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# A LIFESTYLE MODIFICATION INTERVENTION IN HISPANIC ADOLESCENTS

# WITH NONALCOHOLIC FATTY LIVER DISEASE

by

# **BRIANNE MILLER**

# EVIDENCE-BASED PRACTICE PROJECT REPORT

Submitted to the College of Nursing and Health Professions

of Valparaiso University,

Valparaiso, Indiana

in partial fulfillment of the requirements

For the degree of

# DOCTOR OF NURSING PRACTICE

2023

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Student

Advisor

Date



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# DEDICATION

I dedicate this Doctor of Nursing Practice (DNP) project to all the nurse practitioners that work incessantly to optimize the efficacy of lifestyle modification interventions to reduce healthcare disparities and meet the healthcare needs of patients.

# ACKNOWLEDGMENTS

I would like to acknowledge my advisor, Dr. Rebecca Peterson for her continuous support, guidance, and patience with me and my writing. I would also like to acknowledge the project site facilitator and ancillary staff for allowing me this opportunity and overwhelmingly supporting the project. To my mother, my aunt Karen, and Connie, I could not have done this without you. And to Gabe, and my daughter Kailani, thank you for motivating me and believing in me when I did not believe in myself.

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### ABSTRACT

U.S. population studies have confirmed that the Hispanic population has the highest prevalence and the worst prognosis for non-alcoholic fatty liver disease (NAFLD) (Katz et al., 2021). The purpose of this evidence-based practice project was to implement a multicomponent, lifestyle modification intervention in Hispanic pediatric primary care patients to combat the disease process and sequela of NAFLD. The PICOT question for this project was: In Hispanic adolescents aged 10-21 with obesity and NAFLD (P), what is the effect of a multicomponent, lifestyle modification intervention (I), on alanine aminotransferase (ALT) (O), over a 12-week time period (T)? A comprehensive literature search of six databases yielded sixteen pieces of moderate to high-quality evidence supporting lifestyle modifications related to principals of the Mediterranean diet, physical activity, and increased adherence via parental involvement, education, psychosocial support, and frequent follow-up. A sample of 29 Hispanic adolescents, age 10-21, with a history of NAFLD or elevated ALT levels, from an underserved urban pediatric clinic in the Northeastern U.S., were provided an educational intervention based on the Mediterranean diet and physical activity recommendations. Over the next 12 weeks, to promote adherence to the lifestyle changes, four follow-up phone calls were made to promote compliance and provide psychosocial support. Two nutritional educational classes were also offered to all participants. The KIDMED tool was assessed at the beginning and end of the intervention. A Wilcoxon test examined the results of the pre-intervention mean ALT and postintervention mean ALT. No significant difference was found in the results (Z = -1.113, p > .05). The mean pre-intervention was 76.48 (SD = 43.92), and the mean post-intervention was 69.81 (SD = 33.65). These findings suggest more time may be needed to assess the longitudinal benefits of lifestyle interventions on NAFLD in Hispanic adolescents. Future research should address preventable health care disparities related to poor nutrition and improve access to healthy, affordable food in low-socioeconomic neighborhoods.

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*Keywords:* Non-alcoholic fatty liver disease, Hispanic, adolescents, lifestyle modification, alanine aminotransferase levels

# CHAPTER 1

# INTRODUCTION

#### Background

Over the past thirty years, nonalcoholic fatty liver disease (NAFLD), typically referred to as fatty liver, has gone from an obscure liver condition to the most common chronic liver disease worldwide (Cusi et al., 2022; Ge et al., 2020). It is closely associated with obesity and has become the most common liver disease in children in the United States (U.S.) (Vos et al., 2017). The prevalence of NAFLD has increased 2.7 fold from the late 1980s to the current era and at an even higher rate than childhood obesity. NAFLD is a broad term used to describe a chronic liver condition resulting from excess fat accumulation in the liver (Vos et al., 2017). More specifically, it is defined as the presence of intrahepatic fat in greater than 5% of hepatocytes (Cusi et al., 2022). The excess fat buildup is not caused by heavy alcohol use, medications, or other known causes of liver disease. However, it is instead due to an increase in energy intake or a sedentary lifestyle (Francque et al., 2021). NAFLD is usually asymptomatic, slowly progressive, and affects individuals across the lifespan (Franque et al., 2021). Recent studies indicate that nonalcoholic steatohepatitis (NASH), one form of NAFLD, is one of the top causes of liver cancer and the second most common indication for liver transplant in the U.S. (Cusi et al., 2022). Aside from liver cancer and cirrhosis, NAFLD is associated with many other major health complications, including type 2 diabetes, hypertension, dyslipidemia, metabolic syndrome, bowel cancer, cardiovascular disease, and chronic kidney disease (Jang et al., 2018; National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2021; Franque et al., 2021).

There are two main types of NAFLD in pediatrics: nonalcoholic fatty liver (NAFL) and NASH (Vos et al., 2017). NAFL is a milder form of the disease, and NASH is a more severe form (NIDDK, 2021). NAFL is defined as when the child has increased fat on the liver but no signs of inflammation or liver damage; NASH is when the child has increased intrahepatic fat, which has

triggered inflammation in the liver cells, resulting in liver damage (Paquin, 2021). In pediatric NASH, the inflamed hepatocytes try to repair themselves by making new healthy tissue. If the inflammation persists over time, the ability of the liver to overcome the damage may become exhausted, and scar tissue or fibrosis will ensue (Francque et al., 2021). As more and more scar tissue builds up, ultimately, the liver can undergo a nodular transformation, known as cirrhosis (Francque et al., 2021). While NAFL, NASH, and liver fibrosis can be reversed, once a liver has evolved to the most advanced stage of fibrosis, identified as cirrhosis, the damage has already been done, and it is no longer reversible (Paquin, 2021). Liver cirrhosis ultimately leads to liver failure, which has a high mortality risk and risk of developing hepatocellular carcinoma. A liver transplant is the only true cure for cirrhosis (Paquin, 2021). Fortunately, when detected early enough and efforts to reduce the amount of fat on the liver are made, both NAFL and NASH are reversible (Francque et al., 2021).

According to the American Association of Clinical Endocrinology (AACE), clinicians ought to screen for pediatric NAFLD by using plasma aminotransferases in children at high risk of NAFLD, confirming the diagnosis through imaging (either ultrasound or magnetic resonance imaging proton density fat fraction [MRI-PDFF], or liver biopsy in combination with the exclusion of non-NAFLD causes of hepatic steatosis such as Wilson syndrome, mitochondrial disease, and medications (Cusi et al., 2022). Children and adolescents who are at high risk for NAFLD should be screened. his includes those with obesity, prediabetes, type 2 diabetes, and adolescent females with polycystic ovarian syndrome (PCOS) (Cusi et al., 2022). According to the North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN), additional risk factors exist, and screening should also be considered in children with central adiposity, sleep apnea, a family history of NAFLD, hypopituitarism, or are of Hispanic ethnicity (Vos et al., 2017). Research has shown that these risk factors have been associated with an increased prevalence and severity of pediatric NAFLD; yet, the pathophysiology behind these associations remains incompletely understood (Vos et al., 2017). Although the diagnostic

method and screening criteria differ among organizations, a consensus remains that a more efficient, universally available, cost-effective, and non-invasive way that is commonly used in practice to assess improvement in NAFLD, is a decrease in alanine aminotransferase levels (ALT). Despite its limitations, ALT has demonstrated acceptable sensitivity (Utz-Melere et al., 2018). According to NASPGHAN, the cutoff in pediatrics for females is 22 mg/dL and for males is 26 mg/dL (Vos et al., 2017).

Studies have shown that despite the growing prevalence of this disease, less than 5% of people with NAFLD are aware that they have it (Cusi et al., 2022). Recent surveys of primary care providers, endocrinologists, gastroenterologists, and hepatologists in the U.S. indicated a knowledge gap, evidenced by underestimating the prevalence of NAFLD in high-risk groups and underutilizing medications with proven efficacy in NASH (Cusi et al., 2022). Historically, NAFLD has frequently only been identified incidentally due to abnormal blood liver biochemistries or abdominal imaging performed for other indications (Vos et al., 2017). As described above, when unrecognized or untreated, NAFLD can lead to many other major health complications, including irreversible end-stage liver disease, liver cancer, and premature death (Francque et al., 2021). "Identification of children with NAFLD is important because effective treatment is available" (Vos et al., 2017, p. 321).

Due to its rapid increase and high disease burden, a surge of research studies regarding effective treatments to combat NAFLD has emerged over the last five years. Nonetheless, NAFLD has remained a management challenge for pediatricians, general practitioners, nurse practitioners, and subspecialists (Utz-Melere et al., 2018). While lifestyle modifications remain the only evidence-based practice interventions effective at reversing NAFLD in pediatrics, poor provider knowledge of appropriate recommendations, as well as poor patient adherence to lifestyle changes, further inhibits improved outcomes. Interventions must be initiated early in the course of the disease, before the progression of advanced fibrosis has developed, in which case, it is too late (Vos et al., 2017).

#### Data Supporting Need for the Project

#### Global Data

Over the last three decades, NAFLD has been on the rise in most parts of the world, and from 1990 until 2017, NAFLD has more than doubled worldwide, making it the most common chronic liver disease in pediatric and adult populations (Cusi et al., 2022). In 2017, a global burden of disease study added NAFLD as the fifth cause of liver cancer and cirrhosis worldwide (Paik et al., 2021). Currently, an estimated 2 billion people, or approximately 26.2% of the global population, are affected (Szanto et al., 2019; Yu & Schwimmer, 2021). A global systematic review and meta-analysis focused solely on children aged 1-19 estimated NAFLD to be 7.6% or between 5-10% of the studied population (Yu & Schwimmer, 2021). Reported NAFLD rates are highest in the Middle East (32%) and South America (31%), followed by Asia (27%), the U.S. (24%), Europe (23%), and Africa (14%) (Szanto et al., 2019).

### National Data

Chronic liver disease is increasingly recognized as a major disease burden in the U.S., and in 2017 was regarded as the tenth leading cause of death among men, and the fifth cause of death among 45–64-year-olds, the age considered to be the most productive years of life (Paik et al., 2021). A national study that examined chronic liver disease in the U.S., noted more than a 30% increase in the incidence rate, a 9.5% increase in the death rate from 2007 to 2017, and the age-standardized incidence of NAFLD increased more than any other etiology (Paik et al., 2021). As of 2019, in the U.S., NAFLD has surpassed hepatitis C and is now the most common cause of liver transplant in adults younger than 50 years old (Yu & Schwimmer, 2021). This has created a special focus on the importance of preventing and treating pediatric patients with NAFLD, as it is hypothesized that many liver transplant patients with NAFLD began the disease process in childhood (Cusi et al., 2022). Epidemiology research shows that NAFLD is also rapidly emerging among the pediatric population. One study from a large healthcare system outlined that in 2009, the incidence rate was 36 per 100,000, and as of 2018, it increased to 58.2 per 100,000 (Katz et

al., 2021). Data from the 2007-2016 National Health and Nutrition Examination Surveys revealed the prevalence of NAFLD in adolescents aged 12-17 was 13.2%, and 18.7% among young adults aged 18-24. In addition, the prevalence is higher for boys (15.1% age 12-17) than girls (11.3% age 12-17), and higher in Hispanics (15.2%) than Whites (10.1%) and Blacks (9.7%) (Arshad et al., 2021; Szanto et al., 2019). The true prevalence of NAFLD in pediatric patients is unknown due to underdiagnosis, a lack of conformity to diagnostic criteria, and the difficulty of obtaining accurate numbers due to more invasive and time-consuming diagnostic techniques, such as biopsy and MRI (Vos et al., 2017). Thus, current data likely reflects an underrepresentation of the true prevalence (Ge et al., 2020).

#### **Regional and State Data**

The burden related to NAFLD varies among different regions but is increasing in all U.S. states at an unprecedented rate. In most states, NAFLD is the leading cause of cirrhosis and liver cancer (Paik et al., 2021). As of 2017, New York ranked number one among all states to have the highest incidence rates of NAFLD cirrhosis (27.28%) and number two among the states with the highest overall NAFLD incidence (24.57%) (Paik et al., 2021). In a histology-based study in New York City, the prevalence rate of NAFLD in children aged 2-19 was estimated to be 4.5% (Yu & Schwimmer, 2021).

# Ethnic Data

Of major significance to this EBP project, there are notable ethnic disparities in multiple other aspects of NAFLD, including its severity, genetic predisposition, and overall prognosis (Samji et al., 2020). U.S. population studies confirmed that Hispanics have the highest prevalence of NAFLD and the worst disease prognosis (Katz et al., 2021). A meta-analysis showed that among patients with NAFLD, the risk for progression to NASH is higher in Hispanics (RR 1.09; 95% CI, 0.98-1.21), and lower in Blacks (RR 0.72; 95% CI, 0.67-0.87) (Samji et al., 2020). Another systematic review showed that Hispanics had the highest rates of NAFLD hepatocellular carcinoma, and Hispanics and Whites were more likely to be diagnosed with NASH cirrhosis younger than 40 years old than African Americans (Samji et al., 2020). A polymorphism gene identified as the *PNPLA3* variant has been identified as an important genetic risk factor for NAFLD, which is most commonly found in Hispanics (Katz et al., 2021). On the contrary, multiple other cultural, environmental, socioeconomic, and lifestyle risk factors could contribute to hepatic fat variation more than genetic factors (Katz et al., 2021). Evidence shows that low socioeconomic residences correlate with a higher prevalence of lower-cost, sugary, fatrich foods and drinks, two factors that are also common in U.S. Hispanic communities (Szanto et al., 2019).

Global, national, state, and ethnic data outline pervasive disparities in risk factors in Hispanic minority youth for developing NAFLD. Categorizing disparities means nothing if they are not addressed (Katz et al., 2021). NAFLD progression tracks into adulthood and threatens to negatively impact future morbidity and mortality rates. Thus, there is an urgent need for the design, implementation, and evaluation of aggressive evidence-based interventions to combat NAFLD and its disease sequelae among Hispanic youth (Katz et al., 2021).

#### **Clinical Agency Data**

The site for implementing the evidence-based practice (EBP) project is a privately owned, pediatric-focused practice located in an urban city in the Northeast. According to the U.S. Census Bureau (2021), the city where the site is located is approximately 56% Hispanic, which coincides with the large number of Hispanic children that receive services at the site. The site sees an average of 2,500 patients annually, 59% of which are overweight or obese, with an estimated 62% of patients of Hispanic origin and 89% of patients having Medicaid (Providers, personal communication, June 28, 2022). The clinic cares for infants to young adults up to age 21. The site has one full-time pediatric nurse practitioner (NP) and one part-time physician, whom is also the practice owner. The site also has five medical assistants.

Through discussion with the providers, a desire for an intervention to improve NAFLD rates was communicated (Providers, personal communication, May 18, 2022). Through a

random sample chart review of 50 patients, the approximate percentage of NAFLD patients at the clinic is 17%, based on patient charts in which a diagnosis of NAFLD or an elevated ALT had been confirmed with suspected documentation of NAFLD not due to other causes. Thus, compared to national averages, NAFLD is a highly prevalent condition seen in the pediatric population at this site. While providers often recommend general lifestyle modifications, such as increasing exercise, or following a low-fat diet, time constraints during office visits limit dialogue sometimes to nothing more than a few simple words. Moreover, even when such efforts are provided, they are often futile, as success with current practices has remained essentially ineffective (Providers, personal communication, June 28, 2022).

