



## A CLINICAL STUDY ON EFFECTIVENESS OF ASHWAGANDHA (WITANIA SOMNIFERA) ON QUALITY OF LIFE (WHOQOL-BREF) IN APPARENTLY HEALTHY SUBJECTS

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<https://doi.org/10.46607/iamj1008122020>

(Published online: December 2020)

Open Access

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Article Received: 27/11/2020 - Peer Reviewed: 28/11/2020 - Accepted for Publication: 30/11/2020



### ABSTRACT

WHOQOL- BREF is assessment of a multidimensional concept incorporating an individual's perception of health status embedded with physical, psychological, social, and environmental domains. Various types of health issues are common around the globe due to improper sleep pattern and lifestyle. *Ashwagandha* (*Withania Somnifera*) is the intervention of many clinical conditions like, arresting the aging process, procure the body in debilitating condition by creating a sense of mental wellbeing and increase physical fitness. *Ashwagandha* possesses *Vatakaphahara*, *Jara Vyadhi Nashaka*, *Balya* and *Dhatu Vriddhikara* properties. Because of these properties, it acts not only preventive but also promotive and curative effects as well as slowdown *Jara* by breaking the pathogenesis. The present study was opted to analyse the health status (quality of life WHO-QOL BREF) in apparently healthy voluntary subjects. **Objective:** To evaluate the effectiveness of *Ashwagandha* (*Withania Somnifera*) on quality of life (WHOQOL-BREF) in apparently healthy subjects. **Methods:** The study includes randomized, single blind controlled comparative study with pre-test and post-test design. 408 apparently healthy subjects were screened for the features of health. 108 apparently Healthy subjects were selected by considering the inclusion criteria, and categorised into two group, (Group 1- control Group and Group 2- study Group) 54 subjects in each group. Subjects in the study group consumed 12 gm of *Ashwagandha Choorna* (powder) once daily with milk 200ml and the control

group consumed milk 200 ml daily once. WHO-QOL BREF Questionnaire was utilised for analysing the health status of the individuals before intervention, after intervention and follow up. **Results:** In the control group (n=54), the mean score overall quality of life was found to be 65.75 before intervention, after complete intervention quality of life was found to be 67.55 and at the time of follow up quality of life was found 67.55. In the study group (n=54), the mean score overall quality of life was found to be 64.38 before intervention of study, after complete intervention quality of life was found to be 71.58 and at the time of follow up quality of life was found 71.61. **Conclusion:** In this study, subjects were improved to the higher scores among the physical, psychological domains as comparison with the environmental and social domains. Found improvement in the quality of life (WHO BREF) in study group as compared to control group.

**Keywords:** Quality of life, Health status, *Ashwagandha*, *Withania Somnifera*, WHOQOL BREF.

## INTRODUCTION

Balanced or normal state of Dhatu which produces *Sukha* is *Prakruti* is *Arogya* (Health) whereas Abnormal state of *Dhatu* produces *Dukha* is termed as *Vikara* (disease).<sup>1</sup> The person without or minimal abnormality or any disease is known as *Swastha* (healthy).<sup>2</sup> The features of a *Swastha Purusha* (healthy man) are *Doshas* (*Vata*, *Pitta*, *Kapha*), *Agni* (digestive fire), *Dhatu*, *Mala* (waste products) and *Kriya* are normal, *Atma* (soul), *Indriya* (sense organ) and *Manas* (mind) are peaceful is said to be *Swastha* (healthy). *Swastha* (health) implies the equilibrium state in bodily elements, digestive power, *Dhatu*, *Mala* along with mental, sensory and spiritual pleasantness and happiness.<sup>3</sup> According to world health organization (WHO) health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. Health promotion is the process of enabling people to increase control over their health and its determinants, and thereby improve their health. Physical activity provides important health benefits and can enhance the quality of life in adults. Good health is a major resource for social, economic and personal development and an important dimension of quality of life.<sup>4</sup>

