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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

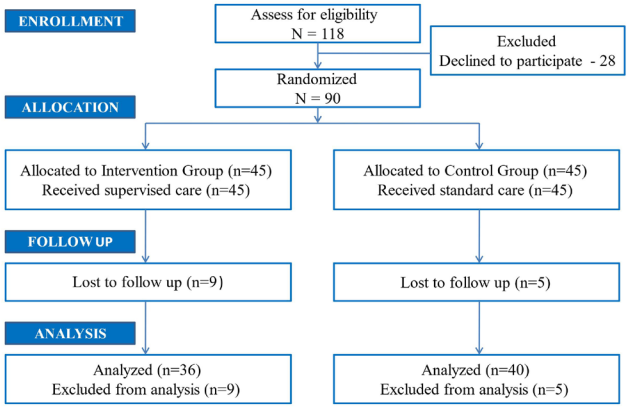
This randomized controlled trial took place at a tertiary care hospital in North Karnataka, India, after obtaining approval from the institutional ethical committee on human subjects (Reference Number: KAHER/EC/21-22/014). The objective was to explore health practices both at the start of the study and 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

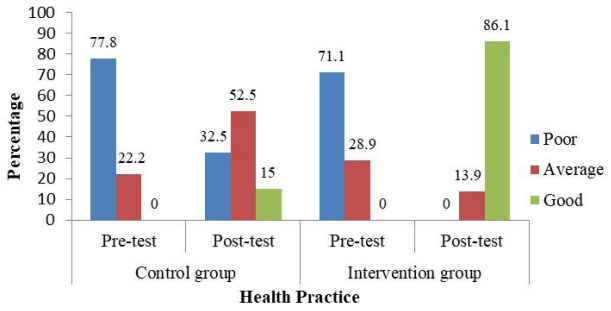


Figure 1: Comparison of control group and intervention group with pre-test and post-test levels of health practices

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.

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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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