Screening for NAFLD at the site occurs routinely between ages 9 and 11 by liver function tests (LFTs), and thereafter at the provider's discretion, mostly in children with obesity, as defined by a body mass index (BMI) greater than the 95<sup>th</sup> percentile. A diagnosis is frequently assumed based on the presence of elevated liver enzymes alone and confirmed by ultrasound. However, ultrasound confirmation is not always performed as not all patients referred for an ultrasound follow-through (Providers, personal communication, July 1, 2022). Standard of care for patients with no prior history of NAFLD but who exhibit elevated aminotransferase levels during screenings have repeat enzymes routinely rechecked after three consecutive months. Patients with persistent aminotransferases more than double the normal range are referred to a gastroenterologist to rule out the presence of other etiologies of liver disease, such as autoimmune, viral, and genetic disorders. LFTs are then monitored quarterly, or at the provider's discretion, based on the time that has elapsed since the last visit, changes in BMI, or reports of lifestyle changes (Providers, personal communication, July 1, 2022).

# Purpose of the Evidence-Based Practice Project

**Purpose Statement and PICOT Question** 

The purpose of this EBP project is to implement a multicomponent, lifestyle modification intervention for the Hispanic pediatric population in a primary care setting to combat the disease process of NAFLD and subsequent sequela.

Specifically, this project will address the following PICOT question: In Hispanic adolescents aged 10-21 with obesity and NAFLD (P), what is the effect of a multicomponent, lifestyle modification program (I), on ALT levels (O), over a 12-week time period (T)?

# EBP Project Description

For the EBP project, the project leader identified Hispanic patients at the site aged 10-21 who have a confirmed diagnosis of NAFLD or elevated ALT levels with suspected NAFLD with documentation of non-NAFLD causes of hepatic steatosis ruled out. Chart reviews of the daily schedule were performed during recruitment days, and the project leader worked closely alongside medical assistants to identify time to speak with the patient and their caregiver. Patients who missed their appointments, or who recently had an appointment were contacted via phone. A multicomponent, lifestyle modification intervention consistent with the Mediterranean diet principles and increased physical activity, were presented to qualifying patients, either in person, or over the phone. Accepting patients received additional educational and supplemental material based on nutrition, as well as a neighborhood resource guide of free local exercise classes and recreational activities available to youth. A motivational, reusable water bottle with time marker was provided to participants. One predetermined or individual goal was also set along with one actionable plan to enhance goal achievement. Demographical surveys and baseline KIDMED scores were collected during initial visits as part of data collection. Phone calls were made once every three weeks to follow up with participants, encourage and assess compliance, and support them or their caregivers towards the self-directed goals. The project leader also invited qualifying participants and their guardians to partake in at least one of two nutrition classes held at the clinic's classroom by the project leader over the next three months.

At the end of the 12 weeks, the primary outcome of the ALT levels were redrawn and compared to the participants' baseline, along with their repeated BMI Z and KIDMED score.

# **CHAPTER 2**

# **EBP MODEL AND REVIEW OF LITERATURE**

# **Evidence-based Practice Model**

### **Overview of EBP Model**

The EBP model chosen for this project was the John Hopkins Nursing Evidence-Based Practice (JHNEBP) Model. This model deeply resonated with the project leader because it is a model developed by nurses, for nurses. Similar to the reasons why nurses pushed for the JHNEBP Model to be constructed, this model was chosen because it offers a problem-solving linear approach with user-friendly tools to guide one through each step of the EBP process (Melnyk & Fineout-Overholt, 2019). This model fit well with this project because the site's primary provider is a pediatric nurse practitioner and the project advisor is a doctoral nurse practitioner, both of whom served as mentors through the EBP process easy.

The model also fit well with how the project started. "The JHNEBP Model begins with inquiry sparked by an individual's or team's genuine curiosity about best practices related to a specific problem and/or a particular patient population" (Dearholt & Dang, 2018 p. 4). When discussing potential EBP project ideas with the site's providers, a genuine curiosity about the etiology of the high prevalence rates of fatty liver in the Hispanic population and how to improve outcomes at the clinic was sparked. This inquiry initiated the PET process (Practice Question, Evidence, and Translation), as outlined by providing "a systematic approach for nurses to develop and refine a practice question, seek out the best evidence, and translate best evidence into practice" (Melnyk & Fineout-Overholt, 2019, p. 413).

The JHNEBP Model is also an open system, and therefore it can be influenced by internal organizational factors such as culture and resources, as well as external factors such as legislation and regulations (Melnyk & Fineout-Overholt, 2019). The internal and external factors surrounding this project were plentiful and thus a model that recognized how such factors influence an EBP project's success was needed. The internal factors included the culture and resources available to the site. The diverse, bicultural, and bilingual staff within the organization influenced and played a large role within the development and implementation of the EBP project. The external factors included the Hispanic culture, dietary habits, language, urban setting, socioeconomic status, pediatric population, parental influence, and lack of access to resources. Thus, this model was chosen to ensure the project's success.

Finally, this model consists of three phases, within which there are a total of 19 prescriptive steps. While this may seem like a lot of steps, all steps allow for a linear and sometimes iterative outline making project advancement easy and assuring (Melnyk & Fineout-Overholt, 2019). See Appendix A for documentation of permission granted to use the JHNEBP model.

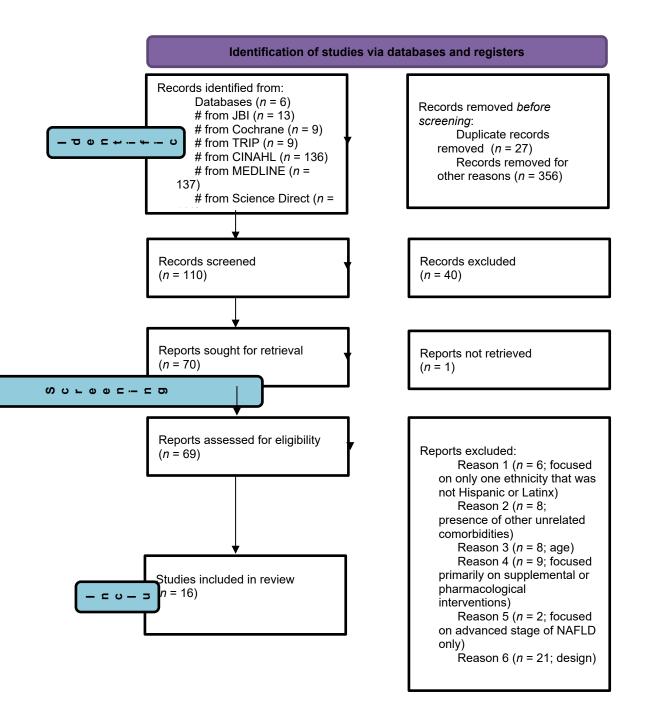
#### Literature Search

### Sources Examined for Relevant Evidence

Six databases were searched multiple times before one final search was conducted. Databases searched included Joanna Briggs Institute (JBI), The Cochrane Library, Turning Research Into Practice (TRIP), Cumulated Index to Nursing and Allied Health Literature (CINAHL), MEDLINE with Full-Text, and Science Direct. Key words and phrases used within searches included "fatty liver", "nonalcoholic fatty liver disease", "non-alcoholic fatty liver disease", treat\*, interven\*, manag\*, therap\*, protocol, program, management, child\*, teen\*, adolescen\*, pediatric\*, youth, "young person", "young adult", "alanine aminotransferase", ALT, and "alanine transaminase". Boolean operators AND, and OR, as well as major subject headings for "fatty liver" OR "nonalcoholic fatty liver disease" were both used within CINAHL and MEDLINE with Full-Text databases. The key words related to Hispanic ethnicity were not incorporated within searches as search results were too limited using this technique. Limiters used included articles published between 2017-current, scholarly (peer-reviewed), English language, and research articles. With the help of the Valparaiso University Research Librarian, a final search identified a total of 493 articles in the databases. Twenty-seven duplicates and another 356 records were excluded by title as they were not relevant to the topic and were removed before screening. A total of 110 records were screened for relevance via abstract, and 40 more records were removed at this step. Thus, 70 reports were sought for retrieval, and one could not be retrieved. Sixty-nine records were then assessed for eligibility. Inclusion criteria consisted of studies that met the criteria of individuals aged 10-21 years old, who had a diagnosis of obesity or NAFLD, not due to other secondary causes, who had undergone a lifestyle intervention, and had ALT or hepatic fat measured both pre and post-intervention. Articles that specifically mentioned Hispanics, Latinos, or Hispanic-Americans as part of the sample were included, although some studies which did not specify ethnicity were also included. Exclusion criteria consisted of all records that assessed only children younger than 10 or adults older than 21, focused on only one specific ethnicity that was other than Hispanic or Latinx, published in another language other than English, had a secondary cause of NAFLD, such as other chronic liver diseases, presence of other non-related comorbidities, did not measure ALT or hepatic fat, or assessed primarily supplemental, pharmacological, or bariatric surgery as the primary intervention. Finally, records that focused only on an advanced stage of NAFLD fibrosis or that were low-level in design (level V-VII) were excluded. The PRISMA flowchart is outlined below.

# Figure 2.1

### Prisma Diagram of Literature Search



### Levels of Evidence

Experts of EBP have developed hierarchies that delineate how to assess the strength of the evidence as well as classify the different levels (Melnyk & Fineout-Overholt, 2019). These taxonomies or hierarchies of evidence help guide practitioners to quickly identify levels of evidence based on the research design (Melnyk & Fineout-Overholt, 2019). The Melnyk and Fineout-Overholt hierarchy was used to level the evidence for this project. There are seven levels of evidence within this rating system, with level I evidence representing the strongest or highest order of scientific evidence and level VII representing the weakest or lowest level pieces of evidence (Melynk & Fineout-Overholt, 2019). Although all levels of evidence were found within the literature search for this project, only the strongest pieces of evidence were selected for this project. Eight level I pieces of evidence were chosen: three clinical practice guidelines (CPGs), three systematic reviews (SR), and two systematic reviews and meta-analyses (SR & MA). Four level II randomized controlled trials (RCTs), one level III quasi-experimental (Q-E) study, and three level IV cohort studies comprised the remaining selection of evidence. The pieces of evidence selected can be referenced in Table 2.1.

#### Analysis and Appraisal of Relevant Evidence

Because simply assigning levels of evidence is not sufficient to assess quality, analysis and appraisal tools were also used to evaluate the evidence. The AGREE II was used to evaluate the CPGs, and the Critical Appraisal Skills Programme (CASP) checklists were used for all other studies. The AGREE II was used because it is a well-validated tool specific for evaluating CPGs and is easy to use. The CASP checklists were chosen to use for all other studies because they accurately assess validity, reliability, and applicability based on study design. They are user-friendly and efficient yet detailed enough that one can quickly, yet comprehensively, reflect on and evaluate the quality of the evidence. After careful evaluation using the appraisal tools, the evidence was rated as either low, moderate, or high. Only evidence that was rated as moderate or high was included in this project. See Table 2.1 for the quality appraisal for each piece of evidence and the Evidence Table (Appendix B) for more detailed information regarding the evidence.

# Table 2.1

Summary of Evidence

Katsagoni et al. (2020)CINAHLI/ SRHigh/ CASPVan Name et al. (2020)CINAHL MEDLINEIII/ Q-EHigh/ CASPSchwimmer et al. (2019)CINAHL MEDLINEII/RCTHigh/ CASPMann et al. (2019)Science DirectI/ SRHigh/ CASPMedrano et al. (2018)CINAHLI/SR & MAHigh/ CASPUtz-Melere et al. (2018)Science DirectI/SR & MAModerate/ CASP	Author/yr	Database(s)	Level of Evidence/Type	Quality/Tool
Cohen et al. (2021)MEDLINEII/ RCTModerate/ CASPGonzalez-Ruiz et al. (2021)CINAHLII/ RCTModerate/ CASPMalecki et al. (2021)CINAHLIV/ CohortHigh/ CASPYurtdas et al. (2021)CINAHLII/ RCTHigh/ CASPYurtdas et al. (2020)Science DirectI/ CPGModerate/ AGREEKatsagoni et al. (2020)CINAHLI/ SRHigh/ CASPVan Name et al. (2020)CINAHLII/ Q-EHigh/ CASPSchwimmer et al. (2019)CINAHLII/RCTHigh/ CASPMann et al. (2019)Science DirectI/ SRHigh/ CASPMedrano et al. (2018)CINAHLI/SR & MAHigh/ CASPUtz-Melere et al. (2018)Science DirectI/SR & MAModerate/ CASP	Cusi et al. (2022)	Science Direct	I/ CPG	High/ AGREE II
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### **Construction of Evidence-based Practice**

### Synthesis of Critically Appraised Literature

In accordance with the JHNEBP Model, after critically appraising the evidence, each article was summarized in the Evidence Table (Appendix B). It was through this process that clear and reiterative themes were identified within the evidence. The themes identified included: (a) diet, (b) exercise, (c) combination lifestyle modification programs, (d) parental involvement, (e) education, (f) frequent check-ins, and (g) psychosocial support.

#### Diet

Fourteen out of sixteen (88%) of the evidence reviewed identified interventions aimed at dietary improvements (Arab et al., 2020; Cohen et al., 2021; Cusi et al., 2022; Gibson et al., 2017; Katsagoni et al., 2020; Lefere et al., 2022; Malecki et al., 2021; Mann et al., 2019; Moran et al., 2017; Schwimmer et al., 2019; Utz-Melere et al., 2018; Van Name et al., 2020; Vos et al., 2017; Yurtdas et al., 2021). Various types of diets were studied in the evidence and included the Mediterranean diet (Arab et al., 2020; Cusi et al., 2022; Malecki et al., 2021; Yurtdas et al., 2021), an energy or caloric-deficit diet (Arab et al., 2020; Cusi et al., 2022; Vos et al., 2017), a conventional low-fat diet (Mann et al., 2019; Yurtdas et al., 2021), a conventional low-carb diet (Katsagoni et al., 2020; Mann et al., 2019), a low-glycemic load diet (Gibson et al., 2017), a restricted free sugar intake diet targeted at less than 3% (Cohen et al., 2021; Schwimmer et al., 2019), and a low omega-6 to omega-3 polyunsaturated fatty acid (PUFA) ratio (4:1) diet that was normocaloric (Van Name et al., 2020). General acquisition of healthy eating habits, such as minimum and maximum portion sizes (Lefere et al., 2022), general dietary guidance to reduce refined sugar and sugary beverages (Arab et al., 2020; Cusi et al., 2022; Mann et al., 2019; Moran et al., 2017; Vos et al., 2017), reduce carbohydrates and fats, and increase water consumption and fiber, were also recommended (Arab et al., 2020; Moran et al., 2017; Utz-Melere et al., 2019; Vos et al., 2017).

Essentially, all of the previously listed diets were considered an improvement within participants' habitual intake and improved various measures of hepatic fat content in all of the studies. Low-sugar, low-carb, low-fat, low-glycemic-index, energy deficit and the Mediterranean diet when accompanied by weight loss, all achieved improvements in hepatic fat measurements (Cohen et al., 2021; Cusi et al., 2022; Gibson et al., 2017; Katsagoni et al., 2020; Lefere et al., 2022; Malecki et al., 2021; Mann et al., 2019; Moran et al., 2017; Schwimmer et al., 2019; Utz-Melere et al., 2018; Yurtdas et al., 2021). A comparison among these types of diets was commonly performed within the evidence to determine the efficacy and degree of effect that each diet had on hepatic fat outcomes (Arab et al., 2020; Gibson et al., 2017; Katsagoni et al., 2020; Malecki et al., 2021; Mann et al., 2019; Utz-Melere et al., 2018; Vos et al., 2017). Most often, caloric-deficit, low-glycemic-index, low-carb and low-fat diets were compared, and no one specific diet was found to be superior to the other (Gibson et al., 2017; Katsagoni et al., 2020; Mann et al., 2019; Utz-Melere et al., 2018; Vos et al., 2017). The percentage of weight loss needed to achieve a significant reduction of intrahepatic fat was also poorly established, estimated at 5-10%, with the overall consensus of greater weight loss being associated with larger improvements in ALT (Arab et al., 2020; Mann et al., 2019).

