

A Study to Explore Meal Patterns and Diet Quality Among Overweight/Obese, Low-Income Women Undergoing a Weight Management Intervention.

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## **Abstract**

Obesity is a public health issue in the United States that impacts men and women of all socioeconomic levels. Obesity is categorized by a body mass index (BMI) of greater than 30 kg/m<sup>2</sup>. In the United States, 33.7% of men and 36.5% of women are currently classified as obese. A population of increasing concern related to obesity is women of low-income. Presently, 42% of women below 130% of the poverty level are obese, compared to 29% of women above 350% of the poverty level. This ever-increasing gap in obesity prevalence places low-income women at a higher risk for developing chronic diseases in comparison to men and women of higher socioeconomic status. Previous research has drawn attention to the need for interventions aimed toward low-income, overweight and obese women to focus on barriers to food security such as savvy shopping and managing food dollars to make changes in overall diet quality, fruit and vegetable consumption, and to combat obesity.

The focus of this thesis is to explore changes in diet quality, meal patterns, and fruit and vegetable consumption in a weight loss intervention customized for low-income, overweight or obese women. This study is a secondary analysis of the \$ensible Weigh pilot study at the University of Kansas Medical Center. The study consisted of 3 months of weight loss sessions, followed by 6 months of weight maintenance sessions. These sessions were a modification of the Diabetes Prevention Program, in which some participants received education on barriers to food security such as food dollar budgeting, community resources, meal planning, and basic culinary skills.

At baseline, 3 months, and 9 months, sociodemographic information and three 24-hour dietary recalls were collected. Twenty-four hour dietary recalls were entered into NDSR 2014. Diet quality was measured using Healthy Eating Index 2010 (HEI-2010) scores, which were

calculated using outputs from NDSR. NDSR outputs were also used to answer questions related to meal and snack consumption as well as fruit and vegetable intake.

Results showed that diet quality from baseline to the end of the weight loss period (47.3 to 57.6, p=0.0477) statistically increased, but not during the weight maintenance period (57.6 to 53.4, p=0.3849). Percent of total calories from meals showed no significant changes across the course of the intervention (p=0.9478 from baseline to 3 months, p=0.9903 from 3 months to 9 months, and p=0.9237 from baseline to 9 months). No statistically significant changes were seen in consumption of total fruits (p = 0.072 from baseline to 3 months, p=0.829 from 3 months to 9 months, and p=0.893 from baseline to 9 months), total vegetables (p=0.355 from baseline to 3 months, p=0.515 from 3 months to 9 months, and p=0.811 from baseline to 9 months), or non-starchy vegetables (p=0.353 from baseline to 3 months, p=0.082 from 3 months to 9 months, and p=0.829 from baseline to 9 months). These results show promise that focusing on interventions tailored to one's socioeconomic status have potential to positively impact diet quality in low-income women who are overweight or obese.

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## Table of Contents

<b>List of Tables and Figures.....</b>	<b>ix</b>
<b>Chapter 1: Introduction.....</b>	<b>1</b>
Statement of Purpose.....	2
Research Questions.....	3
<b>Chapter 2: Review of Literature.....</b>	<b>4</b>
Introduction.....	4
The Issues: Obesity and Poor Diet Quality in Low-Income Women.....	4
<i>Obesity</i> .....	4
<i>Poor Diet Quality</i> .....	5
<i>The Hunger-Obesity Paradox</i> .....	6
Weight Patterns in Low-Income Women.....	6
Diet Quality in Low-Income Women.....	9
Meal Patterns in Low-Income Women.....	11
Fruit and Vegetable Consumption in Low-Income Women.....	14
Conclusions.....	15
<i>Research Findings</i> .....	15
<i>Current Trends in Research</i> .....	16
<i>Gaps in Literature</i> .....	16
<b>Chapter 3: Methods.....</b>	<b>18</b>
Overview.....	18
Sample.....	18
Setting.....	19

Ethics.....	19
Procedures.....	19
<i>Weight Loss Phase</i> .....	19
<i>Weight Maintenance Phase</i> .....	20
<i>Dietary Intervention</i> .....	20
Data Collection.....	21
<i>Sociodemographic Information</i> .....	21
<i>Dietary Intake</i> .....	21
<i>Nutritional Content</i> .....	22
Analysis of Data.....	22
<i>Diet Quality</i> .....	22
<i>Meal Patterns</i> .....	22
<i>Fruit and Vegetable Consumption</i> .....	23
<i>Statistical Analysis</i> .....	23
<b>Chapter 4: Results.....</b>	<b>24</b>
Subject Characteristics.....	24
Dietary Intake.....	25
HEI-2010 Scores.....	27
Meal Patterns.....	30
Fruit and Vegetable Consumption.....	31
<i>Average Fruit Consumption</i> .....	32
<i>Average Total Vegetable Consumption</i> .....	32
<i>Average Non-Starchy Vegetable Consumption</i> .....	32

<b>Chapter 5: Discussion.....</b>	<b>34</b>
Sample.....	34
Dietary Intake.....	35
HEI-2010 Scores.....	36
Meal Patterns.....	38
Fruit and Vegetable Consumption.....	39
Limitations.....	41
Implications and Future Studies.....	42
Conclusions.....	42
<b>References.....</b>	<b>43</b>
<b>Appendix A: Research Consent Form.....</b>	<b>46</b>
<b>Appendix B: Health History and Demographic Questionnaire.....</b>	<b>55</b>
<b>Appendix C: 24-Hour Dietary Recall Form.....</b>	<b>60</b>
<b>Appendix D: University of Minnesota's Guide to Calculating HEI-2010 Scores.....</b>	<b>61</b>

## **List of Tables and Figures**

### **In-Text Tables**

Table 1. Baseline Subject Characteristics.....	24
Table 2. Excluded Data for Dietary Analysis.....	25
Table 3. General Macronutrient Characteristics.....	26
Table 4. General Micronutrient Characteristics.....	26
Table 5. HEI-2010 Scores.....	27
Table 6. Change in HEI-2010 Scores At Various Time Points.....	28
Table 7. Average Number of Meals and Snacks Throughout the Intervention.....	30
Table 8. Average Calories From Meals and Snacks Throughout the Intervention.....	30
Table 9. Percent of Total Calories From Meals and Snacks Throughout the Intervention.....	31
Table 10. Change in Percentage of Total Calories From Meals at Various Time Points.....	31
Table 11. Fruit and Vegetable Consumption (cups) Throughout Intervention.....	31
Table 12. Changes in Total Fruit Consumption (cups) Throughout the Intervention.....	32
Table 13. Changes in Total Vegetable Consumption (cups) Throughout the Intervention.....	32
Table 14. Changes in Non-Starchy Vegetable Consumption (cups) Throughout the Intervention.....	33

### **In-Text Figures**

Figure 1: Paired Profiles for HEI-2010 Score from Baseline to 3 Months.....	28
Figure 2: Paired Profiles for HEI-2010 Score from Baseline to 9 Months.....	29
Figure 3: Paired Profiles for HEI-2010 Score from 3 Months to 9 Months.....	29

## **Chapter 1: Introduction**

Research surrounding low-income obese women has evolved greatly over the years.

There is a shift from focusing on the relationship between food insecurity and obesity (1, 2), to research on diet quality (3) and why it may be compromised due to one's perception of their environment and individual behaviors (4, 5). Low-income adults in the United States are of special concern for the dietetics profession because they consume fewer servings of fruits, vegetables, and dairy products per week when compared to those with higher incomes (6). The decreased consumption of produce may be associated with a limited selection of foods that are high in nutrients due to environmental and financial restraints. These financial challenges for those with a low socioeconomic status may lead to a phenomenon known as the hunger-obesity paradox (7).

The hunger-obesity paradox is defined as weight gain in the presence of chronic hunger (8). The individual enters into a cycle, feasting when monetary resources are high and fasting when funds are low. The feast-famine cycle has negative effects on an individual's metabolism as well as promotion of weight gain over time (7). The inconsistent meal patterns and fasting seen in the hunger-obesity paradox also raise concern for the development of metabolic syndrome and insulin resistance (9).

Irregular meal patterns and fasting is also seen during weight loss attempts in low-income, overweight/obese women. This population, when making independent choices to lose weight, underutilizes recommended strategies such as regular exercise and a balanced, calorie restricted diet in comparison to those of higher socioeconomic status. Weight-loss strategies observed in this population include skipping meals and fasting (10). Previous studies (4, 6, 10, 11) have shed light on meal patterns and diet quality in low-income, overweight/obese women;

however, the reasons as to why these women persist with inconsistent meal patterns remain unclear.

An individual's variety of food also decreases during times of financial restraint. An increased consumption of energy-dense foods containing refined grains, added sugars and fats occurs during this cycle because foods of this nature are perceived to be of lower cost per calorie. Persistently low-quality diets have been shown to increase risk of micronutrient deficiencies such as B vitamins, magnesium, iron, zinc and calcium (6). These findings have led to several studies (1, 3, 4, 7, 10-17) aimed to better understand the dietary habits particularly in low-income, obese women and to help identify possible solutions. Barriers to healthy eating such as lack of knowledge, skills, and time have been brought to the surface, but specific interventions have yet to be addressed (3, 4, 7, 17).

### Statement of Purpose

The hunger-obesity paradox that low-income obese women face raises the risk for vitamin deficiencies (6) as well as weight gain (7), metabolic syndrome, and insulin resistance (9). Factors such as lack of knowledge, budgeting, culinary skills, and time management have been identified as barriers to increasing diet quality as well as to promote weight loss in this population (3, 4, 7, 17). Further investigation is necessary to gain knowledge on how to decrease these barriers while simultaneously addressing weight loss. The purpose of this thesis is to further research meal patterns and diet quality in low-income obese women undergoing a weight loss intervention.

## Research Questions

### *Primary Question*

1. Does diet quality change over the course of a weight management program in overweight and obese low-income women?

### *Secondary Questions:*

1. Do low-income overweight or obese women experience changes in dietary intake or meal patterns throughout the course of a weight management intervention?
2. Does providing nutrition education to these women result in changes of fruit and vegetable consumption following the weight loss or maintenance phase?

## **Chapter 2: Review of Literature**

### Introduction

The purpose of this literature review is to explore research findings on diet quality, meal patterns, and fruit and vegetable consumption among obese women with low income. Over the years, research surrounding this population has evolved from the relationship between food security status and weight (1, 2) to a focus on diet quality (3) and how certain perceptions of one's environment results in poor diet quality (4, 5). In light of previous research, the following questions still need to be answered:

*Does diet quality change over the course of a weight management program in overweight and obese low-income women? Secondly, Do low-income overweight or obese women experience changes in dietary intake or meal patterns throughout the course of a weight management intervention? Finally, Does providing nutrition education to these women result in changes of fruit and vegetable consumption following the weight loss or maintenance phase?*

### The Issue: Obesity and Poor Diet Quality in Low-Income Women

Obesity. Obesity is a significant public health issue that impacts men and women of all socioeconomic levels. Obesity is categorized by a body mass index (BMI) of greater than 30 kg/m<sup>2</sup> (18). In the United States, 33.7% of men and 36.5% of women are currently classified as obese. Non-Hispanic black women have the highest prevalence of obesity at 56.6%, with Hispanic women also above the average at 43.3% (19). These statistics are why women of these ethnicities are of special concern.

Obesity rates of low-income women are of increasing concern. Between 1988 to 1994 and 2007 to 2008, obesity has increased from 34.5% to 42% in women who are below 130% of

the poverty level (18). Currently, 42% of women below 130% of the poverty level are obese, compared to 29% of women above 350% of the poverty level (19). This is concerning, considering the risk obesity poses to the population's health (20).

Obesity increases the risk of multiple conditions, including all-cause mortality (20), type two-diabetes (21), and hypertension. Although obesity increases health risks across all genders, the risk of developing these diseases is more common among women than men (20, 21). In addition, low-income women who are obese have an increased risk for cardiovascular diseases such as myocardial infarctions and stroke (22). However, there are ways to help women prevent such complications. One potential way to prevent obesity and the associated health risks, as well as promote weight loss, is to increase dietary intake of fruits and vegetables (23).

Poor Diet Quality. Fruits and vegetables are rich in dietary fiber as well as vitamins, minerals and phytochemicals, which further aid in weight loss and maintenance. Research shows that consistent consumption of high-nutrient quality foods results in vast health benefits (6). High nutrient containing foods such as fruits and vegetables may help prevent the development of hypertension, coronary artery disease, stroke, and some types of cancers (14). Increasing intake of fruits and vegetables promotes satiety as well as hydration, both of which, combat obesity and aid in weight loss (23, 24), particularly when combined with caloric restrictions (25). Unfortunately, consumption of fruits and vegetables is not common for those of low socioeconomic status (6).

Low-income adults in the United States, when compared to those with higher incomes, consume fewer servings of fruits (0.96 vs 1.03 cups) and vegetables (1.43 vs 1.58 cups) (6, 26). The lack of intake puts this population at risk for micronutrient deficiencies in B vitamins, magnesium, iron, zinc, and calcium (6). The low consumption of fruits and vegetables may be

associated with limited selection of high nutrient-quality foods in the community as well as financial restraints.

*The Hunger-Obesity Paradox.* Such financial limitations have been shown to result in food insecurity (27). Food insecurity is defined as “lack of consistent access to nutritious foods in socially acceptable ways” (p. 1575-1576)(28). Those who are food insecure over the course of several years have been shown to have a greater increase in weight and BMI in comparison to those who are food secure (27). More serious forms of food insecurity have been associated with increased prevalence of obesity, particularly in women of low-income (13). Financial challenges, and a compromise in dietary intake, seen in those with a low socioeconomic status lead to a phenomenon known as the hunger-obesity paradox (7).

The hunger-obesity paradox is weight gain in the presence of chronic hunger (8). The individual enters a cycle, feasting when monetary resources are high and fasting when their funds are low. This cycle has negative effects on an individual’s metabolism as well as promotion of weight gain over time (7). During times of financial restraint and famine an individual’s variety of food also decreases. An increased consumption of energy-dense foods containing refined grains, added sugars and fats occurs during this cycle because foods of this nature are perceived to be of lower cost per calorie (6). These findings have led to several studies (1, 3, 4, 7, 10-17) aimed to better understand the dietary habits in low-income, obese women and to find possible solutions.

