ISSN- O: 2458 - 868X, ISSN–P: 2458 – 8687
National Library of Medicine - ID: 101731606

International Journal of Medical Science and Innovative Research (IJMSIR)
IJMSIR : A Medical Publication Hub
Available Online at: www.ijmsir.com
Volume – 10, Issue – 2, April – 2025, Page No. : 65 – 79

A Single Centric, Randomized, Open Label, Single Arm, Phase III B Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Nutricharge Woman

[1]Dr. D.M. Ravichand, Professor, Department of Pharmacology, Arundathi Institute of Medical Sciences, Beside MLRIT, Dundigal, Gandi Maisamma, Medical - Malkajgiri, Telangana

[2]Dr. P. Archana Reddy, Nakshatra Hospitals, Alkapuri X Roads, Opp Swagath Grand Hotel, Hyderabad

[3]Manisha Bhandari Mishra, Senior Vice President, Trophic Wellness Pvt. Ltd., 142-AB, Kandivali Industrial Estate, Kandivali West, Mumbai - 400067.

Corresponding Author: Dr. D.M. Ravichand, Professor, Department of Pharmacology, Arundathi Institute of Medical Sciences, Beside MLRIT, Dundigal, Gandi Maisamma, Medical – Malkajgiri, Telangana.

Citation this Article: Dr. D.M. Ravichand, Dr. P. Archana Reddy, Manisha Bhandari Mishra, "A Single Centric, Randomized, Open Label, Single Arm, Phase III B Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Nutricharge Woman", IJMSIR - April – 2025, Vol – 10, Issue - 2, P. No. 65 – 79.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

This study evaluates the efficacy, safety, and tolerability of Nutricharge WOMAN in improving hemoglobin levels, menstrual health, skin and hair health, and overall quality of life in women of reproductive age. Conducted as a single-center, randomized, open-label, single-arm Phase IIIb clinical trial, the study enrolled 100 female participants between the ages of 12 and 50. Over a 90-day treatment period, subjects were assessed for hemoglobin levels, menstrual health, and quality of life using standardized scales and laboratory tests. Results indicate a significant improvement in hemoglobin levels, menstrual symptoms, skin and hair health, and overall well-being, with minimal adverse effects.

Keywords: Nutricharge WOMAN, hemoglobin, menstrual health, quality of life.

Introduction

Nutraceuticals have gained considerable attention for their potential benefits in enhancing health and preventing diseases. These bioactive compounds, derived from food sources, offer therapeutic benefits beyond basic nutrition. They have been studied for their roles in boosting immunity, reducing oxidative stress, and managing chronic conditions such as cardiovascular diseases, diabetes, and anemia. With growing awareness of preventive healthcare, nutraceuticals are emerging as a complementary approach to conventional medical treatments.

Nutraceuticals have received considerable zest for their expected safety, potential nutritive and therapeutic effects. These are used as alternative to modern medicines that promote quality of health, increases nutritive value of the diet and prolongs life expectancy. Major constituents of the nutraceuticals are herbals, various nutrients and dietary supplements are involved in preventing different diseases and minimizing pathophysiology of the disease too. It also acts as immune boosting, natural antioxidant, anticancer, anti-

inflammatory, antidiabetic, cardio protective agent in addition to different health promoting effects. Ultimately, they ensure better quality of life and the purpose of this review is to provide summary of current scientific impression in this regard which might be helpful to formulate further innovative research plans in new domains on nutraceuticals.

Nutricharge WOMAN is a specially formulated nutraceutical supplement designed to address nutritional deficiencies commonly observed in women. It aims to enhance hemoglobin levels, support menstrual health, and improve overall well-being. This study investigates the efficacy, safety, and tolerability of Nutricharge WOMAN in improving hemoglobin levels and related health parameters in women of reproductive age, providing valuable insights into its potential role in women's health management (Table-3).

Nutraceuticals may range from isolated nutrients, herbal products, dietary supplements, genetically improved foods, processed food products. Generally, nutraceuticals contain vitamins, lipids, proteins, carbohydrates, minerals and other necessary nutrients. Hippocrates known as the father of medicine, correctly emphasized ―let food be your medicine and medicine be your food". So nutraceuticals are the medicinal foods that play an important role in maintaining well-being, enhancing health, modulating immunity, preventing as well as treating specific diseases and thereby stimulating optimal longevity and quality of life. Thus the field of nutraceuticals can be envisioned as one of the missing blocks in the health benefit of an individual. It has been scientifically proven and supported by various research articles that nutraceuticals are efficacious to treat and prevent various diseased condition (Rama et. al, 2006).

Nutraceuticals are obtained from foods of vegetal or animal origin, and the current interest and ongoing worldwide research aims to shed light and fully clarify their mechanism of action, their safety and efficacy by substantiating their role by means of clinical data. An effort to clarify their mechanism of action will in fact open a door to a next generation of therapeutic agents that do not propose themselves as an alternative to drugs, but, instead, can be helpful to: (i) prevent a cluster of conditions that could occur together (metabolic syndrome), e.g. heart disease, stroke, and type 2 diabetes; (ii) to complement a pharmacological therapy especially for those individuals who do not qualify for a conventional pharmacological therapy.

Methodology

The study conducted was a Single Centre, Randomized, Open label, single arm, Phase III b Clinical study for evaluating the Efficacy safety and Tolerability of Nutricharge WOMAN, a Nutraceutical supplement formulated to address nutritional deficiencies and enhance overall female health—in women of reproductive age. Subjects were screened and assessed for eligibility during visit 1 (Day -3 to 0) based on inclusion and exclusion criteria. Written informed consent was obtained from all eligible patients before initiating the study.

Clinical Examination was assessed as follows:

General physical examination including measurement of pulse, respiratory rate, temperature, blood pressure, weight and height and systemic examination of major systems namely cardiovascular system (CVS), central nervous system (CNS), gastrointestinal (GI) and respiratory system (RS) performed. Gynecology related complaints were recorded in the CRF. Anthropometric measurements - Height, weight, BMI & waist measurement was performed during Visit 2 on Day 0 (Table-1).

