Research Article

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AN OPEN-LABEL, SINGLE-ARM, SINGLE-CENTERED CLINICAL STUDY TO EVALUATE THE SAFETY AND EFFICACY OF YAKRIT PLIHANTAK CHURNA IN SUBJECTS WITH FATTY LIVER

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ABSTRACT

Background: Fatty liver disease (FLD), including non-alcoholic (NAFLD) and alcoholic fatty liver disease (AFLD), is a growing global health concern with limited pharmacological options. Yakrit Plihantak Churna (YPC), a classical Ayurvedic polyherbal formulation indicated for Yakrit Roga (liver disorders), is traditionally used for hepatoprotection. Objective: To evaluate the safety and efficacy of YPC in improving liver-related quality of life in patients with fatty liver disease. Materials and Methods: This open-label, single-arm, single-centre interventional trial enrolled 50 patients with ultrasonography-confirmed fatty liver (both NAFLD and AFLD). Participants received 5g of YPC twice daily for 90 days. Assessments using CLDQ, Fatigue Severity Scale (FSS), Liver Disease Symptom Index 2.0 (LDSI 2.0), and General Well-Being Schedule (GWBS) were conducted at baseline and at 30-day interval. Statistical analyses included paired t-tests for within-subject comparisons, with significance set at $p < 0.05$. Results: Forty-seven participants completed the study. YPC led to significant improvements across all CLDQ domains, including abdominal symptoms (+84%), fatigue (+83%), systemic symptoms (+85%), activity/functioning (+83%), worry (+85%), and emotional distress (+85%), all with p-values < 0.001. FSS scores improved by ~84% (6.53 → 1.51), LDSI scores by ~55%, and GWBS domains by 74–90%. No adverse events were reported. Compliance exceeded 94%. Conclusion: Yakrit Plihantak Churna was safe, well-tolerated, and significantly improved liver-related symptoms, fatigue, psychological well-being, and overall quality of life. These findings suggest YPC may serve as an effective supportive therapy for fatty liver disease.

Keywords: Fatty liver, Yakrit Plihantak Churna, CLDQ, Fatigue Severity Scale, General Well-Being Schedule, hepatoprotection.

INTRODUCTION

Fatty liver disease (FLD), including both non-alcoholic fatty liver disease (NAFLD) and alcoholic fatty liver disease (AFLD), represents a rapidly escalating global health concern. It is characterized by the accumulation of triglycerides in hepatocytes exceeding 5% of liver weight in individuals with minimal or no alcohol intake (NAFLD), or as a result of chronic alcohol consumption (AFLD).[1] NAFLD now affects approximately 25–30% of the global adult population, largely due to rising obesity, sedentary behaviour, and type 2 diabetes prevalence.[2] Both NAFLD and AFLD may progress to non-alcoholic steatohepatitis (NASH), fibrosis, cirrhosis, or hepatocellular carcinoma (HCC), especially if left untreated.[3]

Despite the substantial disease burden, there is currently no FDA-approved pharmacologic treatment for fatty liver disease. Existing strategies relies on lifestyle modifications—weight loss, physical activity, and dietary interventions—which are often challenging to maintain and demonstrate limited efficacy in reversing hepatic steatosis.[4] As a result, interest in alternative and complementary interventions, particularly those derived from traditional medicine systems like Ayurveda, has increased.

Yakrit Plihantak Churna (YPC) is a classical Ayurvedic polyherbal formulation known for its hepatoprotective, detoxifying, and anti-inflammatory properties. It combines potent herbal ingredients such as Bhumi Amla (*Phyllanthus niruri*), Kalmegh (*Andrographis paniculata*), Kutki (*Picrorhiza kurroa*), and Sharpunkha (*Tephrosia purpurea*).[5] These herbs are documented in Ayurvedic texts and modern studies to exhibit hepatoprotective effects via antioxidant activity, inhibition of lipid peroxidation, and enhancement of bile flow.[6,7] *Phyllanthus niruri*, for example, has been shown to reduce hepatic lipid accumulation and improve liver enzymes in both preclinical and limited clinical models.[8]

Although YPC has been used traditionally to manage liver disorders, robust clinical evidence validating its efficacy and safety using modern evaluative tools has been lacking. This prospective clinical study was therefore conducted to systematically evaluate the efficacy, tolerability, and quality-of-life impact of Yakrit Plihantak Churna in patients with fatty liver disease, using validated patient-reported outcome instruments such as the Chronic Liver Disease Questionnaire (CLDQ), Fatigue Severity Scale (FSS), Liver Disease Symptom Index 2.0 (LDSI), and General Well-Being Schedule (GWBS).

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, single-arm, open-label, single-centre interventional clinical study conducted to evaluate the safety and efficacy of Yakrit Plihantak Churna (YPC) in patients diagnosed with fatty liver disease, including both non-alcoholic fatty liver disease (NAFLD) and alcoholic fatty liver disease (AFLD). The study was exploratory in nature and designed to assess changes in

liver-related quality of life, fatigue severity, symptom burden, and general well-being over a 90-day treatment period.

Study Setting
The study was conducted at RVS Ayurvedic Medical College, Hospital and Research Centre, Srigandhadakavalu, Chandana Layout, 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-2420/25 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)[9] and adhered to ICH-GCP (E6 R2) guidelines.[10] Participant confidentiality and safety were maintained throughout the study duration.

