The University of Southern Mississippi
The Aquila Digital Community

Doctoral Projects

Spring 5-2023

IMPLEMENTING A PRESCREENING PROCESS TO FULLY ASSESS RISK FACTORS AND OUTCOMES ASSOCIATED WITH OBESITY AND HEPATIC STEATOSIS TO PREVENT CIRRHOSIS

Shana Broussard

Jennifer Eaglebarger

Follow this and additional works at: https://aquila.usm.edu/dnp_capstone

 Part of the Nutritional and Metabolic Diseases Commons

Recommended Citation

Broussard, Shana and Eaglebarger, Jennifer, "IMPLEMENTING A PRESCREENING PROCESS TO FULLY ASSESS RISK FACTORS AND OUTCOMES ASSOCIATED WITH OBESITY AND HEPATIC STEATOSIS TO PREVENT CIRRHOSIS" (2023). *Doctoral Projects*. 217.
https://aquila.usm.edu/dnp_capstone/217

This Dissertation/Thesis is brought to you for free and open access by The Aquila Digital Community. It has been accepted for inclusion in Doctoral Projects by an authorized administrator of The Aquila Digital Community. For more information, please contact aquilastaff@usm.edu.

IMPLEMENTING A PRESCREENING PROCESS TO FULLY ASSESS RISK FACTORS AND OUTCOMES ASSOCIATED WITH OBESITY AND HEPATIC STEATOSIS TO PREVENT CIRRHOSIS

by

Shana Broussard and Jennifer Eaglebarger

A Doctoral Project
Submitted to the Graduate School,
the College of Nursing and Health Professions
and the School of Leadership and Advanced Nursing Practice
at The University of Southern Mississippi
in Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice

Approved by:

Dr. Lisa Morgan, Committee Chair
Dr. Lakenya Forthner

May 2023

COPYRIGHT BY

Shana Broussard and Jennifer Eaglebarger

2023

Published by the Graduate School

ABSTRACT

Fatty liver disease can be treated if is identified in the initial stages of the disease. Once the disease progresses to fibrosis and/or cirrhosis, there is irreversible damage. The leading cause of non-alcoholic fatty liver disease is obesity. Obesity has reached epidemic proportions, with most obese individuals not fully cognizant of the repercussions of prolonged obesity. Other risk factors for fatty liver disease are uncontrolled diabetes mellitus, hyperlipidemia, and hypertension. Certain medications can also increase the risk of fatty liver disease. Currently, there is no prescreening tool to identify patients who are at risk for fatty liver disease. The researchers developed a prescreening tool in a written format to aid in identifying individuals at risk for fatty liver disease. Once identified as being at risk, the individuals can be instructed on ways to decrease that risk.

The prescreening tool was utilized in a primary clinic setting. Patients who attended the clinic and consented to participate in the study were screened with this tool. Fifteen patients who attended the clinic agreed to participate in the study. The researchers eliminated participants who had already been diagnosed with fatty liver disease or had a history of drug or alcohol abuse. No one under 18 was permitted to participate in the study. Out of the 15 participants, 10 were at risk for developing fatty liver disease. Those 10 participants were then educated on methods to reduce the risk of developing fatty liver disease, including weight loss and the importance of taking prescription medications directed to control any disease processes. The participants were followed up over four weeks, either in person at the clinic or via telehealth visits. The results show that, out of the 10 participants, three lost four pounds, five lost two pounds, and two did not lose any

weight. Out of 10 participants, two took medication for diabetes and four took medication for hyperlipidemia. They all demonstrated compliance with taking the medication regularly and were knowledgeable about the medication. The results showed that most of the participants were able to demonstrate knowledge of methods to decrease their risk for fatty liver disease.

ACKNOWLEDGMENTS

We would like to thank Dr. Lisa Morgan and Dr. Lakenya Forthner for mentoring us during our doctoral project. Special thanks to Memorial Health Systems for allowing us to perform our doctoral project at their facility.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF ILLUSTRATIONS

LIST OF ABBREVIATIONS

A1C	Glycated hemoglobin
BMI	Body Mass Index
DNP	Doctor of Nursing Practice
GI	Gastrointestinal
HIPPA	Health Insurance Portability and Accountability Act
HMG-COA	3-Hydoxy-3-Methylglutaryl Coenzyme A
IRB	Institutional Review Board
LDL	Low-Density Lipoprotein
NAFL	Non-alcoholic Fatty Liver
NAFLD	Non-Alcoholic Fatty Liver Disease
NASH	Non-Alcoholic Steato-Hepatitis
NIH	National Institutes of Health
PDSA	Plan, Do, Study ACT
PICOT	Patient/Population, Intervention, Comparison, Outcomes
U.S.	United States
USM	The University of Southern Mississippi
WHO	World Health Organization

CHAPTER I - INTRODUCTION

The doctoral project's purpose was to identify patients at risk for developing fatty liver disease by using a prescreening tool and educating them on ways to decrease that risk. The doctoral project focused on screening patients in the primary care setting for non-alcoholic fatty liver disease. Non-alcoholic fatty liver disease (NAFLD) is caused by obesity, certain uncontrolled disease processes, and some medications. NAFLD often produces no signs or symptoms, so people are not aware that they have the disease. Untreated NAFLD over time can result in non-alcoholic steatohepatitis which can progress to cirrhosis, and eventually hepatocellular carcinoma. These reasons alone are why it is important to identify individuals at risk early on so that they can be educated on methods to decrease their risk so that the disease does not progress further. This task was accomplished by using a prescreening tool that the researchers had created. The screening tool was created by collecting demographic data. This data included gender, height, weight, medical history, social history, lab review, and screening for medications that increase the risk of fatty liver disease. Once a person had been identified as being at risk for fatty liver disease, education was provided on methods to decrease the risk. Fatty liver disease that is identified early on can be treated and eliminated.

Location and Intervention

The doctoral project was conducted in a primary care clinic that treats patients with acute and chronic issues. All patients who consented to participate in the study were screened for the risk of developing fatty liver disease. To be included in the study, participants had to be over the age of 18 and have a diagnosis of either obesity,

hyperlipidemia, and/or diabetes mellitus, and were flagged as being at risk by the screening tool.

Medication reconciliation was performed on participants to assess the current knowledge level of their medications and compliance with taking the medication. Participants in the study were educated on lifestyle modifications, weight loss, management of diabetes and/or hyperlipidemia, and medication management, if applicable. Initial weights were obtained for all participants. Participants who were diabetic had a random finger stick performed to see how controlled diabetes was.

The researchers followed up with the participants over four weeks. Visits with the participants were conducted either at the clinic or via telehealth. The participants incurred no cost during the study. The goal of the study was to decrease the participant's risk of developing fatty liver disease. The researchers measured that goal through weight loss, control of diabetes and hyperlipidemia, and knowledge and compliance with medications.

Background

Obesity has reached epidemic proportions, especially in the United States, and can lead to major health problems, such as non-alcoholic fatty liver disease (NAFLD). Antunes et al. (2020) define NAFLD as, "the presence of hepatic steatosis with no evidence of hepatocellular injury in the form of ballooning of the hepatocytes" (p. 2). NAFLD is due to an accumulation of fatty deposits within the liver and can be caused by metabolic syndrome, obesity, diabetes, and hyperlipidemia. NAFLD can also be caused by medications, such as tamoxifen, amiodarone, methotrexate, and nutritional status (Antunes et al., 2020). Early identification of individuals at risk for developing NAFLD can be beneficial to the patient's long-term health. Once the risk of the development of

NAFLD is identified early, a care plan can be developed to reduce the risk of future liver failure.

Significance

NAFLD affects 20 to 30% of North Americans but it can be treated or prevented with lifestyle changes (GI Society, 2014). NAFLD is mostly benign; however, left unaddressed, NAFLD can develop into a much more harmful disease state called non-alcoholic steatohepatitis (NASH), which involves inflammation of the liver (GI Society, 2014). Untreated NAFLD over time can result in non-alcoholic steatohepatitis which can progress to cirrhosis and eventually Hepatocellular Carcinoma. NASH is another form of NAFLD, in which inflammation and damage occur within the liver because of fat accumulation (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2021). NAFLD has little to no signs or symptoms. Most primary care clinics do not have a system in place to alert practitioners of whether patients have an elevated risk for developing NAFLD. The researchers felt that a system must be introduced to flag these individuals so that interventions can be initiated to reduce their risk of developing NAFLD before irreversible damage is done to the liver.