### Weight Patterns in Low-Income Women

Several studies (10, 12, 13, 15) have been conducted to better understand weight patterns in overweight/obese low-income women. A handful of these studies (10, 12) used waves of the

National Health and Nutrition Examination Survey (NHANES) to better understand weight changes in the low-income population. A cross-sectional study by Wilde (12) used data from 1999 to 2000 and 2001 to 2002 to observe household food security status. Height and weight were recorded to analyze current food security as well as weight changes over time for individuals (12). The highest weight gain seen over time was seen in women classified as low-income who had previously experienced food insecurity (12).

Kakinami and colleagues (10) gathered NHANES data from 1999 to 2010 and included 5,643 adults older than 20 years of age. This study investigated the relationship between income and weight loss strategies. The researchers explored household income as well as the likelihood of using recommended versus inconsistent weight loss strategies. Households whose income was less than \$20,000 a year were 50% less likely to follow recommended weight loss interventions, which included regular exercise and a balanced, calorically restricted diet. Those of lower incomes, in comparison to households earning  $\geq \$75,000$  a year, were also less likely to make recommended dietary changes such as increasing water consumption, and eating lower amounts of fats and sweets (10). The combination of low-income women experiencing the highest rate of weight gain over time (12) and a decreased likelihood of following recommended weight loss interventions raises the need for additional research on dietary interventions in this population (10).

In 2004 Kaiser (13) studied 561 Latino families in California to establish a relationship between food insecurity and obesity in low-income Latino women. Low-income was defined as below 200% of the poverty line (13). The researchers asked participants to complete a survey that provided information on current and past food security, demographic data, and height and weight. Results from this study showed that 40% of subjects had been food insecure at some

point during childhood. Beyond that, no differences were found between prevalence of obesity and past food insufficiency. Although previous low-income status and food insecurity was not related to weight as an adult, food insecurity paired with hunger was significantly associated with the likelihood of becoming obese. These findings suggest that if a low-income mother is food insecure that she may not have the time and resources to achieve weight loss and seek out nutrition education (13).

Martin and colleagues studied 137 low-income African American women during the course of a weight maintenance intervention (15). These women were required to have a BMI of greater than 25, classifying them as either overweight or obese, and have an annual income of less than \$16,000 per year. The researchers studied weight loss and maintenance periods that followed a primary care intervention. All subjects received the same dietary weight loss intervention; then subjects were randomized into a standard care group or an intervention group for weight maintenance. The intervention group received five months of physician visits, plus one session at six months for weight maintenance. All visits included weight loss instructions by the physician. The standard care group were only seen by the physician as perceived needed by the subject. At these visits, subjects received no specific weight loss instructions; just that they needed to lose weight.

Martin and colleagues (15) found that weight change at nine months was significantly greater ( $p=0.01$ ) in the intervention group ( $-1.52 \pm 3.72\text{kg}$ ) in comparison to the standard group ( $0.61 \pm 3.37\text{kg}$ ). However, at twelve months weight change between groups was no longer significant (intervention  $-1.38 \pm 3.69\text{kg}$ , standard  $-1.16 \pm 3.69\text{kg}$ ). Further, eighteen months post intervention, the experimental group had regained 64% of achieved weight lost ( $-0.49 \pm 3.33\text{kg}$ ).

Martin's (15) findings suggest that continued contact after a weight loss intervention may be needed for successful weight maintenance.

Findings from these studies (10, 12, 13, 15) suggest that low-income women who have experienced food insecurity in the past (12) or are presently food insecure (13) are vulnerable to weight gain over time which is likely to lead to obesity (12, 13). To combat this weight gain, however, weight loss and maintenance studies need to explore combating unconventional habits to lose weight (10) as well as continued personal contact to make an impact on this population (15).

### Diet Quality in Low-Income Women

Two studies (1, 3) gathered data from large databases to research obesity and diet quality in obese women of low-income. Sarlio et al.(1) researched 6,506 Finnish men and women. The study categorized data based on BMI, indicators of economic disadvantage, as well as indicators of food security. Sarlio and colleagues found that if someone was previously food insecure, regardless of current BMI, they were more likely to experience indicators of food insecurity. Indicators included fear of running out of food, buying cheap food unnecessarily, and being without food for at least one day due to current or previous economic issues (1).

Nguyen et al. (3) utilized NHANES data from 2003 to 2010, to focus on the Supplemental Nutrition Assistance Program (SNAP) related to diet quality between those who are participating and not participating in this government assistance program (3). The researchers found that low-income women who are obese are more likely to participate in SNAP programs. After analyzing diet quality in these individuals, they found that in comparison to non-SNAP participants, the population that participated in SNAP had significantly lower intakes of fruits,

vegetables, plant proteins, and seafood. SNAP participants also had higher intake of products with added sugars and overall lower diet quality (3).

Both of these studies (1, 3) utilized large population surveys to provide a more cohesive view of diet quality in this population. They found that history of food insecurity could continue to play a role in one's eating habits (1). Even if low-income women were to utilize resources such as SNAP to increase food security, this population continues to have low intake of nutrient dense foods, such as fruits and vegetables (3).

Two randomized control trials (16, 17) were selected to review overweight/obese, low-income women and their dietary habits. Eicher-Miller (16) studied 219 women who were eligible for Food Stamp Nutrition Education (FSNE). Low-income was defined as less than 130% of the poverty line (16). The researchers studied the effects of FSNE on food security. The experimental group received a five-week nutrition education intervention that was specific to FSNE. Topics covered included but were not limited to USDA guidelines, food safety, menu planning, thrifty shopping, and lifestyle applications. Subjects then received questionnaires regarding nutrition knowledge after each session. The control group received one initial FSNE, then a delayed questionnaire given five weeks after the education session. Eicher-Miller and colleague's found a significant improvement in food security status in the experimental group ( $p=0.03$ ) compared to the control group (16).

Mello (17) recruited a larger number of subjects at 1,874, of which 55% were Hispanic and 80% of the participants were women. Subjects were recruited from a low-income health clinic, but the authors did not define what categorized the participants as low-income (17). Mello (17), similar to Eicher-Miller (16), observed the relationship between food insecurity and dietary behavior. However, all information and education was conducted via telephone (17) instead of

in-person (16). The researchers found that those who were food insecure perceived themselves to have a higher fat intake compared to food secure subjects. Food insecure subjects were less likely to choose lower-fat cuts of meat or fat substitutes. In regard to fruit and vegetable intake, results showed there was no difference between food secure and food insecure low-income individuals. However, food insecure participants relied heavily on fruit juice in comparison to the food secure group (17). Mello (17) and Eicher-Miller (16) both stated that eating habits and diet quality could be improved when there is a focus on knowledge, skills, and attitudes related to healthy eating and food preparation.

### Meal Patterns in Low-Income Women

Two qualitative case studies (4, 11) were selected to review regarding meal patterns among low-income women. Bove (11) in 2006 observed 28 mothers in rural counties in the state of New York. Low-income was defined as less than 200% of the poverty line. The mothers were older than the age of 18 and had at least one child under the age of 12. The researchers conducted in-depth one-on-one interviews once a year over a three-year period, to evaluate the subjects' exercise and eating habits. Additionally, food security and health outcomes were assessed (11). Results showed that food security status constantly changed over the course of three years in 40% of subjects (11). Two-thirds of participant's households were food insecure at one or more interview. Factors that led to such changes included employment status, ebbs and flows of food assistance checks and federal programs, as well as living situations. The fluctuations observed in Bove and colleague's research shed light on the issue of emotional eating and binge eating, particularly during times of increased monetary resources (11).

A reported 60% of participants in Bove et al.'s study reported disordered eating patterns, primarily through restricting their caloric intake during times of limited income and binge eating during episodes of food security (11). Fasting was also commonly seen, as women would fast for up to two days at a time in order to stretch food dollars for their family. In order for these low-income women to cope with the stress of financial restraints, many mentioned increasing their intake of sugar-sweetened beverages such as soda. They also mentioned restricting their diet to only liquids such as coffee or water when their budget was tight. Therefore, the overall diet quality and disordered eating patterns of these women over time has potentially skewed this population's perspective on knowledge of healthy, balanced eating (11).

Baruth (4) conducted similar research in 2008, observing 28 women who were classified as overweight or obese (BMI of greater than  $25 \text{ kg/m}^2$ ). The subjects in this study were all from disadvantaged neighborhoods in Columbia, South Carolina. To be categorized as disadvantaged, a neighborhood had to have 25% or greater of its residents living in poverty. Baruth (4) held focus groups over a two-month period, compared to the three-year study by Bove (11). The focus group in Baruth et al.'s study discussed eating habits and physical activity patterns similar to Bove (11), but additionally looked into specific barriers to bettering one's lifestyle (4).

Psychological reasons were recognized in this focus groups such as depression, feelings of defeat, and recognizing an addiction to food (4). Lack of nutritional knowledge as well as feeling that they had limited time to dedicate towards planning and preparing healthy meals were also acknowledged. The population studied perceived healthful foods to be more expensive (4). Furthermore, low-income women who struggled with being overweight or obese felt that they had a lack of social support. Non-Hispanic black and Hispanic women also had an associated fear that weight loss would alter their curvaceous figure, which has been established as important

to these populations (4). The qualitative data gathered from these studies (4, 11) can provide health professionals and researchers increased insight into the barriers to normalized eating patterns and overall quality of diet.

Two cross-sectional studies (29, 30) have been conducted to better understand meal pattern and how it relates to overall health status. Kerver et al. (29) used data from the third wave of NHANES to understand how eating occurrences may be related to nutrient intakes in US adults. Twenty-four hour recalls from 30,818 NHANES participants were analyzed by eating occasion (i.e. breakfast, lunch, dinner and snack/beverage). The researchers found that those who ate breakfast, lunch, dinner and greater than two snacks had the highest calorie and carbohydrate intake and lowest intake of total fats. Subjects who skipped breakfast but consumed lunch, dinner, and snacks had the lowest intake of micronutrients, excluding sodium. The highest intake of micronutrients was found to be in those who had all three meals plus one or more snacks (29).

A recent study by Eicher-Miller et al. (30) studied the effects of timing of meal, specific eating patterns, and how these issues may affect overall diet quality. The research was a secondary analysis of NHANES years 1999-2004. The researchers obtained 24-hour recalls from adults ages 25-62 resulting in a sample size of 9,326. Eicher-Miller and colleagues looked at energy consumption on every hour in the 24-hour recall and compared it to overall consumption for the day. In addition to looking at consumption every hour, HEI-2005 scores were assigned to each recall to analyze diet quality in relation to meal patterns. The researchers found that those who ate during daytime hours and had energy-balanced eating occurrences had an overall higher diet quality (HEI score). On the contrary, those individuals that frequently had eating occurrences around 12am were associated with the lowest diet quality score (30).

Research shows that low-income women have a variety of barriers that prevent more consistent eating patterns (4, 11). It is possible that promoting energy balanced, evenly timed eating patterns could result in higher overall diet quality (29, 30). Literature (4, 11, 29, 30) shows promise that breaking down these barriers while addressing meal patterns may be beneficial for low-income overweight/obese women.

### Fruit and Vegetable Consumption in Low-Income Women

Two studies (7, 14) were chosen that discussed findings regarding consumption and purchases of fruits and vegetables in low-income women. Henry and colleagues (14) used surveys as well to gather data but studied low-income African American women. The surveys were used to categorize women into various stages of change according to the Transtheoretical model. The Transtheoretical model is characterized by five stages of change; “pre-contemplation, contemplation, preparation, action, and maintenance.” Multiple questionnaires were used to measure self-efficacy and opinions regarding the benefits and drawbacks to increasing fruit and vegetable intake (14). Mothers (n=420) were selected to research the stages of change and how those stages are related to fruit and vegetable consumption (14). The researchers found that the highest variety and consumption of fruits and vegetables occurred in women in later stages of change, such as action and maintenance. Women who had higher self-efficacy scores were more likely to be in a higher stage of change when compared to women with lower scores (14).

Wiig and Smith (7) also conducted a study among low-income mothers. However, the focus was on food stamps and how an individual’s budget plays a role in food selection. The number of subjects was far less than the aforementioned studies at 92 participants, but the study

had no exclusions based on ethnicity. The researchers conducted focus groups to assess food choices and purchasing, as well as a grocery store shopping activity that had subjects prioritize 177 items on a theoretical food budget of \$50 per week (7). The focus groups revealed that the grocery store that subjects used most frequently depended on the proximity to their home as well as available sources of transportation (7). In addition, the researchers found that women reduced their own food intake to spare both the males and children in the household from experiencing hunger. When prioritizing food choices, low-income mothers chose processed meats including ground beef, hot dogs, and deli meats, as they were the highest valued items. Produce was found to be low on the priority list due to the perceived high cost and rate of spoilage (7).

Findings from these studies (7, 14) suggest the need to work on increasing self-efficacy in order to maintain successful dietary changes such as fruit and vegetable intake. Henry (14) and Wiig (7) had similar conclusions that nutrition education should be better tailored to this population by focusing on skills such as budgeting food dollars and meal preparation that involves less processed meats.

## Conclusions

*Research Findings.* A multitude of studies have shown that low-income, obese women face a number of disparities regardless of ethnicity (1, 2, 4, 7, 10-12, 17). These women have several challenges when implementing healthy eating habits, and due to their economic status they have altered views of what comprises a balanced diet (4, 11, 12). The importance of providing customized and culturally appropriate nutrition interventions have the potential to reduce food insecurity (11, 16) but also to promote weight loss and maintenance over time (15).

Nutrition interventions for this population should include educational and nutrition-related skills such as food preparation as well as budgeting (7, 10, 17).

*Current Trends in Research.* The most recent research on low-income, obese women has a wide variety of focuses, but the majority of studies focus on the best ways to implement appropriate interventions. Both implementing minority-specific nutrition education (3) and furthering investigation of current weight loss strategies and trends between different income levels is important (10). The great mass of data, when compiled, may provide a better idea of the road blocks these women face in regards to implementing a healthier lifestyle and promoting weight loss and maintenance. There has also been an increased interest in looking at temporal meal patterns and how timing of meals and snacks may influence one's compliance with dietary guidelines (30).

*Gaps in Literature.* A study such as Kakinami's (10) could not conclude why low-income populations do not utilize conventional weight loss strategies compared to those of higher socioeconomic status. The hunger-obesity paradox has proven to have a significant impact on women's diet quality as well as eating patterns (2, 11), but limited research has been completed on ways to break the feast and famine cycle. Current research has also found a correlation between consistent daytime eating patterns and compliance with dietary guidelines (30). Barriers to healthy eating such as lack of knowledge, skills, and time have been brought to surface, but specific interventions have yet to be addressed (3, 4, 7, 17). The available literature shows that research regarding tailored weight loss strategies needs to be further investigated. Additionally, how quality of intake and meal patterns change throughout the course of a weight loss intervention in this population should be considered. Hopefully these future investigations will

provide weight loss, more consistent eating patterns, and increased diet quality for this population.

