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Multimodal Program Effectiveness on Hepatic Fat Mobilization and Functional Capacity among Patients with Non-alcoholic Fatty Liver

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Abstract

Non-alcoholic fatty liver is an umbrella covering a group of conditions associated with fat deposition and tissue damage. **The aim:** To elucidate the multimodal program effectiveness on hepatic fat mobilization and functional capacity among patients with nonalcoholic fatty liver. **Design:** Quasi experimental design. **Setting:** The National Liver Institute outpatient's clinics at Menoufia Governorate, Egypt. **Subjects:** A purposive sample of 150 adult patients. **Instruments:** An interview structured questionnaire, Nutritional assessment sheet, International physical activity questionnaire, Functional capacity scale and Self-reported compliance sheet. **Results:** The total caloric intake was reduced among the studied group from 2652.66 to 1890.46 Kcal after program application by 6 months. Also, after 3 months BMI and hip circumference were reduced from 34.72 Kg/m^2 and 112.10 Cm to 28.67 Kg/m^2 and 112.10 Cm, respectively. After 3 and 6 months from the program application, patients' compliance progress from 70.0% to 78% respectively. A significant positive correlation between patient's compliance & functional capacity at the three different intervals respectively was present. Oppositely, a significant negative correlation observed between patient's compliance and blood lipids as TCHOL, TG & LDL after 6 months of program application respectively. **Conclusion:** Multimodal program is an efficient approach holistically implemented for resolution of existing fatty liver, prevention of new fat development, improvement in patient's functional capacity, blood pressure, lipid profile, body weight, liver function and enzymes. **Recommendation:** Awareness enhancement regarding multimodal program and control of non-alcoholic fatty liver disease risk factors through mass media is recommended.

Keywords: Functional capacity, Hepatic fat mobilization, Multimodal program & Nonalcoholic fatty liver.

Introduction

Non-Alcoholic Fatty Liver (NAFL) is a dominant cause of multiple liver disorders, which is strongly linked to a poor health related practice. The worldwide prevalence reported 20% to 30% of general population, with incidence of approximately 20 to 30 / 1,000 person-year depending on their characteristics**.** Though not imminently fatal itself, it is linked to numerous diseases such as atherosclerosis, diabetes mellitus, hypertension, heart disease and dyslipidemia. Progression to cirrhosis and hepato-cellular carcinoma can occur if untreated **(Chalasani et al., 2018).** Complex interaction between environmental, nutritional and genetic factors as sedentary life, extra calories, excessive saturated fats, refined carbohydrates and fructose consumption are the causes of this disease. Determination of Non-Alcoholic Fatty Liver Disease (NAFLD) usually by imaging or histology after other causes exclusion as viral hepatitis, heavy consumption of alcohol, using medication causing fatty liver or hereditary disorders. **(Lonardo et al., 2017).**

While NAFLD medical therapy is critical, an integrated multimodal program is an effective, noninvasive creative solution to predict Non-Alcoholic Steato Hepatitis (NASH) resolution instead of liver biopsy, which is expensive, invasive and carries multiple associated risks. This program including an integration between using different approaches of NAFD management together as exercise, diet, patient behavioral counseling, stress management and smoking cessation and using different communication modes together as linguistic, visual, gestural, spatial and audio when apply the program. **(Arora et al., 2019).** Combination of these modalities, collectively seeking the achievement of healthier practices for disease management, through

conveying the ideas, thoughts, feelings, and opinions to be reflected on patient's knowledge, behaviors and attitudes fostering good prognosis **(Atri et al., 2020).**
As a result of the real problem of eating too many calories while exercising too little, generally one size fits all method designed dietitians and physicians for weight loss through calories restriction with dietary modifications in term of avoidance of excessive unhealthy saturated fat, simple carbohydrates while increased the vegetables to 300g and fresh ripe fruits to 200g at least per day to improve the patients' metabolic parameters **(Moore et al., 2020).** Depending on the available evidence, enhancing in mobilization ,regular physical activity with an addition of any kind of exercise whether resistance, aerobic or high-intensity intermittent exercise every day at least 30 minutes through jogging, walking or cycling is beneficial for patients with NAFLD instead of the sedentary life. In Addition to that, to reduce liver steatosis, it is sufficient to gradually lose 3% of weight, while 7% to 10% reduction can ameliorate steatohepatitis and even improve hepatic fibrosis. Also, to control NAFLD progression **(Esteban & Dinani, 2020).**
Behavioral management includes taking action to manage stress, solving problems with multiple procedures, control risk factors, follow healthy balanced diet, being more physically active, maintaining ideal weight, maintain normal sleep pattern, keeping blood pressure and diabetes mellitus under control, giving up smoking, regular laboratory checkup every 3 months, comply with prescribed medication and training about relapse anticipation and prevention (**Abulmeaty, 2017).** Improper disease perception, lack of willingness, other higher priority, low self-esteem, shortage of family and cultural support, improper education and insufficient resources where the common barriers can hinder patients. Therefore, such a multimodal program with its combination nature will overcome most of these barriers with greater dedication and success rates **(Magalhães, Paula et al., 2022).**
There are many benefits resulting from multimodal program application including early disease detection , prevention of further progression; disease regression as a result of **hepatic fat mobilization** (resolution of existing liver fats without development of new fat) , improvement patients' cardiorespiratory fitness, glucose level, patients' mood, sleep pattern, self-esteem and confidence, bone density, muscle strength, flexibility and bulk and functional capacity level which appear in patient's ability to perform daily living activities. Moreover, there will be marked reduction in patient's blood pressure, insulin resistance, visceral fat and fat oxidation, anxiety and depressive symptoms **(Hallsworth & Adams, 2019).**

Significance of the study

NAFLD encompasses a wide range of disorders ranging from simple steatosis (fat accumulate in liver without liver damage) to Non-Alcoholic Steato Hepatitis (NASH) (a stage with inflamed liver) and different fibrosis degree (F1–F4) which consider the strongest predictor for this disease mortality **(Parry & Hodson, 2020).** Several studies had only explored the relationships between several factors such as Mediterranean diet adherence, obesity, high daily fructose consumption, level of physical activity, daytime sleepiness, smoking, stress, and NAFLD, but an implementation of multimodal program haven't been explored yet **(Lahelma et al., 2021).** Therefore, this study was conducted aiming to elucidate the multimodal program effectiveness on hepatic fat mobilization and functional capacity among nonalcoholic fatty liver patients.

