.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

REFERENCES

- Acee, A. M. (2010). Detecting and managing depression in type II diabetes: PHQ-9 is the answer. *Medsurg Nursing : Official Journal of the Academy of Medical-Surgical Nurses*, 19(1), 32. Retrieved from http://utsa.summon.serialssolutions.com/2.0.0/link/0/eLvHCXMw1V3batwwEBVpQktfQtOLm-aC3o2NLa11KfQhZFPWm7SONIG-GdmSQyBx2_WG_n5HkrXuZskH5MkY2xjrjEYz8pkzCFGSZskDn6BhZWkU4yaTNRGGTkitNURMeV0UBVUytCZwGjajAvADXZsnDvzU2P8CofZw1YdoGiivjtpo08-4LOOBEON4cd9m3xMZI72vNu
- Arcury TA¹, Preisser JS, Gesler WM, Powers JM. Access to transportation and health care utilization in a rural region. *J Rural Health*. 2005 Winter;21(1):31-8.
- Adamopoulos, C., Meyer, P., Desai, R. V, Karatzidou, K., Ovalle, F., White, M., ... Ahmed, A. (2011). Absence of obesity paradox in patients with chronic heart failure and diabetes mellitus: a propensity-matched study. *European Journal of Heart Failure*, 13(2), 200–6. <http://doi.org/10.1093/eurjhf/hfq159>
- The American Association for Public Opinion Research. 2016. Standard Definitions: Final Dispositions of Case Codes and Outcome Rates for Surveys. 9th edition. AAPOR.
- American Diabetes Association. (2014). Standards of medical care in diabetes--2014. *Diabetes Care*, 37 Suppl 1, S14–80. <http://doi.org/10.2337/dc14-S014>
- American Heart Association. (2015). Understanding Blood Pressure Readings. Retrieved July 22, 2015, from http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/AboutHighBloodPressure/Understanding-Blood-Pressure-Readings_UCM_301764_Article.jsp
- American Psychiatric Association. (1994). *Quick Reference to the Diagnostic Criteria from DSM-IV*. Washington, DC: Press, Inc.
- Arcury, T. A., Preisser, J. S., Gesler, W. M., & Powers, J. M. (2005). Access to transportation and health care utilization in a rural region. *The Journal of Rural Health : Official Journal of the American Rural Health Association and the National Rural Health Care Association*, 21(1), 31–8. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/15667007>
- Arroll, B. (2010). Validation of PHQ-2 and PHQ-9 to screen for major depression in the primary care population. *Ann Fam Med*, 8(4), 348–353. <http://doi.org/10.1370/afm.1139>
- Bazargan, M., Ani, C. O., Hindman, D. W., Bazargan-Hejazi, S., Baker, R. S., Bell, D., & Rodriguez, M. (2008). Correlates of complementary and alternative medicine utilization in depressed, underserved african american and Hispanic patients in primary care settings. *Journal of Alternative and Complementary Medicine (New York, N.Y.)*, 14(5), 537–44. <http://doi.org/10.1089/acm.2007.0821>
- Beil H, Feinberg RK, Patel SV, Romaine MA. Behavioral Health Integration With Primary Care: Implementation Experience and Impacts From the State Innovation Model Round 1 States. *Milbank Q*. 2019 Apr 7. doi: 10.1111/1468-0009.12379.
- Booth, G. L., Shah, B. R., Austin, P. C., Hux, J. E., Luo, J., & Lok, C. E. (2016). Early specialist care for diabetes: who benefits most? A propensity score-matched cohort study. *Diabetic Medicine : A Journal of the British Diabetic Association*, 33(1), 111–8. <http://doi.org/10.1111/dme.12801>
- Brown, S. (1997). Excess mortality of schizophrenia. A meta-analysis. *The British Journal of Psychiatry*, 171(6), 502–508. <http://doi.org/10.1192/bjp.171.6.502>
- Bryan, C. J., Morrow, C., & Appolonio, K. K. (2009). Impact of behavioral health consultant interventions on patient symptoms and functioning in an integrated family medicine clinic. *Journal of Clinical Psychology*, 65(3), 281–93. <http://doi.org/10.1002/jclp.20539>

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- Buckingham, E., Schrage, E., & Cournois, F. (2013). Why the Treatment of Mental Disorders Is an Important Component of HIV Prevention among People Who Inject Drugs. *Advances in Preventive Medicine, 2013*, 690386. Retrieved from http://utsa.summon.serialssolutions.com/2.0.0/link/0/eLvHCXMw1V1NS8NAEF1EQQR60f8Zu4lod1uk3jwIFqp6EGwojdJkyy9mGrSCvrrndnZbEtLf4Cnk maz7PKSyczkzRshOjJo-Qs2oZtEsdZSDrUKE6nCbqRS9LxT1ZU6CYdZ3ZrAaNjM6PQLujb_HPjX0Y_xJgeOQk4sF656rLU2q-Y9aTOTNjC53ziG7MK4sKP7FBNabS
- Butler, M., Kane, R., McAlpine, D., Kathol, R., Fu, S., Hagedorn, H., & Wilt, T. (2008). *Integration of Mental Health/Substance Abuse and Primary Care No. 173. Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-02-0009*. Rockville, MD. Retrieved from file:///C:/Users/Becky/Downloads/www.ahrq.gov_research_findings_evidence-based-reports_mhsapc-evidence-report.pdf
- Cabassa, L. J., Nicasio, A., & Whitley, R. (2013). Picturing recovery: a photovoice exploration of recovery dimensions among people with serious mental illness. *Psychiatric Services (Washington, D.C.), 64*(9), 837–842. <http://doi.org/10.1176/appi.ps.201200503>
- Cannon, D. S., Tiffany, S. T., Coon, H., Scholand, M. B., McMahan, W. M., & Leppert, M. F. (2007). The PHQ-9 as a Brief Assessment of Lifetime Major Depression. *Psychological Assessment, 19*(2), 247–251. <http://doi.org/10.1037/1040-3590.19.2.247>
- Carrasquillo, O., Patberg, E., Alonzo, Y., Li, H., & Kenya, S. (2014). Rationale and design of the Miami Healthy Heart Initiative: a randomized controlled study of a community health worker intervention among Latino patients with poorly controlled diabetes. *International Journal of General Medicine, 7*, 115–26. <http://doi.org/10.2147/IJGM.S56250>
- CDC. (2011). Health Related Quality of Life. Retrieved July 22, 2015, from <http://www.cdc.gov/hrqol/concept.htm>
- Cepeda, M. S., Boston, R., Farrar, J. T., & Strom, B. L. (2003). Comparison of logistic regression versus propensity score when the number of events is low and there are multiple confounders. *American Journal Of Epidemiology, 158*(3), 280–287. Retrieved from <http://search.ebscohost.com/login.aspx?direct=true&db=mdc&AN=12882951&site=ehost-live>
- Chew, L. D., Bradley, K. A., & Boyko, E. J. (2004). Brief questions to identify patients with inadequate health literacy. *Family Medicine, 36*(8), 588–594. Retrieved from <http://search.ebscohost.com/login.aspx?direct=true&db=mdc&AN=15343421&site=ehost-live>
- Chew, L. D., Griffin, J. M., Partin, M. R., Noorbaloochi, S., Grill, J. P., Snyder, A., Bradley, K. A., Nugent, S. M., Baines, A. D., ... Vanryn, M. (2008). Validation of screening questions for limited health literacy in a large VA outpatient population. *Journal of general internal medicine, 23*(5), 561-6.
- Chwastiak, L. A., Davydow, D. S., McKibbin, C. L., Schur, E., Burley, M., McDonell, M. G., ... Daratha, K. B. (2014). The Impact of Serious Mental Illness on the Risk of Re-hospitalization among Patients with Diabetes. *Psychosomatics, 55*(2), 134–143. <http://doi.org/10.1016/j.psym.2013.08.012>
- Collins, C., Hewson, D. L., Munger, R., & Wade, T. (2010). *Evolving Models of Behavioral Health Integration in Primary Care*. Retrieved from <http://www.milbank.org/uploads/documents/10430EvolvingCare/EvolvingCare.pdf>
- Cully, J. A., Graham, D. P., Stanley, M. A., Ferguson, C. J., Sharafkhaneh, A., Soucek, J., & Kunik, M. E. (2006). Quality of life in patients with chronic obstructive pulmonary disease and comorbid anxiety or depression. *Psychosomatics, 47*(4), 312–319. <http://doi.org/10.1176/appi.psy.47.4.312>
- Danziger, S., Frank, R. G., & Meara, E. (2009). Mental illness, work, and income support programs. *The American Journal of Psychiatry, 166*(4), 398–404. <http://doi.org/10.1176/appi.ajp.2008.08020297>

