

**A FOOD BOX INTERVENTION FOR FAMILIES EXPERIENCING
FOOD INSECURITY AND TYPE 2 DIABETES: A PILOT PROJECT**

By

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ABSTRACT

The negative impacts of type 2 diabetes (T2D) can be exacerbated by food insecurity (FIS), contributing towards overall familial stress, poor health outcomes, and difficulties with diabetes management. Food box interventions may reduce some barriers to healthy eating, including access to fresh produce, transportation, and food cost. The current pilot project was designed to examine the feasibility, acceptability, and satisfaction of a produce food box intervention for families impacted by T2D and FIS, as well as any changes in eating habits and perceived stress. The pilot project was shown to be acceptable to families and participants indicated that they were satisfied with the intervention. Study feasibility was negatively impacted by participant recruitment and retention. Participant eating habits did not change; however, perceived stress was shown to decrease mid-intervention before rebounding post-intervention. Barriers identified throughout the pilot study, as well as via participant response are highlighted.

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CHAPTER 1: INTRODUCTION & LITERATURE REVIEW

Food insecurity (FIS) has been linked to a variety of health conditions, including Type 2 Diabetes (T2D) (Seligman et al., 2007; Tait et al., 2018; Beltran et al., 2021). Independently, experiencing T2D and FIS can have negative psychological impacts, such as depression and low health-related quality of life (Anderson et al., 2001; Varni et al., 2003; Beltran et al., 2021; Wang et al., 2019). Furthermore, many individuals who are experiencing both T2D and FIS report low self-efficacy related to diabetes-management, which can lead to poor adherence to diabetes-related self-care behaviors (Becerra et al., 2016; Heerman et al., 2015). Although effective interventions exist for each condition independently, those impacted by T2D and FIS may also experience additional barriers to overall health, such as limited access and availability of resources, which may exacerbate their experiences with T2D and FIS (Chaufan et al., 2011). Food box intervention programs may reduce some barriers (e.g., access to food) and positively impact diet, health, and reduce familial stress; however, no studies to date have examined the efficacy of food box programs for those experiencing both T2D and FIS. The following literature review will describe T2D and FIS, including current intervention approaches for both conditions. The barriers associated with experiencing both T2D and FIS will be addressed, including gaps in the current research. To address the research gaps, a proposed intervention model using a social-ecological framework will be piloted.

Type 2 Diabetes

Type 2 Diabetes (T2D) is a chronic health condition that impacts the body's ability to turn food into energy (CDC, 2022). Insulin, a hormone produced by the pancreas, allows blood glucose to enter the body's cells to use for energy. Those with T2D have insulin resistance, when the cells do not respond normally to insulin, as well as a deficiency of insulin production by their

pancreas. Low insulin production and insulin resistance results in too much glucose circulating in the bloodstream, which can be damaging to the body. Diabetes-related complications can include heart disease, stroke, kidney disease blindness, and neuropathy (CDC, 2022). Individuals with diabetes are recommended to check their hemoglobin A1C (HbA1c) at least twice per year to assist in their diabetes management. An HbA1c test is a blood test that measures the average blood glucose levels over the past three months. HbA1c is an important clinical marker of disease status, as diabetes-related complications are linked to high HbA1c levels. While individual HbA1c goals are typically set with an individual's physician, 7% or less is a typical goal for many (CDC, 2022).

The prevalence of T2D is highest among adults and most commonly those over 40 years of age. Approximately 10% of adults in the United States have diabetes, with 90-95% of those individuals having T2D (CDC, 2022). The prevalence of diabetes is generally higher in men in comparison to women (Abdurahman et al., 2019; Heerman et al., 2015). While T2D is currently more prevalent in adults, children and adolescents can also have T2D. Youth with T2D are most often diagnosed between the ages of 10 and 19 years old, with an average onset of 13 years old (Pulgaron & Delamater, 2014; Wysocki et al., 2005). Of those children, over 85% are either overweight or obese at diagnosis (Pulgaron & Delamater, 2014). Targeting health-related habits at such a critical timepoint in children and adolescents' lives could potentially decrease the prevalence of diabetes or diabetes-related complications. Children and adults that develop T2D are at risk of severe health complications from the disease, including cardiovascular disorders, retinopathy, neuropathy, renal disease, cognitive decline, and liver diseases (Abdurahman et al., 2019; Pulgaron & Delamater, 2014; The HEALTHY Study Group, 2010).

The healthcare socioeconomic burden of T2D is also significant. Diabetes-related care in outpatient and emergency department visits cost an estimated \$245 billion nationally, with over 75,000 annual deaths (Becerra et al., 2016). In comparison to the general population, those with T2D have a 30% higher risk of emergency department utilization. Furthermore, those with complications associated with T2D have a higher hospital cost per patient than those without complications due to the associated expenses for managing co-morbid conditions associated with T2D (Bo et al., 2004; Pagano et al., 2009).

Factors Related to Type 2 Diabetes

Psychological Factors. There is a strong relationship between T2D and psychological impairment, including depression and low health-related quality of life (Anderson et al., 2001; Varni et al., 2003; Naughton et al., 2014). In fact, depression is the most common psychiatric disorder in individuals with diabetes, with individuals with T2D having a 24% higher risk of developing depression in comparison to individuals without diabetes (Nouwen et al., 2010). McKellar and colleagues (2004) found a direct and significant effect of depressive symptoms on diabetes treatment adherence and in turn, diabetes symptoms. Further, the prevalence of anxiety in those with diabetes is approximately 30-40% (Grigsby et al., 2002; Anderson et al., 2002). Additionally, the presence of depression and anxiety have been associated with increased hyperglycemia and poor treatment adherence (Lustman et al., 2000; Anderson et al., 2002). Perceived stress has also been associated with the development of T2D. This relationship is moderated by socioeconomic status (SES) in some studies, highlighting the differences in stress experiences (Rod et al., 2012; Twig et al., 2016). There is a clear bi-directional psychological impact of experiencing T2D, which can be influenced by several factors, including the social and physical environment.

Social Factors. The social ecological model (Bronfenbrenner, 1979) considers the interaction between different factors and relationships in an individual's life that all influence the development of the individual. The model is comprised of five systems which all impact the development of an individual. The inner-most system, the microsystem, is the immediate environment surrounding an individual such as the individual and their family, school system, or religious organizations. The mesosystem encapsulates the interactions between the microsystems, such as a parent interaction with school staff or community members. The third system, the exosystem, contains the formal and informal social structures that directly influence the individual, such as a neighborhood, parent workplace, or healthcare services. The macrosystem encompasses the social and cultural elements that influence development, such as ethnicity, geographic location, or economic status. Finally, the chronosystem considers time, including the environmental changes that occur over the lifetime that influence development, such as historical events of life transitions.

When examining just the microsystem, the immediate environment surrounding an individual, there is a clear bi-directional relationship between T2D and the ecological factors in the environment. For example, the family system can have a significant influence on factors related to T2D. In fact, children of single-parent households and households with high reported family stress are more likely to be overweight than children from two-parent households or those with less reported familial stress (Huffman et al., 2010). Furthermore, parental knowledge of nutrition and physical activity guidelines is a strong predictor of children's weight status (Hendrie et al., 2011), highlighting the integral role of family environment. Factors such as low income, low education levels, single-living status, and membership in a racial/ethnic minoritized group have all been related to increased T2D risk in adults. In fact, individuals with three or

more social risk factors have an approximately three-fold increase in risk of T2D, even after controlling for obesity, physical inactivity, and dietary intake (Echouffo-Tcheugui et al., 2016). Additionally, individuals that have one or more first-degree relative with diabetes are two to six times as likely to have diabetes in their lifetime (Valdez et al., 2007).

Expanding out further to the exosystem and macrosystem, which encompass the informal and formal social structures and the social and cultural elements that influence development respectively, there is a reciprocal impact on T2D. Neighborhood, income level, and race/ethnicity have all been linked to obesity and T2D (Huffman et al., 2010). For adults, individuals in a racial/ethnic minoritized group and of low SES have been found to have more adverse outcomes from diabetes in comparison to their non-Hispanic White, high SES counterparts (Heisler et al., 2007; Karter et al., 2002; Everson et al., 2002; Robbins et al., 2001). Social influences, such as communities and cultural factors, can also impact those with T2D. In fact, Latinx communities are disproportionally affected by obesity in comparison to their non-Hispanic White counterparts, which contributes to higher overall risk of T2D (Ogden et al., 2012; Pettitt et al., 2014). The prevalence of T2D is twice as high in Latinx adults in comparison to non-Hispanic White adults (Soltero et al., 2019). Further, Latinx youth have higher rates of pre-diabetes (i.e., higher than normal blood sugar, impaired glucose tolerance) in comparison to their non-Hispanic White counterparts, with up to 50% of Latinx children expected to develop T2D within their lifetime (Pettitt et al., 2014; Narayan et al., 2003). There are clear bi-directional relationships between these socioecological factors and T2D, which should be considered when managing diabetes-related care. One individual-level factor that has a strong relationship with diabetes-related care is an individual's diet.

Diet & Eating Habits. Obesity is a common factor associated with the development of T2D. Approximately 50% of individuals with T2D have comorbid obesity (Nguyen et al., 2011). In fact, every kilogram increase in weight increases the risk of T2D by 4.5% (Ford et al., 1997). Children who have obesity are at three times the risk of developing T2D in adulthood in comparison to children without obesity and the rate of youth developing T2D during childhood is rising (Bartz & Freemark, 2011; NIH, 2022). Chronically elevated blood sugar in youth increases risk for developing diabetes-related complications in adulthood (Rohan et al., 2015). Body weight and food consumption are closely tied, therefore diet-related factors are essential to consider in relation to the development of T2D.

Consumption of red meats, processed meats, and sugar-sweetened beverages has been linked to an increased likelihood of T2D development (Bellou et al., 2018; Xi et al., 2014; Schwingshackl et al., 2017). There is evidence that beverages play a unique role in T2D development. Sugar-sweetened beverages (e.g., fruit drinks, soft drinks, iced tea, energy drinks, vitamin water drinks), are associated with weight gain and obesity in adults (Malik et al., 2013). In fact, greater intake of sugar-sweetened fruit juice had a 14% higher risk of T2D development in comparison to those consuming less sugar-sweetened fruit juice (Xi et al., 2014). However, 100% fruit juices have not been associated with a negative impact or increased likelihood of developing T2D (Xi et al., 2014). The sugars in sugar-sweetened beverages increase blood glucose levels, resulting in high glycemic index or further insulin resistance, which are risk factors for T2D (DiMeglio & Matters, 2000).

Consumption of whole grain products, vegetables, and fruit mitigate the development of T2D through reducing potential weight gain (Bellou et al., 2018; Schwingshackl et al., 2017). There is some limited evidence that consumption of dairy products, particularly fermented dairy

products (e.g., cheese, sour cream, buttermilk), is associated with a reduced risk in adiposity (Schwingshackl et al., 2016). In a 2019 Youth Risk Behavioral Study in the United States, 40% of high school students reported eating fruit or drinking 100% fruit juice one or fewer times per day (Merlo et al., 2020). Importantly, reducing the consumption of risk-increasing foods, such as processed meats and sugar-sweetened beverages, is more impactful on T2D development than consuming foods that reduce the risk, such as whole grain products (Schwingshackl et al., 2017).

Interventions Targeting Type 2 Diabetes

Psychosocial Interventions. Treatment approaches for T2D include daily medication, monitoring of blood glucose levels, and lifestyle behavioral changes (Pulgaron & Delamater, 2014). Psychosocial interventions that target diabetes-related distress are also an approach used to manage care for those with T2D in the hopes that reducing distress will allow for better diabetes-related care. However, there are mixed results as to the efficacy of interventions targeting diabetes distress. In particular, a meta-analysis examined interventions that included cognitive- and emotion-focused, social support, coaching, coping skills training, and social and psychological training for diabetes distress. The researchers found low to moderate evidence of reductions in diabetes distress over time and low to moderate impact on HbA1c levels. Further, the interventions examined had only a small reduction in depression and little effect on health-related quality of life (Mathiesen et al., 2019). Researchers have also conducted a systematic review of peer support interventions for diabetes distress for those with T2D. The results showed that the interventions did not significantly improve diabetes distress in comparison to care as usual (Kong et al., 2020). However, a medium effect size on reducing diabetes distress was found when conducting a meta-analysis of randomized controlled trials of interventions focused on problem-solving, mindfulness, cognitive-behavioral, and motivational interviewing strategies

for those with diabetes (Schmidt et al., 2018). Despite intervention focus, T2D self-management programs that adapt to the target individual's age, language, and culture have been shown to be more effective in comparison to generic programs that do not adapt (Guerin et al., 2019).