Efficacy Assessments, Safety & tolerability assessments were performed by MSS scale, SF-36 Quality life questionnaire, 2 ml of blood sample was collected for hemoglobin check, vital signs AE/SAE were recorded in the source document and CRF.

Visit-3- Treatment period (Day 1- Day 90):

Subjects were issued the test products for the entire duration of the study. Subjects were instructed to not take vitamin or mineral supplements during the study. During this period Subjects were assessed for safety and efficacy. Clinical examination and vital signs were performed. Any AE/SAE was recorded in the source document and CRF. MSS scale, SF-36 Quality life questionnaire, 2 ml of Blood sample was collected to assess hemoglobin percentage were assessed during Visit 3 on Day 90 (Figure-1).

At Visit-4 - End of Study Visit/Final Visit (Day 120 ± 3 days), the subjects were assessed at the site for Efficacy assessments: MSS score, SF-36 quality questionnaire, Safety assessments performed by AEs/SAEs. Simultaneously the Compliance assessment on the test product was performed by calling the subjects every 30 days:

Inclusion Criteria

Female subjects between the ages of 12 and 50years who met all specified inclusion criteria were enrolled in the study. Eligibility criteria required that subjects were able to communicate effectively and willing to provide written informed consent. Additionally, participants had to demonstrate, in the judgment of the Principal Investigator, the ability to comply with all protocol requirements and attend scheduled visits for the study duration. Women of childbearing age were required to use adequate contraceptive measures. Furthermore, subjects were included only if they had a hemoglobin (Hb) percentage of 7 or above.

Exclusion Criteria

Subjects were excluded from the study if they had contraindications or hypersensitivity to the study product or a history or presence of any medical condition or disease, as determined by the Investigator. Exclusion criteria included a history of asthma, cardiovascular diseases, or diabetes (Type I or Type II), except for individuals with prediabetes defined by fasting blood glucose levels between 100 and 125 mg/dL or random blood glucose levels between 140 and 199 mg/dL. Subjects with blood pressure above 180/100 mmHg or below 80/50 mmHg, hyperthyroid or hypothyroid disease, or abnormal findings on complete blood count were not included in the study.

Additionally, individuals testing positive for HIV, those with a history of high alcohol intake (more than two standard drinks per day), or those with psychiatric disorders that could impair their ability to provide written informed consent were excluded. Other exclusion factors included any condition that, in the Investigator's opinion, could adversely impact the subject's ability to complete the study, prior participation in any clinical study within 30 days before screening, a history of chronic ailments, or the use of any relevant preparation at the time of enrollment. Subjects with suspected or confirmed poor compliance with protocol or medication were also deemed ineligible. Furthermore, any subject was allowed to voluntarily discontinue participation at any time after providing informed consent and before the completion of the final study visit. The Investigator or Sponsor also retained the discretion to withdraw subjects.

Study Design

The study was conducted at Nakshatra Hospital, Hyderabad, India, and adhered to ethical standards, with written informed consent obtained from all participants prior to any study-related procedures. Eligible subjects

were female, aged 12 to 50 years, able to communicate effectively, willing to provide written informed consent, and deemed capable of complying with protocol requirements by the Principal Investigator. Participants were required to have a hemoglobin level of 7 g/dL or above and to use adequate contraceptive measures if of childbearing potential.

Study Procedures

The study comprised four visits, beginning with Visit 1 (Day -3 to 0), during which subjects underwent screening and eligibility assessment based on predefined inclusion and exclusion criteria. Written informed consent was obtained from eligible participants. Visit 2 (Day 0) involved baseline assessments, including a general physical examination (pulse, respiratory rate, temperature, blood pressure, weight, and height), systemic examination of major systems (cardiovascular, central nervous, gastrointestinal, and respiratory), documentation of gynecological complaints, and anthropometric measurements (height, weight, BMI, and waist circumference) (Table 2). Efficacy assessments included the Menstrual Symptom Severity (MSS) scale, the SF-36 Quality of Life questionnaire, and collection of a 2 mL blood sample for hemoglobin measurement. Safety and tolerability assessments involved recording vital signs and documenting any adverse events (AEs) or serious adverse events (SAEs) in source documents and case report forms (CRFs). Visit 3 (Day 1 to Day 90) marked the initiation of the intervention phase, where subjects received Nutricharge WOMAN tablets for the entire study duration and were advised to avoid other vitamin or mineral supplements. During this period, safety and efficacy were monitored through clinical examinations, vital sign measurements, and documentation of AEs/SAEs. Efficacy assessments, including the MSS scale, SF-36 questionnaire, and hemoglobin measurement, were repeated (Table-3). The final visit, visit 4 (Day 120 ± 3 days), focused on end-of-study assessments, mirroring the procedures conducted at Visit 3, with continued evaluation of efficacy and safety parameters. Compliance with the study product was assessed through monthly phone calls, conducted every 30 days, where subjects were queried about their adherence to the prescribed regimen.

Subject Withdrawal

Subjects retained the right to voluntarily discontinue participation at any time after providing informed consent and before completing the final study visit. Additionally, the Investigator or Sponsor reserved the right to withdraw subjects from the study drug treatment due to safety concerns, noncompliance, or administrative reasons. The Investigator had the discretion to terminate a subject's participation at any time, if deemed necessary. This structured methodology ensured a comprehensive evaluation of Nutricharge WOMAN in terms of efficacy, safety, and tolerability within the target population. Reasons for subject withdrawal were documented and included, but were not limited to, withdrawal of consent by the subject, in which case no further investigational product was administered or study observations conducted. Subjects were withdrawn from the study in the event of serious or intolerable adverse events, including serious adverse events or death, as assessed by the Investigator. Discontinuation could also occur if the Investigator deemed continued participation not in the subject’s best interest, if the subject failed to adhere to study procedures, if protocol deviations warranted withdrawal per the discretion of the Sponsor and Investigator, or if a subject had a positive pregnancy test at any study visit. All 100 subjects successfully complete the study and nothing prompted withdrawal of any subject. The investigational product, Nutricharge

WOMAN, was administered once daily, half an hour after a meal.

