

# GS AYURVEDA MEDICAL COLLEGE & HOSPITAL

N.H.-9, Pilkhuwa, Dist. Hapur (U.P.) - 245304

## CLINICAL STUDY REPORT

*A Randomized Controlled Clinical Trial to Evaluate the Immunomodulatory Profile of a Poly-herbal Compound Oc22 on Apparently Healthy Volunteers.*


[CTRI/2022/05/042366]

[15/05/2022 - 16/09/2022]

**CONFIDENTIAL**

## SIGNATURE PAGES FOR CLINICAL STUDY REPORT

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Signed: 

Date: **08-10-2022**

Name: **Mr. Arun Gaur**

Affiliation: Sponsor

Address: M/s Saatvik Enterprises, Shop No-226,2<sup>nd</sup> floor. Mall-Saviour street, Commercial plot no. C-3, Crossing Republic, Dundaheera, NH-24, Ghaziabad, U.P. 201016, India

Signed: 

Date: **08-10-2022**

Name: **Vd. Shubham Garg**

Affiliation: Principle Investigator

Address: GS Ayurveda Medical College & Hospital, Hapur


Signed: 

Date: **08-10-2022**

Name: **Dr. Yogita Bisht**

Affiliation: Co- Investigator

Address: GS Ayurveda Medical College & Hospital, Hapur

Signed: 

Date: **08-10-2022**

Name: **Dr. Bhavna Singh**

Affiliation: Medical Advisor

Address: GS Ayurveda Medical College & Hospital, Hapur

Signed: 

Date: **08-10-2022**

Name: **Dr. Ankur Singhal**

Affiliation: Medical Advisor

Address: GS Ayurveda Medical College & Hospital, Hapur

## **TITLE PAGE**

Study Title : A Randomized Controlled Clinical Trial to Evaluate Immuno-modulatory Profile of a Poly-herbal Compound OC22 on Apparently Healthy Volunteers

Name of Test Compound : OC22

Indication studied : Immunomodulation

Study description : Efficacy study of a Nutraceutical Compound

Sponsors : M/s Saatvik Enterprises

Study dates : 15/05/2022 - 16/09/2022

Principal Investigator : Vd. Shubham Garg

Co- Investigator : Dr. Yogita Bisht

Sponsor signatory : Mr. Arun Gaur

GCP Statement : This study was performed in compliance with ICH Good Clinical Practice (GCP) including the archiving of essential documents

Date of report : 30/09/22

# 1 SYNOPSIS

<b>NAME OF SPONSOR</b>	- M/s Saatvik Enterprises									
<b>NAME OF FINISHED PRODUCT</b>	- OC22									
<b>NAME OF ACTIVE INGREDIENT(S)</b> -	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="text-align: center;"><i>Prunus dulcis</i></td></tr> <tr><td style="text-align: center;"><i>Elettaria cardamomum</i></td></tr> <tr><td style="text-align: center;"><i>Vitis vinifera</i></td></tr> <tr><td style="text-align: center;"><i>Piper nigrum</i></td></tr> <tr><td style="text-align: center;"><i>Glycyrrhiza glabra</i></td></tr> <tr><td style="text-align: center;"><i>Withania somnifera</i></td></tr> <tr><td style="text-align: center;"><i>Ocimum tenuiflorum</i></td></tr> <tr><td style="text-align: center;"><i>Phoenix dactylifera</i></td></tr> <tr><td style="text-align: center;"><i>Phyllanthus emblica</i></td></tr> </table>	<i>Prunus dulcis</i>	<i>Elettaria cardamomum</i>	<i>Vitis vinifera</i>	<i>Piper nigrum</i>	<i>Glycyrrhiza glabra</i>	<i>Withania somnifera</i>	<i>Ocimum tenuiflorum</i>	<i>Phoenix dactylifera</i>	<i>Phyllanthus emblica</i>
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<i>Ocimum tenuiflorum</i>										
<i>Phoenix dactylifera</i>										
<i>Phyllanthus emblica</i>										
<b>Title of Study</b>	A Randomized Controlled Clinical Trial to Evaluate the Immunomodulatory Profile of a Poly-herbal Compound OC22 on Apparently Healthy Volunteers									
<b>Investigator(s)</b>	<p><b>Principal Investigator: Vd. Shubham Garg</b> Associate Professor Dept. of Dravyaguna GSAMCH, Hapur, U.P., India</p> <p><b>Co-Investigator: Dr. Yogita Bisht</b> Associate Professor Dept. of Kayachikitsa GSAMCH, Hapur, U.P., India</p>									
<b>Study centre</b>	GS Ayurveda Medical College and Hospital									
<b>Study period</b>	From: 15/05/2022      To: 16/ 09/2022									

Objectives	<p><u>Primary Objective</u> -To explore the immunomodulatory activity of a poly-herbal compound OC22 by ISQ (Immune Status Questionnaire) on apparently healthy volunteers</p> <p><u>Secondary Objective</u> - To explore the effect of a poly-herbal compound OC22 on IgG, IgM in apparently healthy volunteers</p>
Methodology	<p><b>Type of study design:</b> A longitudinal prospective double arm interventional study.</p> <p><b>Study Type:</b> Interventional (Clinical) Trial  <b>Sub-type:</b> Double Arm  <b>Endpoint Classification:</b> Efficacy Study  <b>Intervention Model:</b> Longitudinal prospective study  <b>Masking:</b> Open label  <b>Primary Purpose:</b> Supportive Care  <b>Timing:</b> Prospective  <b>Age:</b> 20-40 years  <b>Groups:</b> 2 groups (Group A: Intervention, Group B: Control)  <b>Duration of Trial:</b> 4 months  <b>Setting:</b> OPD no. 7, GS Ayurveda Medical College and Hospital, Pilkhuwa, Hapur, Uttar Pradesh, India  <b>Population:</b> Apparently healthy volunteers i.e., students and staff members of GSAMCH</p>
Number of patients	<p>Planned: 60</p> <p>Analysed: 60</p>
Diagnosis and main criteria for inclusion	<p>1-Apparently Healthy individuals aged 20-40 years of either sex.  2-Individuals giving consent for participation.</p>
Test product, dose and mode of administration	<p>OC22, 6g powder, administered orally with water, once daily i.e. empty stomach in morning for 3 months.</p>
Duration of intervention	<p>3 months</p>
Criteria for evaluation	<p>Primary: Improvement in Immune status by ISQ at baseline and 3 months from Baseline  Secondary: Changes in Immunoglobulin (IgG, IgM) levels at baseline and 3 months from baseline</p>
Statistical methods	<p>T test (paired and unpaired), Repeated measure ANOVA, Wilcoxon sign rank test</p>

## **SUMMARY CONCLUSIONS**

**EFFICACY RESULTS:** The compound is significantly effective in improving the immune status, evaluated through a validated tool i.e. ISQ (Immune status Questionnaire)

The study reveals that Group A (intervention group) has performed better than Group B (control group) which achieves the primary objective of the study.

**SAFETY RESULTS:** The compound is found safe and no adverse effects were encountered during the study duration.

### **CONCLUSION**

The study results suggest that the poly-herbal compound OC22 has significantly improved the immune status of apparently healthy individuals. The compound exhibited no adverse effects and is found to be safe for use.

**DATE OF THE REPORT: 30/09/22**

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## 2. LIST OF ABBREVIATIONS

1. IgG	:	Immunoglobulin G
2. IgM	:	Immunoglobulin M
3. BT	:	Before Treatment
4. AT	:	After Treatment
5. HB	:	Haemoglobin
6.TLC	:	Total Leukocyte Count
7. DLC	:	Differential Leukocyte Count
8. RBC	:	Red Blood Cells
9. PCV	:	Packed-cell Volume
10.MCV	:	Mean Corpuscular Volume
11.MCH	:	Mean Corpuscular Haemoglobin
12.MCHC	:	Mean Corpuscular Haemoglobin Concentration
13.ESR	:	Erythrocyte Sedimentation Rate
14.SGOT	:	Serum Glutamic-oxaloacetic Transaminase
15.SGPT	:	Serum Glutamic Pyruvic Transaminase
16.A/G	:	Albumin Globulin Ratio
17.RFT	:	Renal Function Tests
18.CRP	:	C-reactive Protein
19.pH	:	Potential of Hydrogen
20.F	:	F-Test
21.t	:	Student's t- test
22.df	:	Degree of freedom
23.Sig.	:	Statistical significance
24.ISQ	:	Immune Status Questionnaire

### 3. ETHICS AND REGULATORY APPROVAL

#### 3.1 INDEPENDENT ETHICS COMMITTEE APPROVAL

The study protocol and all its amendments, and the patient information sheet(s), consent form(s) were reviewed and approved by the appropriate independent ethics committee as detailed in table 1 below.

**Table 1: Ethics committee**

Centre name	GS Ayurveda Medical College and Hospital
Ethics committee	IEC GS Ayurveda Medical College and Hospital
Chairman	Dr. P.K. Prajapati
Date of approval of the final protocol	04/04/2022

#### 3.2 ETHICAL CONDUCT OF THE STUDY

The study was performed in accordance with the guidelines of Good Clinical Practice (GCP).

#### 3.3 PATIENT INFORMATION AND CONSENT SHEET

All patients were provided written information sheets and their consent to participate in the study prior to being screened was taken.

The patient information sheet detailed the procedures involved in the study (aim, methodology, potential risks, anticipated benefits) and the investigator explained these to each patient. The patient signed the consent form to indicate that the information had been well explained in his/her own language and understood properly. The patient was then allowed time to consider the information presented before signing and dating the informed consent form to indicate that they fully understood the information, and willingly volunteered to participate in the study. The patient was given a copy of the informed consent form for their information. The original copy of the informed consent was kept in a confidential file in the Investigators' centre records. A sample of the patient information sheet and consent form can be found at appendix.

## 4. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

Table 2 shows the principal study personnel involved in the study.

**Table 2: Principal study personnels**

Title	Name and affiliation
Principal Investigator	Vd. Shubham Garg Associate Professor GS Ayurveda Medical College and Hospital
Co investigator	Dr Yogita Bisht Associate Professor GS Ayurveda Medical College & Hospital
Sponsor	M/s Saatvik Enterprises  Address- Dheeraj Gaur, Shop no. 226, 2nd floor, Mall-Saviour street, Commercial plot no. C-3, Crossing Republic, Dundahera, NH-24, Ghaziabad, U P.201016, India  Type of Sponsor- Pharmaceutical industry-Indian
Clinical Research Associate	Ms. Richa Singh Ramjas College, University of Delhi
Medical Advisor(s)	Dr. Bhavna Singh Principal GSAMC&H  Dr. Ankur Singhal (M.S.) GSAMC&H
Laboratory investigator	Mr. Sanjeev GSAMC&H
Data Management	Mr. Lokesh Singh GSAMC&H

## **5. INTRODUCTION**

**5.1 THERAPEUTIC AREA:** Immunomodulatory activity of a polyherbal compound OC22

### **5.2 RATIONALE FOR THE STUDY:**

A healthy life is the desire of all individuals. In today's era, people are exposed to improper life- style, environment pollution, harmful chemicals like fertilisers, pesticides, preservatives and mental stress which eventually lead to compromised immune functions. The primary aim of healthcare is not just to cure diseases but also to prevent them. Considering the terribly affected immunity of our community, it is the need of the hour to improve community health and prevent chronic diseases by supporting the immune functions of the body. The polyherbal compound OC22 comprises the herbs which have already been used as an immunity booster for years now. References regarding their potent immunity enhancer actions are found in our ancient literature as well as certain folk communities have been using this combination for years in their traditional therapy system. This study has been undertaken to explore the immunomodulatory activity of this polyherbal composition on various subjective and objective immunological parameters.

## 6. STUDY OBJECTIVES

Primary Objective- To explore the immune-modulatory activity of a poly-herbal compound OC22 by ISQ (Immune Status Questionnaire) on apparently healthy volunteers.

Secondary Objective -To explore the effect of a poly-herbal compound OC22 on IgG, IgM in apparently healthy volunteers

## 7. INVESTIGATIONAL PLAN

### 7.1 OVERALL STUDY DESIGN AND PLAN

- IEC approval was taken for the study at first. CTRI registration was done.
- 67 volunteers were screened out of which 60 were selected and enrolled for the study.
- These 60 subjects were randomly divided into 2 groups by computer generated randomisation.
- Baseline subjective and objective assessment of participants was performed.
- Intervention group subjects were administered with 6g powder of poly-herbal compound OC22 with water, once daily i.e. empty stomach in morning for 3 months.
- Post intervention assessment was done for subjective and objective criteria.

**7.1.1. Study Time/Duration of trial:** The trial was of 4 months with weekly telephonic follow up

**7.1.2 Study Location:** OPD no. 7,GS Ayurveda Medical College and Hospital, Pilkhuwa, Hapur, Uttar Pradesh, India

### 7.2 SELECTION OF STUDY POPULATION

The study population comprises students, faculty members and staff members of GS Ayurveda medical College & Hospital, Pilkhuwa, U.P., India.

#### 7.2.1 INCLUSION CRITERIA

- Apparently healthy individuals aged 20-40 years of either sex.
- Individuals giving consent for participation.

### 7.2.2 EXCLUSION CRITERIA

- Individuals with chronic comorbid conditions which might have affected the immune status of the individual.
- Pregnant or lactating mother
- Person on any interventional drug like vitamin/mineral/hormonal supplements/protein supplements etc or any other nutritional supplements

### 7.2.3 Withdrawal of patients from therapy or assessment: None

## 7.3. INTERVENTIONS

**7.3.1 COMPOUND ADMINISTERED:** The OC22 compound was administered. Intervention subjects were administered with 6g powder of this poly-herbal compound with water, once daily i.e. empty stomach in morning for 3 months.

### 7.3.2 DESCRIPTION OF INVESTIGATIONAL PRODUCT

**Poly-herbal compound OC22 Procurement:** The poly-herbal compound received from the manufacturer, comprising the following ingredients:

**Table 3: List of ingredients in OC22**

S.No.	Ingredient	English
1.	<i>Prunus dulcis</i>	Almond
2.	<i>Elettaria cardamomum</i>	Cardamom
3.	<i>Vitis vinifera</i>	Raisins
4.	<i>Piper nigrum</i>	Black Pepper
5.	<i>Glycyrrhiza glabra</i>	Liquorice
6.	<i>Withania somnifera</i>	Winter Cherry
7.	<i>Ocimum tenuiflorum</i>	Basil
8.	<i>Phoenix dactylifera</i>	Dates
9.	<i>Phyllanthus emblica</i>	Indian Gooseberry

### 7.3.3 METHOD OF ASSIGNING PATIENTS TO TREATMENT GROUPS

- Division of the subjects into two groups : using the computerised random sequence generator.
- Each subject was assigned a number and using the above method two groups with 30 members each were formed.
- The two groups were then designated as group A and group B. Using the coin toss method, group A was chosen to be the intervention group and group B as the non-intervention group.

## 7.4 EFFICACY AND SAFETY MEASUREMENTS ASSESSED

### Efficacy Measures Assessed

1. ISQ
2. IgG and IgM
3. General examination: Appearance, Nutrition status, Decubitus, Hair Skin and nail, Eye, Ear, Nose, Throat, Tongue, Pallor, Icterus, Cyanosis, Clubbing, Lymphadenopathy, Edema
4. Vital Signs: Temperature(°F), Pulse rate, Respiratory rate, Blood pressure

### Safety Measures Assessed

1. Laboratory Tests:  
Haematological Investigations: CBC, ESR, KFT, LFT, CRP  
Urine analysis: Urine routine and microscopic investigation

### 7.4.1 STATISTICAL AND ANALYTICAL PLANS

Statistical Analysis plan: The Baseline Characteristics between groups were analysed using the  $\chi^2$  method. If  $p < 0.05$  then it can be concluded that distribution of that variable between groups is significantly different, otherwise not. Pair-T test used to test within group change of repeated observations (BT/AT) and Independent T-test used to compare change between groups.

Test of normality is done and if it reveals significant variation from normality, Non-parametric test "Wilcoxon sign rank test" was done between groups.

Repeated measure ANOVA done when observations are repeated more than two times using General Linear Model which checks for sphericity (This checks if variation between repetitions of observation is constant.). If not assumption of sphericity is violated and then Greenhouse-Geisser correction is used when sphericity is violated (If calculated  $\epsilon > 0.75$ ) and is treated as with significant variation. So within and between variation is checked for significance.

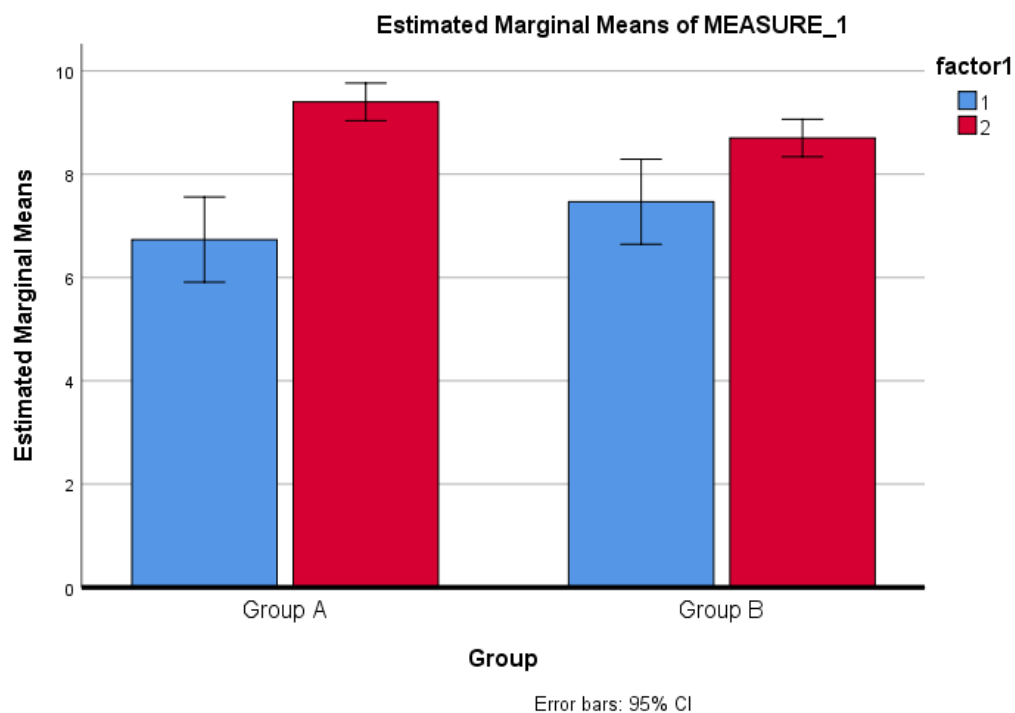
## RESULTS

- Repeated measure ANOVA was used as there were 2 groups which were analysed 3 times during the study course. It reveals that Group A has performed better than Group B. This is true for the study's primary criteria, i.e. Immune Status Questionnaire (ISQ), general health, immune functioning, reduced immunity at present and chronic disease condition.

**Table 4: Descriptive Statistics**

	Group	Mean	Std. Deviation	N
ISQ1	Group A	6.73	2.518	30
	Group B	7.47	1.961	30
	Total	7.10	2.268	60
ISQ3	Group A	9.40	.855	30
	Group B	8.70	1.119	30
	Total	9.05	1.048	60

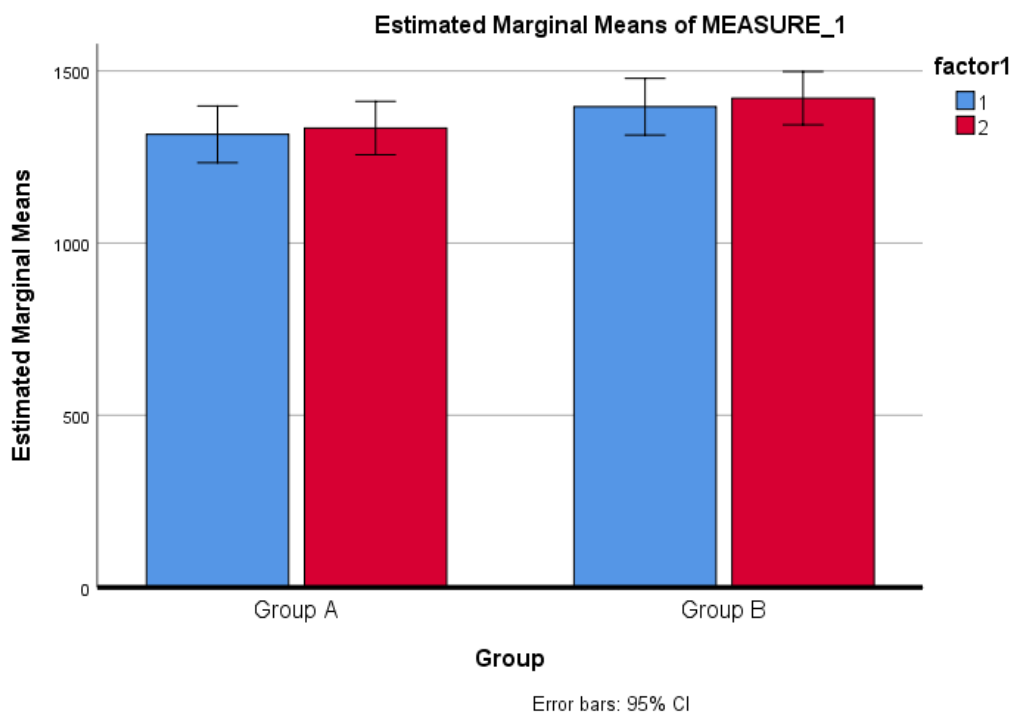
**Figure 1:**



**Table 5: Descriptive Statistics**

	Group	Mean	Std. Deviation	N
IgG_BT	Group A	1315.90	223.481	30
	Group B	1396.13	227.537	30
	Total	1356.02	227.229	60
IgG_AT	Group A	1334.00	182.173	30
	Group B	1420.70	237.363	30
	Total	1377.35	214.281	60

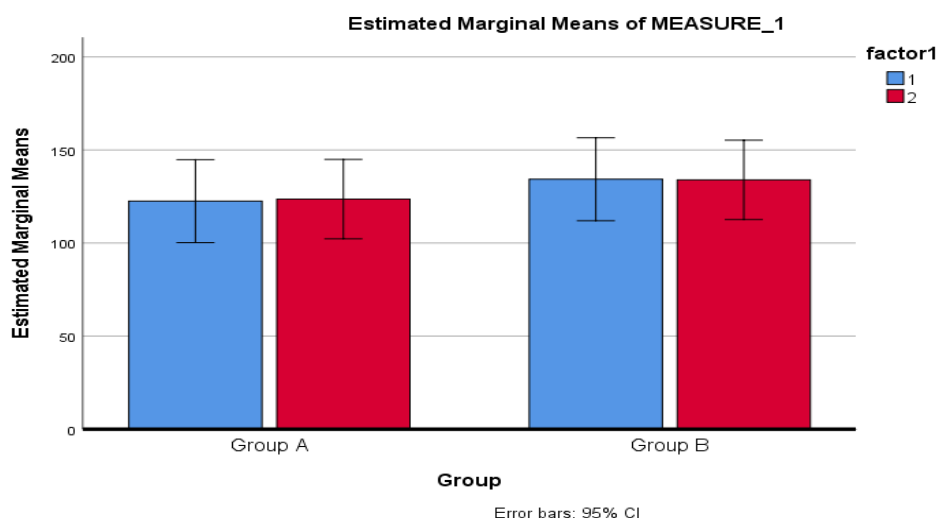
**Figure 2:**



**Table 6: Descriptive Statistics**

	Group	Mean	Std. Deviation	N
IgM_BT	Group A	122.50	53.448	30
	Group B	134.27	67.653	30
	Total	128.39	60.738	60
IgM_AT	Group A	123.58	52.151	30
	Group B	133.91	63.938	30
	Total	128.74	58.080	60

**Figure 3:**



- There is significant improvement in temperature, respiratory rate and immune functioning of the participants of group 1 after completion of 3 months of intervention of nutraceutical compound OC22.
- **Group A:** There is significant improvement in levels of neutrophils, lymphocytes, monocytes, MCV, MCH, total bilirubin (indirect bilirubin), SGOT, SGPT, albumin, globulin, A/G ratio, blood urea, sodium, and urine pH after intervention of 3 months.
- **Group B:** There is significant improvement in levels of TLC, lymphocytes, monocytes, MCV, MCH, MCHC, platelet count, SGOT, SGPT, alkaline phosphatase, albumin, globulin, A/G ratio, blood urea, serum creatinine, sodium, and urine pH.
- This data suggests that Serum Creatinin levels and PH both have significantly declined from BT to AT. Between the group study suggests that there is significant difference in the values of SGPT, serum creatinine and urine pH levels between the participants of group 1 and group 2 after the trial duration.
- **Group A:** Significant changes are seen in values of monocytes, MCV, MCH, total bilirubin, indirect bilirubin, SGOT, albumin, globulin, A/G ratio and serum sodium.
- **Group B:** Significant changes are seen in levels of TLC, monocytes, MCV, MCHC, platelet count, SGOT, SGPT, albumin, globulin, A/G ratio, blood urea, serum creatinine and serum sodium.

## 8.1 DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

**Table 7. list of demographic and other baseline characteristics**

	Valid		Cases Missing		Total	
	N	Percent	N	Percent	N	Percent
Group * Sex	60	100.0%	0	0.0%	60	100.0%
Group * Occupation	60	100.0%	0	0.0%	60	100.0%
Group * MS	60	100.0%	0	0.0%	60	100.0%
Group * Appearance	60	100.0%	0	0.0%	60	100.0%
Group * Nutritional Status	60	100.0%	0	0.0%	60	100.0%
Group * Decubitus	60	100.0%	0	0.0%	60	100.0%
Group * Hair	60	100.0%	0	0.0%	60	100.0%
Group * Skin and Nails	60	100.0%	0	0.0%	60	100.0%
Group * Eyes	60	100.0%	0	0.0%	60	100.0%
Group * Ear nose & throat	60	100.0%	0	0.0%	60	100.0%
Group * Tongue	60	100.0%	0	0.0%	60	100.0%
Group * Pallor	60	100.0%	0	0.0%	60	100.0%
Group * Icterus	60	100.0%	0	0.0%	60	100.0%
Group * Cyanosis	60	100.0%	0	0.0%	60	100.0%
Group * Clubbing	60	100.0%	0	0.0%	60	100.0%
Group * Lymphadenopathy	60	100.0%	0	0.0%	60	100.0%
Group * Edema	60	100.0%	0	0.0%	60	100.0%
Group * Appetite	60	100.0%	0	0.0%	60	100.0%
Group * Bowel	60	100.0%	0	0.0%	60	100.0%
Group * Bladder	60	100.0%	0	0.0%	60	100.0%
Group * Sleep	60	100.0%	0	0.0%	60	100.0%
Group * Diet	60	100.0%	0	0.0%	60	100.0%
Group * Addiction	60	100.0%	0	0.0%	60	100.0%
Group * Socioeconomic Status	60	100.0%	0	0.0%	60	100.0%
Group * Nadi	60	100.0%	0	0.0%	60	100.0%
Group * Mala	60	100.0%	0	0.0%	60	100.0%
Group * Mutra	60	100.0%	0	0.0%	60	100.0%
Group * Jiwah	59	98.3%	1	1.7%	60	100.0%
Group * Shabdh	60	100.0%	0	0.0%	60	100.0%
Group * Sparsh	60	100.0%	0	0.0%	60	100.0%
Group * Netra	60	100.0%	0	0.0%	60	100.0%
Group * Aakriti	60	100.0%	0	0.0%	60	100.0%
Group * Prakriti	60	100.0%	0	0.0%	60	100.0%
Group * Sara	60	100.0%	0	0.0%	60	100.0%
Group * Sanhanana	60	100.0%	0	0.0%	60	100.0%
Group * Satmya	60	100.0%	0	0.0%	60	100.0%
Group * Satva	60	100.0%	0	0.0%	60	100.0%
Group * Pramana	60	100.0%	0	0.0%	60	100.0%
Group * Ahara shakti	60	100.0%	0	0.0%	60	100.0%
Group * Vyayama vyayam	60	100.0%	0	0.0%	60	100.0%

In this study, it was observed that no subject was lost to follow up; study was conducted successfully on all the sixty subjects. All the measures mentioned above in the table were taken up for consideration during study. These included- sex, occupation , marital status, appearance, nutritional status, skin and nails, eyes, ear-

nose & throat, tongue, pallor, icterus, cyanosis, clubbing, lymphadenopathy, edema, appetite, bowel, bladder, sleep, diet, addiction, socioeconomic status, nadi, mala, mutra, jiwah, shabdh, sparsh, netra, aakriti, prakriti, sara, sanhanana, satmya, satva, pramana, aharashakti and vyayamshakti.

During the study subjects were divided randomly (computer generated randomisation) into two separate groups to perform the comparative analysis of the trial drug-OC22 on them. Group A was then assigned to be the intervention group using the coin toss method, while group B was assigned as the non-intervention group. All the measures taken are separately discussed below using tables and chi-square test, a very efficient method of statistical data representation along with the graphs to make the study easier to understand and effective as well.

## DEMOGRAPHIC STUDY

### Sex

**Table 8: Table showing sex wise distribution of groups**

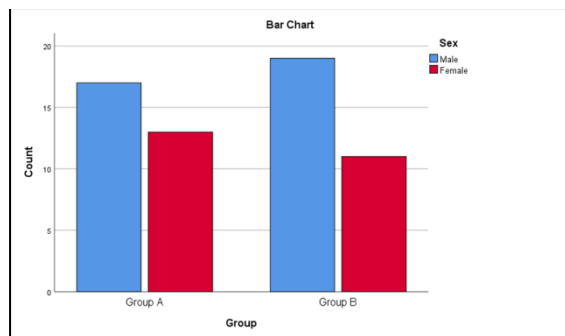
Group		Sex		Total
		Male	Female	
Group A	Count	17	13	30
	% within Group	56.7%	43.3%	100.0%
Group B	Count	19	11	30
	% within Group	63.3%	36.7%	100.0%
Total	Count	36	24	60
	% within Group	60.0%	40.0%	100.0%

**Table 9: Table showing Chi-Square Tests for sex wise**

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.278 <sup>a</sup>	1	.598		
Continuity Correction <sup>b</sup>	.069	1	.792		
Likelihood Ratio	.278	1	.598		
Fisher's Exact Test				.792	.396
N of Valid Cases	60				

- a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 12.00.
- b. Computed only for a 2x2 table

**Figure 1: Bar diagram showing sex wise group significance**



The selection and further division of the subjects was done using random computerised method as described earlier and thus the number of males and females in Group A and Group B varies. Male =17 and female=13 in group A and male=19 and female=11 in group B.

## Occupation

**Table 10: Table showing occupation wise group distribution**

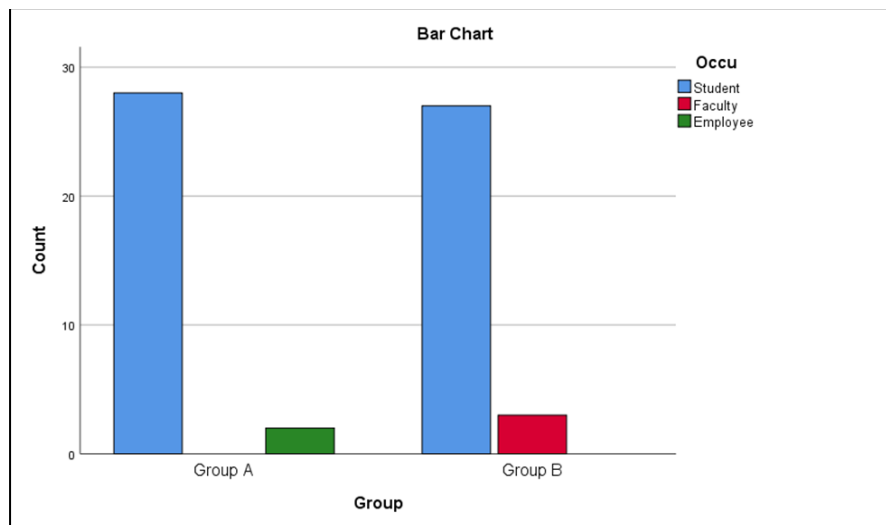
Group	Group	Count	Occupation			Total
			Student	Faculty	Employee	
Group A	Count	28	0	2	30	
	% within Group	93.3%	0.0%	6.7%	100.0%	
Group B	Count	27	3	0	30	
	% within Group	90.0%	10.0%	0.0%	100.0%	
Total	Count	55	3	2	60	
	% within Group	91.7%	5.0%	3.3%	100.0%	

**Table 11: Table showing Chi-Square Tests for occupation wise group distribution**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	5.018 <sup>a</sup>	2	.081
Likelihood Ratio	6.950	2	.031
Linear-by-Linear Association	.097	1	.756
N of Valid Cases	60		

a. 4 cells (66.7%) have expected count less than 5. The minimum expected count is 1.00.

