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AN OPEN-LABEL STUDY TO EVALUATE THE SAFETY AND EFFICACY OF LIVER DETOX FORMULA IN FATTY LIVER DISEASE

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ABSTRACT

Background: Fatty liver disease (FLD), encompassing Alcoholic Fatty Liver Disease (AFLD) and Non-Alcoholic Fatty Liver Disease (NAFLD), has emerged as a major global health challenge. Despite its high prevalence and progression risk to cirrhosis or hepatocellular carcinoma, management continues to rely on lifestyle interventions, which are often difficult to sustain. Liver Detox Formula, a proprietary blend of hepatoprotective Ayurvedic herbs such as Katuki, Kalmegh, and Punarnava, has been traditionally used to support liver health. This clinical study aimed to systematically evaluate the safety, efficacy, and tolerability of Liver Detox Formula in patients with AFLD and NAFLD. Objective: To evaluate the impact of Liver Detox Formula on liver-related symptoms, fatigue, digestive disturbances, and overall quality of life over a 90-day period, using validated patient-reported outcomes and clinician assessments. Materials and Methods: An open-label, single-arm, prospective study was conducted in 50 patients (aged 18–65 years) with clinically confirmed AFLD or NAFLD. Participants received 2 capsules (500 mg each) of Liver Detox Formula twice daily after meals for 90 days. Primary efficacy endpoints included change from baseline in Chronic Liver Disease Questionnaire (CLDQ) and Fatigue Severity Scale (FSS) over a 90-day period. Secondary endpoints included symptom-specific checklist scores, clinician-rated disease severity, and symptom improvement. Safety was monitored via adverse event tracking and compliance logs. Statistical significance was assessed using paired t-tests and Wilcoxon signed-rank tests ($p < 0.05$). Results: Out of 50 enrolled participants, 45 completed the study. CLDQ domain scores showed an average improvement of 82.44% ($p < 0.0001$). FSS scores decreased from 6.6 to 1.5, reflecting an 85% reduction in fatigue ($p = 8.44E-62$). Digestive symptoms improved by 77–100%, while clinician assessments reported >90% reduction in disease severity. No adverse events or serious adverse events were observed. Compliance was high (>90%). Conclusion: Liver Detox Formula was found to be safe, well-tolerated, and effective in significantly improving liver-related symptoms, fatigue, emotional well-being, and daily functioning in patients with fatty liver disease. The findings support its role as a promising complementary therapy. Larger randomized trials are recommended for further validation.

Keywords: Liver Detox Formula, Non Alcoholic Fatty Liver Disease, Alcoholic Fatty Liver Disease, Chronic Liver Disease Questionnaire, Fatigue Severity Scale, hepatoprotective herbs.

INTRODUCTION

Fatty liver disease (FLD), characterized by excessive lipid accumulation in hepatocytes, is increasingly recognized as one of the most common and clinically significant liver disorders worldwide. FLD can be broadly categorized into Non-Alcoholic Fatty Liver Disease (NAFLD) and Alcoholic Fatty Liver Disease (AFLD). NAFLD refers to hepatic steatosis in individuals who consume little to no alcohol, and is closely associated with obesity, insulin resistance, dyslipidemia, and type 2 diabetes mellitus.[1] On the other hand, AFLD arises due to chronic excessive alcohol intake and represents another major contributor to global liver-related morbidity.[2]

The global prevalence of NAFLD is estimated at approximately 25–30% in the general adult population, with even higher rates observed in populations with metabolic syndrome and type 2 diabetes.[3] In India, a recent systematic review reported a prevalence of 30.7%, underscoring its substantial burden in the subcontinent.[4] Alarmingly, both NAFLD and AFLD are not benign conditions; they may evolve into non-alcoholic steatohepatitis (NASH), which can then progress to advanced fibrosis, cirrhosis, portal hypertension, and hepatocellular carcinoma (HCC).[5]

Despite this growing public health challenge, there is no globally approved pharmacologic therapy for FLD. Management currently relies on lifestyle modification, including weight loss, exercise, and dietary changes.[6] While these interventions can lead to histologic improvement in NAFLD, they are often difficult to implement and sustain in real-world settings due to behavioral and socioeconomic constraints.[7] Pharmacological options like vitamin E, pioglitazone, and emerging agents targeting lipid metabolism, oxidative stress, or inflammation have shown limited efficacy and long-term safety data.[8] Consequently, there is increasing interest in exploring complementary and alternative medicine (CAM), including herbal and Ayurvedic remedies, as safer and potentially effective adjuncts or stand-alone therapies for liver health.[9]

Ayurveda, India's traditional medical system, has a long history of utilizing polyherbal formulations for hepatobiliary disorders. The Liver Detox Formula, developed by Planet Ayurveda, is a proprietary blend of hepatoprotective herbs including Katuki (*Picrorhiza kurroa*), Punarnava (*Boerhavia diffusa*), Kalmegh (*Andrographis paniculata*), and other ingredients recognized in Ayurvedic literature for promoting bile flow, reducing hepatic inflammation, and aiding cellular regeneration.[10] These botanicals possess various pharmacological actions relevant to

fatty liver disease, including antioxidant, anti-inflammatory, cholagogic, and lipid-lowering effects.[11]

Preclinical studies have demonstrated that *Picrorhiza kurroa* can reduce ALT/AST levels and exert hepatocyte-stabilizing effects in experimental models of hepatic injury.[12] *Andrographis paniculata* has been shown to inhibit nuclear factor-kappa B (NF-κB), reduce TNF-α levels, and attenuate liver fibrosis in animal models.[13] *Boerhavia diffusa* is known for its diuretic, anti-inflammatory, and antioxidant properties and may help modulate hepatic oxidative stress.[14] While these herbs are used widely in Ayurvedic clinical practice, modern clinical studies evaluating their efficacy through standardized tools and validated endpoints remain limited.

This study was therefore designed to evaluate the safety, efficacy, and tolerability of Liver Detox Formula in patients diagnosed with NAFLD or AFLD. The study used a prospective, open-label, single-arm clinical trial design, which, while exploratory in nature, aimed to generate preliminary real-world data on clinical benefits using validated patient-reported outcome measures (PROMs) and clinician-assessed parameters.
The primary objectives were to assess improvements in liver-related quality of life using the Chronic Liver Disease Questionnaire (CLDQ) and fatigue severity via the Fatigue Severity Scale (FSS). Secondary endpoints included a Symptom-Specific Checklist, Clinician Disease Severity Ratings, and Clinician-Assessed Symptom Improvement. The study duration was 90 days, and assessments were conducted at four timepoints (Day 0, 30, 60, and 90) to monitor symptom trajectory and therapeutic response.

By focusing on PROMs and clinician observations rather than invasive or biochemical endpoints, the study was tailored to reflect real-world clinical practice—particularly in resource-limited settings where diagnostic testing may be inaccessible or unaffordable. Furthermore, the study sought to evaluate whether Liver Detox Formula could offer a well-tolerated, non-invasive therapeutic strategy to improve functional status, digestive comfort, and emotional well-being in patients with fatty liver disease.