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- DE Hert, M., Correll, C. U., Bobes, J., Cetkovich-Bakmas, M., Cohen, D., Asai, I., ... Leucht, S. (2011). Physical illness in patients with severe mental disorders. I. Prevalence, impact of medications and disparities in health care. *World Psychiatry : Official Journal of the World Psychiatric Association (WPA)*, 10(1), 52. Retrieved from http://utsa.summon.serialssolutions.com/2.0.0/link/0/eLvHCXMw1V1Lb5wwELY2qVRVqqqmD_qUfN-CwBjbe-ghTVllag8rdaP2Fhljq6vswjZLr_3tHTNGaKL8gB7QigUDsj_PjMcz3xCSsySNb8mEQkvlHG0l40IzLgrJDVjehhfMaVFWQ2mCjsNmNhvqqN7itfnPB3459Px6s-nk2Mie2qeygTKON3be0_pXPf_mPplfJD4kAz
- Delgado, J., Payne, S., Gilbody, S., Godfrey, C., Gore, S., Jessop, D., & Dale, V. (2011). How reliable is depression screening in alcohol and drug users? A validation of brief and ultra-brief questionnaires. *Journal of Affective Disorders*, 134(1), 266–271. <http://doi.org/10.1016/j.jad.2011.06.017>
- Denzin, N. K., & Lincoln, Y. S. (2000). *Handbook of qualitative research*. Thousand Oaks, Calif.: Sage Publications.
- Desai, M. M., Rosenheck, R. A., Druss, B. G., & Perlin, J. B. (2002). Receipt of nutrition and exercise counseling among medical outpatients with psychiatric and substance use disorders. *Journal of General Internal Medicine*, 17(7), 556–560. <http://doi.org/10.1046/j.1525-1497.2002.10660.x>
- Dilley JA¹, Bekemeier B, Harris JR. Quality improvement interventions in public health systems: a systematic review. *Am J Prev Med*. 2012 May;42(5 Suppl 1):S58-71. doi: 10.1016/j.amepre.2012.01.022
- Druss, B. G., Rohrbaugh, R. M., Levinson, C. M., & Rosenheck, R. A. (2001). Integrated medical care for patients with serious psychiatric illness: a randomized trial. *Archives of General Psychiatry*, 58(9), 861–8. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/11545670>
- Dum, M., Pickren, J., Sobell, L. C., & Sobell, M. B. (2008). Comparing the BDI-II and the PHQ-9 with outpatient substance abusers. *Addictive Behaviors*, 33(2), 381–387. <http://doi.org/10.1016/j.addbeh.2007.09.017>
- Ell, K., Katon, W., Cabassa, L. J., Xie, B., Lee, P.-J., Kapetanovic, S., & Guterman, J. (2009). Depression and diabetes among low-income Hispanics: design elements of a socioculturally adapted collaborative care model randomized controlled trial. *The International Journal of Psychiatry in Medicine*, 39(2), 113. <http://doi.org/10.2190/PM.39.2.a>
- Fazel, S., Khosla, V., Doll, H., & Geddes, J. (2008). The prevalence of mental disorders among the homeless in western countries: systematic review and meta-regression analysis. *PLoS Medicine*, 5(12), e225. <http://doi.org/10.1371/journal.pmed.0050225>
- Friedmann, P. D., Lemon, S. C., Stein, M. D., Etheridge, R. M., & D'Aunno, T. A. (2001). Linkage to medical services in the Drug Abuse Treatment Outcome Study. *Medical Care*, 39(3), 284–95. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/11242322>
- Gall, M., Borg, W. R. ., & Gall, J. P. (1996). *Educational research: An introduction*. (L. P. E. Research, Ed.) (6th ed.). White Plains, NY.
- Gavric, Z., Culafic, A., & Markovic, B. (2011). Correlation between phq-9 score and physical activity level, risk factors and non-communicable diseases in patients in family medicine clinic. *Central European Journal of Medicine*, 6(3), 372–377. <http://doi.org/10.2478/s11536-011-0022-4>
- Gellad, W. F., Haas, J. S., & Safran, D. G. (2007). Race/ethnicity and nonadherence to prescription medications among seniors: results of a national study. *Journal of General Internal Medicine*, 22(11), 1572–8. <http://doi.org/10.1007/s11606-007-0385-z>
- Harder, V. S., Stuart, E. A., & Anthony, J. C. (2010). Propensity score techniques and the assessment of measured covariate balance to test causal associations in psychological research. *Psychological Methods*, 15(3), 234–49. <http://doi.org/10.1037/a0019623>

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- Harris, E. C., & Barraclough, B. (1998). Excess mortality of mental disorder. *The British Journal of Psychiatry : The Journal of Mental Science*, 173, 11–53. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/9850203>
- Heath, B., Wise Romero, R., & Reynolds, K. (2013). *A Standard Framework for Levels of Integrated Healthcare*. Retrieved from http://www.integration.samhsa.gov/integrated-care-models/A_Standard_Framework_for_Levels_of_Integrated_Healthcare.pdf
- Himelhoch, S., McCarthy, J. F., Ganoczy, D., Medoff, D., Kilbourne, A., Goldberg, R., ... Blow, F. C. (2009). Understanding associations between serious mental illness and hepatitis C virus among veterans: a national multivariate analysis. *Psychosomatics*, 50(1), 30–37. <http://doi.org/10.1176/appi.psy.50.1.30>
- Horwitz, R. I., Horwitz, S. M., Haynes RB, T. D. S. D. eds, MH, W., Group, C. D. P. R., Pizzo PA, R. K. E. B. S. C. K. B. J. A., ... Brown EY, V. C. H. R. (1993). Adherence to Treatment and Health Outcomes. *Archives of Internal Medicine*, 153(16), 1863. <http://doi.org/10.1001/archinte.1993.00410160017001>
- Huang, F. Y., Chung, H., Kroenke, K., Delucchi, K. L., & Spitzer, R. L. (2006). ORIGINAL ARTICLES: Using the Patient Health Questionnaire-9 to Measure Depression among Racially and Ethnically Diverse Primary Care Patients. *Journal of General Internal Medicine*, 21(6), 547. <http://doi.org/10.1111/j.1525-1497.2006.00409.x>
- Hutchinson, D. S., Gagne, C., Bowers, A., Russinova, Z., Skrinar, G. S., & Anthony, W. A. (2006). A framework for health promotion services for people with psychiatric disabilities. *Psychiatric Rehabilitation Journal*, 29(4), 241–250. <http://doi.org/http://dx.doi.org/10.2975/29.2006.241.250>
- Kane, C. F., & Ennis, J. M. (1996). Health care reform and rural mental health: Severe mental illness. *Community Mental Health Journal*, 32(5), 445–462. Retrieved from <https://login.libweb.lib.utsa.edu/login?url=http://search.proquest.com/docview/228392523?accountid=7122>
- Katon, W. J., Lin, E. H. B., Von Korff, M., Ciechanowski, P., Ludman, E. J., Young, B., ... McCulloch, D. (2010). Collaborative care for patients with depression and chronic illnesses. *The New England Journal of Medicine*, 363(27), 2611–20. <http://doi.org/10.1056/NEJMoa1003955>
- Kessler, R. C., Heeringa, S., Lakoma, M. D., Petukhova, M., Rupp, A. E., Schoenbaum, M., ... Zaslavsky, A. M. (2008). Individual and societal effects of mental disorders on earnings in the United States: results from the national comorbidity survey replication. *The American Journal of Psychiatry*, 165(6), 703–711. <http://doi.org/10.1176/appi.ajp.2008.08010126>
- Kiely, K. M., & Butterworth, P. (2015). Validation of four measures of mental health against depression and generalized anxiety in a community based sample. *Psychiatry Research*, 225(3), 291–298. <http://doi.org/10.1016/j.psychres.2014.12.023>
- Kim, R., Hickman, N., Gali, K., Orozco, N., & Prochaska, J. J. (2014). Maximizing Retention with High Risk Participants in a Clinical Trial. *American Journal of Health Promotion*, 28(4), 268–274. <https://doi.org/10.4278/ajhp.120720-QUAN-355>
- King G. and Nielsen R. 2019. “Why Propensity Scores Should Not Be Used for Matching.” Political Analysis. Copy at <http://j.mp/2ovYGsW>
- Kroenke, K., & Spitzer, R. L. (2002). The PHQ-9: A New Depression Diagnostic and Severity Measure. *Psychiatric Annals*, 32(9), 509–515. <http://doi.org/10.3928/0048-5713-20020901-06>
- Kuo, Y.-F., Goodwin, J. S., Chen, N.-W., Lwin, K. K., Baillargeon, J., & Raji, M. A. (2015). Diabetes Mellitus Care Provided by Nurse Practitioners vs Primary Care Physicians. *Journal of the American Geriatrics Society*, 63(10), 1980–8. <http://doi.org/10.1111/jgs.13662>
- Latalova, K., Kamaradova, D., & Prasko, J. (2014). Violent victimization of adult patients with severe mental illness: a systematic review. *Neuropsychiatric disease and treatment*, 10, 1925-39. doi:10.2147/NDT.S68321