Individual socioecological factors are critical to consider when developing interventions to target diabetes self-management.

Lifestyle Modifications. Lifestyle modifications, such as changes in diet and exercise, are common behavioral treatments to target obesity in those with T2D (Copeland et al., 2013). Healthy eating is a key strategy for diabetes self-management, specifically for controlling blood glucose. HbA1c concentration can be a strong clinical predictor of diabetes management and changes in HbA1c are often used to evaluate intervention effectiveness, with a 0.5% change being the agreed upon clinically relevant change for physicians and researchers (CDC, 2022). Researchers who conducted a meta-analysis of dietary intervention studies indicated that HbA1c concentrations could be lowered by 0.5% through dietary interventions alone (Andrews et al., 2011). Dietary interventions for T2D have shown improvements in glycemic control, medication adherence, weight, waist circumference, blood pressure, cholesterol, and insulin resistance in comparison to patients who receive treatment as usual (Andrews et al., 2011; Imai et al., 2011). Further, improvements have been shown to be sustained over a 12-month period and were more effective than the addition of physical activity alone (Andrews et al., 2011).

Some comparisons of dietary interventions versus dietary and physical activity changes show no additional benefit of physical activity (Andrews et al., 2011), highlighting the importance of diet in T2D health. Carbohydrates, including different types and quantities, have been closely linked with blood glucose concentrations. Individuals with T2D who adopt a low glycemic load diet have been shown to have reduced cardiovascular risk factors and improved

glycemic control (Brand-Miller et al., 2003; Opperman et al., 2004). T2D dietary interventions that focused on placing more emphasis on eating vegetables before carbohydrates showed better glycemic control during a two-year follow-up in comparison to participants that were educated on portion sizes and a recommended food-exchange system (Imai et al., 2011). Given the close tie between diet and T2D-related physical outcomes, many interventions focus on diet as a primary target for lifestyle modification for better self-management of T2D.

Food Insecurity

Food insecurity (FIS) is defined as a lack of consistent access to enough high-quality or nutritious food for every person in a household to live an active, healthy life (Feeding America, 2022; Beltran et al., 2021). FIS impacts approximately two billion individuals worldwide and approximately one in eight Americans (Beltran et al., 2021; Coleman-Jensen et al., 2020). Within North Carolina as of 2020, approximately one in eight individuals and one in six children are food insecure (Feeding America, 2022). Increasingly, FIS has been identified as a structural barrier and potentially modifiable risk factor associated with risk of developing T2D and poor glycemic control (Seligman et al., 2007; Berkowitz et al., 2013; Beltran et al., 2021). There are different levels of food security, including high and marginal food security (food secure); low food security (food insecure without hunger); and very low food security (food insecure with hunger, moderate; and food insecure with hunger, severe). Category of food security level depends upon access to food and frequency of eating to detect levels of hunger (Bickel et al., 2000).

FIS contributes to nutritional deficiency, reduced food intake, changes in types of food consumed, and childhood obesity over a short-term period (Clemens et al., 2020). Low levels of FIS but not high levels of FIS in women in the United States is associated with weight gain and

obesity (Drewnowski & Specter, 2004). Further, FIS is associated with worse self-perceived health and poorer quality of life (Beltran et al., 2021). Health concerns such as obesity, depression, anxiety, cognitive impairment, and cardiovascular mortality have also been linked to FIS (Beltran et al., 2021; Wang et al., 2019).

Furthermore, experiencing FIS can have a psychological impact as well. Individuals experiencing FIS and economic insecurity have greater odds of psychological distress and poorer psychosocial functioning in comparison to those not experiencing food or economic insecurity, even after controlling for demographic variables such as gender, ethnicity, and age (Carter et al., 2011; Casey et al., 2005). Experiencing FIS has been associated with poor mental health status, including mental health disorders such as depression and anxiety (Casey et al., 2005; Heflin et al., 2005; Temple, 2008; Siefert et al., 2004; Whitaker et al., 2006). Researchers conducted a longitudinal study with women who received welfare in the United States and found that the odds of receiving a diagnosis of depression doubled as a result of experiencing FIS (Heflin et al., 2005; Siefert et al., 2004), highlighting the relationship between FIS and psychological wellbeing.

Household FIS has a significant impact on the psychological wellbeing of children and adolescents within the house as well. Children from FIS households were rated as having lower quality of life by parents in comparison to children not experiencing FIS (Casey et al., 2005). Mental health concerns, including internalizing and externalizing disorders, behavior problems, and academic difficulties have been associated with children experiencing FIS in their lifetime (Casey et al., 2005; Kimbro & Denney, 2015; Grineski et al., 2018; Slopen et al., 2010). Poor social skills were closely related to FIS, including difficulty with self-control (Grineski et al., 2018). However, becoming food secure was associated with improvement in social skills for

girls (Jyoti et al., 2005). Among adolescents, FIS has been linked to higher rates of suicidal ideation and behavior problems in comparison to those not experiencing FIS (Poole-Di Salvo et al., 2016; Alaimo et al., 2002). Importantly, household FIS is associated with higher symptoms of depression in caregivers and poorer quality of relationship between adolescents and caregivers in comparison to households without FIS (Kotchick et al., 2020). Even if caregivers mitigate the impact of FIS on their children, the stress associated with FIS may have an impact on caregiver mental health and relationships within the family system, ultimately impacting the household globally (Kotchick et al., 2020). This notion highlights how multiple systems (e.g., microsystem, mesosystem, exosystem) impact one another within the socioecological model to influence outcome.

Interventions Targeting Food Insecurity

Due to the significant impact of FIS on physical and mental health, including T2D, many interventions often focus on increasing access to healthy food. For example, community gardens, the supplemental nutrition assistance program (SNAP), collective kitchens, food pantries, and soup kitchens all attempt to make it easier for individuals to access food in the community. Traditional interventions (e.g., food pantry, soup kitchens) have inspired alternative interventions (e.g., community gardens, collective kitchens) that allow for more autonomy, education opportunities, and sense of community. In fact, Roncarolo and colleagues (2015) found that individuals utilizing traditional interventions are less involved in the community or civic activities in comparison to those utilizing alternative interventions. Further, those participating in traditional interventions are often more food insecure, have poorer perceived mental and physical health, lower income, and lower education in comparison to those who use alternative interventions. These findings may demonstrate the impact that select barriers, such as

transportation and time may have on selection and access to intervention resources within the community.

It is important to acknowledge the numerous barriers to healthy eating that exist for those who experience FIS, even when there are interventions in place in the community. Families who experience difficulty with access to transportation, work conflicts, or familial obligations may have difficulty accessing these community resources. Further, the availability of fresh food is often limited in community food pantries or still too expensive (Simmet et al., 2016; Kihlstrom et al., 2019). Increased availability of fresh food, especially within the household, has been shown to lead to increased fruit and vegetable consumption habits (Craveiro et al., 2021). Moreover, directly providing individuals with food or groceries is more effective for reducing FIS than income assistance programs (Oronce et al., 2021).

Food Box Programs

Food box programs (e.g., community supported agriculture (CSA) boxes, meal kits) are one approach to reducing barriers to healthy food consumption and increasing availability of fresh produce. Food box interventions have shown changes in eating habits, such as increased consumption of fresh vegetables as well as increased diversity of vegetables consumed (Craveiro et al., 2021; Huyard, 2020). Further, the changes in eating habits are long-lasting, even when the food box interventions end (Huyard, 2020). Positive diet and health impacts have been shown when receiving food boxes, especially in those with lower perceived health (Craveiro et al., 2021). Furthermore, some preliminary findings of food box programs indicate increased vegetable intake and decreased FIS in families with low income (Oronce et al., 2021; Utter et al., 2019).

Barriers to Food Box Programs

Unfortunately, there are several barriers for families to participate in food box programs. Upfront membership fees and subscriptions were noted as a prominent barrier to accessing food box programs (Markow et al., 2016). Many families who experience FIS do not have the disposable income to consistently dedicate towards a food box program and instead, make week-to-week or even day-to-day financial decisions. Furthermore, transportation can be a barrier for many families with FIS and low income. Many food box programs require families to pick up the food boxes at a specific location, which adds to the families' expenses and overall burden (Markow et al., 2016). Customer surveys of food box programs indicate that the majority of customers are White, have middle to high incomes, and are concerned about healthy living and sustainable-living (e.g., eco-friendly, reduced waste) (Craveiro et al., 2021; Markow et al., 2016). There is a substantial gap in the diversity of individuals that have access to food box programs.

Food Insecurity and T2D

Numerous studies have shown a strong association between T2D and FIS (Tait et al., 2018; Beltran et al., 2021; Abdurahman et al., 2019). In fact, those in households that are FIS are 2-3 times more likely to have T2D than adults in food-secure households, even after controlling for factors such as income, employment status, anthropometric measures, and lifestyle factors (Tait et al., 2018). Specifically, Strings and colleagues (2016) showed an association between T2D and FIS for White women and men and Latinx women, but not for Latinx men or Black men or women. The prevalence of T2D increases with FIS level, with the highest prevalence rate of 16.1% in those who have severe FIS in comparison to 11.7% of those who are food-secure. High obesity rates only account for 20% of increased T2D odds (Seligman et al., 2007). Obesity

in women is associated with mild FIS (Abdurahman et al., 2019). After controlling for factors such as physical activity and BMI, T2D prevalence was 120% higher in adults with FIS in comparison to adults who were food-secure (Becerra et al., 2016).

Potential Mechanisms Linking FIS to T2D

Psychological and Biological Response to Food Insecurity. Having FIS is strongly associated with high levels of stress, anxiety, and low self-reported quality of life (Beltran et al., 2021; Epel et al., 2000; Gluck et al., 2004). The chronic stress experienced by individuals with FIS may lead to increased activation of cortisol release pathways, modified metabolic processes, or overconsumption of high-fat and high-sugar foods (Abdurahman et al., 2019; Beltran et al., 2021). These changes in the body can lead to insulin sensitivity, a reduction in glucose tolerance, and increased fat (Beltran et al., 2021; Seligman et al., 2007). In fact, stress is associated with an increase in visceral fat, which is fat that may not be noticeable on the outside but surrounds an individual's internal abdominal organs and can result in severe cardiovascular complications (Seligman et al., 2007; Shuster et al., 2012).

Furthermore, FIS may lead to a biological mechanism to store fat when available, rather than to use as energy (Abdurahman et al., 2019). Many of those individuals experiencing FIS do not have reliable and consistent access to food, whether healthy or unhealthy. Biologically, the ability to conserve energy and protein during times when food is not secure, such as during a famine or when experiencing FIS, may be advantageous. The body's peripheral insulin resistance may help achieve this advantage; however, it may also result in the failure of insulin producing cells and insulin resistance, leading to developing T2D (Seligman et al., 2007). Some researchers suggest that repeated episodes of FIS may exacerbate insulin resistance independently of the pathway through weight gain insulin resistance (Tait et al., 2018).

Managing T2D While Experiencing FIS. Managing T2D among other social and environmental factors (e.g., FIS, low SES, family stressors) can be challenging. In one sample, approximately 21% of those with diabetes reported experiencing FIS and 8.5% of those individuals reported feeling low self-efficacy. Experiencing FIS and low self-efficacy increased healthcare utilization related to T2D by over two-fold (Becerra et al., 2016). Having both T2D and FIS has been associated with poor glycemic monitoring or control and low adherence to guidelines related to medication, physical activity, and diet (Becerra et al., 2016; Heerman et al., 2015; Seligman et al., 2012). Individuals experiencing FIS have been shown to be less adherent to diabetes-related self-care behaviors (Heerman et al., 2015; Becerra et al., 2016). Low adherence can be impacted by the accessibility or ability to afford food or medication, whether the surrounding environment is conducive for physical activity, as well as time constraints due to working conditions. Living in a low-income neighborhood has been associated with more sedentary behavior and less physical activity (Black & Macinko, 2008). Furthermore, ethnic minoritized individuals often have less access to safe facilities for physical activity in their neighborhoods (Frank et al., 2004), leading to a reduction in physical activity.