## **Chapter 3: Methods**

### Overview

Data were collected from the \$ensible Weigh pilot study at the University of Kansas Medical Center. The parent study consisted of low-income women ( $n = 28$ ) equally randomized (1:1) either to a standard or population specific weight loss program. For this thesis project, diet quality, meal patterns, and fruit and vegetable consumption were compared at baseline, 3-months (end of weight loss phase), and 9-months (end of 6-month weight maintenance phase). Due to the small sample size, the two intervention groups were combined for this study.

### Sample

The recruitment sample for this study was 28 low-income women living in the Kansas City metropolitan area. Subjects included were: female, ages 21-70 years old, documented annual household income <185% of the federal poverty level or qualified for low-income programs such as WIC or food stamps, BMI of  $\geq 25.0 \text{ kg/m}^2$ , English speaking, and were capable of attending in-person sessions as well as had access to a telephone for maintenance sessions. Excluded subjects were those who had serious medical risks (i.e. insulin-dependent diabetes, recent cardiac complications, cancer), were currently or planning to become pregnant during the course of the study, those who had no control over food choices or purchases, currently participating in a weight loss program involving physical activity or diet intervention, being treated for disordered eating, had any serious food allergies, or consumed a strict diet (i.e. vegan, Atkins).

Participants were recruited from family medicine clinics, Women, Infants, and Children (WIC) clinics, and safety net clinics in the Kansas City metropolitan area. Strategies for

obtaining participants included flyers, advertisements and speaking at facility group meetings. Subjects were recruited on a rolling basis; a 5-week gap occurred between the initial 19 participants and the additional 9 participants. The study coordinator conversed with individuals on eligibility. If individuals were eligible, they received an explanation of the overall intervention, time commitment, and potential risks and benefits. A signed consent was required before participation (Appendix A). Computer software was utilized to equally assign subjects to the standard or intervention group.

### Setting

All assessments (baseline, 3-months, and 9-months) took place at the Clinical and Translational Science Unit (CTSU). For the weight loss phase (months 0-3), groups met weekly at the demonstration/metabolic kitchen area at the CTSU. Weight maintenance classes (months 4-9) were conducted via group conference call for both the standard and intervention group.

### Ethics

The research project is covered under the parent study through the University of Kansas Medical Center Human Subject Committee (HSC #1503). Each participant was required to sign a consent form before participation. Consent forms are included in the appendix.

### Procedures

Weight Loss Phase. Participants attended in-person weight loss meetings during months 0-3 that were 90 minutes in duration. To initiate changes in diet and physical activity, the Social Cognitive Theory (SCT) was utilized throughout the intervention in both groups (31). Due to the

limited income of participants, a \$5 voucher was given for each session attended in order to cover travel expenses to and from the CTSU building.

The standard weight loss program curriculum was modified from the Diabetes Prevention Program (32). The \$ensible intervention group followed the same structure as the standard program except that lessons on weight loss were condensed to incorporate conversation on barriers to food security and diet quality. Topics for the \$ensible (intervention) group included food dollar budgeting, community resources, meal planning, safe locations for physical activity, and basic culinary skills. Each session, the standard group received a snack prepared by the instructor with no cooking demonstration. In contrast, the \$ensible group either helped prepare a meal to learn culinary skills or the instructor gave the participants a culinary demonstration. Snacks for the \$ensible group were made with primarily cost effective ingredients or foods that could be received from a food pantry.

*Weight Maintenance Phase.* Maintenance sessions for both the Standard and \$ensible groups were conducted during months 4-9. Meetings were held via group conference call and lasted 60 minutes in duration. Phone sessions were conducted because previous trials have resulted in weight loss equivalent to those conducted in person (33, 34). The choice of utilizing group calls during the maintenance phase is also in consideration of reducing travel costs for participants; this tactic has been shown to reduce barriers in low-income populations (35). In the \$ensible group, lesson topics related to food security and budgeting were revisited, such as resources in the community, food dollar budgeting, as well as safe locations to exercise, in comparison to the standard group which there was no probing on such subjects.

*Dietary Intervention.* Energy needs for weight loss and maintenance were estimated using the Mifflin St. Jeor equation (36) multiplied by a factor of 1.4 to account for daily physical

activity. Participants were encouraged to reduce their intake by 500-700 kcal/day below total needs during the weight loss portion (months 0-3). The diet recommended to all subjects was a nutritionally balanced, reduced fat (20-30% of total kcal) diet as recommended by USDA's My Plate (37, 38) and the Academy of Nutrition and Dietetics (39). Throughout the course of the study, subjects were given counseling and examples of portion sizes for grains, meats, fats, vegetables, fruits, and dairy.

### Data Collection

Trained research staff conducted the following assessments at the CTSU at baseline, 3-months, and 9-months. Information gathered at a single session lasted approximately 60 minutes.

*Sociodemographic Information.* Participants filled out questionnaires at each assessment appointment, which provided their sociodemographic characteristics and past medical history (Appendix B).

*Dietary Intake.* Dietary intake was assessed using three standardized multiple-pass 24-hour recalls (Appendix C) accounting for 1 weekend day and 2 weekdays. This method has been shown to best reflect normal intake (40). Interviewers were tested for reliability on delivering a standardized dietary interview and had a computer coding error rate of less than 10%. The first recall for each participant was conducted in person using food models to enhance accuracy. The remaining 2 dietary recalls for each subject were obtained over the telephone. For the two phone calls, subjects were encouraged to use pre-labeled plates, bowls and cups indicating portion sizes to further improve accuracy as well as a one-dimensional portion size handout.

Nutritional Content. To determine the nutrient content of the subjects' intake at each time point, three 24-hour dietary recalls were entered into the Nutrition Data System for Research (NDSR, version 2014, University of Minnesota, Minneapolis, MN).

### Analysis of Data

Diet Quality. Diet quality was calculated using Healthy Eating Index 2010 (HEI-2010) scores (41). HEI-2010 is a measure of one's diet quality in comparison to the recommendations made by 2010 Dietary Guidelines for Americans developed by the USDA (38, 41). There are 9 dietary adequacy components which include total fruit, whole fruit, total vegetables, greens and beans, whole grains, dairy, total protein, seafood and plant proteins, and fatty acid ratio. A high score in each of the adequacy components represents a higher compliance of intake to the USDA guidelines. There are also 3 moderation components: refined grains, sodium, and empty calories. Dietary components that are recommended in moderation have an inverse relationship with scores. HEI-2010 scores were calculated by hand using the NDSR Intake Property (File 4) and Serving Count (File 9) outputs and using the University of Minnesota's, *Guide to Creating Variables Needed to Calculate Score for Each Component of the Healthy Eating Index-2010 (HEI-2010)* (See Appendix D). To calculate these scores, each subject's dietary intake was first assigned a score for each subcomponent based on intake per 1,000 kcals. These HEI component scores were then summed together to obtain an overall score ranging from 0-100. Higher overall scores reflect consumptions closer to the 2010 Dietary Guidelines for Americans.

Meal Patterns. Meal patterns were determined by observing the number of eating occasions and the nutritional content at each eating occurrence using NDSR Meal File and Intake Property outputs. General descriptive statistics for mean number of meals, snacks, and calories

from each time point were conducted. The mean number of snacks was compared to the mean number of meals for each 24-hour recall. Average percent of total calories from meals and snacks for each subject were compared from baseline to 3-months, 3-months to 9-months, as well as from baseline to 9-months in order to obtain a better understanding of how meal patterns may have changed.

*Fruit and Vegetable Consumption.* The Serving Count output files provided by NDSR were used to compare fruit and vegetables consumption. For fruit, average total fruit consumption was compared. Total fruit included fruit juices, citrus fruits, other whole fruits, avocados, and fruit-based snacks such as dried fruits. Vegetable components for this project were total vegetables and non-starchy vegetables. Total vegetables included dark green and yellow vegetables, tomatoes, potatoes, fried vegetables (potatoes, onion rings, etc.), legumes, and vegetables juice. Non-starchy vegetables encompassed dark green and yellow vegetables, tomatoes, and other vegetables such as beets and cabbage to name a few. Averages for each subject at each data collection point (baseline, 3-months, and 9-months) for the 1 weekend day and 2 weekdays were used to compare intake differences during the weight loss phase, weight maintenance phase, and across the overall intervention.

*Statistical Analysis.* To answer the primary question concerning diet quality, a one tailed, paired t-test was conducted at a significance level of 0.05 to see if there was a change in diet quality from baseline to 3 months, 3 months to 9 months, and baseline to 9 months. Dietary patterns as well as fruit and vegetable consumption were analyzed using paired t-tests to determine if there were changes throughout the course of the intervention with a p-value of <0.05 to judge significance. General descriptive statistics of overall dietary components were also run using data from NDSR.

## **Chapter 4: Results**

The purpose of this thesis project was to better understand diet quality and meal patterns in low-income overweight/obese women undergoing a weight loss intervention. Due to the small sample size, the two intervention groups in the \$ensible study were collapsed for this thesis project. Objectives included: observing changes in overall diet quality (HEI-2010 scores), meal and snack patterns, and fruit and vegetable consumption over the course of the 9-month intervention.

### **Subject Characteristics**

Of the screened participants, a total of 28 subjects consented to participate in the parent study. The average age of baseline participants was 46.4 years of which the majority was African American (n=19) with a mean BMI of 44.1 (Class 4 Obesity). The majority of subjects (57.1%) were classified as either marginal or high food security status. Demographic information is provided in Table 1.

**Table 1. Baseline Subject Characteristics**

Subject Characteristic	Total Sample n=28
Age (years)*	46.4 ± 10.9
Ethnicity**	
Hispanic or Latino	2 (7.1)
Non-Hispanic or Latino	18 (64.3)
Other or Unknown	8 (28.6)
Race**	
American Indian or Alaska Native	1 (3.6)
Black or African American	19 (67.9)
White	7 (25.0)
More Than One Race	1 (3.6)
Education Level**	
Some High School	1 (3.6)
High School Graduate or G.E.D.	5 (17.9)
Some College	13 (46.4)
Bachelor's Degree	4 (14.3)
Beyond Bachelor's Degree	5 (17.9)

\*Reported as Mean ± SD, \*\*Reported as N (%)

**Table 1. Baseline Subject Characteristics Continued**

Subject Characteristic	Total Sample n=28
Food Security Status**	
High Food Security	8 (28.6)
Marginal Food Security	8 (28.6)
Low Food Security	6 (21.4)
Very Low Food Security	6 (21.4)
Weight (pounds)*	261.0 ± 53.3
Height (inches)*	64.7 ± 2.8
BMI ( $\text{kg}/\text{m}^2$ )*	44.1± 10.1

\*Reported as Mean ± SD, \*\*Reported as N (%)

### Dietary Intake

A total of 137 dietary recalls were included in the analysis (68 at baseline, 45 at 3-months, and 24 at 9-months). Twelve 24-hour recalls were excluded from analysis due to questions of reliability or atypical consumption. Recalls considered for exclusion were those with  $\leq 800$  kcals or  $\geq 3000$  kcals in one day. Recalls determined not to be typical consumption for that subject were then excluded. Recalls that were coded as unreliable from the interviewer were also removed. Further details on dietary recalls that were excluded are provided in Table 2.

**Table 2. Excluded Data for Dietary Analysis**

Time point	$\leq 800$ kcals and untypical	$\geq 3000$ kcals and untypical	Coded as unreliable
Baseline	5	1	0
3 Months	4	0	1
9 Months	1	0	0

Average energy intake decreased from baseline (1,798.1 kcals) to the end of the 3-month weight loss period (1,301.4 kcals). At the end of the weight maintenance period participants consumed on average 1,591 kcals; less calories than at baseline, but increased from 3-months. Carbohydrate, protein, and fat (Table 3) and micronutrient consumption (Table 4) decreased

from baseline to three months. Pantothenic acid, calcium, and magnesium were below the Dietary Reference Intake (DRI) throughout the intervention.

**Table 3. General Macronutrient Characteristics**

	Baseline n = 28	3 Months n = 17	9 Months n = 9
Energy (kcals)	1798.1 ± 679.9	1301.4 ± 538.3	1590.9 ± 801.2
Carbs (g)	219.5 ± 110.9	149.9 ± 45.2	195.9 ± 88.9
Protein (g)	69.9 ± 25.5	50.6 ± 21.7	62.5 ± 34.4
Fat (g)	72.9 ± 29.7	52.3 ± 23.2	65.4 ± 40.8
Saturated Fatty Acids (g)	26.3 ± 10.3	17.1 ± 7.4	21.4 ± 13.4
Monounsaturated Fatty Acids (g)	25.6 ± 11.2	16.8 ± 8.5	22.3 ± 15.3
Polyunsaturated Fatty Acids (g)	18.8 ± 10.2	14.2 ± 8.4	16.5 ± 9.8
Trans-Fatty Acids (g)	2.7 ± 2.7	1.6 ± 1.1	2.4 ± 1.6
Fiber (g)	14.3 ± 8.3	14.3 ± 5.1	15.1 ± 10.8
% Carbs	47.6 ± 8.3	47.0 ± 9.5	49.8 ± 10.2
% Protein	16.8 ± 4.3	15.7 ± 3.3	15.4 ± 3.8
% Fat	35.5 ± 6.9	35.2 ± 7.8	34.7 ± 9.6

Mean ± SD

**Table 4. General Micronutrient Characteristics**

	DRI	Baseline n = 28	3 Months n = 17	9 Months n = 9
Thiamin (mg)	0.9*	1.4 ± 0.4	1.0 ± 0.4	1.2 ± 0.5
Riboflavin (mg)	0.9*	1.6 ± 0.6	1.2 ± 0.6	1.5 ± 0.8
Niacin (mg)	11*	20.2 ± 7.1	15.1 ± 7.2	16.4 ± 8.3
Pantothenic Acid (mg)	5**	4.2 ± 1.6	3.2 ± 1.6	4.3 ± 2.3
Vitamin B-6 (mg)	1.1* 19-50 years old 1.3* ≥51 years old	1.4 ± 0.6	1.2 ± 0.5	1.4 ± 0.8
Folate (mcg)	320*	334.1 ± 147.5	258.9 ± 157.6	325.4 ± 160.1
Vitamin B-12 (mcg)	2.0*	3.7 ± 1.8	2.2 ± 1.1	3.6 ± 2.1
Calcium (mg)	1000** 19-50 years old 1200** ≥51 years old	789.3 ± 276.5	620.2 ± 233.1	662.3 ± 272.6
Magnesium (mg)	255* 19-30 years old 265* ≥31 years old	226.2 ± 89.3	202.3 ± 53.5	233.8 ± 124.0
Zinc (mg)	6.8*	9.2 ± 4.4	6.2 ± 2.8	8.4 ± 5.7

Mean ± SD, \*EAR, \*\*AI

## HEI-2010 Scores

The mean HEI-2010 score at baseline was 47.3, and increased to 57.6 at 3-months, and decreased to 53.4 by 9-months. Across the course of the intervention mean scores in total vegetables, fatty acids, and sodium continually increased. The biggest changes in subcomponent scores was seen in the sodium subcomponent with a baseline score of 2.7 and increasing to 6.1 at 9 months. HEI-2010 subcomponents and overall mean scores can be found in Table 5.

