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Implementation and Evaluation of Obesity Management Tools

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IMPLEMENTATION AND EVALUATION OF OBESITY MANAGEMENT TOOLS

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2023

Dedication

Dedicated to my wife, daughter, and parents. You all have pushed me and supported me during this journey. Thank you.

IMPLEMENTATION AND EVALUATION OF OBESITY MANAGEMENT TOOLS

by

HUNTER WAYNE TURNIPSEED, MS

DISSERTATION

Presented to the Faculty of the Graduate School of

The University of Texas at El Paso

in Partial Fulfillment

of the Requirements

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THE UNIVERSITY OF TEXAS AT EL PASO

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Chapter I: Introduction

OBESITY

Obesity is caused by the inability of the body to regulate fat storage in a healthy range. Since 1994 the prevalence of obesity has doubled (Flegal et al., 1998). Two-thirds of adults in the United States suffer from this chronic disease (Brunton, 2014; Hales et al., 2020). Obesity is defined as a body mass index (BMI) of 30 kg/m² or above (Mitchell et al., 2011) and is classified into three different ranges: Class 1 (BMI ≥ 30 kg/m²), Class 2 (BMI ≥ 35 kg/m²), or Class 3 (BMI ≥ 40 kg/m²) (Ogden et al., 2015). The World Health Organization (WHO) defines overweight and obesity as an abnormal or excessive fat accumulation (World Health Organization, 2021), and obesity was declared a disease by the WHO in 1997. Common comorbidities associated with obesity include cardiovascular, gastrointestinal, and metabolic diseases (Jung, 1997; MacDonald, 2003; Mitchell et al., 2011; Paeratakul et al., 2002). Obesity increases the risk for the associated comorbidities and can lead to a reduced life expectancy (Xu et al., 2018). As the prevalence of obesity has risen, so has the cost. In 2016 the combined medical cost for adults in the United States was \$260.6 billion (Cawley et al., 2021).

CONCEPTUAL FRAMEWORK

The conceptual framework used for this project is from the field of implementation science. Implementation science studies strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve patient or population outcomes (Bauer et al., 2015). The need for implementation science is great; on average, an evidence-based practice takes 17 years to be incorporated into general practice (Morris et al., 2011). However, in the past, academic researchers did not focus on the research-to-practice gap, which could help explain the 17-year average integration.

Implementation science of evidence-based practice can involve one or more broad types of evaluation: process evaluation, formative evaluation, and summative evaluation (Bauer et al., 2015). The evaluations aim to determine the impact of evidence-based practice and the implementation process.

This research project utilized the Consolidated Framework for Implementation Science (CFIR), a determinant framework (Nilsen, 2015) to guide the implementation and evaluation of the obesity management tools. Using this framework, we identified barriers and facilitators to using these tools in two clinical settings (a private clinic and a Federally Qualified Health Center [FQHC]), and a DPP program.

Twenty different implementation frameworks and theories informed the original CFIR. (Damschroder et al., 2009). CFIR helps guide implementation by providing a framework that consists of underlying constructs. CFIR consists of five overarching domains: Intervention Characteristics, Inner Setting, Outer Setting, Characteristics of Individuals, and Process (Damschroder et al., 2009). Within each domain are the constructs, thirty-nine in total, that can help influence the implementation of different programs in different settings. Domains and their constructs are in Figure 1 (Ament et al., 2012). CFIR has a comprehensive website (www.cfirguide.org) which offers guidance, definitions, and many other resources.

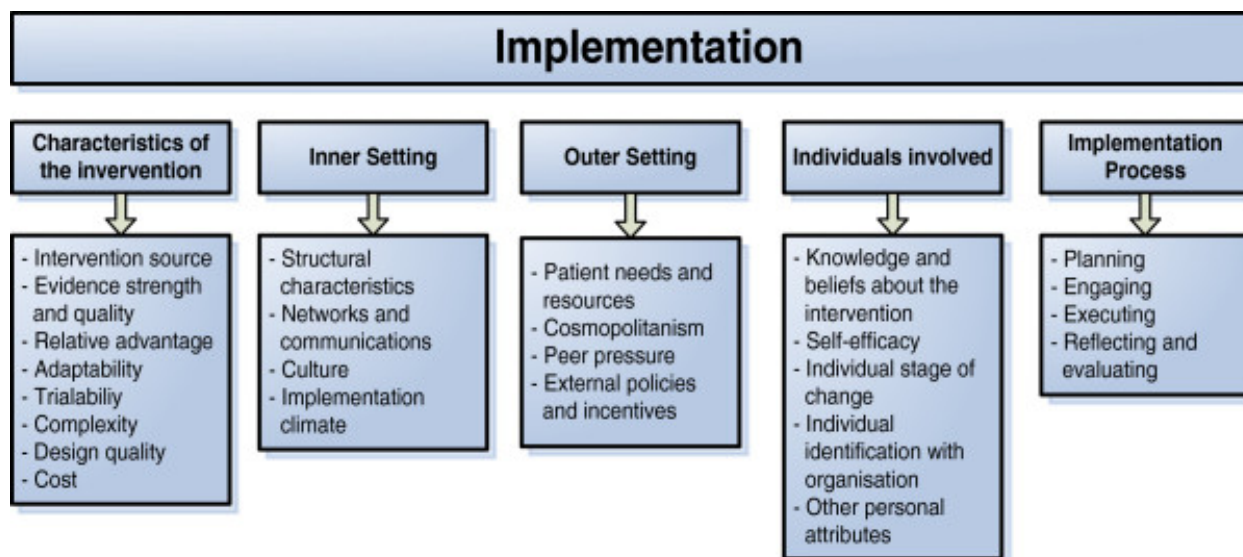


Figure 1. Consolidated Framework for Implementation Science

CFIR has recently updated its domains and constructs. As mentioned previously, the five overarching domains of CFIR were Intervention Characteristics, Inner Setting, Outer Setting, Characteristics of Individuals, and Process, respectively. However, the new version of CFIR has updated the domains to Innovation, Outer Setting, Inner Setting, Individuals, and Implementation Process (Damschroder et al., 2022). The realignment of CFIR eliminated and added some new constructs; this update is depicted in Figure 2 (The Center for Implementation, 2022).

Consolidated Framework for Implementation Research (CFIR) 2.0

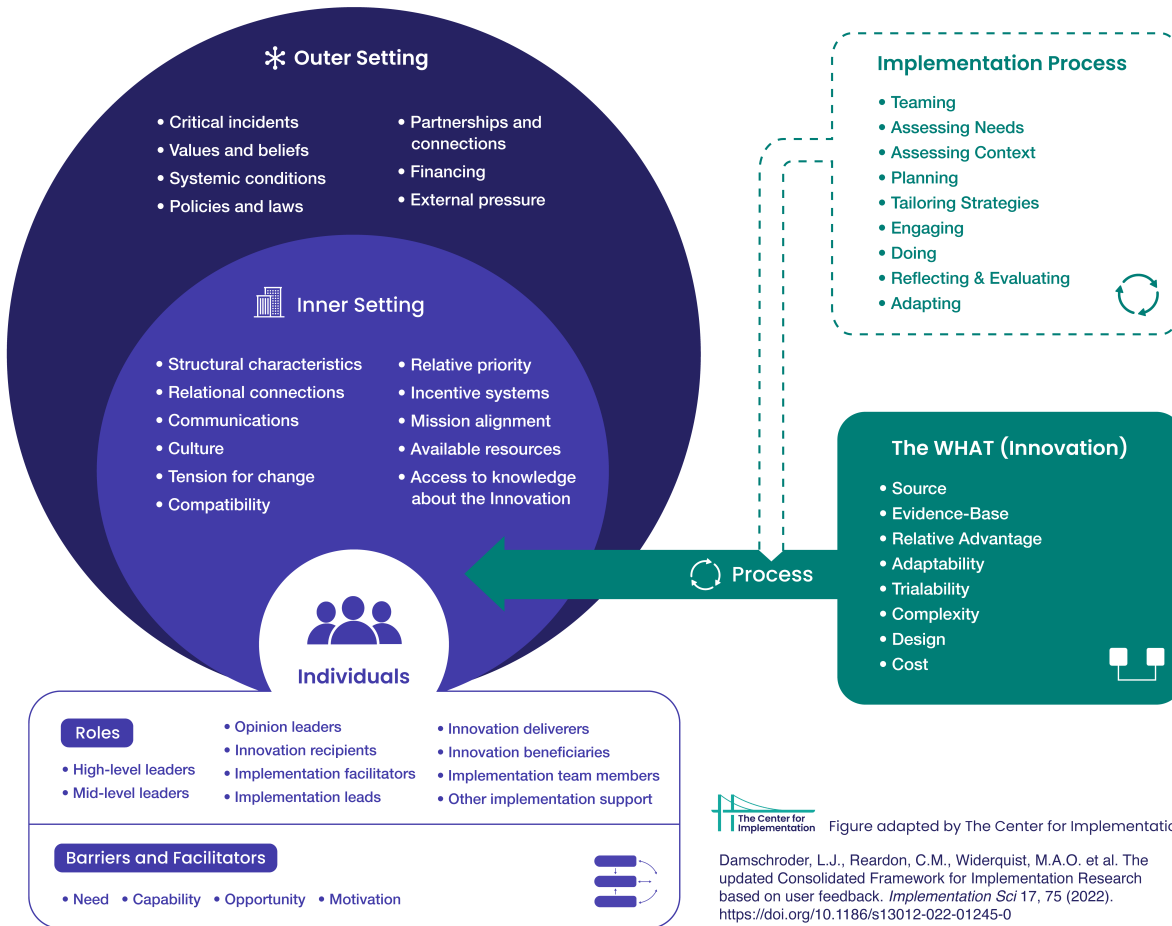


Figure 2 Update CFIR 2.0 domains and constructs

STATEMENT OF THE RESEARCH PROBLEM

Individuals with obesity need access to a healthcare system that can support the diagnosis and treatment of this complex disease. While healthy eating and an active lifestyle are essential components to addressing obesity, diet and exercise alone will not be sufficient without access to the appropriate medical treatment options (Whigham et al., 2023). Through multiple partnerships spanning over seven years, our team has worked with primary care providers (PCPs) in the Paso

del Norte region to identify the needs and gaps that limit the ability of PCPs to engage in effective obesity management with their patients. As a result of these partnerships, we have developed training for staff and providers, a clinical decision support system (CDSS) to help support PCPs in their diagnosis and treatment of obesity, a modified version of Acceptance-based Behavioral Therapy to help patients develop behavioral and psychological strategies for weight loss, and an innovative dietary web-based application, *Small Changes*, that allows patients to design their own weight loss diet plan based on a menu of options designed with regional patient input. Using an implementation science framework, we have evaluated the use of the CDSS and *Small Changes* in two community settings: primary care clinic settings and a community-based Diabetes Prevention Program (DPP).

SIGNIFICANCE OF THE PROBLEM

Minority populations such as Hispanics have experienced an increase in the prevalence of obesity from 42.5% in 2014 (Ogden et al., 2015) to 44.8% in 2018 (Hales et al., 2020). That is, one in every two Hispanic adults has obesity. Also, Hispanics are at a higher risk of comorbidities associated with obesity than Non-Hispanic whites especially Type 2 Diabetes, according to the Centers for Disease Control and Prevention (CDC) (Hales et al., 2020). Hispanics are 1.3 times more likely to die from diabetes and 70% more likely to be diagnosed with diabetes than non-Hispanic whites, according to the U.S. Department of Health and Human Services Office of Minority Health (2018).

However, the demand for obesity treatment and management cannot be met because of the lack of obesity specialists. Therefore, the integration of obesity management tools into a primary care setting is an excellent option for obesity treatment. Also, the importance of DPP as a scalable community-based program and that *Small Changes* provides a structured dietary

approach that we hypothesize will improve weight loss outcomes. However, to test efficacy, we first have to use CFIR to implement the use of *Small Changes* effectively in this setting.

PURPOSE OF THE STUDY

These two studies evaluated the implementation of obesity management tools in primary care clinics in the Paso del Norte area and in a DPP program in Brownsville, TX. The primary goal of this research was to gather information from providers and patients from the Paso del Norte region who had used the CDSS and *Small Changes*. Also, to collect information from DPP coaches and participants who had used *Small Changes* and use that information to help improve the program for implementation on a larger scale.

RESEARCH AIMS

1. Explore the key facilitators and barriers to adopting the CDSS and *Small Changes* in primary care from primary care providers.
2. Explore the key facilitators and barriers to adopting the CDSS and *Small Changes* in primary care from patients.
3. Explore the key facilitators and barriers to adopting *Small Changes* in a Diabetes Prevention Program from coaches.
4. Explore the facilitators and barriers to adopting *Small Changes* in a Diabetes Prevention Program from participants.

The remainder of this dissertation is organized as follows: Chapter II is a literature review of obesity, comorbidities, obesity management in primary care, diabetes prevention program, implementation science, and the Consolidative Framework for Implementation Science. Chapters III and IV are individual manuscripts with brief introductions, methods, results, and discussions

corresponding to Aims 1- 4. Finally, chapter V discusses the overall findings of the entire research effort and future research.

DEFINITION OF TERMS

BMI – Body mass index

CDC- Center for Disease Control and Prevention

CDSS – Clinical Decision Support System

CFIR – Consolidated Framework for Implementation Research

DPP – Diabetes Prevention Program

FDA – Food and Drug Administration

FQHC – Federally Qualified Health Center

NIH – National Institutes of Health

PCP – Primary Care Provider

RGV - Rio Grande Valley

T2D – Type 2 Diabetes Mellitus

WHO – World Health Organization

Chapter II: Review of Literature

OBESITY: BECOMING AN EPIDEMIC

During the 1960s and the 1970s, the prevalence of obesity was relatively low. However, starting in the 1980s to the current day, obesity has steadily increased. In 1971, the prevalence of obesity in adults was only 15% of the population, and by 1994 the rate had risen to 28% (Cutler et al., 2003). This increase in obesity was theorized, at the time, as being caused by the increase in readily available food (Benjamin, 2010), a decrease in energy expenditure (Mitchell et al., 2011), an increase in calorie intake (Cutler et al., 2003), and other internal and external factors (Benjamin, 2010). However, it was not until 2001, when the United States Surgeon General released "The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity" (Komaroff, 2016), did obesity get recognized as an epidemic.

COMORBIDITIES AND WEIGHT STIGMA

A common misperception is that obesity can be addressed by "simply eating less and exercising more." Obesity is a complex disease caused by the body's inability to regulate energy (caloric) intake and/or energy expenditure such that excess energy is stored as fat. This excess accumulation of fat has negative health consequences and increases the risk of other chronic diseases. The common comorbidities associated with obesity are cardiovascular, gastrointestinal, and metabolic (Jung, 1997; MacDonald, 2003; Mitchell et al., 2011; Paeratakul et al., 2002). Also, individuals with a high BMI have a decrease in perceived quality of life and increased early death (Jung, 1997).

Individuals with obesity are subjected to discrimination, also known as weight bias or weight stigma, that can have lasting effects mentally, physically, and emotionally. These effects can lead to weight gain, decreased physical activity, depression, and suicidal thoughts

(Papadopoulos & Brennan, 2015). Weight bias/stigma can come in many different forms and sources. One form of weight bias/stigma is internal and can affect self-efficacy (Rivera & Paredez, 2014), mental health and can create an eating disorder (Papadopoulos & Brennan, 2015).