*Ashwagandha* (*W. Somnifera*) has the property of *Rasayana* as mentioned in literature. It not only maintains the equilibrium of *Dosha* and *Dhatu* of the body but also promotes the health. *Ashwagandha* is *Vataphahara*, *Jara Vyadhi Nashaka*, *Balya* and *Dhatu Vriddhikara* properties. Because of these properties, it shows not only preventive but also promotive and

curative effects as well as slowdown *Jara* by breaking the pathogenesis. *Ashwagandha* improves the quality of life, maintains the positive health, preserves youthfulness and cures morbid sleep, drowsiness, physical as well as mental fatigue, laziness and weakness. It maintains proper balance of the *Tridosha*, stability, cures slothness of the muscles, stimulates the *Agni* (digestion and metabolism), excellence in lustre, complexion as well as voice.<sup>5,6,7</sup> Physical dimensions are “good complexion, clean skin, bright eyes, lustrous hair with body well clothed with firm flesh, not to fat, sweet breath, good appetite, sound sleep, coordinated bodily movements. All the organs of the body are of unexceptional size and function normalcy; all the special senses are intact the resting pulse rate, blood pressure and exercise tolerance are all within the range of normality for the individuals age and gender”.<sup>8</sup> The properties of *Ashwagandha* are *Tikta*, *Katu*, *Madhura Rasa*, *Ushna Veerya*, *Madhura Vipaka*, *Kaphavatahara*, *Rasayana*, *Vedanasthapana*, *Deepana*, *Anuloma*, *Rkatashodhaka*, *Vrishya*, *Dhatu Vriddhikara*, *Bala Pushtiprada*.<sup>9,10</sup> *Withania Somnifera* is an Immuno-modulatory, anti-inflammatory and anti-oxidizing agent. *Ashwagandha* has been used as a *Rasayana*. The root of *Ashwagandha* is regarded as tonic, aphrodisiac, narcotic, diuretic, anthelmintic, and astringent, thermo genic and stimulant. It is commonly used in emaciation of children (when given with milk, it is the best tonic for children), debility from old age, rheumatism, vitiated conditions of *Vata*, leu-

coderma, constipation, insomnia, nervous breakdown, goitre etc.<sup>11</sup>

**Objective:** To evaluate the effectiveness of Ashwagandha (Withania Somnifera) on quality of life (WHOQOL-BREF) in apparently healthy subjects.

**Materials and methods**

This randomized, single blind controlled comparative study with pre-test and post-test design was approved by Institutional Ethics committee Sri Dharmasthala Manjunatheshwara college of Ayurveda and hospital, Hassan, Karnataka India (IEC No: SDM/IEC/92/2016-2017 dt.25 June 2016) and study was conducted in compliance with good clinical practice guidelines, declaration of Helsinki and all other applicable regulations. CTRI no- 2019/05/019009.

**Source of data:** Apparently healthy subjects from OPD of SDM college of Ayurveda and Hospital, Hassan either gender who are fulfilling the criteria of inclusion are selected irrespective of gender and caste etc.

**Method of collection of data (including sampling procedure, if any) Survey-** 408 apparently healthy subjects was screened for the features of Arogya (health). 108 apparently healthy subjects were selected by considering the inclusion criteria.

**Criteria for selection of subjects:**

**Inclusion criteria-** Apparently Healthy subjects who were interested and willing to take *Ashwagandha* (Withania Somnifera) and subjects of age group 18-40 yrs.

**Exclusion criteria-** Pregnant women, lactating women etc.

**Duration of the study:** 60 days for both study and control groups.

**Follow up:** After 1 month of completion on intervention.

**Grouping:** Two groups of 54 persons each was taken.

**Intervention:** The included subjects were randomly divided under two groups, Group 1(control group) and Group 2 (study group).

**Group 1-** In 54 subjects administered 2 Haritaki tablets for *Kostha Shuddhi* with hot water for minimum of 3 days and 200 ml *Dugdha* (milk) for 60 days in empty stomach early in the morning kept as a control.

**Group 2-** In 54 subjects administered 2 Haritaki tablets for *Kostha Shuddhi* with hot water for minimum of 3 days and 12gm of *Ashwagandha Choorna* with 200 ml *Dugdha* (milk) for 60 days in empty stomach early in the morning.

**Medicine Name:** *Ashwagandha Choorna*

**Study Design:** 108 apparently healthy subjects were selected for clinical study. WHO-QOL BREF health assessment Questionnaire on health status was used for analysing the health status of individuals (as per inclusion and exclusion criteria).

**Assessment Criteria:** Health status was analyzed from the score obtained by the questionnaire.

**Subjective Parameters:** Health assessment questionnaire - WHO-QOL BREF

**Statistical Analysis:**

Software 'Statistical Package for Social Sciences', Version 20 was used for the statistical analysis. Data were analysed by using WHO QOL tool, percentage, and proportions.