**Figure 2: bar diagram showing occupation wise group distribution**



Most of the participants in group A were students, only 2 were employee. In case of group B, 27 were students while 3 were faculty members.

## Marital Status

**Table 12: Table showing marital status wise group distribution**

Group	Group	Marital Status		Total
		Un Married	Married	
Group A	Count	30	0	30
	% within Group	100.0%	0.0%	100.0%
Group B	Count	26	4	30
	% within Group	86.7%	13.3%	100.0%
Total	Count	56	4	60
	% within Group	93.3%	6.7%	100.0%

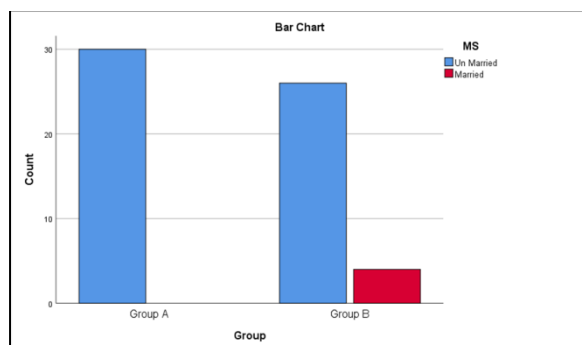
**Table 13: Table showing Chi-Square Tests for marital status wise distribution**

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	4.286 <sup>a</sup>	1	.038		
Continuity Correction <sup>b</sup>	2.411	1	.121		
Likelihood Ratio	5.831	1	.016		
Fisher's Exact Test				.112	.056
Linear-by-Linear Association	4.214	1	.040		
N of Valid Cases	60				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 2.00.

b. Computed only for a 2x2 table

**Figure 3: Bar diagram for marital status wise group presentation**



The subject's marital status was also recorded during the study and though the majority of our subjects were unmarried the exception of 4 members who were married were present in group B.

## Appearance

**Table 14: Table showing appearance wise group distribution**

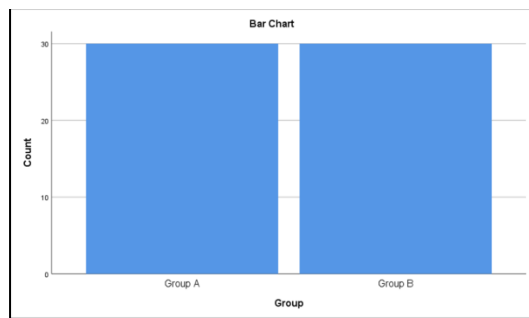
		Appearance	Total
		Healthy	
Group	Group A	Count	30
		% within Group	100.0%
	Group B	Count	30
		% within Group	100.0%
Total	Count	60	
	% within Group	100.0%	

**Table 15: Table showing Chi-Square Tests for appearance wise group significance**

	Value
Pearson Chi-Square	. <sup>a</sup>
N of Valid Cases	60

a. No statistics are computed because Appearance is a constant.

**Figure 4: bar diagram showing appearance wise group presentation**



All the subjects appeared normal during the study and didn't have any physical disability.

## Nutritional Status

**Table 16: Table showing nutritional status wise group distribution**

Group	Group A	Count	Nutritional Status		Total
			Good	Average	
			19	11	30
		% within Group	63.3%	36.7%	100.0%
	Group B	Count	27	3	30
		% within Group	90.0%	10.0%	100.0%
Total		Count	46	14	60
		% within Group	76.7%	23.3%	100.0%

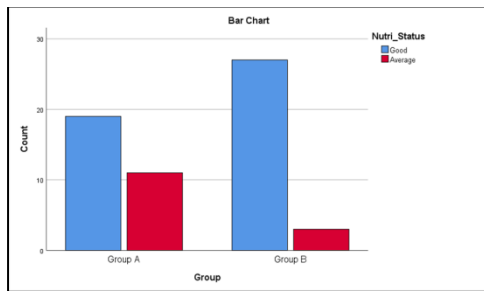
**Table 17: Table showing Chi-Square Tests for nutritional status wise group significance**

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	5.963 <sup>a</sup>	1	.015		
Continuity Correction <sup>b</sup>	4.565	1	.033		
Likelihood Ratio	6.258	1	.012		
Fisher's Exact Test				.030	.015
Linear-by-Linear Association	5.863	1	.015		
N of Valid Cases	60				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 7.00.

b. Computed only for a 2x2 table

**Figure 5: Bar diagram showing nutritional status wise group presentation**



The nutritional status of the majority was good overall but in Group A, 19 subjects were having good nutritional status while the other 11 had average nutritional status. In group B, 27 subjects were having good nutritional status and remaining 3 had average nutritional status.

## Decubitus

**Table 18: Table showing decubitus wise group distribution**

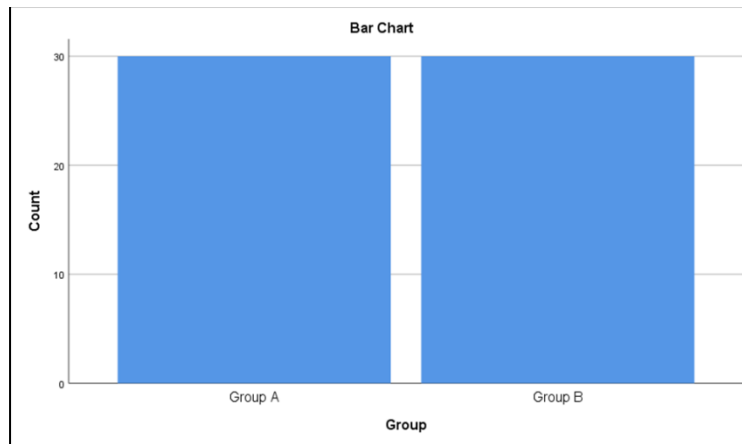
		Decubitus		Total
		Normal		
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total	Count	60	60	
	% within Group	100.0%	100.0%	

**Table 19: Table showing Chi-Square Test for decubitus wise group significance**

	Value
Pearson Chi-Square	. <sup>a</sup>
N of Valid Cases	60

a. No statistics are computed because Decubitus is a constant.

**Figure 6: Bar diagram showing decubitus wise group presentation**



All the participants in both the groups had normal decubitus.

## Hair

**Table 20: Table showing hair wise group distribution**

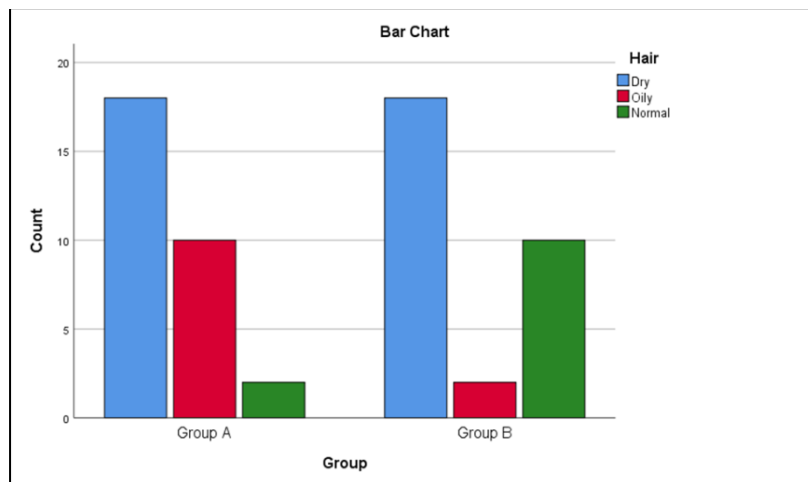
		Hair			Total	
		Dry	Oily	Normal		
Group	Group A	Count	18	10	2	30
		% within Group	60.0%	33.3%	6.7%	100.0%
	Group B	Count	18	2	10	30
		% within Group	60.0%	6.7%	33.3%	100.0%
Total		Count	36	12	12	60
		% within Group	60.0%	20.0%	20.0%	100.0%

**Table 21: Table showing Chi-Square Tests for hair wise group distribution**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	10.667 <sup>a</sup>	2	.005
Likelihood Ratio	11.644	2	.003
Linear-by-Linear Association	1.639	1	.200
N of Valid Cases	60		

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 6.00.

**Figure 7: Bar diagram showing hair wise group presentation**



It was observed that the texture of hair is dry in 18, oily in 10, and normal in 2 in the group A and 18 with dry, 2 with oily, and 10 with normal texture in group B.

## Skin and Nails

**Table 22: Table showing skin and nail wise group distribution**

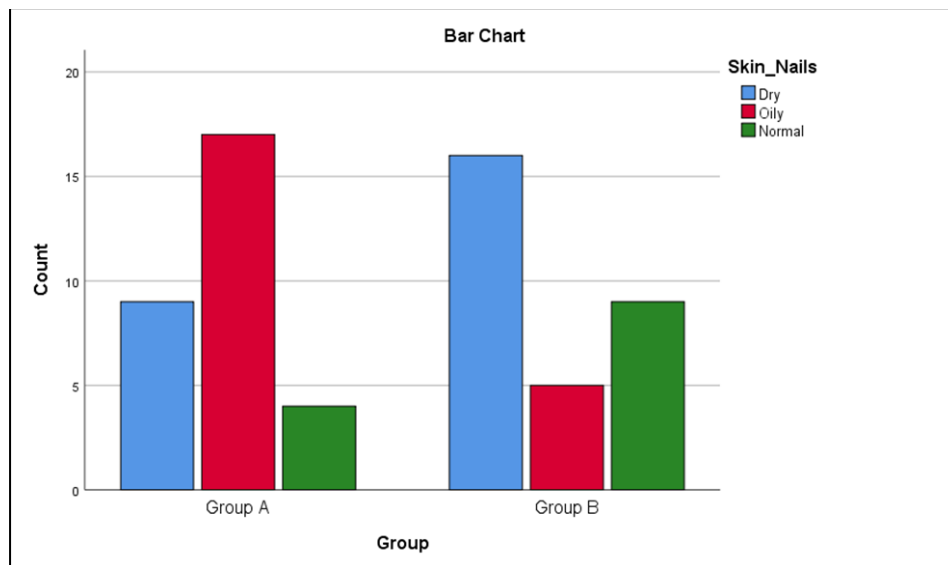
		Skin and Nails			Total	
		Dry	Oily	Normal		
Group	Group A	Count	9	17	4	30
		% within Group	30.0%	56.7%	13.3%	100.0%
	Group B	Count	16	5	9	30
		% within Group	53.3%	16.7%	30.0%	100.0%
Total	Count	25	22	13	60	
	% within Group	41.7%	36.7%	21.7%	100.0%	

**Table 23: Table showing Chi-Square Tests for skin and nail wise group significance**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	10.429 <sup>a</sup>	2	.005
Likelihood Ratio	10.876	2	.004
Linear-by-Linear Association	.110	1	.740
N of Valid Cases	60		

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 6.50.

**Figure 8: Bar diagram showing skin and nail wise group presentation**



The texture of skin and nails showed random variations with 9 having dry texture in group A and 16 in group B. 17 having oily texture in group A and 5 in group B. And 4 having normal texture in group A and 9 in group B.

## Eyes

**Table 24: Table showing eyes wise group distribution**

Group	Group A	Count	Eyes		Total
			NAD	Pain	
		28	2		30
		% within Group	93.3%	6.7%	100.0%
	Group B	30	0		30
		% within Group	100.0%	0.0%	100.0%
Total		58	2		60
		% within Group	96.7%	3.3%	100.0%

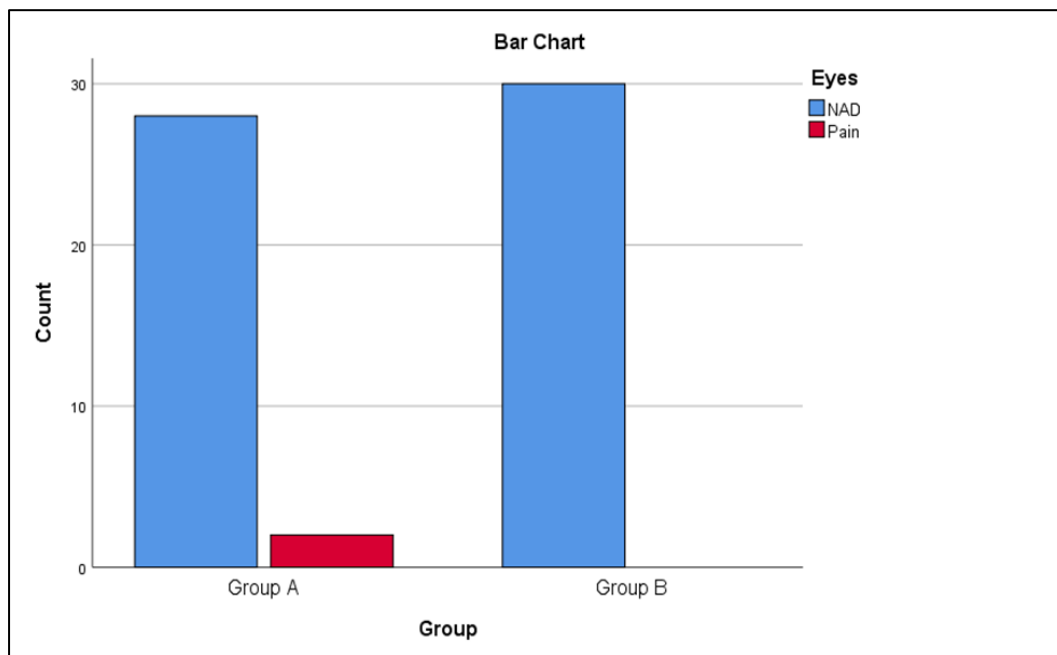
**Table 25: Table showing Chi-Square Tests for eyes wise group significance**

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2.069 <sup>a</sup>	1	.150		
Continuity Correction <sup>b</sup>	.517	1	.472		
Likelihood Ratio	2.842	1	.092		
Fisher's Exact Test				.492	.246
Linear-by-Linear Association	2.034	1	.154		
N of Valid Cases	60				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 1.00.

b. Computed only for a 2x2 table

**Figure 9: Bar diagram showing eyes wise group presentation**



In group A only two subjects had eye pain remaining 28 had no eye disease. In group B all subjects had normal eye functioning with no disease.

### ENT

**Table 26: Table showing ENT wise group distribution**

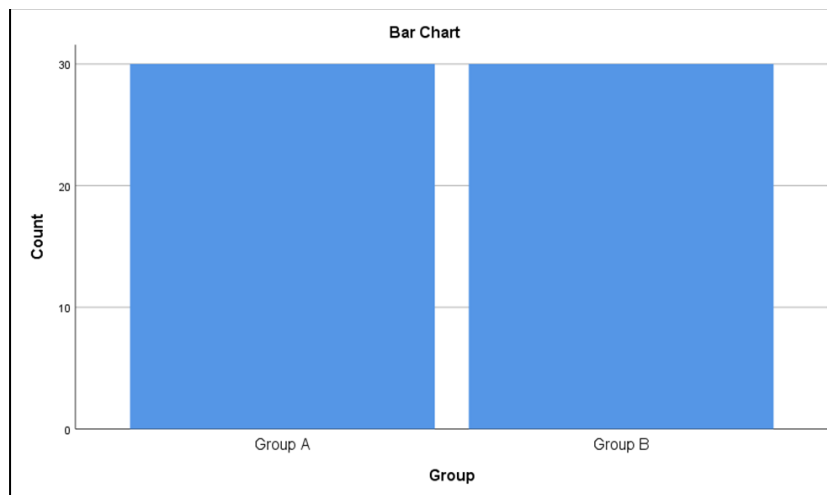
		ENT		Total
		NAD		
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total		Count	60	60
		% within Group	100.0%	100.0%

**Table 27: Table showing Chi-Square Tests for ENT wise group significance**

	Value
Pearson Chi-Square	. <sup>a</sup>
N of Valid Cases	60

a. No statistics are computed because ENT is a constant.

**Figure 10: Bar diagram showing ENT wise group presentation**



Both groups had no subjects with accessible disease in ear, nose and throat (ENT).

## Pallor

**Table 28: Table showing pallor wise group distribution**

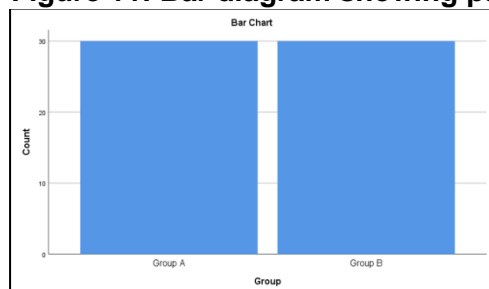
		Pallor Not Present	Total
Group	Group A	Count	30
		% within Group	100.0%
	Group B	Count	30
		% within Group	100.0%
Total		Count	60
		% within Group	100.0%

**Table 29: Table showing Chi-Square Tests for pallor wise group significance**

	Value
Pearson Chi-Square	.a
N of Valid Cases	60

a. No statistics are computed because Pallor is a constant.

**Figure 11: Bar diagram showing pallor wise group presentation**



In both groups none of the subjects had any pallor. All 60 subjects were healthy in appearance with no paleness.

## Icterus

**Table 30: Table showing icterus wise group distribution**

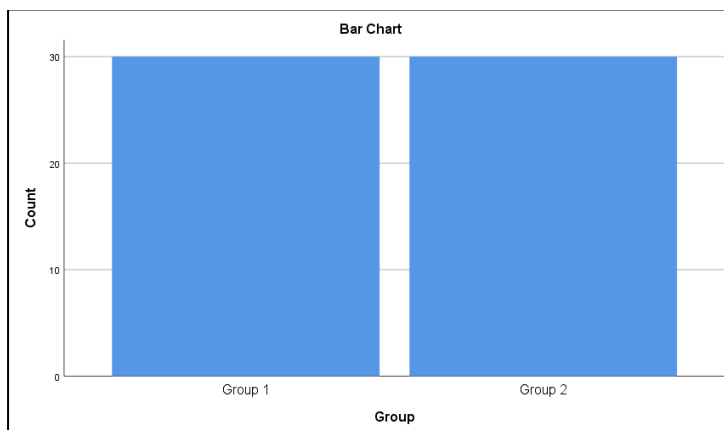
		Icterus		Total
		Not Present		
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total		Count	60	60
		% within Group	100.0%	100.0%

**Table 31: Table showing Chi-Square Tests for icterus wise group significance**

	Value
Pearson Chi-Square	. <sup>a</sup>
N of Valid Cases	60

a. No statistics are computed because Icterus is a constant.

**Figure 12: Bar diagram showing icterus wise group significance**



None of the subjects was observed with icterus. All 60 subjects lacked any such symptoms.

## Cyanosis

**Table 32: Table showing cyanosis wise group distribution**

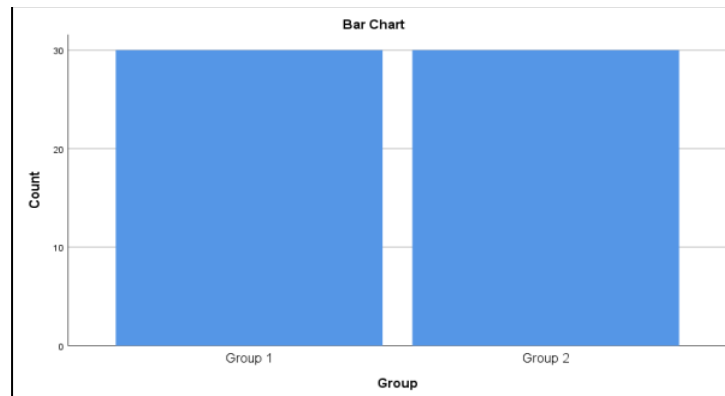
		Cyanosis		Total
		Not Present		
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total		Count	60	60
		% within Group	100.0%	100.0%

**Table 33: Table showing Chi-Square Tests for cyanosis wise group significance**

	Value
Pearson Chi-Square	.a
N of Valid Cases	60

a. No statistics are computed because Cyanosis is a constant.

**Figure 13: Bar diagram showing cyanosis wise group presentation**



Again during the study subjects were not observed to have cyanosis. All the 30 subjects of each group were free of the symptoms.

## Clubbing

**Table 34: Table showing clubbing wise group distribution**

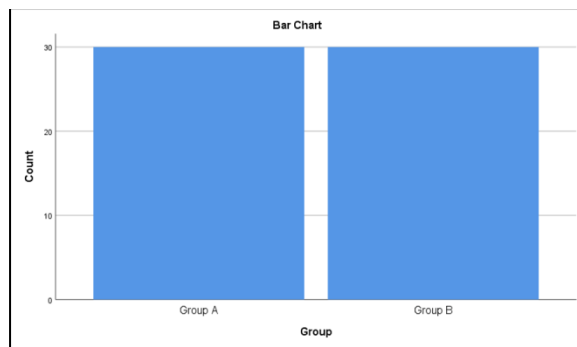
			Clubbing Not Present	Total
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total		Count	60	60
		% within Group	100.0%	100.0%

**Table 35: Table showing Chi-Square Tests for clubbing wise group significance**

	Value
Pearson Chi-Square	.a
N of Valid Cases	60

a. No statistics are computed because Clubbing is a constant.

**Figure 14: Bar diagram showing clubbing wise group presentation**



None of the subjects from any group had the symptoms of clubbing as well. All 60 subjects were free from any such symptoms.

## Lymphadenopathy

**Table 36: Table showing lymphadenopathy wise group distribution**

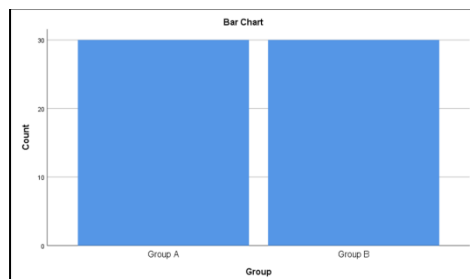
		Lymphadenopathy Not Present		Total
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total	Count	60	60	
	% within Group	100.0%	100.0%	

**Table 37: Table showing Chi-Square Tests for lymphadenopathy wise group significance**

	Value
Pearson Chi-Square	. <sup>a</sup>
N of Valid Cases	60

a. No statistics are computed because Lymphadenopathy is a constant.

**Figure 15: Bar diagram showing lymphadenopathy wise group presentation**



Lymphadenopathy study was also normal among all the 60 subjects and no member of any group had the lymphadenopathy present.

## Edema

**Table 38: Table showing edema wise group distribution**

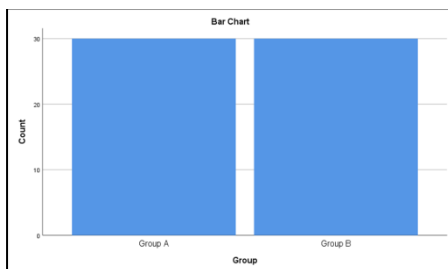
		Edema		Total
		Not Present		
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total		Count	60	60
		% within Group	100.0%	100.0%

**Table 39: Table showing Chi-Square Tests for edema wise group significance**

	Value
Pearson Chi-Square	. <sup>a</sup>
N of Valid Cases	60

a. No statistics are computed because Edema is a constant.

**Figure 16: Bar diagram showing edema wise group presentation**



Edema was not present in the subjects under the inspection for the study of the drug. None of the group had any subject with edema.

## **Appetite**

**Table 40: Table showing Appetite wise group distribution**

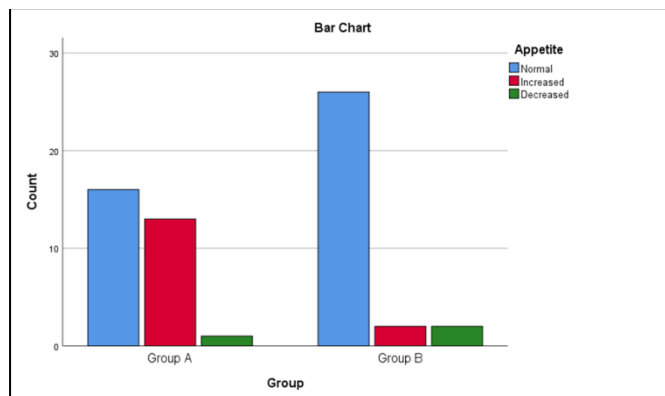
		Appetite			Total	
		Normal	Increased	Decreased		
Group	Group A	Count	16	13	1	30
		% within Group	53.3%	43.3%	3.3%	100.0%
	Group B	Count	26	2	2	30
		% within Group	86.7%	6.7%	6.7%	100.0%
Total		Count	42	15	3	60
		% within Group	70.0%	25.0%	5.0%	100.0%

**Table 41: Table showing Chi-Square Tests for appetite wise group significance**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	10.781 <sup>a</sup>	2	.005
Likelihood Ratio	11.758	2	.003
Linear-by-Linear Association	4.053	1	.044
N of Valid Cases	60		

a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is 1.50.

**Figure 17: Bar diagram showing appetite wise group presentation**



Study showed the subjects experienced an increase in appetite. 13 subjects from Group A i.e. the intervention group experienced an increase in their appetite while the other 16 had no change in the appetite. Also 1 subject experienced decrease in appetite. Result of non-intervention group: The results of group B were different where 2 subjects experienced decrease in appetite while two experienced increase in the appetite however maximum no i.e. 26 experienced no change.

## Bladder

**Table 42: Table showing bladder wise group distribution**

Group	Group A	Count	Bladder		Total
			Regular	Burning	
		29	1		30
		% within Group	96.7%	3.3%	100.0%
	Group B	Count	30	0	30
		% within Group	100.0%	0.0%	100.0%
Total		Count	59	1	60
		% within Group	98.3%	1.7%	100.0%

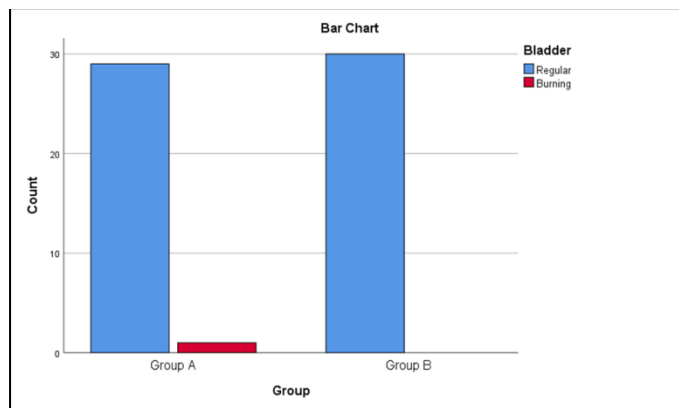
**Table 43: Table showing Chi-Square Tests for bladder wise group significance**

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.017 <sup>a</sup>	1	.313		
Continuity Correction <sup>b</sup>	.000	1	1.000		
Likelihood Ratio	1.403	1	.236		
Fisher's Exact Test				1.000	.500
Linear-by-Linear Association	1.000	1	.317		
N of Valid Cases	60				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is .50.

b. Computed only for a 2x2 table

**Figure 18: Bar diagram showing bladder wise group presentation**



None of the subjects had a complaint of burning bladder in group B while one of the subjects experienced this unease in group A.

## Sleep

**Table 44: Table showing sleep wise group distribution**

Group	Group	Count	Sleep		Total
			Normal	Disturbed	
	Group A	Count	27	3	30
		% within Group	90.0%	10.0%	100.0%
	Group B	Count	24	6	30
		% within Group	80.0%	20.0%	100.0%
Total		Count	51	9	60
		% within Group	85.0%	15.0%	100.0%

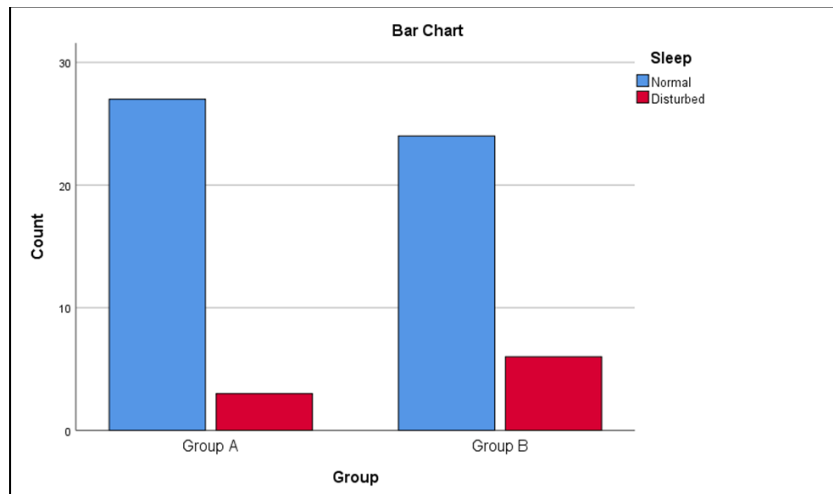
**Table 45: Table showing Chi-Square Tests for sleep wise group significance**

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.176 <sup>a</sup>	1	.278		
Continuity Correction <sup>b</sup>	.523	1	.470		
Likelihood Ratio	1.196	1	.274		
Fisher's Exact Test				.472	.236
Linear-by-Linear Association	1.157	1	.282		
N of Valid Cases	60				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 4.50.

b. Computed only for a 2x2 table

**Figure 19: Bar diagram showing sleep wise group presentation**



Three of the thirty subjects experienced disturbed sleep in group A while the number of such cases was 6 in group B.

## Diet

**Table 46: Table showing diet wise group distribution**

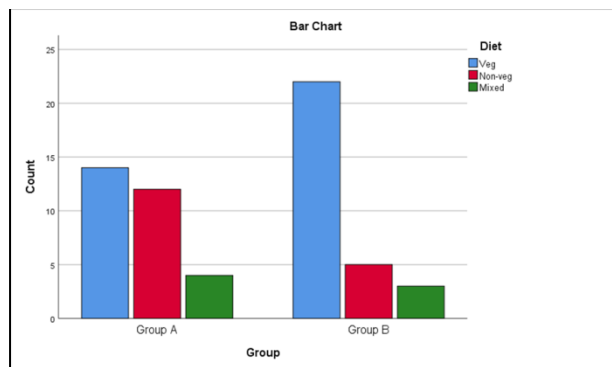
		Diet			Total	
		Veg	Non-veg	Mixed		
Group	Group A	Count	14	12	4	30
		% within Group	46.7%	40.0%	13.3%	100.0%
	Group B	Count	22	5	3	30
		% within Group	73.3%	16.7%	10.0%	100.0%
Total		Count	36	17	7	60
		% within Group	60.0%	28.3%	11.7%	100.0%

**Table 47: Table showing Chi-Square Tests for diet wise group significance**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	4.803 <sup>a</sup>	2	.091
Likelihood Ratio	4.906	2	.086
Linear-by-Linear Association	2.748	1	.097
N of Valid Cases	60		

a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is 3.50.

**Figure 20: Bar diagram showing diet wise group presentation**



In group A, 14 subjects were vegetarian while 12 were non vegetarian and 4 of them had mixed diet. In group B, 22 subjects were vegetarian and 5 were non vegetarian while 3 had mixed diet. The variation was due to their random distribution.

