International Journal of Community Medicine and Public Health
Mishra R et al. Int J Community Med Public Health. 2025 Aug;12(8):3524-3530
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040

DOI: https://dx.doi.org/10.18203/2394-6040.ijcmph20252238

Original Research Article

Development and validation of a yoga module for adults with non-alcoholic fatty liver disease: a feasibility study

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Received: 28 June 2025
Revised: 14 July 2025
Accepted: 17 July 2025

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ABSTRACT

Background: Non-alcoholic fatty liver disease (NAFLD) is a prevailing disorder, increasing at an alarming rate. The existing literature lacks documentation regarding the validation of a specific yoga intervention tailored to meet the needs of individuals with NAFLD. The present study aims to develop and validate a yoga module for adults with NAFLD.
Methods: The module included Joint loosening exercises (Neck, Shoulder, Knee, Trunk), Surya Namaskar, yoga postures (Asana-Ardha Matsyendrasana, Paschimottanasana, Naukasana), yogic breathing techniques (Pranayama-Surya Anuloma, Nadisodhana), and breathing relaxation practices were given for validation to 31 experts followed by a pilot trial on 12 adults with NAFLD.
Results: Validation of the yoga module was done using item-level content validity index (I-CVI), scale-level content validity index using the average method (S-CVI), scale-level content validity index using the universal agreement method (S-CVI/UA), and the reliability score was 0.82, indicating the yoga module is reliable. The study found that 80% of adults with NAFLD accepted the selected yoga practices. Additionally, all adults with NAFLD (n=9) rated the intervention ≥3, indicating overall satisfaction and positive perception. There was significant improvement in controlled attenuation parameter (CAP) after 3 months of intervention.
Conclusions: The newly developed yoga module for NAFLD was shown to be both feasible and beneficial for adult patients during the 3-month pilot trial.

Keywords: Non-alcoholic fatty liver disease, Yoga, Module, Suryanamaskar, Validation

INTRODUCTION

Non-alcoholic fatty liver disease (NAFLD) is a prevailing disorder, increasing at an alarming rate. It includes a range of conditions, from non-alcoholic fatty liver (NAFL) to nonalcoholic steatohepatitis (NASH), fibrosis, and cirrhosis. NAFLD has become a major cause of chronic liver disease globally.[1] The proportion of people living with NAFLD in different parts of the world ranges from 9 to 36.9%.[2]

Studies indicate that the global prevalence of NAFLD is 25.24%, with the highest rates observed in the Middle East and South America, and the lowest in Africa.[3] In India,

however, the prevalence of NAFLD among the general population ranges from 9% to 53%.[4]

Obesity is linked to a higher risk of NAFLD, with estimates suggesting that around 75% of overweight individuals and more than 90% of those with severe obesity have NAFLD.[5,6] While there is no specific age limit for developing NAFLD, its prevalence tends to increase with age. Clinically, patients with NAFLD are often obese and may have insulin resistance and/or type 2 diabetes, dyslipidemia, hypertriglyceridemia, and hypertension. All of these are established risk factors for cardiovascular diseases (CVDs).[7]

Losing weight is the single best remedy that can control or reverse NAFLD.[8] Regular exercise helps in weight loss.[9] Yoga is an emerging form of exercise that is gaining popularity as an affordable and effective preventive and therapeutic approach for managing NAFLD, especially in the absence of licensed medications for the condition and the increasing prevalence of sedentary lifestyles.[10]

Study findings reported that yoga improves “physical fitness", “relaxes mind and body”, and improves “stamina”, across age groups.[11] Consistent and long-term practice of yoga enhances flexibility, builds strength, and boosts the immune system.[12] Previous randomized controlled studies have demonstrated that yoga-based mind-body techniques can help normalize elevated lipid levels compared to control groups.[13,14] Previous findings reported that yoga can normalize the lipid profile in long-term practitioners.[13]

Over the past decade, Pranayama (breathing exercises), Asana (yogic postures), and Dhyana (meditation) have gained widespread recognition in clinical medicine as effective non-pharmacological interventions for various non-communicable diseases. Yoga therapy has demonstrated proven efficacy in managing obesity.[15]

Therefore, a yoga module was proposed that can surpass the problem, as there is currently no established treatment for fatty liver disease. The existing literature lacks documentation regarding the validation of a specific yoga intervention tailored to meet the needs of individuals with NAFLD. To address this gap, the development of a yoga module grounded in both traditional and contemporary yogic texts is proposed. This module will undergo validation by expert practitioners in the field of yoga, followed by an assessment of its practicability for adults diagnosed with NAFLD.

