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## A LIFESTYLE INTERVENTION TO DECREASE RISK OF DEVELOPING TYPE 2 DIABETES MELLITUS IN A RURAL POPULATION

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A LIFESTYLE INTERVENTION TO DECREASE RISK OF DEVELOPING TYPE 2  
DIABETES MELLITUS IN A RURAL POPULATION

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DISSERTATION

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A dissertation submitted in partial fulfillment of the  
requirements for the degree of Doctor of Philosophy in the  
College of Nursing  
at the University of Kentucky

By  
Amanda Culp-Roche  
Lexington, Kentucky  
Director: Dr. Debra K. Moser, Professor of Nursing  
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## ABSTRACT OF DISSERTATION

### A LIFESTYLE INTERVENTION TO DECREASE RISK OF DEVELOPING TYPE 2 DIABETES MELLITUS IN A RURAL POPULATION

Individuals with type 2 diabetes mellitus (T2DM) are at risk for developing life-threatening comorbidities such as cardiovascular disease (CVD). As a consequence, T2DM is associated with increased morbidity and mortality and decreased quality of life, thus highlighting the importance of prevention of T2DM. Further, the prevalence of T2DM is substantially greater in rural populations compared to urban populations, making rural individuals particularly appropriate targets for T2DM prevention.

T2DM is a largely preventable disease that is associated with modifiable risk factors such as poor diet, sedentary lifestyle, and obesity. Lifestyle interventions to improve these modifiable risk factors have been used to decrease the risk of developing T2DM. There is little evidence that supports lifestyle interventions as a means to decrease T2DM risk in rural populations with prediabetes, the precursor of T2DM.

The purpose of this dissertation was to determine whether rural-living individuals with prediabetes would improve modifiable risk factors, specifically diet quality by following a lifestyle intervention; thereby, decreasing their risk of developing T2DM. Specific aims for this dissertation were to, 1) examine and synthesize data from dietary interventions used to reduce risk of T2DM in rural populations in order to identify gaps and guide future research, 2) critically evaluate validity and reliability of indices used to determine diet quality in research, and 3) determine the effect of a risk reduction program on improving diet quality and glucose control (as a measure of T2DM risk) in rural adults with prediabetes and CVD risk factors.

Specific aim one was achieved by a review and synthesis of literature focused on lifestyle and dietary interventions used in rural populations to decrease the risk of developing T2DM. Common goals in these studies were a decrease in weight, decrease in dietary fat and calories, and an increase in physical activity. Decreased weight and increased physical activity were demonstrated in all eight studies, and a decrease in T2DM incidence was also demonstrated in one of the studies. However, diet quality was not

adequately assessed in the majority of the studies. Furthermore, none of the studies were randomized controlled trials and only half used a control group. It was concluded that research using a more robust design is needed to determine the effect of lifestyle changes, specifically diet, on T2DM risk in rural populations. Specific aim two was addressed by a critical analysis of six common indices of dietary quality. Validity and reliability of the Healthy Eating Index, the Alternative Healthy Eating Index, the DASH diet score, the Diet Quality Index-Revised, the Healthy Diet Indicator, and the Diet Quality Score were examined. Five of the six indices are valid and reliable tools for measure diet quality but all five rely on an extensive food frequency questionnaire that may be burdensome for participants. The Diet Quality Score does not provide adequate evidence to support its use in research. It was concluded that a short, reliable, and validated diet screener may be useful in research. Specific aim three was addressed by a secondary data analysis of a longitudinal, randomized controlled study of rural residents with CVD risk factors and prediabetes. Diet quality, measured by the Mediterranean Diet Adherence Screener (MEDAS), and glucose control, measured by hemoglobin A1c, were analyzed in a subpopulation of 62 participants with prediabetes. Neither diet quality nor glucose control improved between baseline, four month, and 12 month post intervention. The reliability and validity of the MEDAS in this population is not known and may have been a factor in the lack of intervention effect related to diet quality. Participants were also not informed of their prediabetes status, thus it is not known if this knowledge would have made an impact on the outcomes of the study. In addition, the small sample size limits the statistical power to determine changes between the intervention and control groups. It was concluded that further research is needed to determine if a high quality diet will reduce T2DM risk in this rural population

Considering the disproportionate prevalence of T2DM in rural populations compared to their urban counterparts, the results of this dissertation demonstrate a continued need for interventions that decrease modifiable risk factors associated with this disease. Interventions that target obesity, poor diet quality, and sedentary lifestyles in at-risk rural populations that are culturally tailored are needed to decrease risk of developing T2DM and the comorbidities associated with this preventable disease.

KEYWORDS: Type 2 diabetes mellitus, risk reduction, lifestyle intervention, high-quality diet, rural population

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06/28/2019

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A LIFESTYLE INTERVENTION TO DECREASE RISK OF DEVELOPING TYPE 2  
DIABETES MELLITUS IN A RURAL POPULATION

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## CHAPTER 1. INTRODUCTION

### Type 2 Diabetes Mellitus

Diabetes mellitus (DM) is one of the most common chronic diseases found worldwide and is a leading cause of mortality and disability. In 2017, nearly four million deaths were attributed to DM<sup>1</sup> and it was the fourth most common cause of disability globally.<sup>2</sup> Based on past trends, it is projected that DM related deaths, worldwide, will increase 31% by 2030.<sup>3</sup> In the United States (U.S.), nearly 253,000 individuals died from DM and its complications, making DM the 7th leading cause of death in 2015.<sup>4</sup> The number of diabetes related deaths is projected to rise a shocking 38% to 385,800 deaths per year by 2030 in the United States.<sup>5</sup> Not only has the number of deaths associated with DM increased, the prevalence of DM has also continued to escalate at an alarming rate.

Over the past four decades, the number of individuals living with DM worldwide has quadrupled.<sup>4</sup> Currently, it is estimated that 425 million adults, worldwide, have DM and this number is expected to increase by a staggering 48% (629 million) by 2045.<sup>1</sup> Similar to global prevalence rates, the number of U.S. adults living with DM has quadrupled over the past four decades.<sup>4</sup> The U.S. is ranked third in the world for the number of adults diagnosed with DM<sup>1</sup> with an estimated 23.1 million U.S. adults diagnosed with DM in 2017.<sup>4</sup> The number of DM cases is expected to increase by an alarming 54% to nearly 55 million by 2030.<sup>5</sup> These population-based estimates do not distinguish between type 1 DM and type 2 DM; however, the majority, over 90%, of DM cases are type 2 diabetes mellitus (T2DM).<sup>4</sup> Thus, the greatest concern related to DM and its complications is associated with T2DM.

## **Type 2 Diabetes Mellitus Defined**

Type 2 diabetes is characterized by abnormally elevated blood glucose caused by decreased function of the insulin secreting beta cells of the pancreas and insulin resistance in the body's insulin-sensitive tissues.<sup>6</sup> When insulin resistance is present, larger amounts of insulin are required in order for the resistant tissue to respond; however, the dysfunctional beta cells are not able to meet this need.<sup>6</sup> Advancing age, family history, and ethnicity are non-modifiable factors that influence the decrease in beta cell function. Increased adiposity resulting from obesity, sedentary lifestyle, and a poor quality diet has been implicated in the development of insulin resistance.<sup>6</sup> Thus, a combination of non-modifiable risk factors and modifiable lifestyle influences impact the development of T2DM.

Individuals are often diagnosed with T2DM after living with its precursor, prediabetes, for several years. Prediabetes is also a result of pancreatic beta cell dysfunction and insulin resistance but is characterized by blood glucose levels lower than the diagnostic criteria of T2DM.<sup>7-9</sup> In the United States, nearly 34% of the population has prediabetes, but less than 12% have been diagnosed by their healthcare provider.<sup>4</sup> Although not every individual with prediabetes will develop T2DM, up to 65% of these individuals will progress to T2DM within six years if left untreated.<sup>7</sup> Prediabetes and early T2DM are often present without symptoms, thus individuals may not realize they have either condition.<sup>4</sup> There is strong evidence that the progression of prediabetes to T2DM can be delayed or prevented; therefore, screening for elevated blood glucose when predisposing factors are present is critical.<sup>7, 10, 11</sup>

## **Predisposing factors & Screening for prediabetes/T2DM**

Predisposing factors for prediabetes and T2DM include increasing age, having a family history of T2DM, being overweight, being physically inactive, having a history of gestational diabetes or having a baby over nine pounds at birth, having polycystic ovarian syndrome (PCOS), or being of a non-white race/ethnicity.<sup>4</sup> The American Association of Clinical Endocrinologists include abnormal high density lipoprotein and /or triglyceride levels, diagnoses of hypertension, nonalcoholic fatty liver disease, metabolic syndrome, certain sleep disorders, chronic use of glucocorticoids, and/or antipsychotic medications as additional predisposing factors leading to prediabetes and T2DM.<sup>11</sup>

There are several screening guidelines available for prediabetes and diabetes. Age between 40-70 and overweight/obesity are the general criteria for prediabetes screening recommended by the United States Preventive Services Task Force (USPSTF).<sup>12</sup> However, O'Brien and his associates found that this screening criteria missed nearly 50% of individuals who met the diagnostic criteria for prediabetes.<sup>12</sup> Using additional screening criteria of at least 1 of the following; family history of diabetes, history of gestational diabetes or polycystic ovarian syndrome, and non-white race, yielded a greater number individuals who met the diagnostic criteria for prediabetes.<sup>12</sup> The American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE) have similar screening recommendations. These organizations recommend screening begin at age 45 or for any age adult who is overweight/obese and has at least one of the predisposing factors. Screening should occur every three years if the initial result is negative for prediabetes or yearly if prediabetes is found.<sup>10, 11</sup>

Screening for prediabetes and T2DM can be accomplished using one of three methods. The ADA and AACE recommends screening using glycated hemoglobin A1c (A1c), fasting plasma glucose (FPG), or a 2-hour oral glucose tolerance test (OGTT).<sup>7, 10, 11</sup> A1c testing has several advantages to the use of either the FPG or OGTT. A1c is more convenient as it does not require the individual to fast for the test, is more stable preanalysis, and is affected less by illness and physiological stress than either FPG or OGTT.<sup>10</sup> A1c levels can be impacted by red blood cell irregularities such as sickle cell disease and other hemoglobinopathies and by rapid red blood cell turnover in conditions such as pregnancy and hemodialysis; therefore, plasma levels should be used to screen individuals with these conditions.<sup>10, 11</sup> Because results from any of these tests can be impacted by various conditions, each require follow up tests to confirm the presence of prediabetes and/or T2DM.<sup>7, 11</sup> Diagnostic criteria for prediabetes is a FPG level between 100mg/dL and 125 mg/dL, an OGTT level between 140 mg/dL and 199 mg/dL, and/or A1c level between 5.7% and 6.4 percent.<sup>10</sup> Results within these ranges demonstrate a greater risk of progression to T2DM.<sup>10</sup>

### **Treatment of Prediabetes to Delay or Prevent the Onset of T2DM**

Intensive lifestyle management is the recommended treatment for prediabetes as there is strong evidence that this intervention can prevent or delay the progression of prediabetes to T2DM.<sup>7, 10, 11</sup> Components of intensive lifestyle management found in both the ADA and ACCE guidelines include medical nutrition therapy, increasing activity, smoking cessation, and improvement of psychosocial factors.<sup>7, 10, 11</sup> Medical nutrition therapy is aimed at helping individuals with prediabetes improve healthy eating patterns in order to reduce weight, normalize blood glucose, lipid levels, and blood pressure, thus

preventing or delaying T2DM and its complications.<sup>10, 11</sup> Diets that emphasize whole grains, fruits, vegetables, legumes, nuts, and moderate alcohol consumption while discouraging red/processed meats, processed foods, and sugar-sweetened drinks have demonstrated reduced risk of developing T2DM.<sup>13-15</sup> Examples of diets found to help reduce the risk of T2DM include Mediterranean-type diets,<sup>13</sup> Dietary Approaches to Stop Hypertension (DASH),<sup>14, 15</sup> and plant-based diets.<sup>14, 15</sup> The current recommendation for physical activity is at least 30 minutes of moderate-intensity activity on at least 5 days per week.<sup>7, 10, 11</sup> Structured physical activity, including aerobic and resistance exercise, helps decrease blood glucose levels,<sup>16</sup> reduce and manage weight,<sup>17</sup> and improve cardiovascular risk factors.<sup>18</sup>

Intensive lifestyle interventions, specifically those that target weight loss through improved diet and increased physical activity demonstrated a 58%, 34%, and 27% reduction in T2DM incidence over three years, 10 years, and 15 years, respectively.<sup>19-21</sup> Other researchers found similar short and long term improvements using similar lifestyle interventions.<sup>22, 23</sup> These findings were consistent among both genders and across a diverse ethnic population.<sup>20</sup> Despite these findings, it is not known whether intensive lifestyle interventions are effective in rural, economically distressed populations.

### **Type 2 Diabetes Mellitus Risk in Rural Areas**

Rural areas of the United States have greater levels of health disparities.<sup>24-27</sup> Some rural areas suffer from greater rates of type 2 diabetes mellitus (T2DM) than other rural and urban regions.<sup>28</sup> Appalachian Kentucky is considered part of the “Diabetes belt”, the geographic area of the United States with a higher prevalence of type 2 diabetes mellitus (T2DM) than other regions of the United States.<sup>24</sup> In general, areas found within this belt



have T2DM prevalence rates greater than 11 percent<sup>24</sup>; however, many parts of Appalachia Kentucky found within this belt have rates of T2DM approaching 18 percent.<sup>29</sup> These health disparate areas also experience a higher rate of diabetes related deaths compared to other areas of Kentucky and the nation.<sup>28, 30, 31</sup> There are few studies that have been conducted in this population aimed at decreasing the risk of developing T2DM, and considering the long-term consequences of T2DM, there is a critical need for more research to reduce this health disparity.

Although intensive lifestyle interventions have demonstrated great effect at reducing T2DM, changes in diet and physical activity can be difficult to implement in any population. This may be especially true in populations that are economically distressed. Appalachia Kentucky is one of the most socioeconomically disadvantaged areas in the United States with high rates of unemployment, lower levels of education, and higher rates of poverty.<sup>32</sup> Healthier foods are often more expensive and more difficult to obtain in this area.<sup>33, 34</sup> Residents in this area may not be aware that T2DM can be delayed or prevented using high quality diets and may believe that they have no control over the disease (fatalism).<sup>35, 36</sup> Dietary changes in this region may also be difficult due to the large impact that culture plays on food preferences.<sup>37, 38</sup> Considering the many potential barriers to change found in this population, use of a theoretical model that addresses both barriers and facilitators that impact acceptance and implementation of a healthy behavior may be helpful.

### **Theoretical Model**

The Theory of Planned Behavior (TPB) helps explain the adoption of new behaviors.<sup>39</sup> In this model, the decision to adopt a certain behavior is influenced by three

considerations. The first consideration is the individual's attitudes and beliefs related to how the behavior may or may not be beneficial to their health and wellbeing. The second consideration is the subjective norms associated with the behavior; is the behavior supported by people who are important to the individual? The third consideration involves the individual's perceived control over the behavior, that is, how difficult or easy it will be to implement the behavior and whether the individual feels confident they can maintain the behavior.<sup>39</sup> These three considerations lead to an intention to change behavior, that is, they help motivate the individual to adhere to healthy behavior (Figure 1.1).<sup>39</sup> Because dietary changes are one of the most difficult lifestyle interventions to put into practice, the use of motivating factors identified by using the TPB can help guide the development and implementation of interventions aimed at adhering to healthier dietary behaviors for individuals at risk of developing T2DM.

### **Purpose of dissertation**

The purposes of this dissertation were to: 1) explore and evaluate the current state of the science related to dietary interventions used in rural populations aimed at reducing the risk of developing T2DM, 2) determine the validity and reliability of dietary indexes used to measure dietary quality in research, and 3) determine the effect of a risk reduction intervention on improving diet quality and glucose control in rural adults at risk of T2DM, specifically those with prediabetes and CVD risk factors. Three manuscripts addressing each of these three purposes are presented in this dissertation.

