"IMPACT OF SUPERVISED AND STRUCTURED DIET AND EXERCISE IN MANAGEMENT OF PATIENTS WITH NON-ALCOHOLIC STEATOHEPATITIS – A RANDOMIZED CONTROLLED TRIAL"

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For the award of the degree of

Doctor of Philosophy

In the Faculty of Nursing

(Medical & Surgical Nursing)

By

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LIST OF ABBREVATIONS

AASLD	Association For the Study of Liver Diseases
ALB	Albumin
ALP	Alkaline Phosphatase
ALT	Alanine Aminotransferase
APASL	Asian Pacific Association for The Study of The Liver
APRI	Aspartate Aminotransferase to Platelet Ratio Index
AST	Aspartate Aminotransferase
BMI	Body Mass Index
CAP	Controlled Attenuation Parameter
CBC	Complete Blood Count
CLD	Chronic Liver Disease
CVD	Cardiovascular Disease
FLiO	Fatty Liver in Obesity
FIB-4	Fibrosis-4 Score
FS	Fibroscan
GLP-1	Glucagon-Like Peptide-1
GRADE	Grades Of Recommendation Assessment, Development and Evaluation
HB	Haemoglobin
HCC	Hepatocellular Carcinoma
HDL	High-Density Lipoprotein
HT	Height
LDL	low-density lipoprotein
LDL-C	Low-Density Lipoprotein Cholesterol

LFT	Liver Function Tests
LSM	Liver Stiffness Measurement
MAFLD	Metabolic-Associated Fatty Liver Disease
MANOVA	Multivariate Analysis Of Variance
MD	Mediterranean Diet
METS	Metabolic Syndrome
NAFLD	Non-Alcoholic Fatty Liver Disease
NASH	Non-Alcoholic Steatohepatitis
NITS	Non-Invasive Tests
PC	Platelet Count
RCT	Randomized Controlled Trial
SD	Standard Deviation
SGOT	Serum Glutamic Oxaloacetic Transaminase
SGPT	Serum Glutamic Pyruvic Transaminase
TASL	Turkish Association for The Study of The Liver
TE	Transient Elastography
TG	Triglycerides
WC	Waist Circumference
WT	Weight

ABSTRACT

Background: Non-alcoholic fatty liver disease (NAFLD) is a very prevalent chronic liver disease characterized by fat accumulation in liver cells. NAFLD is association with metabolic syndrome, obesity, and type 2 diabetes. As these conditions are escalating in epidemic proportions, NAFLD is fast becoming the most common cause of liver disease worldwide. NAFLD encompasses a spectrum of liver disorders, ranging from mild steatosis to the more severe non-alcoholic steatohepatitis (NASH), characterized by inflammation and liver cell damage. Progressive NASH carries substantial risks, including the development of cirrhosis, liver failure, and hepatocellular carcinoma (HCC). Currently, as there are limited therapeutic options available for NASH, there is a pressing need for effective management strategies. To address this, we conducted a randomized controlled trial to evaluate the efficacy of supervised and structured diet and exercise intervention in the management of NASH.

Methodology: This section outlines the research methodology investigating the impact of supervised dietary and exercise interventions on NASH management. A randomized controlled trial (RCT) design was employed, with participants randomized into control and intervention groups. The control group received standard care, which included general dietary and exercise recommendations. The intervention group underwent a supervised calorie restricted mediterranean diet and aerobic exercise regimen, chosen for their documented benefits in liver health. Regular assessments of liver function tests, BMI, Fibroscan, and Controlled Attenuation Parameters were conducted to monitor NASH progression and adherence to recommendations.

Results: The study's outcome revealed significant improvements in liver function tests within the study group, notably showing improvements in SGPT and SGOT levels compared to the control group. Moreover, participants in the study group displayed lower triglyceride (TG) levels, along with favorable readings in Fibroscan and controlled attenuation parameter, indicating improved metabolic control. Importantly, the study group demonstrated greater adherence to prescribed dietary and exercise guidelines, highlighting the pivotal role of supervised interventions in facilitating lifestyle modifications among individuals with non-alcoholic steatohepatitis (NASH). These findings suggest that supervised and structured interventions involving diet and exercise may hold promise in NASH management. However, further exploration through larger-scale, long-term studies is necessary to validate these findings conclusively.

Conclusion: The study demonstrates the efficacy of lifestyle modifications, particularly supervised dietary and exercise interventions, in improving liver function tests, BMI, and metabolic markers in NASH patients. Incorporating these interventions as a standard care may alleviate the burden of this chronic liver condition. However, further research is warranted to investigate long-term effects, optimal regimens, and adjunctive therapies for NASH management.

Keywords: NAFLD, NASH, Lifestyle Modification, Diet, Exercise, Fibroscan

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CHAPTER - 1

INTRODUCTION

1.1 Background of the study

Non-alcoholic steatohepatitis (NASH), a progressive condition within the spectrum of fatty liver diseases, is emerging as a significant global health concern. Structured lifestyle interventions, particularly those that include supervised dietary and exercise regimens, have demonstrated potential in managing NASH. This randomized controlled trial seeks to assess the effectiveness of a comprehensive lifestyle modification program in the treatment of NASH patients.

This study will explore the impact of supervised dietary plans and structured exercise programs on reducing liver inflammation and enhancing overall liver health. The importance of this research stems from the urgent need for evidence-based strategies to manage NASH, particularly in light of the lack of specific pharmacological treatments. By rigorously assessing the effects of these interventions, the study aims to generate valuable insights that could inform future treatment approaches for NASH.

The multifaceted approach, encompassing dietary interventions and physical activity under supervision, seeks to not only alleviate liver pathology but also enhance overall metabolic health. The randomized controlled design ensures robust and unbiased assessments of the intervention's impact, providing a foundation for evidence-based recommendations in clinical practice. As the global burden of NASH continues to escalate, exploring effective and accessible interventions becomes paramount. This trial aspires to bridge existing gaps in NASH management, offering a

comprehensive understanding of the potential benefits of supervised and structured lifestyle modifications. The results from this research could shape clinical guidelines, guide healthcare practitioners, and ultimately improve the quality of life for individuals affected by NASH[1, 2].

Introduction to Non-alcoholic fatty liver disease (NAFLD)

NAFLD is a prevalent condition marked by the buildup of fat in liver cells, known as macroscopic steatosis, without other underlying liver diseases. It ranges from simple steatosis (NAFL) to more severe forms like NASH and is the leading cause of chronic liver disease worldwide [3]. Meta-analyses estimate a global prevalence of around 25%, closely linked to metabolic syndrome. Regional variations show the highest prevalence in the Middle East (32%), followed by South America (30%) and Asia (27%). Understanding the following connections is crucial for addressing the global health impact of NAFLD.

The prevalence of NAFLD in India is estimated at 38.6% among adults, with higher rates in urban areas due to lifestyle and dietary factors. Studies report a prevalence of 49.8% in coastal South India and 53.7% in urban North India compared to 30.2% in rural areas. In rural East India, prevalence is much lower at 8.7%, particularly in non-obese populations. The incidence of NASH in the general population of North Karnataka is 31.23%. NASH, a progressive form of NAFLD is characterized by liver inflammation and damage and has become a significant global health concern. The progression of NAFLD varies among individuals, with about 20-30% of patients potentially advancing to NASH.[4,5] Several factors influence this progression, including genetic predisposition, metabolic dysregulation, oxidative stress, insulin resistance, lifestyle choices, and comorbid conditions such as obesity

and diabetes. Some patients with NASH may progress to cirrhosis, significantly increasing the risk of life-threatening liver complications. Understanding the rates of progression is essential for developing targeted interventions and therapeutic strategies. These efforts are crucial for mitigating the impact of NAFLD on public health. [6]

Progression to Non-alcoholic steatohepatitis (NASH)

NASH is often asymptomatic in its early stages, making early detection and intervention difficult. Once it becomes symptomatic NASH progresses rapidly to cause the entire spectrum of liver disease from cirrhosis to liver cancer. NASH is fast becoming the most common cause of chronic liver disease surpassing other etiologies like alcoholic liver disease, and liver disease caused by hepatitis B and hepatitis C virus. Addressing its impact requires urgent public health initiatives, lifestyle modifications, and continued research to enhance global liver health.[7,8]

Impact on Chronic Liver Disease

The global rise in NAFLD is a major contributor to the growing burden of chronic liver disease (CLD), as it can progress to more severe stages, including NASH, cirrhosis, and hepatocellular carcinoma (HCC).[9,10] Recognizing the progression of NAFLD to advanced liver disease highlights the urgent need for a comprehensive approach to tackling CLD, focusing on the management of risk factors, early diagnosis, and targeted interventions to prevent liver-related complications worldwide. [11,12]

Consequences of NASH

NASH has severe consequences for liver health and overall well-being. As a progressive form of NAFLD, NASH involves liver inflammation and damage that can advance to fibrosis and cirrhosis. In severe cases, it may necessitate liver transplantation. The interplay of metabolic factors and liver inflammation in NASH underscores its broad impact. Effective management requires not only addressing liver damage but also treating associated conditions. Early detection, lifestyle changes, and targeted therapies are crucial for mitigating the adverse effects of NASH on both liver and systemic health. [13,14]

NASH to cirrhosis, liver failure, and cancer

NASH can lead to chronic liver inflammation. Persistent inflammation causes cirrhosis, which may impair the liver function. As cirrhosis advances, the liver's ability to function deteriorates, potentially resulting in liver failure, a life-threatening condition requiring urgent intervention, including liver transplantation. The final and most severe consequence is an increased risk of liver cancer, particularly HCC. [15]

1.2 Need for the study

The lack of proven pharmacological treatments for NASH highlights the need for alternative interventions. While diet and exercise are the primary management strategies, there is limited scientific evidence of their effectiveness. This study focuses on the impact of a supervised and structured diet and exercise program for NASH, with the potential to influence regional healthcare practices and contribute to evidence-based guidelines for more effective, localized treatment options.

The absence of a specific medication for NASH emphasizes the need for continued research and drug development. As NASH remains a significant global health issue, finding effective treatments is essential to slow disease progression, prevent complications like cirrhosis and liver cancer, and improve patient outcomes. Ongoing research is focused on understanding NASH's underlying mechanisms and developing targeted therapies.

Exercise and diet are fundamental to overall health and well-being, playing a crucial role in weight management, mental health, immune function, and longevity. A balanced diet, combined with regular physical activity, supports optimal metabolic function, boosts energy, and reduces the risk of chronic diseases. While the benefits of these lifestyle choices are widely acknowledged, the scientific evidence supporting their effectiveness remains limited and inconclusive. Despite numerous studies highlighting the positive impact of diet and exercise on health, variations in individual responses, research methods, and potential confounding factors contribute to ongoing debates. Therefore, more rigorous research is needed to better understand the complex relationship between diet, exercise, and long-term health outcomes. This study aims to provide clearer insights and refine current recommendations for diet and exercise to improve health management**.**

The current study delves into the impact of supervised and structured diet and exercise on managing patients with NASH through a randomized controlled trial. This research is propelled by the imperative to address the rising prevalence of NASH, aiming to evaluate the efficacy of a carefully monitored regimen involving diet and exercise. The rationale lies in understanding how a systematic approach, guided by supervision, can influence the progression and management of NASH. This randomized controlled trial seeks to contribute valuable insights towards developing

evidence-based strategies for enhancing the therapeutic outcomes in individuals grappling with this challenging liver condition.

Structured and Supervised Diet and Exercise Regimen

A structured and supervised diet and exercise regimen is a key component in managing NASH. This comprehensive approach includes a personalized nutritional plan tailored to address the specific needs of individuals with NASH, alongside a supervised exercise program. The structured nature of this regimen ensures consistency and adherence, while supervision allows for adjustments based on individual progress and challenges. This holistic strategy has been shown to support weight management, improve liver function, and enhance overall health. For individuals with NASH, a well-designed diet and exercise plan not only helps reduce liver fat but also promotes liver health and long-term well-being, ultimately contributing to better disease management and improved outcomes.

Target Population: NASH Patients in North Karnataka

The target population for this study comprises individuals diagnosed with NASH in the North Karnataka region. As a progressive form of NAFLD, NASH presents a significant health challenge, making it essential to understand its prevalence, risk factors, and clinical outcomes within this specific demography. By adopting a population-based approach, the study aims to explore the unique characteristics and challenges faced by NASH patients in North Karnataka. Factors such as lifestyle, dietary habits, and genetic predispositions may influence variations in disease presentation and progression. By concentrating on NASH patients in this region, the study seeks to provide region-specific insights that will contribute to a

more tailored and effective strategy for managing and preventing NASH complications in this population.

1.3 Title of the study

Impact of supervised and structured diet and exercise in management of patients with non-alcoholic steatohepatitis – a randomized controlled trial

1.4 Objectives

- To assess routine health practices among NASH subjects.
- To evaluate the efficacy of a supervised and structured diet and exercise regimen in subjects with NASH attending a tertiary care teaching hospital, in North Karnataka.

1.5 Research Hypotheses

All the hypothesis will be tested at 0.05 level of significance.

H_1: The mean post-test health practice scores of NASH subjects after intervention will significantly differ than mean pre-test health practice scores.

H_2: The post-test of liver stiffness measurement after intervention will significantly reduce than pre-test of liver stiffness measurement.

1.6 Assumptions

The study assumes that:

- Supervised and structured diet and exercise regimen help in reducing liver stiffness in subjects with NASH.

1.7 Delimitations

The study is delimited to:

- Participants with confirmed diagnosis of NASH
- Age of 18-55 years
- Fibroscan score (LSM) of 7-13.9 kilopascals (kPa)

1.8 Operational Definitions:

Impact: It defines, a significant effect of supervised and structured Diet and Exercise by statistical analysis.

Supervised and Structured Diet and Exercise:

Supervised and structured diet and exercise involves a carefully planned and closely monitored program aimed at improving individual needs and metabolic health as well as reducing liver stiffness. Researchers consistently monitor NASH subjects throughout the study period to ensure they accurately follow the recommended diet and exercise plans with the help of mobile app and fit band. which was given to the subjects at first visit readings were monitored through mobile. This supervision helps improve compliance and consistency in implementing the interventions. The structured approach tailors the dietary and exercise plans to meet.

Diet regimen: refers in this study a calorie-restricted modified Mediterranean diet plan which was tailored with the help of dietician, it includes reducing 30% calorie intake below maintenance levels (24 hours calorie requirement) to promote 7 to 10% weight loss and monitored for 6 months.

Exercise regimen: The exercise plan includes (30-45 min/day, 5 days in a week) consists of aerobic exercises pack such as (running, cycling, walking, jogging, and

swimming) among them one exercise has to be selected by choice. And has been monitored on mobile app and fit band for 6 months.

Patient with NASH (Non-Alcoholic Steatohepatitis):

A patient with NASH is an individual diagnosed with a progressive form of NAFLD characterized by liver inflammation, hepatocyte injury, and varying degrees of fibrosis. NASH is typically diagnosed through, imaging (USG and Fibroscan), or blood tests indicating elevated liver enzymes, specifically alanine transaminase (ALT) and aspartate transaminase (AST).

Selection Criteria (Measurable Terms):

- **Age:** Adults aged 18 to 55 years.
- **Liver Enzymes:** Elevated ALT and/or AST levels (e.g., ALT > 30 U/L in males and > 19 U/L in females)
- **Imaging:** Evidence of hepatic steatosis on imaging techniques such as ultrasound and transient elastography.
- **Exclusion:**
    - Alcohol consumption, genetic/metabolic liver diseases.
    - Blood pressure ≥ 130/85 mmHg or use of antihypertensive medication.
- **Clinical Characteristics (Measurable Terms):**
- **Liver Stiffness Measurement:**
    - Using transient elastography (FibroScan) ≥ 7-13.9 kPa for significant fibrosis.
    - **Dyslipidemia:** Triglycerides ≥ 150 mg/dL

- **1.9 Conceptual Framework:**

- A framework provides a concise explanation of a theory or its components that are to be tested in a randomized controlled trial. A conceptual framework is particularly useful in research for organizing the study and contextualizing the interpretation of results. This study utilizes Imogene King's Goal Attainment Theory, which is well-suited for evaluating the impact of supervised and structured diet and exercise on lifestyle modification in participants with NASH.
- King's theory emphasizes the nurse's role in interacting with individuals and groups, stressing the importance of client involvement in decision-making and focusing on both the process of nurse-client interactions and the outcomes of care. [16]
- King's goal attainment theory consists of the following components:
- Role
- Perception
- Judgement
- Action
- Reaction
- Interaction
- Transaction
- **ROLE:**

The role of a person refers to the position that he occupies in the social system which has specific rules and obligations. In this study, the role of the researcher is to perform intervention regarding the impact of supervised and structured diet and

exercise in the management of successful lifestyle modification in subjects with non-alcoholic steatohepatitis.

PERCEPTION:

Perception involves the process by which individuals take in, transform, and store energy from their environment. In this study, the researcher perceives that individuals with NASH may need motivation to adhere to a supervised and structured diet and exercise regimen for effective lifestyle modification over a six-month period.

JUDGEMENT:

Judgement pertains to the goal of nursing, which is to guide individuals in maintaining their health to fulfil their roles effectively. In this study, the researcher's role includes gathering pertinent data. The Judgement involves assessing the willingness of NASH subjects to participate in the intervention focusing on diet and exercise management after interacting with the researcher.

INTERACTION:

Interaction encompasses the verbal and non-verbal exchanges between individuals, involving goal-directed perception and communication. In this study, the researcher engages in continuous interaction to communicate, perceive, assess, and explain the intervention related to diet and exercise management for NASH subjects.

ACTION:

Action is defined as the innate capacity or ability to accomplish a set goal. In this study, a trained researcher undertakes an intervention employing the management of subjects diagnosed with NASH. The experimental group participates in a structured

regimen consisting of a calorie-restricted Mediterranean diet alongside aerobic exercises such as brisk walking, jogging, cycling, and swimming. These activities are scheduled five days a week at a moderate intensity, with each session lasting between 30 to 40 minutes, totaling 150 to 200 minutes per week. In contrast, the control group continues to receive routine standard care throughout the study period.

TRANSACTION:

Transaction involves the interaction between a person and their environment aimed at achieving a specific goal. In this study, transaction refers to evaluating the effectiveness of a supervised and structured diet and exercise regimen among participants with NASH. The researcher communicates with NASH participants about the dietary and exercise management plan, setting mutual goals to achieve or maintain effective lifestyle modifications for managing NASH.

The study and control groups are assessed using blood parameters, LSM, and CAP scores. Following the transaction, the researcher evaluates whether the goals have been met. If improvements are not observed, feedback is provided to refine and enhance the intervention.

The goal of nursing in this context is to support individuals in maintaining their health to fulfill their roles effectively. According to Goal Attainment Theory, this involves communication between the nurse and the client, mutual goal setting, and taking action to achieve these goals.

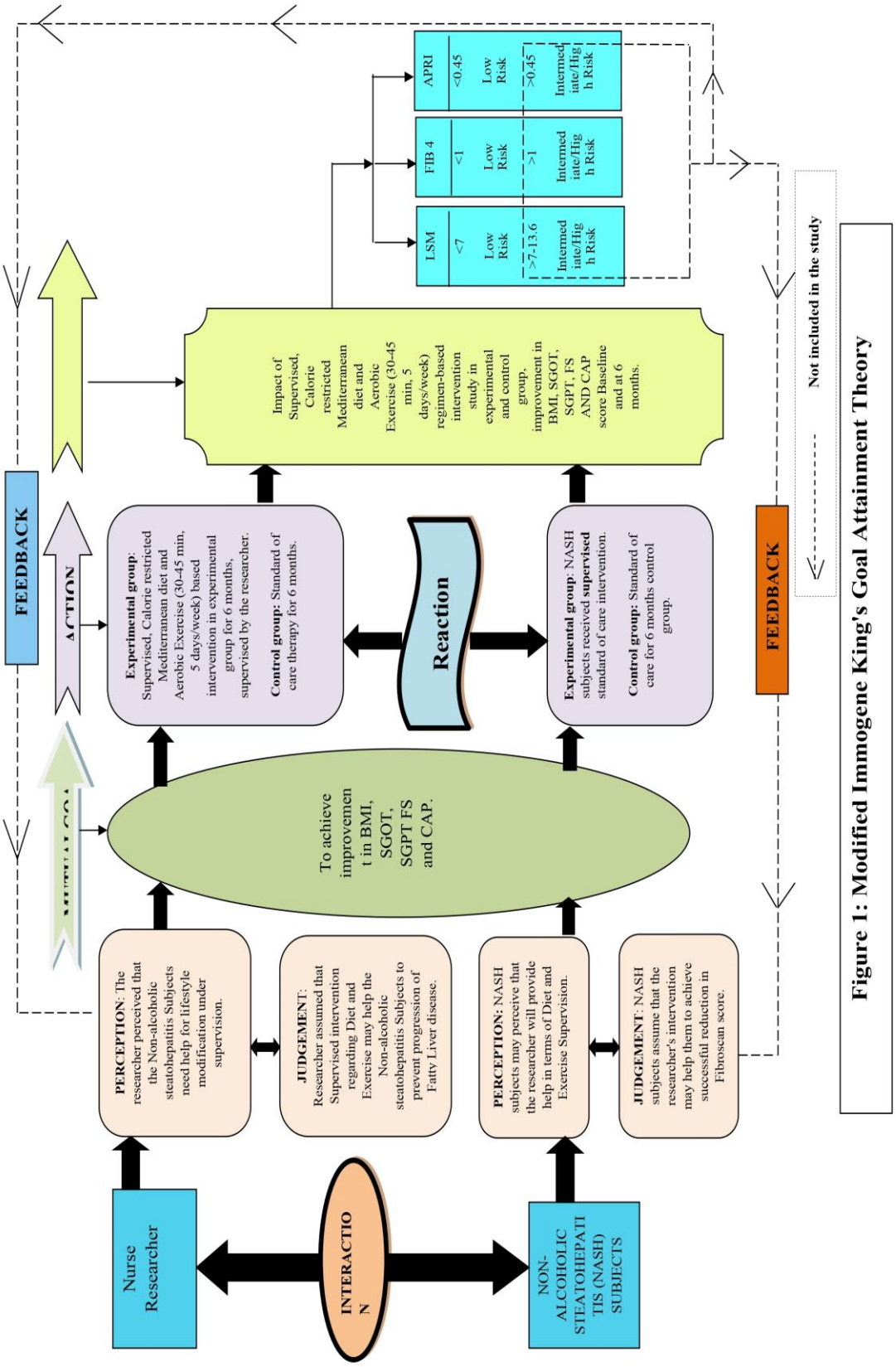


Figure 1: Modified Immogene King's Goal Attainment Theory

CHAPTER – 2

REVIEW OF LITERATURE

A literature review is an essential synthesis of existing research on a specific topic, providing valuable insights into current theoretical and scientific understanding. It entails evaluating and summarizing a range of studies, identifying established knowledge as well as gaps in the literature. Researchers conduct literature reviews to familiarize themselves with the current knowledge landscape, making this step vital in the research process. By offering an overview of previous work related to a particular phenomenon, literature reviews aim to inform readers about established concepts and findings pertinent to the research topic.

In this study, the researcher performed a thorough literature review to enhance understanding of the issue and collect relevant information. This extensive review aimed to enrich the current investigation by integrating insights gained from prior research. It highlights the evolving landscape of supervised and structured diet and exercise interventions in NASH management. While providing valuable insights into the positive impacts on liver health and associated metabolic factors, ongoing research and clinical trials aim to refine these approaches, contributing to the development of comprehensive and effective strategies for NASH management.

In a cross-sectional study to know the prevalence of non-alcoholic steatohepatitis (NASH) in the general population of North Karnataka- out of 730 subjects, 31.23% showed significant fibrosis indicative of NASH on fibroscan. Males (60.52%) and diabetics (22.80%) were notably represented among those with NASH. The study highlights a proportional increase in abnormal liver enzymes and

significant fibrosis with higher body mass index (BMI), while a small percentage with normal BMI exhibited features of lean NASH. The high NASH incidence (31.23%) is attributed to the rising diabetes mellitus and obesity epidemic in the region. [5]

In another study, the serum levels of adiponectin (ADPN), encoded by the patatin-like phospholipase domain-containing protein 3 (PNPLA3), in different stages of Non-Alcoholic Fatty Liver Disease (NAFLD) were studied for its association with disease progression. The study included 60 NAFLD cases, with 10 subjects in stage 1 (simple steatosis) and 50 subjects in stage 2 NASH. Serum ADPN levels were significantly decreased in NASH compared to simple steatosis ($p<0.001$). This suggests an inverse association between ADPN serum levels and the progression of NAFLD.[17]

Another study aimed to assess the knowledge and attitude of the general public regarding NAFLD. Understanding the public's awareness and perception is crucial for developing effective preventive measures against the prevalent chronic liver condition. Among 454 participants, over 72% were female, with 55% aged between 18-30 years. Only 11% reported known NAFLD cases in their families. Participants with family members having NAFLD exhibited significantly higher knowledge levels ($P=0.012$). Minority residents generally showed limited knowledge about NAFLD, the majority displayed favorable or satisfactory attitudes. [18]

A study addressed the global public health gap in NAFLD. This study aimed to develop comprehensive consensus statements and recommendations. A multidisciplinary group of experts collaborated to create a roadmap encompassing epidemiology, care, treatment, awareness, and public health policies, fostering a unified approach to combat the significant burden of NAFLD. The study yielded

consensus statements and recommendations, establishing a foundation for a robust public health response to NAFLD. These outcomes, spanning various domains from epidemiology to policy-making, aim to bridge the existing gaps in awareness, healthcare responses, and public health initiatives, offering guidance to policymakers, healthcare practitioners, research institutions, civil society groups, and affected populations worldwide. [19]

Another study was conducted to comprehensively understand and address the challenges posed by NAFLD, the most prevalent liver condition globally. This includes exploring the spectrum of NAFLD severity, its associations with obesity, insulin resistance, and genetic factors, and critically examining the pathophysiology. The research underscores the global burden of NAFLD, affecting 25% of the population. It illuminates the complexity of NAFLD progression, emphasizing its association with metabolic factors and the challenges in accurate diagnosis, primarily relying on invasive liver biopsy. The study advocates for ongoing efforts to refine non-invasive diagnostic approaches through a combination of blood tests and imaging. [20]

The American Heart Association's recommendations highlight the significant benefits of consistent aerobic exercise for cardiovascular health. Engaging in regular aerobic activities such as running, cycling, walking, jogging, and swimming for about 30–45 minutes per day, five days per week, offers numerous health advantages, including improved heart and lung function, reduced risk of heart disease and stroke, effective weight management through caloric expenditure, and enhanced mental health by boosting mood, cognitive function, and sleep quality. Practical implementation can be achieved through various accessible activities like brisk walking, which provides a simple and effective moderate-intensity workout; outdoor

or stationary cycling, which offers excellent cardiovascular benefits; swimming, which delivers a comprehensive full-body workout with minimal joint stress; and running or jogging, ideal for vigorous-intensity workouts. Adherence to these activities is more likely when individuals choose exercises, they enjoy and can sustain over time. Public health organizations can effectively promote regular aerobic exercise as a vital component of a healthy lifestyle [21].

A study addressing the increasing prevalence of NAFLD and its association with obesity, insulin resistance, and cardiovascular complications, the Turkish Association for the Study of the Liver (TASL) aimed to develop comprehensive guidance. The objective was to create a standardized approach for the diagnosis and treatment of NAFLD, fostering a multidisciplinary understanding of the disease among healthcare professionals. The TASL Guidance, a product of interdisciplinary collaboration, offers a practical application guide for diagnosing and treating NAFLD. It aims to consolidate advancements in the field and provide evidence-based recommendations. [22]

A study aimed to assess the diagnostic accuracy of non-invasive markers for liver fibrosis in patients with NAFLD and determine their suitability for various care settings. Additionally, it investigated the sequential use of these markers to enhance diagnostic precision, reduce healthcare costs, and identify candidates for pharmacological trials. The objective is to establish the association of non-invasive markers with liver-related events and mortality, exploring their potential role in cardiovascular disease (CVD) risk assessment in patients with decompensated liver disease. Non-invasive markers, including blood-based and imaging-based modalities, exhibit high diagnostic accuracy for liver fibrosis. Sequential use enhances diagnostic

precision and cost-effectiveness. These markers show associations with liver-related events and mortality, indicating their utility as prognostic tools. [23]

A study was conducted to assess and present non-invasive investigation methods for the evaluation of hepatic fibrosis, considering the limitations of invasive procedures like liver biopsy. The study aims to explore advancements in serologic tests and imaging techniques as alternative diagnostic tools. This narrative review outlines non-invasive methods for evaluating liver fibrosis, acknowledging the challenges posed by invasive approaches. The study underscores the evolving landscape driven by new molecular perspectives on fibrogenesis, fibrosis regression, and the development of therapeutic antifibrotic agents, emphasizing the need for effective, non-invasive tools in detecting and grading liver fibrosis. [24]

A study aimed to assess the prevalence, spectrum, and metabolic determinants of NAFLD in adults of Central India using Fibroscan. The research aimed to fill the gap in comprehensive population-based studies on NAFLD in the Indian context, considering all stages of steatosis and hepatic damage. Out of the 236 adults analysed, 43.6% exhibited NAFLD as detected by Fibroscan. Steatosis was observed in 12.7% (S1), 12.3% (S2), and 18.6% (S3) of subjects. Factors significantly associated with NAFLD included high body weight, waist circumference, waist-to-hip ratio, fasting sugar, serum glutamate pyruvate transaminase (SGPT), TG levels, and very low-density lipoprotein (VLDL) levels. The study highlights the substantial prevalence of NAFLD in this Central Indian population and identifies key metabolic determinants associated with the condition. [25]

Another study determined the prevalence of NAFLD among morbidly obese Indian women and identified clinically measurable obesity indicators that best predict NAFLD. In this cross-sectional study involving 106 morbidly obese women, 73.6% were diagnosed with NAFLD. Anthropometric variables, including waist circumference, BMI, and waist-height ratio, were significantly different between those with and without NAFLD. Among these indicators, waist–height ratio emerged as the most effective screening tool for diagnosing NAFLD. These findings emphasize the high prevalence of NAFLD in morbidly obese women and suggest waist–height ratio as a valuable surrogate screening tool in resource-constrained settings. [26]

A study conducted in Japan addressed the rising prevalence of NAFLD and its progressive form, NASH, in Japan. The focus is on developing effective screening methods for hepatic fibrosis, hepatocellular carcinoma (HCC), and cardiovascular disease (CVD) in NAFLD patients. Additionally, the guidelines aim to outline practical recommendations for the evolving landscape of NAFLD/NASH therapy, emphasizing ongoing drug trials, including sodium-glucose co-transporter 2 (SGLT2) inhibitors and glucagon-like peptide-1 (GLP-1) analogues. The guidelines propose comprehensive screening and follow-up methods for hepatic fibrosis, HCC, and CVD in NAFLD patients. While several drug trials are underway, including SGLT2 inhibitors and GLP-1 analogues, no specific drug therapy currently exists for NAFLD/NASH. The recommendations are based on a thorough evaluation of clinical evidence collected internationally until October 2018, employing the Grades of Recommendation Assessment, Development and Evaluation (GRADE) system. The guidelines aim to provide essential insights into the definition, screening systems, and current therapies for NAFLD/NASH in the Japanese context. [27]

A study addressing the complexities of NAFLD, aim to evaluate the current treatment landscape, focusing on lifestyle interventions, existing medications like Pioglitazone and Vitamin E, and the ongoing investigations into anti-inflammatory, anti-fibrotic agents, and metabolism modulators. The primary objective is to understand the effectiveness of these interventions in reducing the progression of fibrosis and NASH activity. Additionally, the study aims to highlight the need for non-invasive surrogate biomarkers and imaging tools to facilitate clinical studies and minimize reliance on liver biopsy. While lifestyle interventions remain the cornerstone, Pioglitazone, particularly in diabetic individuals, shows promise in slowing fibrosis progression. Vitamin E, mainly used in children, may have considerations in non-diabetic adults. Several drugs in clinical trials target reduced NASH activity and improved fibrosis .[28]

Another study investigated the effects of short-term therapy with orlistat on components of metabolic syndrome associated with NAFLD and explored its impact on liver fibrosis scores in patients with NAFLD. In a 12-week open-label placebo-controlled clinical study on 50 NAFLD patients, orlistat (120 mg/day) significantly improved anthropometric and metabolic indices, including TG levels and triglyceride-glucose index. Liver enzymes showed improvement, indicating a positive impact on liver health. Notably, orlistat exhibited a favorable effect on the NAFLD fibrosis score (NFS) and Fibrosis-4 score (Fib-4), suggesting potential benefits in ameliorating liver fibrosis. This underscores Orlistat's role in enhancing metabolic parameters and mitigating liver-related complications in NAFLD patients .[29]

Chun et al. conducted a multicentre retrospective study involving 23,889 individuals with NAFLD to explore the link between sarcopenia and severe outcomes in these patients. The study used a gender-specific sarcopenia index and identified

high-risk sarcopenic obesity (SO) based on criteria like the fibrosis-4 index and cardiovascular risk score. The prevalence of SO was 5.4%, with older age, male gender, sarcopenia index, and metabolic syndrome emerging as significant risk factors for high-risk SO. The study found that high-risk SO was associated with a greater likelihood of significant liver fibrosis and cardiovascular disease, emphasizing the need to identify and monitor high-risk SO in NAFLD patients .[30]

Another study. investigated the global prevalence and progression of NAFLD, a chronic liver condition closely linked to metabolic disorders. Between 2016 and 2019, the prevalence of NAFLD was reported to be 38% among adults and approximately 10% among children and adolescents. NAFLD is a progressive disease that significantly increases the risk of mortality from cardiovascular disease, extrahepatic cancers, and liver-related complications. Despite these serious health risks, there are currently no approved pharmacological treatments for NASH, the more severe form of NAFLD. Consequently, the primary treatment strategy focuses on lifestyle modifications, including a diet rich in fruits, nuts, seeds, whole grains, fish, and chicken, while avoiding ultra-processed foods, red meat, sugar-sweetened beverages, and foods cooked at high heat. Regular physical activity, particularly at an intensity where one can talk but not sing, is also recommended, encompassing both leisure-time activities and structured exercise. This approach is emphasized for both children and adults in managing NAFLD.[31]

Sahu et al. conducted a comprehensive review focusing on NAFLD and emerging therapeutic strategies. NAFLD is a prevalent hepatic disorder with a wide spectrum of clinical presentations, ranging from simple steatosis to more severe conditions like fibrosis and cirrhosis, which elevate the risk of hepatic decompensation and liver-related mortality. Additionally, patients with NAFLD are at

an increased risk of cardiovascular events. Despite the severity of these outcomes, current pharmaceutical options for managing NAFLD are limited. The primary recommendations for treatment continue to emphasize lifestyle modifications, such as regular exercise, weight loss, and a balanced diet. Pharmacological treatments that are currently employed include pioglitazone and vitamin E. However, with the rising popularity of bariatric surgery as a treatment option, there is a pressing need for further research to clarify the connections between insulin resistance, hepatic steatosis, and the progression of fibrosis in NAFLD.[32]

Anton M.C. et al. conducted an analytical cross-sectional study in the General Medicine outpatient departments of a tertiary care centre in Chennai, focusing on the prevalence and risk factors of NAFLD among non-alcoholic adults aged 21 to 40 years. The study included 510 participants, both male and female, who underwent ultrasonography to assess the presence of fatty liver. The study found that 61.5% of participants screened positive for NAFLD. Notably, individuals with a higher body mass index (BMI) were at a significantly increased risk-23.09 time higher-of developing NAFLD. Age was also identified as a predictor, with the risk of NAFLD increasing with age. Additionally, the study highlighted a gender disparity, with males being 1.59 times more likely to develop NAFLD than females. The high prevalence of NAFLD observed in this study underscores its status as a common non-communicable disease in India. The findings emphasize the importance of regular screening and early diagnosis to manage and prevent fatty liver disease, alongside the adoption of healthy dietary habits and regular exercise. [33]

Bo Zhang et al. conducted a study aimed at summarizing recent advancements in the treatment of metabolic-associated fatty liver disease (MAFLD), focusing on three main approaches: drug therapy, surgical interventions, and non-drug/non-

surgical treatments. The study sought to highlight key areas for future research and to identify various therapeutic targets for managing MAFLD. Given the complex pathogenesis of MAFLD, the study suggests that drug therapy alone may not be sufficient for effective management. Instead, a comprehensive approach is recommended, where lifestyle modifications play a crucial role. The authors emphasize the importance of multidisciplinary care, involving clinicians, dieticians, psychologists, and exercise physiologists, to support patients in adopting healthier lifestyles. This collaborative effort, combined with appropriate clinical medications, is essential for improving patient outcomes and controlling the progression of MAFLD.[34]

Mahdi Karimi et al. conducted a parallel randomized clinical trial involving 52 overweight and obese patients with NAFLD. The participants were randomly assigned to one of two dietary interventions: a 16:8 intermittent fasting (IF) regimen, where participants fasted from 8 P.M. to 12 P.M. the following day, or a low-calorie diet (LCD) composed of 55% carbohydrates, 30% fat, and 15% protein, for a duration of 12 weeks. Given the absence of a specific pharmacological treatment for NAFLD, intermittent fasting has emerged as a potential alternative for managing obesity and its associated complications. Previous research has indicated that IF may positively impact metabolic health and reduce oxidative stress in NAFLD patients. This randomized controlled trial (RCT) aims to compare the effects of IF and LCD on lipid profiles, glycaemic control, and liver fibrosis in individuals with NAFLD, providing insight into the efficacy of IF as a therapeutic strategy for this condition .[35]

Justification for the Study:

NASH is a progressive form of NAFLD characterized by hepatic inflammation and liver cell damage. It is becoming increasingly prevalent worldwide, with an estimated 3-5% of the global population being affected by NASH. NASH is closely associated with obesity, type 2 diabetes, dyslipidaemia, and metabolic syndrome, making it a significant public health problem. Currently, there is no approved pharmacological treatment for NASH, and lifestyle modifications, including diet and exercise, are considered the corner stone for management of this condition .[36] However, adopting and maintaining an appropriate lifestyle remains challenging for various reasons, and weight loss remains difficult despite intensive and multidisciplinary lifestyle interventions. Therefore, identifying the barriers to lifestyle modifications in patients with NAFLD is crucial for developing efficient and effective interventions [37]. There is growing evidence that lifestyle modifications, particularly structured diet and exercise interventions, can improve liver health and prevent the progression of NASH. This RCT aims to evaluate the impact of supervised and structured diet and exercise in the management of patients with NASH. Therefore, conducting an RCT to evaluate the impact of supervised and structured diet and exercise in the management of patients with NASH would provide valuable insights into the effectiveness of these interventions in improving liver health and reducing disease progression [38]. The rationale for focusing on supervised and structured interventions is based on the premise that individualized, personalized approaches to diet and exercise may be more effective in achieving and sustaining meaningful changes in lifestyle behaviours. In a supervised setting, participants receive guidance, monitoring, and support from trained professionals, which can enhance compliance and adherence to the intervention [39]. By studying the impact of supervised and

structured diet and exercise on outcomes such as liver function, inflammation, fibrosis, and metabolic parameters in patients with NASH, researchers can understand better the mechanisms underlying the benefits of lifestyle modifications in managing this condition. This knowledge can form clinical practice guidelines and help healthcare providers develop evidence-based recommendations for the management of NASH [40]. In conclusion, the justification for the thesis topic on the impact of supervised and structured diet and exercise in the management of patients with NASH lies in the urgent need for effective, non-pharmacological interventions to address the growing burden of this disease. Conducting an RCT to assess the efficacy of these interventions is essential for generating high-quality evidence and improving patient outcomes in the management of NASH.