Problem Statement, Clinical Question, and PICOT

The purpose of the doctoral project was to implement a prescreening tool that would identify individuals at risk for liver disease so that interventions can be implemented earlier to decrease their risk of developing fatty liver disease. The researchers developed a prescreening tool that would help identify individuals that are at risk for fatty liver disease. Once the individuals were identified as being at risk, then they were educated on methods to decrease that risk.

Available Knowledge

NAFLD is the accumulation of fat in the liver. Left untreated, NAFLD can lead to hepatic steatosis, hepatic fibrosis, cirrhosis, and hepatocellular carcinoma. This change occurs gradually over several years. NAFLD can be treated with lifestyle modifications. Weight loss is key to decreasing the accumulated fat in the liver. Another way to improve NAFLD is by controlling diabetes mellitus and hyperlipidemia. Being knowledgeable about and compliant with the medications associated with diabetes mellitus and hyperlipidemia decreases an individual's risk of developing NAFLD. Better management of diabetes mellitus and hyperlipidemia can also aid in weight loss and reducing the fat accumulated in the liver. Studies have shown that individuals who have NAFLD along with type 2 diabetes mellitus were more likely to die from liver disease than those without diabetes (GI Society, 2014).

Needs Assessment

According to the National Institute of Diabetes and Digestive and Kidney Diseases (2021), experts estimate about 24% of U.S. adults have NAFLD and about 1.5% to 6.5% of U.S. adults have NASH" (p. 6). Healthcare practitioners must develop a screening process for this disease and initiate treatment early in the disease process. The researchers determined that a screening tool was needed at Memorial Health System. The study was completed at a Memorial Health Systems Clinic. The hospital admits about 100 patients per month hospitalized for liver disease. Approximately 5% of the inpatient patients have advanced liver disease that was not caused by alcohol abuse. Early identification and interventions for these hospitalized patients could have resulted in the patients not developing advanced liver disease.

Search

A literature review was conducted for a better understanding of NAFLD. The following databases were utilized in the literature search: PubMed, National Institutes of Health (NIH), and Cochrane Library. The terms used to search the databases, either alone or in combination, include fatty liver disease, non-alcoholic fatty liver disease, non-alcoholic steatohepatitis, cirrhosis, hepatocellular carcinoma, hyperlipidemia, diabetes mellitus, obesity, and metabolic syndrome. The search was limited to sources written within the last 15 years to obtain the most relevant data.

Synthesis of Evidence

According to the GI Society (2014), 20 to 30% of people living in North America are affected by NAFLD. NAFLD is defined by Antunes et al. (2020) as the "presence of macrovascular changes without inflammation (steatosis) and lobular inflammation in the absence of significant alcohol use" (p. 2). Hepatic steatosis is the accumulation of fat within the liver which is commonly associated with "metabolic syndrome, obesity, diabetes, and hyperlipidemia" (Antunes et al., 2020, p. 3). Metabolic syndrome is always associated with NAFLD and affects approximately 80% of those who have NAFLD. Other etiologies that contribute to NAFLD are high-risk medications, such as tamoxifen, amiodarone, and methotrexate. Insulin resistance is a primary component in the development of NAFLD. With increased insulin resistance, free fatty acids increase in the liver. Insulin functions as a suppressant to lipase, and if lipase is not suppressed, it is released from adipose tissue. Both insulin resistance and increased insulin levels cause triglycerides to accumulate in the liver, which leads to hepatic steatosis (Antunes et al., 2020).

There are two types of NAFLD, namely non-alcoholic fatty liver (NAFL) and non-alcoholic steatohepatitis (NASH). NASH is an accumulation of fat within the liver, accompanied by inflammation/liver damage. NAFLD is a silent disease, so patients with NAFLD usually do not have symptoms. The most common complaint is right upper quadrant pain. The disease is usually found coincidentally, via imaging. NAFLD is diagnosed based on medical history, labs, imaging, and liver biopsy. The liver biopsy can determine whether the patient's condition is NAFL or NASH (NIDDKD, 2021). According to Dharmalingam and Yamasandhi (2018), NAFLD is a slow, progressive disease; however, in 20% of patients, it progresses rapidly. Progression to fibrosis stage I is from 10 to 14 years in NAFLD and around seven years in NASH, the progression of stages is increased in the presence of arterial hypertension. Cirrhosis and liver failure occur in 11% to 20% of NASH patients within 10–15 years (Bhitkar & Thorat, 2019). During the initial stages of NAFLD, the liver suffers no consequences or damage. However, as the NAFLD progresses over the years, the liver starts to sustain damage. NAFLD is reduced, if not eliminated, by weight loss alone. When the NAFLD becomes NASH, inflammation, and irreversible liver damage follow. Approximately 20% of patients diagnosed with NAFLD develop NASH. Scar tissue starts to form in the liver (fibrosis), and left untreated, fibrosis can lead to cirrhosis and advanced scarring of the liver. Approximately 20% of patients diagnosed with NASH develop cirrhosis. Cirrhosis is a serious medical condition and symptoms can be severe and life-threatening. The only cure for cirrhosis of the liver is a liver transplant. Liver transplants can be difficult to obtain due to the lack of available organs and the screening process to qualify for a liver transplant (GI Society, 2014). The GI Society (2014) states that "11% of patients with

NASH are at risk of death from liver-related illness" (p. 1). Moreover, patients with NAFLD and co-morbidities, such as diabetes mellitus and hyperlipidemia, are at an increased risk for death associated with liver disease.

When evaluating patients for NAFLD, it is imperative to obtain a detailed history and physical that should include family history, co-morbidities (especially hyperlipidemia and diabetes), medication history (both past and present), non-prescription medications (over-the-counter and/or herbal supplements), usual diet, exercise regimen (if any), physical activity level, recent weight fluctuations, such as weight gain of approximately 40 pounds over two to three years, and labs, including a lipid panel, fasting glucose, A1C, hepatic panel, and iron. Once a patient has NAFLD, causative factors such as viral hepatitis and hemochromatosis must be ruled out. Once a family history of liver disease/cirrhosis is identified, lab tests such as antinuclear antibodies, smooth muscle antibodies, alpha 1 antitrypsin, ceruloplasmin, and thyroid-stimulating hormone should be considered. Imaging studies play a crucial role in the diagnosis of NAFLD. The least invasive study is ultrasonography, which is less expensive and 60% to 90% effective in diagnosing NAFLD. Alternative imaging methods include abdominal computed tomography and magnetic resonance imaging. The latter two are more expensive and no studies suggest that they are better than ultrasonography (Antunes et al., 2020). According to Castro (2022), the best defense against fatty liver disease is controlling the blood glucose level, losing weight, and not drinking more than four alcoholic drinks on any day for men or three for women.

Focused Topics and Evidence-Based Findings

The focus of this doctoral project was to develop a prescreening tool to identify individuals at substantial risk for developing NAFLD. Once they had been identified, education on lifestyle modifications (diet and exercise) and medication management for diagnosed co-morbidities, such as hyperlipidemia and diabetes, were initiated. Early identification of the condition and early intervention can prevent the development of NAFLD. Early identification of individuals with NAFLD can prevent the development of hepatic steatosis, cirrhosis, and hepatocellular carcinoma.

Rationale, Framework, Models, Concepts, and Theories

Lifestyle modifications such as diet and exercise and proper medication management of co-morbidities such as hyperlipidemia and diabetes can lead to lowering the body fat percentage, which, in turn, will lower the amount of fat accumulation in the liver or resolve NAFLD altogether. The researchers followed the Plan-Do-Study-Act (PDSA) model for the doctoral project. The PDSA model provides a scientific framework to guide the doctoral project. The PDSA model uses a four-set approach that provides opportunities to:

- Plan a change to improve outcomes for patients.
- Execute the plan.
- Study the plan and make changes as needed.
- Incorporate changes and establish quality improvement for patients and staff members.