METHODS

This feasibility study involved the following steps.

Step 1: developing a yoga module

The yoga module was designed with careful consideration of the participants' needs, potential side effects, energy levels, and both their physical and psychological conditions. The objective was to design a solution that was both effective and feasible, addressing the diverse requirements of the participants to ensure optimal outcomes while minimizing potential challenges or discomfort. This method was achieved by: a methodical review of scientific research publications in PubMed, Scopus and Google Scholar databases linked to yoga and fatty liver; authors with 01 years of professional experience in managing patients with NAFLD; earlier research study by Kayelarasi and Kumar; consideration of scientificevidence of specific yoga practices on NAFLD (e.g., Surya Namaskar and breath control practices); and followed by suggestions from the yoga trainers.[10,16] The 30 minutes yoga module included 08 yoga techniques, consisting of joint loosening exercises (neck, shoulder, knee, and trunk), Surya Namaskar, yoga postures (Asana-Ardha Matsyendrasana, Paschimottanasana, Naukasana), yogic breathing techniques (Pranayama-Surya Anuloma, Nadisodhana), and breathing relaxation techniques to strengthen overall health.

Step 2: validation of the yoga module

Validation was conducted with the involvement of 31 yoga experts. A request letter was emailed to each expert, inviting them to participate in the validation process. Once consent was obtained, a scoring sheet was sent to the experts for validation via a Google form (https://forms.gle/Y32pZMQqpiKrZvUU9). The components of the 30-minute yoga module were included in the Google Form for validation. Each item was described and followed by four response options, which were rated on a scale of 0–4 (0 – not useful, 1 – a little useful, 2 – moderately useful, 3 – very useful, and 4 – extremely useful). The experts' responses were recorded in an Excel sheet and used to calculate the content validity ratio (CVR) for each item using the Lawshe CVR method.[17] According to Ayre and Scally, the critical CVR value for a group of 31 experts is 0.35. Therefore, items with a CVR of 0.35 or higher were retained.[18] The CVR results for the yoga module indicated that these specific yogic practices were deemed essential for adults with NAFLD and were thus finalized.

Additionally, the item-level content validity index (I-CVI), scale-level content validity index using the average method (S-CVI), scale-level content validity index using the universal agreement method (S-CVI/UA), and Cronbach’s alpha for item group reliability (0.82) were computed using IBM statistical package for the social sciences (SPSS) statistics version 26 (IBM Corp., Armonk, NY, USA) (Table 1).

Step 3: feasibility of the study

A pilot study was conducted with twelve (12) adults diagnosed with NAFLD to evaluate the acceptance and feasibility of the validated yoga module. Feasibility was assessed by examining the attrition rate, retention rate, and participant's self-reported difficulty during the practice.

Selection criteria of participants

Participants visiting the gastroenterology OPD at AIIMS, Rishikesh, India, in January 2022 were screened for eligibility. The inclusion and exclusion criteria to enroll participants in the study were: age between 19 to 64 years, liver steatosis >238 dB/m diagnosed with fibroscan, no previous exposure to yoga, and who gave written informed consent. Adults with significant co-morbidity that impedes with yoga, enrolled under any other lifestyle modification program like gym, meditation, yoga, and diagnosed with liver disease of other etiology, were excluded from the study.

Institutional ethical approval was obtained viz. letter no. AIIMS/IEC/20/760. This study was registered on November 20, 2020, with the Clinical Trial Registry of India (CTRI/2020/11/029262). Informed consent was obtained from all participants and experts who took part in the study.

Sampling technique and sample size calculation

Participants were selected by probability simple random sampling technique and the sample size was calculated based on available literature.[19]

Intervention

The yoga sessions were conducted via a virtual platform using Google Meet. The session was conducted in the morning from 7:30 am to 8:00 am. Participants were instructed to attend the sessions wearing loose-fitting clothing, following a fasting period of at least two hours.