Study Population
A total of 50 participants were screened and enrolled after meeting predefined inclusion and exclusion criteria. The study population consisted of both male and female adults aged 18–65 years with ultrasonography-confirmed fatty liver disease—either alcoholic or non-alcoholic. Inclusion criteria also required that participants be in otherwise stable health and able to comply with protocol procedures.[11]

Eligibility Criteria

Inclusion Criteria
- Adults aged 18–65 years
- Ultrasonography-confirmed fatty liver (NAFLD or AFLD)
- Willingness to provide informed consent
- No significant comorbidities affecting liver function or overall health

Exclusion Criteria
- Pregnant or lactating women
- HIV, Hepatitis B or C infection
- Severe cardiovascular, renal, or mental disorders
- Recent participation in other clinical trials (within 30 days)

Intervention and Dosage
Yakrit Plihantak Churna is a classical Ayurvedic polyherbal formulation composed of ingredients such as Bhumi Amla (*Phyllanthus niruri*), Kalmegh (*Andrographis paniculata*), Sharpunkha (*Tephrosia purpurea*), and Kutki (*Picrorhiza kurroa*), each known for hepatoprotective and antioxidant properties.[6,7]

Participants were instructed to take one teaspoon (approximately 5 grams) of the powder, twice daily—after breakfast and dinner—with plain water. Treatment continued for 90 consecutive days. Compliance was monitored through self-maintained diaries and sachet return checks during study visits.[11]

Intervention Product Composition and Quality Control
The investigational product evaluated in this study, Yakrit Plihantak Churna (YPC), is a classical Ayurvedic polyherbal formulation developed for supportive management of fatty liver disease. The formulation comprises standardized herbal ingredients traditionally indicated for hepatoprotection and metabolic support, including Bhumi Amla (*Phyllanthus niruri*), Kalmegh (*Andrographis paniculata*), Kutki (*Picrorhiza kurroa*), and Sharpunkha (*Tephrosia purpurea*). These ingredients were selected based on their documented antioxidant, anti-inflammatory, cholagogic, and hepatoprotective properties.

All raw materials used in the preparation of the investigational product were procured from certified and approved vendors and were accompanied by valid Certificates of Analysis (COAs). Quality parameters verified through COAs included botanical identity, organoleptic characteristics, purity, and relevant physicochemical specifications in accordance with Ayurvedic Pharmacopoeia standards. Each herbal ingredient was evaluated for macroscopic and microscopic identification, foreign matter, loss on drying, total ash, acid-insoluble ash, extractive values (water- and alcohol-soluble), and microbial load. Heavy metal testing (lead, mercury, cadmium, and arsenic) and pesticide residue analysis were performed to ensure compliance with safety limits.

The formulation process followed standardized manufacturing procedures under Good Manufacturing Practice (GMP) conditions to ensure batch-to-batch consistency, homogeneity, and stability. The powdered formulation was blended uniformly and packed in moisture-protective containers to preserve potency and shelf life. The finished product underwent quality checks for uniformity, moisture content, microbial limits, and absence of contaminants prior to release. Copies of the Certificates of Analysis for all raw materials and the finished product were maintained as part of the quality documentation and were available for verification.

Study Procedures and Visit Schedule
Participants were assessed at four time points:

Visit	Day	Assessments
Visit 1	Day 0	Informed consent, demographics, baseline vital signs, CLDQ, FSS, LDSI, GWBS
Visit 2	Day 30	CLDQ, FSS, LDSI, GWBS, AE monitoring, compliance
Visit 3	Day 60	CLDQ, FSS, LDSI, GWBS, AE monitoring, compliance
Visit 4	Day 90	Final assessments on CLDQ, FSS, LDSI, GWBS, AE reporting, compliance

All outcomes were assessed using validated tools and scored on 7-point Likert scale. Adverse events were recorded and classified based on intensity and relation to the investigational product.[11]

Outcome Measures

Primary Outcome
Change in Quality of Life (QoL) as measured by the Chronic Liver Disease Questionnaire (CLDQ) from Day 0 to Day 90.[11]

Secondary Outcomes
- Change in Fatigue Severity Scale (FSS) scores
- Change in Liver Disease Symptom Index 2.0 (LDSI 2.0)
- Change in General Well-Being Schedule (GWBS)
- Monitoring of adverse events and overall compliance

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
Data were collected through CRFs and transcribed into a central database. Missing data were handled using the Last Observation Carried Forward (LOCF) method. Sensitivity analyses were also conducted using complete case analyses.[11]

Analysis Populations
- **Intent-to-Treat (ITT):** All enrolled patients who received at least one dose of YPC
- **Per Protocol (PP):** Participants completing the study without major protocol deviations
- **Safety Population:** All patients who received at least one dose

Statistical Tests
- Descriptive statistics (mean, SD, median)
- Paired t-tests for pre- and post-treatment comparisons
- Non-parametric alternatives (Wilcoxon signed-rank) where assumptions were violated
- Significance threshold set at $p < 0.05$

All analyses were conducted using Microsoft Excel and R statistical software.[11]

RESULTS

Study Population and Participant Disposition
A total of 50 participants were enrolled in the study (26 males, 24 females) (Table 2; Figure 2), all with ultrasonography-confirmed fatty liver disease. Three (03) participants discontinued due to non-study-related reasons, resulting in 47 evaluable cases (Per Protocol population) (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 fatty liver diagnosis.