Access and Affordability of Food. Another potential mechanism that impacts the relationship between T2D and FIS is food access, including the quality of food that is easily accessible and cost efficient. Often those experiencing FIS live in food deserts, which are geographic areas where residents have few to no convenient options for securing affordable and healthy foods, especially fruits and vegetables (The Annie E. Casey Foundation, 2022). Living in food deserts may lead individuals with FIS to rely on cheaper, nonperishable, highly processed products that are more freely accessible in non-grocery stores, such as convenience stores or bodegas (Baker et al., 2006). The easily accessible and more affordable foods are often energy-

dense, high-fat foods that contain more salt, refined grains, unhealthy fats, added sugar, processed carbohydrates, and lower quantities of fiber, which may increase the risk of obesity and T2D (Abdurahman et al., 2019; Beltran et al., 2021; Drewnowski & Darmon, 2005).

Lower quality food and reduced access to healthier alternatives can lead to poor glycemic control, exacerbating or leading to development of T2D (Seligman et al., 2012). Further, some researchers have noted that individuals experiencing episodic underconsumption, such as those with FIS, may overcompensate when food is more available, resulting in a binge-fast cycle that can lead to insulin resistance (Urbszat et al., 2002; Duska et al., 2005; Mansell & Macdonald, 1990). Other researchers have found a relationship between FIS and diabetes in both Type 1 and T2D; however, additional socioeconomic factors also played a key role in the relationship (Clemens et al., 2020).

An important factor to consider in the relationship between T2D and FIS is the impact of financial insecurity and the forced decisions many families and individuals must make. For example, some individuals must choose between spending money on medications or food due to financial restrictions (Gucciardi et al., 2014). For individuals with T2D, not having adequate medication or healthy food options can be detrimental to their health and can eventually result in long-term health complications (Becerra et al., 2016). The negative impact of not having T2D medications can be felt more strongly and immediately than the long-term negative impact of consuming poor quality or less food. Some parents are forced to choose what foods to provide to their children and themselves, sometimes sacrificing their own eating to ensure their children are not hungry or are able to eat some nutritious foods (Clemens et al., 2020). Ultimately, the burden of T2D disproportionately impacts low-income individuals, with the rate of individuals with T2D

living in poverty being twice that of those living in high-income households (Beckles & Chou, 2016).

Implications and Purpose of Current Study

T2D can be influenced by several factors, including one's social and physical environment (e.g., Rod et al., 2012). Likewise, the reciprocal nature of T2D and FIS can have detrimental effects on an individual's physical and mental health and wellbeing. Individuals experiencing FIS may have to choose between eating nutritious foods or purchasing diabetes medication, both of which are recommended as a standard of care for diabetes management according to the American Diabetes Association (2022). Thus, experiencing both T2D and FIS introduces additional stress for families who already experience higher levels of stress, anxiety, and lower quality of life due to FIS alone (e.g., Beltran et al., 2021). Poor diabetes management can also result in additional health complications, therefore requiring more healthcare utilization and cost, which can further exacerbate FIS. Unfortunately, individuals who are most impacted by T2D and FIS due to economic and environmental conditions have the most difficulty receiving intervention services, primarily due to limited access and availability (Chaufan et al., 2011). Given the interconnected relationship between T2D and FIS, it can be challenging for an individual to overcome the barriers to improve their health and wellbeing.

Families who experience FIS and have low income may not access food box programs; however, it is possible they will experience similar dietary and health benefits associated with food box interventions. Researchers have examined food box interventions with FIS and low-income individuals. Preliminary findings support the notion that food box interventions can have positive impacts on diet and health in individuals experiencing food insecurity and low SES (Oronce et al., 2021; Utter et al., 2019). However, there have been no studies to date that have

examined the impact of food box interventions on individuals experiencing T2D and FIS, and none have examined secondary effects on reducing stress or improving psychological wellbeing.

The current study utilizes a social-ecological framework to evaluate the presence of and reduce community barriers in accessing fresh produce through providing a food box delivery program targeting individuals experiencing T2D and FIS. Outcomes from intervening with factors at the microsystem and exosystem levels will be evaluated. It is expected that adapting the social ecological systems by creating easier accessibility to fresh foods can positively impact the family system through reducing perceived stress and introducing healthy foods to their diet. Additionally, psychological distress may be reduced due to less burden associated with acquiring food and having enough food for family members. Creating access to healthy, fresh food may have a systemic impact in a number of areas, ideally improving overall health and wellbeing.

The current study will examine systemic (exosystem) factors that are barriers to utilizing a food box intervention. Additionally, microsystem factors, such as eating habits, perceived stress, and health-related factors (i.e., HbA1c, height, weight) will be monitored before, during, and after the food box intervention to evaluate how it may impact individual-level factors and habits. Furthermore, feasibility and acceptability data will be collected to gain a better understanding of how implementing an intervention within the exosystem impacts the microsystem. The following exploratory questions and hypotheses will be examined in the current study.

The following research questions were proposed:

1. Is the food box intervention feasible and acceptable?
2. What are the barriers to the food box intervention?
3. Will participants be satisfied with the food box intervention?

The following hypotheses were made:

1. Relative to pre-intervention eating habits, produce intake will increase during the food box intervention.
2. Relative to pre-intervention ratings, perceived stress will decrease during the course of the intervention.

CHAPTER 2: METHOD

Study Design

Because food box programs have not been studied with those who have T2D and FIS, a pilot community trial was conducted in Eastern North Carolina to examine feasibility, acceptability, and satisfaction with the intervention. Volunteer participants (defined below) recruited through a local endocrinology clinic received free, fresh produce boxes weekly for a two-month period. Various measures (outlined below) examined variables related to intervention delivery as well as participant-level changes in response to the intervention. Measures collected data before, midway through, and at the end of the food box intervention. Specifically, participants were evaluated on their levels of perceived stress and eating habits before receiving their first food box (pre-intervention), midway through the intervention, and after receiving their last box (post-intervention). Participants also completed a measure evaluating the barriers to healthy eating at pre- and post-intervention time points. At post-intervention, participant responses were collected to evaluate their satisfaction with the food box program and they completed a measure of intervention acceptability. Following the two-month intervention period, participants were offered a local resource list and were connected with their endocrinology clinic social worker for assistance related to FIS and healthy eating.

Food Box Intervention

Food boxes were delivered directly to the participants' homes to reduce additional barriers related to box pickup. The food boxes consisted of a variety of seasonal fruits and vegetables, depending upon weekly availability. The food box donor provided a standard food box, and all participants received the same size food box, regardless of family size. Participants also received informational handouts related to common fruits and vegetables in order to

improve their nutrition/dietary knowledge and remove barriers to using any potentially unfamiliar produce in the boxes.

Participants

The current study conceptualized participants as family units wherein each family has a child or adolescent with a diagnosis of T2D. Participants were recruited by trained research team members during a clinical visit at a pediatric endocrinology clinic in Eastern North Carolina. There were 6 families enrolled in the study. As part of the screener, when determining eligibility for the study, each family unit must have reported experiencing household FIS. Participants were screened for FIS at the endocrinology clinic using the 6-item shortened version of the *Food Security Core-Module Questionnaire* via self-report. Participants who are categorized as very low food security or low food security were referred to the study researchers to evaluate eligibility based on the full FSCMQ responses conducted via interview format. Inclusionary criteria included: having a child under the age of 18 years old in the household with a medical diagnosis of T2D, qualifying as experiencing FIS (with or without hunger) based upon the full FIS interview measure, having at least one English-speaking head of household due to questionnaire limitations and delivery planning logistics, and currently residing in a domestic residence in Pitt, Greene, Wilson, Lenoir, and Edgecombe county. The primary head of household (i.e., adult responsible for monitoring diabetes care and eating habits) provided consent on behalf of the family unit and completed the following measures. The full FIS interview measure was completed after consent; if the family did not identify as food insecure, then they would not complete any other measures and would not be eligible for the food box intervention program.

Clinical staff involved in recruitment were also consented and considered participants in the current study. Staff members provided feedback regarding the recruitment and enrollment processes, including reported and perceived barriers to enrollment.

Measures

Study measures and timeline for data collection are outlined in Table 1. Descriptions and psychometric information for each measure follows.

Table 1. Study Measures by Time Point

Variable (Level of Analysis)	Measure	Time Points
Food Insecurity (Family)	<i>Food Security Core-Module Questionnaire (FSCMQ)</i>	Pre-Intervention
Basic Demographics (Family)	Author developed questionnaire	Pre-Intervention
Family-reported HbA1c, height, weight, other health complications (T2D youth)	Author developed questionnaire	Pre- and Post-Intervention
Barriers to Health Eating (Family)	Author developed questionnaire	Pre- and Post-Intervention
Healthy Eating Habits (T2D youth)	<i>Short Healthy Eating Index (sHEI)</i>	Pre-, Mid-, and Post-intervention
Perceived Stress (Primary Caregiver)	<i>Perceived Stress Scale (PSS-10)</i>	Pre-, Mid-, and Post-intervention
Acceptability (Primary Caregiver)	<i>Acceptability of Intervention Measure (AIM)</i>	Post-intervention
Satisfaction & Barriers to Use (Primary caregiver)	Author developed questionnaire	Post-intervention

Food Insecurity

Food insecurity was measured using the *Food Security Core-Module Questionnaire (FSCMQ)*, which evaluates food security and hunger (Bickel et al., 2000). The FSCMQ was developed by academic researchers, non-government experts, and members of the Department of Agriculture and the Department of Food and Nutrition Services with the focus of measuring the prevalence of food insecure households in the United States. The FSCMQ is a 15-item measure

that evaluates how often the participant and/or family household has concerns about FIS in the last 12 months. Responses are summary scored, where higher scores indicate higher levels of FIS. The results of the FSCMQ place individuals within the categories of food secure, food insecure without hunger, or food insecure with hunger (moderate/severe).

The FSCMQ has been widely studied throughout the United States and other countries worldwide. A systematic review evaluated studies examining the psychometric properties of the FSCMQ, which included more than 15 studies (Marques et al., 2014). The internal consistency has generally been supported, with Cronbach's alpha coefficients that range from .73 to .95. Test-retest reliability has been shown to be $r = 0.75$ and the content validity has been shown to support a one-dimensional structure, supporting the appropriateness of the items in the measure. The sensitivity of the FSCMQ has been found to range from 85% to nearly 100% and the specificity ranging from 80% to nearly 100% (Marques et al., 2014). A shortened six-item version of the FSCMQ is also utilized when time is limited or to reduce burden on the respondent. The six-item form has good concordance with the long-form, correctly identifying food security level for 97.1% of households. The measure has 92% sensitivity and 99.4% specificity for determining overall level of food insecurity (Blumberg et al., 1999). The short form categorizes individuals as having high or marginal food security, low food security, or very low food security.

Participant Demographics and Health-related Information

Demographic data for the whole household was collected via a measure developed for the study. Items included demographics such as number and age of individuals (adults and children) in the household, gender, race/ethnicity, and education level for all individuals in the household.

Monthly household income, individuals in the household with T2D, and zip code was also collected.

Health-related Information

To understand diabetes management of the child or adolescent with T2D, health-related information was collected via a measure developed for the study. Items included participant reported HbA1c, height, weight, and other health complications. Information was collected pre- and post-intervention only for the child/adolescent with T2D.