A total of 100 female subjects aged ≥12 years were enrolled in the study. The investigational product, Nutricharge WOMAN, was administered once daily for 90 days. All prior and concomitant medications were documented in the Prior and Concomitant Medications section of the Case Report Form (CRF) to ensure comprehensive monitoring of potential interactions. The investigational product was prescribed by the Investigator and dispensed to the subjects by the site team. To assess adherence, subjects were instructed to return used and unused medication strips at each study visit, allowing study site personnel to monitor compliance throughout the trial.

Efficacy assessment

Efficacy assessments in the study included multiple parameters to evaluate the impact of Nutricharge WOMAN on the target population. Hemoglobin levels were measured through 2 mL blood collection at Visit 3 and Visit 4 to assess any hematological changes. Additionally, the Menstrual Symptom Severity (MSS) Scale was used to evaluate menstrual health and symptom burden. The SF-36 Quality of Life questionnaire was administered to assess overall well-being and daily functioning. Furthermore, skin and hair health were monitored as additional indicators of the investigational product's efficacy. These assessments provided a comprehensive evaluation of the product's effects over the study duration.

Safety assessments

Safety assessments in the study involved comprehensive monitoring and documentation of all adverse events (AEs) and serious adverse events (SAEs), along with regular evaluations of hematology and blood chemistry. Periodic vital sign measurements, electrocardiograms (ECGs), and physical examinations were conducted as outlined in the Schedule of Assessments. In cases of premature discontinuation, the reason and underlying cause were documented. If withdrawal was due to an AE, monitoring of the event continued until resolution or return to pre-event status. All clinical measurements were performed using standardized and validated methods recognized for their reliability, accuracy, and relevance. Most assessments and study procedures followed established protocols, ensuring consistency in data collection. The efficacy and safety endpoints utilized in this study were considered robust and appropriate in relation to the study objectives.

Primary objective of the study

The primary objective of the study was to evaluate the efficacy of Nutricharge WOMAN in increasing hemoglobin percentage (Hb%) in women of reproductive age. This assessment aimed to determine the impact of the investigational product on hematological parameters, specifically hemoglobin levels, as an indicator of its potential benefit in addressing iron and nutritional deficiencies in this population (Table 4, Figure-2 & 5).

Secondary Objective of the Study

The secondary objectives of the study focused on assessing the safety and tolerability of Nutricharge WOMAN and evaluating changes in quality of life using the Health-Related Quality of Life questionnaire (HRQOL-SF-36) (Table 6). Safety evaluations included comprehensive tracking of adverse events (AEs) and serious adverse events (SAEs), regular hematology and blood chemistry monitoring, periodic vital sign assessments, electrocardiograms (ECGs), and physical examinations as per the Schedule of Assessments. In cases of premature discontinuation, reasons were documented, and if withdrawal was due to an AE, monitoring continued until resolution. Safety assessments

encompassed treatment-emergent AEs, laboratory parameters, and ECG abnormalities, with clinically significant findings recorded in the Case Report Forms (CRFs). Demographic data, including age, sex, race/ethnicity, body weight, height, and BMI, were collected at screening. Medical and surgical history, current conditions, and vital signs (blood pressure, heart rate, respiratory rate, and temperature) were recorded, with blood pressure measured consistently in the same arm across visits (Table-2). Physical examinations, either comprehensive or symptom-directed, were documented in CRFs. ECG abnormalities meeting AE/SAE criteria were reported per protocol. Laboratory tests were conducted as per the Schedule of Assessments, with clinically significant abnormalities recorded as AEs or SAEs. This structured safety monitoring ensured a comprehensive evaluation of Nutricharge WOMAN's tolerability and impact on quality of life (Figure-3).

For potential adverse events (AEs) requiring urgent laboratory results, specific parameters were analyzed in local laboratories for immediate clinical guidance; however, only centrally obtained laboratory results were considered study data. In cases of serious adverse events (SAEs), local lab results were included in safety reporting. Quality control measures ensured data accuracy and reliability, with missing data resolved through site communication. Study sites provided direct access to all study-related documents for monitoring, auditing, and regulatory inspections. Compliance with Good Clinical Practice (GCP) and regulatory requirements was verified through periodic on-site and remote monitoring visits. Source data, including medical records, laboratory reports, investigator notes, and pharmacy logs, were maintained for study reconstruction. The sponsor and designated CRO monitored study centers, ensuring protocol adherence, data integrity, and GCP compliance. Investigator staff received training from the sponsor and CRO before and during the study on study design, regulatory responsibilities, and investigational product details. Case Report Form (CRF) data were entered into a validated database, subjected to quality control checks, and clarified through site queries to ensure data accuracy and completeness.

Statistical Analysis

The statistical analysis was conducted by the responsible biostatistician, following a predefined Statistical Analysis Plan (SAP), which detailed the analysis methods, table specifications, listings, and figures. The SAP was finalized before database lock, and any deviations were documented and justified in the Clinical Study Report (CSR). All analyses were thoroughly documented. Descriptive statistics were used to summarize data, with continuous variables presented as mean, standard deviation (SD), median, minimum, and maximum, while categorical variables were expressed as frequency and percentage. The primary endpoints of the study included changes in hemoglobin levels, menstrual health (flow and cramp intensity), and perceived improvements in stamina, skin glow, and hair fall reduction (Table 7 and Figure 4). Additionally, the study assessed for increased energy levels, and enhancements in quality of life scores. These parameters were evaluated to determine the overall efficacy of Nutricharge WOMAN in promoting women's health and well-being.

The secondary endpoint of the study focused on safety evaluation, assessing the number of adverse events (AEs) and their causal relationship to the study drug. A total of 100 subjects were enrolled, ensuring 80% power, a 5% level of significance, a 5% superiority margin, a 5% standard deviation, and a 10% dropout rate, to effectively evaluate the efficacy and safety of Nutricharge WOMAN.