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- Linmans, J. J., Spigt, M. G., Deneer, L., Lucas, A. E. M., de Bakker, M., Gidding, L. G., ... Knottnerus, J. A. (2011). Effect of lifestyle intervention for people with diabetes or prediabetes in real-world primary care: propensity score analysis. *BMC Family Practice*, *12*(1), 95. <http://doi.org/10.1186/1471-2296-12-95>
- Little, R., & Rubin, D. (2014). *Statistical analysis with missing data*. Retrieved from <https://books.google.com/books?hl=en&lr=&id=AyVeBAAAQBAJ&oi=fnd&pg=PT8&dq=statistical+analysis+with+missing+data+1987&ots=uxWU6xmWbH&sig=CLSdUFDGuV-2Jjtm8AyEVFVYgSE>
- Mackinnon, D. P., & Dwyer, J. H. (1993). Estimating Mediated Effects in Prevention Studies. *Evaluation Review*, *17*(2), 144–158. <http://doi.org/10.1177/0193841X9301700202>
- Martin, A., Rief, W., Klaiberg, A., & Braehler, E. (2006). Validity of the Brief Patient Health Questionnaire Mood Scale (PHQ-9) in the general population. *General Hospital Psychiatry*, *28*(1), 71–77. <http://doi.org/10.1016/j.genhosppsych.2005.07.003>
- McClave, A. K., McKnight-Eily, L. R., Davis, S. P., & Dube, S. R. (2010). Smoking characteristics of adults with selected lifetime mental illnesses: results from the 2007 National Health Interview Survey. *American Journal of Public Health*, *100*(12), 2464–2472. <http://doi.org/10.2105/AJPH.2009.188136>
- Merz, E. L., Malcarne, V. L., Roesch, S. C., Riley, N., & Sadler, G. R. (2011). A Multigroup Confirmatory Factor Analysis of the Patient Health Questionnaire-9 Among English- and Spanish-Speaking Latinas. *Cultural Diversity and Ethnic Minority Psychology*, *17*(3), 309–316. <http://doi.org/10.1037/a0023883>
- Morgan, R. D., Flora, D. B., Kroner, D. G., Mills, J. F., Varghese, F., & Steffan, J. S. (2012). Treating offenders with mental illness: a research synthesis. *Law and Human Behavior*, *36*(1), 37–50. <http://doi.org/10.1037/h0093964>
- Mongeon, M., J. Levi, and J. Heinrich. 2017. Elements of accountable communities for health: A review of the literature. *NAM Perspectives*. Discussion Paper, National Academy of Medicine, Washington, DC. doi: 10.31478/201711a
- National Guideline Clearinghouse. (2014). Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. Rockville MD: Agency for Healthcare Research and Quality (AHRQ). Retrieved from <http://www.guideline.gov/content.aspx?id=48872&search=waist+circumference>
- National Guidelines Clearinghouse. (2011). Hypertension. Clinical management of primary hypertension in adults. Rockville MD: Agency for Healthcare Research and Quality (AHRQ). Retrieved from <http://www.guideline.gov/content.aspx?id=34824>
- Nemet GF¹, Bailey AJ. Distance and health care utilization among the rural elderly. *Soc Sci Med*. 2000 May;50(9):1197-208.
- Ockene, I. S., Tellez, T. L., Rosal, M. C., Reed, G. W., Mordes, J., Merriam, P. A., ... Ma, Y. (2012). Outcomes of a Latino community-based intervention for the prevention of diabetes: the Lawrence Latino Diabetes Prevention Project. *American Journal of Public Health*, *102*(2), 336–42. <http://doi.org/10.2105/AJPH.2011.300357>
- Parker, M. M., Moffet, H. H., Schillinger, D., Adler, N., Fernandez, A., Ciechanowski, P., & Karter, A. J. (2012). Ethnic Differences in Appointment-Keeping and Implications for the Patient-Centered Medical Home-Findings from the Diabetes Study of Northern California (DISTANCE). *Health Services Research*, *47*(2), 572–593. <http://doi.org/10.1111/j.1475-6773.2011.01337.x>
- Parker, R. M., Baker, D. W., Williams, M. V., & Nurss, J. R. (1995). The test of functional health literacy in adults: a new instrument for measuring patients' literacy skills. *Journal of General Internal Medicine*, *10*(10), 537–41. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/8576769>
- Parkerson, G. R., Broadhead, W. E., & Tse, C. K. (1990). The Duke Health Profile. A 17-item measure of health and dysfunction. *Medical Care*, *28*(11), 1056–72. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/2250492>

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- Perez-Cruzado D^{1,2}, Cuesta-Vargas AI^{3,4,5}, Vera-Garcia E^{1,6}, Mayoral-Cleries F⁶. The relationship between quality of life and physical fitness in people with severe mental illness. *Health Qual Life Outcomes*. 2018 May 2;16(1):82. doi: 10.1186/s12955-018-0909-8.
- Pinto-Meza, A., Serrano-Blanco, A., Peñarrubia, M. T., Blanco, E., Haro, J. M., Harzheim, D., ... Geerlings, M. I. (2010). Diagnostic accuracy of Spanish language depression-screening instruments. *Journal of Affective Disorders*, 32(4), 312–319. <http://doi.org/10.1111/j.1525-1497.2006.00409.x>
- Prezio, E. A., Cheng, D., Balasubramanian, B. A., Shuval, K., Kendzor, D. E., & Culica, D. (2013). Community Diabetes Education (CoDE) for uninsured Mexican Americans: a randomized controlled trial of a culturally tailored diabetes education and management program led by a community health worker. *Diabetes Research and Clinical Practice*, 100(1), 19–28. <http://doi.org/10.1016/j.diabres.2013.01.027>
- Priebe, S., Yeeles, K., Bremner, S., Lauber, C., Eldridge, S., Ashby, D., ... Burns, T. (2013). Effectiveness of financial incentives to improve adherence to maintenance treatment with antipsychotics: cluster randomised controlled trial. *BMJ*, 347.
- Qualitative Data Analysis*. (2013). Sage Pubns.
- Ray-Sannerud, B. N., Dolan, D. C., Morrow, C. E., Corso, K. A., Kanzler, K. E., Corso, M. L., & Bryan, C. J. (2012, March). Longitudinal outcomes after brief behavioral health intervention in an integrated primary care clinic. - ProQuest. <http://doi.org/10.1037/a0027029>
- Reuland, D. S., Cherrington, A., Watkins, G. S., Bradford, D. W., Blanco, R. A., & Gaynes, B. N. Diagnostic accuracy of Spanish language depression-screening instruments. *Annals of Family Medicine*, 7(5), 455–62. <http://doi.org/10.1370/afm.981>
- Roberts, L. W., Battaglia, J., & Epstein, R. S. (1999). Frontier Ethics: Mental Health Care Needs and Ethical Dilemmas in Rural Communities. *Psychiatric Services*. Retrieved from <http://ps.psychiatryonline.org/doi/full/10.1176/ps.50.4.497>
- Rosenbaum, P. R., & Rubin, D. B. (2012). Constructing a Control Group Using Multivariate Matched Sampling Methods That Incorporate the Propensity Score. *The American Statistician*. Retrieved from <http://amstat.tandfonline.com/doi/abs/10.1080/00031305.1985.10479383#.VgxA4vViko>
- Rosland, A.-M., Kieffer, E., Spencer, M., Sinco, B., Palmisano, G., Valerio, M., ... Heisler, M. (2015). Do pre-existing diabetes social support or depressive symptoms influence the effectiveness of a diabetes management intervention? *Patient Education and Counseling*. <http://doi.org/10.1016/j.pec.2015.05.019>
- Rothman, R. L., Malone, R., Bryant, B., Shintani, A. K., Crigler, B., Dewalt, D. A., ... Pignone, M. P. (2005). A randomized trial of a primary care-based disease management program to improve cardiovascular risk factors and glycated hemoglobin levels in patients with diabetes. *The American Journal of Medicine*, 118(3), 276–84. <http://doi.org/10.1016/j.amjmed.2004.09.017>
- Rubin, D. B. (2001). Using Propensity Scores to Help Design Observational Studies: Application to the Tobacco Litigation. *Health Services and Outcomes Research Methodology*, 2(3-4), 169–188. <http://doi.org/10.1023/A:1020363010465>
- Saha, S., Chant, D., & McGrath, J. (2007). A systematic review of mortality in schizophrenia: is the differential mortality gap worsening over time? *Archives of General Psychiatry*, 64(10), 1123–31. <http://doi.org/10.1001/archpsyc.64.10.1123>
- Saultz, J. W., & Lochner, J. (2005). Interpersonal continuity of care and care outcomes: a critical review. *Annals of Family Medicine*, 3(2), 159–66. <http://doi.org/10.1370/afm.285>
- Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *Ann Int Med* 2010;152. Epub 24 March.
- Schuntermann, M. F. (1997). [The Duke Health Profile (DUKE)]. *Die Rehabilitation*, 36(1), I–XIV. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/9213865>

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- Scott, K. M., de Jonge, P., Alonso, J., Viana, M. C., Liu, Z., O'Neill, S., ... Kessler, R. C. (2013). Associations between DSM-IV mental disorders and subsequent heart disease onset: beyond depression. *International Journal of Cardiology*, *168*(6), 5293–5299. <http://doi.org/10.1016/j.ijcard.2013.08.012>
- Shackelford, J. R., Sirna, M., Mangurian, C., Dilley, J. W., & Shumway, M. (2013). Descriptive analysis of a novel health care approach: reverse colocation-primary care in a community mental health “home”. *The Primary Care Companion for CNS Disorders*, *15*(5). <http://doi.org/10.4088/PCC.13m01530>
- Short, L. M., & Hennessy, M. (1994). Using structural equations to estimate effects of behavioral interventions. *Structural Equation Modeling: A Multidisciplinary Journal*, *1*(1), 68–81. <http://doi.org/10.1080/10705519409539962>
- Spencer, M. S., Rosland, A.-M., Kieffer, E. C., Sinco, B. R., Valerio, M., Palmisano, G., ... Heisler, M. (2011). Effectiveness of a Community Health Worker Intervention Among African American and Latino Adults With Type 2 Diabetes: A Randomized Controlled Trial. *American Journal of Public Health*, *101*(12), 2253–2260. <http://doi.org/10.2105/AJPH.2010.300106>
- Staten, L., Cutshaw, C., Davidson, C., Reinschmidt, K., Stewart, R., & Roe, D. (2011). Effectiveness of the Pasos Adelante Chronic Disease Prevention and Control Program in a US-Mexico Border Community, 2005-2008. *Preventing Chronic Disease*, *9*. <http://doi.org/10.5888/pcd9.100301>
- Stone GA, Fernandez M, DeSantiago A. Rural Latino health and the built environment: a systematic review. *Ethn Health*. 2019 Apr 19:1-26. doi: 10.1080/13557858.2019.1606899. [Epub ahead of print]
- Stuart, E. A. (2008). Developing practical recommendations for the use of propensity scores: discussion of “A critical appraisal of propensity score matching in the medical literature between 1996 and 2003” by Peter Austin, *Statistics in Medicine*. *Statistics in Medicine*, *27*(12), 2062–5; discussion 2066–9. <http://doi.org/10.1002/sim.3207>
- Sumlin, L. L., Garcia, T. J., Brown, S. A., Winter, M. A., García, A. A., Brown, A., & Cuevas, H. E. (2014). Depression and adherence to lifestyle changes in type 2 diabetes: a systematic review. *The Diabetes Educator*, *40*(6), 731–44. <http://doi.org/10.1177/0145721714538925>
- Swendsen, J., Conway, K. P., Degenhardt, L., Glantz, M., Jin, R., Merikangas, K. R., ... Kessler, R. C. (2010). Mental disorders as risk factors for substance use, abuse and dependence: results from the 10-year follow-up of the National Comorbidity Survey. *Addiction (Abingdon, England)*, *105*(6), 1117–28. <http://doi.org/10.1111/j.1360-0443.2010.02902.x>
- Syed, S. T., Gerber, B. S., & Sharp, L. K. (2013). Traveling towards disease: transportation barriers to health care access. *Journal of community health*, *38*(5), 976-93.
- van der Vaart, R., van Deursen, A. J., Drossaert, C. H., Taal, E., van Dijk, J. A., & van de Laar, M. A. (2011). Does the eHealth Literacy Scale (eHEALS) measure what it intends to measure? Validation of a Dutch version of the eHEALS in two adult populations. *Journal of Medical Internet Research*, *13*(4), e86. <http://doi.org/10.2196/jmir.1840>
- Wagner, E. H. (1998). Chronic disease management: what will it take to improve care for chronic illness? *Effective Clinical Practice : ECP*, *1*(1), 2–4. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/10345255>
- Wagner, E. H. (2000). The role of patient care teams in chronic disease management. *BMJ (Clinical Research Ed.)*, *320*(7234), 569–72. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/10688568>
- Wagner, J. (2012). Chronic Disease Management: Improving Outcomes, Reducing Costs | University of Chicago - SSA. Retrieved from <http://ssa.uchicago.edu/chronic-disease-management-improving-outcomes-reducing-costs>
- Wallace, L. S., Rogers, E. S., Roskos, S. E., Holiday, D. B., & Weiss, B. D. (2006). Brief report: screening items to identify patients with limited health literacy skills. *Journal Of General Internal Medicine*, *21*(8), 874–877. Retrieved from <http://search.ebscohost.com/login.aspx?direct=true&db=mdc&AN=16881950&site=ehost-live>

