RESEARCH ARTICLE

The outcomes of nutritional therapy in patients with non-alcoholic fatty liver disease (NAFLD): Pitfalls in getting fit from fat

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Abstract

Objective: To evaluate the outcomes of nutritional intervention on non-alcoholic fatty liver disease parameters, and to determine the reasons for non-compliance with nutritional therapy.

Method: The interventional study was conducted from May 2020 to October 2022 at the National Institute of Liver and Gastrointestinal diseases, Dow University Hospital, Ojha Campus, Karachi, and comprised patients of either gender aged 18-65 years who had been diagnosed with non-alcoholic fatty liver disease based on abdominal ultrasound. Anthropometrics, physical activity level, and biochemical markers were evaluated at baseline and 6 months after the intervention that involved nutritional assessment, counselling and guidance related to dietary modification and optimisation of physical activity level. The effect of the intervention was evaluated by improvement in liver enzymes, biochemical parameters, anthropometric indices and any change in the level of physical activity. The reasons for noncompliance were also recorded. Data was analysed using SPSS 22.

Results: Out of 118 subjects enrolled, 61(51.69%) completed the study. Most patients were females 81(68.6%), married 25(21.2%) and housewives 64(54.2%). There were 16(26.2%) subjects who had 3-10kg weight reduction. The reduction in serum cholesterol and triglyceride levels was not significant (p>0.05). Also, no significant change was observed in the level of physical activity compared to the baseline (p>0.05). Overall, 27(44.3%) patients showed compliance with treatment. The main reasons for noncompliance were lack of time 21(34.4) and knee joint pain 5(8.2%).

Conclusion: Lifestyle modification can be beneficial for weight-loss in the management of non-alcoholic fatty liver disease. However, awareness of its importance and willingness in initiating real-life practical steps with subsequent adherence to dietary therapy was found lacking in the sample studied.

Keywords: Fatty liver, Non-alcoholic steatohepatitis, Diet therapy, Nutrition, Physical activity. (JPMA 74: 494; 2024)

DOI: https://doi.org/10.47391/JPMA.9300

Introduction

Non-alcoholic fatty liver disease (NAFLD) is a chronic and advancing disease of the liver, and is the most predominant rationale for elevation in liver enzymes.[1] NAFLD is a disease spectrum that begins with benign steatosis[1] followed by steatohepatitis, and ultimately leading to cirrhosis with all its complications, liver failure, and hepatocellular carcinoma (HCC). NAFLD is also the leading cause of liver transplantation following viral hepatitis.[2]

The prevalence of NAFLD in Pakistan is mainly unknown.[3] However, a number of hospital-based surveys and studies on NAFLD have been conducted nationally with variable population groups.[4-6] A cross-sectional study conducted at a tertiary care hospital in Karachi showed the frequency of NAFLD to be 13.5% in healthy young males without comorbid conditions.[7] Another study reported incidental findings of NAFLD prevalence as 47% and non-alcoholic steatohepatitis (NASH) in 12.3% patients.[4] Others showed that 54.6% subjects had fatty liver disease along with diabetes mellitus (DM).[5,8]

Currently, there is no definitive pharmacological treatment for NAFLD except for the treatment of underlying causes, such as DM, dyslipidaemia or obesity. The mainstay of NAFLD treatment remains lifestyle modification in the form of a balanced nutritional diet and physical activity.[9] Provision of counseling related to healthy diet and physical activity is the cornerstone of treatment for every NAFLD patient. NAFLD patients have shown significant reduction in steatosis and histological indices of necro-inflammation by achieving the targeted goal only by adopting healthy diet and physical activity in the absence of pharmacological therapy.[10,11]

On the other hand, literature suggests high attrition rate of up to 80% among participants enrolled in weight-loss programmes. The most frequently reported reasons are

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Submission complete: 22-02-2023 **Review began:** 01-04-2023
Acceptance: 25-10-2023 **Review end:** 04-10-2023

living conditions, male gender and impaired mental health.[12,13] However, such studies were conducted in high-income countries (HICs), where majority of the study participants have better literacy and income as well as different perceptions towards their weight and health.[14] As such, cultural-specific studies are imperative.