More recent evidence that has examined the Mediterranean diet in pediatric NAFLD has demonstrated significant improvements both in one single-arm prospective cohort study (Malecki et al., 2021) as well as when compared to a low-fat diet in one RCT (Yurtdas et al., 2021). While both a low-fat diet and the Mediterranean diet achieved significant reductions in hepatic fat, a greater decrease in ALT [-18.75 (37.50) versus -13.0 (17.50) p = 0.056] and AST levels [-7.0 (22.75) versus -4.5 (12.50) U/L; p = 0.039] was seen in the Mediterranean diet group than with the low-fat diet group. Furthermore, the proportion of adolescents with normal ALT levels increased significantly in the Mediterranean group and did not change in the low-fat diet group (Yurtdas et al., 2021).

The Mediterranean diet, as well as a low omega-6, high omega-3 PUFA diet, were also the only two diets in the literature that improved intrahepatic fat measurements independent of weight loss (Arab et al., 2020; Malecki et al., 2021; Van Name et al., 2020; Yurtdas et al., 2021). One prospective cohort study found that the Mediterranean diet had a significant effect on the reduction in aminotransferase levels, even in the youth who did not achieve weight loss (Malecki et al., 2021). Another high-guality Q-E study was able to control for weight to avoid the confounding factor of weight loss as a mechanism to reduce intrahepatic fat (Van Name et al., 2020). This study demonstrated that a food-based dietary intervention, high in omega-3 and low in omega-6 PUFA intake, improves NAFLD in obese adolescents and restores liver fat content to normal in one-third of participants, in the absence of weight loss (Van Name et al., 2020). This high-quality study is also of special significance because patients were also genotyped for the expression of the PNPLA3 rs738409 gene, a gene commonly found in Hispanic individuals that, when present with obesity, places them at higher risk of NAFLD cirrhosis (Katz et al., 2021; Van Name et al., 2020). While intrahepatic fat content assessed by MRI declined in the adolescents who did not carry the allele, there was only a significant reduction (p = 0.016) of hepatic fat content in the homozygous group (Van Name et al., 2020). Thereby, these diets may be beneficial in lean NAFLD, in youth who have a hard time losing weight, or those who do not desire to lose weight, as well as in those who are carriers of the PNPLA3 rs738409 gene.

Reduction in free-sugar intake was also another popular dietary component that was examined within the evidence (Arab et al., 2020; Cohen et al., 2021; Cusi et al., 2022; Katsagoni et al., 2020; Mann et al., 2019; Moran et al., 2017; Schwimmer et al., 2019; Vos et al., 2017). Schwimmer et al. (2019) reported on the effects of a diet of low sugar intake of less than 3% of daily calories for eight weeks in a high-quality RCT performed on 40 adolescent Hispanic males with NAFLD. "The mean decrease in hepatic steatosis from baseline to week 8 was significantly greater for the intervention diet group (25% to 17%) versus the usual diet group (21% to 20%)" (Schwimmer et al., 2019, p. 256). ALT levels were also significantly decreased for the

intervention diet group (103 U/L to 61 U/L) versus the usual diet group (82 U/L to 75 U/L) (95% CI, 0.53 to 0.81 U/L; p < .001). A follow-up intervention study by Cohen et al. (2021) that included a subsample (n = 29) from the study by Schwimmer et al. (2019), which measured hepatic de novo lipogenesis (DNL) and hepatic fat, found that there was also a significant decrease in hepatic DNL in the treatment group (34.6% to 24.1%) versus the control group (33.9% to 34.6%) which correlated significantly with changes in free-sugar intake (r = 0.48, p = 0.011) and ALT (r = 0.39, p = 0.049). These results suggest and support the hypothesis that hepatic DNL is a critical metabolic abnormality that links increased dietary sugar intake with NAFLD (Cohen et al., 2021).

#### Exercise

Exercise was a common interventional component examined within the evidence, noted within 13 pieces of evidence (Arab et al., 2020; Cusi et al., 2022; Gibson et al., 2017; Gonzalez-Ruiz et al., 2021; Katsagoni et al., 2020; Lefere et al., 2022; Malecki et al., 2021; Mann et al., 2019; Medrano et al., 2018; Moran et al., 2017; Utz-Menere et al., 2018; Vos et al., 2017). Exercise was not studied by itself in eight out of the 13 studies, but was combined with a dietary component, making it difficult to ascertain its direct effect on hepatic fat (Gibson et al., 2017; Katsagoni et al., 2020; Lefere et al., 2022; Malecki et al., 2021; Mann et al., 2017; Katsagoni et al., 2020; Lefere et al., 2022; Malecki et al., 2021; Mann et al., 2019; Moran et al., 2017; Utz-Melere et al., 2018; Vos et al., 2017). However, three pieces of evidence noted exercise to be an effective intervention to reduce intrahepatic fat content in pediatric youth with NAFLD, independent of weight loss or changes in diet (Arab et al., 2020; Cusi et al., 2022; Medrano et al., 2018). Regular exercise not only significantly reduced intrahepatic triglycerides (IHTG) content and ALT levels but also improved cardiovascular risk factors and insulin resistance (Arab et al., 2020; Cusi et al., 2022). While most studies incorporated physical activity, the type of exercise, duration, frequency, and intensity varied.

Two pieces of evidence, one SR & MA and one RCT, solely examined the impact of various types of exercise at different intensity levels, volume, and frequency to better understand

the optimal exercise training dose needed to reduce hepatic fat in youth (Gonzalez-Ruiz et al., 2021; Medrano et al., 2018). Both aerobic and resistance training at moderate-to-vigorous intensities (p = 0.001) for sessions of at least 60 minutes at least three times a week (p = 0.002) significantly reduced hepatic fat content in youth (Medrano et al., 2018). Similarly, a high-intensity (p < 0.001) or combined high and low-intensity exercise program (p = 0.005) both significantly reduced hepatic fat content in youth (Gonzalez-Ruiz et al., 2021). Vos et al. (2017) also referenced another RCT that both an aerobic exercise intervention and a resistance exercise intervention in obese boys found a significant reduction in hepatic fat in both exercise groups compared with a no-exercise control group.

### **Combination Lifestyle Modification Programs**

As both dietary and physical exercise has been shown to dramatically improve intrahepatic fat independently of each other, they were frequently recommended as part of a combination lifestyle modification program (Gibson et al., 2017; Katsagoni et al., 2020; Lefere et al., 2022; Malecki et al., 2021; Mann et al., 2019; Moran et al., 2017; Utz-Melere et al., 2018; Vos et al., 2017). Multidisciplinary clinics that use combination lifestyle modification approaches of moderate to high intensity, as defined by more than 25 contact hours over a 6-month period that is designed to treat pediatric obesity, have reported improved ALT levels and liver histology in children with NAFLD (Vos et al., 2017). A SR & MA concluded that lifestyle changes lead to significant improvements in body mass index (BMI), aminotransferase levels, and hepatic steatosis in children and adolescents with NAFLD (Utz-Melere et al., 2018). A cohort study of 49 children aged 3-16 years old with NAFLD, who participated in a lifestyle modification intervention of moderate aerobic exercise in combination with a Mediterranean diet and reduction of sugar and sugar-containing beverages, followed over a mean of 2.45 +/-1.45 years, found that among those who complied with the lifestyle changes, 100% had a reduction in BMI, as well as significantly lower levels of ALT (p = 0.0028) compared to those who did not comply with the changes (Malecki et al., 2021).

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# Education & Parental Involvement

Making lifestyle changes has historically been challenging; thus, lifestyle modification programs were designed to help children and their families achieve success in making healthy sustainable changes. Increased contact hours spent with patients and their parents through education were noted among four of the studies that implemented lifestyle modification programs (Cohen et al., 2021; Moran et al., 2017; Yurtdas et al., 2021; Schwimmer et al., 2019). A cohort study by Moran et al. (2017), showed how lifestyle interventions aimed at both parents and adolescents through nutritional educational sessions, which also stressed the importance of physical activity over a 4-month span, were an effective strategy for children with NAFLD who were Hispanic and obese. In an RCT by Yurtdas et al. (2021), parents and adolescents both received nutrition advice from a dietician. Nutrition education, meal planning, and meal provision for the entire family helped provide assurance to a diet restricted to less than 3% of sugars in two studies (Cohen et al., 2021; Schiwimmer et al., 2019). Meal planning and nutrition education by dieticians was also performed with adolescents alone (Lefere et al., 2022; Malecki et al., 2021); with meal provision provided only for study participants in one Q-E study (Van Name et al., 2020). Trained physiotherapists and physical educators were also used in the RCT by Gonzalez-Ruiz et al., (2021) to educate and support participants to achieve success in meeting increased physical activity goals.

### Frequent Follow-Up and Psychosocial Support

Frequent follow-up and providing psychosocial support were additional components within the programs that achieved increased compliance in adhering to lifestyle changes (Cohen et al., 2021; Lefere et al., 2022; Malecki et al., 2021; Moran et al., 2017; Schwimmer et al, 2019; Yurtdas et al., 2021; Van Name et I., 2020). Frequent follow-up sessions that provided psychosocial support and encouragement for the continuance of healthy eating and physical activity behaviors were key components of 44% of the studies and varied from twice weekly to every three months. One cohort study exemplified impressive results that had nutritional support through counseling every 15 days over a 4-month period where 93.5% of participants had a significant difference in BMI and a significant reduction (p < 0.05) in ALT from pre-intervention (65.5 U/L) to post-intervention (35.5 U/L) with 71.1% of children showing normal ALT levels post-intervention (Moran et al., 2017). Another study, where participants were followed up closely twice a week through phone calls to provide psychosocial support, assess, and promote adherence, also demonstrated high levels of program adherence and significant reductions (p < 0.05) in hepatic steatosis, ALT, and insulin resistance (Yurtdas et al., 2021).

#### **Recommendation for Best Practice**

Based on the synthesis of evidence, lifestyle modifications have clear and comprehensive health benefits for children and adolescents with NAFLD. Best practice recommendations for reducing hepatic fat and improving ALT levels in Hispanic adolescents with NAFLD include a lifestyle modification program with the following components: (a) a well-balanced diet based on the principles of the Mediterranean diet, (b) a diet that avoids high sugar consumption, including sugar-sweetened beverages, (c) decrease in sedentary activity and increase in moderate to vigorous aerobic exercise and/or resistance training at least 30-60 minutes a day, for at least 3 times a week, and (e) adherence promotion through parental involvement, educational sessions, psychosocial support, and frequent follow-up.

#### **CHAPTER 3**

# **IMPLEMENTATION OF PRACTICE CHANGE**

Based on the disparities of NAFLD in the Hispanic population and the importance of early and effective interventions, best practice recommendations were applied in an EBP project at an urban pediatric primary care office in the Northeastern U.S. In collaboration with clinic staff and the site facilitator, lifestyle modification recommendations based on best practice recommendations were developed. The implementation of the lifestyle modification intervention was divided into three phases and delivered over three months. The three sequential phases consisted of: (a) an initial intervention delivery with parental involvement and obtainment of demographics, baseline KIDMED score, BMI Z-score, and ALT levels, (b) frequent follow-up with psychosocial support via telephone check-ins once every three weeks, and the option to attend two in-person nutrition classes and, (c) repeating final KIDMED score, BMI Z-score, and ALT levels at the end of the 12 weeks.

### **Participants and Setting**

The EBP project took place at an urban pediatric office in the Northeastern U.S. Aside from the project leader, the key stakeholders involved in the development and implementation of this project included the main provider at the site, a pediatric nurse practitioner who has been practicing for more than ten years, the practice owner, a pediatrician who has been practicing for more than 32 years, and the medical assistants, all of whom are local, Hispanic residents bilingual in English and Spanish, knowledgeable about the neighborhood, and who contributed significant insight into the participants' culture and lifestyle. These medical personnel care for more than 2,500 pediatric patients from infancy through age 21. Individuals eligible to participate in the project included Hispanic children and adolescents aged 10-21, who had either a confirmed diagnosis of NAFLD or elevated ALT, with no documented secondary causes of liver disease. Additionally, participants who had elevated ALT levels within the last year and who also would have their routine liver enzymes checked in December of 2022 or January of 2023 were eligible. Careful planning was performed surrounding those who had their routine follow-up visit after the end of the intervention so that insurance covered the cost of testing. Ineligible individuals included those younger than 10 or older than 21, non-Hispanic, had normal ALT levels, or presence of other documented medical conditions of secondary causes of NAFLD.

### **Pre-Intervention Group Characteristics**

Demographical age was collected on an interval scale, and ethnicity, gender and preferred language on a nominal scale. Parental or guardian household income was collected by interval scales via questionnaires at the time of the initial encounter after agreeing to partake in the project (Appendix C). The KIDMED tool was also assessed using interval scales prior to the intervention to assess baseline Mediterranean diet adherence. Special permission to use the KIDMED tool has been granted (Appendix D). Due to copyright laws, the KIDMED has been omitted from this manuscript. ALT levels using interval scales was also collected through electronic medical record (EMR) chart reviews. Percentages of demographics was calculated within the scale parameters. The original sample size was 29 individuals, ranging in age from 10 to 19 with a mean age of 13.75 (SD= 2.84). The sample was made up of 23 males (79%), and 6 females (21%). English was the preferred language in 52% of participants, and Spanish in 48% of the sample. Fifty-two percent of participants (n = 15) identified a household income between \$40,000-49,999.

#### Intervention

Many steps were required to prepare and plan for the intervention. Only after an exhaustive literature search, evidence appraisal, and a synthesis of the literature, were best practice recommendations for the EBP project founded. Based on the evidence and current recommendations, a multimodal intervention was developed. The EBP project included: (a) dietary advice based on the Mediterranean dietary principles, (b) exercise, (c) parental involvement, (d) nutritional education sessions, (e) psychosocial support, and (f) follow-up phone

calls every three weeks. Taking into account the diminished access to resources and lower socioeconomic status of the adolescent population in the urban setting, it was determined that in order for the intervention to be successful and feasible, it needed to be easily accessible and cost-effective for both participants and their parents or guardians. After discussions with the project advisor and site facilitator on ways to maintain cultural competence, cultural humility, and professional diversity through the biased Mediterranean diet, careful consideration of the materials for the lifestyle modification intervention were taken into account. Based on these recommendations, the project leader began to search again for educational material and tools that would aid in the delivery and measure adherence to the evidence-based practice recommendations. In collaboration with the site facilitator, education designed to initiate lifestyle changes based on nutrition was found from local resources, and additional material was created. The materials were a combination of carefully selected outsourced and developed educational materials that were all approved and agreed upon by the project facilitator, the site's medical assistants, and the project leader. The thought process behind all chosen materials was to maintain consistency with the evidence-based practice recommendations while adapting to the Hispanic culture without projecting bias of one culture's specific dietary pattern onto another. Also, it was also determined that the project leader would primarily implement the intervention to increase intervention consistency.