Theoretical framework

The present study is guided by Orem's theory, which based upon philosophy that all "patients wish to care for themselves". They can recover more quickly and holistically if they are allowed to perform their own self-cares to the best of their ability. The theory including three main concepts: Self-care (why and how people care for themselves), self-care deficit (why people can be helped through nursing and nursing systems (explains relationships that must be made and maintained for nursing to be produced. **The Self-care** concept indicating activities that individual initiates and performs on their behalf to maintain life, health, and well-being. The individual's ability to perform self-care activities and including two agents: Self-care agent (person who provides the self-care and has the power to do so and dependent care agent which pointing to person other than one who provides the care .Therapeutic self-care demand is the sum of self-care measures/ actions required to meet the specific self-care requisites of a person at a point in time. **The Self-care deficits concept** specifies when nursing is needed. Nursing is required when a person is incapable or limited in the provision of continuous effective self-care (cannot carry out self-care requisites). **The nursing system concept** describes how the patient's self-care needs will be met by the nurse, nursing responsibilities, roles of the nurse and patient and nurse-patient relationship. Orem's theory was chosen to guide this study because of its usefulness in explaining determination of needs, design nursing system and plan the delivery of care, initiation, conduction and controlling of assisting actions. Orem's theory application help patients to understand the required changes in their behavior to have the requisites met, assisting others in the provision and management of self-care to maintain or

improve human functioning level of effectiveness (**Orem et al., 2009)**.

In the present study, according to Orem, (1) Self Care include activities that the patient will perform on his own which include regular exercise practice**,** healthy food ,plan a healthy diet meals and calculate his daily calories and do regular lab checkup and doctor visit, (2) Self Care Deficit; patient will communicate his /her inquires to research team members through telephone call and follow ups scheduled.(3) Nursing system; nurses responsibilities to be oriented with referral system and community resources ,also nurses will refer patients to the proper health care facilities and utilizing available resources.

Purpose of study

To elucidate the multimodal program effectiveness on hepatic fat mobilization and functional capacity among patients with nonalcoholic fatty liver.

Hypotheses

- Patients who are receiving the multimodal program will exhibit improved liver enzymes and lipid profile post program compared to pre program.
- Patients who are receiving the multimodal program will exhibit a reduction in body weight, number of smoked cigarettes and coffee intake post program compared to pre program
- Patients who are receiving the multimodal program will experience more compliance of healthy dietary intake, physical and behavioral practices with regular exercise post program compared to pre program
- Patients who are receiving the multimodal program will have elevated functional capacity level post program compared to pre program

Methods

Design: Quasi experimental research design.

Setting: The National Liver Institute out patient's clinics at Shebin El-Kom, Menoufia Governorate, Egypt.

Sample: A purposive sample of 150 patients from the National Liver Institute outpatient's clinics at Shebin El-Kom, Menoufia Governorate matching the following **inclusion criteria**. a) Both sexes, b) Adults (18 - 60 years), c) Confirmed diagnostic ultrasonography. **The patients were excluded if they had** a) Hepatitis B or C virus-positive serologic indicators due to its effect on liver enzymes. B) Pregnant and lactating women due to hormonal effect and for maintaining safe pregnancy outcome. c) Patients taking drug as steroids that causing fatty liver. d) Presence of hepatic decompensation, hepatic encephalopathy, ascites, variceal bleeding that negatively affect liver enzymes. e) Patients with chronic kidney diseases; autoimmune diseases; thyroid abnormalities due to its effect on liver function tests**.**

Calculation of the sample size: A study population comprised all patients attended outpatient National Liver Institute clinics at Shebin El-Kom, Menoufia Governorate, Egypt. The flow rate of patients in outpatients' clinics was about 1440 / year. Since the population size is less than 10000, the final sample estimation was calculated using $n=N/1+N\ (e)^{2}$ formula **(Yamane, 1967)**: Where: n= sample size required, N= number of people in the population, e=allowable error (% 0.07) with a 93% level of confidence = 1440/1(1440*.0049) = 178. Patients who actually participated in the study were 150 who completed the interventions while 28 patients were excluded because of lack of participation in the sessions and not completed the questionnaire.

Study instruments

An interviewing structured questionnaire: Developed by the researcher after reviewing relevant literature to identify the patient's socio-demographic data as age, sex, educational level, marital status, occupation, smoking and income status.

Nutritional Assessment Sheet: Adopted from **the National Nutrient Database for Standard Reference (2000)** to assess the dietary and bio-physiological state of patients, it contains three parts:

Part one: Dietary assessment: Including 7 questions regarding dietary practices as meals number, un saturated fats, complex sugar, sodium free food, caffeinated beverage, high fiber and drinking about liter of fluid daily for every 30kg of weight.

Scoring system: A three-point Likert scale was used to measure it (rarely (one point), to some extent/day (two points), and continuously /day) (three point). Answers were calculated to find the total mean scores which categorize as good practice with high score 19-21 or average practice with the score10-14 and poor practice with the score 1-7.

Part two: 24 Hours Dietary Recall: to calculate total calories intake/ day after analyzing nutritional elements of three consecutive days by nutritional specialist.