### **Summary of subsequent chapters**

Chapter two is a systematic, critical review of the current literature related to interventions used in rural populations to reduce the risk of developing T2DM. Electronic

databases were used to identify research specific to reducing the risk of developing T2DM in rural United States populations between the years of 1998 to 2018. Improvement of diet quality was the variable of interest; however, there were no studies found that used only diet as an intervention. Therefore, lifestyle interventions, using dietary changes, physical activity, and behavior change, were assessed. Lifestyle interventions are effective, low-cost, and can be self-managed once studies are completed, making them a good option in economically austere environments. Major gaps identified included the limited number of studies using lifestyle interventions within rural populations and the lack of randomized, controlled trials assessing the impact of high quality diet on reducing the risk of developing T2DM in rural populations within the United States.

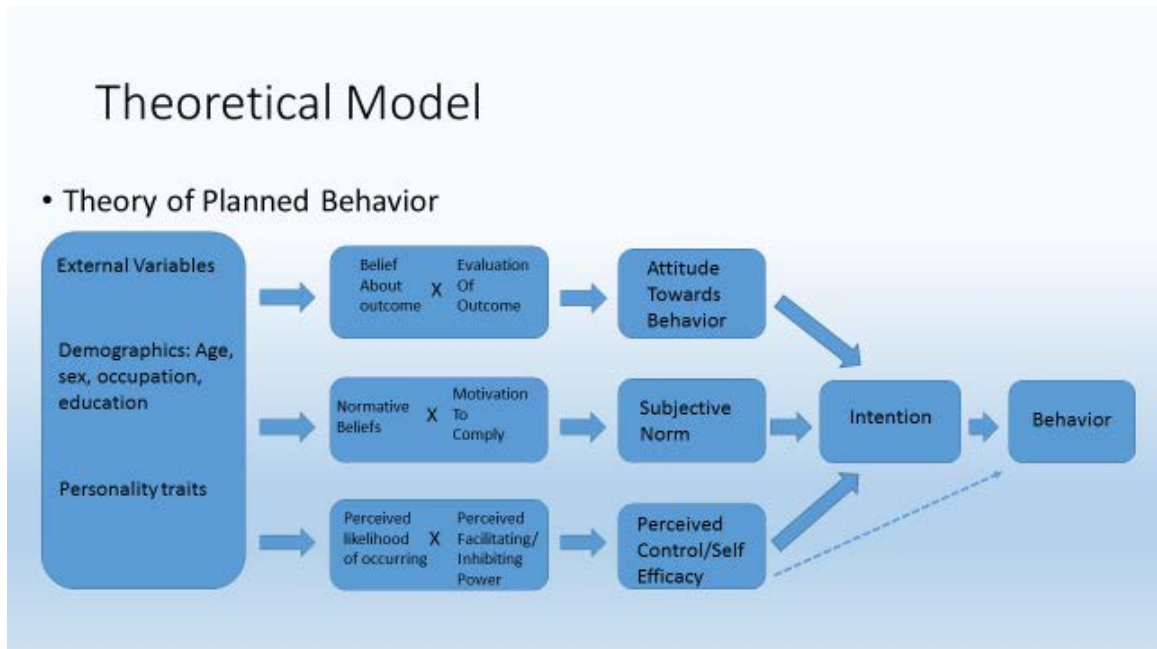
Chapter three is a critical psychometric evaluation of dietary indices used to measure diet quality. Changing and adhering to a high quality diet is a challenge for any individual participating in a lifestyle intervention. These diets are characterized by limitations of alcohol, processed foods, added sugars, sodium, and saturated/trans fats while emphasizing increased consumption of vegetables, fruits, whole grains, healthy oils, low fat dairy, and lean protein.<sup>40</sup> The Healthy Eating Index (HEI), Alternative Healthy Eating Index (AHEI), Dietary Approaches to Stop Hypertension (DASH) score, Healthy Diet Indicator (HDI), Diet Quality Index-Revised (DQI-R), and Diet Quality Score (DQS) instruments were examined to determine reliability and validity of these indices for measuring diet quality in individuals at risk of developing T2DM. Results for five of the six indices were similar, indicating that any one of these five indices would be an appropriate measure of diet quality in populations at risk for T2DM. The DQS was the only index not supported in the evaluation.

In Chapter Four, diet quality and glucose control are examined in participants with prediabetes living in a rural, austere environment. A secondary analysis of data from a longitudinal, experimental study of individuals with cardiovascular disease (CVD) risk factors living in rural Appalachia was conducted.<sup>35, 41</sup> In this analysis, a subsample of 62 individuals with prediabetes had been randomized to either the control or intervention group. Control group participants were referred to a primary care provider for risk factor evaluation related to CVD, of which, prediabetes is one risk factor. Intervention group participants received six culturally tailored, group sessions encouraging lifestyle modifications related to improving diet quality, activity, psychosocial health, and medication adherence.<sup>41</sup> Diet quality was measured using the Mediterranean Diet Adherence scale. Glucose control was assessed using hemoglobin A1c levels.

The intervention group improved their total diet quality scores and their olive oil usage as their main cooking fat between baseline and 12 months compared to the control group. Daily vegetable intake also improved for the intervention group compared to the control group between baseline and four months and baseline and 12 months. Glucose control did not improve for either group between baseline and 12 months. Participants in the intervention group were able to make some improvements in their diet quality after participating in the lifestyle intervention.

Chapter Five synthesizes the findings from the studies within this dissertation and discusses how they help advance the science related to this topic. Future research and practice suggestions related to decreasing the risk of developing T2DM using lifestyle interventions in rural populations are offered for consideration.

**Figure 1.1 Theory of Planned Behavior**



Adapted from Ajzen, I. (2002). Perceived behavioral control, self-efficacy, locus of control, and the Theory of Planned Behavior

## **CHAPTER 2. DIETARY INTERVENTIONS USED TO PREVENT TYPE 2 DIABETES MELLITUS IN AT-RISK, RURAL INDIVIDUALS IN THE UNITED STATES: A SYSTEMATIC LITERATURE REVIEW**

### **Introduction**

#### *Rural residents and risk of type 2 diabetes mellitus*

Nearly 34% of the United States (US) adult population, 18 years and older, has prediabetes, this number increases to nearly 50% in adults aged 65 years and older. Most of these individuals will go on to develop type 2 diabetes mellitus (T2DM), and it is estimated that 2 out of every 5 people in the US will develop diabetes in their lifetime.<sup>42</sup> Individuals living in rural areas are more likely to have diabetes than their urban counterparts.<sup>27</sup> This critical review and synthesis of dietary and lifestyle interventions used to decrease T2DM risk in rural populations with prediabetes and other risk factors will be used to guide further interventions.

Individuals living in rural areas report a diagnosis of diabetes 17% more often than those living in urban areas within the United States (US).<sup>27</sup> The “diabetes belt”, a largely rural area found in southern and Appalachian regions of the US, have diabetes prevalence rates of 11.7% compared to 8.5% in areas outside of this area.<sup>28, 43</sup> Rural residents in this geographical region have higher rates of obesity, poor diet quality, and physical inactivity, known contributors to development of T2DM.<sup>27, 44</sup> Additionally, this population has a greater number of elderly residents, poor healthcare access, lower educational attainment, poverty, and lack of health insurance, all of which contribute to the development of T2DM.<sup>27, 44</sup> Individuals, family members, and community leaders living in this region identified T2DM as one of their top ten concerns.<sup>45</sup>

Concern regarding T2DM is warranted. T2DM is a progressive disease that can lead to cardiovascular and other comorbidities such as stroke, ischemic heart disease, vascular changes leading to blindness, limb loss, kidney disease, obstructive sleep apnea, neuropathies, sexual dysfunction, and depression.<sup>46-53</sup> Individuals with T2DM and its associated comorbidities report lower quality of life.<sup>53, 54</sup> Although some risk factors for T2DM cannot be changed, such as family history, age, ethnicity, or a history of gestational diabetes, lifestyle factors such as being overweight or obese, poor diet, and being sedentary can be modified.<sup>42</sup>

#### *Lifestyle interventions used to decrease T2DM risk*

Lifestyle interventions aimed at decreasing weight, improving diet, increasing physical activity, and improving health behaviors have demonstrated a delay of onset and/or prevention of T2DM in several studies.<sup>20, 21, 23, 55</sup> These interventions are promising, but it is unclear if these interventions are reproducible or sustainable in rural populations. Thus, the purpose of this systematic review of the literature was to critically review and synthesize lifestyle interventions used to decrease T2DM risk in rural populations with risk factor for T2DM in order to guide further interventions.

## **Methods**

#### *Eligibility criteria and sources*

Criteria from the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guideline<sup>56</sup> was used to search the literature. The PubMed, CINAHL, and Cochrane Database of Systematic Reviews databases were used to search for articles using lifestyle interventions to decrease T2DM risk in rural residents in February 2019. Search terms included “diabetes prevention”, “rural”, and “lifestyle intervention”. Articles

were primary research conducted in rural populations found within the United States. Dietary interventions were the primary interest of the review; however, no articles were found and the search term was expanded to “lifestyle interventions”.

#### *Search and study selection*

The filters, date range “01/01/1998 through 12/31/2018” and “English language”, were used with each of the search terms in the PubMed database. The results included a total of 237,153 articles. Using the “AND” operator, each search term was added to the advanced search builder feature, resulting in 212 articles. This search process was repeated in the CINAHL and Cochrane databases. Twenty-one and 15 articles were found in the CINAHL and Cochrane databases, respectively. Articles were independently screened by the primary author. Inclusion criteria included original studies, adults > 18 years of age, residents of the United States living in rural areas, participants identified as at risk of developing T2DM, and use of a lifestyle intervention to reduce T2DM risk. Exclusion criteria included participants with a diagnosis of T2DM, lack of a dietary component in the lifestyle intervention, and inclusion of children in the study. Initial screening of article titles, using the inclusion and exclusion criteria, eliminated 227 studies due to inclusion of children, lack of diabetes risk prevention, lack of an intervention (qualitative or protocol studies), or location of study outside the United States. An additional nine studies were eliminated after reading the abstract due to the study being conducted outside the United States or a lack of lifestyle intervention. The remaining 10 studies were read in their entirety and two additional studies were eliminated as their outcome measures did not meet the inclusion criteria for this review. Four articles overlapped between the PubMed and CINAHL databases. The reference lists of the remaining eight articles were reviewed for



additional articles; however, no additional articles were identified. Figure 2.1 provides a flowchart of the search strategy. Methodological quality of the articles was evaluated to determine replicability of the study and rule out risk of bias. Use of three databases to search for relevant articles minimized possible publication bias.

#### *Data collection process*

A systematic summary of the eight chosen articles was conducted (Table 2.1). Information obtained from each article included; 1) name of authors and publication date, 2) research design, including time frame of study, 3) sample and setting, 4) methods used to measure decreased risk of T2DM, 5) statistical analyses, and 6) primary outcomes of the study. Test significance was included in the outcome measure when reported in the article.

## **Results**

#### *Design, subjects, and settings*

Eight articles were included in this systematic review. Five of the studies used the National Diabetes Prevention Program as the model for the intervention.<sup>57-61</sup> All eight studies used a pre-post design. Five studies used non-equivalent control or comparison groups,<sup>59, 61-63</sup> the other 3 studies did not use a comparison or control group.<sup>58, 60, 64</sup> A total of 4575 participants were included in the 8 studies. The age range for participants in the studies was 18-81 years and all the studies had a majority of female subjects, ranging from 70.3% to 100% of the studies' population. Three of the studies were conducted within disparate populations found within rural areas of the United States, including American Indian and Alaskan Native, African American, and Immigrant Hispanic residents.<sup>57, 58, 63</sup> Two of the studies were conducted in rural Montana,<sup>60, 61</sup> one was located in rural Texas,<sup>63</sup> one study was performed in rural southwest Pennsylvania,<sup>59</sup> two were conducted in rural

areas of Ohio,<sup>62, 64</sup> one study was performed in rural Georgia,<sup>57</sup> and the final study was conducted across several rural and remote areas of the United States.<sup>58</sup>

### *T2DM risk factors*

Two studies used residence within a T2DM prevalent population as their only criteria for inclusion.<sup>63, 64</sup> Obesity, as measured by body mass index (BMI) greater than 25 kg/m<sup>2</sup> and waist circumference greater than 40 inches for males and greater than 50 inches for females as the inclusion criteria.<sup>59</sup> Two studies used BMI greater than 25 kg/m<sup>2</sup> and at least one additional risk factor for cardiovascular disease (CVD) or T2DM; prediabetes (impaired fasting glucose [IFG] impaired glucose tolerance [IGT], or hemoglobin A1c 5.7%-6.4%), high blood pressure (>130/85 or treatment), dyslipidemia (triglycerides > 150 mg/dL, low density lipoprotein >130 mg/dL, high density lipoprotein < 40 mg/dL men or <50 mg/dL women), history of gestational diabetes or having a baby > 9 pounds at birth, as inclusion criteria.<sup>59-61</sup> The Centers for Disease Control and Prevention's diabetes risk assessment (DRA) score and an elevated fasting blood glucose was used in one study as inclusion criteria. The DRA score evaluates risk based on family history, diagnosis of hypertension, age, ethnicity, physical activity, gender, history of gestational diabetes, and a BMI calculation. For this study, a score of 10 on the DRA indicated a "high risk" of T2DM.<sup>57</sup> A history of prediabetes (impaired fasting glucose or impaired glucose tolerance) without a diagnosis of T2DM was used in the final study as inclusion criteria.<sup>58</sup>

### *Lifestyle interventions*

Five studies adapted the curriculum from the national diabetes prevention program (DPP) as the intervention for participants.<sup>57-61</sup> Each of these studies used health or lifestyle coaches to help participants set goals for self-monitoring of daily calories and fat grams

and weekly measurements of weight and minutes of physical activity.<sup>57-61</sup> The curriculum was delivered over 6-16 weekly core sessions and 4-6 post-core sessions and included topics on healthy eating, exercise, fats found in common foods, portion size, stress management, healthy behaviors, and overcoming barriers.<sup>57-61</sup> All five studies used group sessions; however, one group also used monthly individual sessions to help facilitate goal setting and problem-solve barriers.<sup>58</sup> Two of the 5 studies used a combination of face-to-face and technology-enhanced group sessions.<sup>59,61</sup>

One study used community-based participatory research methods to design and implement a “culturally suitable” and “economically sustainable” intervention using health education and walking. Participants were organized into *colonias*, or social networks, led by a neighborhood leader.<sup>63</sup> *Promotores*, or community health workers, conducted the group education intervention which was adapted from the Diabetes Education Empowerment Program (DEEP). The intervention was delivered over 7 weeks and included information on disease prevention, health maintenance, guided physical exercise, nutrition, and healthy meal preparation demonstrations. In addition, participants were encouraged to walk each day using pedometers lent to them by the researchers.<sup>63</sup>

A translation of the Complete Health Improvement Program (CHIP) was used in another study to decrease risk of developing chronic illnesses. Volunteer facilitators delivered the 4-8 week intensive group intervention.<sup>64</sup> Instructional videos, cooking demonstrations, group discussions, and volunteer facilitated exercise were used to help participants learn self-care strategies. Participants were encouraged to eat a plant-based diet with daily restrictions on fat, sugar, sodium, and cholesterol. In addition, 8 glasses of

water and 35 grams of fiber were encouraged, along with 10,000 daily steps and daily flexibility exercises.<sup>64</sup>

The final study used a combination of group and individual sessions to deliver their curriculum.<sup>62</sup> Lecture-based classes, covering topics on stress management, nutrition, healthy eating, food labels, fitness, and disease prevention, were taught by health coaches who were health professionals. Participants met for 12 weekly group classes, and also met with their health coach for 3 monthly individual counseling sessions and three personal training sessions.<sup>62</sup>