The four components of the PDSA model were incorporated into the doctoral project as follows. The planning phase involved implementing the prescreening tool on

patients who meet the screening criteria. The researcher evaluated the prescreening tool and developed a treatment plan, as indicated. During the do phase, the treatment was initiated. Education was provided on lifestyle modifications, weight loss, and disease and medication management. The patients were followed up over four weeks. During the study phase, the treatment plan was evaluated to determine whether the interventions were successful. Success was determined by a weight loss of at least four pounds over four weeks, medication compliance, and knowledge and control of disease processes such as diabetes mellitus and hyperlipidemia. During the active phase, whether the measures had been successful, the patients were educated on the continuation of the current treatment plan with strict follow-up for continued care with their primary care provider. The primary care provider can modify the plan, as necessary.

Specific Aims

This doctoral project aimed to identify individuals at risk for fatty liver disease early on, to prevent or reverse its progression. With the use of a prescreening tool designed to identify at-risk individuals in a primary care setting, providers can use that information to develop a plan to reduce the risk for that patient. The specific aims of the research include the following:

- Use the prescreening tool during routine clinic visits for individuals over 18 who are obese or have diabetes or hyperlipidemia.
- Educate at-risk individuals who are obese on lifestyle interventions that will assist with weight loss. Weight loss alone will decrease their risk.

- Educate at-risk individuals who have diabetes mellitus or hyperlipidemia on the importance of controlling these disease processes with medication compliance.

DNP Essentials

According to the American Association of Colleges of Nursing (2006), the DNP degree includes eight essential elements for nursing practice. The DNP Essentials are regarded as the underpinning of core competencies to be achieved by nurses who receive a doctoral degree. The DNP Essentials used in the doctoral project were Essential I, Essential III, and Essential VII.

Essential I: Scientific Underpinnings for Practice

The nursing discipline focuses on positive changes in health status affected by nurses' actions or processes. For Essential I in this doctoral project, the use of the prescreening tool in primary care clinics to identify individuals at risk for NAFLD will positively affect the patient's health.

Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice

The interventions were formatted following the latest evidence-based guidelines. The doctoral project was designed to promote effective and efficient patient-centered care.

Essential VII: Interprofessional Collaboration for Improving Patient and Population Health Outcomes

Essential VII involves collaborating to prevent disease in individuals to improve the health of the nation. The prescreening tool for fatty liver disease allows earlier

interventions for individuals identified as being at risk. A prescreening tool could aid in the prevention of the development of fatty liver disease.

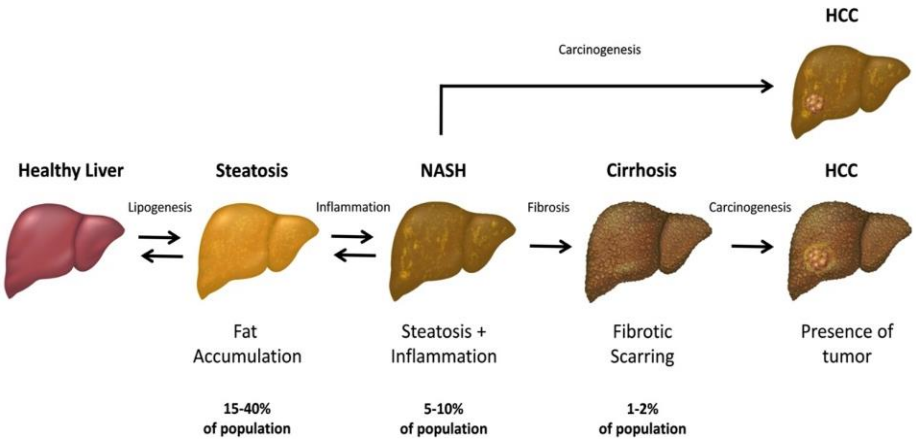
Summary

NAFLD can lead to dire consequences over years. People at risk for fatty liver disease must be identified early so that interventions can be initiated promptly which will not only prevent the individual from having irreversible damage to their liver but will also help with cost savings. Implementing a prescreening process in primary care clinics will reduce the number of individuals who will develop cirrhosis of the liver in the long term, enabling them to live a healthier lifestyle.

Table 1

Management Algorithm for NAFLD

Prediabetes or Type 2 Diabetes	**Prevention of prediabetes turning into diabetes or control of Diabetes Mellitus**
Overweight or Obese	Recommend weight loss of at least 5 % of total body weight.
Hyperlipidemia or Hypertension	Control of Hyperlipidemia and Hypertension



This Photo by Unknown Author is licensed under CC BY

Figure 1. Stages of Fatty Liver Disease

Figure 1 shows the stages of liver disease from a normal healthy liver to steatosis (NAFLD) to steatosis inflammation (NASH) to cirrhosis and finally hepatocellular carcinoma (American Liver Foundation [ALF], 2023).

CHAPTER II – METHODOLOGY

Context

The goal of this doctoral project was to show that screening patients for NAFLD in a primary care setting with early interventions for at-risk individuals will decrease their risk of developing advanced liver disease in the future. Prevention of liver disease will improve the participant's overall health. An added benefit is saving them from costly medical treatments in the future.

Intervention

Participants were recruited during routine visits to the clinic. Once the participants were identified as obese and/or had diabetes or hyperlipidemia, they were informed about the screening tool and asked if they would like to participate in the study. Once the participant consented to participate in the study, the researcher completed the screening tool. Participants that were obese/and or diagnosed with diabetes or hyperlipidemia were informed of the screening tool and asked whether they would like to participate in the study.

Once the screening tool indicated that the person was at risk for developing fatty liver disease, the researchers would educate the participant from their perspective part of the study. One researcher focused on lifestyle modifications and weight loss. The other researcher focused on the management of high-risk disease processes that increase the risk of fatty liver diseases, such as diabetes, hypertension, metabolic syndrome, and hyperlipidemia. This researcher also focused on medication compliance and adherence, by instructing the participant on their medications.

When developing a treatment plan for a participant, it is important to consider their socioeconomic status. The participant may not be able to afford the medications or healthier food options. In these cases, a complete change in diet or medication compliance may not be successful overall. The participant must be educated on subtle changes that are easier to implement and adhere to, such as decreasing carbohydrates and sugar by half instead of eliminating them from the diet.

Participants were taught to exercise at least three days a week for 150 minutes (about two and a half hours) a week. Exercises may include walking or swimming. For medication management, patients were counseled on the correct use of oral and injectable medications, the indications for the medications, and the side effects. Every effort was made to ensure that the medication is affordable and available to the participant. If the participant was diabetic, education was provided on how to manage and control diabetes. Education includes performing finger stick blood glucose levels at the correct time, as well as administering sliding scale insulin if prescribed and indicated. Uncontrolled diabetes and obesity will only worsen the progression of NAFL to NASH.

Lifestyle Modifications

Participants were provided with a diet log to record food intake. The purpose of the diet log is so that the researcher can review dietary intake and educate the participant on any appropriate required changes. An example of corrective education would be, if a participant consumes more than 325 grams of carbohydrates per day, more education is required to enforce a total dietary carbohydrate intake of between 225 to 325 grams per day. If the diet log shows that a participant is consuming more than 24 grams of sugar per day for women or 36 grams per day for men, they will be educated to decrease the total

amount of sugar in their diet. Solid fats and added sugar adds empty calories but few to no nutrients. The participant will be educated on decreasing their typical consumption of these types of foods/drinks by half. New habits are easier to adhere to since it is a more subtle change versus excluding these types of foods from their diet altogether. Participants were instructed on portion control, and they were also instructed on safe, cost-effective exercises, such as walking or swimming, to reduce their weight.

Medication and Disease Management

The participants were instructed on managing chronic diseases such as diabetes, hyperlipidemia, and hypertension. Education on medications and compliance with taking these medications, if applicable. Education was provided on the indication for the medication, the action of the medication, and the potential side effects. Non-compliance with medications will lead to uncontrolled disease states, which will exacerbate fatty liver disease progressively over time.