Previous studies have been done among other disease populations, such as DM, gout and others, to delineate the factors involved in non-compliance with therapy.[15] These are multifactorial, including differences in age, gender, education, social or cultural restrictions, or other comorbidities[16,17]

There is a lack of data on nutritional status of NAFLD patients and on reasons of noncompliance with dietary therapy in Pakistani population. The current study was planned to evaluate the outcomes of nutritional intervention on NAFLD parameters, and to determine the reasons for non-compliance with nutritional therapy.

Patients and Methods

The interventional study was conducted from May 2020 to October 2022 at the National Institute of Liver and Gastrointestinal diseases, Dow University Hospital, Ojha Campus, Karachi, and comprised patients of either gender aged 18-65 years who had been diagnosed with NAFLD based on abdominal ultrasound. Pregnant or lactating women, and patients with concomitant systemic diseases, like tuberculosis, autoimmune disorders and extra-hepatic malignancies, were excluded.

After approval from the ethics review committee of Dow University of Health Sciences (DUHS), Karachi, the sample size was calculated using PASS version 2021[18] based on 95% confidence interval (CI) and 97% power of study with cholesterol paired mean difference of 21.46±37.38 and mean triglyceride (TG) difference of 64.0±123.1.[19]

After initial recruitment, each patient was subjected to 6-month lifestyle intervention in the shape of diet and physical activity counselling. The last follow-up was completed in April 2021. The participants first visited the gastroenterology (GI) clinic for screening and detailed analysis. After taking written informed consent, socio-demographic data was collected, including age, gender, ethnicity, education and occupation, using an interview-based questionnaire. This was followed by baseline biochemical parameters, including liver function tests (LFTs), fasting lipid profile, glycated haemoglobin (HBA1c), fasting blood sugar (FBS) and random blood sugar (RBS).

The patients were then referred to a registered dietician (RD) for nutritional assessment, counselling and intervention. A past 24-hour dietary recall was taken to calculate baseline energy expenditure in kilo-calories (kcal) and protein intake (grams) using the Diabetic Exchange List.[20] Weight and height were measured in light clothing and without shoes by electronic weighing machine and stadiometre. Body mass index (BMI) was calculated for each participant using Asian cut-off values.[21]

The RD provided education about a diet of low calories, low saturated fat, low cholesterol and low trans-fat. Personalised diet charts with calculated individual calories (1200, 1400 or 1600 kcal) based on basal energy expenditure was given to each patient in both English and Urdu. Resources containing basic information on portion size, food pyramid, healthy eating guidelines and tips, and examples to reduce maximum caloric intake per day were delivered to each participant. It was tailored according to individual needs, and comorbid disease, if any.

The International Physical Questionnaire-Short Form (IPAQ-SF) was used to assess baseline physical activity levels.[22]

Follow-up patients underwent second and third meetings with the RD after 1 month and then again at 3 months during which evaluation was done to document compliance with dietary recommendations. Each process was individually tailored, and consisted of 15-20 minutes of face-to-face meetings. The techniques used were mainly motivational interviewing and active listening during which the nutritionist, the patients and care-givers worked together, focussing on enhancing motivation and facilitating behaviour changes regarding healthy diet and lifestyle in terms of physical activity level.

Final assessment was done in the GI clinic by the gastroenterologist and the RD at the end of 6 months to document overall response to nutritional intervention in terms of change in baseline weight reduction, and reduction in calorie intake. Patients who failed to adhere to the targeted therapy even after repeated counselling were labelled as non-compliant and non-adherent. In such cases, factors/reasons leading to non-compliance were assessed.

During the last visit, LFTs, fasting lipid profile, HBA1c, FBG and RBG were repeated.

The outcome was efficacy of the dietary therapy that was measured in terms of at least 5-7% weight reduction,[23] normal or improved lipid profile values, normal or improved liver enzyme values, and reasons behind non-compliance among relevant participants.

