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A Clinical Study: Impact Of Lifestyle Intervention on Fatty Liver disease Progression

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ARTICLE DETAILS

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ABSTRACT

A brownish hue is imparted to face tissue because of the breakdown of ancient red blood cells. A liver problem might be the cause of black urine or discolored feces. As bilirubin builds up a byproduct of regular hemoglobin collapse the skin and eyes turn yellow, a condition known as jaundice. This is a classic indicator of liver issues. Due to its multi-essential role, the liver is occasionally susceptible to illness. Liver damage can occur as a result of being overweight and overindulging in alcohol use. A lot of people in India's cities deal with fatty liver [1], which often goes undiagnosed until it develops into a more dangerous condition like hepatitis, which causes jaundice. At first, it's completely innocuous, but as it develops, it becomes a likely slow murderer. A large number of obese or diabetic individuals with extra fat in their life led to the initial naming of the condition as fatty liver disease in 1980. In the time after, scientists learned that some types of liver fat are completely harmless. When liver fat reaches 5 to 10% of its entire weight, it's a clear sign of fatty liver disease. After that point, the liver is considerably more vulnerable to injury, scarring, swelling, and eventual failure. A lack of proper and balanced diet, as well as an excessive consumption of unhealthy foods (such as those that are highly processed or include a lot of fat), is a major contributor to the condition, even if the exact cause is unclear.

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Role of fatty liver

The liver is responsible for maintaining homeostasis in the body's metabolic processes through more than 300 distinct actions. The liver is responsible, under normal circumstances, for generating the nutrients that the body's fifty trillion or more cells need. The liver performs a variety of tasks, including:

The production of bile is essential for the elimination of harmful waste products and for healthy digestion.

• Amino acids are building blocks for proteins and clotting factors, which are essential for all cellular processes, including repair, development, and healing. • It is the largest store house of many vitamins such as Vitamin A, D, K, B12, [15] iron and minerals. The liver also converts all the BComplex vitamins, Nutrients in foods and supplements into their active forms and made them available for body functions.

• It has gigantic stores of energy by producing glucose from the different sugars in the diet and stores it in the form of glycogens and converts glycogens to glucose when glucose levels are low.

Purpose of the study:

This quasi experimental study should improve non alcoholic fatty liver disease progression in this this study I was provide low caloric about 1000-1500 kcal diet menu to the patients.After 3 months of study period I was observe changes in patients e;g, Liver function tests ALT,AST, Changes in weight and BMI.This diet menu will improve fatty liver progression. If populations will take this diet menu then improve in Obesity and Fatty Liver Progression.

1) Methodology:

Study design: Conduct a one-group pre- and post-test in a quasi-experimental research.

Study site: The study will carried out at jiwandeep hospital, Anand region (with prior permission)

Sample size: 40 above

Study Duration: 3 Months after approval of institutional ethics committee.

Eligibility Criteria:

Inclusion criteria: Age 18-75 years.

- Already diagnosed non-alcoholic fatty liver patients based on blood tests including AST and ALT , imaging study including ultrasound.
- Presence of metabolic comorbidities including diabetes, hypertension, cholestrol and dyslipidemia.
- □ Non hospitalized patients.
- □ Conduct the weekly follow-up of the participants.
- □ Ability to provide informed consent.
- □ Ability to read and understand the questions in the choosen language (e;g. Hindi, Gujarati and English).

Exclusion criteria:

- □ Pregnancy or lactation.
- □ Other liver disease e;g viral hepatitis (hepatitis B,C).
- □ Alcoholic fatty liver patients.

□ **Data Sources:**

□ Hypothesis related data will be collected in proper format after carrying out the follow-up.

□ **Data collection:**

The data will be collected in two ways:

1. During before conducting weekly follow-up.(Provide questionnaire, demographic and

clinical details of diagnosed patients blood tests and ultrasound.)