CHAPTER - 3

MATERIALS AND METHODS

The research materials and methods provide a structured model and framework, integrating theoretical principles to guide research within specific paradigms. It facilitates a systematic approach to problem-solving, steering research from inception to conclusion. This section is thorough, covering key elements such as research approach, design, setting, participant demographics, sampling technique, inclusion criteria, and data collection tools. Additionally, it delineates methodological strategies for data collection, ensuring accuracy and reliability, and includes detailed plans for data analysis to assess intervention effectiveness. This methodological approach ensures a robust framework for research and comprehensive evaluation of intervention impact, involving the identification and completion of the program while shaping data gathering and organization processes.

3.1 Research Approach:

A quantitative, evaluative research approach was used in this study.

3.2 Research Design:

The research design adopted for the present study was Randomized Controlled Trial.

Group	Randomization	Pre-treatment	Intervention	Post-treatment
S	R	Q_1	X	Q_2
C	R	Q_1	-	Q_2

Key:

S is the study group

C is the control group

R is the randomization of the sample

Q_1 is the pre-intervention assessment

Q_2 is the post-intervention assessment

X is the intervention that is supervised and structured diet and exercise study program

3.3 Randomization of the participants:

In our study, we conducted a single-blind RCT using the Sequentially Numbered Opaque Sealed Envelopes (SNOSE) method to randomize participants into two parallel arms. One arm received routine standard of care (control), while the other was assigned to a supervised and structured diet and exercise program (study). The randomization process was carried out by the investigator using a computer-based Research Randomizer. The sealed envelopes were kept confidential and securely stored. Participants were then randomly assigned by the investigator through the process of opening sealed envelopes in her presence. The study group participants attended a supervised and structured diet and exercise program. It involves a comprehensive approach to patient care and monitoring throughout the study period.

3.4 Variables under Study

Independent variable: supervised and structured diet and exercise

Dependent variable:

Waist Circumference (WC), Weight (WT) and Body Mass Index (BMI)

Triglyceride (TG), Alanine aminotransferase (ALT), Aspartate aminotransferase (AST)

Fibroscan (FS) - Controlled Attenuation Parameter (CAP) and Liver stiffness measurement (LSM)

Fibrosis 4 (FIB 4)

Aspartate Aminotransferase to Platelet Ratio Index (APRI) scores.

3.5 Research Setting

The setting selected for the study was Gastroenterology Out Patient Department of Karnataka Lingayat Education Society Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi.

3.6 Study Population

The study population was first time diagnosed with Non-alcoholic steatohepatitis patients, who were attending the Gastroenterology OPD at KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi.

3.7 Sample

The sample for the present study were Non-alcoholic steatohepatitis participants, who were attending Gastroenterology OPD of KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi.

3.8 Sample Size

The required sample was calculated using the following formula

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\frac{\beta}{2}}\right)^2 (S_1^2 + S_2^2)}{(\bar{X}_1 - \bar{X}_2)^2}$$

where $Z_{1-\alpha/2}$ is associated with the significance level and $Z_{1-\beta/2}$ is associated with the test's power. For a significance level of 5%, $Z_{1-\alpha/2}$ = 1.96 and for a test power of 80%, $Z_{1-\beta/2}$ = 1.64. $\bar{X}_1$represents the mean of the first group (26.05) and $\bar{X}_2$represents the mean of the second group (27.92). Similarly, S_1 denotes the standard deviation of the first group (4.24) and S_2 denotes the standard deviation of the second group (3.91).[41] The required sample size was 26.

As 20% dropout was added, the required sample size was 32. Therefore, 45 samples in each group were recruited.

3.9 Sampling Technique

For the present study, simple random sampling technique by envelope method was used.

3.10 Sampling Criteria

Inclusion criteria:

- Age 18-55 years
- Confirmed diagnosis of NASH established either by
    1) Abnormal LFT
    2) Abnormal Fibro scan: that is raised median stiffness (in patients with fatty liver).
- Participant's demonstration of understanding study requirement procedure, willingness to comply with all protocol-required evaluations

Exclusion criteria:

- Excessive and regular use of alcohol prior to initial screening
- Use of drugs associated with NASH for more than 12 consecutive weeks in one year before start of study
- Participants with hypothyroidism, diabetes mellitus and unstable cardiovascular disease and history of malignancy in the past 5 years
- Participation in any other therapeutic clinical study in the last 3 months

3.11 Administrative and Ethical Considerations

Hospital authority: Formal permission was obtained from the Director, Medical Superintendent and Head of Gastroenterology department of KLEs Dr. Prabhakar Kore Hospital & MRC

Approval from the Institutional Ethical Committee: The ethical clearance was obtained from the Ethics Committee on Human Subjects, KAHER, Belagavi (Ref. No. KAHER/EC/21-22/014).

Protection of human rights: Informed consent was obtained from the participants who participated in the study. The researcher explained the nature and purpose of study to all the participants. Assurance was given to them that the anonymity of each individual would be maintained as well as the confidentiality of the information obtained.

CTRI registration: The study has been registered in CTRI (Clinical Trials Registry-India) under the registration number CTRI/2022/02/040411.

3.12 Data collection instruments and techniques

3.12.1 Description of the Tool

The following tools were used:

Tool 1: Socio demographic data

It includes information such as gender, age (in years), marital status, education, occupation.

Tool 2: 4-point Likert Health Practice Scale

This scale comprises of 30 items rated on a 4-point scale, designed to assess self-perceived ability in adopting health-practices. It encompasses Nutrition, Exercise, Sleep and Responsible Health Practices. Responses range from 0 to 3 i.e. Never – 0; Rarely – 1; Sometimes – 2; Always – 3. Maximum score is 90 and minimum score is 0. Scores are calculated by summing the ratings of individual items, and then total scores. The total score ranges from 0 to 90. Higher scores indicate greater self-efficacy in health practices. These scores were converted into percentages and participants were subsequently categorized into groups reflecting good, average, or poor health practices.

Scoring:

≤50% - Poor health practice

51-75% - Average health practice

≥76% - Good health practice

3.12.2 Content Validity of the Tool

To ensure the tool's content validity, it underwent scrutiny by experts, who were provided with the blueprint, objectives, checklist, and validation certificate. A panel consist of experts from the Nursing department, Doctors specializing in Gastroenterology, Hepatology, Dietician and Physiotherapist. Their valuable feedback was meticulously analyzed, resulting in refinements aimed at enriching the tool's content comprehensiveness.

3.12.3 Reliability of Tool

To test the reliability, the tools were administered to 28 Non-alcoholic steatohepatitis participants.

4-point Likert Health Practice scale: Reliability of the tool was tested using internal consistency reliability. The Cronbach's alpha obtained was r=0.87, which was highly significant.

Hence, the tool was found to be reliable.

3.12.4 Data Collection Procedure

a. The data was collected from July 2021 to May 2023.
b. Ethical clearance was obtained from Ethics Committee on Human Subjects, KAHER
c. Formal permission was taken from the administrators of the selected hospital
d. NASH subjects were enrolled based on inclusion and exclusion criteria
e. Purpose and need for the study were explained to them
f. Informed consent was obtained from the participants, who were

enrolled for the study, assuring them the confidentiality and anonymity

g. They were randomly assigned into study group and control group using envelope method.

h. The socio-demographic data and pretest were assessed using 4-point likert health practice assessment scale with structured interview schedule.

i. Intervention in the form of supervised and structured diet and exercise study comprising of five follow-ups, each session lasting for approximately 40-60 minutes was given by the researcher during their visits at every follow-up. pamphlet was made on NASH (Liver Health).

j. Supervised and structured diet and exercise study: The study began with the enrolment of patients who met the exclusion and inclusion criteria, followed by a thorough clinical evaluation. At baseline, participants underwent a series of investigations including a CBC, LFT, Lipid Profile, and Fibroscan to establish their health status. Throughout the study, patients were regularly followed-up at 6 weeks, 12 weeks, 18 weeks, and 24 months. During these visits, they underwent clinical examinations and repeat CBC, LFT, and Lipid profile tests to monitor their progress. Additionally, at the 24-week mark, they underwent a Fibroscan to evaluate liver stiffness and fibrosis. During the study period, participants in the study group were supervised by the researcher in terms of their diet and exercise regimen.

k. The dietary component comprises a calorie-restricted, modified Mediterranean diet designed to achieve a 30% reduction in calorie intake below maintenance levels, targeting a 7–10% weight loss to enhance metabolic health (detailed in Annexure no. VII). A Calorie deficit

modified Mediterranean diet plan was prepared for each participant by an in-house dietician, and their adherence to the diet was monitored through weekly phone calls and a diet diary. Recognizing the challenges associated with strict adherence to the diet plan, the permissible flexibility of one cheat meal day per week was incorporated to enhance sustainability and participant compliance.

l. Similarly, an Aerobic Exercise regimen was provided to participant by the in-house physiotherapy department, and their exercise routine was monitored using a fitness band and a mobile application, with data recorded weekly. The exercise regimen consists of aerobic exercises such as running, cycling, walking, jogging, and swimming, performed for 30–45 minutes per day, five days per week for every individual.

m. The control group received routine standard of care including diet and exercise counselling. At baseline, participants underwent a series of investigations including a CBC, LFT, Lipid Profile, and Fibroscan to establish their health status. Throughout the study, patients were regularly followed-up at 6 weeks, 12 weeks, 18 weeks, and 24 weeks similar to the subjects in the study group.

n. Both the study and control group participants were assessed for their health practices using self-prepared and validated health practice scale, it was conducted at the baseline and at the end of the study (24 weeks).

o. A self-prepared and validated “TRANSFORMING LIVES WITH LIVER HEALTH” module was distributed to all the participants.

3.12.5 Data Analysis

The data analysis was performed in alignment with the study objectives and hypothesis testing. Both descriptive and inferential statistical methods were used to analyze the collected data. Descriptive statistics, including frequency, mean, median, standard deviation, and mean percentage, were utilized to provide a comprehensive overview of the data. Inferential statistics, such as the chi-square test, RMANOVA, Mann-Whitney U test and t-test, were employed to identify significant associations and differences among the groups. A significance level of $p < 0.05$ was established to determine the statistical significance.

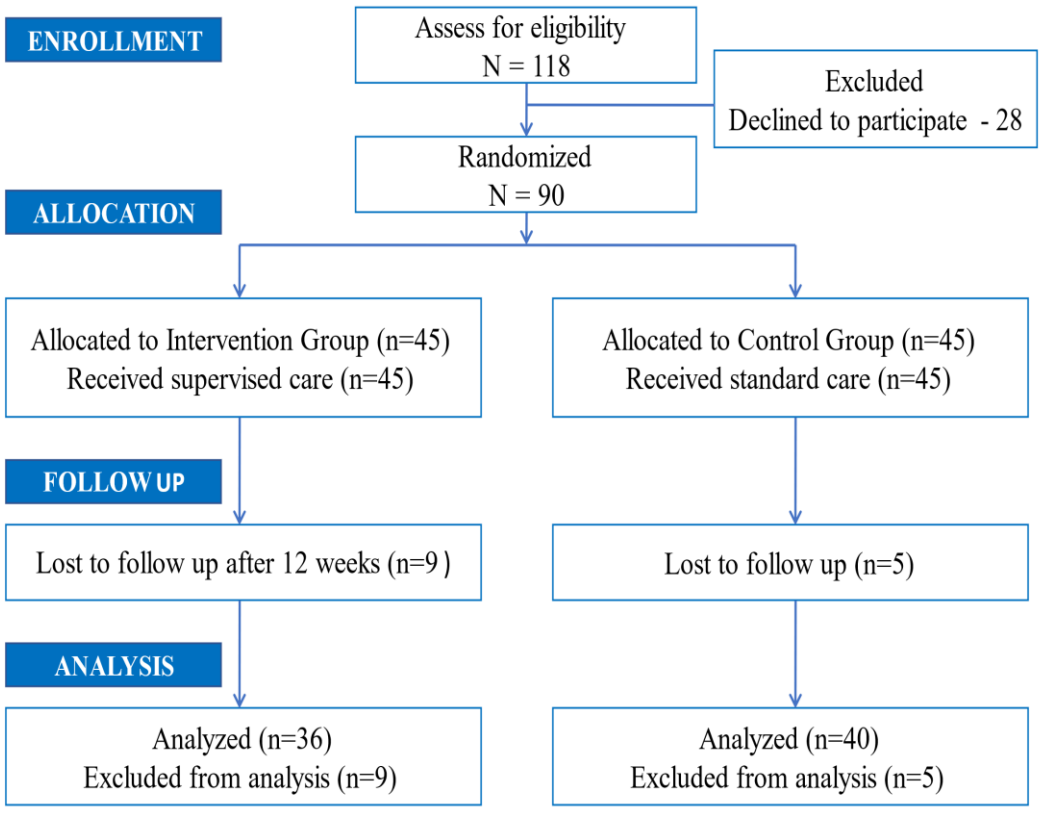


Figure 2: Schematic representation of CONSORT flow diagram

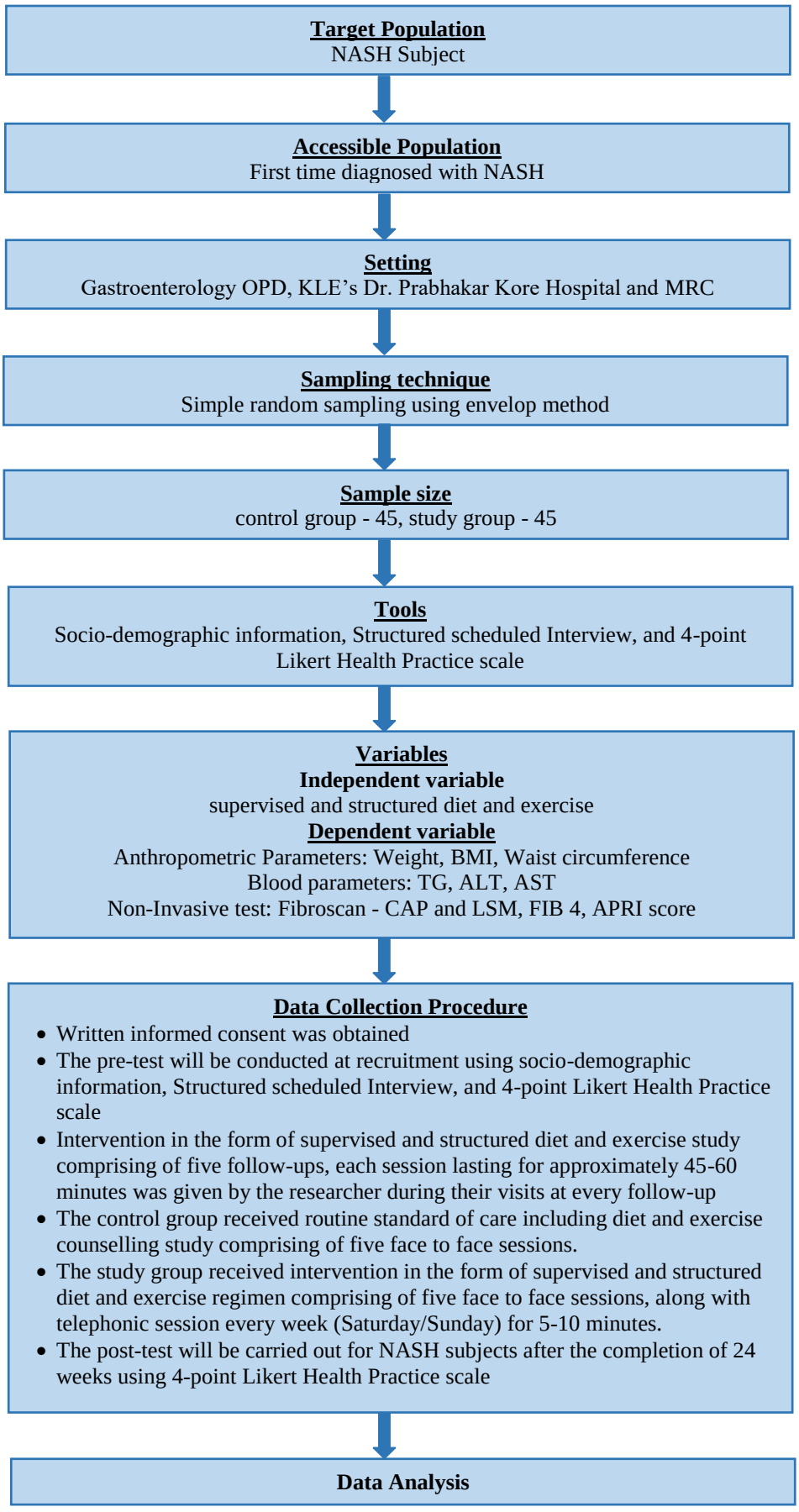


Figure 3: Schematic Representation of Research Methodology

CHAPTER - 4

RESULTS

This chapter presents a detailed analysis of a RCT that assesses the effects of a structured and supervised diet and exercise regimen on managing NASH in patients. The analysis focuses on organizing and synthesizing data to evaluate the study's hypotheses. To gain valuable insights into the research problem, the data was systematically processed and analysed to uncover patterns and relationships among different data sets. This involved organizing, tabulating, analysing, and interpreting the collected data using both descriptive and inferential statistical techniques. The data analysis was conducted using MS Excel and SPSS software.

- Pre and posttest were assessed using 4-point Likert health practice assessment scale
- Anthropometric Parameters - WC, Weight and BMI
- Blood Parameters - TG, ALT, AST
  - Non-invasive Test Parameters -FS (CAP, LSM), FIB 4 and APRI scores.

Table 1: Comparison of Demographic Profile of Control Group and Study Group at the Baseline

Demographic profile	Control group (n=45)	%	Study group (n=45)	%	Total	%	Chi-square	p-value
Gender								
Male	23	51.11	23	51.11	46	51.11	0.0000	1.0000
Female	22	48.89	22	48.89	44	48.89		
Age groups								
<=30yrs	6	13.33	5	11.11	11	12.22	1.1960	0.5500
31-40yrs	14	31.11	19	42.22	33	36.67		
>=41yrs	25	55.56	21	46.67	46	51.11		
Education								
Secondary	15	33.33	15	33.33	30	33.33	0.0000	1.0000
Graduate	30	66.67	30	66.67	60	66.67		
Occupation								
Housewife	7	15.56	3	6.67	10	11.11	7.5150	0.0570
Self-employed	6	13.33	4	8.89	10	11.11		
Private employee	28	62.22	38	84.44	66	73.33		
Govt employee	4	8.89	0	0.00	4	4.44		
Marital status								
Married	7	15.56	8	17.78	15	16.67	0.0800	0.7770
Unmarried	38	84.44	37	82.22	75	83.33		
Total	45	100.00	45	100.00	90	100.00		

Table 1 compares the demographic characteristics of the control group (n=45) and the study group (n=45). Both groups had identical gender distributions, with 51.11% male and 48.89% female participants. The control group had a higher proportion of participants aged 31-40 years (31.11%), while the study group had more individuals aged 41 years and above (55.56%). The mean ages were similar, with 40.42 years in the control group and 38.84 years in the study group. Educational levels were evenly distributed, with 66.67% of participants in each group holding a graduate degree. The

study group had a higher percentage of private employees (84.44%) compared to the control group (62.22%). Marital status was comparable, with approximately 16-18% of participants in both groups being married.

Table 2: Comparison of all parameters at baseline in control group and study group by Independent t-test

Variables	Control group (n=45)		Study group (n=45)		Effect size	t-value	p-value
	Mean	SD	Mean	SD			
WC	96.42	6.90	95.47	6.92	0.14	0.6561	0.5551
Weight	82.53	10.24	82.13	11.99	0.04	0.1702	0.8652
BMI	30.29	2.76	31.73	4.59	-0.39	-1.7990	0.0755
Hb	13.81	1.60	13.46	1.75	0.21	0.9789	0.3303
PC	3.93	1.17	4.05	1.03	-0.11	-0.5040	0.6155
SGOT	49.11	12.84	50.84	9.94	-0.15	-0.7159	0.4759
SGPT	57.04	16.06	52.96	10.54	0.31	1.4283	0.1567
Albumin level	4.22	0.59	4.16	0.61	0.10	0.4744	0.6364
TG	242.04	75.37	241.78	48.15	0.00	0.0200	0.9841
FS (LSM)	11.16	1.61	10.96	1.59	0.13	0.5924	0.5551
CAP	274.87	3.59	277.58	10.81	-0.38	-1.5970	0.1138
FIB 4	0.59	0.24	0.63	0.31	-0.15	-0.8033	0.4239
APRI	0.27	0.09	0.27	0.11	0.00	-0.2034	0.8393

Table 2 compares baseline parameters between the control and study groups using an independent t-test. The analysis found no significant differences across all variables, indicating that the two groups were well-matched at baseline. Parameters such as waist circumference, weight, BMI, haemoglobin levels, platelet counts, liver enzymes (SGOT, SGPT), albumin, triglycerides, FS (LSM) and CAP values, FIB-4 and APRI score values showed no significant variation between the groups.

Table 3: Comparison of the waist circumference (WC) scores in the control group and study group at different treatment time points by Independent t-test

Times	Control group (n=40)		Study group (n=36)		Effect size	t-value	p-value
	Mean	SD	Mean	SD			
Baseline	96.42	6.90	95.47	6.92	0.14	0.6561	0.5135
6 weeks	95.53	6.99	90.24	7.08	0.75	3.5668	0.0006
12 weeks	95.38	7.03	87.78	7.26	1.06	5.0456	0.0001*
18 weeks	95.50	8.86	85.28	7.22	1.27	5.3142	0.0001*
24 weeks	95.60	9.27	84.78	6.87	1.34	5.7298	0.0001*
Baseline - 6 weeks	0.89	2.85	5.22	5.77	-1.00	-4.5146	0.0001*
Baseline - 12 weeks	1.04	3.17	7.69	6.69	-1.35	-6.0181	0.0001*
Baseline - 18 weeks	0.92	4.53	11.31	7.14	-1.78	-5.8056	0.0001*
Baseline - 24 weeks	0.82	10.10	11.81	6.95	-1.29	-5.5726	0.0001*

*$p<0.05$

Table 3 compares WC between the control and study groups at various treatment stages. At baseline, WC was similar between groups (Control: Mean = 96.42, SD = 6.90; Study: Mean = 95.47, SD = 6.92) with no significant difference (p = 0.5135). However, at 6 weeks, the study group had a significantly lower WC (Mean = 90.24, SD = 7.08) compared to the control group (Mean = 95.53, SD = 6.99) (p = 0.0006). This difference persisted at 12, 18, and 24 weeks (all p = 0.0001*). The study group also showed significantly greater reductions in WC from baseline at all time points, with the largest change of -11.81 cm at 24 weeks (p = 0.0001*). Overall, the study group experienced significantly greater reductions in WC, indicating the effectiveness of the treatment.

Table 4: Comparison of different treatment time points with WC scores in the control group and study group by dependent t-test and RMANOVA

Groups	Changes from	Mean Diff.	% of effect	t-value	p-value	RMANOVA		
						Effect size	F-value	p-value
Control group (n=40)	Baseline to 6 weeks	0.89	0.92	2.0891	0.0425	0.0280	1.1110	0.2980
	Baseline to 12 weeks	1.04	1.08	2.2108	0.0323			
	Baseline to 18 weeks	0.92	0.55	0.7834	0.5188			
	Baseline to 24 weeks	0.82	0.62	0.3758	0.7091			
Study group (n=36)	Baseline to 6 weeks	5.22	5.47	6.0695	0.0001*	0.7920	132.987	0.0001*
	Baseline to 12 weeks	7.69	8.05	7.7052	0.0001*			
	Baseline to 18 weeks	11.31	11.84	9.5022	0.0001*			
	Baseline to 24 weeks	11.81	12.37	10.1887	0.0001*			

*$p<0.05$

Table 4 details WC changes in the control and study groups using dependent t-tests and RM ANOVA. For the control group, WC changes were modest and not consistently significant. The study group showed consistently significant improvements.

Table 5: Comparison of the weight scores in the control group and study group at different treatment time points by Independent t-test

Times	Control group (n=40)		Study group (n=36)		Effect size	t-value	p-value
	Mean	SD	Mean	SD			
Baseline	82.53	10.24	82.13	11.99	0.04	0.1702	0.8652
6 weeks	81.96	10.20	80.27	12.17	0.15	0.7135	0.4774
12 weeks	82.07	10.76	78.58	12.22	0.30	1.4375	0.1541
18 weeks	82.08	11.06	74.53	11.09	0.68	2.9664	0.0041*
24 weeks	81.40	11.22	70.72	11.04	0.96	4.1728	0.0001*
Baseline - 6 weeks	0.58	1.69	1.87	0.87	-1.01	-4.5601	0.0001*
Baseline - 12 weeks	0.47	3.03	3.56	1.03	-1.52	-6.4771	0.0001*
Baseline - 18 weeks	1.00	4.24	6.53	1.30	-2.00	-7.5133	0.0001*
Baseline - 24 weeks	1.68	5.58	10.33	1.88	-2.32	-8.8608	0.0001*

*$p<0.05$

Table 5 compares weight measurements between the control and study groups at various treatment stages. At baseline, there was no significant difference in weight between the groups (Control: Mean = 82.53, SD = 10.24; Study: Mean = 82.13, SD = 11.99, p = 0.8652). Differences remained insignificant at 6 weeks (Control: Mean = 81.96, SD = 10.20; Study: Mean = 80.27, SD = 12.17, p = 0.4774) and 12 weeks (Control: Mean = 82.07, SD = 10.76; Study: Mean = 78.58, SD = 12.22, p = 0.1541). However, by 18 weeks, the study group (Mean = 74.53, SD = 11.09) showed significantly greater weight loss compared to the control group (Mean = 82.08, SD = 11.06, p = 0.0041). At 24 weeks, the study group (Mean = 70.72, SD = 11.04) had a significantly greater weight loss than the control group (Mean = 81.40, SD = 11.22, p = 0.0001).

The study group consistently showed greater weight reductions from baseline at each time point: 6 weeks (Study: Mean = 1.87, SD = 0.87; Control: Mean = 0.58,

SD = 1.69, p = 0.0001), 12 weeks (Study: Mean = 3.56, SD = 1.03; Control: Mean = 0.47, SD = 3.03, p = 0.0001), 18 weeks (Study: Mean = 6.53, SD = 1.30; Control: Mean = 1.00, SD = 4.24, p = 0.0001), and 24 weeks (Study: Mean = 10.33, SD = 1.88; Control: Mean = 1.68, SD = 5.58, p = 0.0001). The study group consistently achieved significantly greater weight reductions throughout the study.

Table 6: Comparison of weight scores at different treatment time points in the control group and study group by dependent t-test and RMANOVA

Groups	Changes from	Mean Diff.	% of effect	t-value	p-value	RMANOVA		
						Effect size	F-value	p-value
Control group (n=40)	Baseline to 6 weeks	0.58	0.70	2.2997	0.0263	0.0560	2.3180	0.0600
	Baseline to 12 weeks	0.47	0.57	1.0341	0.3067			
	Baseline to 18 weeks	1.00	1.21	1.4928	0.1435			
	Baseline to 24 weeks	1.68	2.03	1.8981	0.0651			
Study group (n=36)	Baseline to 6 weeks	1.87	2.27	14.4155	0.0001*	0.9290	457.119	0.0001*
	Baseline to 12 weeks	3.56	4.33	23.0504	0.0001*			
	Baseline to 18 weeks	6.53	7.95	30.1736	0.0001*			
	Baseline to 24 weeks	10.33	12.58	32.9393	0.0001*			

*p<0.05

Table 6 shows weight changes from baseline at 6, 12, 18, and 24 weeks for both groups, along with RMANOVA results. RMANOVA revealed a significant difference in weight changes between groups (F = 457.119, p = 0.0001). Post-hoc comparisons confirmed significant mean differences between the control and study groups at all time points: 6 weeks (t = 14.4155, p = 0.0001), 12 weeks (t = 23.0504, p = 0.0001), 18 weeks (t = 30.1736, p = 0.0001), and 24 weeks (t = 32.9393, p =

0.0001). These results indicate that the intervention in the study group led to significantly greater weight reductions compared to the control group.

Table 7: Comparison of the Body Mass Index (BMI) Scores in the Control Group and Study Group at Different Treatment Time Points by Independent t-test

Times	Control group (n=40)		Study group (n=36)		Effect size	t-value	p-value
	Mean	SD	Mean	SD			
Baseline	30.29	2.76	31.73	4.59	-0.39	-1.7990	0.0755
6 weeks	30.18	2.68	31.00	4.64	-0.22	-1.0331	0.3044
12 weeks	30.25	2.89	30.32	4.62	-0.02	-0.0866	0.9312
18 weeks	30.31	3.15	29.45	4.49	0.23	0.9732	0.3336
24 weeks	30.30	3.34	28.00	4.52	0.59	2.5329	0.0134*
Baseline - 6 weeks	0.11	0.60	0.72	0.35	-1.28	-5.9116	0.0001*
Baseline - 12 weeks	0.04	1.13	1.40	0.40	-1.78	-7.6159	0.0001*
Baseline - 18 weeks	0.15	1.65	2.53	0.54	-2.17	-8.2652	0.0001*
Baseline - 24 weeks	0.16	1.93	3.97	1.03	-2.57	-10.5721	0.0001*

*$p<0.05$

Table 7 compares BMI scores between the control and study groups at various time points using independent t-tests. At baseline, no significant difference was found between the groups (mean difference = -1.44, p = 0.0755). This trend continued at 6 weeks (mean difference = -0.83, p = 0.3044) and 12 weeks (mean difference = -0.07, p = 0.9312). At 18 weeks, the difference was also non-significant (mean difference = 0.86, p = 0.3336). However, by 24 weeks, the study group had a significantly lower

BMI (mean = 28.00, SD = 4.52) compared to the control group (mean = 30.30, SD = 3.34) with a mean difference of 2.29 (p = 0.0134).

Changes from baseline showed significant differences at all time points, with the study group demonstrating greater reductions in BMI: from baseline to 6 weeks (mean difference = -0.61, p = 0.0001), 12 weeks (mean difference = -1.37, p = 0.0001), 18 weeks (mean difference = -2.38, p = 0.0001), and 24 weeks (mean difference = -3.81, p = 0.0001). Overall, the study group experienced significantly greater reductions in BMI over time, especially at 24 weeks.

Table 8: Comparison of BMI scores at different treatment time points in the control group and study group by dependent t-test and RMANOVA

Groups	Changes from	Mean Diff.	% of effect	t-value	p-value	RMANOVA		
						Effect size	F-value	p-value
Control group (n=40)	Baseline to 6 weeks	0.11	0.37	1.2678	0.2115	0.0060	0.2550	0.9060
	Baseline to 12 weeks	0.04	0.13	0.2322	0.8174			
	Baseline to 18 weeks	0.15	0.50	0.5862	0.5611			
	Baseline to 24 weeks	0.16	0.54	0.5313	0.5983			
Study group (n=36)	Baseline to 6 weeks	0.72	2.28	13.8221	0.0001*	0.8970	306.035	0.0001*
	Baseline to 12 weeks	1.40	4.43	23.4492	0.0001*			
	Baseline to 18 weeks	2.53	7.97	27.9948	0.0001*			
	Baseline to 24 weeks	3.97	12.52	23.2484	0.0001*			

*p<0.05

Table 8 compares BMI changes within the control and study groups at various treatment intervals using dependent t-tests and repeated measures ANOVA (RMANOVA). In the control group, BMI changes were minor and statistically

insignificant across all time points. From baseline to 6 weeks, the mean BMI difference was 0.11 with a t-value of 1.2678 (p = 0.2115), and RMANOVA showed a small effect size (0.0060) with an F-value of 0.2550 (p = 0.9060). Similar trends were observed at 12, 18, and 24 weeks, with no significant BMI changes.

In contrast, the study group demonstrated substantial and highly significant reductions in BMI at all time points. From baseline to 6 weeks, the mean BMI difference was 0.72, with a t-value of 13.8221 (p = 0.0001*). RMANOVA indicated a large effect size (0.8970) with an F-value of 306.035 (p = 0.0001*). The reductions were even more pronounced at 12, 18, and 24 weeks, with highly significant mean differences.

Overall, the study group experienced significantly greater BMI reductions compared to the control group, with RMANOVA confirming the treatment's significant and substantial impact on BMI changes in the study group.

Table 9: Comparison of SGOT/AST scores in the control group and study group at different treatment time points by Independent t test

Times	Control group (n=40)		Study group (n=36)		Effect size	t-value	p-value
	Mean	SD	Mean	SD			
Baseline	49.11	12.84	50.84	9.94	-0.15	-0.7159	0.4759
6 weeks	41.91	12.81	40.02	8.41	0.18	0.8269	0.4105
12 weeks	41.89	12.44	32.31	6.32	1.02	4.6037	0.0001*
18 weeks	39.45	12.20	25.42	4.66	1.66	6.4865	0.0001*
24 weeks	33.75	14.11	19.75	3.87	1.56	5.7575	0.0001*
Baseline - 6 weeks	7.20	6.96	10.82	5.12	-0.60	-2.8127	0.0061*
Baseline - 12 weeks	7.22	9.10	18.53	7.06	-1.40	-6.5879	0.0001*
Baseline - 18 weeks	9.88	9.79	25.75	8.11	-1.77	-7.6492	0.0001*
Baseline - 24 weeks	15.58	15.03	31.42	9.03	-1.32	-5.4923	0.0001*

*$p<0.05$ indicates significant

Table 9 compares SGOT levels between the control and study groups at various time points. At baseline, SGOT levels were similar between the groups (control: 49.11 ± 12.84, study: 50.84 ± 9.94), with no significant difference (t = -0.7159, p = 0.4759). Over time, significant differences emerged. At 6 weeks, the mean difference was not significant (control: 41.91 ± 12.81, study: 40.02 ± 8.41; t = 0.8269, p = 0.4105). However, by 12 weeks, the study group's SGOT significantly decreased compared to the control group (control: 41.89 ± 12.44, study: 32.31 ± 6.32; t = 4.6037, p = 0.0001*). This trend continued at 18 weeks (control: 39.45 ± 12.20, study: 25.42 ± 4.66; t = 6.4865, p = 0.0001*) and 24 weeks (control: 33.75 ± 14.11, study: 19.75 ± 3.87; t = 5.7575, p = 0.0001*).

Both groups showed significant reductions from baseline at all time points, with the study group exhibiting more pronounced changes: 6 weeks (t = -3.62, p = 0.0001*), 12 weeks (t = -11.31, p = 0.0001*), 18 weeks (t = -15.88, p = 0.0001*), and 24 weeks (t = -15.84, p = 0.0001*). Overall, the study group experienced significantly greater reductions in SGOT levels over time, particularly after 12 weeks, indicating the effectiveness of the treatment in lowering SGOT levels.

Table 10: Comparison of SGOT/AST scores at different treatment time points in control group and study group by dependent t test and RMANOVA

Groups	Changes from	Mean Diff.	% of effect	t-value	p-value	RMANOVA		
						Effect size	F-value	p-value
Control group (n=40)	Baseline to 6 weeks	7.20	14.66	6.9399	0.0001*	0.4940	38.1370	0.0001*
	Baseline to 12 weeks	7.22	14.71	5.3224	0.0001*			
	Baseline to 18 weeks	9.88	20.11	6.3791	0.0001*			
	Baseline to 24 weeks	15.58	31.71	6.5533	0.0001*			
Study group (n=36)	Baseline to 6 weeks	10.82	21.28	14.1845	0.0001*	0.9200	405.004	0.0001*
	Baseline to 12 weeks	18.53	36.45	17.6175	0.0001*			
	Baseline to 18 weeks	25.75	50.64	19.0558	0.0001*			
	Baseline to 24 weeks	31.42	61.79	20.8792	0.0001*			

*p<0.05

Table 10 compares SGOT/AST levels between the control and study groups over various time points. At baseline, SGOT levels were similar between the groups, with no significant differences. However, significant reductions in SGOT levels were observed in both groups as treatment progressed. In the control group, reductions ranged from 7.20 to 15.58 over the treatment period, with substantial effect sizes

(0.4940 to 0.9200). RMANOVA confirmed significant improvements (F-value range: 38.1370 to 405.004, $p < 0.0001$) at all time points. Similarly, the study group showed more pronounced decreases in SGOT levels, with changes ranging from 10.82 to 31.42, higher effect sizes, and percentage effects (21.28% to 61.79%). RMANOVA results for the study group also revealed highly significant improvements (F-value range: 38.1370 to 405.004, $p = 0.0001$). Overall, both groups exhibited significant reductions in SGOT levels, with the study group showing particularly strong improvements, highlighting the effectiveness of the treatment.