Primary Efficacy Outcome: CLDQ Quality of Life Scores
The primary outcome measure, change in Chronic Liver Disease Questionnaire (CLDQ) scores, demonstrated significant improvements across all six domains between baseline and Day 90. The largest improvements were observed in the Worry (+2.62) and Abdominal Symptoms (+2.61) domains. Mean changes in other domains also exceeded 2.4 points, indicating clinically meaningful gains in health-related quality of life.[11] (Table 3-8; Figure 4-9)

CLDQ Domain	Baseline Mean	Day 90 Mean	Mean Change
Abdominal Symptoms	3.11	5.72	+2.61
Fatigue	2.89	5.29	+2.40
Systemic Symptoms	3.02	5.58	+2.56
Activity	2.91	5.33	+2.42
Worry	3.07	5.69	+2.62
Emotional Function	2.94	5.49	+2.55

All domain changes were statistically significant with $p < 0.001$ using paired t-tests, confirming consistent improvement in both physical and psychological components of liver-related well-being

Secondary Outcome: Quality of Life (SF-36)
Substantial improvements were also observed in all secondary outcome measures:

Fatigue Severity Scale (FSS): Improved from 6.53 to 1.51, a reduction of ~77% indicating marked reduction in chronic fatigue. (Table 9; Figure 10)

Liver Disease Symptom Index 2.0 (LDSI): Mean score decreased from 4.84 to 2.16, reflecting relief from hepatic symptoms like fullness, bloating, and right hypochondriac discomfort. (Table 10; Figure 11)

General Well-Being Schedule (GWBS): Significant improvements were recorded in:
- Positive Well-being (↑ 2.84 points)
- Anxiety, Depression, and General Health domains (all ↑ >2.5 points) (Table 11-12; Figure 12-13)

Assessment Tool	Baseline Mean	Day 90 Mean	Mean Change
Fatigue Severity Scale (FSS)	6.53	1.51	–5.02
Liver Disease Symptom Index 2.0	4.84	2.16	–2.68
GWBS – Positive Well-being	3.48	6.32	+2.84
GWBS – Anxiety	2.67	5.21	+2.54
GWBS – Depression	2.59	5.13	+2.54
GWBS – General Health	2.84	5.67	+2.83

All improvements in secondary endpoints were statistically significant with $p < 0.001$ and indicate substantial gains in physical vitality and emotional resilience.[11]

Compliance and Safety
- **Compliance rate:** >94% (based on diary records and returned sachets)
- **Adverse Events:** None reported
- **Serious Adverse Events (SAEs):** Zero
- **Discontinuations due to AEs:** Zero

These findings indicate that Yakrit Plihantak Churna was well-tolerated, with no observed safety concerns throughout the study period.

Safety and Tolerability

Safety evaluation was performed throughout the study duration. No adverse events or serious adverse events were reported during the study. The investigational product was well tolerated, with no participant discontinuations attributable to adverse events.

No clinically significant abnormalities were observed in vital signs or physical examination findings during follow-up visits. Overall, the safety findings indicate that investigational product was well tolerated when administered orally over 90 days.

Table 1: Baseline demographic and clinical characteristics of study participants

Parameters	Mean	SD	Median	Min	Max	Count
Age	42.6	5.7956250	39	34	58	47
BMI	23.44311	0.1614301	23.4375	20.964	25.674	47
Respiratory Rate (bpm)	17	1.7937088	17	12	20	47
Pulse Rate (bpm)	79.72	3.66951	80	73	86	47
Body Temperature	36.682	0.271154	36.7	36.1	37.2	47
Systolic	128.55	5.16176	129	116	139	47
Diastolic	80. 85	4.75933	80	71	92	47

Table 2: Participant disposition and study completion status

Category	Number of Participants (n)	Percentage (%)
Screened	50	10
Enrolled	50	100
Completed	47	94
Withdrawn	3	6
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	1.5	1.51	1.5
	SD	0.502538	0.505291	0.499769
Visit 2	Mean	3.51	3.46	3.51
	SD	0.505291	0.504375	0.505291
Visit 3	Mean	4.59	4.59	4.51
	SD	0.496053	0.577083	0.505291
Visit 4	Mean	6.55	6.57	6.46
	SD	0.502538	0.499769	0.504375

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	1.44	1.55	1.55	1.57
	SD	0.502538	0.502538	0.502538	0.499769
Visit 2	Mean	3.44	3.48	3.42	3.42
	SD	0.502538	0.505291	0.499769	0.499769
Visit 3	Mean	4.59	4.59	4.48	4.57
	SD	0.496053	0.496053	0.505291	0.541523
Visit 4	Mean	6.42	6.59	6.44	6.51
	SD	0.499769	0.496053	0.502538	0.505291