Evaluation of the Intervention

To study the intervention, the researchers assessed the impact of the doctoral project, based on weight loss, and demonstrated knowledge of disease processes with compliance with medications. The researchers initially obtained the starting weight of each participant and then reassessed the weight at the end of the doctoral project. Participants that had lost an average of four pounds over the four weeks, were considered successful for that portion of the doctoral project. Participants that had not lost any weight were advised to follow up with a primary care physician to discuss alternatives. The physician should obtain a baseline for disease management and medication interventions, reviewing previous labs provided some insight into how well the disease

process had been managed. Obtaining a participant's initial knowledge related to medications and disease management provided a baseline to work with. During each follow-up contact with the participant, knowledge of diabetes and medications was assessed. At the end of the study, if possible, blood sugar levels or cholesterol levels were reassessed to assess compliance with medications. An improvement in the lab results from baseline and the patient explaining their medications and compliant with taking them this doctoral project will have been a success.

Population of Interest Sample

The sample of patients were overweight and obese patients. The sample also included patients diagnosed with diabetes mellitus or hyperlipidemia. According to the World Health Organization (WHO, n.d.), overweight and obesity are defined as abnormal or excessive fat accumulation that presents a health risk. A person with a Body Mass Index (BMI) of over 25 is overweight and, with a BMI over 30, is considered obese. Participants had to be on medication for either diabetes mellitus or hyperlipidemia. The goal was to enroll between 20–30 participants in the study. Participation was determined by the prescreening tool results. The doctoral project ran over four weeks.

Setting

The setting for our doctoral project was an employee health clinic at Memorial Hospital. The Memorial Hospital clinic took care of 5,000 employees and their dependents. Patients could make an appointment or walk in for a visit. All visits were free of charge to the patient. The clinic managed acute and chronic issues.

Measures

The outcomes were measured based on weight loss over four weeks. The weight of the selected participants was obtained on day one and re-evaluated after four weeks. The final weight could be obtained at home or in the office, but the same scale had to be used for the first and last weighing. For the outcome related to medication education, initially, the researcher assessed the patient's knowledge of medications for hyperlipidemia or diabetes mellitus and noted the initial blood glucose and cholesterol levels to assess how well diabetes and hyperlipidemia had been controlled, providing a reference point to work from. Over the four weeks, the researchers visited the participants in person or via telehealth for education on lifestyle modifications, disease management, and medication management. At the end of the four weeks, the participants were questioned about their medications and their purpose of it, and repeat finger-stick glucose or lipids were evaluated to assess for improvements. The clinic visits were at no charge to the participant.

Analysis Statistics

The doctoral project was measured by both quantitative and qualitative data. The researchers examined quantitative data such as weights and lab values and studied qualitative data such as participant knowledge of medications, diet, lifestyle changes, and disease processes. The researchers used a descriptive statistical method to analyze the data. The model discussed here summarizes features from a collection of information or data sets. The independent variables would be weight loss, control of the disease process, and medication knowledge. The researchers used the PDSA model to plan a change, implement the change, observe the results, and then act on what was found.

Ethical Considerations: Institutional Review Board for Proposed Implementation

The personal information of the participants in the study was protected, following HIPPA and IRB guidelines. No identifying information about the participants was listed in the study. Physical data were locked in a drawer in the researcher's office and/or stored on a password-protected computer system. After the study, the physical data was shredded. Participant safety is a fundamental factor in the study. The risks and benefits of participating in the study were discussed with the participants. Providing education on methods to decrease the risk of the development of fatty liver disease poses no threat to the participants. Participation in the study was completely voluntary, and the participants could withdraw from the study at any time. The participants in the study received no compensation. This doctoral project has been reviewed and approved by The University of Southern Mississippi Institutional Review Board and the Memorial Hospital Review Board. The publication of data gained from this doctoral project will be limited to the requirements set by the Institutional Review Board (IRB) of The University of Southern Mississippi (Protocol # 22-1519). Thus, there is no intention to publish the research findings outside The University of Southern Mississippi's digital repository, *Aquila*.

Project Timeline

The project was projected to run over four weeks. The researchers performed weekly visits with the participants. The visits were completed via telehealth or at the clinic face-to-face.

Summary

This doctoral project used a screening tool in a primary care clinic to screen individuals at risk for NAFLD. The researchers screened patients during routine regular

visits to the clinic to identify whether they were at risk for fatty liver disease. Conditions that increase the risk are obesity, diabetes mellitus, hyperlipidemia, and hypertension. Once patients were identified as at risk for NAFLD, interventions were initiated, including lifestyle modification and management of disease processes through medication compliance. The projected time limit for the doctoral project was four weeks. The goal was to show that, by using a prescreening tool to identify patients at risk for NAFLD, early interventions can reduce the long-term risk of advanced liver disease. By a participant demonstrating weight loss of at least four pounds and medication compliance, the study had achieved its goal. By participating in the study, participants can reduce or eliminate their risk of developing NAFLD.

CHAPTER III – RESULTS

The information discussed in Chapter III analyses the results of the implemented intervention. Fifteen patients consented to participate in the study and allowed the researcher to use the prescreening tool. Out of the 15 patients, only 10 were identified as at risk for developing fatty liver disease. To participate in the study, participants had to be over the age of 18, considered to be at risk for fatty liver disease, considered to be overweight or obese, and/or have a pre-existing medical condition of diabetes mellitus or hyperlipidemia. They did not qualify to participate in the study if they had a known history of liver disease, alcohol, or drug abuse, or were under the age of 18.

Results, Measures, and Outcomes

During a routine clinic day, the patients who presented to the clinic were informed about the doctoral project and asked whether they would like to participate. Patients who wanted to participate had to sign a consent form. The screening tool was completed by the researcher during the visit. An initial height and weight were obtained on all participants. The body mass index (BMI) score was calculated. A thorough history, physical examination, and medication reconciliation were performed by the researcher. Past lab results were reviewed if the labs were available. They were reviewed by the researcher, and, if the patient was identified as diabetic, a finger stick glucose level was checked. With the results from the screening tool, the researcher identified those at risk for the development of NAFLD. An individualized treatment plan was then developed to help the patient to develop lifestyle habits to decrease their risk of developing fatty liver disease. The participants were followed up for four weeks. The study included both males and females, with an age range from 20 to 40+ years. Out of the 10 participants in the

study, all were classified as overweight or obese. The average BMI was 35 initially. Three of the participants lost four pounds, five lost two pounds, and two lost no weight over the four weeks. Two participants in the study were identified as having diabetes mellitus and were taking prescribed medication. The average random glucose at the outset was 160 mg/dl. Four participants were identified as having hyperlipidemia and were taking medication as prescribed.

Table 2

Sociodemographic Characteristics of Study Participants

Demographics	
Age	Participants
20–30	0
30–40	5
40+	5
Gender	
Male	5
Female	5

Table 3

Weight and BMI of Study Participants

Weight	BMI
Participant 1 203 pounds	36
Participant 2 194 pounds	34.4
Participant3 290 pounds	41.6
Participant 4 210 pounds	26.2
Participant 5 200 pounds	33.3
Participant 6 180 pounds	32
Participant 7 178 pounds	30
Participant 8 200 pounds	40
Participant 9 185 pounds	37
Participant 10 190 pounds	35

Steps and Details

Week 1

The prescreening tool was used during the first week, and an individualized treatment plan was developed for all those identified as high risk for developing fatty liver disease. An initial height and weight were obtained for baseline data for those identified as overweight or obese. The participant was asked to record a food and exercise diary for the week and the results would be reviewed the following week. A finger stick glucose level was determined for the participants identified as diabetic for a baseline blood sugar range. Participants identified as diabetic or with hyperlipidemia

were quizzed about their medications, if applicable, and their compliance with the medications. The participants were provided with written instructions on their prescribed medications, including indication, route, and side effects. Education was provided about the use of a medication planner to

Week 2

The participants either returned to the clinic for a visit or a telehealth visit was performed. During the visit, the food diary was reviewed with the participants. The researcher identified areas where participants required further instructions and provided instructions in those areas. Safe and inexpensive exercise routines were discussed with the participants, and they were told to continue logging their food intake in a food diary or on a free food-tracking app on their phones Logging food intake in a food diary or an app would keep the participants aware of their food choices. The participants were instructed to weigh themselves on the same scale first thing in the morning after using the restroom and to record the weight to track results. The participants taking medications were quizzed on their medications to assess their knowledge and compliance with these medications, and further instructions were provided as applicable.