Table 11: Comparison of SGPT/ALT scores in the control group and study group at different treatment time points by Independent t test

Times	Control group (n=40)		Study group (n=36)		Effect size	t-value	p-value
	Mean	SD	Mean	SD			
Baseline	57.04	16.06	52.96	10.54	0.31	1.4283	0.1567
6 weeks	44.87	13.78	43.20	7.69	0.16	0.7084	0.4806
12 weeks	42.31	11.66	34.67	6.28	0.85	3.8725	0.0002
18 weeks	42.88	11.01	27.19	4.43	2.03	7.9769	0.0001*
24 weeks	42.85	13.99	20.61	3.28	2.58	9.3034	0.0001*
Baseline - 6 weeks	12.18	10.56	9.76	4.92	0.31	1.3951	0.1665
Baseline - 12 weeks	14.73	12.24	18.29	9.33	-0.33	-1.5496	0.1248
Baseline - 18 weeks	14.65	11.32	25.00	9.90	-0.98	-4.2202	0.0001*
Baseline - 24 weeks	14.68	12.16	31.58	10.25	-1.51	-6.5145	0.0001*

*$p<0.05$ indicates significant

Table 11 compares SGPT levels between the control and study groups over various treatment time points. At baseline, the mean SGPT levels were similar, with a

non-significant difference of 4.09 (t = 1.4283, p = 0.1567). However, as treatment progressed, significant differences emerged. By 12 weeks, the study group showed a significant reduction in SGPT levels compared to the control group (mean difference = 7.64, t = 3.8725, p = 0.0002*). This trend continued, with even more pronounced reductions at 18 weeks (mean difference = 15.68, t = 7.9769, p = 0.0001*) and 24 weeks (mean difference = 22.24, t = 9.3034, p = 0.0001*).

Both groups exhibited significant decreases from baseline across all time points, but the study group consistently showed larger reductions. These results highlight the effectiveness of the treatment in lowering SGPT levels, with the study group demonstrating particularly strong improvements throughout the study period.

Table 12: Comparison of SGPT/ALT scores at different treatment time points in control group and study group by dependent t test and RMANOVA

Groups	Changes from	Mean Diff.	% of effect	t-value	p-value	RMANOVA		
						Effect size	F-value	p-value
Control group (n=40)	Baseline to 6 weeks	12.18	21.35	7.7375	0.0001*	0.5440	46.4340	0.0001*
	Baseline to 12 weeks	14.73	25.83	8.0730	0.0001*			
	Baseline to 18 weeks	14.65	25.68	8.1821	0.0001*			
	Baseline to 24 weeks	14.68	25.73	7.6313	0.0001*			
Study group (n=36)	Baseline to 6 weeks	9.76	18.42	13.3061	0.0001*	0.9040	328.412	0.0001*
	Baseline to 12 weeks	18.29	34.54	13.1511	0.0001*			
	Baseline to 18 weeks	25.00	47.21	15.1479	0.0001*			
	Baseline to 24 weeks	31.58	59.64	18.4889	0.0001*			

*p<0.05

Table 12 indicates a detailed analysis of SGPT scores between the control group and study group across different treatment time points using dependent t-tests and RMANOVA analysis. Initially, both groups exhibited comparable SGPT scores at baseline, with no significant differences observed. However, significant reductions in SGPT levels in the study group were evident as treatment progressed.

Table 13: Comparison of TG scores in the control group and study group at different treatment time points by using Independent t test

Times	Control group (n=40)		Study group (n=36)		Effect size	t-value	p-value
	Mean	SD	Mean	SD			
Baseline	242.04	75.37	241.78	48.15	0.00	0.0200	0.9841
6 weeks	243.49	47.91	180.87	30.91	1.59	7.3676	0.0001*
12 weeks	243.76	54.17	158.36	33.98	1.94	8.9584	0.0001*
18 weeks	255.70	48.71	149.08	20.14	3.10	12.2203	0.0001*
24 weeks	254.45	81.59	142.78	22.30	2.15	7.9444	0.0001*
Baseline - 6 weeks	-1.44	65.55	60.91	57.98	-1.01	-4.7798	0.0001*
Baseline - 12 weeks	-1.71	68.00	83.42	60.86	-1.32	-6.2579	0.0001*
Baseline - 18 weeks	-15.60	60.95	92.53	53.72	-1.89	-8.1651	0.0001*
Baseline - 24 weeks	-14.35	92.81	98.83	49.92	-1.59	-6.5154	0.0001*

*p<0.05

Table 13 provides a comparative analysis of (TG) scores between the groups, across various treatment time points. Initially, at baseline, both groups exhibited similar TG levels, with no significant difference observed (baseline, mean difference = 0.27, t(DF) = 0.0200, p = 0.9841),by end of the 24 weeks significant improvements observed between both the groups (24 weeks, mean difference = 111.67, t(DF) =

7.9444, p = 0.0001*). The study group demonstrated significant improvement, with scores decreasing from a baseline of 241.78 to 142.78 by the end of 24 weeks. In contrast, the control group showed no improvement, as scores increased slightly from 242.04 at baseline to 254.45 at the end of the 24-week period. Notably, significant differences became evident as the treatment progressed in the study group.

Table 14: Comparison of TG scores at different treatment time points in the control group and study group by dependent t test and RMANOVA

Groups	Changes from	Mean Diff.	% of effect	t-value	p-value	RMANOVA		
						Effect size	F-value	p-value
Control group (n=40)	Baseline to 6 weeks	-1.44	-0.60	-0.1478	0.8832	0.0340	1.3600	0.2510
	Baseline to 12 weeks	-1.71	-0.71	-0.1688	0.8667			
	Baseline to 18 weeks	-15.60	-6.45	-1.6187	0.1136			
	Baseline to 24 weeks	-14.35	-5.93	-0.9779	0.3341			
Study group (n=36)	Baseline to 6 weeks	60.91	25.19	7.0471	0.0001*	0.8480	195.659	0.0001*
	Baseline to 12 weeks	83.42	34.50	9.1947	0.0001*			
	Baseline to 18 weeks	92.53	38.27	10.3349	0.0001*			
	Baseline to 24 weeks	98.83	40.88	11.8796	0.0001*			

*p<0.05

Table 14 compares triglyceride (TG) levels between the control and study groups across different treatment time points. At baseline, TG levels were nearly identical in both groups, with no significant difference (mean difference = 0.27, t = 0.0200, p = 0.9841). The control group showed minimal and non-significant changes in TG levels throughout the treatment period, with slight decreases at 18 and 24 weeks but lacking statistical significance. In contrast, the study group demonstrated significant and progressive reductions in TG levels at all time points. From baseline to

6 weeks, the study group saw a significant drop (mean difference = 60.91, t = 7.0471, p < 0.0001*), which continued to decrease significantly at 12 weeks (mean difference = 83.42, t = 9.1947, p < 0.0001*), 18 weeks (mean difference = 92.53, t = 10.3349, p < 0.0001*), and 24 weeks (mean difference = 98.83, t = 11.8796, p < 0.0001*). RMANOVA confirmed significant overall effects in both groups, with the study group showing larger effect sizes, indicating a substantial clinical impact of the treatment on TG levels. Overall, the study group experienced significant reductions in TG levels, highlighting the treatment's effectiveness, while the control group remained relatively stable.

Table 15: Comparison of CAP scores in the control group and study group at baseline and 24 weeks treatment time points by independent t test

Times	Control group (n=40)		Study group (n=36)		Effect size	t-value	p-value
	Mean	SD	Mean	SD			
Baseline	274.87	3.59	277.58	10.81	-0.38	-1.5970	0.1138
24 weeks	268.48	17.52	213.17	21.87	2.81	12.2224	0.0001*
Baseline - 24 weeks	6.15	17.36	61.89	22.01	-2.83	-12.3168	0.0001*

*p<0.05

Table 15 compares CAP scores between the control and study groups at baseline and after 24 weeks of treatment. Initially, both groups had similar CAP scores with no significant difference (mean difference = -2.71, t = -1.5970, p = 0.1138). After 24 weeks, the study group showed a significant reduction in CAP scores (mean = 213.17) compared to the control group (mean = 268.48), with a highly significant mean difference of 55.31 (t = 12.2224, p = 0.0001*). From baseline to 24

weeks, the control group had a small, non-significant reduction, while the study group experienced a substantial decrease (mean reduction = 61.89), resulting in a significant mean difference of -55.74 (t = -12.3168, p = 0.0001*). This indicates the study group's treatment was notably more effective in improving CAP scores.

Table 16: Comparison of CAP scores at the baseline and at 24 weeks treatment time points in the control group and study group by dependent t-test and RMANOVA

Groups	Changes from	Mean Diff.	% of effect	t-value	p-value	RMANOVA		
						Effect size	F-value	p-value
Control group (n=40)	Baseline to 24 weeks	6.15	2.24	2.2406	0.0308*	0.1140	5.0200	0.0310*
Study group (n=36)	Baseline to 24 weeks	61.89	22.30	16.8681	0.0001*	0.8900	284.531	0.0001*

*p<0.05

Table 16 compares the changes in CAP scores from baseline to 24 weeks between the control and study groups. The control group showed a modest, statistically significant reduction in CAP scores (mean reduction = 6.15, 2.24% change, t = 2.2406, p = 0.0308*, effect size = 0.1140). In contrast, the study group exhibited a substantial and highly significant reduction (mean reduction = 61.89, 22.30% change, t = 16.8681, p = 0.0001*, effect size = 0.8900). RMANOVA results supported these findings, with the study group showing a much larger and more consistent treatment effect. Overall, the study group experienced a significantly greater improvement in CAP scores, indicating a highly effective treatment.

Table 17: Comparison of Liver Stiffness Measurement [Fibro scan] (LSM FS) scores in the control group and study group at baseline and 24 weeks treatment time points by Independent t-test

Times	Control group (n=40)		Study group (n=36)		Effect size	t-value	p-value
	Mean	SD	Mean	SD			
Baseline	11.16	1.61	10.96	1.59	0.13	0.5924	0.5551
24 weeks	10.47	2.39	6.84	1.25	1.99	8.1660	0.0001*
Baseline - 24 weeks	0.68	1.28	4.05	1.25	-2.66	-11.5843	0.0001*

*p<0.05

Table 17 compares LSM, FS scores between the control and study groups at baseline and after 24 weeks of treatment. At baseline, both groups had similar FS scores (control: 11.16, study: 10.96, mean difference = 0.20, p = 0.5551). After 24 weeks, the control group showed a modest decrease to 10.47, while the study group had a significantly larger reduction to 6.84 (mean difference = 3.63, p < 0.0001*). Both groups improved, but the study group experienced a notably greater reduction in FS scores, indicating a more effective treatment.

Table 18: Comparison of Liver Stiffness Measurement [Fibro scan] (LSM) scores at baseline and 24 weeks treatment time points in the control group and study group by dependent t-test and RMANOVA

Groups	Changes from	Mean Diff.	% of effect	t-value	p-value	RMANOVA		
						Effect size	F-value	p-value
Control group (n=40)	Baseline to 24 weeks	0.68	6.07	3.3509	0.0018*	0.2240	11.2290	0.0020*
Study group (n=36)	Baseline to 24 weeks	4.05	36.93	19.3944	0.0001*	0.9150	376.142	0.0001*

*p<0.05

Table 18 compares FS scores between the control and study groups at baseline and after 24 weeks. The control group showed a moderate 6.07% reduction in FS scores (mean difference = 0.68, p = 0.0018*), confirmed by a significant RMANOVA F-value (11.2290, p = 0.0020). In contrast, the study group exhibited a substantial 36.93% reduction (mean difference = 4.05, p < 0.0001*), with a large effect size and highly significant RMANOVA F-value (376.142, p < 0.0001). The study group demonstrated a markedly greater improvement in FS scores compared to the control group.

Table 19: Comparison of the Fibrosis-4 (FIB-4) scores in the control group and study group at baseline and 24 weeks treatment time points by Independent t-test

Times	Control group (n=40)		Study group (n=36)		Effect size	t-value	p-value
	Mean	SD	Mean	SD			
Baseline	0.59	0.24	0.63	0.31	-0.15	-0.8033	0.4239
24 weeks	0.52	0.25	0.42	0.18	0.47	1.7847	0.0784
Baseline - 24 weeks	0.06	0.24	0.22	0.23	-0.68	-2.9328	0.0045*

*p<0.05

Table 19 compares FIB-4 scores between the control and study groups at baseline and after 24 weeks. Baseline scores were similar (control: 0.59 vs. study: 0.63, p = 0.4239). After 24 weeks, the control group's mean decreased to 0.52, while the study group decreased to 0.42. The study group showed a significantly greater improvement from baseline to 24 weeks (mean difference = -0.16, t = -2.9328, p = 0.0037*), indicating more effective treatment in reducing FIB-4 scores compared to the control group.

Table 20: Comparison of Fibrosis-4 (FIB-4) scores in the Control Group and Study Group at Baseline and 24 Weeks Treatment Time Points by dependent t-test and RMANOVA

Groups	Changes from	Mean Diff.	% of effect	t-value	p-value	Effect size	F-value	p-value
Control group (n=40)	Baseline to 24 weeks	0.06	9.68	1.5110	0.1389	0.0510	2.0890	0.1560
Study group (n=36)	Baseline to 24 weeks	0.22	33.93	5.5731	0.0001*	0.4450	28.037	0.0001*

*p<0.05

Table 20 compares FIB-4 scores from baseline to 24 weeks for both groups. The control group showed a modest decrease (mean difference = 0.06, t = 1.5110, p = 0.389) with a small effect size (0.0510). In contrast, the study group experienced a significant reduction (mean difference = 0.22, t = 7.1040, p = 0.0001*), with a larger effect size (0.5731). RMANOVA confirmed significant improvements in the study group, highlighting the greater effectiveness of the treatment in reducing FIB-4 scores.

Table 21: Comparison of aspartate aminotransferase to platelet ratio index (APRI) scores in the study and control group at baseline and 24 weeks treatment time points by Independent t-test

Times	Control group (n=40)		Study group (n=36)		Effect size	t-value	p-value
	Mean	SD	Mean	SD			
Baseline	0.27	0.09	0.27	0.11	0.00	-0.2034	0.8393
24 weeks	0.21	0.08	0.15	0.05	0.06	4.0396	0.0001*
Baseline - 24 weeks	0.06	0.06	0.12	0.10	-0.06	-3.3692	0.0012*

*p<0.05

Table 21 compares APRI scores between groups at baseline and after 24 weeks. Both groups started with similar scores (mean = 0.27). After 24 weeks, the control group's score decreased to 0.21, while the study group's score reduced more significantly to 0.15. This resulted in a notable difference (mean difference = 0.06, t = 4.0396, p = 0.0001*). Both groups showed significant reductions, but the study group had a larger improvement, indicating more effective treatment.

Table 22: Comparison of APRI scores at baseline and 24 weeks treatment time points in the control group and study group by dependent t-test and RMANOVA

Groups	Changes from	Mean Diff.	% of effect	t-value	p-value	RMANOVA		
						Effect size	F-value	p-value
Control group (n=40)	Baseline to 24 weeks	0.06	20.70	6.2985	0.0001*	0.4010	26.0820	0.0001*
Study group (n=36)	Baseline to 24 weeks	0.12	42.79	7.1040	0.0001*	0.5770	47.760	0.0001*

*p<0.05

Table 22 compares APRI scores from baseline to 24 weeks. The control group saw a significant reduction with a mean difference of 0.06 (20.70% effect, t = 6.2985, p = 0.0001*). The study group experienced a larger reduction of 0.12 (42.79% effect, t = 7.1040, p = 0.0001*). RMANOVA showed significant improvements for both groups, but the study group had a greater effect size, indicating a more pronounced treatment benefit.

Table 23: Comparison of all parameters in the the control group and study group at baseline and 12 weeks of treatment among patients lost to follow-up by Mann-Whitney U test

Variables	Time	Control group (n=5)			Study group (n=9)			U-value	Z-value	P-value
		Mean	SD	Mean rank	Mean	SD	Mean rank			
WC	BL	98.20	4.49	10.20	91.00	6.65	6.00	9.00	1.7333	0.0830
	12W	97.20	6.61	10.80	87.33	6.78	5.67	6.00	1.1333	0.0829
WT	BL	78.20	9.36	5.90	86.44	14.06	8.39	14.50	-1.0000	0.3173
	12W	78.60	8.88	6.60	83.22	14.10	8.00	18.00	-0.5333	0.5938
BMI	BL	28.95	2.93	5.80	30.73	4.75	8.44	14.00	-1.0667	0.2861
	12W	29.06	2.14	6.50	29.50	4.63	8.06	17.50	-0.6000	0.5485
HB	BL	13.28	1.95	8.10	12.82	1.84	7.17	19.50	0.3333	0.7389
	12W	13.70	1.17	9.90	12.41	1.57	6.17	10.50	1.5333	0.1252
PC	BL	3.92	1.13	6.80	4.21	0.90	7.89	19.00	-0.4000	0.6892
	12W	3.95	0.77	9.20	3.58	0.28	6.56	14.00	1.0667	0.2861
SGOT	BL	47.40	6.02	7.60	49.56	11.04	7.44	22.00	0.0000	1.0000
	12W	38.00	8.86	9.60	31.78	5.97	6.33	12.00	1.3333	0.1824
SGPT	BL	53.20	18.07	6.20	56.00	9.81	8.22	16.00	-0.8000	0.4237
	12W	31.20	5.54	5.60	35.78	6.55	8.56	13.00	-1.2000	0.2301
Alb	BL	4.34	0.74	7.70	4.07	0.53	7.39	21.50	0.0667	0.9468
	12W	4.50	0.88	8.90	4.07	0.53	6.72	15.50	0.8667	0.3861
TG	BL	257.60	55.49	9.10	242.44	34.31	6.61	14.50	1.0000	0.3173
	12W	165.00	27.28	5.60	188.56	29.29	8.56	13.00	-1.2000	0.2301

Table 23 summarizes the Mann-Whitney U test results comparing the control and study groups at baseline and after 12 weeks among patients lost to follow-up. At baseline, no significant differences were observed between the groups in all the parameters. After 12 weeks, the study group showed slight improvements in anthropometric parameters (waist circumference, weight, and BMI) and liver function

tests (SGOT and SGPT) compared to the control group, which were not statistically significant. However, there is a possibility that the tendency to improvement in the above parameters might have reached statistical significance if the subjects had continued for the full 24-weeks study duration.

Table 24: Comparison of pre-test and post-test levels of health practices in the study and control groups

Levels	Control group				Study group			
	Pretest (n=45)	**%**	**Post-test** (n=40)	**%**	**Pretest** (n=45)	**%**	**Post-test** (n=36)	**%**
Poor	35	77.8	13	32.5	32	71.1	00	00
Average	10	22.2	21	52.5	13	28.9	5	13.9
Good	00	00	6	15	00	00	31	86.1
Total	45	100	40	100	45	100	36	100

Table 24 compares health practices between the control and study groups at pre-test and post-test. Initially, 71.1% of the study group had poor health practices, compared to 77.8% in the control group. After the intervention, the study group showed a complete absence of poor practices and a significant improvement, with 86.1% achieving a good level. In contrast, the control group still had 32.5% with poor practices and only 15% at a good level. These results highlight a marked improvement in health practices in the study group following the intervention.

SUMMARY

The result analysis of the RCT investigating the impact of supervised and structured diet and exercise in managing NASH revealed notable findings. The study group, subjected to the interventions, exhibited significant improvements in anthropometric measurements, LFT, and TG. This underscores the potential effectiveness of lifestyle modifications in managing NASH. Furthermore, the study group showed better adherence to dietary and exercise recommendations, indicating the importance of supervised interventions in promoting lifestyle changes among NASH patients. These results suggest that supervised and structured diet and exercise interventions could play a pivotal role in NASH management, warranting further exploration in larger, long-term studies to confirm these findings and their potential implications for clinical practice. There is a significant difference in the reduction of liver stiffness by FS score between the study group and the control group after 6 months. Hypothesis $\mathbf{H_1}$ and $\mathbf{H_2}$ is accepted, at the end of the study.

CHAPTER – 5

DISCUSSION

This chapter delves into the major findings of the study, providing a detailed comparison with other studies that have yielded similar results. The main aim of this study was to evaluate the impact of Supervised and Structured Diet and Exercise in management of patients with NASH. The discussion is centred around the study's objective, with a thorough analysis of the collected data. The chapter not only highlights the key results but also views them within the broader context of existing literature, offering a comprehensive understanding of the study's contributions to the field.

In the present randomized control trial, all patients were monitored over 6 months while adhering to a structured and supervised diet and exercise program. Follow-up assessments were conducted at baseline, 6 weeks, 12 weeks, 18 weeks, and 24 weeks. During these follow-ups, patients underwent clinical examinations, weight monitoring (BMI), and blood tests including LFT and lipid profiles. Fibroscan measurements (LSM & CAP values) were performed at baseline and 24 weeks. Our findings revealed significant improvements in BMI, LFT, lipid profiles, and Fibroscan results (LSM & CAP values), and APRI and FIB-4 scores.

5.1 Anthropometric Parameters

Waist Circumference

This RCT aimed to evaluate the effects of a structured diet and exercise regimen on waist circumference among patients with NAFLD over a 24-week period. A total of

90 participants were enrolled and randomly allocated into two groups: the intervention group (n=45) and the control group (n=45). Participants in the intervention group adhered to a structured and supervised diet and exercise program, while those in the control group continued with their usual lifestyle after receiving general counselling on the importance of diet and exercise for NAFLD management, but without specific guidance or supervision. Baseline characteristics, including anthropometric measurements, LFT, lipid profiles, intrahepatic fat (assessed via CAP), and liver fibrosis (measured by LSM), were well-matched between the two groups.

Following the 24-weeks intervention period, the study group demonstrated a pronounced reduction in waist circumference from a baseline measurement of 95.47 cm to 84.78 cm. Conversely, the control group showed minimal change, with waist circumference decreasing from 96.42 cm to 95.60 cm. The progressive decline in waist circumference in the intervention group was observed at various time points throughout the study: baseline (95.47 cm), 6 weeks (90.24 cm), 12 weeks (87.78 cm), 18 weeks (85.28 cm), and 24 weeks (84.78 cm). These findings suggest a sustained and consistent improvement associated with the structured intervention.

The observed reduction in waist circumference aligns with previous studies that have evaluated similar interventions among patients with NAFLD/NASH. Alexis St. George et al. (2020) conducted a comparable RCT in which participants were randomly assigned to one of three groups: moderate-intensity exercise, low-intensity exercise, and a control group. The exercise groups received consistent counselling and supervision, while the control group was only advised on the importance of exercise without monitoring. After a 3-month period, participants in the moderate- and low-intensity exercise groups exhibited significant reductions in waist circumference,

weight, and BMI compared to the control group. Specifically, the intervention groups demonstrated reductions in waist circumference of -2.3±4.4 cm and -1.7±4.3 cm, respectively, while the control group exhibited a minimal increase of +1.4±3.6 cm These results underscore the efficacy of structured exercise training in reducing abdominal obesity and improving clinical outcomes in NAFLD patients [42].

Further supporting these findings, Alireza et al. (2015) conducted an RCT involving clinically diagnosed NAFLD patients divided into three groups: aerobic exercise, resistance exercise, and a control group. Over an eight-week period, participants in the exercise groups received tailored training and supervision from exercise physiotherapists, while the control group did not engage in any structured exercise regimen. The results demonstrated significant improvements in waist circumference, weight, and BMI among participants in both the aerobic and resistance exercise groups compared to the control group, further highlighting the benefits of structured exercise interventions [43].

The effectiveness of structured diet and exercise interventions in reducing waist circumference can be attributed to multiple underlying mechanisms. Firstly, aerobic exercise has been shown to enhance hepatic insulin sensitivity and promote fat oxidation, thereby reducing visceral adiposity, which is strongly associated with waist circumference[44,45]. Moreover, resistance training contributes to muscle mass gain, increasing basal metabolic rate and enhancing overall energy expenditure, which further supports the reduction of abdominal fat [46].

Furthermore, dietary interventions involving caloric restriction and improved macronutrient distribution have been associated with significant reductions in waist circumference and overall fat mass. Reducing carbohydrate intake, particularly

refined sugars and saturated fats, while promoting the consumption of high-fiber foods and lean proteins, has been linked to improved lipid metabolism and decreased visceral fat accumulation [47,48].

Moreover, Ezpeleta et al. (2024) reported a marked reduction in waist circumference among participants undergoing supervised diet and exercise therapy over a three-month period. The study group exhibited a reduction in waist circumference ranging from -6.85 cm to -3.19 cm, whereas the control group demonstrated only minor changes from -2.30 cm to -1.26 cm. These findings reinforce the efficacy of structured interventions in reducing waist circumference among NAFLD patients and are consistent with the results of our present study [49].

Collectively, these findings from various clinical trials provide robust evidence supporting the effectiveness of structured dietary and exercise interventions in reducing waist circumference among NAFLD patients. Such reductions in abdominal obesity are likely to contribute positively to overall metabolic health and potentially mitigate the progression of NAFLD to more severe disease states.

Weight

Our 24-week study involving a supervised diet and exercise regimen demonstrated a significant reduction in weight among the study group compared to the control group. The data indicates a continuous downward trend in weight for the study group: from an initial baseline of 82.13 kg, reducing to 80.27 kg at 6 weeks, 78.58 kg at 12 weeks, 74.53 kg at 18 weeks, and 70.72 kg at 24 weeks. In contrast, the control group showed minimal changes: from a baseline of 82.53 kg to 81.96 kg at 6 weeks, 82.07 kg at 12 weeks, 82.08 kg at 18 weeks, and 81.40 kg at 24 weeks.

The significant weight reduction observed in the study group can be attributed to several factors, including the supervised diet that likely induced a consistent caloric deficit essential for weight loss [50]. Additionally, the structured exercise regimen promoted higher energy expenditure, contributing to the overall weight reduction [51]. The combination of dietary restrictions and exercise may have had a synergistic effect of enhanced metabolic rate and promoted fat oxidation [52]. Furthermore, aerobic exercise improves insulin sensitivity, which can aid in weight loss among individuals with metabolic conditions like NAFLD [53].

Our findings are consistent with recent studies demonstrating that structured diet and exercise interventions are effective in promoting weight loss among NAFLD patients. A study by Ezpeleta et al. (2024) compared alternate-day fasting with exercise, fasting alone, exercise alone, and a control group. The combination group, which alternated between fasting (600 kcal per day) and normal intake alongside moderate-intensity aerobic exercise, showed significantly greater weight reduction than the exercise-only and control groups after three months. These findings align with our results, which revealed even greater weight loss over our six-month follow-up [52].

Similarly, Araceli et al. (2019) conducted a study involving NAFLD obese patients assigned to two calorie-restricted diets: the American Heart Association (AHA) diet and the Fatty Liver in Obesity (FLiO) diet, both combined with 10,000 steps of daily activity for six months. The study reported significant weight loss (9.7% and 10.1%) and BMI reduction (AHA: 33.7 to 30.2, FLiO: 33.3 to 30.1). Our findings align with these results, further reinforcing the benefits of structured dietary and exercise interventions for NAFLD [54].

In addition, a recent study by Kim et al. (2022) examined the effects of high-intensity interval training (HIIT) and dietary modifications on weight loss and liver health in NAFLD patients. They reported that participants undergoing HIIT combined with a Mediterranean-style diet exhibited significant reductions in weight and liver fat content over a 24-week period [55].

Furthermore, Zhang et al. (2023) conducted a meta-analysis of various interventions for NAFLD patients, including supervised exercise regimens and dietary adjustments. Their findings confirmed that combined interventions are consistently more effective at promoting weight loss and improving liver health compared to either intervention alone [56].

The consistent weight reduction observed in our study supports the notion that a supervised diet and exercise regimen can effectively reduce weight among NAFLD patients. The findings are corroborated by similar studies emphasizing the importance of combining dietary restrictions with exercise for optimal weight loss. Further research could explore the mechanistic pathways involved and the long-term effects of such interventions.

Body Mass Index (BMI)

Our study demonstrated consistent improvements in BMI among participants in the study group over the course of 24 weeks. The BMI decreased progressively from 31.73 at baseline to 31.00 at 6 weeks, 30.32 at 12 weeks, 29.45 at 18 weeks, and 28.00 at 24 weeks. In contrast, the control group exhibited minimal changes, with BMI starting at 30.29 and showing slight fluctuations: 30.18 at 6 weeks, 30.25 at 12 weeks, 30.31 at 18 weeks, and 30.30 at 24 weeks. No significant reduction was observed in the control group over the same period.

The significant improvement in BMI observed in our study group can be attributed to several factors, including the longer intervention duration of 24 weeks, which is more effective in producing significant BMI reductions compared to shorter-term interventions [57]. Additionally, the combination of supervised dietary interventions and physical activity proved more effective in enhancing BMI improvement than either intervention alone [58,59]. Regular exercise and dietary adjustments contribute to energy expenditure and fat oxidation, resulting in reduced BMI [56,59]. Furthermore, adopting specific dietary patterns, such as the Mediterranean diet, has demonstrated positive effects on BMI and liver health in NAFLD patients [58].

Previous studies examining diet and exercise interventions for NAFLD/NASH have reported varying outcomes concerning BMI improvement. For instance, Bertha et al. (2019) conducted a 6-month randomized study that resulted in substantial BMI reductions: from 33.7 to 30.2 in the study group and from 33.3 to 30.1 in the control group. This study supports the notion that structured dietary and exercise interventions can effectively reduce BMI [59].

Similarly, Amal et al. (2024) investigated the effects of a Mediterranean diet and lifestyle interventions in 200 NAFLD patients. Their findings revealed a substantial decrease in BMI in the intervention group compared to the non-intervention control group, highlighting the effectiveness of comprehensive lifestyle modification [58].

On the other hand, a study by Ryan et al. (2020) compared a Mediterranean diet with a low-fat, high-carbohydrate diet among non-diabetic patients over a shorter duration of six weeks. Although reductions in hepatic fat content were observed in both groups, no significant weight loss or BMI improvement was noted. This discrepancy

suggests that shorter intervention periods may be insufficient for achieving meaningful BMI reduction [57].

Additionally, a meta-analysis by Zhang et al. (2023) confirmed that combined interventions involving supervised exercise and dietary adjustments consistently yield better BMI reduction outcomes compared to singular interventions [56].

In conclusion, the substantial BMI improvements observed in our study emphasize the importance of long-term interventions involving structured dietary and exercise regimens. These findings align with previous studies from 2018–2024, further supporting the effectiveness of comprehensive lifestyle modification in improving BMI among NAFLD patients.

5.2 Blood Parameters

Liver Function Tests

The significant reduction in liver enzymes (SGOT and SGPT) seen in the intervention group of our study shows that structured diet and exercise programs can effectively reduce liver inflammation in patients with NAFLD/NASH. In our study, SGOT levels dropped from 50.84 to 19.75, and SGPT levels from 52.96 to 20.61, while the control group had smaller reductions, with SGOT going from 49.11 to 33.75 and SGPT from 57.04 to 42.85. This improvement in the intervention group may be due to factors like calorie reduction, better insulin sensitivity, and lower liver fat, all achieved through combined diet and exercise.

Recent research supports these findings. A 2023 review found that online lifestyle programs combining dietary advice and exercise helped lower ALT levels in NAFLD patients, proving that combining dietary changes with exercise is effective [60].

Additionally, guidelines recommend losing 7%–10% of body weight through calorie-restricted diets and regular exercise to reduce liver enzymes and improve liver health in NAFLD patients [61].

The improvements observed could be due to various reasons. Exercise, especially aerobic and resistance training, helps improve insulin sensitivity and mitochondrial function. Aerobic exercise is particularly good at reducing liver fat, while resistance training supports muscle health and improves metabolism [49,53].

Previous studies also support our findings. For example, Romeo et al. (2017) showed that combining diet changes with aerobic exercise led to better reductions in SGOT (from 50.9 to 30.2) and SGPT (from 86.42 to 43.17) than diet alone [62]. Maharshi et al. (2023) also reported improvements in liver enzymes when diet and exercise were combined, while control groups without structured interventions saw little change [63].

In conclusion, our study aligns with other research suggesting that structured lifestyle changes are essential for effectively managing NAFLD/NASH. The significant reduction in liver enzymes achieved through combined diet and exercise likely results from calorie reduction, improved insulin sensitivity, and decreased liver fat. These findings highlight the importance of supervised lifestyle interventions in treating NAFLD/NASH patients.

Triglyceride (TG)

The present study demonstrated a substantial reduction in serum TG levels within the intervention group over the 24-week period, with levels declining from 241.78 mg/dL at baseline to 142.78 mg/dL at the conclusion of the study. In contrast, the control group exhibited negligible changes, with baseline TG levels of 242.04 mg/dL and

241.45 mg/dL at 24 weeks. The marked improvement observed in the intervention group can be attributed to several interconnected mechanisms, primarily related to caloric deficit, enhanced insulin sensitivity, and improved lipid metabolism resulting from the integration of dietary and exercise interventions.

The reduction in TG levels observed in our study is consistent with emerging evidence highlighting the efficacy of combined dietary and physical activity interventions in ameliorating dyslipidemia associated with NAFLD/NASH. Notably, dietary patterns emphasizing reduced caloric intake, particularly those aligned with the Mediterranean diet, have been associated with improved lipid profiles, including significant reductions in serum TG concentrations [64]. Moreover, structured exercise regimens, including aerobic and resistance training, have demonstrated their capacity to enhance mitochondrial function and improve insulin sensitivity, contributing to favorable lipid metabolism and reduced hepatic fat accumulation [65].

Recent systematic reviews and meta-analyses further support the notion that lifestyle interventions incorporating both dietary modification and physical exercise are more effective in reducing serum TG levels than interventions focused solely on dietary changes. For instance, a 2021 systematic review reported a trend toward significant improvement in TG levels among patients with NAFLD adhering to Mediterranean diet-based interventions [66]. Furthermore, a RCT conducted in 2025 emphasized the importance of comprehensive lifestyle changes, demonstrating significant reductions in TG levels following the implementation of diversified interventions encompassing both diet and physical activity [67].

The underlying mechanisms driving these improvements can be attributed to enhanced lipid metabolism and improved insulin sensitivity resulting from aerobic

and resistance training. Such adaptations contribute to reductions in hepatic fat content, ultimately manifesting as decreased serum TG levels [68]. The findings from our study align with the broader literature, emphasizing the critical role of synergistic lifestyle interventions in mitigating hypertriglyceridemia and associated metabolic complications in patients with NAFLD/NASH.

In conclusion, the present study proves the efficacy of supervised diet and exercise interventions in significantly reducing serum TG levels among patients with NAFLD/NASH. The findings emphasize the importance of adopting a multifaceted approach to lifestyle modification that addresses dietary intake, physical activity, and metabolic health to achieve meaningful improvements in lipid profiles and potentially attenuate disease progression.

5.3 Non-invasive assessments

Non-invasive assessments, such as Fibroscan, have been strongly recommended by the European Association for the Study of the Liver (EASL) and the American Association for the Study of Liver Diseases (AASLD) for evaluating liver fibrosis in NAFLD patients due to their non-invasiveness, high diagnostic accuracy, and reproducibility [69,70]. Vibration-controlled transient elastography (VCTE), which provides LSM values, has emerged as a widely used and validated tool for detecting liver fibrosis, particularly in NAFLD/NASH patients. Studies have consistently reported the high diagnostic accuracy of transient elastography (TE) in predicting advanced fibrosis, with meta-analyses and large cohort studies highlighting its utility in clinical practice [71,72].

LSM plays a pivotal role in assessing fibrosis, which remains a primary determinant of prognosis in NAFLD patients. Advanced fibrosis is associated with an increased

risk of liver-related complications and cardiovascular mortality, making early detection and monitoring essential [73].TE has been acknowledged as a reliable, non-invasive, and cost-effective technique for screening and monitoring liver stiffness. Studies conducted in various populations, including Indian NAFLD patients, have demonstrated comparable diagnostic thresholds to those used in Western populations, thereby validating its applicability across diverse demographics [74].

Recent guidelines by the American College of Gastroenterology have established cut-off values of less than 6 kPa to rule out significant fibrosis and 8.2 kPa to confirm it, providing clear benchmarks for clinical assessment [61]. In our present study, NAFLD/NASH participants with baseline LSM scores ranging from more than 7 kPa (indicating significant fibrosis) to less than 14 kPa (excluding advanced fibrosis and cirrhosis) were enrolled. The intervention group, which adhered to a structured diet and exercise regimen, exhibited a substantial reduction in mean LSM values from 10.96 to 6.84 over the study period. Conversely, the control group showed a negligible decrease, with mean LSM values changing from 11.16 to 10.47.

The improvements observed in our study can be attributed to several interrelated mechanisms, including enhanced insulin sensitivity, caloric deficit, reduction in hepatic fat content, and improved mitochondrial function due to structured lifestyle interventions [75]. Consistent with our findings, George et al. (2023) reported minimal changes in LSM values among patients subjected to Mediterranean or low-fat diets over a three-month period. The lack of significant improvement in their study could be due to the short intervention duration and the absence of an exercise component, highlighting the importance of incorporating physical activity for meaningful changes in liver stiffness [76].

In contrast, Sofiya et al. (2022) demonstrated substantial reductions in LSM values across groups that followed Mediterranean diets with high meal frequency and those combined with physical activity over a 6 to 12-month period. This underscores the role of extended interventions and the inclusion of physical activity in effectively managing liver stiffness in NAFLD/NASH patients [75]. Furthermore, recent studies continue to advocate for the integration of dietary modification and exercise as a synergistic approach for reducing liver stiffness and improving overall liver health [77,78].

Controlled Attenuation Parameter (CAP)

The CAP, measured through Fibroscan, is a reliable non-invasive tool increasingly utilized for assessing hepatic steatosis in NAFLD patients. It offers higher sensitivity and objectivity than conventional ultrasound (USG) and is recommended by the European Association for the Study of the Liver (EASL) for diagnosing hepatic steatosis, with a diagnostic threshold of >275 dB/m [79]. CAP provides an accurate, quantitative measure of hepatic fat content, making it a valuable tool for early detection and monitoring of NAFLD progression and treatment effectiveness.

In this study, CAP values were classified based on standardized thresholds: S0 (<238 dB/m, <10% fat), S1 (238-260 dB/m, 11%-33% fat), S2 (260-290 dB/m, 34%-66% fat), and S3 (>290 dB/m, 67% or more fat), as established by Abhishek et al. (2022) [80]. Our findings demonstrated a substantial decrease in CAP values among the study group from 277.58 to 213.17 dB/m over six months. In contrast, the control group showed only a slight decrease from 274.87 to 268.48 dB/m over the same period. This significant improvement in the study group highlights the efficacy of structured

lifestyle interventions, specifically combining diet and exercise, in reducing hepatic fat content.

The mechanisms contributing to these improvements likely involve enhanced lipid oxidation, reduced hepatic lipogenesis, and improved insulin sensitivity. Regular physical activity, particularly aerobic exercises, promotes fatty acid oxidation and mitochondrial efficiency, thereby reducing intrahepatic triglyceride accumulation. Concurrently, dietary interventions aimed at caloric restriction and optimized nutrient composition contribute to decreased lipid synthesis and overall metabolic enhancement.