## First Phase

During the project's first phase, the project leader performed convenience sampling by attending the site from the last week of August 2022, until the last week of September 2022. During this time, the project leader performed daily and weekly schedule and chart reviews to identify Hispanic teenagers with an established diagnosis of NAFLD or elevated ALT with no other documented or suspected cause of liver disease since the beginning of the year. Individuals who met criteria and had: (a) an appointment at the clinic during the first 35 days of the project, (b) an appointment in the 12 weeks prior to the start of project, or (c) those who

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would have their ALTs repeated in December 2022 or January 2023, were targeted to receive the intervention. First, the site facilitator or medical assistant established permission for the project leader to speak with the parent or guardian and their child. An initial demographic form and survey of the KIDMED tool was delivered in person by the project leader or over the phone. A total of 29 eligible participants were reached. The project leader then provided the accepting participant a folder with supplemental educational material and a reusable time-marker water bottle. The folder was given in person to patients who had in-house visits and mailed along with the water bottle to those who received the initial intervention over the phone. The project leader then engaged the parent or guardian and the accepting participant in an educational and interactive discussion on their NAFLD diagnosis. During this time, the project leader reviewed each resource within the folder, educated both parent or guardian and the patient on specific nutritional and physical activity lifestyle modifications that would improve the patient's liver and overall health. Nutritional principles of the Mediterranean diet, such as increasing intake of plant foods, whole grains, nuts and legumes, consuming healthy fats such as olive oil in place of other fats or oils, consuming red meat infrequently, and in small amounts, eating fish and poultry in low to moderate amounts a few times a week, cutting out sugary beverages, and consuming less high-fat processed foods were the main points discussed. Conversations about cooking and sharing meals at home, as well as increasing physical activity and exercising at least 3 times a week at moderate to vigorous intensity for at least 60 minutes within the community either individually or as a family was also discussed. Materials used within the folder are located in the appendix and included nutritional education about sugary beverages (Appendix E), a MyPlate Planner with delineation of proper portion sizes (Appendix F), How to choose healthy foods (Appendix G), You Have the Power to Improve Your Families Health (Appendix H), and a prescription for healthy living (Appendix I). A neighborhood resource guide of local gyms with free youth-based exercise classes or recreational activities was also provided within the folder, however, it was omitted from this manuscript to protect the site's identity. Moreover, the majority

of materials were provided in both English and Spanish, and conversations occurred in the patient's preferred language, either English or Spanish. After an in-depth initial discussion with participants and their parents, using suggestions from the prescription of healthy living, one individualized, actionable goal was encouraged to be set.

#### Second Phase

During the project's next phase, four follow-up phone calls were made to participants and their parents to encourage adherence, reeducate, assess challenges, offer suggestions, and provide support for the proposed lifestyle change. During phone calls, participants and their parents were also invited to attend a nutrition class over the 12-week time period. The first nutrition class took place in early December and received no attendees. In an effort to improve adherence to the second class, additional reminders were made via telephone, and flyers were also made (Appendix J) and mailed to participants. The second nutrition class took place mid-December and achieved four participants in attendance, with two other non-participatory attendants of the clinic as well.

## Third Phase

Lastly, during the project's final phase, the KIDMED score was again reassessed and scored for data collection. This occurred during the final phone call. Additionally, participants had their ALT levels redrawn, and chart reviews were performed to obtain post-intervention ALT and BMI Z-score.

#### Comparison

Through discussions with the site providers as well as chart reviews, it is clear that there is a need for a practice change intervention regarding NAFLD in Hispanic adolescents. A chart review revealed that screening and diagnostic measures vary among providers, and recommendations for disease treatment vary as well. Despite providers' documented treatment recommendations to eat a low-fat, low-sugar, or calorie-restricted diet, elevated ALT levels were persistently noted. The random sample of 50 Hispanic youth, ages 10 to 21, treated at this clinic

demonstrated that 17% of them had elevated LFTs, and 82% of those had persistent elevated levels even after the standard recommendation of diet change. The providers unanimously agreed that the Hispanic population at the site is more commonly, and more severely affected by NAFLD, and the site requested a practice change.

#### Outcomes

The primary outcome evaluated was ALT, comparing levels pre and post-intervention. ALT was reviewed in the EMR of participating clients. Paired t-tests were the primary statistical analysis chosen to compare ALT levels from pre to post-intervention. The paired t-test is the appropriate test as it compares two means of interval data among the same participants at different times. According to the evidence, improved ALT levels among adherent participants to lifestyle modifications link the behaviors with decreased hepatic fat in Hispanic adolescents. Based on the evidence, increased adherence to lifestyle modifications is projected to remediate improved ALT outcomes post-intervention. Nonadherent participants can also explain and account for nil improvements. According to NASPGHAN, ALT is currently the recommended screening test for NAFLD because it is minimally invasive with a sensitivity of 88% and specificity of 26% in children age 10 and older (Vos et al. 2017).

A secondary outcome of adherence was measured with the KIDMED tool. The KIDMED tool is the most widely used scoring system used to assess adherence to the Mediterranean diet in children and adolescents and it has repeatedly demonstrated acceptable validity and reliability within the literature (Altavilla & Caballero-Perez, 2019). The KIDMED tool uses an ordinal scoring system of equal to or < 3 (low quality), 4-7 (needs improvement) and > or equal to 8 (optimal).

Another secondary outcome of data that was collected was BMI Z-score. BMI Z-score is routinely measured at each visit. The BMI Z-score was collected through chart reviews of participants after follow-up visits when routine liver function tests were performed. As noted in the background above, NAFLD is closely associated with obesity, and a reduction in BMI Z-score would be expected of those who displayed increased adherence to the lifestyle changes.

#### Time

Implementation of the project began in late August 2022, coinciding with Valparaiso University's fall semester and, as discussed with the site facilitator, when many children and adolescents schedule annual physicals needed for starting a new school year. In order to complete the planning of the project's design, many hours were spent researching, developing, and organizing the participant handouts, folders, and supplemental materials needed for the initial visit, follow-up phone calls, as well as planning for the nutritional education classes. The timeline necessary for the successful completion of the project is 12 weeks, as elevated ALT is routinely measured after three months at the site. See Gannt chart in Appendix K for implementation calendar.

#### **Protection of Human Subjects**

Patient safety and anonymity will be maintained throughout this project in accordance with the University's policies, procedures, and ethical considerations to protect the rights and welfare of the human beings participating in this EBP project. The project leader completed the human subjects research training course through the Collaborative Institutional Training Initiative Program prior to the project's planning and design in April 2022 (Appendix L). Approval to complete the project was submitted to the practice site and Valparaiso University's IRB during the project's planning phase and was deemed exempt from both parties. To protect the site's identity, all identifiable information linked with the site has been omitted from this manuscript. Participation in the EBP project was voluntary, where participants could freely disenroll or withdraw at any point if they so wished. The site's providers maintained standard of care despite non-participation or disenrollment from the EBP project. The risks and benefits of the project's intervention were discussed with participants during the initial office visit. Participant confidentiality and anonymity was maintained during the implementation phase by not disclosing information to individuals outside of the project's involvement. Participants' identifiable information of

participants on the project leader's laptop in a password-protected file. Information was accessed during the follow-up phone calls performed from both the site's location and the project leader's home. The project leader's laptop remained locked by password to prevent others from accessing the data, even in the case the laptop was lost. Upon completion of the project, all phone numbers and names will immediately be deleted from the file. Hard copies of the demographic questionnaires and KIDMED assessment tools did not contain identifiable information, only the participants name, which once information was transferred to the computer was shredded. Participants' biochemical data was also only reviewed by EMR on site solely by the project leader, where only applicable coded data needed for data analysis was transferred to one excel spreadsheet on the project leader's personal secure USB drive, protected by password, which will be permanently deleted after project completion.

## **CHAPTER 4**

## FINDINGS

This chapter presents the results of the data analysis for the primary and secondary outcomes of this project. The purpose of this EBP project was to implement a lifestyle modification intervention to combat the disease process of NAFLD and subsequent sequela. The project took place in a pediatric primary care setting and was targeted specifically for the Hispanic pediatric population. Demographic information for the participants and key project findings are presented. Based on the literature review, a lowered ALT was identified as the primary target outcome for the post-intervention follow-up. Overall, the primary outcome data showed that the participants decreased their ALT mean from pre- to post- intervention. Although the findings were not statistically significant, they were clinically significant. On the other hand, both of the secondary outcomes did show statistically significant improvements from pre- to post-intervention data. BMI Z-score and KIDMED score were the secondary outcomes that demonstrated a statistically significant decrease from pre- to post-intervention.

The primary outcome data for ALT met three out of four assumptions for parametric testing: homogeneity of variance, interval level data, and independence. Normal distribution was the one assumption that was not demonstrated in this data. A Shapiro-Wilk test of normality showed that pre (W = 0.839, p < 0.05), and post intervention ALT (W = 0.871, p < 0.05) data were statistically significantly different from a normal distribution. Therefore, the paired-samples *t* test could not be used, and instead the Wilcoxon Matched Pairs Signed Rank test was chosen to complete the data analysis on the primary outcome of ALT. This test was chosen because it is the nonparametric equivalent to the paired-samples *t* test. For the secondary outcome of BMI Z-score and KIDMED score, a paired-samples *t* test was performed. The normality assumption was verified using the Shapiro-Wilk test for these outcomes. Descriptive statistics were used to describe the demographical data of the sample.

#### **Participants**

The original sample size for this project was 29 with a majority of participants who were male (n = 23, 79%), and identified with an annual household income of \$40,000- 49,000 (n = 15, 52%). A little more than half (n = 15, 52%) of the original participants preferred English, and the other half of participants (n = 14, 48%) preferred Spanish. Sixty-two percent (n = 18) of the original sample was age 10-14, and 37.8% (n = 11) were age 15-19.

The attrition rate during this project was 31%, with a total of 21 individuals completing the follow-up data collection, and 8 individuals who were lost to follow-up. The attrition was due to individuals: not answering their phone, having a disconnected phone, changing providers, and failing to show up to their appointment.

Testing was completed to ascertain if differences existed between the original sample (n = 29) and the post-intervention follow-up group (n = 21). A chi-square test of independence was calculated comparing the results of gender, preferred language, and household income. No significant relationship was found within the two groups for gender ( $X_{2}(1) = .452$ , p = > 0.05), or preferred language ( $X_2(1) = .514$ , p = > 0.05). In the original sample there were 23 males (n = 29; 79%), and 6 females (21%). In the post-intervention group, there were 16 males (n = 21; 76%), and 5 females (23%). There were 15 participants in the original sample (n = 29; 52%) who preferred English, and 10 participants (48%) in the post-intervention group (n = 21) who preferred English. Gender and preferred language are independent of each other. A chi-square test of independence was calculated comparing household income within the original sample (n = 29), and the post-intervention group (n = 21). A significant interaction was found ( $X_2$ 9) = 63, p =< 0.001). Household income was significantly different between the original sample and the postintervention group because the one participant who preferred not to respond and the two participants within the original sample who identified an annual income of \$10,000-19,999 bracket were lost to follow-up. An independent-samples t test compared the mean age among the original sample (n = 29) and those who were in the post-intervention group (n = 21). No

significant difference was found in age (t(27) = -.733, p > 0.05). The mean age of the original sample (n = 29; M = 13.75, SD = 2.84) was not significantly different from the mean of those in the final sample who completed ALT post-intervention (n = 21; M = 14.00, SD = 2.98) (see Table 4.1 for the results).

# Table 4.1

# Descriptive Demographic Data for Baseline and week 12 Participants

Demographic	Baseline	Week twelve	
	( <i>n</i> = 29 )	( <i>n</i> = 21 )	
Number of Participants	29	21	
Attrition Rate		31%	
Age (years)			
Mean ( <i>SD</i> )	13.75 (2.84)	10.66 (2.98)	
Range	10-19	10-19	
Gender			
Male	23 (79.3%)	16 (76.2%)	
Female	6 (21.7%)	5 (23.8%)	
Preferred Language			
English	15 (51.7%)	10 (47.6%)	
Spanish	14 (48.3%)	11 (52.4%)	
Household income			
Less than \$10,000	0 (0%)	0 (0%)	
\$10,000-19,999	2 (6.9%)	0 (0%)	
\$20,000-29,999	3 (10.3%)	1 (4.8%)	
\$30,000-39,999	4 (13.8%)	4 (19.0%)	
\$40,000-49,999	15 (51.7%)	13 (61.9%)	
More than \$50,000	4 (13.8%)	3 (14.3%)	
No response	1 (3.4%)	0 (0%)	

#### Changes in Outcomes

The purpose of this EBP project was to determine the effect of a multicomponent lifestyle modification intervention in Hispanic adolescents aged 10-21 with obesity and NAFLD on ALT levels, over a 12-week time period. Therefore, the primary outcome for this project was the evaluation of the change in ALT. Secondary outcomes included BMI Z-score and KIDMED score to further evaluate the clinical and lifestyle significance of the intervention.

## Statistical Testing and Significance

Statistical Package for Social Sciences 25 (SPSS25) was the program used to complete data analysis. Primary outcome data of ALT did not have a normal distribution and thus, did not meet all four assumptions that are required to use parametric testing. Because this EBP project used a within-group design, the primary outcome data were analyzed using the Wilcoxon Signed Rank test. For both of the secondary outcome data, normal distribution was met and therefore, the parametric paired-samples *t* test was performed.

## Findings

#### Primary Outcome

**ALT Levels.** A Wilcoxon test examined the results of the pre- intervention mean ALT and post- intervention mean ALT. No significant difference was found in the results (Z = -1.113, p > .05). However, post- intervention ALT results were clinically different from pre- intervention ALT results. Pre- intervention ALT ranged from 32-202, and post- intervention ALT ranged from 28-176. The mean on the pretest was 76.48 (SD = 43.92), and the mean on the post was 69.81 (SD = 33.65). Thirteen participants had negative differences in their ALT, demonstrating improvement, and eight participants had positive differences in ALT, demonstrating no improvement and elevations of ALT. Table 4.2 presents the ALT collected from each participant at baseline and at their final week twelve visit.

Although no statistical significance was found on the data collected, the overall results can still be considered clinically significant. More than half (n = 13,62%) of the post-intervention

group decreased their ALT compared to pre-intervention, demonstrating improvement in the levels (see Table 4.2). The overall range of ALT, as well as mean ALT was also lowered from pre- to post-intervention demonstrating improvement in severity as a whole.

# Table 4.2

Participant	Baseline ALT	Repeat ALT
1	64	62
2	94	98
3	101	70
4	73	78
5	39	38
6	46	49
7	38	33
8	115	102
9	33	-
10	57	59
11	32	-
12	48	40
13	75	40
14	124	114
15	57	69
16	37	44
17	123	-
18	45	-
19	53	58
20	46	-
21	202	176
22	69	-

Participant Data for Primary Outcomes

23	61	76
24	79	78
25	196	-
26	89	78
27	112	-
28	32	28
29	78	76

## Secondary Outcomes

**BMI** *z* **Scores.** A paired-samples *t* test was calculated to compare the mean preintervention BMI Z-score to the mean post-intervention BMI Z-score. The mean on the preintervention was 1.86 (SD = 0.73), and the mean on the post-intervention was 1.76 (SD = 0.68). A significant decrease from the start of the intervention was found (*t* (20) = 2.518, *p* = 0.02).