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- Walton, J. W., Snead, C., Collinsworth, A. W., & Schmidt, K. L. (2012). Reducing Diabetes Disparities Through the Implementation of a Community Health Worker–Led Diabetes Self-Management Education Program. *Family & Community Health, 35*(2), 161–171. Retrieved from http://journals.lww.com/familyandcommunityhealth/Abstract/2012/04000/Reducing_Diabetes_Disparities_Through_the.10.aspx
- Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Dennison Himmelfarb, C., ... Wright, J. T. (2018). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. *Journal of the American College of Cardiology, 71*(19), e127 LP-e248. <https://doi.org/10.1016/j.jacc.2017.11.006>
- Woltmann, E., Grogan-Kaylor, A., Perron, B., Georges, H., Kilbourne, A. M., & Bauer, M. S. (2012). Comparative effectiveness of collaborative chronic care models for mental health conditions across primary, specialty, and behavioral health care settings: systematic review and meta-analysis. *The American Journal of Psychiatry, 169*(8), 790–804. <http://doi.org/10.1176/appi.ajp.2012.11111616>
- Zhang, P., Tao, G., & Anderson, L. A. (2003). Differences in access to health care services among adults in rural America by rural classification categories and age. *The Australian Journal of Rural Health, 11*(2), 64–72. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/12780496>
- Zhong, Q., Gelaye, B., Fann, J. R., Sanchez, S. E., & Williams, M. A. (2014). Cross-cultural validity of the Spanish version of PHQ-9 among pregnant Peruvian women: a Rasch item response theory analysis. *Journal of Affective Disorders, 158*, 148–153. <http://doi.org/10.1016/j.jad.2014.02.012>
- Zurovac J, Peterson GG, Stewart KA, Kranker K, Wells K, Gilman B, Blue L, Day T, Hoag S, Moreno L. Effects of a Behavioral Health and Chronic Illness Care Intervention on Patient Outcomes in Primary Care Practices in the Dakotas. *J Health Care Poor Underserved. 2019;30(2):702-720.* doi: 10.1353/hpu.2019.0051.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

APPENDICES

Appendix A	Revised Project Timeline
Appendix B	Program Logic Model
Appendix C	Sí Texas Mid-Point Implementation Evaluation: Key Informant Interview General Guide
Appendix D	Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide
Appendix E	Sí Texas Summative Implementation Evaluation: Focus Group Guide- SPMI Population
Appendix F	Implementation Evaluation Measures
Appendix G	Patient-Centered Integrated Behavioral Health Care Checklist
Appendix H	Patient Health Questionnaire – 9 (PHQ-9)
Appendix I	Duke Health Profile
Appendix J	TRIP for Salud y Vida Enrollment and Baseline Assessment Form
Appendix K	TRIP for Salud y Vida Baseline Clinical Assessment Form
Appendix L	TRIP for Salud y Vida 12-Month Clinical Assessment Form
Appendix M	TRIP Metrics Assessment Form
Appendix N	BRIEF Health Literacy Screening Tool (BRIEF)

Subgrantee: Rural Economic Assistance League, Inc.
Project Title: TRIP for Salud y Vida

Appendix A. REAL, Inc. 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											
Planning & Program Administration																																									
Program awarded																																									
SEP development & approval																																									
Protocol development																																									
Instrument development																																									
IRB approval process																																									
Staff training																																									
Program start																																									
Program implementation																																									
Program recruitment & enrollment																																									
Data Collection																																									
<i>Baseline (0-6 months)</i>																																									
<i>Intermediate (6 month)</i>																																									
<i>Final (12 month)</i>																																									
Data analysis* & reporting																																									
HRiA (quarterly reporting)																																									
Data cleaning & analysis ^{1,2}																																									
Report writing & editing ^{1,2}																																									
Report to CNCS ^{1,2}																																									
Reports to partners/stakeholders ^{1,2}																																									
Reports to general public/scientific com. ^{1,2}																																									
*HRiA has been contracted by MHM as the Sí Texas program evaluator. All data analyses and reporting will be done on a collaborative basis with the subgrantee; ¹ Annual; ² Final																																									

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Appendix B. Program Logic Model

Inputs		Activities	Outputs	Outcomes	
				Short and Intermediate	Long
<ul style="list-style-type: none"> REAL, Inc. Transportation Coordination Network system Coastal Community Center (CPC) South Coastal Health Education Center (AHEC) Consumer Voices Leadership Group 	<ul style="list-style-type: none"> Assignment of a navigator and case manager Assignment of a consumer attendant Home and telephone nurse assessments Development of an individualized transportation plan Coordination and delivery of tailored transportation services to behavioral and clinical appointments Coordination and delivery of transportation services to and from community health and other health care services Consumer enrollment in a community-health worker led diabetes self-management education (DSME) for the diabetes subgroup Implementation of community-based health and disease management classes tailored to consumer needs (i.e., physical activity, self-management education, food and nutrition education) 	<ul style="list-style-type: none"> Recruit 500 total consumers to participate in the Trip for Salud y Vida program (intervention group [n=250] and external comparison group [n=250]) Provider and staff training to systematically implement TRIP for Salud y Vida Increased enrollment of consumers in services Integration of Voices Leadership Group in planning Development of tailored consumer transportation care plans Incorporation of transportation scheduling Consumer training and use of transportation services and scheduling software Consumer referral to partner and/or community resources Ongoing quality improvement among partner staff 	<ul style="list-style-type: none"> Improvement in consumer’s health behaviors <ul style="list-style-type: none"> Health literacy Dietary habits Physical activity Improvement in overall quality of life Improved appointment keeping Increased use of TRIP Salud y Vida transportation services for health care as measured by number of trips by type (e.g., care appointment, education) 	<ul style="list-style-type: none"> Improvement in consumer health outcomes <ul style="list-style-type: none"> Blood pressure HbA1c BMI PHQ-9 	

EXTERNAL FACTORS: Partner programs maintain funding and able to serve the community. Community educational resources are offered.

ASSUMPTIONS: Consumers remain healthy and able to participate in the educational activities as well as independent transit services.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

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

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

INTERVIEW GOALS

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

INTRODUCTION/INFORMED CONSENT

- Thank you for taking the time out of your day to meet with us. My name is [name] I am a researcher at Health Resources in Action, and today I am joined by my colleague [name] who will assist me during our interview.
- Our goal today is to collect perspectives about the implementation of your Sí Texas project. We hope to learn what has gone well during this initial phase of the project. We are also interested in learning about any challenges that may have been encountered during this period, and your perspectives about what's ahead for the program.
- The interview should last approximately 45 minutes to one hour. I want to remind you that this interview is voluntary and confidential. What we talk about in this space stays in this space so feel free to share your opinion openly and honestly without worrying that it will be repeated. You may choose not to answer any questions during the interview and we can stop at any time. Your interview answers will be summarized in a report along with the interviews from other interview participants.
- I will not identify [name of subgrantee], your name, or your organization's name with your responses in any publication. At the end of the study, we will return to many of our interviewees and ask to re-interview them after the program period has ended. However, participating in this interview does not mean you have to participate in a subsequent interview. The final interview is also voluntary.
- Do you have any questions about the study or how your responses will be used? I would also like to record our session today to make sure our notes are complete and correct, but we will delete the recording after we verify and save our notes. We won't use names in our notes. Are you okay with me recording our discussion?
- As a reminder, when you answer a question, please do not use client's/patient's names. We would appreciate you provide more general examples if you would like to describe a specific situation.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

INTERVIEW QUESTIONS

1. Key Informant Background

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

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

2. Level of Integrated Behavioral Health

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

3. Program Components and Population

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

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- 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 not 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 not 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?

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

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?