**Table 5. HEI-2010 Scores**

Variable	Possible Score	Baseline (n = 28)	3 Months (n = 17)	9 Months (n = 9)
Total Fruit	5	1.8 ± 1.7	2.7 ± 1.8	2.4 ± 2.2
Whole Fruit	5	2.1 ± 1.8	3.0 ± 1.8	2.1 ± 2.1
Total Vegetables	5	3.0 ± 1.6	3.7 ± 1.2	3.7 ± 1.7
Green and Beans	5	2.1 ± 2.2	1.5 ± 2.1	3.7 ± 2.2
Whole Grains	10	2.9 ± 2.7	5.8 ± 4.1	3.9 ± 3.2
Dairy	10	4.9 ± 3.1	4.6 ± 2.9	4.7 ± 3.4
Total Protein Foods	5	4.8 ± 0.6	4.4 ± 1.2	4.4 ± 1.3
Seafood and Plant Protein	5	2.0 ± 2.2	2.5 ± 2.4	1.4 ± 2.1
Fatty Acids	10	4.2 ± 1.6	4.5 ± 3.3	5.0 ± 2.4
Refined Grains	10	5.6 ± 3.1	7.3 ± 3.0	6.2 ± 3.6
Sodium	10	2.7 ± 3.1	3.5 ± 2.9	6.1 ± 3.0
Empty Calories	20	11.3 ± 6.2	14.4 ± 4.9	11.7 ± 4.7
HEI-2010 Score	100	47.3 ± 12.6	57.6 ± 10.1	53.4 ± 15.3

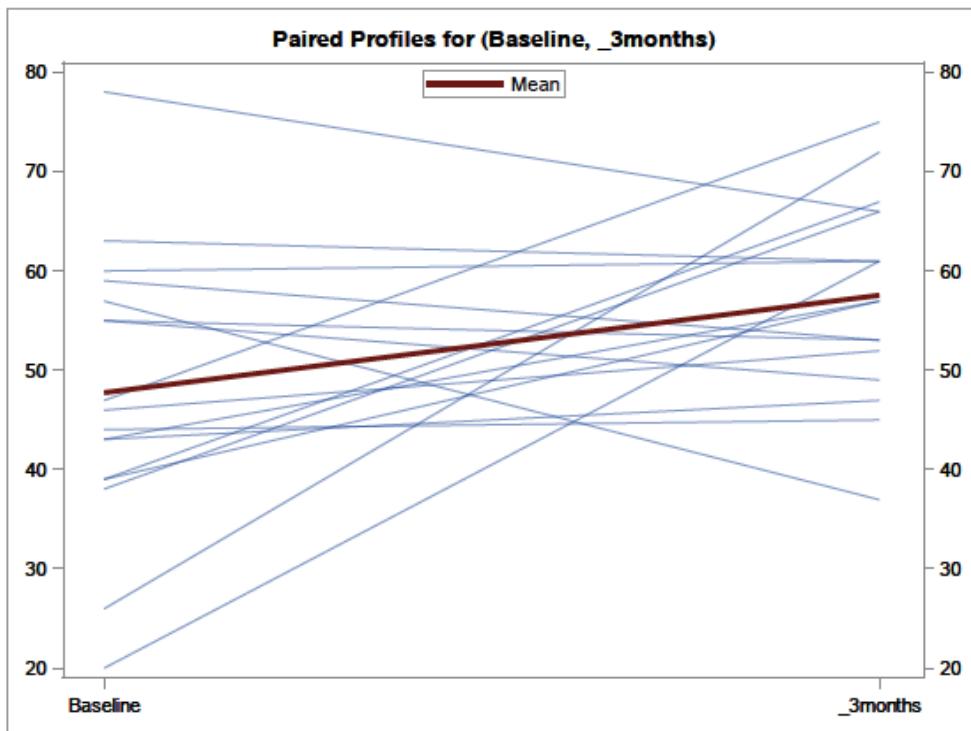
Mean ± SD

There were three comparisons conducted for analyzing HEI-2010 scores (baseline to 3 months, baseline to 9 months, and 3 months to 9 months) using paired t-tests. The largest average change in score was seen from baseline to 3 months (+9.8, p= 0.0477). No other significant changes in HEI-2010 scores were observed (Table 6). Further illustration of changes in HEI-2010 scores can be seen in Figures 1, 2, and 3.

**Table 6. Change in HEI-2010 Scores At Various Time Points**

n	Baseline	3 Months	Δ	P-value
17	47.8 ± 14.1	57.6 ± 10.1	+9.8 ± 18.9	0.0477
n	Baseline	9 Months	Δ	P-value
9	51.7 ± 14.9	55.3 ± 15.3	+3.7 ± 19.3	0.5847
n	3 Months	9 Months	Δ	P-value
9	59.0 ± 12.2	55.3 ± 15.3	-3.6 ± 12.0	0.3849

Mean ± SD

**Figure 1: Paired Profiles for HEI-2010 Score from Baseline to 3 Months**

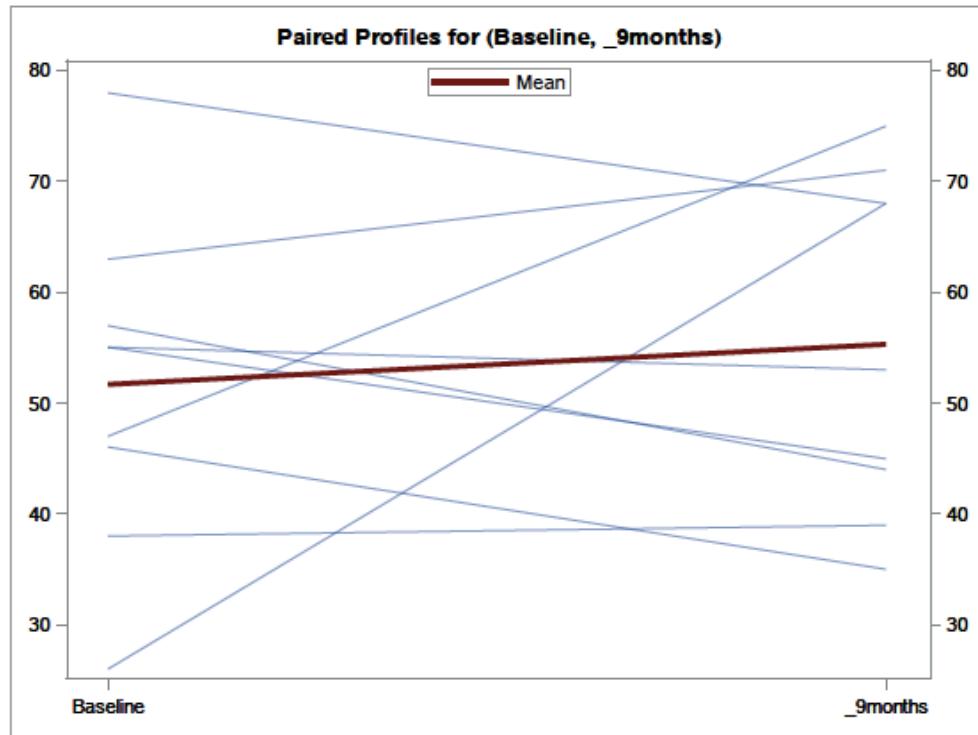


Figure 2: Paired Profiles for HEI-2010 Score from Baseline to 9 Months

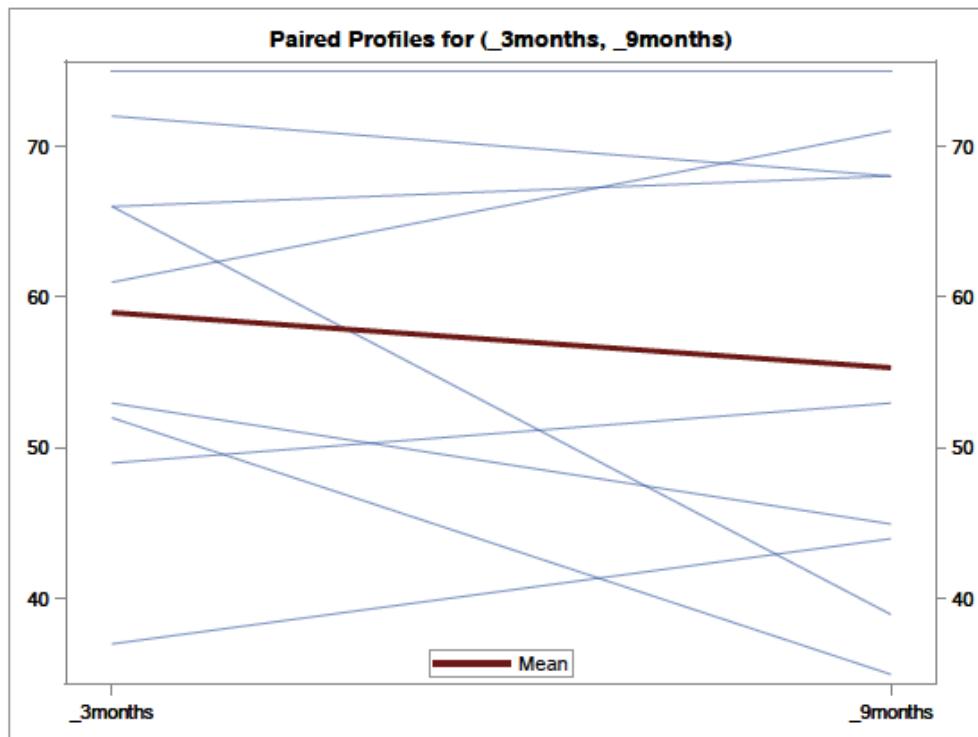


Figure 3: Paired Profiles for HEI-2010 Score from 3 Months to 9 Months

## Meal Patterns

The mean number of meals each subject reported was 2.5 (baseline), 2.5 (3-months), and 2.4 (9-months) throughout the course of the intervention. Average total calories from meals decreased from 1492.3 kcals at baseline to 1052.5 kcals at the end of the weight loss period. Observed eating patterns of 24-hour recalls showed 28.6% (baseline), 23.5% (3 months), and 11.1% (9 months) of subjects reporting  $\leq 2$  total eating occasions in one day and 25.0% (baseline), 29.4% (3 months), and 33.3% (9 months) were observed to have  $\geq 8$  hours in between any sort of eating occasion. Descriptive statistics for meals and snacks are provided in Tables 7 and 8.

**Table 7. Average Number of Meals and Snacks Throughout the Intervention**

	Baseline n = 28	3 Months n = 17	9 Months n = 9
Meals	2.5 $\pm$ 0.4	2.5 $\pm$ 0.4	2.4 $\pm$ 0.6
Snacks	1.3 $\pm$ 1.0	1.0 $\pm$ 0.8	1.4 $\pm$ 1.2

Mean  $\pm$  SD

**Table 8. Average Calories From Meals and Snacks Throughout the Intervention**

	Baseline n = 28	3 Months n = 17	9 Months n = 9
Meals	1492.3 $\pm$ 654.9	1052.5 $\pm$ 434.2	1236.1 $\pm$ 634.2
Snacks	281.9 $\pm$ 268.8	181.5 $\pm$ 180.4	300.0 $\pm$ 290.9

Mean  $\pm$  SD

To observe total percentage of calories from meals and snacks, a Person Correlation Coefficient was used to determine the relationship between percentage of calories from meals and percentage of calories from snacks. Meals alone were analyzed due to a correlation coefficient of -0.916 and a p-value of <0.0001. Table 9 shows the mean values of percent of total calories from meals and snacks throughout the course of the intervention.

**Table 9. Percent of Total Calories From Meals and Snacks Throughout the Intervention**

	Baseline n = 28	3 Months n = 17	9 Months n = 9
Meals	83.1 ± 14.3	83.0 ± 14.2	80.0 ± 11.9
Snacks	13.6 ± 11.7	12.9 ± 13.4	14.3 ± 12.5

Mean ± SD

Paired t-tests were used to observe changes in percentage of total calories from meals from baseline to 3-months, baseline to 9-months, and 3-months to 9-months. There were no significant changes as seen in Table 10.

**Table 10. Change in Percentage of Total Calories From Meals at Various Time Points**

n	Baseline	3 Months	Δ	P-value
17	82.7 ± 3.0	83.0 ± 3.0	+0.4 ± 22.7	0.9478
n	Baseline	9 Months	Δ	P-value
9	80.0 ± 5.2	80.0 ± 1.2	+0.0 ± 11.5	0.9903
n	3 Months	9 Months	Δ	P-value
9	80.8 ± 5.5	80.0 ± 1.2	-0.9 ± 26.5	0.9237

Mean ± SD

### Fruit and Vegetable Consumption

Three components of fruit and vegetable intake were measured: average total fruit, average total vegetables, and average total non-starchy vegetables. Means for each component of fruit and vegetable intake can be found in Table 11.

**Table 11. Fruit and Vegetable Consumption (cups) Throughout Intervention**

	Baseline n = 28	3 Month n = 17	9 Month n = 9
Total Fruit	0.5 ± 0.6	0.6 ± 0.6	0.7 ± 0.7
Total Vegetables	1.3 ± 0.7	1.3 ± 0.7	1.4 ± 1.2
Non-Starchy Vegetables	0.9 ± 0.6	1.0 ± 0.7	1.2 ± 1.1

Mean ± SD

Average Fruit Consumption. Using the paired t-test, total fruit consumption remained consistent with mean changes of +0.1 (baseline to 3 months), -0.1 (3 month to 9 months), and 0.0 (baseline to 9 months). There were no significant changes in average total fruit consumption over the course of the study (Table 12).