Table 1: Key Baseline Demographic Characteristics

Parameter	Statistics	Treatment Group (N=100)
Age (years)	n	100
	Mean ± SD	23.83 ± 8.48
	Median	23.00
	Quantile	17.00;30.00
	Range	12.00 - 48.00
Height (Cms)	n	100
	Mean ± SD	163.02 ± 8.49
	Median	167.00
	Quantile	159.50;170.00
	Range	143.00 - 175.00
Weight (Kgs)	n	100
	Mean ± SD	54.79 ± 9.28
	Median	54.02
	Quantile	47.55;63.06
	Range	36.01 - 74.01
BMI (Kg/m^2)	n	100
	Mean ± SD	20.51 ± 2.29
	Median	20.40
	Quantile	18.70;21.92
	Range	14.70 - 25.60

Note: n=Total number of subjects; SD=Standard Deviation.

Table 2: Summary of baseline characteristics

Parameter	Statistics	Visit 2 (Day 0)	Visit 3 (Day 90)	Visit 4 (Day 120)
Heart/Pulse Rate (beats per minute)	n	100	100	100
	Mean ± SD	73.86 ± 7.73	81.80 ± 7.71	83.25 ± 6.84
	Median	72.00	80.00	82.00
	Quantile	69.00; 76.00	76.00; 90.00	76.00; 86.00
	Range	61.00 - 96.00	70.00 - 96.00	72.00 - 98.00
Systolic Blood Pressure (mm Hg)	n	100	100	100
	Mean ± SD	114.48 ± 12.29	115.93 ± 9.53	117.62 ± 8.55
	Median	117.00	120.00	120.00
	Quantile	103.50; 124.00	110.00; 120.00	114.00; 122.50
	Range	90.00 - 136.00	96.00 - 130.00	98.00 - 134.00
Diastolic Blood Pressure (mm Hg)	n	100	100	100
	Mean ± SD	78.02 ± 7.21	81.53 ± 7.29	81.95 ± 6.03
	Median	78.00	80.00	80.00
	Quantile	72.00; 84.00	76.00; 88.00	80.00; 86.00
	Range	62.00 - 94.00	70.00 - 96.00	70.00 - 96.00
Temperature (°F)	n	100	100	100
	Mean ± SD	97.84 ± 0.50	98.36 ± 0.33	98.27 ± 0.37
	Median	97.70	98.40	98.40
	Quantile	97.40; 98.20	98.20; 98.60	98.20; 98.60
	Range	97.20 - 98.80	97.40 - 98.80	97.40 - 98.60
Respiratory Rate (breaths per minute)	n	100	100	100
	Mean ± SD	17.11 ± 0.72	17.30 ± 0.58	17.26 ± 0.61
	Median	17.00	17.00	17.00
	Quantile	17.00; 18.00	17.00; 18.00	17.00; 18.00
	Range	16.00 - 19.00	16.00 - 18.00	16.00 - 18.00

Figure 1: Changes in Hemoglobin Levels Over Time

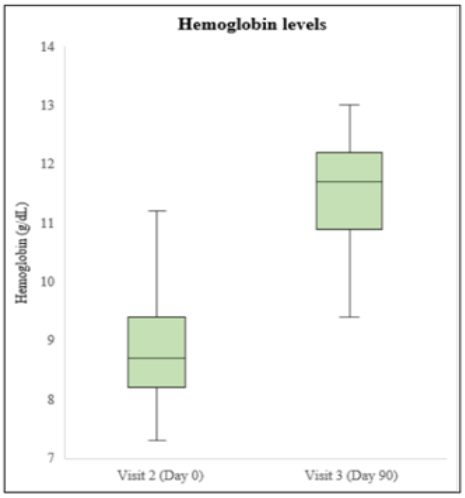


Table 3: Hemoglobin Level Changes Categorized by Abnormalities over Time

Lab	Visit 2 (Day 0)		Visit 3 (Day 90)		p-value
	n (%)	Mean ± SD	n (%)	Mean ± SD	
Hemoglobin (g/dL)	**100 (100.00%)**	**8.83 ± 0.89**	**100 (100.00%)**	**11.53 ± 0.84**	**<0.001**
Normal			37 (37.00%)	12.35 ± 0.27	
Abnormal NCS	84 (84.00%0	8.82 ± 0.91	53 (53.00%)	10.95 ± 0.68	
Abnormal CS	16 (16.00%)	8.86 ± 0.81	10 (10.00%)	11.55 ± 0.34	

Note: N- Total number of subjects in the group; n- Number of subjects; SD- Standard Deviation; p-value is calculated using paired t-test.

Figure 2: Hemoglobin Level Variation for Categories Below and Above 10g/dL over Time

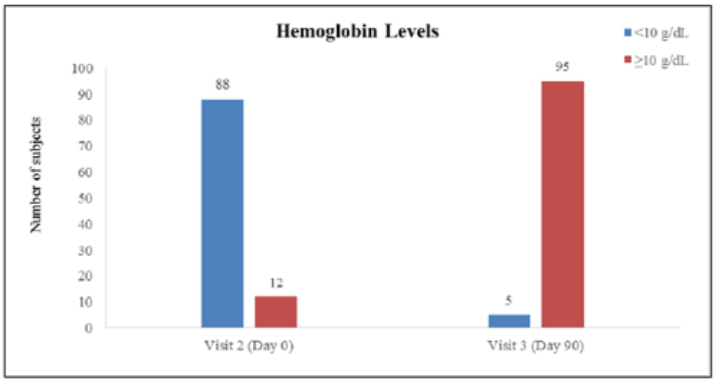


Table 4: Evaluation of Hemoglobin Variations by Abnormality Categories over Time

Lab	Visit 2 (Day 0)		Visit 3 (Day 90)		p-value
	n (%)	Mean ± SD	n (%)	Mean ± SD	
Hemoglobin (g/dL)	**100 (100.00%)**	**8.83 ± 0.89**	**100 (100.00%)**	**11.53 ± 0.84**	**<0.001**
<10 g/dL	**88 (88.00%)**	**8.6 ± 0.66**	**5 (5.00%)**	**9.64 ± 0.21**	
Abnormal NCS	74 (74.00%)	8.59 ± 0.67	5 (5.00%)	9.64 ± 0.21	
Abnormal CS	14 (14.00%)	8.64 ± 0.58			
≥10 g/dL	**12 (12.00%)**	**10.52 ± 0.36**	**95 (95.00%)**	**11.63 ± 0.74**	
Normal			37 (37.00%)	12.35 ± 0.27	
Abnormal NCS	10 (10.00%)	10.54 ± 0.39	48 (48.00%)	11.09 ± 0.55	
Abnormal CS	2 (2.00%)	10.4 ± 0	10 (10.00%)	11.55 ± 0.34	

Note: N- Total number of subjects in the group; n- Number of subjects; SD- Standard Deviation; p-value is calculated using paired t-test.