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

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

Sí Texas Summative Implementation Evaluation: Key Informant Interview General Guide

CORE INTERVIEW GOALS

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

INTRODUCTION/INFORMED CONSENT (2 MIN)

- Hi, my name is [name] and I am a researcher at Health Resources in Action. I am also joined by my colleague [name] who will assist me during our interview. Thank you for taking the time to speak with us today.
- We are speaking with a variety of people to better understand the implementation of [name of subgrantee Sí Texas program]. We are interested in learning what has worked well, challenges that may have been encountered, and any advice or lessons learned that could inform future planning or sustainability of programs like [name of subgrantee Sí Texas program].
- The interview should last approximately [INSERT TIME: 30-60 minutes]. I want to remind you that this interview is voluntary and confidential. What we talk about in this space stays in this space so please feel free to share your opinions openly and honestly. You may choose not to answer any questions during the interview and we can stop at any time. We are conducting several interviews such as this one and will be writing a summary report that pulls out common themes. We will not identify you in our report or any future publication.
- Do you have any questions about the study or how your responses will be used? I would also like to record our session today to make sure our notes are complete and correct, but we will delete the recording after we verify and save our notes. We won't use names in our notes. Are you okay with me recording our discussion?
- As a reminder, when you answer a question, please do not use client's/patient's names. We would appreciate you provide more general examples if you would like to describe a specific situation.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

INTERVIEW QUESTIONS

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

Key Informant Background (3 MIN)

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

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

2. Now I'd like to talk about the program's goals and its specific activities. What do you see as the goals of [name of subgrantee Sí Texas program]? What were you hoping to achieve for participants?
 - a. [SUBGRANTEE SPECIFIC PROBES: How about goals or desired outcomes for the wider community—for example, family members or care givers? Operational goals for [name of subgrantee Sí Texas program] (e.g., improving show rates to appointments, reducing wait times, etc.)?]
3. Can you walk me through the program: after a participant enrolled in the intervention group, what services or activities did they receive?
 - a. After a participant enrolled in the control/comparison group, what services or activities did they receive?
 - b. What changes, if any, were made to the services or activities offered to intervention participants? How about comparison/control group participants? Why?
 - i. How did these changes affect the program?
4. Since implementing the [name of subgrantee Sí Texas program], to what extent have primary care and behavioral health services been connected or coordinated? How have these services been connected or coordinated?
 - a. How easy or hard has it been to connect or coordinate these services? Why? (If applicable)
 - i. What has made services more or less connected or coordinated?
 - ii. What changes were made to better connect or coordinate services?
 - b. [SUBGRANTEE SPECIFIC PROBE: How are primary care providers involved in patient care? [OR] How are behavioral health providers/health coaches involved in patient care?]
 - c. [SUBGRANTEE SPECIFIC PROBE: Do warm handoffs occur between primary care and behavioral health? How do warm hand offs work? Since the program started, have any changes been made to how warm hand offs work?]

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

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.)

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

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?

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Appendix E. Sí Texas Summative Implementation Evaluation: Focus Group Guide- SPMI Population

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

NEIRB 120170278
#96105.0

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

[PLEASE NOTE: This focus group guide is for participants with Severe Persistent Mental Illness (SPMI) and their caregivers/guardians. Informed consent will be obtained prior to the focus group, and all participants will be reminded of consent guidelines in the group setting to reinforce consent.]

INTRODUCTION SCRIPT (5 MIN)

- Hi everyone. My name is [name] and this is [name]. We are from a company called Health Resources in Action, a nonprofit that does research about health and health care. [OPTIONAL IF BEHAVIORAL HEALTH COUNSELOR/SPECIALIST IS CO-FACILITATING: I am also joined by [name] from [name of organization] who will be helping me with our discussion today.]
- I want to take a few moments to remind everyone about the informed consent form you all signed prior to our group. You should all have a copy of that consent form in front of you.
- We are working with [subgrantee name] [name of program/service/study] to understand how the [name of program/services/study] worked and your experience in the [name of Sí Texas program].
- We also want to ask you about your ideas to make the [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 in the group. This is fine. Please feel free to share your opinions, the good and the bad.
- 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. Even if you signed the consent form before coming here today, you can still decide not to participate in the group. If you decide to leave, this decision will not affect your relationship with us, the [name of subgrantee], or any services that the [name of subgrantee] provides to you. We may also ask participants to leave the room if we feel the conversation is upsetting.
- We are not asking questions today about your health conditions or diagnoses, and there is no reason for anyone here to feel like you have to share that information in the group. We ask

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

that you not share any private information about yourself, your family members, or other people in this group. If you want to share an example, please share that information in a general way without using names.

- We also want to do everything we can to make sure what we talk about in the group stays private, so we are asking everyone not to share anything you hear today with anyone outside of the group. We are asking everyone to do this to make sure everyone feels comfortable sharing their opinions. We will definitely not share anything we hear today with anyone outside the group, but I want you all to know that we cannot guarantee privacy for the entire group.
- We want everyone to be aware there are certain kinds of information that we are required by law to report to authorities such as statements about assault, abuse, or neglect.
- We will be writing up a report of the general ideas we hear today from your group and other groups we talk with, but no one's name will be used in our summary. No one will be able to tell it was you who said something in our report.
- We expect our time together will be about an hour and a half. Again, you can leave anytime for any reason. If you need to go to the restroom, please feel free to leave, but we'd appreciate it if you would go one at a time.
- If you feel upset at any time today during our group conversation, it is okay to leave the room and meet with one of the counselors. [Name of behavioral health support person] is sitting just outside our session today and is available to you if you would like to talk to someone.
- [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 audio 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?
- Does anyone have a cell phone? If you have a cell phone or any technology that makes noise, would you please turn off it off or use vibrate mode. Thank you!
- Do you have any questions before we introduce ourselves and get started?

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

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 and 2) something about yourself – such as what you like to do for fun. [AFTER ALL PARTICIPANTS INTRODUCE THEMSELVES, MODERATOR TO ANSWER QUESTIONS]

CAREGIVER NOTE

Thanks everyone. It sounds like we have a pretty diverse group! I just want to note that some of our group participants today are here in support of their family member or friend. I want to encourage all those here as support persons to share, even if a question is directed at a [name of program/service/study] participant. Any feedback about [name of program/service/study] is very welcome! Thanks!

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. From what you can remember, how did you hear about the [program/service/study]?
 - b. Who talked to you about it?
 - c. Did you have an opportunity to ask questions about the [program/service/study]?
 - d. How easy or hard was it to understand the information provided to you about the [program/service/study]?
3. For those who participated in the [name of subgrantee program/service/study], why did you join the [program/service/study]?
 - a. What concerns, if any, did you have about joining the program/service/study?
4. For those of you who are family members or are here supporting a program participant, what concerns, if any, did you have about the program/service/study when you learned about it?

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

5. 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 another patient receiving services here at [name of subgrantee] 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?
 - i. Support persons: how was this program/service/study similar or different to health services your family member or friend received before the program/service/study?

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

6. 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, REFERRALS, CARE COORDINATION, COMMUNICATION BETWEEN PROVIDERS, ETC.)]
 - a. What did you like best about the program/service/study? Why?
 - i. In what ways has the program/service/study met your needs or the needs of your family member or friend?
 - ii. What was helpful to you or your family member or friend?
 - b. What did you not like about the program/service/study?
 - c. What could have made your experience or the experience of your family member or friend better?
7. What did you think about the program/clinic staff (e.g., how they treated you, how comfortable you felt around them, etc.)?
8. How easy or hard was it to participate in the program/service/study?
 - a. What made it easier to participate in the program/service/study?
 - i. What helped you participate in the program/service/study? [PROBE: COST, SCHEDULE, LANGUAGE, TRANSPORTATION, INCENTIVES, ETC.]
 - ii. **Support persons**, what has helped you serve your family member or friend as they have participated in the [name of program/service/study]?
 - b. What made it harder to participate in the program/service/study? [PROBE: COST, SCHEDULE, LANGUAGE, TRANSPORTATION, POLITICAL EVENTS, HURRICANE HARVEY, ETC.]
 - i. What got in the way of you participating in the program/service/study? [PROBE: COST, SCHEDULE, LANGUAGE, TRANSPORTATION, INCENTIVES, ETC.]
 - ii. **Support persons**, what has not helped you serve your family member or friend as they have participated in the [name of program/service/study]?

PROGRAM VALUE/IMPACT (10-15 MIN)

9. 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.]
 - b. **Support persons**, how has your family member or friend's participation in [name of program/service/study] affected you or your ability to them?
10. How can the program/service/study be improved?
 - a. What else could the program/service/study do to improve participants' health or how **support persons** are able to help participants?
 - 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?
11. Thinking about your experience in the [name of program/service/study], would you sign up for the program/service again? Why or why not?

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

- 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.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Appendix F: Implementation Evaluation Measures

Research question/subquestions	Logic Model Elements/Components <i>What are we measuring to answer this research question?</i>	Quantitative Indicator(s) Captured <i>What data is being collected by subgrantee that we could use to capture this?</i>	Qualitative Data <i>What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?</i>	Qualitative/quantitative Indicator(s) Needed <i>If gap, what quantitative data do we need?</i>
REACH: Did the TRIP for Salud y Vida program reach its intended target population?				
--	Demographic characteristics of participants	Eligibility criteria data	<ul style="list-style-type: none"> • 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 TRIP for Salud y Vida 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 REAL, Inc. implement the TRIP for Salud y Vida model with fidelity?				
What are the resources of the program?	Input: REAL, Inc.: Transportation coordination, nurse coordination and navigation	--	What is your current role?	Yes/No
What are the resources of the program?	Input: Transportation Coordination Network: Collaborative team coordination, behavioral and clinical education coordination and REDCap database system	--	What is your current role?	Yes/No

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Research question/subquestions	Logic Model Elements/Components <i>What are we measuring to answer this research question?</i>	Quantitative Indicator(s) Captured <i>What data is being collected by subgrantee that we could use to capture this?</i>	Qualitative Data <i>What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?</i>	Qualitative/quantitative Indicator(s) Needed <i>If gap, what quantitative data do we need?</i>
What are the resources of the program?	Input: Coastal Plains Community Center (CPCC): Behavioral health staff, electronic medical record and care coordination	--	<ul style="list-style-type: none"> To what extent have information/data systems/your EMR been changed to support the program? What is your current role? 	Yes/No
What are the resources of the program?	Input: South Coastal Health Education Center (AHEC): Community education and navigation	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the resources of the program?	Input: Consumer Voices Leadership Group	--	How has the partnership been helpful in promoting implementation of program activities?	Yes/No
What are the program activities and how have they been operationalized?	Activity: Assignment of a navigator and case manager	--	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	Yes/No
What are the program activities and how have they been operationalized?	Activity: Assignment of a mobility navigator	--	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