Part three: Bio-physiological measurements

1. **Anthropometric measurements:** Measuring waist and hip circumference to calculate waist to hip ratio.
2. **Body composition analysis** using the multi-frequency Bioelectrical Impedance Analyzer (BIA) apparatus to measure body weight, height and calculate Body Mass Index (BMI), fat percentage, fat mass, fat free mass, visceral fat, total body water, Basal Metabolic Rate (BMR)/ Calories, metabolic age, bone mass and physical rate.
3. **Laboratory investigations:** including Fasting Blood Glucose (FBG), hemoglobin A1C (Hb-A1C), the Homeostasis Model Assessment-estimated Insulin Resistance HOMA IR, Total

CHOLesterol (TCHOL), Triglycerides (TG), Low-Density Lipoprotein-Cholesterol (LDL-C) and High-Density Lipoprotein-Cholesterol (HDL-C) and liver function enzymes include ALT, AST.

4. **Measuring Systolic and Diastolic Blood Pressure (SBP & DBP)/ mmHg.**

International Physical Activity Questionnaire Short Form (IPAQ-SF): Developed by **Oh et al., (2017)** used to firstly to measure the frequency and duration of walking, moderate to vigorous physical activity undertaken for more than 10 continuous minutes across all contexts (work, home and leisure) during a seven-days period. Secondly to calculate Metabolic Equivalents (MET-minutes per week), derived by assigning standardized MET values of 3.3, 4 and 8 for walking, moderate intensity and vigorous intensity, respectively. It is composed of two branches, physical activity level and sitting hours per day.

Scoring system:

Physical activity, were classified into three categories

1- **Inactive**, which meets neither minimally active nor health enhancing physically active.
2- **Minimally active**, which meets any of the following three criteria:

- ≥ 3 days of vigorous activity for 20 min/day.
- ≥ 5 days of moderate intensity activity or walking for 30 min/day.
- ≥ 5 days of any combination of walking and moderate intensity or vigorous intensity activities achieving 600 MET min/week.

3- **Health-Enhancing Physically Active (HEPA):** It divided into two criteria

- Vigorous intensity activity on three or more days / week accumulating 1500 MET min/week.
- Seven days of any combination of walking, moderate intensity, or vigorous intensity activities achieving at least 3000 MET min/week.

Sitting time

A single question says ‘‘during the last 7 days, how much time did you usually spend sitting on a week day?’’ This estimate included time spent sitting in a variety of domains (i.e., leisure, work and recreation).

Scoring system: Sitting time used by **Ryu et al., (2015)** was divided into the following categories< 5 hrs. /day, 5 - 9 hrs. /day and ≥ 10hrs/day**.**

The Functional Capacity Scale: Developed by **Marshall & Bested (2007)** to assess patient’s functional capacity level, it consists of ten questions each one incorporate energy rating, symptom severity, concentration level and sleep / resting versus ability to perform activity of daily living.

Scoring system: It has 10 point Likert scale ranged from 0 to 10; zero refer to absence of energy, very low concentration; bed ridden all day and cannot do self-care (e.g. need bed bath to be given) to 10 score which indicating no symptoms, excellent concentration, over achiever (sometimes may less sleep than the average individual). Answers were computed for 24 hours per day to obtain total mean scores per day.

Self-reported compliance sheet: Adopted by **Ali et al., (2017) to** evaluate patient's compliance with given multimodal instruction of dietary, physical activity, medication and behavioral intervention.

Scoring system: It was comprised of three-point Likert scale from zero for non-compliance at all, one for compliance to some extent and two for completely compliance with multimodal interventions then total score of total compliance was computed and categorize as 6-8 good compliance or 3-5 average compliance and 0-2 poor compliance.

Method

Written approval was obtained from the hospital directors and the head of the internal medicine outpatient clinics after an explanation of the study purpose to collect data.

Instruments development:

- The validity and reliability of the recalculated food intake using Nutritional Assessment Sheet adopted from the National Nutrient Database for Standard Reference. Intra-class correlation coefficients between recalculated and original values were above 0.99 for all elements. While in the present study the internal validity was obtained by using (2 tailed) 0.05 and the internal consistency (r =0.89 p-value <0.001), and test re-test reliability using cronbach’s alpha was 0.89 **(Yao et al., 2019).**
- The validity of IPAQ-SF scale was conducted using Pearson correlation. The significant value obtained using (2 tailed) 0.05 and the internal consistency (r =0.790 p-value <0.001). The reliability ranging from 0.66 to 0.88. Test re- test reliability using Cronbach’s alpha was 0.660 **(lee et al., 2011).**
- The validity of Functional Capacity Scale was content validity by the interrater (test–retest) reliability was quantified with an intraclass correlation coefficient that was (0.75 to 0.87), interrater reliability ranges from 0.95 to 0.98 **(Gross & Battie, 2022).**
- The validity of Self-reported compliance sheet was adopted from **Ali et al., (2017)** using content validity in which Pearson Product Moment correlation was conducted. The significant value obtained by (significant 2 tailed)0.05 and the internal consistency (r = 0.89 and P-value<0.001

Ethical Considerations

- Formal approval was taken from the Research Ethics Committee of the Faculty of Nursing at Menoufia University **(Ethics code, 876).**
- An official permission was obtained from the authorities of the National liver institute after explaining the purpose of the study and method of data collection.
- An oral consent of patients to participate in this study was obtained after explaining the purpose of study, patients reassured about their information confidentiality stating that information used only for the study purpose.
- The researchers explain that patients in the study were entirely voluntary and anonymity through coding data. Also, refusal to participate would not affect their care.

Pilot study: Prior to data collection, a pilot study was done on 15 patients (10%) to assess the usability and clarity of the instruments and participants in the pilot study were excluded.

Data collection:

- Data collection started from February 2022, to November, 2022. Patients who met the study inclusion criteria were selected.