These findings are further supported by Isabella et al. (2022), who compared various interventions, including the Mediterranean diet, low glycaemic index diet (LGID), aerobic and resistance exercises, and their combinations over 45 and 90 days. Their study reported significant CAP reductions across all intervention groups except the control group, with the most substantial improvements observed in groups combining exercise and supervised diet [81]. Our study's longer duration of six months demonstrated even more pronounced CAP reductions, highlighting the importance of sustained interventions for optimal improvements in hepatic fat content.

This study contributes to the growing evidence supporting CAP as an effective tool for monitoring treatment response in NAFLD patients undergoing lifestyle interventions. The use of CAP measurement provides clinicians with a non-invasive, accurate, and efficient approach for evaluating therapeutic outcomes and guiding patient management.

Non-Invasive Assessment of Liver Fibrosis: APRI and FIB-4 scores

Various blood parameters, either individually or in combination, have been extensively evaluated for non-invasive assessment of liver fibrosis. Among these, the APRI and FIB-4 scores are the most commonly employed. The FIB-4 score, in particular, is preferred due to its widespread availability and practicality for bedside use via digital platforms such as laptops and cell phones.

The APRI score is a well-established tool for evaluating liver fibrosis severity, where higher scores are indicative of more advanced fibrosis. In the present study, the baseline APRI scores were identical in both the control and study groups (0.27), suggesting a comparable level of fibrosis initially. After 24 weeks of intervention, the APRI score in the control group decreased marginally from 0.27 to 0.21, indicating no significant improvement. Conversely, the study group demonstrated a substantial reduction in APRI score from 0.27 to 0.15, which was statistically significant ($p<0.0001$).

The FIB-4 score, another commonly used blood-based non-invasive test, incorporates AST, ALT, platelet count, and age to assess liver fibrosis. The baseline FIB-4 scores were 0.63 for the study group and 0.59 for the control group, with a mean difference of 0.06 that was not statistically significant. After the 24-week intervention, the FIB-4 score decreased from 0.63 to 0.42 in the study group, while the control group showed a reduction of only 0.22. This result was statistically significant ($p<0.0001$).

Several studies have evaluated APRI and FIB-4 scores for liver fibrosis assessment. Behinaz et al. (2021) conducted a study involving 205 NAFLD patients using fibroscan, APRI, and FIB-4 scores. Their findings suggested that both APRI and FIB-4 are valuable tools for assessing liver fibrosis, with APRI appearing as a suitable

alternative to fibroscan [82]. In another recent study by Kumar et al. (2024), the diagnostic accuracies of APRI and FIB-4 scores in predicting various fibrosis stages were compared against fibroscan in NAFLD/NASH patients. This study calculated AST/ALT ratios, APRI, and FIB-4 scores using standard formulas alongside fibroscan values. The authors reported that higher AST/ALT ratios, APRI, and FIB-4 scores corresponded with more severe fibrosis grades. Moreover, APRI exhibited the highest correlation with fibroscan findings, particularly for advanced liver fibrosis [83].

Additionally, a study by Catalina et al. (2024) closely resembled the present study's methodology. In their trial, patients were divided into three groups: (a) Conventional diet (CD) according to AASLD guidelines with energy restriction and 10,000 steps per day; (b) Mediterranean diet with high meal frequency (MDHMF), seven meals per day, and 10,000 steps per day; and (c) Mediterranean diet with physical activity (MDPA), including four to five meals per day and 35-minute exercise sessions three times a week. These groups were closely monitored for six or twelve months, with weekly follow-ups and dietary adherence tracking. Significant improvements in anthropometric, metabolic, and liver parameters were recorded in all groups at 6 and 12 months. The findings of the present study, which employed a similar 6-month supervised intervention, are consistent with those of Catalina et al., highlighting the efficacy of structured diet and exercise regimens in ameliorating NAFLD/NASH symptoms [84].

Despite the evidence supporting lifestyle interventions for NAFLD management, integration into routine clinical practice remains challenging. Barriers such as inadequate training, resources, and time continue to impede effective implementation. Additionally, the absence of multidisciplinary teams, essential for providing comprehensive care, further limits the widespread adoption of these interventions [83].

Patient-related factors, including limited awareness about NAFLD and inadequate social support, can adversely affect adherence to lifestyle modifications. Addressing these issues requires a multifaceted approach involving education, personalized lifestyle strategies, and interventions targeting specific barriers and motivators. Such strategies have the potential to enhance the adoption and long-term adherence to lifestyle interventions as the cornerstone of NAFLD/NASH management [82,84].

The results of this study strongly support the efficacy of supervised diet and exercise interventions in improving liver function and metabolic control among NAFLD/NASH patients. Future research should focus on the synergistic effects of combining lifestyle modifications with emerging pharmacological therapies for NASH. Furthermore, identifying reliable surrogate endpoints capable of predicting long-term clinical outcomes remains a critical area of investigation. Integrating novel biomarkers with traditional non-invasive tests such as APRI and FIB-4 could enhance diagnostic accuracy and facilitate the early detection of liver fibrosis progression.

Overall, this study contributes to the growing literature supporting the implementation of supervised lifestyle interventions in the management of NAFLD/NASH. Larger, long-term randomized controlled trials are necessary to validate the present findings and assess the feasibility and cost-effectiveness of these interventions across diverse patient populations.

Health practices assessment

The comparative analysis of health practices between the control and study groups before and after the intervention provides valuable insights into the effectiveness of structured health interventions. At the pre-test stage, most participants exhibited poor health practices, with 71.1% of the study group and 77.8% of the control group falling

into this category. However, following the intervention, the study group demonstrated remarkable improvement, with 86.1% achieving a good level of health practices and no participants remaining in the poor practices category. In contrast, the control group still showed significant deficiencies, with 32.5% having poor practices and only 15% achieving a good level at the post-test stage.

The substantial improvement within the study group can be attributed to several key factors. First, the structured, nurse-led intervention likely played a critical role in raising awareness, motivation, and adherence to health practices. Research has consistently shown that effective health education and personalized counselling are crucial for promoting lifestyle changes in patients with NASH and NAFLD [60,85]. Such tailored interventions provide the necessary knowledge and empower patients to actively manage their health through self-monitoring and consistent behavioral changes.

Furthermore, the intervention's comprehensive design, which integrated personalized lifestyle modifications, technological support, and continuous follow-ups, significantly contributed to its success. Digital health tools, particularly mobile app-based platforms, have demonstrated considerable potential in facilitating sustained lifestyle changes. Funuyet-Salas et al. (2024) showed that mobile app-based coaching interventions effectively enhance adherence to lifestyle modifications by providing continuous support, feedback, and monitoring. This technological integration likely improved adherence rates and contributed to the significant progress observed in the study group [86].

Psychological and behavioral aspects also played an essential role in the observed improvements. Studies suggest that interventions tailored to address individual

beliefs, motivations, and readiness to change result in better adherence compared to generalized recommendations [85]. Incorporating motivational interviewing techniques and setting clear, achievable goals within the intervention framework likely enhanced participants' commitment to adopting healthier practices.

Conversely, the control group's persistently poor health practices can be explained by the absence of structured guidance, minimal external support, and lack of consistent monitoring. Standard care without targeted interventions is often insufficient to drive effective lifestyle changes [60]. Without ongoing encouragement, personalized feedback, and educational support, patients struggle to maintain the necessary lifestyle adjustments, especially when faced with challenges like limited knowledge, inadequate resources, or low motivation.

These findings emphasize the importance of structured, nurse-led interventions complemented by technological tools in effectively managing NASH. The significant improvement observed in the study group demonstrates the potential of a multidisciplinary approach combining education, behavioral strategies, and digital health resources. Future studies should focus on optimizing these interventions to enhance accessibility and effectiveness across diverse patient populations and clinical settings.

CHAPTER - 6

SUMMARY

The current study was carried out to assess the impact of a supervised and structured diet and exercise regimen in managing patients with NASH. In this randomized controlled trial, patients followed a structured program over six months, with follow-up assessments conducted at baseline, 6 weeks, 12 weeks, 18 weeks, and 24 weeks. During these follow-ups, clinical examinations, BMI measurements, and blood tests, including LFT and lipid profiles, were performed. Additionally, Fibroscan measurements (LSM & CAP values) were done at baseline and at 24 weeks. The results showed significant improvements in BMI, LFT, lipid profiles, Fibroscan values (LSM & CAP), and APRI and FIB-4 scores.

Objective:

- To assess routine health practices among NASH subjects
- To assess the efficacy of supervised exercise and structured diet regimen in subjects with non-alcoholic steatohepatitis (NASH) attending a tertiary care teaching hospital, in North Karnataka - as

Research Hypotheses:

All the hypothesis will be tested at 0.05 level of significance.

H_1: The mean post-test health practice scores of NASH subjects after intervention will significantly differ than mean pre-test health practice scores.

H_2: The post-test of liver stiffness measurement after intervention will significantly reduce than pre-test of LSM.

Hypothesis **H_1** and **H_2** is accepted, at the end of the study.

Major Findings of the study:

The findings from this RCT evaluating the impact of supervised and structured diet and exercise interventions in NASH management are as follows …

- The study group showed a substantial decrease in waist circumference from the baseline, decreasing from 95.47 to 84.78, compared to the control group, wherein it dropped from 96.42 to 95.60.
- Significant and persistent weight loss was seen in the study group from 82.13 at baseline to 70.72 as compared to a drop from 82.13 to 81.40 in the control group at the end of the study period.
- The study group's BMI showed a significant decline from 31.73 at the beginning of the study to 28.00 at the end of the study period, compared to a insignificant decrease in the control group from 30.29 to 30.30.
- In the study a significant reduction in SGOT from 50.84 to 19.75 and SGOT levels from 52.96 to 20.61 were recorded in the study group as compared to the control group wherein SGOT levels changed from 49.11 to 33.75 and SGPT from 57.04 to 42.85.
- The serum triglyceride levels showed a significant improvement from 241.78 to 142.78 in the study group compared to a minimal change from 242.04 to 241.45 in the control group at the end of the study period.
- The LSM which is the most important parameter to demonstrate the effectiveness of a structured and supervised diet and exercise in the management of NASH showed a significant improvement from 10.96 to 6.84 in the study group compared to the control group wherein small drop from 11.16 to 10.47 was recorded.

- Similarly, the (CAP value) CAP that represents the hepatic fat content showed a significant decrease from 277.58 to 213.17 in the study group compared to a slight decrease from 274.87 to 268.48 in the control group.
- The APRI score which is a marker of liver fibrosis dropped significantly in the study group from 0.27 to 0.15. The control group recorded a drop from 0.27 to 0.21 only, suggesting a highly significant P value (<0.0001).
- The FIB 4 score, another marker of liver fibrosis improved from 0.63 to 0.42 in the study group. The control group showed a reduction from 0.59 to 0.52 which was statistically significant (P<0.0001).
- Finally, the study group demonstrated better adherence to dietary and exercise recommendations, highlighting the importance of supervised interventions in promoting lifestyle modifications among NASH patients. These findings underscore the potential of lifestyle modifications as a crucial component of NASH management and provide valuable insights into the benefits of incorporating dietary and exercise interventions into the standard care of NASH patients. However, further research is needed to explore the long-term effects of these interventions, optimal dietary and exercise regimens, and the potential role of adjunctive therapies in the management of NASH.

CHAPTER - 7

CONCLUSION

This study demonstrates that supervised and structured diet and exercise interventions can significantly improve anthropometric parameters, LFT, metabolic parameters and non-invasive liver fibrosis test scores in patients with NASH. Our study findings highlight the critical role of lifestyle modifications with active and supervised patient participation in managing NASH. Our study strongly supports the role of supervised and structured diet and exercise interventions in improving liver function, reversing liver inflammation and fibrosis and overall having a positive impact on the metabolic health.

The rising incidence in epidemic proportions of the Metabolic Syndrome, which includes obesity, diabetes mellitus, and hypertension, is a major contributor to the prevalence of fatty liver disease. Timely health interventions can prevent or delay the onset of these risk factors, thereby reducing the incidence of liver disease. Future research to demonstrate the combined role of supervised life style changes with new emerging drug therapies is in place. Public health initiatives are essential for the prevention, early diagnosis, and treatment of NAFLD/NASH and Metabolic Syndrome, as well as for minimizing their negative health impacts. While our study emphasizes the effectiveness of lifestyle changes in resolving and potentially reversing NASH, further research is needed to evaluate the long-term effects of these interventions, determine the most effective regimens, and consider the role of adjunctive therapies.

NURSING IMPLICATIONS

1. **Nursing Practice:** Nurses play a crucial role in the management of NAFLD by educating patients about the condition, its risk factors, and its progression. They provide valuable guidance on lifestyle modifications, including dietary changes, exercise routines, and weight management, while also counselling patients on the importance of adhering to prescribed medications. Additionally, nurses are essential in monitoring liver function, identifying signs of disease progression, and evaluating the effectiveness of treatment interventions. By collaborating with healthcare providers, they can develop personalized care plans that optimize the management of NAFLD and its associated comorbidities. Furthermore, given the complex nature of NAFLD and its links to various metabolic conditions, nurses facilitate multidisciplinary care by coordinating communication among healthcare professionals, including physicians, dieticians, physical therapists, and psychologists, ensuring holistic support that meets the diverse needs of patients.
2. **Nursing Education:** Nursing education should emphasize the promotion of evidence-based practice by developing critical appraisal skills that enable students to integrate research findings into clinical decision-making. Students need to learn how to evaluate research studies on NAFLD management, including randomized controlled trials, systematic reviews, and clinical guidelines. Furthermore, integrating NAFLD content into the curriculum is essential for providing a comprehensive understanding of this liver disorder, covering its pathogenesis, risk factors, clinical manifestations, and management strategies across courses such as pathophysiology, pharmacology, adult health, and community health nursing. Additionally, nursing students should have supervised clinical practice experiences in settings where they can engage with patients

suffering from NAFLD, such as primary care clinics, gastroenterology units, or liver transplant centers, allowing them to observe and participate in patient assessment and management under the guidance of experienced nursing preceptors.

3. **Nursing Administration:** Nursing administrators should prioritize staff education and training on NAFLD, focusing on its pathophysiology, risk factors, clinical manifestations, and management strategies. This can be achieved through workshops, seminars, and online training modules designed to meet the specific needs of nursing staff in areas where NAFLD patients are frequently encountered. Additionally, administrators can implement community outreach initiatives to raise awareness about NAFLD, its risk factors, and preventive measures by collaborating with local organizations, schools, and community centers. These initiatives may include educational sessions, screenings, and the distribution of resources aimed at promoting lifestyle modifications, medication adherence, and self-management skills among at-risk individuals and patients with NAFLD.
4. **Nursing Research:** Longitudinal research is crucial for understanding the long-term effects of lifestyle modifications, such as diet and exercise, on NAFLD management and patient outcomes, as well as for evaluating the long-term prognosis of affected individuals. These studies can provide insights into the risks of disease progression and complications like fibrosis, cirrhosis, and hepatocellular carcinoma (HCC), thereby guiding clinical practice and encouraging adherence to healthy behaviors. Additionally, further research is needed to optimize lifestyle interventions that promote sustained weight loss and improve metabolic health while addressing health disparities in NAFLD prevalence and access to care among different populations. Nurses play a vital role in advancing knowledge and improving clinical outcomes by participating in

research, implementing evidence-based guidelines, and engaging in continuous professional development to enhance the quality of care for patients with NAFLD.

LIMITATIONS:

Despite the promising findings, there are few limitations to consider in this study. The sample size was relatively small, which may limit the generalizability of the results. The study duration was relatively short, and the long-term effects of supervised and structured diet and exercise interventions on NASH management remain unknown. The study also lacked a placebo group, which could have provided additional insights into the efficacy of the interventions. Moreover, the study relied on self-reported dietary and exercise adherence, which may introduce bias. The study did not explore potential confounding factors such as medication use, comorbidities, and socioeconomic status, which could influence the outcomes. Future research should address these limitations to provide a more comprehensive understanding of the role of lifestyle modifications in NASH management.

OUTCOME OF THE STUDY:

- The study resulted in the development of a module titled “TRANSFORMING LIVES WITH LIVER HEALTH”.

RECOMMENDATIONS:

Based on the findings of the study, the following recommendations can be suggested:

- Conduct longitudinal studies with larger sample sizes and extended follow-up periods to evaluate the long-term effects of interventions on NASH progression and patient outcomes.

- Implement comparative effectiveness studies to identify the most effective dietary and exercise regimens for managing NASH.
- Investigate the potential benefits of adjunctive therapies, such as pharmacological agents or bariatric surgery, alongside lifestyle modifications for improved NASH management.
- Explore the impact of lifestyle interventions on other metabolic complications related to NASH, including cardiovascular disease and type 2 diabetes, to gain a comprehensive understanding of their benefits.
- Continue research in these areas to clarify the role of lifestyle modifications in managing NASH and enhancing patient outcomes.

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ANNEXURES

ANNEXURE I

ETHICAL CLEARANCE CERTIFICATE

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Formerly known as KLE University)
(Deemed-to-be-University established u/s 3 of the UGC Act, 1956)
Accredited **'A' Grade** by NAAC (2nd Cycle) Placed in **Category 'A'** by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India
☎: 0831-2444444 **FAX:** 0831-2493777 **Web:** http://www.kledeemeduniversity.edu.in **E-mail**: info@kledeemeduniversity.edu.in

Ref.No.KAHER/EC/21-22/ 014 29th July 2021

To,
Ms. Geeta Desai,
Part-Time Ph.D. Research Scholar,
2020-21Batch, Faculty of Nursing,
KAHER, Belagavi.

Dear Research Scholar,

The KAHER Ethics Committee on Human Subjects for Ph.D. Research Project met on **the 7th and 8th June, 2021** to consider your application for approval of the research project **"Impact of supervised and structured diet and exercise in management of patients with Non alcoholic Steatohepatitis-A Randomized Controlled Trial"**

As there are no ethical issues involved in your proposed research project, the committee has provided approval for this research project.

You are requested to report to Ethical Committee of the following:

1. Any deviation from or change of the protocol.
2. Any changes in study documents.

(Dr. Sheetal U. Harakuni)
Member-Secretary
Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.

(Dr. B.C. Kotintot)
Chairman
Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.

CC to:

- Special Officer to Hon. Vice Chancellor, KAHER, Belagavi
- The Registrar, KAHER, Belagavi.
- The Director Research Foundation, KAHER, Belagavi.
- The Director Academic Affairs, KAHER, Belagavi.

ANNEXURE II

PERMISSION LETTER

KLES
DR. PRABHAKAR KORE HOSPITAL
&
MEDICAL RESEARCH CENTRE
NEHRUNAGAR, BELAGAVI-590010.
KARNATAKA - INDIA

ಕೆ.ಎಲ್.ಇ. ಸಂಸ್ಥೆಯ
ಡಾ. ಪ್ರಭಾಕರ ಕೋರೆ ಆಸ್ಪತ್ರೆ ಮತ್ತು
ವೈದ್ಯಕೀಯ ಸಂಶೋಧನಾ ಕೇಂದ್ರ
ನೆಹರು ನಗರ, ಬೆಳಗಾವಿ - 590 010, ಕರ್ನಾಟಕ

Phone : 0831 - 2473777 (16 Lines)
Fax : 0831 - 2470732
E-mail : medicaldirector@klehospital.org
Website : http://www.klehospital.org

REF.NO: KLES/Dr.PK-HOSP/ADM-CS/GEN/21-22/ 3275 Date: 26 October 2021

To
The Principal
KAHER Institute of Nursing Sciences
Nehru Nagar, Belagavi

Sub: Permission to conduct PhD Dissertation work at KLES Dr Prabhakar Kore Hospital & MRC, Belagavi

Madam,

1. Kindly refer to your letter dated 19th October 2021 on the subject mentioned above to the undersigned.

2. After perusal, the Medical Director & Chief Executive has permitted Ms Geeta Desai, part time research scholar of Doctor of Philosophy in nursing to conduct the PhD dissertation work. The topic chosen is entitled 'Impact of supervised and structured diet and exercise in Management of patients with Non Alcoholic Steatohepatitis- A Randomized controlled trial' under the guidance of Dr Santosh Hajare, Professor and HOD, Dept of Gastroentrology, KLES Dr PK Hospital & mRC, Belagavi. The study would be entirely conducted at the KLES Dr Prabhakar Kore Hospital & MRC, Belagavi in the Department of Gastroentrology OPD from October 2021 to January 2023.

3. The hospital will not have any financial implications for the study. However, any incidental expenses occur to be borne by the investigators.

4. As per the hospital policy, you are **NOT** permitted to give away any information/materials/data/statistics of the hospital to a third party. You will not send the information gathered in the hospital for publication in any form to any individual/organization. You cannot modify, copy, reproduce, republish, upload, post, transmit or distribute materials of the hospital's documents. If published, the research outcome should mention the conflict of interest and financial/any reimbursement received by the beneficiary. The investigator's suitable acknowledgement of the institution about the source of research material obtained to be mentioned, which the institution will appreciate. We wish you the best of luck in your research endeavour.

Thanking you,

Yours faithfully,

Administrator-CS (Academics)
For **Medical Director & Chief Executive**

Copy to:
- **Ms Geeta Desai**
  Part time research scholar of Doctor of Philosophy (PhD) in Nursing Sciences
  Department of Nursing Sciences
  KAHER Institute of Nursing Sciences, Belagavi
- **Dr Santosh Hajare-** Prof & HOD–Dept of Gastroentrology, KLES Dr PK Hospital, Belagavi

Sushma/D/ADM-CS/PL

ANNEXURE –III - INFORMED CONSENT FORM

TITLE: "IMPACT OF SUPERVISED AND STRUCTURED DIET AND EXERCISE IN MANAGEMENT OF PATIENTS WITH NON-ALCOHOLIC STEATOHEPATITIS – A RANDOMIZED CONTROLLED TRIAL''.

Investigator: MRS .GEETA S DESAI

Guide: DR. SANTOSH HAJARE

Co-guide: DR SUMITRA L ARIBENCHI

Objective: To assess the effectiveness of supervised and structured diet and exercise regimen in non-alcoholic steatohepatitis (NASH) in the population of North Karnataka.

Introduction: You are being invited to participate in this study "Impact of supervised and structured diet and exercise in management of patients with non-alcoholic steatohepatitis. A randomized controlled trial" which is being conducted by Mrs. .Geeta S Desai ,Ph.D. research scholar at KLE Academy of Higher Education and Research ,under the guidance of Dr. Santosh Hajare MD DM DNB(GASTRO) PROFESSOR and co-guidance of Dr. Sumitra L Aribenchi DEAN FACULTY OF NURSING , INS BELAGAVI.

Explanation of Procedure: In this study, you will have to answer some questions about socio-demographic details and self-rated abilities of physical health practices, dietary practices and your medical history. You will be in regular communication with the investigators via telephone or face to face meets for the study period.

You will be told about certain beneficial exercises and told to perform them in a supervised manner as per our study schedule. Regular communication will be conducted with regard to meals consumed and your dietary practices in order to reach the optimum fitness goal.

Blood tests will be done in the in-hospital laboratory as per the study schedule.

Withdrawal From The Study: Your participation in this study will be voluntary. You are free to decide whether to participate or not in the study. In case you decide not to participate in the study, you will be able to withdraw your participation.

Possible Risk: There will be no any risk involved in the study. The interview will only be used for the sake of information regarding assessment of the effectiveness of supervised and structured diet and exercise regimen in non-alcoholic steatohepatitis (NASH) population. Blood investigations will be collected safely by a licensed technician in the hospital laboratory.

Privacy and Confidentiality: Your identity will not be revealed. All the information collected will be coded so that no one will know your identity. The data collected from you will be kept confidential and only aggregated data will be published.

Financial Incentives: You will not receive any payment for participating in this study.

Cost of study: The cost of the study will be borne by the investigator. There will be no additional cost by you to participate in this study.

Authorization of Publication: Results of this study may be published for scientific purposes and/or presented to scientific groups; however you will not be identified.

Question: If you have any questions about the study, you should contact Ms.GEETA S DESAI (Ph.D. Scholar, JNMC, Nehru Nagar, Belagavi) Mobile no-9741757838 Email Id- sgeeta.desai@gmai.com or guide DR. SANTOSH HAJARE (KAHER, Nehru Nagar Belagavi-590010.). If you have any question about your right as a study participant, you may contact, Chairperson, Institutional Ethical Committee, J. N. Medical College, KAHER, Belagavi @ 0831-2473777 Extension 4052.

Legal Rights:

By signing this consent form, we are not waving any of your legal rights.

Consent Statement:

I am making a voluntary decision to participate in the study. My signature below indicates that I have decided to participate and I have read the information provided above (or the information provided above has been read to me) and I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the Participant: **Signature of the Participant or left thumb impression:**

Name of the Witness: **Signature of the Witness:**

Name of the Researcher: **Signature of the Researcher:**

Date:

Place:

ಅನುಬಂಧ –II ತಿಳುವಳಿಕೆಯುಳ್ಳ ಒಪ್ಪಿಗೆ ಪತ್ರ

ಶೀರ್ಷಿಕೆ: "ಆಲ್ಕೊಹಾಲ್ಯುಕ್ತವಲ್ಲದ ಸ್ಟೀಟೊಹೆಪಟೈಟಿಸ್ ರೋಗಿಗಳ ನಿರ್ವಹಣೆಯಲ್ಲಿ ಮೇಲ್ವಿಚಾರಣೆ ಮತ್ತು ರಚನಾತ್ಮಕ ಆಹಾರ ಮತ್ತು ವ್ಯಾಯಾಮದ ಪರಿಣಾಮ - ಯಾದೃಚ್ ಕ ನಿಯಂತ್ರಿತ ಪ್ರಯೋಗ' '.

ತನಿಖಾಧಿಕಾರಿ: ಶ್ರೀಮತಿ. ಗೀತಾ ಎಸ್ ದೇಸಾಯಿ

ಮಾರ್ಗದರ್ಶಿ: ಡಾ.ಸಂತೋಷ್ ಹಜಾರೆ

ಉದ್ದೇಶ:

ಉತ್ತರ ಕರ್ನಾಟಕದ ಜನಸಂಖ್ಯೆಯಲ್ಲಿ ಆಲ್ಕೊಹಾಲ್ಯುಕ್ತವಲ್ಲದ ಸ್ಟೀಟೊಹೆಪಟೈಟಿಸ್ (ಎನ್ ಎ ಎಸ್ ಎಚ್) ನಲ್ಲಿ ಮೇಲ್ವಿಚಾರಣೆ ಮತ್ತು ರಚನಾತ್ಮಕ ಆಹಾರ ಮತ್ತು ವ್ಯಾಯಾಮದ ಕಟ್ಟುಪಾಡುಗಳ ಪರಿಣಾಮಕಾರಿತ್ವವನ್ನು ನಿರ್ಣಯಿಸುವುದು.

ಪರಿಚಯ:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮನ್ನು ಆಹ್ವಾನಿಸಲಾಗುತ್ತಿದೆ"ಆಲ್ಕೊಹಾಲ್ಯುಕ್ತವಲ್ಲದ ಸ್ಟೀಟೊಹೆಪಟೈಟಿಸ್ ರೋಗಿಗಳ ನಿರ್ವಹಣೆಯಲ್ಲಿ ಮೇಲ್ವಿಚಾರಣೆ ಮತ್ತು ರಚನಾತ್ಮಕ ಆಹಾರ ಮತ್ತು ವ್ಯಾಯಾಮದ ಪರಿಣಾಮ - ಯಾದೃಚ್ ಕ ನಿಯಂತ್ರಿತ ಪ್ರಯೋಗ' '. ಇದನ್ನು ಶ್ರೀಮತಿ ಗೀತಾ ಎಸ್ ದೇಸಾಯಿ, ಪಿಎಚ್‌ಡಿ ನಡೆಸುತ್ತಿದ್ದಾರೆ. ಕೆಎಲ್‌ಇ ಅಕಾಡೆಮಿ ಉನ್ನತ ಶಿಕ್ಷಣ ಮತ್ತು ಸಂಶೋಧನೆಯಲ್ಲಿ ಸಂಶೋಧನಾ ವಿದ್ವಾಂಸ ಡಾ. ಸಂತೋಷ್ ಹಜಾರೆ ಎಂಡಿ ಡಿಎಂ ಡಿಎನ್‌ಬಿ (ಗ್ಯಾಸ್ಟ್ರೊ) ಪ್ರೊಫೆಸರ್ ಮತ್ತು ಡಾ. ಸುಮಿತ್ರಾ ಎಲ್ ಅರಿಬೆಂಚಿ ಡೀನ್ ಫ್ಯಾಕಲ್ಟಿ ಆಫ್ ನರ್ಸಿಂಗ್, ಇನ್ಸ್ ಬೆಳಗಾವಿಯವರ ಮಾರ್ಗದರ್ಶನದಲ್ಲಿ.

ಕಾರ್ಯವಿಧಾನದ ವಿವರಣೆ:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ, ನೀವು ಸಾಮಾಜಿಕ-ಜನಸಂಖ್ಯಾ ವಿವರಗಳು ಮತ್ತು ದೈಹಿಕ ಆರೋಗ್ಯ ಅಭ್ಯಾಸಗಳು, ಆಹಾರ ಪದ್ಧತಿಗಳು ಮತ್ತು ನಿಮ್ಮ ವೈದ್ಯಕೀಯ ಇತಿಹಾಸದ ಸ್ವಯಂ-ರೇಟೆಡ್ ಸಾಮರ್ಥ್ಯಗಳ ಬಗ್ಗೆ ಕೆಲವು ಪ್ರಶ್ನೆಗಳಿಗೆ ಉತ್ತರಿಸಬೇಕಾಗುತ್ತದೆ. ಅಧ್ಯಯನದ ಅವಧಿಗೆ ನೀವು ದೂರವಾಣಿ ಅಥವಾ ಮುಖಾಮುಖಿ ಭೇಟಿಯ ಮೂಲಕ ತನಿಖಾಧಿಕಾರಿಗಳೊಂದಿಗೆ ನಿಯಮಿತವಾಗಿ ಸಂವಹನ ನಡೆಸುತ್ತೀರಿ. ಕೆಲವು ಪ್ರಯೋಜನಕಾರಿ ವ್ಯಾಯಾಮಗಳ ಬಗ್ಗೆ ನಿಮಗೆ ತಿಳಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ನಮ್ಮ ಅಧ್ಯಯನದ ವೇಳಾಪಟ್ಟಿಯ ಪ್ರಕಾರ ಅವುಗಳನ್ನು ಮೇಲ್ವಿಚಾರಣೆಯ ರೀತಿಯಲ್ಲಿ ನಿರ್ವಹಿಸಲು ಹೇಳಲಾಗುತ್ತದೆ.

ಗರಿಷ್ಠ ಫಿಟ್‌ನೆಸ್ ಗುರಿಯನ್ನು ತಲುಪಲು ಸೇವಿಸುವ ಮತ್ತು ನಿಮ್ಮ ಆಹಾರ ಪದ್ಧತಿಗಳಿಗೆ ಸಂಬಂಧಿಸಿದಂತೆ ನಿಯಮಿತ ಸಂವಹನವನ್ನು ನಡೆಸಲಾಗುತ್ತದೆ.

ಅಧ್ಯಯನದ ವೇಳಾಪಟ್ಟಿಯಂತೆ ಆಸ್ಪತ್ರೆಯ ಪ್ರಯೋಗಾಲಯದಲ್ಲಿ ರಕ್ತ ಪರೀಕ್ಷೆ ನಡೆಸಲಾಗುವುದು.

ಅಧ್ಯಯನದಿಂದ ಹಿಂತೆಗೆದುಕೊಳ್ಳುವಿಕೆ:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿರುತ್ತದೆ. ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಬೇಕೆ ಅಥವಾ ಬೇಡವೇ ಎಂದು ನಿರ್ಧರಿಸಲು ನೀವು ಸ್ವತಂತ್ರರು. ಒಂದು ವೇಳೆ ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸದಿರಲು ನಿರ್ಧರಿಸಿದರೆ, ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ಹಿಂಪಡೆಯಲು ನಿಮಗೆ ಸಾಧ್ಯವಾಗುತ್ತದೆ.

ಸಂಭವನೀಯ ಅಪಾಯ :

ಅಧ್ಯಯನದಲ್ಲಿ ಯಾವುದೇ ಅಪಾಯವಿಲ್ಲ. ಆಲ್ಕೊಹಾಲ್ಯುಕ್ತವಲ್ಲದ ಸ್ಟೀಟೊಹೆಪಟೈಟಿಸ್ (ಎನ್ ಎ ಎಸ್ ಎಚ್) ಜನಸಂಖ್ಯೆಯಲ್ಲಿ ಮೇಲ್ವಿಚಾರಣೆ ಮತ್ತು ರಚನಾತ್ಮಕ ಆಹಾರ ಮತ್ತು ವ್ಯಾಯಾಮದ ಕಟ್ಟುಪಾಡುಗಳ ಪರಿಣಾಮಕಾರಿತ್ವದ ಮೌಲ್ಯಮಾಪನಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಮಾಹಿತಿಗಾಗಿ ಮಾತ್ರ ಸಂದರ್ಶನವನ್ನು ಬಳಸಲಾಗುತ್ತದೆ. ಆಸ್ಪತ್ರೆಯ ಪ್ರಯೋಗಾಲಯದಲ್ಲಿ ಪರವಾನಗಿ ಪಡೆದ ತಂತ್ರಜ್ಞರಿಂದ ರಕ್ತ ತನಿಖೆಯನ್ನು ಸುರಕ್ಷಿತವಾಗಿ ಸಂಗ್ರಹಿಸಲಾಗುತ್ತದೆ.

ಗೌಪ್ಯತೆ ಮತ್ತು ಗೌಪ್ಯತೆ

ನಿಮ್ಮ ಗುರುತು ಬಹಿರಂಗಗೊಳ್ಳುವುದಿಲ್ಲ. ಸಂಗ್ರಹಿಸಿದ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಕೋಡ್ ಮಾಡಲಾಗುವುದು ಇದರಿಂದ ನಿಮ್ಮ ಗುರುತು ಯಾರಿಗೂ ತಿಳಿಯುವುದಿಲ್ಲ. ನಿಮ್ಮಿಂದ ಸಂಗ್ರಹಿಸಿದ ಡೇಟಾವನ್ನು ಗೌಪ್ಯವಾಗಿಡಲಾಗುತ್ತದೆ ಮತ್ತು ಒಟ್ಟು ಡೇಟಾವನ್ನು ಮಾತ್ರ ಪ್ರಕಟಿಸಲಾಗುತ್ತದೆ.

ಹಣಕಾಸು ಪ್ರೋತ್ಸಾಹಕಗಳು :

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು ಯಾವುದೇ ಪಾವತಿಯನ್ನು ಸ್ವೀಕರಿಸುವುದಿಲ್ಲ.

ಅಧ್ಯಯನದ ವೆಚ್ಚ :

ಅಧ್ಯಯನದ ವೆಚ್ಚವನ್ನು ತನಿಖಾಧಿಕಾರಿ ಭರಿಸುತ್ತಾರೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮಿಂದ ಯಾವುದೇ ಹೆಚ್ಚುವರಿ ವೆಚ್ಚವಿರುವುದಿಲ್ಲ.

ಪ್ರಕಟಣೆಯ ಅಧಿಕಾರ :

ಈ ಅಧ್ಯಯನದ ಫಲಿತಾಂಶಗಳನ್ನು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಗಳಿಗಾಗಿ ಪ್ರಕಟಿಸಬಹುದು ಮತ್ತು / ಅಥವಾ ವೈಜ್ಞಾನಿಕ ಗುಂಪುಗಳಿಗೆ ಪ್ರಸ್ತುತಪಡಿಸಬಹುದು; ಆದಾಗ್ಯೂ ನಿಮ್ಮನ್ನು ಗುರುತಿಸಲಾಗುವುದಿಲ್ಲ.

ಪ್ರಶ್ನೆ :

ನೀವು ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ, ನೀವು ಸಂಪರ್ಕಿಸಬೇಕು ಶ್ರೀಮತಿ . ಗೀತಾ ಎಸ್ ದೇಸಾಯಿ (ಪಿಎಚ್. ಡೋಫ್, ಜೆಎನ್ಎಂಸಿ, ನೆಹರು ನಗರ, ಬೆಳಗಾವಿ) ಮೊಬೈಲ್ ಸಂಖ್ಯೆ- ಇಮೇಲ್ ಐಡಿ– ಅಥವಾ ಮಾರ್ಗದರ್ಶಿ ಡಾ. ಸಂತೋಷ್ ಹಜಾರೆ (ಕಾಹೇರ್, ನೆಹರು ನಗರ ಬೆಳಗಾವಿ -590010.).

ಅಧ್ಯಯನದ ಪಾಲ್ಗೊಳ್ಳುವವರಾಗಿ ನಿಮ್ಮ ಹಕ್ಕಿನ ಬಗ್ಗೆ ನಿಮಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆ ಇದ್ದರೆ, ನೀವು ಅಧ್ಯಕ್ಷರು, ಸಾಂಸ್ಥಿಕ ನೈತಿಕ ಸಮಿತಿ, ಜೆ. ಎನ್. ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಕಾಹೆರ್, ಬೆಳಗಾವಿ @ 0831-2473777 ವಿಸ್ತರಣೆ 4052 ಅನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಕಾನೂನು ಹಕ್ಕುಗಳು:

ಈ ಒಪ್ಪಿಗೆ ಫಾರ್ಮ್ಗೆ ಸಹಿ ಮಾಡುವ ಮೂಲಕ, ನಾವು ನಿಮ್ಮ ಯಾವುದೇ ಕಾನೂನು ಹಕ್ಕುಗಳನ್ನು ಅಲೆಯುತ್ತಿಲ್ಲ.