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Research question/subquestions	Logic Model Elements/Components <i>What are we measuring to answer this research question?</i>	Quantitative Indicator(s) Captured <i>What data is being collected by subgrantee that we could use to capture this?</i>	Qualitative Data <i>What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?</i>	Qualitative/quantitative Indicator(s) Needed <i>If gap, what quantitative data do we need?</i>
What are the program activities and how have they been operationalized?	Activity: Home and telephone nurse assessments	<ul style="list-style-type: none"> • Number of clinic visits/Follow-up care visits • Nature of contact • Number and duration of contacts 	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: Development of an individualized transportation plan	<ul style="list-style-type: none"> • Transportation plan received 	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: Coordination and delivery of tailored transportation services to behavioral and clinical appointments	<ul style="list-style-type: none"> • TRIP Transportation Data • Used REAL in past 6 months • Reservation method • Purpose of TRIP • Trip information • Reason for no show or cancelation • Rescheduled no show or canceled trip • Transportation plan received 	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

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Research question/subquestions	Logic Model Elements/Components <i>What are we measuring to answer this research question?</i>	Quantitative Indicator(s) Captured <i>What data is being collected by subgrantee that we could use to capture this?</i>	Qualitative Data <i>What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?</i>	Qualitative/quantitative Indicator(s) Needed <i>If gap, what quantitative data do we need?</i>
What are the program activities and how have they been operationalized?	Activity: Coordination and delivery of transportation services to and from community health and other health care services	<ul style="list-style-type: none"> • TRIP Transportation Data • Used REAL in past 6 months • Reservation method • Purpose of TRIP • Trip information • Reason for no show or cancelation • Rescheduled no show or canceled trip • Transportation plan received 	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: Consumer enrollment in a community-health worker led diabetes self-management education (DSME) for the diabetes subgroup	Attendance and participation in self-management education by type and location	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: Implementation of community based health and disease management classes tailored to consumer needs	Attendance at community-level educational events	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

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Research question/subquestions	Logic Model Elements/Components <i>What are we measuring to answer this research question?</i>	Quantitative Indicator(s) Captured <i>What data is being collected by subgrantee that we could use to capture this?</i>	Qualitative Data <i>What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?</i>	Qualitative/quantitative Indicator(s) Needed <i>If gap, what quantitative data do we need?</i>
Are the components different than what was planned? If so, why?	Output: Recruit 500 total consumers to participate in the Trip for Salud y Vida program (intervention group [n=250] and external comparison group [n=250]).	<ul style="list-style-type: none"> • Enrollment rate (number enrolled & number invited to participate) • Number of participants enrolled and consented by partners 	--	None
Are the components different than what was planned? If so, why?	Output: Provider and staff training to systematically implement TRIP for Salud y Vida to better address behavioral and clinical needs.	--	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: Increased enrollment of consumers in services.	<ul style="list-style-type: none"> • Enrollment rate (number enrolled & number invited to participate) • Number of participants enrolled and consented by partners 	--	Previous enrollment numbers
Are the components different than what was planned? If so, why?	Output: Integration of Voices Leadership Group in planning.	--	Now that the program has been implemented, to what extent are primary care and behavioral health services connected, coordinated, combined, if at all?	Yes/No

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Research question/subquestions	Logic Model Elements/Components <i>What are we measuring to answer this research question?</i>	Quantitative Indicator(s) Captured <i>What data is being collected by subgrantee that we could use to capture this?</i>	Qualitative Data <i>What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?</i>	Qualitative/quantitative Indicator(s) Needed <i>If gap, what quantitative data do we need?</i>
Are the components different than what was planned? If so, why?	Output: Development of tailored consumer transportation care plans.	Transportation plan received	Since beginning enrollment, to what extent has the program been able to deliver all the program services that had been planned as part of the program intervention?	None
Are the components different than what was planned? If so, why?	Output: Incorporation of transportation scheduling.	Reservation method	Now that the program has been implemented, to what extent are primary care and behavioral health services connected, coordinated, combined, if at all?	Yes/No
Are the components different than what was planned? If so, why?	Output: Consumer training and use of transportation services and scheduling software.	Reservation method	Now that the program has been implemented, to what extent are primary care and behavioral health services connected, coordinated, combined, if at all?	Yes/No
Are the components different than what was planned? If so, why?	Output: Consumer referral to partner and/or community resources	<ul style="list-style-type: none"> • Number of participants enrolled and consented by partners 	Now that the program has been implemented, to what extent are primary care and behavioral health services connected, coordinated, combined, if at all?	None

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Research question/subquestions	Logic Model Elements/Components <i>What are we measuring to answer this research question?</i>	Quantitative Indicator(s) Captured <i>What data is being collected by subgrantee that we could use to capture this?</i>	Qualitative Data <i>What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?</i>	Qualitative/quantitative Indicator(s) Needed <i>If gap, what quantitative data do we need?</i>
Are the components different than what was planned? If so, why?	Output: Integration of standard measurement protocols, and ongoing quality improvement among partner staff to emphasize integration of transportation services and increased communication/collaboration between partners.	<ul style="list-style-type: none"> Integration and offering of Trip for Salud y Vida as a program Integration of shared metrics into data collection processes 	--	None
INTEGRATION: What level of Integrated Behavioral Health did TRIP for Salud y Vida achieve as a result of implementing the program?				
What level of Integrated Behavioral Health did they achieve as a result of implementing the program?	IBH Level	Score (measured by IBH Checklist)	--	None
To what extent have providers and program staff adopted the components of the program at 6 and 12 months?	--	<ul style="list-style-type: none"> Integration and offering of Trip for Salud y Vida as a program Integration of shared metrics into data collection processes 	<ul style="list-style-type: none"> Now that the program has been implemented, to what extent are primary care and behavioral health services connected, coordinated, combined, if at all? 	None

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Research question/subquestions	Logic Model Elements/Components <i>What are we measuring to answer this research question?</i>	Quantitative Indicator(s) Captured <i>What data is being collected by subgrantee that we could use to capture this?</i>	Qualitative Data <i>What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?</i>	Qualitative/quantitative Indicator(s) Needed <i>If gap, what quantitative data do we need?</i>
What are the facilitators and barriers to adoption?	--	Feedback about intervention	<ul style="list-style-type: none"> • 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? 	None
To what extent do providers buy-in to the program, and how has that buy-in affected implementation?	--	Feedback about intervention	<ul style="list-style-type: none"> • Have you heard any feedback from providers about program implementation? • What are some of the general themes from their feedback been? 	None

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Research question/subquestions	Logic Model Elements/Components <i>What are we measuring to answer this research question?</i>	Quantitative Indicator(s) Captured <i>What data is being collected by subgrantee that we could use to capture this?</i>	Qualitative Data <i>What questions do we ask in our interview protocol to cover this? Do we need to augment our interview protocol to cover gaps?</i>	Qualitative/quantitative Indicator(s) Needed <i>If gap, what quantitative data do we need?</i>
To what extent did the comparison groups receive program-like components?				
<p>--</p>	<p>--</p>	<p>--</p>	<ul style="list-style-type: none"> • When a participant is randomized/enrolled in the control/comparison group of your program, what can they expect to receive or participate in terms of services or activities? • Since the program started, has anything changed about the services that control group participants received or activities they have access to at your clinic? In what way? • What do you see as the impact of this workflow change, if any? • Have these changes had any effects on patient care for those participants not enrolled in the study? In what way? 	<ul style="list-style-type: none"> • Number of patients in internal comparison group that receive 1 program-like component • Number of patients in internal comparison group that receive more than 1 program-like component

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

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

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Appendix G: Patient-Centered Integrated Behavioral Health Care Checklist

Patient-Centered Integrated Behavioral Health Care Principles & Tasks



About This Tool

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

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

Principles of Care	We apply this principle in the care of		
	None	Some	Most/All
	of our patients		
1. Patient-Centered Care			
Primary care and behavioral health providers collaborate effectively using shared care plans.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Evidence-Based Care			
Patients are offered treatments for which there is credible research evidence to support their efficacy in treating the target condition.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Accountable Care			
Providers are accountable and reimbursed for quality care and outcomes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Core Components & Tasks

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

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

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

**PATIENT HEALTH QUESTIONNAIRE-9
(PHQ-9)**

Over the last 2 weeks, how often have you been bothered by any of the following problems?
(Use "✓" to indicate your answer)

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

FOR OFFICE CODING 0 + _____ + _____ + _____
=Total Score: _____

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

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

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

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Appendix I: Duke Health Profile

FORM A: FOR SELF-ADMINISTRATION BY THE RESPONDENT (revised 4-2000)
DUKE HEALTH PROFILE (The DUKE)

Copyright © 1989-2014 by the Department of Community and Family Medicine,
Duke University Medical Center, Durham, N.C., U.S.A.

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

Copyright ©1994-2014 by the Department of Community and Family Medicine
Duke University Medical Center, Durham, N.C., U.S.A.

<u>Item</u>	<u>Raw Score*</u>	
8 =	_____	<u>PHYSICAL HEALTH SCORE</u>
9 =	_____	
10 =	_____	
11 =	_____	
12 =	_____	
Sum =	_____ x 10 =	

<u>Item</u>	<u>Raw Score*</u>	
1 =	_____	<u>MENTAL HEALTH SCORE</u>
4 =	_____	
5 =	_____	
13 =	_____	
14 =	_____	
Sum =	_____ x 10 =	

<u>Item</u>	<u>Raw Score*</u>	
2 =	_____	<u>SOCIAL HEALTH SCORE</u>
6 =	_____	
7 =	_____	
15 =	_____	
16 =	_____	
Sum =	_____ x 10 =	

<u>GENERAL HEALTH SCORE</u>		
Physical Health score =	_____	
Mental Health score =	_____	
Social Health score =	_____	
Sum =	_____ + 3 =	

<u>PERCEIVED HEALTH SCORE</u>		
<u>Item</u>	<u>Raw Score*</u>	
3 =	_____	

<u>Item</u>	<u>Raw Score*</u>	
1 =	_____	<u>SELF-ESTEEM SCORE</u>
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.