Week 3

The participants either returned to the clinic for a visit or a telehealth visit was performed. The researcher again reviewed the food diary for the last week and continued education on healthier food options. The participants were asked about their exercise routine for the week and their experiences with performing them. The participants on medications were quizzed on their medication to assess their knowledge of and compliance with the medication, and further instructions were provided as applicable.

Week 4

The participants returned to the clinic for a final visit. All 10 participants were able to attend the clinic for a final in-person visit. The final weights of all participants were measured. Three of the participants lost 4 pounds, five lost 2 pounds, and two lost no weight over the four weeks. The average BMI at the start of the doctoral project was 35, and, in the end, the average BMI was 34. The participants on diabetes medication all showed an understanding of what the medication was used for and the side effects. They all demonstrated compliance with taking the medication. The final average random blood sugar level of the participants was 135 mg/dl. The participants who were on medications for dyslipidemia all demonstrated an understanding of what medication was used for any of the side effects. They all demonstrated compliance with taking the medication. The participants were encouraged to continue making healthier food choices and exercising routinely. They were also encouraged to continue managing their diabetes mellitus or hyperlipidemia and taking prescribed medications as ordered. Prescription compliance will effectively decrease their risk of developing fatty liver disease in the future. They were encouraged to follow up with their primary care provider to continue improving their health.

Table 4

Final Weight and BMI Participants

WEIGHT	BMI
Participant 1- 199 pounds	35.2
Participant 2- 194 pounds	34.4
Participant 3- 288 pounds	40.3
Participant 4- 206 pounds	25.2
Participant 5- 198 pounds	32.8
Participant 6- 176 pounds	31.5
Participant 7- 178 pounds	30
Participant 8- 198 pounds	39.5
Participant 9- 183 pounds	36.7
Participant 10- 188 pounds	34

Education Provided

Obesity Management

Weight loss provides many benefits to participants. The benefits include health and lifestyle benefits. According to Frey (2021), one does not have to lose hundreds of pounds to enjoy the physical health benefits of weight loss, as even losing a small amount of weight can improve one's overall health. Studies have shown that just a 5% to 10% decrease in your weight can benefit your health. Losing weight can lead to the following benefits:

- Decreased risk of diabetes
- Lowered blood pressure.
- Improved cholesterol levels
- Decreased risk of heart disease
- Decreased risk of certain cancers
- Decreased risk of fatty liver disease
- Improved mobility
- Decreased joint pain.
- Improved blood sugar levels
- Decreased risk of stroke
- Reduced back pain.
- Decreased risk or improvement of osteoarthritis.
- Decreased risk or improvement in symptoms of sleep apnea.

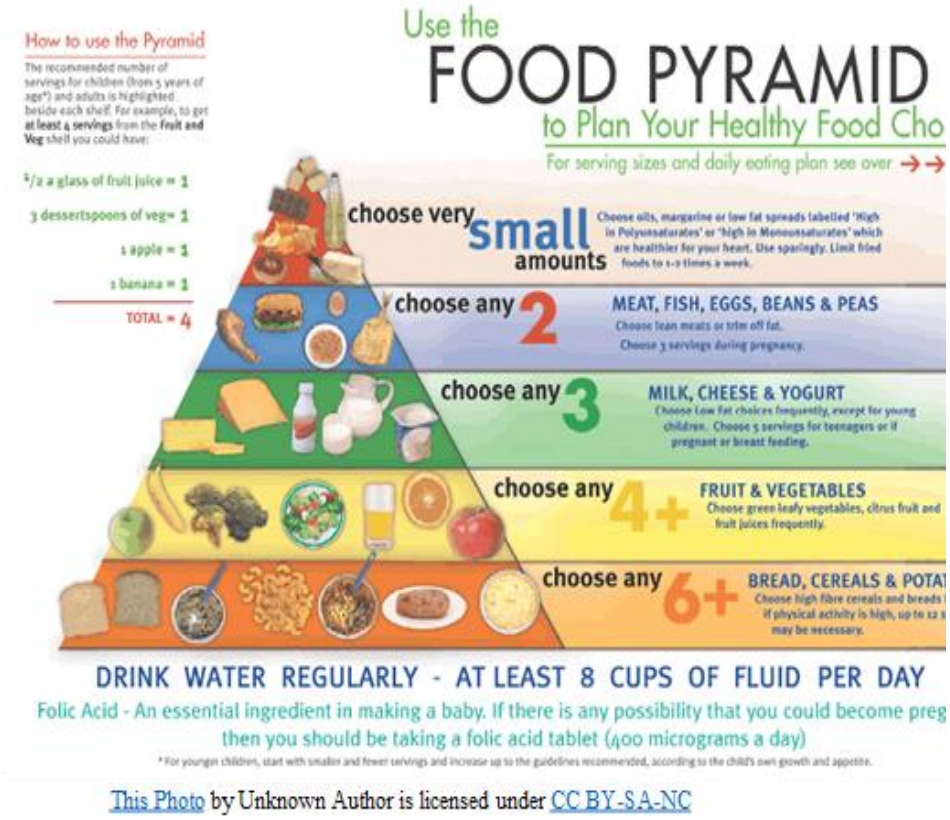
Lifestyle Benefits

In addition to the health benefits, one may also experience an improved lifestyle with weight loss. People who have successfully lost weight report the following:

- More active social life
- Greater confidence
- Better sleep
- Improved energy
- Decreased stress.
- Improved body image
- Improved mood

According to the American Heart Association (2017), there are five steps to lose and keep weight off. The participants were instructed on these steps.

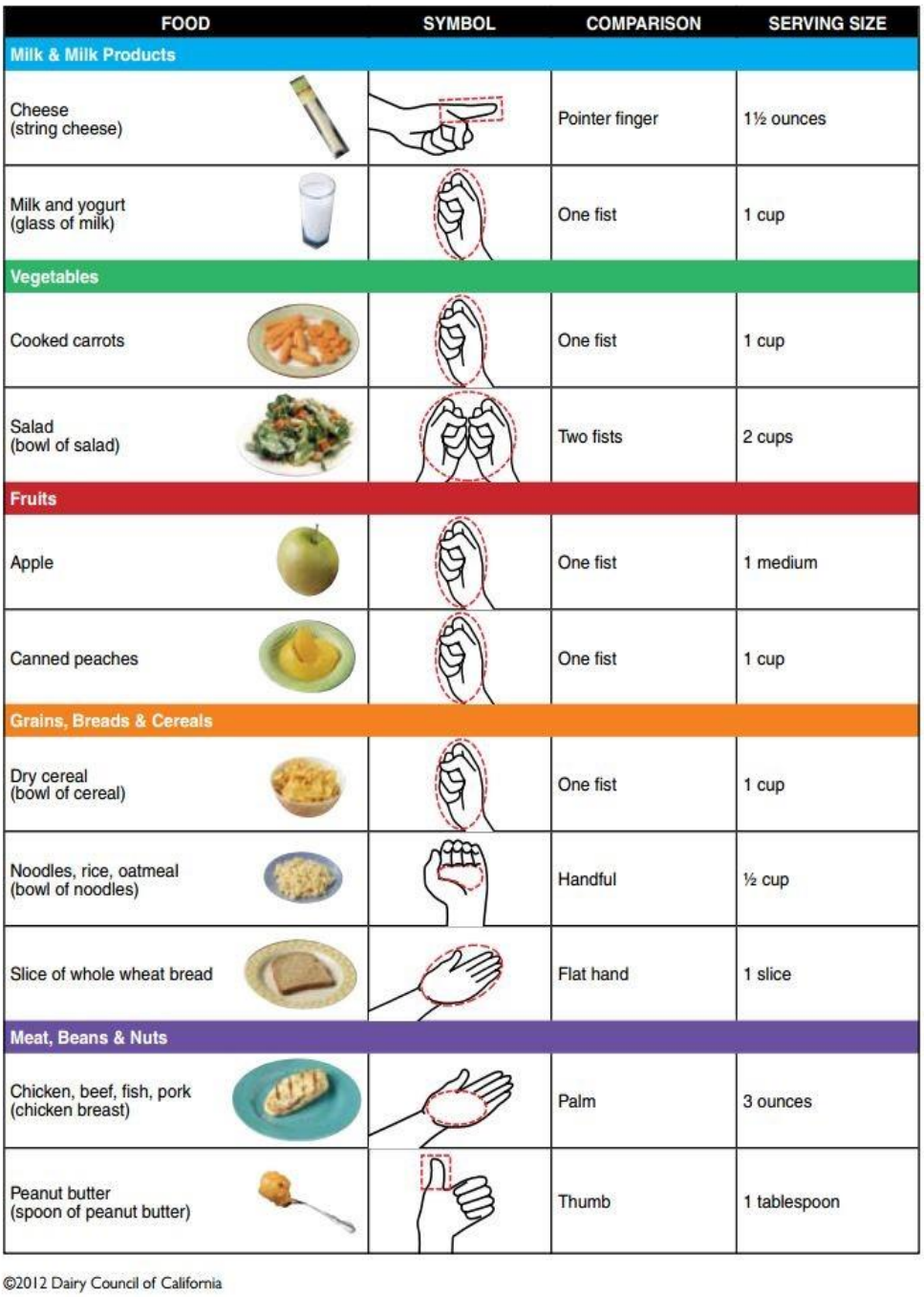
1. *Set realistic goals*. Know where you are today with your weight so that you know where you want to be. Set yourself up for success with short-term goals. Short-term goals can seem more achievable and keep you on track toward your long-term goals.
2. *Understand how much and why you eat.* Use a food diary or tracking app to understand what, how much, and when you are eating. Be mindful of your eating habits and aware of your roadblocks.
3. *Manage portion sizes*. smaller portions can help to prevent overeating. Learn the difference between a portion and a serving and how to keep portions reasonable. A portion is the amount of food you choose to eat at one time, whether in a restaurant, from a package, or in your kitchen. A portion is 100% under your control. A serving size is the amount of food listed on a product's nutrition facts label.
4. *Make smart choices.* You do not have to give up all your favorite foods. Learn to make smart food choices and simple substitutions instead. Discover healthy snacks and how fruits and vegetables and whole grains help keep you feeling full for longer.
5. *Be physically active.* Physical activity is anything that increases your heart rate, such as walking. Aim for at least 150 minutes of moderate activity per week. Move more with more intensity and sit less.