ಒಪ್ಪಿಗೆ ಹೇಳಿಕೆ:

ನಾನು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಸ್ವಯಂಪ್ರೇರಿತ ನಿರ್ಧಾರ ತೆಗೆದುಕೊಳ್ಳುತ್ತಿದ್ದೇನೆ. ಕೆಳಗಿನ ನನ್ನ ಸಹಿ ನಾನು ಭಾಗವಹಿಸಲು ನಿರ್ಧರಿಸಿದ್ದೇನೆ ಮತ್ತು ಮೇಲೆ ಒದಗಿಸಿದ ಮಾಹಿತಿಯನ್ನು ನಾನು ಓದಿದ್ದೇನೆ (ಅಥವಾ ಮೇಲೆ ಒದಗಿಸಿದ ಮಾಹಿತಿಯನ್ನು ನನಗೆ ಓದಲಾಗಿದೆ) ಮತ್ತು ನನಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳುವ ಅವಕಾಶ ನೀಡಲಾಯಿತು ಮತ್ತು ನನ್ನ ತೃಪ್ತಿಗೆ ಅವರಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ ಎಂದು ಸೂಚಿಸುತ್ತದೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರು:

ಅಥವಾ ಎಡ ಹೆಬ್ಬೆರಳು ಅನಿಸಿಕೆ:

ಭಾಗವಹಿಸುವವರ ಸಹಿ

ಸಾಕ್ಷಿಯ ಹೆಸರು:

ಸಾಕ್ಷಿಯ ಸಹಿ:

ಸಂಶೋಧಕರ ಹೆಸರು:

ಸಂಶೋಧಕರ ಸಹಿ:

ದಿನಾಂಕ:

ಸ್ಥಳ:

अनुलग्नक –II सूचित संमती फॉर्म

शीर्षकः "पर्यवेक्षी आणि संरक्षित आहाराचा प्रभाव आणि नॉन अल्कोहोलिक स्टीटोहेपेटायटीस असलेल्या रुग्णांच्या व्यवस्थापनात व्यायाम - एक यादृच्छिक नियंत्रित चाचणी' '.

अन्वेषक: श्रीमती. गीता एस देसाई
मार्गदर्शक: डॉ. संतोष हजारे

उद्देशः

उत्तर कर्नाटकातील लोकसंख्येमध्ये नॉन-अल्कोहोलिक स्टीटोहेपेटायटीस (एनएएसएच) मधील पर्यवेक्षी आणि संरचित आहार आणि व्यायामाच्या पद्धतीची प्रभावीता तपासण्यासाठी.

परिचय:

आपल्याला या अभ्यासामध्ये भाग घेण्यासाठी आमंत्रित केले जात आहे "पर्यवेक्षी आणि संरक्षित आहाराचा प्रभाव आणि नॉन अल्कोहोलिक स्टीटोहेपेटायटीस असलेल्या रुग्णांच्या व्यवस्थापनात व्यायाम - एक यादृच्छिक नियंत्रित चाचणी' '. श्रीमती. गीता एस. देसाई, पीएच.डी. केएलई अकॅडमी ऑफ उच्च शिक्षण व संशोधन येथे संशोधक डॉ. संतोष हजारे एमडी डीएम डीएनबी (गॅस्ट्रो) प्रोफेसर यांच्या मार्गदर्शनाखाली आणि डॉ सुमित्रा एल अरिबेची डीन नर्सिंग अध्यापक, इन बेलागावी यांचे सह-मार्गदर्शन.

प्रक्रियेचे स्पष्टीकरण:

या अभ्यासामध्ये, आपल्याला सामाजिक-लोकसंख्याशास्त्रीय तपशील आणि शारीरिक आरोग्य पद्धती, आहारविषयक पद्धती आणि आपल्या वैद्यकीय इतिहासाची स्वत: ची रेटिंग-क्षमता याबद्दल काही प्रश्नांची उत्तरे द्यावी लागतील. अभ्यासाच्या कालावधीसाठी आपण दूरध्वनीद्वारे किंवा आमनेसामने भेट घेण्याद्वारे चौकशीकर्त्यांशी नियमित संवाद साधता.

आपल्याला काही फायदेशीर व्यायामांबद्दल सांगितले जाईल आणि आमच्या अभ्यासाच्या वेळापत्रकानुसार पर्यवेक्षी पद्धतीने ते करण्यास सांगितले जाईल. इष्टतम तंदुरुस्तीच्या उद्दीष्ट्यापर्यंत पोहोचण्यासाठी नियमितपणे संप्रेषण केले जाणारे जेवण आणि आपल्या आहारविषयक सराव संदर्भात आयोजित केले जाईल.

अभ्यासाच्या वेळापत्रकानुसार रुग्णालयात प्रयोगशाळेत रक्त तपासणी केली जाईल.

अभ्यासामधून पैसे काढणे:

या अभ्यासामध्ये आपला सहभाग ऐच्छिक असेल. अभ्यासात भाग घ्यायचा की नाही याचा निर्णय घेण्यास तुम्ही मोकळे आहात. जर आपण अभ्यासामध्ये भाग न घेण्याचे ठरविले तर आपण आपला सहभाग मागे घेण्यास सक्षम असाल.

संभाव्य जोखीम :

अभ्यासामध्ये कोणताही धोका असणार नाही. मुलाखत केवळ पर्यवेक्षी आणि संरक्षित आहाराची प्रभावीता आणि अल्कोहोलिक नसलेल्या स्टीटोहेपेटायटीस (एनएएसएच) लोकसंख्येमधील व्यायामाच्या पथ्येच्या मूल्यांकनासाठी वापरली जाईल. रुग्णालयाच्या प्रयोगशाळेत परवानाधारक तंत्रज्ञांद्वारे रक्त तपासणी सुरक्षितपणे केली जाईल.

गोपनीयता

आपली ओळख प्रकट होणार नाही. संकलित केलेली सर्व माहिती कोडित केली जाईल जेणेकरून कोणालाही आपली ओळख कळू नये. आपल्याकडून गोळा केलेला डेटा गोपनीय ठेवला जाईल आणि केवळ एकत्रित केलेला डेटा प्रकाशित केला जाईल.

आर्थिक प्रोत्साहनः

या अभ्यासामध्ये भाग घेण्यासाठी आपल्याला कोणतेही देय प्राप्त होणार नाही.

अभ्यासाची किंमत :

अभ्यासाची किंमत अन्वेषक तपासेल. या अभ्यासामध्ये भाग घेण्यासाठी आपल्याकडून कोणतीही अतिरिक्त किंमत आकारली जाणार नाही.

प्रकाशन अधिकृत करणे :

या अभ्यासाचे निकाल वैज्ञानिक उद्देशाने प्रकाशित केले जाऊ शकतात आणि / किंवा वैज्ञानिक गटांसमोर सादर केले जाऊ शकतात; तथापि आपण ओळखले जाणार नाही.

प्रश्नः

आपल्याला अभ्यासाबद्दल काही प्रश्न असल्यास आपण संपर्क साधावा कु. श्रीमती. गीता एस देसाई (पीएच. डोफ, जेएनएमसी, नेहरू नगर, बेलागावी) मोबाइल नंबर- ईमेल आयडी- किंवा मार्गदर्शक डॉ. संतोष हजारे (काहेर, नेहरू नगर बेलागावी-590010.) अभ्यासाचा सहभागी म्हणून आपल्या हक्काबद्दल आपल्याला काही प्रश्न असल्यास आपण अध्यक्ष, संस्थात्मक नैतिक समिती, जे. एन. मेडिकल कॉलेज, काहेर, बेलागावी @ 0831-2473777 विस्तार 4052 वर संपर्क साधू शकता.

कायदेशीर हक्क :

या संमती फॉर्मवर स्वाक्षरी करून आम्ही आपले कोणतेही कायदेशीर हक्क लुटत नाही.

संमती विधान :

मी अभ्यासामध्ये भाग घेण्यासाठी ऐच्छिक निर्णय घेत आहे. खाली माझी स्वाक्षरी सूचित करते की मी भाग घेण्याचे ठरविले आहे आणि मी वर दिलेली माहिती वाचली आहे (किंवा वर दिलेली माहिती मला वाचली गेली आहे) आणि मला प्रश्न विचारण्याची संधी मिळाली आणि त्या माझ्या समाधानाला उत्तरे दिली गेली.

सहभागीचे नावः

सहभागीची सही

किंवा डाव्या अंगठ्याचा ठसा :

साक्षीदाराचे नाव :

साक्षीदाराची सही :

संशोधकाचे नाव :

संशोधकाची सही :

तारीख :

ठिकाणः

ANNEXURE –IV

TOOL FOR DATA COLLECTION

SECTION – I

SOCIO DEMOGRAPHIC DATA

Please place tick mark (√) against each item:

Name:

Age (in years):

Gender

1. Male
2. Female

Religion

1. Hindu
2. Muslim
3. Christian
4. Others

Education

1. No formal education
2. Primary education
3. Secondary education
4. Graduate

Occupation

1. Farmer
2. Government employee
3. Private employee
4. Self employed

Marital Status

1. Married
2. Unmarried

SECTION – II

HEALTH PRACTICE ASSESSMENT

Description: Dear participants, read the statement carefully and mark a tick (√) where ever you feel most appropriate.

Sl. No	HEALTH PRACTICE ASSESSMENT ITEMS	Never	Rarely	Sometimes	Always
1.	Do you regularly include green leafy vegetables into your meals?				
2.	Do you avoid eating junk foods such as chocolate, bakery items, pizza, and burgers?				
3.	Do you make it a point to have breakfast at the same time every day?				
4.	Do you maintain a habit of consuming balanced meals regularly?				
5.	Do you ensure to eat meals at appropriate times?				
6.	Do you tailor your food intake according to your daily energy requirements?				
7.	Have you ever experimented with dieting?				
8.	Do you believe in the importance of a balanced diet that includes protein, healthy fats, and fiber-rich carbohydrates for good health?				
9.	Do you have habit of eating while watching TV?				
10.	Do you try to minimize consuming non-vegetarian food frequently?				
11.	Do you make it a habit to include fruits in your daily diet?				
12.	Do you limit your meal intake before bedtime?				
13.	Do you have any food allergies or sensitivities				
14.	Do you have a routine of waking up early in the morning?				
15.	Do you consistently get 4 to 6 hours of sleep each night?				
16.	Do you follow a consistent bedtime routine?				
17.	Do you acknowledge the positive impact of adequate sleep on your health?				
18.	Do you take breaks for rest during the day?				
19.	Do you track your sleep patterns using any tools or apps?				
20.	Does your sleep environment promote peace and relaxation?				
21.	Do you engage in regular physical activity such as cycling, running, walking, or playing sports like football, volleyball, or cricket?				
22.	Do you enjoy indoor games like badminton, skipping, or table tennis during your free time?				
23.	Are you enthusiastic about participating in extracurricular activities?				
24.	Do you recognize the positive effects of physical activity on your health?				

25.	Do you focus on achieving and maintaining a healthy body composition?				
26.	Do you find that regular exercise enhances your overall bodily function?				
27.	Does exercising contribute to improving your physical fitness levels?				
28.	Do you find satisfaction in engaging in exercise activities?				
29.	Do you notice an increase in muscle strength through regular exercise?				
30.	Do you experience a reduction in stress and tension as a result of exercising?				

Scoring: Never – 0; Rarely – 1; Sometimes – 2; Always – 3; Maximum score: 90; Minimum score: 0

ವಿಭಾಗ 1

ಸಾಮಾಜಿಕ ಜನಸಂಖ್ಯಾ ಮಾಹಿತಿ

ದಯವಿಟ್ಟು ಕೆಳಗಿನ ಐಟಂಗಳನ್ನು ಟಿಕ್ ಮಾರ್ಕ್ ಮಾಡಿ (√) :

ಹೆಸರು:

ವಯಸ್ಸು (ವರ್ಷಗಳಲ್ಲಿ):

ಲಿಂಗ

1. ಪುರುಷ
2. ಮಹಿಳೆ

ಧರ್ಮ

1. ಹಿಂದೂ
2. ಮುಸ್ಲಿಂ
3. ಕ್ರಿಶ್ಚಿಯನ್
4. ಇತರೆ

ಶಿಕ್ಷಣ

1. ಶಿಕ್ಷಣವಿಲ್ಲ
2. ಪ್ರಾಥಮಿಕ ಶಿಕ್ಷಣ
3. ಮಾಧ್ಯಮಿಕ ಶಿಕ್ಷಣ
4. ಪದವೀಧರ

ಉದ್ಯೋಗ

1. ರೈತ
2. ಸರ್ಕಾರಿ ಉದ್ಯೋಗಿ
3. ಖಾಸಗಿ ಉದ್ಯೋಗಿ
4. ಸ್ವಯಂ ಉದ್ಯೋಗಿ

ವೈವಾಹಿಕ ಸ್ಥಿತಿ

1. ವಿವಾಹಿತರು
2. ಅವಿವಾಹಿತ

ವಿಭಾಗ-2
ಆರೋಗ್ಯಾಭ್ಯಾಸದ ಮೌಲ್ಯಮಾಪನ ವಿವರಗಳು

ದಯವಿಟ್ಟು ತಮಗೆ ಹೆಚ್ಚು ಸೂಕ್ತವಾದ ಆಯ್ಕೆಯನ್ನು ಗುರುತಿಸಿ (ಟಿಕ್ ಮಾರ್ಕ್ ✓ ಮಾಡಿ)

ಕ್ರ. ಸಂಖ್ಯೆ	ಆರೋಗ್ಯಾಭ್ಯಾಸದ ಮೌಲ್ಯಮಾಪನ ವಿವರ	ಎಂದಿಗೂ ಇಲ್ಲ	ಅಪರೂಪ	ಕೆಲವೊಮ್ಮೆ	ಯಾವಾಗಲೂ
1	ನೀವು ನಿಯಮಿತವಾಗಿ ನಿಮ್ಮ ಊಟದಲ್ಲಿ ಹಸಿರು ಎಲೆಗಳ ತರಕಾರಿಗಳನ್ನು ಸೇರಿಸುತ್ತೀರಾ				
2	ನೀವು ಚಾಕೊಲೇಟ್, ಬೇಕರಿ ಆಹಾರ, ಪಿಜ್ಜಾ, ಬರ್ಗರ್ ಮುಂತಾದ ಜಂಕ್ ಫುಡ್ ಗಳನ್ನು ತಿನ್ನುವುದನ್ನು ತಪ್ಪಿಸುತ್ತೀರಾ?				
3	ನೀವು ಪ್ರತಿದಿನ ಅದೇ ನಿಗದಿತ ಸಮಯದಲ್ಲಿ ಉಪಹಾರ ಸೇವಿಸುತ್ತೀರಾ?				
4	ನೀವು ನಿಯಮಿತವಾಗಿ ಸಮತೋಲಿತ ಆಹಾರವನ್ನು ಸೇವಿಸುವ ಅಭ್ಯಾಸವನ್ನು ಹೊಂದಿದ್ದೀರಾ?				
5	ಸರಿಯಾದ ಸಮಯಕ್ಕೆ ಊಟ ಮಾಡುವ ಅಭ್ಯಾಸ ನಿಮಗಿದೆಯೆ				
6	ನಿಮ್ಮ ದೈನಂದಿನ ಶಕ್ತಿಯ ಅವಶ್ಯಕತೆಗಳಿಗೆ ಅನುಗುಣವಾಗಿ ನಿಮ್ಮ ಆಹಾರ ಸೇವನೆಯನ್ನು ನೀವು ಸರಿಹೊಂದಿಸುತ್ತೀರಾ?				
7	ನೀವು ಎಂದಾದರೂ ಡಯಟ್ (ಆಹಾರ ಪದ್ಧತಿಯನ್ನು) ಅನುಸರಿಸಿದ್ದೀರಾ				
8	ಉತ್ತಮ ಆರೋಗ್ಯಕ್ಕಾಗಿ ಪ್ರೋಟೀನ್, ಆರೋಗ್ಯಕರ ಕೊಬ್ಬಿನ ಅಂಶ ಮತ್ತು ಫೈಬರ್ ಭರಿತ ಕಾರ್ಬೋಹೈಡ್ರೇಟ್‌ಗಳನ್ನು ಒಳಗೊಂಡಿರುವ ಸಮತೋಲಿತ ಆಹಾರದ ಪ್ರಾಮುಖ್ಯತೆಯನ್ನು ನೀವು ನಂಬುತ್ತೀರಾ				
9	ನಿಮಗೆ ಟಿವಿ ನೋಡುತ್ತಾ ತಿನ್ನುವ ಅಭ್ಯಾಸವಿದೆಯೇ?				
10	ಮಾಂಸಾಹಾರವನ್ನು ಆಗಾಗ್ಗೆ ಸೇವಿಸುವುದನ್ನು ಕಡಿಮೆ ಮಾಡಲು ನೀವು ಪ್ರಯತ್ನಿಸುತ್ತೀರಾ?				
11	ನಿಮ್ಮ ದೈನಂದಿನ ಆಹಾರದಲ್ಲಿ ನೀವು ಹಣ್ಣುಗಳನ್ನು ಸೇರಿಸುತ್ತೀರಾ?				
12	ಮಲಗುವ ಮುನ್ನ ನೀವು ನಿಮ್ಮ ಆಹಾರ ಸೇವನೆಯನ್ನು ಮಿತಿಗೊಳಿಸುತ್ತೀರಾ?				
13	ನೀವು ಯಾವುದೇ ಆಹಾರ ಅಲರ್ಜಿಯನ್ನು ಹೊಂದಿದ್ದೀರಾ?				
14	ನೀವು ಮುಂಜಾನೆ ಬೇಗ ಏಳುವ ಅಭ್ಯಾಸವನ್ನು ಹೊಂದಿದ್ದೀರಾ				
15	ನೀವು ಪ್ರತಿರಾತ್ರಿ 4-6 ಗಂಟೆಗಳ ಕಾಲ ನಿರಂತರವಾಗಿ ನಿದ್ರೆ ಮಾಡುತ್ತೀರಾ?				
16	ನೀವು ಪ್ರತಿರಾತ್ರಿ ಸ್ಥಿರವಾದ ಮಲಗುವ ಸಮಯವನ್ನು ಅನುಸರಿಸುತ್ತೀರಾ				
17	ಪ್ರತಿದಿನ ಸರಿಯಾದ ನಿದ್ರೆ ನಿಮ್ಮ ಆರೋಗ್ಯದ ಮೇಲೆ ಉತ್ತಮ ಫಲಿತಾಂಶಗಳನ್ನು ನೀಡಿದೆಯೇ?				

18	ಈ ಸಮಯದಲ್ಲಿ ನೀವು ದೈನಂದಿನ ಕೆಲಸದ ಸಮಯದಲ್ಲಿ ವಿಶ್ರಾಂತಿಗಾಗಿ ವಿರಾಮಗಳನ್ನು ತೆಗೆದುಕೊಳ್ಳುತ್ತೀರಾ? ದಿನ?				
19	ಯಾವುದೇ ಉಪಕರಣಗಳು ಅಥವಾ ಮೊಬೈಲ್ ಅಪ್ಲಿಕೇಶನ್‌ಗಳನ್ನು ಬಳಸಿ ನಿಮ್ಮ ನಿದ್ರೆಯ ಮಾದರಿಗಳನ್ನು ನೀವು ಟ್ರ್ಯಾಕ್ ಮಾಡುತ್ತೀರಾ				
20	ನೀವು ಶಾಂತಿಯುತ ಮತ್ತು ಆರಾಮದಾಯಕ ಮಲಗುವ ವಾತಾವರಣವನ್ನು ಹೊಂದಿದ್ದೀರಾ?				
21	ನೀವು ನಿಯಮಿತ ಸೈಕ್ಲಿಂಗ್, ಓಡುವುದು, ವಾಕಿಂಗ್, ಅಥವಾ ಫುಟ್‌ಬಾಲ್, ವಾಲಿಬಾಲ್, ಕ್ರಿಕೆಟ್ ನಂತಹ ಕ್ರೀಡೆಗಳನ್ನು ಆಡುವುದು ಇತ್ಯಾದಿ ದೈಹಿಕ ಚಟುವಟಿಕೆಗಳನ್ನು ಹೊಂದಿದ್ದೀರಾ?				
22	ನೀವು ಒಳಾಂಗಣ ಕ್ರೀಡೆಗಳಾದ ಬ್ಯಾಡ್ಮಿಂಟನ್, ಸ್ಕಿಪ್ಪಿಂಗ್, ಅಥವಾ ಟೇಬಲ್ ಟೆನ್ನಿಸ್ ನಿಮ್ಮ ಬಿಡುವಿನ ವೇಳೆಯಲ್ಲಿ ಆಡಿ ಆನಂದಿಸುತ್ತೀರಾ?				
23	ನೀವು ಪರ್ಯೇತರ ಚಟುವಟಿಕೆಗಳಲ್ಲಿ ಭಾಗವಹಿಸಲು ಉತ್ಸುಕರಾಗಿದ್ದೀರಾ?				
24	ನಿಮ್ಮ ದೈಹಿಕ ಚಟುವಟಿಕೆಯಿಂದಾಗಿ ನಿಮ್ಮ ಆರೋಗ್ಯದ ಮೇಲಾಗುವ ಉತ್ತಮ ಪರಿಣಾಮಗಳನ್ನು ನೀವು ಗುರುತಿಸುತ್ತೀರಾ?				
25	ನೀವು ಆರೋಗ್ಯಕರ ದೇಹವನ್ನು ಕಾಪಾಡಿಕೊಳ್ಳುವುದರ ಕಡೆಗೆ ಗಮನಹರಿಸುತ್ತೀರಾ?				
26	ನಿಯಮಿತ ವ್ಯಾಯಾಮವು ನಿಮ್ಮ ಒಟ್ಟಾರೆ ದೇಹದ ಕಾರ್ಯಕ್ಷಮತೆಯನ್ನು ಸುಧಾರಿಸುತ್ತದೆ ಎಂದು ನೀವು ಭಾವಿಸುತ್ತೀರಾ?				
27	ನಿಮ್ಮ ದೈಹಿಕ ಸಾಮರ್ಥ್ಯದ ಸುಧಾರಣೆಗೆ ವ್ಯಾಯಾಮವು ಸಹಾಯಕಾರಿಯಾಗಿದೆಯೇ?				
28	ನಿಮ್ಮನ್ನು ವ್ಯಾಯಾಮದಲ್ಲಿ ತೊಡಗಿಸಿಕೊಳ್ಳುವುದರಲ್ಲಿ ನೀವು ತೃಪ್ತಿಯನ್ನು ಕಾಣುತ್ತೀರಾ?				
29	ನಿಯಮಿತ ವ್ಯಾಯಾಮದ ಮೂಲಕ ಸ್ನಾಯುಗಳ ಶಕ್ತಿ ಹೆಚ್ಚಳವನ್ನು ನೀವು ಗಮನಿಸುತ್ತೀರಾ?				
30	ವ್ಯಾಯಾಮದ ಪರಿಣಾಮವಾಗಿ ನೀವು ನಿಮ್ಮ ಉದ್ವೇಗ ಮತ್ತು ಮಾನಸಿಕ ಒತ್ತಡ ಕಡಿಮೆಯಾಗುವುದನ್ನೂ ಅನುಭವಿಸುತ್ತೀರಾ				

ಸ್ಕೋರಿಂಗ್ ಸಂಖ್ಯೆ:-

ಎಂದಿಗೂ ಇಲ್ಲ - 0 ; ಅಪರೂಪ - 1 ; ಕೆಲವೊಮ್ಮೆ - 2 ; ಯಾವಾಗಲೂ – 3 ; ಗರಿಷ್ಠ ಸ್ಕೋರ್ – 90 ; ಕನಿಷ್ಠ ಸ್ಕೋರ್ - 0

भाग- 1

कृपया योग्य उत्तरासमोर (√) अशी खूण करा

*** नाव :**

*** वय (वर्षे) :**

*** लिंग**
1) पुरुष
2) महिला

*** धर्म**
1) हिंदू
2) मुस्लिम
3) ख्रिश्चन
4) इतर

*** शिक्षण**
1) अशिक्षित
2) प्राथमिक शिक्षण
3) माध्यमिक शिक्षण
4) पदवीधर

*** व्यवसाय**
1) शेती
2) शासकीय कर्मचारी
3) खासगी कर्मचारी
4) स्वयंरोजगार

*** वैवाहिक स्थिती**
1) विवाहित
2) अविवाहित

भाग- 2

आरोग्य पद्धती मुल्यांकन यादी

वर्णन :प्रयि सहभागींनो, वधिान काळजीपूर्वक वाचा व आवश्यक व योग्य त्याठकिाणी (√) अशी खूण करा.

अ.क्र	आरोग्य पद्धती मुल्यांकन यादी	कधीही नाही	अभावाने	कधीतरी	नेहमी
1.	तुम्ही नयिमतिपणे तुमच्या आहारात हरिव्या पालेभाज्यांचा समावेश करता का?				
2.	तुम्ही चॉकलेट, बेकरी पदार्थ, पझ्झिा व बर्गरसारखे जंक फूड खाणे टाळता का?				
3.	तुम्ही रोज एकाचवेळी न्याहरी करण्याचा क्रम पाळता का?				
4.	तुम्ही नयिमतिपणे संतुलति आहार घेण्याची सवय पाळली आहे का?				
5.	तुम्ही योग्यवेळी जेवण घेण्यास प्राधान्य देता का?				
6.	तुम्ही तुमच्या दैनंदनि उर्जेच्या गरजेनुसार अन्न ग्रहण करता का?				
7.	तुम्ही कधी डाएटगिचा प्रयोग केला आहे का?				
8.	चांगल्या आरोग्यासाठी प्रथनि, आरोग्यदायी मेद व फायबरयुक्त कर्बचा समावेश असलेल्या संतुलति आहाराच्या महत्वावर तुमचा वशि्वास आहे का?				
9.	तुम्हाला टीव्ही पाहताना खाण्याची सवय आहे का?				
10.	तुम्ही वारंवार होणारा मांसाहार कमी करण्याचा प्रयत्न करता का?				
11.	रोजच्या आहारात फळांचा समावेश करण्याची सवय तुम्ही ठेवलीय का?				
12.	झोपण्यापूर्वी तुम्ही तुमचे जेवण मर्यादीत ठेवता का?				
13.	तुम्हाला एखादी आहार ॲलर्जी वा संवेदनशीलता आहे का?				
14.	तुम्हाला रोज सकाळी लवकर उठण्याची सवय आहेका?				
15.	तुम्हाला रोज रात्री 4 ते 6 तासांची झोप सातत्याने मळिते का?				
16.	तुम्ही रोज झोपण्याची वेळ पाळता का?				
17.	पुरेशा झोपेचा तुमच्या आरोग्यावर सकारात्मक प्रभाव पडतो हे तुम्ही मान्य करता का?				
18.	तुम्ही दविसभरात वशि्रांतीसाठी ब्रेक घेता का?				
19.	एखादे साधन वा ॲपच्या साहाय्याने तुम्ही तुमच्या झोपेवर लक्ष ठेवता का?				
20.	तुमचे झोपेचे ठकिाण शांतता व वशि्रांतीला पोषक आहे का?				
21.	सायकलगि, धावणे, चालणे यांसारख्या शारीरकि हालचाली कवि फुटबॉल, व्हॉलीबॉल, क्रकिेट आदी खेळांत तुम्ही रमता का?				
22.	मोकळ्या वेळेत तुम्ही बॅडमटिन, स्कपिगि कवि टेबल टेनसिसारख्या इनडोअर खेळांचा आनंद घेता का?				
23.	तुम्ही अभ्यासेतर उपक्रमांमध्ये सहभागी होण्यासाठी उत्साही असता का?				
24.	शारीरकि हालचालींचा आरोग्यावर होणाऱ्या सकारात्मक परणिामांबाबत तुम्ही अवगत आहात का?				

25.	नरिोगी शरीररचना राखणे वा ती साध्य करण्याकडे तुम्ही लक्ष देता का?				
26.	नयिमति व्यायामामुळे तुमचे एकूण शारीरकि कार्य वाढते, असे तुम्हाला आढळले आहे का?				
27.	तुमची शारीरकि तंदुरुस्तीची पातळी सुधारण्यासाठी व्यायामाचा हातभार लागतो का?				
28.	व्यायामाच्या उपक्रमांमध्ये गुंतल्याने तुम्हाला समाधान मळिते का?				
29.	नयिमति व्यायामामुळे स्नायूंची ताकद वाढल्याचे आढळले आहे का?				
30.	व्यायाम केल्याने ताण व तणाव कमी झाल्याचा अनुभव आला आहे का?				

गुण :कधीही नाही- 0, अभावाने- 1, कधीतरी- 2, नेहमी- 3, कमाल स्कोर- 90, कमिान स्कोर- 0

ANNEXURE – V

INTERVENTION DEVELOPMENT CHART

Intervention for Control group	
Face to face Sessions (After completion of every 6 week)	
Duration: 45-60 minutes	
Session 1 (Baseline)	✓ Educating dietary guidelines for weight loss ✓ 3% reduction of initial body weight ✓ Setting 1 day prescription calorie ✓ Improving the eating habits of individual eating patterns ✓ Encouraging for exercise
Session 2 (6 weeks)	✓ Reduction of calorie intake and training of low calorie food ✓ 4-5% reduction of initial body weight ✓ Maintain or change 1 day prescription calorie ✓ Improving the eating habits of individual eating patterns ✓ Exercise targets were set to support weight management (30-45 mins/day, 5 days/week)
Session 3 (12 weeks)	✓ Educating how to choose food when eating out and calorie information of eating out ✓ Training for how to read nutrition facts label ✓ 5-6% reduction of initial body weight ✓ Maintain or change 1 day prescription calorie ✓ Improving the eating habits of individual eating patterns ✓ Exercise targets were set to support weight management (30-45 mins/day, 5 days/week)
Session 4 (18 weeks)	✓ Educating dietary guidelines for weight-loss maintenance ✓ 6-7% reduction of initial body weight or maintain weight loss ✓ Maintain or change 1 day prescription calorie ✓ Improving the eating habits of individual eating patterns ✓ Exercise targets were set to support weight management (30-45 mins/day, 5 days/week)
Session 5 (24 weeks)	✓ Educating dietary guidelines for weight-loss maintenance ✓ 7-10% reduction of initial body weight or maintain weight loss ✓ Maintain or change 1 day prescription calorie ✓ Improving the eating habits of individual eating patterns ✓ Exercise targets were set to support weight management (30-45 mins/day, 5 days/week)

Intervention for Study group		
	Face to face Sessions (After completion of every 6 week)	**Telephonic session (Every Saturday/Sunday)**
	Duration: 45-60 minutes	**Duration: 5-10 minutes**
Session 1 (Baseline)	✓ Educating dietary guidelines for weight loss ✓ 3% reduction of initial body weight ✓ Setting 1 day prescription calorie ✓ Improving the eating habits of individual eating patterns ✓ Encouraging for exercise	Telephonic session conducted by the researcher for every individual on following aspects: **1. Dietary Routine:** - Could you please provide an update on your daily dietary intake over the past week? - Are you following the planned diet as recommended? - Have you encountered any difficulties or challenges in adhering to the prescribed diet plan? - If any adjustments were made, could you specify what changes were implemented and why? **2. Exercise Routine:** - Could you describe your physical activity and exercise routine throughout the past week? - Are you able to follow the exercise regimen as suggested? - Have you experienced any barriers or difficulties in maintaining regular physical activity? **3. Weight and waist circumference Recordings:** - Could you share the weight measurements recordings? - Could you share the waist circumference recordings? **4. Challenges and Adaptation:** - Are there any specific aspects of the dietary or exercise plan you find difficult to adapt to? - Would you like me to suggest modifications to make the regimen more manageable and sustainable for you? **5. Additional Concerns:** - Do you have any other concerns or difficulties you would like to discuss regarding your current diet or exercise plan?
Session 2 (6 weeks)	✓ Reduction of calorie intake and training of low-calorie food ✓ 5% reduction of initial body weight ✓ Maintain or change 1 day prescription calorie ✓ Improving the eating habits of individual eating patterns ✓ Exercise targets were set to support weight management (30-45 mins/day, 5 days/week)	
Session 3 (12 weeks)	✓ Educating how to choose food when eating out and calorie information of eating out ✓ Training for how to read nutrition facts label ✓ 4-6% reduction of initial body weight ✓ Maintain or change 1 day prescription calorie ✓ Improving the eating habits of individual eating patterns ✓ Exercise targets were set to support weight management (30-45 mins/day, 5 days/week)	
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ANNEXURE -VI

SAMPLE OF DATA COLLECTION FORM

SL No: 18
PATIENT NAME:
O P NO: 1013828
AGE: 34 SEX: F
EDUCATION: PUC OCCUPATION: House wife
TREATING DOCTOR: Dr. Santosh Hazare

HISTORY:

PRESENT: Weight gain
Acidity
Bloating
Fatigue

PAST: No past history related to present condition.
No family history

DIAGNOSIS: NAFLD

Lifestyle:

Sedentary: ✓

Heavy:

Diet:

Type of diet: Vegetarian

Required Calories/Day:

30% Calorie Deficit from needed calories per day over 6 months.

Method of monitoring:

1. Food Dairy ✓
2. Phone Calls ✓

Exercise:

Duration: 30 to 45 minutes per day, weekly 5 days

Type of Exercise:

1. Walking ✓
2. Swimming
3. Cycling ✓
4. Jogging
5. Combined Exercise

Method of monitoring:

1. Mobile App ✓
2. Personal Supervision ✓
3. Fit Band ✓

Name:
Sex: F Age: 34 Height: 155 cm

1	Duration Date	Baseline	6 weeks	12 weeks	18 weeks	24 weeks	Remarks
2	Waist Circumference	98	95	93	94	92	
3	Weight	78	76	75	72	68	
4	Body Mass Index (BMI)	32.47	31.69	31.2	30	28.3	
5	AST/SGOT (Aspartate Aminotransferase)	52	30	27	24	20	
6	ALT/SGPT (Alanine Transaminase)	65	40	36	25	21	
7	Triglycerides (TG)	190	187	175	169	152	
8	Haemoglobin (Hb)	16.2	15.8	15.1	14.8	14.5	
9	Platelet Count (PC)	4.56	5.4	4.60	3.8	3.6	
10	Albumin (Alb)	4.5	4.5	3.8	3.9	4.2	
11	FIB -4 Score	0.54	0.51	0.51	0.48	0.39	
12	APRI Score	0.29	0.26	0.29	0.21	0.23	
13	Controlled attenuation parameter (CAP)	270	—	—	—	240	
14	Fibroscan (FS)	9.8	—	—	—	7.1	
15							

ANNEXURE -VII

30% CALORIE DEFICIT DIET PLAN

TIME	MENU	AMOUNT
Early morning- 6a.m. 7a.m.	Lime water + Almond Milk	1 Glass + 4No. 1 Cup (100 ml)
Breakfast- 8:00 a.m.	Milk/Curd + Salad **Cereal:** Upma/Poha or Idly/Bread or Chapati/Roti **Protein:** Egg white or boiled sprouted pulse or Paneer	½ Cup + 100gm 1 Katori 2 No. 1 No. (30gm) 1 No. ½ Katori ½ Katori
Mid-morning- 11:00 a.m.	Fruit / Fruit juice Buttermilk/ Soup/ Ambli	1 No. / 100 gm 1 Glass (200 ml)
Lunch- 1:30 p.m.	Salad Chapati/Roti Rice/Navani/Saave Dal Vegetable Curd	100 gm 1 No. (30 gm each) 1 Katori ½ Katori 1 Katori ½ Cup
Evening snack- 5:30 p.m.	Tea/Coffee/Milk Churmura + Putana Bread/Biscuit	1 Cup 2 Katori + ½ Katori 3/2 No.
Dinner- 8:00 p.m.	Same as lunch	
Bed time- 10:30 p.m.	Milk	1 Cup (100 ml)

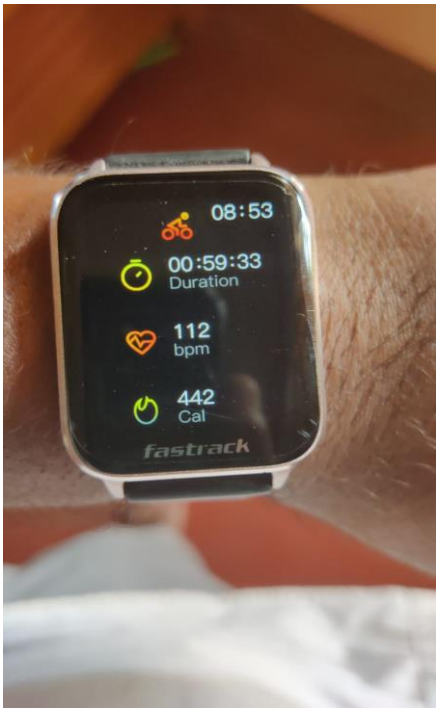
Calories – 1493.2 Kcal/Day
Carbohydrate – 215.9 gm/Day Protein – 53.82 gm/Day
Fat – 40.42 gm/Day
% of CHO = 57.83%
% of protein = 14.42%
% of fat = 24.36%

ANNEXURE -VIII

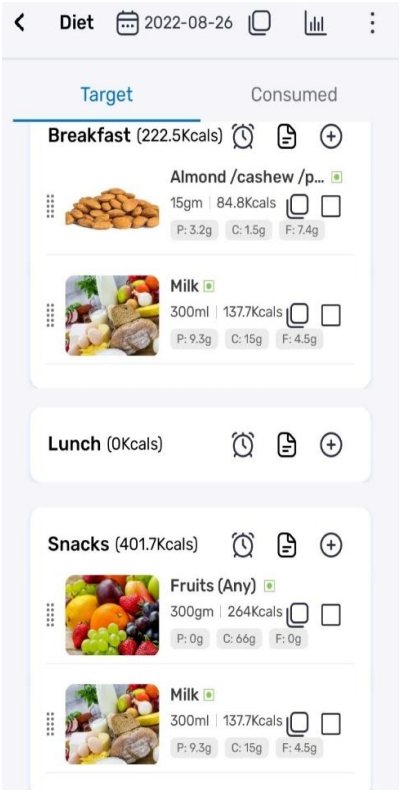
SAMPLE COPY OF FILLED DIET DIARY, AND FITNESS BAND BY USING MOBILE APPLICATION

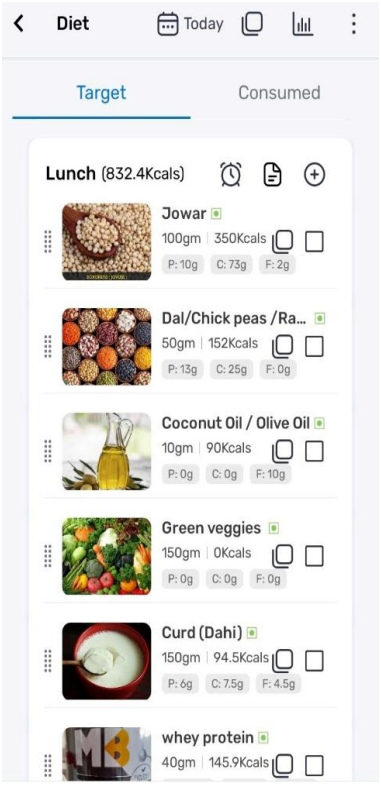
Aerobic exercise (Cycling) monitored by using fitness

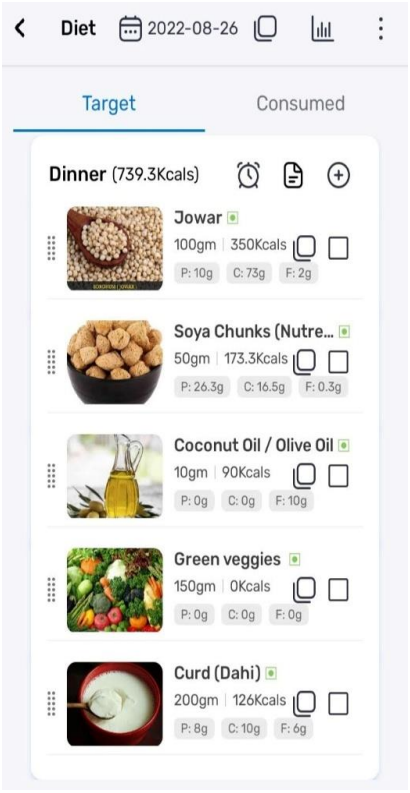




Diet Monitored by using Mobile app diary







ANNEXURE -IX

CERTIFICATES



14th Annual Conference of Indian Society of Gastroenterology Karnataka Chapter

ISGKCON-2024

Theme: "Best Practices in Clinical Gastroenterology"

CERTIFICATE OF APPRECIATION

Presented to

GEETA S DESAI

for securing First Place in the E-poster on the topic

Prevalence and Spectrum of Metabolic Dysfunction Associated Steatotic Liver Disease (MASLD) in General Population of North Karnataka

at the 14th Annual Conference of Indian Society of Gastroenterology Karnataka Chapter held on 19th & 20th of October 2024, at Father Muller Convention Centre, Mangaluru.