## Addiction

**Table 48: Table showing addiction wise group distribution**

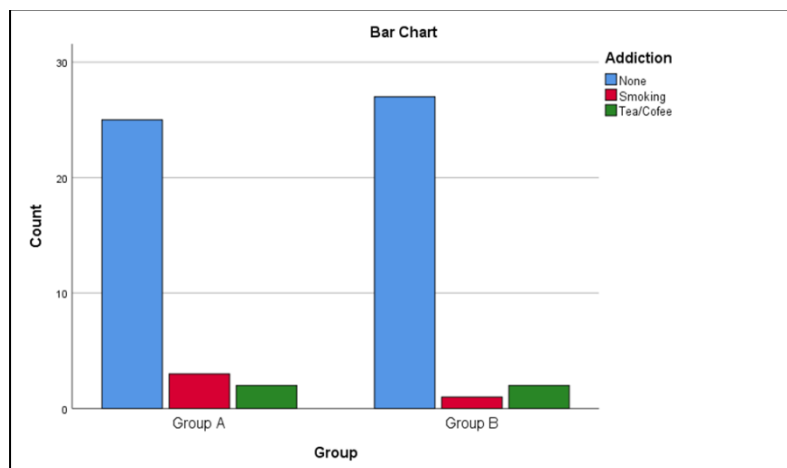
		Addiction			Total	
		None	Smoking	Tea/Coffee		
Group	Group A	Count	25	3	2	30
		% within Group	83.3%	10.0%	6.7%	100.0%
	Group B	Count	27	1	2	30
		% within Group	90.0%	3.3%	6.7%	100.0%
Total		Count	52	4	4	60
		% within Group	86.7%	6.7%	6.7%	100.0%

**Table 49: Table showing Chi-Square Tests for addiction wise group significance**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	1.077 <sup>a</sup>	2	.584
Likelihood Ratio	1.123	2	.570
Linear-by-Linear Association	.223	1	.636
N of Valid Cases	60		

a. 4 cells (66.7%) have expected count less than 5. The minimum expected count is 2.00

**Figure 21: Bar diagram showing addiction wise group presentation.**



The 3 of the subjects under study in group A had smoking addiction while 2 of them had tea and coffee addiction. The Remaining 25 had no addiction. In group B, 1 had an addiction to smoking, 2 had an addiction to tea and coffee and 27 of them had no addiction.

## Socioeconomic Status

**Table 50: Table showing socioeconomic status wise group distribution**

Group	Socioeconomic Status	Count	Middle Class	Upper Class	Total
			Class	Class	
Group A	Count	29	1	30	
	% within Group	96.7%	3.3%	100.0%	
Group B	Count	30	0	30	
	% within Group	100.0%	0.0%	100.0%	
Total	Count	59	1	60	
	% within Group	98.3%	1.7%	100.0%	

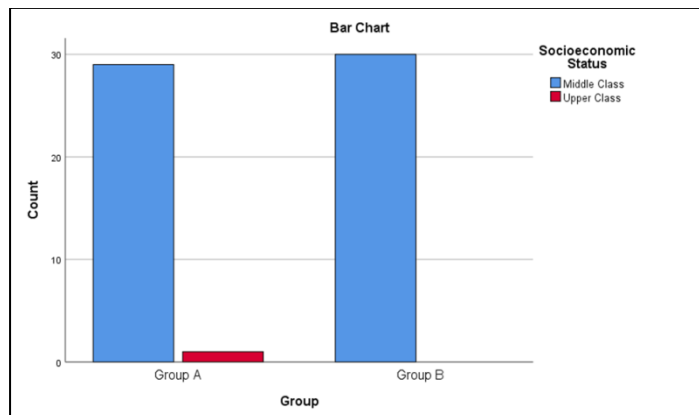
**Table 51: Table showing Chi-Square Tests for Socioeconomic status wise group significance**

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.017 <sup>a</sup>	1	.313		
Continuity Correction <sup>b</sup>	.000	1	1.000		
Likelihood Ratio	1.403	1	.236		
Fisher's Exact Test				1.000	.500
Linear-by-Linear Association	1.000	1	.317		
N of Valid Cases	60				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is .50.

b. Computed only for a 2x2 table

**Figure 22: Bar diagram showing socioeconomic status wise group presentation**



All the subjects mostly were from middle class except for 1 in group A belonging to upper class.

## Nadi

**Table 52: Table showing nadi wise group distribution**

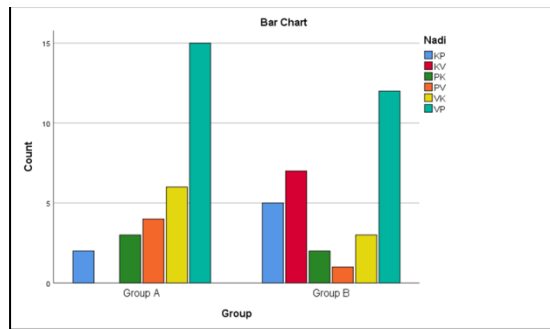
Group	Group	Count	Nadi						Total
			KP	KV	PK	PV	VK	VP	
Group A	Count	2	0	3	4	6	15	30	
	% within Group	6.7%	0.0%	10.0%	13.3%	20.0%	50.0%	100.0%	
Group B	Count	5	7	2	1	3	12	30	
	% within Group	16.7%	23.3%	6.7%	3.3%	10.0%	40.0%	100.0%	
Total	Count	7	7	5	5	9	27	60	
	% within Group	11.7%	11.7%	8.3%	8.3%	15.0%	45.0%	100.0%	

**Table 53: Table showing Chi-Square Tests for nadi wise group significance**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	11.619 <sup>a</sup>	5	.040
Likelihood Ratio	14.515	5	.013
N of Valid Cases	60		

a. 10 cells (83.3%) have expected count less than 5. The minimum expected count is 2.50.

**Figure 23: Bar diagram showing nadi wise group presentation**



The Nadi of the subjects varied from kaphaj-pittaj to kafajvataj and pittajkhafaj and pittajvataj, vatajkhafaj and vatajpittaj. 2 in group A and 5 in group B had kaphaj-pittajNadi. 7 in group B had kafajvatajNadi, with none in group A. 3 subjects had pittajkhafajnadi in group A and 2 in group B. 4 in group A had pittajvataj and 1 in group B. Vatajkhafajnadi is present in 6 subjects of group A and 3 subjects of group B. 15 subjects in group A and 12 in group B had vatajpittajNadi.

## Mala

**Table 54: Table showing mala wise group distribution**

Group	Group	Count	Mala		Total
			P	B	
Group A	Count	23	7	30	
	% within Group	76.7%	23.3%	100.0%	
	Count	24	6	30	
	% within Group	80.0%	20.0%	100.0%	
Total	Count	47	13	60	
	% within Group	78.3%	21.7%	100.0%	

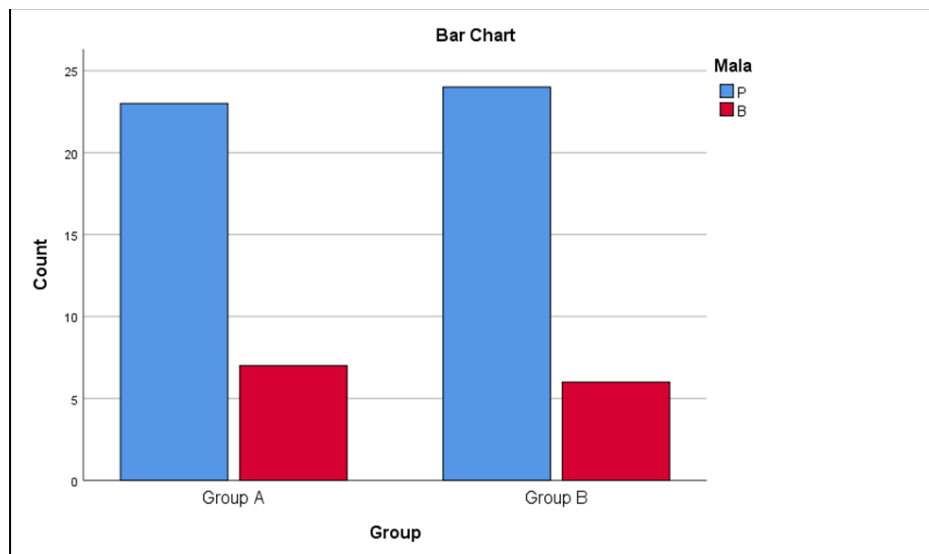
**Table 55: Table showing Chi-Square Tests for mala wise group significance**

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.098 <sup>a</sup>	1	.754		
Continuity Correction <sup>b</sup>	.000	1	1.000		
Likelihood Ratio	.098	1	.754		
Fisher's Exact Test				1.000	.500
Linear-by-Linear Association	.097	1	.756		
N of Valid Cases	60				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 6.50.

b. Computed only for a 2x2 table

**Figure 24: Bar diagram showing mala wise group presentation**



In group A, 23 have prakrit mala while 7 have badhit flow. In group B, 6 have badhit flow while 24 had prakrit flow.

## Mutra

**Table 56: Table showing mutra wise group distribution**

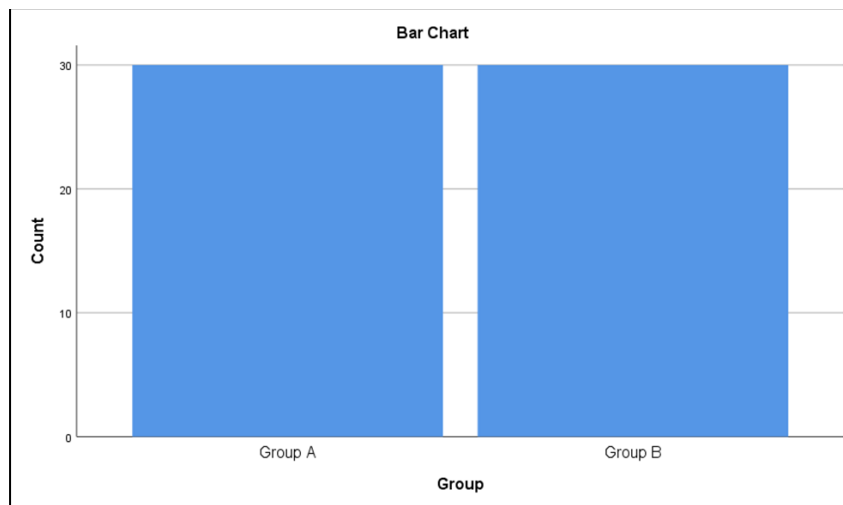
		Mutra		Total
		P		
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total	Count		60	60
	% within Group		100.0%	100.0%

**Table 57: Table showing Chi-Square Tests for mutra wise group significance**

	Value
Pearson Chi-Square	. <sup>a</sup>
N of Valid Cases	60

a. No statistics are computed because Mutra is a constant.

**Figure 25: Bar diagram showing mutra wise group presentation**



Both groups had normal mutra flow as per the study since only healthy candidates were taken as the subject.

## Jawah

**Table 58: Table showing jawah wise group distribution**

Group	Group A	Count	Jawah		Total
			UCoated	Coated	
		28	2		30
		% within Group	93.3%	6.7%	100.0%
	Group B	Count	26	3	29
		% within Group	89.7%	10.3%	100.0%
Total		Count	54	5	59
		% within Group	91.5%	8.5%	100.0%

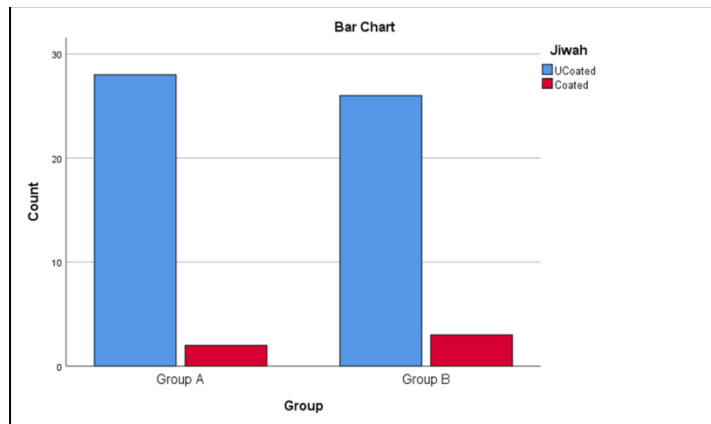
**Table 59: Table showing Chi-Square Tests for jawah wise group significance**

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.257 <sup>a</sup>	1	.612		
Continuity Correction <sup>b</sup>	.002	1	.968		
Likelihood Ratio	.258	1	.611		
Fisher's Exact Test				.671	.484
Linear-by-Linear Association	.253	1	.615		
N of Valid Cases	59				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 2.46.

b. Computed only for a 2x2 table

**Figure 26: Bar diagram showing jiwah wise group presentation**



28 subjects in group A while 26 in group B had non coated jiwah leaving 2 in group A and 3 in group B with coated jiwah.

## Shabdh

**Table 60: Table showing shabdh wise group distribution**

Group	Group	Count	Shabdh		Total
			S	AS	
	Group A	Count	30	0	30
		% within Group	100.0%	0.0%	100.0%
	Group B	Count	28	2	30
		% within Group	93.3%	6.7%	100.0%
Total	Count	58	2	60	
	% within Group	96.7%	3.3%	100.0%	

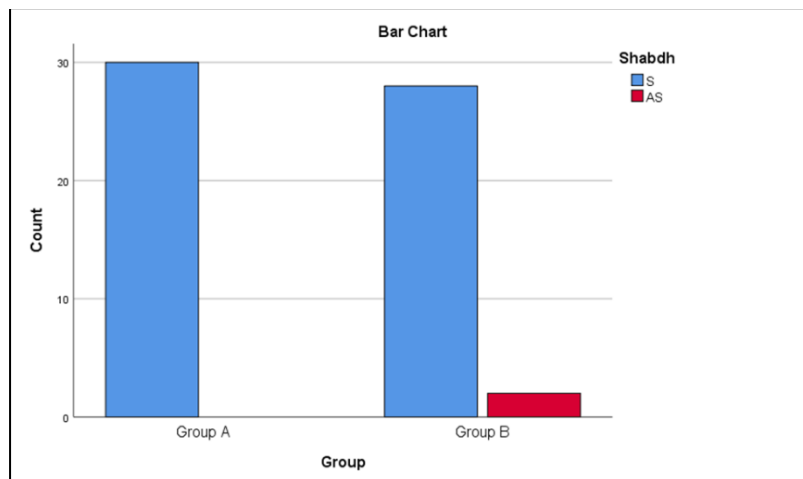
**Table 61: Table showing Chi-Square Tests for shabdh wise group significance**

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2.069 <sup>a</sup>	1	.150		
Continuity Correction <sup>b</sup>	.517	1	.472		
Likelihood Ratio	2.842	1	.092		
Fisher's Exact Test				.492	.246
Linear-by-Linear Association	2.034	1	.154		
N of Valid Cases	60				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 1.00.

b. Computed only for a 2x2 table

**Figure 27: Bar diagram showing shabdh wise group presentation**



In group A all subjects had spashtshabdh while in group B two subjects had aspastshabdh.

## Sparsh

**Table 62: Table showing sparsh wise group distribution**

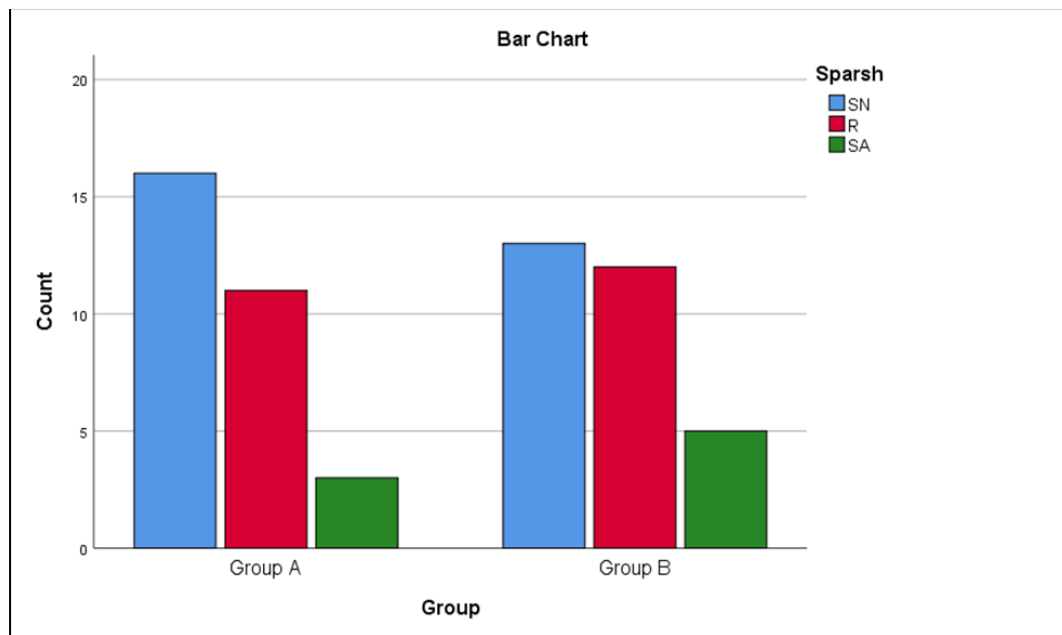
Group	Group		Sparsh			Total
			SN	R	SA	
Group A	Count	16	11	3	30	
	% within Group	53.3%	36.7%	10.0%	100.0%	
Group B	Count	13	12	5	30	
	% within Group	43.3%	40.0%	16.7%	100.0%	
Total	Count	29	23	8	60	
	% within Group	48.3%	38.3%	13.3%	100.0%	

**Table 63: Table showing Chi-Square Tests for sparsh wise group significance**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	.854 <sup>a</sup>	2	.653
Likelihood Ratio	.860	2	.651
Linear-by-Linear Association	.829	1	.363
N of Valid Cases	60		

a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is 4.00.

**Figure 28: Bar diagram showing sparsh wise group presentation**



In group A, 16 while in group B, 11 members had snigdhsparsh. In group A, 11 while in group B, 12 subjects have ruksh and 3 in group A and 6 in group B have sadharansparsh type.

## Netra

**Table 64: Table showing netra wise group distribution**

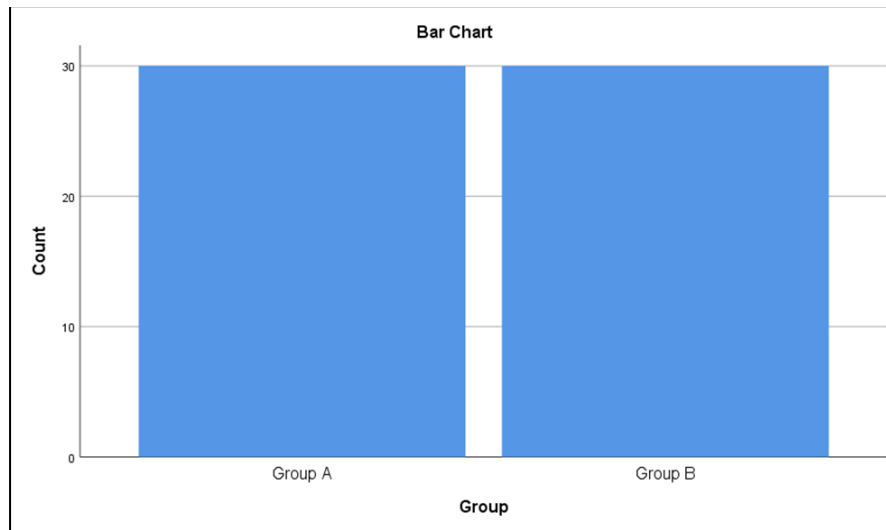
		Netra		Total
		P		
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total		Count	60	60
		% within Group	100.0%	100.0%

**Table 65: Test showing Chi-Square Tests for netra wise group significance**

	Value
Pearson Chi-Square	.a
N of Valid Cases	60

a. No statistics are computed because Netra is a constant.

**Figure 29: Bar diagram showing netra wise group presentation**



The netra were normal functioning in all the subjects of both groups A and B with no subject having any eye disease.

### Aakriti

**Table 66: Table showing aakriti wise group distribution**

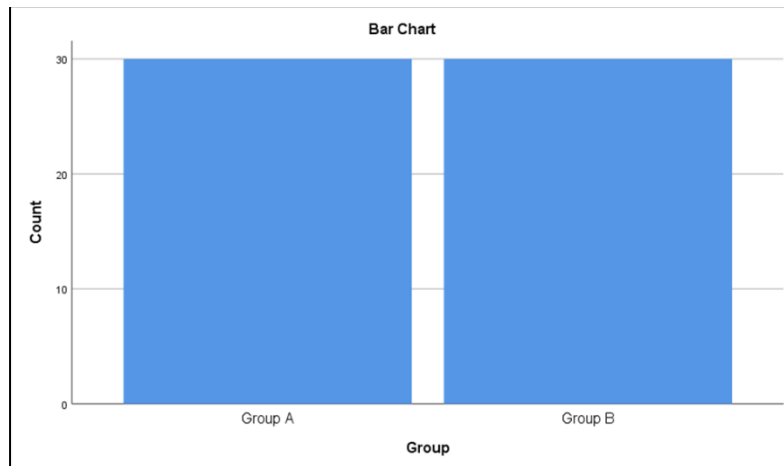
		Aakriti	Total
		M	
Group	Group A	Count	30
		% within Group	100.0%
	Group B	Count	30
		% within Group	100.0%
Total		Count	60
		% within Group	100.0%

**Table 67: Table showing Chi-Square Tests for aakriti wise group significance**

	Value
Pearson Chi-Square	. <sup>a</sup>
N of Valid Cases	60

a. No statistics are computed because Aakriti is a constant.

**Figure 30: Bar diagram showing Aakriti wise group presentation**



All the subjects in both the groups had madhyamakriti.

## Prakriti

**Table 68: Table showing Prakriti wise group distribution**

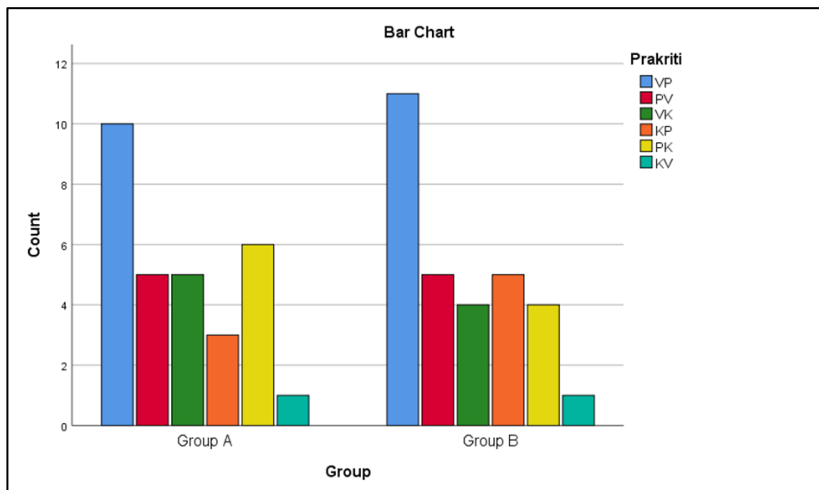
Group	Group	Count	Prakriti					Total	
			VP	PV	VK	KP	PK		KV
	A	Count	10	5	5	3	6	1	30
		% within Group	33.3%	16.7%	16.7%	10.0%	20.0%	3.3%	100.0%
	B	Count	11	5	4	5	4	1	30
		% within Group	36.7%	16.7%	13.3%	16.7%	13.3%	3.3%	100.0%
Total		Count	21	10	9	8	10	2	60
		% within Group	35.0%	16.7%	15.0%	13.3%	16.7%	3.3%	100.0%

**Table 69: Table showing Chi-Square Tests for Aakriti wise group significance**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	1.059 <sup>a</sup>	5	.958
Likelihood Ratio	1.067	5	.957
Linear-by-Linear Association	.102	1	.750
N of Valid Cases	60		

a. 6 cells (50.0%) have expected count less than 5. The minimum expected count is 1.00.

**Figure 31: Bar diagram showing Prakriti wise group presentation**



The prakriti of the subjects varied from kapha-pitta to kafa-vata and pitta-kapha and pitta vata, vata-kapha and vata pitta. 10 in group A and 11 in group B had vata-pitta prakriti. 5 in each group had pitta vata prakriti. 5 subjects had vata kapha prakriti in group A and 4 in group B. 3 in group A had kapha pitta and 5 in group B. Pitta Kapha Prakriti is present in 6 subjects of group A and 4 subjects of group B. 1 subject in group A and 1 in group B had kapha vata prakriti.

## Vikriti

**Table 70 : Table showing Vikriti wise group distribution**

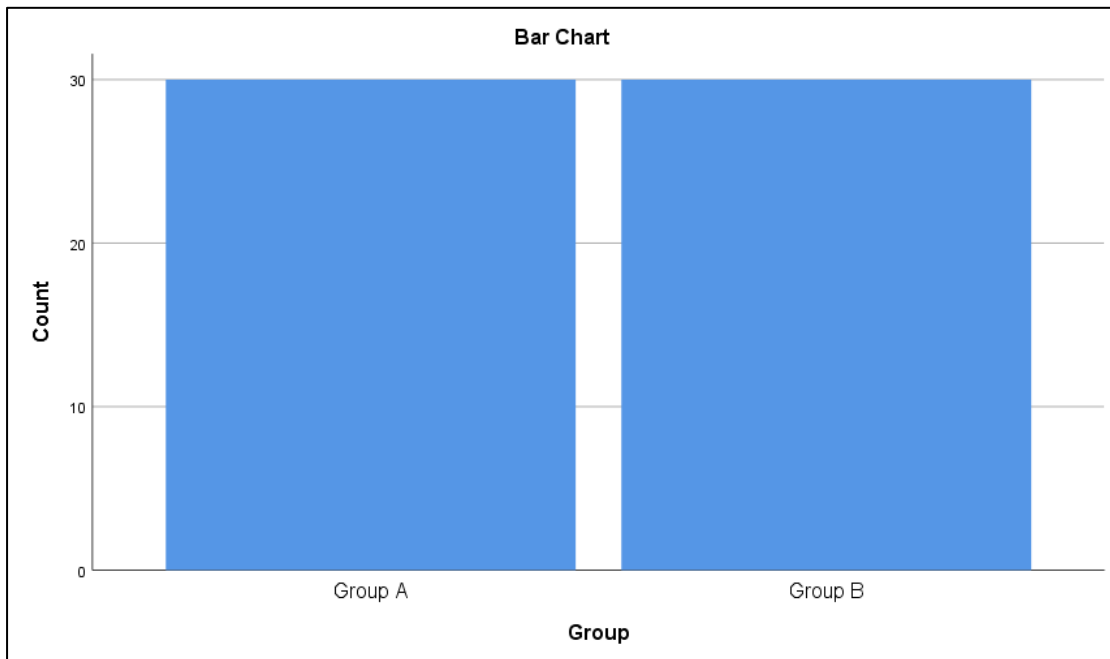
		Vikriti		Total
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total		Count	60	60
		% within Group	100.0%	100.0%

**Table 71: Table showing Chi-Square Tests for vikriti wise group significance**

	Value
Pearson Chi-Square	. <sup>a</sup>
N of Valid Cases	60

a. No statistics are computed because Vikriti is a constant.

**Figure32 : Bar diagram showing Vikriti wise group presentation**



## Sara

**Table 72: Table showing Sara wise group distribution**

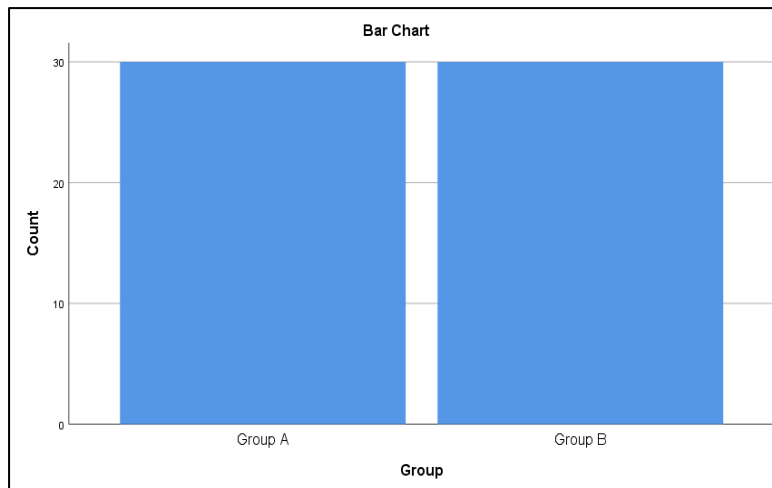
			Sara	
			M	Total
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total	Count	60	60	
	% within Group	100.0%	100.0%	

**Table 73: Table showing Chi-Square Tests for Sara wise group significance**

	Value
Pearson Chi-Square	. <sup>a</sup>
N of Valid Cases	60

a. No statistics are computed because Sara is a constant.

**Figure 33: Bar diagram showing sara wise group presentation**



## Sanhanana

**Table 74: Table showing Sanhanana wise group distribution**

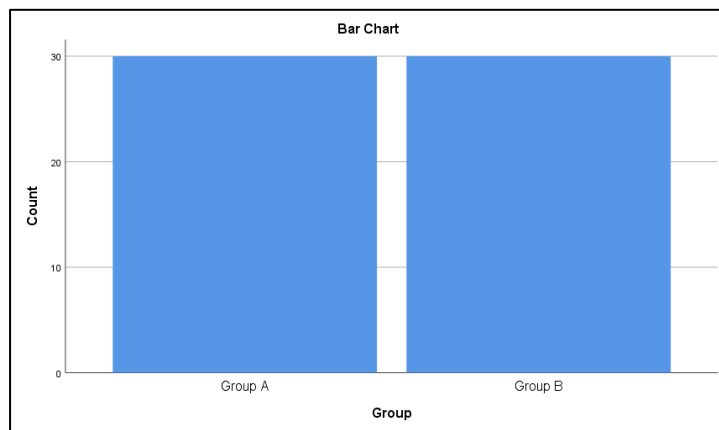
			Sanhanana	Total
			M	
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total	Count	60	60	
	% within Group	100.0%	100.0%	

**Table 75: Table showing Chi-Square Tests for sanhanana wise group significance**

	Value
Pearson Chi-Square	. <sup>a</sup>
N of Valid Cases	60

a. No statistics are computed because Sanhanana is a constant.

**Figure 34: Bar diagram showing snahana wise group presentation**



## Satmya

**Table 76: Table showing Satmya wise group distribution**

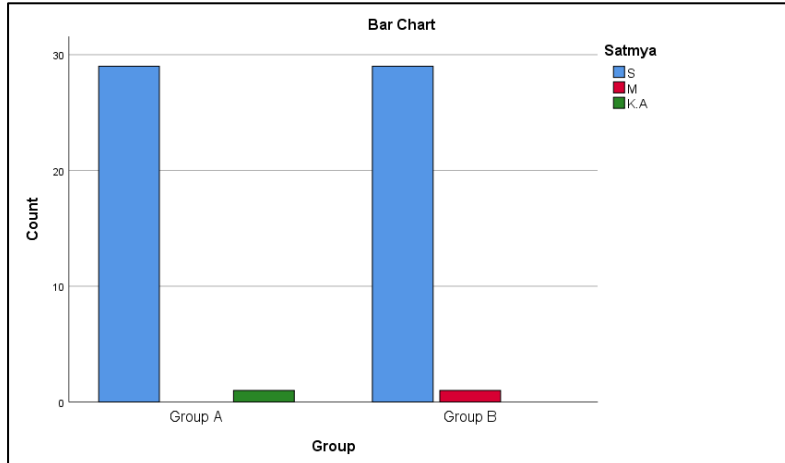
		Satmya			Total	
		S	M	K.A		
Group	Group A	Count	29	0	1	30
		% within Group	96.7%	0.0%	3.3%	100.0%
	Group B	Count	29	1	0	30
		% within Group	96.7%	3.3%	0.0%	100.0%
Total	Count	58	1	1	60	
	% within Group	96.7%	1.7%	1.7%	100.0%	

**Table 77: Table showing Chi-Square Tests for satmya wise group significance**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	2.000 <sup>a</sup>	2	.368
Likelihood Ratio	2.773	2	.250
Linear-by-Linear Association	.203	1	.653
N of Valid Cases	60		

a. 4 cells (66.7%) have expected count less than 5. The minimum expected count is .50.