This Photo by Unknown Author is licensed under CC BY-SA-NC

Figure 2. Healthy Food Pyramid

(Harvard School of Public Health, 2008).



FOOD	SYMBOL	COMPARISON	SERVING SIZE
Milk & Milk Products			
Cheese (string cheese)		Pointer finger	1½ ounces
Milk and yogurt (glass of milk)		One fist	1 cup
Vegetables			
Cooked carrots		One fist	1 cup
Salad (bowl of salad)		Two fists	2 cups
Fruits			
Apple		One fist	1 medium
Canned peaches		One fist	1 cup
Grains, Breads & Cereals			
Dry cereal (bowl of cereal)		One fist	1 cup
Noodles, rice, oatmeal (bowl of noodles)		Handful	½ cup
Slice of whole wheat bread		Flat hand	1 slice
Meat, Beans & Nuts			
Chicken, beef, fish, pork (chicken breast)		Palm	3 ounces
Peanut butter (spoon of peanut butter)		Thumb	1 tablespoon

©2012 Dairy Council of California

Figure 3. Portion Sizes

(Harvard School of Public Health, 2023).

Medication Management

Poor medication compliance can have devastating consequences for a patient, including an increased risk of morbidity and death, and costs the healthcare system billions of dollars (Ross, 2020). Several factors can discourage patients from remaining compliant with their medication, including side effects, costs, and forgetfulness. Participants in this study were asked about current compliance with taking medications. Participants were also encouraged to use a medication planner if forgetfulness was a contributor to non-compliance. Side effects were discussed, and the participants were instructed on ways to combat the side effects. Medication costs identified as a barrier to compliance resulted in the participant being encouraged to talk to the prescribing provider about affordable medication. For this doctoral project, the researcher focused on medications for diabetes mellitus and/or dyslipidemia. The only medication that the participants in the study used for diabetes mellitus was metformin. There were a few participants with dyslipidemia and the only medication prescribed was Crestor (rosuvastatin).

According to Epocrates (n.d.), metformin is a biguanide. Metformin is indicated for the treatment of diabetes mellitus type 2. It decreases hepatic glucose and improves insulin sensitivity. Metformin is available in immediate and extended-release forms and has different strengths, ranging from 500 to 2,000 mg tablets. Common side effects of Metformin are diarrhea, nausea, vomiting, flatulence, indigestion, abdominal discomfort, anorexia, headache, rash, and a metallic taste in the mouth. The approximate retail price for metformin tablets is approximately $10 for 180 500 mg immediate release, $16 for 180 extended releases, $15 for 180 850 mg extended release, $28 for 180 750 mg

extended release, $140 for 60 1,000 mg extended release and $14 for 180 1,000 mg regular tablets and must be taken with a meal to decrease potential gastrointestinal upsets.

According to Up to Date (2023), Crestor (rosuvastatin) is prescribed for the treatment of dyslipidemia. Crestor is an inhibitor of 3-hydoxy-3-methylglutaryl coenzyme A (HMG-COA) reductase, the rate-limiting enzyme in cholesterol synthesis; this then results in a compensatory increase in the expression of LDL (low-density lipoprotein) receptors on hepatocyte membranes and stimulation of LDL catabolism. Crestor also improves endothelial function, reduces inflammation at the site of coronary plaque, and inhibits platelet aggregation with anticoagulant effects. Common side effects are headache, myalgia, abdominal pain, nausea, arthralgia, dizziness, constipation, insomnia, and gynecomastia. Generic versions of Crestor range around $10 for 30 tablets. Crestor must not be taken with red yeast rice due to the possible adverse and toxic effects.

Table 5

Outcomes

Outcome Measure	Initial Visit	Final Visit	Outcome Achieved
Screen patients for risk of developing fatty liver disease with the use of a prescreening tool	15 participants were screened for fatty liver disease. Out of the 15 participants, 10 were at risk for fatty liver disease. They agreed to participate in the study.		Yes. Participants were screened using a prescreening tool on the initial visit and those at risk for the development of fatty liver disease were identified.
Patients identified as at risk for developing the fatty liver disease will be educated on lifestyle interventions that will decrease their risk for developing the fatty liver. This will be measured by weight loss. The goal is for the patient to have a 4-pound weight loss over the four weeks.	Initial weights were measured of all participants and recorded for baseline data. Education was initiated for lifestyle modifications that would assist the participant in weight loss. Education was provided over 4 weeks.	Final weights were taken. Out of the 10 participants 3 lost 4 lbs. 5 lost 2 lbs. 2 lost 0 lbs.	No. All the participants did not meet the initial set goal of 4 lbs. weight loss over 4 weeks. A barrier to weight loss, according to some of the participants, was the timeline of 4 weeks. Another barrier to weight loss was a lack of time for exercise and resources to be able to eat healthier food options.
Patients identified as being diabetic or having hyperlipidemia will be educated on the importance of being compliant with these medications. This outcome will be measured by the patient demonstrating knowledge of the medication and a decrease in blood glucose if diabetic.	Initial finger stick glucose levels were checked on diabetic patients. There were only 2 diabetic patients, who were on oral hypoglycemics. The average random blood sugar was approximately 150 mg/dl. Patients were initially screened on their current knowledge and level of compliance with the medication. Instruction was provided over the four weeks on medications associated with diabetes mellitus or hyperlipidemia, including the importance of taking them as prescribed.	Only 2 of the 10 participants were diabetic. The average random blood sugar was 140 mg/dl. Both participants demonstrated knowledge of what the hypoglycemic medication was used for and the potential side effects. They reported compliance with taking the medication as prescribed. The patients on Crestor could recall what the Crestor was used for and its potential side effects. They verbalized compliance by taking Crestor as prescribed.	Yes. All participants demonstrated knowledge of and compliance with their medications.