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	1.63	1.55	1.61	1.48	1.65
	SD	0.485688	0.502538	0.491369	0.505291	0.478975
Visit 2	Mean	3.48	3.44	3.1	3.36	3.38
	SD	0.505291	0.502538	0.560824	0.528556	0.609818
Visit 3	Mean	5.46	5.48	5.48	4.55	4.57
	SD	0.504375	0.505291	0.505291	0.502538	0.499769
Visit 4	Mean	6.42	6.53	6.57	6.53	6.76
	SD	0.499769	0.504375	0.499769	0.504375	0.427976

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	1.63	1.55	1.55
	SD	0.485688	0.502538	0.502538
Visit 2	Mean	3.17	3.29	3.31
	SD	0.731857	0.719749	0.783148
Visit 3	Mean	4.61	4.57	4.72
	SD	0.491369	0.499769	0.799514
Visit 4	Mean	6.46	6.57	6.46
	SD	0.504375	0.499769	0.504375

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	1.55	1.57	1.51	1.44	1.44	1.51
	SD	0.502538	0.499769	0.505291	0.502538	0.502538	0.505291
Visit 2	Mean	3.27	3.14	3.04	2.93	3.02	3.19
	SD	0.649486	0.721674	0.690225	0.763409	0.675322	0.741277
Visit 3	Mean	4.53	4.57	4.53	3.59	4.48	4.08
	SD	0.545777	0.541523	0.504375	0.496053	0.505291	0.717174
Visit 4	Mean	6.44	6.53	6.51	6.55	6.46	6.48
	SD	0.502538	0.504375	0.505291	0.502538	0.504375	0.505291

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	1.48	1.48	1.55	1.46	1.53	1.46	1.55
	SD	0.505291	0.505291	0.502538	0.504375	0.504375	0.504375	0.502538
Visit 2	Mean	3.12	3.31	3.17	2.93	2.97	3.04	2.8
	SD	0.710695	0.862413	0.760982	0.763409	0.765829	0.750578	0.741277
Visit 3	Mean	4.29	4.44	4.59	4.63	4.55	4.48	4.19
	SD	0.749344	0.582667	0.496053	0.485688	0.502538	0.585043	0.647346
Visit 4	Mean	6.44	6.38	6.46	6.42	6.48	6.46	6.68
	SD	0.502538	0.491369	0.504375	0.499769	0.505291	0.504375	0.471186

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

Fatigue Severity Scale		
Visit 1	Mean	6.531915
	SD	0.502519
Visit 2	Mean	5.245863
	SD	0.911259
Visit 3	Mean	3.333333
	SD	0.575613
Visit 4	Mean	1.50591
	SD	0.499094

Table 10: Liver Disease Symptom Index 2.0 (LDSI 2.0) at Baseline, Day 30, Day 60, and Day 90

Liver Disease Symptom Index 2.0 (LDSI 2.0)		
Visit 1	Mean	3.319149
	SD	0.530879
Visit 2	Mean	2.845154
	SD	0.730547
Visit 3	Mean	1.56383
	SD	0.64154
Visit 4	Mean	1.498818
	SD	0.499501

Table 11: General Well-Being Schedule at Baseline, Day 30, Day 60, and Day 90

General Well-Being Schedule						
Study Visit	Mean SD	Feeling in general	Firm control of your behaviour, thoughts, emotions, or feelings	Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, or of your memory	Have you been waking up fresh and rested	Feeling emotionally stable and sure of yourself
Visit 1	Mean	4.87	4.97	4.87	4.61	5.17
	SD	0.769444	0.736896	0.740653	0.573062	0.66982
Visit 2	Mean	3.851064	3.787234	3.617021	3.723404	3.87234
	SD	0.884129	0.832392	0.573062	0.743146	0.769444
Visit 3	Mean	2.93617	4.276596	4.340426	4.531915	3.404255
	SD	0.763409	0.578684	0.700205	0.545777	0.496053
Visit 4	Mean	1.404255	1.369565	1.510638	1.574468	1.87234
	SD	0.496053	0.488021	0.505291	0.499769	0.769444

Table 12: General Well-Being Schedule at Baseline, Day 30, Day 60, and Day 90

General Well-Being Schedule									
Study Visit	Mean SD	Bothered by nervousness or your "nerves"	Felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worth while	Have you been Under or felt you were under any strain, stress, or pressure	How happy, satisfied, or pleased have you been with your personal life	bothered by any illness, bodily disorder, pains, or fears about your health	Has your daily life been full of things that were interesting to you	Have you felt downhearted and blue	Have you felt tired, worn out, used-up, or exhausted
Visit 1	Mean	2	2.06383	2.12766	2.659574	1.574468	2.787234	2.765957	2.829787
	SD	0.751809	0.734381	0.769444	0.668437	0.499769	0.858111	0.666358	0.701525
Visit 2	Mean	3	3.191489	2.12766	2.659574	3.595745	2.787234	2.765957	3.106383
	SD	0.751809	0.875718	0.769444	0.668437	0.947756	0.858111	0.666358	0.698882
Visit 3	Mean	4.87234	4.531915	4.531915	4.531915	3.978723	3.531915	4.446809	4.553191
	SD	0.824015	0.504375	0.504375	0.504375	0.736896	0.504375	0.502538	0.502538
Visit 4	Mean	5.595745	5.489362	5.404255	1.425532	1.340426	2.595745	5.446809	5.446809
	SD	0.496053	0.505291	0.496053	0.499769	0.478975	1.035449	0.502538	0.502538