The participants practiced yoga for three months, five days a week. They were also asked to provide feedback on the overall three-month yoga intervention. However, three participants discontinued due to personal reasons. Additionally, the participants completed a qualitative exit survey (Figure 1).

Outcome measures

The primary outcome was the improvement in Fibroscan scores following 3 months of yoga intervention.

RESULTS

Development and validation of the yoga module

Based on an extensive literature review, eight (08) yoga practices were included in the designed module to assess its effectiveness in managing NAFLD. The module included joint loosening exercises (neck, shoulder, knee, and trunk), Surya Namaskar, yoga postures (Asana-Ardha Matsyendrasana, Paschimottanasana, Naukasana), yogic breathing techniques (Pranayama-Surya Anuloma, Nadisodhana) and breathing relaxation practices. Thirty-one (31) yoga experts from various schools of yoga in India were involved in the validation process: AYUSH department (19%), Sarv Samridhi Yoga Center 7 (22%), Dev Sanskriti Vishwa Vidhyalaya (10%), and 51% were from various yoga schools. Among 31 yoga experts (13 males, and 18 females), 21 were yoga instructors, 7 were faculty, and 03 were PhD scholars with Master's degrees in yoga. Whereas, 20 experts had M.Sc. degrees, and 11 experts were graduates of yoga. Experts' ages ranged from 22 to 66 years, with a mean age of 30.7±8.83. Experts professional experience in yoga, following formal training, ranged from 1 to 15 years, with a mean of 4.47±2.57 years (Table 1). As a recommendation, the majority of experts have suggested incorporating yogic counseling to enhance participation and retention rates. Table 1 presents a list of yoga practices along with their CVR scores (Table 2).

Table 1: Demographic characteristics of validation experts (n=31).

Demographic characteristics	Frequency (%)
Age (mean) (22 to 66 years)	30.7±8.83
Gender	
Male	13 (42)
Female	18 (58)
Educational qualification	
Graduate	11 (35)
Masters' degree	20 (65)
Designation	
Faculty	07 (22)
Yoga instructors	21 (68)
Ph.D. scholars	03 (10)
Professional experience (years)	
1 to 15 (mean)	4.47±2.57
Area of work	
AYUSH department	06 (19)
Sarv Samridhi Yoga Center	07 (22)
Dev Sanskriti Vishwa Vidhyalaya	03 (09)
Other yoga schools	15 (50)

Acceptability and practicability of yoga practices

Out of the 30 patients screened for the study, 15 met the eligibility criteria and were invited to participate. However, 3 participants declined, resulting in an acceptance rate of 80%. Nine (09) participants completed the study, while three (03) dropped out due to personal reasons, leading to an attrition rate of 25%. Thus, twelve (12) adults with NAFLD (8 males, 4 females) who provided consent and completed baseline data were included in the study. The average age of participants was 40.1±6.76 years. Weekly, five (5) supervised yoga sessions were conducted for a duration of three months. Ultimately, eight (08) patients completed the intervention and post-assessment, while three (03) dropped out due to personal reasons. No adverse events were reported during the intervention. Patients was reinforced to continue yoga to maintain a healthy lifestyle.

Regarding treatment satisfaction based on the duration of practice, all (09) participants (100%) rated their response as ≥3, indicating a satisfactory experience. Additionally, two (02) participants recommended offering yoga sessions in the evening as well. There was significant improvement in controlled attenuation parameter (CAP) after 3 months of intervention (Figure 1 and Table 3).