Another form of weight bias/stigma is external experiences and other people's perceptions of obesity. This type of bias/stigma can affect income, relationships, social-behavioral, mental health, substance use, and education (Papadopoulos & Brennan, 2015). However, since the research of weight bias/stigma is still relatively new, further research needs to be done in the field.

OBESITY MANAGEMENT IN PRIMARY CARE

Obesity is a complex, chronic, and progressive disease caused by the body's inability to regulate fat storage in a healthy range. These intrinsic causes are varied and can include gene mutations, hormonal dysregulation, differential fat oxidation, infections, and environmental toxins. There are also extrinsic contributors that can drive the expression of the disease, including built environment, food access, and socio-economic factors (Dhurandhar, 2022).

Individuals with obesity need access to a healthcare system that can support the diagnosis and treat this complex disease. While healthy eating and an active lifestyle are essential components to addressing obesity, diet and exercise alone will not be sufficient without access to the appropriate medical treatment options. Therefore, a more encompassing approach is needed to treat this complicated disease.

Primary care providers (PCP) are a cornerstone in healthcare systems, but few receive training specific to obesity management and may not see obesity as a disease that needs

treatment in a clinical setting (Hayes et al., 2017; Sinfield et al., 2013). Challenges and barriers to delivery of evidence-based clinical obesity management include PCP bias, lack of skills to discuss obesity, insufficient knowledge of treatment options, and lack of communication between PCPs and patients. These challenges had clinical implications, such as delayed or no diagnosis of overweight or obesity, frustration between patient and PCP, a lack of continuity of care, and delayed obesity treatment until comorbidities developed (Hayes et al., 2017).

In a primary care setting, medical providers can use the combination of pharmacotherapy, nutrition therapy, behavioral therapy, and referrals for surgical options. Treatments that include diet, exercise, and behavioral lifestyle modifications produce a 5-10% weight loss and can help improve blood pressure, blood cholesterol, and blood sugars (Blackburn, 1995). Additional benefits of a 5 – 10% weight loss are improvements in quality of life (Kolotkin et al., 2001), mobility (Rejeski et al., 2012), depression (Faulconbridge et al., 2012), and sexual dysfunction (Ryan & Yockey, 2017; Wing et al., 2010). When pharmacotherapy is included with other lifestyle modifications, the expected weight loss can be between 5-15% (Egan & White, 2015), and with surgery, the percentage of weight loss is higher, upwards of 61.2% of excess weight (Buchwald et al., 2004). Benefits associated with a weight reduction are reduced risk for heart disease and diabetes and a possible decrease in medications for comorbidities (Warburton & Nicol, 2019). However, PCPs and staff receive little to no training in standard obesity management practices.

DIETARY MODIFICATION

Dietary intake for weight loss is a deficit of 500 – 750 Kcal/day according to the *Guideline for Management of Overweight and Obesity in adults*, called *Obesity Guidelines* henceforth (Jensen et al., 2014). This deficit should produce an average weight loss of 0.5 - 0.75

kg/wk which is 1 – 1.5 lbs/wk. A typical diet that is prescribed is 1,500 – 1,800 kcal/day for men and 1,200 – 1,500 kcal/day for women (Jensen et al., 2014). However, there is an option for daily caloric intake that accounts for an individual's body weight: >113 kg (1,500 – 1,800 kcal/day) and <113 kg (1,200 – 1,500 kcal/day) (Look AHEAD Research Group, 2010; Wadden et al., 2020). Currently, the *Dietary Guidelines for Americans: 2020 – 2025* gives the recommendation that a person's nutritional needs be met by nutrient-dense foods and beverages. The guidelines recommend foods and beverages that include all types of fruits and vegetables, grains (with half being from whole grains), dairy (cheese, yogurt, and milk), oils (vegetable oils and foods containing oils such as nuts or fish), and protein (animal and plant-based). Also recommended is < 10% of daily calories from added sugars, < 10% of daily calories from saturated fats, < 2,300 milligrams per day of sodium, and alcohol in moderation or less, which is ≤ 2 drinks for men and ≤ 1 drink for women per day (U.S Department of Agriculture and U.S. Department of Health and Human Services, December 2020). The *2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults* suggest a reduced-calorie diet that aligns with the individual's reduced weight for weight loss maintenance (Jensen et al., 2014).

PHYSICAL ACTIVITY

The recommendation of at least 150 minutes/week of moderate physical activity (Jakicic et al., 2019; Jensen et al., 2014). This can include walking, swimming, cycling, and other forms of activity. The inclusion of resistance training may help promote weight maintenance, mobility, and an increase in fat-free mass (Boulé NG & Prud'homme D., 2020; Rosenbaum et al., 2018). Another option is high-intensity interval training (HIIT); this could help by reducing the amount of time required to achieve the same benefits as moderate-intensity activity (Boulé NG &

Prud'homme D., 2020). For weight loss maintenance, it is suggested that 200 – 300 minutes/week of aerobic activity by the *Obesity Guidelines* (Jensen et al., 2014).

BEHAVIORAL THERAPY

Lifestyle modification such as behavioral therapy for weight loss, includes strategies for the creation of skills to handle barriers (Mauro et al., 2008) and help modify behaviors that help weight loss outcomes (Burgess et al., 2017). The *Obesity Guidelines* suggest that behavioral therapy includes feedback and support from a trained professional, and a curriculum that is structured and includes problem-solving and goal setting. Also, weekly monitoring of an individual's weight and daily monitoring of food intake and physical activity daily (Wadden et al., 2020).

PHARMACOLOGICAL

The use of pharmacological treatments may be needed to help manage obesity. For consideration of pharmacological treatment, a patient would have a BMI > 30 kg/m² or a BMI of 27 – 30 kg/m² with comorbidities (Khalil et al., 2020; Lee & Dixon, 2017; Saunders et al., 2018). There are three classes of anti-obesity pharmacotherapy: appetite suppressant, altered absorption, and increased energy expenditure. However, there is no current FDA-approved drug for increased energy expenditure.

SURGERY

Weight loss surgery is an option for individuals with a BMI higher than 40 kg/m² or higher than a BMI of 35 kg/m² with severe comorbidities, according to the NIH 1991 guideline. Additionally, if a patient suffers from Type 2 Diabetes Mellitus, has a BMI of 30 – 35 kg/m², and previous treatment has been unable to control high blood sugars can also be considered for weight loss surgery (Arterburn et al., 2020). The option of surgery has strong evidence of safety

and efficacy to suggest that results are greater for long-term weight loss compared to nonsurgical options (Arterburn et al., 2020).

DIABETES PREVENTION PROGRAM

The prevalence of prediabetes in 2022 in the United States is over one-third (38.0%, 96 million) of adults eighteen or older and almost half of adults over the age of sixty-five (48.8%, 26.4 million) (Centers for Disease Control and Prevention, 2022). A glycated hemoglobin (A1C) test is used to help diagnose prediabetes and Type 2 Diabetes Mellitus and indicates an average blood sugar level for the past 2 to 3 months. An A1C test below 5.7% is normal, 5.7 – 6.4% is diagnosed as prediabetes, and an A1C of 6.5% or higher on two separate test indicates diabetes. Men have the highest percentage of prediabetes (41.0%) compared to women (32.0%), and prevalence of prediabetes was similar between all racial/ethnic groups (Centers for Disease Control and Prevention, 2022). A person with prediabetes has an increased chance of developing Type 2 Diabetes Mellitus. This transition for individuals from prediabetes to Type 2 Diabetes Mellitus happens about 5.0-10.0% per year (Glechner et al., 2018). Type 2 Diabetes Mellitus, if not properly managed, is associated with many complications such as high blood pressure, lower extremity amputations, neuropathy, diabetic ketoacidosis, and cardiovascular diseases (American Diabetes Association, 2022; Centers for Disease Control and Prevention, 2022)

The National Diabetes Prevention Program was created in 2010 to help address the increase in prediabetes and type 2 diabetes in the United States (Diabetes Prevention Program Research Group, 2002). This intensive lifestyle intervention is considered one of the most pivotal in lifestyle modification for diabetes prevention. A leading risk factor for developing diabetes is excess weight, so the National Diabetes Prevention Program focuses on weight loss as a primary goal. The Diabetes Prevention Program had 5.0-7.0% weight loss and included moderate-

intensity physical activity of 150 minutes or more per week for over two years; the result was a 58.0% reduction in diabetes incidence (Cefalu et al., 2016; Knowler et al., 2002). The study had over 3,234 participants, randomly assigned into three different groups: metformin (a diabetes medication), intensive lifestyle intervention, or placebo (Knowler et al., 2002). Participants in the intensive lifestyle intervention and metformin were able to reduce their chance of developing Type 2 Diabetes Mellitus by 33% (Knowler et al., 2002).

IMPLEMENTATION SCIENCE

Implementation science, the study of methods that increase the use of evidence-based practices, is fairly new in the field of nutrition education and behavior (Swindle et al., 2019). However, there are a variety of models, theories, and frameworks that can help guide researchers in investigating their programs. Implementation has three primary aspects: context, strategies, and outcomes. Implementation context is where the program is implemented, implementation strategies are what actions or improvements the organization or system plans to make, and implementation outcomes are the constraints used to evaluate (Swindle et al., 2019). It takes on average seventeen years for original research to make it to practice for public health impact (Green, 2008).

Implementation strategies offer various approaches with different stakeholders in mind (Powell et al., 2015; Swindle et al., 2019; Waltz et al., 2015). This research project used the Consolidative Framework for Implementation Science (CFIR). CFIR is a determinant framework that helps guide implementation context by allowing the identification of barriers to and facilitators of implementation outcomes (Swindle et al., 2019).

CONSOLIDATIVE FRAMEWORK FOR IMPLEMENTATION SCIENCE (CFIR)

The CFIR was developed in 2009 and synthesized nearly 500 published sources across multiple disciplines. This synthesis of information, which included theories related to dissemination, innovation, organizational change, implementation, knowledge translation, and research uptake that have been published in peer-review journals, was compiled into one framework that is used to help guide and assess potential barriers to implementation (Damschroder et al., 2009). The CFIR consists of five overarching domains (intervention characteristics, inner setting, outer setting, characteristics of individuals, and implementation process) and thirty-nine constructs that can influence an intervention's potential effectiveness and implementation (Damschroder et al., 2009).

A systematic review was done in 2016 to determine how CFIR has been applied, the types of studies using CFIR, and the implementation research contribution (Kirk et al., 2015). Twenty-six studies were identified. The most common setting of studies used in the review was twenty in a healthcare system. Most studies using CFIR in the review used the framework during or post-implementation to identify barriers.

CFIR Domains

The domains of CFIR are the intervention characteristics, outer setting, inner settings, characteristics of individuals, and process. Domains can interact in complex ways to elicit implementation effectiveness. The selection of the five overarching domains came from Pettigrew and Whipp (Pettigrew & Whipp, 1992), the Promoting Action on Research Implementation in Health Science (PARiHS) framework (Rycroft-Malone et al., 2002), and Fixsen *et al.* (Fixsen et al., 2005). Damschroder's "Fostering implementation of health services

research findings into practice: a consolidated framework for advancing implementation science” article (2009) describes domains, constructs, and sub-constructs below.

Intervention Characteristics

The intervention characteristics domain helps identify the key characteristics of an intervention that can influence the success of the implementation (Greenhalgh et al., 2004; Rabin et al., 2008). The domain has eight constructs: adaptability, complexity, cost, design quality and packaging, evidence strength and quality, intervention source, relative advantage, and trialability.

Outer Setting

The outer setting domain helps to identify the outside barriers and facilitators that can affect implementation. These external influences can include national, state, and local policies, the needs of patients in the area, and other factors outside the entity implementing the intervention. The outer setting has four constructs: cosmopolitanism, external policies and incentives, patient needs and resources, and peer pressure.

Inner Setting

The inner setting domain helps to identify barriers and facilitators within the implementing organization that can affect the implementation of an intervention (Dopson & Fitzgerald, 2005). The inner setting domain has five constructs and nine subconstructs. The five constructs are structural characteristics, network and communications, culture, implementation climate, and readiness for implementation. The nine subconstructs fall under the two constructs. Implementation climate: tension for change, compatibility, relative priority, organizational incentives and rewards, goals and feedback, and learning climate. Readiness for implementation: leadership engagement, available resources, and access to knowledge and information.

Characteristics of Individuals

The characteristics of individuals domain identifies barriers and facilitators in the individuals that are involved in implementing the intervention. The domain comprises five constructs: individual identification with the organization, individual stage of change, knowledge and beliefs about the intervention, other personal attributes, and self-efficacy.

Process

Process is the last domain in CFIR and can help to identify any barriers and facilitators during the implementation process. The domain has four constructs and four subconstructs. The four constructs are engaging, executing, planning, and reflecting and evaluating. The four subconstructs under the engaging construct are opinion leaders, formally appointed internal implementation leaders, champions, and external change agents.

CFIR 2.0

Recently CFIR has gone through an overhaul of its domains, constructs, and definitions. CFIR was developed in 2009 by Damschroder and colleagues (Damschroder et al., 2009), and after a decade of service, the developers set out to update the framework. This update is outlined in a recent publication by Damschroder and colleagues (Damschroder et al., 2022). In addition, Damschroder took feedback from fifty-nine articles that provided input about CFIR and follow-up surveys from users of CFIR.

CONCLUSION

The prevalence of adults with obesity and associated comorbidities emphasizes the need for effective treatment. This project aimed to implement and evaluate obesity management tools: CDSS and *Small Changes* in primary care practices and *Small Changes* in a DPP community-based program. The primary goal of this research was to gather information from providers,

patients, coaches, and participants that have experience with the obesity management tools and use that information to help improve the program for implementation on a larger scale.

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Chapter III: A Mixed Methods Evaluation of Obesity Management Tools in Primary Care: A Clinical Decision Support System and Online Nutrition Program

INTRODUCTION

In the United States, the prevalence of adults with obesity has risen to 39%, meaning that one in every three adults has this disease (Flegal et al., 1998). However, the current projection for adults in the United States is that almost half the population will be suffering from obesity (Ward et al., 2019). The health and financial implications of the growing prevalence of obesity are staggering (Cawley et al., 2021), but significant impact can be made at a population level if clinically relevant (as little as 5% weight loss (Douketis et al., 2005; Hamman et al., 2006; Unick et al., 2011)) can be achieved in a scalable way.

A critical component to achieving population-level, clinically meaningful weight loss is to have primary care physicians (PCPs; physicians, nurse practitioners, or physician assistants) treat patients for this disease. There are greater numbers of and geographic access to PCPs compared to obesity specialists (Whigham et al. 2023). However, the training received by PCPs regarding obesity management is minimal (Whigham et al., 2023). To help PCPs integrate obesity management into their practices, a clinical decision support system (CDSS) and an online nutrition program known as *Small Changes* were developed.

The CDSS program was designed to help PCPs feel more comfortable providing obesity management for their patients. The program guides a PCP step-by-step to conduct obesity-specific history and physical examination and treatment-specific lifestyle review. The CDSS also guides the PCP in considering which current medications may interfere with weight loss and makes alternative recommendations. In addition, the CDSS offers patient-specific indications and contraindications for FDA-approved anti-obesity medications. Additional items included in

the CDSS are diagnostic references and dialogue guides to help PCPs communicate with the patient in a non-stigmatizing way. Through the CDSS platform, PCPs can enroll patients in the weight loss program *Small Changes*.