The findings from this study are expected to contribute to the growing body of clinical literature on evidence-based Ayurvedic hepatoprotective therapies and provide a foundation for designing larger randomized controlled trials in the future.

MATERIALS AND METHODS

Study Design and Setting
This was a prospective, open-label, single-arm, single-centre interventional clinical study conducted to evaluate the safety, efficacy and tolerability of Liver Detox Formula in adults diagnosed with Alcoholic Fatty Liver Disease (AFLD) or Non-Alcoholic Fatty Liver Disease (NAFLD). The study was exploratory in nature and designed to assess changes in liver-related symptoms, fatigue severity, and quality of life over a 90-day treatment period.

Study Setting
The study was conducted at RVS Ayurvedic Medical College, Hospital and Research Centre, Srigandhadakavalu, Bangalore-560091. The site functioned as the sole investigative centre for participant recruitment, treatment administration, and follow-up assessments. Pranav Diabetes Center was not involved in participant recruitment, clinical procedures, data collection, analysis, or study conduct; its role was limited solely to providing independent ethical review and approval. A No Objection Certificate from Pranav Diabetes Center has been obtained to confirm absence of any conflict of interest.

Ethical Approval and Regulatory Compliance
Ethical clearance for the study was obtained from the Pranav Diabetes Center Ethics Committee (PDCEC/SRS-2419/25 NOV 24) prior to initiation of any study-related procedures.
Name of Ethics Committee: Pranav Diabetes Center Ethics Committee
Ethics Committee Approval: Obtained prior to study initiation
Type: Institutional Ethics Committee

Although the study was conducted at RVS Ayurvedic Medical College, Hospital, and Research Centre, ethical approval was obtained from the Pranav Diabetes Center Ethics Committee because the study site did not have a formally constituted and registered Institutional Ethics Committee at the time of study initiation. The approving Ethics Committee is an accredited and competent body authorized to review and approve clinical research protocols and provide ethical oversight for the conduct of the study at the specified site.

The Ethics Committee reviewed the complete study Protocol, Informed Consent Form, and all relevant study documents and approved the conduct of the study at RVS Ayurvedic Medical College, Hospital, and Research Centre. Written informed consent was obtained from all participants prior to enrollment.

The study was conducted in accordance with the Declaration of Helsinki (2013)[15] and adhered to ICH-GCP (E6 R2) guidelines.[16] Participant confidentiality and safety were maintained throughout the study duration.

Study Population
Fifty adult participants aged 18–65 years with a confirmed clinical diagnosis of NAFLD or AFLD were screened and enrolled.

Eligibility Criteria

Inclusion Criteria
- Age 18–65 years.
- Confirmed diagnosis of AFLD or NAFLD (clinical history or previous imaging).
- Ability and willingness to comply with the study procedures.
- Provision of written informed consent.

Exclusion Criteria
- Advanced liver disease (cirrhosis, hepatic failure, or hepatocellular carcinoma).
- Pregnancy or lactation.
- Known co-infections such as HIV, Hepatitis B, or Hepatitis C.
- Use of investigational drugs or supplements within 30 days prior to screening.
- Any severe comorbidity or psychiatric illness likely to affect participation or adherence.
- History of substance abuse (other than alcohol in AFLD).
- Non-compliance with prior clinical follow-up schedules.

Intervention and Dosage
Participants received two capsules (500 mg each) of Liver Detox Formula, administered orally twice daily after meals (morning and evening) for a total of 90 days. The investigational product, supplied by Planet Ayurveda, contains a proprietary blend of Ayurvedic herbs including *Picrorhiza kurroa*, *Andrographis paniculata*, and *Boerhavia diffusa* - each documented in

traditional and modern pharmacopoeias for their hepatoprotective effects.[10–14]

Participants were counseled on dose timing and compliance. A daily dosing diary and capsule count verification at visits were used to monitor adherence.

Intervention Product Composition and Quality Control
The investigational product evaluated in this study, Liver Detox Formula, is an oral polyherbal capsule developed for supportive management of Alcoholic Fatty Liver Disease (AFLD) and Non-Alcoholic Fatty Liver Disease (NAFLD). The formulation comprises standardized Ayurvedic herbs traditionally recognized for hepatoprotective, anti-inflammatory, antioxidant, and cholagogic properties. Key ingredients include *Picrorhiza kurroa* (Katuki), *Andrographis paniculata* (Kalmegh), and *Boerhavia diffusa* (Punarnava), among other supportive botanical components selected for their complementary mechanisms in promoting liver health.

All raw materials used in the preparation of the investigational product were procured from qualified and certified suppliers and were accompanied by valid Certificates of Analysis (COAs). Quality parameters verified through COAs included botanical identity, organoleptic characteristics, purity, and compliance with pharmacopoeial standards. Raw herbs were evaluated for parameters such as foreign matter, loss on drying, extractive values, and ash values (total ash and acid-insoluble ash). Microbial load testing was conducted to ensure compliance with acceptable limits. Heavy metals (lead, arsenic, cadmium, and mercury), pesticide residues, and aflatoxins were tested to confirm safety within permissible regulatory limits.

The finished product was manufactured under controlled conditions in accordance with Good Manufacturing Practices (GMP) applicable to Ayurvedic formulations. Standard in-process quality checks ensured uniformity of capsule weight, content consistency, and appropriate disintegration characteristics. The capsules were formulated for oral administration at a dose of 500 mg per capsule, ensuring batch-to-batch consistency, stability, and suitability for long-term use. All quality control documentation, including Certificates of Analysis for raw materials and finished batches, was maintained as part of regulatory and clinical trial records and was available for verification.

Study Procedures and Visit Schedule
Study assessments were conducted at **four time points**:
Visit 1 – Day 0 (Screening/Baseline)
Visit 2 – Day 30 (± 3 days)
Visit 3 – Day 60 (± 3 days)
Visit 4 – Day 90 (± 3 days; End of Treatment)
At each visit, the following procedures were performed:

Clinical Assessments
- Vital signs: blood pressure, respiratory rate, pulse, body temperature.
- BMI calculation.
- Physical examination focusing on liver-related signs and general systemic health.

Patient-Reported Outcome Measures (PROMs)
Chronic Liver Disease Questionnaire (CLDQ): Assessing six domains including fatigue, systemic symptoms, emotional function, and abdominal discomfort.
Fatigue Severity Scale (FSS): Measuring the degree and impact of fatigue on daily functioning.
Symptom-Specific Checklist: Capturing symptoms such as abdominal pain, nausea, appetite changes, and digestive disturbances.

Clinician Assessments
Clinician Disease Severity Assessment: Evaluating disease severity across seven dimensions including symptom burden, quality of life, and gastrointestinal function.
Clinician-Assessed Symptom Improvement: Graded improvement in fatigue, appetite, liver-related discomfort, and digestive function using a 5-point Likert scale.

Safety Monitoring
- Monitoring and documentation of adverse events (AEs) or serious adverse events (SAEs).
- Review of participant diaries for self-reported side effects or discomfort.

Compliance Monitoring
Participant adherence to the prescribed dosing schedule was evaluated by:

Daily treatment diaries.
Returned capsule count at each follow-up visit.
A compliance rate ≥80% was defined as "fully compliant."