Table 5: Evaluation of Overall Health

Parameter	Visit 2 (Day 0)		Visit 3 (Day 90)		Visit 4 (Day 120)	
	n	%	n	%	n	%
Overall health	**100**	**100.00%**	**100**	**100.00%**	**100**	**100.00%**
Fair	55	55.00%	4	4.00%	4	4.00%
Good	43	43.00%	50	50.00%	50	50.00%
Very Good	2	2.00%	44	44.00%	44	44.00%
Excellent	-	-	2	2.00%	2	2.00%

Note: n- Number of subjects.

Figure 3: Progress in Overall Health

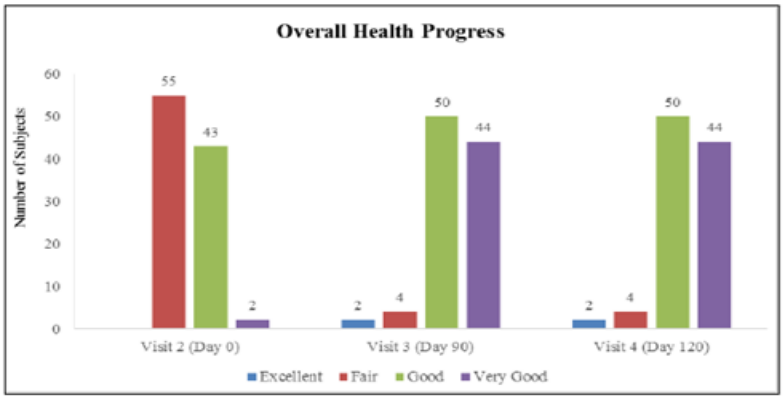


Table 6: Overview of Menstrual period (Menstrual cycle, cramps and flow)

Parameter	Visit 2 (Day 0)		Visit 3 (Day 90)		Visit 4 (Day 120)	
	n	%	n	%	n	%
Menstrual Cycle						
Duration of menstrual cycle	**100**	**100.00%**	**100**	**100.00%**	**100**	**100.00%**
4-5 days	10	10.00%	34	34.00%	34	34.00%
4-6 days	4	4.00%	-	-	-	-
5-6 days	13	13.00%	27	27.00%	27	27.00%
5-8 days	5	5.00%	-	-	-	-
6-7 days	44	44.00%	32	32.00%	32	32.00%
6-8 days	7	7.00%	1	1.00%	1	1.00%
7-8 days	4	4.00%	6	6.00%	6	6.00%
8-9 days	12	12.00%	-	-	-	-
8-10 days	1	1.00%	-	-	-	-
Regularity of menstrual cycle	**100**	**100.00%**	**100**	**100.00%**	**100**	**100.00%**
Irregular	-	-	4	4.00%	4	4.00%
Somewhat Regular	73	73.00%	35	35.00%	35	35.00%
Very Regular	27	27.00%	61	61.00%	61	61.00%
Any premenstrual symptoms	**100**	**100.00%**	**100**	**100.00%**	**100**	**100.00%**
No	-	-	15	15.00%	15	15.00%
Yes	100	100.00%	85	85.00%	85	85.00%
Menstrual Cramp						
Severity of menstrual cramps	**100**	**100.00%**	**100**	**100.00%**	**100**	**100.00%**
Mild	19	19.00%	41	41.00%	41	41.00%
Moderate	49	49.00%	59	59.00%	59	59.00%
Severe	32	32.00%	-	-	-	-
Menstrual Flow						
Heaviness of menstrual flow	**100**	**100.00%**	**100**	**100.00%**	**100**	**100.00%**
Heavy	61	61.00%	7	7.00%	7	7.00%
Moderate	39	39.00%	75	75.00%	75	75.00%
Light	-	-	18	18.00%	18	18.00%
Any changes in menstrual flow during the course of cycle	**100**	**100.00%**	**100**	**100.00%**	**100**	**100.00%**
No	91	91.00%	74	74.00%	74	74.00%
Yes	9	9.00%	26	26.00%	26	26.00%

Note: n- Number of subjects.