**KIDMED Scores.** A paired-samples *t* test was calculated to compare the mean preintervention KIDMED score to the mean post-intervention KIDMED score. The mean on the preintervention was 1.12 (*SD* = 2.13), and the mean on the post-intervention was 3.12 (*SD* = 2.40). A significant increase from pre-intervention to post was found (*t* (24) = -8.165, *p* < 0.001). Table 4.3 outlines participant data for all secondary outcomes.

A Cronbach's alpha was calculated for pre- and post-intervention KIDMED scores. Cronbach's alpha is a measure of internal consistency. Cronbach's alpha for pre-intervention KIDMED scores was .701 and for post-intervention KIDMED scores was .614, demonstrating good internal consistency.

# Table 4.3

Participant	Baseline BMI z Score	Repeat BMI z Score	Baseline KIDMED	Repeat KIDMED
1	1.94	1.81	- 2	1
2	1.58	-	4	-
3	2.78	2.81	-3	-3
4	1.35	-	-2	0
5	1.70	-	1	4
6	2.12	1.90	3	5
7	2.68	2.48	0	1
8	2.51	2.50	-1	2
9	1.48	1.49	1	3
10	3.09	3.09	0	2
11	1.75	1.62	4	5
12	2.69	2.23	5	7
13	3.09	-	3	7
14	3.08	-	-4	-
15	1.08	-	0	-
16	2.00	2.40	4	2
17	2.33	1.90	2	1
18	.84	.80	3	6
19	1.07	1.07	2	3
20	2.82	-	0	-
21	2.55	2.16	-1	3
22	1.54	1.42	1	4

# Participant Data for Secondary Outcomes

23	1.71	1.52	0	3
24	.81	.80	2	3
25	.59	.59	4	7
26	1.36	1.35	-1	0
27	1.22	-	-2	-
28	1.01	1.01	1	3
29	2.30	1.92	2	6

#### **CHAPTER 5**

## DISCUSSION

The PICOT question for this EBP project was: In Hispanic adolescents aged 10-21 with obesity and NAFLD (P), what is the effect of a multicomponent lifestyle modification intervention (I) on ALT (O) over a 12-week time period (T)? An education-based intervention centered around principles of the Mediterranean diet, meant to improve dietary habits and increase physical activity levels, was provided to 29 participants and their parents with a previously documented diagnosis of NAFLD or elevated ALT. Participants were followed every three weeks by phone calls and invited to attend two nutrition classes held by the project leader over 12 weeks. Participants each identified incremental targeted goals to improve health-related lifestyle behaviors. Baseline ALT, BMI Z-score, and KIDMED scores were calculated using appropriate statistical testing to compare pre- and post-intervention group outcomes.

This chapter will address the project findings. Statistical analyses for the primary and secondary outcomes will be explained, the strengths and limitations of this EBP project will be discussed, and the relevance of the JHNEBP model used to guide the implementation of this project will be evaluated. Finally, recommendations for future areas of nursing education and research needed to improve pediatric NAFLD outcomes will be suggested.

#### **Explanation of Findings**

This section will compare the project's findings to the relevant literature selected to support the project's intervention. Explanations as to why results were achieved will be discussed.

## **Primary Outcomes**

## ALT Levels

Although the data analysis for all participants who completed the intervention did not demonstrate a statistically significant difference between pre- and post-intervention ALT (p > .05) a clinical significance was found as overall ALT improved from pre- to postintervention. Post-intervention ALT range and mean lowered from pre-intervention values. Most (61%; n = 13) of post-intervention participants had negative differences in their ALT, demonstrating improvement after the lifestyle intervention. Despite no statistical significance in SPSS, the clinical significance and overall improvement in ALT range and mean are consistent with evidence found in the literature (Cohen et al., 2021; Gibson et al., 2017; Gonzalez-Ruiz et al., 2021; Katsagoni et al., 2020; Lefere et al., 2022; Malecki et al., 2021; Mann et al., 2019; Moran et al., 2017; Schwimmer et al., 2021; Utz-Melere et al., 2018; Van Name et al., 2021; Yurtdas et al., 2021). The lack of statistical significance found within this project can potentially be subject to the small sample size and length of time of the intervention.

Studies demonstrated statistically significant improvements in ALT but occurred on a much larger scale and for a much longer time. These studies included 49-202 participants, and they were followed for at least six months up until 2.45 +/- 1.45 years (Gonzalez-Ruiz et al., 2021; Lefere et al., 2022; Malecki et al., 2021). Studies of shorter duration with smaller sample sizes that demonstrated statistically significant reductions in ALT implemented intensive interventions with additional resources not feasible for this project site (Moran et al., 2017; Schwimmer et al., 2019; Yurtdas et al., 2021). A cohort study by Moran et al. (2017) included the support of a registered dietician who provided additional 1-hour group sessions to children and parents twice a month for four months. A RCT by Yurtdas et al. (2021) took place over 12 weeks; however, it incorporated a dietician who provided twice weekly phone calls and communicated daily meal plans via social media with participants and their parents. Additional technology was also used in this intervention to analyze dietary records to provide feedback for participants on additional ways to improve their diet (Yurtdas et al., 2021). An even shorter RCT of 8 weeks by Schwimmer et al. (2019) demonstrated statistically significant reductions in ALT. This study included pre-intervention staff who replaced all sugar-containing products in participants'

households in the intervention group, provided individualized meal planning, and supplied meals for the entire household to ensure restriction of sugar intake and intervention diet adherence. The artificiality of food delivery was a notable limitation within this study, highlighting the increased likelihood of adherence but low practicality within a real-world setting. Such efforts were impractical and unfeasible within this EBP project and could explain the lack of statistical significance in post-intervention ALT.

Limitations within this project's intervention could explain a lack of statistical significance. The length of intervention for this project was limited to 12 weeks and included a final sample size of 21 participants. A nutritionist or dietician was not employed at the project site to develop individualized meal plans, nor was a tailored computer program to calculate proportioned targets of macros or assess dietary mistakes. Providing food, meals, or twice weekly phone calls and hourly twice monthly in-person group sessions were not sustainable interventions for this project's implementation. The intervention of this project was limited in funds and primarily developed and delivered by one person, in a low socioeconomic neighborhood. The involvement of a dietician, funding for additional support, such as ancillary staff, or a multidisciplinary approach with shared intervention responsibility may have been able to achieve a more intensive intervention and thus obtain statistical significance.

A final rationalization to explain the lack of statistical significance achieved during this project could be related to the timing of post-intervention ALT and the temporary and imperfect measure of ALT. The timing of most participants post-intervention ALT fell near or after the winter holidays when it is well known that families celebrate with sugary foods and consume excess calories. Further, ALT levels can vary 10 to 30% from day to day and fluctuate up to 45% during a single day (Alanine Aminotransferase, 2023). Such timing could have caused a transient increase in ALT, a well-documented limitation of this measure.

## **Secondary Outcomes**

#### BMI Z-Scores

BMI Z-score was a secondary outcome measured in this project. As noted within the literature, NAFLD is characterized by excess visceral adiposity, and its overall prevalence is more common in obese individuals (Katsagoni et al., 2020). The data analysis for all participants who completed the post-intervention follow-up visit in this EBP project demonstrated a statistically significant difference between the pre-intervention BMI Z-score and week 12 (p = 0.02). This finding is in line with the majority of evidence found within the literature that measured BMI or BMI Z-score (Gonzalez-Ruiz et al., 2021; Lefere et al., 2022; Malecki et al., 2021; Moran et al., 2017; Utz-Melere et al., 2017; Yurtdas et al., 2021). This finding supports the theory that significant reductions in BMI can be achieved through lifestyle changes, even over shorter periods of time. Significant reductions in BMI (p < .001) were found after a 4-month lifestyle intervention by Moran et al. (2017), a 12-week RCT by Yurtdas et al. (2021), and a 6-month RCT by Gonzalez-Ruiz et al. (2021). Similar results of BMI reduction and improvements following a lifestyle modification, the Mediterranean diet, and increased physical activity intervention were found amongst those who were 100% compliant with the lifestyle recommendation changes over 2.5 years (Malecki et al., 2020).

Additionally, the mean age for the final sample of this project was 10.66 years old, which coincides with the typical onset of puberty in both girls and boys (Reinehr et al., 2017). Therefore, it is possible that the start of puberty played a part in achieving significant reductions in BMI Z-scores, as it was found in one study that the onset of puberty was significantly (p = .024) more frequently found in boys with BMI reduction (76.9%) (Reinehr et al., 2017). The majority of the final sample in this project was younger and male (76.2%), suggesting pubertal changes such as increases in height and subsequent fat loss could have positively affected BMI Z-score outcomes. Lack of performing and documenting Tanner staging in each participant to confirm or deny a confounding effect was not performed.

A final limitation that should be noted within this project was the variability in time-lapse when comparing pre-and post-intervention measurements. While pre- and post-intervention scores were compared, it should be noted that participants who received the initial intervention via phone and mail had the pre-intervention BMI Z-scores taken from chart reviews. Thus, the comparison accuracy may be skewed due to earlier BMI Z-scores taken from the last in-house visit. Such variability could have allowed for more time for individuals to grow or lose weight and contributed to a lack of standardization.

## KIDMED Scores

The KIDMED is a commonly used and established tool that measures Mediterranean Diet Quality Index. It was developed by Serra-Majem et al. (2001) to evaluate adherence to the MD in children and adolescents. The scores are graded based on responses to 16 dietary statements, ranging from 0 to 12 points. A score of less than or equal to three indicates low adherence, a score of four to seven indicates moderate compliance, and a score of greater than or equal to eight indicates high compliance to a MD (Serra-Majem et al., 2001).

The data analysis for all participants who completed the post-intervention KIDMED questionnaire demonstrated a statistically significant difference compared to their preintervention scores (p < 0.001). The mean on the pretest was 1.12 (SD = 2.13), and the mean on the posttest was 3.12 (SD = 2.40). These results indicate that participants significantly improved their dietary habits to achieve increased adherence to a MD. These findings are consistent with the evidence in the literature that promoted adherence of adolescents with NAFLD to adopt a MD to improve ALT levels (Arab et al., 2020; Cusi et al., 2022; Malecki et al., 2021; Yurtdas et al., 2021). Only one RCT specifically used the KIDMED tool, and significant improvements from baseline to week 12 (p < 0.001) were also found (Yurtdas et al., 2021).

Incidentally, according to the KIDMED scoring system, the pre-and post-intervention scores in this project demonstrated a low adherence to an MD. When attempting to understand and explain these results, it is difficult to assess if adherence to a MD is responsible for

improvements in ALT and BMI Z-score or if simple dietary improvements and increased physical activity are responsible for improvements. These findings highlight the bias of the MD in research, the need for further research to adapt the MD to other cultures, and the need for dietary research on specific recommendations within Hispanic and Latinx cultures.

#### Strengths and Limitations of the DNP Project

## Strengths

The project manager believes there were many parts to the project that contributed to the project's overall success. The parental involvement, printed materials, and follow-up phone calls helped participants improve dietary and physical activity habits. Many participants' parents expressed interest and gratitude throughout the follow-up phone calls and by those who attended the nutrition class. Simple changes of swapping from white rice to brown rice and lard to olive oil or making a game out of trying new types of fruits or vegetables with their kids were some examples of dietary changes taken on by parents and guardians to improve their child's health. Some parents said they hung the printed materials on the refrigerator as visual reminders for themselves and their children when choosing and preparing meals. The follow-up phone calls also increased accountability and served as a reminder for continuous efforts to be made towards their previously set lifestyle goal.

The ease and practicality of the intervention played a prominent role in the project's success. Minor dietary and physical activity improvements within one's lifestyle are attainable, and simple adjustments are accessible when adequately framed. Adopting a diet emphasizing deprivation or restriction, such as only eating low-fat or low-carb, is often unsustainable in the long term (Mignini et al., 2020). Research has shown that dieting has a less than 20% success rate; It is suggested that successful sustainable weight loss is attributed to a balanced, personalized diet comprised of healthier food choices and a more active lifestyle (Mignini et al., 2020).

Finally, the site facilitator and office staff where this project was implemented were incredibly supportive and contributed to the project's success. The staff support and insight into the community, and Hispanic culture, aided in developing and delivering the project materials. The project manager helped provide potential resources to use for printed materials, as well as identify participants who met inclusion criteria. The office staff at the site assisted with the Spanish translation of materials and, when needed, translation during conversations with participants and their families. Further, the project manager and the office staff at the site promoted attendance to the second nutrition class by creating more copies of fliers that were hung around the office and inviting individuals who had in-person visits that would benefit from the education. In addition, the secretarial staff at the site were accommodating by calling participants to schedule follow-up appointments and providing appointment reminders.

## Limitations

Some limitations of this project were related to the difference in delivery of the initial intervention. Due to this project's specific population characteristics, initial in-person intervention delivery was only plausible for some participants. Many qualifying participants did not have in-person visits during the project's initial phase. Thus, the adaptation to recruit qualifying participants by phone calls was both a limitation and a necessary adaptation of this project to increase the sample size.

Another limitation was that demographic variables differed significantly among preand post-intervention groups according to stratified incomes. Because two participants were lost to follow-up within the post-intervention group, a statistical significance within characteristics between groups was found. Participants who identified with the lowest income interval were lost to follow-up, suggesting that this project's intervention may not be best suited for people with very low incomes. This difference among pre- and postintervention groups suggests that the perceived barrier to achieving lifestyle change may be reflected by one's ability to afford healthy food. Further reflection on conversations with families during the nutrition class and follow-up phone calls echoed this idea, as some parents identified the cost of food as a barrier to eating healthy.

Additionally, this EBP project took place at one clinic that served a lowersocioeconomic population. The sample size of this project was also small and solely focused on Hispanic adolescents. Thus, the findings are specific to a population of a particular homogenous character. Although grouped into one epidemiological category, NAFLD is affected differently by ethnicity and socioeconomic status.

Other limitations of this project were the overall poor adherence to a MD, and that the KIDMED questionnaire was based on retrospective self-reporting. This type of data collection could lead to an error of recall bias and misreporting, especially if the participants or their parents felt inclined to show improvement in dietary habits to the person who had previously encouraged such behaviors. Nonetheless, some participants reported no change in dietary habits despite receiving the intervention, highlighting their ability to be truthful and the difficulty they can experience when trying to implement changes in lifestyle habits. To prevent participants from committing self-reporting bias errors, a phone application that makes it easy to track their dietary habits could be considered for future interventions to improve the quality of data collected.

Lastly, a significant amount of time and money went into the initial intervention delivery, follow-up phone calls, nutrition class development, and mailing of materials. The project leader covered the cost of the reprinting of materials. In retrospect, delegating responsibilities among ancillary staff could have supported the nutrition class and initial intervention better. The nutrition class and education could have been more easily translated by including a collaborating dietician or nutritionist with more profound knowledge to answer questions and who could have been consulted throughout the intervention.

#### Sustainability

Since the completion of the project, the site has adopted components of the EBP project, such as incorporating multiple printed materials within visits. The prescription for healthy living is now used at the end of visits, and the posters for healthy eating habits and sugary beverages have now been hung on each exam room wall. Because these materials provide education and promote generalized prescriptions for healthy living, in addition to NAFLD, they can be recommended for many other related diseases, such as hypertension, diabetes, hyperlipidemia, and obesity. The follow-up phone calls and nutrition classes were only performed by the project leader during the intervention. These practices require a high level of motivation and dedication. They will not be maintained to sustain the project at the clinic site, as current employees have no monetary incentive to take on additional roles.