<u>Item</u>	<u>Raw Score*</u>	<u>Revised</u>	
2 =	_____	_____	<u>ANXIETY SCORE</u>
5 =	_____	_____	
7 =	_____	_____	
10 =	_____	_____	
12 =	_____	_____	
14 =	_____	_____	
Sum =	_____	_____	

<u>Item</u>	<u>Raw Score*</u>	<u>Revised</u>	
4 =	_____	_____	<u>DEPRESSION SCORE</u>
5 =	_____	_____	
10 =	_____	_____	
12 =	_____	_____	
13 =	_____	_____	
Sum =	_____	_____	

<u>Item</u>	<u>Raw Score*</u>	<u>Revised</u>	
4 =	_____	_____	<u>ANXIETY-DEPRESSION (DUKE-AD) SCORE</u>
5 =	_____	_____	
7 =	_____	_____	
10 =	_____	_____	
12 =	_____	_____	
13 =	_____	_____	
14 =	_____	_____	
Sum =	_____	_____	

<u>PAIN SCORE</u>		
<u>Item</u>	<u>Raw Score*</u>	<u>Revised</u>
11 =	_____	_____

<u>DISABILITY SCORE</u>		
<u>Item</u>	<u>Raw Score*</u>	<u>Revised</u>
17 =	_____	_____

* 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.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Appendix J: TRIP for Salud y Vida Enrollment and Baseline Assessment Form

Confidential

Page 1 of 5

Trip Salud Y Vida Enrollment And Baseline Assessment

We will now ask you a few questions and begin the enrollment for the TRIP program.

Data Entry ID [Initials of person entering data] _____

CPCC CASE NUMBER - CPCC consumer ID number enter here _____

TRIP Program ID [DO NOT READ: ASSIGNED BY CPCC PER CLIENT AND TRIP PROGRAM GROUP - SEE INFORMED CONSENT FOR NUMBER] _____

Informed Consent Completed Yes
 No

Please circle the answer that best represents your response.

6. How often do you have someone help you read hospital materials?

- 1 - Always
- 2 - Often
- 3 - Sometimes
- 4 - Occasionally
- 5 - Never

7. How often do you have problems learning about your medical condition because of difficulty understanding written information?

- 1 - Always
- 2 - Often
- 3 - Sometimes
- 4 - Occasionally
- 5 - Never

8. How often do you have a problem understanding what is told to you about your medical condition?

- 1 - Always
- 2 - Often
- 3 - Sometimes
- 4 - Occasionally
- 5 - Never

9. How confident are you filling out medical forms by yourself?

- 1 - Not at all
- 2 - A little bit
- 3 - Somewhat
- 4 - Quite a bit
- 5 - Extremely

I would like to ask you for your opinion and about your experience using the internet for health information. For each statement tell me which response best reflects your opinion and experience right now.

	1 - Strongly Disagree	2 - Disagree	3 - Undecided	4 - Agree	5 - Strongly Agree
10. I know how to find helpful health resources on the Internet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. I know how to use the Internet to answer my health questions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. I know what health resources are available on the Internet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. I know where to find helpful health resources on the Internet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. I know how to use the health information I find on the Internet to help me	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. I have the skills I need to evaluate the health resources I find on the Internet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. I can tell high quality health resources from low quality health resources on the Internet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. I feel confident in using information from the Internet to make health decisions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Over the last 2 weeks, how often have you been bothered by any of the following problems?

18. Little interest or pleasure in doing things

0 Not at all
 1 Several days
 2 More than half the days
 3 Nearly every day

19. Feeling down, depressed or hopeless

0 Not at all
 1 Several days
 2 More than half the days
 3 Nearly every day

20. Trouble falling or staying asleep, or sleeping too much

0 Not at all
 1 Several days
 2 More than half the days
 3 Nearly every day

21. Feeling tired or having little energy

0 Not at all
 1 Several days
 2 More than half the days
 3 Nearly every day

22. Poor appetite or overeating

0 Not at all
 1 Several days
 2 More than half the days
 3 Nearly every day

23. Feeling bad about yourself - or that you are a failure or have let yourself or your family down

0 Not at all
 1 Several days
 2 More than half the days
 3 Nearly every day

24. Trouble concentrating on things, such as reading the newspaper or watching television

0 Not at all
 1 Several days
 2 More than half the days
 3 Nearly every day

25. 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 Not at all
 1 Several days
 2 More than half the days
 3 Nearly every day

26. Thoughts that you would be better off dead, or of hurting yourself

0 Not at all
 1 Several days
 2 More than half the days
 3 Nearly every day

STOP IF Q27 IS NEARLY EVERY DAY - FOLLOW CPCC EMERGENCY CRISIS CARE PROTOCOL.



27. 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

0 Not at all
 1 Several days
 2 More than half the days
 3 Nearly every day

INSTRUCTIONS TO BE READ: 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 item.)

28. I like who I am

12 Yes, describes me exactly
 11 Somewhat describes me
 10 No, doesn't describe me at all

29. I am not an easy person to get along with 20 Yes, describes me exactly
 21 Somewhat describes me
 22 No, doesn't describe me at all

30. I am basically a healthy person 32 Yes, describes me exactly
 31 Somewhat describes me
 30 No, doesn't describe me at all

31. I give up too easily 40 Yes, describes me exactly
 41 Somewhat describes me
 42 No, doesn't describe me at all

32. I have difficulty concentrating 50 Yes, describes me exactly
 51 Somewhat describes me
 52 No, doesn't describe me at all

33. I am happy with my family relationships 62 Yes, describes me exactly
 61 Somewhat describes me
 60 No, doesn't describe me at all

34. I am comfortable being around people 72 Yes, describes me exactly
 71 Somewhat describes me
 70 No, doesn't describe me at all

Today would you have any physical trouble or difficulty:

35. Walking up a flight of stairs 82 None
 81 Some
 80 A Lot

36. Running the length of a football field 92 None
 91 Some
 90 A Lot

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

37. Sleeping 102 None
 101 Some
 100 A Lot

38. Hurting or aching in any part of your body 112 None
 111 Some
 110 A Lot

39. Getting tired easily 122 None
 121 Some
 120 A Lot

40. Feeling depressed or sad 132 None
 131 Some
 130 A Lot

41. Nervousness 142 None
 141 Some
 140 A Lot

DURING THE PAST WEEK: How often did you:

42. Socialize with other people (talk or visit with friends or relatives) 150 None
 151 Some
 152 A Lot

43. Take part in social, religious, or recreation activities (meetings, church, movies, sports, parties) 160 None
 161 Some
 162 A Lot

DURING THE PAST WEEK: How often did you:

44. Stay in your home, a nursing home, or hospital because of sickness, injury or other problem. 172 None
 171 Some
 170 A Lot

Thank you, now we will complete a short paper questionnaire [DO NOT READ - COMPLETE THE S-TOFHLA ON PAPER AND ENTER CPCC ID].

Now I would like to ask you a few questions about how you get to doctor's appointments.

45. Have you missed a doctor's appointment in the past 6 months because you did not have a way to get there? 1 - YES
 2 - NO

46. Have you missed a doctor's appointment in the past 3 months because you did not have a way to get there? 1 - YES
 2 - NO

47. Are you licensed to drive a car or truck? 1 - YES
 2 - NO

48. Do you own a vehicle, a car or truck, that runs safely? 1 - YES
 2 - NO

49. If you need a ride to get to the doctor's office, do you have someone in your family or a friend who provides you with rides? 1 - YES
 2 - NO
 3 - REFUSED

50. Is it ever difficult to ask for rides to get to the doctor from family or friends? 1 - Not at all difficult
 2 - Somewhat difficult
 3 - Very difficult

51. Have you used public transportation services such as REAL, Inc. in the past 12 months to get to doctor or other health care appointments? 1 - YES
 2 - NO

[DO NOT READ - ANSWER ONLY] BASELINE CLINIC ASSESSMENT SCHEDULED 1 - Clinic appointment today
 2 - Yes, scheduled within 7 days
 3 - Health metrics collected within last 45 days
 4 - No, not scheduled

Finally, I would like to schedule a 6-month appointment for the project. NAVIGATOR SCHEDULE 6-MONTH APPOINTMENT FOR CLINICAL AND BEHAVIORAL ASSESSMENTS 1 - YES SCHEDULED
 2 - NO NOT SCHEDULED

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Appendix K: TRIP for Salud y Vida Baseline Clinical Assessment Form

Confidential

Page 1 of 2

Trip For Salud Y Vida Baseline Clinical Assessment

Clinical Variables and Transportation Action Plan Upload or Manual Entry

CPCPC Consumer ID Number - MUST ENTER

TRIP Program ID [assigned by CPCPC by clinic and group]

Initials of Person Entering Data

Date for Data Entry

Mental Health Diagnosis from CPCPC

Does consumer have a type 2 diabetes diagnosis?

- 1 - YES
 2 - NO

Baseline A1c Availability - CHECK ONE OPTION

- 1 - A1c test completed in past 45 days, enter below
 2 - A1c test scheduled for today, enter below
 3 - A1c test scheduled within 45 days
 4 - A1c test will NOT be scheduled
 5 - Other [SPECIFY]

Specify A1c Test Other

Date of Baseline hbA1c

Baseline hbA1c test reading - Enter value

Baseline systolic blood pressure

Date of baseline systolic blood pressure

Baseline diastolic blood pressure

Date of baseline diastolic blood pressure

Baseline height in inches

Date of baseline height

01/28/2019 9:42pm

projectredcap.org



Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Confidential

Page 2 of 2

Baseline weight in pounds

Date of baseline weight

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Appendix L: TRIP for Salud y Vida 12-Month Clinical Assessment Form

Confidential

Page 1 of 2

Trip For Salud Y Vida 12-Month Clinical Assessment

Clinical Variables and Transportation Action Plan Upload or Manual Entry

CPCPC Consumer ID Number - MUST ENTER

TRIP Program ID [assigned by CPCPC by clinic and group]

Initials of Person Entering Data

Date for Data Entry

Mental Health Diagnosis from CPCPC

Does consumer have a type 2 diabetes diagnosis?