Dr. D Sreenivasa, President, ISG Karnataka Chapter
Dr. Ravindra B S, Secretary, ISG Karnataka Chapter
Dr. Aravind Gubbi, Treasurer, ISG Karnataka Chapter
Dr. Bailuru Vishwanath Tantry, Organizing Chairman, ISGKCON 2024
Dr. Shivaprasad B, Secretary, ISGKCON 2024
Dr. Apoorva Srijayadeva, Treasurer, ISGKCON 2024



BELAGAVI INSTITUTE OF MEDICAL SCIENCES

COLLEGE OF NURSING

DR. B R Ambedkar Road BIMS Campus Belagavi- 590001

(In association with KSNC, RGUHS Bengaluru and TNAI New Delhi)

Email. bimsnursingnationalconference@gmail.com Office No - 08312491391

NATIONAL CONFERENCE *On*

Nursing Professionals towards Legalistic Orientation

–An Odyssey through Forensics

Certificate

This is to certify Mr/Mrs/Miss Geeta S. Desai *has*

Presented Paper/Poster titled Incidence of non-alcoholic fatty liver disease (NAFLD)/ non-alcoholic steatohepatitis (NASH) in female population of North Karnataka

in the national conference on Nursing Professionals towards Legalistic Orientation - An Odyssey through Forensics, Held on 17th and 18th November 2023.

Organised by College of Nursing BIMS Belagavi.

Mr. Sachin Paramashetti, Assistant Professor, Organizing Secretary
Mr. Prakash Kodli, Principal GSON, Co-Chairperson
Mr. Namdev Malagi, Principal GCON, Chairperson
Dr. Ashok Kumar Shetty, Dean & Director

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed-to-be-University)
Accredited 'A+' Grade by NAAC (3rd Cycle) Placed in 'Category A' by MoE, (GoI)

INSTITUTE OF NURSING SCIENCES
NEHRU NAGAR, BELAGAVI

National Conference

Certificate of Award

Is here by awarded to

Dr./Prof./Mr./Ms./Mrs. Geeta. Desai has Presented Paper/ Poster in National Conference on **"Fostering Innovation in Midwifery: Moving forward in maternal & Newborn Care"** in association with SOMI and TNAI (KSB). Has Secured Runners up Prize, Organized by KAHER Institute of Nursing Sciences Belagavi, Karnataka, India, on 22nd and 23rd March 2024

Title of the Paper/Poster: EFFICACY OF SUPERVISED DIET AND EXERCISE IN THE MANAGEMENT OF NON-ALCOHOLIC STEATOHEPATITIS IN FEMALE POPULATION

TNAI President | SOMI Secretary | Organizing Secretary | Organizing Chairperson





"ISGKCON 2K22"

13th Annual Conference of Indian Society of Gastroentrology Karnataka Chapter

Hosted By: Department of Medical Gastroenterology SDM University Dharwad

in association with

G. I. CLUB, API & ASI - Hubballi-Dharwad

A Constituent unit of SHRI DHARMASTHALA MANJUNATHESHWARA UNIVERSITY

Certificate of Participation

This is to certify that

Dr Geeta S Desai

has presented a **Poster Presentation** titled as

Prevalence Of NAFLD/ NASH In General Population Of North Karnataka

1st Prize

in the **ISGKCON - 2K22**

held at Ishavaasyam (Manjushree Block), SDM College of Medical Sciences & Hospital, Dharwad on 24th - 25th September 2022.

Dr. Ganesh Puri, President, ISGKC

Dr. Rajkumar Wadkar, Secretary, ISGKC

Dr. Sanjeev Chatni, Organizing Chairman, ISGKCON 2022

Dr. Preetham Hukkeri, Organizing Secretary, ISGKCON 2022

Dr. Laxmikant Desai, Organizing Secretary, ISGKCON 2022



BENGALURU

64th ISGCON

21st-24th DECEMBER 2023

ANNUAL CONFERENCE OF THE INDIAN SOCIETY OF GASTROENTEROLOGY

64th Annual Conference of Indian Society of Gastroenterology

Certificate of Participation

This is to Certify that

GEETA DESAI

has presented E-Poster on

EFFICACY OF SUPERVISED DIET AND EXERCISE IN MANAGEMENT OF NON-ALCOHOLIC FATTY LIVER DISEASE(NAFLD)/ NON-ALCOHOLIC STEATOHEPATITIS(NASH)

In **ISGCON 2023** held from 21st – 24th December 2023

Dr Mathew Philip
Secretary General

Dr Sandeep Nijhawan
President

KLE

KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE NEHRU NAGAR, BELAGAVI-590010

Jawaharlal Nehru Medical College

(A Constituent Unit of KLE Academy of Higher Education & Research)

(Deemed-to-be University)

Accredited A+ Grade by NAAC (3rd Cycle) & Placed in Category 'A' by MHRD (GoI)

This is to certify that

Dr GEETA S. DESAI

has participated & presented a ***Paper / Poster entitled***

Prevalence of Nonalcoholic Fatty Liver Disease (NAFLD)/Nonalcoholic Steatohepatitis in Female Population of North Karnataka

in the **41st JNMC Scientific Society Annual CME - 2023,**

organized by KAHER's J. N. Medical College, Belagavi; held on 8th & 9th April 2023

Dr. (Mrs.) N. S. Mahantashetti
President
41st JNMC Scientific Society Annual CME 2023

Dr. Anita Dalal
Organising Chairperson
41st JNMC Scientific Society Annual CME 2023

Dr. M. B. Bellad
Organising Chairperson
Scientific Committee

Dr. Shantala Herlekar
Scientific Society Secretary

Dr. Swapnil Pattanshetti
Scientific Society Secretary

41st JNMC SCIENTIFIC SOCIETY ANNUAL CME

THEME : WOMENS HEALTH – NEWER PERSPECTIVES IN EVERY DAY PRACTICE

8th & 9th April 2023

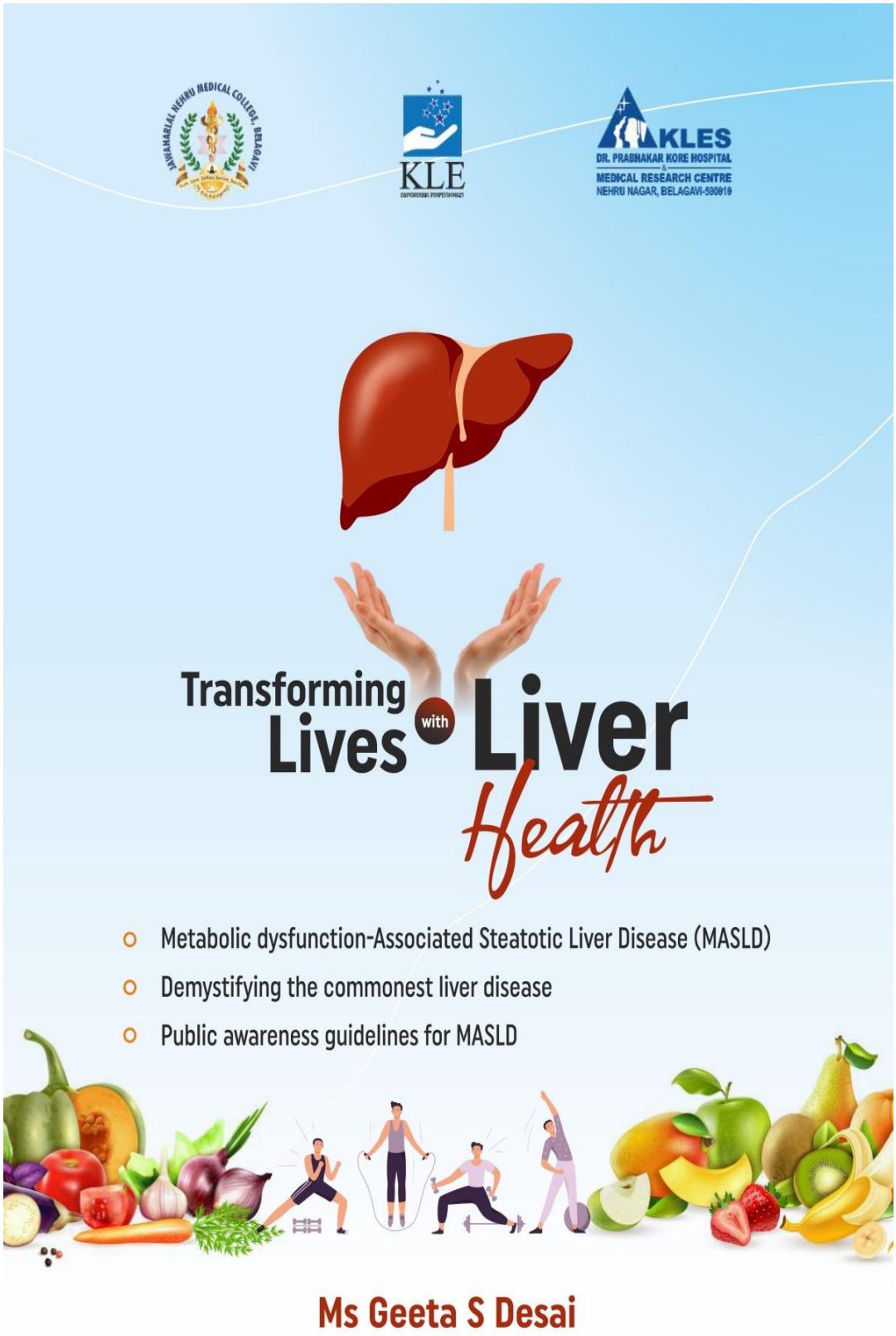
ANNEXURE - X

“TRANSFORMING LIVES WITH LIVER HEALTH” MODULE RELEASED ON 15/8/2024



ANNEXURE -XI

MODULE



Acknowledgment

This module presents collaborative efforts, integrating the latest research and expert insight while highlighting the importance of liver health.
A bibliography has been included to acknowledge our sources and provide further reference.
We extend our sincere gratitude to the individuals listed below who supported us in this endeavor.

- **Col. M. Dayanand**
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  J N Medical College, Belagavi, Karnataka
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  Principal, KAHER Nursing Science, Belagavi
- **Prof. (Dr). Sangeeta Kharde,**
  Dean, KAHER Nursing Science, Belagavi
- **All teaching and non teaching OPD staff**
  Department of Gastroenterology and Hepatology
  J. N. Medical College, Belagavi, Karnataka
- **All the experts / External evaluators**
- **All the participants of the research project who took part in the learning**

Transforming Lives with Liver Health

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Medical Officer, Department of Gastroenterology and Hepatology, Belagavi

MODULE OUTLINE

PROGRAM OVERVIEW

BACKGROUND

MASLD is the most common cause of liver disease. As it is a lifestyle-induced condition, adopting healthy habits can prevent it entirely. This module provides easy-to-understand information for the general population and those at high risk, empowering individuals to make informed lifestyle choices, such as maintaining a balanced diet, exercising regularly, and managing stress levels, to potentially reverse the disease process and prevent future complications.

1. Know your Liver
2. Introduction to MASLD
3. Symptoms and Risk Factors
4. The Importance of Early Diagnosis
5. Lifestyle Modifications and Weight Management
6. Medical Treatment Options
7. Monitoring and Follow-Up
8. Role of a Multidisciplinary Team
9. Psychological Impact and Support
10. Special Considerations
11. Frequently Asked Questions
12. Resources and Support
13. References

PURPOSE OF THE MODULE

This module aims to deliver thorough education to both the general public and healthcare professionals regarding Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD) and its effective management strategies. By concentrating on this particular liver condition, the module intends to improve knowledge and awareness about the significance of maintaining liver health.

Transforming Lives with Liver Health

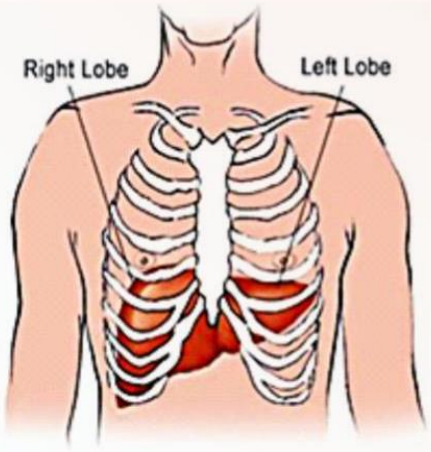
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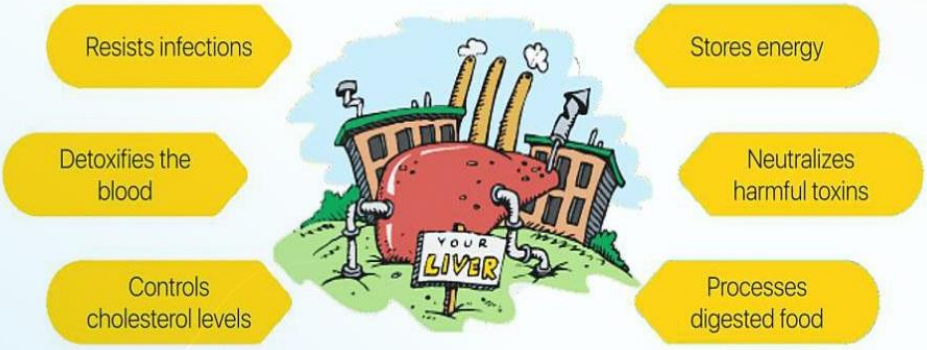
KNOW YOUR LIVER

Liver - Anatomy, Location and Structure

- Body's largest internal organ
- Made of cells called hepatocytes
- Located in the upper right corner of the abdomen
- Soft, reddish brown and wedge shaped, Weighing 1400 gm (women) and 1600 gm (men)
- Front divided into
- Large right lobe and smaller left lobe
- Two more lobes between left and right



Liver functions



Transforming Lives Liver Health

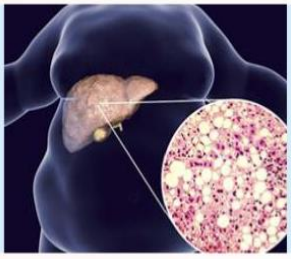
1

Introduction to MASLD

"Understanding your liver health is the first step towards a healthier future."

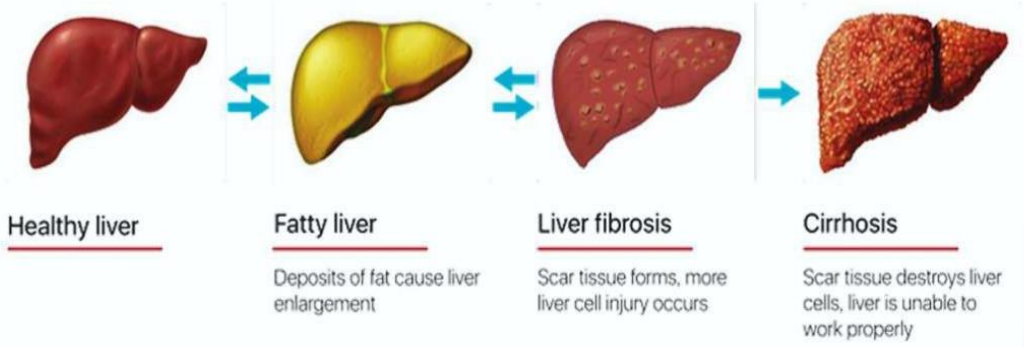
Understanding MASLD

Metabolic dysfunction-Associated Steatotic Liver Disease (MASLD) is a condition where excess fat builds up in the liver of people who drink little or no alcohol.



MASLD is a significant public health concern, affecting an estimated 25-30% of the global population. The condition is associated with metabolic syndrome and its components, such as obesity, type 2 diabetes, hypertension, and dyslipidemia.

MASLD includes a range of liver conditions from simple steatosis (fatty liver) to Metabolic dysfunction-associated SteatoHepatitis (MASH), which involves liver inflammation and can progress to fibrosis, cirrhosis, and even hepatocellular carcinoma (liver cancer).



While simple steatosis is relatively benign, MASH is more serious and can lead to significant liver damage and other health complications.

MASLD is a significant public health concern, affecting an estimated 25-30% of the global population. The condition is associated with metabolic syndrome and its components, such as obesity, type 2 diabetes, hypertension, and dyslipidemia.

MASLD includes a range of liver conditions from simple steatosis (fatty liver) to Metabolic dysfunction-associated SteatoHepatitis (MASH), which involves liver inflammation and can progress to fibrosis, cirrhosis, and even hepatocellular carcinoma (liver cancer).

Symptoms and Risk Factors

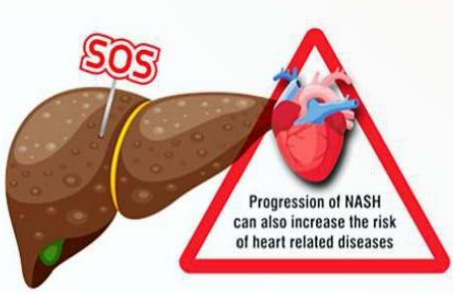
"Know the signs and symptoms, reduce the risks."

Symptoms

MASLD is often a silent disease, particularly in its early stages. Many people with MASLD have no symptoms and are unaware of their condition.

When symptoms do occur, they are typically non-specific and can include fatigue, weakness, weight loss, and discomfort in the upper right abdomen.

As the disease progresses to MASH or cirrhosis, more severe symptoms such as jaundice, abdominal swelling, and gastrointestinal bleeding may develop.



Risk Factors

1. Obesity: The most significant risk factor for MASLD. Excess body fat, especially visceral fat, promotes insulin resistance and fat accumulation in the liver. Obesity rates have been rising globally, contributing to the increasing prevalence of MASLD.

2. Type 2 Diabetes: Individuals with type 2 diabetes are at a higher risk of developing MASLD due to insulin resistance. Poorly controlled blood sugar levels can exacerbate liver fat accumulation and inflammation.

3. High Cholesterol and Triglycerides: Dyslipidemia, characterized by high levels of cholesterol and triglycerides, is commonly associated with MASLD. Abnormal lipid metabolism contributes to fat buildup in the liver.

4. Sedentary Lifestyle: Physical inactivity is a major risk factor for MASLD. Lack of regular exercise can lead to weight gain, insulin resistance, and metabolic dysfunction.

5. Other Factors: These include genetic predisposition, age, sex (MASLD is more common in men), and certain medical conditions such as polycystic ovary syndrome (PCOS) and sleep apnea.

Managing MASLD involves addressing these risk factors through lifestyle changes and medical interventions.

Transforming Lives with Liver Health

3



Prevalence of MASLD



Most People With MASH Are Between The Ages Of 40 And 60.



MASH is more common in young men (2-3 times).



The prevalence is higher in women after 60 years of age.

4

The Importance of Early Diagnosis

"Early detection saves lives; don't wait for liver health."

Early diagnosis of MASLD is crucial because it can significantly impact the management and outcome of the disease. Screening for MASLD should be considered in individuals at high risk, such as those with obesity, type 2 diabetes, or metabolic syndrome.

Screening Methods



Blood tests | Ultrasound/FibroScan | Liver biopsy for pathology | X-ray, CT andMRI

1. Blood Tests:

Liver enzyme tests (ALT and AST) are commonly used to assess liver function. Elevated levels may indicate liver inflammation or damage. However, normal liver enzyme levels do not exclude MASLD.

2. Imaging Studies:

IUltrasound: The most commonly used imaging technique for detecting liver fat. It's non-invasive and widely available but less sensitive for detecting mild steatosis.

IFibroScan (Transient Elastography): Measures liver stiffness and can assess the degree of fibrosis. It is more accurate than ultrasound for detecting advanced fibrosis and cirrhosis.

IMRI (Magnetic Resonance Imaging): Provides a detailed assessment of liver fat and fibrosis. MRI-based techniques like MR elastography are highly sensitive but more expensive and less available than ultrasound and FibroScan.

3. Liver Biopsy:

Considered the gold standard for diagnosing MASH and assessing the severity of liver damage. However, it is invasive, carries risks, and is not routinely performed for all patients.

Regular monitoring and follow-up are essential for managing MASLD, especially for patients with MASH or advanced fibrosis.

Monitoring involves periodic blood tests, imaging studies, and clinical assessments to track disease progression and response to treatment.

Early intervention with lifestyle modifications can prevent disease progression and improve long-term outcomes.

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Lifestyle Modifications and Weight Management

"Healthy habits today, healthier liver tomorrow."

Lifestyle modifications are the cornerstone of managing and preventing MASLD.

The primary focus should be on achieving and maintaining a healthy weight, adopting a balanced diet, and regular physical activity. These changes can significantly reduce liver fat, improve liver function, and prevent disease progression.



1. Caloric Restriction and Balanced Diet:

- Reducing calorie intake is essential for weight loss.
- A personalized plan that creates a moderate calorie deficit can help patients achieve sustainable weight loss.
- It is important to avoid crash diets, which can lead to rapid weight loss and potential complications.
- A balanced diet that includes a variety of nutrients is essential for weight management.
- Patients should focus on whole, unprocessed foods and avoid fad diets that promise rapid weight loss.
- A diet rich in fruits, vegetables, whole grains, lean proteins, and healthy fats is recommended.
- Practicing portion control helps prevent overeating. Using smaller plates, eating slowly, and paying attention to hunger and fullness cues can assist in managing portion sizes.

2. Reduce Saturated Fat and Sugar:

- Limiting the intake of saturated fats (found in red meat, butter, and processed foods) and added sugars (found in sugary drinks, desserts, and candies) is crucial. These nutrients contribute to liver fat accumulation and insulin resistance.

3. Mediterranean Diet:

- This diet is recommended for its health benefits and effectiveness in managing MASLD. It emphasizes the consumption of vegetables, fruits, whole grains, legumes, nuts, olive oil, and fish.
- The Mediterranean diet is rich in antioxidants and anti-inflammatory compounds, which can improve liver health.

4. Hydration:

- Drinking plenty of water and staying hydrated is important for overall health. Patients should limit the consumption of sugary beverages and alcohol.

Control your weight gain



Combination of hypocaloric diet and moderate-intensity exercise provide best likelihood of sustained weight loss.

Weight loss of at least 3-5% body weight helps to improve steatosis.

Weight loss of 7-10% to improve majority of histopathological features of NASH including fibrosis.

Diet for healthy liver (Mediterranean Diet)

Weekly:
Moderate portions poultry, eggs, cheese and yogurt

Every day: Base each meal around vegetables, fruits, whole wheat grains, olive oil, beans, nuts, legumes, & seeds, herbs and spices



Less often:
Red meat and sweets

Often: Twice each week fish & seafood

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1. **Aerobic Exercise:**
   - Engaging in at least 150 minutes of moderate-intensity aerobic exercise per week (such as brisk walking, cycling, or swimming) can improve insulin sensitivity and reduce liver fat. For more significant benefits, patients can aim for 300 minutes per week.

2. **Resistance Training:**
   - Incorporating resistance exercises (such as weightlifting or bodyweight exercises) at least twice a week can help build muscle mass, enhance metabolism, and improve overall strength and fitness.

3. **Active Lifestyle:**
   - Encouraging patients to be more active throughout the day, such as taking the stairs instead of the elevator, walking during breaks, and reducing sedentary time, can contribute to better health outcomes.

4. **Behavioral Changes:**
   - Addressing behavioral aspects of eating and activity is key to successful weight management.
   - This includes identifying and managing triggers for overeating, developing healthy coping strategies for stress, and creating a supportive environment for making healthy choices.

5. **Setting Realistic Goals:**
   - Patients should set achievable and realistic weight loss goals.
   - Aiming for a gradual weight loss of 1-2 pounds per week is generally considered safe and sustainable. Celebrating small successes along the way can boost motivation.

6. **Professional Support:**
   - Seeking support from healthcare providers, dietitians, and weight loss programs can provide guidance, accountability, and encouragement.
   - Group support or counseling may also be beneficial for some patients.

Weight management is a critical component of MASLD treatment and prevention. Achieving and maintaining a healthy weight can significantly reduce liver fat, improve liver function, and prevent the progression of MASLD to more severe stages.

Maintaining weight loss can be challenging, but adopting lifelong healthy habits is crucial for long-term success.

Patients should focus on making sustainable changes rather than seeking quick fixes. Education about nutrition, physical activity, and behavior change is essential to empower patients to take control of their health.

Medical Treatment Options

"Effective management of underlying conditions can improve liver health."

While lifestyle modifications are the primary treatment for MASLD, medical treatment may be necessary for some patients, particularly those with MASH or advanced fibrosis.

Currently in India, Saroglitazar is the only medication approved for MASLD, and several drugs are under investigation.

Medications



1. **Saroglitazar:**
   a) Saroglitazar 4 mg OD, is a medication that has shown promise in treating Metabolic Associated Steatotic Liver Disease (MASLD) and Metabolic Associated Steatohepatitis (MASH).
   b) It is a dual peroxisome proliferator-activated receptor (PPAR) agonist, which means it works by activating two types of receptors in the body, PPAR-alpha and PPAR-gamma. These receptors play a key role in regulating lipid (fat) and glucose (sugar) metabolism, as well as reducing inflammation.

2. Insulin Sensitizers:
   a) Medications like pioglitazone, which are used to treat type 2 diabetes, can improve insulin sensitivity and reduce liver fat. Pioglitazone has shown promise in patients with MASH, although its use is limited by potential side effects and is not approved for the indication.

3. Antioxidants:
   a) Vitamin E has been studied for its potential benefits in MASH. It has antioxidant properties that may reduce liver inflammation and damage. However, long-term safety and efficacy need further investigation and is not approved for the indication.

4. GLP-1 Agonists:
   a) Drugs like liraglutide and semaglutide, used to treat type 2 diabetes, have shown potential in reducing liver fat and inflammation. These medications help with weight loss and improve insulin sensitivity but are not approved for the indication.

5. Statins:
   a) Statins, which are commonly used to lower cholesterol, may also benefit patients with MASLD by improving lipid profiles and reducing cardiovascular risk. However, their direct effects on liver fat are still being studied and these are not approved for the indication.

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6. **Fibrosis-Targeted Therapies:**
   Several experimental drugs aim to reduce liver fibrosis and inflammation. These include antifibrotic agents, immune modulators, and other novel compounds. Clinical trials are ongoing to evaluate their safety and efficacy.

In addition to medications, managing comorbid conditions like diabetes, hypertension, and dyslipidemia is crucial for patients with MASLD.

Controlling blood sugar, blood pressure, and lipid levels can help reduce the risk of liver-related complications and improve overall health.

Patients should work closely with their healthcare providers to develop a comprehensive treatment plan tailored to their needs.

Regular monitoring and follow-up are essential to assess the effectiveness of treatment and make necessary adjustments.

Monitoring and Follow-Up

"Stay vigilant, stay healthy."

Regular monitoring and follow-up are essential for managing MASLD, particularly for patients with MASH or advanced fibrosis. Continuous assessment helps track disease progression, evaluate the response to treatment, and adjust management plans as needed.

Monitoring Strategies

1. **Routine Check-ups:** Regular visits to healthcare providers are important for ongoing assessment and management. These check-ups should include a review of symptoms, physical examination, and evaluation of lifestyle adherence.

2. **Liver Function Tests:** Periodic blood tests to measure liver enzymes (ALT, AST) and other markers of liver function are crucial. These tests help detect liver inflammation and damage.

3. **Imaging Studies:** Repeated imaging studies, such as ultrasound, FibroScan, or MRI, can assess changes in liver fat and fibrosis. FibroScan is particularly useful for monitoring liver stiffness and fibrosis progression.

4. **Liver Biopsy:** In certain cases, a repeat liver biopsy may be necessary to evaluate the severity of liver inflammation and fibrosis. This is typically reserved for patients with suspected progression or when other diagnostic methods are inconclusive.

5. **Metabolic Parameters:** Monitoring blood sugar, cholesterol, triglycerides, and blood pressure is important for managing metabolic risk factors associated with MASLD. Regular assessment helps ensure that these parameters are well controlled.

6. **Patient Self-Monitoring:** Patients should be educated about self-monitoring their symptoms and health changes. Keeping a journal of diet, exercise, and symptoms can provide valuable insights for both the patient and the healthcare provider.

Effective communication between patients and healthcare providers is crucial for successful monitoring and follow-up.

Patients should be encouraged to ask questions, express concerns, and actively participate in their care. Healthcare providers should provide clear instructions, support, and resources to help patients adhere to their management plans.

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Role of a Multidisciplinary Team

"Teamwork in healthcare enhances your journey to wellness."

Managing MASLD effectively often requires a multidisciplinary approach, involving various healthcare professionals. This team-based approach ensures comprehensive care that addresses all aspects of the disease.

Benefits

1. **Comprehensive Care:**

   A multidisciplinary team can provide a holistic approach to managing MASLD. This includes addressing

   - Gastroenterologist & Hepatologist - Liver health, Metabolic conditions
   - Dietician - Dietary needs
   - Physiotherapist - Physical activity, and
   - Psychologist -Psychological well-being.

2. **Personalized Treatment:**

   Each patient's needs are unique. A multidisciplinary team can develop personalized treatment plans tailored to individual risk factors, preferences, and goals.

3. **Coordinated Care:**

   Effective communication and coordination among healthcare providers ensure that all aspects of the patient's care are addressed. This reduces the risk of fragmented care and improves overall outcomes.

Psychological Impact and Support

"Caring for your mind is as important as caring for your body."

Living with a chronic condition like MASLD can affect mental health. Addressing psychological aspects is crucial for comprehensive care.

Psychological Support

1. **Counseling:**
   Counseling and psychotherapy can help patients manage stress, anxiety, depression, and other mental health issues related to MASLD. Professional support can improve coping strategies and emotional well-being.

2. **Support Groups:**
   Joining support groups allows patients to share their experiences, challenges, and successes with others facing similar issues. Support groups provide a sense of community and can offer practical advice and emotional support.

3. **Mindfulness and Relaxation Techniques:**
   Practices such as mindfulness meditation, deep breathing exercises, and yoga can help reduce stress and improve mental health. These techniques promote relaxation and can be integrated into daily routines.

Special Considerations

"Special situations require special care."

MASLD affects various populations differently. Special considerations are necessary for managing MASLD in children, during pregnancy, and in older adults.

MASLD in Children

- Increasing prevalence due to rising obesity rates.
- Focus on family-based lifestyle interventions.

Pregnancy and MASLD

- Manageable with careful monitoring and lifestyle adjustments.
- Consultation with healthcare providers is essential.

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Frequently Asked Questions

"Informed patients make better health choices."

Common Questions

1. **What is MASLD, and how is it different from MASH?**

   MASLD is a condition where excess fat accumulates in the liver without significant alcohol intake. MASH is a more severe form of MASLD that includes liver inflammation and damage.

2. **Can MASLD be reversed?**

   Yes, especially in the early stages. Lifestyle changes such as diet, exercise, and weight loss can reduce liver fat and inflammation.

3. **What are the best dietary choices for someone with MASLD?**

   A diet rich in vegetables, fruits, whole grains, lean proteins, and healthy fats (such as the Mediterranean diet) is recommended.

4. **How often should I get my liver checked?**

   The frequency of monitoring depends on individual risk factors and disease severity. Regular check-ups with healthcare providers are essential.

5. **What lifestyle changes are most effective?**

   Weight loss through a balanced diet and regular physical activity is the most effective strategy. Managing metabolic conditions and avoiding alcohol are also important.

The Department of Gastroenterology at KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi is committed to raising awareness about MAFLD

The Department of Gastroenterology at KLE Hospital has recognized the alarming rise in Non-Alcoholic Fatty Liver Disease (MAFLD) and has taken a proactive approach to address this growing public health concern. Recognizing the importance of early detection and intervention, the department has embarked on a comprehensive screening program, organizing free camps every third Saturday of the month, as well as on special occasions and for various clubs and foundations. These camps offer a range of tests including anthropometry, LFT (Liver Function Tests), Fibroscan, and Hep B and C screening, enabling the team to assess the health of participants' livers. For individuals identified with abnormal results, the department offers comprehensive counseling and guidance, recommending follow-up consultations with gastroenterologists at KLE Hospital.

Our department is committed to raising awareness about MAFLD and providing accessible screening services, fostering a healthier future for the community. Here are some pictures for the screening camp organized by the Department of Gastroenterology.

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REGISTER HERE
BLOOD SAMPLE COLLECTION
VASH 24x7
ACT NOW
Ayushman Bhav



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Resources and Support

"Empower yourself with knowledge and support."

Helpful Resources

1. NASH 24x7: https://www.nash24x7.com/
2. American Liver Foundation: https://www.liverfoundation.org
2. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): https://www.niddk.nih.gov/health-information/liver-disease
3. Mayo Clinic: https:// www.mayoclinic.org / diseases-conditions / nonalcoholic-fatty-liver-isease / symptoms-causes/syc-20354567
4. Cleveland Clinic: https://my.clevelandclinic.org/health/diseases/15831-fatty-liver-disease
5. American Association for the Study of Liver Diseases (AASLD): https://www.aasld.org/publications /practice-guidelines/nonalcoholic-fatty-liver-disease.
6. Liver Foundation UK: https://britishlivertrust.org.uk/information-and-support/living-with-a-liver-condition/liver-conditions/non-alcohol-related-fatty-liver-disease-nafld/
7. Fatty Liver Foundation: https://www.fattyliverfoundation.org/
8. National Health Service (NHS) - UK: https://www.nhs.uk/conditions/non-alcoholic-fatty-liver-disease/
9. WebMD: https://www.webmd.com/hepatitis/fatty-liver-disease
10. Johns Hopkins Medicine : https://www.hopkinsmedicine.org/health/conditions-and-diseases/ non alcoholic-fatty-liver-disease
11. American Gastroenterological Association (AGA): https://www.gastro.org/practice-guidance/ gi-patient-center/topic/nonalcoholic-fatty-liver-disease-nafld.
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Department of Gastroenterology

Jawaharlal Nehru Medical College, Belagavi

KLE Academy of Higher Education & Research, Belagavi

(Deemed-to-be-University) Accredited 'A+' Grade by NAAC (3rd cycle) | Placed in Category 'A' by MoE (GoI)

KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi






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ANNEXURE - XII

PUBLICATIONS

The Scientific Temper (2023) Vol. 14 (4): 1106-1112
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RESEARCH ARTICLE

Prevalence of non-alcoholic steatohepatitis in a general population of North Karnataka

Geeta S. Desai[1], Santosh Hajare[2*], Sangeeta Kharde[3]

Abstract

This study aims to investigate the prevalence of non-alcoholic steatohepatitis (NASH) in the general population of North Karnataka. A cross-sectional population-based study was conducted in the city of Belagavi, where in total of 730 subjects were included. The subjects were screened for the presence of liver disease with a detailed history, anthropometric measurements, and blood tests including liver function tests, lipid profile, and blood sugars, liver stiffness was measured by using the fibroscan. Out of 730 subjects, 228 (31.23%) had significant fibrosis suggestive of NASH on fibroscan. Of these 138 (60.52%) were males and 90(39.47%) were females. Of the total number of subjects having NASH 52 (22.80%) were diabetics and 64 (28.07%) were hypertensive. The study also revealed as the body mass index (BMI) increases the proportion of subjects with abnormal liver enzymes and significant liver fibrosis increased proportionately suggestive of NASH. Also, a small number of subjects (22.6%) with low or normal BMI had features suggestive of lean NASH. The incidence of NASH in the general population of North Karnataka is 31.23% This high incidence could be due to the prevailing growing epidemic of diabetes mellitus and obesity in the community.

Keywords: Cirrhosis, Fibroscan, Liver function enzymes, Non-alcoholic fatty liver disease, NAFLD, Liver Fibrosis.

Introduction

Hepatic steatosis, often known as fatty liver, is the medical term for the intrahepatic accumulation of fat that accounts for 5 to 10% of the liver weight. This results either due to excessive intake of alcohol or excessive calories. When fatty liver results without a significant history of alcohol intake, it is labeled as NAFLD (Nassir *et al.*, 2015). Non-alcoholic fatty liver disease (NAFLD) is commonly associated with excessive intake of calories, obesity, hypertension, type 2 Diabetes Mellitus, dyslipidemia, cardiovascular disease, chronic kidney disease and sleep apnoea (Glass *et al.*, 2019). Non-alcoholic fatty liver disease causes the entire spectrum of liver disease ranging from benign fatty liver, to non-alcoholic steatohepatitis (NASH), cirrhosis, decompensated cirrhosis with portal hypertension and hepatocellular carcinoma (Ghevariya *et al.*, 2014; Adams and Feldstein, 2010, Sheka *et al.*, 2020)

The prevalence of NAFLD grew globally from 25.5% in 2005 to 35.5% in 2016 due to increased sedentary behavior and lifestyle changes, with the highest incidence in the West and Middle East and the lowest in Africa. NASH is expected to be present in 59.10% of NAFLD patients, with a global prevalence of 6.4% (Riazi *et al.*, 2022; Pedrosa *et al.*, 2018). NAFLD is diagnosed by simple imaging of the liver like ultrasonography/CT of the liver. Over the years liver biopsy was the gold standard for diagnosing NASH with classical features of steatohepatitis on biopsy. However, liver biopsy has numerous drawbacks, including the risk of bleeding, high procedural costs, and inaccurate sampling as it only represents 1/50000 of the liver volume and does not precisely reflect the whole liver's anatomy (Wai *et al.*, 2003; Danaf *et al.*, 2022). To overcome these limitations the diagnosis of NASH and its progression is recently being monitored using non-invasive, highly sensitive tests with consistent results such as FIB score, APRI score (using liver function test and platelets counts), and measuring

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liver stiffness LSM with Fibroscan or MRI elastography (Papagianni *et al.*, 2015; Piazzolla and Mangia, 2020; Paul, 2020; Sasso *et al.*, 2012).