Data was analysed using SPSSS 22. Descriptive statistics was reported for baseline demographic, nutritional, biochemical characteristics, compliance status, and the degree of weight-loss. Quantitative variables, including lipid profile and LFTs, comparison of mean values before and after nutrition therapy was done using paired sample t test or Wilcoxon signed rank test as per appropriate distribution. For qualitative outcome, physical therapy,

proportion difference before and after the therapy was assessed using McNemar test. For quantitative variables, two-independent sample t test or Mann-Whitney test was applied as per appropriate distribution. P<0.05 was considered significant.

Results

Of the 118 subjects enrolled with mean age 44.6±11.1 years, 81(68.6%) were females, 64(54,2%) were educated up to at least the 10th grade, 25(21.2%) were married, 64(54.2%) were housewives, 64(54%) had DM, and 77(65%) had mild fatty liver on ultrasound (Table 1). The study was completed, however, by 61(51.69%) subjects (Figure), and subsequent comparisons were limited to these subjects.

Among these subjects, physical activity, BMI, LFT and lipid profile values changed post-intervention, but the difference was not significant on any count (Table 2).

Post-intervention, the maximum weight reduction was 10kg achieved by 2(3.3%) patients, while weight-loss 5-10kg was noted in 5(8.2%), and modest weight-loss 1-5kg was noted in 24(39.3%). However, no change or even reciprocal weight-gain was noted in 30(49.2%) patients. Overall, weigh-loss was achieved in 31(50.8%) patients.

Table-1: Demographic, nutritional and biochemical characteristics (n=118).

Characteristics	n (%)	Characteristics	n (%)
Mean Age (years)[a]	44.6±11.1	**Fatty liver on US**	
Height (m)[a]	1.64±0.07	Mild	77 (65.3)
Weight (kg)[a]	78.2±15.8	Moderate	41 (34.7)
BMI (kg/m^2)[a]	28.9±5.2	**Protein**[a]	64.2±14.3
Gender		**Calories**[a]	2134.6±260.8
Male	37 (31.4)	**NAFLD Categories**	
Female	81 (68.6)	DM	64 (54.2)
Marital Status		Obese	5 (4.2)
Single	88 (74.6)	Metabolic Syndrome	5 (4.2)
Married	25 (21.2)	Dyslipidaemia	19 (16.1)
Widow	5 (4.2)	Combination	24 (20.3)
Occupation		Lean NASH	1 (0.8)
Professional	12 (10.2)	**Liver Function Tests**[a]	
Housewife	64 (54.2)	TB (mg/dl)	0.6 (0.4)
Labour	29 (24.5)	SGPT (IU/L)	50.2 (36.3)
Others	13 (11.01)	ALP (IU/L)	110.5 (49.3)
Education		GGT (IU/L)	68.2 (101.9)
Uneducated	36 (30.5)	SGOT (IU/L)	39.2 (26.7)
Read-Only	8 (6.8)	**Fasting lipid profile**[b]	
Primary	10 (8.5)	Cholesterol (mg/dl)	200.3±82.8
Matric	22 (18.6)	HDL (mg/dl)	40±10.1
Intermediate	23 (19.5)	LDL (mg/dl)	130.6±46.5
Graduation	13 (11)	TG (mg/dl)	186.1±88.1
Post-Graduation	6 (5.1)		

US: Ultrasound, DM: Diabetes mellitus, BMI: Body mass index, NAFLD: Non-alcholic fatty liver disease, NASH: Non-alcoholic steatohepatitis, TB: Total bilirubin, SGPT: Serum glutamic pyruvic transaminase, ALP: Alkaline phosphatase, GGT: Gamma glutamyl transferase, SGOT: Serum glutamic-oxaloacetic transaminase, HDL: High-density lipoprotein, TG: Triglycerides, LDL: Low-density lipoprotein; [a]Values represented as median (interquartile range); [b]Values represented as mean±standard deviation.