Figure 4: Assessment of Menstrual Cramps and Flow

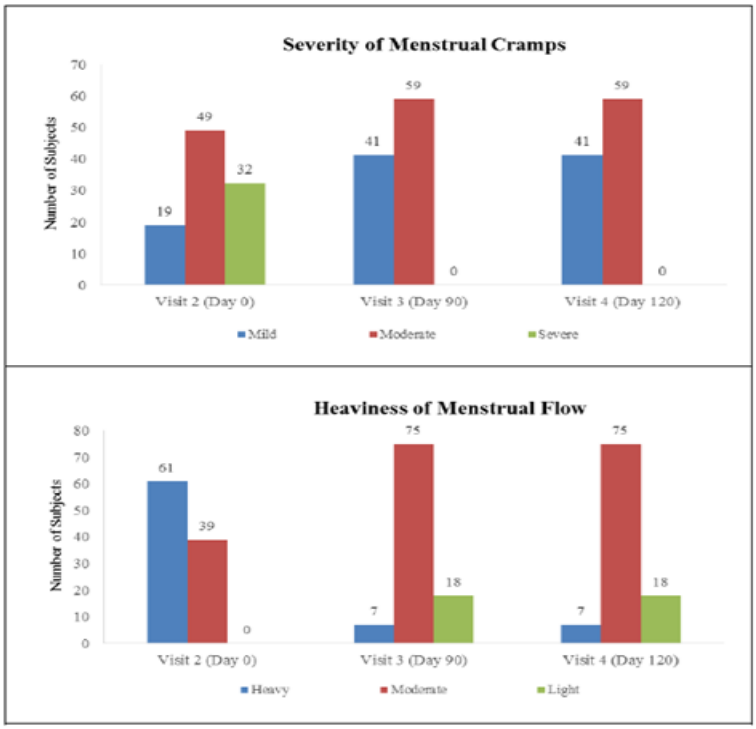


Table 7: Summary of Working Stamina

Parameter	Visit 2 (Day 0)		Visit 3 (Day 90)		Visit 4 (Day 120)	
	n	%	n	%	n	%
Working Stamina						
Energy levels during menstrual cycle	100	100.00 %	100	100.00 %	100	100.00 %
High	1	1.00%	2	2.00%	2	2.00%
Moderate	84	84.00%	94	94.00%	94	94.00%
Low	15	15.00%	4	4.00%	4	4.00%
Any impact of menstrual cycle on efficiency at work or in daily activities	100	100.00 %	100	100.00 %	100	100.00 %
No	91	91.00%	98	98.00%	98	98.00%
Yes	9	9.00%	2	2.00%	2	2.00%

Note: n- Number of subjects.

Figure 5: Change in energy levels during menstrual cycle

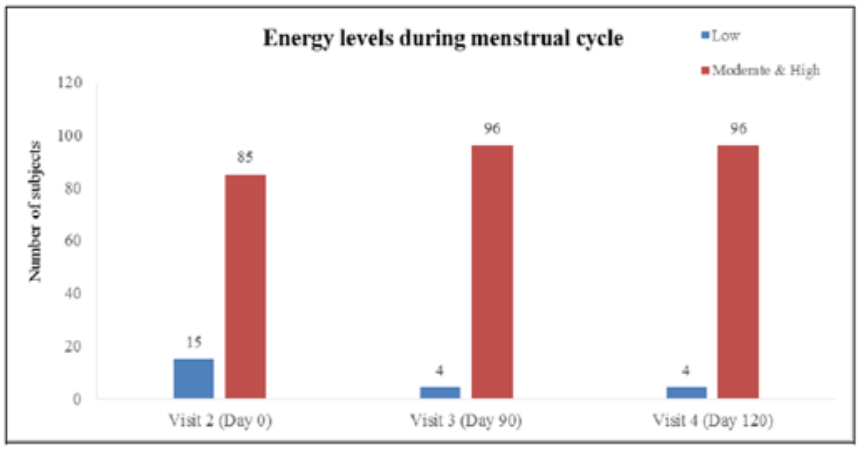
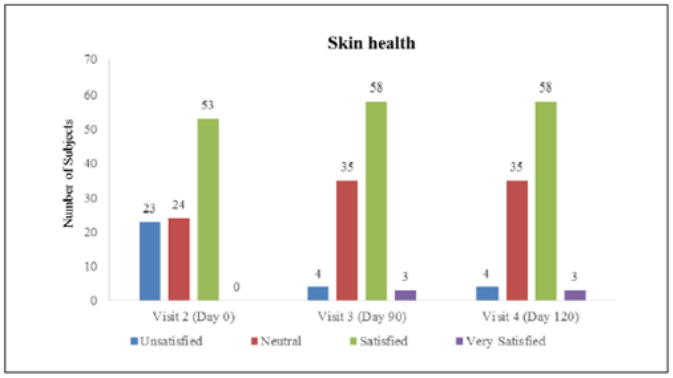


Table 8: Assessment of skin and hair health

Parameter	Visit 2 (Day 0)		Visit 3 (Day 90)		Visit 4 (Day 120)	
	n	%	n	%	n	%
Skin and hair health						
Satisfactory level with respect to health of skin	100	100.00%	100	100.00%	100	100.00 %
Unsatisfied	23	23.00%	4	4.00%	4	4.00%
Neutral	24	24.00%	35	35.00%	35	35.00%
Satisfied	53	53.00%	58	58.00%	58	58.00%
Very Satisfied	-	-	3	3.00%	3	3.00%
Satisfactory level with respect to health of hair	100	100.00%	100	100.00%	100	100.00 %
Unsatisfied	31	31.00%	5	5.00%	5	5.00%
Neutral	19	19.00%	32	32.00%	32	32.00%
Satisfied	50	50.00%	63	63.00%	63	63.00%

Note: n- Number of subjects.

Figure 6: Hair and skin health evaluation



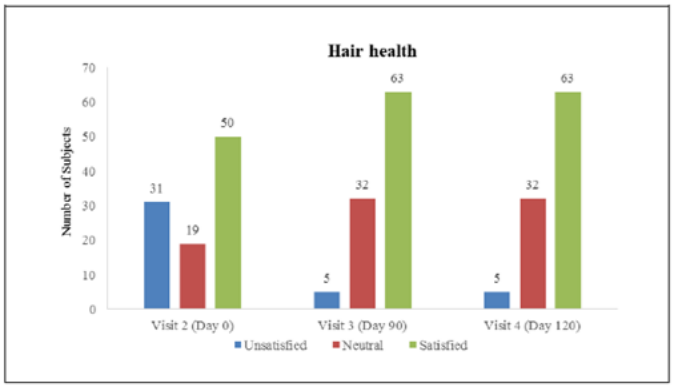


Table-9: Overview of general health

Parameter	Visit 2 (Day 0)		Visit 3 (Day 90)		Visit 4 (Day 120)	
	n	%	n	%	n	%
General Health						
Regular physical activity or exercise	100	100.00%	100	100.00%	100	100.00%
No	54	54.00%	50	50.00%	50	50.00%
Yes	46	46.00%	50	50.00%	50	50.00%
Stress levels on a typical day	100	100.00%	100	100.00%	100	100.00%
Low	6	6.00%	39	39.00%	39	39.00%
Moderate	94	94.00%	61	61.00%	61	61.00%
Any chronic health conditions	100	100.00%	100	100.00%	100	100.00%
No	100	100.00%	99	99.00%	99	99.00%
Yes	-	-	1	1.00%	1	1.00%