2. After 3months we will collect the data of adherence rate .(Daily food logs)

Common risk factors

Including, obesity, type 2 diabetes, high blood pressure

Study Procedure:

- I will identify the hospital from where I will have possible candidates of non alcoholic fatty liver patients for the follow-up.
- I will have acquire permission from the hospital management department to conduct the follow-up.
- Once, I have permission I will take the participants physically from the Jiwandeep Hospital, Anand with the help of gastroenterologist doctor

The basic questionnaire form and consent form will be explained to the participant and request them fill up it properly. Completed forms will be collected after 30 mins of understanding and filling of participants.

- The collected forms will be examined and any that are found to be incomplete will not be considered for the study.
- □ I will take the patients who had already diagnosed with blood tests including AST and ALT, ultrasound which was done by the lab technician and examine the previous diet and physical activity.
- □ After that I will provide new weekly diet in detail and aware of doing daily physical activity.
- □ I will request them to note down 7 days diet menu and physical activity which will consumed by patients in particular diary.
- □ We will conduct the weekly follow-up , during follow-up period I will evaluate every day adherence of diet and activity.
- □ After 3months we will calculate adherence rate and doing blood tests of the participants and evaluate measurement between previous and after 3months weight and laboratory values

Adherence rate measurement: It can be measured by the percentage of dietary

recommendations the patient follows:

□ These may include: Number of meals aligned with the prescribed plan,avoidance of restricted foods(e.g; high fat,sugary), inclusion of recommended foods(e;g, fruits, vegetable, protein)

□ Collect data:

□ Daily food logs: Ask the patient to maintain a daily food diary for 3 months.

□ Dietitian Review: conduct weekly reviews.

□ High adherence: >80%, Moderate adherence: 50-80%, low adherence: <50%.

Rationale:

- Studying how changes in lifestyle affect the development of fatty liver disease is important for a number of reasons. Including:

- Public health concern: Fatty liver disease is becoming a global health issue, often linked to obesity, diabetes and metabolic syndrom. Lifestyle interventions like diet and exercise, could be key in slowing its progression.
- Lack of effective drug treatments: Since there are currently no FDA approved medications for fatty liver disease lifestyle interventions are the main treatment option.
- Fatty liver disease can progress to cirrhosis, liver failure or liver cancer. Researching lifestyle interventions could help identify practical, cost effective ways to prevent these complication.
- Justification:
- Weight loss and fat reduction in the liver.
- Dietary modifications improve liver health.
- Reduction in inflammation and fibrosis progression.

Objectives:

Primary objective: To determine the effectiveness of lifestyle intervention on reducing fat accumulation in patients with non-alcoholic fatty liver disease.

Secondary objective: To evaluate the adherence of the lifestyle intervention of non alcoholic fatty liver disease patients.

Aim: To assess the effectivness of lifestyle modification including (diet and exercise) on the progression of fatty liver disease.

Methods

- Study Design: The Quasi experimental study (one group pre test - post test)
- Observational study
- Participants: Non-alcoholic fatty liver participants.
- Data collection: In jiwandeep hospital, Anand.
- Baseline liver assessments including (AST,ALT,BMI and ultrasound)
- Follow-up evaluations: Conduct weekly follow-ups and given the diet record page to the patient.
- Statistical analysis: t-test.

Results:

The quasi experimental study included 50 patients as the total number of patients, out of which 15 females and 35 males. In this study , the majority of the patients belonged to the age group of years 27-71 years. P-value is significant 0.05. Comparision between preALT and post ALT test, pre AST and post AST and BMI.Also observe the weight variation. And achieved moderate diet adherence rate up to 50-70% of the patients. If patients follow this weekly diet menu continuously, then improve in obesity and liver function.

Conclusion:

This study included the results of 50 patients from the urban area of non alcoholic fatty liver disease where 15 females and 35 males. This quasi experimental study patients who adhere to the low caloric diet up to three months expected to experience weight reduction which correlates with improvement in non alcoholic fatty liver disease. Also improvement in Post ALT and post AST, BMI and ultrasound (grade 1,2,3) fatty liver. Liver function tests which showed improvement in weight reduction up to 5 to 7kg and liver health.

Discussion:

This research work was a quasi experimental study to assess NAFLD with a doctor, the conversation typically revolves around diagnosis, causes, lifestyle modifications and diet changes to prevent disease progression.