Four phases were utilized for data collection:

Assessment phase:

- The patient's database was collected using all structured instruments: -Personal data using instrument and physical activity level, sitting time, functional capacity and compliance with the given multimodal interventions were assessed.
- Each patient underwent bio-physiological measurements by bioelectrical impedance analyzer (BIA) apparatus. Each patient was instructed to remove watches, jewelry and belts, and requested to place their hands and arms around the machine's handle while standing barefoot on the platform. Finally, the patient's data is documented in an excel sheet.
- The waist circumference was measured using a measuring tape midway between the lowest rib and the iliac crest. Also, hip circumference was the measurement from the mid-way between the largest part of the hips and the smallest part of the waist just above belly button, then waist to hip ratio was calculated.
- Draw blood sample from the antecubital vein while the patient is in the setting position after fasting at least 8 hours and send Biomedicine Laboratory for testing lipid profiles, FBG, Liver Enzymes.
- Also, measuring blood pressure while the patient in sitting position and blood pressure apparatus at the heart level.
- All patients were interviewed in the outpatient's clinics of National Liver Institute three days / week (Saturday, Monday and Wednesday) , each day about 6 to 7 patients with approximately 20 patients / week and 75 patients / month.
- Depending on the patient's educational level and comprehension, each interview lasted between 35 to 45 minutes.
- The base line data collection takes about two months from the first of January to March.

Planning phase:

- After patient's assessment, data obtained were used to formulate multimodal nursing programs. Goals, priority of care was taking firstly in consideration. An illustratively designed multimodal (audio, video, brochure and demonstrations) were prepared to be introduced to each patient as a guide for all data related to protocol of interventions. An illustrative structured colored booklet was prepared for patients as a guide for all relevant information related to interventions.
- This booklet contains all information about NAFLD, contributing factors, symptoms, complications, prevention, and management, with a focus on nutrition, exercise, and behavioral adjustment or lifestyle modification. Moreover, for patients who cannot read and write, pictures were used to clarify instructions and educational interventions.
- The expertise of this field reviewed the information included in this booklet to check the content relevance, clarity and feasibility.
- The researchers take permission from the director of outpatients' clinics to allocate special room supplied with data show served as the location for conducing sessions for patients.

Implementation phase:

- Four sessions were applied for the half of the total sample (75 patients).
- Every session is conducted on Monday of every week per month.
- By the same technique collect the second half of the sample (75 patients) and the session carried out by the same process.
- Two months (from the first of March to the first of May) were taken for implementing the multimodal nursing intervention.
- Each session took from 60 to 90 minutes; designed multimedia presentations (audio, video, brochure, and demonstrations) were designed.
- A group of what's app was formulated by the researcher for informing patients about time of each session, attach all multimodal linguistic, visual, gestural, spatial and audio contents after each cession.

- **The 1st session** included verbal instruction about NAFLD (definition, risk factors, manifestations, prevention, complications and management) these instructions were supplemented by multimedia presentation, animation and sounds.
- **The 2nd session** included a detailed healthy diet. The dietary program were individualized for each patient based on the Balanced Caloric Moderate Deficit Diet (BCDD), it took 6 months to conduct through subtracts a set amount of calories from a person's daily energy expenditures through a reduced-energy diet (– 500 kcal/day) using the guidelines established by the **National Heart, Lung, and Blood Institute (NHLBI, 2000)** and **Weight-loss and weight-management devices. FDA, (2022).** The main mechanism of weight-reduction was to reduce total caloric intake. This was achieved by average self-reported intake by participants and subtracts 500 kcals, therefore would cause weight losses of roughly 1 pound per week (0.5kg). It provides food choices that contain healthful amounts of complex carbohydrates, proteins, and unsaturated fats. These guidelines enable participants to tailor their eating to their individual food preferences. Still, to ensure healthy weight loss and adequate nutrient intake, women should not consume fewer than 1200 calories per day, and men no fewer than 1500 calories. BCDD is therefore individualized diets and vary in their total amounts of calories.it was achieved through nutritional specialist to provide the most suitable diet for each patient and reinforcing the need for adherence with nutrition by knowing the participant caloric intake per day, the researcher subtracts 500 kcals. Then estimates the percentage of CHO, fat and protein through dividing total calories on 55% to estimate the percentage of CHO, and dividing total calories on 15% to estimate total caloric intake from protein and then sum the total percentage of protein and CHO and submit from the total calories to know the percentage of fats or divided the total calories on 30% to estimate the percentage of the total calories from fats. Also, the allowed and prohibited food was explained as appropriate intake of fruit and vegetable-rich diets. Consuming less fructose, total fat, trans fat, and saturated fat (Mediterranean diet) and limiting total calories intake, avoiding fast food, meal planning consider recommending habitual daytime food consumption with avoidance of caloric dense nighttime meals such as skipping morning and midday meals which increase the odds of sonographic steatosis by 20% and 73% respectively. Also, avoid calorie-dense dinners that are linked to 40% less weight loss, 50% lower reduction in waist circumference, 42% lower reduction on HOMA-IR, and 15% increase in TG and increase water intake for more clarification to patients supplemented by an illustrative guidance through colored brochure, video and text.
- As well as behavioral modification about different anxiety reduction methods and problem solving, smoking cessation or reduction, regular physical checkup and associated diseases follow up, coffee moderation 2-3 servings of regular brewed coffee/ day limited to less than 100 mg. Shift work may be instructed to eat at the start of or close to the end of their shift. Jet lag which promotes sleep hygiene to match sleep and wake times during workdays, weekends and sleep for 7-9 hours of sleep nightly and maintain medication adherence.
- **3rd session** includes a protocol of moderate physical activity in the form of unsupervised walking for an hour daily or at least 5 times /week =150-200 min weekly exercise from 10.000 steps walking / day, aerobic bicycling and strengthen training. Also, giving instruction about gradual weight reduction through moderate 7%-10% weight loss significant >10% for obese and overweight patients with nonalcoholic steatohepatitis (NASH) that's supplemented by motivational video about weight reduction and exercises **(Ahmed et al., 2019).**
- At the beginning of each session, the researchers had refreshed the previously given instructions, and then started the new one. Furthermore, the researchers permitted patients to ask any question to reinforce the program application.
- Each patient was followed up by phone calls for ensuring that they follow the instructions as illustrated by the researchers and remembering them, the patients who followed and complied with the program were highly motivated when seeing improvements in their investigation and measurements.