Barriers to Healthy Eating

To better understand barriers to healthy eating that participants may face in order to evaluate feasibility, a measure was developed for the current study. Questions were adapted from the *Supplemental Nutrition Assistance Program (SNAP) participant survey*, which was created by the United States Department of Agriculture (Gearing et al., 2021) to understand the environmental factors that limit the adequacy of SNAP allotments. Questions relate to barriers that impact shopping for or preparing foods that align with a healthy diet. Additional barriers were added based upon prior survey-based or focus group research results where participants indicated barriers they experienced in the pursuit of healthy eating (Bishop et al., 2019; Seguin et al., 2014). Additionally, to better understand participant perspective and available community supports, questions were adapted from the *SNAP participant survey* pertaining to the understanding of importance of a healthy diet, implementation of healthy diet, and community-level food options or supports available. The resulting *Barriers to Healthy Eating* survey developed for the current study is a 5-item survey that was administered to participants prior to and following the intervention period (see Appendix B).

Perceived Stress

The *Perceived Stress Scale* (PSS-10) is a 10-item self-report measure used to evaluate the degree to which an individual perceives stress in their general life (Cohen & Williamson, 1988). Participants rate the frequency of their feelings and life events over the past month, specifically targeting feelings of unpredictability, lack of control, and overload. The PSS-10 uses a five-point scale ranging from zero (never) to four (very often). A total score is calculated using reverse coding for some items and used to describe overall perceived stress, with higher scores indicating higher perceived stress. The PSS-10 was administered to the primary caregiver pre-intervention, halfway through the intervention, and post-intervention to evaluate changes in perceived stress over time.

The psychometric properties of the PSS-10 were evaluated in a national sample of 2,387 adults in the United States. The PSS-10 internal consistency was found to be adequate, which a Cronbach's alpha of .78. The concurrent criterion validity with the amount of stress experienced during an average week was moderate ($r = .39, p < .001$) as well as the convergent validity, which was shown by expected negative associations with perceived health status ($r = -.22, p < .001$). Other researchers have found similarly good internal consistency reliability, ranging from .77-.91 (Reis et al, 2010; Mitchell et al., 2008) and convergent validity based on measures of physical and mental health associations (Mitchell et al., 2008; Roberti et al., 2006; Wu & Amntmann, 2013). Numerous studies have consistently identified a two-factor structure for the PSS-10 highlighting the negative and positive components of the stress experience (Baik et al., 2019).

Eating Habits

The *Short Healthy Eating Index* (sHEI) (Colby et al., 2020) was used to estimate dietary intake of food groups to assess participants eating habits, particularly their produce intake. The

sHEI was administered to the primary caregiver to estimate the child or adolescent with T2D's eating habits at the beginning, halfway through, and at the end of the intervention period to evaluate change in eating habits over time. The sHEI is a 22-item measure that evaluates quantity of food consumed in various food groups (e.g., fruits, vegetables, starches, beans, sugar-sweetened beverages). The sHEI was derived from the Healthy Eating Index (HEI) ($r = .79$) and shows good convergent validity with additional dietary measures, such as the *Dietary Screener Questionnaire* (DSQ) based on specific categories of food groups ($r = .29 - .66$).

Feasibility and Acceptability

Intervention feasibility was evaluated based on program recruitment number, attrition rates, and percentage of accurate delivery events (e.g., on the day as expected, no missing boxes/items). A recruitment goal to evaluate feasibility was set at ten participants within a two month recruitment period, given project budget and time constraints. While some feasibility study guidelines suggest a relative goal of around 30 participants (Teresi et al., 2022), modifications to the expected recruitment goal were made to better match study parameters (i.e., timeline, staff capacity, recruitment clinic size). Further, an attrition rate of <20% was established as a feasibility indicator, consistent with standard implementation study thresholds for participant recruitment feasibility (Pearson et al., 2020). Delivery accuracy was also considered within feasibility, where a goal of 90% accuracy was set for total deliveries.

Acceptability of the intervention was evaluated using the *Acceptability of Intervention Measure (AIM)* (Weiner et al., 2017). The *AIM* is a measure of implementation outcomes that evaluates intervention acceptability. It shows internal consistency ($\alpha = .89$), reliability ($\alpha = .85$), and sensitivity (41%). Participants were administered the *AIM* measure following completion of

the intervention period. The *AIM* is rated on a one through four Likert-style rating, with higher scores indicating greater approval.

Satisfaction

Participant satisfaction was assessed post-intervention using a 16-item survey designed for the study. The survey consists of four open-ended questions targeting barriers to intervention usage, costs and benefits of the intervention, and desired changes. Closed-ended questions include ten Likert-style rating questions with responses ranging from strongly disagree (1) to strongly agree (5). The questions evaluate satisfaction with the food box intervention, areas of potential difficulty with using the intervention, and willingness to participate again in the program. Three additional questions include sliding-scale responses to indicate how many people in the household used the food box, how many people currently live in the household, and what percentage of the food box was used on average (0-100%).

Data Analysis

Descriptive statistics were used to analyze sociodemographic characteristics of the participants. To evaluate the social acceptability of the food box program, descriptive statistics were used to analyze participant responses on the satisfaction survey, dropout rates, and accurate delivery information. A qualitative analysis was used to evaluate participant responses to open-ended questions on the satisfaction survey. To determine whether eating habits and perceived stress changed throughout the intervention, Bayesian repeated measures ANOVA was used for hypothesis testing using JASP software (Version 0.18.3). For small pilot trials that lack statistical power to detect effects using traditional null hypothesis testing, calculating a Bayes factors can offer a continuous measure of the evidence for and against hypotheses and help identify potentially promising premises (Wagenmakers et al., 2018). Bayes factors quantify the

probability of the null hypothesis relative to the alternative hypothesis. A prior of one was used for the analyses of eating habits and perceived stress changes. A Bayes Factor (BF_{10}) reflects how likely data arise from the hypothesized model (H_1) compared to the null model (H_0). A Bayes Factor (BF_{10}) > 1 typically quantifies evidence in favor of the alternative hypothesis, while a $BF_{10} < 3$ is typically quantified as anecdotal evidence.

CHAPTER 3: RESULTS

Participants

The total pilot study consisted of six family-units, who all identified as African American, non-Hispanic/Latino. The number of individuals living within each family-unit ranged from two to six individuals (median = 4), with the majority of households having one individual with T2D (average age 13.33). The average age of adults (i.e., over 18-years-old) in the household was 47.17 years (median = 45.5) ranging from 35- to 60-years old. The average age of children in the household was 12.67 years (median = 14), with a range of one-year-old to 17-years-old. The sample of primary caregivers consisted entirely of individuals who identified as female/women ($n = 6$). The sample of children with T2D consisted of 4 girls and 2 boys, as identified by caregivers. More detailed descriptive statistics can be found in Table 2. For most households ($n = 5$), the highest level of education was a high school degree, with one household having some college courses without a degree. All family units ($n = 6$) were considered below the federal poverty line based on income and number of individuals within the household.

Table 2. Participant Household Demographics ($n = 6$)

	Mean	Median	Mode	Range
Number of individuals in household	3.83	4	2, 4	2-6
Number of individuals in household with T2D	1.83	1	1	1-4
Age of adults (over 20 years) in household	47.17	45.5	35, 38, 50	35-60
Age of children in household	12.67	14	13, 14	1-17
Age of child with T2D in household	13.33	13.5	14, 13	11-15

The child with T2D within the household were, on average, 192.4 pounds, with an average height of 65.9 inches. The average body mass index (BMI) was 31.12, calculated based on reported height and weight. More detailed descriptive statistics regarding the children with T2D can be found in Table 3. HBA1C levels were not reported for 67% of the sample ($n = 4$) due to household caregivers reportedly not knowing the child's current or most recent HBA1C level. Of the data provided, the average HBA1C level was 9 (range 6-14). Fifty percent of the children with T2D also had another chronic health condition, including asthma, high blood-pressure, kidney failure, and heart disease.

Table 3. Type 2 Diabetes Participant Demographics ($n = 6$)

	Mean	Median	Mode	Range
HBA1C (pre-intervention)	9	7	---	6-14
Weight (pounds)	192.4	180	---	130-280
Height (inches)	65.9	64	63	63-73.5
BMI (calculated)	31.12	29.5	---	23-45.2

Feasibility

Recruitment

Prior to enrollment, ten families were recruited by the endocrinology clinic to determine eligibility for the study. Of those families, six were enrolled in the study, three were lost to follow-up as detailed below, and one family declined participation. As such, the recruitment goal of ten participants was not met. Barriers to contacting and screening families included: family member being in hospital, limited transportation, health concerns, time constraints, and job

conflicts. Phone calls and text messages were used to contact participants. Due to the limited recruitment numbers and efforts to increase the likelihood of contact with participants, there was no pre-determined cap on number of contact efforts. The average number of contacts until a decision point (i.e., enrolled, lost to follow-up, declined) was 9.6 (median = 7) phone calls and 6.1 (median = 3.5) text messages, which includes reciprocal messaging (e.g., calling to leave a voice message and returning calls). The average number of days from initial contact to enrollment for those who participated in the study was 19.2 days (median = 15).

Clinical staff at the endocrinology clinic were interviewed to assess their perceived barriers to recruitment, as well as estimates of the number of individuals deemed eligible for the study. Based on their collective report, approximately 26 households were deemed potentially eligible for the study (based on county of residence and diabetes status). Of those 26 households, 16 households (62%) attended their routine endocrinology appointment and were able to complete screening documents. Of the 16 households that attended the appointment and were offered screening measures to determine eligibility, six households (38%) did not participate in screening. Per clinical staff report, the households provided some of the following reasons for declining the screening process: too much paperwork to complete in addition to visit, already receiving food stamps, difficulty reading documents, and did not want to take food away from other families in need. Based on clinical staff report, all households that were approached by clinical staff for participation ($n = 10$) following the initial screening were interested in their information being passed along for further enrollment.

Attrition

The attrition rate for the pilot study consisted of one household unit that unenrolled in the study after one-month due to health-related family circumstances. Of the remaining household

units ($n = 5$), 80% ($n = 4$) of households completed all data-measurement time points (pre-, mid-, post-intervention). One household was lost to contact at the post-intervention time point; however, they did receive all food box deliveries for the entire duration of the study. The overall study attrition rate was 33%, suggesting limitations in feasibility based on the pre-determined attrition goal rate of <20%.

Delivery Data

All food boxes were delivered within the expected timeframe on the predetermined delivery dates. All deliveries were made by one of two different study team members who, together, logged a total of 1,288 total miles during the intervention period. The deliveries took place between May and July on a weekly basis.

Outcome Measures

Participant responses were collected pre-intervention, mid-intervention (i.e., one month after receiving deliveries), and post-intervention. Pre-intervention data were collected between two months to one week prior to intervention. Post-intervention timeline for collecting data ranged from two weeks to one month post-intervention.

Barriers to Healthy Eating

Prior to intervention, all participants ($n = 6$) completed a measure related to the barriers families experience to healthy eating to aide in evaluating intervention feasibility. Based on survey data, 67% of participants were in relative agreement that on most days, people within their household eat a healthy diet (Agree $n = 3$; Strongly Agree $n = 1$). The remaining 33% disagreed ($n = 1$) or strongly disagreed ($n = 1$) with the statement. When asked whether people within the household understand the importance of healthy eating, 67% of participants agreed ($n = 3$) or strongly agreed ($n = 1$), whereas 33% of participants disagreed with the statement.

Participants reported specific barriers to shopping for foods that are a part of a healthy diet. All participants ($n = 6$) reported the barrier of food affordability. Thirty-three percent of participants ($n = 2$) reported that transportation and the fact that healthy foods are more perishable were barriers to shopping for healthy foods. Additional barriers reported were: distance to store, cultural norms/traditions, and physical disability/limitations. Fifty percent of participants reported that their knowledge of food health ($n = 3$) was a barrier to preparing healthy meals. Additionally, 33% of participants reported the barriers of physical disability/limitations, food familiarity, lack of time, and lack of storage as barriers to preparing healthy meals. Participants also reported barriers of food availability and the appeal of healthy food as barriers to preparing healthy meals. Frequencies of reported barriers to healthy eating and preparing healthy meals are listed in Table 8. Finally, participants were asked to report the types of food supports available in their community. Fifty percent of participants ($n = 3$) indicated they have a food bank/pantry available within their community. Thirty-three percent of participants ($n = 2$) reported the availability of a soup kitchen within their community. Alternatively, 50% of participants ($n = 3$) indicated they do not have any community food supports ($n = 1$), or they are not aware of any supports ($n = 2$) within their community.