Discussion before dietary changes (pre-diagnosis diet) with the doctor.

Patient concerns: ‘’ I feel fatigued and have discomfort in my upper right abdomen.

Doctor response: ‘’ Fat accumulation in the liver. This suggests NAFLD. Your diet and lifestyle play major role in manage this condition.

Assessment:

Current eating habits (high sugar, refined carbs, processed foods, saturated fats)

Alcohol consumption, physical activity levels and weight history.

Symptoms like fatigue, digestive issues.

Patient diet history:

Provide properly instructions to follow given healthy diet menu.

Exercise Recommendation: At least 150min per week of moderate exercise (walking, cycling) Patient experience and follow up discussion: Conduct weekly follow-up upto 3 months and measurement of weight variation and adherence rate of diet menu.

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Appendices:

Questionnaire forms:

Name:

Gender:

Height: Weight:

1) Do you know about cirrhosis?

2) Do you suffering from cholesterol, high blood pressure and diabetes?

3) How many servings of fruits and vegetables do you consume daily?

4) Do you smoking cigarettes?

5) Do you noticed unexplained fatigue and weight gain and loss?

6) Do you have abdominal pain?

7) How often do you engage in physical exercise?

नाम:

लिंग:

ऊंचाई:

वजन:

1) क्या आप सिरोसिस के बारे में जानते हैं?

2) क्या आप कोलेस्ट्रॉल, उच्च रक्तचाप और मधुमेह से पीड़ित हैं?

3) आप प्रतिदिन कितने फल और सब्ज़ियाँ खाते हैं?

4) क्या आप सिगरेट पीते हैं?

5) क्या आपको बिना किसी कारण के थकान और वजन बढ़ने और घटने का एहसास हुआ है?

6) क्या आपको पेट में दर्द रहता है?

7) आप कितनी बार शारीरिक व्यायाम करते हैं?

નામ:

લિંગ:

ઊંચાઈ:

વજન:

1) શું તમે સિરોસિસ વિશે જાણો છો?

2) શું તમે કોલેસ્ટ્રોલ, હાઈ બ્લડ પ્રેશર અને ડાયાબિટીસથી પીડિત છો?

3) તમે દરરોજ ફળો અને શાકભાજીની કેટલી સર્વિંગ ખાઓ છો?

4) શું તમે સિગારેટ પીઓ છો?

5) શું તમે ન સમજાય તેવા થાક અને વજનમાં વધારો અને ઘટાડો નોંધ્યો છે?

6) શું તમને પેટમાં દુખાવો છે?

7) તમે કેટલી વાર શારીરિક કસરત કરો છો?

Informed Consent Form for patient

INFORMED CONSENT FORM

SHIVAM PHARMACEUTICAL STUDIES AND RESEARCH CENTRE, VALASAN- 282

INSTITUTIONAL ETHICAL COMMITTEE

Proposed Project:

Inform Consent Form for Participation

I _____,

Voluntary agree to participate in a survey based study titled "A CLINICAL STUDY: IMPACT OF LIFESTYLE INTERVENTIONS ON FATTY LIVER DISEASE PROGRESSION". The purpose of this study, as explained to me by the researcher, is to assess and understand the lifestyle interventions of fatty liver and adherence of new weekly diet. This study will include questions related to physical, mental, and social well-being, aimed at identifying challenges and outcomes associated with recovery from COVID-19.

I understand that:

1) **Participants** is voluntary, and I may withdraw from the study at any time without giving a reason.
2) **Confidentiality** will be maintained, and my responses will only be used for research purposes.
3) **Follow-up Involvement:** The study involves evaluate previous diet and medications and provide new weekly diet chart and physical activities.

Signature of Investigator **Signature of Guide**

Diet record page for patients:

Fatty liver disease nutritional diet diary:

(Week:_____) Day:_____

Day	Morning	Breakfast	Mid - morning	Lunch	Evening snacks	Dinner	Notes (symptoms, energy levels)
Monday							
Tuesday							
Wednesday							
Thursday							
Friday							
Saturday							
Sunday							

: Additional sections for weekly tracking:

:Water intake: how many glass per day?_____

: How many days doing physical Activity: (e.g; walking, yoga):_____

:Symptoms noticed: (e.g, fatigue, nausea):_____

:Foods that discomfort:_____

Diet chart for patients:

Fatty Liver diet menu for patients:

Every day foods include may 1000-1500 calories per day.