**Table 12. Changes in Total Fruit Consumption (cups) Throughout the Intervention**

n	Baseline	3 Months	Δ	P-value
17	0.5 ± 0.2	0.6 ± 0.1	+0.1 ± 0.8	0.720
n	Baseline	9 Months	Δ	P-value
9	0.8 ± 0.3	0.7 ± 0.2	-0.1 ± 1.0	0.829
n	3 Months	9 Months	Δ	P-value
9	0.8 ± 0.2	0.7 ± 0.2	0.0 ± 0.8	0.893

Mean ± SD

Average Total Vegetable Consumption. A slight increase in total vegetable consumption was observed over the course of the intervention using paired t-tests. However, these changes were not statistically significant at any of the time points (Table 13).

**Table 13. Changes in Total Vegetable Consumption (cups) Throughout the Intervention**

n	Baseline	3 Months	Δ	P-value
17	1.1 ± 0.7	1.3 ± 0.7	+0.2 ± 0.9	0.355
n	Baseline	9 Months	Δ	P-value
9	1.3 ± 0.8	1.4 ± 1.2	+0.2 ± 0.7	0.515
n	3 Months	9 Months	Δ	P-value
9	1.3 ± 0.8	1.4 ± 1.2	+0.1 ± 1.2	0.811

Mean ± SD

Average Non-Starchy Vegetable Consumption. Consumption of non-starchy vegetables showed an increase over the course of the intervention, with the largest increase in consumption observed between baseline and 9 months (mean of +0.3 cups). No significance was found however throughout the time points (Table 14).

**Table 14. Changes in Non-Starchy Vegetable Consumption (cups) Throughout the Intervention**

n	Baseline	3 Months	Δ	P-value
17	0.8 ± 0.6	1.0 ± 0.7	+0.2 ± 0.7	0.353
n	Baseline	9 Months	Δ	P-value
9	0.9 ± 0.8	1.2 ± 1.1	+0.3 ± 0.4	0.082
n	3 Months	9 Months	Δ	P-value
9	1.1 ± 0.8	1.2 ± 1.1	+0.1 ± 1.0	0.829

Mean ± SD

## **Chapter 5: Discussion**

This thesis project aimed to measure diet quality, meal patterns, and fruit and vegetable consumption in low-income, overweight women undergoing a weight loss intervention addressing barriers to increasing diet quality and food security. Due to the increased prevalence of obesity in women of low-income in comparison to higher incomes (19) and the health risks associated with obesity (20) this population is of special concern. Previous studies (7, 14, 17) have shed light on barriers to healthy eating habits in this population such as nutritional knowledge, culinary skills, and overall attitude towards healthful foods. The hope of this study was to witness changes in diet quality, meal patterns, and fruit and vegetable intake when low-income women participated in an intervention specific to decreasing anticipated barriers to healthier eating.

### **Sample**

Out of the initial 28 subjects at baseline, only nine completed the entirety of the study. The subjects being of low socioeconomic status is a possible reason for the high attrition rate. One reason for drop out was multiple changes in employment status throughout the course of the intervention, which often resulted in an inability to continue to attend classes or participate in follow-up appointments. Organizing transportation to and from in-person classes and appointments was also an issue for several participants. Various life events also prevented full participation. Though the parent student originally observed two different intervention groups, the 19 subjects dropping out throughout the course of the intervention resulted in collapsing data for this project, which impacted the overall dietary analysis.

The average age of baseline participants was 46.4 years of which the majority were African American (n=19) with a mean BMI of 44.1 (Class 4 Obesity). Though this study included those who were overweight or obese, the baseline statistics support previous research (19) that women who are African American as well as low-income have a higher prevalence of obesity in comparison to other races or socioeconomic statuses. A high percentage of subjects at baseline were considered food insecure (42.86%). The combination of high prevalence of food insecurity and obesity in low-income women parallels previous research (13, 27).

### Dietary Intake

This study took a closer look at the macronutrient consumption as well as specific micronutrients throughout the course of the weight loss intervention. During the weight loss period (months 0-3), average total calorie intake decreased by 496.7 kcals. The decrease showed adherence to the intervention's goal of decreasing caloric intake by 500-700 kcals below total needs for the weight loss portion of the study. Subjects also decreased consumption of saturated fatty acids (26.3 to 17.1 grams) and trans-fatty acids (2.7 to 1.6 grams) from baseline to 3 months. However, on average subjects consumed 35% of total calories from fat throughout the intervention, thus not meeting the recommended low-fat diet (37-39) consisting of 20-30% of total calories from fat.

Specific micronutrients were analyzed due to findings from Seligman and colleagues (6), who expressed that low-income populations are at increased likelihood to have insufficient consumption of specific nutrients. Data showed that the subjects consistently fell below the Dietary References Intake (DRI) for pantothenic acid, calcium, and magnesium. Nutrients such as vitamin B6, folate, and zinc also fell below the DRI at the conclusion of the weight loss

portion of the study. The decline in these micronutrients could be due to the caloric restriction (-496.7 kcals) during this time period. The results reiterate findings from Seligman (6) that persistently low-quality diets, particularly during the hunger-obesity paradox, increase risk for deficiency in B vitamins, magnesium, iron, zinc and calcium. The persistently low intakes of pantothenic acid, calcium, and magnesium seen in this study are concerning for potential development of deficiencies over time.

### HEI-2010 Scores

The primary objective of this study was to determine if diet quality would change throughout the course of a weight loss intervention for overweight or obese, low-income women. Healthy Eating Index 2010 (HEI-2010) scores were calculated from 24-hour recalls over the course of the intervention to measure overall diet quality. It was predicted that subjects would have a significantly higher diet quality (HEI-2010 score) from baseline to 3 months, baseline to 9 months, and no change from 3 months to 9 months.

Trends in HEI-2010 scores showed an increase both from baseline to 3 months and baseline to 9 months, but a decrease in diet quality from 3 to 9 months. It was found that the HEI-2010 score from baseline to three months was significant while the remaining time points were not. In comparison to the general American population (42), participants in this study exceeded average HEI-2010 subcomponent scores at 3 months and 9 months for total vegetables (3.7 vs. 3.4), whole grains (5.8 vs. 2.9), refined grains (7.3 vs. 6.2), and empty calories (14.4 vs. 12.6). Additionally, subcomponent scores at 9 months were greater in greens and beans (3.7 vs. 2.9), fatty acid ratio (5.0 vs 4.67), and sodium (6.1 vs 4.2).

All of these dietary components were discussed during the educational sessions, thus reinforcing consumption of produce and whole grains and limiting fat, sodium, and excess calories. Although some diet quality subcomponents were greater than that of the general American population, the average total HEI-2010 scores were below the average U.S. score of 59 during the entirety of this study (42).

The 9.8 point mean increase in HEI-2010 scores during the weight loss phase, though weakly statistically significant ( $p=0.0477$ ), showed that there was an overall shift in diet quality from baseline to 3 months. The change in diet quality during this time period was due to increased scores in total fruit, whole fruit, total vegetables, whole grains, sodium, and empty calories. Increasing consumption of fruits, vegetables, and whole grains as well as restricting sodium and empty calories were all emphasized in the intervention. The increases observed from baseline to 3-months could be considered clinically relevant as it could potentially decrease the risk of micronutrient deficiencies (6). The decrease in diet quality scores observed during the weight maintenance period (3 to 9 months) could have resulted from the decline in fruit and whole grain consumption as well as the increase in consumption of empty calories as reflected by the subcomponent HEI-2010 scores.

Finding from this study are similar to those reported by Kakinami and colleagues (10). Kakinami et al. (10) found that individuals of lower socioeconomic status attempting to lose weight were less likely to follow a more healthful diet in comparison to those of higher socioeconomic status. In order to combat poor diet quality in this population, research (16, 17) suggests interventions should focus on decreasing barriers to food security in order to obtain a higher quality diet. The present study was not successful in attaining this goal, possibly because of attrition rates, small sample size, and lack of power analysis. Future research should include a

larger sample in order to account for anticipated participant drop out in this population as well as establish what changes in HEI-2010 score equate to clinical relevance.

### Meal Patterns

In order to observe meal patterns, the mean number of meals and snacks as well as average calories from meals and snacks were observed. Due to encouragement throughout the intervention to establish a balanced meal pattern and to avoid long periods of time without eating, it was predicted that there would be an increase in the number of meals and snacks from baseline to 3 months and baseline to 9 months, but no change from 3 to 9 months during the intervention. Contrary to what was expected, the number of meals and snacks stayed consistent across the intervention period with an average of 2.5 meals and 1 snack per day. Although the number of eating occasions stayed consistent, calories from meals and snacks varied over the course of the intervention. Calories from meals decreased by 439.8 kcals during the weight loss period. These decreases could be due to the overall goal of the weight loss period to decrease caloric intake. Mean calories from snacks were highest at 9 months, increasing by 18.1 kcals from baseline and 118.5 kcals from 3 months.

The shift in calories from snacks and meals throughout the course of the intervention show that even though the number of eating occasions may not change, the amount of calories consumed can vary. A study by Kerver and colleagues (29) found that those who consistently consumed three meals and one to two snacks per day had the highest intake of micronutrients. Since the average number of meals consumed in the present study was approximately 2.5 per day, it is possible that participants could have been consuming inadequate micronutrients due to not consuming three meals per day.

Throughout the course of this study, the number of participants reporting  $\geq 8$  hours between eating occasions (7 subjects at baseline, 5 subjects at 3 months, and 3 subjects at 9 months) decreased as well as those reporting  $\leq 2$  total eating occasions (8 subjects at baseline, 4 subjects at 3 months, and 1 subject at 9 months). These irregular meal patterns and periods of periodic fasting are comparable to findings of Kakinami and colleagues (10) who concluded that lower income individuals are inclined to fast and skip meals to achieve weight loss in comparison to those of higher incomes. Research by Cahill (43) showed that 4-16 hours post-feeding the body is in an early fasting state. During early fasting, one's body relies on stored fuel such as lipids and glycogen due to a lack of exogenous glucose (43). The present study did not assess the reason for inconsistent meal patterns reported. This area is in need of further investigation.

When observing mean percentage of total calories from meals, a decreasing trend was observed. The decrease in percent of calories from meals was a result of a higher number of calories from snacks. However, when looking at only subjects who could be paired at the various time points, no significant difference was found. It appears that the subjects' meal patterns throughout the course of this intervention remained consistent. No previous studies have observed meal patterns in such a way in low-income, overweight women before. Research on temporal eating patterns, intermittent fasting, and diet quality, such as that conducted by Eicher-Miller and colleagues (30), specifically in low-income populations should be further explored.

### Fruit and Vegetable Consumption

Another objective of this study was to detect changes in fruit and vegetable intake over the course of the intervention. Fruit and vegetable consumption is a topic of concern because

low-income populations consume fewer servings in comparison to those of higher socioeconomic status (6, 26). Fruit and vegetable intake was measured by looking at mean servings (cups) of total fruit, vegetables, and non-starchy vegetables consumed. Previous research (14) has shown that increasing self-efficacy in low-income women results in an increase in variety of foods consumed, including an increase in consumption of fruits and vegetables. It was expected that fruit and vegetable intake would increase after baseline and that subjects would maintain an increased fruit and vegetable consumption over the course of the weight maintenance period (3 to 9 months).

The results showed an increasing trend in total vegetables, non-starchy vegetables, and total fruit consumed across the intervention. However, paired t-test results showed little overall change in total fruit consumption. The lack of trends could be due to the paired t-test including only those who participated in 9 month testing ( $n = 9$ ). Another possible reason is the low priority to purchase produce in this population due to the perceived high cost and rate of spoilage (7). Overall subject's fruit (0.6 vs 1.0 cups) and vegetable (1.3 vs 1.6 cups) intake continued to be less than those of higher socioeconomic status throughout the course of the intervention. These findings were similar to previous research (6, 26).

Previous studies (7, 14) have called the need to tailor nutrition education to this target population by focusing on aspects such as savvy shopping and managing food dollars to make changes in overall diet quality and fruit and vegetable consumption. This current study showed the potential of interventions tailored to one's socioeconomic status to make changes in produce consumption, specifically total and non-starchy vegetables.

## Limitations

There were several limitations to this study. First, the study had a small sample size. As the parent study progressed, the number of participants continued to decrease resulting in a collapsing of the two intervention groups for the current study. Because of the collapsing of groups, not every participant received the same intervention. Some did not receive education, resources, and cooking classes related to combating food insecurity.

The declining sample size resulted in a large confidence interval when conducting paired t-test analyses making it increasingly difficult to find statistically significant results. P-values also had to be adjusted to account for multiple comparisons (i.e. baseline to 3-months, baseline to 9-months, 3-months to 9-months) making it arduous to find statistical significance. Given that the current study is based off of a pilot study, no power analysis was calculated to determine a fitting sample size. Future research will need to be conducted with an established power and larger sample size.

The results of this study were also dependent on the clarity and level of detail of the dietary interviewers throughout the course of the study. Even with the utilization of the multiple-pass approach for 24-hour recalls and visual aids to increase accuracy, the recalls still cannot be determined as 100% accurate. There is also the possibility of subject bias in under reporting or over reporting certain foods, consciously omitting foods, misjudgment of portions, as well as loss of memory of what was consumed.

Another limitation is that this research project is a secondary analysis conducted after the conclusion of the parent study. This is a limitation because obtaining any further dietary details was not possible. Meal patterns as well as fruit and vegetable consumption were not measures

of the parent study, presenting limitations for this secondary analysis. There was no way to add additional surveys and assessments to look at these two components.

### Implications and Future Studies

The increase observed in diet quality scores from baseline to 3-months, in combination with increased fruit, total and non-starchy vegetable intake seen during this time point shows promise. These results imply that focusing on meal planning, budgeting, and culinary skills with low-income women can result in changes in dietary intake for the better. More research still needs to be conducted on a larger scale to see if these trends are consistent. Future studies implementing weight loss interventions in overweight or obese low-income women should additionally explore micronutrient adequacy in a larger sample size as well as further investigate temporal meal patterns and how that may be related to overall diet quality in the target population.

### Conclusion

The current study explored dietary changes in low-income, overweight or obese women undergoing a weight loss intervention. The increase in diet quality, fruit, and vegetable consumption seen amid the weight loss portion displays promise that interventions designed to reduce barriers to food security can make an impact in this population. However, no significant changes were seen following the weight maintenance period. Therefore, future diet and weight loss studies should aim for a larger sample size and further stress the importance of maintaining diet quality during the weight maintenance intervention.