Table 4. Participant Reported Barriers

Barriers to shopping for healthy food	Frequency
Affordability	100%
Transportation	33%
Healthy foods are more perishable	33%
Cultural norms/traditions	17%
Physical disability/limitations	17%
Distance to store	17%
Barriers to preparing healthy food	
Knowledge of food health	50%
Physical disability/limitation	33%
Food familiarity	33%
Lack of storage	33%
Lack of time	33%
Food availability	17%
Appeal of healthy food	17%

Acceptability

Four participants completed the acceptability measure at the end of the intervention period. Participants reported agreeing (75%; $n = 3$) or completely agreeing (25%; $n = 1$) with the statements, “The food box intervention meets my approval” and “The food box intervention is appealing to me”. Participants indicated they agree (25%; $n = 1$) or completely agree (75%; $n = 3$) with the statement, “I like the food box intervention.” Finally, participants reported that they

agree (50%; $n = 2$) and completely agree (50%; $n = 2$) with the statement, “I welcome the food box intervention.”

Satisfaction

The satisfaction questionnaire included Likert-style ratings to evaluate various aspects of satisfaction and usage related to the food box intervention. Responses were rated on a one through five scale, with higher scores indicating stronger agreement (i.e., Strongly Agree). Response frequency to the Satisfaction questionnaire can be found in Table 7. Overall, participants agreed (75%; $n = 3$) or strongly agreed (25%; $n = 1$) that they were satisfied with the food box program. All participants reported that 100% of their household used the foods from the food boxes. When asked how much of the food boxes were utilized, participants reported an average usage of 82.5% (range 50-100; mode = 100). Participants reported the barriers and challenges that impacted usage of the food box. Identified barriers and challenges were the level of ripeness of the food, the presence of leftover food from the previous week, and frequency of food usage in the home (e.g., bananas are used more frequently than broccoli). Participants reported the benefits of the food box intervention as saving money and time, creating opportunities to try new recipes and food options, convenience, being helpful for meal preparations, and having extra fruits and vegetables in the home. When asked about the potential costs of using the food box intervention, all participants ($n = 4$) reported there were no costs associated with the intervention for their family. Participants were asked what changes they would make to the food box intervention. Fifty percent of the participants ($n = 2$) reported they did not have any suggested changes, while the remaining 50% reported they would improve the ripeness of produce (i.e., over-ripe and under-ripe), as well as increase the frequency of delivery.

Table 5. Satisfaction Questionnaire Participant Responses

Satisfaction Questionnaire	Completely Agree (n)	Agree (n)	Disagree (n)
The delivery system was easy to use	2	2	---
I am happy with the way the food box program was run	2	2	---
Using food from the food boxes was challenging	---	1	3
I felt confident using the food from the food box	2	2	---
I had enough food-related knowledge to use the food box	2	2	---
I had the appropriate supplies to use the foods in the food box	2	2	---
I had enough time in my day to use the foods in the food box	1	3	---
Overall, I am satisfied with the food box program	1	3	---
I am familiar with most of the foods in the food box	---	4	---
I would participate in a food box program like this long-term (i.e., more than 6 months)	1	3	---

Eating Habits

Hypothesis 1 stated that, relative to pre-intervention eating habits, produce intake would increase during the food box intervention. No evidence of changes in produce intake were found across pre-, mid-, and post-intervention (see Table 4). The data are 0.44 times more likely under

H_1 than under H_0 , suggesting no evidence for H_1 in this small sample. The hypothesis was not supported. Rather, there was anecdotal evidence in support of the null hypothesis that no changes in eating habits occurred throughout the intervention. Visual plots of the data allow additional interpretation for this small pilot sample. As shown in Figure 1, two participants remained steady in produce intake over time, one decreased intake slightly, and one had a spike in intake at mid-intervention. Overall, no clear patterns or changes in eating habits were observed.

Table 6. Eating Habits Descriptives & Model Comparison ($n = 4$)

Time	Mean	SD	SE	Coeff. of Variation	95% Credible Interval	
					Lower	Upper
Pre	5.00	2.83	1.41	0.57	0.50	9.50
Mid	6.25	3.40	1.70	0.55	0.83	11.67
Post	4.75	2.06	1.03	0.43	1.47	8.03
Models		P(M data)		BF _M	BF ₁₀	error %
Eating habits change (H_1)		0.30		0.44	0.44	0.76
Null (H_0)		0.70		2.29	1.00	---

Note. All models include subject, and random slopes for all repeated measures factors.

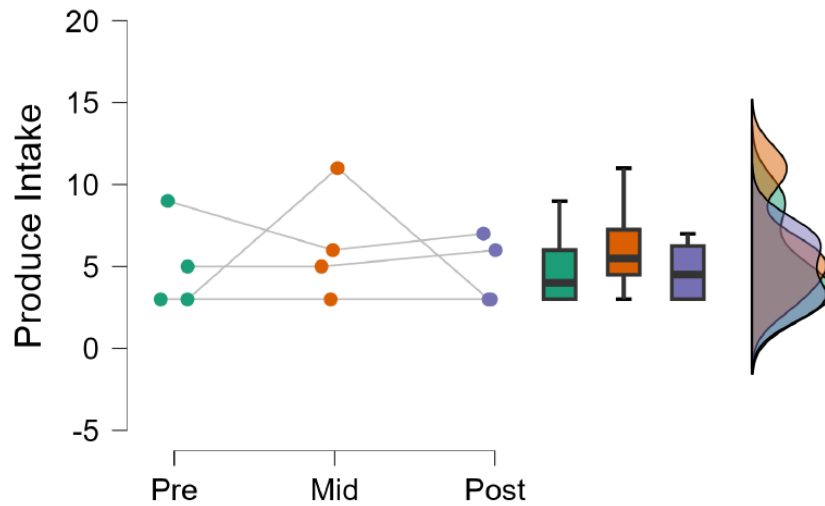


Figure 1. Changes in Eating Habits Across Study Time Points

Perceived stress

Hypothesis 2 was that, relative to pre-intervention stress, perceived stress would decrease during the food box intervention. The data are 2.02 times more likely under H_1 than under H_0 , suggesting that there is anecdotal evidence supporting the alternative hypothesis (See Table 5). Visual plots of the data (shown in Figure 2), highlight a slight decrease in perceived stress at the mid-intervention time point in comparison to pre-intervention. There is a slight increase in perceived stress for 75% of participants from mid-intervention to post-intervention, resembling similar perceived stress levels as the pre-intervention time point. See Table 5 for descriptive statistics of each time point for the 4 participants who completed all phases of the study and Table 6 for descriptive statistics for all participants.

Table 7. Perceived Stress Scales Descriptives & Model Comparison ($n = 4$)

Time	Mean	SD	SE	Coeff. of Variation	95% Credible Interval	
					Lower	Upper
Pre	20.75	5.68	2.84	0.27	11.71	29.79
Mid	14.00	6.73	3.37	0.48	3.29	24.71
Post	16.50	9.75	4.87	0.59	0.99	32.01

Models	$P(M data)$	BF_M	BF_{10}	error %
Stress changes (H_1)	0.67	2.02	2.02	0.78
Null (H_0)	0.33	0.50	1.00	---

Note. All models include subject, and random slopes for all repeated measures factors.

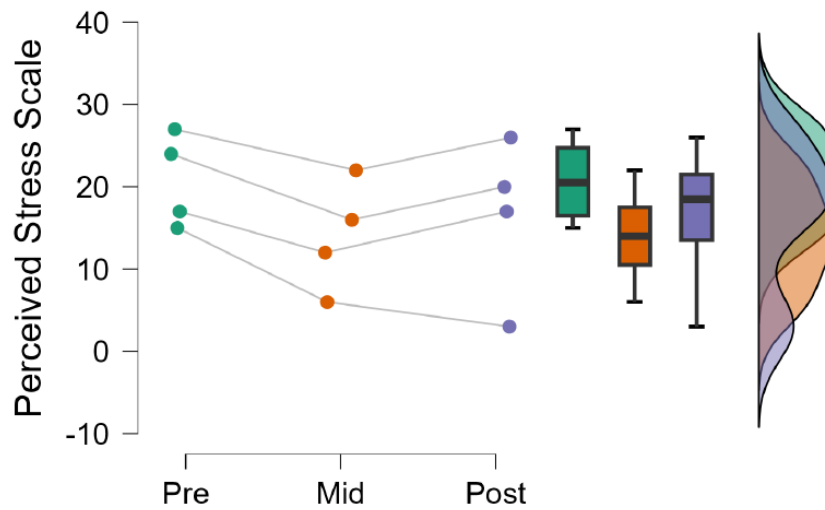


Figure 2. Changes in Perceived Stress Across Study Time Points

Table 8. Perceived Stress Participant Responses

Perceived Stress Scores	N	Mean(SD)	Range
Pre-intervention	6	21.5 (4.93)	15-27
Mid-intervention	6	15.0 (5.76)	6-22
Post-intervention	4	16.5 (9.75)	3-26

CHAPTER 4: DISCUSSION

The current study evaluated the feasibility, acceptability, and satisfaction of a food box intervention program aimed to reduce barriers to healthy eating for families impacted by FIS and T2D. Barriers to utilizing the food box intervention, as well as changes in produce intake and perceived stress were also examined. Given the lack of programs targeting T2D and FIS, a pilot community project was developed for the current study. Participants were conceptualized as family units wherein a child or adolescent in the family has T2D and the family endorsed any level of FIS. Participants received fresh produce boxes weekly, for a two-month period, delivered to their home. Data was collected pre-, mid-, and post-intervention.

Perceived Barriers to Healthy Eating

According to participant responses, families from this pilot study who experienced FIS reported strongly agreeing with the importance of consuming a healthy diet for overall health. In fact, most families also reported that their families consume foods in accordance with a healthy diet. However, participants also endorsed several barriers that impact their family's ability to purchase fresh foods that are a part of a healthy diet. The most identified barrier to purchasing healthy food was the affordability of the food. Participants also noted that transportation and the perishability of the food were additional common barriers that impacted their ability to regularly consume healthy foods. These reported barriers highlight the systemic challenges to healthy eating, particularly for families living in more rural areas or food deserts. While programs within the exosystem (e.g., welfare programs, Supplemental Nutrition Assistance Program [SNAP]) attempt to reduce some barriers (i.e., cost), families continue to face more central microsystemic and individual factors (i.e., availability of food/food quality, transportation), that maintain these barriers to healthy eating. Moreover, when access to food is removed as a factor (e.g., delivered

food boxes), families continue to experience barriers to consuming healthy food choices. For example, when participants were asked about barriers that impact their preparation or inclusion of healthy food in their meals, knowledge of food nutrition was prominently reported as a barrier. Several other barriers were reported, such as physical disability/limitations, food familiarity, lack of time, lack of storage, food availability, and healthy food appeal. Broadly, families endorsed an understanding of and value in healthy eating behaviors; however, they also endorse a variety of barriers to accessing and utilizing healthy foods to achieve a healthy lifestyle. Alternative food programs have encountered similar experiences, with participants continuing to experience barriers to access and/or usage despite attempts reduce barriers (e.g., transportation, cost) (Cohen et al., 2019; Stroud & Sastre, 2023). The current study findings are consistent with previous literature highlighting the multi-systemic barriers (i.e., micro-, exo-, and macrosystemic) to accessing healthy food options due to logistic, cultural, and stigma-related barriers to accessing, preparing, and consuming healthier food options (Fong et al., 2016; Martin et al., 2003; Penne & Goedeme, 2021).

For those impacted by T2D, food choices and overall health behaviors are important aspects to diabetes management and overall wellbeing. In particular, for individuals and families impacted by FIS, microsystemic factors such as community resources are important supports in addition to more exosystemic supports (i.e., SNAP benefits). Within the current study, while some participants reported knowledge of available community resources (e.g., soup kitchen, food pantries), half of participants reported not knowing what resources were available or stated that they did not have any resources within their community. In these cases, families may be living in a food desert, as well as a community resource desert, further exacerbating barriers and concerns. Moreover, support services that are available may not adequately meet participants' needs that

are specifically related to T2D, such as reduce carbohydrates and refined sugars, and therefore, families may not utilize or be aware of such services (Simmet et al., 2016; Kihlstrom et al., 2019). The interactions between the micro- and exosystem (i.e., the mesosystem) is seemingly resulting in additional barriers for participants, particularly those within food- and resource-deserts. As such, a fresh produce delivery service is well-suited to meet the needs of families impacted by FIS and T2D, to reduce barriers within the systems and increase access to fresh, healthy foods.