Small Changes is a web-based dietary weight loss program. The idea behind *Small Changes* is for patients to follow a structured diet with familiar foods, all while making small changes to achieve weight loss. The program used interviews from the Paso del Norte region to adapt the food choice to meet the needs of the area. Not only were the food choices adapted to the region, but the program is also available in English and Spanish. Additional *Small Changes* is HIPAA-compliant which is required by health care settings.

We conducted a mixed methods study using the Consolidative Framework for Implementation Science (CFIR) to evaluate the implementation of the CDSS and *Small Changes* in primary care. Our findings can potentially facilitate the adoption of these clinical obesity management tools and ultimately help more PCPs provide obesity management.

METHODS

Research Design

This mixed methods approach was used to evaluate the implementation of clinical obesity management tools, the clinical decision support system (CDSS) (see Appendix 1), and *Small Changes* (see Appendix 2) in primary care settings. We used the determinant framework, CFIR, for planning and evaluating the implementation of the two components of the clinical obesity management program. In addition, interviews from the primary care facilities were done with the physicians that used the tools and their patients.

Setting, Population, and Eligibility Criteria

The study was conducted at two primary care clinics in the Paso del Norte area. One clinic was a private practice; the other was a non-profit, Federally Qualified Health Center. Interviews were conducted with PCPs and patients. PCPs at the two primary care clinics implementing the obesity management tools and the patients enrolled in the program were invited to complete interviews. Interviews were conducted via online video conference, lasted 1 – 1.5 hours, and were audio/video recorded.

Instrumentation

Interviews and Data Collection

Interview guides were developed using CFIR as a guideline. All interviews were conducted individually using a video conference platform. The PCP (Appendix 3) interview guide included questions regarding their experience with the CDSS and *Small Changes* with their patients. In contrast, the patient's guide (Appendix 4) asked questions about their experience with the PCP and *Small Changes*. As the tools were already implemented into the settings before the interview guides were developed, we focused the interviews on evaluating the implementation of the tools in their respective settings. Thus, we selected at least one construct from each of the five domains (Intervention Characteristics, Outer Setting, Inner Setting, Characteristics of Individuals, and Process) that aligned with our research questions. However, with the release of CFIR 2.0, we realigned our coding with the new domains and constructs during the qualitative data analysis. This realignment allowed us to focus on three domains (Innovation, Inner Setting, and Implementation Process) and eight constructs (evidence-based, relative advantage, adaptability, complexity, design, culture, reflecting and evaluating, and adapting) that most aligned with our research questions and helped us to identify the key

facilitators and barriers to adoption of these tools. Interviews were conducted after the first 12-16 weeks of the program.

Quantitative data includes demographics from providers and patients. Demographic information collected was age, sex, and occupation from both providers and patients during interviews. Additional quantitative data collected were weight, height, BMI, body fat percentage, muscle mass weight, and clinic visits. Medical records provided these measurements of the patients.

Statistical Analysis

Quantitative Analysis

All data collected were analyzed using SPSS version 28. Patients with a minimum of two clinic visits will be used for analysis. Weight, BMI, body fat percentage, and muscle mass were compared pre-post and separated by biological sex. Variables that are normally distributed were analyzed using paired *t*-test for continuous measurements and a Wilcoxon Signed-Rank Test if not normally distributed.

Qualitative Analysis

We used semi-structured interviews with three PCPs and four patients. Interview data were analyzed using thematic analysis. This analysis helped determine patterns of common words and phrases from interviewees. Interview questions were opened ended and designed using the interview guide tool on www.cfirguide.org. We used the criteria for trustworthiness established by Lincoln and Guba (Lincoln & Guba, 1985). Deductive coding was completed using the CFIR2.0 domains and constructs. If appropriate, additional codes were derived from the data (inductive). Identified themes were summarized and reported here.

Data Storage and Protection of Research Participants

A study protocol was submitted to the UTHealth Institutional Review Board (IRB, HSC-SPH-22-0520). As a result, the study was “determined to qualify for exempt status according to 45 CFR 46.104(d)” (see Appendix 7).

Personal information collected from hard copies was kept locked in a filing cabinet in a secure access room. Participants were assigned a study ID number, and their data was stored with that ID number.

All electronic information, such as interviews and recordings, has been retained on a password-protected, encrypted server. Participants were asked to provide verbal consent captured via video/audio recording before the interview. No identifiable information was used when interview recordings were transcribed, and confidentiality was maintained. Data collected, physical or digital, will be kept for at least three years and then properly disposed of.

RESULTS

Quantitative Data

Demographics

Providers

Interviews were done with three out of four providers using the CDSS and *Small Changes* in their practice (one provider was unavailable for an interview). Of the interviewed providers, one provider is at a private medical facility, two are at an FQHC, and both clinics are in El Paso, TX. All interviewees identify themselves as female, with a mean age of 43.7 ± 4.0 . One is a physician, and two are nurse practitioners, with a mean of 13.0 ± 5.6 years of medical practice.

Patients

Patient data are reported for the private clinic only. The provider-initiated care using the CDSS for a total of 33 patients, but only 16 returned for any follow-up visit. Data are presented here for patients who completed at least two clinic visits with the CDSS provider. Sixteen of thirty-three patients are continuing care with the CDSS provider and the time of final data collection (March 21, 2023).

The sixteen patients included in the quantitative analysis had a mean age of 51.7 ± 12.5 years of age. All patients identified as female ($n = 9$) or male ($n = 7$). Additional demographics are in Table 1.

Table 1. Demographics of patients with two or more clinic visits

	N	First Visit Weight	First Visit Body Fat (%)	First Visit Muscle Mass	First Visit BMI	Clinic Visits	Treatment Length (Weeks)
Female	9	114.8	46.5	28.8	41.8	7.9	41.1
Male	7	123.5	37.1	44.0	42.1	4.9	24.3
Total	16	118.6	42.2	35.7	42.0	6.6	33.8

Quantitative Analysis

Quantitative data for patients were separated by male and female for analysis, and data were tested for normal distribution. Data were not normally distributed, and a Wilcoxon Signed-Rank Test was used for analysis. Percent change in weight for women and men at baseline and 12 weeks are presented in Figure 3.

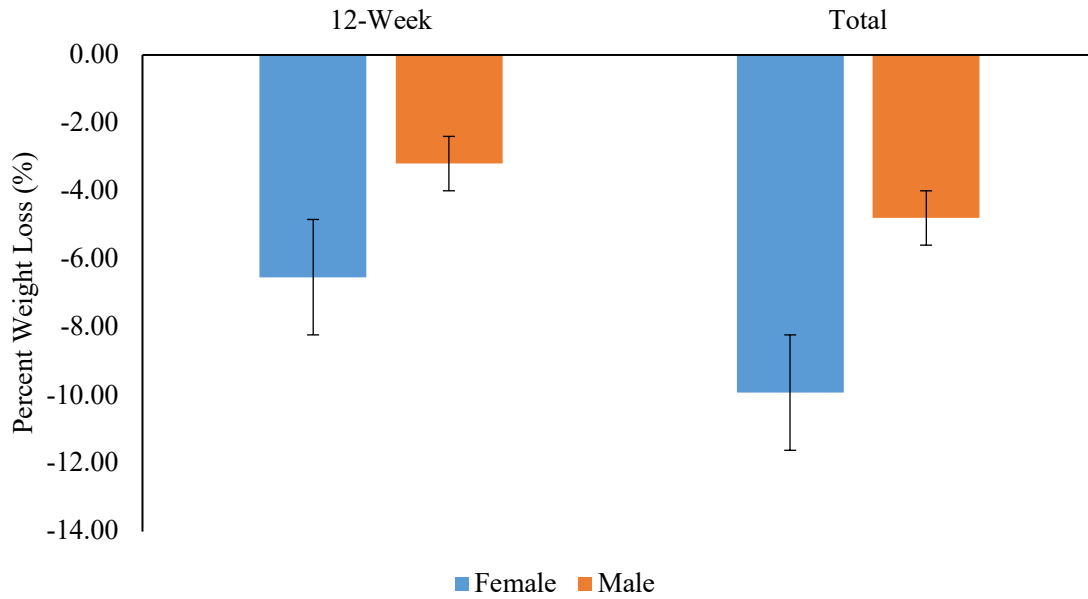


Figure 3. Mean percent weight loss for women and men at 12 weeks and total duration

Total mean weight loss was 7.7% (3.2 to -18.7%), with 63% losing at least 5% and 31% losing at least 10% of their initial weight (Figure 4). Body fat percent decreased by 3.2%. Weight loss at 12 weeks was 5.0% (0.75 to -14.6%).

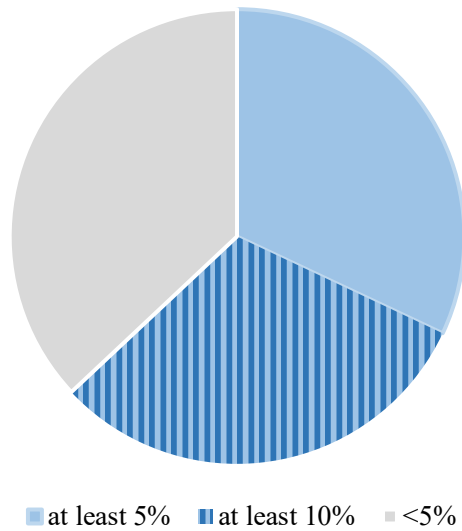


Figure 4. Clinically meaningful weight loss of at least 5% and 10%

Mean BMI for all patients at baseline was 42.0 ± 12.5 compared to 39.7 ± 12.2 ($p = 0.2$).

The mean change in BMI for all patients at 12 weeks and the total are presented in Figure 5.

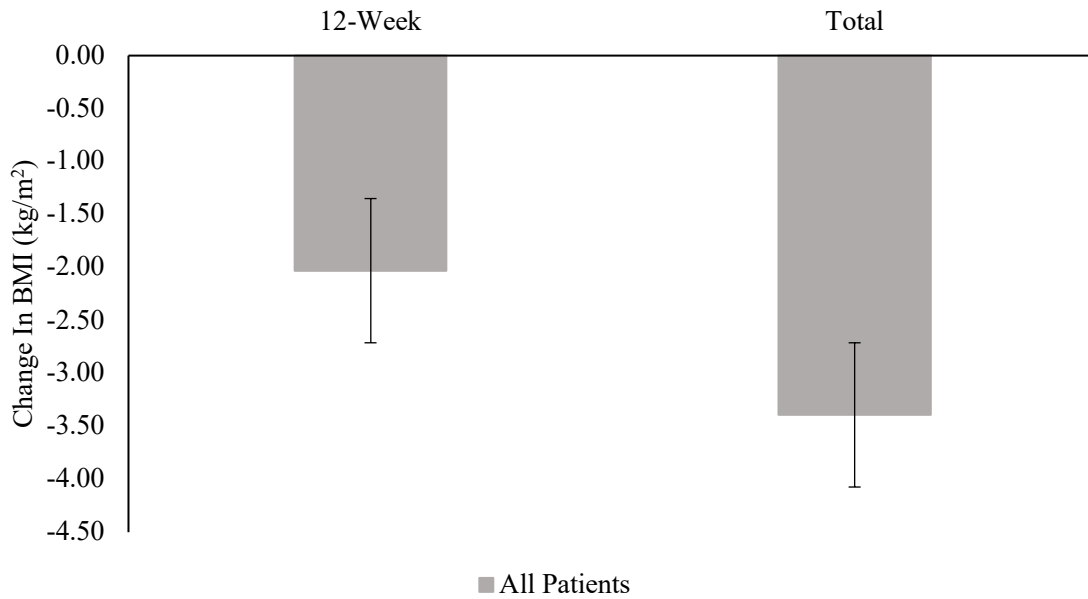


Figure 5. Mean change in BMI for all patients

Qualitative Data

For each group (providers and patients), results of their interviews are categorized by three main CFIR domains: innovation, inner setting, and implementation process.

Providers

Innovation Domain

Innovation Evidence-Base: The providers reported feeling comfortable with the evidence of CDSS and *Small Changes* because they know the developers and the developers are “obesity experts.” However, providers noted that although the evidence behind the CDSS and *Small Changes* was adequate to convince them of the value of using the programs, to be able to expand use within their clinic and convince other providers to use the programs, it would be helpful to have data showing beneficial changes in weight and positive experiences from their patients. For

example, one provider said: “I would just need numbers. Again, what percent of patients lose weight when they're on it versus when they're not on it" regarding *Small Changes*.

Innovation Relative Advantage: When asked about the advantage of the CDSS, the providers felt that the CDSS was comprehensive and user-friendly. One provider stated that “it's giving me the medication options that I wasn't comfortable with or even familiar with prior to using it. And I think also giving me more confidence to discuss surgery options with patients.” Another provider said, “I'll be able to manage obesity a lot more with many of my patients. Like I said, just the way that the ease of implementation and just the way the user-friendliness of the software.” However, providers mentioned that a disadvantage of the CDSS was it runs as a separate program, and the integration into their electronic health records would be ideal.

Innovation Adaptability: Providers were asked about the adaptability of the CDSS in their clinics. They talked about the length of time their initial typical appointments take and that the inclusion of obesity management would likely increase that time. When asked what changes they have made to their usual practice, one provider mentioned that “it would be normally like a 20-minute visit. It would be more helpful to have it as a 40-minute to just be thorough” when referring to a standard appointment time. Another provider said, “the change we made is that one day a week on Fridays, we're only open half day, and so when I first started trying to implement obesity management into the practice, I was trying to put those visits in between my primary care visits, but I noticed that it was setting me too far behind [and now weight loss patients are scheduled on Fridays with longer appointment times].”

Innovation Complexity: When providers were asked about the complexity of the CDSS, they found the CDSS easy to navigate and felt the program was not difficult. One provider mentioned that “I don't see any parts being difficult,” and another provider stated that “I think

it's easy to use.” Also, providers felt that *Small Changes* can be useful to their patients. However, one provider mentioned that for patients who are less savvy with technology “it’s a little difficult for them to be able to access the recipe, especially if they’re trying to use an iPad or their phone.”

Innovation Design: The providers found the design of the CDSS to be “very comprehensive” and “helpful because it really breaks it down and gives a step-by-step guide.” Also, providers understood what the CDSS is intended for, with one provider stating, “a guide for providers who are not particularly familiar, who haven't gotten really their feet wet into specific obesity management and so even though in training we’re exposed somewhat to obesity management, and we know kind of what needs to be addressed, we don't really know how to implement it.” Another provider said the CDSS can “allow medical providers to more effectively easily manage obesity with their patients.”

Inner Setting Domain

Culture: When providers were asked about their clinic’s culture affecting the use of the CDSS, none articulated any clinic inner setting cultural characteristics that impacted use of the CDSS. However, the research team noted that some providers commented throughout the interview on the weight stigma from other PCPs and “roadblocks.” They included the time needed to use the CDSS, the reluctance to use new programs, and the idea that obesity is self-inflicted.

Implementation Process Domain

Reflecting & Evaluation: Providers were asked about the implementation of the CDSS and *Small Changes*. Providers received training with the CDSS and found it useful to see the program and get hands-on experience before using the CDSS with their patients. Also, providers

felt confident that the CDSS would be effective with their patients. One provider said, “one thing that is changed is my confidence in being able to address it [obesity],” when asked if the CDSS changed how they manage obesity with their patients. The same provider said, “the first appointment starts in sad tears and ends in happy tears.” The providers were also asked how they felt about the CDSS as a whole, with one provider stating, “I think it was very well developed. It was very well thought out. It hits all the points of obesity management that the evidence shows we need to be addressing.”