Unintended Consequences

This doctoral project was partially successful in that not all participants in the study obtained the anticipated results. The participants were successful in medication compliance; however, the goal of everyone losing approximately one pound per week was not successful. The researchers believe that, if a longer period as possible and follow-up with the participants over a longer period had been possible, the long-term weight loss goal might have been met.

Summary

In conclusion, the doctoral project provided an increased understanding of the dangers of NAFLD. Participants identified as at risk for developing fatty liver disease enrolled in the study and a treatment plan was developed. The participants were instructed on lifestyle modifications, such as weight loss to decrease the risk of developing fatty liver disease. The initial goal was for participants to lose about one pound per week for an average loss of four pounds over four weeks. Out of the 10 participants, only three lost four pounds, five lost two pounds, and two lost no weight. Barriers to weight loss that were identified were limited financial resources to afford healthier food options, lack of time to perform exercise routines, and lack of motivation and willpower. The participants who were on medications for diabetes and or dyslipidemia were followed up over four weeks and instructed on the importance of being compliant with their medication. They were also instructed on the indications for the medication and potential side effects. At the end of the study, all were compliant with taking medication and were able to explain what the medication was and why they were taking it. The average fasting glucose at the end of the study was approximately 140

mg/dl. The participants agreed to continue with lifestyle modifications to lose weight and to remain compliant with the medications so that they can decrease their risk of developing fatty liver disease. The participants plan to follow up with their primary care provider.

CHAPTER IV – CONCLUSION

Chapter IV analyzes the compiled results of the doctoral project. The fundamental findings are interpreted and discussed. The measured outcomes are linked to the significance and relevance of the doctoral project. As a final point, the principal investigator offers recommendations and suggests a strategy for sustainability.

Key Findings, Relevance, and Strengths

After the interventions were implemented over the four weeks, the researchers evaluated all the data, and the outcomes were reviewed. The doctoral project was partially successful. The researchers were able to improve the participants' awareness of their risk for developing NAFLD. The participants showed an overall improvement in their knowledge of medication management and demonstrated compliance with taking the medications. Most of the participants in the study lost weight, and the average weight loss was two pounds over the four-week timeframe. Two participants did not lose any weight during the program, but they admitted that they did not follow the recommendations. They stated that, due to a lack of time and financial resources, they were unable to exercise or eat healthier options. The study's strength was that the participants were instructed on methods to help them decrease their risk of developing NAFLD. For weight loss, they were instructed on inexpensive ways to make healthier food choices and on inexpensive and safe exercises. Participants were also instructed on the importance of taking medications as prescribed to decrease the risk. The weakness of the study was the relatively brief timeframe, had the study run over a longer period, there may have been better results.

Interpretation

The results of the use of the prescreening tool to identify individuals at risk for NAFLD provided useful information. Once individuals were identified, the providers were able to instruct the patient on ways to reduce their risk. This knowledge assisted the participants in decreasing the risk of fatty liver disease and gave them the knowledge to make lifestyle changes. If the patient makes these lifestyle changes, their overall health will improve.

Limitation

The most significant limitation of the doctoral project was time constraints due to the limited time allowed. Given more time, participants could have benefited more from the education provided. The researchers might have seen a greater range of weight loss. If time had allowed, the researchers could have rechecked fasting labs to assess how controlled diabetes mellitus or hyperlipidemia are.

Sustainability

There are a few preconditions for the sustainable use of the prescreening tool for NAFLD in primary care clinics. First, the clinic directors will have to agree to the use of the prescreening tool or another tool to identify individuals at risk for NAFLD. Second, the providers will have to develop a treatment plan for those identified as at risk. Third, the information technology department for the facility will have to develop a template for the tool, so that the tool can be included in an electronic health record.

Recommendations

A future study of the long-term benefits of the early identification of and intervention for individuals at risk for NAFLD could provide insight into the need for

screening all patients in the primary care setting. The researchers believe it would be interesting to see whether the participants in this study continue with the lifestyle changes begun during this study and remain compliant with medications in the future.

Summary

Nonalcoholic liver disease can be prevented if risk factors are identified early, and interventions are taken to decrease those risk factors. The doctoral project focused on identifying individuals that were at risk for NAFLD and then instructing them on methods to decrease that risk. The researchers used a screening tool that aided in the identification of individuals at risk for fatty liver disease. The individuals were followed over four weeks and instructed on ways to decrease their risk for fatty liver disease. The goal of the doctoral project was to have at-risk individuals lose weight and be compliant with medications. The participants in the study were compliant with medications and all participants lost weight. This doctoral project showed that it is imperative to identify individuals that are at risk for fatty liver disease and educate them on interventions to decrease their risk.

APPENDIX A – Memorial Hospital Approval Letter

Memorial
Building a Healthier Community

11 OCT, 2022

Jennifer G. Eaglebarger
(228) 575-1900
Gulfport, MS 39501

RE: Screening for Non-Alcoholic Fatty Liver Disease

Dear Jennifer Eaglebarger,

The above research project was reviewed and approved on 11 Oct 2022 by the Chair of the Research Oversight Committee for one (1) year pending IRB approval.

Please note that the following guidelines must be followed:

1. Any death, or serious injury, that could lead to a death must be reported *immediately* to the Research Oversight Committee. Such reports are required routinely and are not unique to this study.
2. The Investigator agrees to protect the confidentiality of the study subjects, to the extent possible and ensure that case study documentation is kept secure at all times. The Investigator further agrees that he/she will promptly report any compromise in confidentiality to the Research Oversight Committee
3. The Research Oversight Committee shall continue to review the investigation until the investigation is complete or terminated. Each research protocol shall be reconsidered at least annually **following** receipt of a progress report from the Principal Investigator. The progress report may be brief, but it must include:
    a. Any unexpected findings or untoward reactions or complications,
    b. An indication of how many subjects have been studied,
    c. If no suitable subjects have been found after one (1) year from the date of approval, a request for continued activation of the approval,
    d. In the event the study is to continue, and the investigator wishes to continue to participate, a reconsideration of the protocol will be made annually.

If you have any questions, please feel free to contact Kecia Jackson, Research Coordinator at (228) 575-1825.

Sincerely,

Matthew L. Safley, DO Electronic Signature

Matthew Safley, DO
Research Oversight Chair

APPENDIX B - IRB Approval Letter

Office *of*
Research Integrity

THE UNIVERSITY OF SOUTHERN MISSISSIPPI

118 COLLEGE DRIVE #5116 • HATTIESBURG, MS | 601.266.6756 | WWW.USM.EDU/ORI

NOTICE OF INSTITUTIONAL REVIEW BOARD ACTION

The project below has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services regulations (45 CFR Part 46), and University Policy to ensure:

- The risks to subjects are minimized and reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered involving risks to subjects must be reported immediately. Problems should be reported to ORI via the Incident submission on InfoEd IRB.
- The period of approval is twelve months. An application for renewal must be submitted for projects exceeding twelve months.

PROTOCOL NUMBER:	22-1519
PROJECT TITLE:	Implementing a Prescreening Process to Fully Assess Risk Factors and Outcomes Associated with Obesity and Hepatic Steatosis in order to Prevent Cirrhosis by Shana Broussard and Jennifer Eaglebarger
SCHOOL/PROGRAM	Systems Leadership & Health Outcome
RESEARCHERS:	PI: Shana Broussard Investigators: Broussard, Shana~Eaglebarger, Jennifer~Morgan, Lisa~
IRB COMMITTEE ACTION:	Approved
CATEGORY:	Expedited Category
PERIOD OF APPROVAL:	30-Jan-2023 to 29-Jan-2024

Donald Sacco, Ph.D.
Institutional Review Board Chairperson

APPENDIX C – Prescreening Tool

Prescreening Tool for Fatty Liver Disease
Protocol #: 22-1519

Demographic Information

Age_____ Gender_____ Ethnicity_____

Height_____ Weight_____ BMI_____

ETOH use _____ Tobacco Use _____ Illegal Drug Use _____

Medical History

HTN____ heart disease_____ Hyperlipidemia _____ Diabetes Mellitus _____ Obesity_____ Liver Disease_____ lung disease_____ Neurological Disorders_____ Autoimmune disease_____ Mental Illness_____ Musculoskeletal Disease_____ Genitourinary Disease_____ Cancer_____ Other disease not listed_____

Lab values (historical or current)-provider fills out.