Evaluation phase:

- All instruments, with the exception of the first instrument, were used to assess each patient through the scheduling of meetings on the same follow-up day for first time assessment and reassessment after three and six months (The minimum allowed time for program results to be reflected on patient outcomes for evaluation) as a follow-up.

Statistical Analysis

Data were collected, tabulated, statistically analyzed using version 22 (SPSS, Inc, Chicago, Illinois, USA). Mean and Standard deviation reflected the quantitative data while qualitative data were presented as numbers and percentages. The used tests of significance included paired t-test, Wilcoxon test, Marginal Homogeneity test and Spearman correlation. P value of <0.05 was considered statistically significant.

Results

Table (1): Socio-demographic data of studied patients

Socio-demographic data	Study sample (N=150)	
	No	%
Age (Mean± SD)	47.00±11.85	
Sex		
Male	72	48.0
Female	78	52.0
Occupation		
Required physical effort.	27	18.0
Required mental effort.	45	30.0
Housewife/ not work	78	52.0
Educational level		
Elementary education	33	22.0
Middle education	72	48.0
University & above	45	30.0
Residence		
Urban	72	48.0
Rural	78	52.0
Income		
Not enough	78	52.0
Enough	72	48.0

Table (2): Studied patient's multimodal practices distribution at different intervals

Multimodal practices	Studied Sample (N=150)			P value
	Pre	Post	Follow up	
	No (%)	No (%)	No (%)	
Dietary practice				
- **Poor**	36(24%)	18(12%)	15(10%)	**0.001*****
- **Average**	108(72%)	36(24%)	15(10%)	
- **Good**	6(4%)	96(64%)	130(80%)	
Total caloric intake (Kcal) (Mean± SD)	2652.66±414.04	2161.32±286.97	1890.46±327.47	**0.001*****
Coffee intake				
- Never/reduce drinking post intervention	51(34%)	6(4.0%)	15(10%)	
- 1 - 2 / day	45(30%)	114(76%)	108(72%)	0.014**
- ≥ 3 cups / day	54(36%)	30(20%)	27(18%)	
Physical activity				
- **Inactive**	111(74%)	21(14%)	12(8%)	**0.001*****
- **Moderate**	33(22%)	117(78%)	96(64%)	
- **High**	6(4%)	12(8%)	42(28%)	
Physical rate (Mean± SD)	24.12 ± 11.43	36.06±12.63	47.22±15.05	**0.001*****
Sitting time				
- **< 5 hrs/ day**	0 (0%)	57 (38%)	126 (84%)	**0.001*****
- **5 - 9 hrs/ day**	39 (26%)	87 (58%)	18 (12%)	
- **≥ 10 hrs/ day**	111(74%)	6 (4%)	6 (4%)	
Smoking				
- Never- reduce / stop smoking (post intervention)	107(71.3%)	108(72%)	119(79.3%)	
- Sometimes	25(16.7%)	32(21.3%)	28(18.7%)	**0.001*****
- Always	18(12%)	10(6.7%)	3(2%)	

****: Highly significant,* ***: Significant*

Table (3): Body composition and bio-physiological measurements of studied patients at different intervals

Body composition &bio-physiological measurements	Studied Sample (N=150)			P value
	Pre	Post	Follow up	
Body composition				
BMI/Kg/m^2	34.72±7.23	31.22±6.14	28.67±5.85	**0.001*****
Fat percentage	35.77± 9.91	31.90± 8.37	29.38±7.56	**0.001*****
Fat mass	34.88±13.58	31.22± 11.39	28.50±10.26	**0.001*****
Bone mass	3.018 ± 0.35	3.25 ± 0.35	3.44 ± 0.37	**0.001*****
Fat free mass	57.81± 7.28	57.82± 7.27	57.80± 7.27	**0.001*****
Visceral fat	12.30±4.75	10.38±4.17	8.48±4.06	**0.001*****
Total body water	44.79 ± 7.89	47.21 ± 7.55	49.17 ± 7.75	**0.001*****
BMR /Calories	1514.47± 173.27	1585.56±157.12	1828.58±209.58	**0.001*****
Metabolic age	57.36±17.06	46.96±13.12	41.16±11.89	**0.001*****
Anthropometric measurements				
WC/cm	110.74±16.06	101.06±13.55	94.66±12.50	**0.001*****
Hip Circumference/cm	121.92±16.32	112.10±14.81	105.04±14.38	**0.001*****
Waist to hip ratio	0.90±.06	0.90± .06	0.90±.07	0. 935*
Blood pressure				
SBP	126.40±23.85	118.70±16.39	116.90±15.57	**0.001*****
DBP	85.10±12.93	81.30±9.146	79.20±7.27	**0.001*****

****: Highly significant, *: Nonsignificant*

Table (4): Laboratory investigations of studied patients at different intervals

Investigations	Studied sample (N=150)			P value
	Pre	Post	Follow up	
Liver enzymes				
ALT	35.34±28.23	28.74±18.81	25.60±16.85	**0.001*****
AST	29.96±19.75	25.30±15.37	22.36±13.53	**0.001*****
Blood profile				
TG	135.68±55.	114.14±52.01	102.78±46.05	**0.001*****
TCHOL	224.34±53.43	197.00±38.95	179.20±33.39	**0.001*****
LDL	150.02±46.39	129.60±40.73	118.14±39.92	**0.001*****
HDL	46.92±10.49	53.36 ±9.40	58.80±9.32	**0.001*****
Blood Glucose				
Hb (A1C)	5.89±1.19	5.44±1.11	5.14±1.019	**0.001*****
HOMA IR	3.66±1.6	3.01±1.65	2.54±1.46	**0.001*****