This EBP project used printed materials, follow-up calls, and nutrition classes to increase adherence. This project did not require self-monitoring; this was done to decrease participant burden, increase sample size, and promote sustainability. However, if the project leader had the opportunity to redo the project or for others who would want to replicate something similar, the recommendation would be to include additional self-monitoring tools to provide improved feedback. Another recommendation would be the addition of a dietician or nutritionist who could be utilized for project development and nutrition classes. Finally, the inclusion of Tanner staging pre- and post-intervention would be recommended for purposes of better understanding the effect of puberty on outcomes.

#### **Relevance for EBP Model**

The JHNEBP model was used to guide the practice question, evidence selection, and translation of this EBP project. The JHNEBP model was instrumental in guiding this EBP project. Each step guided the project leader throughout the EBP process and allowed for a simple and primarily linear way for project advancement. A significant strength of the JHNEBP model is that it is an open system model, and as such, learning and practice are influenced by the evidence as well as internal and external factors (Dang & Dearholt, 2017). As the project leader and

interdisciplinary team moved through the PET process, significant discussions surrounding internal and external factors and their role in the EBP intervention and outcome were considered. While moving forward through the learning and practice cycle, additional insights triggered new EBP practice challenges and adaptations to maintain a culturally competent intervention that still adhered to best practices. The repetitive cycle of inquiry, learning, and practice continuously identified the need for seeking additional evidence and practice improvement manipulations.

Another beneficial aspect of the JHNEBP model was the Translation Action and Planning Tool. It assisted in developing an intervention that aligned with the organizational goals and priorities, fit the site, was feasible in expectations and delivery, and was acceptable to all. This tool was beneficial as it helped ensure that the project intervention was acceptable to both the leader and stakeholders. Thus, the stakeholders, including the medical assistants and NP, gave significant input into selecting the materials. The tool also helped plan the delivery of the initial intervention to disrupt workflow minimally. The input provided by staff at the site further secured support and resources for the plan, as the staff supported their role within the project.

Despite its strengths, the JHNEBP model has some weaknesses. One weakness is that the model has 19 prescriptive steps, which may be cumbersome to some. Another area for improvement within the model is that the steps in the evidence phase to critically appraise and summarize each piece of evidence before determining if sufficient evidence exists may be tedious when the PICOT question needs to be refined and multiple searches must be performed.

#### **Recommendations for the Future**

The findings from this EBP project have provided valuable information regarding an effective lifestyle modification intervention in Hispanic adolescents with NAFLD. In the targeted population, poor compliance with previously prescribed lifestyle recommendations was significantly improved following this intervention.

#### Research

This EBP project aimed to evaluate the influence of a multicomponent, lifestyle modification intervention on ALT, BMI Z-score, and KIDMED score among Hispanic adolescents with NAFLD. The post-intervention results were measured at a 12-week follow-up visit. The 3-month duration of the project only allowed a limited amount of time for participants to work on lifestyle modification change. It would be beneficial to continue the intervention for a more extended period of time to assess if additional time spent with participants could result in significant reductions in ALT. Another unanswered research dilemma is the percentage of BMI Z -score reduction in Hispanic adolescents needed to achieve ALT normalization.

Although the evidence supported adopting principles inherited from the MD, its promotion within research as the healthiest cultural diet is inherently biased (Burt, 2021, p. 41). While the Mediterranean region is composed of many cultures and ethnicities, the lack of research on other cultural diets noted within the evidence has resulted in a hyperfocus on the MD over other cultural diets. Ultimately, promoting the MD as the benchmark marginalizes people from other cultures (Burt, 2021). To better serve and include the Hispanic community, future research considerations should include diverse cultural dietary behaviors inherent to Hispanic and Latinx cultures, or at least additional ways to maintain cultural competence, cultural humility, and professional diversity through the biased MD. Doing so will improve cultural humility among professionals, diversify dietary research, and promote a more evidence-based dietary approach (Burt, 2021).

## Education

NAFLD is now the most prevalent liver disease in childhood, and U.S. population studies have confirmed that Hispanics have the highest prevalence and the worst disease prognosis (Katz et al., 2021). Nurses and APRNS are ideally situated within the healthcare system to transform this nation's healthcare radically. Nurses comprise the largest health provider group in the U.S. and work in various healthcare settings (Rosseter, 2022). They have the basic knowledge and unique opportunity to promote healthy lifestyle behaviors. However, there is room in nursing education to improve knowledge of nutrition as well as ways to communicate effective behavioral counseling. While the specific requirements of nursing programs differ, nutrition is not usually emphasized in most undergraduate and graduate nursing programs (Zeldman & Andrade, 2020). Effective lifestyle counseling would not only benefit the specific dietary recommendations to treat pediatric NAFLD, but it would also help prevent most associated diseases of NAFLD, such as obesity, hypertension, hyperlipidemia, and type 2 diabetes. Nurses need to receive adequate nutrition knowledge, counseling skills, and improved confidence in undergraduate and graduate programs to offer nutrition advice to patients properly. Improving nutrition knowledge and counseling skills within the nursing profession could lead to improved patient outcomes.

In 2010, the Patient Protection and Affordable Care Act (ACA) initiated the transformation of the U.S. healthcare model that promoted a preventive approach. The emphasis towards primary and preventative quality care included the need for well-prepared healthcare professionals. Advanced Practice Registered Nurses (APRNs) who hold the Doctor of Nursing Practice (DNP) degree are prepared to meet this increased need by providing leadership in community health centers, promoting the application of EBP, and advocating for and directing future policy initiatives. APRNs can fill the knowledge gap within the noted literature and apply EBP to improve NAFLD screening rates to increase recognition and overcome underdiagnosis. APRNs can fill needs within underserved and low socioeconomic neighborhoods to improve primary care and address the racial disparity of NAFLD in the Hispanic population. APRNs can advocate and lobby to address preventable healthcare disparities related to poor nutrition and improve access to healthy, affordable food in low-socioeconomic neighborhoods.

## Conclusion

The traditional medical model, geared to react to and treat chronic disease rather than prevent it, has failed the U.S. nation. Instead of maintaining a reactionary approach to disease, it is time action is taken to prevent it. Many chronic diseases in the U.S. can be remediated by implementing EBP lifestyle interventions. Lifestyle modification interventions aim to create behavioral change and promote healthier choices. Doctoral APRNs have the knowledge and skill necessary to translate research into practice. The DNP is equipped and prepared to research, critically appraise evidence, and determine appropriate practices needed to design interventions that guide health professionals in making best practice changes.

Dietary improvements and increased physical exercise are the first-line therapy for pediatric NAFLD. However, despite traditional methods to passively counsel patients and families, the implementation and sustainability of healthy lifestyle change has remained challenging for patients and the healthcare team. This EBP project demonstrates that Hispanic adolescents and families can follow a reduced sugar, MD-type diet and implement healthy positive lifestyle changes for up to 12 weeks when nutritional education classes, additional resource materials, and frequent follow-up phone calls highly support the intervention. Lifestyle modifications made through incremental changes can improve ALT and BMI Z-scores in Hispanic adolescents with obesity and NAFLD. The DNP is particularly well-suited to implement similar EBP interventions within the clinical setting, as they possess the knowledge and expertise needed to implement such practice changes and improve outcomes.

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## Biography

Ms. Brianne Miller graduated from the State University of New York (SUNY) at New Paltz in 2009 with a Bachelor of Arts degree in Spanish. She decided to continue her education and graduated from Valparaiso University's accelerated nursing program in 2012, obtaining a Bachelor of Science in Nursing. Brianne began her nursing career in the emergency department at Porter Regional Hospital in Valparaiso, Indiana. After gaining some experience, she combined her passion for nursing and travel and embarked on a journey as a travel nurse around the country. She has worked in seven different states as an emergency room nurse and has over ten years of experience. Brianne chose to become a nurse practitioner to pursue her passion for wellness and preventative care. She currently holds certifications in Advanced Cardiac Life Support (ACLS), Pediatric Advanced Life Support (PALS), Trauma Nursing Core Course (TNCC), and National Institutes of Health (NIH) Stroke. Brianne is also an active member of the Sigma Theta Tau International Honor Society of Nursing- Zeta Epsilon Chapter. She recently completed a nurse coach course to become a board-certified nurse coach. To fulfill her passion for primary care, personal development, and life-long learning she is on track to graduate from Valparaiso University with her Doctor of Nursing Practice degree with a Family Nurse Practitioner specialty in May 2023.

## ACRONYM LIST

- AACE: American Association of Clinical Endocrinology
- ALT: Alanine aminotransferase level
- BMI: Body mass index
- CASP: Critical Appraisal Skills Programme
- CPG: Clinical practice guideline
- DNL: De novo lipogenesis
- EBP: Evidence-based practice
- EMR: Electronic medical record
- IHTG: Intrahepatic triglycerides
- JHNEBP: John Hopkins Nursing Evidence-Based Practice
- LFT: Liver function test
- MD: Mediterranean Diet
- MRI-PDFF: Magnetic resonance imaging proton density fat fraction
- NAFL: Nonalcoholic fatty liver
- NAFLD: Nonalcoholic fatty liver disease
- NASH: Nonalcoholic steatohepatitis
- NASPGHAN: North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition
- NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases
- NP: Nurse practitioner
- PCOS: Polycystic ovarian syndrome
- PUFA: Polyunsaturated fatty acids
- Q-E: Quasi-experimental
- RCT: Randomized controlled trial
- SR: Systematic review
- SR & MA: Systematic review and meta-analysis

# U.S.: United States

## Appendix A

# JOHNS HOPKINS EBP MODEL AND TOOLS- PERMISSION



Thank you for your submission. We are happy to give you permission to use the Johns Hopkins Evidence-Based Practice model and tools to adhere to our legal terms noted below. No further permission for use is necessary.

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Downloads:

2022 JHEBP Tools- Printable Version

2022 JHEBP Tools- Electronic Version

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# Appendix B

## Evidence Table

Lead Author/ Year/Quality	Purpose/ Design/Sample	Interventions	Measurement/ Outcomes	Results/ Findings	Strengths/ Limitations
		Level I Evidence			
Arab/ 2020/ Moderate	<ul> <li>Purpose: To improve patient care and awareness of NAFLD and assist stakeholders in the decision- making process related to NAFLD.</li> <li>Design: Clinical practice guideline</li> </ul>			A reduction in calorie intake to 1200-1800 kcal/day and the achievement of a weight reduction of 7- 10% is beneficial in NAFLD management. A low-refined sugar diet based on the Mediterranean diet is beneficial in the management of NAFLD. Moderate coffee consumption is recommended in patients with NAFLD.	Strengths: Written by Latin- American specialists in different clinical areas Limitations: Does not differentiate age-specific population guidelines; Method of literature search is not delineated

				Regular exercise (aerobic, resistance, or combined) should be part of the first line of non- pharmacological treatment of NAFLD.	
Cusi/ 2022/ High	<ul> <li>Purpose: To provide endocrinologists and primary care clinicians with practical evidence- based recommendations for the diagnosis and management of NAFLD and NASH.</li> <li>Design: Clinical practice guideline</li> </ul>	-		Clinicians should recommend lifestyle changes in children with NAFLD, promoting the adoption of dietary changes to create an energy deficit, with reduction in sugar consumption as first-line lifestyle modification and increased physical activity aiming for BMI optimization.	Strengths: Addresses pediatric NAFLD diagnosis and management considerations in the U.S. Limitations: Recom- mendatio n is ambiguous. Does not provide specific recom- mendations for Hispanics.
Gibson/ 2017/ High	<b>Purpose:</b> To evaluate the efficacy of nutrition and physical activity interventions in the clinical management of pediatric NAFLD.	a) Vitamin E supplementation combined with hypocaloric diet/	Primary outcomes: degree of histological	Five RCTs noted a greater decrease in ALT in the Vitamin E	<b>Strengths:</b> Provided quality information of

Design: Systematic review Sample: 13 RCTs and 2 articles with data of extension of RCTs. Overall evaluated a total of 821 pediatric patients with NAFLD over 4 weeks- 24 months.	nutritional counseling and exercise $(n = 6)$ b) Probiotic supplementation with hypocaloric diet and aerobic exercise $(n = 2)$ c) Omega-3 fatty acid supplementation with hypocaloric diet, and increased physical activity (n = 5) d) Dietary modification of low glycemic load diet with nutritional education, grocery lists, food preparation demonstrations and addition of 33g glucose/bottle a	change (fat, inflammation, or fibrosis), hepatic fat measured by MRS, change in US echogenicity, change in ALT, AST, or GGT. Secondary outcomes: Changes to outcomes of cardiovascular risk (HDI, LDL, triglycerides, total cholesterol), IR (2-hour OGTT, fasting insulin levels, fasting glucose levels, fasting glucose or insulin ratio's), and anthropometry (weight, BMI.	and lifestyle intervention arm compared to controls. Two RCTs evaluated probiotic supplementation found a significant decrease in ALT in those treated with <i>L</i> <i>rhamnosus</i> strain GG compared to placebo. Four of five RCTs found ALT, AST, and GGT were significantly reduced in omega-3 fatty acid supplementation	each study on tables. Limitations: Some lifestyle intervention outcomes were confounded by nutritional supplements. Not specially for Hispanics.
	education, grocery lists, food preparation demonstrations and addition of	levels, fasting glucose levels, fasting glucose or insulin ratio's), and	ALT, AST, and GGT were significantly reduced in omega-3 fatty	

				Generalized lifestyle modification targeting weight loss through reduced energy intake and increased physical activity should remain the first line of treatment for pediatric NAFLD.	
Katsagoni/ 2020/ High	<ul> <li>Purpose: To assess the efficacy of dietary and lifestyle interventions on several NAFLD-related parameters in children and adolescents with imaging or biopsy-proven NAFLD.</li> <li>Design: Systematic review</li> <li>Sample: 10 RCT assessing the effects of diet or physical activity on children with NAFLD.</li> </ul>	Dietary intervention of low-fructose, low-glycemic, low-fat, glucose beverages, fructose beverages, low- energy, low- sugar, nutritional education, low- carbohydrate. Diet plus physical activity where dietary interventions were based on a specific plan, or on nutrition modification sessions.	Laboratory results of IHTG levels, AST, GGT, and ALT; liver echogenicity, by US or liver histology; anthropometric measurements (weight, BMI, waist circumference, percent of weight loss); parameters of glucose metabolism; measures of dyslipidemia.	Five RCTs reports effects on diet and liver characteristics and found that resolution of NAFLD or ALT was not found, but baseline comparison within randomized groups was ALT, AST, GGT, and IHTG was improved in the diet group with low sugars in 1 RCT, no significant difference between a low- GI, and low-fat	Strengths: Provided in- depth tables, discussion, and analysis of interventions and outcomes Limitations: Lack of longer duration RCT to assess the effectiveness of lifestyle changes on children with NAFLD

		Physical activity interventions were based on aerobic-exercise sessions, or on high-intensity aerobic exercise, sometimes with psychological support, were also given to both groups.		diet groups, and no change in HFF% in 1 RCT. Three RCT evaluated the effects of diet and physical activity and found resolution of NAFLD was noted in all studies. One RCT evaluated the effects of different types of physical activity and found that the AT+RT showed lower levels of ALT compared to baseline.	
Mann/ 2019/ High	<b>Purpose:</b> To achieve a broader view than covered in other systematic reviews to date to determine the most effective treatment for pediatric NAFLD, and assess the heterogeneity in trial design and whether it may limit the conclusions drawn from RCTs.	Dietary intervention of low fructose, low glycemic load, low-fat without caloric restriction, or low- carbohydrate for	Histology, radiology US, radiology MRI, Biochemical markers	Three RCTS found ALT and hepatic fat on MRS improved after 6 months in the low-fat and low-fructose diets, but 4 weeks of low-	Strengths: Identified differences in time to sustain significant improvement in outcomes. Limitations:
	<b>Design:</b> Systematic review	4 weeks-6 months.		fructose had no effect on ALT or MRS.	Intervention outcomes of lifestyle were