**Figure 35: Bar diagram showing satmya wise group presentation**



## Satva

**Table 78: Table showing Satva wise group distribution**

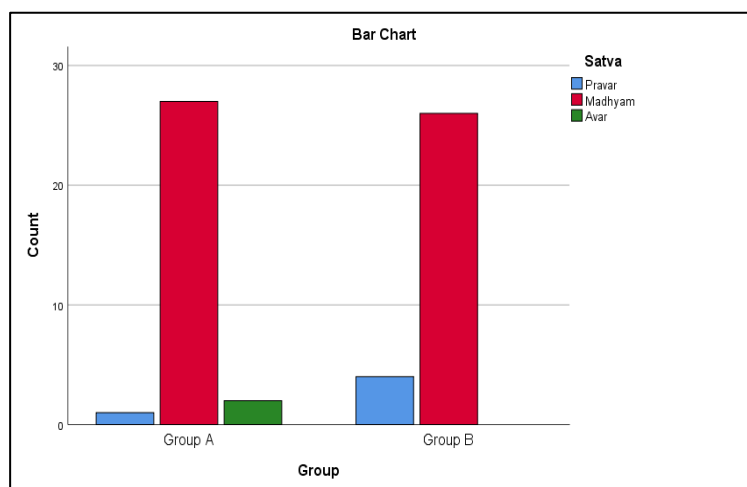
		Satva				
			Pravar	Madhyam	Avar	Total
Group	Group A	Count	1	27	2	30
		% within Group	3.3%	90.0%	6.7%	100.0%
	Group B	Count	4	26	0	30
		% within Group	13.3%	86.7%	0.0%	100.0%
Total		Count	5	53	2	60
		% within Group	8.3%	88.3%	3.3%	100.0%

**Table 79: Table showing Chi-Square Tests for satva wise group significance**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	3.819 <sup>a</sup>	2	.148
Likelihood Ratio	4.719	2	.094
Linear-by-Linear Association	3.589	1	.058
N of Valid Cases	60		

a. 4 cells (66.7%) have expected count less than 5. The minimum expected count is 1.00.

**Figure 36: Bar diagram showing satva wise group presentation**



### Pramana

**Table 80: Table showing Pramana wise group distribution**

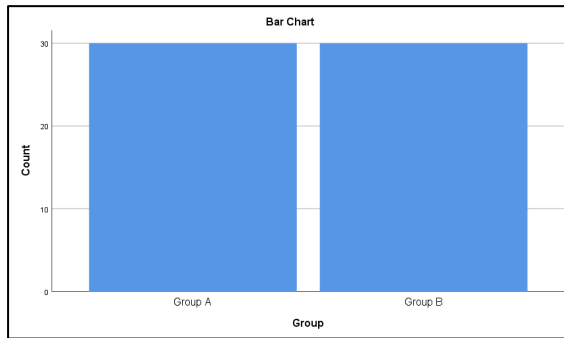
			Pramana	Total
			Madhyam	
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total	Count		60	60
	% within Group		100.0%	100.0%

**Table 81: Table showing Chi-Square Tests for Pramana wise group significance**

	Value
Pearson Chi-Square	. <sup>a</sup>
N of Valid Cases	60

a. No statistics are computed because Pramana is a constant.

**Figure 37: Bar diagram showing pramana wise group presentation**



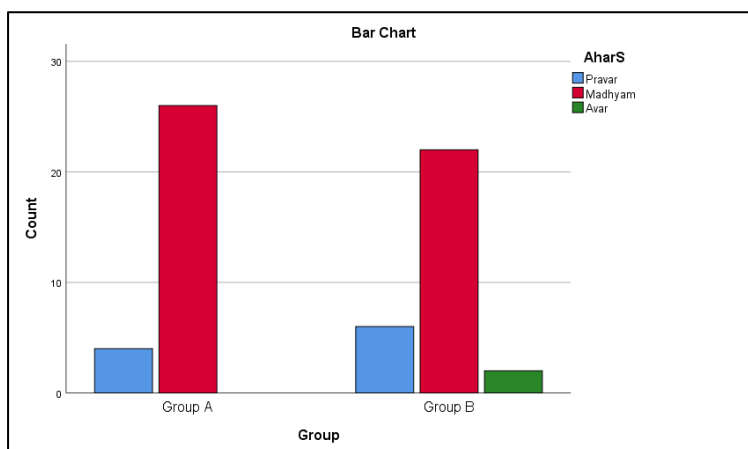
## Ahar Shakti

**Table 83: Table showing Chi-Square Tests for Ahar Shakti wise group significance**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	2.733 <sup>a</sup>	2	.255
Likelihood Ratio	3.509	2	.173
Linear-by-Linear Association	.000	1	1.000
N of Valid Cases	60		

a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is 1.00.

**Figure 38: Bar diagram showing agar shakti wise group presentation**



## VyayamShakti

**Table 84: Table showing Vyayam Shakti wise group distribution**

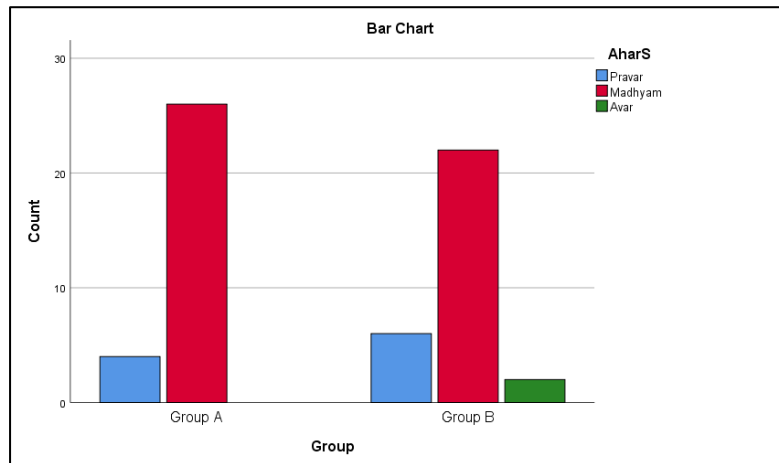
			VyayamS			
			Pravar	Madhyam	Avar	Total
Group	Group A	Count	1	25	4	30
		% within Group	3.3%	83.3%	13.3%	100.0%
	Group B	Count	5	11	14	30
		% within Group	16.7%	36.7%	46.7%	100.0%
Total	Count		6	36	18	60
	% within Group		10.0%	60.0%	30.0%	100.0%

**Table 85: Table showing Chi-Square Tests for VyayamShakti wise group significance**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	13.667 <sup>a</sup>	2	.001
Likelihood Ratio	14.386	2	.001
Linear-by-Linear Association	1.639	1	.200
N of Valid Cases	60		

a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is 3.00.

**Figure 39: Bar diagram showing vyayam shakti wise group presentation**



Interpretation: The data on Vyayam Shakti suggests that 83.3% subjects of Group 1 had Madhyam Vyayam shakti in comparison to 36.7% in Group 2. Overall, In Group 1, a few (3.3%) had vyayam shakti as pravar than 16.7% in Group 2. The distribution of subjects by vyayam shakti is significantly different ( $\chi^2$  with 2DF=13.67,  $p=0.001$ ).

## Vaya

**Table 86: Table showing Vaya wise group distribution**

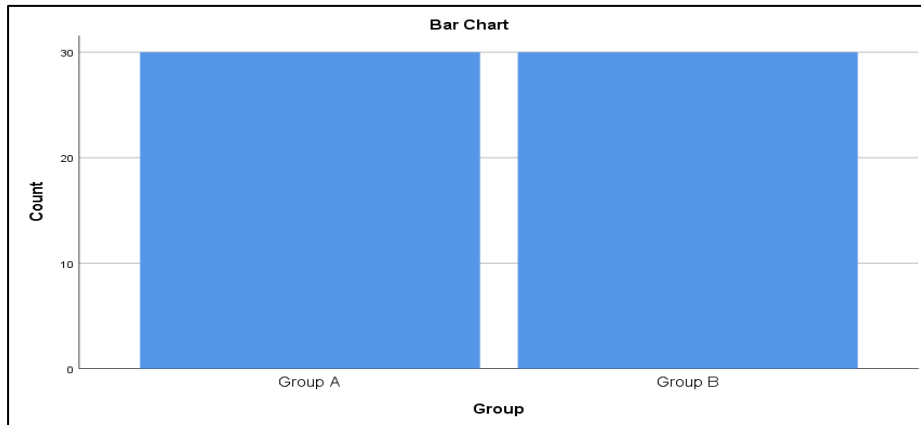
			Vaya	
			1	Total
Group	Group A	Count	30	30
		% within Group	100.0%	100.0%
	Group B	Count	30	30
		% within Group	100.0%	100.0%
Total	Count		60	60
	% within Group		100.0%	100.0%

**Table 87: Table showing Chi-Square Tests for Vaya wise group significance**

	Value
Pearson Chi-Square	.a
N of Valid Cases	60

a. No statistics are computed because Vaya is a constant.

**Figure 40: Bar diagram showing vaya wise group presentation**



**Table 88 : Tests of Normality (Suggests that all these variables are not normally distributed; So, non-parametric tests of significance should be used. However used both parametric and non-parametric for purpose of option below).**

	Group	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		Sig.
		Statistic	df	Sig.	Statistic	df	
Age	Group 1	.225	30	.000	.877	30	.002
	Group 2	.237	30	.000	.717	30	.000
Temp	Group 1	.498	30	.000	.392	30	.000
	Group 2	.427	30	.000	.646	30	.000
Pulse rate	Group 1	.212	30	.001	.871	30	.002
	Group 2	.179	30	.015	.933	30	.059
Respiratory rate	Group 1	.312	30	.000	.772	30	.000
	Group 2	.436	30	.000	.589	30	.000
SBP	Group 1	.264	30	.000	.879	30	.003
	Group 2	.260	30	.000	.890	30	.005
DBP	Group 1	.241	30	.000	.873	30	.002
	Group 2	.368	30	.000	.697	30	.000

**Table 89 : a. Lilliefors Significance Correction  
Group Statistics**

	Group	N	Mean	Std. Deviation	Std. Error Mean
Age	Group 1	30	21.97	1.474	.269
	Group 2	30	23.43	4.695	.857
Temp	Group 1	30	98.210	.3642	.0665
	Group 2	30	98.380	.0484	.0088
Pulse rate	Group 1	30	81.20	11.205	2.046
	Group 2	30	77.27	11.089	2.025
Respiratory rate	Group 1	30	17.53	1.252	.229
	Group 2	30	16.57	.898	.164
SBP	Group 1	30	115.30	9.094	1.660
	Group 2	30	119.33	10.148	1.853
DBP	Group 1	30	76.63	7.439	1.358
	Group 2	30	77.67	6.789	1.240
ISQ1	Group 1	30	6.73	2.518	.460
	Group 2	30	7.47	1.961	.358
GH1	Group 1	30	6.33	2.881	.526
	Group 2	30	6.60	2.328	.425
IFunc1	Group 1	28	7.43	1.731	.327
	Group 2	29	7.69	1.105	.205
RedImm1	Group 1	30	.30	.466	.085
	Group 2	30	.17	.379	.069
Wt1	Group 1	30	60.8533	10.37822	1.89479
	Group 2	29	66.1331	11.09279	2.05988
HT1	Group 1	30	164.3837	7.31205	1.33499
	Group 2	29	167.4407	8.70422	1.61633
BMI1	Group 1	30	22.3367	2.95384	.53929
	Group 2	29	23.2500	3.71330	.68954
IgG	Group 1	30	1315.900 0	223.4809 8	40.80186
	Group 2	30	1396.133 3	227.5365 4	41.54230
IgM	Group 1	30	122.5033	53.44835	9.75829
	Group 2	30	134.2733	67.65328	12.35174

**Table 90 : Independent Samples Test (Parametric t-test)**

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	T	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Age	Equal variances assumed	9.660	.003	-1.632	58	.108	-1.467	.898	-3.265	.332
	Equal variances not assumed			-1.632	34.657	.112	-1.467	.898	-3.291	.358
Temp	Equal variances assumed	7.102	.010	-2.534	58	.014	-.1700	.0671	-.3043	-.0357
	Equal variances not assumed			-2.534	30.025	.017	-.1700	.0671	-.3070	-.0330
Pulse rate	Equal variances assumed	.040	.842	1.367	58	.177	3.933	2.878	-1.828	9.694
	Equal variances not assumed			1.367	57.994	.177	3.933	2.878	-1.828	9.695
Respiratory rate	Equal variances assumed	2.450	.123	3.437	58	.001	.967	.281	.404	1.530
	Equal variances not assumed			3.437	52.580	.001	.967	.281	.402	1.531
SBP	Equal variances assumed	.187	.667	-1.621	58	.110	-4.033	2.488	-9.013	.947

	Equal variances not assumed			-1.621	57.316	.110	-4.033	2.488	-9.015	.948
DBP	Equal variances assumed	.948	.334	-562	58	.576	-1.033	1.839	-4.714	2.647
	Equal variances not assumed			-562	57.521	.576	-1.033	1.839	-4.715	2.648
ISQ1	Equal variances assumed	1.496	.226	-1.259	58	.213	-.733	.583	-1.900	.433
	Equal variances not assumed			-1.259	54.712	.214	-.733	.583	-1.901	.434
GH1	Equal variances assumed	.910	.344	-.394	58	.695	-.267	.676	-1.620	1.087
	Equal variances not assumed			-.394	55.555	.695	-.267	.676	-1.622	1.088
IFunc1	Equal variances assumed	6.135	.016	-.681	55	.499	-.261	.383	-1.029	.507
	Equal variances not assumed			-.676	45.632	.502	-.261	.386	-1.038	.516
Redlmun1	Equal variances assumed	6.153	.016	1.216	58	.229	.133	.110	-.086	.353
	Equal variances not assumed			1.216	55.687	.229	.133	.110	-.086	.353
Wt1	Equal variances assumed	.001	.974	-1.889	57	.064	-5.27977	2.79560	-10.87787	.31833

	Equal variances not assumed			-1.886	56.426	.064	-5.27977	2.79881	-10.88553	.32599
HT1	Equal variances assumed	1.553	.218	-1.463	57	.149	-3.05702	2.09013	-7.24244	1.12840
	Equal variances not assumed			-1.458	54.669	.150	-3.05702	2.09636	-7.25880	1.14475
BMI1	Equal variances assumed	.987	.325	-1.047	57	.299	-.91333	.87200	-2.65948	.83282
	Equal variances not assumed			-1.043	53.429	.301	-.91333	.87539	-2.66881	.84215
IgG	Equal variances assumed	.178	.674	-1.378	58	.174	-80.23333	58.22847	-196.79027	36.32360
	Equal variances not assumed			-1.378	57.981	.174	-80.23333	58.22847	-196.79107	36.32441
IgM	Equal variances assumed	1.807	.184	-.748	58	.458	-11.77000	15.74134	-43.27971	19.73971
	Equal variances not assumed			-.748	55.052	.458	-11.77000	15.74134	-43.31568	19.77568

It is observed from the statistical analysis that there is significant change in temperature, respiratory rate and immune functioning after 3 months of intervention in group 1 participants.

**Table 91 : : Hypothesis Test Summary**

	Null Hypothesis	Test	Sig.	Decision
1	The medians of Age are the same across categories of Group.	Independent-Samples Median Test	.796 <sup>a</sup>	Retain the null hypothesis.
2	The distribution of Age is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.612	Retain the null hypothesis.
3	The medians of Temp are the same across categories of Group.	Independent-Samples Median Test	.000 <sup>a</sup>	Reject the null hypothesis.
4	The distribution of Temp is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.000	Reject the null hypothesis.
5	The medians of Pulse rate are the same across categories of Group.	Independent-Samples Median Test	.121 <sup>a</sup>	Retain the null hypothesis.
6	The distribution of Pulse rate is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.253	Retain the null hypothesis.
7	The medians of Respiratory rate are the same across categories of Group.	Independent-Samples Median Test	.010 <sup>a</sup>	Reject the null hypothesis.
8	The distribution of Respiratory rate is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.002	Reject the null hypothesis.
9	The medians of SBP are the same across categories of Group.	Independent-Samples Median Test	.333 <sup>a</sup>	Retain the null hypothesis.
10	The distribution of SBP is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.097	Retain the null hypothesis.
11	The medians of DBP are the same across categories of Group.	Independent-Samples Median Test	.605 <sup>a</sup>	Retain the null hypothesis.
12	The distribution of DBP is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.473	Retain the null hypothesis.
13	The medians of ISQ1 are the same across categories of Group.	Independent-Samples Median Test	.439 <sup>a</sup>	Retain the null hypothesis.
14	The distribution of ISQ1 is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.240	Retain the null hypothesis.
15	The medians of GH1 are the same across categories of Group.	Independent-Samples Median Test	1.000 <sup>a</sup>	Retain the null hypothesis.
16	The distribution of GH1 is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.910	Retain the null hypothesis.
17	The medians of IFunc1 are the same across categories of Group.	Independent-Samples Median Test	.937 <sup>a</sup>	Retain the null hypothesis.
18	The distribution of IFunc1 is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.498	Retain the null hypothesis.
19	The medians of RedImm1 are the same across categories of Group.	Independent-Samples Median Test	.360 <sup>a</sup>	Retain the null hypothesis.

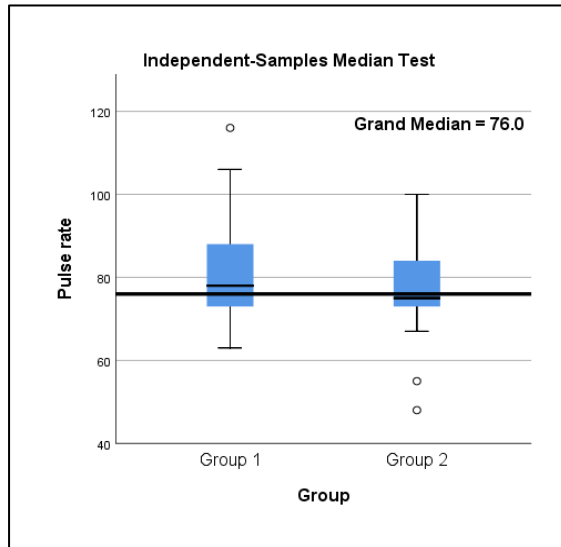
20	The distribution of RedImm1 is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.226	Retain the null hypothesis.
21	The medians of Wt1 are the same across categories of Group.	Independent-Samples Median Test	.027 <sup>a</sup>	Reject the null hypothesis.
22	The distribution of Wt1 is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.037	Reject the null hypothesis.
23	The medians of Wt2 are the same across categories of Group.	Independent-Samples Median Test	.027 <sup>a</sup>	Reject the null hypothesis.
24	The distribution of Wt2 is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.041	Reject the null hypothesis.
25	The medians of Wt3 are the same across categories of Group.	Independent-Samples Median Test	.516 <sup>a</sup>	Retain the null hypothesis.
26	The distribution of Wt3 is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.135	Retain the null hypothesis.
27	The medians of HT1 are the same across categories of Group.	Independent-Samples Median Test	.154 <sup>a</sup>	Retain the null hypothesis.
28	The distribution of HT1 is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.078	Retain the null hypothesis.
29	The medians of Ht2 are the same across categories of Group.	Independent-Samples Median Test	.154 <sup>a</sup>	Retain the null hypothesis.
30	The distribution of Ht2 is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.078	Retain the null hypothesis.
31	The medians of HT3 are the same across categories of Group.	Independent-Samples Median Test	.154 <sup>a</sup>	Retain the null hypothesis.
32	The distribution of HT3 is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.078	Retain the null hypothesis.
33	The medians of BMI1 are the same across categories of Group.	Independent-Samples Median Test	.898 <sup>a</sup>	Retain the null hypothesis.
34	The distribution of BMI1 is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.404	Retain the null hypothesis.
35	The medians of BMI are the same across categories of Group.	Independent-Samples Median Test	.891 <sup>a</sup>	Retain the null hypothesis.
36	The distribution of BMI is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.544	Retain the null hypothesis.
37	The medians of BM3 are the same across categories of Group.	Independent-Samples Median Test	.898 <sup>a</sup>	Retain the null hypothesis.
38	The distribution of BM3 is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.862	Retain the null hypothesis.
39	The medians of IgG are the same across categories of Group.	Independent-Samples Median Test	.796 <sup>a</sup>	Retain the null hypothesis.
40	The distribution of IgG is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.280	Retain the null hypothesis.

41	The medians of IgM are the same across categories of Group.	Independent-Samples Median Test	.796 <sup>a</sup>	Retain the null hypothesis.
42	The distribution of IgM is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.706	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .050.

a. Yates's Continuity Corrected Asymptotic Sig.

**Figure 41: Graph showing Median Test of pulse rate for both the groups.**



## Respiratory rate across Group

**Table 92: Independent-Samples Median Test Summary**

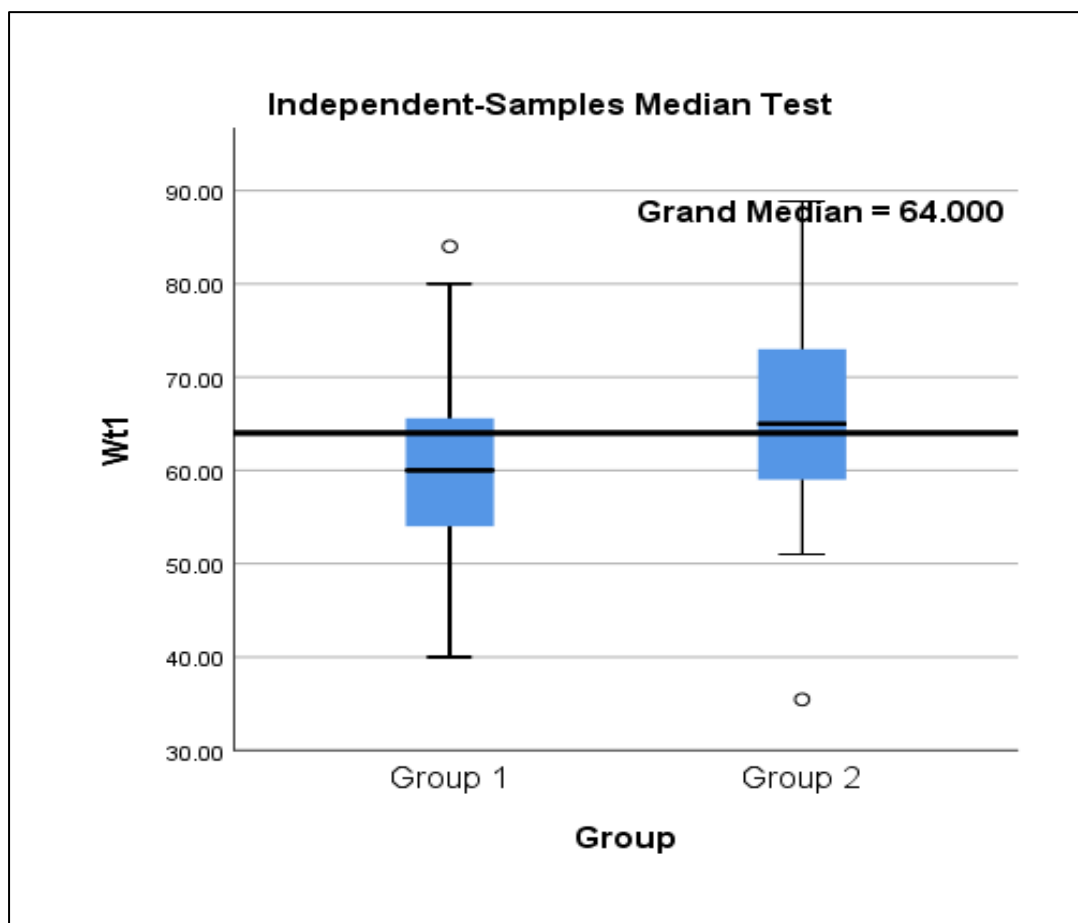
Total N		60
Median		16.000
Test Statistic		8.076 <sup>a</sup>
Degree Of Freedom		1
Asymptotic Sig.(2-sided test)		.004
Yates's Continuity Correction	Chi-Square	6.674
	Degree Of Freedom	1
	Asymptotic Sig.(2-sided test)	.010

a. Multiple comparisons are not performed because there are less than three test fields.

**Table 93 :Independent-Samples Median Test Summary**

Total N		59
Median		64.000
Test Statistic		6.110 <sup>a</sup>
Degree Of Freedom		1
Asymptotic Sig.(2-sided test)		.013
Yates's Continuity Correction	Chi-Square	4.886
	Degree Of Freedom	1
	Asymptotic Sig.(2-sided test)	.027

a. Multiple comparisons are not performed because there are less than three test fields.



**Table 94: Descriptive Statistics**

	Group	Mean	Std. Deviation	N
ISQ 1	Group 1	6.73	2.518	30
	Group 2	7.47	1.961	30
	Total	7.10	2.268	60
ISQ 2	Group 1	9.20	.761	30
	Group 2	5.93	1.741	30
	Total	7.57	2.118	60
ISQ 3	Group 1	9.40	.855	30
	Group 2	8.70	1.119	30
	Total	9.05	1.048	60

**Table 95: Tests of Within-Subjects Effects (Immune status questionnaire)**

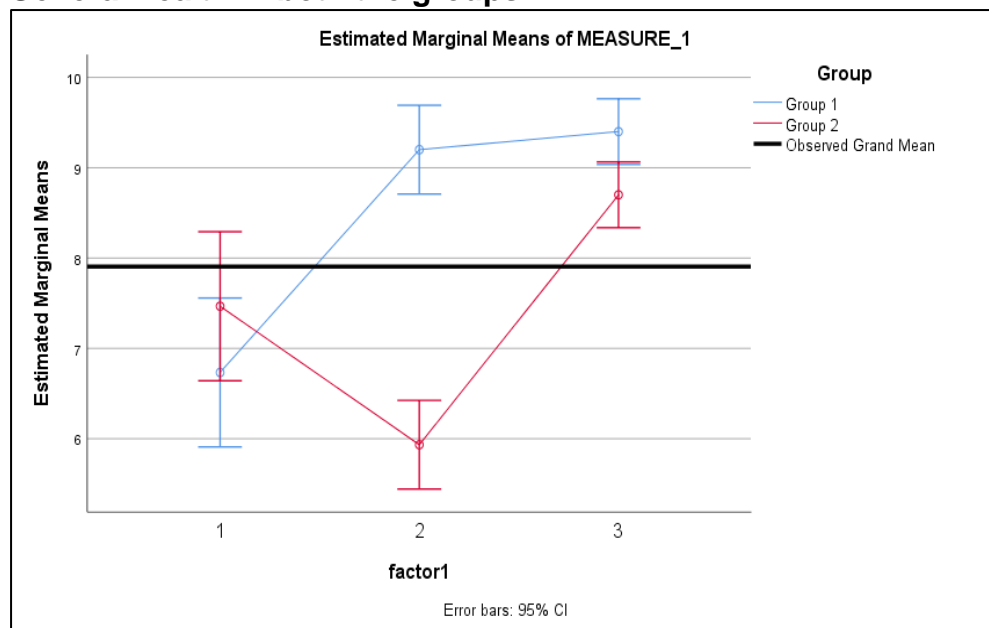
Measure: immune status questionnaire

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
--------	-------------------------	----	-------------	---	------

factor1	Sphericity Assumed	124.411	2	62.206	40.911	.000
	Greenhouse-Geisser	124.411	1.412	88.100	40.911	.000
	Huynh-Feldt	124.411	1.462	85.099	40.911	.000
	Lower-bound	124.411	1.000	124.411	40.911	.000
factor1 * Group	Sphericity Assumed	123.211	2	61.606	40.517	.000
	Greenhouse-Geisser	123.211	1.412	87.251	40.517	.000
	Huynh-Feldt	123.211	1.462	84.278	40.517	.000
	Lower-bound	123.211	1.000	123.211	40.517	.000
Error(factor1 )	Sphericity Assumed	176.378	116	1.520		
	Greenhouse-Geisser	176.378	81.905	2.153		
	Huynh-Feldt	176.378	84.794	2.080		
	Lower-bound	176.378	58.000	3.041		

It is seen that there is significant improvement in immune status questionnaire score after 3 months of intervention in group 1 participants.

**Figure 42: Graph showing patterns of estimated marginal means of General health in both the groups:**



The graph is showing almost similar consistency of both the groups from the observed grand mean while analysing the general health. Better scores are seen in group 1 participants.

**Table 96 : Descriptive statistics of General health of both the groups at visit 1, 2 and 3**

### Descriptive Statistics

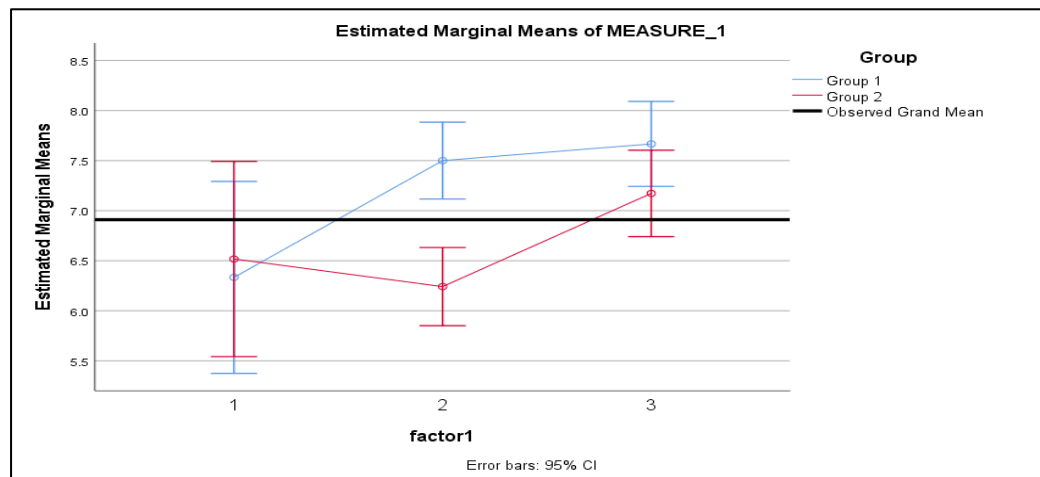
	Group	Mean	Std. Deviation	N
GH1	Group 1	6.33	2.881	30
	Group 2	6.52	2.324	29
	Total	6.42	2.601	59
GH2	Group 1	7.50	1.106	30
	Group 2	6.24	.988	29
	Total	6.88	1.219	59
GH3	Group 1	7.67	1.213	30
	Group 2	7.17	1.104	29
	Total	7.42	1.177	59

**Table 97: Tests of Within-Subjects Effects (immune function)**

Measure: immune function

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
factor1	Sphericity Assumed	29.259	2	14.629	6.276	.003
	Greenhouse-Geisser	29.259	1.070	27.350	6.276	.013
	Huynh-Feldt	29.259	1.093	26.775	6.276	.013
	Lower-bound	29.259	1.000	29.259	6.276	.015
factor1 * Group	Sphericity Assumed	15.360	2	7.680	3.295	.041
	Greenhouse-Geisser	15.360	1.070	14.358	3.295	.072
	Huynh-Feldt	15.360	1.093	14.057	3.295	.071
	Lower-bound	15.360	1.000	15.360	3.295	.075
Error(factor1)	Sphericity Assumed	265.736	114	2.331		
	Greenhouse-Geisser	265.736	60.978	4.358		
	Huynh-Feldt	265.736	62.287	4.266		
	Lower-bound	265.736	57.000	4.662		
	Quadratic	68.126	57		1.195	

There is significant improvement in immune function status after intervention of the compound.



**Figure 43: Graph showing estimated marginal means of immune functioning in both the groups**

The graph shows similar consistencies of both the groups. Group 1 exhibits better results in immune functioning than group 2.