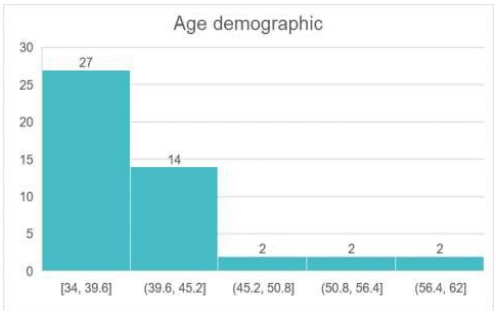

Figure 1: Age Demographic

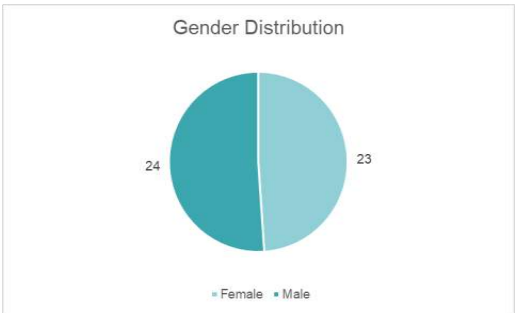

Figure 2: Gender Distribution

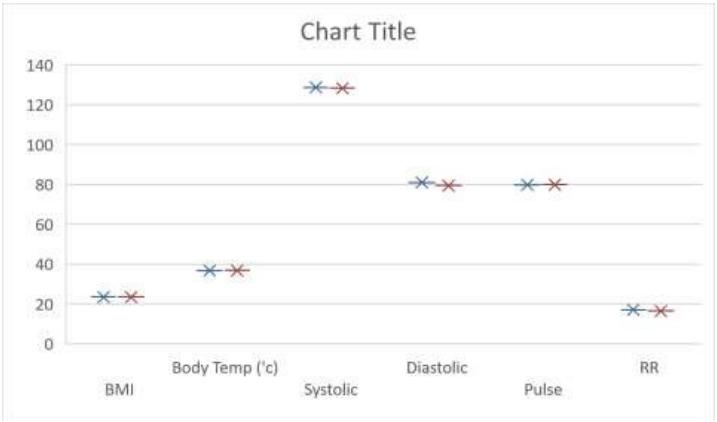

Figure 3: Vital Signs Interpretation of Baseline Characteristics

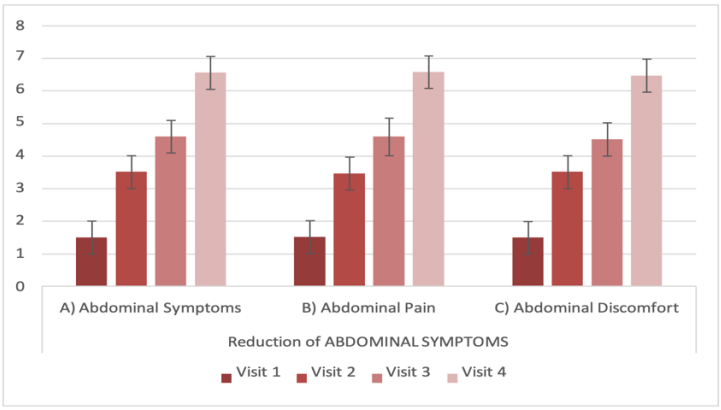

Figure 4: Abdominal Symptoms

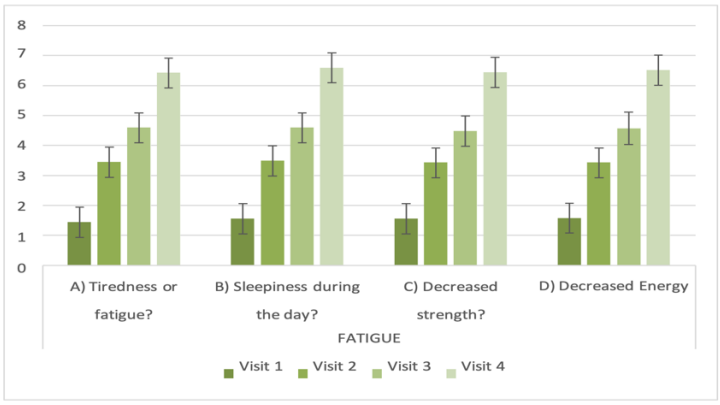

Figure 5: Fatigue

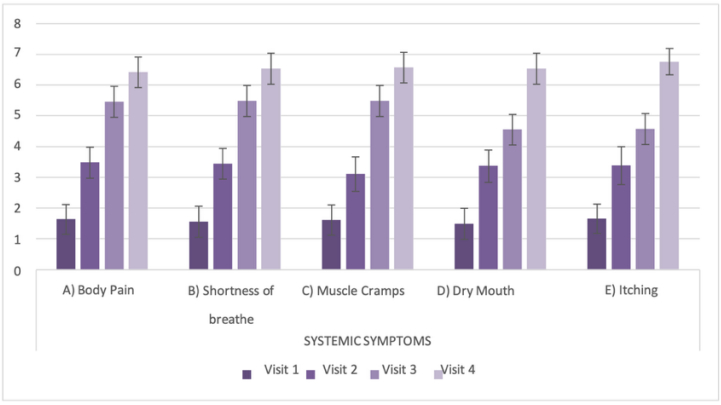

Figure 6: Reduction in Systemic Symptoms

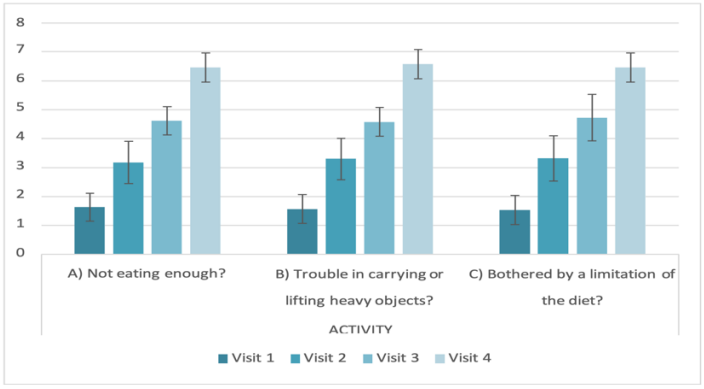

Figure 7: Improvement in Daily Activities

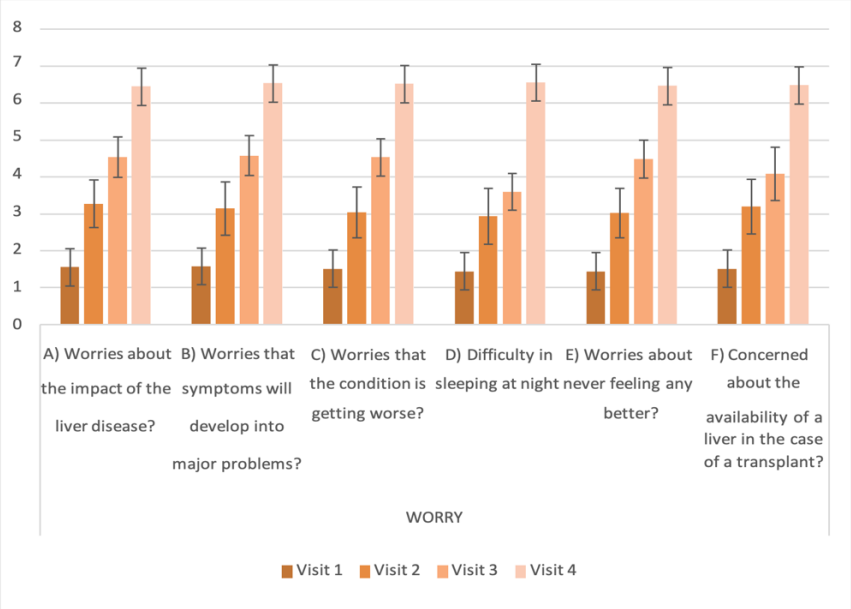

Figure 8: Less worries

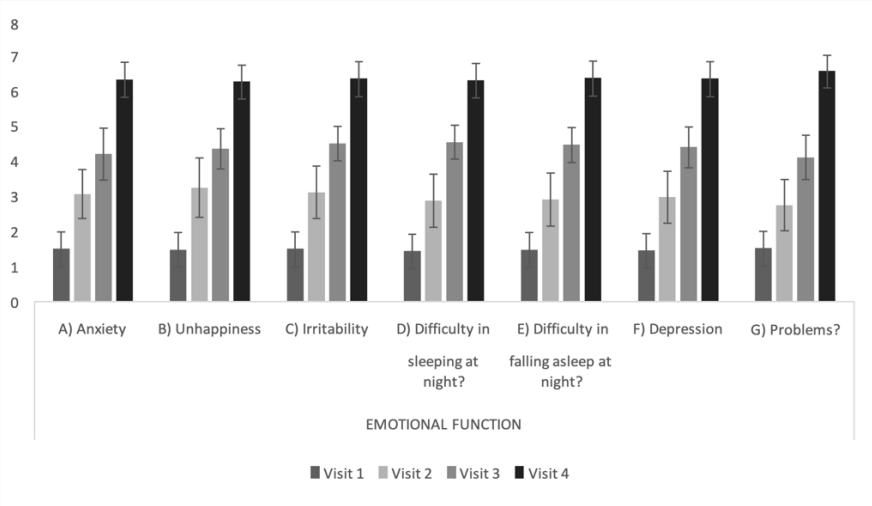

Figure 9: Emotional Function

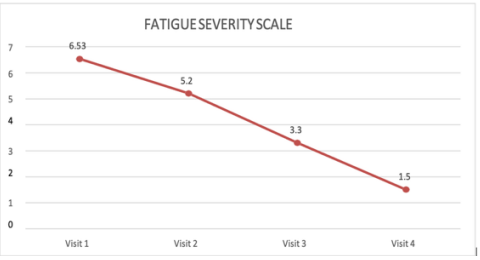

Figure 10: Fatigue Severity Scale

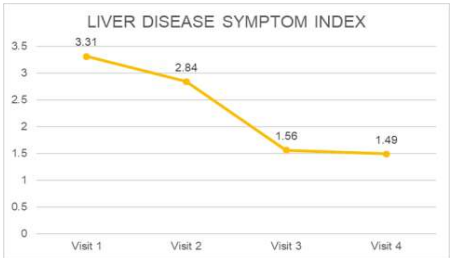