#### *Outcome measures*

Seven of the studies had a primary outcome measure of weight loss.<sup>57, 59-64</sup> Crude incidence of T2DM was the primary outcome measure for the 8<sup>th</sup> study with weight loss as a secondary outcome.<sup>58</sup> Additional secondary outcomes for studies included improvement in hemoglobin A1c<sup>62</sup> and fasting blood glucose.<sup>57-59, 64</sup> Dietary measurements included in secondary outcomes included servings of sugar-sweetened beverages, fruits, vegetables, whole grains, and trans fat.<sup>62</sup> All studies used physical activity was a part of the intervention; however, only 4 studies reported change in physical activity as a secondary outcome.<sup>58, 60-62</sup>

#### *Analyses*

One sample t-tests or paired t-tests were used to determine if mean weight at baseline was significantly different from mean weight at post-intervention in these studies.<sup>60, 63, 64</sup> Three studies used a more robust *intention to treat* analyses to calculate mean weight loss between groups, the highest weight of the participant was substituted for any missing values for that individual.<sup>57, 59, 61</sup> These studies used multivariate, one factor

ANOVA,<sup>57</sup> repeated measures ANOVA,<sup>59</sup> and multiple regressions<sup>61</sup> to determine mean weight changes between baseline and post intervention for between groups and within groups. No significant differences were found between comparison and intervention groups for these studies.<sup>57, 59, 61</sup> Linear regression using independent variables including baseline weight, age, gender, days of exercise, and consumption of sugar-sweetened beverages were used to determine the relationship between these factors and weight change for individuals who completed this study.<sup>62</sup> Proportional hazard regression models were used in this study to estimate hazard ratios of diabetes between groups of individuals who completed the program and groups who did not complete the program, controlling for baseline demographic and clinical diabetes risk factors.<sup>58</sup> In addition, multiple linear regression models were used in this study to investigate the relationship between secondary outcome measures based on post-intervention assessments for participants completing and not completing the program, controlling for age, gender, and baseline measures for each outcome.<sup>58</sup>

### *Study outcomes*

Participants in all studies demonstrated significant weight loss, measured by either pounds, kilograms or BMI. Average weight loss ranged from 1.7 kg to 7.5 kg for participants in studies that used this measurement.<sup>57-62, 65</sup> Average BMI improvement ranged from 0.19 kg/m<sup>2</sup> to 1 kg/m<sup>2</sup> in studies using this measurement.<sup>63, 64</sup> Crude incidence of T2DM was reported as 3.5% per year for individuals completing all 16 classes of the intervention compared to 7.5% per year for those not completing all 16 classes of the intervention in this study.<sup>58</sup> Fasting blood glucose improved by 4 mg/dL (p= .001), 6.4 mg/dL (p= .037), and 8.1 mg/dL (p= .001) in the studies reporting a change in this

measurement.<sup>57, 58, 64</sup> Nearly 54% of participants in one study improved hemoglobin A1c by 1.5% on average over the course of the study.<sup>62</sup> Four studies reported that at least half of their participants reported a significant increase in weekly physical activity.<sup>58, 60-62</sup> One study reported an improvement in diet quality among participants; 67% improved their intake of fruits and vegetables, 54% improved their intake of whole grains, and 54% percent decreased their intake of trans-fat and high fructose corn syrup.<sup>62</sup>

## **Discussion**

T2DM risk reduction has been largely ignored in rural populations. There were few studies found that addressed this health disparity. Of these, none were randomized controlled trials and only 5 of the studies used a control or comparison group.<sup>57, 59, 61, 62</sup> The lack of randomization is a limitation as there could be potential bias in assigning participants to groups. Studies without comparison and/or control groups may not be representative of the study population and limits the generalizability of the results. The studies using comparison groups assigned participants to intervention and comparison groups by county of residence or other geographical criteria. Differences in socioeconomic factors can be present between counties and may impact homogeneity of the sample; thus, randomized groups would help improve the validity of the findings.

All of the studies had a goal of weight loss as a means of decreasing T2DM risk among participants and participants in all eight studies decreased their mean weight. Overweight and obesity are a major risk factor for T2DM and participants who were able to lose 7% of their body weight demonstrated a 58% decreased risk of developing T2DM in the national DPP study.<sup>20</sup> Therefore, the outcome of weight loss in these studies is an encouraging finding. Improvements between baseline and post intervention FBG or

hemoglobin A1c were reported following the intervention in these studies.<sup>58, 59, 62, 64</sup> Impaired fasting glucose and hemoglobin A1c level between 5.7% and 6.4% are indicators of prediabetes and associated with an increased risk of developing T2DM;<sup>66</sup> therefore, improvements in these measures may further improve participants risks of developing T2DM.<sup>66</sup> Although improvements in these measures are encouraging, these results are limited in predicting the risk of developing T2DM.

Incidence of T2DM was measured in only one of the reviewed studies post intervention and annually for three years.<sup>58</sup> Participants who did not complete the core DPP program had double the incidence of T2DM compared to participants who did complete the core DPP program.<sup>58</sup> These results demonstrate the importance of longitudinal studies and support the use of lifestyle interventions to reduce the risk of developing T2DM. Further longitudinal studies using T2DM incidence to assess the impact of lifestyle interventions are needed.

An adapted version of the national DPP was used in five studies to educate participants regarding calories, dietary fats, portions, and physical activity to help participants lose weight; thereby, decreasing their T2DM risk.<sup>57-61</sup> The DPP has been used across diverse cultures, among men and women, and in differing age groups;<sup>20, 21</sup> however, it has not been studied extensively in rural populations. The DPP was also developed to be delivered to individual participants; interestingly, all the studies in this review used the intervention in group sessions with favorable outcomes.<sup>57-61</sup> The DPP intervention was also delivered to remote groups using the internet in both synchronous and asynchronous formats with outcomes comparable to the face-to-face groups.<sup>59, 61</sup> These studies

demonstrate that the DPP may be beneficial to rural populations; however, randomized controlled trials would provide a better evaluation of the outcomes.

Lack of an objective measurement of diet quality was a notable limitation for most of the studies reviewed. Participants were educated about a healthy diet in all of the studies, but diet quality was measured in only one study.<sup>62</sup> An improvement in fruit, vegetable, and whole grain consumption was reported along with a decrease in both trans-fat and high fructose syrup consumption.<sup>62</sup> High quality diets which encourage fruits, vegetables, whole grains and discourage fats and added sugars have demonstrated a decrease risk of developing T2DM.<sup>67-70</sup> Thus, it is important to measure quality of diet in addition to amount of calories and/or fat intake.

Four of the studies reported an improvement in weekly physical activity between baseline and post intervention with over half of the participants in three of the studies meeting the DPP goal of >150 minutes of weekly exercise.<sup>58, 60, 61</sup> The remaining study reported an increase in weekly activity.<sup>62</sup> Comparisons of physical activity between the studies was limited as an objective method of measuring this outcome was not used and studies largely relied on self-report. In addition, a clear definition of what constituted physical activity was not found in the studies. Verification of these results are needed using an objective measures of physical activity such as an accelerometer.

Community-based participatory research may have played a part in demonstrating improved participant outcomes in two the studies.<sup>57, 63</sup> This type of research uses stakeholder input to identify specific needs of the community, develop meaningful and useful interventions, deliver interventions, and problem-solve difficulties.<sup>71-73</sup> CBPR builds upon the strengths of the population while helping participants overcome barriers to



participation in the intervention.<sup>63, 74-76</sup> It is also an effective way to build academic-community partnerships in areas with health disparities and enhance trusting relationships between rural communities and research institutions.<sup>71-73</sup> These types of interventions encourage needed social support in areas with few medical, educational, or financial resources.<sup>63, 64, 74-78</sup> Social support encourages accountability, provides encouragement, role-models healthy behaviors, and assists with problem-solving among participants.<sup>63, 64, 74-78</sup> These type of interventions may also help build upon the strengths found within rural populations such as resilience and social capital.<sup>44</sup>

Theories used to design and implement interventions include Social Cognitive Theory<sup>59</sup> which uses goal-setting to help patient make long-term changes in health behavior,<sup>79</sup> the Ecological Model<sup>63</sup> which considers the participant's social, economic, and physical environments,<sup>80</sup> and the Transtheoretical Model that assists interventionists to assess the participants' readiness to change behavior.<sup>81</sup> Studies that used these theoretical models reported a loss of weight for their participants.<sup>59, 63</sup>

Behavioral change was augmented using many different tenets of self-care strategies and were supported using aspects of social support in all the studies. Lifestyle coaches, health coaches, volunteer facilitators, or lay health workers delivered the intervention, helped participants set goals, and worked with participant to identify and overcome barriers.<sup>57-64</sup> The use of coaches, facilitators, and lay health workers support and empower participants to make decisions and behavioral changes that can improve health by helping them identify motivators, goals, and barriers.<sup>82</sup> Social support, goal-setting, and identification of barriers are behavior change strategies which have demonstrated improvements in T2DM risk.<sup>20</sup>

### *Limitations*

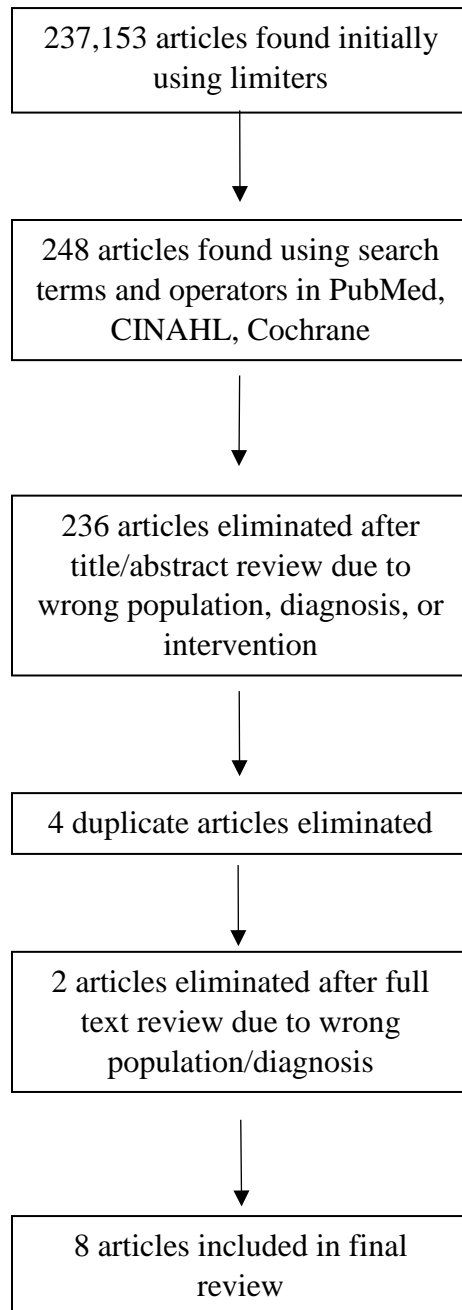
A few gaps in the literature were noted. First, there were few studies to review regarding this population despite the obvious need. The long-term effects of T2DM impact the already limited resources available to this population and a need for interventions that reduce this risk are critical. Secondly, there were no randomized, controlled trials to review. Studies were pre-post design and several did not have a control or comparison group, this limits the validity of the findings as the results for one-group designs may not be representative of rural populations and there may be differences between the intervention and comparison groups that could bias results. Third, although the focus of this review was mainly on dietary interventions used in rural U.S. populations to decrease the risk of developing T2DM, all the literature found incorporated both a dietary and physical activity component. Poor diet and decreased physical activity are risk factors for T2DM<sup>20, 23, 83</sup> but it is unknown which has a greater impact on disease development. It has been found that improving diet has a greater impact on weight than physical activity and that using both only improved weight loss by less than 3 pounds compared to improving diet alone.<sup>84</sup> Further, the impact of diet quality compared to physical activity on incidence of T2DM is not known in rural populations.

### **Conclusion**

Findings from these studies demonstrate that lifestyle modifications can decrease weight and fasting blood glucose, two risk factors associated with T2DM. Additionally, the DPP can be adapted for use in rural populations and can be delivered in groups and through technology, such as telehealth and web-based modalities, with favorable outcomes. Only one of the studies followed participants for an extended period of time.

However, it was encouraging to see that individuals in that study, who completed the lifestyle intervention, had decreased T2DM incidence over three annual follow-ups compared to those who did not complete the intervention. However, more longitudinal studies are needed to further evaluate these results. Diet quality is an important component to decreasing the risk of developing T2DM but only one study objectively measured quality of diet compared to self-reports of daily calories and fat found in the other studies. Improvement in diet quality was reported, but further studies that objectively measure diet quality as part of the intervention to decrease risk of T2DM in rural populations are needed to assess the value of food quality compared to food quantity in this population. The results found in this paper provide an important starting point for further studies aiming to reduce T2DM risk in rural populations.

**Figure 2.1: Systematic Review**



**Table 2.1: Dietary interventions to decrease T2DM risk in rural U.S. populations**

<b>Study</b>	<b>Design</b>	<b>Sample</b>	<b>Results</b>	<b>Limitations</b>
Boltri et al. (2011)	Pre-post 2 churches participated in a 6 week DPP group 3 churches participated a 16 week DPP group intervention aimed at decreasing weight and FBG	37 adults from rural GA churches	There was no difference between groups for wt. loss or FBG. Weight decreased 1.7kg from baseline to post intervention, decreased to 0.9 kg baseline to 12 month follow up. FBG decreased 6.41 mg/dL from baseline to post intervention and 7.78 mg/dL from baseline to 12 month follow up.	Small sample size, lack of randomized control group, questionable generalizability
Drozek et al. (2014)	Pre-post, 4-8 weeks (16 classes) intervention aimed at improving diet quality (plant-based) and increasing physical activity	225 self-selected 24-81 years living in rural Appalachia Ohio.	90% of participant completed the intervention. Significant improvement in BMI (-3.5%, p = <.001) and FPG (-4.1%, p = <.001)	Lack of control group, self-selection of participants, short study period, questionable generalizability
Jiang et al. (2013)	Pre-post demonstration project implementing 16 week 2 Diabetes Prevention Program aimed at decreasing weight and T2DM risk by improving eating habits and physical activity. Post intervention follow up annually x 3 years.	1891 American Indian and Alaskan Native adults across 80 tribes in 18 states who completed the program. Average age 46.6 years	T2DM incidence~3.5% for completers vs. 7.5% for non-completers. Average 9.6 pound weight loss post intervention, 22.5% of participants achieved 7% weight loss goal. 17.5% maintained this goal 3 years post intervention. FPG decreased ~4 mg/dL from baseline to post intervention	Lack of control group, loss of participants to follow-up, questionable generalizability

**Table 2.1 (continued): Dietary interventions to decrease T2DM risk in rural U.S. populations**

<b>Study</b>	<b>Design</b>	<b>Sample</b>	<b>Results</b>	<b>Limitations</b>
McKnight et al. (2018)	Pre-post replication study with 12 weekly group session, 3 monthly group sessions and 3 individual counseling and personal training sessions-diabetes prevention group aimed at decreasing weight and T2DM risk	347 individuals at risk for T2DM living in rural OH, aged 45-64 who completed the program.	Diabetes prevention (DP) group (n=62) 41% lost > 5kg, 48% lost 5% of more of their total weight. FFL group (n=228) 20% lost > 5 kg. All participants (n=347) 67% increased fruits/vegetables, 54% increased whole grains, 54% decreased trans fats, 59% avoided high fructose corn syrup, and 56% used nutrition labels. DP group 54% improved A1c by 1.5%	Questionable generalizability (motivated participants), long-term weight regain unknown, no control group. Comparisons made between groups with potentially different populations (obese vs. prediabetic)
Millard et al (2010)	Pre-post with comparison group. 8 week intervention using Community-based participatory research approach aimed at reducing T2DM risk in an immigrant Hispanic population.	81 participants (38 intervention), average age 35 living in rural Texas. Intervention group completed at least 50% of classes to be included in analysis.	Intervention group decreased BMI by 0.19 (p = .005). Comparison group did not decrease BMI	Generalizability, 20% of participants excluded in analysis for poor attendance. Non-randomization of comparison group