	Sample: 21 RCTs evaluated a total of 1307 participants, mean age 12.6 years, 63% male with intervention raging from 1-24 months.	Weight loss by lifestyle intervention was another intervention that combined diet with exercise; most studies used a low-fat calorie restricted diet with aerobic exercise of at least 30 minutes, 3 times a week, supported by education and advice. Metformin, antioxidants PUFA, Probiotics		Eight RCTs of weight loss by lifestyle intervention of low-fat, or calorie restricted diet with exercise of 30- 45 minutes/day 3 times a week found an improvement in ALT or US echogenicity, with or without weight loss.	sometimes confounded by combination supplemental products.
Medrano/ 2018/ High	<b>Purpose:</b> To elucidate the effects of supervised-exercise training (ET) interventions on hepatic fat content and NAFLD prevalence in children and adolescents and to provide information about the optimal ET prescription (type, intensity, frequency, and volume) needed to reduce hepatic fat content in youths. <b>Design:</b> Systematic review and meta-analysis	All studies conducted supervised-ET, but the type, intensity, volume, frequency, and duration of ET varied across studies. Types of ET included aerobic, resistance,	Hepatic fat was measured via imaging (US or MRI).	Both aerobic and resistance ET interventions were associated with a significant reduction of hepatic fat content compared with control groups (p < 0.05).	Strengths: Appropriate statistical analysis provides more meaningful understanding of findings regarding recom- mendations for physical activity

	combination of	Only vigorous	in pediatric
Sample: 16 articles; 5 RCTs, 2	aerobic and	and moderate to	NAFLD
non-RCTs, 9 intervention studies	resistance,	vigorous	
without control group (pre-post	while 2	intensities and a	Limitations:
studies). Comprised 1201 youth	compared the	volume of at	None identified
with NAFLD age 6-19 who	effects of	least 60 minutes	
participated in at least 8 weeks of	aerobic vs	per session	
ET.	resistance,	were associated	
	general	with a significant	
	exercises (ball	reduction of	
	games, jogging,	hepatic fat	
	etc),	content (p <	
	supervised	0.001).	
	activities (biking,	· · · · /	
	walking,	Comparing pre	
	running) or	and post hepatic	
	recreational	content in ET	
	sports. Intensity	groups found	
	varied from	that only aerobic	
	moderate to	ET performed at	
	vigorous.	least at	
	Frequency	moderate to	
	varied from 2-7	vigorous	
	sessions a week	intensity, for at	
	for 30-90	least 60 minutes	
	minutes per	a session for at	
	session, and	least 3 times a	
	duration from	week had	
	12-52 weeks.	significant	
	Some also other	reduction in the	
	type of lifestyle	reduction of	
	intervention,	hepatic fat (p =	
	such as	0.002).	
	nutritional,	0.002).	
	motivational		
	interviewing,		
	behavior		
			l

		modification therapy, or psychological support.			
Utz-Melere/ 2018/ High	<ul> <li>Purpose: To assess the impact of lifestyle interventions through aerobic exercise and a balanced diet on body mass index (BMI), serum aminotransferase levels and hepatic steatosis in children and adolescents with NAFLD.</li> <li>Design: Systematic review and meta-analysis</li> <li>Sample: 19 studies (8 RCTs, 3 nonrandomized controlled clinical trials, 8 non-controlled clinical trials) that evaluated 923 youth with NAFLD aged 6-18</li> </ul>	A diet ranging from 1300-1900 Kcal/day with 50-65% from carbohydrates, 10-30% from fat and 12-20% from protein. In some studies, 10 g of fiber were added to diet. Details of diet not reported in 7 studies. All studies assessed aerobic exercise, ranging from once week to daily workouts 60 minutes on average. Duration ranged from 4-52 weeks.	BMI, aminotransferas es, and presence of hepatic steatosis assessed using abdominal US, MRI/MRS, or by histologic data.	The intervention was beneficial for ALT and hepatic steatosis in 10 studies; but 4 studies showed no significant effect ( $p <$ 0.001). Heterogeneity was high ( $p <$ 0.001) and the pooled effect was estimated using random- effects model. The risk of steatosis reduced by 61% after the interventions (RR grouped= 0.39; 95% CI: 0.27 to 0.56). Ten studies showed a benefit from the intervention on ALT levels.	Strengths: Multiple tables with in-depth information and analysis for easy visualization of comparisons and effects on outcomes Limitations: Results discussed are brief and combined with explanation of intervention

			Combined effect using a random model was – 1.35 (95% CI -1.92 to -0.78). In 5 studies, showed no effect on AST. The combined effect was -1.00 standard deviation (95% CI: -1.59 to - 0.40).	
Vos/ 2017/ High	<ul><li>Purpose: To suggest preferred evidence-based approaches to guide screening and clinical care of children with NAFLD.</li><li>Design: Clinical practice guideline</li></ul>		Lifestyle modifications to improve diet and increase physical activity are recommended as first-line treatment for all children with NAFLD. Avoidance of sugar- sweetened beverages is recommended as a strategy to decrease adiposity.	Strengths: Strong clinical practice guideline considers North American population of youth with NAFLD Limitations: Published in 2017

		Level II Evidence		high-intensity physical activity and limiting screen time activities <2 hours per day is recommended for all children including those with NAFLD.	
Cohen/ 2021/ Moderate	<ul> <li>Purpose: To test the effect of a longer-term dietary sugar restriction on hepatic de novo lipogenesis (DNL) in adolescent boys with NAFLD who participated in an 8-week RCT study testing the effects of a low-sugar diet compared with their usual diet.</li> <li>Design: Randomized controlled trial</li> <li>Sample: Hispanic (95%) adolescent boys (<i>n</i> = 40) age 11-16 with NAFLD</li> </ul>	A diet low in free sugars for 8 weeks	Hepatic DNL was measured as percentage contribution to plasma triglyceride palmitate using a 7-day metabolic labeling protocol with heavy water. Hepatic fat was measured by MRI-PDFF	Hepatic DNL was significantly decreased in the treatment group (from 34.6% to 24.1%) versus the control (33.9% to 34.6%), which was paralleled by greater decreases in hepatic fat (25.5% to 17.9% vs 19.5% to 18.8%). Percentage change in DNL during the intervention correlated significantly with changes in free-	Strengths: Targeted population of Hispanic adolescents with NAFLD Limitations: Small sample size of only boys with relatively short duration of intervention

				sugar intake ( $r = 0.48$ , $p = 0.047$ ), and ALT ( $r = 0.39$ , $p = 0.049$ ), but not hepatic fat ( $r = 0.13$ , $p = 0.532$ ).	
Gonzalez-Ruiz/ 2021/ Moderate	<ul> <li>Purpose: To examine the impact of a 6-month physical education intervention, considering various levels of exercise intensity, on hepatic fat and cardiometabolic health outcomes in adolescents with excess adiposity.</li> <li>Design: Randomized controlled clinical trial</li> <li>Sample: Adolescents (n = 120) age 11-17 with excess adiposity (Tanner stage II-IV) with a BMI above the 85<sup>th</sup> percentile</li> </ul>	Standard physical education lessons (CTRL) High-intensity physical education (HIPE) Low-to- moderate intensity physical education (LIPE) Combined HIPE and LIPE (PLUS) Trained physiotherapist and physical educators supervised each training session. Participants entered a run-in period that	The primary outcome was hepatic fat content measured by controlled attenuation parameter (CAP). Secondary outcomes were traditional cardiovascular markers, such as body composition, serum lipids, aminotransferas es, and health- related physical fitness components.	Adjusted mixed effects linear models revealed a significant decrease in CAP levels in HIPE (- 20.02dM/m, $p$ < 0.0001) ( $p$ = 0.001 vs CTRL group) and PLUS (- 16.25dB/m, $p$ = 0.005) groups. The physical fitness components were increased in the HIPE and PLUS group relative to the baseline ( $p$ < 0.05), and the HIPE group showed a reduction in total cholesterol and LDL levels ( $p$ < 0.05).	Strengths: Measured hepatic fat via CAP, as well as multiple secondary outcomes related to NAFLD and other cardiometabolic risk factors. Limitations: Did not include NAFLD as diagnosis for adolescents

Schwimmer/       Purpose: To determine the effects       The intervention discussed of a decussition at the hepatic level.       Primary outcome was the hepatic level.         Schwimmer/       Purpose: To determine the effects of a det low in free sugars (those sugars added to foods and beverages and occurring naturally in fruit juices) in adolescent boys with NAFLD.       The intervention dividualized or the patic level.		1	· · · ·	1		1
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beverages and occurring naturally in fruit juices) in adolescent boysmenu planning and provision ofhepatic steatosissteatosis from baseline toadolescents with NAFLD.	2019/ High	of a diet low in free sugars (those	diet consisted of	outcome was	decrease in	Targeted
beverages and occurring naturally in fruit juices) in adolescent boysmenu planning and provision ofhepatic steatosissteatosis from baseline toadolescents with NAFLD.	-	sugars added to foods and	individualized	change in	hepatic	
in fruit juices) in adolescent boys and provision of steatosis baseline to with NAFLD.		beverages and occurring naturally	menu planning		steatosis from	adolescents
					baseline to	with NAFLD.
		with NAFLD.	study meals for	estimated by	week 8 was	

Design: Randomized controlled trail Sample: Hispanic (95%) adolescent boys ( <i>n</i> = 40) age 11-16 with histologically diagnosed NAFLD and evidence of active disease (hepatic steatosis >10% and ALT >45U/L)	the entire household to restrict free sugar intake to less than 3% of daily calories. Twice- weekly phone calls assessed diet adherence. Usual diet participants consumed their regular diet. Study lasted for 8 weeks	MRI-PDFF measurement between baseline and 8 weeks. Minimum clinically important difference was assumed to be 4%. There were 12 secondary outcomes, including ALT level and diet adherence.	significantly greater for the intervention diet group (25% to 17%) vs the usual diet group (21%-20%) and the adjusted week 8 mean difference was - 6.23% (95% CI, -9.45% to - 3.02%; p<.001). Of the 12 secondary outcomes, 7 were null and 5 were statistically significant including ALT level and diet adherence. ALT geometric mean decrease from baseline to week 8 was significantly greater for the intervention diet group (103 U/L to 61 U/L) vs the usual diet group	Limitations: Intervention is strict was highly controlled; This may be difficult for adherence in patient population when unable to account for provision of meals. Only included boys.
			group (103 U/L to 61 U/L) vs the	

\_\_\_\_\_

				means at week 8 was $0.65U/L$ (95% CI, $0.53$ to 0.81 U/L; p < .001). Adherence to the diet was high in the intervention group (18 of 20 reported intake of <3% of calories from free sugar during the intervention).	
Yurtdas/ 2021/ High	<ul> <li>Purpose: To evaluate the effect of the Mediterranean diet (MD) versus low-fat diet (LFD) on hepatic steatosis, inflammation, and oxidative stress in adolescents with obesity and NAFLD.</li> <li>Design: Randomized controlled trial</li> <li>Sample: Adolescents with NAFLD and obesity defined by BMI&gt; 95<sup>th</sup>% (<i>n</i> = 44) age 11-18</li> </ul>	MD and conventional LFD groups for 12 weeks MD: Target macronutrient energy contributions were 40% from carbohydrates, 35%-40% from fat (with <10% from saturated fat), and 20% from protein. Participants were instructed to consume fish and legumes at least 2-3x a	Dietary status, anthropometry, body composition, biochemical parameters, and hepatic steatosis determined by US.	At the end of the intervention, a statistically significant decrease was found in the grade of hepatic steatosis, ALT, AST, and GGT in both groups ( $p < 0.05$ ). There was no statistically significant difference in the degree of liver fat between the groups ( $p < 0.875$ ). A greater decrease of ALT	Strengths: Evaluated multiple parameters of hepatic steatosis, and inflammatory markers of NAFLD in youth. Limitations: Relatively small sample size; attrition rate due to Covid-19 was high.

		<ul> <li>week; walnuts (20g/day); and olive oil (30-45 g/day) every day.</li> <li>LFD: Target macronutrient energy contributions for the LFD were 50-60% from carbohydrates,</li> <li>&lt; 30% from fat (with &lt; 10% from saturated fat), and 20% from protein.</li> <li>Participants were instructed to consume low- fat foods.</li> </ul>		and AST was seen in the MD than the LFD group. The proportion of adolescents with normal ALT levels increased significantly in the MD group, it did not change in the LFD group.		
			Level IIII Eviden	ce		
Van Name/ 2020/ High	<b>Purpose:</b> To examine whether 12 weeks of a low n-6:n-3 PUFA ratio (4:1) diet affects intrahepatic fat content, assessed by MRI, in obese youth with fatty liver. Also, given the interaction between the <i>PNPLA3 rs</i> 738409 variant and n- 6:n-3 PUFA ratio of dietary intake on fatty liver, this study also explore whether this variant	The intervention diet lasted for 12 weeks and consisted of a low n-6 to n-3 PUFA ratio of 4:1, and macronutrient content was 50- 55% daily total calories from	HFF% measured by abdominal MRI, ALT, lipids, insulin sensitivity and plasma OXLAMs	After 12 weeks HFF% decreased by 25.8% ( $p$ = 0.009) despite stable weight. There was a 34.4% reduction in ALT ( $p$ = 0.001).	<b>Strengths:</b> Was able to control for weight to avoid the confounding factor of weight loss as a mechanism to reduce intrahepatic fat; Assessed for	

affected individual responses to the	ne carbohydrates,		PNPLA3 gene
diet.	20% from	HFF% declin	ed and effect of
	protein, and 25-	in both the n	ot- diet on
<b>Design:</b> Quasi-experimental	30% from fat	at-risk (CC/C	
	with saturated	and at-risk (0	GG) participants
Sample: Children and adolescent	ts fat comprising	PNPLA3	were thoroughly
( <i>n</i> = 20) age 9-19 with a BMI > or	8-10% of daily	rs738409	phenotyped and
equal to the 95 <sup>th</sup> % for age and	total caloric	genotype	strict dietary
gender and hepatic fat fraction	intake. The	groups, with	
measured by MRI > or equal to	study personnel	significant	adherence
5.5% diagnosed with NAFLD.	provided all	reduction (p	
	needed dietary	0.016) HFF%	
	intake to	reduction in t	
	participants (not	GG group.	Limitations:
	for the entire		Small sample
	family), the diet		size, and the
	was		lack of a control
	normocaloric to		intervention; Did
	pre-study food		not formally
	intake, and		measure
	assessed by the		physical activity
	dietician.		which could
	Parents were		have
	present during		confounded
	diet education		results
	sessions which		
	were held		
	weekly for the		
	first 4 weeks,		
	and meal plans		
	were given to		
	follow diet.		