Evaluation of the Food Box Intervention

Given that a food box intervention program may assist in reducing some barriers to healthy food options, it is important to evaluate the program to determine if the intervention is truly reducing barriers, identify any enduring barriers, and determine overall satisfaction. The current study was framed around a set of exploratory questions, as well as two initial outcomes of the intervention; the results of which are reviewed below.

Is the Food Box Intervention Feasible and Acceptable?

Based on the pre-established feasibility criteria (i.e., recruitment goals, attrition rates), the current pilot project is not feasible in the current design state. One of the primary aspects of feasibility evaluated is related to participant recruitment. That is, participants need to see a value and need in the intervention program such that they are willing to engage in the intervention. The current study did not meet the recruitment goal set as an indicator of project feasibility. Based on eligibility criteria, 26 households were identified as potentially eligible to participate during the two month enrollment timeframe. Of those potentially eligible, 38% of patients were willing to complete the documentation and interested in determining eligibility for the study. A total of six participants were enrolled in the study, which falls below the recruitment goal set to evaluate

feasibility. Some patients reported that they did not want to complete the eligibility documents because they had trouble reading the documents or were overburdened by paperwork at the medical appointment. Others did not perceive a need for food box delivery because of their access to food or not wanting to take away from other families in need. As such, there are several barriers to the feasibility of the program, including size of the target population, time/effort to enroll, and overall perception of the program. Stigma and perceptions of need have been shown to impact and reduce access to need-based services. For example, some individuals may report experiencing shame or worry about being perceived as needy or dependent if they accept supportive services (Kissane, 2012; Sherman, 2013). Concerns related to stigma have prevailed even when services are embedded within community medical clinics in attempts to normalize usage as well as reduce access (Greethal et al., 2019; Stroud & Sastre, 2023). As such, it may be beneficial in future studies to increase the focus on psychoeducation and reducing potential areas of stigma in order to increase participation and feasibility. A focus of a strengths-based approach may be beneficial in engaging future participants, rather than a sole focus on perceived need alone (White et al., 2021). Further, reducing the paperwork and/or implementing more interview-based questions rather than self-report may support individuals who may be hesitant due to increased workload.

An additional aspect of feasibility related to participant recruitment were the barriers to contacting participants. Contact with participants is an essential component of the intervention process, not only for data collection, but for the organization and planning related to the delivery services. In the current study, several barriers to contacting participants were encountered. Contact was made challenging or was absent due to: family health concerns, transportation to the study enrollment location, time constraints, job demands, and being lost to follow-up (e.g., phone

off, no return phone call). These barriers to contact impacted the feasibility of the intervention program, as the timeline to initiate the program was extended and some participants were unable to complete the program due to loss of contact. In fact, attrition in the study was directly related to loss of contact and family health concerns, which resulted in the withdrawal or loss of participation of 33% of participants. As such, the feasibility and overall sustainability of the intervention is closely tied to the ability to contact and obtain engagement from participants. Future studies may benefit from closer collaboration with participant medical team, as participants likely routinely visit these providers, as well as more opportunities for contact to reduce the likelihood of losing contact due to family-level changes (e.g., changing phone numbers, moving, job transitions).

A final aspect of feasibility is considering whether any practical barriers impacted the delivery of the intervention. For the current small-scale pilot study, the intervention was delivered as expected, with no missed deliveries or unforeseen changes to the program. However, it is important to note that multiple study members were needed to carry out the deliveries and a large number of miles were driven to accomplish deliveries. Thus, future food box intervention programs must build in consideration for delivery costs, such as staff time, gas, and mileage, which may be considerably more in rural than urban areas. Further, creating multiple food centers to ease and support deliveries may ease transportation concerns, as deliveries will be more proximal to participants.

Participant acceptability was a key outcome examined in the current study. Based on participant responses post-intervention, all participants agreed that the intervention program was acceptable, as indicated by four indices. Participants endorsed that they liked the intervention, they welcome the intervention and agreed or strongly agreed that the intervention met their

approval and was appealing. Based on responses, the intervention program was 100% acceptable to participants in the study. It is worth noting that the measure used to assess acceptability is often positively skewed when evaluating intervention acceptability (Feldman Hamm et al., 2023). Moreover, given the small sample size of the current pilot project, a 100% acceptability response may be easier to obtain. However, acceptability rates are well within the range of acceptable and therefore, the intervention program can be viewed as overall acceptable by participants.

What are the Barriers to the Food Box Intervention?

Although participants were broadly satisfied with the food box intervention, they were asked to provide any barriers or changes to the program that they would make to inform future interventions. Participants reported some barriers to using the food boxes, including the level of ripeness of the food, the presence of leftovers or having excess foods, and frequency of food usage within the home. Proposed changes to the intervention included ameliorating the ripeness concerns of the food and increasing the frequency of delivery.

Will Participants be Satisfied with the Food Box Intervention?

Overall, all participants endorsed satisfaction with the intervention program. All participants in the household utilized the foods from the food box, and most of the foods within the food box (82.5%) were consumed. Further, participants reported several benefits to using the food box, including saving money and time, creating new opportunities to try new foods and recipes, overall convenience, helpful with meal preparation, and having extra fruits and vegetables in the home. No additional costs were reported by participants to use the food boxes, suggesting that the benefits of the food box intervention most certainly outweigh the potential

costs. In fact, all participants reported that they would be interested in participating in a similar program again for a longer-term duration (i.e., more than 6 months).

Initial Outcomes of the Food Box Intervention

Changes in Eating Habits

Participants provided data on their eating habits, including daily portion sizes for a variety of foods. The current study focused on participant intake of produce (i.e., fruits, vegetables), due to the food provided in the food box intervention. Participants' consumption of produce was measured prior to the intervention, halfway through the intervention (i.e., 1 month into intervention), and following the intervention's completion. Overall, no changes in produce intake were found between any data collection time point. As previously stated, participants reported consuming produce prior to the intervention and endorsed an understanding of the importance of eating healthy, including consuming fresh produce. As such, participants likely utilized the produce in the food boxes as a replacement for the produce they were previously purchasing, rather than increasing their intake of produce overall. Participants reported consuming most of the contents of the food boxes, supporting overall healthy eating and potentially maintaining participant healthy eating lifestyles. However, one household reported an increase in their produce intake at the mid-intervention time point, highlighting some individual-level changes in eating habits. It is important to highlight that one reported barrier to enrollment in the intervention was prospective participants reporting that they did not want to take away resources from other families in need. It is possible that the families who declined to participate would be better targeted by this intervention, as they may not have the resources to obtain their desired amount of produce and thus, would demonstrate an increase in produce intake with a food box intervention.

Changes in Perceived Stress

Perceived stress was measured at three time points (pre-, mid-, post-intervention) throughout the study. There was a decrease in perceived stress between the pre-intervention and mid-intervention periods. During this point in the intervention, participants have received four food boxes over the course of a one-month period. The perceived stress of the participants seemed to rebound once the intervention was over, which may highlight a perceived support via the food box intervention. This is consistent with some studies, which have shown that dietary adherence and eating habits and correlated with perceived stress (Booker et al., 2024; Jalo et al., 2024) For example, one study showed that an increase in dietary adherence was correlated with decreased perceived stress (Booker et al., 2024). For some participants, the loss of the food box intervention may have returned participants to their pre-intervention diets and thus, prior perceived stress levels, as they were no longer reaping the benefits of the intervention. However, it is important to acknowledge that perceived stress was evaluated broadly and not specific as it related to food insecurity. As such, a number of factors could have influenced the variation in perceived stress. Moreover, the fluctuations in perceived stress may captured the impact of larger macrosystemic influences. For example, the distribution of benefits and government supports may influence stress levels throughout a monthly period for families. Further, the monthly and season-related stressors that vary may likely impact participant perceived stress and thus, may be captured in rating scales.

Beyond Feasibility: Sustainability of the Food Box Intervention

While sustainability of the current intervention was not directly measured, it is an important factor to consider, particularly as adjustments may be made for future studies. There are no widespread agreed upon guidelines to determine intervention sustainability; however,

within the current study, common outcomes identified across sustainability studies were utilized to evaluate the current pilot project. In particular, outcomes examined were: benefits for participants, maintenance of relationships/partnerships/networks, replication and/or scale-up of the initiative, adaptation in response to new evidence/contextual influences, and gaining future funds to continue initiative (Flynn et al., 2022). Within the context of the current study, there are factors that align with the intervention sustainability, while others suggest difficulty with sustainability. Specifically, participants endorsed strong benefits of the intervention, with little to no cost on their behalf, as well as very few recommended changes. This strongly supports intervention sustainability over time. However, the difficulties surrounding continued participant contact, attrition, and barriers to enrollment impact future sustainability of the intervention. Moreover, the overall cost and logistics in planning a similar intervention are significant, leading to additional barriers to sustainability and a need for adaptations to the intervention. Acquiring steady funding and a team to be able to adapt to new challenges as they arise may be key to overall sustainability. As such, without any additional support or structural changes, the current intervention is not sustainable long-term. Incorporation of a similar project into an established medical clinic, such as a T2D clinic, should be prepared to address these factors of sustainability, namely cost and attrition over time. However, establishing a care team to build rapport, dependency, and reliability may better support maintaining participant relationship long-term and thus, reduce attrition and barriers to contact. Use of funding sources or insurance reimbursement for a similar intervention to promote overall health changes would be recommended as well due to the substantial total cost of a potential long-term project with a high volume of participants. Moreover, establishing community connections and resources, such as

working closely with local farms and community gardens to provide produce would allow for increased sustainability and mutually beneficial community support.

Limitation, Barriers Identified, and Future Directions

There are several limitations and barriers that were identified in the current pilot project. Importantly, the small sample size of the current study limited the data analysis and strength of the study. Further, the psychometric performance of study measures were not confirmed due to limited sample size. Feasibility and/or pilot studies are often completed with a small sample size (e.g., 12-30 participants) and may be informative regarding broad themes, but not necessarily used in estimating treatment effects (In, 2017; Sim, 2019). While considering this, the current pilot study's sample size was well below typical pilot samples and therefore, there is an increased limitation on treatment effect interpretation and overall strength of results. However, the recruitment challenges encountered, which led to the small sample size, highlighted some important barriers to address in future implementation studies. In particular, transportation barriers, time/job constraints, additional paperwork, and misperceptions related to the intervention program (i.e., forgoing the intervention so other families could use resources) are areas in which future studies can target. Participants identified barriers across ecological systems, highlighting the integrated and additive nature of systemic barriers on families, particularly those impacted by FIS and T2D. While targeting logistical barriers within the microsystem can benefit families short-term, the potential stigma and misperceptions perpetuated within the macro- and exosystem are additional areas of impact in order to support resource access and support for families. Targeting the stigma of using support resources through education and reframing may benefit future studies and aid in reaching more individuals and families.

Mixed-method approaches are useful when evaluating pilot projects, particularly for evoking participant values and potential changes to the intervention. As a component of the current study, family perception, stress, and eating habits were evaluated; however, given constraints in evaluating all family members separately, an overall primary caregiver was the primary reporter on behalf of the household. This presents a limitation within the current study, as it is possible that the primary caregiver responded in accordance with their own perspective and habits, rather than in a manner that was representative of the family as a whole, or importantly, the individual with T2D. As this intervention is attempting to target individuals with T2D to promote healthy eating habits, it is difficult to determine if those individuals specifically received benefits from the food box intervention above and beyond the familial impact. Further, relying on participant self-report, rather than a direct measure of food intake, is another limitation to the study, as self-report is susceptible to estimation inaccuracies, as well as social desirability and measurement biases. As data collection can bring awareness to behaviors and spark behavioral changes, reducing the data collection time frame as well as implementing a retrospective report to collect data may be beneficial in future studies to reduce biases and inaccuracies. However, within a clinical setting, self-report and parent-report measures are often used to obtain information in a quick and efficient manner, thus making the current data potentially representative of responses that could be provided in a clinical setting rather than a research-controlled environment.