Day	Time	Meal
Monday	**Morning**	Warm water with lemon (1 glass around 250 ml and 10cal)+7 cashews and 7 almonds(around 8gm and 7gm, approx 112cal)
	Breakfast	1medium piece of paneer (around50gm,200cal)+ 1medium orange 70cal,around 162gm)
	Mid -morning	1bowl of cooked daliya made with mixture of green vegetables (around 200gm,190cal)+ 2tabspoon sunflowerseeds (80gm,40cal)
	Lunch	1 medium bowl of cooked urad dal(around 400gm,240cal)+ 1chapati(about 40gm,approx 90cal)+ 1glass buttermilk (around 250ml,approx 60cal)
	Evening snacks	Salad including medium size of 1cucumber (around 100gm, approx 16cal) 1Tomato (around 100gm, approx 18cal) 1 carrot(around 100 gm, approx 35 cal) 1 raddish(around 25 gm, approx 5cal)
	Dinner	2thick medium bajra roti(around 100gm,approx 280cal)+ 1bowl cabbage sabji(150gm,approx 45cal) + 1small bowl yogurt (around 200gm,approx 150cal)
Tuesday	**Morning**	1 medium glass of warm turmeric water(around 240ml, approx 10 cal) + 3 walnuts and 3 almonds (both around 3gm, approx 21cal)
	Breakfast	1cup of roasted makhana (about 40gm, approx 120cal) + 1apple (around 180gm, approx 95cal)
	Mid morning	Salad including medium size of 1cucumber (around 100gm, approx 16cal) 1Tomato (around 100gm, approx 18cal) 1 carrot(around 100 gm, approx 35 cal) 1 raddish(around 25 gm, approx 5cal) + 1 small bowl of chickpeas (about 160gm, approx 260cal)
	Lunch	1 or 2 whole wheat chapati(around 50gm, approx 130cal) with cooked 1 bowl palak(around 180gm,approx, 45cal) + 1 glass of butter milk (around 240ml,approx 50cal)
	Evening snacks	2 medium bowl of cooked moong beans(around 300gm, approx 240cal) + 1medium pomegranate (around 100gm, approx 200cal) + 1tabspoon sunflower seeds (about 15gm,approx 60cal)
	Dinner	1medium bowl of unpolished rice(around 150gm,approx 165cal) + 2 medium bowl of masoor dal(around 300gm,approx 300cal)
wenesday	**Morning**	Low fat 1glass of milk(about 240ml,approx 100cal) + 2 or 3