Outcome Measures

Primary Outcome
- Change in CLDQ total and domain scores from baseline to Day 90.
- Change in FSS score from baseline to Day 90.

Secondary Outcome
- Change in scores from the Symptom-Specific Checklist.
- Clinician-rated improvement using Disease Severity Assessment and Symptom Improvement Score.
- Patient compliance rate.
- Occurrence and severity of adverse events.

Safety Assessment
Safety was evaluated throughout the study through monitoring of:
- Adverse events
- Physical examination findings
- Vital signs
- Overall tolerability

All adverse events were recorded and assessed for severity and possible relationship to the study product.

Statistical Analysis
All data were captured in validated case report forms (CRFs) and transferred into a central database. Data integrity checks and query resolutions were handled by the Samahitha Research Solutions team.

Analysis Populations
Intent-to-Treat (ITT): All enrolled participants who received at least one dose.
Per Protocol (PP): Participants completing the study without major deviations.
Safety Population: All participants receiving at least one dose for AE/SAE analysis.

Statistical Methods
Descriptive statistics (mean, standard deviation, median, range) were computed for continuous variables.

Paired t-tests or Wilcoxon signed-rank tests were used to compare baseline vs. follow-up scores.
A p-value < 0.05 was considered statistically significant.
Last Observation Carried Forward (LOCF) was used to handle missing data.[17]

Software

Statistical analyses were performed using R software and Microsoft **Excel** for visualization and tabulation.

RESULTS

Study Population and Participant Disposition

A total of 50 participants were screened and enrolled in the study. Of these, 45 participants (90%) completed the study, while 05 (10%) participants were lost to follow-up (Table 2). All enrolled participants who received at least one dose of the investigational product and had post-baseline assessments were included in the efficacy and safety analyses.

The study population consisted of participants aged 18–65 years (Table 1; Figure 1) with a clinical diagnosis of Alcoholic Fatty Liver Disease (AFLD) or Non-Alcoholic Fatty Liver Disease (NAFLD).

Primary Efficacy Outcomes

Chronic Liver Disease Questionnaire (CLDQ)

Significant improvements were observed in all six CLDQ domains from baseline to Day 90:
Abdominal Symptoms: Mean scores improved from 1.44–1.71 at baseline to 6.42–6.55 at Visit 4, showing 81.83–84.17% improvement ($p = 5.7 \times 10^{-50}$). (Table 3; Figure 4)
Fatigue: Tiredness, sleepiness, decreased strength, and energy improved significantly, with mean scores increasing from 1.28–1.86 to 6.37–6.55 (75.17–87.83% improvement; $p = 1.42 \times 10^{-52}$). (Table 4; Figure 5)
Systemic Symptoms: Body pain, breathlessness, muscle cramps, dry mouth, and itching improved from 1.48–3.13 to 6.42–6.60 (71.50–82.67% improvement; $p = 2.96 \times 10^{-51}$). (Table 5; Figure 6)
Activity Limitations: Difficulties related to diet and physical activity improved from 1.31–1.71 to 6.40–6.46 (81.83–85.83% improvement; $p = 2.29 \times 10^{-47}$). (Table 6; Figure 7)
Worries: Disease-related concerns significantly reduced, with scores increasing from 1.00–1.97 to 6.40–6.62 (81.83–93.67% improvement; $p = 1.93 \times 10^{-54}$). (Table 7; Figure 8)
Emotional Function: Anxiety, depression, irritability, and sleep disturbances improved from 1.40–2.11 to 6.40–6.62 (78.17–85.00% improvement; $p = 1.17 \times 10^{-57}$). (Table 8; Figure 9)
All changes were statistically significant ($p < 0.0001$) using paired t-tests. Improvements exceeded the minimal clinically important difference (MCID) of 0.5–1.0 points per domain.

Fatigue Severity Scale (FSS)

The mean FSS score dropped from 6.6 at baseline to 1.5 at Day 90, an 85% reduction ($p < 0.0001$). (Table 9; Figure 10) This consistent and sharp decline across visits indicates robust improvement in fatigue symptoms, a hallmark of fatty liver disease.

Secondary Outcomes

Symptom-Specific Checklist

Symptom-specific evaluation showed significant improvement in abdominal discomfort, pain, nausea, and digestive disturbances across four visits. The frequency of abdominal discomfort or pain reduced from a mean of 4.42 at baseline to 1.55 at Visit 4 (81.13% improvement), while experienced nausea decreased from 3.53 to 1.62 (77.05% improvement). The severity of abdominal discomfort or pain improved from 4.33 to 1.55 (81.52% improvement). (Table 10; Figure 11) Notably, both severity of nausea and nausea affecting daily life showed complete resolution by Visit 4.

Reduction in digestive disturbances improved progressively, with mean scores increasing from 1.22 at Visit 1 to 5.00 at Visit 4 (63% improvement). (Table 11; Figure 12) Overall changes were statistically significant ($p = 9.96 \times 10^{-35}$), indicating marked improvement in gastrointestinal symptoms.

All p-values for symptom change were statistically significant ($p < 0.0001$).

Clinician Disease Severity Assessment

Clinician-based evaluation demonstrated significant improvement in disease severity across all assessed parameters between Visit 1 and Visit 4. Mean scores for overall symptom severity, impact on daily activities, overall quality of life, fatigue, abdominal pain, nausea and vomiting, and diarrhea or constipation decreased from 2.68–3.00 at baseline to 1.06–1.15 at Visit 4, indicating a shift from severe symptoms and poor quality of life to mild symptoms with minimal functional impact. (Table 12; Figure 13)

More than 90% potential improvement was observed across all indicators, with statistically significant changes ($p = 2.0 \times 10^{-52}$), demonstrating substantial clinical improvement following the intervention.

Clinician-Assessed Symptom Improvement

From Day 30 to Day 90, clinician-scored symptom improvement rose from 1.63 to 4.11, corresponding to a 73.5% gain toward complete resolution (p = 1.02E-34). (Table 13; Figure 14)

Compliance and Safety

Compliance rate: 90% of participants adhered to ≥80% of prescribed doses.
Adverse Events (AEs): No AEs or Serious AEs (SAEs) were reported.
Protocol Violations: None recorded.
Mortality: 0%.

Safety and Tolerability

Importantly, the formulation was well tolerated by all participants. No adverse events (AEs) or serious adverse events (SAEs) were reported throughout the 90-day period, and compliance exceeded 90%. This contrasts with many conventional hepatoprotective agents (e.g., pioglitazone, vitamin E, obeticholic acid), which are often associated with side effects including weight gain, pruritus, and elevated transaminases.[21]

The excellent safety profile, combined with substantial symptom relief and functional improvement, underscores the Liver Detox Formula's potential role as a complementary or even standalone therapy, especially in populations where access to specialty care or expensive diagnostics is limited.