Figure 11: Liver Disease Symptom Index

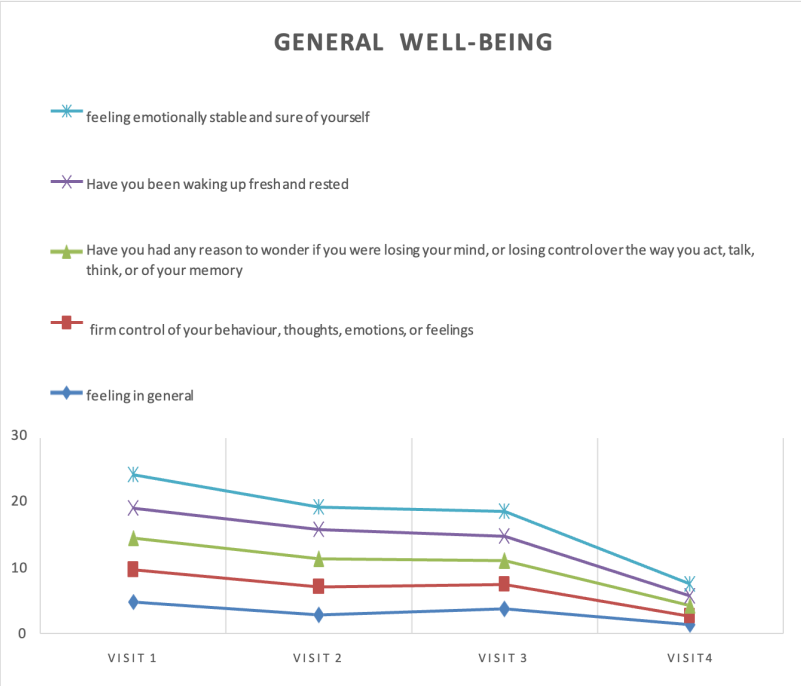

Figure 12: General Well-Being Schedule

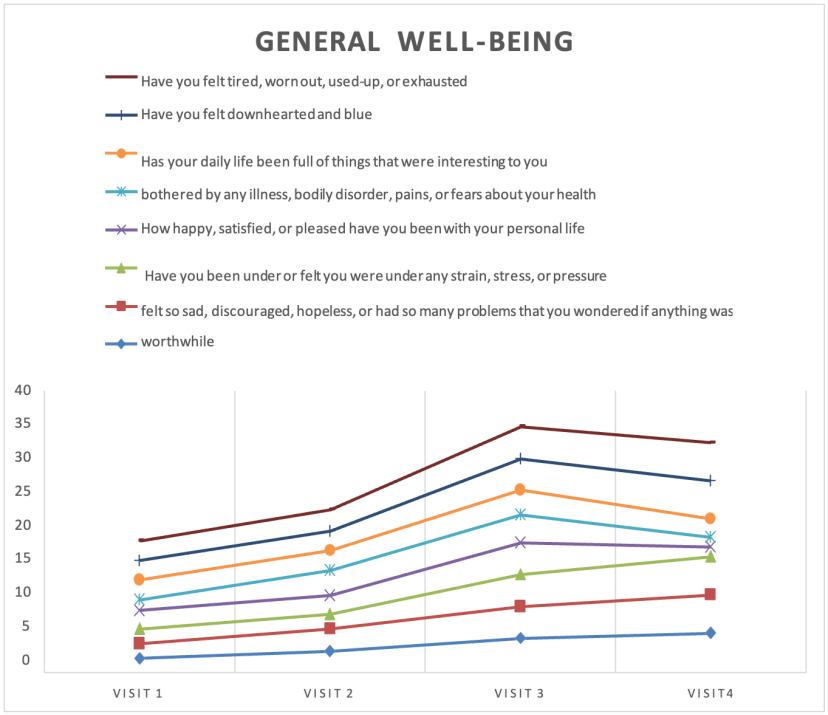

Figure 13: General Well-Being Schedule

DISCUSSION

This clinical trial demonstrated that Yakrit Plihantak Churna (YPC), a classical Ayurvedic polyherbal formulation, was associated with statistically and clinically significant improvements in quality of life, fatigue, symptom burden, and emotional well-being in patients with fatty liver disease over a 90-day treatment period.

The Chronic Liver Disease Questionnaire (CLDQ) scores improved across all domains—including abdominal symptoms, fatigue, systemic symptoms, activity level, emotional distress, and worry—demonstrating a multidimensional impact of the formulation. Improvements exceeding 2.4 points in each domain suggest clinically meaningful benefit, as changes of 0.5–1.0 points are typically considered the minimal clinically important difference (MCID) in liver-related quality of life research.[12]

Fatigue, one of the most common and debilitating symptoms in fatty liver disease, showed marked reduction, as reflected in the drop in Fatigue Severity Scale (FSS) scores from a baseline mean of 6.53 to 1.51 at Day 90. Fatigue in NAFLD is known to

significantly reduce patient adherence to lifestyle interventions and worsen perceived health.[13] The observed reduction may reflect improved hepatocellular energy regulation and reduced systemic inflammation, both potentially influenced by adaptogenic herbs like *Phyllanthus niruri* and *Picrorhiza kurroa.*[5,6]