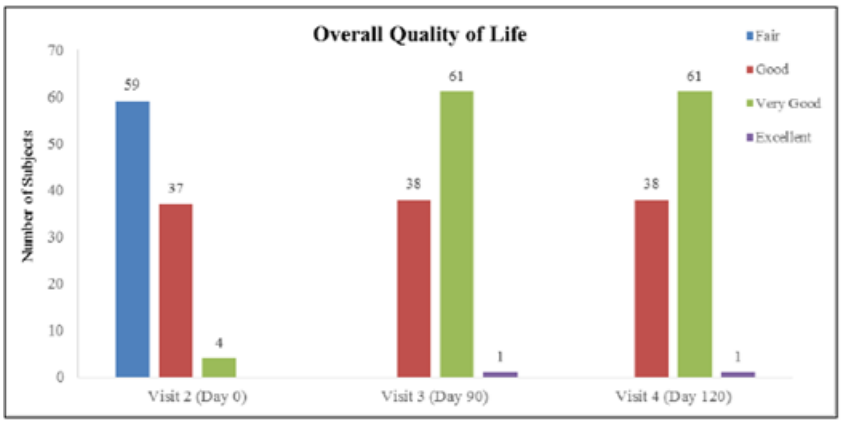
Note: n- Number of subjects.

Table 10: Progress of quality of life

Parameter	Visit 2 (Day 0)		Visit 3 (Day 90)		Visit 4 (Day 120)	
	n	%	n	%	n	%
Overall quality of life	100	100.00%	100	100.00%	100	100.00%
Fair	59	59.00%	-	-	-	-
Good	37	37.00%	38	38.00%	38	38.00%
Very Good	4	4.00%	61	61.00%	61	61.00%
Excellent	-	-	1	1.00%	1	1.00%

Note: n- Number of subjects.

Figure 7: Improvement in overall quality of life



Efficacy Conclusions

The study demonstrated a significant improvement in hemoglobin levels, with mean values increasing from 8.83 ± 0.89 g/dL (range: 7.30–11.20) at Visit 2 to 11.53 ± 0.84 g/dL (range: 9.40–13.00) at Visit 3. At Visit 2, 88 subjects had hemoglobin <10 g/dL, which reduced to 5 subjects at Visit 3, while those with hemoglobin ≥10 g/dL increased from 12 subjects (Visit 2) to 95 subjects (Visit 3).

Health assessments indicated a notable overall improvement. Self-reported health ratings increased significantly, with 55 subjects initially reporting their health as ―fair‖ at Visit 2. By Visit 4, 44 of these subjects rated their health as ―very good,‖ and 2 subjects reported it as ―excellent‖.

The majority of participants reported menstrual cycle durations ranging between 4–7 days. Cycle regularity showed marked improvement, with the number of participants reporting ―very regular‖ cycles increasing from 27 at Visit 2 to 61 at both Visit 3 and Visit 4 (Figure-5).

A significant reduction in menstrual cramps was observed. At Visit 2, 32 participants experienced severe cramps. By Visit 3, no cases of severe cramps were reported, indicating a complete resolution in this group.

Heavy menstrual flow decreased considerably over the study period. At Visit 2, 61 participants reported heavy flow. This number dropped to just 7 participants by Visit 3 and remained stable at Visit 4. The majority of participants transitioned to reporting moderate flow.

Energy levels during menstruation improved, with moderate levels increasing from 84 subjects (Visit 2) to 94 subjects (Visit 3 and 4), while those experiencing low energy reduced from 15 subjects to 4 subjects. Skin and hair health satisfaction increased, with satisfaction in skin health rising from 53 subjects (Visit 2) to 58 subjects (Visit 3 and 4), and satisfaction in hair health improving from 50 subjects (Visit 2) to 63 subjects (Visit 3 and 4) (Table-8 & Figure 6).

Physical activity levels increased, with subjects engaging in regular exercise rising from 46 (Visit 2) to 50 (Visit 3 and 4). Stress levels improved, with those experiencing "low stress" increasing from 6 subjects at Visit 2 to 39 subjects at Visit 3 and 4. Chronic health conditions remained rare, with only 1 subject reporting a condition at Visit 3 and 4. Overall quality of life improved, with subjects rating their quality of life as "very good" increasing from 4 subjects (Visit 2) to 61 subjects (Visit 3 and 4) and "excellent" in 1 subject at Visit 3 and 4 (Table 9 &10, Figure 7).

Table 11: Overview of Adverse Events during the study

AE		n	%
Fever			
Severity: Mild	*Action Take: No change in IP*	1	1.00%
Treatment: No	*Relation: Not Related to IP*		
Outcome: Resolved			
Headache			
Severity: Mild	*Action Take: No change in IP*	1	1.00%
Treatment: No	*Relation: Not Related to IP*		
Outcome: Resolved			
Vomiting			
Severity: Moderate	*Action Take: No change in IP*	1	1.00%
Treatment: No	*Relation: Not Related to IP*		
Outcome: Resolved			

Note: n- Number of subjects.

A total of 3 adverse events were reported in 3 subjects in the study. Among the 3 adverse events 1 event was fever, severity was mild, no treatment given for the adverse event, not related to study drug. 1 was headache, severity was mild, no treatment given for the adverse event, not related to study drug and 1 event was vomiting severity was moderate, no treatment given for the adverse event, not related to study drug. The outcome of all 3 adverse events reported in the study was resolved. No SAEs and deaths were reported in the study (Table:11).

NUTRICHARGE WOMAN significantly improved hemoglobin levels, skin health, menstrual health, hair health, and overall quality of life from baseline to study completion. It presents a promising option for enhancing Hb%, reducing hair loss, improving skin health, and supporting women's overall well-being.