Table 1: Baseline demographic and clinical characteristics of study participants

Parameters	Mean	SD	Median	Min	Max	Count
Age	43.28888889	6.672951583	42	31	58	45
BMI	22.67311111	1.691716211	22.86	18.79	25	45
Respiratory Rate (bpm)	17.57777778	1.529837913	18	13	20	45
Pulse Rate (bpm)	79.88888889	3.644561466	81	73	88	45
Body Temperature	36.69555556	0.26453695	36.7	36.2	37.3	45
Systolic	126.7333333	5.45393936	125	117	137	45
Diastolic	80.57777778	3.614924172	80	73	88	45

Table 2: Participant disposition and study completion status

Category	Number of Participants (n)	Percentage (%)
Screened	50	100
Enrolled	50	100
Completed	45	90
Withdrawn	5	10
Reason for Withdrawal	Lost to follow up	NA
Adverse Events	NA	NA

Table 3: Chronic Liver Disease Questionnaire (CLDQ)-Abdominal Symptoms at Baseline, Day 30, Day 60, and Day 90

Abdominal Symptoms				
Study Visit	Mean SD	A) Reduction of Abdominal Symptoms	B) Reduction of Abdominal Pain	C) Reduction of Abdominal Discomfort
Visit 1	Mean	1.71	1.71	1.44
	SD	0.505525	0.458368	0.545875
Visit 2	Mean	3.48	3.44	3.48
	SD	0.505525	0.502519	0.505525
Visit 3	Mean	4.53	4.44	4.55
	SD	0.504525	0.586033	0.545875
Visit 4	Mean	6.42	6.55	6.55
	SD	0.499495	0.502519	0.502519

Table 4: **Chronic Liver Disease Questionnaire (CLDQ)-Fatigue at Baseline, Day 30, Day 60, and Day 90**

Fatigue					
Study Visit	Mean SD	A) Tiredness or fatigue?	B) Sleepiness during the day?	C) Decreased strength?	D) Decreased Energy
Visit 1	Mean	1.62	1.86	1.31	1.28
	SD	0.613814	0.756787	0.514438	0.458368
Visit 2	Mean	3.44	3.46	3.37	3.44
	SD	0.502519	0.504525	0.49031	0.502519
Visit 3	Mean	4.53	4.51	4.6	4.6
	SD	0.504525	0.505525	0.579969	0.579969
Visit 4	Mean	6.42	6.37	6.51	6.55
	SD	0.499495	0.49031	0.505525	0.502519

Table 5: Chronic Liver Disease Questionnaire (CLDQ)-Systemic Symptoms at Baseline, Day 30, Day 60, and Day 90

Systemic Symptoms						
Study Visit	Mean SD	A) Body Pain	B) Shortness of breathe	C) Muscle Cramps	D) Dry Mouth	E) Itching
Visit 1	Mean	1.71	3.13	1.75	1.48	1.66
	SD	0.45836777	0.660578	0.52895934	0.548644	0.476731
Visit 2	Mean	3.46	3.51	3.44	3.2	3.06
	SD	0.50452498	0.505525	0.50251891	0.504525	0.750757
Visit 3	Mean	4.62	4.6	4.66	4.68	4.57
	SD	0.49031015	0.53936	0.47673129	0.633254	0.543093
Visit 4	Mean	6.6	6.42	6.6	6.44	6.44
	SD	0.49543369	0.499495	0.49543369	0.502519	0.502519

Table 6: Chronic Liver Disease Questionnaire (CLDQ)-Activity at Baseline, Day 30, Day 60, and Day 90

Activity				
Study Visit	Mean SD	A) Not eating enough?	B) Trouble in carrying or lifting heavy objects?	C) Bothered by a limitation of the diet?
Visit 1	Mean	1.71	1.31	1.66
	SD	0.50552503	0.468179	0.522233
Visit 2	Mean	3.24	3.28	3.28
	SD	0.74332042	0.694858	0.661342
Visit 3	Mean	4.64	4.75	4.53

	SD	0.48409032	0.802144	0.814639
Visit 4	Mean	6.42	6.46	6.4
	SD	0.49949469	0.504525	0.495434

Table 7: Chronic Liver Disease Questionnaire (CLDQ)-Worry at Baseline, Day 30, Day 60, and Day 90

Worry							
Study Visit	Mean SD	A) Worries about the impact of the liver disease?	B) Worries that symptoms will develop into major problems?	C) Worries that the condition is getting worse?	D) Difficulty in sleeping at night	E) Worries about never feeling any better?	F) Concerned about the availability of a liver in the case of a transplant?
Visit 1	Mean	1.4	1.35	1	1.4	1.97	1.688
	SD	0.495434	0.48409	0	0.495434	0.783027	0.514438
Visit 2	Mean	2.77	2.91	3.02	3.02	3	3.06
	SD	0.670444	0.70137	0.722649	0.722649	0.738549	0.687552
Visit 3	Mean	4.53	4.51	4.53	4.6	4.64	4.57
	SD	0.504525	0.505525	0.547723	0.53936	0.48409	0.543093
Visit 4	Mean	6.4	6.44	6.62	6.51	6.44	6.4
	SD	0.495434	0.502519	0.49031	0.505525	0.502519	0.495434

Table 8: Chronic Liver Disease Questionnaire (CLDQ)- Emotional Function at Baseline, Day 30, Day 60, and Day 90

Emotional Function								
Study Visit	Mean SD	A) Anxiety	B) Unhappiness	C) Irritability	D) Difficulty in sleeping at night?	E) Difficulty in falling asleep at night?	F) Depression	G) Problems
Visit 1	Mean	1.71	2.11	1.57	1.4	1.4	1.57	1.68
	SD	0.505525	0.745356	0.621175	0.495434	0.495434	0.499495	0.468179
Visit 2	Mean	2.93	3.35	2.86	3.02	3.02	2.86	2.82
	SD	0.719848	0.802144	0.786245	0.783027	0.722649	0.756787	0.716332
Visit 3	Mean	4.22	4.53	4.57	4.31	4.51	4.6	4.42
	SD	0.635642	0.504525	0.499495	0.733058	0.588612	0.495434	0.621175
Visit 4	Mean	6.44	6.4	6.42	6.5	6.42	6.62	6.51
	SD	0.502519	0.495434	0.499495	0.502519	0.499495	0.49031	0.505525

Table 9: Fatigue Severity Scale at Baseline, Day 30, Day 60, and Day 90

Fatigue Severity Scale		
Visit 1	Mean	6.6
	SD	0.488518
Visit 2	Mean	5.5
	SD	0.506143
Visit 3	Mean	3.5
	SD	0.97021
Visit 4	Mean	1.5
	SD	0.501036

Table 10: Symptom Specific Checklist at Baseline, Day 30, Day 60, and Day 90

Symptom Specific Checklist						
Study Visit	Mean SD	Experienced abdominal discomfort or pain	Experienced nausea	Severity of your abdominal discomfort or pain	The severity of your nausea	Nausea affects your daily life
Visit 1	Mean	4.42	3.53	4.33	4.33	4.33
	SD	0.499495	0.504525	0.603023	0.6742	0.476731
Visit 2	Mean	3.6	2.68	3.51	3.48	3.53
	SD	0.495434	0.596285	0.505525	0.505525	0.504525
Visit 3	Mean	2.48	2.68	1.75	3.28	2.37
	SD	0.548644	0.596285	0.434613	1.100046	0.49031
Visit 4	Mean	1.55	1.62	1.55	0	0
	SD	0.502519	0.49031	0.502519	0	0