Patients

Innovation Domain

Innovation Relative Advantage: Patients were asked to compare other programs for weight loss they had used before with *Small Changes*. One patient mentioned that they had tried “at least 20 to 50 different diets” and felt this program was simple to use. Another patient said they “tried over 52 different types of weight loss programs” and “would be promised the moon and stars,” whereas this program “does not overpromise” yet still leads to meaningful weight loss results. Also, an advantage of the program perceived by several patients was the increased accountability from them to their provider.

Innovation Complexity: With regard to the complexity of *Small Changes*, patients found the diet program easy to use. Many chose to save or print the recipes for ease of access or in case they encountered technical difficulties accessing the program online. One patient mentioned that they “saved the meal plan, just in case the website just didn’t work.”

Innovation Design: When patients were asked about the program as a whole, they mentioned that it is “really important to find a provider that has that balance of, you know, being able to offer structured program but then be able to add those elements ... to personalize it for,

you know, each individual.” Another patient commented, “I think it's a great program. I've enjoyed being part of it. I'm glad I've gotten results cause I really didn't think I was ever gonna get results.”

Inner Setting Domain

Culture: When asked if their personal or family culture affected the use of the program, none of the patients articulated any personal inner setting family culture characteristics that impacted use of the program. However, the research team noted that all patients commented throughout the course of the interview on personal experience with weight stigma from family members (as well as self-stigma) that seemed to drive repeated attempts to lose weight (note quotes above regarding high number of dietary approaches attempted).

Implementation Process Domain

Reflecting & Evaluation: When asked about the program's effectiveness, one patient said, “first thing I liked was that I didn't have to plan my meals out other than picking them, and I think that was something that other programs [didn't have] that I've struggled with. So, for me, like the biggest thing was just knowing this is what I can have today and having options but then not having too many options.” Patients also felt that the program has been meeting their needs for weight loss. As one patient noted, “it does not take up a lot of my time. It meets my need of weight loss and personal management.”

Additionally, during interviews with patients, there was an overarching compassionate atmosphere. When asked about working with their PCP that has used these tools, one patient stated, “she could read the situation and not make me feel guilty when I did not want to do something.”

DISCUSSION

This study aimed to explore key determinants of the adoption of CDSS and *Small Changes* in primary care from both PCPs and patients. We gathered qualitative and quantitative data from PCPs and patients in the Paso del Norte region that had experience with these obesity management tools. The information obtained will be used further to enhance the tools and the implementation of the comprehensive obesity management program into primary care clinics.

The PCPs interviewed found the CDSS to be comprehensive and easy to use. This comprehensiveness contributed to the PCPs' ability to talk with their patients about weight comfortably. However, to get other PCPs on board with using the CDSS and addressing obesity in their practice, there is a need for additional empirical data, such as the amount of weight lost by patients. PCPs also provided a desire for the CDSS to have the ability to be integrated into their electronic health records. This would allow for time to be saved as, currently, PCPs have been entering identical information into the CDSS and their electronic health records software.

The patients interviewed from the private clinic expressed gratitude that their PCP took the time to understand their individual situation. This one-on-one compassionate approach resulted in patients feeling supported, which led to renewed enthusiasm for their weight-loss journey. In addition, they felt this weight loss journey was different because they had accountability paired with compassion in the interactions with their PCP. The application of weight loss support tools (*Small Changes*, medication, or a combination) in conjunction with this compassionate accountability was a notable and effective approach for the patients.

Patients who continue the obesity treatment are seeing clinically meaningful weight loss, with two-thirds losing over 5% of their body weight and a third losing over 10% of their body

weight, demonstrating that treatment of obesity in a primary care setting can elicit clinically significant weight loss.

CONCLUSIONS

With the majority of patients losing a clinically meaningful amount of weight and those interviewed reporting positive experiences with their PCP, along with improvements in treatment efficacy on the part of the PCPs, this combination of software tools is effective in this pilot implementation study. The next steps include continued refining of the software based on input from PCPs and patients, as well as designing an integrated “training-to-practice” model in which PCPs participate in a brief Continuing Medical Education (CME) program that uses the software followed by support for integrating the software into their usual clinic flow. Additional empirical data demonstrating the success of the tools along with integration into the electronic health records will also likely enhance further implementation into primary care setting.

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Chapter IV: Diabetes Prevention Program Enhanced with An Online Nutrition Program Evaluation

INTRODUCTION

In the United States, over 96 million, or 38% of adults have prediabetes (Centers for Disease Control and Prevention, 2022). As a person with prediabetes continues to have trouble regulating blood glucose levels, ultimately, the disease will progress to Type 2 Diabetes Mellitus (T2D). For people with excess weight, weight loss is the most effective way to prevent transition from prediabetes to T2D. Thus, the Diabetes Prevention Program (DPP) has at its primary goal weight loss of at least 7% (Diabetes Prevention Program Research Group, 2002).

The Rio Grande Valley has a higher prevalence of diabetes in adults at 30.7% compared to 12.3% nationwide (Fisher-Hoch et al., 2012; Millard et al., 2017). Thus, the UTHealth School of Public Health Brownsville Campus has partnered with organizations across the Rio Grande Valley to provide a DPP program, the Rio Grande Valley (RGV) Coordinated Diabetes Prevention Program. While the program has significant reach, engaging over 200 people per year, program leaders continue to strive to have the average weight loss of participants reach 7%. To support that goal, we undertook a cluster randomized controlled trial to implement the *Small Changes* weight loss program into half of the DPP groups during the 2022-2023 iteration of the program. *Small Changes* is an online structured nutrition program focused on weight loss. Participants enter information about themselves (e.g. height, weight, age, sex, activity level) that is used to identify their total daily energy requirement (see Appendix 2). The algorithm then assigns them to a target calorie level that is approximately 500 Calories below their total daily energy requirement. The participant is then guided through developing a meal plan based on foods they enjoy, are familiar with, and fit their lifestyle. The resulting meal plan provides

detailed guidelines to follow for each meal so that the total calories consumed each day are in alignment with their target calorie level for weight loss. The recipes are designed with a macronutrient distribution throughout the day that minimizes hunger and optimizes fat loss over lean mass loss. The meal plan can be refreshed regularly to offset boredom or address changes in preferences. As the person loses weight, the target calorie level is stepped down to ensure long-term maintenance of a calorie deficit in support of continued weight loss. The *Small Changes* program provides structure to dietary guidance that does not currently exist within DPP curricula.

For initial evaluation of the implementation of *Small Changes* we used a mixed method approach based on the Consolidated Framework for Implementation Science (CFIR). Here we report the qualitative evaluation and the quantitative results from the initial 6 months of the groups randomized to receive *Small Changes*.

METHODS

Research Design

Using the constructs of the determinant framework CFIR, we developed a semi-structured interview guide for DPP group coaches and participants. This mixed methods approach was used to evaluate the implementation of *Small Changes* (see Appendix 2).

Setting, Population, and Eligibility Criteria

The study was conducted in a community partner-led DPP program in the Rio Grande Valley. The DPP program consists of community-based group programs run by trained coaches. Referrals for the program come from surrounding clinics and other community partners in the area. The UTHealth School of Public Health Brownsville Campus coordinates the program. Interviews were conducted with DPP coaches and DPP participants who received *Small*

Changes. Interviews were conducted via online video conference, lasted 0.25 – 1 hours, and were audio/video recorded.

Instrumentation

Interviews and Data Collection

Interview guides were developed using the original version of CFIR. All interviews were conducted individually using a video conference platform or telephone, based on the interviewee's preference. The coach's interview guide (Appendix 5) had questions about their experience with *Small Changes* in the DPP program. The participants in the DPP program were asked about their experience with *Small Changes* in the context of DPP (Appendix 6). We selected at least one construct from each of the five domains (Intervention Characteristics, Outer Setting, Inner Setting, Characteristics of Individuals, and Process) that aligned with our research questions. However, with the release of CFIR 2.0 midway through our study, we completed the interview with the original CFIR questions but for our coding we aligned the questions with the new domains and constructs. This realignment consolidated the qualitative analysis down to three domains (Innovation, Inner Setting, and Implementation Process) and eight constructs (evidence-based, relative advantage, adaptability, complexity, design, culture, reflecting and evaluating, and adapting). Additionally, this aligned with our research questions and helped us identify the key facilitators and barriers to adopting this tool.

Quantitative data, including demographic information such as age, sex, and occupation, was collected during interviews with both coaches and participants. Participants were also asked about the number of people in their households. Additional data included weight, height, BMI, waist circumference, blood pressure, and HbA1c. The DPP research team provided these data. During the analysis, participants were split into “active” and “non-active” groups for a

preliminary analysis of measurements from enrollment to six months. Active was defined as having logged in within the last three months, and that login date could not be the same as the created date. If a participant did not create an account or had not logged in within the last three months, they were considered non-active.

Qualitative data were from personal interviews with coaches and participants involved with the DPP cohorts that received *Small Changes*. Interviews were conducted after the first 12-16 weeks of the program.

Statistical Analysis

Quantitative Analysis

All data collected were analyzed using SPSS version 28. Measurement data collected from Brownsville DPP team were analyzed a Mann-Whitney Rank-Sum Test as the data were not normally distributed and compared non-active ($n = 32$) to active ($n = 20$) users at their six-month measurements. A p-value of ≤ 0.05 was considered statistically significant.

Qualitative Analysis

We used semi-structured interviews with 3 DPP coaches (who coached a total of 5 groups) and 19 DPP participants. Interview data were analyzed using thematic analysis. This analysis helped determine patterns of common themes from interviewees. Interview questions were opened ended and designed using the interview guide tool on www.cfirguide.org. We used the criteria for trustworthiness established by Lincoln and Guba (Lincoln & Guba, 1985). Deductive coding was completed using the CFIR domains and constructs. If appropriate, additional codes were derived from the data (inductive). Identified themes were summarized and reported here.

Data Storage and Protection of Research Participants

The study protocol was approved by the UTHealth Institutional Review Board (IRB, HSC-SPH-18-0378).

A locked filing cabinet in a secure access room was used to store hard copies of the personal information collected. An ID number was assigned to participants, and any information collected was stored with that ID number.

A password-protected encrypted server was used to store all electronic information, such as interviews and recordings. Also, participants were asked to provide verbal consent captured via video/audio recording before the interview. No identifiable information was used when interview recordings were transcribed, and confidentiality was maintained. Data collected, physical or digital, will be kept for at least three years and then properly disposed of.

RESULTS

Quantitative Data

Demographics

DPP Coaches

Three coaches led five different DPP cohorts that used *Small Changes*. These three coaches had a mean age of 48.7 ± 13.6 years. All three interviewees self-identified as Hispanic females. Two coaches are community health workers, and one is a research assistant.

DPP Participants

A summary of weights and BMI for all DPP participants at enrollment and six months are provide below in Table 2. Decreases in number of participants at 6 months (compared to baseline) is a result of participants who dropped out of the program or for whom data was not

able to be collected; DPP dropout rates (%) represent the number of people who are confirmed dropouts from the overall DPP program (no longer attending group meetings).

Table 2. Weight and BMI measurements at enrollment and 6 months

	N	Enrollment Weight	Enrollment BMI	N	6-Month Weight	6-Month BMI	DPP Dropout Rate (%)
Active	24	88.8	35.7	20	88.3	35.4	8.0
Non-Active	57	89.4	35.0	32	84.0	32.6	28.0
Total	81	89.2	35.2	52	87.2	34.3	22.0

Table 3. Program enrollment and engagement summary by cohort

	Coach	N	Enrollment Month	Created an Account	Active Users	Decrease in <i>Small Changes</i> Engagement*	DPP Dropout Rate
Cohort 1	A	19	May 2022	57%	16%	42%	16%
Cohort 2	A	20	July 2022	85%	30%	55%	30%
Cohort 3	B	15	Sept 2022	93%	46%	46%	29%
Cohort 4	C	13 [†]	Oct 2022	69%	38%	31%	38%
Cohort 5	B	16	Oct 2022	75%	19%	56%	13%

*Decrease in *Small Changes* engagement was calculated by subtracting the number of active users from the number who created an account, then dividing by the total number of cohort members.

[†]1 participant from Cohort 4 was ineligible to use *Small Changes* because they did not use a smartphone, so this participant was not included in the table.

DPP program enrollment was progressive, e.g. Cohort 1 enrollment was completed and the program started in May 2022, Cohort 2 in July, Cohort 3 in September, Cohort 4 and 5 in October. Two of the coaches (Coaches A and B in Table 3) led 2 cohorts each, and Coach C led one cohort.

Active vs. Non-active

At 6 months (Table 4), non-active individuals using *Small Changes* had lost on average of 2.91cm in waist circumference. In contrast, the active individuals lost an average 4.04cm ($p =$

0.273). Both groups had their blood pressure rise at the 6-month measurement. The non-active individuals increased both their systolic blood pressure by an average of 1.45mm Hg and diastolic blood pressure by 0.55mm Hg. Additionally, the active individuals increased both their systolic blood pressure by an average of 3.63mm HG and diastolic blood pressure by 2.95mm Hg. There was no statistical significance between groups for systolic blood pressure ($p = 0.177$), diastolic blood pressure ($p = 0.140$), and HbA1c ($p = 0.280$).

Table 4. Active and non-active participants at enrollment and 6 months

	Active users ($n=20$)		Non-Active users ($n=32$)		p-value (Baseline)	P- value (6 mo)	p-value (change)
	Enrollment	6 mo	Enrollment	6 mo			
Waist Circumference†	109.3 (9.3)	104.4 (12.1)	108.1 (15.3)	105.2 (13.3)	0.68	0.71	0.27
Systolic Blood Pressure	123.3 (20.7)	127.0 (16.4)	123.12 (12.60)	124.6 (15.8)	0.50	0.52	0.18
Diastolic Blood Pressure	74.9 (14.1)	76.5 (10.2)	73.06 (8.27)	73.6 (9.7)	0.46	0.27	0.14
Weight	89.9 (14.8)	86.9 (16.4)	88.9 (20.0)	87.5 (19.6)	0.62	0.92	0.041*
BMI	36.5 (7.2)	35.2 (7.2)	34.3 (6.3)	33.8 (6.1)	0.24	0.58	0.037*
HbA1c	5.8 (0.42)	5.7 (0.3)	5.8 (0.4)	5.6 (0.3)	0.62	0.44	0.28

†1 participants waist circumference was not captured at the 6 months measurement. All other measurements were captured for that participant.

However, there was a statistically significant difference in weight and BMI at 6 months. Non-active participants lost an average of 1.38kg, while active participants lost an average of 3.07kg ($p = 0.041$) (Figure 6). Non-active group decreased their BMI by an average of 0.54kg/m² and the active group decreasing their BMI by an average of 1.31kg/m². This difference between groups was statistically significant with a $p = 0.037$.