**Table 2.1 (continued): Dietary interventions to decrease T2DM risk in rural U.S. populations**

<b>Study</b>	<b>Design</b>	<b>Sample</b>	<b>Results</b>	<b>Limitations</b>
Piatt et al. (2013)	Quasi-experimental design, 4 groups (face to face (FF), DVD, Internet (INT), self-selection (SS)). 12 week intervention aimed at decreasing weight and CV risk focusing on healthy food choices & calorie/fat intake.	493 participants, average age 51 years living in rural southwestern Pennsylvania. 260 completed intervention & were included in analysis.  Groups determined by county participant lived in	Significant weight loss among all groups between baseline & 3 month time point. Significant weight loss among all groups between 3 month & 12 month time point. 5% weight loss goal met by 57.2 % FF, 56.7% DVD, 62% INT, & 66.7% SS participants at 3 month, >90% of these participants maintained 5% weight loss at 6 month point. Proportion of FF, DVD, SS participants with impaired fasting glucose decreased from baseline to 3 month & 12 months	Generalizability, attrition, non-standardized intervention to fit community needs, non-randomized groups
Vadheim et al. (2010)	Translational study of DPP, pre-post design, no control group conducted over 10 month (16 weekly, 6 monthly sessions) aimed at reducing T2DM risk	101 participants (84 completed 16 week core, 65 completed 6 month post core), average age 51 years, living in rural Montana	>2/3 of participants completing core and post-core had > 5% weight loss, with 52% of those participants have >7% weight loss. Mean participation = 14 core sessions, 4 post core sessions. Participants self-measured fat and calorie intake an average of 9 weeks.	Lack of control group, self-report of diet and activity

**Table 2.1 (continued): Dietary interventions to decrease T2DM risk in rural U.S. populations**

<b>Study</b>	<b>Design</b>	<b>Sample</b>	<b>Results</b>	<b>Limitations</b>
Vadheim, et al. (2017)	Translational study of DPP, pre-post design using telehealth group compared to face-to-face group. Conducted over 16 weekly core sessions and 6 monthly post core sessions aimed at reducing weight.	894 participants (256 telehealth, 638 face-to-face) completed the core and post core sessions. Average age 51.7 (SD 12.1), 84% female. Living in rural Montana	There was no significant difference in weight loss between groups. Participants lost an average of 5.9 kg (SD 4.6). 38% of telehealth group met 7% weight loss goal and 41% of face-to-face group met 7% weight loss goal.	Self-reported diet measures, lack of randomization of groups, lifestyle coaches were not blinded to participant outcomes



## CHAPTER 3. A CRITICAL ASSESSMENT OF INSTRUMENTS FOR THE MEASUREMENT OF DIET QUALITY FOR PATIENTS WITH TYPE 2 DIABETES MELLITUS

### Introduction

Diet or nutritional management is one of the cornerstones of treatment for T2DM.<sup>85</sup>  
<sup>86</sup> The American Diabetes Association, American Association of Clinical Endocrinologists, and International Diabetes Federation recommend diets that are high in non-starchy vegetables, fruits, low fat dairy, legumes and nuts, and low fat protein while limiting servings of added sugars, solid fats, sodium, and alcohol.<sup>86-88</sup> These recommendations are also consistent with the *Dietary Guidelines for Americans*; a set of recommendations by the United States Department of Agriculture (USDA)<sup>5</sup> which defines “high quality” foods that individuals should regularly consume and which foods are not “high quality” and should be avoided or consumed in limited amounts.

As numbers of individuals affected by T2DM worldwide continues to escalate, improvement of dietary quality becomes more important. According to the World Health Organization, there are 347 million people with diabetes, approximately 90% of those individuals have T2DM.<sup>89</sup> Currently in the United States and worldwide, diabetes is the 7<sup>th</sup> leading cause of death.<sup>4, 89</sup> There are many factors associated with development of T2DM; however, overconsumption of soda, other sugar-sweetened drinks, and highly processed carbohydrates are a contributor to obesity, a major risk factor for the development of T2DM.<sup>86-88</sup> Diets low in refined carbohydrates and added sugars and higher in fiber content are associated with better control of T2DM.<sup>90-94</sup> The dietary approaches to stop hypertension (DASH), Mediterranean type, and lower carbohydrate diets are all

examples of dietary interventions used to decrease the risk of developing and/or controlling T2DM and are considered to be high quality diets.<sup>95-105</sup>

Many lifestyle interventions used to decrease risk of developing T2DM include a dietary component; therefore, it is essential to measure adherence to the diet intervention being used. Diet indices have been used by researchers to measure adherence by calculating a diet quality score at baseline and post intervention, and to track diet quality over time. These scores are compared to determine if an improvement in diet quality has occurred and thus can be used to determine adherence to a recommended diet. The purpose of the review is to assess the validity and reliability of these indices and determine their usefulness in measuring diet quality and adherence for individuals participating in a dietary intervention.

## **Methods**

### *Rationale for Indices*

The Healthy Eating Index-2015 (HEI-2015), the Alternative Healthy Eating Index (AHEI-2010), the DASH diet score and the Diet Quality Index-Revised are commonly used dietary quality indices based on United States nutrition guidelines.<sup>106-108</sup> The Healthy Diet Index (HDI) and the Dietary Quality Score (DQS) are two dietary quality indices based on European nutrition guidelines.<sup>109-112</sup> These indices are used to calculate scores based on food frequency questionnaire data or two week diet histories provided by participants; higher scores indicate consumption of higher quality diets.<sup>106, 108, 109, 111-113</sup> Although shorter diet screeners have been used to assess diet quality, this review will focus on diet indices that have been validated using detailed food frequency questionnaires and food histories and have been used extensively in research. A critical review of the six major diet

indices that are used to assess diet quality based on nutritional guidelines will be presented in this paper.

## **Results**

### *Healthy Eating Index (HEI)*

The Healthy Eating Index was first developed in 1995 by the USDA Center for Nutrition Policy and Promotion; it was revised and updated in 2005, 2010, and 2015.<sup>107, 114, 115</sup> The scoring for this index is based on USDA food patterns that quantify the recommendations found in the *Dietary Guidelines for Americans* (DGA).<sup>115</sup> The original HEI had 10 components, of which, five components addressed adequate intake of foods from the five food groups, four components addressed foods to be consumed in moderation, and one component measured food variety.<sup>115</sup> The HEI was updated in 2005 after the new federal dietary guidelines were released. Based on these guidelines, the HEI-2005 incorporated 12 components, nine components to address adequate intake of key food groups and three components to address foods to be consumed in moderation.<sup>114</sup> The HEI has been updated regularly based on updates to dietary guidelines published by Health and Human Services and the United States Department of Agriculture. The HEI-2010 retained the 12 total components but updated nomenclature of the components.<sup>114</sup> The HEI-2015 has 13 total components.<sup>107</sup> The empty calories category was deleted and saturated fats and added sugars were added. The recommendation is to limit both of these components to less than 10% per day of total caloric intake.<sup>107</sup> Legumes are now accounted for between both the two vegetable and two protein food components instead of either component; legumes are counted as a protein first and once that recommendation is met, they are then counted

as vegetable.<sup>107</sup> Weighting standards remain similar. Scoring parameters were refined, if needed, to improve continuity across all components.<sup>107</sup>

Each component of the HEI has a standard score based on 1,000 kilocalories. Maximum scores for each component are based on the least-restrictive recommendations for energy level, sex, and/or age.<sup>107</sup> A maximum score of five is assigned for the components of *total fruit, whole fruit, total vegetables, greens and beans, total protein foods, and seafood and plant proteins*. A maximum score of 10 is assigned for the components *whole grains, dairy, and fatty acids*.<sup>107</sup> Components that should be consumed in moderation are reverse scored; they are assigned higher scores based on smaller amounts. *Sodium, refined grains, saturated fats, and added sugars* have a maximum score of 10 each.<sup>107</sup> The total score for the entire index equals 100; scores greater than 80 are considered “good,” scores of 51-80 indicate a “need for improvement,” and scores of less than 51 are considered “poor”.<sup>114</sup>

HEI-2015 used menu exemplars from the United States Department of Agriculture, the National Heart, Lung, and Blood Institute, Harvard Medical School, and the American Heart Association to assess construct and criterion validity and reliability.<sup>116</sup> In addition diet information from the National Health and Nutrition Survey 2011-2012 and National Institutes of Health-AARP Diet and Health Survey was used to assess validity and reliability of the index.<sup>116</sup> Total scores for the exemplar diets ranged 87.8-100 for the HEI-2015.<sup>116</sup> These high scores indicate HEI indices meet criteria for construct validity. Concurrent criterion validity was tested using data from known divergent groups in order to evaluate if the HEI-2015 could accurately determine differences among the groups.<sup>107</sup> It was shown there were mean differences for both versions between total scores for men

and women (59.7 vs. 57.2,  $p < .01$  HEI-2015), young adults and older adults (55.0 vs. 62.8,  $p < .01$  HEI-2015) and smokers and non-smokers (53.3 vs. 59.7,  $p < .01$  HEI-2015).<sup>116</sup> Similar scores for past HEI indices were reported.<sup>25, 114</sup>

Using data from NHANES 2011-2012 for the HEI-2015, moderate correlations were found between 5 component scores and total score for HEI-2015 ( $r = .46-.58$ ). Principal component analysis indicated that there was no single covariate that explained the variation in scores for the HEI-2015, reflecting the ability to detect multi-dimensional variations in diet.<sup>107</sup> Internal consistency (validity) was measured using the standardized Cronbach alpha which revealed a coefficient of .67 for the HEI-2015, demonstrating only a moderate level of reliability.<sup>107</sup> However, the sample used from the NHANES was not homogenous, that is, diets among individuals in the United States population can be vastly different compared to the DGA standards. Therefore, this evaluation of reliability is considered acceptable.<sup>107</sup> Each version of this index has been widely used in assessing dietary quality, intervention compliance and prediction of chronic illnesses such as T2DM, cancer, obesity, depression, and cardiometabolic disease.<sup>117-122</sup> However, the newest version is the best one to use as it is based on the most recent dietary guidelines.

#### *Alternative Healthy Eating Index (AHEI)*

The Alternative Healthy Eating Index (AHEI) was first introduced in 2002 by McCullough and Willett.<sup>108</sup> Dietary quality and adherence, as indicated by the HEI, were not as predictive of chronic illness as these authors thought could be achieved. The AHEI incorporates distinctions between unsaturated and saturated fats, types of carbohydrates, and varying protein sources.<sup>108</sup> It has been used in multiple trials assessing the risk of developing chronic disease.<sup>117, 118, 123-125</sup>

Nine components make up the AHEI based on input from nutrition experts and dietary patterns consistently found among individuals with chronic illnesses. Some of these components are also found on the HEI but had some items removed, for example, potatoes were not included in the vegetable component.<sup>108</sup> Total scores range from 2.5 (worst) to 87.5 (best). Higher intakes of components equaled a greater score. Individuals received a score of 10 for each of the following components; >5 servings of vegetables, > 4 servings of fruit, a 4:1 of poultry or fish versus red meat, >1 serving of nuts or soy products, >15 grams whole grains, ratio of  $\geq 1$  polyunsaturated vs. saturated fats,  $\leq .5\%$  kcal of transfat, 1.5-2.5 servings of alcohol for men or .5-1.5 servings for women. Use of a daily multivitamin > 5 years resulted in a score of 7.5 while a score of 2.5 was given to everyone else.<sup>108</sup>

Psychometric testing was conducted using data from 38,615 men enrolled in the Health Professionals Follow-up Study and 67,271 women from the Nurse's Health Study.<sup>108</sup> Primary outcome variables included initial development of cardiovascular disease (CVD), cancer, or non-trauma related death. The authors used pooled logistic regression to account for covariant changes over time in order to assess multiple risk factors. A moderate inverse relationship was found between high AHEI scores and both CVD and major chronic illness in men, (RR=.61, 95% CI .49-.75 and RR=.80, 95% CI .71-.91  $p < .001$  respectively). Women also had reduction of risk for both CVD and major chronic illness with high AHEI score (RR=.72, 95% CI .60-.86,  $p < .001$  and RR=.89, 95% CI .82-.96,  $p < .009$ ). There was no significant relationship found between the AHEI and incidence of cancer.<sup>108</sup>

The AHEI was updated in 2010 based on new data related to diet and development of chronic illness.<sup>117</sup> Diet quality was based on 11 components with a total score between 0 and 110; higher scores indicated better diet quality adherence.<sup>117</sup> Scores for vegetables, fruit, and alcohol remained unchanged. Women received a score of 10 for whole grain consumption of 75 grams/day while men received a score of 10 for 90 grams/day.<sup>117</sup> A score of 10 was received for no consumption of sugar-sweetened beverages or fruit juice,  $\geq 1$  serving of nuts and legumes, 0 servings of red/processed meat per day,  $\leq .5$  servings of trans fat, 205 mg/d of long-chain fatty acids,  $\geq 10$  % of energy from polyunsaturated fatty acids, and sodium intake in the lowest decile.<sup>117</sup>

Primary outcome variables included CVD, diabetes, cancer, and non-traumatic death. For this study, the authors used multivariate Cox proportional hazard models to calculate hazard ratios for each disease by quintiles of the dietary score; lowest and highest quintiles were compared. Adjustments for potential confounders were made.<sup>117</sup> The AHEI was strongly correlated to the AHEI-2010 for both men and women ( $r=.77$  men and  $.67$  women,  $P=.001$ ), indicating good construct reliability. Pooled, multivariate adjusted quintiles (comparing the lowest and highest) for men and women for major chronic illness had an RR of  $.81$  (CI 95%,  $.77, .87$ ,  $P<.001$ ) for both the AHEI and the AHEI-2010.<sup>117</sup> Inverse relationships between the AHEI-2010 and pooled, multivariate adjusted risk of CVD ( $.76$ , CI 95%  $.71, .81$ ,  $P<.001$ ), diabetes ( $.67$  95%CI,  $.61, .74$ ,  $P=<.001$ ), and stroke ( $.80$ , 95%CI,  $.71, .91$ ,  $P=.001$ ) were found.<sup>117</sup> A RR of  $.93$  (95% CI  $.88, .99$ ,  $P=.01$ ) for cancer was found significant for women but not men. Divergent validity is evident between sexes by the strong correlation of the AHEI-2010 and the HEI-2005 ( $r=.62$  women,  $.68$  men,  $P=<.001$ ); most probably related to shared components of vegetables, whole fruit,

low sodium, and whole grains.<sup>117</sup> Bosire et al. found a strong correlation between the AHEI-2010 and the HEI-2005 ( $r = .55$ ,  $P < .0001$ )<sup>126</sup> while Jacobs et al. found an even stronger association between the indices ( $r = .67$ ,  $P = .003$ ).<sup>37</sup> A strong Spearman correlation between the AHEI-2010 and the DASH diet have also been reported (.73).<sup>127</sup>

#### *Dietary Approaches to Stopping Hypertension (DASH) Score*

The DASH diet was developed by Sacks, et al. in 1994 as an experiment to test the effect of a diet high in vegetables, fruit, low-fat dairy, whole cereal products, fish, chicken, and lean meat on blood pressure.<sup>128</sup> The effect of this diet has been studied on chronic illnesses such as T2DM, heart failure, obesity, and mood disorders.<sup>99, 106, 125, 127, 129, 130</sup> The DASH score was developed by Fung, et al. to measure adherence to a DASH-style diet in relation to incidence of coronary heart disease (CHD) and stroke.<sup>106</sup> Like the HEI and AHEI, scores are based on answers to food frequency questionnaires. Scores are calculated based on eight components. Consumption of fruits, vegetables, nuts and legumes, low-fat dairy, and whole grains received scores ranging from 1 for poor intake to 5 for high intake.<sup>106</sup> Scores for sodium, red meat/processed food, and sweetened beverages were scored inversely; a score of 5 for low intake and a score of 1 for high intake. A score of 40 is the best total score possible.<sup>106</sup> These authors reported an inverse relationship between a high DASH diet score and both CHD and stroke (RR=.76, 95% CI .67-.85,  $P < .001$  and RR=.82, 95% CI, .71-.94,  $P < .002$  respectively) based on comparison of the lowest and top quintiles.<sup>106</sup>