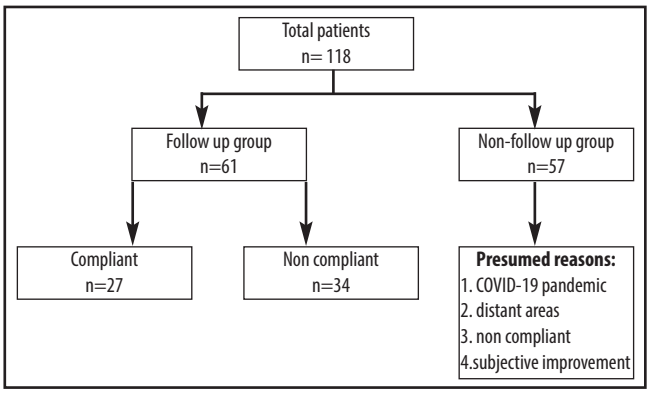

Figure: Study flowchart.

Table-2: Baseline and post-intervention comparison (n=61).

Characteristics	Before n (%)	After n (%)	*p*-value
Physical Activity			
Inactive	36 (59)	34 (55.7)	0.549¥
Minimally active	22 (36.1)	23 (37.7)	
Highly active	3 (4.9)	4 (6.6)	
Body Mass Index (kg/m^2)			
Underweight (<18.5)	0 (0)	2 (3.3)	-
Normal (18.5-22.9)	**9 (14.8)**	7 (11.5)	
Overweight (23 to 27)	**17 (27.9)**	16 (26.2)	
Obese (27.1-28.9)	10 (16.4)	11 (18)	
Morbidly obese (<29)	25 (41)	25 (41)	
Liver Function Tests[a]			
TB (mg/dl)	0.47 (0.3)	0.46 (0.23)	0.346$^{\sigma}$
SGPT (IU/L)	32 (20)	26 (29.5)	0.451$^{\sigma}$
ALP(IU/L)	104 (42)	100 (40.5)	0.441$^{\sigma}$
GGT (IU/L)	27 (74.5)	33 (85)	0.694$^{\sigma}$
SGOT (IU/L)	28 (17.5)	25 (21.5)	0.575$^{\sigma}$
Lipid Profile Tests (md/dl)[b]			
Cholesterol	179.1±39.9	157.6±37.6	0.061$^{€}$
HDL	35.8±10.7	37.4±11.4	0.473$^{€}$
LDL	116.8±29	114.5±30.4	0.768$^{€}$
TG	217.3±115.5	153.3±67.4	0.085$^{€}$

¥Mcnemar test, $^{\sigma}$Wilcoxon Signed Rank test, $^{€}$Paired sample *t*-test

[a]Values represented as median (interquartile range),

[b]Values represented as mean± standard deviation,

TB: Total bilirubin, SGPT: Serum glutamic pyruvic transaminase, ALP: Alkaline phosphatase, GGT: Gamma glutamyl transferase, SGOT: Serum glutamic-oxaloacetic transaminase, HDL: High-density lipoprotein, LDL: Low-density lipoprotein, TG: Triglycerides

Table-3: Compliance with nutritional therapy (n=61).

Characteristics	n (%)	Characteristics	n (%)
Compliant	27 (44.3)	**Degree of Weight Loss**	
Non-compliant	**34 (55.7)**	<3 kg	15 (24.6
Reason of Non-compliance		5–10 kg	5 (8.2)
Joint pain	5 (8.2)	3-5 kg	11 (18.0)
Lack of time	21 (34.4)	>10 kg	2 (3.3)
Family constraints	1 (1.6)	Static	15 (24.6)
Others (no reason, asthenia)	3 (4.9)	Weight Gain	15 (24.6)
Multifactorial	4 (6.6)		

Overall, 27(44.3%) patients showed compliance with treatment. The main reasons for noncompliance were lack of time 21(34.4) and knee joint pain 5(8.2%) (Table 3).

Discussion

Weight reduction through lifestyle modification is a proven effective strategy for NAFLD patients.[24] The current study was conducted by a multidisciplinary team, including gastroenterologist and RD, and provided individualised counselling for healthy diet and appropriate physical activity for the NAFLD patients. Results demonstrated the effectiveness of the nutritional intervention for weight reduction among 61 NAFLD patients, and up to 10kg weight-loss was observed.