**Scoring pattern of the questionnaire**

**1) WHO QOL BREF<sup>12</sup>**

a) Following questions from 1-2 and 5-25 belonging to various domains of WHO-QOL was positively graded as shown in the table.

**Table 1:** WHO-QOL Positive Scale Grading

Not at all	1
A little	2
A moderate amount	3
Very much	4
An extreme amount	5

b) Questions 3, 4 and 26 were graded negatively as shown in the table

**Table 2:** WHO-QOL Negative Scale Grading

Not at all	5
A little	4
A moderate amount	3
Very much	2
An extreme amount	1

Following are 26 questions containing 4 domains like, physical, psychological, socio-economic and environmental.

The question 1 and 2 are two subjective questions with positive scale grading

1. How would you rate your quality of life?
2. How satisfied are you with your health?

The remaining 24 questions are taken for the calculation

1. To what extent do you feel that (physical) pain prevents you from doing what you need to do?
2. How much do you need any medical intervention to function in your daily life?
3. How much do you enjoy life?
4. To what extent do you feel your life to be meaningful?
5. How well are you able to concentrate?
6. How safe do you feel in your daily life?
7. How healthy is your physical environment?
8. Do you have enough energy for everyday life?
9. Are you able to accept your bodily appearance?
10. Have you enough money to meet your needs?
11. How available to you is the information that you need in your day-to-day life?
12. To what extent do you have the opportunity for leisure activities?
13. How well are you able to get around?
14. How satisfied are you with your sleep?
15. How satisfied are you with your ability to perform your daily living activities?
16. How satisfied are you with your capacity for work?
17. How satisfied are you with yourself?
18. How satisfied are you with your personal relationships?
19. How satisfied are you with your sex life?

20. How satisfied are you with the support you get from your friends?

21. How satisfied are you with the conditions of your living place?

22. How satisfied are you with your access to health services?

23. How satisfied are you with your transport?

24. How often do you have negative feelings such as blue mood, despair, anxiety, depression?

**Statistical Calculation:**

The WHOQOL-BREF (WHO Quality of Life-Bref) produces four domain scores. There are also two items that were examined separately: question number one is about an individual overall perception of quality of life and question number two is about an individual overall perception of health. Domain scores were scaled in a positive direction (i.e. higher scores denote higher quality of life). The mean score of items within each domain is used to calculate the domain score. Mean scores are then multiplied by 4 in order to make domain scores comparable with the scores used in the WHOQOL-100, and subsequently transformed to a 0-100 scale, using the formula below.

A method for the manual calculation of individual scores is below:

Physical domain= ((6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18) x4.

Psychological domain= (Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26)) x4.

Social Relationships domain= (Q20 + Q21 + Q22) x4.

Environment domain=(Q8 +Q9 + Q12 + Q13 + Q14 + Q23 +Q24 +Q25) x4.

**Response scales:** For this WHOQOL, there are 4-5-point response scales concerned with the intensity Capacity, frequency and evaluation of states or behaviour. So, these facts were also assessed.

**Table 3:** Method for converting raw scores to transformed scores

DOMAIN 1			DOMAIN 2			DOMAIN 3			DOMAIN 4		
Raw Score	Transformed scores		Raw Score	Transformed scores		Raw Score	Transformed scores		Raw Score	Transformed scores	
	4-20	0-100		4-20	0-100		4-20	0-100		4-20	0-100
7	4	0	6	4	0	3	4	0	8	4	0
8	5	6	7	5	6	4	5	6	9	5	6
9	5	6	8	5	6	5	7	19	10	5	6
10	6	13	9	6	13	6	8	25	11	6	13
11	6	13	10	7	19	7	9	31	12	6	13
12	7	19	11	7	19	8	11	44	13	7	19
13	7	19	12	8	25	9	12	50	14	7	19
14	8	25	13	9	31	10	13	56	15	8	25
15	9	31	14	9	31	11	15	69	16	8	25
16	9	31	15	10	38	12	16	75	17	9	31
17	10	38	16	11	44	13	17	81	18	9	31
18	10	38	17	11	44	14	19	94	19	10	38
19	11	44	18	12	50	15	20	100	20	10	38
20	11	44	19	13	56				21	11	44
21	12	50	20	13	56				22	11	44
22	13	56	21	14	63				23	12	50
23	13	56	22	15	69				24	12	50
24	14	63	23	15	69				25	13	56
25	14	63	24	16	75				26	13	56
26	15	69	25	17	81				27	14	63
27	15	69	26	17	81				28	14	63
28	16	75	27	18	88				29	15	69
29	17	81	28	19	94				30	15	69
30	17	81	29	19	94				31	16	75
31	18	88	30	20	100				32	16	75
32	18	88							33	17	81
33	19	94							34	17	81
34	19	94							35	18	88
35	20	100							36	18	88
									37	19	94
									38	19	94
									39	20	100
									40	20	100