Table 11: Reduction in experiencing digestive disturbances at Baseline, Day 30, Day 60, and Day 90

Reduction in experiencing digestive disturbances		
Visit 1	Mean	1.22
	SD	0.420437
Visit 2	Mean	2.28
	SD	0.458368
Visit 3	Mean	3.57
	SD	0.499495
Visit 4	Mean	5
	SD	0

Table 12: Clinician Disease Severity Assessment at Baseline and Day 90

Clinician Disease Severity Assessment								
Study Visit	Mean SD	The severity of the patient's symptoms	Impact of the patient's symptoms on their daily activities	The patient's overall quality of life	The severity of the patient's fatigue	The severity of the patient's abdominal pain	The severity of the patient's nausea and vomiting	The severity of the patient's diarrhea or constipation
Visit 1	Mean	2.84	3	3	3	3	2.77	2.68
	SD	0.366529	0	0	0	0	0.420437	0.468179
Visit 4	Mean	1.15	1.06	1.06	1.08	1.11	1.06	1.06
	SD	0.366529	0.252262	0.252262	0.287799	0.317821	0.252262	0.252262

Table 13: Clinician-Assessed Symptom Improvement at Baseline, Day 30, Day 60, and Day 90

Clinician-Assessed Symptom Improvement							
Study Visit	Mean SD	How has the patient's fatigue changed since the last evaluation?	Based on your assessment and patient report, how has abdominal discomfort changed?	How would you rate changes in the patient's digestive issues?	Has there been a change in the patient's appetite as observed or reported?	Have observable signs of liver dysfunction improved?	Considering both patient feedback and your clinical evaluation, how would you describe the overall change in liver-related symptoms?
Visit 1	Mean	0	0	0	0	0	0
	SD	0	0	0	0	0	0
Visit 2	Mean	1.622222	1.777778	1.6	1.622222	1.511111	1.644444
	SD	0.49031	0.420437	0.495434	0.49031	0.588612	0.48409
Visit 3	Mean	2.888889	2.8	2.955556	2.733333	2.866667	3
	SD	0.80403	0.894427	0.824499	0.780443	0.842075	0.825723
Visit 4	Mean	4.022222	4.333333	4.022222	4.133333	4.133333	4
	SD	0.865734	0.768706	0.839071	0.894427	0.842075	0.825723