In India, the prevalence of NAFLD/NASH ranges from 6.7 to 55%. Most patients have liver enzyme elevations and many are asymptomatic (Duseja *et al.*, 2015). However, the prevalence varies with the geographical locations (urban or rural areas), age of the population, and incidence of comorbidities in that place. According to a National Family Health Survey, in Karnataka state (India), the prevalence of non-communicable diseases, including Type 2 diabetic mellitus (14.8%) and hypertension (25.9%) were found to be high which are risk factors for developing NAFLD/ NASH (James *et al.*, 2022). Hence this study was designed to estimate the prevalence rate of NAFLD/NASH in North Karnataka regions using liver function tests and non-invasive Fibroscan (Liver stiffness i.e. LSM score) of the liver.

Materials And Methods

Study design

A cross-sectional, population-based study was conducted at Jawaharlal Nehru Medical College and KLES Dr Prabhakar Kore Hospital and Medical Research Center, Belagavi, Karnataka. The study received approval from the Institutional Ethics Committee on Human Subjects (Ref.No.KAHER/EC/21-22/014). A total of 730 subjects were included in the study. Subjects aged between 18 to 80 years without a prior history of liver diseases were included in the study. All the subjects below the age of 18, or who had a prior history of heavy alcohol consumption or had liver diseases associated with alcohol consumption and subjects diagnosed with Hepatitis B and C were excluded from the study. All the selected subjects were screened for liver diseases with detailed history, anthropometric measurements (height, weight, body mass index), liver function tests, blood sugars, hypertension and ultrasound abdomen and liver fibrosis. Those subjects with evidence of fatty liver on USG imaging were labeled as having NAFLD. Those patients with abnormal LSM on Fibroscan with or without abnormal liver function tests were labeled as NASH.

Laboratory analysis

Serum samples of the selected subjects were collected and analyzed using a Hitachi Cobas C analyzer. The following parameters were analyzed- blood sugar, total cholesterol, triglycerides, ALT/SGOT and AST/SGPT. Serum alanine aminotransferase (ALT) is a specific indicator of liver inflammation with a standard range of 0 to 40 U/L. Serum aspartate aminotransferase (AST) is an indicator of liver damage or injury with a normal range of 14 to 20 U/L (males) and 10 to 36 U/L (females).

Fibroscan

Fibroscan/Ultrasound elastography is primarily used to assess liver stiffness/hardness and fatty alterations.



Figure 1: Fibroscan 430 MINI

It is mainly used for determining the NAFLD and NASH stages. The FIBROSCAN 430 MINI (Echosens/Device ID-03662264001192;18/08/2021) instrument was employed in the current investigation to conduct the analysis (Figure 1). It operates by assessing the speed of shear waves. In this procedure, a tiny transducer on the end of an ultrasonic probe transmits a 50-MHz wave into the liver. The probe also incorporates a transducer that can monitor the shear

Table 1: Baseline demographic characteristics of the study (n = 730)

Variables		*Sub Category*	*Number of Subjects (%)*
Age	< = 20	6	0.8
	21–30	114	15.6
	31–40	216	29.6
	41–50	188	25.8
	51–60	146	20.0
	61–70	51	7.0
	71–80	6	0.8
	> 80	3	0.4
Sex	Male	353	48.4
	Female	377	51.6
BMI	< 18.5	32	4.4
	18.5–24.9	268	36.7
	25.0–29.9	305	41.8
	> = 30	125	17.1
DM	No	640	87.7
	Yes	90	12.3
HTN	No	616	84.4
	Yes	114	15.6
LFT	Normal	586	80.3
	Abnormal	144	19.7

Note: BMI -Body Mass Index, DM -Diabetes Mellitus, HTN - Hyper Tension,
LFT - Liver Function Test.

Table 2: Fibroscan Scores in all subjects

Variables	Subcategory	Fibroscan	
		Normal	Abnormal
		Number of subjects (%)	
Fibrosis Score	F0	502 (68.76%)	0
	F1	0	99 (43.4%)
	F2	0	70 (30.7%)
	F3	0	38 (16.7%)
	F4	0	21 (9.2%)
		502 (68.76%)	228 (31.23%)

wave's velocity as it travels through the liver (in m/sec). The liver stiffness, which is measured in kilopascals, can then be obtained by converting the shear wave velocity. The fibrosis score F0 (0–7 kPa) indicates no scarring on the liver, F0-F1 (7–8.2) indicates mild scaring (mild fibrosis), F2 (8.3–9.7 kPa) indicates moderate scarring (significant fibrosis), F3 (9.7–13.6 kPa) indicates severe scarring with obstructive blood flow (advanced fibrosis) and F4 (> 13.6 kPa) indicates cirrhosis of the liver. The fibroscan reports were reviewed by the gastroenterologist.

Statistical analysis

Data is analyzed using SPSS software version 21 and Excel. Categorical variables are given in the form of a frequency table. The chi-square test analyses categorical variables. The Shapiro-Wilk test and QQ plot check the normality of the variable. Mann Whitney U test compares the distributions of variables over Fibroscan. *p-value* less than or equal to 0.05 indicates statistical significance.

Results

Baseline demographic characteristics of the study (n = 730) is shown in Table 1.

Distribution of subjects based on Fibroscan

Table 2 indicates that, out of 730 subjects, 502 subjects were found to have normal fibroscan with fibrosis score of

Table 3: Association of fibroscan scores with different variables

Variables	Subcategory	F0		F1		F2		F3		F4		Total	
		N	%	N	%	N	%	N	%	N	%	N	%
		Chi-square (d.f. = 7) = 84.759, p < 0.001											
Age	< = 20	5	1	0	0	1	1.4	0	0	0	0	6	0.8
	21–30	105	20.9	6	6.1	3	4.3	0	0	0	0	114	15.6
	31–40	149	29.7	31	31.3	23	32.9	10	26.3	3	14.3	216	29.6
	41–50	141	28.1	24	24.2	11	15.7	10	26.3	2	9.5	188	25.8
	51–60	61	12.2	31	31.3	26	37.1	13	34.2	15	71.4	146	20
	61–70	35	7	6	6.1	5	7.1	4	10.5	1	4.8	51	7
	71–80	5	1	0	0	1	1.4	0	0	0	0	6	0.8
	> 80	1	0.2	1	1	0	0	1	2.6	0	0	3	0.4
		Chi-square (d.f. = 1) = 19.664, p < 0.001											
Sex	Male	215	42.8	58	58.6	39	55.7	27	71.1	14	66.7	353	48.4
	Female	287	57.2	41	41.4	31	44.3	11	28.9	7	33.3	377	51.6
		Chi-square (d.f. = 3) = 86.97, p < 0.001											
BMI	< 18.5	30	6	0	0	2	2.9	0	0	0	0	32	4.4
	18.5–24.9	219	43.6	26	26.3	16	22.9	5	13.2	2	9.5	268	36.7
	25.0–29.9	206	41	46	46.5	31	44.3	16	42.1	6	28.6	305	41.8
	> = 30	47	9.4	27	27.3	21	30	17	44.7	13	61.9	125	17.1
		Chi-square (d.f. = 1) = 33.679, p < 0.001											
DM	No	464	92.4	83	83.8	50	71.4	33	86.8	10	47.6	640	87.7
	Yes	38	7.6	16	16.2	20	28.6	5	13.2	11	52.4	90	12.3
		Chi-square (d.f. = 1) = 39.022, p < 0.001											
HTN	No	452	90	75	75.8	58	82.9	25	65.8	6	28.6	616	84.4
	Yes	50	10	24	24.2	12	17.1	13	34.2	15	71.4	114	15.6
		Chi-square (d.f. = 1) = 29.416, p < 0.001											
LFT	Normal	430	85.7	73	73.7	47	67.1	23	60.5	13	61.9	586	80.3
	Abnormal	72	14.3	26	26.3	23	32.9	15	39.5	8	38.1	144	19.7

Note: - d.f. = degree of freedom, BMI -Body Mass Index, DM -Diabetes Mellitus, HTN - Hyper Tension, LFT - Liver Function Test.

Table 4: Association of abnormal fibro scan scores (NASH)with different variables

Variables	*subcategory*	*Normal*		*Abnormal*		*Total*	
		N	*%*	*N*	*%*	*N*	*%*
		Chi-square (d.f. = 7) = 84.759, p < 0.001					
Age	< = 20	5	0.68	1	0.13	6	0.8
	21–30	105	14.38	9	1.23	114	15.6
	31–40	149	20.41	67	9.17	216	29.6
	41–50	141	19.31	47	6.43	188	25.8
	51–60	61	8.35	85	11.64	146	20
	61–70	35	4.79	16	2.19	51	7
	71–80	5	0.68	1	0.13	6	0.8
	> 80	1	0.13	2	0.27	3	0.4
		Chi-square (d.f. = 1) = 19.664, p < 0.001					
Sex	Male	215	29.45	138	18.9	353	48.4
	Female	287	39.31	90	12.32	377	51.6
		Chi-square (d.f. = 3) = 86.97, p < 0.001					
BMI	< 18.5	30	4.1	2	0.27	32	4.4
	18.5–24.9	219	30	49	6.71	268	36.7
	25.0–29.9	206	28.21	99	13.56	305	41.8
	> = 30	47	6.43	78	10.68	125	17.1
		Chi-square (d.f. = 1) = 33.679, p < 0.001					
DM	No	464	63.56	176	24.1	640	87.7
	Yes	38	5.2	52	7.1	90	12.3
		Chi-square (d.f. = 1) = 39.022, p < 0.001					
HTN	No	452	61.91	164	22.46	616	84.37
	Yes	50	6.84	64	8.76	114	15.6
		Chi-square (d.f. = 1) = 29.416, p < 0.001					
LFT	Normal	430	58.9	156	21.36	586	80.26
	Abnormal	72	9.86	72	9.86	144	19.72

Note: - d.f. - degree of freedom, BMI -Body Mass Index, DM -Diabetes Mellitus, HTN - Hyper Tension, LFT - Liver Function Test.

F0, 228 subjects were found to be abnormal fibroscans with fibrosis scores ranging from F1 to F4. Among these subjects 99 (43.4%) were diagnosed with F1 score, 70 (30.7%) had F2 scores, 38 (16.7%) subjects had F3, and 21 (9.2%) subjects had F4 scores (Tables 3 and 4).

Fibro scan scores with different variables

The majority of the subjects included in the study were between 21 to 60 years. Most of the subjects with abnormal fibroscan scores were between 30 to 60 years. Out of 228, 138 males and 90 females had abnormal fibroscan scores. The majority of the subjects included in this study had a normal BMI or were overweight. Most of the subjects with normal fibroscans were either having low BMI or normal BMI. Out of 144 subjects with abnormal liver function tests, 72 subjects had abnormal fibroscans suggestive of NASH and the remaining and out of 586 subjects with normal liver function tests only 156 had abnormal values suggestive of NASH (Tables 5 and 6).

Figure 2 shows that, fibroscan score's sensitivity was 74.6% and specificity was 74.3%. Area under the ROC curve is 0.816 (95% CI: 0.784–0.843; p <0.001).

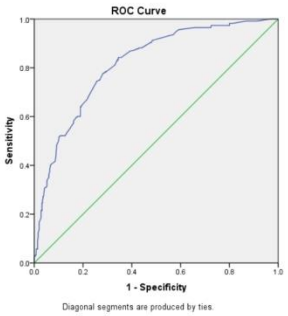


Figure 2: ROC curve

both AST and ALT levels may be elevated or normal, and their values alone do not rule out the presence of NAFLD, as highlighted by studies conducted by Noguchi *et al.* (1995) and Charatcharoenwitthaya *et al.* (2012). Among patients with NAFLD, ALT elevations are more frequently observed than elevations in AST. Notably, ALT levels tend to be higher in non-alcoholic steatohepatitis (NASH) compared to simple steatosis, as indicated by the findings of Mofrad *et al.* (2003).

Our study findings show that, the age of the subjects were between 20 to 80 years. Most of the subjects with abnormal scan were between 21 to 30 years (n=114;15.6%) between 31 to 40 years (n = 216;29.6%), 41 to 50 years (n = 188;25.8%) and 51 to 60 years (n = 146;20%). In a study conducted by Lin *et al.* (2011), it was observed that the majority of participants fell within the age range of 21 to 60 years. Among those without fibrosis, the predominant age group was 21 to 50 years. Subjects with abnormal FibroScan scores were mostly distributed between 30 to 60 years, with 67 (29.38%) participants aged 31 to 40 years, 47 (20.60%) in the 41 to 50 years, and 85 (37.28%) between 51 to 60 years. It can be seen that younger subjects have less fibrosis and fibroscan scores increase with age. However, age is insignificantly associated with fibroscan scores and fibrosis (Pradat *et al.*, 2002)

In our study, 90 (12.3%) subjects were diabetics. Of them, 52 had abnormal fibroscans and 38 were normal. Also, of the 640 non-diabetic subjects only 176 had abnormal fibrosis. Diabetes is significantly associated with NASH. Out of 228 subjects with NASH, 52 (22.80%) subjects had Diabetic Mellitus and 176 (77.19%) subjects were non-diabetics, which was statistically significant. Type II diabetes mellitus hastens the advancement of simple fatty liver to a more severe NASH (Tomah *et al.*, 2020; Dharmalingam and Yamasandhi, 2018). Additionally, our study also found that, 114 (15.6%) were hypertensive. Of them, 64 had abnormal fibroscans and 50 were normal. Of the 616 non-hypertensives, 164 had abnormal fibrosis and 452 were normal. Out of the 228 subjects with NASH, 64 had hypertension and 164 were normotensives. Hypertension is not significantly associated with the development of fibrosis (Tables 3 and 4).

The majority of the subjects included in this study had a normal BMI or were overweight. Few subjects were obese and those who were underweight were the least in number. Most of the subjects with normal fibroscans were either had low BMI 30 of 32 or a normal BMI 219 out of 268. The majority of subjects with abnormal fibroscan scores were either overweight 99 subjects out of 206 or obese 78 out of 125 subjects. Only 2 of the 32 subjects who were underweight with low BMI had abnormal fibrosis. As the BMI of the subjects increased they had more risk of fibrosis with increased fibroscan scores. As the BMI increases beyond normal that is >24.9 there will be the development of steatosis, hepatitis and also an increase in fibrosis This shows a significant association of abnormal liver fibroscan scores with BMI (Eilenberg *et al.*, 2021)

In our study, 144 had abnormal liver function tests. Of them, 72 subjects had abnormal fibroscans suggestive of NASH and the remaining 72 had normal fibroscans. 586 subjects had normal liver function tests, of them 430 had normal fibroscan scores whereas only 156 had abnormal values suggestive of NASH (Table 3).

In the present study, the sensitivity of the fibroscan score prediction with AUROC of 0.80 was found to be 74.6% and the specificity was 74.3%. Thus, it could be postulated that fibroscan along with liver function tests can be used to diagnose NASH from NAFLD. Also, different stages of NASH fibrosis can also be predicted after the fibroscan scores.

Conclusion

The study shows that the prevalence of NAFLD/NASH is relatively high in North Karnataka, that is 31.23%. The prevalence of diabetic mellitus and obesity with high BMI is a significant risk factor for the development of NASH. Fibroscan which is a simple and non-invasive test for assessing firmness of the liver along with liver function tests can be used to predict significant fibrosis of the liver that is NASH. Thus, fibroscan and liver function tests can be used to screen for significant liver diseases in the general population.

Policymakers can use these tests to estimate the burden of significant liver diseases in the population so that appropriate interventions can be planned to reduce the mortality and morbidity of the population leading to advanced liver disease.

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RESEARCH ARTICLE

Evaluation of health practices among individuals with non-alcoholic fatty liver disease: A randomized controlled trial

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Abstract

The current strategy for addressing non-alcoholic fatty liver disease (NAFLD) emphasizes lifestyle adjustments aimed at promoting weight loss. Recommendations include dietary changes and regular physical activity to support patients with NAFLD in achieving their weight loss objectives. However, there is a lack of comprehensive data assessing the efficacy of these approaches. In this randomized controlled trial (RCT) encompassing 90 meticulously chosen individuals diagnosed with NAFLD, participants were divided into intervention (n = 45) and control (n = 45) groups. Across a duration of six months, the intervention consisted of a customized dietary and exercise program designed specifically for NAFLD management, which was implemented, with pre-and post-tests conducted at the beginning and at the end of 6 months. The findings revealed that, the intervention led to improvements in health practices, particularly within the intervention group as compared to the control group, underscoring its significance in managing NAFLD.

Keywords: Diet, Exercise, Non-alcoholic fatty liver disease, Health practices, Lifestyle.

Introduction

Non-alcoholic fatty liver disease (NAFLD) stands out as a significant global public health concern, with India being no exception to its prevalence (Younossi, 2018). Studies indicate that NAFLD ranks as the most prevalent liver disorder in the country, affecting a substantial portion of the population, with estimates ranging from 9 to 53% (Duseja *et al.*, 2021; Amarapurkar *et al.*, 2007). This condition is intricately linked to factors such as excess weight, obesity, and metabolic risks stemming from sedentary lifestyles and high caloric intake (Stefan *et al.*, 2019). Within the spectrum of NAFLD, non-alcoholic steatohepatitis (NASH) signifies a more severe manifestation characterized by hepatic inflammation, fibrosis, and hepatic steatosis. It poses a heightened risk of progressing to liver cirrhosis and hepatocellular carcinoma (HCC) (Duseja *et al.*, 2020). It's noteworthy that not all cases of simple steatosis evolve into NASH or cirrhosis, and some individuals with NASH may revert to simple steatosis or even regain a normal liver status spontaneously (Sanyal *et al.*, 2022). Current clinical guidelines prioritize lifestyle modifications, particularly dietary adjustments and increased physical activity, as cornerstones of NAFLD management. Moreover, lifestyle interventions have been observed to alleviate the advancement of NAFLD and lower the likelihood of developing severe liver conditions like cirrhosis and hepatocellular carcinoma. While pharmaceutical treatments primarily target associated conditions like type 2 diabetes mellitus (T2DM), hypertension, and dyslipidemia to decelerate NAFLD advancement, emphasizing lifestyle adjustments remains paramount in management (Smith *et al.*, 2023). Attaining a weight reduction of 7 to 10% is emphasized as crucial for enhancing liver enzymes, BMI, FS, CAP value, and overall quality of life (Duseja *et al.*, 2015). Assessing health behaviors among those with NAFLD is vital for comprehending and tackling the multifaceted aspects of this common liver ailment. Lifestyle alterations, such as dietary modifications and boosted physical activity, are acknowledged as primary approaches in managing NAFLD (Nourian *et al.*, 2020). However, the effectiveness of these interventions relies on understanding the current health

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practices of individuals with NAFLD and evaluating the impact of targeted interventions on their lifestyle behaviors. Therefore, the objective of this study was to evaluate the health practices of individuals with NAFLD before and after implementing interventions, shedding light on the effectiveness of lifestyle modifications in improving overall health outcomes in this population.

Materials and Methods

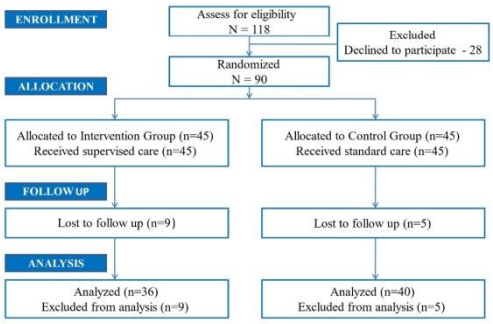
This randomized controlled trial took place at a tertiary care hospital in North Karnataka, India, after obtaining approval from the institutional ethical committee on human subjects (Reference Number: KAHER/EC/21-22/014). The objective was to explore health practices both at the start of the study and after its completion at the 6-month mark. The study employed a thorough patient care and monitoring strategy throughout its duration. It commenced with patient enrollment based on predetermined inclusion and exclusion criteria, followed by a comprehensive clinical assessment. Throughout the study, regular follow-up visits were scheduled at 6-week intervals. The study placed significant emphasis on dietary and exercise supervision by the researcher, recognizing their importance in achieving the study's objectives. Each participant benefited from individualized support, receiving a personalized Mediterranean diet plan crafted by the in-house dietitian alongside an exercise regimen tailored by the physiotherapy department. Adherence to these plans was monitored through weekly phone calls and data recorded using fitness bands and mobile applications. This comprehensive approach aimed to meticulously evaluate the impact of supervised diet and exercise on managing NASH. A pre-test was administered before the intervention, and a post-test was conducted after six months of intervention.

A self-framed questionnaire was developed to evaluate health practices, specifically among individuals with non-alcoholic steatohepatitis. Subject specialist doctors and nursing faculties validated the questions included in this questionnaire. The study employed a structured interview format to administer the questionnaire, which comprised 30 items, wherein participants rated the frequency of there be health practice assessment on a scale from 0 to 3, representing 0- never, 1- rarely, 2- sometimes, and 3- strongly agree, respectively. This 30-item tool was designed primarily to evaluate individuals' capacity for engaging in health-promoting actions, encompassing aspects such as nutrition, exercise, and sleep, yielding a total score range of 0 to 90. These scores were then converted into percentages. Scores of ≤50% indicated poor health practices, while those between 51 and 75% were considered average, and scores of ≥76% were indicative of good health practices. Subsequently, participants were categorized based on their scores into groups reflecting good, average, or poor health practices.

Consort Flowchart

In this study, initially, 118 eligible subjects were identified. However, 28 individuals declined participation, resulting in a final cohort of 90 subjects (Flowchart 1). Using a simple randomized envelop method, these subjects were randomly allocated into two groups, each comprising 45 participants. The intervention group was assigned to receive a closely monitored diet and exercise program, while the control group would undergo standard care. At the end of the study, 14 subjects were lost to follow-up, leaving 76 subjects who completed and were included in the analysis (Intervention-36 and Control-40). Data collection took place at baseline and at intervals of 6 months, followed by statistical analysis to compare outcomes between the groups. The data was imported and organized in Microsoft Excel. Subsequently, the data was analyzed using descriptive statistics. The study findings are expected to provide valuable insights into the potential benefits of supervised diet and exercise programs for managing NASH, potentially informing future treatment strategies.

Table 1 presents the demographic breakdown of both the intervention and control groups. In terms of gender distribution, there was equal representation, with males comprising 51.11% and females 48.89% in both groups. Regarding age, the control group showed a higher percentage of individuals aged 31 to 40 years (31.11%) compared to the intervention group (42.22%). In contrast, the intervention group had a larger proportion of participants aged 41 years and older (46.67%) than the control group (55.56%). Despite these variances, the mean age between the two groups remained similar, with the control group averaging 40.42 years and the intervention group 38.84 years. Regarding religion, the majority in both groups identified as Hindu (93.33%). Educationally, there was an equal distribution of graduates (66.67%) and those with secondary education (33.33%) in both sets. In terms of occupation, the intervention group showed a higher percentage of private employees (84.44%) compared to the



Flowchart 1: Consort flow chart

Table 1: Distribution of demographic characteristics

Demographic characteristics	*Control group n = 45*		*Intervention group n = 45*	
	n	*%*	*n*	*%*
Gender				
Male	23	51.11	23	51.11
Female	22	48.89	22	48.89
Age (in years)				
>18–30	6	13.33	5	11.11
31–40	14	31.11	19	42.22
>41	25	55.56	21	46.67
Religion				
Hindu	42	93.33	42	93.42
Muslim	2	4.44	1	2.22
Christian	1	2.22	2	4.44
Education				
Secondary	15	33.33	15	33.33
Graduates	30	66.67	30	66.67
Occupation				
Housewife	7	15.56	3	6.67
Self-employed	6	13.33	4	8.89
Private employee	28	62.22	38	84.44
Government	4	8.89	0	0.00
Marital status				
Married	7	15.56	8	17.78
Unmarried	38	84.44	37	82.22

control group (62.22%). Finally, regarding marital status, both groups had comparable proportions of married individuals (control - 15.56% and intervention - 17.78%) and unmarried individuals (control - 84.44% and intervention - 82.22%).

Figure 1 depicts the comparison of health practices between the groups. Initially, the intervention group showed 71.1% for poor health practices, while the control group had a slightly higher percentage at 77.8%. In terms of average health practices, the intervention group showed 28.9%, contrasting with the control group's 22.2%. Notably, no scores were recorded for the good level in either group during the pre-test phase.

Following the intervention, notable changes were observed. The intervention group showed no scores for poor health practices, while the control group had 32.5% (Table 2). Additionally, in terms of average health practices, the intervention group achieved 13.9%, markedly lower than the control group's 52.5%. Most strikingly, the intervention group demonstrated a substantial improvement, with 86.1% achieving a good level, while the control group only reached 15%. These results underscore a notable improvement in the intervention group as compared to the control group after the six-month intervention period.

Table 2: Comparison of control group and intervention group with pre-test and post-test levels of health practices

Levels	*Control group*				*Intervention group*			
	Pre-test	*%*	*Post-test*	*%*	*Pre-test*	*%*	*Post-test*	*%*
Poor	35	77.8	13	32.5	32	71.1	00	00
Average	10	22.2	21	52.5	13	28.9	5	13.9
Good	00	00	6	15	00	00	31	86.1
Total	45	100	40	100	45	100	36	100

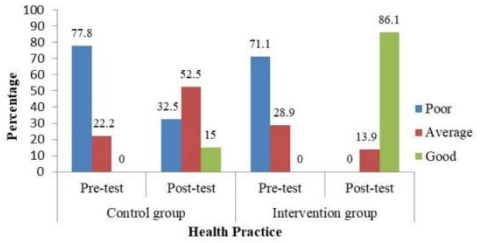


Figure 1: Comparison of control group and intervention group with pre-test and post-test levels of health practices

Discussion

Our study revealed a notable difference between both groups, signifying substantial alterations among those adhering to supervised diet and exercise routines, thereby positively influencing lifestyle adjustments. Conversely, Li *et al.* (2023) study offers an alternative viewpoint regarding the influence of supervised diet and exercise routines on lifestyle modifications. Their findings propose that although significant changes were noted among participants following supervised interventions, these changes did not manifest into notable disparities between the study and control groups. Li *et al.,* argue that despite adherence to diet and exercise regimes, lifestyle modifications remained relatively similar between the two groups, indicating that factors beyond supervised interventions may influence lifestyle behaviors. This highlights the complexity of behavior change and suggests that additional factors may need to be considered when evaluating the effectiveness of diet and exercise interventions in promoting lifestyle modifications.

Our study noted prevalent poor health practices among participants during the pre-test, emphasizing the need for targeted interventions to improve overall health outcomes. These findings align with Smith *et al.* (2019) research, which also identified suboptimal health behaviors. However, our study observed a slightly higher proportion of poor health practices, indicating potential variations across different study populations. Moreover, while Smith *et al.,* found participants with good health practices, none were observed

in our study, suggesting a greater need for targeted interventions to promote healthier lifestyles. In contrast, Wang *et al.* (2023) investigated a mobile application-based lifestyle intervention for weight loss in NAFLD patients. Their study showed a significant increase in the likelihood of achieving weight loss with the intervention compared to standard treatments. However, unlike previous findings, Wang *et al*. research did not demonstrate significant improvements in physiological and biochemical markers, suggesting variability in the efficacy of mobile app-based interventions among NAFLD patients. Further exploration into intervention success factors is warranted.

Our research demonstrated substantial enhancements in health practices, encompassing dietary, exercise, and lifestyle modifications, observed from the pre-test to the post-test phase. In a parallel study, Javanmar *et al.* (2017) explored the effects of telenursing on dietary behavior and self-efficacy in individuals diagnosed with NAFLD. Their 12-week telephone intervention aimed to bolster participants' adherence to prescribed regimens. In the intervention group, participants employed self-report questionnaires to monitor their dietary intake and physical activity routines, while the control group received standard care. After the intervention, both groups exhibited heightened self-efficacy in adhering to dietary and physical activity guidelines. However, statistical analysis unveiled a significant increase solely within the intervention group ($p < 0.001$). Telenursing has emerged as a potent strategy in reinforcing patients' dedication to adopting healthy behaviors through heightened awareness. Incorporating regular follow-up and telephone consultations after appointments may help to maintain these behaviors and promote enhanced treatment results.

In our study, we implemented a six-month intervention incorporating supervised diet and exercise to evaluate the efficacy of lifestyle modification practices. Notable enhancements were noted between the pre-test and post-test assessments. Likewise, Nourian *et al.* (2020) conducted a simultaneous randomized controlled trial to evaluate the impact of lifestyle modification education grounded in the health belief model (HBM) on individuals diagnosed with NAFLD. Their findings indicated that a two-month intervention centered on the HBM significantly enhanced participants' comprehension, reduced liver enzyme levels, and improved ultrasonographic findings.

Conclusion

This study sheds light on a notable divergence in health practices among participants diagnosed with NAFLD during the pre-test phase. Following a 6-month intervention, significant improvements in health practices were evident in post-test assessments. Our findings underscore the effectiveness of personalized supervision in positively impacting NAFLD participants through enhancements in health practices. Integrating personalized coaching into clinical practice could efficiently support behavior modification with minimal risk of adverse events. Persistent modifications in lifestyle, encompassing dietary and exercise habits, hold promise for care providers in terms of yielding favorable outcomes. Individualized coaching provides significant value in bolstering patients' self-efficacy through tailored support, verbal encouragement, and constructive feedback regarding physical activity and dietary adherence, all while remaining cost-effective.

Acknowledgment

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The results of the current study on diet and exercise intervention, indicate that a significant majority (75%) of participents exhibited poor health practices during pre-test. In contrast, one fourth (25%) demonstrated average health practices, with none falling into good health practices

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Open Access Original Article

Incidence of Non-alcoholic Fatty Liver Disease (NAFLD)/Non-alcoholic Steatohepatitis (NASH) in the Female Population of North Karnataka: A Cross-Sectional Study

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Abstract

Background: India is currently facing an epidemic of type 2 diabetes mellitus (T2DM) and obesity which are high-risk factors for the development of non-alcoholic fatty liver disease (NAFLD). A non-invasive tool, the vibration-controlled transient elastography (VCTE; FibroScan, Echosens, Paris, France) is used to diagnose NAFLD.

Aim: To identify the prevalence, spectrum, and metabolic determinants of NAFLD in Indian adult women using liver function tests (LFT) and non-invasive FibroScan (liver stiffness measure, i.e., LSM score) of the liver through a cross-sectional population-based study in the city of Belagavi.

Methods: The subjects were screened for the presence of liver disease with a detailed history, anthropometric measurements, LFTs, blood sugars, and FibroScan of the liver to assess liver steatosis and liver fibrosis.

Results: The study included 2448 women with 860 (35.13%) having NAFLD (controlled attenuation parameter {CAP}>275 dB/m) as detected by FibroScan. Nearly, 58.8% of the participants with T2DM had NAFLD. Participants with NAFLD had higher BMI and waist circumference. When univariate logistic regression was applied, those with T2DM were 14.5 times (95% CI, 4.55, 6.52) likely to have CAP>275 dB/m. Similarly, those with higher BMI>23 mg/m^2 were 1.34 (95% CI, 1.68, 2.37) times more likely to have CAP >275 dB/m. The risk of NAFLD increases by ~1% for every one-year increase in age.

Conclusion: NAFLD in women is the most common non-communicable disease in India; a prevalence of 35.13% was observed in the present study in women. Higher BMI, presence of metabolic risk factors, and incremental age were associated with a high risk of developing NAFLD in women.

Categories: Gastroenterology, Public Health
Keywords: bmi, liver fibrosis, fibro scan, diabetes, nafld

Introduction

Indian National Association for Study of the Liver (INASL) describes non-alcoholic fatty liver disease (NAFLD) as a spectrum ranging from non-alcoholic fatty liver (NAFL), non-alcoholic steatohepatitis (NASH), NASH with fibrosis, NASH-cirrhosis, and NASH-hepatocellular carcinoma (HCC) [1]. In NAFLD, >5-10% of hepatocytes are fatty which is not associated with other known causes of steatosis like alcohol, viruses, drugs, toxins, autoimmune disease, or iron overload but frequently accompanied by Insulin Resistance (IR) [2]. Recent data suggests NAFLD is a hepatic component of metabolic syndrome [3]. Therefore, these subjects also have comorbidities like type 2 diabetes mellitus (T2DM), and hypertension apart from obesity (cardiovascular risk factors) leading to high cardiovascular, all-cause, and liver-related mortality [3-5].

High rates of NAFLD in adults >18 years are being observed in the Middle East and South America, followed by Asia, North America, Europe, and Africa [3]. India is currently facing the brunt of T2DM and obesity while NAFLD has catapulted into a substantial public health problem in India [6]. A meta-analysis published in India reported a NAFLD prevalence of 38.6% [1,7], and up to 20% of those who are obese may develop NASH [5]. Nearly, 30-40% of individuals have elevated liver enzymes at diagnosis [5]. The gender-specific NAFLD prevalence was 39.4% among males and 35.4% among females in India [7].

Patients with NAFLD/NASH and significant fibrosis are mostly asymptomatic thereby early-stage diagnosis and management play a significant role in prevention and treatment [8]. Non-invasive diagnostic tools can now be used to assess the likelihood of significant fibrosis and predict the risk of disease progression and

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decompensation [9]. One of the frequently used non-invasive tools is vibration-controlled transient elastography (VCTE; FibroScan, Echosens, Paris, France) across the country. It uses the ultrasonic attenuation of echoes (controlled attenuation parameter, CAP) which supplements the ability to quantify hepatic steatosis. The results are fairly accurate since the CAP values gradually increase, with increasing severity of steatosis. The European Association for the Study of the Liver (EASL) has recently recommended a CAP cut-off of ≥275 dB/m for the detection of hepatic steatosis [1,10]. The present prospective community-based cross-sectional study, aimed to identify the prevalence, spectrum, and metabolic determinants of NAFLD in Indian adult women using liver function tests (LFT) and non-invasive FibroScan (liver stiffness measure, i.e., LSM score) of the liver.

Materials And Methods

Study design

This cross-sectional descriptive survey was carried out among women at the Department of Gastroenterology, Karnatak Lingayat Education Society's (KLES) Dr. Prabhakar Kore Hospital and Medical Research Centre, Jawaharlal Nehru Medical College, Belagavi, Karnataka. Women aged 18 to 80 without a prior history of liver diseases were included in the study. They were screened for liver disease with detailed history, anthropometric measurements, liver function tests (LFTs), blood sugars, and FibroScan of the liver to assess liver steatosis and liver fibrosis. The study excluded women who were consuming a significant amount of alcohol or who had overt cirrhosis, previously diagnosed hepatitis B virus or hepatitis C virus infection, biliary diseases, and pregnant females.

Study procedure

A written consent was obtained from all the women before enrollment. The screening was done by recording medical history. Anthropometric measurements included height (cm), weight (kg), waist circumference (cm), hip circumference (cm), and waist-to-hip ratio. BMI as per the Asian BMI criteria and blood pressure were recorded. After an overnight fast, a FibroScan of the liver and biochemical tests (serum glutamate pyruvate transaminase (SGPT) and serum glutamic-oxaloacetic transaminase (SGOT), were performed. Subjects were categorized as having NAFLD if there was evidence of fatty liver on imaging. Subjects with abnormal LSM on FibroScan with or without abnormal liver function tests were labelled as NASH.

All the participants eligible for the study underwent a FibroScan test. This is a non-invasive method that has been proposed for the assessment of liver fibrosis by measuring liver stiffness. It uses the principle of transient elastography. Vibrations of mild amplitude and low frequency (50 Hz) are transmitted by the ultrasound transducer probe, mounted on the axis of a vibrator, which induces a plastic shear wave that propagates through the underlying tissues. The degree of hepatic fibrosis can be determined by the liver's hardness. The results were represented in kilopascals (kPa). The test takes about 10 minutes. The eligible participants were instructed to lie supine on the examination table. On the right side of the lower chest wall (6th or 7th intercostal space), a technician positioned the FibroScan (FibroScan Mini 430, Echosens, Paris, France; Device ID-03662264001192; August 18, 2021) probe between the ribs. The liver was then subjected to a given a series of painless pulses. A total score for LSM was produced after the data were recorded on the apparatus. A gastroenterologist used this data to predict the possibility of fibrosis or fatty liver. FibroScan measures the LSM score in kPa and the CAP score in decibels per meter (dB/m) [3,11].

A CAP score can be between 100 and 400 dB/m, steatosis with CAP is graded as follows: (S), ≤ S0 ≥ S1, ≥ S2, and ≥ S3 were <275 dB/m no steatosis, > 275 dB/m, > 319 dB/m, and > 337 dB/m, respectively [12]. Liver fibrosis has four stages: F0 to F1 fibrosis score (no or little liver damage; 2 to 7 kPa), F2 fibrosis (moderate liver scarring; 7.5 to 10 kPa), F3 fibrosis (severe liver scarring; 10 to 14 kPa), and F4 fibrosis (cirrhosis; 14 kPa or higher) [3].

Ethical committee review

All procedures were followed according to the guidelines of the Indian Council of Medical Research (ICMR), to protect the rights of the patients. Approval for the study has been obtained from the KAHER (KLE Academy of Higher Education and Research) Ethics Committee on Human Subjects (KAHER/EC/21-22/014).

Statistical analysis

Data was analyzed using IBM SPSS Statistics for Windows, Version 21 (IBM Corp., Armonk, NY) and Microsoft Excel, Version 2013 (Microsoft Corporation, Redmond, WA). Categorical variables are given in the form of a frequency table. The chi-square test analyses categorical variables. The Shapiro-Wilk test and QQ plot check the normality of the variable. Mann-Whitney U test compares the distributions of variables over FibroScan; a p-value less than or equal to 0.05 indicates statistical significance.

Results

A total of 2588 healthy women were screened; 140 participants did not meet the inclusion criteria therefore, the total cohort comprised of 2448 women (Figure *1*). The baseline demographics of all the selected

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participants are shown in Table *1*.