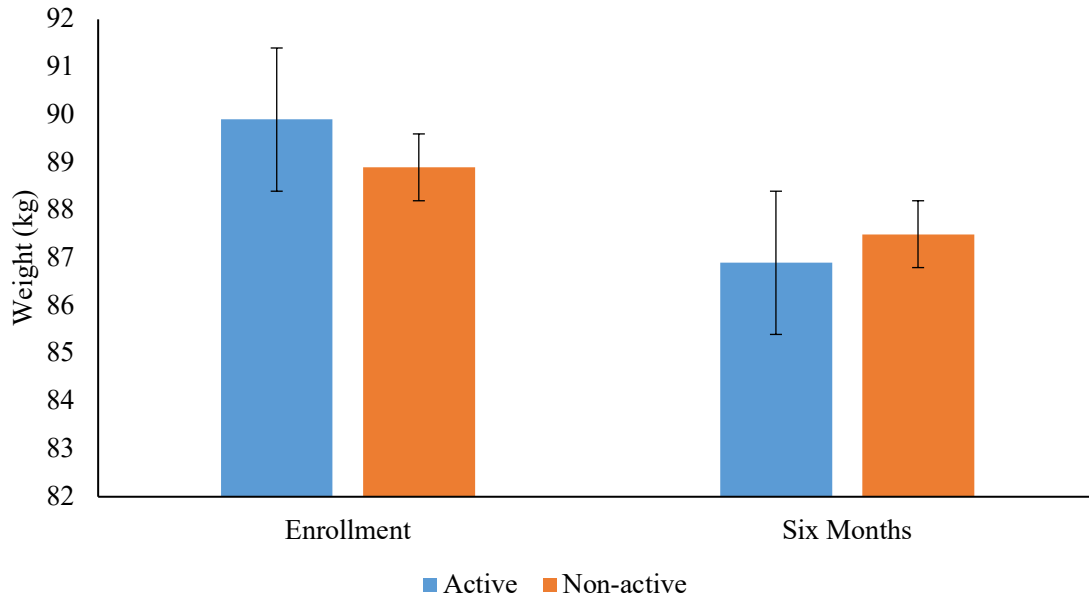


Figure 6. Mean weight between active and non-active users from enrollment to 6 months

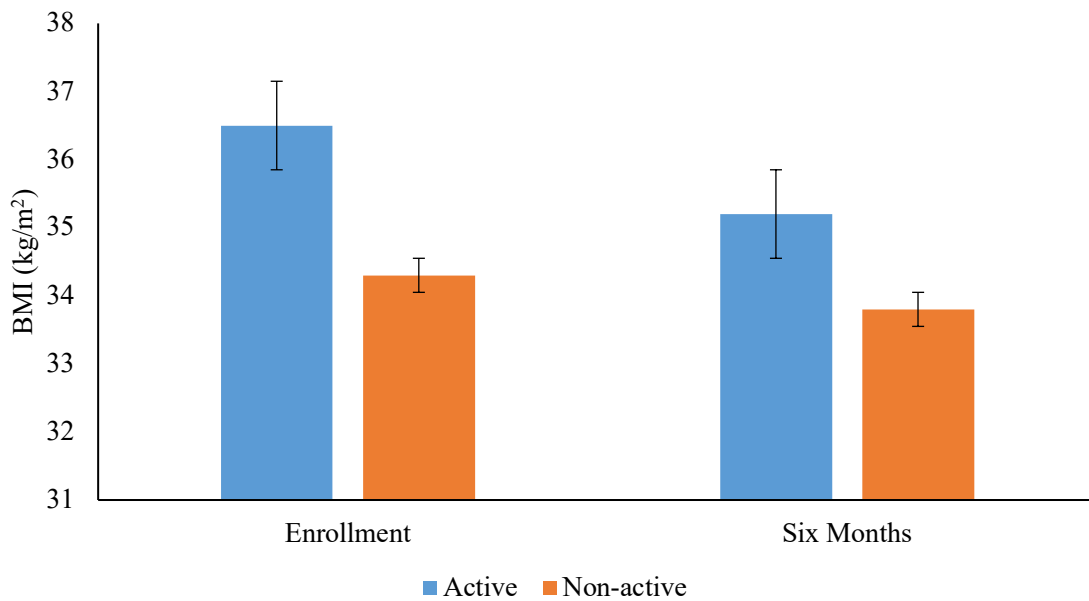


Figure 7. Mean BMI between active and non-active users from enrollment to 6 months

Five out of thirty-two (15.6%) non-active users lost at least 5% body weight and three participants (9.4%) active users lost at least 7% of their initial weight (Figure 8).

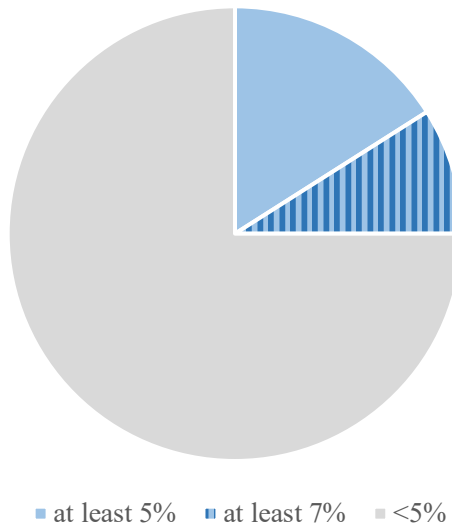


Figure 8. Non-active users' weight loss of at least 5% and 7% of their initial weight at 6 months

However, the participants that were actively using *Small Changes* at six months experienced different results. There were eight out of twenty active users, or 40%, reached at least 5% weight loss, and four, or 20%, of active users reached at least 7% weight loss at six months (Figure 9).

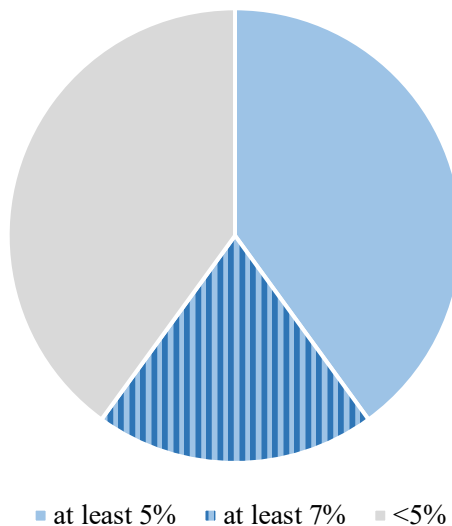


Figure 9. Active users' weight loss of at least 5% and 7% of their initial weight at 6 months

Qualitative Data

DPP Participants Interviewed

We interviewed nineteen DPP participants across five different cohorts. The participants interviewed had a mean age of 47.0 ± 9.2 years and a mean household of 4.4 ± 2.4 people. All participants interviewed self-identified as female ($n = 16$) or male ($n = 3$). Also, all participants identified as Hispanic ($n = 17$) or Latino ($n = 2$). Participants reported their occupations as housekeepers ($n = 6$), not employed ($n = 6$), caregiver ($n = 3$), retired ($n = 1$), bakery worker ($n = 1$), cosmetologist ($n = 1$), and a chef ($n = 1$).

The interview themes from the DPP coaches and DPP participants are categorized by three main CFIR domains: innovation, inner setting, and implementation process.

DPP Coaches

Innovation Domain

Innovation Evidence-Base: Despite undergoing a training program about *Small Changes* prior to the start of the DPP program, when the DPP coaches were asked about the evidence supporting *Small Changes* they were unaware of any.

Innovation Relative Advantage: Coaches were asked questions about the advantage of *Small Changes*. No coach expressed any advantage to using *Small Changes* but did mention some disadvantages. One coach mentioned that *Small Changes* was “time-consuming, not laid out, not structured. I feel the idea behind it is good.” Another coach stated, “these programs [DPP and *Small Changes*] don’t go hand in hand” with another coach stating that “it’s contradicting.”

Innovation Complexity: Coaches were asked about the complexity of *Small Changes* and one coach stated, “I find it difficult because we must not only explain DPP and *Small Changes*.” Another coach mentioned the “difficulty of it being online compared to an app.”

Inner Setting Domain

Culture: When asked about the fit of *Small Changes* with the local culture, one coach said, “I also think that *Small Changes* is for people with more resources, for people that have money. I see that the White community have more access, for example, farmers market. The people that go there, are not Hispanic, not the people in the Valley.” The same coach also mentioned, “we as Hispanics were not taught healthy eating growing up.” The other coaches did not articulate a response about cultural barriers.

Implementation Process Domain

Reflecting & Evaluation: A common theme from coaches was that they felt they did not have enough training with *Small Changes*. One coach mentioned that “It would have helped to get training on *Small Changes* because we could have asked questions, questioned the menus, asked why these food choices, and give you all our feedback.” The same coach also stated, “I was out sick, I never got trained in it. I missed when some of you all came into explain it. I never got trained on it.”

DPP Participants

Innovation Domain

Innovation Relative Advantage: Participants were asked to compare other programs they have used to *Small Changes*. Most participants found the diet program helpful, with one participant stating, “*Small Changes* is the one that has helped me lose weight, the others have not,” and another said, “it fits my lifestyle; I do not have to make extreme changes”. Another participant stated, “there is a program that is like keto and intermittent fasting, and when I finally got to eat again, I would overindulge, I would be starving. This [referring to *Small Changes*] program doesn’t make me feel like that.” Additionally, participants expressed the food choices *Small Changes* provides were easy and better than others, with one participant mentioning,

“these are foods I love to eat” and another stating, “I’ve tasted meal preps, and boy were they weird stuff, there’s better options with your program.” Also a participant expressed that *Small Changes* gave them the freedom to do “whatever I want” when it came to picking food options. Lastly, participants expressed an educational gain using *Small Changes* with a participant stating, “the application is really good, it’s educational” and another mentioning that “the tips were so helpful.”

However, some participants mentioned some disadvantages of using *Small Changes*, such as the cost of food, with one participant expressing, “I haven’t used it, for economic reasons, some of the foods are really expensive” and another stating, “sometimes I do my weekly shopping, and I don’t have enough money to buy the type of foods that are included in the recipe.”

Innovation Adaptability: Participants were asked questions about the adaptability of *Small Changes* in their life. The majority of the participants would modify recipes, with one participant describing, “overall, these choices were great, because they are not very different to what I would normally eat if I were not on a diet, but eventually I got tired of them, and I would modify them a little bit.” Another simply stated, “I would modify” when asked if they were using the recipes. Some participants would modify recipes by adding additional items: “sometimes I add chicken to the quesadilla,” another stated, “I made small modifications to the recipes such as the spices,” and one participant “would swap some carb options for vegetable.”

Another common theme was that participants would follow the diet from “time to time” or note that they “haven’t used it 100%.” One participant stated, “I don’t always use it; for example, on the weekends, I have a little fun, but then by Monday, I try to get back to my routine.”

Innovation Complexity: Participants were asked questions about the complexity of *Small Changes*. A common theme was simplicity and ease of use. Participants felt that *Small Changes* was “easy to use.” One participant expressed that “it was easy for me to change my diet and easy for me to use. I had no problems,” another mentioned that, “Its versatile and easy to use.”

However, some participants expressed difficulties with *Small Changes* related to getting logged into the program. One participant mentioned that “It was challenging, I’m not a tech savvy person.” Another said, “they gave me access to *Small Changes*, but I do not use the internet on my phone,” and another participant stated, “I struggled initially to open the application. I’m not very tech-savvy, so initially, I did not log in.” The research team adapted the *Small Changes* log in process midway through enrollment which eliminated many of the log in problems, but participants also experienced technical issues once they had gotten into the program. The research team is working on identifying the cause of the reported problems. One participant said “I never got to log on, not by choice, but because it never let me go. I would input all my information and it would not let me log in,” and another mentioned, “sometimes I put my date of birth, and that allows me to log in 2-3 times, but then the other times it wouldn’t even let me access it.” Lastly, one participant mentioned that the “application is finicky, sometimes it works and lets you in, sometimes it doesn't.” Some participants worked around technical difficulties by printing their recipes (a feature offered within the program).

Innovation Design: Participants were asked about the design of *Small Changes*. One participant mentioned that “it’s all comprehensive,” and another said, “I didn’t see anything that was missing.” Also, a participant stated, “it’s great, I would get my reminders to use the app, I would get reminders to update my weight. This app makes you feel like you’re getting 1:1

experience.” However, some participants did not like *Small Changes*, with one expressing that “I do use it, but I don’t like that it’s the same options.”

Inner Setting Domain

Culture: When asked if their personal or family culture affected the use of *Small Changes*, one participant mentioned that “as a Hispanic, I have struggled with large portions,” and another mentioned that “as a Hispanic, sometimes you eat foods that aren’t good for your health.” Also, some participants did mention that “the application is very culturally appropriate” and that “it gives you options to the cultural things too, not just the American diet.” Additionally, one participant stated, “it has a lot of options that are Mexican and teaching us to eat what we like but in the appropriate portions is excellent,” and another stated, “it had ingredients Hispanics don’t use, don’t like, and don’t want to eat it.”

Implementation Process Domain

Reflecting & Evaluation: The participants were asked questions regarding the adoption of *Small Changes* in their life. One participant mentioned “it’s a great application, it’s me that needs the discipline.” Another said, “this is something I have to work on myself and not go crazy on the weekends,” and one participant said, “I need to have more self-discipline.” Also, some participants expressed additional events in their life that affected the adoption of *Small Changes*. One participant mentioned that “I had a lot of personal things going on in my life, and I just didn’t put the effort on my end,” and another stated, “my job absorbs me.”

During the interviews, researchers noticed that most participants would express a self-stigma and mental anguish when talking about their personal experiences that seem to affect their adoption of *Small Changes*. One participant mentioned that “when my husband died, I lost a lot of weight because I wasn’t eating, and I just kept walking around in circles, all confused,” and

the same participant called themselves “a big giant bubble fish” during the interview. Also, researchers noticed that many participants would laugh at themselves when talking about their experience with weight.

DISCUSSION

Integrating the summary presented in Table 3 with the interviews provides useful insights about uptake and use of *Small Changes* in the context of overall DPP program engagement. As noted from the interviews, technical challenges with login were a significant barrier we identified early in the implementation process (during the enrollment process for cohorts 1). Modifications were made to the enrollment process that removed the requirement to remember a password or use an email address (the two biggest barriers we observed) while still maintaining HIPAA security requirements. As we can see from Table 3, the percent of participants who created an account increased markedly and remained relatively high for cohorts 2 through 5 indicating the modified log in procedure can be partially credited for improving enrollment rates for *Small Changes*. However, active users by cohort were not consistently higher across cohorts 2 through 5. One explanation could be rates of dropout from the overall DPP program (i.e., if participants are not engaged in DPP as a program, they will not be engaged in using *Small Changes*). However, dropout rate was highest in Cohort 4, which also had the 2nd highest rate of active users, and dropout rate was lowest in Cohort 5, which also had the lowest rate of active users (except for Cohort 1 whose low active user rate was likely primarily due to log in barriers). Another explanation could be ongoing technical challenges. During interviews, participants described technical challenges that seem to be due to user error or lack of comfort with technology, but they also described trouble with logging in that could be problems within the software. Further consideration of the decrease in *Small Changes* engagement, as shown in Table

3, leads to an interesting observation: the largest decreases in *Small Changes* engagement were in cohorts 2 and 5, which were also the *second* cohorts for the two coaches who led more than one cohort. Given the perceptions expressed by the coaches during the interviews, we surmise that the larger drop of *Small Changes* engagement was at least partially influenced by coaches whose prior (somewhat negative) experience with *Small Changes* influenced enthusiasm for use in their subsequent cohorts. This emphasizes the importance of addressing the need for enhanced training for the coaches. Interview comments from the coaches indicate they also want more training. Despite the concerns expressed by the coaches and participants, the participants that actively used *Small Changes* lost more weight and had a greater decrease in their BMI compared to non-active participants.