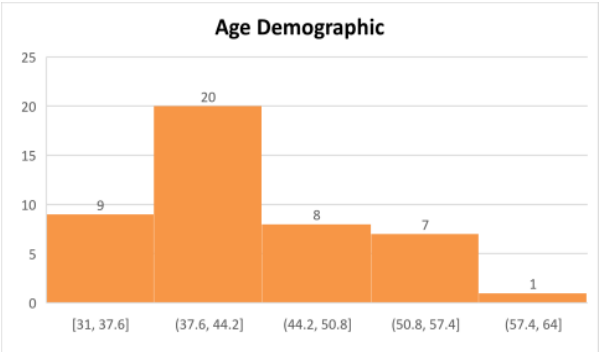

Figure 1: Age Demographic

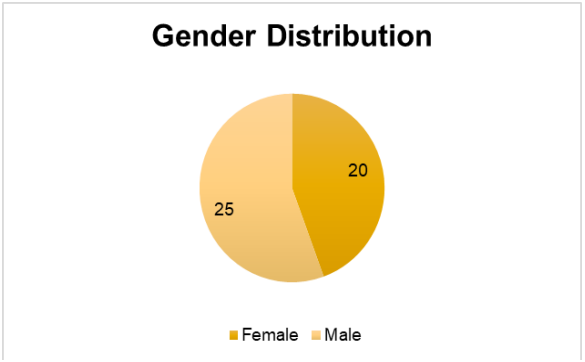

Figure 2: Gender Distribution

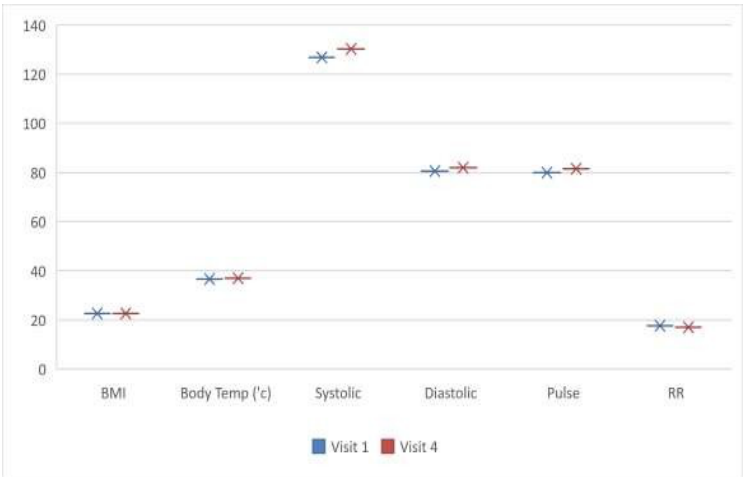

Figure 3: Vital Signs Interpretation of Baseline Characteristics

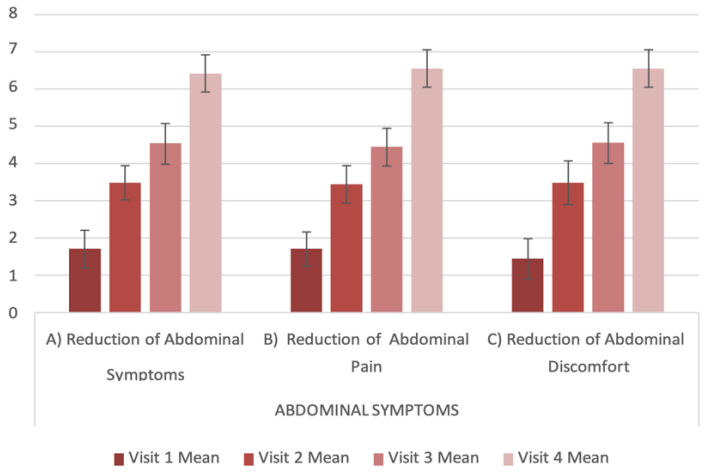

Figure 4: Improvement in reducing in Abdominal Symptoms

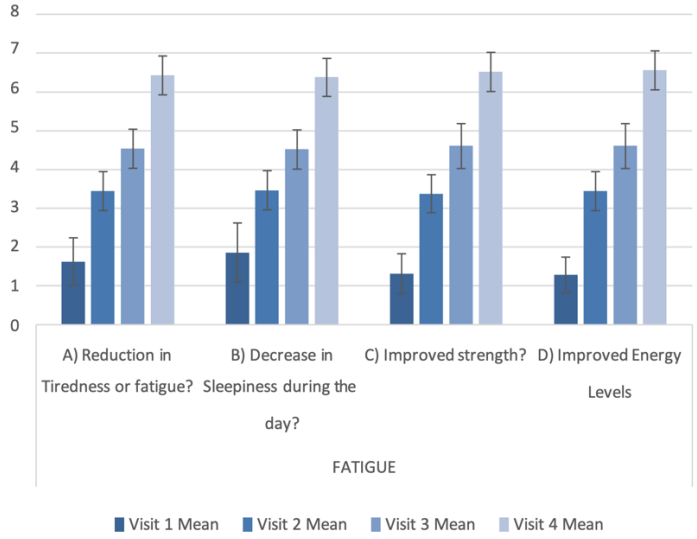

Figure 5: Improvement in reducing fatigue

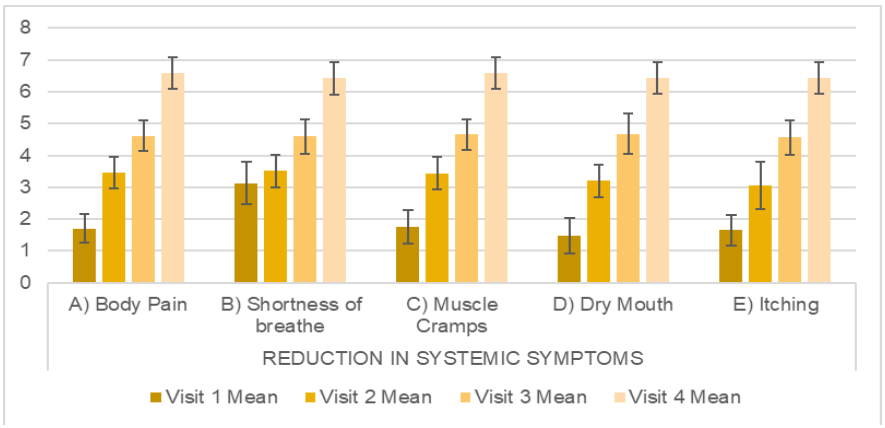

Figure 6: Improvement in reducing systemic symptoms

Figure 7: Improvement in daily activities

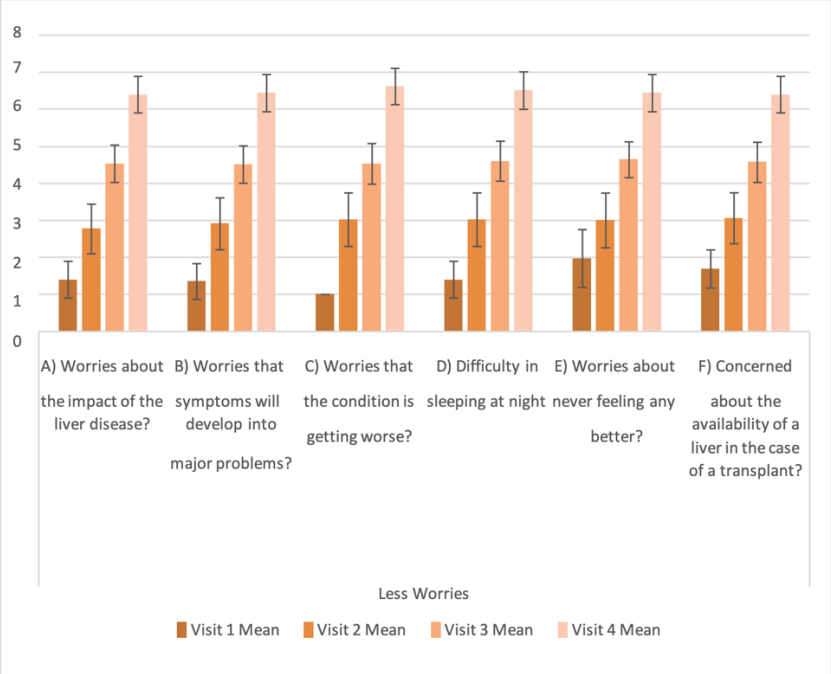

Figure 8: Less worries

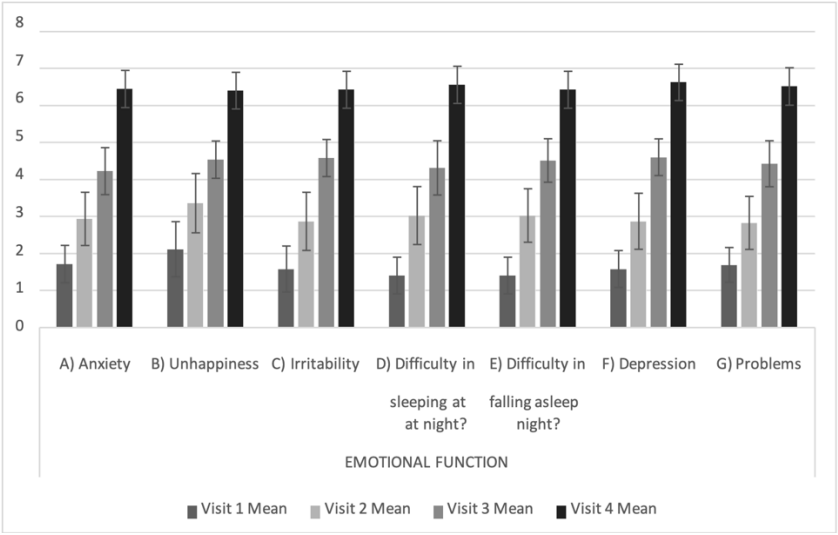

Figure 9: Improvement in emotional function

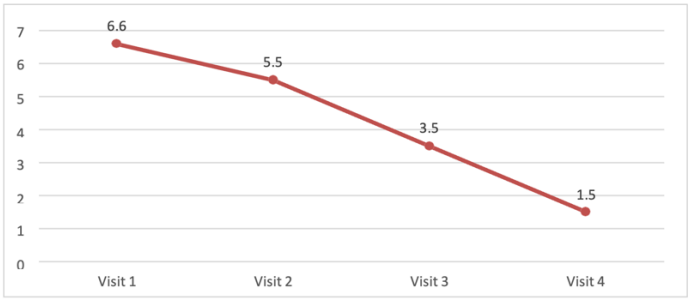

Figure 10: Fatigue Severity Scale

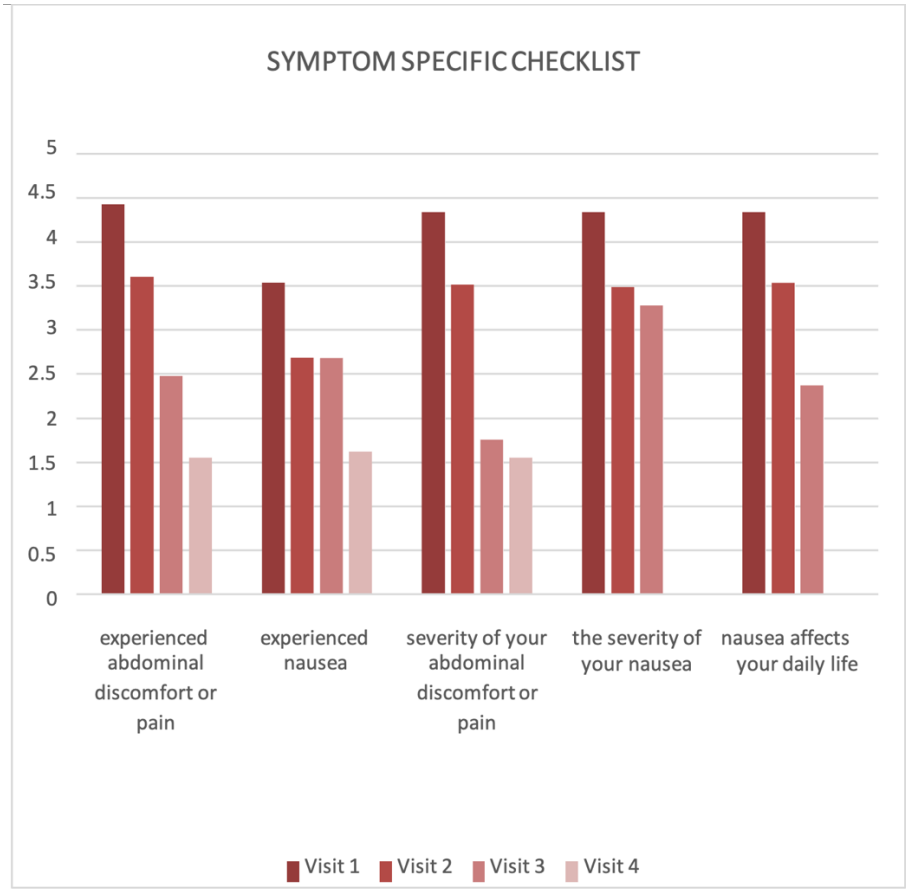