## Level IV Evidence

Lefere/ 2022/	Purpose: To assess the	Treatment is	Weight loss,	After 6 month of	Strengths:
Moderate	therapeutic efficacy of lifestyle	multimodal, and	liver steatosis	lifestyle	_

intervention on the severity of liver	focuses on	measured by	intervention, the	Large sample
steatosis and fibrosis by serial	increasing the	US and based	median weight	size
transient elastography (TE),	level of physical	on CAP, ALT	loss was 16.0%.	
ultrasound, and aminotransferase	activity, dietary	and IR		Limitations:
levels in children and adolescents	intervention,		The severity of	Intensive
enrolled in a structured residential	acquiring		liver steatosis,	lifestyle
lifestyle program.	healthy eating		both on US and	modification
	habits, and		based on CAP	was a monitored
Design: Prospective cohort	psychological		values,	program in an
	support.		decreased	inpatient tertiary
Sample: Children and adolescents	Patients follow		significantly (p	care center
(n = 204) with severe obesity, aged	an		< 0.001).	
8-18 years old with severe obesity	individualized		Resolution of	
admitted at a tertiary center	and monitored		steatosis	
	program,		occurred in	
	consisting of		47.1% with	
	both aerobic		baseline	
	and anaerobic		steatosis. The	
	exercise of 3		severity of liver	
	hours a week,		fibrosis also	
	guided by the		decreased	
	physiotherapist.		significantly	
	They also		compared with	
	participated in		baseline (p <	
	group activities,		0.001).	
	group games,		Regression of	
	and supervised		fibrosis stage	
	team sports for		was observed in	
	at least 1 hour a		75.0%, while	
	day. The diet is		resolution was	
	not based on		achieved in 35	
	caloric		patients.	
	calculations and			
	restrictions but,		At the end of	
	on defined		treatment after 1	
	minimum and		year, the	
	maximum		improvements	<u> </u>

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Malecki/ 2021/	Purpose:	portions for every meal, based on the Flemish nutrition pyramid and adjusted for age and sex. Patients were encouraged to drink water throughout the day. Special attention was also given to parental involvement. Participants	BMI, ALT, AST,	were sustained because fibrosis regressed at least 1 stage in all patients with baseline fibrosis. Fasting ALT and IR decreased significantly over the 1-year period ( $p <$ 0.001).	Strengths:
High	To evaluate the effectiveness of lifestyle modifications as a method of improving liver function indexes in children with NAFLD.	were recommended to modify their	and GGT	group, 35 children (71.43%) were	Duration of follow up, feasible intervention to
	Design:	lifestyle: moderate aerobic physical		obese, and 7 (14.29%) were overweight. In	apply in real- world setting
	Prospective cohort	exercise (at least 60 minutes		44.9% BMI loss	Limitations:
	Sample:	5 times a week)		was achieved, in the others	Lack of a control
	Children and adolescents $(n = 49)$ age 3-16 with a diagnosis of	and additionally the		BMI gain was noted. In the	group of overweight
	NAFLD	Mediterranean diet. It was		group with initial increased ALT	children without NAFLD
		recommended		levels, a significant	undergoing lifestyle
		to avoid sugar and sugar-		reduction in	modification.
		containing		ALT, AST and	Difficult to
		beverages. Screen time		GGT levels were found	assess patient involvement in
		was less than 2			diet and

hours a day. Weight reduction was not recommended in children with BMI within reference values. Participants were followed over 2.45 +/- 1.45 years.	compared to baseline. This study showed, even partial compliance to lifestyle modification without weight reduction resulted in decline in ALT level.Recommendatio n of the Mediterranean diet resulted in a reduction of BMI and an improvement in biochemical parameters in a significant amount of	exercise recommendations.
	patients. Lifestyle modification has a significant effect on the decrease in aminotransferas e levels, even in those children who fail to	

				achieve weight loss.	
Moran/ 2017/ High	Purpose: To evaluate the effect of a lifestyle intervention program on metabolic and hepatic alterations compatible with NAFLD in children. Design: Cohort Sample: Mexican adolescents and children ( <i>n</i> = 46) age 6-16 years old with BMI above the 95 <sup>th</sup> %, and NAFLD	A 4-month nutritional counselling program attended every 15 days for a 1- hour session by both children and their parents or guardians. Sessions were held by a dietician and a medical doctor. The sessions provided educational material about the importance of an adequate food intake, emphasized lowering the amount of refined sugar and sugary sodas, reducing the amount of carbohydrates and fat consumed every day and increasing fiber intake.	BMI, ALT, and AST	Significant differences in BMI were observed at the end of the intervention. BMI were reduced in 43 children (93.5%) and were increased in 3 children (6.5%). There was simultaneous reduction in BMI and ALT and AST in 38 of the 46 participants (82.6%). At the end of the intervention, 33 participants (71.7%) showed normal ALT levels. The results showed that alterations in hepatic function compatible with NAFLD in children can improve with a lifestyle	Strengths: Target population, feasible intervention to apply in real- world setting, appropriate statistical analysis Limitations: Short duration of study, small sample size

Participants also	intervention	
attended a	program	
session about	focused on	
the importance	improving	
and health	dietary intake	
benefits from	and physical	
physical activity,	activity.	
based in		
accordance with		
the US physical		
activity pyramid.		
During follow up		
sessions, the		
adoption of		
healthy eating		
behaviors and		
preferences		
were explored		
and encouraged		
to maintain		
healthy lifestyle		
modifications.		
Participants		
controlled their		
lifestyle freely		
by themselves		
at home.		

Appendix	С
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Date:		Name:	:		
Age:		Sex:	A. Male	B. Female	
Preferred Language:	A. English	B. Spanish			
Household income: A	A. less than \$10,000				
H	B. \$10,000 to \$19,999	9			
(	C. \$20,000 to \$29,999	9			
Ι	D. \$30,000 to \$39,99	9			
Η	E. \$40,000 to \$49,999	9			
Ι	F. more than \$50,000	)			
(	G. Prefer not to				

## Appendix D

# CAMBRIDGE UNIVERSITY PRESS LICENSE TERMS AND CONDITIONS

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A Lifestyle Intervention in Hispanic Adolescents with				

Project Name				
Nonalcoholic Fatty Liver Disease				
Client / Sponsor	Valparaiso University			
Product	NAFLD			
Portions	Table 1			
Specific Languages	English, Spanish			
Requestor Location	Valparaiso University			
United States				
Attn: Valparaiso University				

### Appendix E

#### ALL THE CALORIES IN SUGARY DRINKS CAN HARM YOUR FAMILY'S HEALTH

and bring on obesity, type 2 diabetes and heart disease.

LAS CALORÍAS EN LAS BEBIDAS AZUCARADAS PUEDEN PERJUDICAR LA SALUD DE TU FAMILIA

y causar obesidad	, diabetes tipo 2	y enfermed	lades cardíacas.
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DRINK	# OF PACKETS OF SUGAR You're Drinking	# OF CALORIES	MILES YOU HAVE TO WALK TO BURN OFF THOSE CALORIES*	
BEBIDA	# DE PAQUETES DE AZÚCAR Que estás tomando	# DE CALORÍAS	MILLAS QUE TIENES QUE CAMINAR PARA QUEMAR ESAS CALORIAS	
20 oz. Soda / Soda de 20 oz.	16	240	3.03	
23 oz. Sweetened Tea / Té azucarado de 23 oz.	18	360	4.55	
16 oz. Energy Drink / Bebida energética de 16 oz.	15	280	3.54	
32 oz. Sports Drink / Bebida deportiva de 32 oz.	14	200	2.52	
20 oz. Fruit Punch / Ponche de fruta de 20 oz.	19	280	3.54	
40 oz. Large Lemonade / Limonada grande de 40 oz.	25	370	4.68	
<b>24 oz. Med. Frozen Vanilla Coffee /</b> Café helado de vainilla mediano de 24 oz.	32	650	8.21	

\*According to the Mayo Health Clinic, a 160 lb. person will burn 277 calories an hour walking 3.5 mph. / \*Según la Clínica de Salud Mayo, una persona de 160 lb. quemará 277 calorias por hora caminando a 35 MPH.

#### TRY THESE HEALTHY ALTERNATIVES:

WATER: Add slices of lemons, limes, oranges, watermelon, cucumber or mint for a refreshing drink.

UNSWEETENED TEAS: If you want a little sweetening, just add a few drops of honey. SELTZER/CLUB SODA WITH A SPLASH OF 100% JUICE: Mix one part juice (like cranberry, orange or grape) with 3 parts seltzer for a low calorie bubbly treat. COFFEE: Just stay away from the fancy sweetened ones.

LOW-FAT (1%) or FAT-FREE (SKIM) MILK: Always a good, healthy choice.



GET MORE HEALTHY TIPS!

#### PRUEBA ESTAS ALTERNATIVAS SALUDABLES:

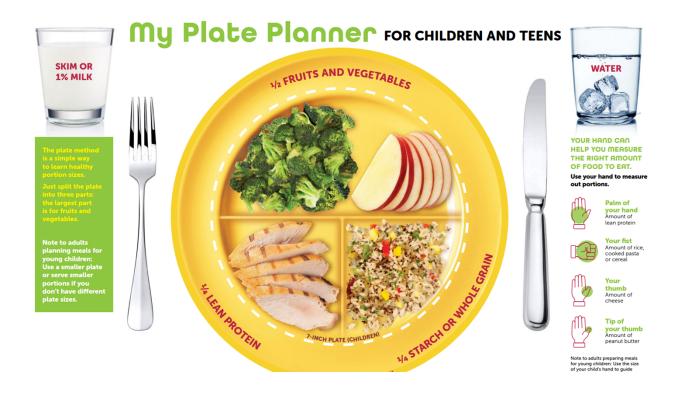
AGUA: Agrega rodajas de limón, naranja, sandía, pepino o menta para una bebida refrescante. TÉS SIN AZÚCAR: Si quieres un poco de dulce, sólo agrégale unas gotas de miel.

SELTZER/CLUB SODA CON UN POCO DE JUGO DE FRUTA 100%: Mazcia una parte de jugo (corno arándano, naranja o uva) con tres partes de Seltzer para una bebida burbujeante baja en calorías. CAFÉ: Evita los cafés azucarados elaborados.

LECHE BAJA EN GRASA (1%) o SIN GRASA (DESCREMADA): Es siempre una opción buena y saludable.

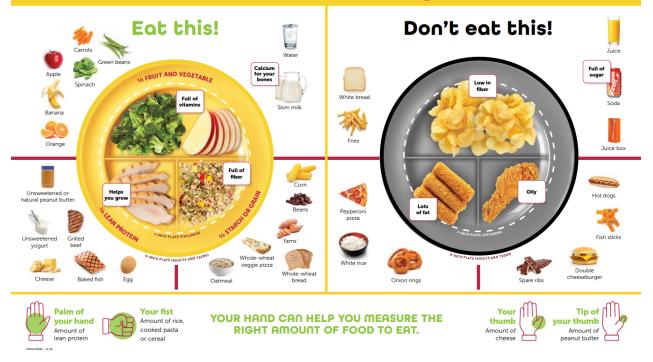
IOBTÉN MÁS CONSEJOS SALUDABLES!

# Appendix F



# Appendix G

# How to Choose Healthy Foods



#### Appendix H



#### **Avoid Sugary Drinks**

- Sugary drinks are unhealthy. Don't serve them at home or drink them on the go.
- Offer water, plain 1% or skim milk, or whole fruit instead of 100% fruit juice or a juice drink.

#### **Get Moving**

- Children and teens need at least 60 minutes of physical activity each day.
- Involve the whole family in chores to get them moving, such as vacuuming, sweeping and making beds.
- Dance, play games at the park or ride bikes together as a family.

#### **Get Enough Sleep**

- A good night's sleep helps keep everyone healthy. Children need 10 to 11 hours of sleep a night. Teens need eight to 10 hours of sleep a night.
- Keep a regular and consistent sleep schedule for your family.
- Keep electronics out of bedrooms and always avoid
- caffeinated beverages.

#### **Step Away From the Screen**

 Don't let media devices get in the way of sleep and physical activity. Set aside media-free family time (mealtimes) and locations (bedrooms).



Convierta la hora de la comida en tiempo en familia

- Compre, cocine y consuma alimentos saludables con su familia.
- Llene por lo menos la mitad del plato con frutas y verduras en cada comida y anime a sus hijos a hacer lo mismo.

#### Evite las bebidas azucaradas

- Las bebidas azucaradas no son saludables. No las sirva en su casa ni las beba por fuera.
- Sirva agua, leche natural con 1 % de grasa o descremada o una fruta entera en lugar de jugo 100 % de fruta o una bebida de jugo.

#### Muévase

- Los niños y adolescentes necesitan, por lo menos, 60 minutos de actividad física por día.
- Involucre a toda la familia en los quehaceres domésticos, como pasar la aspiradora, barrer y tender las camas.
- Bailen, jueguen en el parque o anden en bicicleta juntos en familia.

#### Duerma lo suficiente

- Dormir bien en la noche lo ayudará a mantenerse saludable. Los niños necesitan de diez a once horas de sueño por noche. Los adolescentes necesitan entre ocho y diez horas de sueño por noche.
- Mantenga un horario regular y constante de sueño para su familia.
- Mantenga los aparatos electrónicos fuera de los dormitorios y evite siempre las bebidas con cafeína.

#### Aléjese de la pantalla

 No permita que los dispositivos de comunicación se interpongan en el camino del sueño y de la actividad física. Reserve tiempo (las comidas) y lugares (las habitaciones) en familia donde no se utilicen dispositivos.

# Appendix I

# Prescription for Healthy Eating and Active Living

Patient N	Name Date				
Use with the	corresponding pages of the Guide to Healthy Eating and Active Living in NYC.				
□ <u></u>	Eat fruits and vegetables every day (page 4)				
• 10	Eat smaller portions (pages 5-7)				
• 5	Drink water instead of sugary drinks (page 8)				
• *	Replace junk food with healthier snacks (page 9)				
• 🗳	Cook nutritious meals (page 13)				
□ Ŷ	Move more (page 16)				
How will	you do this?				
Date of N	Next Visit				

Health Care Provider Signature

# Receta para una alimentación saludable y una vida activa

No	Nombre del paciente				Fecha	
		s páginas correspondientes la ciudad de Nueva York.*		ía para una alin	nentación sa	ludable y una
	S. S. S.	Coma frutas y verduras	diariam	ente (pág. 4)		
	¶@I	Coma porciones más p	equeñas	(pág. 5-7)		
	b	Tome agua en vez de b	ebidas a	zucaradas (pág	ş. 8)	
	Ő	Intercambie la comida	chatarra	por bocadillos	más saluda	bles (pág. 9)
	Š	Cocine comidas nutritiv	as (pág.	13)		
	Ŕ	Muévase más (pág. 16)	)			
5?	ómo lo	grar esto?				
Fe	cha de	la siguiente visita				

Firma del proveedor de atención de salud

Appendix J



# FREE NUTRITION CLASSES!

# JOIN US FOR FOOD & EDUCATION NUTRITION CLASSES FREE TO PARENTS AND KIDS! CREATE BETTER HEALTH.

# TOPICS INCLUDE:

- NUTRIENTS
- FOOD GROUPS
- SMART DRINK CHOICES
  - · LABEL READING
- SIMPLE GROCERY SHOPPING STRATEGIES
  - · SIMPLE HEALTHY RECIPE SWAPS

Mark your Calendars:

# Appendix K

	•	Tas	Task Name	Duration	Start	End
1		$\Diamond$	NAFLD Lifestyl	4 mths	8/25/2022	12/14/2022
2			Phase 1: Educ	30 days	8/25/2022	10/5/2022
3	D	-	Phase 2: 4 Fol	3 mths	9/19/2022	12/9/2022
4	D	4	Phase 2: 3 nut	35 days	10/12/2022	11/29/2022
5	D		Phase 3: Redr	45 days	11/25/2022	1/26/2023



# Appendix L



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