**Table 98 : Descriptive Statistics**

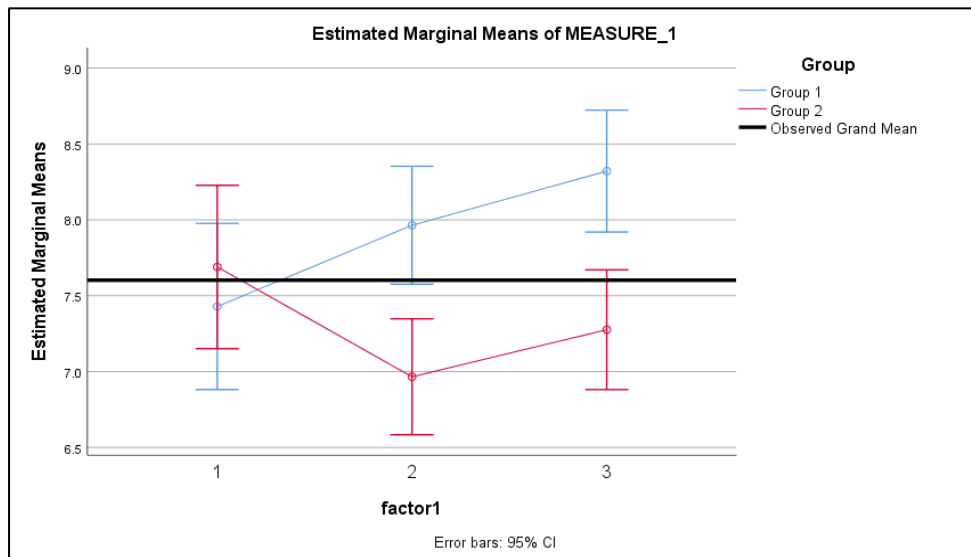
	Group	Mean	Std. Deviation	N
IFunc1	Group 1	7.43	1.731	28
	Group 2	7.69	1.105	29
	Total	7.56	1.439	57
IFunc2	Group 1	7.96	1.170	28
	Group 2	6.97	.865	29
	Total	7.46	1.135	57
IFunc3	Group 1	8.32	1.124	28
	Group 2	7.28	.996	29
	Total	7.79	1.176	57

**Table 99: Tests of Within-Subjects Effects (Reduced immunity at present)**

Measure: Reduced immunity at present

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
factor1	Sphericity Assumed	3.374	2	1.687	3.784	.026
	Greenhouse-Geisser	3.374	1.468	2.298	3.784	.039
	Huynh-Feldt	3.374	1.526	2.211	3.784	.038
	Lower-bound	3.374	1.000	3.374	3.784	.057
factor1 * Group	Sphericity Assumed	15.655	2	7.827	17.559	.000
	Greenhouse-Geisser	15.655	1.468	10.664	17.559	.000
	Huynh-Feldt	15.655	1.526	10.260	17.559	.000
	Lower-bound	15.655	1.000	15.655	17.559	.000
Error(factor1)	Sphericity Assumed	49.035	110	.446		
	Greenhouse-Geisser	49.035	80.739	.607		
	Huynh-Feldt	49.035	83.915	.584		
	Lower-bound	49.035	55.000	.892		

There is significant improvement in reduced immunity at present scores after 3 months of intervention.



**Figure 44: Graph showing estimated marginal means of “Reduced immunity at present” of both the groups**

This graph represents linear consistency of group 1 while erratic consistency of group 2 during the study. It exhibits better scores in group 1 participants than group 2 participants.

**Table 100 : Descriptive Statistics**

	Group	Mean	Std. Deviation	N
RedImmun1	Group 1	.30	.466	30
	Group 2	.17	.379	30
	Total	.23	.427	60
RedImmun2	Group 1	.03	.183	30
	Group 2	.10	.305	30
	Total	.07	.252	60
RedImmun3	Group 1	.03	.183	30
	Group 2	.17	.379	30
	Total	.10	.303	60

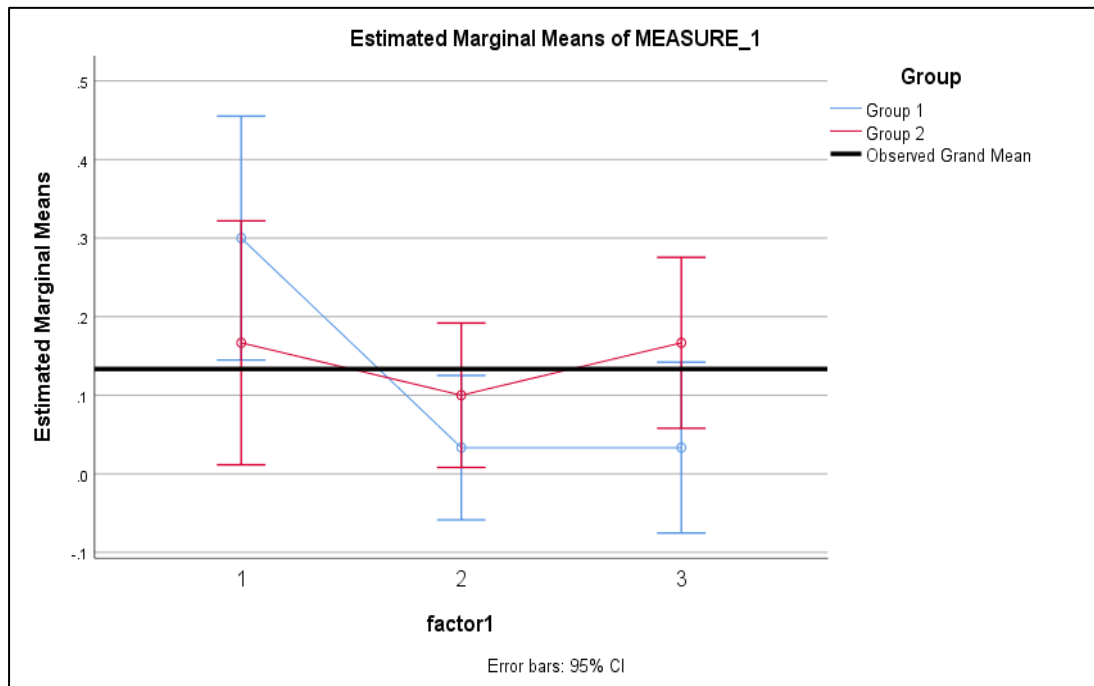
**Table 101 : Tests of Within-Subjects Effects (Chronic disease)**

Measure: Chronic disease

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
factor1	Sphericity Assumed	.933	2	.467	5.913	.004
	Greenhouse-Geisser	.933	1.427	.654	5.913	.009
	Huynh-Feldt	.933	1.478	.631	5.913	.008
	Lower-bound	.933	1.000	.933	5.913	.018
factor1 * Group	Sphericity Assumed	.578	2	.289	3.660	.029
	Greenhouse-Geisser	.578	1.427	.405	3.660	.044
	Huynh-Feldt	.578	1.478	.391	3.660	.043
	Lower-bound	.578	1.000	.578	3.660	.061
Error(factor1)	Sphericity Assumed	9.156	116	.079		
	Greenhouse-Geisser	9.156	82.760	.111		

Huynh-Feldt	9.156	85.723	.107		
Lower-bound	9.156	58.000	.158		

There is significant improvement in chronic disease score after 3 months of intervention.



**Figure 45: Graph showing estimated marginal means of chronic disease condition in both the groups**

The graph shows a significant decrease in the occurrence of chronic disease in group 1 participants. Group 2 participants exhibit almost linear consistency after 3 months of study trial.

## INTERPRETATION

Repeated measure ANOVA was used as there were 2 groups which were analysed 3 times during the study course. It reveals that Group A has performed better than Group B. This is true for the study's primary criteria, i.e. Immune Status Questionnaire (ISQ), general health, immune functioning, reduced immunity at present and chronic disease condition.

There is significant improvement in temperature, respiratory rate and immune functioning of the participants of group 1 after completion of 3 months of intervention of neutraceutical compound OC22.

**Table102 : DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS**

		group a	group b
		N=30	N=30
Gender	Male	17	19
	Female	13	11
Age ( Years)	n	30	30
	Mean	21.97	23.43
	min	20	20
	max	25	38
Height (metre)	n	30	30
	Mean	164.38	167.10
	min	148.59	149
	max	182.88	182.88
Weight (Kgs)	n	30	30
	Mean	60.85	65.80
	min	40	35.45
	max	84	88.85
BMI (KG/m2 )	n	30	30
	Mean	22.34	23.23
	min	16.6	15.95
	max	30.10	32.60

A) The selection and further division of the subjects was done using random computerised method as described earlier and thus the number of males and females in Group A and Group B varies i.e. male =17 and female=13 in group A and male=19 and female=11 in group B.

- B) The participants were divided into 3 groups i.e. students, faculty and employees. Most of our subjects were students except 2 members in each group. 28 students and 2 employees in group A whereas 27 students and 3 faculty members in group B.
- C) The subject's marital status was also recorded during the study and though the majority of our subjects were unmarried the exception of 4 members who were married were present in group B.
- D) All the subjects appeared normal during the study and didn't have any physical disability.
- E) The nutritional status of the majority was good overall but in Group A, 19 subjects were having good nutritional status while the other 11 had average nutritional status. In group B, 27 subjects were having good nutritional status and remaining 3 had average nutritional status
- F) All the participants in both the groups had normal decubitus.
- G) It was observed that the texture of hair is dry in 18, oily in 10, and normal in 2 in the group A and 18 with dry, 2 with oily, and 10 with normal texture in group B.
- H) The texture of skin and nails showed random variations with 9 having dry texture in group A and 16 in group B. 17 having oily texture in group A and 5 in group B. And 4 having normal texture in group A and 9 in group B.
- I) In group A only two subjects had eye pain remaining 28 had no eye disease. In group B all subjects had normal eye functioning with no disease.
- J) Both groups had no subjects with accessible disease in ear, nose and throat (ENT).
- K) In both groups none of the subjects had any pallor. All 60 subjects were healthy in appearance with no paleness.
- L) None of the subjects was observed with icterus. All 60 subjects lacked any such symptoms.
- M) Again during the study subjects were not observed to have cyanosis. All the 30 subjects of each group were free of the symptoms.
- N) None of the subjects from any group had the symptoms of clubbing as well. All 60 subjects were free from any such symptoms.

- O) Lymphadenopathy study was also normal among all the 60 subjects and no member of any group had the lymphadenopathy present.
- P) Edema was not present in the subjects under the inspection for the study of the drug. None of the group had any subject with edema
- Q) Study showed the subjects experienced an increase in appetite. 13 subjects from Group A i.e. the intervention group experienced an increase in their appetite while the other 16 had no change in the appetite. Also 1 subject experienced decrease in appetite. Result of non-intervention group: The results of group B were different where 2 subjects experienced decrease in appetite while two experienced increase in the appetite however maximum no i.e. 26 experienced no change.
- R) Bowel moment of most of the subjects was normal. 3 of the subjects of group A experienced constipation while in group B two of the subjects experienced it.
- S) None of the subjects had a complaint of burning bladder in group B while one of the subjects experienced this unease in group A.
- T) Three of the thirty subjects experienced disturbed sleep in group A while the no of such cases was 6 in group B
- U) In group A, 14 subjects were vegetarian while 12 were non vegetarian and 4 of them had mixed diet. In group B, 22 subjects were vegetarian and 5 were non vegetarian while 3 had mixed diet. The variation was due to their random distribution.
- V) The 3 of the subjects under study in group A had smoking addiction while 2 of them had tea and coffee addiction. The Remaining 25 had no addiction. In group B, 1 had an addiction to smoking, 2 had an addiction to tea and coffee and 27 of them had no addiction.
- W) All the subjects mostly were from middle class except for 1 in group A belonging to upper class.
- X) The Nadi of the subjects varied from kaphaj-pittaj to kapha-vata and pittajkhafaj and pittajvataj, vatajkhafaj and vatajpittaj. 2 in group A and 5 in group B had kapha-pitta Nadi. 7 in group B had kafajvatajNadi, with none in group A. 3 subjects had pittajkhafajnadi in group A and 2 in group B. 4 in group A had pittajvataj and 1 in group B.

Vatajkhafajnadi is present in 6 subjects of group A and 3 subjects of group B. 15 subjects in group A and 12 in group B had vata pitta Nadi.

- Y) In group A all subjects had spashtshabd while in group B two subjects had aspashtshabd.
- Z) The netra were normal functioning in all the subjects of both groups A and B with no subject having any eye disease.

## 9. SAFETY EVALUATION:

**9.1 ADVERSE EVENTS (AE's):** no adverse effects were encountered during the course of study

### 9.2 CLINICAL LABORATORY EVALUATION

**Table 103: Group 1: Paired Samples Statistics**

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	IgG_BT	1315.90	30	223.481	40.802
	IgG_AT	1334.00	30	182.173	33.260
Pair 2	IgM_BT	122.50	30	53.448	9.758
	IgM_AT	123.58	30	52.151	9.521
Pair 3	HB_BT	14.10	30	1.737	.317
	HB_AT	13.95	30	1.701	.310
Pair 4	TLC_BT	6883.3333	30	2081.62459	380.05091
	TLC_AT	6536.6667	30	1490.54106	272.13432
Pair 5	Neutro_BT	59.9667	30	9.60777	1.75413
	Neutro_AT	54.4667	30	7.02573	1.28272
Pair 6	Lympho_BT	33.6000	30	8.56859	1.56440
	Lympho_AT	38.0667	30	6.19195	1.13049
Pair 7	Eosin_BT	1.73	30	.980	.179
	Eosin_AT	1.43	30	.626	.114
Pair 8	Mono_BT	4.70	30	1.705	.311
	Mono_AT	5.97	30	2.025	.370
Pair 9	Basso_BT	.00 <sup>a</sup>	30	.000	.000
	Basso_AT	.00 <sup>a</sup>	30	.000	.000
Pair 10	RBC_BT	4.5817	30	.53852	.09832
	RBC_AT	4.4477	30	.56476	.10311
Pair 11	PCV_BT	41.3300	30	4.85459	.88632
	PCV_AT	41.7067	30	5.04544	.92117
Pair 12	MCV_BT	90.2733	30	6.99053	1.27629
	MCV_AT	94.3667	30	7.52230	1.37338
Pair 13	MCH_BT	30.1333	30	2.97962	.54400
	MCH_AT	31.1667	30	2.98367	.54474
Pair 14	MCHC_BT	33.2333	30	1.04000	.18988
	MCHC_AT	32.9667	30	.88992	.16248
Pair 15	PlateletCnt_BT	2.0780	30	.85608	.15630
	PlateletCnt_AT	2.2550	30	.88178	.16099
Pair 16	ESR_BT	13.6667	30	5.13496	.93751

	ESR_AT	14.1000	30	4.80911	.87802
Pair 17	Bill_Total_BT	.8933	30	.24059	.04393
	Bill_Total_AT	.7433	30	.20625	.03766
Pair 18	Dir_Bill_BT	.3100	30	.07120	.01300
	Dir_Bill_AT	.2800	30	.06103	.01114
Pair 19	Ind_Bill_BT	.5833	30	.18020	.03290
	Ind_Bill_AT	.4633	30	.15862	.02896
Pair 20	SGOT_BT	42.9667	30	18.45121	3.36871
	SGOT_AT	31.9667	30	8.02360	1.46490
Pair 21	SGPT_BT	34.5000	30	25.76385	4.70381
	SGPT_AT	27.9667	30	13.31963	2.43182
Pair 22	Alkaline_Phosp_BT	212.3333	30	74.16586	13.54077
	Alkaline_Phosp_AT	195.7667	30	31.02467	5.66430
Pair 23	Tprotein_BT	6.5900	30	.44902	.08198
	Tprotein_AT	6.5933	30	.29935	.05465
Pair 24	Albumin_BT	3.7667	30	.40457	.07386
	Albumin_AT	3.5600	30	.43834	.08003
Pair 25	Globulin_BT	2.8233	30	.43603	.07961
	Globulin_AT	3.0333	30	.30437	.05557
Pair 26	A_G_Ratio_BT	1.3533	30	.30932	.05647
	A_G_Ratio_AT	1.1733	30	.29235	.05338
Pair 27	RFT	26.7333	30	5.78305	1.05584
	BloodUrea_AT	24.5333	30	3.72071	.67931
Pair 28	SerumCreatin_BT	.8167	30	.16418	.02997
	SerumCreatin_AT	.7823	30	.20708	.03781
Pair 29	Sodium_BT	140.5333	30	1.69651	.30974
	Sodium_AT	139.2033	30	1.16219	.21219
Pair 30	Potassium_BT	3.9500	30	.20129	.03675
	Potassium_AT	3.9033	30	.17905	.03269
Pair 31	Calcium_BT	8.5933	30	.40932	.07473
	Calcium_AT	8.5267	30	.25180	.04597
Pair 32	Result	1.00 <sup>a</sup>	30	.000	.000
	CRP_AT	1.00 <sup>a</sup>	30	.000	.000
Pair 33	Physical Examine	21.67	30	7.232	1.320
	Volume_AT	22.50	30	7.851	1.433
Pair 34	PH_BT	6.150	30	.2330	.0425
	PH_AT	5.250	30	.4689	.0856
Pair 35	Specific_Gravt_BT	1.02583	30	.033530	.006122
	Specific_Gravt_AT	1.02083	30	.007081	.001293

a. The correlation and t cannot be computed because the standard error of the difference is 0.

**Table 104: Paired Samples t-test**

	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
				Lower	Upper			
Pair 1 IgG_BT - IgG_AT	-18.100	119.394	21.798	-62.682	26.482	-.830	29	.413

Pair 2	IgM_BT - IgM_AT	-1.077	15.800	2.885	-6.976	4.823	-.373	29	.712
Pair 3	HB_BT - HB_AT	.143	.755	.138	-.139	.425	1.040	29	.307
Pair 4	TLC_BT - TLC_AT	346.66667	1690.28325	308.60209	-284.49547	977.82881	1.123	29	.271
Pair 5	Neutro_BT - Neutro_AT	5.50000	10.83019	1.97731	1.45594	9.54406	2.782	29	.009
Pair 6	Lympho_BT - Lympho_AT	-4.46667	9.46767	1.72855	-8.00195	-.93138	-2.584	29	.015
Pair 7	Eosin_BT - Eosin_AT	.300	1.119	.204	-.118	.718	1.469	29	.153
Pair 8	Mono_BT - Mono_AT	-1.267	2.677	.489	-2.266	-.267	-2.591	29	.015
Pair 10	RBC_BT - RBC_AT	.13400	.41412	.07561	-.02063	.28863	1.772	29	.087
Pair 11	PCV_BT - PCV_AT	-.37667	3.06658	.55988	-1.52175	.76841	-.673	29	.506
Pair 12	MCV_BT - MCV_AT	-4.09333	4.99841	.91258	-5.95977	-2.22690	-4.485	29	.000
Pair 13	MCH_BT - MCH_AT	-1.03333	2.28161	.41656	-1.88530	-.18137	-2.481	29	.019
Pair 14	MCHC_BT - MCHC_AT	.26667	1.14269	.20863	-.16002	.69336	1.278	29	.211
Pair 15	PlateletCnt_BT - PlateletCnt_AT	-.17700	.55289	.10094	-.38345	.02945	-1.753	29	.090
Pair 16	ESR_BT - ESR_AT	-.43333	6.37172	1.16331	-2.81257	1.94591	-.372	29	.712
Pair 17	Bill_Total_BT - Bill_Total_AT	.15000	.28376	.05181	.04404	.25596	2.895	29	.007
Pair 18	Dir_Bill_BT - Dir_Bill_AT	.03000	.08367	.01528	-.00124	.06124	1.964	29	.059
Pair 19	Ind_Bill_BT - Ind_Bill_AT	.12000	.21877	.03994	.03831	.20169	3.004	29	.005
Pair 20	SGOT_BT - SGOT_AT	11.00000	19.18692	3.50304	3.83549	18.16451	3.140	29	.004
Pair 21	SGPT_BT - SGPT_AT	6.53333	16.65209	3.04024	.31534	12.75132	2.149	29	.040
Pair 22	Alkalin_Phosp_BT - Alkalin_Phosp_AT	16.56667	85.50769	15.61150	-15.36243	48.49576	1.061	29	.297
Pair 23	Tprotein_BT - Tprotein_AT	-.00333	.48883	.08925	-.18587	.17920	-.037	29	.970
Pair 24	Albumin_BT - Albumin_AT	.20667	.53041	.09684	.00861	.40472	2.134	29	.041
Pair 25	Globulin_BT - Globulin_AT	-.21000	.39944	.07293	-.35915	-.06085	-2.880	29	.007
Pair 26	A_G_Ratio_BT - A_G_Ratio_AT	.18000	.31228	.05701	.06339	.29661	3.157	29	.004
Pair 27	RFT - BloodUrea_AT	2.20000	5.79179	1.05743	.03731	4.36269	2.081	29	.046
Pair 28	SerumCreatin_BT - SerumCreatin_AT	.03433	.19961	.03644	-.04020	.10887	.942	29	.354
Pair 29	Sodium_BT - Sodium_AT	1.33000	2.09386	.38228	.54814	2.11186	3.479	29	.002
Pair 30	Potassium_BT - Potassium_AT	.04667	.29212	.05333	-.06241	.15575	.875	29	.389
Pair 31	Calcium_BT - Calcium_AT	.06667	.49294	.09000	-.11740	.25073	.741	29	.465
Pair 33	Physical Examine - Volume_AT	-.833	11.148	2.035	-4.996	3.329	-.409	29	.685
Pair 34	PH_BT - PH_AT	.9000	.4807	.0878	.7205	1.0795	10.256	29	.000

Pair 35	Specific_Gravn_B T - Specific_Gravn_A T	.005000	.033114	.006046	-.007365	.017365	.827	29	.415
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There is significant improvement in levels of neutrophils, lymphocytes, monocytes, MCV, MCH, total bilirubin (indirect bilirubin), SGOT, SGPT, albumin, globulin, A/G ratio, blood urea, sodium, and urine pH after intervention of 3 months.

**Table 105 : Group 2: Paired Samples Statistics**

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	IgG_BT	1396.13	30	227.537	41.542
	IgG_AT	1420.70	30	237.363	43.336
Pair 2	IgM_BT	134.27	30	67.653	12.352
	IgM_AT	133.91	30	63.938	11.673
Pair 3	HB_BT	14.26	30	1.768	.323
	HB_AT	14.27	30	1.879	.343
Pair 4	TLC_BT	7563.3333	30	1647.87917	300.86020
	TLC_AT	6763.3333	30	1599.67310	292.05901
Pair 5	Neutro_BT	59.0333	30	8.26494	1.50896
	Neutro_AT	55.1667	30	8.66258	1.58156
Pair 6	Lympho_BT	32.4667	30	9.17543	1.67520
	Lympho_AT	37.0333	30	7.24680	1.32308
Pair 7	Eosin_BT	1.83	30	1.117	.204
	Eosin_AT	1.57	30	.935	.171
Pair 8	Mono_BT	4.93	30	1.999	.365
	Mono_AT	6.23	30	1.813	.331
Pair 9	Basso_BT	.00 <sup>a</sup>	30	.000	.000
	Basso_AT	.00 <sup>a</sup>	30	.000	.000
Pair 10	RBC_BT	4.7143	30	.64248	.11730
	RBC_AT	4.5897	30	.59993	.10953
Pair 11	PCV_BT	42.0633	30	5.26134	.96059
	PCV_AT	42.7067	30	5.32560	.97232
Pair 12	MCV_BT	89.4533	30	6.88926	1.25780
	MCV_AT	93.2000	30	9.65759	1.76323
Pair 13	MCH_BT	30.0500	30	3.09713	.56546
	MCH_AT	30.8333	30	3.77910	.68997
Pair 14	MCHC_BT	33.5033	30	.93236	.17023
	MCHC_AT	33.0333	30	1.03335	.18866
Pair 15	PlateletCnt_BT	2.0203	30	.65922	.12036
	PlateletCnt_AT	2.4007	30	.77231	.14100
Pair 16	ESR_BT	14.0000	30	6.51259	1.18903
	ESR_AT	14.4667	30	4.38440	.80048
Pair 17	Bill_Total_BT	.8583	30	.27857	.05086
	Bill_Total_AT	.7667	30	.25506	.04657
Pair 18	Dir_Bill_BT	.3167	30	.08743	.01596
	Dir_Bill_AT	.2900	30	.06074	.01109
Pair 19	Ind_Bill_BT	.5567	30	.16750	.03058
	Ind_Bill_AT	.4767	30	.20625	.03766
Pair 20	SGOT_BT	56.8000	30	38.13804	6.96302
	SGOT_AT	32.1333	30	13.64004	2.49032
Pair 21	SGPT_BT	45.1000	30	30.10367	5.49615
	SGPT_AT	25.9667	30	9.59340	1.75151
Pair 22	Alkalin_Phosp_BT	236.4333	30	90.92994	16.60146
	Alkalin_Phosp_AT	197.6667	30	41.30236	7.54075

Pair 23	Tprotein_BT	6.7000	30	.34938	.06379
	Tprotein_AT	6.6033	30	.38190	.06973
Pair 24	Albumin_BT	3.9600	30	.37195	.06791
	Albumin_AT	3.6500	30	.47976	.08759
Pair 25	Globulin_BT	2.7400	30	.29896	.05458
	Globulin_AT	2.9533	30	.25289	.04617
Pair 26	A_G_Ratio_BT	1.4233	30	.26088	.04763
	A_G_Ratio_AT	1.2233	30	.25822	.04714
Pair 27	RFT	28.6000	30	5.58076	1.01890
	BloodUrea_AT	23.7333	30	4.46390	.81499
Pair 28	SerumCreatin_BT	.9033	30	.15862	.02896
	SerumCreatin_AT	.7533	30	.14794	.02701
Pair 29	Sodium_BT	141.0000	30	3.00574	.54877
	Sodium_AT	138.7000	30	1.64317	.30000
Pair 30	Potassium_BT	3.9667	30	.22024	.04021
	Potassium_AT	3.8933	30	.14606	.02667
Pair 31	Calcium_BT	8.6533	30	.47324	.08640
	Calcium_AT	8.5167	30	.25337	.04626
Pair 32	Result	1.00 <sup>a</sup>	30	.000	.000
	CRP_AT	1.00 <sup>a</sup>	30	.000	.000
Pair 33	Physical Examine	22.00	30	6.513	1.189
	Volume_AT	24.00	30	6.618	1.208
Pair 34	PH_BT	5.883	30	.4292	.0784
	PH_AT	5.500	30	.7192	.1313
Pair 35	Specific_Gravt_BT	1.02167	30	.007112	.001298
	Specific_Gravt_AT	1.02000	30	.006823	.001246

a. The correlation and t cannot be computed because the standard error of the difference is 0.

**Table 106 : Paired Samples t-test**

	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
				Lower	Upper			
Paired Sample 1 IgG_BT - IgG_AT	-24.567	104.797	19.133	-63.699	14.565	-1.284	29	.209
Paired Sample 2 IgM_BT - IgM_AT	.367	10.834	1.978	-3.679	4.412	.185	29	.854
Paired Sample 3 HB_BT - HB_AT	-.007	.773	.141	-.295	.282	-.047	29	.963
Paired Sample 4 TLC_BT - TLC_AT	800.0000	1456.49556	265.91849	256.13562	1343.86438	3.008	29	.005
Paired Sample 5 Neutro_BT - Neutro_AT	3.86667	10.42124	1.90265	-.02469	7.75802	2.032	29	.051
Paired Sample 6 Lympho_BT - Lympho_AT	-4.56667	11.05374	2.01813	-8.69420	-.43913	-2.263	29	.031
Paired Sample 7 Eosin_BT - Eosin_AT	.267	1.552	.283	-.313	.846	.941	29	.354
Paired Sample 8 Mono_BT - Mono_AT	-1.300	2.336	.427	-2.172	-.428	-3.048	29	.005
Paired Sample 10 RBC_BT - RBC_AT	.12467	.34106	.06227	-.00269	.25202	2.002	29	.055

Pai r 11	PCV_BT - PCV_AT	-.64333	2.27288	.41497	-1.49204	.20537	- 1.55 0	2 9	.132
Pai r 12	MCV_BT - MCV_AT	-3.74667	4.83034	.88190	-5.55035	-1.94299	- 4.24 8	2 9	.000
Pai r 13	MCH_BT - MCH_AT	-.78333	2.04974	.37423	-1.54872	-.01795	- 2.09 3	2 9	.045
Pai r 14	MCHC_BT - MCHC_AT	.47000	1.16238	.21222	.03596	.90404	2.21 5	2 9	.035
Pai r 15	PlateletCnt_BT - PlateletCnt_AT	-.38033	.51710	.09441	-.57342	-.18725	- 4.02 9	2 9	.000
Pai r 16	ESR_BT - ESR_AT	-.46667	5.88823	1.07504	-2.66537	1.73203	-.434	2 9	.667
Pai r 17	Bill_Total_BT - Bill_Total_AT	.09167	.34940	.06379	-.03880	.22214	1.43 7	2 9	.161
Pai r 18	Dir_Bill_BT - Dir_Bill_AT	.02667	.11121	.02030	-.01486	.06819	1.31 3	2 9	.199
Pai r 19	Ind_Bill_BT - Ind_Bill_AT	.08000	.23104	.04218	-.00627	.16627	1.89 7	2 9	.068
Pai r 20	SGOT_BT - SGOT_AT	24.66667	40.27948	7.35399	9.62606	39.70727	3.35 4	2 9	.002
Pai r 21	SGPT_BT - SGPT_AT	19.13333	30.31869	5.53541	7.81215	30.45452	3.45 7	2 9	.002
Pai r 22	Alkalin_Phosp_B T - Alkalin_Phosp_A T	38.76667	89.52468	16.34490	5.33760	72.19573	2.37 2	2 9	.025
Pai r 23	Tprotein_BT - Tprotein_AT	.09667	.49583	.09053	-.08848	.28181	1.06 8	2 9	.294
Pai r 24	Albumin_BT - Albumin_AT	.31000	.67892	.12395	.05649	.56351	2.50 1	2 9	.018
Pai r 25	Globulin_BT - Globulin_AT	-.21333	.41251	.07531	-.36737	-.05930	- 2.83 3	2 9	.008
Pai r 26	A_G_Ratio_BT - A_G_Ratio_AT	.20000	.41356	.07551	.04557	.35443	2.64 9	2 9	.013
Pai r 27	RFT - BloodUrea_AT	4.86667	6.08409	1.11080	2.59483	7.13850	4.38 1	2 9	.000
Pai r 28	SerumCreatin_B T - SerumCreatin_A T	.15000	.19783	.03612	.07613	.22387	4.15 3	2 9	.000
Pai r 29	Sodium_BT - Sodium_AT	2.30000	3.44564	.62908	1.01338	3.58662	3.65 6	2 9	.001
Pai r 30	Potassium_BT - Potassium_AT	.07333	.25180	.04597	-.02069	.16736	1.59 5	2 9	.122
Pai r 31	Calcium_BT - Calcium_AT	.13667	.53400	.09750	-.06273	.33607	1.40 2	2 9	.172

Pair 33	Physical Examine - Volume_AT	-2.000	8.769	1.601	-5.274	1.274	-1.249	2	.222
Pair 34	PH_BT - PH_AT	.3833	.8875	.1620	.0519	.7147	2.366	2	.025
Pair 35	Specific_Gravt_B T - Specific_Gravt_A T	.001667	.010532	.001923	-.002266	.005599	.867	2	.393

There is significant improvement in levels of TLC, lymphocytes, monocytes, MCV, MCH, MCHC, platelet count, SGOT, SGPT, alkaline phosphatase, albumin, globulin, A/G ratio, blood urea, serum creatinine, sodium, and urine pH.