****: Highly significant*

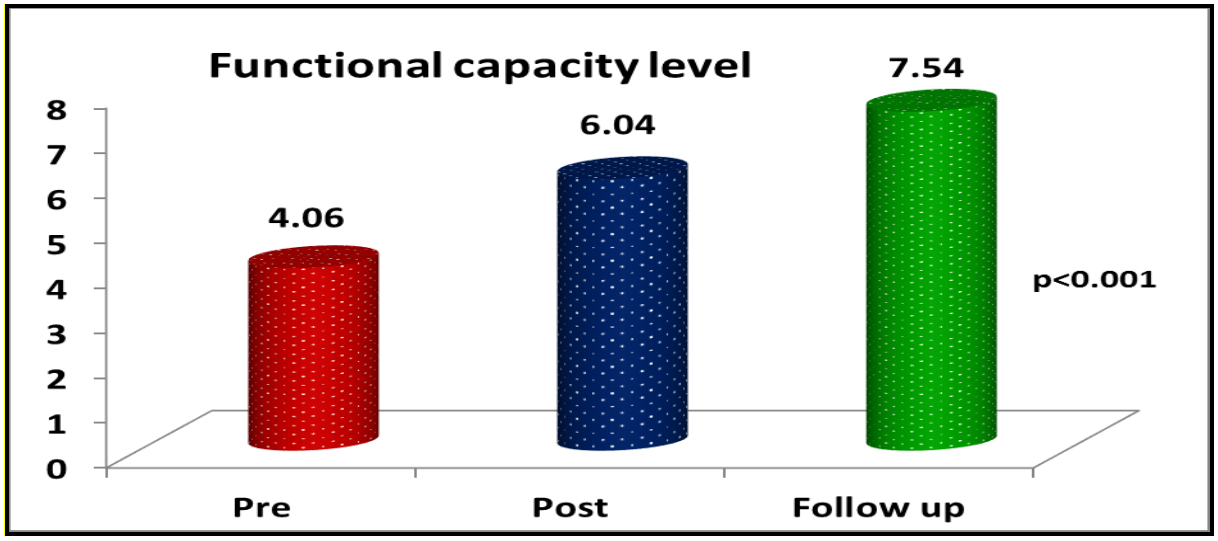

Figure (1): Functional capacity level of studied patients at different intervals

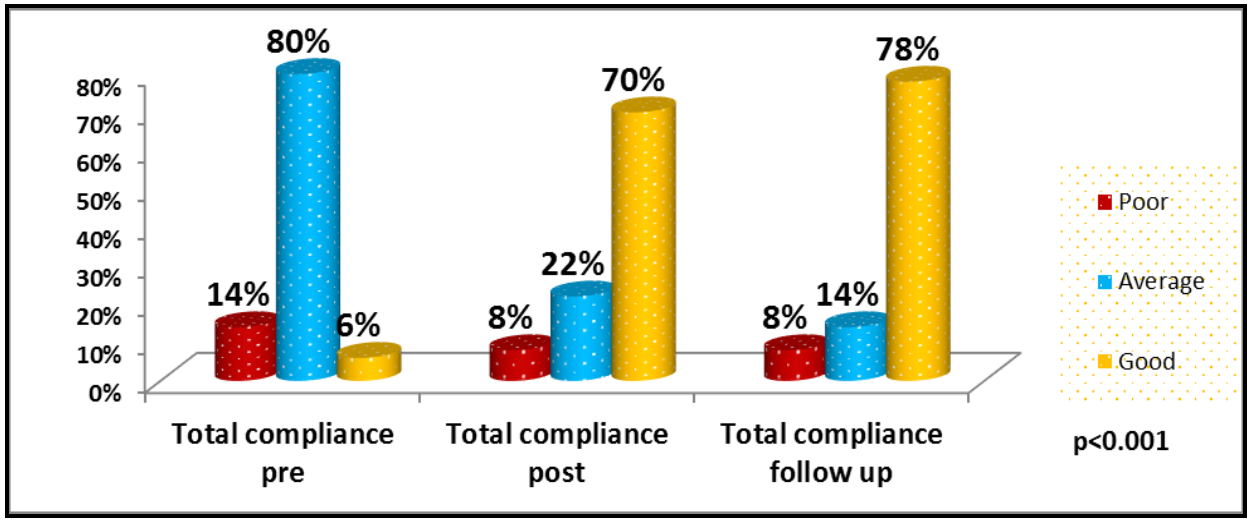

Figure (2): Total compliance score of studied patients at different intervals.

Table (5): Correlation between patient's compliance and related outcomes at different intervals (N=150).

Patient's outcomes	Total Patient's compliance					
	Pre		Post		Follow up	
	r	P value	r	P value	r	P value
Functional capacity	0.282	0.001***	0.640	0.001***	0.791	0.001***
Body composition						
BMI	-0.274	0.001***	-0.346	0.001***	-0.590	0.001***
Fat percentage	-0.285	0.001***	-0.202	0.013**	-0.313	0.001***
Fat mass	-0.280	0.001***	-0.187	0.022**	-0.300	0.400*
Visceral fat	0.021	0.853*	-0.0521	0.001***	-0.731	0.001***
Blood profile						
TCHOL	-0.274	0.001***	-0.461	0.001***	-0.635	0.001***
TG	-0.364	0.001***	-0.320	0.001***	-0.345	0.001***
HDL	0.064	0.437*	0.211	0.01**	0.279	0.001***
LDL	-0.239	0.003**	-0.239	0.001***	-0.432	0.001***
Blood glucose						
HbA1c	-0.067	0.419*	-0.135	0.100**	-0.273	0.001***
Homa IR	0.019	0.814*	-0.073	0.371*	-0.214	0.009*
Blood pressure						
SBP	-0.390	0.001***	-0.400	0.001***	-0.492	0.001***
DBP	-0.375	0.001***	-0.362	0.001***	-0.533	0.001***

(R)Correlation coefficient *(+) Positive correlation* *(-) Negative correlation*
(***) High significant (**) Significant (*) Non-significant

Table (1): Presents the mean age of studied patients was 47 years. More than half of them were female, housewife, lived in rural area and gain money not enough to their expense (52% for all). About 48.0% of studied patients had middle education.