- 1 - YES
 2 - NO

12-Month A1c Availability - CHECK ONE OPTION

- 1 - A1c test completed in past 45 days, enter below
 2 - A1c test scheduled for today, enter below
 3 - A1c test scheduled within 45 days
 4 - A1c test will NOT be scheduled
 5 - Other [SPECIFY]

Specify A1c Test Other

Date of 12-month hbA1c

12-month hbA1c test reading - Enter value

12-month systolic blood pressure

Date of 12-month systolic blood pressure

12-month diastolic blood pressure

Date of 12-month diastolic blood pressure

12-month height in inches

Date of 12-month height

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Confidential

Page 2 of 2

12-month weight in pounds

Date of 12-month weight

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Appendix M: TRIP Metrics Assessment Form

Confidential

Page 1 of 6

12 - Month TRIP Metrics Assessment

We will now ask you a few questions and begin the 6-month TRIP program evaluation questions. When you first enrolled in the program you agreed to complete two additional surveys at 6 and 12 months. This is the 6-month survey, you do not need to participate or answer any questions. Please let me know if you prefer not to complete the survey.

Data Entry ID [Initials of person entering data]

CPCP CASE NUMBER - CPCP consumer ID number enter here

TRIP Program ID [DO NOT READ: ASSIGNED BY CPCP PER CLIENT AND TRIP PROGRAM GROUP - SEE INFORMED CONSENT FOR NUMBER]

Oral Informed Consent Completed

- Yes
 No

Please give me the answer that best represents your response.

How would you rate your overall health?

- 1 - Excellent
 2 - Good
 3 - Fair
 4 - Poor

6. How often do you have someone help you read hospital materials?

- 1 - Always
 2 - Often
 3 - Sometimes
 4 - Occasionally
 5 - Never

7. How often do you have problems learning about your medical condition because of difficulty understanding written information?

- 1 - Always
 2 - Often
 3 - Sometimes
 4 - Occasionally
 5 - Never

8. How often do you have a problem understanding what is told to you about your medical condition?

- 1 - Always
 2 - Often
 3 - Sometimes
 4 - Occasionally
 5 - Never

9. How confident are you filling out medical forms by yourself?

- 1 - Not at all
- 2 - A little bit
- 3 - Somewhat
- 4 - Quite a bit
- 5 - Extremely

I would like to ask you for your opinion and about your experience using the internet for health information. For each statement tell me which response best reflects your opinion and experience right now.

	1 - Strongly Disagree	2 - Disagree	3 - Undecided	4 - Agree	5 - Strongly Agree
10. I know how to find helpful health resources on the Internet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. I know how to use the Internet to answer my health questions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. I know what health resources are available on the Internet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. I know where to find helpful health resources on the Internet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. I know how to use the health information I find on the Internet to help me	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. I have the skills I need to evaluate the health resources I find on the Internet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. I can tell high quality health resources from low quality health resources on the Internet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. I feel confident in using information from the Internet to make health decisions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Over the last 2 weeks, how often have you been bothered by any of the following problems?

18. Little interest or pleasure in doing things

- 0 Not at all
- 1 Several days
- 2 More than half the days
- 3 Nearly every day

19. Feeling down, depressed or hopeless

- 0 Not at all
- 1 Several days
- 2 More than half the days
- 3 Nearly every day

20. Trouble falling or staying asleep, or sleeping too much	<input type="radio"/> 0 Not at all <input type="radio"/> 1 Several days <input type="radio"/> 2 More than half the days <input type="radio"/> 3 Nearly every day
21. Feeling tired or having little energy	<input type="radio"/> 0 Not at all <input type="radio"/> 1 Several days <input type="radio"/> 2 More than half the days <input type="radio"/> 3 Nearly every day
22. Poor appetite or overeating	<input type="radio"/> 0 Not at all <input type="radio"/> 1 Several days <input type="radio"/> 2 More than half the days <input type="radio"/> 3 Nearly every day
23. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	<input type="radio"/> 0 Not at all <input type="radio"/> 1 Several days <input type="radio"/> 2 More than half the days <input type="radio"/> 3 Nearly every day
24. Trouble concentrating on things, such as reading the newspaper or watching television	<input type="radio"/> 0 Not at all <input type="radio"/> 1 Several days <input type="radio"/> 2 More than half the days <input type="radio"/> 3 Nearly every day
25. 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	<input type="radio"/> 0 Not at all <input type="radio"/> 1 Several days <input type="radio"/> 2 More than half the days <input type="radio"/> 3 Nearly every day
26. Thoughts that you would be better off dead, or of hurting yourself	<input type="radio"/> 0 Not at all <input type="radio"/> 1 Several days <input type="radio"/> 2 More than half the days <input type="radio"/> 3 Nearly every day

STOP IF Q26 IS NEARLY EVERY DAY - FOLLOW CPCC EMERGENCY CRISIS CARE PROTOCOL.



-
27. 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
- 0 Not at all
 - 1 Several days
 - 2 More than half the days
 - 3 Nearly every day
-

INSTRUCTIONS TO BE READ: 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 item.)

28. I like who I am
- 12 Yes, describes me exactly
 - 11 Somewhat describes me
 - 10 No, doesn't describe me at all
-

29. I am not an easy person to get along with
- 20 Yes, describes me exactly
 - 21 Somewhat describes me
 - 22 No, doesn't describe me at all
-

30. I am basically a healthy person
- 32 Yes, describes me exactly
 - 31 Somewhat describes me
 - 30 No, doesn't describe me at all
-

31. I give up too easily
- 40 Yes, describes me exactly
 - 41 Somewhat describes me
 - 42 No, doesn't describe me at all
-

32. I have difficulty concentrating
- 50 Yes, describes me exactly
 - 51 Somewhat describes me
 - 52 No, doesn't describe me at all
-

33. I am happy with my family relationships
- 62 Yes, describes me exactly
 - 61 Somewhat describes me
 - 60 No, doesn't describe me at all
-

34. I am comfortable being around people
- 72 Yes, describes me exactly
 - 71 Somewhat describes me
 - 70 No, doesn't describe me at all
-

Today would you have any physical trouble or difficulty:

35. Walking up a flight of stairs
- 82 None
 - 81 Some
 - 80 A Lot
-

36. Running the length of a football field
- 92 None
 - 91 Some
 - 90 A Lot
-

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

37. Sleeping
- 102 None
 - 101 Some
 - 100 A Lot
-

38. Hurting or aching in any part of your body
- 112 None
 - 111 Some
 - 110 A Lot
-

39. Getting tired easily 122 None
 121 Some
 120 A Lot

40. Feeling depressed or sad 132 None
 131 Some
 130 A Lot

41. Nervousness 142 None
 141 Some
 140 A Lot

DURING THE PAST WEEK: How often did you:

42. Socialize with other people (talk or visit with friends or relatives) 150 None
 151 Some
 152 A Lot

43. Take part in social, religious, or recreation activities (meetings, church, movies, sports, parties) 160 None
 161 Some
 162 A Lot

DURING THE PAST WEEK: How often did you:

44. Stay in your home, a nursing home, or hospital because of sickness, injury or other problem. 172 None
 171 Some
 170 A Lot

Now I would like to ask you a few questions about how you get to doctor's appointments.

45. Have you missed a doctor's appointment in the past 6 months because you did not have a way to get there? 1 - YES
 2 - NO

46. Have you missed a doctor's appointment in the past month (30 days) because you did not have a way to get there? 1 - YES
 2 - NO

47. Are you licensed to drive a car or truck? 1 - YES
 2 - NO

48. Do you own a vehicle, a car or truck, that runs safely? 1 - YES
 2 - NO

49. If you need a ride to get to the doctor's office, do you have someone in your family or a friend who provides you with rides? 1 - YES
 2 - NO
 3 - REFUSED

50. Is it ever difficult to ask for rides to get to the doctor from family or friends? 1 - Not at all difficult
 2 - Somewhat difficult
 3 - Very difficult

51. Have you used public transportation services such as REAL, Inc. in the past 12 months to get to doctor or other health care appointments? 1 - YES
 2 - NO

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Confidential

Page 6 of 6

Have you attended any community education classes?	<input type="radio"/> 1 - Yes <input type="radio"/> 2 - No
--	---

How often have you attended community education sessions?	<input type="radio"/> 1 - Once in last 6 months <input type="radio"/> 2 - Once per month <input type="radio"/> 3 - 1 to 2 sessions per month <input type="radio"/> 4 - Weekly <input type="radio"/> 5 - NEVER ATTENDED
---	--

What has been your favorite TRIP program event and why?	_____
---	-------

What is the main reason you have not attended a community education session?	_____
--	-------

[DO NOT READ - ANSWER ONLY] 12-Month CLINIC ASSESSMENT SCHEDULED	<input type="radio"/> 1 - Clinic appointment today <input type="radio"/> 2 - Yes, scheduled within 7 days <input type="radio"/> 3 - Health metrics collected within last 45 days <input type="radio"/> 4 - No, not scheduled
--	---

Finally, I would like to thank you for your participation in the TRIP evaluation program. Please contact REAL, Inc. if you have any questions about the program.

Subgrantee: Rural Economic Assistance League, Inc.

Project Title: TRIP for Salud y Vida

Appendix N: BRIEF Health Literacy Screening Tool (BRIEF)

BRIEF Health Literacy Screening Tool (BRIEF)

Please circle the answer that best represents your response.

1. How often do you have someone help you read hospital materials?
 1. Always
 2. Often
 3. Sometimes
 4. Occasionally
 5. Never

2. How often do you have problems learning about your medical condition because of difficulty understanding written information?
 1. Always
 2. Often
 3. Sometimes
 4. Occasionally
 5. Never

3. How often do you have a problem understanding what is told to you about your medical condition?
 1. Always
 2. Often
 3. Sometimes
 4. Occasionally
 5. Never

4. How confident are you filling out medical forms by yourself?
 1. Not at all
 2. A little bit
 3. Somewhat
 4. Quite a bit
 5. Extremely