**Table 107: Between Group Statistics**

BT-AT=d	Group	N	Mean	Std. Deviation	Std. Error Mean
IgG_d	Group 1	30	-18.1000	119.39368	21.79820
	Group 2	30	-24.5667	104.79724	19.13327
IgM_d	Group 1	30	-1.0767	15.79962	2.88460
	Group 2	30	.3667	10.83399	1.97801
HB_d	Group 1	30	.1433	.75507	.13786
	Group 2	30	-.0067	.77323	.14117
TLC_d	Group 1	30	346.6667	1690.28325	308.60209
	Group 2	30	800.0000	1456.49556	265.91849
Neutro_d	Group 1	30	5.5000	10.83019	1.97731
	Group 2	30	3.8667	10.42124	1.90265
Lympho_d	Group 1	30	-4.4667	9.46767	1.72855
	Group 2	30	-4.5667	11.05374	2.01813
Eosin_d	Group 1	30	.3000	1.11880	.20426
	Group 2	30	.2667	1.55216	.28338
Mono_d	Group 1	30	-1.2667	2.67728	.48880
	Group 2	30	-1.3000	2.33637	.42656
Basso_d	Group 1	30	.0000	.00000 <sup>a</sup>	.00000
	Group 2	30	.0000	.00000 <sup>a</sup>	.00000
RBC_d	Group 1	30	.1340	.41412	.07561
	Group 2	30	.1247	.34106	.06227
PCV_d	Group 1	30	-.3767	3.06658	.55988
	Group 2	30	-.6433	2.27288	.41497
MCV_d	Group 1	30	-4.0933	4.99841	.91258
	Group 2	30	-3.7467	4.83034	.88190
MCH_d	Group 1	30	-1.0333	2.28161	.41656
	Group 2	30	-.7833	2.04974	.37423
MCHC_d	Group 1	30	.2667	1.14269	.20863
	Group 2	30	.4700	1.16238	.21222
PlateletCnt_d	Group 1	30	-.1770	.55289	.10094
	Group 2	30	-.3803	.51710	.09441
ESR_d	Group 1	30	-.4333	6.37172	1.16331
	Group 2	30	-.4667	5.88823	1.07504
Bill_Total_d	Group 1	30	.1500	.28376	.05181
	Group 2	30	.0917	.34940	.06379
Dir_Bill_d	Group 1	30	.0300	.08367	.01528
	Group 2	30	.0267	.11121	.02030
Ind_Bill_d	Group 1	30	.1200	.21877	.03994
	Group 2	30	.0800	.23104	.04218
SGOT_d	Group 1	30	11.0000	19.18692	3.50304
	Group 2	30	24.6667	40.27948	7.35399
SGPT_d	Group 1	30	6.5333	16.65209	3.04024
	Group 2	30	19.1333	30.31869	5.53541

Alkalin_Phosp_d	Group 1	30	16.5667	85.50769	15.61150
	Group 2	30	38.7667	89.52468	16.34490
Tprotein_d	Group 1	30	-.0033	.48883	.08925
	Group 2	30	.0967	.49583	.09053
Albumin_d	Group 1	30	.2067	.53041	.09684
	Group 2	30	.3100	.67892	.12395
Globulin_d	Group 1	30	-.2100	.39944	.07293
	Group 2	30	-.2133	.41251	.07531
A_G_Ratio_d	Group 1	30	.1800	.31228	.05701
	Group 2	30	.2000	.41356	.07551
BloodUrea_d	Group 1	30	2.2000	5.79179	1.05743
	Group 2	30	4.8667	6.08409	1.11080
SerumCreatin_d	Group 1	30	.0343	.19961	.03644
	Group 2	30	.1500	.19783	.03612
Sodium_d	Group 1	30	1.3300	2.09386	.38228
	Group 2	30	2.3000	3.44564	.62908
Potassium_d	Group 1	30	.0467	.29212	.05333
	Group 2	30	.0733	.25180	.04597
Calcium_d	Group 1	30	.0667	.49294	.09000
	Group 2	30	.1367	.53400	.09750
CRP_d	Group 1	30	.0000	.00000 <sup>a</sup>	.00000
	Group 2	30	.0000	.00000 <sup>a</sup>	.00000
Volume_d	Group 1	30	-.8333	11.14817	2.03537
	Group 2	30	-2.0000	8.76907	1.60101
Colour_d	Group 1	30	.0000	.00000 <sup>a</sup>	.00000
	Group 2	30	.0000	.00000 <sup>a</sup>	.00000
Transparency_d	Group 1	30	.0333	.31984	.05839
	Group 2	30	.1667	.37905	.06920
Albumin1_d	Group 1	30	.0333	.80872	.14765
	Group 2	30	.2333	.62606	.11430
Sugar_d	Group 1	30	.0000	.00000 <sup>a</sup>	.00000
	Group 2	30	.0000	.00000 <sup>a</sup>	.00000
Ketone_d	Group 1	30	.0000	.00000 <sup>a</sup>	.00000
	Group 2	30	.0000	.00000 <sup>a</sup>	.00000
PH_d	Group 1	30	.9000	.48066	.08776
	Group 2	30	.3833	.88749	.16203
Specific_Gravt_d	Group 1	30	.0050	.03311	.00605
	Group 2	30	.0017	.01053	.00192
RBC1_d	Group 1	30	-.0333	.41384	.07556
	Group 2	30	.0667	.36515	.06667
PUS_Cell_d	Group 1	30	1.0333	2.00832	.36667
	Group 2	30	.5667	1.92414	.35130
EpithelialCell_d	Group 1	30	.0000	1.33907	.24448
	Group 2	30	.4667	1.83328	.33471
Casts_d	Group 1	30	.0333	.18257	.03333
	Group 2	30	.0000	.00000	.00000
Crystals_d	Group 1	30	.0667	.25371	.04632
	Group 2	30	.0000	.00000	.00000
Bacteria_d	Group 1	30	.0333	.41384	.07556
	Group 2	30	.1333	.57135	.10431

a. t cannot be computed because the standard deviations of both groups are

**Table 108: Levene's Test for equality of variances & t-test**

**Independent Samples Test**

	Levene's Test for Equality of Variances		t-test for Equality of Means					
	F	Sig.	t	df	Sig. (2-taile	Mean Difference	Std. Error Differenc	95% Confidence Interval of the Difference

					d)		e	Lower	Upper
IgG_d	.691	.409	.223	58	.824	6.46667	29.00420	-51.59155	64.52489
IgM_d	2.721	.104	-.413	58	.681	-1.44333	3.49763	-8.44461	5.55794
HB_d	.902	.346	.760	58	.450	.15000	.19732	-.24497	.54497
TLC_d	.143	.707	-1.113	58	.270	453.3333 3	407.3670 2	-1268.767	362.1003 6
Neutro_d	.065	.800	.595	58	.554	1.63333	2.74406	-3.85949	7.12616
Lympho_d	.145	.705	.038	58	.970	.10000	2.65720	-5.21897	5.41897
Eosin_d	.739	.394	.095	58	.924	.03333	.34933	-.66592	.73259
Mono_d	.120	.731	.051	58	.959	.03333	.64875	-1.26529	1.33195
RBC_d	.008	.929	.095	58	.924	.00933	.09795	-.18673	.20540
PCV_d	.833	.365	.383	58	.703	.26667	.69690	-1.12832	1.66165
MCV_d	.034	.854	-.273	58	.786	-.34667	1.26907	-2.88699	2.19366
MCH_d	.008	.929	-.446	58	.657	-.25000	.55998	-1.37091	.87091
MCHC_d	.010	.921	-.683	58	.497	-.20333	.29760	-.79903	.39237
PlateletCnt_d	.014	.905	1.471	58	.147	.20333	.13821	-.07333	.48000
ESR_d	.113	.738	.021	58	.983	.03333	1.58398	-3.13735	3.20402
Bill_Total_d	.167	.684	.710	58	.481	.05833	.08218	-.10617	.22283
Dir_Bill_d	1.119	.294	.131	58	.896	.00333	.02541	-.04753	.05419
Ind_Bill_d	.001	.973	.689	58	.494	.04000	.05809	-.07628	.15628
SGOT_d	3.448	.068	-1.678	58	.099	-13.66667	8.14570	-29.97206	2.63873
SGPT_d	2.283	.136	-1.995	58	.051	-12.60000	6.31536	-25.24158	.04158
Alkalin_Pho sp_d	.024	.877	-.982	58	.330	-22.20000	22.60253	-67.44388	23.04388
Tprotein_d	.374	.543	-.787	58	.435	-.10000	.12712	-.35446	.15446
Albumin_d	.901	.347	-.657	58	.514	-.10333	.15730	-.41820	.21153
Globulin_d	.145	.705	.032	58	.975	.00333	.10484	-.20652	.21318
A_G_Ratio_ d	.435	.512	-.211	58	.833	-.02000	.09461	-.20939	.16939
BloodUrea_ d	.003	.956	-1.739	58	.087	-2.66667	1.53363	-5.73657	.40323
SerumCreati n_d	.135	.715	-2.254	58	.028	-.11567	.05131	-.21838	-.01296
Sodium_d	3.125	.082	-1.318	58	.193	-.97000	.73613	-2.44353	.50353
Potassium_ d	4.463	.039	-.379	58	.706	-.02667	.07041	-.16761	.11428
Calcium_d	.063	.803	-.528	58	.600	-.07000	.13268	-.33560	.19560
Volume_d	1.191	.280	.451	58	.654	1.16667	2.58958	-4.01695	6.35028
Transparenc y_d	4.464	.039	-1.472	58	.146	-.13333	.09055	-.31459	.04792
Albumin1_d	.588	.446	-1.071	58	.289	-.20000	.18672	-.57377	.17377
PH_d	10.04 3	.002	2.804	58	.007	.51667	.18427	.14781	.88553
Specific_Gra vt_d	.619	.435	.525	58	.601	.00333	.00634	-.00937	.01603
RBC1_d	.001	.981	-.992	58	.325	-.10000	.10076	-.30170	.10170
PUS_Cell_d	.002	.969	.919	58	.362	.46667	.50779	-.54979	1.48313
EpithelialCel l_d	4.053	.049	-1.126	58	.265	-.46667	.41449	-1.29636	.36302
Casts_d	4.291	.043	1.000	58	.321	.03333	.03333	-.03339	.10006
Crystals_d	9.609	.003	1.439	58	.155	.06667	.04632	-.02605	.15939
Bacteria_d	1.001	.321	-.776	58	.441	-.10000	.12880	-.35783	.15783

This data suggests that Serum Creatinine levels and PH both have significantly declined from BT to AT.

Between groups study suggest that there is significant difference in the values of SGPT, serum creatinine and urine pH levels between the participants of group 1 and group 2 after the trial duration.

### Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of Colour_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	1.000	Retain the null hypothesis.
2	The distribution of Transparency_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.149	Retain the null hypothesis.
3	The distribution of Albumin1_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.161	Retain the null hypothesis.
4	The distribution of Sugar_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	1.000	Retain the null hypothesis.
5	The distribution of Ketone_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	1.000	Retain the null hypothesis.
6	The distribution of RBC1_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.557	Retain the null hypothesis.
7	The distribution of PUS_Cell_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.315	Retain the null hypothesis.
8	The distribution of EpithelialCell_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.398	Retain the null hypothesis.
9	The distribution of Casts_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.317	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

### Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
10	The distribution of Crystals_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.154	Retain the null hypothesis.
11	The distribution of Bacteria_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.321	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

**Table 109: Tests of Normality**

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
IgM_BT	.170	60	.000	.869	60	.000
IgM_AT	.133	60	.010	.904	60	.000
TLC_BT	.089	60	.200*	.959	60	.044
TLC_AT	.123	60	.024	.942	60	.007
Eosin_BT	.274	60	.000	.729	60	.000
Eosin_AT	.319	60	.000	.694	60	.000
Mono_BT	.177	60	.000	.946	60	.010
Mono_AT	.171	60	.000	.955	60	.027
MCV_AT	.165	60	.000	.919	60	.001
MCH_BT	.147	60	.003	.929	60	.002
MCH_AT	.150	60	.002	.921	60	.001
MCHC_BT	.289	60	.000	.832	60	.000
MCHC_AT	.250	60	.000	.889	60	.000
PlateletCnt_BT	.158	60	.001	.914	60	.000
PlateletCnt_AT	.132	60	.011	.910	60	.000
ESR_AT	.120	60	.031	.947	60	.011
Bill_Total_BT	.163	60	.000	.957	60	.035
Bill_Total_AT	.256	60	.000	.657	60	.000
Dir_Bill_BT	.300	60	.000	.823	60	.000
Dir_Bill_AT	.364	60	.000	.652	60	.000
Ind_Bill_BT	.181	60	.000	.917	60	.001
Ind_Bill_AT	.268	60	.000	.634	60	.000
SGOT_BT	.191	60	.000	.702	60	.000
SGOT_AT	.209	60	.000	.793	60	.000
SGPT_BT	.236	60	.000	.670	60	.000
SGPT_AT	.281	60	.000	.600	60	.000
Alkalin_Phosp_BT	.238	60	.000	.857	60	.000
Alkalin_Phosp_AT	.258	60	.000	.662	60	.000
Albumin_BT	.168	60	.000	.934	60	.003
Albumin_AT	.241	60	.000	.859	60	.000
Globulin_AT	.259	60	.000	.853	60	.000
A_G_Ratio_BT	.162	60	.000	.930	60	.002
A_G_Ratio_AT	.307	60	.000	.694	60	.000
BloodUrea_AT	.163	60	.000	.899	60	.000
SerumCreatin_BT	.158	60	.001	.934	60	.003
SerumCreatin_AT	.148	60	.002	.916	60	.001
Sodium_BT	.212	60	.000	.808	60	.000
Sodium_AT	.280	60	.000	.882	60	.000
Potassium_BT	.176	60	.000	.955	60	.027
Potassium_AT	.163	60	.000	.931	60	.002
Calcium_BT	.121	60	.029	.928	60	.002
Calcium_AT	.136	60	.007	.959	60	.041

For variables which are not normal as reveal by Shapiro-Wilk test, Non-parametric analysis is repeated to test changes from BT to AT using

**Table 110: Wilcoxon Sign Rank Test.**

Group A

Group 1	IgM_AT - IgM_BT	TLC_AT - TLC_BT	Eosin_AT - Eosin_BT	Mono_AT - Mono_BT	MCV_AT - MCV_BT	MCH_AT - MCH_BT	MCHC_AT - MCHC_BT
Z	-.093 <sup>b</sup>	-.844 <sup>b</sup>	-1.374 <sup>b</sup>	-2.416 <sup>c</sup>	-3.920 <sup>c</sup>	-2.383 <sup>c</sup>	-1.235 <sup>b</sup>
Asymp. Sig. (2-tailed)	.926	.399	.169	.016	.000	.017	.217

PlateletCnt_AT - PlateletCnt_BT	ESR_A T - ESR_B T	Bill_Total_A T - Bill_Total_B T	Dir_Bill_A T - Dir_Bill_B T	Ind_Bill_A T - Ind_Bill_B T	SGOT_A T - SGOT_B T	SGPT_A T - SGPT_B T	Alkalin_Phosp_AT - Alkalin_Phosp_BT
-1.503	-.553	-2.697	-1.882	-2.826	-2.987	-1.777	-1.306
.133	.580	.007	.060	.005	.003	.076	.191

Albumin_AT - Albumin_BT	Globulin_AT - Globulin_BT	A_G_Ratio_AT - A_G_Ratio_BT	BloodUrea_AT - RFT	SerumCreatin_AT - SerumCreatin_BT	Sodium_AT - Sodium_BT	Potassium_AT - Potassium_BT	Calcium_AT - Calcium_BT
-2.000	-2.653	-2.654	-1.723	-.743	-2.973	-1.000	-.239
.045	.008	.008	.085	.457	.003	.317	.811

Significant changes are seen in values of monocytes, MCV, MCH, total bilirubin, indirect bilirubin, SGOT, albumin, globulin, A/G ratio and serum sodium.

**Table 111: Group B**

	IgM_AT - IgM_BT	TLC_AT - TLC_BT	Eosin_AT - Eosin_BT	Mono_AT - Mono_BT	MCV_AT - MCV_BT	MCH_AT - MCH_BT	MCHC_AT - MCHC_BT
Z	-.473 <sup>b</sup>	-2.634 <sup>b</sup>	-.935 <sup>b</sup>	-2.665 <sup>c</sup>	-3.565 <sup>c</sup>	-1.923 <sup>c</sup>	-2.242 <sup>b</sup>
Asymp. Sig. (2-tailed)	.636	.008	.350	.008	.000	.054	.025

PlateletCnt_AT - PlateletCnt_BT	ESR_AT - ESR_BT	Bill_Total_AT - Bill_Total_BT	Dir_Bill_AT - Dir_Bill_BT	Ind_Bill_A T - Ind_Bill_B T	SGOT_AT - SGOT_BT	SGPT_AT - SGPT_BT	Alkalin_Phosp_AT - Alkalin_Phosp_BT	Albumin_AT - Albumin_BT
-3.415	-.434	-1.761	-1.188	-1.918	-3.763	-4.348	-1.913	-2.007
.001	.664	.078	.235	.055	.000	.000	.056	.045

	Globulin_AT - Globulin_BT	A_G_Ratio_AT - A_G_Ratio_BT	BloodUrea_AT - RFT	SerumCreatin_AT - SerumCreatin_BT	Sodium_A T - Sodium_B T	Potassium_AT - Potassium_BT	Calcium_AT - Calcium_BT
	-2.637	-2.524	-3.574	-3.275	-3.382	-1.402	-1.532
	.008	.012	.000	.001	.001	.161	.126

a. Wilcoxon Signed Ranks Test

Significant changes are seen in levels of TLC, monocytes, MCV, MCHC, platelet count, SGOT, SGPT, albumin, globulin, A/G ratio, blood urea, serum creatinine and serum sodium.

### Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of IgG_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.918	Retain the null hypothesis.
2	The distribution of IgM_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.976	Retain the null hypothesis.
3	The distribution of HB_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.778	Retain the null hypothesis.
4	The distribution of TLC_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.171	Retain the null hypothesis.
5	The distribution of Neutro_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.745	Retain the null hypothesis.
6	The distribution of Lympho_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.842	Retain the null hypothesis.
7	The distribution of Eosin_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.969	Retain the null hypothesis.
8	The distribution of Mono_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.682	Retain the null hypothesis.
9	The distribution of Basso_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	1.000	Retain the null hypothesis.
10	The distribution of RBC_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.965	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

### Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
11	The distribution of PCV_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.605	Retain the null hypothesis.
12	The distribution of MCV_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.970	Retain the null hypothesis.
13	The distribution of MCH_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.857	Retain the null hypothesis.
14	The distribution of MCHC_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.511	Retain the null hypothesis.
15	The distribution of PlateletCnt_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.137	Retain the null hypothesis.
16	The distribution of ESR_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.812	Retain the null hypothesis.
17	The distribution of Bill_Total_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.425	Retain the null hypothesis.
18	The distribution of Dir_Bill_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.685	Retain the null hypothesis.
19	The distribution of Ind_Bill_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.388	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

### Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
20	The distribution of SGOT_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.153	Retain the null hypothesis.
21	The distribution of SGPT_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.008	Reject the null hypothesis.
22	The distribution of Alkalin_Phosp_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.559	Retain the null hypothesis.
23	The distribution of Tprotein_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.378	Retain the null hypothesis.
24	The distribution of Albumin_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.313	Retain the null hypothesis.
25	The distribution of Globulin_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.882	Retain the null hypothesis.
26	The distribution of A_G_Ratio_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.533	Retain the null hypothesis.
27	The distribution of BloodUrea_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.063	Retain the null hypothesis.
28	The distribution of SerumCreatin_d is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.025	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

- **Group A:** Significant improvement in levels of neutrophils, lymphocytes, monocytes, MCV, MCH, total bilirubin (indirect bilirubin), SGOT, SGPT, albumin, globulin, A/G ratio, blood urea, serum sodium, and urine pH observed after intervention.
- **Group B:** Significant improvement in levels of TLC, lymphocytes, monocytes, MCV, MCH, MCHC, platelet count, SGOT, SGPT, alkaline phosphatase, albumin, globulin, A/G ratio, blood urea, serum creatinine, sodium, and urine pH seen.
- Serum Creatinin levels and PH both have significantly declined from BT to AT. Between the group study suggests that there is significant difference in the values of SGPT, serum creatinine and urine pH levels between the participants of group 1 and group 2 after the trial duration.
- **Group A:** Significant changes seen in values of monocytes, MCV, MCH, total bilirubin, indirect bilirubin, SGOT, albumin, globulin, A/G ratio and serum sodium.
- **Group B:** Significant changes seen in levels of TLC, monocytes, MCV, MCHC, platelet count, SGOT, SGPT, albumin, globulin, A/G ratio, blood urea, serum creatinine and serum sodium.

### 9.3 SAFETY CONCLUSIONS

No adverse events or serious ill effects encountered during the study. The laboratory findings related to liver function, kidney function and blood components were found within normal range even after intervention of the study compound.

All vital signs and physical findings indicated a normal healthy state of the volunteers after the trial.

The compound is found safe and no adverse effects were encountered during the study duration.

## 10. CONCLUSIONS

The compound is found effective in immunomodulation as evidenced by improvement in ISQ scores after the intervention in this study. Analysis of immunoglobulins IgG and IgM showed no significant difference in their values. Vital signs, physical findings and other observations suggest that the compound doesn't have any serious ill-effects on general well being.

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Available from:  
[https://www.researchgate.net/publication/325216543\\_Anti-inflammatory\\_immune-modulatory\\_and\\_antioxidant\\_effects\\_of\\_date\\_fruit\\_Phoenix\\_dactylifera\\_extract\\_in\\_rats\\_treated\\_with\\_AICl3\\_Corresponding\\_authors](https://www.researchgate.net/publication/325216543_Anti-inflammatory_immune-modulatory_and_antioxidant_effects_of_date_fruit_Phoenix_dactylifera_extract_in_rats_treated_with_AICl3_Corresponding_authors)
7. J F WilodVersprille L, J A E van de Loo A, Mackus M, Arnoldy L, A L Sulzer T, Vermeulen SA, Abdulahad S, Huls H, Baars T, Scholey A, Kraneveld AD, Garssen J, Verster JC. Development and Validation of the Immune Status Questionnaire (ISQ). *Int J Environ Res Public Health*. 2019 Nov 27;16(23):4743. doi: 10.3390/ijerph16234743. PMID: 31783555; PMCID: PMC6926937.

## 12. APPENDICES

### 12.1 Case Report Form

**R00**

### CASE- REGISTRATION FORM

#### Demographic form

#### Participant's Information

Name: \_\_\_\_\_ Date: \_\_\_\_\_  
Father's Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
Contact Number: \_\_\_\_\_ Occupation: \_\_\_\_\_  
Whatsapp Number: \_\_\_\_\_  
Date of Birth: \_\_\_\_\_ Gender: \_\_\_\_\_  
Marital Status: \_\_\_\_\_ Nationality: \_\_\_\_\_  
Email Address: \_\_\_\_\_

#### Emergency Contact:

Name: \_\_\_\_\_  
Relationship to patient: \_\_\_\_\_ Contact number: \_\_\_\_\_

#### Details of Investigators

1. Principle investigator: **Vd. Shubham Garg**  
Contact number: 9997772737
2. Co-investigator: **Dr. Yogita Bisht**  
Contact number: 9958288312

#### Details of Ayurveda Experts

Ayurveda Expert 1- **Dr. Bhavna Singh**

Ayurveda Expert 2- **Dr. Ankur Singhal**

By signing below, I acknowledge that the information I provided is correct to the best of my knowledge.

Participant's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Place: \_\_\_\_\_

## CONSENT FORM

I ....., a resident of....., have been informed about the ongoing clinical trial of a polyherbal compound OC22 for a period of 7 weeks on healthy volunteers. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I also understand that my anonymity will be ensured and my personal information will not be disclosed.

I shall be responsible for informing the investigators regarding the medication requirements and any known medical condition. I shall be solely responsible for any other unusual event or health issues they may be encountered during the period of the trial.

The investigators have fully explained to me the purpose of the study and options of withdrawal.

I hereby give my consent voluntarily in full consciousness to participate as a participant in this research.

Name of the participant: Signature:

Address of participant:

Witness 1 signature:

Relation to the participant:

Contact number of witness 1:

Address of witness 1:

Witness 2 signature:

Relation to the participant:

Contact number of witness 2:

Address of witness 2:

Date:

Place:

## Case-record form

### General examination

Appearance:	
Nutrition status:	
Decubitus:	
<b>Hair:</b>	
Skin and nails:	
Eyes:	
Ear, nose and throat:	
Tongue:	
Pallor:	
Icterus:	
Cyanosis:	
Clubbing:	
Lymphadenopathy:	
Edema:	

### **Vitals:**

Temperature:	
Pulse rate:	
Respiratory rate:	
Blood pressure	

### **Personal history**

Appetite:	
Bowel:	
Bladder:	
Sleep:	

Diet:	
Addiction:	
Socio-economic status:	

### **AYURVEDIC EXAMINATION**

#### **ASHTVIDH PAREEKSHA**

Nadi	
Mala	
Mutra	
Jiwha	
Shabdh	
Sparsh	
Drik / netra	
Aakriti	

#### **DASHVIDH PAREEKSHA**

Prakriti	
Vikriti	
Sara	
Sanhanana	
Satmya	
Satva	
Pramana	
Aahar-shakti	
Vyayam-shakti	
Vaya	

**ASSESSMENT CRITERIA (VISIT -1) Date:**

- **Subjective criteria: Immune Status questionnaire (ISQ) - reliable, validated and short self-assessment questionnaire investigating the past 12 months' immune status.**

S.No.	Items	NEVER	SOMETIMES	REGULARLY	OFTEN	(ALMOST) ALWAYS
1.	Sudden High Fever					
2.	Diarrhea					
3.	Headache					
4.	Skin problems (eg. acne & eczema)					
5.	Muscle & joint pain					
6.	Common cold					
7.	Coughing					

**How you feel at this moment?**

A	I score my general health the following grade (0= very bad; 10= very good)	....	....
B	I score my immune functioning the following grade (0= very bad; 10= very good)	....	....
C	Do you have reduced immune functioning at this moment?	Yes	No
D	Do you have any chronic disease? If yes, please specify: .....	Yes	No

**VISIT- 2**

S.No.	Items	NEVER	SOMETIMES	REGULARLY	OFTEN	(ALMOST) ALWAYS
1.	Sudden High Fever					
2.	Diarrhea					
3.	Headache					
4.	Skin problems (eg. acne & eczema)					
5.	Muscle & joint pain					
6.	Common cold					
7.	Coughing					

**How you feel at this moment?**

A	I score my general health the following grade (0= very bad; 10= very good)	....	....
B	I score my immune functioning the following grade (0= very bad; 10= very good)	....	....
C	Do you have reduced immune functioning at this moment?	Yes	No
D	Do you have any chronic disease? If yes, please specify: .....	Yes	No

**VISIT- 3**

S.No.	Items	NEVER	SOMETIMES	REGULARLY	OFTEN	(ALMOST) ALWAYS
1.	Sudden High Fever					
2.	Diarrhea					
3.	Headache					
4.	Skin problems (eg. acne & eczema)					
5.	Muscle & joint pain					
6.	Common cold					
7.	Coughing					

**How you feel at this moment**

A	I score my general health the following grade (0= very bad; 10= very good)	....	....
B	I score my immune functioning the following grade (0= very bad; 10= very good)	....	....
C	Do you have reduced immune functioning at this moment?	Yes	No
D	Do you have any chronic disease? If yes, please specify: .....	Yes	No

**ISQ scoring instructions:**

Raw Score	Final Score
>=15	0
14	1
13	2
11,12	3

10	4
8,9	5
7	6
6	7
5	8
3,4	9
=<2	10

Each item of the ISQ will be scored as follows: Never = 0 points; Sometimes = 1 point; Regularly = 2 points; Often = 3 points; (Almost) always = 4 points; The sum score of the 7 ISQ items will be calculated. To obtain the final ISQ score, the "raw" ISQ scores will be translated as follows: Interpretation: 0 = very poor, 10 excellent perceived immune status. Cut off for reduced immune functioning :ISQ<6

**Parameters for Assessment (Objective):**

	Visit-1(Date )	Visit-2(Date )	Visit-3(Date )
IgG IgM CBC: Hb- TLC DLC RBC- Platelet count- CRP-			
Weight			
Height			
BMI			
Urine analysis			

## 12.2 Ethics Committees and Subject Information



### GS AYURVEDA MEDICAL COLLEGE & HOSPITAL

NH-24, PILKHUWA, DISTT. - HAPUR (U.P.) - 245 304

E-mail : gsmedicalcollege@gmail.com, info@gsayurvedamedicalcollege.com, Website : www.gsayurvedamedicalcollege.com

Contact No.: 0122-2327400, Fax No.: 0122-2327499, Toll-free No.: 1800 180 3009

(Approved by CCIM & Ministry of Ayush, New Delhi; Affiliated to CCS University, Meerut)

#### INSTITUTIONAL ETHICS COMMITTEE

IEC – GSAMCH/2022-P

Date: 04/04/22

To,

Vd. Shubham Garg  
Associate Professor, Dravyaguna  
GS Ayurveda Medical College and Hospital

Dr. Yogita Bisht  
Associate Professor, Kayachikitsa  
GS Ayurveda Medical College and Hospital

The Institutional Ethics Committee of GS Ayurveda Medical College and Hospital reviewed and discussed your application to conduct the clinical trial entitled **"A Randomized Controlled Clinical Trial to Evaluate the Immunomodulatory Profile of a Polyherbal Compound OC22 on Apparently Healthy Volunteers"**. Submitted by Vd. Shubham Garg and Dr. Yogita Bisht. The following documents were reviewed,

- Study Protocol
- Patient Information Sheet and Informed Consent Form (including updates if any) in English and or vernacular language.
- CRF/ Assessment parameters & Other relevant documents attached

**We approve the study to be conducted in its presented form.**

**Please note:**

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
  - Inform EC in case of any change of study procedure, site and investigator
  - Annual report to be submitted to EC
  - The study has to be conducted as per approved protocol. Any amendments in the Protocol/ ICF/ CRF has to be approved from IEC before implementation
  - Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/ Ongoing/ Terminated) should be reported annually.

On Behalf of ethics committee, we wish you success in your research.

(Dr. PK Prajapati)

Chairman  
Institutional Ethics Committee

## 12.3 Randomisation Code



The screenshot shows a web browser window with the address bar displaying "random.org/sequ". The page header features the "RANDOM.ORG" logo in a large, bold, monospace font, with the tagline "True Random Number Service" underneath. A navigation menu includes links for Home, Lists & More, Statistics, Login, Games, Drawings, Testimonials, Numbers, Web Tools, and Learn More. Below the menu is a search bar with the placeholder text "Search RANDOM.ORG" and a "Search" button.

### Random Sequence Generator

Here is your sequence:

58	51
17	20
19	25
31	26
4	33
28	54
37	59
3	56
36	43
2	24
60	46
11	15
23	16
57	5
50	44
48	39
40	32
12	6
47	8
10	7
22	53
29	13
55	52
38	27
9	34
41	21
49	45
14	35
30	42
1	18

Timestamp: 2022-05-20 06:12:58 UTC

[Again!](#) [Go Back](#)

Note: The numbers are generated left to right, i.e., across columns.