Construct validity for the DASH score was supported by a very strong correlation to the HEI-2010 ( $r = .74$ ,  $p < .05$ ) and the alternative Mediterranean diet score ( $r = .63$ ,  $p < .05$ ) in an ethnically diverse population of men and women at risk for T2DM<sup>125</sup> Other authors



found the DASH score had a stronger association to the AHEI ( $r=.75$ ,  $p<.05$ ) than to the HEI-2005 ( $r=.61$ ,  $p<.05$ ) in men at risk for T2DM.<sup>31</sup> Additionally, correlations between these indices were supported by George et al. ( $r=.55-.70$ ,  $p<.0001$ ) among post-menopausal women with chronic disease risks.<sup>123</sup>

### *Diet Quality Index-Revised*

The original Diet Quality Index was developed by Patterson and colleagues in 1989 to assess the associations between dietary patterns and chronic disease in the United States.<sup>131</sup> The index measured intake based on 8 food groups and nutrients recommended by the Committee on Diet and Health of the National Research Council Food and Nutrition Board.<sup>131</sup> The index was updated in 1999 to reflect more current dietary recommendations from the United States Department of Agriculture (USDA).<sup>112</sup> The Diet Quality Index-Revised (DQI-R) was assessed using data from the Continuing Survey of Food Intakes by Individuals (CSFII). Dietary intake data was collected in 3202 adults (>18 years old) using two 24 hour recall measurements.<sup>112</sup> CSFII food codes, nutrient values, and the Food Pyramid serving database were used to convert dietary intake into nutrient and food measurements.<sup>112</sup>

Based on these food and nutrient measurements, ten components for the DQI-R were developed. The 10 components include; total fat ( $\leq 30\%$  daily energy intake), saturated fat ( $\leq 10\%$  daily energy intake), dietary cholesterol ( $< 300$  mg/day), fruit (2-4 servings/day), vegetables (3-5 servings/day), grains (6-11 servings/day), calcium (% based on age), iron (% based on age), diversity, and moderation.<sup>112</sup> Diversity was defined as a range of foods needs to obtain nutritive and non-nutritive components. Moderation was defined as limitation of food constituents that contribute to excessive risk (sugar, sodium,

fats).<sup>112</sup> Each component is assigned a score of 0 to 10. Scores for fruits, vegetables, grains, calcium, and iron ranged from 0-10 based on the recommended intake. Scores for fats, saturated fats, and cholesterol were based on 3 levels of intake;  $\leq 30\%$  received 10 points,  $> 30\%$  received 5 points, and  $> 40\%$  received 0 points. Diversity was scored across four primary food subgroups (grains, vegetables, fruits, and meat/dairy), each group received 2.5 points based on intake. Moderation was scored across 4 categories for a maximum of 10 points, individuals received 0-2.5 points based on intake of added sugar, discretionary fats, sodium, and alcohol.<sup>112</sup>

The mean DQI-R score for participants was 63.4 ( $\pm 13.2$ ). The range of scores for each component of the DQI-R improved with the total DQI-R score, indicating a consistent improvement between both quality and quantity and demonstrating concurrent validity.<sup>112</sup> For example, the lowest DQI-R scores (0-40) were associated with the highest percentage of energy from fat (44%) and the highest DQI-R scores ( $>80$ ) were associated with the lowest percentage of fats (24%,  $P = < 0.01$ ).<sup>112</sup> The index was not found to be strongly correlated to energy intake ( $r = 0.02$ ) which indicates that the index is not overly influenced by foods which contain excess energy but have little nutritive quality, for example soft drinks and alcohol. A least squares regression analysis was performed on the index to assess the proportion of variability for each component. Regression coefficients for 6 of the components (percentage of energy from saturated fats, cholesterol intake, recommended intake of iron, dietary moderation score, percentage of recommended fruit, and percentage of recommended vegetables) ranged between 0.94 and 1.10. Percentage of energy from fat, diet diversity, and percentage of recommended grains explained more variability of the overall scores ( $\beta = 1.7, 1.3, \text{ and } 1.17$  respectively).<sup>112</sup> These scores

indicate that the total DQI-R explains the complexity of the dietary pattern better than a single component of the index.

Reproducibility and validity of the DQI-R was assessed using two food frequency questionnaires (FFQ) and two one-week diet records, conducted one year apart, in a population of 127 men aged 40-75.<sup>110</sup> Average intake of 131 foods in nine categories was measured over the past one year using each FFQ.<sup>110</sup> Correlations between serum levels of biomarkers and the DQI-R were also assessed. Scores for each individual were assigned according to the DQI-R. Comparing the 2 FFQs, a reproducibility correlation of 0.76 was obtained for the total DQI-R scores. Reproducibility correlations for individual components of the DQI-R using the 2 FFQs ranged from 0.41 to 0.76. Validity correlations for individual components of the DQI-R ranged from 0.06 to 0.71 in the comparison of the 2 FFQs.<sup>110</sup> Comparing the results of the DQI-R scores from the diet records to the FFQs, validity correlations for the first FFQ was 0.66 and 0.72 for the second FFQ. The reasonably close correlations between these two measures demonstrate concurrent validity of the total DQI-R score. Mean DQR-I scores were 69.5 and 67.2 for the first and second FFQ respectively, revealing reasonable reproducibility. The DQI-R scores were positively correlated with serum levels of alpha-carotene, beta-carotene, lutein, and alpha-tocopherols, and dietary intakes of vitamins B6 and C, fiber, folate, magnesium, and calcium ( $p < 0.05$ ). An inverse correlation was found between DQI-R and levels of serum cholesterol and dietary intake of fat, saturated fats, monounsaturated fat, and cholesterol ( $p < 0.05$ ). These results are an expected finding associated with high quality diets.<sup>110</sup>

A comparison of the DQI-R, AHEI, and HEI to examine the relationship between these indices and plasma concentrations of inflammatory markers and endothelial

dysfunction was conducted.<sup>132</sup> Inflammation and endothelial dysfunction are associated with the development of T2DM.<sup>132</sup> Although these diet indices were significantly correlated, ranging from 0.60 to 0.80 ( $p < 0.0001$ ), only the AHEI was associated with a lower concentration of inflammatory markers and endothelial dysfunction after adjustments for age, smoking status, physical activity level, alcohol intake, and BMI were made. C-reactive protein levels were 30% lower in the top quintile of the AHEI compared to the bottom quintile ( $P, 0.05$ ).<sup>132</sup> The AHEI assigns points for diets with a high ratio of polyunsaturated fats compared to saturated fats; whereas, the HEI and DQI-R do not assign points based on this distinction which may partly explain the findings. Quality of carbohydrates is not emphasized in either the HEI or DQI-R unlike the AHEI, and refined grains may not be helpful in reducing inflammation.<sup>132</sup>

### *Healthy Diet Index*

The Healthy Diet Index (HDI) was developed by Huijbregts and colleagues to assess the association between dietary patterns and mortality using an international population.<sup>109</sup> This index was based on the World Health Organization's (WHO) nutrition guidelines for preventing chronic disease or disability.<sup>109</sup> Huijbregts et al. used dietary data collected from a random sample of 3045 men aged 50-70 years from Finland, Italy, and the Netherlands during the years 1969-1970.<sup>109</sup> Dietary patterns and mortality rates were assessed for the next 20 years. This cohort of men was chosen as the dietary intake of these populations was found to be stable during the prior 10 years in the larger Seven Countries Study.<sup>109</sup> Dietary data were collected using a cross-check dietary history in which food consumption patterns are estimated based on the prior 6-12 months.

Participants recorded the foods consumed at breakfast, lunch, dinner, and in-between meal snacks and intake of foods was confirmed during an interview with participants.<sup>109</sup>

A dichotomous value was assigned for each food group or nutrient based on the WHO guidelines which resulted in nine components. The nine components include; saturated fatty acids, polyunsaturated fatty acids, protein, complex carbohydrates, dietary fiber, fruits and vegetables (combined), pulses, nuts and seeds (combined), monosaccharides and disaccharides, and cholesterol.<sup>109</sup> One point was assigned for intake that complied with the WHO guidelines, intake that fell outside the recommended intake was assigned a zero. The best possible score was nine and the worst possible score was zero.<sup>109</sup> Dietary intake was found to be significantly different between the cohorts for all nine components. For example, daily energy intake from monosaccharides and disaccharides ranged from 5% in Montegiorgio (Italy) to 25% in eastern Finland; and daily energy intake from fruits and vegetables ranged from 137% in Montegiorgio (Italy) to 333% in the Netherlands.<sup>109</sup> According to the authors, the minimum HDI was 0 and the maximum score was eight. Participants were grouped into three groups, low HDI (<2), medium HDI (2), and high HDI (>2).<sup>109</sup>

Analysis of the interaction between HDI and country was not found to be significant ( $P > 0.20$ ); Cox's proportional hazard analysis of pooled data was used to assess the HDI and mortality. The HDI was found to be inversely associated with all-cause mortality; a crude analysis revealed a 15% lower risk of death in the high HDI group. Adjusting for confounders (age, smoking, alcohol consumption), risk from cardiovascular death was 18% lower in the high HDI group. Each component of the HDI was analyzed in the model and was not found to be significant, indicating the total score (dietary pattern) explained

the results.<sup>109</sup> A revised version of the HDI, based on updated WHO guidelines was implemented in 2003 and a 10% decreased all-cause mortality was reported among elderly populations in Europe and the United States using this revised version.<sup>133</sup> There was a strong positive correlation found between the original HDI and the AHEI ( $r = +0.3$ ,  $P = 0.001$  and  $r = +0.4$ ,  $P = 0.001$ , respectively).<sup>134</sup> However, individuals with T2DM were found to have less healthy diets compared to control group individuals using the original HDI but not for the AHEI.<sup>134</sup> A significant improvement in fasting blood glucose was also associated with the original HDI among the participants with T2DM but not with the AHEI in this group.<sup>134</sup> One reason posited was that the AHEI allows for a wider range of intake compared to the predefined, dichotomous score of the original HDI.<sup>134</sup>

#### *Diet Quality Score*

The Diet Quality Score (DQS) was developed using a shorter 48 item FFQ to help determine the association of diet and cardiovascular (CV) risk factors.<sup>111</sup> A sample of 6542 Danish men and women, aged 30-60 years old, completed both a 48 item FFQ and a 198 validated FFQ in order to assess the validity of the DQS. This index was developed to be a simple, rough method for classifying individuals into groups of high, average, and low dietary quality.<sup>111</sup> The 48 item FFQ was used to assess intake of foods recommended in the Danish Dietary Guidelines. A three-point scoring system was developed to assess intake across four food groups, fish, fruits, vegetables, and fats. The FFQ included questions about the types of bread spreads, cooking fats, fish, and vegetables consumed by the participants over the past one week. Fruit intake was based on pieces per day.<sup>111</sup> Vegetable servings greater than 5/week were assigned 3 points, 3-4 servings/week were assigned 2 points, and less than 2 servings/week were assigned 1 point. More than three pieces of fruit/day were

assigned 3 points,  $\geq 3$  pieces/week and  $\leq 2$  pieces/day were assigned 2 points, and  $\leq 2$  pieces of fruit/week were assigned 1 point. Servings of fish were assigned 3 points for  $\geq 200$ grams/week, 2 points for  $\geq 1$  gram/week, and 1 point for no intake. Fats were summarized into 3 points for no fat used or olive oil used for spreads and/or cooking, 2 points for use of margarine for both spreads and cooking, and 1 point for use of butter and/or lard for spreads or cooking. Healthy dietary habits, scored between 7- 9 points had a significantly positive association with HDL level ( $p = 0.023$ ) and a significantly negative association with TC, TG, LDL, homocysteine levels ( $p = <0.0001$ ), waist circumference ( $p = 0.0031$ ), and ischemic heart disease risk score ( $p = <0.0001$ ). Spearman's correlation coefficients between the DQS and 198 item FFQ ranged from -0.05 (vitamin A) to 0.55 (fruits),  $p = <0.0001$ .

The eight component DQS was compared to serum levels of total cholesterol (TC), low density lipoproteins (LDL), high density lipoproteins (HDL), triglycerides (TG), and homocysteine and clinical measurements of blood pressure (BP), BMI, waist circumference, and ischemic heart risk (Copenhagen Risk Score) to assess associations between the DQS and CV risk.<sup>111</sup> There was no association found between the DQS and BMI.<sup>111</sup>

## **Discussion**

### *Strengths and weaknesses*

All six indices have strengths and weaknesses (Table 3.1). Construct validity was well addressed for each measure in the HEI, AHEI, DASH, DQI-R, and HDI. In fact, several groups of investigators conducted comparisons of these indices with moderate to high agreement among the instruments.<sup>118, 123, 126, 132, 134, 135</sup> All six indices used recognized

high quality diets and validated food frequency questionnaires or diet histories as comparators in benchmark testing, lending a high degree of credibility to the outcomes and providing a basis for comparison.<sup>106-112, 133</sup> In addition, all the indices are relatively short ranging from seven to 13 components and scoring is straightforward; thereby, making interpretation less complicated for researchers. However, most of the indices rely on food frequency questionnaires which are typically greater than 100 items each or require participants to record their daily dietary intake for 1-2 weeks in order to construct the diet quality score. Completing the questionnaires and diet histories could be burdensome for participants; thereby, leading to incomplete questionnaires and causing each index to be less accurate.<sup>106, 108, 109, 112, 113</sup> A shorter 48 item FFQ is used to generate the DQS; however, this index should only be used for a crude analysis of dietary quality as it has not been extensively retested and reliability and validity are questionable.<sup>111</sup>

Only the HEI-2015 and previous versions of this index have evidence of internal consistency reliability and factorial, divergent, and concurrent validity. Although the HEI-2015 did not reach the desired Cronbach alpha of .70, it is very close and is a good measure considering that most people do not meet many of the dietary recommendations set by the USDA. This index was tested against four known high quality diets, including the DASH diet, to assess construct validity. The authors of this index tested differences among known divergent groups and correlations among both individual components and total scores.<sup>116</sup>

Reproducibility and reliability testing for the DQI-R were found to be acceptable and it is a widely used measure of diet quality in research. While the DASH diet score and AHEI do not address internal consistency, both indices seem to have stronger predictive capacities for T2DM, cancer, heart disease, and other chronic illnesses than the HEI or the



HDI.<sup>106, 117, 135</sup> Lower concentrations of inflammatory markers and endothelial dysfunction, potential influences in the development of T2DM, were associated with the high AHEI scores but not for the HEI or DQI-R.<sup>132</sup> The fact that the AHEI was developed specifically to predict chronic illness and has demonstrated that capability does convey confidence in its use for this issue.

#### *Summary of indices used to measure high quality diet adherence in T2DM*

Five of the indices have been used to assess the risk of developing T2DM with a high degree of success; this is most likely due to the close correlation of components found in each of the measurement tools.<sup>125, 132, 134, 136, 137</sup> Although these dietary indices were developed to assess dietary patterns, several of these instruments have been used to measure adherence to high quality diet patterns by comparing the baseline scores to scores obtained post intervention to determine whether the quality of the diet has improved.<sup>134, 136, 137</sup> These indices may be valuable in determining the effect of dietary interventions (Table 3.2).

#### *Limitations*

Side-by-side comparisons of the indices in randomized, controlled trials may be helpful in determining superiority of indices in the assessment of adherence to a high quality diet. Further testing of each index in multi-ethnic populations to determine diet quality, adherence, and outcomes for individuals with T2DM based on cultural norms may be warranted. Considering that each of these indices rely on potentially burdensome food frequency questionnaires or diet histories to generate their respective scores, use of a dietary index that is less burdensome for participants but has comparable validity and

reliability is needed. Testing of these indices using shorter, validated FFQs or 24-hour diet recalls in controlled trials could decrease burden for participants.

## **Conclusions**

Diet has been recognized as a targeted self-care strategy for individuals with T2DM. Adherence to a high quality diet has been recommended to reduce the risk of developing T2DM, decrease symptoms and long-term complications related to the disease, and improve participant outcomes. Reliable and valid tools are needed to evaluate adherence to dietary interventions. Based on current data, the HEI, AHEI, DASH diet score, DQI-R, and HDI are valuable measures of diet quality and may be used to assess diet adherence in diet interventions.