Figure 11: Symptom Specific Checklist

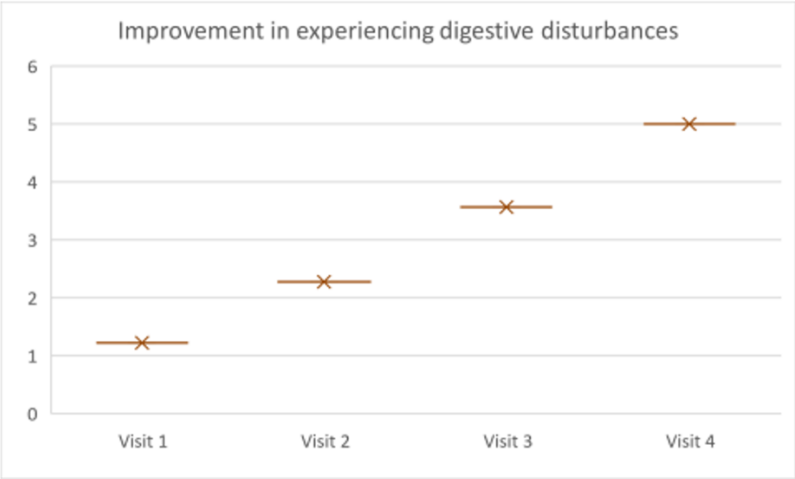

Figure 12: Improvement in experiencing digestive disturbances

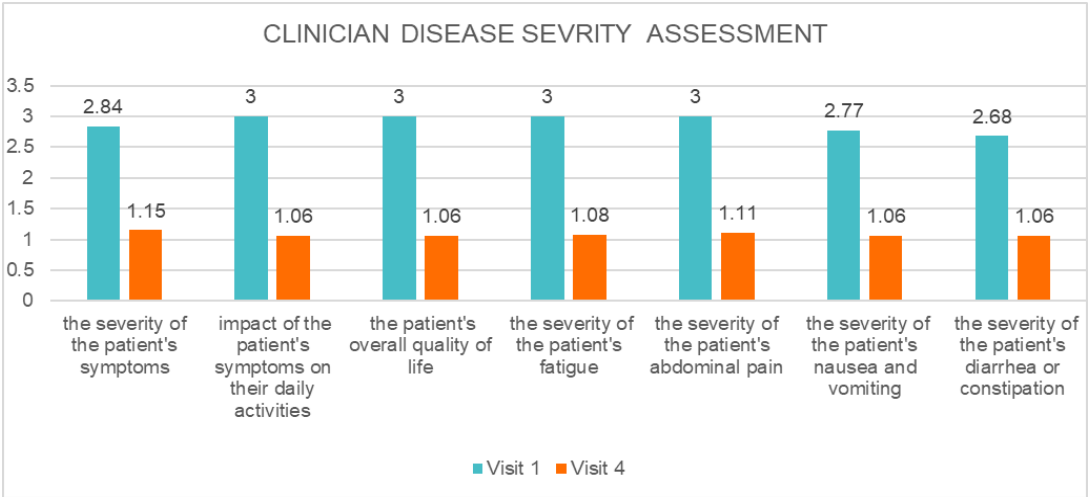

Figure 13: Clinician Severity Assessment

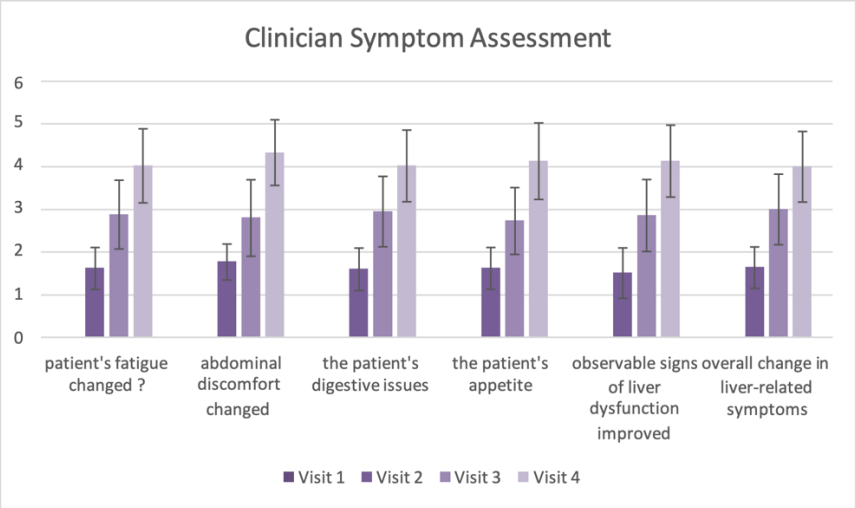

Figure 14: Clinician-Assessed Symptom Improvement

DISCUSSION

This open-label clinical trial demonstrated that the Liver Detox Formula, a proprietary Ayurvedic polyherbal capsule, was highly effective in improving clinical symptoms, quality of life, and fatigue in patients diagnosed with Non-Alcoholic Fatty Liver Disease (NAFLD) or Alcoholic Fatty Liver Disease (AFLD) over a 90-day treatment period. The findings are supported by statistically significant improvements across all primary and secondary outcome measures, including validated patient-reported outcome tools and clinician-assessed scores.