Effectiveness of the yoga module

The practicability of the yoga module was evaluated based on participant's subjective responses regarding discomfort, pain, and flexibility after yoga practice. Responses were coded on a scale from 0 to 2, i.e., 0 for negative remarks, 1 for neutral, and 2 for highly positive remarks. Participants were divided into two mutually exclusive groups based on their scores. Those who scored in the third quartile (Q3) were classified as having lower efficacy, while those with scores equal to or greater than Q3 were classified as having higher efficacy. The efficacy domain had a range of five responses, from 0 to 7. The mean±standard deviation of the responses was 6.35±0.86, with an interquartile range of 7 (7.4). Participants' responses were then categorized as either below or above the third quartile (Q3). Seventy-five percent (6/9) of participants scored at or above Q3, indicating high efficacy of the yoga module. When analysed separately, 60% of participants reported improvement in flexibility. No participants reported discomfort or pain. A checklist was provided to assess participants' subjective experience of the usefulness of the individual yoga practices, rated on a scale from 0 to 3 (with 0 being "not useful" and 3 being "extremely useful"). Eighty (80%) percent of participants reported feeling relaxed and noticed improvements after the yoga intervention. No adverse events were recorded, suggesting that the yoga module was both safe and practicable.

Table 2: Experts scoring (two iterations) on individual practices for the yoga module.

Yoga practice items	Ne	N	N/2	N-Ne/2	CVR	Remarks	I-CVI	Sum of I-CVI	S-CVI/UA	Cronbach's alpha
Joint loosening warm up (standing) (one cycle 5 minutes)										
Neck bending stage								12.13	0.81	0.82
Forward and backward bending/stretching	27	31	15.5	11.5	0.74	Retained	0.87			
Right and left bending/ stretching	25	31	15.5	9.5	0.61	Retained	0.81			
Right and left twisting	24	31	15.5	8.5	0.55	Retained	0.77			
Neck rotation	24	31	15.5	8.5	0.55	Retained	0.77			
Shoulder movement										
Shoulder stretch	25	31	15.5	9.5	0.61	Retained	0.81			
Shoulder rotation	26	31	15.5	10.5	0.68	Retained	0.84			
Trunk movement-alert posture	24	31	15.5	8.5	0.55	Retained	0.77			
Knee movement- alert posture	24	31	15.5	8.5	0.55	Retained	0.77			
Surya Namaskar ((sun salutation) (2-3 rounds with 12 steps in 10 minutes)	25	31	15.5	9.5	0.61	Retained	0.81			
Asanas										
Sitting Asana										
Ardha Matsyendrasana (half lord of the fishes pose (2 rounds in 2 minutes)	27	31	15.5	11.5	0.74	Retained	0.87			
Paschimottanasana (back stretching pose) (2-4 rounds in 2 minutes)	24	31	15.5	8.5	0.55	Retained	0.77			
Lying down Asana										
Naukasana (2 rounds in 2 minutes)	26	31	15.5	10.5	0.68	Retained	0.84			
Pranayama										
Surya Anuloma (5-10 cycles in 2 minutes)	24	31	15.5	8.5	0.55	Retained	0.77			
Nadisodhana (5-10 cycles in 2 minutes)	24	31	15.5	8.5	0.55	Retained	0.77			
Breathing awareness relaxation (one round 5 minutes)	27	31	15.5	11.5	0.74	Retained	0.87			

Ne-Total number of experts replied; N-total number of experts; CVR-content validity ratio; I-CVI-item level content validity index; S-CVI/UA-scale-level content validity index based on the universal agreement method.

Table 3: Demographic characteristics of participants (n=12).

Demographic characteristics	Frequency (%)
Age 25-50 (in years) (mean age)	40.1±6.76
Gender	
Male	08 (67)
Female	04 (33)
CAP scores (n=9)	
Baseline	295±46.9
3-month	294±48.6

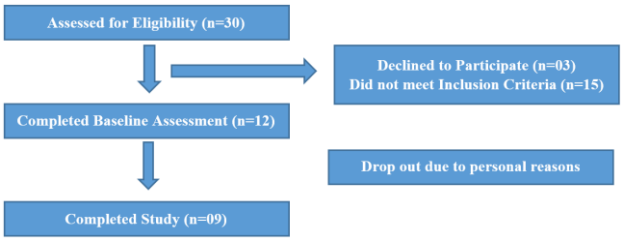

Figure 1: Recruitment of participants.