Total Cholesterol_____ LDL_____ HDL_____ Triglycerides_____ HgbA1C_____ ALT_____ AST_____

Finger Stick Glucose_____

*FIB-4 Index- calculated by using Age, AST, ALT, and Platelet Count, may use MD Calc to get a result- this test score predicts fibrosis score.

Medications that increase the risk for fatty liver disease

- Amiodarone (Cordarone) (Yes/No)
- Diltiazem (Cardizem) (Yes/No)
- Tamoxifen (Nolvadex) (Yes/No)
- Chronic Steroid Use (Yes/No

APPENDIX D – Consent Form Sample

STANDARD (SIGNED) INFORMED CONSENT PROCEDURES

By federal regulations (45 CFR 46.116), all consent documentation must address each of the required elements listed below (purpose, procedures, duration, benefits, risks, alternative procedures, confidentiality, whom to contact in case of injury, and a statement that participation is voluntary).

Signed copies of the consent form should be provided to all participants.

Last Edited 11/02/2022.

Today's date:

PROJECT INFORMATION

Project Title: Screening for Fatty Liver Disease

Protocol Number: 22-1519

Principal Investigator: Shana Broussard, MSN FNP-C & Jennifer Eaglebarger, MSN, FNP-C

Phone: [redacted] Email: Shana.Broussard@usm.edu and Jennifer.Eaglebarger@usm.edu

College: Nursing and Health Professionals

School and Program: School of Leadership & Advanced Nursing Practice - Doctor of Nursing Practice Program

RESEARCH DESCRIPTION

1. Purpose:

The purpose of this project is to identify individuals that are at risk for fatty liver disease. If they are identified at an early stage, then interventions such as lifestyle modification and disease management by compliance with medications can reverse any liver damage that they may already have and prevent the possible development of cirrhosis of the liver and hepatocellular carcinoma.

2. Description of Study:

The study involves using a prescreening tool on clinic patients to help identify at-risk individuals for fatty liver disease. If the person is identified as being at risk, then they are informed about the study and asked if they would like to participate. If they do agree to participate in the study, then proper consent will be obtained. The timeline for the project is 4 weeks. The participation goal is 20-40 participants. Weekly visits for four weeks will be scheduled. The visits can be performed in the clinic or through telehealth. Week 1 involves screening the patients in the clinic using the prescreening tool. Initial weights are obtained. The goal is for the patient to lose around 4 lbs. in the 4-week time frame. Baseline knowledge of medications and compliance with medications is obtained. Past labs are reviewed if available with particular attention to CBC, CMP, FSG, and HgbA1C levels. If a participant is identified as being diabetic, obese, or having hyperlipidemia, then initial instruction is provided. Educational handouts will be provided using Up to Date or Krames materials. Week 2-3, Educate on lifestyle changes and dietary changes to assist with weight loss and improve health. Instructions will be provided on cost-effective exercises to improve health and assist with weight loss. The education provided will be tailored toward the participant's individual needs. Diabetics will be instructed on how uncontrolled diabetes leads to fatty liver disease. Obese participants will be instructed on how obesity will lead to fatty liver disease and other health problems. Participants with Hyperlipidemia will be instructed on how uncontrolled hyperlipidemia will lead to fatty liver disease and other health problems. Medication education will be provided with emphasis that this one factor is important to manage current disease states. Noncompliance with taking medications will lead to worsening health problems. On Week 4, a final weight will be obtained. Participants will be asked to tell you about their medications and explain why it is important to be compliant with taking medications as prescribed. 3. Benefits: The benefit of participating in this study is increased knowledge in the prevention of fatty liver disease, management of diabetes, hyperlipidemia, and obesity, increase knowledge of medications, and a healthier lifestyle with weight reduction.

4. Risks:

There is no known risk in participating in this study.

5. Confidentiality:

All records for this study will be kept in a locked file drawer in the researcher's office behind a locked door. No identifying information for the participant will be on any records. Once the study is complete the records will be destroyed by the hospital's shred policy. 6. Alternative Procedures: If the participant is unable to come to the clinic for the weekly visits for four weeks, then telehealth visits will be an option for them. 7. Participant's Assurance: This project and this consent form have been reviewed by USM's Institutional Review Board, which ensures that research projects involving human subjects follow federal regulations. Any questions or concerns about rights as a research

participant should be directed to the Chair of the Institutional Review Board, The University of Southern Mississippi, 118 College Drive #5125, Hattiesburg, MS 39406-0001, 601-[redacted]. Any questions about this research project should be directed to the Principal Investigator using the contact information provided above.

CONSENT TO PARTICIPATE IN RESEARCH

Participant's Name:

I hereby consent to participate in this research project. All research procedures and their purpose were explained to me, and I had the opportunity to ask questions about both the procedures and their purpose. I received information about all expected benefits, risks, inconveniences, or discomforts, and I had the opportunity to ask questions about them. I understand my participation in the project is completely voluntary and that I may withdraw from the project at any time without penalty, prejudice, or loss of benefits. I understand the extent to which my personal information will be kept confidential. As the research proceeds, I understand that any new information that emerges and that might be relevant to my willingness to continue my participation will be provided to me.

_____ _____

Research Participant Person Date

Explaining the Study

_____ _____

Participant Signature Date

REFERENCES

American Association of Colleges of Nursing (AACN). (2006, October). *The essentials of doctoral education for advanced nursing practice.* https://www.aacnnursing.org/DNP/DNP-Essentials

American Heart Association (AHA). (2017, January 9). *5 steps to lose weight and keep it off.* https://americanheartassociation.org/5-steps-to-lose-weight-and-keep-it-off

American Liver Foundation (ALF). (2023, March 2). *Stages of fatty liver disease.* https://liverfoundation.org/about-your-liver/how-liver-diseases-progress/

Antunes, C., Azadfard, M., Hoilet, G., & Gupta, M. (2020, October 24). *Fatty liver.* Stat Pearls Publishing. https://www.ncbi.mlm.nih.gov/books/NBK441992

Bhitkar, H., & Thorat, S. (2019). Clinico-pathological profile of hepatic involvement in type 2 diabetes mellitus patients attending tertiary care hospital in Maharashtra. *Journal of Medical and Clinical Research.* https://dx.doi.org/10.18535/jmscr/v7i8.167

Castro, M. R. (2022, September 23). Diabetes: How do I help protect my liver? *Mayo Clinic.* https://www.mayoclinic.org/disease-conditions/diabetes/expert-answers/diabetes/faq-20058461

Darlingham, M., & Yamasandhi, P.G. (2018, May-June). Nonalcoholic fatty liver disease and type 2 diabetes mellitus. *Indian Journal of Endocrinology Metabolism, 22*(3), 421-428. DOI: 10.4103/ijem.IJEM_585_17.PMID.30090738.

Epocrates. (n.d.). *Metformin.* https://online.epocrates.com/drugs/787/metformin.

Frey, M. (2021, May 13). The benefits of losing weight. *Very Well Fit.* https://verywellfit.com/benefits-of-losing-weight-3495571

GI Society. (2014). The dangers of non-alcoholic fatty liver disease. *Canadian Society of Intestinal Research.* https://badgut.org/information-centre/a-z-digestive-topics/the dangers-of-non-alcoholic-fatty-liver-disease/

Harvard School of Public Health. (2008). The healthy eating pyramids. *The Nutrition Source.* https://www.hsph.harvard.edu/nutritionsource/healthy-eating-pyramid/

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). (n.d.). *Nonalcoholic fatty liver diseases (NAFLD) and nonalcoholic steatohepatitis (NASH).* National Institutes of Health. https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). (2021, April). *Definition and facts of NAFLD and NASH.* National Institutes of Health. https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash/definition-facts

Ross, S. M. (2020, January 8). What is medication compliance: 5 things providers should know. *Cureatr.* https://blog.cureatr.com/what-is-medication-compliance-5-things-providers-should-know

Up To Date. (2023). *Rosuvastatin.* http://www.uptodate.com

World Health Organization (WHO). (n.d.). *Obesity.* https:// www.who.int/health-topics/obesity#tab=tab_1