Table (2): Explains the total calorie intake reduced among studied patient from 2652.66 to 1890.46 Kcal after program application by 6 months as pre intervention only 4% of patients were following good dietary practice and highly active but after six months they become 80% and 28% respectively with high statistically significant differences at p value = 0.001. Also, pre intervention more than two thirds of the studied patients (74%) sit ten or more hours per day and more than a third of them (36%) drink three or more cups of coffee per day moreover 12% of them smoke. All these percent improved after program application by six months to be 4%, 18% and 2% respectively with high statistically significant differences at p value = 0.001.

Table (3): Reveals that after program application by three months BMI and hip circumference were reduced from 34.72 Kg/m^2 and 112.10 Cm to 28.67 Kg/m^2 and 112.10 Cm respectively with high

statistically significant difference p (0.001). In sum, after program application by three and six months, there were statistically significant improvements in all body composition and blood pressure with P value 0.001 except waist to hip ratio P value 0. 935.

Table (4): Illustrates that after program application by three and six months, there were statistically significant improvements in all laboratory investigation's results of liver enzymes, lipids profile and blood glucose with P value 0.001.

Figure (1): Clarifies that there is high statistically significant improvement in functional capacity level after program application by three and six months with p value < 0.001.

Figure (2): Shows that only 6% of the studied patient were apply good compliance pre intervention, but after three and six months of program application, their percent increased to 70.0% and 78% respectively , with high statistically significant difference P<0.001.

Table (5): Illustrates that there is a positive correlation between patient's compliance and functional capacity at three different intervals respectively p (0.001). Oppositely, there is a high statistically significant negative correlation between patient's compliance and BMI at the three different intervals respectively p (0.001). There is statistically significant negative correlation between patient's compliance and body fat composition with p (0.001& 0.400) respectively. There is a high statistically significant negative correlations between patient's compliance and blood lipids as TCHOL, TG & LDL at p value (0.001) after six months of program application respectively.

Discussion

Non- alcoholic fatty liver disease is expected to be the first cause of cirrhosis and hepatocellular carcinoma in the next five years. This increased problem worldwide strongly associated with obesity, Insulin Resistance (IR), Type 2 Diabetes Mellitus (T2DM) and dyslipidemia **(Godoy-Matos et al., 2020).** There are no effective or approved pharmaceutical treatments available right now. Multimodal interventions are the program of choice to be used together with communication multimode for optimal effectiveness **(Arab et al., 2018).**

Concerning patient's health related practices; the current study found a significant improvement in healthy dietary practice after three and six months of program application. In the same line with these findings were **Moneim et al., (2018)** who found a significant reduction of dairy product made with full cream and chicken skin/meat fat intake with follow up. Additionally, there was a change in the type of added fat, with less butter, margarine, and corn/sunflower oils added, while more olive oil was consumed. Also, there was a highly significant reduction in total energy consumption, dietary carbohydrates, and fat. This was due to the patient's desire to follow a healthy diet and lose weight, which enables them to perform activities of daily living.

In relation to patient's activity practice, pre-intervention more than two third of studied patients didn't perform any activity while after six month of the program application a third of them become highly active. This finding was similar to **Katsagoni et al., (2017)** who reported that interventions combining exercise and diet showed significant improvement in NAFLD activity score post intervention. Additionally **Moneim et al., (2018)** found that, before intervention only less than quarter of patients were practicing exercise, primarily walking, that increased to two thirds of patients post intervention.

Regarding sitting time, the majority of studied patients were inactive (sitting more than 10 hours) pre intervention, while the majority of them become sit less than 5 hours after six months of program application. This finding was consistent with **Heredia et al., (2022)** who observed a highest weight loss among intervention group who were active. The majority of them concordantly self-perceived increasing their physical activity levels and reducing sitting time post intervention. This result could be related to perceived disease severity which needed to be controlled.

As regards coffee intake, there was a reduction of daily intake post six months of program application. This result was consistent with **Kositamongkol et al., (2021)** who showed consumption reduction to one or two cups /day after intervention compared to more than two cups/day pre intervention. This was related to realization of moderate coffee benefit on metabolism and on fat mobilization.

Regarding cigarette smoking, there was a statistically significant reduction in the number of smoked cigarettes post six months of program application. This result was comparable to that of a study by **Yoshioka et al. (2020)** which revealed that over the follow-up period following the most recent health checkup, exercise frequency significantly increased while smoking dropped. This was due to patients' understanding of the dangers of smoking and its effet on the disease.

Total calorie intake, the present study showed a significant reduction in total calory intake post six months of program application. This finding was congruent with **Haigh et al., (2022)** whom clarified that post intervention; the participants were broadly acceptable to follow caloric intake modification as prescribed with significant improvement in

determining the dietary components that have the biggest positive effects on liver-related outcomes. This result could be related to good caloric intake having an important role in reducing weight and in liver fat mobilization.

The present study revealed that there was a reduction in BMI, waist and hip circumference three and six months after program application with statistically significant difference. This was in agreement with **Katsagoni et al., (2020)** who mentioned that BMI and WC were significantly decreased after intervention in both groups, compared to baseline. Additionally, this result was consistent with **Arora et al., (2022)** who noted that the intervention group experienced greater weight loss than the control group. The proportion of patients who lost weight in the intervention group was four times than in the control group. The mean WC was lower in the intervention than control group. This was due to their commitment to the intervention to prevent disease progression of and complications.