**Table 3.1: Description of Six Dietary Indices**

Instrument (year)	No. components	Scoring and range	Normative values
Healthy Eating Index-2015 (2015)	13	5 points for recommended amounts of total fruits, whole fruits, total vegetables, greens & beans, total protein foods, and seafood & plant proteins. 10 points for recommended amounts of whole grains, dairy, fatty acids, 10 points for moderation of refined grains, sodium, added sugars, and saturated fats. Based on USDA diet recommendations	0 worst total score 100 best total score
Alternative Healthy Eating Index (2010)	11	10 points for each (per day): 4+fruits, 5+vegetables, 75g whole grains women & 90g whole grains for men, 0 servings sugar sweetened drinks/fruit juice, $\geq 1$ serving nuts/legumes, 0 servings red/processed meats, $\leq 5\%$ of energy trans-fat, 25mg long chain fats, $\geq 10\%$ energy PUFA, lowest decile sodium, 0.5-1.5 (women) & 1.5-2.5 drinks (men) ETOH	0 worst total score 110 best total score
DASH score (2006)	8	5 points for highest quintile: fruits, vegetables, whole grains, low-fat dairy, nuts & legumes. 5 points for lowest quintile: low sodium, sweetened beverages, red/processed meats	8 worst total score 40 best total score
Diet Quality Index-Revised (1999)	10	10 points each for restricting fat, saturated fat, and dietary cholesterol to goal, 5 points for moderate restriction, and 0 points for not restricting. 10 points each for meeting $>100\%$ daily servings for fruits, vegetables, grains, calcium, and iron, 5 points for meeting 50-99% daily servings and 0 points for meeting $< 50\%$ of daily servings. 10 points for diversity score $\geq 6$ , 5 points for score $\geq 3$ , $<6$ , and 0 points for score $< 3$ . 10points for moderation score $\geq 7$ , 5 points for score $\geq 4$ , $< 7$ , and 0 points for score $< 4$ . Based on U.S diet recommendations	0 worst score, 100 best score
Healthy Diet Index-Revised (1997)	9	Dichotomous score, 1 point for daily energy intake: $< 10\%$ saturated fatty acids, 3% - 7% polyunsaturated fatty acids, 10% - 15% protein, 50% - 70% complex carbohydrates, 27% - 40% dietary fiber (g), $>40\%$ fruits and vegetables (g), $>30\%$ pulses, nuts & seeds (g), 0%-10% monosaccharides/disaccharides, & 0%-300% cholesterol (mg). 0 points for not meeting cut-offs. Based on WHO nutrition guidelines	0 worst score, 9 best score
Dietary Quality Score (2005)	12	3 points for meeting weekly recommended servings of vegetables and fish, daily servings of fruit, 2 points for obtaining some servings, 1 point for not meeting recommendations. 3 points for not using fats or using olive oil, 2 points for using margarine, 1 point for using animal fats daily. Based on Danish Dietary guidelines	1-3 unhealthy diet, 4-6 average diet, $> 8$ healthy diet

**Table 3.2: Critical Assessment of Six Dietary Indices**

First Author (year)	Purpose	Design	Sample	Reliability	Evidence of Validity	Comments
<b>HEI-2005</b>						
Guenther (2013)	Assess validity and reliability of HEI-2010, re-evaluate validity and reliability of HEI-2005	Cross-sectional	N= 8262 respondents of the NHANES 2003-2004 dietary component	Cronbach $\alpha$ = .68 HEI-2010 Cronbach $\alpha$ = .65 HEI-2005	Concurrent, convergent, divergent, and factor validity supported Mean HEI-2010 49.80 (men) 52.7 (women)	Content validity confirmed in prior analysis
Chiuve (2012)	Assess association between HEI-2005 & AHEI	Cross-sectional	N= 112,524 combined Nurse's Health Study & Health Professionals Follow-up Study	Not reported	High correlation between HEI-2005 & AHEI ( $r = .65, P < .001$ women $r = .68, P < .001$ men) Mean HEI-2005 62.3 (women) 62.7 (men)	AHEI-2010 had stronger predictor factor for CHD and diabetes
Huffman (2011)	Assess differences in diet between African Americans and Haitian Americans with and without diabetes using the HEI-2005 & AHEI	Cross-sectional	N=471, 225 African American & 246 Haitian American men and women	Not reported	Not reported, Mean HEI-2005 for those with T2DM 63.4 (12.5)	Significant differences between HEI-2005 and AHEI found in relation to diabetes status, HEI-2005 showed higher scores in people with diabetes
de Koning (2011)	Assess relationship between HEI-2005, AHEI, DASH diet score, alternative Mediterranean diet score and predict incidence of T2DM & CVD in men	cross-sectional	N= 41,615 men from the Health Professionals Follow-up Study	Not reported	High correlation between HEI-2005 & DASH ( $r = .61, P < .05$ ) Moderate correlation between HEI-2005 & AHEI ( $r = .41, P < .05$ ) Mean HEI-2005= 67.4 (9.8)	All indices demonstrated reduced risk of T2DM, DASH more significant

**Table 3.2 (continued): Critical Assessment of Six Dietary Indices**

First Author (year)	Purpose	Design	Sample	Reliability	Evidence of Validity	Comments
<b>HEI-2005</b>						
Gao (2008)	Assess diet quality in a multi-ethnic population Compare original HEI & HEI-2005 to predict obesity	Longitudinal	N=6236 men and women in the Multi-Ethnic Study of Atherosclerosis (MESA)	Not reported	Poor agreement between indices found Pittman's test $r=.04$ , $P=.003$ . Mean HEI-2005=55.2 (10.7)	both indices predictive of obesity
<b>AHEI</b>						
McCullough (2006)	Assess diet quality and predict incidence of chronic illness	cross-sectional	N=38,615 men (Health Professionals' Follow-Up Study), 67,271 women (Nurses' Health Study)	Not Reported	Not Reported	Predictive of risk of cancer (men only), CVD, major chronic illness
Fung (2007)	Assess diet quality and predict risk of T2D M in women	Prospective	N=80,029 women (Nurses' Health Study)	Not reported	Not Reported, Mean AHEI= 44.4(11.7)	Higher AHEI scores correlated with lower T2DM risk
Turner-McGrievy (2008)	Assess dietary quality of a vegan of ADA diet in individuals with T2DM	Random, controlled trial	N= 99, 49 vegan group, 50 ADA diet group	Not reported	Not reported	Greater reduction in A1c levels among vegans vs ADA participants
Fung (2005)	Assess association between diet quality indices. Also looked at endothelial dysfunction and inflammatory markers	Cross-sectional	N= 690 women (Womens Health Study)	Not reported	Moderately correlated with the HEI ( $r=.60$ $P<.0001$ ) Mean AHEI= 43 (11)	AHEI had strongest association with biomarkers
Akbaraly (2010)	Assess dietary adherence to guidelines	Longitudinal	N= 339 (Whitehall II study)	Not reported	Adherence levels described as similar to other studies	Lower AHEI =higher prevalence of metabolic syndrome

**Table 3.2 (continued): Critical Assessment of Six Dietary Indices)**

First Author (year)	Purpose	Design	Sample	Reliability	Evidence of Validity	Comments
<b>DASH Diet Score</b>						
Jacobs (2015)	Assess risk of diabetes among a multi-ethnic cohort using AHEI-2010, aMED, DASH diet scores, and HEI-2010	longitudinal	N= 89,185 (MEC study)	Not reported	All indices strongly correlated: DASH/AHEI ( $r.68 P<.05$ )	DASH inversely associated with T2DM
Barnes (2013)	Assess association between CVD risk and DASH diet score in youth with T1DM or T2DM	longitudinal	N=797 (SEARCH for Diabetes in Youth Study)	Not reported	Not reported	No significant change in mean DASH score for youth with T1DM or T2DM over time
Morton (2012)	Assess dietary adherence of individuals with T2DM and a DASH diet	Cross-sectional	N= 5867 adults (NHANES 2003-2004, 2005-2006)	Sensitivity analysis performed, no substantial change	Reported findings similar to 3 other studies	Compliance to DASH diet among individuals with T2DM low
Liese (2009)	Assess association of incidence of T2DM and DASH diet	Cross-sectional	N= 865 (IRAS study)	Not reported	Significant interaction among racial groups, DASH score, and incidence of T2DM	Adherence to DASH diet inversely associated with T2DM in white population
Fung (2008)	Evaluate association between DASH diet score and risk of CHD and stroke in women	longitudinal, repeated measures	N= 88,514 (Nurses' Health Study)	Not reported	DASH scores better in normal weight women and non-smokers	DASH scores associated with lower plasma levels of CRP and Interleukin 6

**Table 3.2 (continued): Critical Assessment of Six Dietary Indices**

<b>First Author (year)</b>	<b>Purpose</b>	<b>Design</b>	<b>Sample</b>	<b>Reliability</b>	<b>Evidence of Validity</b>	<b>Comments</b>
<b>Diet Quality Index-Revised</b>						
Haines (1999)	Assess dietary guidelines compared to revised DQI scoring	Cross-sectional	N= 3202 adults aged > 18 years (CSFII study)	Not reported	Concurrent validity reported: High scores correlated with decreased energy from fat & greater servings of fruits/vegetables/grains	Developed to assess dietary changes in populations but useful in determining individual compliance with dietary recommendations.
Newby (2003)	Assess reproducibility and validity of DQI-R using a FFQ	Longitudinal, repeated measures	N= 127 men aged 40-75 (Health Professionals Follow-up study)	Not reported	Mean DQI-R scores for 2 FFQs 69.5 & 62.0, indicating close agreement on repeated measure. Reproducibility correlation 0.72. Correlations between FFQs 0.66 & .072. DQI-R scores significantly correlated with plasma measurements of $\alpha$ -carotene, $\beta$ -carotene, lutein, $\alpha$ -tocopherol, and inversely associated with cholesterol.	Reasonable reproducibility and validity.

**Table 3.2 (continued): Critical Assessment of Six Dietary Indices**

<b>First Author (year)</b>	<b>Purpose</b>	<b>Design</b>	<b>Sample</b>	<b>Reliability</b>	<b>Evidence of Validity</b>	<b>Comments</b>
<b>Diet Quality Index-Revised</b>						
Fung (2005)	Assess association between diet quality scores and markers of inflammation and endothelial dysfunction	Cross-sectional	N= 690 women aged 43-69 years (Nurses' Health Study)	Not reported	Higher AHEI and aMED scores were associated with lower concentrations of inflammatory biomarkers and endothelial dysfunction. HEI and DQI-R were not associated with inflammatory biomarkers or endothelial dysfunction	AHEI and aMED may better predict risk of inflammatory-linked diseases such as T2DM
<b>Health Diet Index Revised</b>						
Huijbregts (1997)	Investigate the association between dietary patterns and mortality	Longitudinal, repeated measures	N= 3045 men aged 50-70 years (Seven Countries Follow-up study)	Not reported	HDI inversely associated with mortality in elderly men over a 20 year period. After adjusting for confounders, men in the healthiest diet group had a 13% reduction in relative risk	HDI is useful in comparing dietary patterns across diverse cultures and is useful in predicting all-cause mortality
Murray (2013)	Determine dietary quality of individuals with T2DM using several diet quality indices	Cross-sectional	N= 111 adults, mean age 56 (Ireland)	Not reported	Participants with T2DM had lower quality diet vs. control population using the HDI; lower consumption of Mediterranean diet using the MDS and aMDS. No difference in diet quality was found between AHEI groups.	Participants with T2DM have overall poorer diets compared to those without T2DM



**Table 3.2 (continued): Critical Assessment of Six Dietary Indices**

<b>First Author (year)</b>	<b>Purpose</b>	<b>Design</b>	<b>Sample</b>	<b>Reliability</b>	<b>Evidence of Validity</b>	<b>Comments</b>
<b>Health Diet Index Revised</b>						
Jankovic (2014)	Investigate the association between WHO guidelines for nutrition and all-cause mortality using the HDI-R	Eleven prospective cohort studies	N= 396,391 adults >60 years (Europe and United States)	Not reported	Median HDI scores ranged 40-54 points across all cohorts. For a 10 point increase in HDI, a 10% decrease in all-cause mortality was reported.	High quality diet is associated with a decreased risk of death in elderly participants across diverse cultures
Mertens (2018)	Investigate whether adherence to a high quality diet as assessed by the HDI, DASH score and the AEHI was associated with CVD incidence and risk markers	Prospective, longitudinal	N= 1867 men, mean age 57 years at baseline (Caerphilly Prospective Study)	Not reported	DASH score inversely associated with CVD and CVA incidence but not CHD (16.6 year follow up). AHEI was inversely associated with CVA incidence and CRP. HDI was not associated with disease incidence or risk markers	Better compliance with high quality diets may reduce risk of CVD risk and incidence
<b>Dietary Quality Score</b>						
Toft (2007)	To develop and assess the validity of the DQS and investigate any association of the DQS with CVD risk factors	Longitudinal, population	N= 6542 Danish adults, aged 30-60 (Inter99 study)	Not reported	High score associated with low intake of saturated fat & high intakes of fiber, vitamins/minerals, fruits, vegetables, fish, & whole grains. Inverse association found CVD risk factors	Scoring was not clear, validity is questionable, and results need to be replicated. May be useful for crude diet quality classification

## **CHAPTER 4. CARDIOVASCULAR LIFESTYLE INTERVENTION DOES NOT IMPROVE OVERALL DIET QUALITY NOR BLOOD GLUCOSE CONTROL FOR RURAL ADULTS WITH PREDIABETES**

### **Introduction**

An estimated 84 million Americans have prediabetes, that is nearly 34% of the United States population.<sup>4</sup> Prediabetes is the presence of either impaired glucose tolerance and/or impaired fasting glucose.<sup>138</sup> Individuals with prediabetes have a greater risk of developing T2DM, cardiovascular disease, and microvascular disease.<sup>139-142</sup> Preventive interventions focused on increasing activity, losing weight, and improving diet has been suggested to be beneficial for adults with prediabetes.<sup>14, 20, 23, 143-145</sup> Prediabetes is the optimum state to implement dietary changes before the long-term consequences of T2DM, CVD, and other associated illnesses have developed.

Poor quality of diet, consisting of red meats, sweets, fried foods, and soft drinks contribute to insulin resistance, elevated blood glucose, and elevated body mass index, known risk factors for T2DM.<sup>145, 146</sup> In addition, poor quality diets demonstrated a much greater risk of developing T2DM over a four year period, compared to high quality diets.<sup>147</sup> High quality diets, such as the Mediterranean diet, which emphasizes fruits, vegetables, nuts, legumes, lean meats, and whole grains and discourages red meats, refined grains, refined sweets, and sugary beverages have demonstrated improvement of prediabetes and prevention of T2DM.<sup>68, 69, 148, 149</sup>

Prediabetes are more prevalent in rural areas compared to urban areas in the United States,<sup>150</sup> and is most noted in the southeastern Appalachian region.<sup>28, 151</sup> Diet is an important part of the Appalachian culture, and meals often consist of calorie-packed fatty, fried, and starchy foods such as bacon, fried potatoes, soup beans, and cornbread.<sup>38</sup> Most

interventions aimed at improving rates of prediabetes in Appalachian and rural populations focus on weight loss and increasing activity, not on diet. In southeastern and Appalachian rural area of Kentucky, a lifestyle modification intervention program called “HeartHealth” was developed to reduce CVD risk by improving cardiovascular disease knowledge, diet quality, activity, and mental health in rural adults who were at high risk of CVD development. In this randomized controlled study, the effect of the HeartHealth program on CVD risk reduction was examined in xx rural adults. What is not clear from the parent study is whether adults with prediabetes can improve diet quality and improve glucose levels as results of a CVD risk reduction program. Therefore, the specific aim of this secondary data analysis study was to determine the effect of a CVD risk reduction on improving diet quality and blood glucose control (i.e., A1c level) in rural adults with prediabetes and CVD risk factors. In this study, we assess the intervention effect at four months and 12 months follow up.