DISCUSSION

This study aimed to create a comprehensive yoga module specifically designed for adults with non-alcoholic fatty liver disease, drawing on traditional and modern yogic texts, recent scientific research, and expert recommendations. During olden times, yoga was practiced for spiritual enlightenment and good health as a supplementary benefit among those who practiced it. Whereas, contemporary yoga mainly focuses on health and fitness. Hatha yoga is a branch of yogic practice that incorporates physical postures (yoga poses) and breathing techniques, focusing on enhancing health. Therefore, the yoga module was primarily based on these principles.

The yoga module included in the present study was validated by Thirty-one (31) experts from various yoga centers and schools. Criteria for selecting experts from multiple centers or schools for validation were considered important to avoid biases by a particular expert. Similar findings were reported in a study conducted by Hariprasad et al and Malik et al.[20,21]

The majority (68%) were yoga instructors followed by faculty (23%) and PhD scholars (9%) with experience varying from 1 to 15 years (4.47±2.57). In contrast, a study conducted by Jagannathan et al involved experts with an average work experience of 14.8 years.[22] However, a study by Mohanty et al selected experts who were actively engaged in teaching yoga.[23] Thus, the balance in selecting experts for validation strengthened the results of the present study as the experts involved were not only from research or teaching backgrounds but also had adequate practical experience. In the present study experts also recommended including yogic counseling to increase the retention rate.

The validation process for the yoga module began, with the decision to retain or reject each yoga practice item based on the CVR score. The majority (100%) of experts endorsed the selected yoga practices. The analysis was conducted manually using the CVR calculation method (Lawshe, 1975), further supported by the work of Jagannathan et al.[17,20] Yoga practice items with a CVR score of 1.37 or higher were retained.

The present study showed the acceptability of selected Yoga practice items among patients was 80%. Moreover, 100% of patients (09/09) rated ≥3 for indicating satisfactory response. However, 2 participants suggested for conducting the yoga session in the evening also. There were no reported adverse events during the yoga practice. Hence, our findings indicate feasibility in conducting the yoga practices. Results also suggest improvement in health condition as measured by CAP score after 3 months of regular practice 5 days a week for 30 mins.

However, some participants mentioned that they needed time to memorize the yoga practices. On average, each participant took 1 to 2 weeks to learn and memorize the practices. Clear, concise, and detailed descriptions of each yoga practice were provided, along with verbal guidance and clarification of any doubts during the online sessions.

To the best of our knowledge, this is the first time a specific yoga module for non-alcoholic fatty liver has been developed with components. Overall, compliance was strong, with the majority of participants practicing yoga at home. While many participants initially experienced some difficulties with certain yoga postures, after 1-2 weeks of practice, they found it easier to perform the exercises. Study findings were supported by Panda on NAFLD patients.[16,24]

Strengths

The module was developed systematically based on comprehensive literature reviews and insights from various yogic texts. The experts selected for the validation process came from diverse schools of yoga and had extensive experience in both teaching and practice, ensuring a balanced perspective and strengthening the study's credibility. Furthermore, the positive feedback and favourable outcomes in the outcome variables, despite the short duration of the intervention, highlighted the effectiveness of the new yoga module.

Limitations

The current yoga module has no significant limitations, although a few participants mentioned that it took them 1-2 weeks to memorize and learn the correct yoga practices. Additionally, retaining participants for a long duration proved to be challenging.

CONCLUSION

The newly developed yoga module for NAFLD was shown to be both feasible and beneficial for adult patients during the 3-month pilot trial. The enthusiastic participation and positive feedback from participants confirm the module's effectiveness. No adverse events were reported during the practice, indicating that the yoga module is safe and can be incorporated into other lifestyle intervention programs to improve health. The module's efficacy relies not only on its content but also on the quality of training, participants' adherence, and dietary restrictions, particularly concerning fast food. This study may serve as a guide for future research aimed at developing and validating yoga modules for patients with liver diseases.

ACKNOWLEDGEMENTS

Authors would like to thank all the experts for generously dedicating their time to validate the module, as well as to the participants for their enthusiastic involvement.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Mishra R, Gupta R, Goyal B, Bhadoria AS, Kalyani CV, Sharma SK, et al. Development and validation of a yoga module for adults with non-alcoholic fatty liver disease: a feasibility study. Int J Community Med Public Health 2025;12:3524-30.