Moreover, the primary caregiver reported their feedback and opinions directly to the study investigator, who enrolled participants, delivered food products, and collected data. As such, there may have been a conflict of interest, despite all attempts to clarify the desire for honesty and genuine feedback, as the current study is a feasibility/acceptability, and pilot study

intended to identify areas of change. Finally, there were limitations inherent in the intervention length, which was a two-month period due to financial restrictions. There may be a greater potential for changes in perceived stress and eating habits, along with a greater identification of barriers over time, if the intervention period could be extended to better match other food intervention timelines (i.e., 4-6 months). Future food box intervention programs can continue to build upon the current pilot intervention, addressing the barriers identified and limitations to better support participant needs.

It would be beneficial in future studies to utilize a randomized control trial design, particularly as sample size and intervention periods increase (Teresi et al., 2021). Evaluating changes in perceived stress and eating habits amongst a control group may highlight important factors and facilitators outside of the intervention that are influencing participants, further enhancing intervention efforts.

Conclusions

Overall, the food box intervention program was found to be acceptable to participants; however, the study is not feasible with the current design. In particular, participant recruitment and retention were an identified area of improvement. Some barriers to recruitment were noted, including willingness to complete additional tasks, engagement in other food-related supports (i.e., SNAP benefits), and declining due to the perception of taking resources away from others. Barriers to contacting participants were noted throughout the intervention, primarily related to family health concerns, transportation, time/job constraints, and overall lost-to-follow-up. Participants reported overall satisfaction with the food box intervention program, with limited-to-no drawbacks of participating in the program. Families consumed the majority of the food boxes, and all members of the household utilized the foods from the food box. Suggested changes for

future intervention programs were increasing the frequency of delivery, as well as addressing the ripeness of the food (over- and under-ripe). While no changes in produce intake were found as a result of the intervention, a decrease in perceived stress was found between participant's pre-intervention responses to their responses mid-intervention. When the intervention period was completed, no differences were found between pre- and post-intervention perceived stress responses.

The results of the current pilot study intervention support the notion that addressing barriers within the exosystem through a food box delivery intervention program would be an acceptable and satisfactory intervention. In particular, the intervention showed effectiveness in targeting microsystem factors in families impacted by FIS and T2D, including a potential decrease in familial stress. Further, barriers identified in the current study can be targeted and addressed within the next intervention program to further increase the success of the food box intervention program. Due to limited feasibility within the scope of the current project, adapting future projects to better prepare for expected costs, timeline, and participant contact barriers, would be beneficial for establishing a feasible, sustainable, and satisfactory intervention.

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APPENDIX A: IRB APPROVAL LETTER



EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board
4N-64 Brody Medical Sciences Building- Mail Stop 682
600 Moya Boulevard · Greenville, NC 27834
Office 252-744-2914 · Fax 252-744-2284 ·
rede.ecu.edu/umcirm/

Notification of Initial Approval: Expedited

From: Biomedical IRB
To: [Jennifer Donelan](#)
CC: [Christy Walcott](#)
[Jennifer Donelan](#)
Date: 2/14/2023
Re: [UMCIRB 22-002175](#)
A Food Box Intervention

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) occurred on 2/14/2023. The research study is eligible for review under expedited category # 7. The Chairperson (or designee) deemed this study no more than minimal risk.

As the Principal Investigator you are explicitly responsible for the conduct of all aspects of this study and must adhere to all reporting requirements for the study. Your responsibilities include but are not limited to:

1. Ensuring changes to the approved research (including the UMCIRB approved consent document) are initiated only after UMCIRB review and approval except when necessary to eliminate an apparent immediate hazard to the participant. All changes (e.g. a change in procedure, number of participants, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the UMCIRB before they are implemented;
2. Where informed consent has not been waived by the UMCIRB, ensuring that only valid versions of the UMCIRB approved, date-stamped informed consent document(s) are used for obtaining informed consent (consent documents with the IRB approval date stamp are found under the Documents tab in the ePIRATE study workspace);
3. Promptly reporting to the UMCIRB all unanticipated problems involving risks to participants and others;
4. Submission of a final report application to the UMCIRB prior to the expected end date provided in the IRB application in order to document human research activity has ended and to provide a timepoint in which to base document retention; and
5. Submission of an amendment to extend the expected end date if the study is not expected to be completed by that date. The amendment should be submitted 30 days prior to the UMCIRB approved expected end date or as soon as the Investigator is aware that the study will not be completed by that date.

APPENDIX B: MEASURES

Page 1

Barriers Measure

Please complete the survey below.

Thank you!

On most days, I/people in my household eat a healthy diet.

- ☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

I/people in my household understand the importance of eating healthy to stay healthy.

- ☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

Which of the following reasons keeps you (or the primary food shopper) from shopping for foods that are a part of a healthy diet?

In this survey, a healthy diet means a variety of food from all five food groups (fruits, vegetables, grains, dairy, and protein foods). It also means not eating too much saturated fat, salt, or sugar, and getting the right amount of calories for you.

Check all that apply.

- ☐ Distance to store
☐ Transportation
☐ Store hours
☐ Affordability (food prices)
☐ Physical disability/limitations
☐ Amount of time available to shop at the store
☐ Healthy foods are more perishable
☐ Cultural norms/traditions
☐ Safety concerns (in and around the stores)
☐ Other
☐ None of the above, I am able to shop for foods that are a part of a healthy diet

Please describe the "other" reason that keeps you from shopping for foods that are a part of a healthy diet.

Which of the following reasons keep you (or the primary food shopper) from preparing meals that are part of a healthy diet?

Check all that apply.

- ☐ Lack of time to prepare meals from scratch
☐ Lack of equipment (working stove, pots and pans) to prepare food
☐ Lack of storage to keep cooked or fresh food
☐ Don't know how to cook from scratch
☐ Don't always know what foods are a part of a healthy diet
☐ Physical disability/limitation
☐ Household members don't like home cooked healthy meals
☐ The change is too big from my current diet
☐ Strange or unusual foods (food familiarity)
☐ Healthy food does not satisfy hunger
☐ Healthy food is unappealing
☐ Other
☐ My diet is already healthy

Please describe the "other" reason that keeps you from preparing meals that are a part of a healthy diet.

Which of the following community food options/supports are available in your community?

Check all that apply.

- ☐ Food bank/pantry
- ☐ Free meals served at a food kitchen/soup kitchen
- ☐ Free meals served at church/school/community center
- ☐ Don't know
- ☐ Other places where food is available to those in need
- ☐ There is no community food support available in my community

Please describe the other places where food is available to those in need.

Acceptability of Intervention Measure (AIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The food box intervention meets my approval.	①	②	③	④	⑤
2. The food box intervention is appealing to me.	①	②	③	④	⑤
3. I like the food box intervention.	①	②	③	④	⑤
4. I welcome the food box intervention.	①	②	③	④	⑤

Satisfaction Survey

The delivery system was easy to use

☐ Strongly Disagree ☐ Disagree ☐ Undecided ☐ Agree ☐ Strongly Agree

I am happy with the way the food box program was run

☐ Strongly Disagree ☐ Disagree ☐ Undecided ☐ Agree ☐ Strongly Agree

Using food from the food boxes was challenging

☐ Strongly Disagree ☐ Disagree ☐ Undecided ☐ Agree ☐ Strongly Agree

I felt confident using the food from the food box

☐ Strongly Disagree ☐ Disagree ☐ Undecided ☐ Agree ☐ Strongly Agree

I had enough food-related knowledge to use the food box

☐ Strongly Disagree ☐ Disagree ☐ Undecided ☐ Agree ☐ Strongly Agree

I had the appropriate supplies (e.g., pans, knives, microwave, steamer) to use the foods in the food box

☐ Strongly Disagree ☐ Disagree ☐ Undecided ☐ Agree ☐ Strongly Agree

I had enough time in my day to use the foods in the food box

☐ Strongly Disagree ☐ Disagree ☐ Undecided ☐ Agree ☐ Strongly Agree

Overall, I am satisfied with the food box program

☐ Strongly Disagree ☐ Disagree ☐ Undecided ☐ Agree ☐ Strongly Agree

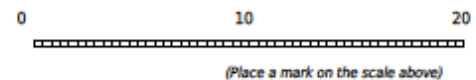
I was familiar with most of the foods in the food box

☐ Strongly Disagree ☐ Disagree ☐ Undecided ☐ Agree ☐ Strongly Agree

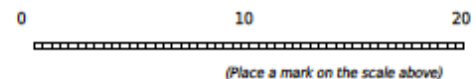
I would participate in a food box program like this long-term (e.g., more than 6 months)

☐ Strongly Disagree ☐ Disagree ☐ Undecided ☐ Agree ☐ Strongly Agree

How many people in your household used the foods from the food box?



How many people are currently living in your household?



09/23/2022 6:28pm

projectredcap.org



What percentage of the foods in the box did you use on average?

0 50 100



(Place a mark on the scale above)

What barriers and challenges got in the way of using the foods in the food box?

What benefits did you find from having the food box?

What costs came from using the food box?

What would you change about the food box system?

Perceived Stress Scale

Please complete the survey below.

Thank you!

The questions in this scale ask about your feelings and thoughts during the last month. In each case, you will be asked to indicate how often you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer fairly quickly. That is, don't try to count up the number of times you felt a particular way; rather indicate the alternative that seems like a reasonable estimate.

- | | | |
|-------|---|--|
| 1) | In the last month, how often have you been upset because of something that happened unexpectedly? | ☐ Never
☐ Almost never
☐ Sometimes
☐ Fairly often
☐ Very often |
| <hr/> | | |
| 2) | In the last month, how often have you felt that you were unable to control the important things in your life? | ☐ Never
☐ Almost never
☐ Sometimes
☐ Fairly often
☐ Very often |
| <hr/> | | |
| 3) | In the last month, how often have you felt nervous and stressed? | ☐ Never
☐ Almost never
☐ Sometimes
☐ Fairly often
☐ Very often |
| <hr/> | | |
| 4) | In the last month, how often have you felt confident about your ability to handle your personal problems? | ☐ Never
☐ Almost never
☐ Sometimes
☐ Fairly often
☐ Very often |
| <hr/> | | |
| 5) | In the last month, how often have you felt that things were going your way? | ☐ Never
☐ Almost never
☐ Sometimes
☐ Fairly often
☐ Very often |
| <hr/> | | |
| 6) | In the last month, how often have you found that you could not cope with all the things that you had to do? | ☐ Never
☐ Almost never
☐ Sometimes
☐ Fairly often
☐ Very often |
| <hr/> | | |
| 7) | In the last month, how often have you been able to control irritations in your life? | ☐ Never
☐ Almost never
☐ Sometimes
☐ Fairly often
☐ Very often |
| <hr/> | | |
| 8) | In the last month, how often have you felt that you were on top of things? | ☐ Never
☐ Almost never
☐ Sometimes
☐ Fairly often
☐ Very often |

-
- 9) In the last month, how often have you been angered because of things that happened that were outside of your control?
- ☐ Never
 - ☐ Almost never
 - ☐ Sometimes
 - ☐ Fairly often
 - ☐ Very often
-
- 10) In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?
- ☐ Never
 - ☐ Almost never
 - ☐ Sometimes
 - ☐ Fairly often
 - ☐ Very often
-

Healthy Eating Index

Please complete the survey below.

Thank you!

On average, how many servings of fruit (not including juice) do you eat per day?

Example: 1 serving fruit = 1/2 cup cut-up fruit, 1/2 banana, or one small piece of whole fruit (apple, orange, pear).
One small piece of whole fruit is the size of a baseball.
1/2 cup cut-up fruit is the size of a computer mouse.

- ☐ Less than one
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6 or more
- ☐ Choose not to answer

On average, how many servings of 100% fruit juice do you drink per day?

Note: Do not include fruit flavored drinks such as Hi-C, Tang, Sunny-D, etc.