## **Methods**

### *Design and sample*

This study is a secondary analysis of data collected from the parent randomized controlled trial that used a 12-week intervention program, called ‘*HeartHealth*’. The *HeartHealth* intervention was a lifestyle modification intervention program focused on reduction of CVD risk factors through educational and skill-building activities in rural Appalachia Kentucky. Participants used goal-setting and barrier/facilitator management strategies to achieve lifestyle changes. The intervention was delivered over three months by community health workers living in the area. Data collection occurred at baseline, four months, and at 12 months follow up.

Residents of 52 counties in southeastern Kentucky were recruited from primary care clinics, community centers, self-referrals, participant referrals and flyers posted within the community. Rural adults who had at least 2 of the following CVD risk factors were recruited 1) diagnosis of hypertension or taking medications diagnosed for hypertension or found to be hypertensive by us 2) diagnosis of hyperlipidemia or taking medication for treating abnormal lipid levels, or any lipid abnormality found on our screening 3) diagnosis of type 2 diabetes or HgA1c > 7% found on our screening 4) overweight or obese (body mass index  $\geq 25$  kg/m<sup>2</sup>) 5) clinical diagnosis of depression, on medications for depression or found to have depressive symptoms (score of > 9 on the PHQ-9) by our baseline screening 6) sedentary lifestyle meaning that the individual does not engage in at least 30 minutes of moderate activity for at least 4 days per week 7) Consumes a diet high in saturated fats and low in fruits and vegetables. Exclusion criteria included; 1) known coronary artery disease, cerebrovascular disease, history of acute coronary syndrome or PAD 2) taking medications (e.g., protease inhibitors) that interfere with lipid metabolism 3) cognitive impairment (cognitive impairment will be assessed using the Mini-Cog); 4) chronic drug abuse 5) end-stage renal or liver or pulmonary disease or current active cancer 6) gastrointestinal disease that requires special diets (e.g., Crohn's disease; celiac disease)

Among a total of 352 rural adults participating in the parent study, only 86 adults at baseline assessment had prediabetes, defined as hemoglobin A1c levels greater than 5.7% but less than 6.5 percent<sup>152, 153</sup> without a confirmed diagnosis of T2DM. Of the 86 adults, we selected a subsample of individuals with prediabetes (n=62) who completed the diet quality screener at all three time points (baseline, four months, and 12 months).

## Measures

### *Demographic characteristics*

Self-reported demographic characteristics including age, gender, marital status, education level, employment status, and financial status were collected using structured questionnaires at baseline.

### *Diet quality*

Diet quality was assessed using the 14-item Mediterranean Diet Screener (MEDAS).<sup>154</sup> Possible total scores range from 0-14, a higher score indicate better adherence to Mediterranean diet.<sup>154</sup> Each item was scored as either 0 or 1 based on the MEDAS criteria.<sup>154</sup> One point was assigned for each of the following: Olive oil used as the main cooking fat (yes= 1 point); consuming more/less than daily servings for olive oil ( $\geq 4$  tablespoon), vegetables ( $\geq 2$  serving), fruits ( $\geq 3$  serving), red meat ( $<1$  serving), animal fat ( $<1$  serving), sugar-sweetened/carbonated drinks ( $<1$  serving); consuming more/less than weekly servings of wine ( $> 7$  glasses) legumes ( $\geq 3$  servings), fish ( $\geq 3$  servings), commercially made sweets ( $\leq 2$  servings), nuts ( $\geq 3$  servings), tomato-based products ( $\geq 2$  servings); and replacing red meat with white meat (yes/no). Total scores of five or fewer points were considered 'poor' adherence to Mediterranean diet, 6-9 point were 'moderate' adherence to Mediterranean diet, and scores above 10 were considered 'high' adherence to Mediterranean diet.<sup>154</sup> Schroder et al., confirmed relative and construct validity of the MEDAS using a validated food frequency questionnaire.<sup>155</sup> MEDAS has been used in adults at high risk of T2DM and CVD and demonstrated a strong inverse association between high quality diets and obesity indexes<sup>154</sup> and test-retest reliability.<sup>156</sup> It has been

validated that higher scores on the MEDAS were correlated with lower fasting glucose and a decreased 10 year coronary artery risk.

### *Blood glucose control*

Blood glucose control was assessed using hemoglobin A1c (A1c), which is the percentage of glycated hemoglobin (hemoglobin with glucose attached). A1c estimates the individual's average blood glucose over the past 90-120 days and is one recommended test for monitoring prediabetes and T2DM.<sup>10, 11</sup> Blood glucose control level was assessed using a portable A1c monitor (A1cNow, BayerContour, NJ) from non-fasting fingerstick samples. This Clinical Laboratory Improvement Amendments waived device has demonstrated validity and reliability for monitoring A1c levels.<sup>157</sup>

### *Protocol*

Study approval was obtained by the University of Kentucky Institutional Review Board. The study was explained to eligible participants and informed consent was obtained by trained, local nurses who performed baseline assessments immediately after enrollment. Control group participants were referred to a primary care physician. Intervention group participants were referred to a primary care physician and received the HeartHealth intervention. The intervention was comprised of six biweekly small-group sessions, lasting 1-1.5 hours. Sessions focused on self-care of CVD risk factors, healthy eating, physical activity, depression and stress reduction, management of other health problems, and medication adherence and/or smoking cessation. The nutrition module specifically addressed increasing fruits, vegetables and whole grains, decreasing saturated and trans fats, reducing sodium, and reducing overall fat. Intervention fidelity was continuously monitored throughout sessions by the primary study's co-investigators, each of whom are

experts in self-management interventions. Follow-up data collection was scheduled by the nurses once the intervention was complete.

### *Data analysis*

SPSS version 24 (SPSS Inc., Chicago, IL) was used for data analyses. Verification and cleaning of data were conducted prior to analysis. A descriptive analysis of participants' baseline demographic characteristics, total MEDAS score, and A1c was conducted. The sample was characterized using frequencies and percentages or means and standard deviation as appropriate to the level of measurement. Chi-square tests or t-tests were used to assess for baseline differences in demographic, A1c, and MEDAS scores between the intervention and control groups.

Repeated measures of analysis of variance (ANOVA) was used to determine within-group and between-group differences over time in mean total MEDAS scores at baseline, four months, and 12 months. A p-value of  $\leq 0.05$  was used to determine significance. McNemar's test was used to determine changes between baseline and four month and baseline and 12 month MEDAS component scores, a p-value  $\leq 0.05$  was used to determine significance.

## **Results**

### *Sample characteristics*

Baseline demographic characteristics are presented in Table 4.1. The sample was primarily middle-aged (mean age = 48), Caucasian (97 %), female (84 %), married or cohabitating (61 %), employed at least part-time (73 %), and indicated they had sufficient income (77 %). Nearly 95% of the sample had at least a high school education. There was

a significant difference in the number of men in the control group compared the intervention group ( $p = .008$ ), eight men were in the control group compared to two men in the intervention group.

#### *Changes in diet quality and blood glucose*

The results of repeated measures ANOVA for diet quality and glucose control are presented in Table 4.2. While there was a significant change in mean for the total MEDAS score between baseline and 12 months ( $P = 0.022$ ), there was no significant difference in the mean score between control and intervention groups (0.316). At baseline assessment, 90% of total sample had low diet quality, determined by a total MEDAS score of 5 or less. Individual components of the MEDAS were assessed using McNemar's test to determine changes between binomial data; results are reported in Table 4.3. Individual components were scored as "0" if the recommended servings were not consumed or "1" if the recommended servings were consumed. It was determined that a greater number of the intervention group consumed at least two servings of vegetables per day compared to the control group between baseline and 12 months ( $P = 0.008$ ). The percentage of individuals who used olive oil as the main daily cooking fat was increased for both groups between baseline and 12 months ( $P = 0.021$ ). Interestingly, no one in the intervention group increased their olive oil consumption to more than four tablespoons per day at any time point but two individuals in the control group did increase consumption to the recommended amount between baseline and 12 months. One individual in the control group reported meeting the recommended glasses of wine per week between baseline and 12 months; however, no one in the intervention group reported meeting this



recommendation at any time point. There were no individuals in either group who reported meeting the recommended servings of fish per week.

Mean glucose control did not improve for either group between baseline and four months or baseline and 12 months ( $P = 0.563$  *control*,  $P = 0.536$  *intervention*). Mean A1c for the control group was 5.85 ( $\pm .15$ ) at baseline, 5.67 ( $\pm .39$ ) at four months, and 5.72 ( $\pm .52$ ) at 12 months. Mean A1c for the intervention group was 5.88 ( $\pm .16$ ) at baseline, 5.76 ( $\pm .51$ ) at 4 months, and 5.92 ( $\pm .83$ ) at 12 months.

## **Discussion**

It is known that consuming high quality diet can decrease the risk of developing T2DM for adults with prediabetes.<sup>136</sup> In this study, we examined whether diet quality and glucose control was improved for a rural Appalachian population at risk for CVD and with prediabetes following a lifestyle intervention program which included nutritional education and support. We found that both the intervention and control groups improved their total diet quality scores between baseline and 12 months, demonstrating a lack of intervention effect. However, neither group improved their glucose control. There may be several reasons associated with these findings.

Analysis of individual components revealed that an increased percentage of individuals in both groups were using olive oil as their main cooking fat at 12 months compared to baseline which may have contributed to the total MEDAS score. Individuals in the control group were referred to a primary care physician for usual care related to their CVD risk, this may have included counseling or education about using olive oil as a replacement for other less heart-healthy cooking fats. The percentage of individuals in the intervention group who increased daily servings of vegetables was greater compared to the

control group; this may reflect an effect from the intervention for this nutritional component. Consumption of red meat, commercial sweets, nuts, fish, and wine did not change for the intervention group at any time point and contributed to the low diet quality scores. Individuals received education about improving consumption of vegetables, fruit, whole grain, fiber, and “good fats” and were also educated about limiting sodium and “bad fats” but individuals were not specifically educated about a Mediterranean type diet. Educating the intervention participants on the benefits of a Mediterranean type diet may have led to improved MEDAS scores for these individuals.

Poor dietary quality was likely associated with the lack of improvement in A1c levels in this study. Others have found an association between poor diet quality, insulin resistance, and T2DM.<sup>158</sup> Individuals in this study were not informed of their probable prediabetes at baseline. This may be an additional factor associated with the lack of diet quality improvement. Participants were not aware of their increased risk of developing T2DM, thus they may have focused on activities they believed were important to reducing their CVD risk such as reducing sodium, managing blood pressure, and/or medication adherence.

Poor diet adherence is a finding that is supported by other researchers.<sup>159-161</sup> Many barriers have been identified in the literature in regards to self-management of glucose control using lifestyle changes. Lack of dietary self-control was one such barrier.<sup>162</sup> Others have found that changing lifelong habits and negative attitudes toward a new lifestyle, lack of motivation to change, poor social support, and practical ability to change lifestyle (cost and availability) were barriers in middle to older aged participants.<sup>163</sup> This study did address some of these barriers by using small group sessions conducted by local nurses to

help build social support among participants and provide suggestions for overcoming difficulties. Goal setting was another strategy used to help participants overcome poor motivation and address negative attitudes.

Still others found that limited financial resources make changes to diet quality difficult to implement.<sup>164, 165</sup> The majority of participants in this study indicated that, financially, they “had enough to get by”; however, it is not clear whether the cost of healthier foods impacted their food choices and led to poorer quality diets. It has been found that foods contributing to better health outcomes cost more than those associated with chronic illness.<sup>166, 167</sup> Food stores in the poorer economic regions of Appalachia Kentucky have higher overall food prices and the most nutritious food options cost more than less nutritious foods.<sup>33, 34</sup>

Access to healthier food options may be another barrier for individuals living in rural, economically disadvantaged areas. According to the United States Department of Agriculture, many areas of Appalachia have been classified as a rural food deserts.<sup>168</sup> These areas are low income census tracts with high rates of poverty ( $\geq 20\%$ ) where at least a third of the residents live further than 10 miles from a large grocery store.<sup>168</sup> Because of the long distances to healthier food choices, many residents may choose to purchase processed foods with longer shelf lives. Reducing the risk of food waste may prompt some residents in these areas to purchase processed versus fresh foods. Therefore, the cost and availability of healthier foods may have impacted participants’ ability and/or desire to further improve dietary patterns.

Culture also plays a role in the selection of foods. The dietary culture within the Appalachian region of Kentucky is known to consist of large amounts of saturated fats and

foods that are salty, sugary, and starchy.<sup>38</sup> This pattern is contrary to a Mediterranean dietary pattern and may further explain the less than optimal lack of improvement in dietary quality scores. Several of the foods assessed on the MEDAS, including olive oil, fish, and wine, are not culturally important to this population and may not be widely available. Considering the historical value placed on diet within this culture, changes to dietary patterns may be best assessed using an alternative diet quality measure.

### *Limitations*

This study was conducted in southeastern Appalachia Kentucky; thus the generalizability of these findings may not be applicable to other rural areas of the United States. However, many rural areas of the United States and the rest of the world have similar issues of poverty, poor access to high quality foods, chronic illness, and lower education levels. Further, this was a secondary data analysis which had a focus on cardiovascular risk factors, thus the intervention was not specific to prediabetes and T2DM risk factors. Although CVD and T2DM share some risk factors, it should not be assumed that CVD and T2DM interventions are interchangeable. The *HeartHealth* intervention did not solely focus on improving dietary patterns and individuals did not know they had prediabetes; therefore, changes to diet may have been viewed as less important compared to other aspects of the intervention such as increasing activity or decreasing stress. Use of the MEDAS to assess dietary patterns was a limitation in this analysis as many of the foods found in this measure may not be available or culturally appropriate to this population. This study's small sample size also limited statistical power to detect changes in both MEDAS scores and A1c. Finally, the intervention was conducted over a short period of time;

lifestyle changes require consistent, long-term commitment in order to make them a permanent part of a participant's behavior.

## **Conclusion**

There are several risk factors associated with the development of T2DM, some of which are not modifiable and beyond an individual's control. However, changes to lifestyle have demonstrated a decreased risk of developing this often devastating and disabling disease. To date, few longitudinal interventions focusing on lifestyle have been implemented in rural populations. Although fresh, healthy foods tend to cost more than processed foods; healthier, less expensive, and more widely available foods such as dried legumes, oats, and frozen vegetables can be used to improve dietary quality. These foods can also be used to modify traditional recipes to improve cultural acceptance. The lack of improvement in dietary quality emphasizes the need for longer term interventions to provide ongoing education, role-modeling, and support.