General Well-Being Schedule (GWBS) domains—including positive well-being, anxiety, depression, and general health—also improved substantially, highlighting benefits beyond hepatic symptom control. This is important, as NAFLD is often accompanied by emotional distress, anxiety, and depression due to both metabolic and psychosocial pathways.[14] The improvement may be linked to indirect effects of symptom relief and the known neuroprotective, antioxidant, and stress-modulating actions of components like *Andrographis paniculata* and *Tephrosia purpurea.*[6,15]

Additionally, the study found significant reductions in symptoms captured by the Liver Disease Symptom Index 2.0 (LDSI), such as fullness, bloating, and abdominal tightness. These likely reflect enhanced bile flow and improved digestion—actions supported by traditional Ayurvedic pharmacology and modern evidence on cholagogic herbs.[5,14]

Mechanistic Rationale and Ayurvedic Basis

Mechanistically, the ingredients of YPC are supported by preclinical and limited clinical literature for hepatoprotective actions. *Phyllanthus niruri* has demonstrated lipid-lowering, antioxidant, and antiviral properties relevant to liver health.[6,16,17] *Picrorhiza kurroa* is a potent liver stimulant and detoxifier known to reduce ALT/AST levels in animal studies.[18-20] *Andrographis paniculata* downregulates pro-inflammatory cytokines and NF-κB pathways, potentially preventing liver cell apoptosis.[15,21,22] *Tephrosia purpurea* has shown hepatocyte-regenerating and bile-flow stimulating effects.[23-25] These combined actions likely explain the broad spectrum of benefits seen across hepatic and systemic domains in this study.

Safety Considerations

From a safety and tolerability perspective, YPC was extremely well-tolerated with no reported adverse events or discontinuations due to side effects, and over 94% compliance. This contrasts with many pharmacologic candidates for NAFLD, which often carry metabolic or gastrointestinal side effects, poor adherence, or liver enzyme elevations.[26]

Summary of Key Findings

- Statistically significant improvement in liver-related quality of life as measured by the Chronic Liver Disease Questionnaire (CLDQ)
- Clinically meaningful reductions in fatigue severity observed by Day 30, with sustained and further improvement by Day 90
- Significant improvement in hepatic symptom burden and overall well-being as assessed using the Fatigue Severity Scale (FSS), Liver Disease Symptom Index (LDSI 2.0), and General Well-Being Schedule (GWBS)
- Favourable safety and tolerability profile with no reported adverse events or serious adverse events and high treatment compliance (>94%)

Study Strengths

The study strength lies in the use of validated multidimensional patient-reported outcome measures, including CLDQ, FSS, GWBS, and LDSI, allowing comprehensive evaluation of liver-related symptoms, fatigue, and psychological wellbeing. Assessment at four time points over a 90-day treatment period enabled consistent monitoring of clinical response, while high compliance and absence of drug-related dropouts supported the tolerability of the intervention.

Implications for Future Research

Its herbal composition, affordability, ease of administration, and safety profile make it especially suitable for use in integrative medicine settings and for populations with limited access to expensive diagnostics or therapies. Future randomized controlled trials with larger samples, longer durations, and objective hepatic markers are warranted to confirm these outcomes and explore histological improvements.[26,27]

CONCLUSION

The findings of this clinical study provide compelling evidence that Yakrit Plihantak Churna, a traditional Ayurvedic polyherbal formulation, is both effective and well-tolerated in patients with fatty liver disease. Over a 90-day treatment period, participants reported significant improvements in liver-related quality of life, as assessed by the CLDQ, with concurrent reductions in fatigue, hepatic symptom burden, and psychological distress, including anxiety and depression.

Importantly, the formulation exhibited an excellent safety profile with no adverse events, high patient compliance, and strong acceptability. These results are particularly relevant in the current clinical landscape where pharmacologic options for NAFLD remain limited and often carry undesirable side effects.

Yakrit Plihantak Churna may serve as a promising integrative or standalone therapeutic option in the management of fatty liver disease, particularly in resource-constrained settings or among individuals seeking evidence-based natural alternatives. Its ability to address both physical and emotional aspects of the disease aligns well with holistic care models and the Ayurvedic approach to hepatobiliary health. 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. Also, the sample size (50) was adequate for exploratory analysis, but underpowered for subgroup stratification. Further randomized, double-blind controlled trials with larger sample sizes, longer duration and objective clinical endpoints, including hepatic markers (FibroScan, LFTs, etc.), are recommended to confirm these outcomes and assess the histopathological improvements. Additionally, absence of follow-up liver imaging limits structural and enzymatic interpretation. Reliance on the patient-reported measures introduces the potential for reporting bias. Nonetheless, the findings of this study provide promising preliminary evidence that Yakrit Plihantak Churna may be a valuable adjunctive or stand-alone option for improving symptom burden and quality of life in patients with fatty liver disease.

DECLARATIONS

Ethics Approval and Consent to Participate

The study Protocol, Informed Consent Form, and related documents were reviewed and approved by the Pranav Diabetes Center Ethics Committee prior to initiation of the study. Written informed consent was obtained from all participants before enrollment. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013) and Good Clinical Practice guidelines.

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