Example:
1 serving of juice = 1/2 cup 100% fruit juice (apple, grape, orange, etc.)
1 cup of juice = 1 juice box

- ☐ Less than one
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6 or more
- ☐ Choose not to answer

On average, how many servings of vegetables do you eat per day?

Note: Any vegetable or 100% vegetable juice counts as a member of the vegetable group.

Example:
1 serving = 1 cup raw vegetables, 1 cup of salad, 1/2 cup cooked vegetables, or 1/2 cup 100% vegetable juice.
1 cup raw vegetables is the size of a baseball.
1/2 cup cooked vegetables is the size of a computer mouse.

- ☐ Less than one
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6 or more
- ☐ Choose not to answer

On average, how many servings of green vegetables (e.g., spinach, green beans, kale, broccoli, zucchini.) do you eat per day?

Note: Do not include starchy vegetables like green peas.

Example:
1 serving = 1 cup raw vegetables, 1/2 cup cooked vegetables.
1 cup raw vegetables is the size of a baseball.
1/2 cup cooked vegetables is the size of a computer mouse.

- ☐ Less than one
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6 or more
- ☐ Choose not to answer

On average, how many servings of starchy vegetables (e.g., corn, green peas, potatoes) do you eat per day? Example: 1 serving = 1 cup raw vegetables, 1/2 cup cooked vegetables. 1 cup raw vegetables is the size of a baseball. 1/2 cup cooked vegetables is the size of a computer mouse.	☐ Less than one ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 or more ☐ Choose not to answer
On average, how many servings of grains do you eat per day? Example: 1 serving = 1 slice of bread, 1/2 cup grits, 1 cup of ready-to-eat cereal, 1/2 cup oatmeal, 1 small tortilla, 1/2 cup cooked rice, 1/2 cup pasta 1 cup ready-to-eat cereal is the size of a baseball.	☐ Less than one ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 or more ☐ Choose not to answer
On average, how often do you eat grains? Examples: 1 serving=1 slice of bread, 1/2 cup grits, 1 cup of ready-to-eat cereal, 1/2 cup oatmeal, 1 small tortilla, 1/2 cup cooked rice, or 1/2 cup pasta	☐ A couple times per week ☐ A couple times per month ☐ A couple times per year ☐ Almost never ☐ Never ☐ Choose not to answer
On average, how many servings of whole grains (e.g., wheat bread, whole grain crackers, brown rice, oatmeal) do you eat per day? Examples: 1 serving=1 slice whole wheat bread, 5-6 whole grain crackers, 3 cups popcorn, 1/2 cup cooked brown rice, 1/2 cup oatmeal	☐ Less than one ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 or more ☐ Choose not to answer
On average, how often do you eat whole grains? Examples: 1 serving=1 slice whole wheat bread, 5-6 whole grain crackers, 3 cups popcorn, 1/2 cup cooked brown rice, 1/2 cup oatmeal	☐ A couple times per week ☐ A couple times per month ☐ A couple times per year ☐ Almost never ☐ Never ☐ Choose not to answer
On average, how many servings of milk do you eat or drink per day? Examples: 1 serving= 1 cup of milk, 1 cup of yogurt, 1.5 ounces of natural cheese, 2 ounces of processed cheese 1 cup of milk is the size of a carton of milk 1 serving of cheese is the size of your index finger	☐ Less than one ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 or more ☐ Choose not to answer
On average, how often do you drink or eat milk products? Examples: 1 serving= 1 cup of milk, 1 cup of yogurt, 1.5 ounces of natural cheese, 2 ounces of processed cheese 1 cup of milk is the size of a carton of milk 1 serving of cheese is the size of your index finger	☐ A couple times per week ☐ A couple times per month ☐ A couple times per year ☐ Almost Never ☐ Never ☐ Choose not to answer

On average, how many servings of low-fat milk products do you eat per day?

Examples: 1 serving= 1 cup of skim milk, 1 cup of low-fat yogurt, 1.5 ounces of low-fat cheese
1 cup of milk is the size of a carton of milk
1 serving of cheese is the size of your index finger

- ☐ Less than one
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6 or more
☐ Choose not to answer

On average, how often do you drink or eat low-fat milk products?

Examples: 1 serving= 1 cup of skim milk, 1 cup of low-fat yogurt, 1.5 ounces of low-fat cheese

- ☐ A couple times per week
☐ A couple times per month
☐ A couple times per year
☐ Almost Never
☐ Never
☐ Choose not to answer

On average, how many servings of beans (legumes) do you eat per day?

Note: all foods made from dry beans, canned beans, peas, and lentils are considered part of this group.

Examples: 1 serving= 1/2 cup cooked beans
1/2 cup cooked beans is the size of a computer mouse.

- ☐ Less than one
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6 or more
☐ Choose not to answer

On average, how many servings of nuts or seeds do you eat per day?

Examples: 1 serving= 1tbsp of peanut butter, 1/2 ounces of nuts or seeds
1tbsp of peanut butter is the size of the top of your thumb.

- ☐ Less than one
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6 or more
☐ Choose not to answer

On average, how many servings of seafood do you eat per day?

Note: All foods made of fish, shrimp, crab, and shellfish are considered part of this group.

Examples: 1 serving= 3 ounces of fish
3 ounces of fish is the size of a deck of cards.

- ☐ Less than one
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6 or more
☐ Choose not to answer

On average, how often do you eat seafood?

Note: All foods made of fish, shrimp, crab, and shellfish are considered part of this group.

Examples: 1 serving=3 ounces of fish.

- ☐ A couple times per week
☐ A couple times per month
☐ A couple times per year
☐ Almost never
☐ Never
☐ Choose not to answer

On average, how many servings of sugar-sweetened beverages do you drink per day?

Examples: 12 oz. of soft drinks/soda, fruit flavored drinks, sweetened coffee, and sweet tea.
Do not include milk or 100% fruit juice.
12 oz. of soda is the size of one can.

- ☐ Less than one
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6 or more
☐ Choose not to answer

On average, how often do you drink sugar-sweetened beverages?

Examples: 12 oz. of soft drinks/soda, fruit flavored drinks, sweetened coffee, and sweet tea.
Do not include milk or 100% fruit juice.

- ☐ A couple times per week
- ☐ A couple times per month
- ☐ A couple times per year
- ☐ Almost never
- ☐ Never
- ☐ Choose not to answer

On average, how much added sugars do you consume per day?

Note: Added sugars are often in foods such as breads, cakes, candy, sweet tea, jam, ice cream, or sugar added to food at the table. Do not include naturally occurring sugars such as lactose in milk or fructose in fruits.

Examples: white sugar, brown sugar, raw sugar, corn syrup, corn-syrup solids, high-fructose corn syrup, malt syrup, maple syrup, pancake syrup, fructose sweetener, liquid fructose, honey, molasses, and dextrose.

- ☐ None/almost none
- ☐ Some
- ☐ A lot
- ☐ Choose not to answer

How many servings of saturated fat do you consume on average per day?

Note: Saturated fats for these purposes should be considered to be solid fats. Solid fats are fats that are solid at room temperature.

Examples: butter, cakes, cookies, Crisco, coconut oil, beef fat (tallow, suet), chicken fat (lard), stick margarine, and shortening.

- ☐ None/almost none
- ☐ Some
- ☐ A lot
- ☐ Choose not to answer

On average, how much water do you drink per day?

- ☐ None/almost none
- ☐ Some
- ☐ A lot
- ☐ Choose not to answer

Food Security Measure

Page 1

These questions are about the food eaten in your household in the last 12 months and whether you were able to afford the food you need.

Which of these statements best describes the food eaten in your household in the last 12 months:

- ☐ Enough of the kinds of food we want to eat
- ☐ Enough but not always the kinds of food we want
- ☐ Sometimes not enough to eat
- ☐ Often not enough

Here are some reasons why people don't always have enough to eat. For each one, tell me if that is a reason why YOU don't always have enough to eat.

- ☐ Not enough money for food
- ☐ Not enough time for shopping or cooking
- ☐ Too hard to get to the store
- ☐ On a diet
- ☐ No working stove available
- ☐ Not able to cook or eat because of health problems

Here are some reasons why people don't always have the quality or variety of food they want. For each one, please tell me if that is a reason why YOU don't always have the kinds of food you want to eat.

- ☐ Not enough money for food
- ☐ Kinds of food I/we want not available
- ☐ Not enough time for shopping or cooking
- ☐ Too hard to get to the store
- ☐ On a special diet

Now I'm going to read you several statements that people have made about their food situation. For these statements, please tell me whether the statement was often true, sometimes true, or never true for you/your household in the last 12 months.

I/we worried whether my/our food would run out before I/we got money to buy more.

- ☐ Often true
- ☐ Sometimes true
- ☐ Never true
- ☐ Don't know

The food that I/we bought just didn't last, and I/we didn't have money to get more.

- ☐ Often true
- ☐ Sometimes true
- ☐ Never true
- ☐ Don't know

I/we couldn't afford to eat balanced meals.

- ☐ Often true
- ☐ Sometimes true
- ☐ Never true
- ☐ Don't know

I/we relied on only a few kinds of low-cost food to feed my/our child/children because (I was/we were) running out of money to buy food.

- ☐ Often true
- ☐ Sometimes true
- ☐ Never true
- ☐ Don't know

I/we couldn't feed my/our child/children a balanced meal, because I/we couldn't afford that.

- ☐ Often true
- ☐ Sometimes true
- ☐ Never true
- ☐ Don't know

My/our children were not eating enough because I/we just couldn't afford enough food.

- ☐ Often true
- ☐ Sometimes true
- ☐ Never true
- ☐ Don't know

In the last 12 months, did you or others in the household ever cut the size of your meals or skip meals because there wasn't enough money for food?

- ☐ Yes
☐ No
☐ Don't know

How often did this happen?

- ☐ Almost every month
☐ Some months but not every month
☐ Only 1 or 2 months
☐ Don't know

In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money to buy food?

- ☐ Yes
☐ No
☐ Don't know

In the last 12 months, were you ever hungry but didn't eat because you couldn't afford enough food?

- ☐ Yes
☐ No
☐ Don't know

In the last 12 months, did you lose weight because you didn't have enough money for food?

- ☐ Yes
☐ No
☐ Don't know

In the last 12 months, did you/others in your household ever not eat for a whole day because there wasn't enough money for food?

- ☐ Yes
☐ No
☐ Don't know

How often did this happen?

- ☐ Almost every month
☐ Some months but not every month
☐ Only 1 or 2 months
☐ Don't know

In the last 12 months, did you ever cut the size of your child's meals because there wasn't enough money for food?

- ☐ Yes
☐ No
☐ Don't know

In the last 12 months, did any of the children ever skip meals because there wasn't enough money for food?

- ☐ Yes
☐ No
☐ Don't know

How often did this happen?

- ☐ Almost every month
☐ Some months but not every month
☐ Only 1 or 2 months
☐ Don't know

In the last 12 months, was your child/children ever hungry but you just couldn't afford more food?

- ☐ Yes
☐ No
☐ Don't know

In the last 12 months, did your child/children ever not eat for a whole day because there wasn't enough money for food?

- ☐ Yes
☐ No
☐ Don't know

Thank you for answering the questions regarding food security.

6-Item Food Security Measure

Please complete the survey below.

Thank you!

Below are several statements that people have made about their food situation. For these statements, please respond for you/your household based on the last 12 months.

- | | |
|--|---|
| 1) The food that I/we bought just didn't last, and I/we didn't have money to get more. | ☐ Often true
☐ Sometimes true
☐ Never true |
| <hr/> | |
| 2) I/we couldn't afford to eat balanced meals. | ☐ Often true
☐ Sometimes true
☐ Never true |
| <hr/> | |
| 3) In the last 12 months, did you/your household ever cut the size of your meals or skip meals because there wasn't enough money for food? | ☐ Yes
☐ No |
| <hr/> | |
| 4) If you answered "Yes" to the question above, how often did this happen? | ☐ Almost every month
☐ Some months but not every month
☐ Only 1 or 2 months
☐ I responded "No" to the question above |
| <hr/> | |
| 5) In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money for food? | ☐ Yes
☐ No |
| <hr/> | |
| 6) In the last 12 months, were you ever hungry but didn't eat because there wasn't enough money for food? | ☐ Yes
☐ No |
-