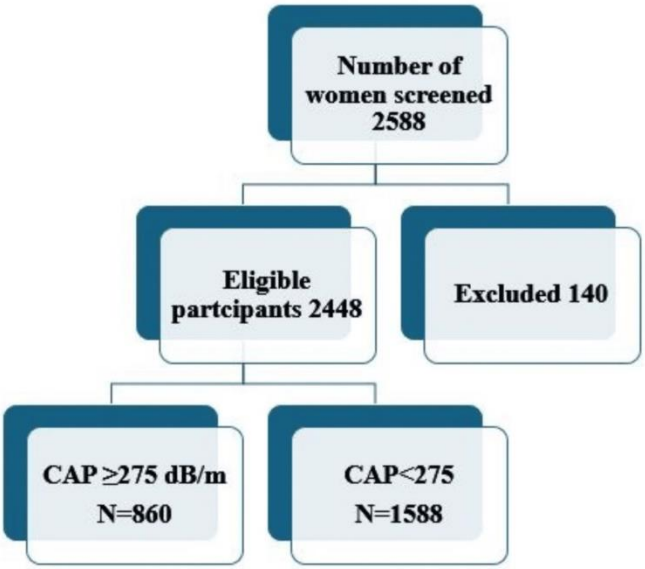


FIGURE 1: Patient disposition.

CAP: controlled attenuation parameter, dB/m: decibels per meter, N: number of participants in the study.

Variable	Groups	Number (%)
Age (years)	Age<20	17 (0.69)
	Age:20-35	639 (26.1)
	Age:35-50	1174 (47.96)
	Age:50-65	539 (22.02)
	Age>65	79 (3.23)
BMI (mg/m^2)	Underweight	105 (4.29)
	Normal	476 (19.44)
	Overweight	438 (17.89)
	Obese	1429 (58.37)
WC (cm)	<80	221 (9.03)
	>80	2227 (90.97)
T2DM	Yes	923 (37.7)
	No	1525 (62.3)
HT	Yes	747 (30.51)
	No	1701 (69.49)
HT and DM together	Yes	567 (23.16)

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	No	1881 (76.84)
SGOT (U/L)	Normal	1300 (53.1)
	Elevated	1148 (46.9)
SGPT (U/L)	Normal	1717 (70.14)
	Elevated	731 (29.86)
CAP score (dB/m)	Normal	1588 (64.87)
	S1	384 (15.69)
	S2	63 (2.57)
	S3	413 (16.87)
FS (kPa)	F0-F1	1475 (60.33)
	F2	589 (24.09)
	F3	270 (11.04)
	F4	111 (4.54)
NASH	No	1797 (73.41)
	Yes	651 (26.59)
NACH	No	2351 (96.04)
	Yes	97 (3.96)

TABLE 1: Baseline demographics (N=2448).

WC: waist circumference; T2DM: type 2 diabetes mellitus; HT: hypertension; SGOT: serum glutamic-oxaloacetic transaminase; SGPT: serum glutamic pyruvic transaminase; CAP: controlled attenuation parameter; dB/m: decibels per meter; FS: fibrosis score kilopascals (kPa); NASH: non-alcoholic steatohepatitis; NACH: non-alcoholic cirrhosis.

Alcohol within permissible limits: 10 mg/day; BMI (India): underweight <18.5 kg/m2, normal weight 18.5–22.9 kg/m2, overweight >23 kg/m2, obese >25kg/m2.

The participants included in the study were screened for fatty liver by ultrasound examination. Further, they underwent FibroScan evaluation for steatosis (CAP in dB/m) and fibrosis (LSM in kPa). The mean (±SD) age of the participants was 42.94 (±11.4) years and 1174 (47.96%) women were in the age group of 35-50 years (Table *1*) while 1813 (74.06%) women were aged below 50 years. The mean BMI of the participants was 26.04 (±4.6) mg/m2 with 1429 (58.37%) of the participants categorized as obese. The mean waist circumference (WC) of the participants was 98.11 (±17.3) cm with 2227 (90.97%) of the participants having WC>80 cm. The mean liver enzyme value for SGOT was 47.03 (±32.31) U/L while for SGPT, it was 48.5 (±32.83) U/L. The mean CAP score of the participants was 263.69 (±53.5) dB/m. The personal history of the participants revealed that 923 (37.7 %) had T2DM while 747 (30.51 %) had hypertension. Table *2* depicts the summary of all the variables.

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Variable	N	Mean	SD	Median	Min	Max
Age (years)	2448	42.94	11.42	42	18	83
BMI (mg/m^2)	2448	26.04	4.61	26	2.6	41.5
SGOT (U/L)	2448	47.03	32.31	38	8	182
SGPT (U/L)	2448	48.5	32.83	38	6.2	211
FS (kPa)	2448	7.23	3.54	6.2	2.7	50.5
CAP score (dB/m)	2448	263.69	53.5	253	165	391
WC (cm)	2448	98.11	17.3	94	43	156

TABLE 2: Summary of all demographic variables.

WC: waist circumference; SGOT: serum glutamic-oxaloacetic transaminase; SGPT: serum glutamic pyruvic transaminase; CAP: controlled attenuation parameter; dB/m: decibels per meter; FS: Fibrosis score kilopascals (kPa), SD: standard deviation.

FibroScan score 2 (F2) was observed in 328 (35.5%) of the participants with T2DM, 250 (33.5%) of the participants with hypertension, and 558 (25.1%) of the participants with WC >80 cm (Figure *2*). A greater number of participants with both comorbidities (DM+HT) had higher FibroScan scores (p<0.001). A greater number of the participants with T2DM had steatosis of varying grades (Figure *3*).

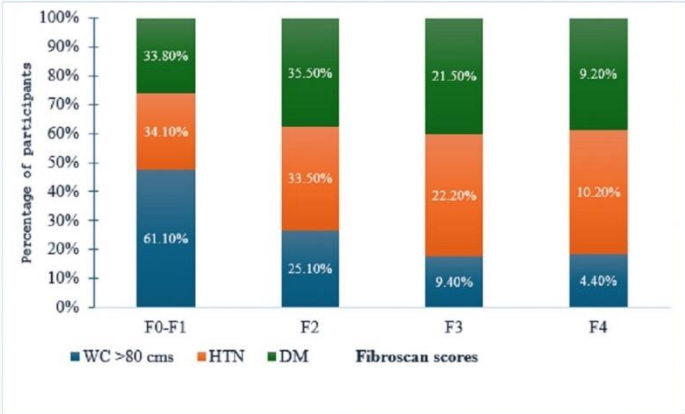


FIGURE 2: FibroScan scores associated with comorbidities (N=2448).

WC: waist circumference; DM: diabetes mellitus; HT: hypertension.

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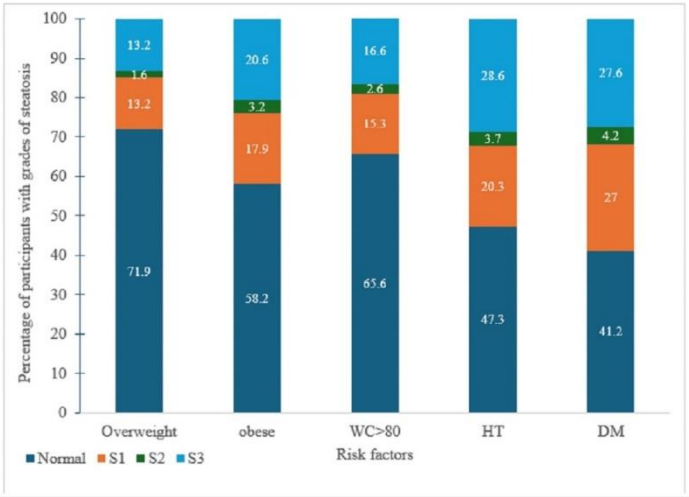


FIGURE 3: Steatosis scores associated with comorbidities (N=2448).

WC: waist circumference; DM: diabetes mellitus; HT: hypertension.

The study results noted that 35.13% of the participants had NAFLD (CAP≥275 dB/m) as detected by FibroScan®, 15.69% of participants had steatosis grade 1 (S1), 2.57 % of participants had steatosis grade 2 (S2), and 16.87% participants had steatosis grade 3 (S3) (Table *1*). Not surprisingly, 35.13 % of the participants had NASH and 4.40% of the participants had non-alcoholic cirrhosis. The proportion of participants with NAFLD was upscaled to 62% in the presence of BMI>23 kg/m2, T2DM, and hypertension together. Apart from higher BMI, participants with NAFLD had elevated liver enzymes, WC>80 cm, and high Fibroscan scores (Table 3).

Variable	Low CAP (n %)	High CAP (n %)	P-value
BMI			
Underweight	81 (77.1)	24 (22.9)	<0.001
Normal	360 (75.6)	116 (24.4)	
Overweight	315 (71.9)	123 (28.1)	
obese	832 (58.2)	597 (41.8)	
WC			
WC<80 cm	128 (57.9)	93 (42.1)	0.028
WC>80 cm	1460 (65.6)	767 (34.4)	
T2DM	380 (41.2)	543 (58.8)	<0.001
HT	353 (47.3)	394 (52.7)	<0.001

TABLE 3: CAP scores as per demographic variables and associated risk factors.

WC: waist circumference; T2DM: type 2 diabetes mellitus; HT: hypertension; CAP: controlled attenuation parameter.

High CAP score ≥275 dB/m; low CAP score <275; p-value ≤0.05 is statistically significant.

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The mean age of participants with NAFLD was 45.15 years and the mean age of controls (low CAP <275) was 41.7 years. The mean BMI of participants with NAFLD was 27.3 mg/m2 while that of controls was 25.3 mg/m2. The mean SGOT in participants with NAFLD was 54.7 U/L while that of controls was 42.8 U/L. The mean SGPT in participants with NAFLD was 59.4 U/L while that of controls was 42.6 U/L. This indicates higher levels of liver transaminases in NAFLD. A greater number of participants with T2DM had NAFLD (58.8%).

Table 4 depicts the results of univariate and multivariate logistic regression for NAFLD. When univariate logistic regression was applied to calculate the odds ratio and its 95% CI for each of the independent variables, those with T2DM were 14.5 times (95% CI, 4.55, 6.52) likely to have CAP≥275 dB/m. Similarly, those with higher BMI >23 mg/m2 were 1.34 (95% CI, 1.68, 2.37) times more likely to have CAP ≥275 dB/m. The risk of NAFLD increases by ~1% for every one-year increase in age.

Risk factors	Unadjusted. OR (95%CI)	Adjusted. OR(95%CI)	P-value
Age (Year)	1.03 (1.02,1.03)	1.01 (1.01,1.02)	< 0.001
Obese	2 (1.68,2.37)	1.68 (1.39,2.03)	< 0.001
T2DM	5.45 (4.55,6.52)	4.59 (3.73,5.66)	< 0.001
HT	2.96 (2.47,3.54)	1.2 (0.97,1.5)	0.099

TABLE 4: Results of univariate and multivariate logistic regression for NAFLD.

T2DM: type 2 diabetes mellitus; HT: hypertension, OR: odds ratio, NAFLD: non-alcoholic fatty liver disease.

P-value ≤0.05 is statistically significant.

Discussion

This cross-sectional study found that 860 (35.13%) out of 2448 women had NAFLD diagnosed using FibroScan in Belgavi (India). This is more likely to be just the tip of the iceberg since the adoption of less healthy and more Westernized lifestyles is directly proportional to the rising prevalence of NAFLD all around the globe. This ultimately signals higher morbidity and mortality in the coming years. A meta-analysis comprising 23,581 participants noted a gender-specific NAFLD prevalence of 35.4% (95% CI 23.5- 48.3%; I^2 98.5%) among adult women [7]. In a study in Bhopal (India), the prevalence of NAFLD was 43.6% [3]. Community-based studies reflect the prevalence rate of NAFLD in urban Mumbai as 16.6%, urban Chennai as 32%, and rural Haryana as 30.7% across gender [13-15].

A meta-analysis demonstrated a higher overall prevalence of NAFLD among adults in South Asia, especially in those with metabolic disorders. In the South Asian population, NAFLD was associated with T2DM, hypertension, dyslipidemia, general obesity, central obesity, and metabolic syndrome [4].

Along similar lines, the present study also showed a higher prevalence of NAFLD in women with T2DM and obesity. Women with larger waist circumference were considerably more likely to develop NAFLD. This parameter has been well-established in past research too as strong associations with NAFLD.

The waist circumference (WC) is an anthropometric measurement of obesity related to abdominal (central visceral) adiposity, which is an important predictor of the development of T2DM and NAFLD [16]. Asians are more vulnerable to T2DM and have a higher prevalence of NAFLD, which may be caused by an abnormal deposition of visceral fat [3].

All causes of death, including cardiovascular disease, myocardial infarction, and ischemic stroke, increase across all age groups in the order of no NAFLD, grade 1 NAFLD, and grade 2 NAFLD, and with age [17]. The incidence rate of cardiovascular disease for patients with T2DM and no NAFLD in the 20-29-year age group was 0.40 per 1000-person years; whereas, for patients with T2DM with grade 2 NAFLD in the ≥70-year age group, the rate was 23.25 per 1000 person-years [17]. Therefore, in the present study women with T2DM and NAFLD are at high risk of future CVD. The most important risk factor for NAFLD is T2Dm which is incidentally also a clinical predictor of adverse outcomes like developing clinical decompensation and hepatocellular carcinoma [18].

This calls for action to early screening in overweight and obese women. FibroScan (transient elastography) is an easy, rapid, accurate, and non-invasive screening test that measures liver stiffness through the estimation of the velocity of propagation of a shear wave through liver tissue. LSM carried in high-risk

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patients can funnel down the number of patients who require biopsy evaluation [19]. There are various studies substantiating the use of FibroScan in NAFLD. In a previously reported study from the same center, the sensitivity of the FibroScan score prediction with an area under the curve (AUC) of 0.80 was found to be 74.6% and the specificity was 74.3% [20]. Wong et al. reported the AUC values of transient elastography for F3 or higher and F4 disease as 0.93 and 0.95, respectively [21]. Another study from India showed similar efficacy of FibroScan in NAFLD in patients from Northern India [19].

Limitations

This is a cross-sectional study data. Though the pooled cohort was large, the lipid profile and duration of metabolic disorders were not available. It is a single-center community study thereby giving only a glimpse of the prevalence of NAFLD in women.

Conclusions

This is one of the largest cross-sectional single hospital-based studies focused on screening for non-alcoholic fatty liver disease (NAFLD), particularly among women. NAFLD in women is the most common non-communicable disease in India; a prevalence of 860/2448 (35.13%) was observed in the present study in women. Higher BMI, presence of metabolic risk factors, and incremental age were associated with a high risk of developing NAFLD in women. Community-based screening or mass screening is needed to arrest this epidemic through the implementation of awareness programs and healthy lifestyle practices. Early diagnosis is the key which can be achieved with easy, reliable, and non-invasive tools like FibroScan.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Concept and design: Geeta S. Desai, Santosh Hajare

Acquisition, analysis, or interpretation of data: Geeta S. Desai, Santosh Hajare, Sandesha Ghorpade

Drafting of the manuscript: Geeta S. Desai, Santosh Hajare, Sandesha Ghorpade

Critical review of the manuscript for important intellectual content: Geeta S. Desai, Santosh Hajare, Sandesha Ghorpade

Supervision: Santosh Hajare

Disclosures

Human subjects: Consent was obtained or waived by all participants in this study. KAHER (KLE Academy of Higher Education and Research) Ethics Committee on Human Subjects issued approval KAHER/EC/21-22/014. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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ANNEXURE -XIII

LIST OF VALIDATIONS

SL.NO	NAME	DESIGNATION
1	Dr. Sonal Asthana	Lead Liver Transplant Surgeon ASTER CMI Hospital, Hebbal, Bangalore, Karnataka
2	Dr. Mallikarjun Satpal	Gastroenterologist and Hepatologist ASTER CMI Hospital, Hebbal, Bangalore, Karnataka
3	Dr. Amol Satwane	Assistant Professor Dept of Gastroenterology KLES Dr. Prabhakar Kore Hospital & MRC Belagavi, Karnataka
4	Dr. Sudarshan Chaugale	Assistant Professor Dept of Surgical Gastroenterology KLES Dr. Prabhakar Kore Hospital & MRC Belagavi, Karnataka
5	Dr. Anand Heggannavar	Professor and HOD Dept of Orthopaedic Manual Therapy KLES Institute of Physiotherapy JNMC Campus Nehru Nagar, Belagavi, Karnataka
6	Dr. Dhanpal H N	Principal and Professor Dept of Psychiatry Nursing Victory College of Nursing Bangalore, Karnataka
7	Dr. C C Gaddgi	Professor and HOD Dept. of Medical-Surgical Nursing Smt. M C Vasantha College of Nursing Naubad, Bidar, Karnataka
8	Dr. Dinesh Minalkar	Vice Principal and HOD Smt. M C Vasantha College of Nursing Naubad, Bidar, Karnataka
9	Dr. Sumitra Arbenchi	Professor and Dean KAHER Institute of Nursing Sciences Belagavi, Karnataka
10	Mrs. Savitri Marakatti	Dietitian Dept of Gastroenterology KLES Dr. Prabhakar Kore Hospital & MRC Belagavi, Karnataka

ANNEXURE - XIV

DETAIL OF METHODS AND VALIDATION OF BLOOD INVESTIGATIONS

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ALTP

cobas®

Alanine Aminotransferase acc. to IFCC with pyridoxal phosphate activation

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08056773190	Alanine Aminotransferase acc. to IFCC (450 tests)	System-ID 2013 001	**cobas c** 303, **cobas c** 503
Materials required (but not provided):			
10759350190	Calibrator f.a.s. (12 x 3 mL)	Code 20401	
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 20391	
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 20391	
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 20392	
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 20392	
08063494190	Diluent NaCl 9 % (123 mL)	System-ID 2906 001	
08062986190	Pyridoxal phosphate (950 tests)	System-ID 2012 001	

English

System information

ALTP: ACN 20130

Intended use

In vitro test for the quantitative determination of alanine aminotransferase (ALT) with pyridoxal phosphate activation in human serum and plasma on Roche/Hitachi **cobas c** systems.

Summary[1,2]

The enzyme alanine aminotransferase (ALT) has been widely reported as present in a variety of tissues. The major source of ALT is the liver, which has led to the measurement of ALT activity for the diagnosis of hepatic diseases. Elevated serum ALT is found in hepatitis, cirrhosis, obstructive jaundice, carcinoma of the liver, and chronic alcohol abuse. ALT is only slightly elevated in patients who have an uncomplicated myocardial infarction.

Although both serum aspartate aminotransferase (AST) and ALT become elevated whenever disease processes affect liver cell integrity, ALT is the more liver-specific enzyme. Moreover, elevations of ALT activity persist longer than elevations of AST activity.

The addition of pyridoxal phosphate to the assay causes an increase in aminotransferase activity. The activation is higher for AST than for ALT. Pyridoxal phosphate activation prevents falsely low aminotransferase activity in patient samples with insufficient endogenous pyridoxal phosphate (vitamin B_6 deficiency).

Test principle

This assay follows the recommendations of the IFCC, but was optimized for performance and stability.[3,4]

ALT catalyzes the reaction between L-alanine and 2-oxoglutarate. The pyruvate formed is reduced by NADH in a reaction catalyzed by lactate dehydrogenase (LDH) to form L-lactate and NAD^+ . Pyridoxal phosphate serves as a coenzyme in the amino transfer reaction. It ensures full enzyme activation.

$$\text{L-Alanine} + \text{2-oxoglutarate} \xrightarrow{\text{ALT}} \text{pyruvate} + \text{L-glutamate}$$

$$\text{Pyruvate} + \text{NADH} + \text{H}^+ \xrightarrow{\text{LDH}} \text{L-lactate} + \text{NAD}^+$$

The rate of the NADH oxidation is directly proportional to the catalytic ALT activity. It is determined by measuring the decrease in absorbance.

Reagents - working solutions

Alanine Aminotransferase acc. to IFCC (ALTL)

R1 TRIS buffer: 224 mmol/L, pH 7.3 (37 °C); L-alanine: 1120 mmol/L; albumin (bovine): 0.25 %; LDH (microorganisms): ≥ 45 µkat/L; stabilizers; preservative

R3 2-Oxoglutarate: 94 mmol/L; NADH: ≥ 1.7 mmol/L; additives; preservative

R1 is in position B and R3 is in position C.

Pyridoxal phosphate (PYP, Cat. No 08062986190)

R2 Pyridoxal phosphate: 730 µmol/L; additives; preservative

R2 is in position B.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	12 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum
Plasma: Li-heparin and K_2-EDTA plasma

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

See the limitations and interferences section for details about possible sample interferences.

Stability:	3 days at 15-25 °C[5]
	7 days at 2-8 °C[5]
	> 7 days at (–60)-(–80) °C

Sample stability claims were established by experimental data by the manufacturer or based on reference literature and only for the temperatures/time frames as stated in the method sheet. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory.

Materials provided

See "Reagents – working solutions" section for reagents.

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ASTP

cobas®

Aspartate Aminotransferase acc. to IFCC with pyridoxal phosphate activation

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08056838190	Aspartate Aminotransferase acc. to IFCC (500 tests)	System-ID 2022 001	**cobas c** 303, **cobas c** 503
Materials required (but not provided):			
10759350190	Calibrator f.a.s. (12 x 3 mL)	Code 20401	
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 20391	
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 20391	
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 20392	
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 20392	
08063494190	Diluent NaCl 9 % (123 mL)	System-ID 2906 001	
08062986190	Pyridoxal phosphate (950 tests)	System-ID 2012 001	

English

System information

ASTP: ACN 20220

Intended use

In vitro test for the quantitative determination of aspartate aminotransferase (AST) with pyridoxal phosphate activation in human serum and plasma on Roche/Hitachi **cobas c** systems.

Summary[1,2]

The enzyme aspartate aminotransferase (AST) is widely distributed in tissue, principally hepatic, cardiac, muscle, and kidney. Elevated serum levels are found in diseases involving these tissues. Hepatobiliary diseases, such as cirrhosis, metastatic carcinoma, and viral hepatitis also increase serum AST levels. Following myocardial infarction, serum AST is elevated and reaches a peak 2 days after onset.

2 isoenzymes of AST have been detected, cytoplasmic and mitochondrial. Only the cytoplasmic isoenzyme occurs in normal serum, while the mitochondrial, together with the cytoplasmic isoenzyme, has been detected in the serum of patients with coronary and hepatobiliary disease.

The addition of pyridoxal phosphate to the assay causes an increase in aminotransferase activity. The activation is higher for AST than for ALT. Pyridoxal phosphate activation prevents falsely low aminotransferase activity in patient samples with insufficient endogenous pyridoxal phosphate (vitamin B_6 deficiency).

Test principle

This assay follows the recommendations of the IFCC, but was optimized for performance and stability.[3,4]

AST in the sample catalyzes the transfer of an amino group between L-aspartate and 2-oxoglutarate to form oxaloacetate and L-glutamate. The oxaloacetate then reacts with NADH, in the presence of malate dehydrogenase (MDH), to form NAD^+. Pyridoxal phosphate serves as a coenzyme in the amino transfer reaction. It ensures full enzyme activation.

$$\text{L-Aspartate} + \text{2-oxoglutarate} \xrightarrow{\text{AST}} \text{oxaloacetate} + \text{L-glutamate}$$

$$\text{Oxaloacetate} + \text{NADH} + H^+ \xrightarrow{\text{MDH}} \text{L-malate} + NAD^+$$

The rate of the NADH oxidation is directly proportional to the catalytic AST activity. It is determined by measuring the decrease in absorbance.

Reagents - working solutions

Aspartate Aminotransferase acc. to IFCC (ASTL)

R1 TRIS buffer: 264 mmol/L, pH 7.8 (37 °C); L-aspartate: 792 mmol/L; MDH (microorganism): ≥ 24 µkat/L; LDH (microorganisms): ≥ 48 µkat/L; albumin (bovine): 0.25 %; preservative

R3 NADH: ≥ 1.7 mmol/L; 2-oxoglutarate: 94 mmol/L; preservative

R1 is in position B and R3 is in position C.

Pyridoxal phosphate (PYP, Cat. No 08062986190)

R2 Pyridoxal phosphate: 730 µmol/L; additives; preservative

R2 is in position B.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	12 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum.
Plasma: Li-heparin and K_2-EDTA plasma

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

See the limitations and interferences section for details about possible sample interferences.

Stability:[5]	4 days at 20-25 °C
	7 days at 4-8 °C
	3 months at -20 °C

Sample stability claims were established by experimental data by the manufacturer or based on reference literature and only for the temperatures/time frames as stated in the method sheet. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

See "Order information" section

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ALB2

cobas®

Albumin Gen.2

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08056692 190	Albumin Gen.2 (750 tests)	System-ID 2009 001	Roche/Hitachi **cobas c** 503

Materials required (but not provided):

10759350 190	Calibrator f.a.s. (12 x 3 mL)	Code 20401	
10759350 360	Calibrator f.a.s. (12 x 3 mL, for USA)	Code 20401	
05117003 190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 20391	
05947626 190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 20391	
05947626 160	PreciControl ClinChem Multi 1 (4 x 5 mL, for USA)	Code 20391	
05117216 190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 20392	
05947774 190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 20392	
05947774 160	PreciControl ClinChem Multi 2 (4 x 5 mL, for USA)	Code 20392	
08063494 190	Diluent NaCl 9 % (123 mL)	System-ID 2906 001	

English

System information

ALB2-G: ACN 20090

Intended use

In vitro test for the quantitative determination of albumin in human serum and plasma on Roche/Hitachi **cobas c** systems.

Summary[1,2]

Albumin is a carbohydrate-free protein, which constitutes 55-65 % of total plasma protein. It maintains plasma oncotic pressure, and is also involved in the transport and storage of a wide variety of ligands and is a source of endogenous amino acids. Albumin binds and solubilizes various compounds, e.g. bilirubin, calcium and long-chain fatty acids. Furthermore, albumin is capable of binding toxic heavy metal ions as well as numerous pharmaceuticals, which is the reason why lower albumin concentrations in blood have a significant effect on pharmacokinetics.

Hyperalbuminemia is of little diagnostic significance except in the case of dehydration. Hypoalbuminemia occurs during many illnesses and is caused by several factors: compromised synthesis due either to liver disease or as a consequence of reduced protein uptake; elevated catabolism due to tissue damage (severe burns) or inflammation; malabsorption of amino acids (Crohn's disease); proteinuria as a consequence of nephrotic syndrome; protein loss via the stool (neoplastic disease). In severe cases of hypoalbuminemia, the maximum albumin concentration of plasma is 2.5 g/dL (380 µmol/L). Due to the low osmotic pressure of the plasma, water permeates through blood capillaries into tissue (edema). The determination of albumin allows monitoring of a controlled patient dietary supplementation and serves also as an excellent test of liver function.

Test principle[3]

Colorimetric assay

At a pH value of 4.1, albumin displays a sufficiently cationic character to be able to bind with bromcresol green (BCG), an anionic dye, to form a blue-green complex.

$$\text{Albumin} + \text{BCG} \xrightarrow{\text{pH 4.1}} \text{albumin-BCG complex}$$

The color intensity of the blue-green color is directly proportional to the albumin concentration in the sample and is measured photometrically.

Reagents - working solutions

R1 Citrate buffer: 95 mmol/L, pH 4.1; preservatives, stabilizers

R3 Citrate buffer: 95 mmol/L, pH 4.1; bromcresol green: 0.66 mmol/L; preservatives, stabilizers

R1 is in position B and R3 is in position C.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

Reagent handling

Ready for use

Storage and stability

Shelf life at 15-25 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	26 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum.
Plasma: Li-heparin and K_2-EDTA plasma

Do not use fluoride plasma.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

See the limitations and interferences section for details about possible sample interferences.

Stability:[4]	2.5 months at 20-25 °C
	5 months at 4-8 °C
	4 months at -20 °C

Sample stability claims were established by experimental data by the manufacturer or based on reference literature and only for the temperatures/time frames as stated in the method sheet. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory.

Materials provided

See "Reagents – working solutions" section for reagents.

The instrument test values are checked for accuracy and precision. by running Internal quality controls of Bio rad level I and level II twice of day. And the laboratory also participates in external quality control programme of Bio rad once a months.

Dr. ANIL M.
MD
Chief of Clinical Biochemistry
KLES Hospital and MRC,
BELGAUM 10.

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TRIGL

cobas®

Triglycerides

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08058687 190	Triglycerides (1000 tests)	System-ID 2113 001	Roche/Hitachi **cobas c** 503

Materials required (but not provided):

10759350 190	Calibrator f.a.s. (12 x 3 mL)	Code 20401	
10759350 360	Calibrator f.a.s. (12 x 3 mL, for USA)	Code 20401	
05117003 190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 20391	
05947626 190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 20391	
05947626 160	PreciControl ClinChem Multi 1 (4 x 5 mL, for USA)	Code 20391	
05117216 190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 20392	
05947774 190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 20392	
05947774 160	PreciControl ClinChem Multi 2 (4 x 5 mL, for USA)	Code 20392	
08063494 190	Diluent NaCl 9 % (123 mL)	System-ID 2906 001	

English

System information

TRIGL: ACN 21130

Intended use

In vitro test for the quantitative determination of triglycerides in human serum and plasma on Roche/Hitachi **cobas c** systems.

Summary[1,2,3,4,5,6]

Triglycerides are esters of the trihydric alcohol glycerol with 3 long-chain fatty acids. They are partly synthesized in the liver and partly ingested in food.

The determination of triglycerides is utilized in the diagnosis and treatment of patients having diabetes mellitus, nephrosis, liver obstruction, lipid metabolism disorders and numerous other endocrine diseases.

The enzymatic triglycerides assay as described by Eggstein and Kreutz still required saponification with potassium hydroxide. Numerous attempts were subsequently made to replace alkaline saponification by enzymatic hydrolysis with lipase. Bucolo and David tested a lipase/protease mixture; Wahlefeld used an esterase from the liver in combination with a particularly effective lipase from Rhizopus arrhizus for hydrolysis.

This method is based on the work by Wahlefeld using a lipoprotein lipase from microorganisms for the rapid and complete hydrolysis of triglycerides to glycerol followed by oxidation to dihydroxyacetone phosphate and hydrogen peroxide. The hydrogen peroxide produced then reacts with 4-aminophenazone and 4-chlorophenol under the catalytic action of peroxidase to form a red dyestuff (Trinder endpoint reaction). The color intensity of the red dyestuff formed is directly proportional to the triglyceride concentration and can be measured photometrically.

Test principle[6]

Enzymatic colorimetric test.

$$\text{triglycerides} + 3\ H_2O \xrightarrow{\text{LPL}} \text{glycerol} + 3\ \text{RCOOH}$$

$$\text{glycerol} + \text{ATP} \xrightarrow[Mg^{2+}]{\text{GK}} \text{glycerol-3-phosphate} + \text{ADP}$$

$$\text{glycerol-3-phosphate} + O_2 \xrightarrow{\text{GPO}} \text{dihydroxyacetone phosphate} + H_2O_2$$

$$H_2O_2 + \text{4-aminophenazone} + \text{4-chlorophenol} \xrightarrow{\text{peroxidase}} \text{4-(p-benzoquinone-monoimino)-phenazone} + 2\ H_2O + HCl$$

Reagents - working solutions

R1 PIPES buffer: 50 mmol/L, pH 6.8; Mg^{2+}: 40 mmol/L; sodium cholate: 0.20 mmol/L; ATP: ≥ 1.4 mmol/L; 4-aminophenazone: ≥ 0.13 mmol/L; 4-chlorophenol: 4.7 mmol/L; lipoprotein lipase (Pseudomonas spec.): ≥ 83 µkat/L; glycerol kinase (Bacillus stearothermophilus): ≥ 3 µkat/L; glycerol phosphate oxidase (E. coli): ≥ 41 µkat/L; peroxidase (horseradish): ≥ 1.6 µkat/L; preservative, stabilizers

R1 is in position B.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

H412 Harmful to aquatic life with long lasting effects.

Prevention:

P273 Avoid release to the environment.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	26 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum
Plasma: Li-heparin and K_2-EDTA plasma.

Roche

CALIBRATION CERTIFICATE

HOSPITAL/LAB NAME	: KLES DR. PRABHAKAR KORE HOSPITAL & MRC
ADDRESS	: NEHARU NAGAR, BELAGAVI KARNATAKA-590010
ANALYSER	: COBAS PRO ANALYZER
SERIAL NO	: 22D5-05 (SSU), 22P7-01 (ISE), 22S1-02(C503), 42A7-01 (E801).
INSTALLATION PLACE	: HI TECH LABORATORY, DEPT. OF BIOCHEMISTRY
DATE	: 22 JUNE, 2024

This is to certify that the above mentioned analyzer was calibrated by the following procedure as per manufacturer's recommendations.

1. PHOTOMETER CHECK

PREVIOUS DATA		CURRENT DATA	
340 nm	1.2484	340 nm	1.0401
376 nm	1.0510	376 nm	0.8273
415 nm	1.0019	415 nm	0.8077
450 nm	0.9746	450 nm	0.8019
480 nm	0.9541	480 nm	0.7954
505 nm	0.9480	505 nm	0.7971
546 nm	0.9328	546 nm	0.7910
570 nm	0.9279	570 nm	0.7924
600 nm	0.9197	600 nm	0.7862
660 nm	0.8983	660 nm	0.7735
700 nm	0.8864	700 nm	0.7665
800 nm	0.8634	800 nm	0.7548

The above mentioned values are found to be with in the standard specified by our Principles, **ROCHE DIAGNOSTICS, GERMANY.**

ROCHE DIAGNOSTICS INDIA. PVT. LTD
CIN – U85195MH1988PTC141417

Regional Office:
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Tel. : +91 (22) 6697 4900
Fax : +91 (22) 6697 4909
www.roche-diagnostics.co.in

Roche

2. Position adjustment of Pipettor probe, Sipper probe, Barcode Reader, Cap Opener, and Bead Mixer mechanism.
3. Gripper Adjustment check.
4. Temperature monitor for Detection unit, incubator, and reagent disk
5. Pipettor probes LLD voltage, sipper probes LLD voltage, and Pressure sensors check.
6. SSU Sampler Adjustment check.
7. Mechanism checks, Instrument Checks, Pipetting accuracy checks.

All the checks and calibration were done and the system is being used under recommended conditions. Next calibration is due on 21th June, 2025

For Roche Diagnostics India Pvt. Ltd.

Sunil Jadhav,
Senior Technical Service Specialist,
Hubli

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Roche

CALIBRATION CERTIFICATE

HOSPITAL/LAB NAME	: KLES DR. PRABHAKAR KORE HOSPITAL & MRC
ADDRESS	: NEHARU NAGAR, BELAGAVI KARNATAKA-590010
ANALYSER	: COBAS PURE ANALYZER
SERIAL NO	: 22G1-06 (SSU), 22C6-06 (C303), 22D1-05 (E402).
INSTALLATION PLACE	: HI TECH LABORATORY, DEPT. OF BIOCHEMISTRY
DATE	: 20 JUNE, 2024

This is to certify that the above mentioned analyzer was calibrated by the following procedure as per manufacturer's recommendations.

1. PHOTOMETER CHECK

PREVIOUS DATA		CURRENT DATA	
340 nm	0.9145	340 nm	1.3082
376 nm	0.8669	376 nm	1.0762
415 nm	0.8526	415 nm	1.0233
450 nm	0.8411	450 nm	0.9852
480 nm	0.8363	480 nm	0.9570
505 nm	0.8369	505 nm	0.9439
546 nm	0.8264	546 nm	0.9151
570 nm	0.8269	570 nm	0.9095
600 nm	0.8231	600 nm	0.8918
660 nm	0.8240	660 nm	0.8671
700 nm	0.8211	700 nm	0.8527
800 nm	0.8163	800 nm	0.8309

The above mentioned values are found to be with in the standard specified by our Principles, **ROCHE DIAGNOSTICS, GERMANY.**

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3. Gripper Adjustment check.
4. Temperature monitor for Detection unit, incubator, and reagent disk
5. Pipettor probes LLD voltage, sipper probes LLD voltage, and Pressure sensors check.
6. SSU Sampler Adjustment check.
7. Mechanism checks, Instrument Checks, Pipetting accuracy checks.

All the checks and calibration were done and the system is being used under recommended conditions. Next calibration is due on 19th June, 2025

For Roche Diagnostics India Pvt. Ltd.

Sunil Jadhav,
Senior Technical Service Specialist,
Hubli

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ANNEXURE – V PAMPHLET

What is NAFLD/MASLD?

In our body, liver absorbs all the extra sugar and converts it into fat so that it can be stored for the future. Liver is called fatty, when stored fat exceeds more than 5% of the liver weight.

Fatty liver is commonly related to alcohol but often it can happen in people who don't consume alcohol, but have lifestyle problems, such as

- Obesity
- Diabetes
- Hypertension
- High Cholesterol and triglycerides

This type of Fatty liver is called NAFLD (Non Alcoholic Fatty Liver Disease) or MASLD (Metabolic dysfunction-associated steatotic liver disease).

What is NASH?

NAFLD can progress to inflammation of the liver and this condition is Non-Alcoholic Steatohepatitis (NASH).

NASH Symptoms

NASH is often termed as silent disease, patients may have no symptoms until advanced stages. However, some patients may feel symptoms, such as moderate pain or discomfort in the upper right area of the abdomen and/or fatigue.

How is NASH Diagnosed?

The doctor can order certain diagnostic tests when he suspects NASH

1. Routine blood Test to check raised liver enzymes like AST and ALT
2. Abdominal Ultrasound
3. Fibroscan or elastography to ascertain the liver stiffness
4. MRI/ MRE
5. Less often, liver biopsy to examine liver cells for the extent of scarring

Risk factors to look out for

Type 2 Diabetes Mellitus

Hypertension

Obesity

High Cholesterol and triglycerides

Progression of NAFLD/MASLD

Progression of NASH can also increase the risk of heart related diseases.

Act before it's too late !

With no intervention, NAFLD/MASLD can progress to a more serious condition called NASH. Severe NASH is not reversible.

The Right Move!

Efficient and sustained lifestyle modification can have an impact on NASH and even on fibrosis, provided the weight loss is of at least 10% of bodyweight, and is sustained.

Good lifestyle habits will help considerably!

- Avoid fried food, use only unsaturated fats.
- Control your portions, eat less but frequently.
- Drink water throughout the day to keep you hydrated
- Reduce or minimize your sugar intake.
- Add lots of fruits, nuts and green vegetables in your diet.
- Avoid or minimize alcohol.

Eat slowly!

Your stomach needs at least 20 mins. after the beginning of the meal to send satiety messages to your brain. If you eat too quickly, you may overeat.