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## **Appendix A: Research Consent Form**

**Page 1 of 9**

**The \$ensible Weigh Program**

### **RESEARCH CONSENT FORM**

The \$ensible Weigh Program: An Intervention Tailored for Low Income Women

Funding Sources: *Frontiers* Pilot and Collaborative Studies Funding Program and the

KUMC Research Institute Clinical Pilot Program

Principal Investigator: Jeannine Goetz, PhD

Phone number: 913-588-1449

You are being asked to join a research study. Participating in research is different from getting standard medical care. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at the University of Kansas Medical Center (KUMC).

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read it carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating.

This research study will take place at the University of Kansas Medical Center (KUMC) with Dr. Jeannine Goetz as the researcher. About 30 people will be in the study at KUMC.

#### **Why am I being asked to take part in this study?**

You are being asked to take part in this study because you are an overweight and low income woman living in Kansas City.

#### **Why is this study being done?**

Low income women are at greater risk of both obesity and food insecurity (not having consistent access to nutritious and adequate amounts of food). Most weight loss programs targeted at low income women do not focus on gaining skills and knowledge to reduce food insecurity.

By doing this study, researchers hope to learn if a weight loss program especially designed to address food insecurity is more effective compared to a standard weight loss program.

**Page 2 of 9**  
**The \$ensible Weigh Program**

**How long will I be in the study?**

If you are eligible and decide to participate in this study, your participation will last approximately 9 months.

**What will I be asked to do?**

If you agree to participate, you will be asked to sign a consent form. You will receive a copy of your consent form for your records.

You will randomly be assigned (like flipping a coin) to one of the following weight management programs:

- Standard weight management program: You will be given information on diet and exercise. You will have meetings to discuss barriers to exercise and nutrition and ways to solve these problems. You will be given healthy snack ideas and planning tools.
- \$ensible Weigh Program: You will be given information on diet and exercise with an emphasis on food security. You will be provided with additional information on community resources such as those for food, transportation, and safe places to exercise. A weekly cooking demonstration will be provided using inexpensive ingredients and common food pantry items.

You will have a 1 in 2 chance (50%) of being assigned to either program. There are several components to the programs, outlined below. The main difference between the two programs is the content of the group meetings.

For either program you will be asked to do the following:

- Maintain confidentiality of the group and not disclose the information discussed in your meetings.
- Be aware that all meetings will be audio recorded to evaluate the quality and uniformity of curriculum delivery. Recordings will not be transcribed. The recordings will be saved to our University's secure server for 15 years, as required by KUMC policy, labeled using cohort and week numbers, and erased from all recording devices. The recordings will be treated confidentially, like all other data collected in the study.
- Try to attend all of the group meetings. You will be asked to attend at least 9 out of every 12 scheduled meetings. Attendance is defined as participant presence at the start of the meeting through the end of the meeting. Failure to attend the minimum required meetings may result in dismissal from the project.

There are two phases in the weight management program: a weight loss and weight maintenance phase.

### **Weight loss phase**

This phase will last 3 months and will consist of:

- 1) **Group meetings:** You will be asked to participate in weekly in-person meetings with other study participants. The meetings will last about 1 ½ hours. They will take place at the KU - Clinical Research Center located at 4350 Shawnee Mission Parkway, Fairway, KS 66205. The sessions will be led by a trained health educator. Before each meeting, you will be weighed in a private area.
  - a) **Standard program:** You and the other participants will have the opportunity to share your experiences, to discuss strategies for sticking to your diet and exercise plans, and to offer support. You will participate in general weight loss lessons and be given a homework assignment to complete before the next session.
  - b) **\$ensible weigh program:** You and the other participants will have the opportunity to share your experiences, to discuss strategies for sticking to your diet and exercise plans, and to offer support. You will participate in weight loss lessons that will cover topics related to food insecurity. You will receive additional information on community resources such as those for food, transportation, and safe places to exercise. Your lesson will include a weekly cooking demonstration using low cost and staple ingredients.
- 2) **Diet:** You will be asked to eat a nutritionally balanced, low fat diet. The study team will calculate how many calories you can eat in order to lose weight. You will be given examples of meal plans consisting of suggested servings of grains, proteins, fruits, vegetables, dairy, and fats based on your calorie needs. You will be shown appropriate portion sizes.
- 3) **Exercise:** You will be asked to participate in exercise, at about 150 minutes per week. You will choose your own activities based on what you find most convenient and enjoyable. You will be given a pedometer and you will be asked to wear it to keep track of the number of steps you have taken.
- 4) **Diet and exercise logs:** You will be asked to keep track of your diet and exercise. Each day, you will need to record your food and beverage intake, minutes of exercise, and total number of steps taken. You will be asked to bring your logs to group each week.

### **Weight maintenance phase**

This phase will last 6 months and will consist of:

- 1) **Group meetings:** You will continue to participate in meetings with other study participants but they will be conducted over the phone. For the first 3 months, the meetings will occur every week. For the last 3 months, the meetings will occur every other week. The sessions will be led by a trained health educator. You will be provided with instructions on how to call in to the meeting. The meetings will last about an hour.

**Page 4 of 9**  
**The \$ensible Weigh Program**

- 2) Diet: You will be asked to continue to eat a nutritionally balanced, low fat diet. The study team will calculate how many calories you can eat in order to maintain your weight loss.
- 3) Exercise: You will continue to exercise 150 minutes per week. You will continue to wear your pedometer to keep track of the number of steps you have taken.
- 4) Diet and exercise logs: You will continue to keep track of your diet and exercise. You will be asked to either email or call your health educator with your log information each week. You will be provided with a digital scale and asked to report your weight each week when you email or call your health educator.
- 5) Focus group: At the end of the program, you will be asked to attend a focus group which will last approximately 1 hour. You will be asked questions about what you liked and disliked about the program and what changes you would make to it.

**Study visits (Months 0, 3, and 9)**

Regardless of which program you are assigned to, you will be asked to come to the KU-Clinical Research Center for 3 study visits. Each visit will take about 1 hour. You will be asked to fast (not eat or drink anything but water) for at least 8 hours before the study visit. The following activities will occur at the study visits:

- 1) Your weight, height, and waist circumference will be measured.
- 2) Your blood pressure will be measured.
- 3) A trained staff member will ask you about everything you ate or drank on the previous day. You will also be asked to schedule two additional times for the staff member to call and ask again about what you had to eat or drink on the previous days.
- 4) You will be asked to complete several questionnaires about your eating and exercise habits and food security status.
- 5) You will be asked to wear an accelerometer, which is a device that keeps track of the amount and intensity of your day-to-day activity. The device is worn around your waist on a belt provided by the study team. The study team will fit the device to you and provide instructions for how to use it. You will be asked to wear it for 7 consecutive days and return it to the study team by mail using a postage-paid padded envelope provided by the study.

**What are the possible risks or discomforts?**

Weight Loss

**Page 5 of 9**  
**The \$ensible Weigh Program**

There are minimal risks associated with moderate calorie restriction when supervised by a registered dietitian, as will be done in this program.

**Group meeting risks**

It is possible that confidentiality of the group sessions would not be maintained as other subjects may disclose information heard during a meeting.

**Exercise risks**

There are certain risks and discomforts that may be associated with exercise that include temporary shortness of breath, muscle fatigue, muscle soreness, sweating, and physical discomfort. Also, there exists the possibility of an undiagnosed medical problem that may surface during exercise. These include abnormal blood pressure response, fainting, irregular, fast, or slow heart rate, and in rare instances, heart attack, stroke, or death. The study team will work with you to gradually increase your physical activity levels to minimize these risks.

**Questionnaire risks**

There is a risk of feeling uncomfortable while answering some of the questions in the questionnaires. If you feel uncomfortable at any time, you may skip a question or stop answering questions all together.

**Pregnancy risks**

If you become pregnant while taking part in this study, please inform the study team; you will not be able to continue the study.

**Possibility of unknown risks**

There may be other risks of the study that are not yet known.

**Are there benefits to being in this study?**

You may or may not benefit from this study. Researchers hope that the information from this research study may be useful for developing a weight loss program for women who experience food insecurity.

**Will it cost anything to be in the study?**

You will not incur expenses for assessments directly related to this study. Specifically covered are the following:

- Group meetings
- Use of accelerometer
- Pedometer, which is yours to keep.
- Digital scale, which is yours to keep.

You or your insurance will be billed for standard medical care that is not part of the study. Your insurance or government health program may not cover certain items if you are part of a research study. You may want to talk to your insurance company before deciding to participate.

**Page 6 of 9**  
**The \$ensible Weigh Program**

**Will I get paid to participate in the study?**

You will receive \$20.00 for each of the three study visits. You will receive \$5.00 for each in-person group meeting you attend to help cover your transportation costs. You will also receive \$20 for attending the focus group session at the end of the program. You may receive up to \$140.00 if you complete all study visits, attend all in-person group meetings, and attend the focus group. If your participation in this study ends early, you will be paid only for the study visits and in-person group meetings you have completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available in approximately 1-2 business days. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments from participating in research studies are \$600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

**Will the researchers get paid for doing the study?**

The research team and the institution (KUMC Research Institute, Inc.) will receive payments from the funding sources, *Frontiers* Pilot and Collaborative Studies Funding Program and the KUMC Research Institute Clinical Pilot Program, for conducting this study. Payments will be used for research purposes only.

**What happens if I get hurt or sick during in the study?**

If you have a serious side effect or other problem during this study, you should immediately contact Dr. Goetz at 913-588-1449. If it is after 5:00 p.m., a holiday or a weekend, you should call 660-864-5483. A member of the research team will decide what type of treatment, if any, is best for you at that time.

If you have a bodily injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party, but you will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

If you think you have been harmed as a result of participating in research at the

**The \$ensible Weigh Program**

University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow payment to persons who are injured in research at KUMC.

**Do I have to be in the study?**

Being in research is voluntary. You can choose whether or not to participate. Even if you decide not to join the study, you can still come to KUMC for services and treatment.

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

**What other choices do I have?**

You can choose not to be in the study. You can talk to your doctor about other weight loss options. Alternate methods of weight control include dieting, counseling, surgery, drug therapies, and exercise. These may be pursued at a variety of settings including clinics, hospitals, and private businesses.

**How will my information remain confidential?**

The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

**Can I stop being in the study?**

You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC.

**Could my participation be stopped early?**

This study might be stopped, without your consent, by the investigator. Your participation also might be stopped by the investigator if it is in your best interest or if you do not follow the study requirements.

The investigator will not be obligated to provide you with any treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

**Who can I talk to about the study?**

Before you sign this form, Dr. Goetz or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not

**Page 8 of 9**  
**The \$ensible Weigh Program**

involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**CONSENT**

Dr. Goetz or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.

***You will be given a signed copy of the consent form to keep for your records.***

---

Print Participant's Name

---

Signature of Participant

---

Time

---

Date

---

Print Name of Person Obtaining Consent

---

Signature of Person Obtaining Consent

---

Date

**Page 9 of 9**  
**The \$ensible Weigh Program**

**PERMISSION TO CONTACT YOU IN THE FUTURE**

We would like to contact you via phone and/or email, 1 and 2 years after you end the study. You will be asked questions about your dietary/physical activity patterns and food security. We will also ask for your current body weight. We anticipate these calls/surveys will take approximately 10 – 15 minutes.

- Yes, I agree to allow the study team to contact me in the future.  
 No, I do not agree to allow the study team to contact me in the future.

---

Print Participant's Name

---

Signature of Participant

---

Time

---

Date

---

Print Name of Person Obtaining Consent

---

Signature of Person Obtaining Consent

---

Date

## **Appendix B: Health History and Demographic Questionnaire**

### **\$ensible Weigh Study General Health History Screener & Demographic Questionnaire**

Last Name \_\_\_\_\_ First Name \_\_\_\_\_ Middle Initial \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

Home Phone: (    ) \_\_\_\_\_ Cell Phone: (    ) \_\_\_\_\_

Work Phone: (    ) \_\_\_\_\_ Email: \_\_\_\_\_

Preferred Method of Contact: \_\_\_\_\_

Social Security Number: \_\_\_\_\_ (for study payment only)

Age: \_\_\_\_\_ Date of Birth: \_\_\_\_\_ Gender: M    F

Which of the following would you say best represents your ethnicity?

- Hispanic or Latino (1)
- Not Hispanic or Latino (2)
- Other or Unknown (3)

Which of the following would you say best represents your race?

- American Indian or Alask Native (1)       White (5)
- Asian (2)     More than one race (6)
- Native Hawaiian or Other Pacific Island (3)     Unknown (7)
- Black or African American (4)

Which of the following would you say best represents your education level?

- Special Education (1)     Some College (6)
- Up to Eight Grade (2)     Bachelor's Degree (7)
- Some High School (3)     Beyond Bachelor's Degree (8)
- High School Graduate or G.E.D (4)                           Don't Know (99)
- Post High School, Not College (5)

**For office use only: BMI: \_\_\_\_\_ Eligible?  Yes  No**

Please provide your estimated current height and weight: Ht: \_\_\_\_\_ inches  
Wt: \_\_\_\_\_ pounds

1. Do you have or have you ever had any of the following medical conditions?

	Approximate Date/Year of Diagnosis	Describe the Problem
Heart Attack	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Angina (chest pain on exertion)	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Irregular Heart Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Other Heart Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Stroke	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Fainting Spells	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
High Blood Pressure	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
High Cholesterol	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Thyroid Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Cancer	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Kidney Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Liver Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Gout	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Bowel Disorder	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Diabetes	<input type="checkbox"/> yes <input type="checkbox"/> no	Type: _____
Asthma	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Arthritis	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Seizures/convulsions	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Emotional/Psychiatric Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Drug/Alcohol Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Eating Diorder	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
Other: _____	<input type="checkbox"/> yes <input type="checkbox"/> no	_____

**Please use the space below to write additional information about any of the above conditions**

2. Are you currently pregnant?      yes   no

3. Were you pregnant within the past 6 months?      yes   no

4. Do you plan to become pregnant in the next 9 months? yes no

5. Have you had a hysterectomy? yes no

6. Do you have regular periods? yes no

If NO please explain:

---

7. When was your last menstrual period? DATE: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

8. Do you take :

Birth Control Pills? yes no

Estrogens (ie. Premarin)? yes no

Progesterone (ie. Provera)? yes no

9. Do you have any medical problems that would prevent you from participating in a regular exercise program? yes no

If yes, please describe the

problem: \_\_\_\_\_

---

10. Have you lost or gained more than 10 lbs. within the past 3 months? yes no

a. If "yes" how much weight did you lose or gain? \_\_\_\_\_ lbs.

b. Was it a gain or loss? gain loss

11. Have you had any surgery in the past 12 months? yes no

If yes, please describe the

surgery: \_\_\_\_\_

---

12. Allergies: Have you ever had a reaction to any of the following? If yes, please explain.

Milk/dairy products	Y	N	_____
Eggs	Y	N	_____
Soy products	Y	N	_____
Corn products	Y	N	_____
Wheat gluten	Y	N	_____
Other food	Y	N	_____
Vitamins	Y	N	_____

Drugs or medications      Y      N      \_\_\_\_\_

13. Do you currently take any medication (over-the-counter or prescription)?     yes     no

If "yes" please list all medications that you are currently taking on a regular basis:

**MEDICATION**

**REASON FOR TAKING**

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

14. Do you currently take any nutritional or herbal suppelements (i.e., Rip Fuel, Metabolife, Creatine, Ginkgo, Vitamin Supplements)?     yes     no

If "yes" please list all supplements that you are currently taking on a regular basis:

**SUPPLEMENT**

**REASON FOR TAKING**

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

15. Have you participated in a regular exercise program over the past 3 months which consists of at least 20 minutes of activity of moderate intensity, continuous activity , 3 day a week or any amount of Resistance Trianing?     yes     no

If "yes" please describe:

<b>Activity</b>	<b>Duration (minutes)</b>	<b>Days/Week</b>
i.e., jogging	25 min.	2 days/week

_____	_____
_____	_____
_____	_____
_____	_____

16. Over the last 6 months, on how many weekdays (Monday through Friday) do you usually drink wine, beer, or liquor on average?