Training will need to address the perceived conflict between dietary recommendation of DPP and *Small Changes*. *Small Changes* was designed intentionally to meet patients where they are. Rather than emphasizing nutrition first, it emphasizes using familiar foods that fit into the individual's lifestyle as a starting point, but provides recipes and instructions for meal preparation that, if followed, will ensure a person maintains a caloric deficit that results in weight loss. Based on use descriptions from participants (e.g. using *Small Changes* during the week, but not on the weekends), the approach of *Small Changes* could, if understood well by coaches and participants, be used to optimize compliance to a calorie-restricted diet while *mostly* following the dietary guidelines of DPP. In other words, the majority of meal options in *Small Changes* do align with dietary guidelines from DPP; the options that may seem to contradict DPP guidelines are options that are intended to be used sparingly by participants so they do not have to "go off their diet" over the weekend (as noted in the example above) or on special occasions, but rather

can integrate choices that will allow them to maintain their caloric deficit while still participating in social activities such as eating in restaurants or celebrating with family-favorite recipes.

Aside from the technology barriers, the other two barriers noted by participants were cost and cultural appropriateness, but these were not consistently noted by all participants. In fact, some participants specifically noted the program was culturally appropriate. With regards to cost, there is a range of meal costs the participants could choose from (e.g. cornflakes, peanut butter and jelly sandwich, and bean burrito, as well as teriyaki salmon bowl and carne asada). It is unclear if they fully understood the range of cost options.

Another important observation unrelated to the use of *Small Changes* is that several participants expressed self-blame for their challenges with weight loss. This finding is in alignment with many studies in the weight stigma literature (Papadopoulos & Brennan, 2015; Rivera & Paredez, 2014). We also noticed varying degrees of readiness for change. In the context of this DPP program when some patients are told by a provider that they must participate, we would expect readiness to change to be lower than those who seek a program on their own. This lack of readiness to change was often reflected in participants' comments who did not regularly use *Small Changes*.

CONCLUSION

Although changes need to be made to enhance engagement and despite feedback from coaches that the program does not work well, active use of *Small Changes* seems to improve weight loss in this DPP program. The primary focus for improvements include: 1) more rigorous training for coaches that will be designed with their input based on experience from this initial iteration and that will address the perceived discordance between *Small Changes* and DPP and aspects that cultural features and cost options; 2) additional technical support offered through

follow-up phone calls with participants who are not actively using the program; and 3) facilitation of printing the meal plans for participants if they prefer.

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Chapter V: Summary of Findings and Implications for Research

SUMMARY OF RESULTS

This research sought to understand how the CDSS and *Small Changes* were implemented in primary care and a community DPP program.

Accordingly, the aims of this research were to explore the key facilitators and barriers to adopting the CDSS and *Small Changes* in primary care from primary care providers and patients and the key facilitators and barriers to adopting *Small Changes* in a Diabetes Prevention Program from coaches and participants.

The first study explored the key facilitators and barriers to adopting the CDSS and *Small Changes* in two primary care facilities in the Paso del Norte region. One clinic was private, and the other was a Federally Qualified Health Center (FQHC). The key findings from interviews with PCPs included:

- The CDSS was comprehensive and easy to use.
- The CDSS increased self-efficacy with overall obesity treatment and with prescribing weight loss medication.
- Integration of the CDSS into the electronic health record is preferred.
- PCPs wanted hands-on experience with *Small Changes*.
- Efficacy data would be useful for uptake by other PCPs in their clinic.

The key findings from interviews with patients included:

- Patients appreciated both the compassion and accountability from their PCP.
- Patients found *Small Changes* easy to use and helpful in their weight loss efforts.

Key findings from the quantitative data included:

- 62.5% of patients lost 5% of their body weight.

- 31.25% of patients lost 10% of their body weight.

For the second study, we explored the key facilitators and barriers to adopting *Small Changes* in a community lead DPP program. We conducted interviews with coaches and participants and were provided the measurement data for participants from baseline to 6 months. The key findings from the interviews were:

- Coaches expressed the need for additional training with *Small Changes*
- Coaches perceived conflicting dietary guidelines between DPP and *Small Changes*.
- The most prevalent barriers to participants use of *Small Changes* were technological, but for those participants who did not experience technology barriers, the program was well-liked.

The following are the key findings from the quantitative data:

- 40% of active participants lost 5% of their body weight in 6 months.
- 20% of active participants lost 7% of their body weight in 6 months.

RESEARCH IMPLICATIONS

The results from the first study indicated that PCPs using the CDSS with patients seeking obesity treatment are losing weight. Dissemination of these positive findings could help recruit more PCPs to adopt these tools into their practice.

The results from the second study indicate that participants actively using *Small Changes* lost more weight than those who did not use *Small Changes*, with 20% reaching the goal of 7% weight loss at 6 months. However, reports of perceived contradiction between *Small Changes* and DPP likely need to be addressed for better implementation of *Small Changes* in a DPP setting.

Overall, the implementation evaluation in the clinic setting was positive, and served to identify additional areas to address moving forward that will enhance further implementation and dissemination. The interviews from the patients confirm that the provider is delivering care in a compassionate and informed way. This is especially important given the evidence that weight stigma from healthcare providers is a significant barrier to treatment for people with obesity (Papadopoulos & Brennan, 2015; Rivera & Paredes, 2014). This finding needs to be further confirmed with a broader array of providers. The interviews with providers confirm that the software enhances their level of comfort with the full spectrum of clinical obesity management. Additional supporting evidence for the impact of the tools, along with further development that will further reduce time required (e.g. integration into EHRs) are priorities for our next steps with this work.

Additional implications for the clinical program have just recently come to light: the recent advancements in FDA-approved anti-obesity medications with high efficacy and safety have driven a dramatic increase in attention to clinical obesity management by health care plan managers. In the state of Texas, this includes plan managers for Employee Retirement System (ERS), Teacher Retirement System (TRS), UT System, and Texas Medicaid. While access to increasingly effective medications for the treatment of obesity is exciting, the rapid rise in costs of covering those through insurance plans is causing many concerns. Two big areas of concern – ensuring providers are prescribing the medications appropriately (not over-prescribing) and ensuring lifestyle management (especially dietary guidance) is included in treatment – are both areas that are addressed by the combination of the CDSS and *Small Changes*. This development is still in early stages, but there is growing interest in seeing how the combination of the CDSS and *Small Changes* could be used across a healthcare system to address these concerns.

In contrast to the clinic setting, the implementation research results from the DPP setting were more mixed. Simplification of the log in process significantly improved uptake of *Small Changes*, but other barriers, possibly including negative perceptions of coaches, also need to be addressed to optimize uptake of and engagement with *Small Changes*. Despite these challenges, there was encouraging evidence that use of *Small Changes* within this DPP program does improve weight loss.

These two implementation projects had relatively different success rates. A distinct difference between the two settings that could explain the difference in implementation success is the individuals responsible for implementing the tools. In the clinic setting, the PCPs who pilot tested the CDSS and *Small Changes* with their patients were PCPs who had originally sought training from our team to better learn clinical management of obesity, and subsequently participated in discussions that drove the development of the CDSS and *Small Changes*. In contrast, the decision to implement *Small Changes* in the DPP program was made by program leadership, and although training was provided to the coaches who were responsible for implementation, it seems the training was insufficient to develop adequate understanding of and buy-in for using *Small Changes* in the DPP program. The importance of these aspects of training will be considered for future efforts to integrate *Small Changes* into DPP.

Taken as a whole, lessons learned from these implementation research projects are very valuable as guides for next steps, helping us to understand how to more effectively use technology to enhance delivery of weight loss support in both clinical and community settings in a scalable way.

Appendices

APPENDIX 1: CLINICAL DECISION SUPPORT SYSTEM

Sample screen from Obesity Clinical Decision Support System (CDSS). Medical History and Physical (H&P) Exam component of the CDSS completed with simulated patient data. PCPs use the software to guide them through the steps needed for obesity management (as shown by the tabs at the top).

Measurements

Lifestyle

Weight/Diet History

Family History

H & P Exam

Medication Review

Recommendations

History and Physical Exam

Select below for each condition (no = patient does not have condition, history = patient has had this condition in the past, current = patient currently has condition, diagnose = patient needs tests to confirm or rule out diagnosis). *If leaving all buttons for a condition blank, the program will consider this "no"

Diabetes mellitus (type 2) No History Current Diagnose

Pre-diabetes No History Current Diagnose

Hyperinsulinemia No History Current Diagnose

Hypertension No History Current Diagnose

- Na-Sensitive Hypertension No History Current Diagnose

Anemia No History Current Diagnose

Fatty liver disease No History Current Diagnose

Hypothyroidism No History Current Diagnose

Kidney disease No History Current Diagnose

Cushing's Syndrome No History Current Diagnose

UT Calculi No History Current Diagnose

- Oxalate No History Current Diagnose

- Phosphate No History Current Diagnose

- Urate No History Current Diagnose

Sleep Apnea No History Current Diagnose

Backache/sciatic pain No History Current Diagnose

Joint pain No History Current Diagnose

Flat feet No History Current Diagnose

Recurrent skin infection No History Current Diagnose

Eating Disorders No History Current Diagnose

Anorexia No History

Bulimia No History Current Diagnose

Binge eating disorder No History Current Diagnose

Physical Exam Adaptations

Diagnostic Reference

Vital Signs Adaptations



Head and Neck Exam Adaptations



Cardiovascular Exam Adaptations



Breast Exam Adaptations



Lung Exam Adaptations



Abdominal Exam Adaptations



Gynecological Exam Adaptations



Musculoskeletal Exam Adaptations



Skin Exam Adaptations



APPENDIX 2: SMALL CHANGES

Small Changes is designed to allow patients to have choices in selecting the meal plan they will follow as part of their weight loss program, while ensuring the diet meets essential requirements for nutrition and healthy weight loss. Adaptations made for Small Changes included a regional data base of meals based on extensive diet and lifestyle interviews completed with patients from the Paso del Norte region. In addition, educational materials were written to address regionally specific questions and barriers from the interviews. The app is HIPAA-compliant (required for use in health care settings) and includes a provider portal to allow health care providers to enroll patients and track their progress. The program functions in English or Spanish.

For successful weight loss, the most important aspect of any weight loss diet plan is compliance which is increased by the inclusion of familiar foods in the plan. To enhance compliance, menu options include both options from local restaurants and made-from-scratch items that include recipes (Figure A.1). Patients are encouraged to select options that most closely match their usual diet to ensure the weight loss plan will only require “small changes” that can lead to be impacts on weight and health.

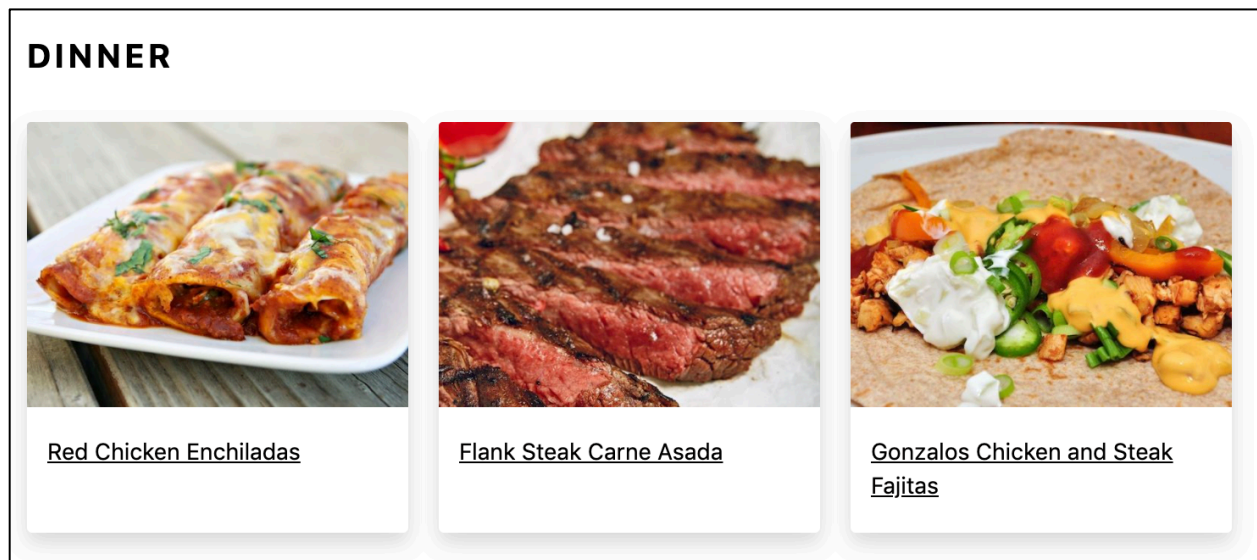


Figure A. 1. Example of dinner options for meal plan. The patient selected these 3 options for dinner and chooses any 1 option each evening. Note: options include one restaurant meal from Gonzalos, a locally owned El Paso restaurant.

Another feature that enhances compliance is a recipe multiplier. Patients can make multiple batches of a single recipe and store for quick meal options throughout the week, or they can multiply the recipe by adding non-weight loss portions for friends or family who will be consuming the meal with them (Figure A.2).

INGREDIENTS
TO MAKE 1 WEIGHT-LOSS PORTION AND 3 REGULAR PORTIONS :

[Change Number of Portions:](#) ^

Your serving size has been updated.

Weight Loss Portions: 1
 Regular Portions: 3

[Save](#)

Figure A. 2. Patients can adjust recipes to include additional portions.

Other features within Small Changes include Timely Tips which provide bi-lingual educational information about challenges commonly faced during weight loss and topics that were of interest to patients who participated in our regional in-depth diet and lifestyle interviews. In addition, patients are encouraged to track their progress by entering their weight or body composition, their step count, and their waist and hip measurements (Figure A.3).

TODAY

See My Flexcipes
 Carefully follow your flexcipes for each meal, every day, to lose weight.

Read My Timely Tips
 Weight loss tips and strategies to ensure your success.

Review or Log My Progress
 Measuring your progress is important to understand if your weight-loss program is working.

MY TIMELY TIPS

Week 1

GET GROCERIES THE SMART WAY

GET YOUR TOOLS READY

UNDERSTANDING YOUR MEASUREMENTS AND PROGRESS

MY PROGRESS

Body Composition

Step Count

Waist-to-Hips Ratio

Figure A. 3. Features of Small Changes include Timely Tips and Progress Tracking.

Patients are allowed additional flexibility with the option to change their meal plan biweekly. This also ensures that as they lose weight, the calorie content of their meal plan is adjusted accordingly so they will continue to make progress toward their weight loss goal (Fig. A.4).

MY PROGRAM	
✓	Program Started: Thursday, February 11th
✓	Meal Plan Renewal 1 Tuesday, February 23rd
✓	Meal Plan Renewal 2 Tuesday, March 9th
✓	Meal Plan Renewal 3 Tuesday, March 23rd
✓	Meal Plan Renewal 4 Tuesday, April 6th
✓	Meal Plan Renewal 5 Tuesday, April 20th
✓	Meal Plan Renewal 6 Tuesday, May 4th
✓	Meal Plan Renewal 7 Tuesday, May 18th
○	Program End: Thursday, June 3rd

Figure A. 4. Biweekly meal plan renewal allows patients to select new menu options and ensures calorie content of the meal plan supports ongoing weight loss.