**Table 4.1: Baseline sample characteristics (N = 62)**

<b>Variable</b>	<b>Total Sample (n = 62)</b>	<b>Intervention (n = 36)</b>	<b>Control (n = 26)</b>	<b>P value</b>
Age (years)	48 ±13.17	48 ±13.45	48 ±2.55	<i>.811</i>
Gender (female)	52 (84%)	34 (94%)	18 (69%)	<i>.008</i>
Marital Status (married, cohabitate)	38 (61%)	21 (58%)	17 (65%)	<i>.574</i>
Education	13.4 ±2.31	13.53 ±2.41	13.23 ±2.20	<i>.621</i>
Ethnicity (Caucasian)	60 (97%)	36 (100%)	24 (92%)	<i>.172</i>
Employment (Employed outside home)	45 (72%)	25 (69%)	20 (76%)	<i>.789</i>
Income (enough/more than enough to make ends meet)	48 (78%)	30 (83%)	18 (69%)	<i>.424</i>

**Table 4.2: Mean and standard deviation for diet quality and blood glucose control**

	<b>Baseline</b>	<b>4 Month</b>	<b>12 Month</b>	<b>Group X Time (p value)</b>
<b>Hemoglobin A1c (n = 58)</b>				<i>0.580</i>
<i>Intervention (n = 33)</i>	5.88 (± 0.158)	5.76 (± 0.507)	5.92 (± 0.834)	<i>0.563</i>
<i>Control (n = 25)</i>	5.85 (± 0.153)	5.67 (± 0.392)	5.72 (± 0.513)	<i>0.536</i>
<b>*Total MEDAS Score (n = 62)</b>				<i>0.022</i>
<i>Intervention (n = 36)</i>	3.72 (±1.60)	4.08 (±1.73)	3.92 (±1.65)	<i>0.177</i>
<i>Control (n = 26)</i>	2.85 (±1.29)	3.54 (±1.45)	3.62 (±1.60)	<i>0.572</i>

\*MEDAS: Mediterranean Diet Adherence Screener

**Table 4.3: Percent adherent to MEDAS sub-scores**

	<b>Change from baseline to 4 months</b>	<b>Group X Time (p value)</b>	<b>Change from baseline to 12 months</b>	<b>Group X Time (p value)</b>
<b>Olive oil main cooking fat</b>				
<i>Control</i>	4 (15.4%)	0.625	5 (19.2%)	0.250
<i>Intervention</i>	1 (2.8%)	1.000	7 (19.4%)	0.125
<i>Total</i>	5 (8.1%)	1.000	12 (19.4%)	0.021
<b>Olive oil &gt; 4 TBS/day</b>				
<i>Control</i>	1 (3.8%)	1.000	2 (7.7%)	1.000
<i>Intervention</i>	0	**	0	**
<i>Total</i>	1 (1.6%)	1.000	2 (3.4%)	1.000
<b>Vegetables &gt; 2 servings/day</b>				
<i>Control</i>	3 (11.5%)	0.500	4 (15.4%)	0.375
<i>Intervention</i>	7(19.4%)	0.125	10 (27.8)	0.008
<i>Total</i>	10 (16.1%)	0.039	14 (22.6%)	0.003
<b>Fruit &gt; 3 servings/day</b>				
<i>Control</i>	2 (7.7%)	1.000	3 (11.5%)	0.625
<i>Intervention</i>	5 (14.7%)	0.375	7 (20%)	0.125
<i>Total</i>	7 (11.7%)	0.219	10 (16.4%)	0.065
<b>Red meat &lt; 1 serving/day</b>				
<i>Control</i>	8 (30.8%)	1.000	8 (30.8%)	1.000
<i>Intervention</i>	12 (35.3%)	1.000	13 (37.1%)	1.000
<i>Total</i>	20 (33.3%)	1.000	21 (34.4%)	1.000
<b>Substitute lean meat for red meat</b>				
<i>Control</i>	12 (46.2%)	1.000	13 (50.0%)	1.000
<i>Intervention</i>	25 (73.5%)	0.039	24 (68.6%)	0.143
<i>Total</i>	37 (61.7%)	0.189	37 (60.7%)	0.230
<b>Butter &amp; like fats &lt; 1 servings/day</b>				
<i>Control</i>	16 (61.5%)	0.057	13 (50.0%)	0.267
<i>Intervention</i>	12 (64.7%)	0.109	13 (37.1%)	0.180
<i>Total</i>	28 (46.7%)	0.839	26 (42.6%)	1.000
<b>Sugar sweetened drinks &lt; 1 serving/day</b>				
<i>Control</i>	14(53.8%)	0.063	13 (50.0%)	0.125
<i>Intervention</i>	22 (64.7%)	1.000	19 (54.3%)	0.549
<i>Total</i>	36 (60.0%)	0.302	32 (52.5%)	1.000
<b>Legumes &gt; 3 servings/week</b>				
<i>Control</i>	2 (7.7%)	1.000	1 (3.8%)	1.000
<i>Intervention</i>	2 (5.9%)	1.000	3 (8.6%)	0.625
<i>Total</i>	4 (6.7%)	1.000	4 (6.6%)	1.000
<b>Nuts &gt; 3 servings/week</b>				
<i>Control</i>	0	**	2 (7.7%)	1.000
<i>Intervention</i>	4 (11.8%)	1.000	4 (11.4%)	1.000
<i>Total</i>	4 (6.7%)	0.754	6 (9.8%)	1.000



**Table 4.3 (continued): Percent adherent to MEDAS sub-scores**

	<b>Change from baseline to 4 months</b>	<b>Group X Time (p value)</b>	<b>Change from baseline to 12 months</b>	<b>Group X Time (p value)</b>
<b>Commercial sweets &lt; 3 servings/week</b>				
<i>Control</i>	17 (65.4%)	1.000	17 (65.4%)	1.000
<i>Intervention</i>	25 (73.5%)	1.000	25 (71.4%)	1.000
<i>Total</i>	42 (70%)	1.000	42 (68.9%)	1.000
<b>Tomato products &gt; 2 servings/ week</b>				
<i>Control</i>	14 (53.8%)	0.549	11 (42.3%)	1.000
<i>Intervention</i>	23 (67.6%)	1.000	25 (71.4%)	0.727
<i>Total</i>	37 (61.7%)	0.581	36 (59.0%)	0.815
<b>Fish &gt; 3 servings/week</b>				
<i>Control</i>	0	**	0	**
<i>Intervention</i>	0	**	0	**
<i>Total</i>	0	**	0	**
<b>Wine &gt; 7 glasses/week</b>				
<i>Control</i>	0	**	0	**
<i>Intervention</i>	0	**	0	**
<i>Total</i>	0	**	0	**

\*\*0 servings reported by individuals, p value could not be calculated

## **CHAPTER 5. SUMMARY**

### **Background and purpose**

The primary goal of this dissertation was to develop a better understanding of the impact of lifestyle interventions, primarily improving dietary quality, on reducing the risk of developing type 2 diabetes mellitus (T2DM) in rural populations within the United States. Disparate numbers of individuals living in rural areas of the United States suffer from T2DM compared to their urban counterparts.<sup>28, 169</sup> Three manuscripts are presented within this dissertation: 1) a literature review to evaluate the current research using lifestyle interventions to decrease the risk of developing T2DM in rural populations, 2) a comparison of the validity and reliability of dietary indices used to assess improvement of diet quality within research studies, and 3) a secondary data analysis to determine changes in dietary quality following a lifestyle intervention among rural Appalachia Kentucky individuals with CVD risk factors and who are at risk of developing T2DM. These three manuscripts present evidence for improving dietary quality to decrease the risk of developing T2DM and present the challenges toward achieving that goal.

T2DM is a chronic illness that, in some cases, can be prevented or delayed using lifestyle modifications.<sup>21, 23, 83</sup> Lifestyle modification, such as improved diet quality, are not well utilized in rural populations. Many of the reasons for this underused intervention center on culture, economics, and lack of resources. This chapter will synthesize the findings from each study presented and discuss how these findings contribute to prevention of T2DM in rural populations in the United States. Future research recommendations will also be presented.

## Summary of findings

The systematic literature review presented in Chapter Two provides a summary of lifestyle interventions used to reduce the risk of developing T2DM in rural populations. Educating participants about T2DM, reducing fat and calories, increasing activity, or using a combination of all three were measures were found to be helpful at reducing weight, BMI, fasting glucose, and/or hemoglobin A1c levels. Tracking fat grams, calories, and minutes of activities were used consistently throughout all the studies in the review; these strategies were used in landmark studies targeting weight loss which led to a decreased risk of developing T2DM<sup>20, 23, 55</sup> and continue to be important steps in the National Diabetes Prevention Program.<sup>170</sup> In addition, use of community-based participatory research (CBPR), community health workers (CHW) or health coaches to provide social support, goal-setting strategies, and technology helped achieve positive study outcomes. Attrition was high in studies in which participants had transportation difficulties;<sup>75</sup> therefore, using technology to deliver interventions may improve participation and help reach participants in remote areas who, otherwise, would not be able to participate in the study. Goal-setting lets participants determine what aspects of diabetes risk reduction is important to them and allows them to decide how they want to participate in the study. Goal-setting strategies have demonstrated improved participation in self-care activities among individuals with T2DM.<sup>171</sup> CBPR, CHW, coaching, and social support are all integral in developing rural health interventions as these practices help assure that interventions are both culturally and socially acceptable to the populations they target and may motivate participants to engage in the intervention.<sup>63, 75, 172, 173</sup>

Chapter Three presents a critical analysis of the psychometric properties of six dietary indices commonly used to assess dietary quality of participants in research. The Diet Quality Index-Revised (DQI-R), Healthy Diet Index (HDI), Diet Quality Score, Healthy Eating Index (HEI), Alternative Healthy Eating Index (AHEI), and the DASH score were each assessed in this analysis. Construct and concurrent criterion validity were demonstrated for the HEI. Internal consistency measured by the Cronbach alpha was .68, just under the accepted level of .70; however, because the average American does not meet the recommended daily dietary guidelines set forth by the United States Department of Agriculture, this level is considered satisfactory.<sup>113</sup> Measures of internal consistency was not found for any of the other instruments. Most of the indices have shared components, thus strong correlations between several of the indices were found.<sup>125, 134, 174</sup> Several of the indices had high predictive values for cardiovascular disease and type 2 diabetes mellitus.<sup>117, 135, 175, 176</sup> Five of the indices demonstrated acceptable validity and reliability in psychometric testing and would be appropriate measures for assessing dietary quality among participants at risk for developing T2DM. However, participant burden is relatively high considering that 100+ item food frequency questionnaires or lengthy diet histories are used to generate these scores,<sup>106, 108, 109, 113, 131</sup> thus a less burdensome measure with similar validity and reliability may be beneficial. Use of the DQS was not supported as there were few studies evaluating its validity and reliability.

An evaluation of dietary quality among rural participants with prediabetes both before and after a lifestyle intervention compared to a control group is presented in Chapter Four. Ninety-two percent of participants in both groups scored low on the 14 item Mediterranean Diet Adherence Scale (MEDAS), indicating that these participants had poor

quality diets. Participants in the intervention group did have a significant improvement in the total MEDAS score at the 12 month post intervention time point. The intervention group also had an improvement in their use of olive oil as their daily cooking fat between baseline and 12 months and an improvement in daily vegetable intake between baseline and 12 months, compared to the intervention group. No change in glucose control was found for either group. Age was the only significant association found in regression modeling; older participants had slightly better MEDAS scores compared to younger participants in both groups. It is not clear why older participants had slightly better scores, but traditions such as consumption of home-grown foods may be one explanation. There are several potential reasons for the lack of improved dietary quality, including the difficulties associated with diet change such as habits, preference, and cultural conflict. In addition, access to and affordability of high quality foods may impact participants' ability to change dietary patterns. Finally, considering the cultural traditions regarding food and the poor availability of Mediterranean-type foods in this region, the MEDAS may not be an appropriate measure of dietary quality in this population despite the short and easily administered format of this tool.

### **Impact of the dissertation**

This dissertation presents several important contributions to the literature: 1) it presents evidence that many rural individuals at risk for developing T2DM do not consume a high quality diet, 2) diet quality is not consistently assessed within this population to guide interventions, 3) group interventions and those delivered through technology achieve results consistent with individual and face-to-face interventions, and 4) cultural and

environmental considerations should be taken into account before choosing a specific diet quality index to assess dietary patterns.

### **Limitations**

There are limitations to this dissertation that should be noted. First, there was a very small number of articles to explore to assess the impact of lifestyle intervention on decreasing the risk of developing T2DM in rural populations. Second, the dietary indices examined in this dissertation were based on nutritional guidelines and there may be other indices which may be helpful in assessing diet quality. Finally, it is important to note that the individuals in the secondary data analysis were being studied based primarily on their CVD risk factors, and the results may not be generalizable to individuals with T2DM risk factors. In addition, they were not aware of the prediabetes found on screening; it is not known if this knowledge may have motivated them to focus on diet changes rather than other lifestyle factors. Studies that focus specifically on individuals at high risk of developing T2DM may provide better clarity into this evident health disparity among rural populations.

### **Recommendations for future studies**

Lifestyle interventions have consistently demonstrated a reduced risk of developing T2DM compared to pharmacological interventions over long-term follow up.<sup>21, 83</sup> Dietary changes have been a large part of those lifestyle interventions. Recommendations for future research and nursing practice include a greater emphasis on high quality diets to capture the benefits of whole foods versus focusing on fat and calorie content. Although low fat and low calorie diets do help individuals lose weight and reduce their diabetes risk,<sup>21, 23, 55</sup> these individuals may miss out on the many benefits associated with high quality diets. It

is known that fiber, antioxidants, and other nutrients found in whole grains, dairy, fruits and cruciferous/green leafy vegetables are associated with a lower risk of T2DM.<sup>70, 177, 178</sup> Dietary interventions using culturally important and more easily accessible foods items that can be included in a high quality diet should be explored in this population. Further assessment of dietary patterns using measures which are culturally appropriate and have low participant burden is also warranted to help guide future interventions.

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**VITA**  
**Amanda Culp-Roche**

**Education**

<b>Institution</b>	<b>Degree</b>	<b>Date Conferred</b>	<b>Field of Study</b>
University of Kentucky	MSN	May 2009	MSN, Nursing, family practice APRN
Clarion University of PA	BSN	Dec 2006	BSN, Nursing
Edinboro University of PA	transferred		Nursing
St. Vincent School of Nursing	RN Diploma	June 1994	Diploma, Nursing

**Professional Experience**

<b>Research</b>		
<b>Dates</b>	<b>Institution and Location</b>	<b>Position</b>
March 2016-2018	University of Kentucky, Lexington, KY	(Diversity Researchers Equalizing Access for Minorities) DREAM scholar
<b>Academic</b>		
August 2015- present	University of Kentucky, College of Nursing, Lexington, KY	Clinical Title Series NUR 350/352/354/452/453  Academic advisor  IPE facilitator
August 2011-present	University of Kentucky, College of Nursing, Lexington, KY	Clinical Faculty  NUR 863/869/211/413
August 2007-May 2009	University of Kentucky, College of Nursing, Lexington, KY	Teaching Assistant  NUR 863

<b>Clinical</b>		
June 2017-present	UK Internal Medicine, Division of Rheumatology, Lexington, KY	Nurse Practitioner
Aug 2016-present (prn)	UK CON Phyllis Corbin Clinic Wilmore, KY	Nurse Practitioner
April 2010-May 2016	Winchester Family Practice, Winchester, KY	Nurse Practitioner
Oct 2009-April 2010	First Onsite Clinic, Frankfort, KY	Nurse Practitioner
July 2009-April 2010	The Little Clinic, Richmond, KY March 2008-May 2009	Nurse Practitioner
March 2008-May 2009	Clark Regional Medical Center, Winchester, KY	Staff nurse
Dec 2006-Aug 2007	University of Kentucky Good Samaritan Clinic, Lexington, KY	BSN Intern
June 2006-Dec 2006	Intelistaf, Lexington, KY	Travel nurse
Oct 2003-June 2006	Titusville Area Hospital, Titusville, PA	RN Supervisor
Sept 2002-Oct 2003	Hamot Heart Hospital Erie, PA	Staff nurse
Apr 1998-June 2006	Visiting Nurse Association, Meadville, PA	Home health nurse
Oct 1996-Apr 1998	Bethesda Children's Home, Meadville, PA	Staff nurse
Sept 1994-Oct 1996	Sunset Manor Nursing Home, Titusville, PA	RN charge nurse

## Awards and Honors

<b>Dates</b>	<b>Institution</b>	<b>Award</b>
May 2019	University of Kentucky	High Merit Teaching Award
May 2018	University of Kentucky	High Merit Teaching Award
May 2017	University of Kentucky	High Merit Teaching Award
May 2009	University of Kentucky	Alumni Association Presidential Award
Dec 2006	Clarion University of Pennsylvania	Summa cum laude

## Publications

Hatcher, J., Voigts, K., **Culp-Roche, A.**, Adegboyega, A., Scott, T. (2018). Rural Grandparent Headed Households: A Qualitative Description. *Online Journal of Rural Nursing and Health Care*. 18(1), 39-60. doi.org/10.14574/ojrnhc.v18i1.486

**Culp-Roche, A.** & Adegboyega, A. (2016). Analysis of Kentucky's Law Protecting the Rights of Schoolchildren With Type 1 Diabetes Mellitus: Application of Kingdon's Policy Stream Model. *Policy, Politics, & Nursing Practice*. 17(1), 5-14. doi: 10.1177/1527154416629684.