Impact on Quality of Life and Fatigue

The Chronic Liver Disease Questionnaire (CLDQ) scores showed remarkable improvement in all six domains, with mean domain changes exceeding 80% and p-values < 0.0001. These changes are clinically meaningful, as minimal clinically important differences (MCIDs) for CLDQ domains typically range from 0.5 to 1.0 points.[18] Improvements in fatigue, abdominal discomfort, emotional well-being, and systemic symptoms directly reflect both the hepatoprotective and adaptogenic mechanisms of the formulation. This aligns with prior research indicating that improvements in liver function and inflammation translate to enhanced quality of life.[19]

Similarly, Fatigue Severity Scale (FSS) scores declined by 85%, confirming a marked reduction in perceived fatigue. Fatigue is a hallmark symptom in FLD and has been associated with mitochondrial dysfunction, inflammatory cytokine activation, and impaired metabolic regulation.[20] Herbs like *Andrographis paniculata* and *Boerhavia diffusa*, both included in the Liver Detox Formula, are known for their anti-inflammatory and energy-modulating properties, potentially explaining the observed effects.[11,13]

Symptom Relief and Digestive Health

Symptom-specific improvements—particularly in abdominal discomfort, pain, nausea, and digestive disturbances—are noteworthy. For example, nausea-related impact on daily life dropped from 4.33 to 0.0 by Day 90, suggesting complete resolution in a majority of participants. These effects are likely due to the cholagogic, antiemetic, and carminative properties of components like *Picrorhiza kurroa* and Kalmegh.[10,12] These herbs enhance bile flow, support hepatic detoxification, and regulate gastrointestinal motility, mechanisms supported in both Ayurvedic theory and modern hepatology.

Clinician-Assessed Improvements

The objective clinical assessments by investigators mirrored patient-reported outcomes. Mean disease severity scores

improved by over 90% across all seven dimensions, including fatigue, GI symptoms, and activity limitation. Likewise, the symptom improvement scores increased by 73.5%, affirming real-world clinical efficacy beyond subjective metrics. These findings enhance the reliability of the study outcomes and reduce bias inherent in open-label designs.

Mechanistic Rationale and Ayurvedic Basis

The observed therapeutic benefits are consistent with the multimodal pharmacological actions of the herbal ingredients contained in the formulation. *Picrorhiza kurroa* (Katuki) has been widely reported to exhibit hepatocyte regenerative activity along with antioxidant and lipid-lowering effects in experimental models, supporting hepatic recovery and metabolic balance.[12,22,23] *Andrographis paniculata* (Kalmegh) possesses potent anti-inflammatory properties and has been shown to suppress key inflammatory mediators such as TNF-α and NF-κB, which play central roles in the pathogenesis of non-alcoholic steatohepatitis and progressive hepatic inflammation.[13,24,25] Similarly, *Boerhavia diffusa* (Punarnava) demonstrates diuretic, antioxidant, and hepatoprotective actions that contribute to improved detoxification and reduction of oxidative stress–related liver injury.[14,26,27]

The combination of these herbs enables the Liver Detox Formula to exert therapeutic effects through multiple physiological pathways, including enhancement of bile secretion, modulation of oxidative stress, regulation of inflammatory responses, and support of metabolic homeostasis. Such polyherbal synergy aligns with Ayurvedic therapeutic principles and likely contributed to the broad, multi-domain clinical improvements observed in the study.[28-30]

Safety Considerations

Safety findings from the study were reassuring, with no adverse events (AEs) or serious adverse events (SAEs) reported throughout the 90-day treatment period. No clinically significant abnormalities in vital signs or general health status were observed during follow-up, and there were no protocol violations related to safety. Treatment compliance exceeded 90%, further supporting tolerability and acceptability of the intervention.

This favourable safety profile is particularly important in the management of fatty liver disease, where conventional pharmacologic options may be associated with metabolic, gastrointestinal, cardiovascular, or hepatic adverse effects, especially with long-term use. The absence of treatment-related side effects in this study supports the potential suitability of Liver Detox Formula for continued or adjunctive use in patients with Alcoholic and Non-Alcoholic Fatty Liver Disease.

Summary of Key Findings

- Statistically significant improvement in liver-related quality of life as measured by CLDQ across all domains.
- Clinically meaningful reduction in fatigue severity, with FSS scores.
- Marked improvement in gastrointestinal and liver-related symptoms, including abdominal discomfort, nausea, and digestive disturbances.
- Progressive clinician-assessed improvement in disease severity.
- Favorable safety and tolerability profile with no reported adverse or serious adverse events and high treatment compliance.

Study Strengths

The strengths of this study include its prospective design, use of validated multidimensional outcome measures such as the CLDQ, FSS, and symptom checklist, and longitudinal assessment over a 90-day period through four scheduled visits. High participant retention and excellent treatment compliance supported data reliability, while the inclusion of both patient-reported outcomes and independent clinician evaluations provided a comprehensive assessment of clinical response.

Implications for Future Research

Given its favorable safety profile, affordability, and promising preliminary clinical outcomes, the Liver Detox Formula may have potential for integration into holistic liver care approaches. Future research should prioritize randomized, blinded controlled trials to strengthen evidence quality, along with the inclusion of objective biochemical markers such as ALT, AST, and GGT and radiological assessments to better evaluate hepatic changes. Studies exploring its effectiveness in specific NAFLD phenotypes, including diabetic and obesity-associated disease, as well as comparative trials against conventional or nutraceutical hepatoprotective therapies, are warranted to further define its clinical role.

CONCLUSION

This prospective, open-label clinical study demonstrated that the Liver Detox Formula, a proprietary Ayurvedic polyherbal capsule, was associated with clinically meaningful improvements in fatigue, gastrointestinal symptoms, and liver-related quality of life among patients with alcoholic and non-alcoholic fatty liver disease. Over a 90-day treatment period, participants experienced substantial reductions in fatigue severity and marked enhancement in CLDQ-assessed quality-of-life outcomes, accompanied by improvements in nausea, abdominal discomfort, digestive function, and overall clinical status as evaluated by independent clinicians. The intervention was well tolerated, with no adverse events reported and high treatment compliance observed throughout the study duration.

These findings suggest that a multi-targeted herbal approach, incorporating hepatoprotective, anti-inflammatory, cholagogic, and antioxidant properties of ingredients such as *Picrorhiza kurroa*, *Andrographis paniculata*, and *Boerhavia diffusa*, may provide a practical complementary or stand-alone therapeutic option for symptom management in fatty liver disease, particularly in settings where conventional pharmacologic options remain limited. While the outcomes are encouraging, the open-label, non-comparator study design necessitates cautious interpretation.

The open-label, non-randomized design without a comparator arm limits causal inference and the ability to attribute outcomes solely to the intervention. Further randomized, double-blind controlled trials with larger sample sizes and objective clinical endpoints, including liver enzymes, imaging assessments, and metabolic biomarkers, are recommended to validate efficacy and long-term safety. Additionally, reliance on patient-reported measures introduces the potential for reporting bias. Nonetheless, this study provides important preliminary clinical evidence supporting the potential role of the Liver Detox Formula as a safe, affordable, and effective intervention for improving patient well-being in fatty liver disease.

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