APPENDIX 3: PROVIDER INTERVIEW GUIDE

Introduction

- Hello, my name's Hunter Turnipseed. I'll be leading our interview today. As I mentioned over email, I am currently working with Dr. Leah Whigham to understand the Obesity Management Program. Joining us in our interview is Dr. Ashley Toney with UTHealth.
- I'd like to start by thanking you for taking the time to speak with us. Your feedback is valuable and will be used to inform our team's future design decisions. Just to confirm, we'd like to keep this interview to (30-60 minutes). Does that still work for you?
- Great. If you need a break or to stop at any time, please let me know.
- During this interview, I'll ask you a few questions around the Obesity Management Program. Please be aware that there are no wrong answers — you're the expert here! We're doing interviews like these to hear things from your perspective. Also, please don't worry that you're going to hurt our feelings. We're doing this to improve the program, so we need to hear your honest reactions.
- With your permission, I'd like to record this meeting. The recording will only be used to help us in our research, and it won't be shared with anyone except those with a need-to-know. Recording this meeting also helps me, because I don't have to take as many notes! Is that okay?
- Finally, by agreeing to this form, you voluntarily agree to participate in this study. We will capture your consent to participate in this study by an audio recording taken during your interview. Do you hereby authorize the collection and use of your information, as described above?
- Great. Do you have any questions for me at this time?

Questions for Providers
Demographics and Experience

To start, I'd like to hear a little bit about you.

1. What's your age, sex, and occupation?
Age:
Gender:
Race/ethnicity:
Occupation:
2. How long have you been providing medical care for patients?
3. What, if any, experience have you had with providing obesity management?
4. Are you currently using the CDSS/ Small Changes with your patients, have you used it in the past, or are you planning to use it in the future?

[questions below will be framed in the appropriate tense based on provider's past, current, or intended (future) use of the program]

Questions: Clinical Decision Support System (CDSS)

- What do you know about CDSS? What is your understanding of how it works? (CID-KBI)
- What evidence, if any, are (were) you aware of that makes (made) you believe the CDSS will work with your patients? (ICD-ECQ)
- What about the CDSS – aspects or features – lead (led) you to believe it will (would) help you treat your patients? (ICD-ECQ)

Different tabs using that and seeing where it leads, gives me the confidence that it will work or lead to a good decision – very comprehensive.

- How did you learn to use the CDSS or what training about CDSS have you had access to? Can you describe your experience learning how to use the CDSS? (ICD-C) (RI-AKI) (Ad)
 - Was it easy or hard and why? Was that effective or are there ways that process could be improved? (ICD-C)
 - What additional training would be useful? (RI-AKI) (Ad)
- How does the CDSS compare to what you have used in the past? What kinds of tools or programs have you used in the past that are similar to the CDSS? (ICD-RA)

- How has the use of the CDSS changed how you manage obesity with your patients?
See above
- How well do you think the CDSS will serve (serves) your needs in helping patients with obesity? (OSD-PNR)
- Are there any disadvantages of using CDSS? (ICD-RA)
- Please describe for me how you have used the CDSS with your patients? (ICD-C)
- How easy or complex is it to use the CDSS? Which parts are easier, and which are difficult? (ICD-C)
- In what ways was the CDSS useful? In what ways was it not useful? (ICD-C)
- Do you think CDSS will be (Is the CDSS) effective with your patients? (CID-KBI)
- How confident are you that the CDSS will help you better serve your patients? Why? (ICD-ECQ)
- Is there any information you need to feel more confident about the CDSS? (ICD-ECQ)
- How do you think your practices culture (general beliefs, values, assumptions) will affect the implementation of the CDSS? (ISD-CULT)
- What changes have you had to make to your usual practice in order to implement CDSS? (ICD-A) (Im)
- Does CDSS conflict with any other program or service your practice provides? (ICD-A)

- What kind of evidence do you need about the effectiveness of the CDSS to get other providers to use CDSS? (ICD-ECQ) (Man)
- Overall, how do you feel about using the CDSS with your patients? (CID-KBI)
- How confident are you that you will (continue to) use the CDSS with your patients? (CID-SE)
- What do you think about the CDSS as a whole? (ICD-C)
- Do you have any additional comments about CDSS you would like to share?

Questions: Small Changes (SC)

- What do you know about SC? What is your understanding of how it works? (CID-KBI)
- What evidence, if any, are you aware of that makes you believe SC will work with your patients? (ICD-ECQ)
- What features of SC lead you to believe it will work with your patients? (ICD-ECQ)
- How did you learn to use SC with your patients or what training about SC have you had access to?
 - Was that effective or are there ways that process could be improved? (ICD-C)
 - What additional training would be useful? (RI-AKI) (Ad)
- What kind of apps, programs, or tools have you used with your patients in the past that are similar to SC?
- How has the use of the SC changed how you manage obesity with your patients?
- How well do you think SC will serve (serves) your needs in helping patients with obesity? (OSD-PNR)

- Are there any disadvantages of using SC? (ICD-RA)
- Please describe for me how you have used the SC with your patients? (ICD-C)
- How easy or complex is it to use SC? Which parts are easier, and which are difficult? (ICD-C)
- In what ways was SC is useful? In what ways was it not useful? (ICD-C)
- Do you think SC will be (Is SC) effective with your patients? (CID-KBI)
- How confident are you that SC will help you better serve your patients? Why? (ICD-ECQ)
- Is there any information you need to feel more confident about SC? (ICD-ECQ)
- How do you think your practices culture (general beliefs, values, assumptions) will affect the implementation of SC? (ISD-CULT)
- What changes have you had to make to your usual practice in order to implement SC? (ICD-A) (Im)
- Does SC conflict with any other program or service your practice provides? (ICD-A)
- What kind of evidence do you need about the effectiveness of SC to get other providers to use SC? (ICD-ECQ) (Man)
- Overall, how do you feel about using SC with your patients? (CID-KBI)
- How confident are you that you will (continue to) use SC with your patients? (CID-SE)

- Do you have any additional comments about SC you would like to share?

Conclusion

- Thank you for your time today. If we have additional question, would you be open to speaking with us again in the future?

APPENDIX 4: PATIENT INTERVIEW GUIDE

Introduction

- Hello, my name's Hunter Turnipseed. I'll be leading our interview today. As I mentioned over email, I am currently working with Dr. Leah Whigham to understand the Obesity Management Program. Joining us in our interview is Dr. Ashley Toney with UTHealth.
- I'd like to start by thanking you for taking the time to speak with us. Your feedback is valuable and will be used to inform our team's future design decisions. Just to confirm, we'd like to keep this interview to (30-60 minutes). Does that still work for you?
- Great. If you need a break or to stop at any time, please let me know.
- During this interview, I'll ask you a few questions around the Obesity Management Program. Please be aware that there are no wrong answers — you're the expert here! We're doing interviews like these to hear things from your perspective. Also, please don't worry that you're going to hurt our feelings. We're doing this to improve the program, so we need to hear your honest reactions.
- With your permission, I'd like to record this meeting. The recording will only be used to help us in our research, and it won't be shared with anyone except those with a need-to-know. Recording this meeting also helps me, because I don't have to take as many notes! Is that okay?
- Finally, by agreeing to this form, you voluntarily agree to participate in this study. We will capture your consent to participate in this study by an audio recording taken during your interview. Do you hereby authorize the collection and use of your information, as described above?
- Great. Do you have any questions for me at this time?
- Explain confidentiality

Questions for Participants:
Demographics

To start, I'd like to hear a little bit about you. What is your:

- Age?
- Self-identified gender?
- Race and/or ethnicity?
- Occupation?
- How many people live in your household?

Overall Program:

As you may know, we've been working with Dr. XXXX and other providers to build tools and provide resources that help her work with patients who would benefit from weight loss. We will refer to this during our conversation as the 'program.' The program includes both working with Dr. XXXX AND using Small Changes for dietary guidance. Can you confirm that you have been doing both? (if yes)

- When did you start the program/How long have you been using the program?
- What is your understanding of how the program works?
- How effective has the program been for you? (CID-KBI)
- Is there any information you need to understand the program better?
- What kind of programs, apps, or tools have you used in the past for weight loss? How does this program compare to other programs you know of? (ICD-RA)
 - Did you experience any barriers with other diet apps? (OSD-PNR)
 - Do you feel SC will help the barriers you have experienced in the past? (OSD-PNR)
- How well do you think the program is meeting/will meet your needs for weight loss? (OSD-PNR)

- Are there any disadvantages about the program compared to other programs? (ICD-RA)
- How does your personal or family culture (general beliefs, values, assumptions) affect your use of the program? (ISD-Cul)
- What changes, besides dietary, have you made in your everyday life? (ICD-Ad)
- Does this program conflict with any other programs in your life? (ICD-Ad)
- Would you refer family members or friends to use this type of program? (RI-AKI)
- How confident are you that you will continue to visit/follow up with your pcp about your weight? (CID-SE)
- How confident are you that you will continue to SC? (CID-SE)

Small Changes (SC):

Now we would like to talk about Small Changes, the online diet planning program you used.

- How did you learn to use SC?
- Has the use of SC changed how you manage your weight? If so, how?
- Are there any disadvantages of using SC? (ICD-RA)
- Please describe for me how you have used SC?
- How easy or complex is it to use SC for you? Which parts are easier, and which are more difficult? (ICD-C)

- Have you found the following helpful? What did you find useful? If not, why not? (ICD-DQP)

Recipes?

Recipe multiplier?

Measurement tools?

Tips read?

Any other topics that would be usefeul?

Weight entry?

Overall User interface?

- What do you think about the program as a whole? (ICD-DQP)
- Do you have any additional comments about the program you would like to share? (RI-AKI)

Explain overall project and partnership, CCHI and clinic role in the community.

Conclusion

- Thank you for your time. If we have additional questions, would you be open to speaking with us again in the future?

APPENDIX 5: DPP COACH INTERVIEW GUIDE

DPP Coach Interview Guide (Qualitative Evaluation Questions)

Interview Questions	Notes	Data from Small Changes
<p>1. <i>To start, I'd like to hear a little bit about you. What is your:</i></p> <ul style="list-style-type: none"> • 1a. Age Range 18-25 25-40 40-65 • 1b. Self-identified gender? • 1c. Race and/or ethnicity? • 1d. Occupation? 		
<p><i>First, we want to ask you about DPP broadly. After that, we will ask you some questions specific to Small Changes. So, to start with, please answer these questions with regard to DPP:</i></p>		
<p>2. In your experience, what are DPP participant barriers to the following?</p> <ul style="list-style-type: none"> • 2a. Confidence in their ability to be healthy • 2b. Attendance • 2c. Retention • 2d. Engagement • 2e. Weight Loss • 2f. Increasing physical activity 		
<p>3. In your experience, what enhances or helps your participants achieve success in the following areas?</p> <ul style="list-style-type: none"> • 3a. Confidence in their ability to be healthy • 3b. Attendance • 3c. Retention • 3d. Engagement • 3e. Weight Loss 		

<ul style="list-style-type: none"> • 3f. Increasing physical activity 		
<p>4. What has been your experience using the new DPP bingo card? How has it impacted participant motivation? Are there any changes you recommend us making to this incentive process?</p>		
<p>5. Now we want to understand more about how well you think the DPP program works and your thoughts on ways the program can be improved?</p> <p><i>[Probe for group support, accountability, incentives, setting, schedule, topics, coaching style]</i></p>		
<p>6. Can you describe any aspect of the program that works well for the participants in DPP?</p>		
<p>7. Can you describe any aspect of the program that can be improved?</p>		
<p>8. In your experience, which methods work the best to encourage participants to make healthy changes to their diet?</p> <p><i>[Probe for meal planning, food diary, group accountability]</i></p>		
<p align="center">Questions only for coaches randomized to the Small Change App Intervention, based on the CFIR constructs:</p>		
<p align="center"><i>Now we are going to ask you about Small Changes specifically. First, we want to ask you about your knowledge & beliefs regarding the Small Changes program.</i></p>		

<p>9. What is your understanding of how Small Changes works? (CID-KBI)</p>		
<p>10. How well do you feel Small Changes is working with your group participants? (CID/KBI)</p> <p><i>Probe: How effective has it been? (CID-KBI)</i></p>		
<p><i>[If effective, probe:]</i></p> <p>11. What features of Small Changes contributed to the effectiveness amongst participants?</p>		
<p>12. How confident are you that Small Changes has helped participants reach their goals? Why? (ICD-ECQ)</p>		
<p>13. How confident are you that you would recommend Small Changes to future participants? (CID-SE)</p>		
<p>14. How confident are you that Small Changes will continue to help DPP participants reach their goals? (CID-SE)</p>		
<p>15. What kind of proof would you need about the effectiveness of Small Changes to convince other coaches to use Small Changes? (ICD-ECQ)</p>		
<p><i>Next, we want to understand how Small Changes compares to what you have been doing in DPP before now. Can you briefly describe what the dietary approach in the DPP program is?</i></p>		

<p>16. How does Small Changes compare with that approach? (ICD-RA)</p>		
<p>17. Are there any disadvantages of using Small Changes? (ICD-RA)</p>		
<p>18. What changes have you had to make to your usual coaching in order to implement Small Changes? (ICD-A)</p>		
<p>19. Does Small Changes conflict with any aspect of DPP? (ICD-A)</p>		
<p>20. How easy or complex is Small Changes for you to explain to participants? (ICD-C)</p> <p><i>[Probe: Which parts are most easy to explain; which aspects are more challenging to explain? (ICD-C)]</i></p>		
<p><i>Next, we want to understand what might be happening in the lives of participants that impact how well they can use Small Changes.</i></p>		
<p>21. What barriers have you noticed, or do you anticipate participants face? (OSD-PNR)</p> <p><i>[Probe: internet access, time constraints]</i></p>		
<p>22. How well do you think Small Changes meets the needs of the individuals in your group? (OSD-PNR)</p>		
<p><i>Next, we want to ask you about using Small Changes within the context of the DPP program.</i></p>		

<p>23. How do you think the Diabetes Prevention Program’s culture (general beliefs, values, assumptions) is affecting the use of Small Changes? (ISD-CULT)</p>		
<p>24. How well does Small Changes fit with the local culture of participants in terms of recipe choices, language (dialect), and terminology? (ISD-CULT)</p>		
<p>25. What training have you had about obesity in general? (RI-AKI)</p>		
<p>26. What training about Small Changes have you had access to? (RI-AKI)</p>		
<p>27. What training do you still need? (RI-AKI)</p>		
<p>Concluding Questions and Remarks</p>		
<p>28. Do you have any comments about Small Changes you would like to share?</p>		
<p>29. Would you be open to speaking with us again in the future</p>		

APPENDIX 6: DPP PARTICIPANT INTERVIEW GUIDE

DPP Participant Interview Guide (Qualitative Evaluation Questions)

Guía de Entrevista Para Participantes del DPP (Preguntas de Evaluación Cualitativa)

Interview Questions	Notes	Data from Small Changes
<p><i>To start, I would like to know a little bit more about you. Can you tell me:</i></p> <ul style="list-style-type: none"> • Your Age Range 18-25 25-40 40-65 • Self-identified gender? • Race and/or ethnicity? • Occupation? • How many people live in household? <p><i>Para empezar, me gustaría saber un poco más sobre usted. ¿Puede decirme:</i></p> <ul style="list-style-type: none"> • Fecha de nacimiento • ¿Género autoidentificado? • ¿Raza y/o etnia? • ¿Ocupación? • ¿Cuántas personas viven en el hogar? 		
<p>Tell us about your personal experience with weight loss?</p>		

<p><i>(Probes: at what age did you first start to struggle with your weight? What has been your highest adult weight? Approximately how many times have you tried to lose weight in the past? What strategies have been most successful for you?)</i></p> <p>Cuéntanos sobre su experiencia personal con la pérdida de peso?</p> <p><i>(Sondas: ¿A qué edad comenzo a batallar con su peso? ¿Cuál ha sido su peso adulto más alto? ¿Aproximadamente cuántas veces ah intentado perder peso en el pasado? ¿Qué estrategias han sido más exitosas para usted?)</i></p>		
<p>Are you currently using the Small Changes program?</p> <p><i>[Probe: If yes, have you found it useful?] [Probe: If not, why have you not used it? What do you not like about SC? What are you using/doing for your diet? Skip to conclusion]</i></p>		<ul style="list-style-type: none"> • Created an account on • Last login