(0)     Never

(4)     2 days/week

- (1)  Less than once/month      (5)  3 days/week  
(2)  1-2 times/month      (6)  4 days/week  
(3)  1 day/week      (7)  5 days/week
17. On those weekdays that you drink wine, beer, or liquor how many drinks do you have?  
**(Please provide one number, not a range.)** \_\_\_\_\_

18. Over the last 6 months, on how many weekend days (Saturday and Sunday) do you usually drink wine, beer, or liquor?
- (0)  Never      (4)  1 weekend day/week  
(1)  Less than once/month      (5)  2 weekend days/week  
(2)  1-2 times/month
19. On those weekend days that you drink wine, beer, or liquor how many drinks do you have?  
**(Please provide one number, not a range.)** \_\_\_\_\_
20. In the past year, have you regularly smoked cigarettes, pipes, cigars, or used chewing tobacco?

Please describe daily habit

Cigarettes	<input type="checkbox"/> yes	<input type="checkbox"/> no	_____
Pipe	<input type="checkbox"/> yes	<input type="checkbox"/> no	_____
Cigars	<input type="checkbox"/> yes	<input type="checkbox"/> no	_____
Chewing Tobacco	<input type="checkbox"/> yes	<input type="checkbox"/> no	_____

**THANK YOU!**

## **Appendix C: 24-Hour Dietary Recall Form**

Page 1

Was intake: Typical? Considerable more than usual? Considerably less than usual? Why?

Was recall: Reliable? Unable to recall 1 or more meals? Unreliable for other reasons? Why?

---

**Vitamin/Mineral/Supplement Use/Dosage?**

## **Appendix D: University of Minnesota's Guide to Calculating HEI-2010 Scores**



### **Guide to Creating Variables Needed to Calculate Scores for Each Component of the Healthy Eating Index-2010 (HEI-2010)**

#### **Purpose**

The purpose of this document is to describe how the variables needed to calculate scores for each component of the Healthy Eating Index-2010 (HEI-2010) may be calculated using data available in NDSR output files. The description provided herein is specific to recall, record, and record-assisted recall record types.

#### **Background on the Healthy Eating Index-2010**

The Healthy Eating Index (HEI) is a tool developed by the United States Department of Agriculture and the National Cancer Institute to evaluate the extent to which diets are consistent with the Dietary Guidelines for Americans [1]. Possible index points range from 0-100, with a higher score indicating greater consistency of the diet with the Dietary Guidelines for Americans.

With each release of the new Dietary Guidelines for Americans the HEI is updated. The HEI-2010, which conforms to the 2010 Dietary Guidelines for Americans [2], includes twelve dietary components (nine adequacy and three moderation components) that reflect key aspects of diet quality, including fruit, vegetables, grains, dairy, protein foods, fatty acids, sodium, and empty calories. Table 1 lists the components, the optimal (maximum) number of points, and the criteria for assignment of the lowest and highest possible scores for each component. For more detail regarding scoring assignment see the publication by Guenther et al. [2] which describes the HEI-2010.

## **Calculating a HEI-2010 Score using Data Available in NDSR Output Files**

In order to calculate a HEI-2010 score, one must have measures for each of the index components, and these measures need to conform to the units of measure included in the index. For example, fruit and vegetable servings must be in cup equivalents. An approach for quantifying each of these components using NDSR output is described as follows:

### ***Total Fruit***

Before a score for the total fruit component of the HEI-2010 may be assigned, one must generate an estimate of ‘total fruit servings in cup equivalents per 1,000 kcal’. The steps for creating this variable are as follows:

- 1) Calculate ‘total fruit servings in cup equivalents’ by totaling the following fruit subgroups in output file 09 and dividing this total by two: [FRU0100 + FRU0200 + FRU0300 + FRU0400 + FRU0500 + FRU0600 + FRU0700]/2.

The total must be divided by two because fruit servings in the NCC Food Serving Count System are in  $\frac{1}{2}$  cup rather than 1 cup equivalents (see NDSR User Manual Appendix 10 for detailed information about the NCC Food Serving Count System).

- 2) Divide total daily energy intake (from output file 04) by 1,000, and then divide ‘total fruit servings in cup equivalents’ (variable created in step 1) by the result of this calculation.

### ***Whole Fruit***

Before a score for the whole fruit component of the HEI-2010 may be assigned, one must generate an estimate of ‘whole fruit servings in cup equivalents per 1,000 kcal’. The steps for creating this variable are as follows:

- 1) Calculate ‘whole fruit servings in cup equivalents’ by totaling the following fruit subgroups in output file 09 and dividing this total by two: [FRU0300 + FRU0400 + FRU0500 + FRU0600 + FRU0700]/2.

The total must be divided by two because fruit servings in the NCC Food Serving Count System are in  $\frac{1}{2}$  cup rather than cup equivalents (see NDSR User Manual Appendix 10 for detailed information about the NCC Food Serving Count System).

- 2) Divide total daily energy intake (from output file 04) by 1,000, and then divide ‘whole fruit servings in cup equivalents’ (variable created in step 1) by the result of this calculation.

### ***Total Vegetables***

Before a score for the total vegetables component of the HEI-2010 may be assigned, one must generate an estimate of ‘total vegetable servings in cup equivalents per 1,000 kcal’. The steps for creating this variable are as follows:

- 1) Calculate ‘total vegetable servings in cup equivalents’ by totaling the following vegetable subgroups in output file 09 and dividing this total by two: [VEG0100 + VEG0200 + VEG0300 + VEG0400 + VEG0800 + VEG0450 + VEG0700\* + VEG0600 + VEG0900 + VEG0500]/2.

\*Include VEG0700 (legumes) only after the ‘total protein foods’ standard is met. To determine this, first calculate ‘total protein foods servings in ounce equivalents per 1,000 kcal’ as described in the ‘total protein foods’ section of this document, with VEG0700 (legumes) excluded from the calculation. If a study participant’s ‘total protein foods’ intake estimate is  $\geq 2.5$  oz eq/1,000 kcal, include VEG0700 (legumes) in ‘total vegetables’ and ‘greens and beans’ calculations and exclude it from the ‘total protein foods’ and ‘seafood and plant proteins’ calculations. If the estimate is  $< 2.5$  oz eq/1000 kcal, include VEG0700 (legumes) in the ‘total protein foods’ and ‘seafood and plant proteins’ calculations and exclude from ‘total vegetables’ and ‘greens and beans’ calculations.

The total must be divided by two because vegetable servings in the NCC Food Serving Count System are in  $\frac{1}{2}$  cup rather than cup equivalents (see [NDSR User Manual](#) Appendix 10 for detailed information about the NCC Food Serving Count System).

- 2) Divide total daily energy intake (from output file 04) by 1,000, and then divide ‘total vegetable servings in cup equivalents’ (variable created in step 1) by the result of this calculation.

### ***Greens and Beans***

Before a score for the greens and beans component of the HEI-2010 may be assigned, one must generate an estimate of ‘greens and beans in cup equivalents per 1,000 kcal’. The steps for creating this variable are as follows:

- 1) Calculate ‘greens and beans in cup equivalents’ by totaling the following vegetable subgroups in output file 09 and dividing this total by two: [VEG0100 + VEG0700\*]/2.

\*Include VEG0700 (legumes) only after the ‘total protein foods’ standard is met. To determine this, first calculate ‘total protein foods servings in ounce equivalents per 1,000 kcal’ as described in the ‘total protein foods’ section of this document, with VEG0700 (legumes) excluded from the calculation. If a study participant’s ‘total protein foods’ intake estimate is  $\geq 2.5$  oz eq/1,000 kcal, include VEG0700 (legumes) in ‘total vegetables’ and ‘greens and beans’ calculations and exclude it from the ‘total protein foods’ and ‘seafood and plant proteins’ calculations. If the estimate is  $< 2.5$  oz eq/1000 kcal, include VEG0700 (legumes) in the ‘total protein foods’ and ‘seafood and plant proteins’ calculations and exclude from ‘total vegetables’ and ‘greens and beans’ calculations.

The total must be divided by two because vegetable servings in the NCC Food Serving Count System are in  $\frac{1}{2}$  cup rather than cup equivalents (see [NDSR User Manual](#) Appendix 10 for detailed information about the NCC Food Serving Count System).

- 2) Divide total daily energy intake (from output file 04) by 1,000, and then divide ‘greens and beans in cup equivalents’ (variable created in step 1) by the result of this calculation.

### ***Whole Grains***

Before a score for the whole grains component of the HEI-2010 may be assigned, one must generate an estimate of ‘whole grain servings in ounce equivalents per 1,000 kcal’. The version of NDSR used to enter the dietary data will determine which of the following steps to follow.

#### NDSR 2013 or subsequent version used for dietary data entry

- 1) Divide total daily energy intake (from output file 04) by 1,000, and then divide whole grains in ounce equivalents (from output file 04) by the result of this calculation.

#### NDSR 2012 or earlier version used for dietary data entry\*

- 1) Calculate ‘whole grain servings in ounce equivalents’ by totaling the following grain subgroups in output file 09: GRW0100 + GRW0200 + GRW0300 + GRW0400 + GRW0500 + GRW0600 + GRW0700 + GRW0800 + GRW1000 + GRW0900 + GRW1100 + GRW1200 + GRW1300.
- 2) Divide total daily energy intake (from output file 04) by 1,000, and then divide ‘whole grain servings in ounce equivalents’ (variable created in step 1) by the result of this calculation.

\* Whole grains in ounce equivalents were not added until NDSR 2013. Restoring data from previous versions of NDSR into NDSR 2013 will not generate whole grains in ounce equivalents in the output. The data must have been entered in NDSR 2013 in order to use the NDSR 2013 step.

### ***Dairy***

Before a score for the dairy component of the HEI-2010 may be assigned, one must generate an estimate of ‘dairy servings in cup equivalents per 1,000 kcal’. The steps for creating this variable are as follows:

- 1) Calculate ‘dairy servings in cup equivalents’ by totaling the following dairy subgroups in output file 09: DMF0100 + DMR0100 + DML0100 + DMN0100 + DMF0200 + DMR0200 + DML0200 + DML0300 + DML0400 + DCF0100 + DCR0100 + DCL0100 + DCN0100 +

$DYF0100 + DYR0100 + DYL0100 + DYF0200 + DYR0200 + DYL0200 + DYN0100 + [DOT0100 * 3] + DOT0300 + DOT0400 + DOT0500 + DOT0600.$

\*DOT0100 (frozen dairy desserts) must be divided by 3 to convert to cup equivalents because 1.5 cups of a frozen dairy dessert is considered to be a cup equivalent in the dairy group, but a  $\frac{1}{2}$  cup of frozen dairy dessert counts as a servings in the NCC Food Serving Count System (see [NDSR User Manual](#) Appendix 10 for detailed information about the NCC Food Serving Count System).

- 2) Divide total daily energy intake (from output file 04) by 1,000, and then divide ‘dairy servings in cup equivalents’ (variable created in step 1) by the result of this calculation.

### **Total Protein Foods**

Before a score for the total protein foods component of the HEI-2010 may be assigned, one must generate an estimate of ‘total protein foods servings in ounce equivalents per 1,000 kcal’. The steps for creating this variable are as follows:

- 1) Calculate ‘total protein foods servings in ounce equivalents’ by totaling the following protein subgroups in output file 09:  $MRF0100 + MRL0100 + MRF0200 + MRL0200 + MRF0300 + MRL0300 + MRF0400 + MRL0400 + MCF0200 + MCL0200 + MRF0500 + MPF0100 + MPL0100 + MPF0200 + MFF0100 + MFL0100 + MFF0200 + MSL0100 + MSF0100 + MCF0100 + MCL0100 + MOF0100 + MOF0200 + MOF0300 + MOF0400 + MOF0500 + MOF0600 + MOF0700 + [VEG0700 * x 2]$

\*Include VEG0700 (legumes) only if the ‘total protein foods’ standard is not met if excluded. To determine this, first calculate ‘total protein foods servings in ounce equivalents per 1,000 kcal’ as described in the ‘total protein foods’ section of this document, with VEG0700 (legumes) excluded from the calculation. If a study participant’s ‘total protein foods’ intake estimate is  $\geq 2.5$  oz eq/1,000 kcal, include VEG0700 (legumes) in ‘total vegetables’ and ‘greens and beans’ calculations and exclude it from the ‘total protein foods’ and ‘seafood and plant proteins’ calculations. If the estimate is  $< 2.5$  oz eq/1000 kcal, include VEG0700 (legumes) in the ‘total protein foods’ and ‘seafood and plant proteins’ calculations and exclude from ‘total vegetables’ and ‘greens and beans’ calculations.

VEG0700 must be multiplied by two because  $\frac{1}{4}$  cup legumes and beans are considered an ounce equivalent of protein, but they are in  $\frac{1}{2}$  cup servings in the NCC Food Serving Count System (see [NDSR User Manual](#) Appendix 10 for detailed information about the NCC Food Serving Count System).

- 2) Divide total daily energy intake (from output file 04) by 1,000, and then divide ‘total protein foods servings in ounce equivalents’ (variable created in step 1) by the result of this calculation.