However, non-compliance was one of major findings of the study. The reasons for non-compliance included lack of time, joint pain and cultural reasons. Such findings are in line with studies conducted among Pakistani populations living in Pakistan and abroad.[25,26] For instance, results of qualitative interviews from 20 female residents of Larkana, Sindh, revealed that participation in physical activity opportunities were influenced by the facilities available and parents' consent for their daughters to participate.[25] Similarly, even where environment friendly to physical activity and exercise was available, Pakistani migrants, particularly women, usually hesitated to participate.[26] The main reasons are lack of understanding about the importance of physical activity for health, and the tendency to consider daily household chores as an alternative for exercise. Thus, there is need to raise awareness regarding health benefits of physical activity for the prevention and management of chronic diseases, such as NAFLD. Moreover, separate parks and gymnasium for women can increase the chance of their participation in sports and exercise.

A study in a tertiary hospital in Italy, 46 newly-diagnosed NAFLD male and female subjects were recruited by Chiara Gelli et.al.[27] The interventions related to med-diet and physical activity resulted in physical activity level increasing from 49% at baseline to 60% post-intervention. However, the current study found no significant improvement in physical activity level compared to baseline. This might be due to the fact that the study participants belonged to low socio-economic status with limited literacy, which can limit health literacy as well.

In the current study, 57(48.3%) patients did not come to the clinic for follow-up visits despite being given reminder calls as per telephonic conversation, the main reason cited was lockdowns as the study period coincided with the active phase of the coronavirus disease-2019 (COVID-19) pandemic, others lived in distant areas and were unable to keep up with the follow-ups. Many participants missed the follow-up visits as it was not possible for them to follow the diet recommended by the RD. During the pandemic all over the world the purchasing power for food had declined,[28] there was loss of employment, and price hike that could contribute to food insecurity and reduced diet diversity.[29]

Also, some participants in the current study reported improved dyspeptic symptoms and wellbeing post-intervention, and, therefore, lost interest in visiting the clinic for follow-up. The tendency to skip follow-up visits to healthcare facilities is a common trend in Pakistan and other low- and middle-income countries (LMICs). For instance, Mohiuddin reported that >25% and around 70% patients did not pay any follow-up visit to an endocrinologist and a general physician, respectively.[30] There is a need to create awareness regarding the importance of follow-up visits among patients and caregivers.

It is interesting to note that some of the current participants had refused to visit the clinic for follow-up, but reported following dietary and physical activity modification at home, and even reported having lost weight. However, such reports are open to self-information bias. Also worth noting is the fact that a few patients in the non-compliant group also lost weight, which was probably because of partial compliance.

To the best of our knowledge, the current study is the first in Pakistan targeting to achieve weight reduction by lifestyle modification, and exploring reasons for non-adherence to weight-loss intervention.

However, the current study has limitations. A considerable number of the participants were married, stay-at-home women holding no formal education. Such a profile would have translated into limited health literacy. Besides, the study used only one method, the Diabetic Exchange list for diet assessment. As all data assessment methods have strengths and limitations, the use of two or more methods would have led to more authentic findings.

Large-scale technology-based interventions are recommended for effective weight reduction among NAFLD patients. Using technology for weight reduction can be more cost-effective and target-oriented for patients living in rural areas where healthcare facilities are limited.

Conclusion

Lifestyle modification can be beneficial for weight-loss in NAFLD management. However, awareness of its importance and willingness in initiating real-life practical steps with subsequent adherence to dietary therapy was found lacking in the sample studied.

Disclaimer: None.

Conflict of Interest: None.

Source of Funding: None.

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SSS: Conceived idea, designed, drafting and clinical consultation.
BHA: Dietary intervention and counselling/follow-up sessions.
SN: Drafted the study discussion, writing and refining the draft.
WF: Data analysis and interpretation.
AAD: Data Collation and Writing Methodology.
AS: Writing and refining the draft.