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Article

## Development and Validation of the Immune Status Questionnaire (ISQ)

Livia J. F. Wilod Versprille <sup>1</sup>, Aurora J. A. E. van de Loo <sup>1,2</sup>, Marlou Mackus <sup>1</sup>, Lianne Arnoldy <sup>1</sup>, Titia A. L. Sulzer <sup>1</sup>, Sterre A. Vermeulen <sup>1</sup>, Smedra Abdulahad <sup>1</sup>, Hendrikje Huls <sup>1</sup>, Ton Baars <sup>1</sup>, Andrew Scholey <sup>3</sup>, Aletta D. Kraneveld <sup>1,2</sup>, Johan Garssen <sup>1,4</sup> and Joris C. Verster <sup>1,2,3,\*</sup>

- <sup>1</sup> Utrecht Institute for Pharmaceutical Sciences (UIPS), Division of Pharmacology, Utrecht University, 3584 CG Utrecht, The Netherlands; l.j.f.wilodversprille@students.uu.nl (L.J.F.W.V.); a.j.a.e.vandeloo@uu.nl (A.J.A.E.v.d.L.); marloumackus@gmail.com (M.M.); lamoldy@students.uu.nl (L.A.); titiasulzer@gmail.com (T.A.L.S.); s.a.vermeulen@students.uu.nl (S.A.V.); s.abdulahad96@gmail.com (S.A.); ingridhuls@hotmail.com (H.H.); t.baars@fingerprint.nl (T.B.); a.d.kraneveld@uu.nl (A.D.K.); j.garsen@uu.nl (J.G.)
- <sup>2</sup> Institute for Risk Assessment Sciences (IRAS), Faculty of Veterinary Medicine, Utrecht University, 3584 CM Utrecht, The Netherlands
- <sup>3</sup> Centre for Human Psychopharmacology, Swinburne University of Technology, Melbourne, VIC 3122, Australia; andrew@scholeylab.com
- <sup>4</sup> Immunology Platform for Specialized Nutrition, Danone Nutricia Research, 3584 CT Utrecht, The Netherlands
- \* Correspondence: j.c.verster@uu.nl; Tel.: +31-30-253-6909

Received: 4 October 2019; Accepted: 24 November 2019; Published: 27 November 2019



**Abstract:** The self-assessment of perceived immune status is important, as this subjective observation leads individuals to decide whether or not to seek medical help or adapt their lifestyle. In addition, it can be used in clinical settings and research. The aim of this series of studies was to develop and validate a short questionnaire to assess perceived immune functioning. Five surveys were conducted among Dutch and International young healthy adults (18–30 years old), and two others among older age groups with various health complaints. For the first study, an existing immune functioning scale was modified and elaborated resulting in 23 immune-health-related items, of which the occurrence was rated on a 5-point Likert scale. A student sample was surveyed, and the results were used to shorten the 23-item listing into a 7-item scale with a predictive validity of 85%. Items include “sudden high fever”, “diarrhea”, “headache”, “skin problems (e.g., acne and eczema)”, “muscle and joint pain”, “common cold” and “coughing”. The scale is named Immune Status Questionnaire (ISQ), and it aims to assess perceived immune status over the preceding year. The second study revealed that the ISQ score correlated significantly with a 1-item perceived immune functioning ( $r = 0.383$ ,  $p < 0.0001$ ). In the third study, the final Likert scale descriptors were determined (“never”, “sometimes”, “regularly”, “often” and “(almost) always”). The fourth study showed that the test–retest reliability of the ISQ is acceptable ( $r = 0.80$ ). The fifth study demonstrated the association of ISQ scores with various neuropsychological and health correlates in an international sample, including perceived health and immune fitness, as well as levels of stress, fatigue, depression and anxiety. Study 6 demonstrated significant associations between ISQ scores and experiencing irritable bowel syndrome (IBS) symptoms in a sample of insomnia patients. Study 7 compared the effect of a dietary intervention in participants reporting “poor health” versus “normal health”. It is shown that ISQ scores can differentiate between those with poor and normal health, and that an effective intervention is associated with a significant improvement in ISQ scores. Data from Study 7 were further used to determine an ISQ cut-off value for reduced immune functioning, and a direct comparison with 1-item perceived immune functioning scores enabled constructing the final scoring

multiple items. A study introducing the IFQ revealed significant associations of IFQ scores with the number of general physician visits, general health and experiencing problematic internet use [23]. Although it has not been used in clinical practice, our group used the IFQ in two of our studies [19,22]. This led to the identification of certain shortcomings. Specifically, the IFQ does not capture some of the common aspects of a compromised immune function, such as muscle and joint pain or the common cold. On the other hand, it does include some relatively less common items, such as meningitis, slow healing wounds and boils.

The immune system assessment questionnaire (ISAQ) was developed as an alternative scale [24]. The ISAQ is an elaborate questionnaire with high specificity but moderate sensitivity to identify immune dysfunction. Sievers et al. [18] altered the ISAQ to obtain the infectious disease questionnaire (or "ID screen"). The ID screen is used to investigate infectious diseases and their risk factors, rather than overall immune functioning. Although it has been more extensively validated, it is not a suitable alternative for the ISQ, largely because it specifically targets identification of infectious disease rather than overall immune status. Finally, the Sickness questionnaire (SicknessQ) of Andreasson et al. [17] was developed to investigate symptoms of immune activation related to sickness behavior. Andreasson reported significant associations between SicknessQ scores and depression, anxiety, self-rated health and a single item of feeling sick. Despite the development of these questionnaires, a literature search did not identify any studies using the IFQ, ISAQ, the ID screen or the SicknessQ in clinical practice. This may be caused by the fact that the scales were elaborate and focusing on specific aspects of immune symptom functioning (e.g., infectious disease risk) rather than providing a global rating of general immune fitness assessed over a relevant period of time (e.g., the past year). Therefore, the aim of the current series of studies was to develop, validate and implement a short and cost-effective immune status questionnaire, with applicability in multiple settings, including clinical practice, research and self-assessment.

**2. Materials and Methods**

To develop and validate the ISQ, five studies were conducted. The ISQ was implemented in two subsequent studies [25,26]. The seven studies (summarized in Figure 1) are detailed in following sections. The studies were conducted by Utrecht University and the Ethics Committee of the Faculty of Social and Behavioral Sciences of Utrecht University granted ethical approval (approval code FETC17-061).

<b>Development &amp; validation of the ISQ</b>	
<b>Study</b>	<b>Aim</b>
Study 1	Selection of ISQ items
Study 2	Comparison to 1-item perceived immune functioning
Study 3	Improving the scoring format of the ISQ Cronbach's alpha, reliability of the ISQ Comparison to 1-item perceived immune functioning
Study 4	Test-retest reliability
Study 5	Comparison to 1-item perceived immune functioning Cronbach's alpha Relation to mood correlates
<b>Implementation of the ISQ</b>	
Study 6	Association with insomnia and IBS complaints
Study 7	Impact of dietary change on ISQ scores Selecting a cut off score for reduced immune fitness

Figure 1. Overview of the studies.

For study 1, a stepwise linear regression analysis was conducted to investigate which items significantly impacted the total IFQ score and should be included in the ISQ. The model should predict the IFQ score for at least 85%. For Studies 2 and 3, a Spearman correlation analysis was conducted to investigate the relationship between the ISQ and the 1-item perceived immune functioning and general health scores. In all text and tables throughout the manuscript Spearman's rho is referred to as "r". In Study 3, reliability analysis was conducted by computing Cronbach's alpha, Spearman–Brown split-half, the average inter-item correlation, and the average item-total correlation. In Study 4, data from two different test occasions on which the same sample completed the ISQ were compared using nonparametric independent samples Mann–Whitney U tests, and a Spearman correlation analysis was conducted to investigate test-retest reliability.

In Study 5, the ISQ was tested in an international sample and scores were correlated (Spearman's rho) with the assessed health outcomes (e.g., depression and stress). In Study 6, ISQ scores were correlated with IBS outcomes by computing nonparametric Spearman's rho correlations. Differences between men and women, between those formally diagnosed with insomnia and those with self-reported insomnia complaints, and between those reporting sleep initiation or sleep maintenance problems, or both, were computed using nonparametric independent samples Mann–Whitney U tests. In Study 7, ISQ scores were compared (1) before versus after the dietary change, (2) between men and women, (3) between participants with a "poor" and "normal" health and (4) between rural and urban living location, using nonparametric independent samples Mann–Whitney U tests. Outcomes were considered significant if  $p < 0.05$ . In addition, to determine a cut off point for reduced immune functioning, a direct comparison was made via linear data fitting, between ISQ scores and 1-item perceived immune functioning scores. For the 1-item perceived immune functioning scale, reduced immune fitness is assumed if a score below 5.5 is obtained. The corresponding ISQ score is proposed as ISQ cut off point for reduced immune functioning.

### 3. Results

#### 3.1. Development of the ISQ (Study 1)

N = 295 participants completed the survey. The study outcomes are summarized in Table 1.

**Table 1.** Demographics and results for Study 1.

	Total	Men	Women	p-Value
<b>Total number of participants</b>	n = 279 (100%)	n = 99 (35.5%)	n = 180 (64.5%)	0.0001 *
<b>Reduced immune function</b>	n = 60 (21.5%)	n = 11 (11.1%)	n = 49 (27.2%)	0.001 *
<b>Chronic disease</b>	n = 32 (11.5%)	n = 6 (6.0%)	n = 26 (14.4%)	0.029 *
	Mean (SD)	Mean (SD)	Mean (SD)	p-Value
<b>Age (years)</b>	22.9 (3.4)	22.7 (3.4)	23.0 (3.4)	0.459
<b>Perceived general health</b>	8.4 (1.2)	8.5 (1.2)	8.4 (1.2)	0.249
<b>Perceived immune functioning</b>	8.6 (1.5)	8.9 (1.3)	8.4 (1.6)	0.014 *
<b>IFQ score</b>	35.8 (7.5)	33.5 (5.0)	37.1 (8.3)	0.0001 *
<b>ISQ score</b>	16.1 (3.8)	15.0 (2.9)	16.7 (4.1)	0.0001 *

p-values are considered significant if  $p < 0.05$  (indicated by \*). Abbreviations: IFQ = immune functioning questionnaire, ISQ = immune status questionnaire.

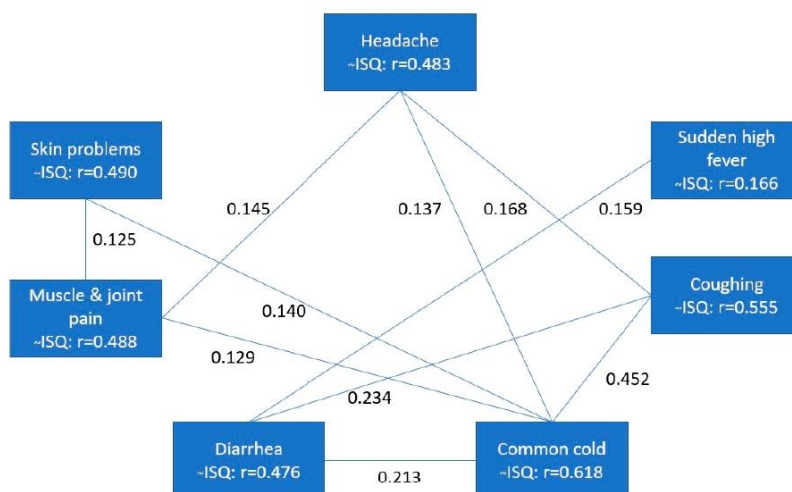
Significantly more women completed the survey than men. Men reported significantly better immune functioning than women. A stepwise regression analysis was performed to construct the ISQ. The total score of all 23 items was used to identify which items significantly contributed to predicting the total score (see Figure 2). These items then would form the ISQ.

**Table 6.** Correlation between ISQ scores with the old and new scoring.

ISQ Item	Correlation	p-Value
Sudden high fever	0.639	0.0001 *
Diarrhea	0.828	0.0001 *
Headache	0.801	0.0001 *
Skin problems	0.909	0.0001 *
Muscle and joint pain	0.840	0.0001 *
Common cold	0.654	0.0001 *
Coughing	0.704	0.0001 *
Total ISQ score	0.782	0.0001 *

Correlations are considered significant if  $p < 0.05$ , indicated with \*.

The ISQ scores had a mean ( $\pm$ SD) of 7.7 ( $\pm$ 3.1). The Tukey’s Hinges 25, 50 and 75 percentiles are 5, 7 and 10, respectively. Several tests were performed to investigate the internal consistency reliability of the ISQ. Cronbach’s alpha was 0.471, while the Spearman–Brown split-half reliability was 0.452. Furthermore, the inter-item correlations were calculated, as well as the correlations between individual item scores and the total ISQ score. These are depicted in Figure 3.



**Figure 3.** Relationship between individual ISQ items and the total ISQ score. Spearman’s rho correlations ( $r$ ) were computed. Only significant correlations ( $p < 0.05$ ) between the ISQ items are shown by connecting lines. Significant correlations of individual items with the total ISQ score ( $\sim$ ISQ) are also shown. Abbreviation: ISQ = immune status questionnaire.

It is evident from Figure 3 that all individual items are highly and significantly correlated ( $r > 0.4$  in all cases) with the total ISQ score. In contrast, the correlations between the single ISQ items are low (around  $r = 0.1$ ) and often not statistically significant, with the exception of coughing and the common cold.

Correlations between the ISQ score and 1-item perceived immune functioning and general health are summarized in Table 7. For all items, except sudden high fever and muscle and joint pain, significant correlations were found with 1-item perceived immune functioning and general health.

**Table 7.** Spearman's rho correlations between the ISQ scores and single items with perceived immune functioning and general health.

--	Perceived Immune Functioning		Perceived General Health	
	Correlation	p-Value	Correlation	p-Value
<b>Sudden high fever</b>	−0.089	0.131	0.074	0.210
<b>Diarrhea</b>	−0.151	0.010 *	−0.176	0.003 *
<b>Headache</b>	−0.190	0.001 *	−0.212	0.0001 *
<b>Skin problems</b>	−0.167	0.005 *	−0.193	0.001 *
<b>Muscle and joint pain</b>	0.006	0.915	−0.062	0.295
<b>Common cold</b>	−0.341	0.0001 *	−0.226	0.0001 *
<b>Coughing</b>	−0.204	0.001 *	−0.212	0.0001 *
<b>ISQ score</b>	−0.314	0.0001 *	−0.318	0.0001 *

Correlations are considered significant if  $p < 0.05$ , indicated with \*.

### 3.4. Test Re-Test Reliability of the ISQ (Study 4)

A total of 53 participants (26.4% men and 73.6% women) completed the ISQ at two test moments, separated by 8 or 10 days. Their mean (SD) age was 18.9 (1.0) years old. A total of 37.7% of them reported reduced immune resistance and 13.2% reported having a chronic disease. Their mean (SD) 1-item perceived immune functioning and general health scores were 7.4 (1.3) and 7.6 (1.0), respectively. The mean (SD) ISQ scores on the test and re-test session were 8.4 (3.7) and 8.2 (3.6), respectively, and did not significantly differ from each other ( $p = 0.504$ ). The test re-test reliability of the ISQ was 0.796 ( $p < 0.0001$ ), with significant correlations for all individual items (see Table 8).

**Table 8.** Test re-test reliability of the ISQ.

ISQ Item	Correlation	p-Value
<b>Sudden high fever</b>	0.508	0.0001 *
<b>Diarrhea</b>	0.665	0.0001 *
<b>Headache</b>	0.827	0.0001 *
<b>Skin problems</b>	0.719	0.0001 *
<b>Muscle and joint pain</b>	0.793	0.0001 *
<b>Common cold</b>	0.758	0.0001 *
<b>Coughing</b>	0.837	0.0001 *
<b>Total ISQ score</b>	0.796	0.0001 *

Correlations are considered significant if  $p < 0.05$ , indicated with \*.

### 3.5. Study 5: Exploration Health Correlates of the ISQ in an International Sample

A total of 333 participants completed the survey, of which 246 were on holiday and 87 worked in Fiji. The majority were residents of Australia (14.1%), Europe (73.6%) and USA (9.0%). The mean (SD) age of the sample was 24.8 (6.7) years old (56.5% were women). Their mean (SD) ISQ score was 5.8 (3.2). The distribution of ISQ scores is displayed in Figure 4 with a minimum and maximum score of 0 and 20, respectively. The Tukey's Hinges 25, 50 and 75 percentiles are 4, 6 and 8, respectively. Cronbach's alpha was 0.632.

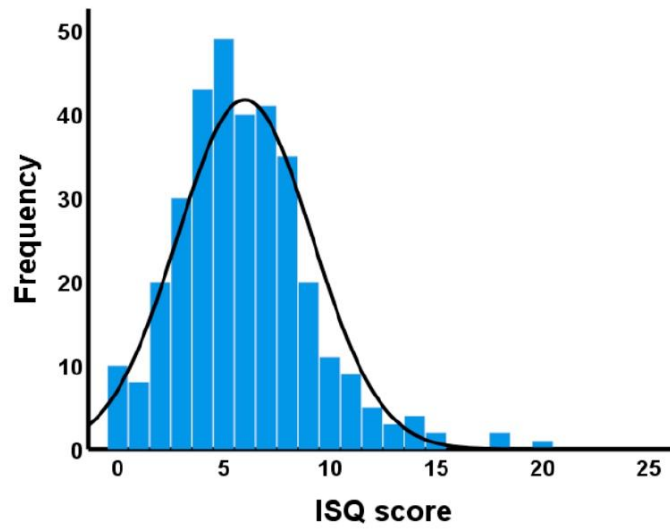


Figure 4. Distribution of ISQ scores. Higher ISQ scores imply poorer immune status.

No significant differences were found between participants who were in Fiji on holiday or for work, nor were any relevant sex differences observed. In this study, the ISQ correlated significantly with 1-item perceived immune functioning ( $r = -0.385, p < 0.0001$ ) and general health ( $r = -0.244, p < 0.0001$ ).

ISQ scores correlated significantly with past year’s stress, anxiety, depression and fatigue (see Figure 5). No significant correlations were found between the ISQ score and anger/hostility. The correlation between ISQ and being active was also not statistically significant.

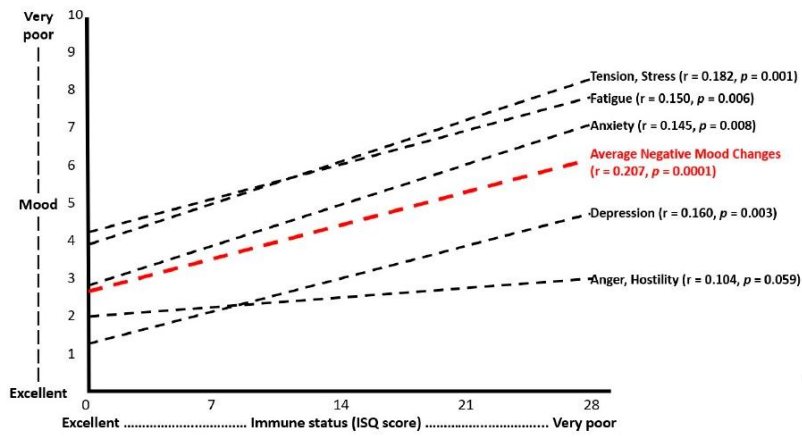


Figure 5. Relationship between ISQ scores and mood.

Immune status was assessed with the immune status questionnaire (ISQ). An average “negative mood changes score” was computed by averaging the scores on the 5 mood scales. Spearman’s rho correlations ( $r$ ) were considered statistically significant if  $p < 0.05$ .

### 3.6. Study 6: Relationship of ISQ with Irritable Bowel Syndrome in an Insomnia Sample

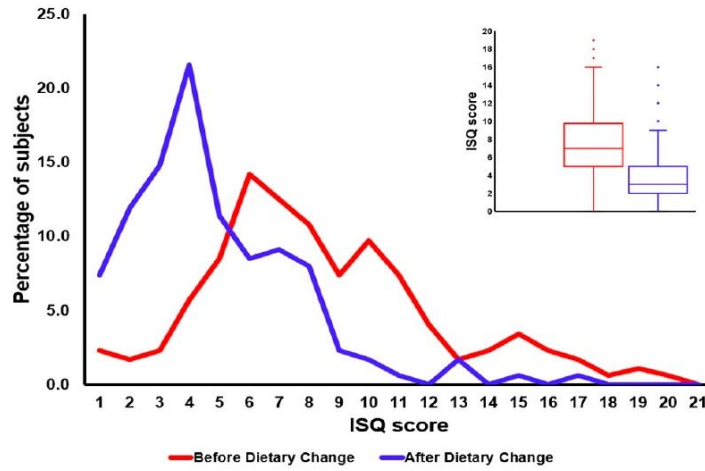
In this study, 487 participants completed the ISQ. Their mean (SD) age was 37.1 (13.4) years old, and 85.3% of the sample were women. The analysis revealed that ISQ scores were significantly correlated with 1-item perceived immune functioning. ISQ scores correlated significantly ( $p < 0.0001$ ) with the overall IBS score ( $r = 0.448$ ), and the IBS subscale scores for constipation ( $r = 0.224$ ), pain ( $r = 0.418$ ) and diarrhea ( $r = 0.411$ ). ISQ scores also correlated significantly with sleep quality ( $r = -0.22$ ). ISQ scores in women ( $9.5 \pm 9.3$ ) were significantly higher ( $p = 0.009$ ) than those in men ( $8.3 \pm 3.8$ ). ISQ scores in those formally diagnosed with insomnia ( $n = 133$ ,  $ISQ = 9.8 \pm 3.7$ ) were significantly higher ( $p = 0.021$ ) than ISQ scores in participants with self-reported insomnia complaints that were not formally diagnosed ( $n = 354$ ,  $ISQ = 9.1 \pm 4.0$ ). ISQ scores also differentiated between the nature of insomnia. That is, those who report problems with both sleep initiation and sleep maintenance had significantly higher ISQ scores than those who reported only sleep maintenance problems ( $10.2 \pm 3.9$  versus  $8.2 \pm 3.6$ , respectively,  $p = 0.0001$ ). Those who reported only sleep initiation problems had a mean (SD) ISQ score of  $9.2$  ( $4.1$ ), which did not significantly differ from the two other groups. Detailed results of this study not pertinent to the development and validation of the ISQ are discussed elsewhere [22].

### 3.7. Study 7: ISQ Scores in Dutch Participants with Poor Versus Normal Health: The Impact of a Dietary Change

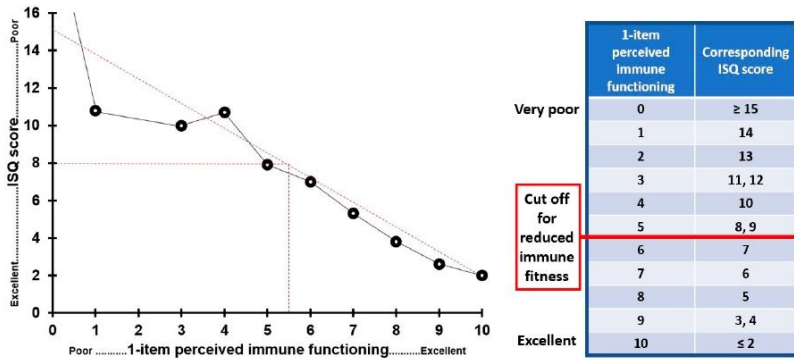
A total of 391 participants with a mean age of 54 years old completed the survey. Of the sample, 35.1% were men, and 45.0% reported to have poor health before switching to consuming RFM products. After the dietary change to RFM significant improvements on health and mood scores were reported, and the strongest improvements were reported by participants from the “poor health” group (discussed in detail elsewhere [26]). The health improvements in the “poor health” group were accompanied by a significant reduction in ISQ scores, suggesting improved immune fitness (see Figure 6).

The absolute difference in ISQ scores between the “poor health” group ( $ISQ = 7.4 \pm 3.8$ ) and “normal health” group ( $ISQ = 4.3 \pm 2.7$ ) was 3.1, and statistically significant ( $p < 0.001$ ). In the “poor health” group,  $\Delta ISQ$  ( $ISQ$  before –  $ISQ$  after switching to RFM) was most pronounced ( $\Delta ISQ = -3.6$ ,  $p < 0.001$ ), but also the “normal health” group reported an improvement in immune fitness ( $\Delta ISQ = -1.8$ ,  $p < 0.001$ ). Overall, 76.0% of subjects reported an improvement in ISQ score after switching to RFM, 17.4% reported no change and 6.6% reported a worsening of immune status. Women had more health complaints before switching to RFM than men, which was reflected in significantly higher ISQ scores in women ( $p < 0.010$ ). In both the “poor health” group and the “normal health” group sex differences in dietary change effects were small ( $\Delta ISQ < 1$ ) and not significant. ISQ scores did not significantly differ according to living location (i.e., urban versus rural). Other results of this study, not pertinent to the development and validation of the ISQ, are discussed in the original article [26].

To determine an ISQ cut off score for reduced immune functioning, scores were compared with 1-item perceived immune functioning ratings that were obtained for the same time period ( $n = 902$ ). These were scored on a scale ranging from 0 (poor) to 10 (excellent). The same scoring system is used for educational grading in The Netherlands, with a score of 5.5 as cut off for pass/fail the exam. The same cut off was used to determine a cut off for the ISQ. The results are summarized in Figure 7. The data suggest a linear relationship between ISQ and 1-item perceived immune functioning scores. It appears that a cut off for reduced immune function equals an ISQ score of 8.



**Figure 6.** The distribution of ISQ scores before and after the dietary change to consume raw fermented milk (RFM) products. A leftward shift of the distribution indicates improved immune fitness after the dietary change. The right top box plot figure shows the minimum, first quartile (Q1), median, third quartile (Q3) and maximum ISQ scores obtained before and after the dietary change. A significant reduction ( $p < 0.0001$ ) in mean ISQ scores was found after the dietary change, suggesting improved immune fitness (discussed in detail elsewhere [26]).



**Figure 7.** Comparison of ISQ and 1-item perceived immune functioning scores. ISQ and 1-item perceived immune functioning ratings were covering the same time period. The best fitting line through the data points is used to determine a cut off point for reduced immune functioning.

3.8. Final ISQ

To improve clarity, an adjustment was made to the ISQ using the time frame “past 12 months” instead of “past year” to report immune status. For example, if the survey is completed in August 2019, the time frame should be “August 2018 to August 2019”. A minority of participants, however, may interpret “past year” as “2018”. Literature confirms that in this way more precise responses are obtained for a minority of participants that interpret the time frame wrong [24].

To ease the understanding and interpretation of the ISQ sum score, here we propose to recalculate the original ISQ scores (score range 0 to 28) into a new 0–10 scoring format. This is accomplished using the score translation made in Figure 7, where we compared ISQ scores with a 1–point perceived immune functioning completed for the same time period (see Figure 7). Adopting the new scoring format yields a easier to interpret ISQ outcome scale. The final ISQ scoring ranges from 0 (poor) to 10 (excellent), with higher scores corresponding with better immune functioning. The final ISQ and its scoring instructions are attached as Appendix A.

The final ISQ consists of 7 items that can be scored on a Likert scale ranging from Never (0) or Sometimes (1), to Regularly (2), Often (3) and (Almost) Always (4). The ISQ score can be calculated by adding up the scores on the individual items, and subsequently recode the sum score to the 0 (poor) to 10 (excellent) scale. The proposed cut off ISQ score for reduced immune functioning is 5.

In conjunction with the ISQ, it is advised to also assess current immune and health status (see Appendix A). Therefore, two items were added to rate (Question A) perceived immune functioning and (B) perceived general health on a scale ranging from 0 (very poor) to 10 (excellent). In addition, one question (C) asks whether participants experience perceived reduced immune fitness at this moment (to be answered “yes” or “no”), and another question (D) asks whether participant suffer from a chronic disease (to be answered “yes” or “no”). In the development of the ISQ it was not inquired what disease the participants are suffering from. It is thus unknown if the chronic disease was immune-related. In the final ISQ it is therefore asked to specify the chronic disease(s) they suffer from if this question is answered affirmative. The answer can be used to further categorize study participants.

#### 4. Discussion

The ISQ is a short and practical scoring form and useful for clinical practice and research requiring a quick screening of a participant’s immune status of the past 12 months. In a series of studies, the ISQ was developed and validated. The final ISQ consists of 7 items rating past year’s immune status, by inquiring about the incidence of specific immune-related complaints. The combined scores on the items correlated significantly, albeit modest, with perceived immune fitness and several psychological correlates, such as stress and depression.

The IFQ [19] served as the basis for developing the ISQ. Based on scientific literature, several items were added. Subsequently, the new listing was shortened into the ISQ. Significant correlations of ISQ scores were found with the 1–item perceived immune functioning rating and a variety of health outcomes. The strengths of this research include the extensive validation in different studies. The ISQ is particularly useful in situations with time constraints, where the use of extensive questionnaires is not appropriate. The ISQ is also multi-applicable, since it can be used both in the clinic as for the individual as self-assessment in research surveys and screening in clinical trials.

Across studies, even though statistically significant, the magnitude of the observed sex differences in ISQ scores is small around 1 or less on a scale ranging from 0 to 28. Therefore, the observed differences in ISQ scores between men and women do not seem to have great clinical relevance. Whereas Studies 1–5 contained primarily healthy participants, Study 7 had a larger subsample of participants reporting having a chronic disease. ISQ scores (before the dietary change) differed significantly between those with chronic diseases (i.e., “poor health” status) and healthy participants (i.e., “normal health” status).

To have a validated cut-off point at which a certain ISQ score indicates poor immune status and/or warrants further medical investigation would be of great value as it will significantly enhance the applicability of the ISQ in clinical practice. Using the original ISQ data (scoring range 0 to 28, i.e., before applying the final scoring format) suggests that a cut-off point for “poor” immune status should be 8 (see Figure 7). Indeed, the chronic disease group in Study 7 had an ISQ scores of around 8, whereas the “normal health” groups had a raw ISQ score around 4. These findings are also in line with Study 5, which showed that insomnia patients with IBS complaints had average ISQ scores ranged from 8 to 10, depending on the nature of sleep complaints. With the final scoring format of the ISQ

(scoring range 0 to 10), a cut off of an “original” ISQ score of 8 corresponds to a “final” ISQ score of 5. Thus, ISQ scores < 6 are thought to indicate a poor past year’s immune status.

It may be argued that the relatively low internal consistency, as measured with Cronbach’s alpha, is a limitation of the ISQ. However, this observation was expected and does not invalidate the ISQ. It is common that scales with a low number of unique items have a low Cronbach’s alpha [28]. This reflects the fact that immune status is a broad concept that is defined by many factors. The expression of various diseases and health complaints may contribute to it. The 7 items of the ISQ are all unique predictors of the broad concept of immune status, and correlational analysis revealed that their interrelationship is therefore low. Only the items coughing and common cold are stronger related ( $r = 0.452$ ), but individually can contribute independently from each other. This can be explained by the fact that coughing is associated with a wide assortment of assortment of clinical associations and etiologies including the common cold [29]. The observed correlations in the current study between mood outcomes and ISQ were low to moderate, while at the same time these mood outcomes are often highly interrelated. This further underlines that immune fitness is a complex concept that can be independently influenced by a large number of immune-related variables.

Finally, additional validation studies should be conducted to improve our understanding of the ISQ, and to determine how the self-rated immune functioning scores relate to objective biomarkers of immune fitness. For example, ISQ scores could be related to biomarkers of immune functioning, such as blood cytokine levels. In this context, previous research has shown significant correlations between self-rated health and immune biomarkers in both patients [30] and healthy volunteers [31–33]. However, another study revealed that perception of immune functioning was unrelated to immune biomarkers, including serum antibodies and blood lymphocytes [34]. Similar to our studies, the authors did find a strong relationship between perceived immune functioning and (changes in) mood. Together, up to now research investigating the relationship between objective and subjective assessments of immune functioning yielded inconsistent results. Therefore, evaluating the association of ISQ scores in relation to immune biomarkers will be the aim of future research.

## 5. Conclusions

The ISQ is a reliable, validated and short self-assessment questionnaire investigating the past 12 month’s immune status. It can be complemented by a 1-item rating of current perceived immune fitness, as suggested in our final format of the ISQ (see Appendix A).

**Author Contributions:** Conceptualization, design and methodology L.J.F.W.V., A.J.A.E.v.d.L., L.A., S.A., H.H., T.B., A.D.K., J.G., A.S., and J.C.V.; data collection, L.J.F.W.V., A.J.A.E.v.d.L., M.M., L.A., T.A.L.S., S.A., H.H., T.B., and S.A.V.; formal analysis and preparing the original draft, L.J.F.W.V. and J.C.V.; all authors critically reviewed the paper and approved the final version.

**Funding:** This research received no external funding.

**Conflicts of Interest:** A.D.K. has received grants/research support from Top Institute Pharma, NWO, Janssen, GSK, Nutricia Research, and Friesland Campina. A.S. has held research grants from Abbott Nutrition, Arla Foods, Bayer Healthcare, Cognis, Cyvex, GlaxoSmithKline, Naturex, Nestle, Martek, Masterfoods, Wrigley, and has acted as a consultant/expert advisor to Abbott Nutrition, Barilla, Bayer Healthcare, Danone, Flordis, GlaxoSmithKline Healthcare, Masterfoods, Martek, Novartis, Unilever, and Wrigley. J.G. is part-time employee of Nutricia Research and received research grants from Nutricia research foundation, Top Institute Pharma, Top Institute Food and Nutrition, GSK, STW, NWO, Friesland Campina, CCC, Raak-Pro, and EU. Over the past 3 years, J.C.V. has received grants/research support from the Dutch Ministry of Infrastructure and the Environment, Janssen Research and Development, and Sequential, and has acted as a consultant/advisor for Clinilabs, More Labs, Red Bull, Sen-Jam Pharmaceutical, Toast!, and ZBiotics. The other authors have no potential conflicts of interest to disclose.