### ***Seafood and Plant Proteins***

Before a score for the seafood and plant proteins component of the HEI-2010 may be assigned, one must generate an estimate of ‘seafood and plant proteins servings in ounce equivalents per 1,000 kcal’. The steps for creating this variable are as follows:

- 1) Calculate ‘seafood and plant proteins servings in ounce equivalents’ by totaling the following seafood, nuts, seeds, and soy subgroups in output file 09: MFF0100 + MFL0100 + MFF0200 + MSL0100 + MSF0100 + MOF0500 + MOF0600 + MOF0700 + [VEG0700\* x 2]

\*Include VEG0700 (legumes) only if the ‘total protein foods’ standard is not met if excluded. To determine this, first calculate ‘total protein foods servings in ounce equivalents per 1,000 kcal’ as described in the ‘total protein foods’ section of this document, with VEG0700 (legumes) excluded from the calculation. If a study participant’s ‘total protein foods’ intake estimate is  $\geq 2.5$  oz eq/1,000 kcal, include VEG0700 (legumes) in ‘total vegetables’ and ‘greens and beans’ calculations and exclude it from the ‘total protein foods’ and ‘seafood and plant proteins’ calculations. If the estimate is  $< 2.5$  oz eq/1000 kcal, include VEG0700 (legumes) in the ‘total protein foods’ and ‘seafood and plant proteins’ calculations and exclude from ‘total vegetables’ and ‘greens and beans’ calculations.

VEG0700 must be multiplied by two because  $\frac{1}{4}$  cup legumes and beans are considered an ounce equivalent of protein, but they are in  $\frac{1}{2}$  cup servings in the NCC Food Serving Count System (see [NDSR User Manual](#) Appendix 10 for detailed information about the NCC Food Serving Count System).

- 2) Divide total daily energy intake (from output file 04) by 1,000, and then divide ‘seafood and plant proteins servings in ounce equivalents’ (variable created in step 1) by the result of this calculation.

### ***Fatty Acids***

Before a score for the fatty acids component of the HEI-2010 may be assigned, one must generate a ratio of polyunsaturated fatty acids (PUFAs) and monounsaturated fatty acids (MUFAs) to saturated fatty acids (SFAs). The step for creating this variable is as follows:

- 1) Calculate the sum of total PUFAs (from output file 04) and total MUFA (from output file 04),
- 2) Divide the sum of total PUFAs and total MUFA (variable created in step 1) by total SFAs (from output file 04).

### ***Refined Grains***

Before a score for the refined grains component of the HEI-2010 may be assigned, one must generate an estimate of ‘refined grain servings in ounce equivalents per 1,000 kcal’. As with

whole grains, the version of NDSR used for entry of dietary data will determine which of the following steps to follow to determine the refined grains components.

NDSR 2013 or subsequent version used for dietary data entry

- 1) Divide total daily energy intake (from output file 04) by 1,000, and then divide refined grains in ounce equivalents (from output file 04) by the result of this calculation.

NDSR 2012 or earlier versions steps

- 1) Calculate ‘refined grain servings in ounce equivalents’ by totaling the following grain subgroups in output file 09: GRS0100 + GRR0100 + GRS0200 + GRR0200 + GRS0300 + GRR0300 + GRS0400 + GRR0400 + GRS0500 + GRR0500 + GRS0600 + GRR0600 + GRS0700 + GRR0700 + GRS0800 + GRR0800 + GRS1000 + GRR1000 + GRS0900 + GRR0900 + GRR1300 + GRS1300.
- 2) Divide total daily energy intake (from output file 04) by 1,000, and then divide ‘refined grain servings in ounce equivalents’ (variable created in step 1) by the result of this calculation.

***Sodium***

Before a score for the sodium component of the HEI-2010 may be assigned, one must generate an estimate of ‘sodium intake (grams) per 1,000 kcal’. The steps for creating this variable are as follows:

- 1) Calculate ‘sodium intake in grams’ by dividing the sodium variable in output file 04 (sodium intake in milligrams) by 1,000.
- 2) Divide total daily energy intake (from output file 04) by 1,000, and then divide ‘sodium intake in grams’ (variable created in step 1) by the result of this calculation.

***Empty Calories***

Before a score for the empty calories component of the HEI-2010 may be assigned, the percent of total calories from solid fats, alcohol (above >13 g/1,000 kcal\*), and added sugars must be calculated.

The version of NDSR you have used or restored your data in will determine which of the following steps to follow, since ‘solid fats’ was added as a variable in NDSR 2014 (it was not available in earlier versions of the program). If you have data from a previous version of NDSR, you may restore that data into NDSR 2014 or a subsequent version of the program and it will provide you with the total for solid fats. If you do not have NDSR 2014 or a subsequent version

of the program (or have **NOT** restored your data into NDSR 2014) you will need to follow the procedures for calculating Empty Calories using NDSR 2013 or older version below.

\* Only alcohol above 13 g/1,000 kcal (the threshold level indicative of moderate drinking) is considered to contribute to 'empty calories'

Calculating Empty Calories using NDSR 2014 or a subsequent version of the program (or older data that HAS BEEN RESTORED into NSDR 2014 or a subsequent version of the program)

- 1) Calculate calories from solid fats and added sugars as follows:

Solid fats (g)<sup>a</sup> x 9 kcal/gram = kcal from solid fats

Added sugars (by total sugars) (g)<sup>a</sup> x 4 kcal/gram = kcal from added sugars

<sup>a</sup>From output file 04

- 2) Calculate the calories from excess alcohol using the following formulas:

- a) First determine the grams of allowable alcohol:

Total daily energy intake (kcal)<sup>a</sup> x 0.013 (g/kcal allowable alcohol) = allowable alcohol (g)

- b) If alcohol (g)<sup>a</sup> is < than the allowable alcohol (g)<sup>b</sup>, then energy from excess alcohol = 0

- c) If alcohol (g)<sup>a</sup> is > than the allowable alcohol (g)<sup>b</sup>, then estimate energy from excess alcohol using the following equation:

[Alcohol (g)<sup>a</sup> – allowable alcohol (g)<sup>b</sup>] x 7 kcal/g = kcal from excess alcohol

<sup>a</sup> From output file 04

<sup>b</sup> Allowable alcohol as calculated from step 2a

- 3) Sum the following variables created in steps 1 through 2:

kcal from solid fats + kcal from added sugars + kcal from excess alcohol = kcal from empty calories

- 4) Using the total daily energy intake estimate from output file 04, complete the following calculation:

[kcal from empty calories / total kcal] x 100 = % energy from empty calories

Calculating Empty Calories Using NDSR 2013 or older versions

If your data is from NDSR 2013 or an older version of the program, 'solid fats' must be calculated because it is not available as a variable in the output files. There are a couple

possible approaches to creating an estimate of solid fats. One approach, which is modeled after the way in which fats are estimated in the USDA MyPyramid Equivalents Database 2.0, is described in detail in this document. Another possible approach, which is far simpler to carry out, is also described.

To calculate the percent of energy from empty calories, with solid fat estimates modeled after the USDA MyPyramid Equivalents Database approach, proceed through the following steps:

- 1) Calculate grams of solid fats using the approach described in a publication by Miller et al. who developed and evaluated a method for calculating the HEI-2005 using NDSR [3]. In brief, the approach involves summing the grams of 'excess' fat in animal meats and dairy, fat in hydrogenated oils, and fat(s) from food items in which the predominant fat(s) are saturated and/or *trans* fat. Use output file 01 (component/ingredient file) to identify the foods that meet these criteria, and sum the total or a fraction of the total fat content of these items to calculate grams of solid fat. In output file 01 many foods are broken down to the ingredient level (e.g. individual ingredient in potato chips such as potato, soybean oil, and salt are provided) but some foods items are not disaggregated (e.g. peanut butter is not broken down into its ingredients which are likely roasted peanuts, sugar, hydrogenated soybean oil, salt, etc.). Foods that are not disaggregated to ingredients may be an issue because some of the fat in the product (e.g. oil from roasted peanuts in peanut butter) might be considered an oil, not a 'solid fat'. Consequently, in the absence of knowing the amount of each ingredient, the researcher would need to develop assumptions about the relative amount of each type of fat ('oil' versus 'solid fat') in products that are not disaggregated.
- 2) Calculate the calories from the following two variables:  
Solid fats (g)<sup>a</sup> x 9 kcal/gram = kcal from solid fats  
Added sugars (by total sugars) (g)<sup>b</sup> x 4 kcal/gram = kcal from added sugars
  - <sup>a</sup>Solid fats as calculated from step 1
  - <sup>b</sup>From output file 04
- 3) Calculate the calories from excess alcohol using the following formulas:
  - a) First determine the grams of allowable alcohol:  
Total daily energy intake (kcal)a x 0.013 (g/kcal allowable alcohol) = allowable alcohol (g)
  - b) If alcohol (g)a is < than the allowable alcohol (g)b, then energy from excess alcohol = 0
  - c) If alcohol (g)a is > than the allowable alcohol (g)b, then estimate energy from excess alcohol using the following equation:

$$[\text{Alcohol (g)}^{\text{a}} - \text{allowable alcohol (g)}^{\text{b}}] \times 7 \text{ kcal/g} = \text{kcal from excess alcohol}$$

<sup>a</sup> From output file 04

<sup>b</sup> Allowable alcohol as calculated from step 3a

- 4) Sum the following variables created in steps 2 and 3:

kcal from solid fats + kcal from added sugars + kcal from excess alcohol = kcal from empty calories

- 5) Using the total daily energy intake estimate from output file 04, complete the following calculation:

$$[\text{kcal from empty calories} / \text{total kcal}] \times 100 = \% \text{ energy from empty calories}$$

To calculate the percent of energy from empty calories using an alternative (simpler) approach to estimating solid fats, saturated and *trans* fatty acids are used as a proxy measure of solid fats\*. To calculate the percent of energy from empty calories using this alternative approach, proceed through the following steps:

- 1) Calculate the calories from the following three variables in output file 04:

$$\text{Saturated fat (g)} \times 9 \text{ kcal/gram} = \text{kcal from saturated fat}$$

$$\text{Total } trans \text{ fat (g)} \times 9 \text{ kcal/gram} = \text{kcal from } trans \text{ fat}$$

$$\text{Added sugars (by total sugars) (g)} \times 4 \text{ kcal/gram} = \text{kcal from added sugars}$$

- 2) Calculate the calories from excess alcohol using the following formulas:

- a) First determine the grams of allowable alcohol:

$$\text{Total daily energy intake (kcal)}^{\text{a}} \times 0.013 \text{ (g/kcal allowable alcohol)} = \text{allowable alcohol (g)}$$

- b) If alcohol (g)<sup>a</sup> is < than the allowable alcohol (g)<sup>b</sup>, then energy from excess alcohol = 0

- c) If alcohol (g)<sup>a</sup> is > than the allowable alcohol (g)<sup>b</sup>, then estimate energy from excess alcohol using the following equation:

$$[\text{Alcohol (g)}^{\text{a}} - \text{allowable alcohol (g)}^{\text{b}}] \times 7 \text{ kcal/g} = \text{kcal from excess alcohol}$$

<sup>a</sup> From output file 04

<sup>b</sup> Allowable alcohol as calculated from step 2a

3) Sum the following variables created in steps 1 and 2:

kcal from saturated fat + kcal from *trans* fat + kcal from added sugars + kcal from excess alcohol = kcal from empty calories

4) Using the total daily energy intake estimate from output file 04, complete the following calculation:

$$[\text{kcal from empty calories} / \text{total kcal}] \times 100 = \% \text{ energy from empty calories}$$

\*In the 2010 Dietary Guidelines, it is clear that polyunsaturated and monounsaturated fatty acids should be the primary source of fat in the American diet, with intake of saturated fatty acids kept below 10% of total calories and *trans* fatty acid consumption kept as low as possible [4]. Thus, using the sum of saturated and *trans* fatty acids as a proxy measure for 'solid fats' as defined in the HEI-2010 [2] may be a reasonable approach because it is in line with the intent of the 2010 Dietary Guidelines.

**Table 1:** Healthy Eating Index-2010 components and standards for scoring

Component	Optimum Score	Standard for Maximum Score	Standard for Minimum Score of Zero
Total Fruit <sup>a</sup>	5	≥0.8 cup eq/1,000 kcal	No fruit
Whole Fruit <sup>b</sup>	5	≥0.4 cup eq/1,000 kcal	No whole fruit
Total Vegetables <sup>c</sup>	5	≥1.1 cup eq/1,000 kcal	No vegetables
Greens and Beans <sup>c</sup>	5	≥0.2 cup eq/1,000 kcal	No dark-green vegetables or beans or peas
Whole Grains	10	≥1.5 oz eq/1,000 kcal	No whole grains
Dairy <sup>d</sup>	10	≥1.3 cup eq/1,000 kcal	No dairy
Total Protein Foods <sup>e</sup>	5	≥2.5 oz eq/1,000 kcal	No protein foods
Seafood and Plant Proteins <sup>ef</sup>	5	≥0.8 oz eq/1,000 kcal	No seafood or plant proteins
Fatty Acids <sup>g</sup>	10	(PUFAs+MUFAs)/SFAs >2.5	(PUFAs+MUFAs)/SFAs ≤1.2
Refined Grains	10	≤1.8 oz eq/1,000 kcal	≥4.3 oz eq/1,000 kcal
Sodium	10	≤1.1 gram/1,000 kcal	≥2.0 grams/1,000 kcal
Empty Calories <sup>h</sup>	20	≤19% of energy	≥50% of energy

<sup>a</sup> Includes 100% fruit juice.

<sup>b</sup> Includes all forms except fruit juice.

<sup>c</sup> Includes any beans and peas not counted as Total Protein Foods.

<sup>d</sup> Includes all milk products, such as fluid milk, yogurt, cheese, and fortified soy beverages.

<sup>e</sup> Beans and peas are included here (and not with vegetables) when the Total Protein Foods standard is otherwise not met.

<sup>f</sup> Includes seafood, nuts, seeds, soy products (other than beverages) as well as beans and peas counted as Total Protein Foods.

<sup>g</sup> Includes seafood, nuts, seeds, soy products (other than beverages) as well as beans and peas counted as Total Protein Foods.

<sup>h</sup> Calories from solid fats, alcohol, and added sugars; threshold for counting alcohol is >13 g/1000 kcal.

## References

1. Guenther P, Reedy J, Krebs-Smith J: **Development of the Healthy Eating Index-2005.** *J Am Diet Assoc* 2008, **108**:1896-1901.
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