<p>¿Está utilizando el programa Small Changes?</p> <p><i>[Sonda: En caso afirmativo, ¿lo ha encontrado útil?]</i> <i>[Sonda: Si no, ¿por qué no lo has usado? ¿Qué es lo que no te gusta de SC? ¿Qué estás usando/haciendo para tu dieta? Saltar a la conclusión]</i></p>		
<p>Describe for me how you use the program day to day?</p> <p><i>[probe: frequency, following recipes/making substitutions, understanding how to use choices]</i></p>		<ul style="list-style-type: none"> •
<p>Can you describe your experience while you learned how to use Small Changes?</p> <p>¿Puedes describir su experiencia mientras aprendía a usar Small Changes?</p>		
<p>Did you use the recipes on the Small Changes website?</p> <p><i>[Probe: If so, did you prefer to access them online, or did you print them? Did you use the recipes as recommended by the program?]</i></p>		<ul style="list-style-type: none"> • Last meal update

<p>¿Uso las recetas en línea que se encuentran en Small Changes?</p> <p><i>[Sonda: Si es así, ¿prefirió acceder las recetas en línea o las imprimió? ¿Uso las recetas según lo recomendado por el programa?]</i></p>				
<p>We see that you selected [read breakfast items] for breakfast. How did those work for you? Which did you choose most often?</p> <p><i>Repeat for other meals</i></p>		Breakfast	Morning Snack	Lunch
		Afternoon Snack	Dinner	
<p>Would additional options be helpful ...</p>				
<p>Are there any other foods you would have liked during the diet plan?</p>				
CFIR Questionnaire				
<p>What is your understanding of how Small Changes works? (how would you describe it to a friend)</p> <p>¿Que es su comprensión de cómo funciona Small Changes?</p>				

<p>Do you think Small Changes has been effective in helping you meet your goals? (CID-KBI) (ICD-ECQ)</p> <p><i>[If effective, probe:]</i> In what ways could the Small Changes program be improved to help you meet your goals?</p> <p>¿Usted cree que Small Changes ha sido efectivo en ayudarlo a alcanzar tus metas?</p> <p><i>¿De qué manera se podría mejorar el programa de Small Changes para ayudarla a alcanzar sus metas?</i></p>		<ul style="list-style-type: none"> • Starting weight lbs • Current weight lbs
<p><i>[If they seem not convinced that the program works, ask],</i> what kind of evidence would convince you differently? (CID-KBI)</p> <p>¿Que tipo de evidencia la convencería de manera diferente?</p>		
<p>Do you think you would keep using Small Changes once the DPP program is over? Why? (CID-SE)</p> <p>¿Cree que seguiría usando Small Changes una vez que termine el</p>		

<p>programa DPP? ¿Por qué?</p>		
<p><i>Next, I am going to ask you some questions about strengths and qualities of the Small Changes Program</i></p> <p><i>A continuación, voy a hacerle algunas preguntas sobre las fortalezas y cualidades del Programa de Small Changes</i></p>		
<p>Have you ever participated in other weight loss programs in the past? (note: you may need to build upon earlier answers from question about personal experience with weight loss)</p> <p>¿Alguna vez ha participado en otros programas de pérdida de peso en el pasado?</p>		
<p>How does Small Changes compare to those programs? (ICD-RA)</p> <p>¿Cómo se compara Small Changes con esos programas?</p>		
<p>Are there any disadvantages to using Small Changes compared to other programs? (<i>probe</i>) (ICD-RA)</p> <p>¿Hay alguna desventaja en el uso de Small Changes en</p>		

<p>comparación con otros programas?</p>		
<p>Were there any modifications that you made to Small Changes to make it work better in your life?</p> <p><i>[Probe: changes to recipe, changes to meal frequency, skipping meals, only following intermittently] (ICD-A)</i></p> <p>¿Hubo alguna modificación que le hizo a Small Changes para que funcionara mejor en su vida?</p>		
<p>Does Small Changes conflict with any other programs or your lifestyle? (ICD-A)</p> <p>¿Small Changes entra en conflicto con otros programas o su estilo de vida?</p>		
<p>Did you find that the Small Changes program was easy or challenging to follow? (ICD-C)</p> <p>¿Encontró que el programa de Small Changes fue fácil o difícil de seguir?</p>		

<p>Can you describe what parts of the program are easier to follow, and which were more challenging to follow? (ICD-C)</p> <p>¿Puede describir qué partes del programa son más fáciles de seguir y cuáles fueron más difíciles de seguir?</p>		
<p><i>Next, we want to ask you about the hands-on experience of the software</i></p> <p><i>A continuación, queremos preguntarle sobre la experiencia práctica de su uso de Small Changes</i></p>		
<p>How was the overall experience of navigating the website?</p> <p><i>Probes: was there anything confusing? is there anything that would make the website easier to navigate?</i></p> <p>¿Cómo fue su experiencia general de navegar el programa en su telefono o computadora?</p> <p>Sondas: ¿hubo algo confuso? ¿Hay algo que haga que el sitio web sea más fácil de navegar?</p>		
<p>Did you use the tips featured on the website? If so, were they useful?</p>		<ul style="list-style-type: none"> • (still ask the question and see what they say – unless they already told us above that they did not read any tips – then we can skip this question)

<p><i>[probe: other topics for tips? How many read?</i></p> <p>(if they don't seem to know what the tips are, say 'these are brief articles addressing common questions about weight loss – they can be accessed from your dashboard')</p> <p>¿Utilizaste los consejos que aparecen en el sitio web? Si es así, ¿fueron útiles? (Si no parecen saber cuáles son los consejos, diga 'Estos son artículos breves que abordan preguntas comunes sobre la pérdida de peso, se puede acceder a ellos desde su tablero')</p>		
<p>Did you find the recipes helpful?</p> <p>Probes: were they easy to follow? Did you understand the instructions? Is there anything that would have made the recipes better?</p> <p>¿Le han resultado útiles las recetas?</p> <p>Sondas: ¿fueron fáciles de seguir? ¿Entendí las instrucciones? ¿Hay algo que hubiera mejorado las recetas?</p>		

<p>What do you think about the Small Changes as a whole? (ICD-DQP)</p> <p>¿Qué piensa de el Programa Small Changes en su conjunto?</p>		
<p>What challenges have you experienced in your weight loss journey? (OSD-PNR)</p> <p>(note: this may have already been covered – if so, say ‘you have already described some of the challenges experienced in your weight loss journey such as... Are there any additional challenges we haven’t talked about?)</p> <p>¿Qué tipos de desafíos a pasado en su experiencia de pérdida de peso? Que otras batallas ah tenido durante su lucha en bajar de peso?</p>		
<p>Do you think your culture (general beliefs, values, assumptions) affects your use of Small Changes? (ISD-CULT)</p> <p>¿Cree que su cultura (creencias generales, valores, suposiciones) afecta tu uso de Small Changes?</p>		

<p><i>Now we are going to switch to a quick survey. This survey is to get your feedback on Small Changes, and your feedback could be used to help improve Small Changes.</i></p> <p><i>Ahora vamos a cambiar a una encuesta rápida. Esta encuesta es para obtener sus comentarios sobre Small Changes, y sus comentarios podrían usarse para ayudar a mejorar el Programa.</i></p>		
<p>Small Changes Feedback Survey</p>		
<p><i>Please answer the following questions about the Small Changes plan:</i></p> <p><i>Responda las siguientes preguntas sobre el plan de Small Changes:</i></p>		
<p>Overall, how satisfied were you with the program?</p> <ul style="list-style-type: none"> <input type="radio"/> Very satisfied <input type="radio"/> Satisfied <input type="radio"/> Unsatisfied <p>En general, ¿qué tan satisfecha estabas con el programa?</p> <ul style="list-style-type: none"> <input type="radio"/> Muy satisfecho <input type="radio"/> Satisfecho <input type="radio"/> Insatisfecho 		
<p>If Unsatisfied Answered:</p> <p><i>Sorry to hear that you were unsatisfied! Would you kindly tell us what we could have done better?</i></p> <p>Would you like us to follow up with you regarding your concerns?</p> <ul style="list-style-type: none"> <input type="radio"/> Yes 		

<p><input type="radio"/> No</p> <p>¡Lamento escuchar que no estabas satisfecho! ¿Podría decirnos qué podríamos haber hecho mejor?</p> <p>¿Le gustaría que le demos un seguimiento con respecto a sus inquietudes?</p> <p><input type="radio"/> Sí <input type="radio"/> No</p>		
<p><i>If satisfied/very satisfied Answered:</i></p> <p>Have you already recommended this program to a friend or family member, or will you recommend it to someone in the future?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>¿Ya ha recomendado este programa a un amigo o familiar, o se lo recomendará a alguien en el futuro?</p> <p><input type="radio"/> Sí <input type="radio"/> No</p>		
<p>Compared to other diet plans, the Small Changes plan made me feel:</p>		

<ul style="list-style-type: none"> ○ Less hungry than other diet plans ○ About as hungry as other diet plans ○ More hungry than other diet plans <p>En comparación con otros planes de dieta, el plan Small Changes me hizo sentir:</p> <ul style="list-style-type: none"> ○ Menos hambre que otros planes de dieta ○ Casi tan hambriento como otros planes de dieta ○ Más hambre que otros planes de dieta 		
<p>Compared to other diet plans, the Small Changes plan was:</p> <ul style="list-style-type: none"> ○ More tasty than other diet plans ○ About as tasty as other diet plan ○ Less tasty than other diet plans <p>En comparación con otros planes de dieta,</p>		

<p>el plan de Small Changes fue:</p> <ul style="list-style-type: none"> ○ Más sabroso que otros planes de dieta ○ Casi tan sabroso como otro plan de dieta ○ Menos sabroso que otros planes de dieta 		
<p>Compared to other diet plans, the Small Changes plan was:</p> <ul style="list-style-type: none"> ○ Easier to follow than other diet plans ○ About as easy/difficult to follow as other diet plans ○ More difficult to follow than other diet plans <p>En comparación con otros planes de dieta, el plan de Small Changes fue:</p> <ul style="list-style-type: none"> ○ Más fácil de seguir que otros planes de dieta ○ Casi tan fácil / difícil de seguir 		

<p>como otros planes de dieta</p> <ul style="list-style-type: none"> ○ Más difícil de seguir que otros planes de dieta 		
<p>Compared to other diet plans, the Small Changes plan was:</p> <ul style="list-style-type: none"> ○ Easier to follow than other diet plans ○ About as easy/difficult to follow as other diet plans ○ More difficult to follow than other diet plans <p>En comparación con otros planes de dieta, el plan de Small Changes fue:</p> <ul style="list-style-type: none"> ○ Más fácil de seguir que otros planes de dieta ○ Igual de fácil / difícil de seguir como otros planes de dieta ○ Más difícil de seguir que otros planes de dieta 		

<p>Were you satisfied with the variety of foods offered during the diet?</p> <ul style="list-style-type: none"> ○ Completely satisfied ○ Somewhat satisfied ○ Unsatisfied <p>We see that you selected [read breakfast items] for breakfast. How did those work for you? Which did you choose most often? Repeat for other meals.</p> <p>¿Estaba satisfecha con la variedad de alimentos ofrecidos durante la dieta?</p> <ul style="list-style-type: none"> ○ Completamente satisfecho ○ Algo satisfecho ○ Insatisfecho <p>Vemos que seleccionó [leer artículos de desayuno] para el desayuno. ¿Cómo funcionaron para ti? ¿Cuál elegiste con más frecuencia? Repita para otras comidas.</p>		
<p>The plan was 16 weeks long. Was this length:</p> <ul style="list-style-type: none"> ○ Just right ○ Too long 		

<ul style="list-style-type: none"> ○ Too short <p>El plan duro 16 semanas. Esta longitud:</p> <ul style="list-style-type: none"> ○ Justo ○ Demasiado largo ○ Demasiado corto 		
<p>Do you have any other thoughts or comments to share with us?</p> <p>¿Tiene alguna otra idea o comentario para compartir con nosotros?</p>		
Conclusion		
<p style="text-align: center;"><i>Thank you so much for your time today; before we wrap up, do you have any comments about Small Changes you would like to share?</i></p> <p style="text-align: center;"><i>Muchas gracias por su tiempo hoy; Antes de terminar, ¿tiene algún comentario sobre Small Changes que le gustaría compartir?</i></p>		
<p>Would you be open to speaking with us again in the future?</p> <p>¿Estaría dispuesto a hablar con nosotros de nuevo en el futuro?</p>		

APPENDIX 7: IRB OUTCOME LETTER



Committee for the Protection of Human Subjects

6410 Fannin Street, Suite 1100
Houston, Texas 77030

Dr. Leah Whigham Grendell
UT-H - SPH - El Paso Regional Campus

June 23, 2022

HSC-SPH-22-0520 - Obesity Management Program Evaluation

The above named project is determined to qualify for exempt status according to 45 CFR 46.104(d).

CATEGORY #2 : *Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording), if at least one of the following criteria is met:*

- a. *information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects;*
- b. *any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or*
- c. *the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.*

(NOTE: The exemption under Category 2 DOES NOT APPLY to research involving survey or interview procedures or observation of public behavior when individuals under the age of 18 are subjects of the activity except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. This exemption does not apply to research involving children when information is identifiable.)

CHANGES: Should you choose to make any changes to the protocol that would involve the inclusion of human subjects or identified data from humans, please submit the change via iRIS to the Committee for the Protection of Human Subjects for review.

INFORMED CONSENT DETERMINATION:

Waiver of Documentation of Informed Consent

INFORMED CONSENT: When Informed consent is required, it must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. Please note that only copies of the stamped approved informed consent form can be used when obtaining consent.

Vita

My professional background started with my BS in Exercise Sport Science with a minor in Nutrition, followed by my MS in Kinesiology from Texas Tech University. I worked on multiple clinical studies on controlled feeding interventions, physical activity, and psychosocial factors in obesity under Dr. Emily Dhurandhar. The skills I obtained included ultrasound imaging, indirect calorimetry, and many forms of body composition measurements, including DEXA. During my graduate years, I taught Personal Fitness and Wellness classes and mentored undergraduate students with research. My thesis was “Pain as a Barrier to Physical Activity in Severe Obesity and the Alter-G Anti-Gravity Treadmill as a Potential Therapeutic Tool.”

Following my MS degree, I was accepted to the Interdisciplinary Health Sciences Ph.D. program at the University of Texas at El Paso. I was awarded the Paso del Norte Health Foundation Fellowship and the Doctoral Excellence Fellowship for all four years of my Ph.D. I am a research associate with Dr. Leah Whigham, at the Center for Community Health Impact (Bocchieri-Ricciardi et al.) director at UTHHealth El Paso campus. The CCHI uses a community-driven, science-informed approach to translate the science of obesity, nutrition, and physical activity into practical applications in community settings. As a part of the CCHI, I have worked in interdisciplinary teams and community-based research across multiple cities, states, and research sites. While I have supported many projects at the CCHI over the past four years, my dissertation's primary research focus and topic was the Implementation and Evaluation of Obesity Management Tools. I will continue my professional development as a postdoctoral scholar.

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