		walnuts and almonds (about 3gm, approx 25cal)
	Breakfast	1medium apple(180gm,approx 95cal) + 1cup cutted papaya (about140gm,approx, 60cal)
	Midmorn -ing	1medium bowl of veg kodari including mix of garlic and onion with medium ghee or oil(about200gm,approx 220cal+ salad including medium size of 1cucumber (around 100gm, approx 16cal) 1Tomato (around 100gm, approx 18cal) 1 carrot(around 100 gm, approx 35 cal) 1 raddish(around 25 gm, approx 5cal) + 1 small bowl of chickpeas (about 160gm, approx 260cal)
	Lunch	1medium bowl of unpolished rice(around 150gm,approx 165cal) + with 1 or 2 medium bowl of cooked chana dal(around 400gm, approx 440cal)
	Evening snacks	Low fat paneer serving size(around 100gm,approx 170cal)made with green vegetables like onion, tomato
	Dinner	1medium bajara thick chapati(around 60gm,approx 160cal) + 1bowl of karela(100gm,30cal) or brinjal subji(100gm, approx 35cal) + one cup of low fat yogurt(around 240gm,approx 150cal)
Thursday	**Morning**	1 glass Warm water with lemon(250ml,approx 10cal) + 7 cashews and almonds (around 8gm and 7gm,approx 112cal)of both
	Breakfast	2medium orange (240gm,approx 120cal) + 1medium apple (around 180gm,approx 95cal) + 1medium pomegranate(280gm,approx 130cal)
	Midmorn -ing	1bowl of coocked daliya made with mix of green vegetables(200gm,approx190cal) + 2tabspoon sunflowerseeds(around 80gm,approx 40cal)
	Lunch	1or 1/2 bowl of cooked chickpeas(around 80gm,approx 250cal) +1or 1/2 bowl cooked urad dal (around 400gm,approx 240cal) + 1chapati (40gm,approx 90cal) + 1 glass butter milk(250ml, approx 60cal)
	Evening snacks	1bowl of roasted makhana(around 40gm,approx 120cal) + salad including medium size of 1cucumber (around 100gm, approx 16cal) 1Tomato (around 100gm, approx 18cal) 1 carrot(around 100 gm, approx 35 cal) 1 raddish(around 25 gm, approx 5cal) + 1 small bowl of chickpeas (about 160gm, approx 260cal)
	Dinner	2thick medium bajara chapati(around 100gm,approx, 280kcal) + green vegetables like cooked 1 bowl cabbage subji(150gm,approx 45cal) + 1 small bowl of low fat yogurt (around 200gm,approx 150cal)
Friday	**Morning**	1glass turmeric water(around 240ml,approx 10cal) + 3walnut(around 3.6gm,approx 21cal) + almonds(around 3gm,approx 20cal)
	Breakfast	Fruits like 2apple(around 300gm,approx 190cal) + 2 kiwi(200gm,approx 100cal) + 1small cup of cutted papaya (around 150gm,approx 60cal) + 2 spoon flaxseeds (around

		14gm,approx 110cal)
	Midmorn -ing	1 or 1/2 bowl Cooked rajama(around 100gm,approx 150cal) with less oil + salad including medium size of 1cucumber (around 100gm, approx 16cal) 1Tomato (around 100gm, approx 18cal) 1 carrot(around 100 gm, approx 35 cal) 1 raddish(around 25 gm, approx 5cal)
	Lunch	1or1/2 bowl of unpolished rice(120gm,approx 140cal) + 1 or 1/2 bowl toor dal (around 200gm,approx 260cal) + 1glass buttermilk(around 400gm,approx 50cal)
	Evening snacks	1bowl ragi murmura (around 40gm,approx 130cal)
	Dinner	1bowl of spinach (palak)around (200gm,approx 60cal) +1 jowar atta thick roti (around 60gm,approx 150cal) + 1cup of yogurt (around 200gm,approx 150cal)
Saturday	**Morning**	1glass low fat milk(around 240ml,approx 100kcal) + 5 cashew(around 8gm,approx 48cal) +1Amla(about 30gm,approx 15cal)
	Breakfast	1bowl sprouted moong(around 100gm,approx 100cal) + 1apple(around 150gm,approx 95cal)+ 1/2 bowl grapes (100gm, 55cal)
	Midmorn -ing	2tabspoon flaxseeds(around15gm,approx80cal) +boiled methiseeds(fenugreek seeds)(around10gm,approx 35cal)
	Lunch	1bowl Unpolishedrice(around150gm,approx 120cal)+1bowl masoordal(200gm,approx 230cal) + 1 glass buttermilk(around 250ml, approx 50cal)
	Evenings snacks	1/2bowl veg kodri including onion,garlic,dhaniya(green coriender)around(100gm,approx130cal)+1Amla(around 15gm,approx30cal)
	Dinner	1or2 thick bajara chapati(around120gm,approx144cal)+1bowl pumpkin sabji(around170gm,approx90cal+1bowl yogurt(200gm,approx150cal)+salad including1medium onion(around80gm,approx48cal)+1 Tomato(around100gm,approx20cal)
Sunday	**Morning**	1glass of low fat milk(around250gm,approx125cal)+1Amla(around10gm, Approx 15cal)+5,6Almonds(around7gm,approx35cal)
	Breakfast	1bowl veg oats(around250gm,approx175cal)+Fruits 1apple(150gm,approx95cal)+1kiwi (around 100gm, approx 50cal)
	Midmorn	1bowl