**Appendix A**

**Immune Status Questionnaire (ISQ)**

Please indicate how often you have had the following complaints **in the past 12 months**:

	Never	Sometimes	Regularly	Often	(Almost) always
Sudden high fever					
Diarrhea					
Headache					
Skin problems (e.g. acne & eczema)					
Muscle and joint pain					
Common Cold					
Coughing					

**How you feel at this moment?**

<b>A</b>	I score my general health the following grade (0 = very bad; 10 = very good)	....	....
<b>B</b>	I score my immune functioning the following grade (0 = very bad; 10 = very good)	....	....
<b>C</b>	Do you have reduced immune functioning at this moment?	Yes	No
<b>D</b>	Do you have a chronic disease? If yes, please specify: .....	Yes	No

**Figure A1.** Immune Status Questionnaire (ISQ).

**Table A1.** ISQ Scoring instructions.

Raw Score	Final Score
≥15	0
14	1
13	2
11, 12	3
10	4
8, 9	5
7	6
6	7
5	8
3, 4	9
≤2	10

Each item of the ISQ can be scored as follows: Never = 0 points; Sometimes = 1 point; Regularly = 2 points; Often = 3 points; (Almost) always = 4 points; Calculate the sum score of the 7 ISQ items. To obtain the final ISQ score, translate the "raw" ISQ scores as follows: Interpretation: 0 = very poor, 10 excellent perceived immune status. Cut off for reduced immune functioning: ISQ < 6.

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## 12.5 Consent for using Immune Status Questionnaire



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### Soliciting Consent for using Immune Status Questionnaire

2 messages

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**Vd.Shubham Garg** <vdshubhamgarg@gmail.com> Thu, Feb 3, 2022 at 9:07 PM  
To: j.c.verster@uu.nl  
Cc: Divya Gupta <vddivyagarg@gmail.com>, Dr Yogita Bisht <yogitabisht06@yahoo.co.in>

Hello Dear Joris C. Verster Sir,

Greetings from India!  
Hope you are doing well in these unprecedented times of COVID-19.

I'm Vaidya (Dr) Shubham Garg, an Ayurveda Researcher, Practitioner and Academician in India. I am associated with GS Ayurveda Medical College and Hospital as Associate Professor in Department of Dravyaguna (Ayurveda pharmacology & Materia Medica).

We are working on a project regarding a novel poly-herbal compound and came across your publication on Development and Validation of the Immune Status Questionnaire (ISQ) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6926937/> . We found the tool interesting and appropriate for our study. So, in this regard we seek your kind permission to use this tool in our study for the welfare of community.

Waiting for your keen response and approval.

Best regards,  
Vaidya Shubham Garg,  
B.A.M.S., M.D., D.I.Y., C.C.H.M.,  
Associate Professor,  
Department of Dravyaguna,  
GS Ayurveda Medical College and Hospital,  
Hapur, Uttar Pradesh, India, 245304  
Email :- [vdshubhamgarg@gmail.com](mailto:vdshubhamgarg@gmail.com)  
Mobile :- +91-9997772737

---

**Verster, J.C. (Joris)** <J.C.Verster@uu.nl> Fri, Feb 4, 2022 at 1:44 PM  
To: Vd.Shubham Garg <vdshubhamgarg@gmail.com>  
Cc: Divya Gupta <vddivyagarg@gmail.com>, Dr Yogita Bisht <yogitabisht06@yahoo.co.in>

Dear Vaidya Shubham Garg,

Feel free to use the ISQ (see attached). For the purpose of the study you could adapt the time period of assessment (standard set at past 12 months). In the appendix of the article you can see how to recode the raw score of the ISQ into a 0-10 score. Good luck with your study. If you need any help I am happy to collaborate/consult.

Best regards,

Joris

[Quoted text hidden]

## 12.6 Patient data listings

Enrl. No.	GROUP	Name	Gender	Age	Occupation
R001	B	Rashik Goyal	M	23	Student
R002	B	Deepak Sharma	M	23	Student
R003	B	Vaseem	M	24	Student
R004	B	Rahul Singh	M	26	Student
R005	A	Yasmeen	F	23	Student
R006	A	Vanshika Garg	F	20	Student
R007	A	Vanisha	F	20	Student
R008	A	Shubham Bhardwaj	M	22	Student
R009	B	Manish Sharma	M	20	Student
R010	B	Riya Yadav	F	20	Student
R011	B	Ankur Sharma	M	21	Student
R012	B	Krishna Mohan	M	21	Student
R013	A	Mohd. Sahil	M	20	Student
R014	B	Aman Goyal	M	23	Student
R015	A	Faisal Ali	M	22	Student
R016	A	Imran	M	20	Student
R017	B	Md. Waliullah	M	21	Student
R018	A	Md. Israfeel Ansari	M	22	Student
R019	B	Utkarsha Prajapati	F	20	Student
R020	A	Neha Verma	F	23	Student
R021	A	Anushka Yadav	F	20	Student
R022	B	Aakil	M	22	Student
R023	B	Mahima Saxena	F	20	Student
R024	A	Anshu	F	25	Student
R025	A	Shubham Maheshwari	M	23	Student
R026	A	Akshat Shukla	M	20	Student
R027	A	Shilpam Sharma	M	22	Student
R028	B	Dr. Vishwendra	M	38	Faculty
R029	B	Dr. Archna	F	37	Faculty
R030	B	Mohd. Samad	M	23	Student
R031	B	Munazir khan	M	27	Student
R032	A	Mohd. Rashid	M	23	Student
R033	A	Md. Sharik Akeel	M	24	Student

Enrl. No.	GROUP	Name	Gender	Age	Occupation
R034	A	Tanveer	M	23	Student
R035	A	Sajid	M	23	Student
R036	B	Zeeshan	M	23	Student
R037	B	Mushir	M	24	Student
R038	B	Sabiya	F	25	Student
R039	A	Surbhi Gautam	F	23	Student
R040	B	Aparna Sharma	F	26	Student
R041	B	Reshmi Babu	F	32	Faculty
R042	A	Akash	M	21	Employee
R043	A	Anchal	F	23	Student
R044	A	Chhama Tyagi	F	23	Employee
R045	A	Abhishek Kumar	M	21	Student
R046	A	Atul Chauhan	M	20	Student
R047	B	Tushar Kant Sharma	M	21	Student
R048	B	Babli Shah	F	22	Student
R049	B	Dhruv Panday	M	20	Student
R050	B	Nisha Gupta	F	20	Student
R051	A	Neha Sharma	F	20	Student
R052	A	Tanya Tyagi	F	23	Student
R053	A	Saima Ali	F	23	Student
R054	A	Merajul Hasan	M	24	Student
R055	B	Ashish Kumar Gond	M	21	Student
R056	A	Yavar Abbas	M	21	Student
R057	B	Bhumika Bansal	F	20	Student
R058	B	Anushka Sengar	F	20	Student
R059	A	Divya Nath	F	22	Student
R060	B	Kshitiz	M	20	Student

12.7 Certificate of Analysis



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TEST REPORT

Page : 1 of 4

Issued to : M/s. Saatvik Enterprises  
 Flat 1003, Tower 3, White Orchid,  
 Caur City 2, Plot 3-C, Sector 16-C, Greater Noida (W)  
 Gautam Buddha Nagar, UP - 201301

ULR No. : TC554721100002753F  
 Sample code : F/202106150025  
 Report No. : AFLPL/F/150621025  
 Date of Issue : 28/06/2021

SAMPLE PARTICULARS

- |   |  |
|---|--|
| 1 Name of the Sample : Smooth Life Nutrients (Food Supplements) | 8 Test Method Deviation : N.A.<br>if any |
| 2 Group/Grade : Nutraceuticals and Functional Food              | 9 Date of Recd. : 15/06/2021             |
| 3 Brand Name, if any : N.A.                                     | 10 Customer Ref. No. : N.A.              |
| 4 Sample Description : Brown colour coarse powder               | 11 Sample Pkg : PET Jar                  |
| 5 Sampling Method : Sample not drawn by us                      | 12 Mfg. Date : N.A.                      |
| 6 Attachments : N.A.  | 13 Exp. Date/Best Before : N.A.          |
| 7 Lot No./Batch No. : N.A.                                      | 14 Sample Qty. : 200 g                   |

TEST RESULTS

Test Started on : 15/06/2021

Test Completed on : 28/06/2021

SL. No.	Parameter	Unit	Results	Specification/ Requirement as per API	Test Method
	Chemical Testing	-	-	-	-
1	Loss on drying	%	9.78	-	API, Part-II Vol III
2	pH	-	3.70	-	API, Part-II Vol III
3	Total Ash	%	4.16	-	API, Part-II Vol III
4	Acid Insoluble Ash	%	0.16	-	API, Part-II Vol III
5	Water Soluble Extractive	%	44.79	-	API, Part-II Vol III
6	Alcohol Soluble Extractive	%	38.25	-	API, Part-II Vol III
	Heavy Metals	-	-	-	-
7	Arsenic	mg/kg	BLQ(LOQ-0.05)	3.0, Max.	AFLPL/SOP/CH/INH/267 based on API, Part-I, Vol-VI
8	Cadmium	mg/kg	BLQ(LOQ-0.05)	0.3, Max.	AFLPL/SOP/CH/INH/267 based on API, Part-I, Vol-VI
9	Lead	mg/kg	BLQ(LOQ-0.05)	10.0, Max.	AFLPL/SOP/CH/INH/267 based on API, Part-I, Vol-VI
10	Mercury	mg/kg	BLQ(LOQ-0.05)	1.0, Max.	AFLPL/SOP/CH/INH/267 based on API, Part-I, Vol-VI
	Toxins	-	-	-	-

Nidhi Gupta  
 (Section Incharge Chemical)  
 Authorised Signatory

Diksha Bharti  
 (Sr. Analyst Instrumentation)  
 Authorised Signatory

Adarsh Bala  
 (Section Incharge Microbiology)  
 Authorised Signatory

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 CIN : U24100DL2011PTC219942 Website : www.avonfoodlab.com



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## TEST REPORT

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ULR No. : TC554721100002753F  
Sample code : F/202106150025  
Report No. : AFLPL/F/150621025  
Date of Issue : 28/06/2021

## TEST RESULTS

Test Started on : 15/06/2021

Test Completed on : 28/06/2021

SL. No.	Parameter	Unit	Results	Specification/ Requirement as per API	Test Method
11	Aflatoxin B1	mcg/kg	BLQ(LOQ-0.5)	2.0, Max.	AFLPL/SOP/CH/INH/53
12	Aflatoxin B2	mcg/kg	BLQ(LOQ-0.5)	-	AFLPL/SOP/CH/INH/53
13	Aflatoxin G1	mcg/kg	BLQ(LOQ-0.5)	-	AFLPL/SOP/CH/INH/53
14	Aflatoxin G2	mcg/kg	BLQ(LOQ-0.5)	-	AFLPL/SOP/CH/INH/53
	Biological Parameters	-	-	-	-
15	Total Plate Count	cfu/g	3.1 x 10 <sup>2</sup>	1 x 10 <sup>5</sup> , Max.	API, Part II, Volume III:2010
16	Yeast & Mould Count	cfu/g	<10	1 x 10 <sup>5</sup> , Max.	API, Part II, Volume III:2010
17	E. coli	per g	Absent	Absent	API, Part II, Volume III:2010
18	Salmonella	per g	Absent	Absent	API, Part II, Volume III:2010
19	Staphylococcus aureus	per g	Absent	Absent	API, Part II, Volume III:2010
20	Pseudomonas aeruginosa	per g	Absent	Absent	API, Part II, Volume III:2010
	Pesticide Residues	-	-	-	-
21	Alachor	mg/kg	BLQ(LOQ-0.01)	0.02, Max.	AFLPL/SOP/CH/INH/232
22	Aldrin & Dieldrin (Sum of)	mg/kg	BLQ(LOQ-0.01)	0.05, Max.	AFLPL/SOP/CH/INH/232
23	Azinphos - Methyl	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/232
24	Bromopropylate	mg/kg	BLQ(LOQ-0.01)	3.0, Max.	AFLPL/SOP/CH/INH/232
25	Chlorfenvinphos	mg/kg	BLQ(LOQ-0.005)	0.5, Max.	AFLPL/SOP/CH/INH/232
26	Chlorpyrifos	mg/kg	BLQ(LOQ-0.01)	0.2, Max.	AFLPL/SOP/CH/INH/232
27	Chlorpyrifos - Methyl	mg/kg	BLQ(LOQ-0.01)	0.1, Max.	AFLPL/SOP/CH/INH/232
28	Deltamethrin	mg/kg	BLQ(LOQ-0.01)	0.5, Max.	AFLPL/SOP/CH/INH/232
29	Dichlorvos	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/232
30	Endrin	mg/kg	BLQ(LOQ-0.01)	0.05, Max.	AFLPL/SOP/CH/INH/232
31	Ethion	mg/kg	BLQ(LOQ-0.01)	2.0, Max.	AFLPL/SOP/CH/INH/232
32	Fenitrothion	mg/kg	BLQ(LOQ-0.005)	0.5, Max.	AFLPL/SOP/CH/INH/232

Nidhi Gupta  
(Section Incharge Chemical)  
Authorised Signatory

Diksha Bharti  
(Sr. Analyst Instrumentation)  
Authorised Signatory

Adarsh Bala  
(Section Incharge Microbiology)  
Authorised Signatory

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## TEST REPORT

Page : 3 of 4

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Flat 1003, Tower 3, White Orchid,  
Caur City 2, Plot 3-C, Sector 16-C, Greater Noida (W)  
Gautam Buddha Nagar, UP - 201301

ULR No. : TC554721100002753F  
Sample code : F/202106150025  
Report No. : AFLPL/F/150621025  
Date of Issue : 28/06/2021

### TEST RESULTS

Test Started on : 15/06/2021

Test Completed on : 28/06/2021

SL. No.	Parameter	Unit	Results	Specification/ Requirement as per API	Test Method
33	Fenvalerate	mg/kg	BLQ(LOQ-0.01)	1.5, Max.	AFLPL/SOP/CH/INH/232
34	Fonofos	mg/kg	BLQ(LOQ-0.01)	0.05, Max.	AFLPL/SOP/CH/INH/232
35	Lindane (γ-Hexachlorocyclohexane)	mg/kg	BLQ(LOQ-0.01)	0.6, Max.	AFLPL/SOP/CH/INH/232
36	Malathion	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/232
37	Methidathion	mg/kg	BLQ(LOQ-0.01)	0.2, Max.	AFLPL/SOP/CH/INH/232
38	Parathion	mg/kg	BLQ(LOQ-0.01)	0.5, Max.	AFLPL/SOP/CH/INH/232
39	Parathion - methyl	mg/kg	BLQ(LOQ-0.01)	0.2, Max.	AFLPL/SOP/CH/INH/232
40	Permethrin	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/232
41	Phosalone	mg/kg	BLQ(LOQ-0.01)	0.1, Max.	AFLPL/SOP/CH/INH/232
42	Piperonyl butoxide	mg/kg	BLQ(LOQ-0.01)	3.0, Max.	AFLPL/SOP/CH/INH/232
43	Pirimiphos - methyl	mg/kg	BLQ(LOQ-0.01)	4.0, Max.	AFLPL/SOP/CH/INH/232
44	Diazinon	mg/kg	BLQ(LOQ-0.01)	0.5, Max.	AFLPL/SOP/CH/INH/232
45	Quintozene	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/232
46	Dithiocarbamate (as CS <sub>2</sub> )	mg/kg	BLQ(LOQ-0.01)	2.0, Max.	AFLPL/SOP/CH/INH/232
47	Heptachlor (sum of heptachlor & heptachlor epoxide)	mg/kg	BLQ(LOQ-0.002)	0.05, Max.	AFLPL/SOP/CH/INH/232
48	Pyrethrins (sum of)	mg/kg	BLQ(LOQ-0.01)	3.0, Max.	AFLPL/SOP/CH/INH/232
49	Cypermethrin (and isomers)	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/232
50	Endosulfan (Sum of isomers & endosulfan Sulphate)	mg/kg	BLQ(LOQ-0.01)	3.0, Max.	AFLPL/SOP/CH/INH/232
51	Chlordane (sum of cis-trans & oxychlordan)	mg/kg	BLQ(LOQ-0.01)	0.05, Max.	AFLPL/SOP/CH/INH/232
52	DDT	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/232
53	Hexachlorocyclohexane Isomers	mg/kg	BLQ(LOQ-0.01)	0.3, Max.	AFLPL/SOP/CH/INH/232
54	Hexachlorobenzene	mg/kg	BLQ(LOQ-0.01)	0.1, Max.	AFLPL/SOP/CH/INH/232

Nidhi Gupta  
(Section Incharge Chemical)  
Authorised Signatory

Diksha Bharti  
(Sr. Analyst Instrumentation)  
Authorised Signatory

Adarsh Bala  
(Section Incharge Microbiology)  
Authorised Signatory

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## TEST REPORT


Page : 4 of 4


Issued to : M/s. Saatvik Enterprises  
Flat 1003, Tower 3, White Orchid,  
Caur City 2, Plot 3-C, Sector 16-C, Greater Noida (W)  
Gautam Buddha Nagar, UP - 201301


ULR No. : TC554721100002753F  
Sample code : F/202106150025  
Report No. : AFLPL/F/150621025  
Date of Issue : 28/06/2021

BLQ : Below Limit of Quantification, LOQ : Limit of Quantification.

Remark : In the opinion of the undersigned the sample referred to above is of standard quality as defined in the act & the rules made thereunder for the reason given below :- As per API Pat-II Vol-III

  
Nidhi Gupta  
(Section Incharge Chemical)  
Authorised Signatory

  
Diksha Bharti  
(Sr. Analyst Instrumentation)  
Authorised Signatory

  
Adarsh Bala  
(Section Incharge Microbiology)  
Authorised Signatory

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## TEST REPORT

Page : 1 of 2

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Caur City 2, Plot 3-C, Sector 16-C, Greater Noida (W)  
Gautam Buddha Nagar, UP - 201301

Sample code : F/202104150025  
Report No. : AFLPL/F/150421025  
Date of Issue : 05/05/2021

### SAMPLE PARTICULARS

- |   |   |
|---|---|
| 1 Name of the Sample : Smooth Life Nutrients (Food Supplements) | 8 Test Method Deviation : N.A<br>if any |
| 2 Group/Grade : Nutraceuticals and Functional Food              | 9 Date of Recd. : 15/04/2021            |
| 3 Brand Name, if any : N.A.                                     | 10 Customer Ref. No. : N.A.             |
| 4 Sample Description : Brown colour food supplement             | 11 Sample Pkg : PET Jar                 |
| 5 Sampling Method : Sample not drawn by us                      | 12 Mfg. Date : N.A.                     |
| 6 Attachments : N.A.  | 13 Exp. Date/Best Before : N.A.         |
| 7 Lot No./Batch No. : Trial                                     | 14 Sample Qty. : 300 g                  |

### TEST RESULTS

Test Started on : 15/04/2021

Test Completed on : 05/05/2021

SL. No.	Parameter	Unit	Results	Specification/ Requirement	Test Method
	Chemical Testing	-	-	-	-
	Nutritional Facts	-	-	-	-
1	Energy	kcal/100g	413.19	-	IS : 14433 : 2007 (2018)
2	Protein (N x 6.25)	g/100g	27.73	-	IS : 7219 : 1973 (2015)
3	Carbohydrate	g/100g	47.98	-	IS : 1656 : 2007 (2018)
4	Sugar (as Total Sugar)	g/100g	26.42	-	IS : 2650 : 1975
5	Total Fat	g/100g	12.26	-	IS : 4684 : 1975 (2015)
6	Saturated fatty acids	g/100g	0.90	-	AOAC : 996.06 : 2019
7	Trans fatty acids	g/100g	BLQ(LOQ-0.1)	-	AOAC : 996.06 : 2019
8	Dietary Fibre	g/100g	12.04	-	IS : 11062 : 1984 (2010)
	Vitamins	-	-	-	-
9	Vitamin-A	mg/kg	BLQ(LOQ-2.0)	-	AFLPL/SOP/CH/INH/96
10	Vitamin-C	mg/100g	143.32	-	IS : 5838 : 1970 (2015)
11	Calcium	mg/100g	219.9	-	AFLPL/SOP/CH/INH/163
12	Iron	mg/100g	9.32	-	AFLPL/SOP/CH/INH/255 based on AOAC : 2015.01 :

Dipankar Gharti  
(Sr. Analyst Instrumentation)  
Authorised Signatory

Nishi Gupta  
(Section Incharge Chemical)  
Authorised Signatory

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## TEST REPORT

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Gautam Buddha Nagar, UP - 201301

Sample code : F/202104150025  
Report No. : AFLPL/F/150421025  
Date of Issue : 05/05/2021


### TEST RESULTS


Test Started on : 15/04/2021

Test Completed on : 05/05/2021

SL. No.	Parameter	Unit	Results	Specification/ Requirement	Test Method
12					2019
13	Potassium	mg/100g	106.86	-	IS : 12760 : 2012
14	Sodium	mg/100g	83.78	-	AFLPL/SOP/CH/INH/255 based on AOAC : 2015.01 : 2019

BLQ : Below Limit of Quantification, LOQ : Limit of Quantification.

  
Diksha Bharti  
(Sr. Analyst Instrumentation)  
Authorised Signatory

  
Mdhi Gupta  
(Section Incharge, Chemical)  
Authorised Signatory

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### Smooth Life Nutrients (Food Supplements)

NUTRITION INFORMATION per 100g	
Total Calories	413.20 Kcal
Protein (N x 6.25)	27.7 g
Carbohydrate	48.0 g
Total Fat	12.3 g
Sugar	26.4 g
Saturated fatty acids	0.90 g
Trans fatty acids	0.0 g
Dietary Fibre	12.0 g
Vitamin A	0.0 g
Vitamin C	143.3 mg
Calcium	220.0 mg
Iron	9.3 mg
Potassium	106.9 mg
Sodium	83.8 mg

\* The above values are calculated on the result of the Report No : - AFLPI/E/150421025



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**TEST REPORT**

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ULR No. : TC554721100002753F  
 Sample code : F/202106150025  
 Report No. : AFLPL/F/150621025  
 Date of Issue : 28/06/2021

**SAMPLE PARTICULARS**

1 Name of the Sample : Smooth Life Nutrients (Food Supplements)	8 Test Method Deviation : N.A. if any
2 Group/Grade : Nutraceuticals and Functional Food	9 Date of Recd. : 15/06/2021
3 Brand Name, if any : N.A.	10 Customer Ref. No. : N.A.
4 Sample Description : Brown colour coarse powder	11 Sample Pkg : PET Jar
5 Sampling Method : Sample not drawn by us	12 Mfg. Date : N.A.
6 Attachments : N.A.	13 Exp. Date/Best Before : N.A.
7 Lot No./Batch No. : N.A.	14 Sample Qty. : 200 g

**TEST RESULTS**

Test Started on : 15/06/2021

Test Completed on : 28/06/2021

SL. No.	Parameter	Unit	Results	Specification/Requirement as per API	Test Method
1	Chemical Testing	-	-	-	-
1	Loss on drying	%	9.78	-	API, Part-II Vol III
2	pH	-	3.70	-	API, Part-II Vol III
3	Total Ash	%	4.16	-	API, Part-II Vol III
4	Acid Insoluble Ash	%	0.16	-	API, Part-II Vol III
5	Water Soluble Extractive	%	44.79	-	API, Part-II Vol III
6	Alcohol Soluble Extractive	%	38.25	-	API, Part-II Vol III
	Heavy Metals	-	-	-	-
7	Arsenic	mg/kg	BLQ(LOQ-0.05)	3.0, Max.	AFLPL/SOP/CH/INH/267 based on API, Part-I, Vol-VI
8	Cadmium	mg/kg	BLQ(LOQ-0.05)	0.3, Max.	AFLPL/SOP/CH/INH/267 based on API, Part-I, Vol-VI
9	Lead	mg/kg	BLQ(LOQ-0.05)	10.0, Max.	AFLPL/SOP/CH/INH/267 based on API, Part-I, Vol-VI
10	Mercury	mg/kg	BLQ(LOQ-0.05)	1.0, Max.	AFLPL/SOP/CH/INH/267 based on API, Part-I, Vol-VI
	Toxins	-	-	-	-

Adarsh Bala  
 (Section Incharge Microbiology)  
**Authorised Signatory**

Diksha Bharti  
 (Sr. Analyst Instrumentation)  
**Authorised Signatory**

Nidhi Gupta  
 (Section Incharge Chemical)  
**Authorised Signatory**

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**TEST REPORT**

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Issued to : M/s. Saatvik Enterprises  
 Flat 1003, Tower 3, White Orchid,  
 Caur City 2, Plot 3-C, Sector 16-C, Greater Noida (W)  
 Gautam Buddha Nagar, UP - 201301

ULR No. : TC554721100002753F  
 Sample code : F/202106150025  
 Report No. : AFLPL/F/150621025  
 Date of Issue : 28/06/2021

**TEST RESULTS**

Test Started on : 15/06/2021

Test Completed on : 28/06/2021

SL. No.	Parameter	Unit	Results	Specification/Requirement as per API	Test Method
11	Aflatoxin B1	mcg/kg	BLQ(LOQ-0.5)	2.0, Max.	AFLPL/SOP/CH/INH/53
12	Aflatoxin B2	mcg/kg	BLQ(LOQ-0.5)	-	AFLPL/SOP/CH/INH/53
13	Aflatoxin G1	mcg/kg	BLQ(LOQ-0.5)	-	AFLPL/SOP/CH/INH/53
14	Aflatoxin G2	mcg/kg	BLQ(LOQ-0.5)	-	AFLPL/SOP/CH/INH/53
	Biological Parameters	-	-	-	-
15	Total Plate Count	cfu/g	3.1 x 10 <sup>2</sup>	1 x 10 <sup>5</sup> , Max.	API, Part II, Volume III:2010
16	Yeast & Mould Count	cfu/g	<10	1 x 10 <sup>5</sup> , Max.	API, Part II, Volume III:2010
17	E.coli	per g	Absent	Absent	API, Part II, Volume III:2010
18	Salmonella	per g	Absent	Absent	API, Part II, Volume III:2010
19	Staphylococcus aureus	per g	Absent	Absent	API, Part II, Volume III:2010
20	Pseudomonas aeruginosa	per g	Absent	Absent	API, Part II, Volume III:2010
	Pesticide Residues	-	-	-	-
21	Alachor	mg/kg	BLQ(LOQ-0.01)	0.02, Max.	AFLPL/SOP/CH/INH/120
22	Aldrin & Dieldrin (Sum of)	mg/kg	BLQ(LOQ-0.01)	0.05, Max.	AFLPL/SOP/CH/INH/232
23	Azinphos - Methyl	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/120
24	Bromopropylate	mg/kg	BLQ(LOQ-0.01)	3.0, Max.	AFLPL/SOP/CH/INH/120
25	Chlorfenvinphos	mg/kg	BLQ(LOQ-0.005)	0.5, Max.	AFLPL/SOP/CH/INH/232
26	Chlorpyrifos	mg/kg	BLQ(LOQ-0.01)	0.2, Max.	AFLPL/SOP/CH/INH/232
27	Chlorpyrifos - Methyl	mg/kg	BLQ(LOQ-0.01)	0.1, Max.	AFLPL/SOP/CH/INH/232
28	Deltamethrin	mg/kg	BLQ(LOQ-0.01)	0.5, Max.	AFLPL/SOP/CH/INH/232
29	Dichlorvos	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/232
30	Endrin	mg/kg	BLQ(LOQ-0.01)	0.05, Max.	AFLPL/SOP/CH/INH/232
31	Ethion	mg/kg	BLQ(LOQ-0.01)	2.0, Max.	AFLPL/SOP/CH/INH/120
32	Fenitrothion	mg/kg	BLQ(LOQ-0.005)	0.5, Max.	AFLPL/SOP/CH/INH/232

Adarsh Bala  
 (Section Incharge Microbiology)  
 Authorised Signatory

Diksha Bharti  
 (Sr. Analyst Instrumentation)  
 Authorised Signatory

Nidhi Gupta  
 (Section Incharge Chemical)  
 Authorised Signatory

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ULR No. : TC554721100002753F  
Sample code : F/202106150025  
Report No. : AFLPL/F/150621025  
Date of Issue : 28/06/2021

### TEST RESULTS

Test Started on : 15/06/2021

Test Completed on : 28/06/2021

SL. No.	Parameter	Unit	Results	Specification/Requirement as per API	Test Method
33	Fenvalerate	mg/kg	BLQ(LOQ-0.01)	1.5, Max.	AFLPL/SOP/CH/INH/232
34	Fonofos	mg/kg	BLQ(LOQ-0.01)	0.05, Max.	AFLPL/SOP/CH/INH/120
35	Lindane (γ-Hexachlorocyclohexane)	mg/kg	BLQ(LOQ-0.01)	0.6, Max.	AFLPL/SOP/CH/INH/232
36	Malathion	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/120
37	Methidathion	mg/kg	BLQ(LOQ-0.01)	0.2, Max.	AFLPL/SOP/CH/INH/120
38	Parathion	mg/kg	BLQ(LOQ-0.01)	0.5, Max.	AFLPL/SOP/CH/INH/120
39	Parathion - methyl	mg/kg	BLQ(LOQ-0.01)	0.2, Max.	AFLPL/SOP/CH/INH/120
40	Permethrin	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/232
41	Phosalone	mg/kg	BLQ(LOQ-0.01)	0.1, Max.	AFLPL/SOP/CH/INH/120
42	Piperonyl butoxide	mg/kg	BLQ(LOQ-0.01)	3.0, Max.	AFLPL/SOP/CH/INH/232
43	Pirimiphos - methyl	mg/kg	BLQ(LOQ-0.01)	4.0, Max.	AFLPL/SOP/CH/INH/120
44	Diazinon	mg/kg	BLQ(LOQ-0.01)	0.5, Max.	AFLPL/SOP/CH/INH/120
45	Quintozene	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/232
46	Dithiocarbamate (as CS2)	mg/kg	BLQ(LOQ-0.01)	2.0, Max.	AFLPL/SOP/CH/INH/119
47	Heptachlor (sum of heptachlor & heptachlor epoxide)	mg/kg	BLQ(LOQ-0.002)	0.05, Max.	AFLPL/SOP/CH/INH/232
48	Pyrethrins (sum of)	mg/kg	BLQ(LOQ-0.01)	3.0, Max.	AFLPL/SOP/CH/INH/232
49	Cypermethrin (and isomers)	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/232
50	Endosulfan (Sum of isomers & endosulfan Sulphate)	mg/kg	BLQ(LOQ-0.01)	3.0, Max.	AFLPL/SOP/CH/INH/232
51	Chlordane (sum of cis-trans & oxychlordan)	mg/kg	BLQ(LOQ-0.01)	0.05, Max.	AFLPL/SOP/CH/INH/232
52	DDT	mg/kg	BLQ(LOQ-0.01)	1.0, Max.	AFLPL/SOP/CH/INH/232
53	Hexachlorocyclohexane Isomers	mg/kg	BLQ(LOQ-0.01)	0.3, Max.	AFLPL/SOP/CH/INH/232
54	Hexachlorobenzene	mg/kg	BLQ(LOQ-0.01)	0.1, Max.	AFLPL/SOP/CH/INH/232

Adarsh Bala  
(Section Incharge Microbiology)  
Authorised Signatory

Diksha Bharti  
(Sr. Analyst Instrumentation)  
Authorised Signatory

Nidhi Gupta  
(Section Incharge Chemical)  
Authorised Signatory

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BLQ : Below Limit of Quantification, LOQ : Limit of Quantification.

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(Section Incharge Microbiology)  
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