Discussion

Efficacy in Hemoglobin Improvement

- Nutricharge WOMAN significantly improved hemoglobin levels.
- Effectively addressed anemia and its associated symptoms in women of reproductive age.

Menstrual Health Benefits

- Reduction in menstrual cramps, heavy menstrual bleeding, and irregular cycles.

Improvement in Energy and Daily Functioning

- Participants reported increased energy levels, contributing to enhanced daily performance and overall well-being.

Positive Effects on Skin and Hair Health

- Notable decrease in hair fall.
- Improvement in skin appearance, including enhanced skin glow.

Safety and Tolerability

- The supplement was well-tolerated with minimal adverse effects.
- Demonstrated a favorable safety profile for long-term use.

Psychological and Lifestyle Impact

- Reduction in perceived stress levels.

- Improved engagement in physical activity.

Enhanced Quality of Life

- Significant improvement in overall quality of life scores, indicating a broad spectrum of health benefits.

Conclusion

Nutricharge WOMAN demonstrated significant efficacy in improving hemoglobin levels, menstrual health, and overall quality of life in women of reproductive age. The supplement was well-tolerated, with minimal adverse effects reported throughout the study. Participants experienced enhanced skin and hair health, along with improved energy levels and well-being. A notable reduction in menstrual cramps and heavy flow was observed, contributing to better menstrual health. The supplement also led to higher satisfaction levels regarding overall health, including skin and hair condition. Additionally, stress levels decreased, and a greater number of participants reported engaging in regular physical activity by the end of the study. The study findings suggest that Nutricharge WOMAN can serve as an effective nutritional intervention for women experiencing deficiencies. Given these promising results, further large-scale, multi-center trials are recommended to confirm the benefits across diverse populations.

References

1. Rama R, Govindaraju V, Rao S. Nutraceuticals: Potential role in health and disease prevention. J Clin Biochem Nutr. 2006;39(1):50-57.
2. Kalra EK. Nutraceutical-definition and introduction. AAPS Pharm Sci. 2003;5(3):27-30.
3. Patel VB, Preedy VR. Handbook of nutrition, diet, and epigenetics. Springer; 2017.
4. Nasri H, Bahmani M, Shahinfard N, Nafchi AM, Saberianpour S, Kopaei MR. Medicinal plants and bioactive natural compounds in the treatment of anemia: A review. J Renal Inj Prev. 2014;3(3):137-140.
5. Gupta RC, Srivastava A, Lall R. Nutraceuticals in health and disease prevention. Springer; 2016.
6. Dror DK, Allen LH. The importance of vitamin B12 for children: A review. Am J ClinNutr. 2008;87 (6): 1447-1453.
7. Kaur S, Kaur N, Sidhu P. Role of nutraceuticals in prevention of diseases. Asian J Pharm Clin Res. 2019;12(2):50-54.
8. Faridi S, Mahta A, Ali RM, Faridi F. Nutraceuticals: Role in prevention and treatment of various diseases. J Adv Pharm Technol Res. 2019;10(2):55-64.
9. Balasubramanian P, Duraisamy R, Saravanan A, et al. Functional foods and nutraceuticals: An overview. J Food Sci Technol. 2020;57(5):1857-1869.
10. González-Sarrías A, Azorín-Ortuño M, Yáñez-Gascón MJ, et al. The effect of a polyphenol-rich diet on iron metabolism in women with iron deficiency anemia. Br J Nutr. 2013;110(12):2262-2271.
11. Rizzo G, Lagana AS, Rapisarda AMC, et al. Vitamin B12 among vegetarians: Status, assessment, and supplementation. Nutrients. 2016;8(12):767.
12. Rajeswari G, Naga Jyothi V. Role of functional foods and nutraceuticals in health and disease: A review. Int J Adv Res Med Sci. 2021;3(1):10-18.
13. Choudhury H, Pandey M, Hua CK, et al. An update on natural compounds in the remedy of diabetes mellitus: A systematic review. J Tradit Complement Med. 2018;8(3):361-376.
14. Aluko RE. Functional foods and nutraceuticals. Springer; 2012.
15. Lobo V, Patil A, Phatak A, Chandra N. Free radicals, antioxidants and functional foods: Impact on human health. Pharmacogn Rev. 2010;4(8):118-126.

16. Quagliani D, Felt-Gunderson P. Closing America's fiber intake gap: Communication strategies from a food and fiber summit. Nutrients. 2017;9(8):708.
17. Mishra S, Sharma V, Pandey H. Nutraceuticals and their role in human health: A review. Pharma Innov J. 2020;9(4):248-252.
18. Cornelli U. Antioxidant use in nutraceuticals. Clin Dermatol. 2009;27(2):175-194.
19. Tripathi P, Misra A, Kesharwani P. Nutraceuticals in the prevention and treatment of metabolic syndrome. J Control Release. 2019;295:60-76.
20. KandasamyP, Arulselvan P, Marimuthu S, Kumar S, Banu R. Role of flavonoids as nutraceuticals in human health. Int J Pharm Sci Rev Res. 2018; 51 (1): 1-6.
21. Papanikolaou Y, Fulgoni VL. Grains, dietary fiber, and cardiometabolic health: A review of the evidence. Nutrients. 2020;12(8):2345.
22. Sánchez-Sánchez JL, Mera D, Salinas-Martínez AM, et al. Effect of omega-3 fatty acids on quality of life in women with dysmenorrhea. J Obstet Gynaecol Res. 2019;45(2):239-246.
23. Cummings JH, Engineer A. The use of prebiotics and probiotics in health and disease. Food Nutr Bull. 2018;39(2):61-71.
24. Hassan W, Noreen H, Rehman S, et al. Association of iron with oxidative stress in women suffering from anemia. J Nutr Metab. 2017;2017:1-6.
25. Gibson RS, Heath AL, Ferguson EL. Risk of zinc deficiency in populations consuming plant-based diets. J Nutr. 2008;138(12):1987-1992.