In contrast, this finding was contradicted with **Katsagoni, et al., (2020)** who found that patients did not report any significant improvements in anthropometrics parameters at the end of their study. This contradiction could be related to their study being conducted in a pediatric population with NAFLD and low adherence to the program instructions besides short duration of intervention.

Laboratory investigations, the current study reported a statically significant improvement in all investigations after three and six months of program application. This result was consistent with **Koutoukidis et al., (2019)** who stated that interventions were statistically significantly associated with improvements in biomarkers investigations. Also, this finding was congruent with **Katsagoni et al., (2020)** who reported that after 6-months, both glucose level and fat improved compared to baseline. Liver enzymes improvements including ALT, AST, GGT, and IHTG were also reported. As well as improvements in dyslipidemia associated factors as TCHOL, TG, HDL, LDL, or oxidized LDL post intervention compared to baseline. Moreover, this result was in congruent with **Moneim et al., (2018)** who found that concerning liver enzymes, the mean level of AST and ALT decreased significantly post intervention. TCHOL, LDL and TG levels had decreased significantly after intervention. This is related to the patient's compliance with lifestyle modifications, which resulted in better investigations.

Body fat distribution, the current study showed a statically significant improvement in body composition post intervention. This result was consistent with **Ghodsbin et al., (2018)** who observed significant improvements in liver fat distribution among two thirds of the intervention versus least percentage of control group. Moreover, the results of this study were consistent with **Arab et al., (2018)** who found a significant reduction in the intervention group fat mass, visceral fat and trunk fat mass but not fat free mass after two months of intervention. Also, this finding was congruent with **Arora et al., (2022)** who reported that body-fat percentage significantly reduced in the intervention group. This result could be related to modifications of caloric intake and physical exercise.

Regarding Patient's blood pressure, the present study demonstrated a statically significant reduction in the systolic and diastolic blood pressure post intervention. This result was consistent with **Moneim et al., (2018)** who mentioned that there is a significant improvement in the amount of liver fat, together with lipid profile, liver enzymes, blood pressure, fasting blood glucose and waist circumference following program application. This was related to engaging in practicing exercise and reducing fatty and salted foods.

Functional capacity, the present study reported a significant improvement in function capacity level following multimodal program application. This result was consistent with **Tincopa et al., (2022)** who found that over a 6-month period, the majority of patients had significant improvement in physical function capacity. This was a result of improved diet, liver function tests and reduced blood lipid which subsequently improved functional capacity.

Patients' compliance, results showed that the majority of studied sample had average compliance pre intervention while there was statically significant improvement in compliance post intervention. This finding was in the same line with **Scragg et al., (2021)** who concluded that more than two thirds of patients offered this intervention were enrolled and adhered within 6 months compared to an uptake rate of less than quarter reported at baseline. Also, the majority of patients reported to make compliance easier and take personal responsibility for adhering to the intervention. This result could be related to the patient's motivation to engage in intervention to prevent disease progression.

Relationship between patient's compliance and related outcomes, the current study revealed a significant positive correlation between patient's compliance and functional capacity at different intervals. This result was congruent with **Ivashkin et al., (2021)** who revealed that there was a positive correlation between patients' compliance and satisfaction and significant improvement in functional capacity including laboratory (transaminases, lipid profile; $p < 0.001$) and ultrasound

(steatosis, $p < 0.001$) parameters, and improvement in symptoms ($p < 0.001$) after 24 weeks of intervention. This was due to patient's adherence to better lifestyle with improved anthropometric, physiological and biochemical indicators which improved functional capacity as result.

Additionally, there was a significant negative correlation between patient's compliance and BMI. This result was in agreement with **Arab et al., (2018)** who reported that after 2-months of lifestyle modification education there was a significant improvement in patient's compliance to intervention resulted in significant reduction in weight and BMI which indicate negative correlation. These improvements could be related to the result of the reduction in total calorie intake and physical activity.

Also, there was a statistically significant negative correlation between patient's compliance and body composition related to fat percentage, fat mass follow up. This result was supported with **Marin-Alejandre et al., (2019)** who found that after 6 months of intervention, patient's compliance was inversely associated with liver fat content, body-fat percentage and total fat mass with statistically significant difference. This result could be related to the effect of adherence to intervention instructions on reducing total fat mass.

Moreover, there was a significant negative correlation between patient's compliance and lipid profile as TCHOL, TG & LDL post intervention. This finding was congruent with **Marin-Alejandre et al., (2019)** who found that after 6 months of program application, there was inverse significant correlation between patient's compliance and lipid percentage. This was due to the more the patients adhered to better practices of good dietary intake and physical activity so lipid profile results were reduced.

Finally, all hypotheses of the study were supported by the study findings.

Limitation

Liver enzymes have limited predictive value for liver function assessment rather than using the gold standard liver biopsy method.

Conclusion

Multimodal program is an efficient approach for resolution of existing fatty liver, prevention of new fat development, improvement in patient's functional capacity, blood pressure, lipid profile, body weight, liver function and liver enzymes.

Recommendations

For nursing practice

- Generalization of multimodal NAFLD management program by supervised organizational policies is recommended.
- Awareness enhancement regarding multimodal prevention and control of NAFL risk factors through mass media by authorized personnel is recommended.
- Supervised multimodal NAFLD management program application should be incorporated into routine nursing care in the National Liver Institute out patient's clinics.
- Periodic and continuous in-services training for the National Liver Institute nurses on NAFLD prevention, control and remission strategies is recommended.
- An illustrated colored pamphlet about multimodal program should be distributed among all patients in the National Liver Institute out patient's clinics.

For future research

- Study replication with large probability sample and different geographical area is recommended.
- Transition to liver biopsy is recommended for liver function assessment rather than liver enzymes for more accuracy.
- Future studies seriously needed to identify the detailed processes by which each intervention particularly resolves each stage of liver disease as different exercise doses.

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