**Table 4:** Assessment Table

Health Status	Score	Percentage	Total
Domain 1			
Domain 2			
Domain 3			
Domain 4			

**Table 5:** Screening / enrolment- Total 408 screened subjects and 114 subjects included in study.

<b>Patient Enrolment</b>	
Screening for eligibility= Total 408 Subjects	
Total subjects selected =114 subjects	
Randomized (n=114)	
Allocated in Group 1(n=57)	Allocated in Group 2 (n=57)
Baseline evaluation (n=57)	Baseline evaluation (n=57)
Evaluation after intervention 60 days (n=54)	Evaluation after intervention 60 days (n=54)
Dropout (3 subjects)	Dropout (3 subjects)
Follow up 90 day (n=54)	Follow up 90 day (n=54)
<b>Efficacy analysis (n=54)</b>	<b>Efficacy analysis (n=54)</b>

**Observational & Results**

Among 408 screened subjects and 114 subjects were included in study. Though the majority of 246

(60.30%) subjects were males and 162 (39.70%) subjects were females. (Table No.06)

**Table 6:** Gender Distribution of the Subjects in screening

Gender	Frequency	Percentage
Male	246	60.30
Female	162	39.70
Total	408	100

Among 114 subjects included in study 114 (100%) were males. (Table No.07)

**Table 7:** Gender Distribution of the Subjects in included in study

Gender	Frequency	Percentage
Male	114	100
Total	114	100

The age group of subjects showed that among 114, the majority of 112 (98.22%) subjects belonged to the age group of 18 to 25 completed years followed by 02 (1.75%) subjects belonged to 26-35 years. (Table No. 8).

**Table 8:** Age Distribution of the Subjects

Age (in completed years)	Frequency	Percent
18 - 25	112	98.22
26 - 35	02	1.75
36 - 45	00	00
Total	114	100

Among 114 subjects, majority of 102 (89.45%) had completed the schooling till PUC and 12 (10.52%) subjects were graduates. (Table No. 09)

**Table 9:** Educational Status of Subjects

Educational qualification	Frequency	Percent
Below Graduation (PUC)	102	89.45
Graduate	12	10.52
Postgraduate	00	00
Total	114	100

Among 114 subjects, majority of 84 (73.67%) subjects having joint family and 30 (26.33%) subjects having nuclear family. (Table No. 10)

**Table 10:** Type of family

Type of family	Frequency	Percent
Joint	84	73.67
Nuclear	30	26.33
Total	114	100

Among 114 subjects, majority of 70 (61.39%) subjects having poor housing condition, 32 (28.09%) subjects having moderate housing condition, 10 (8.77%) sub-

jects having good housing condition and 02 (1.75%) having very good housing condition. (Table No. 11)

**Table 11:** Housing condition-

Housing condition	Frequency	Percent
Poor	70	61.39
Moderate	32	28.09
Good	10	08.77
Very good	02	01.75
Total	114	100

Among 114 subjects, all the subject having mixed food (vegetarian and non-vegetarian) (Table No. 12)

**Table 12:** Food Habits (Vegetarian or Mixed)

Food (vegetarian and non-vegetarian)	Frequency	Percent
Vegetarian	00	00
Mixed	114	100
Total	114	100

Among 114 subjects, majority 86 (75.44%) consume the food timely and 28 (24.56) consume untimely. (Table no.13)

**Table 13:** Food consumption (Timely consumption / Untimely consumption / frequent food intake)

Food consumption (Timely consumption / Untimely consumption / frequent food intake)	Frequency	Percent
Timely consumption	86	75.44
Untimely consumption	28	24.56
Frequent food intake	00	00
Total	114	100

Among 114 subjects, majority 78 (68.40%) were of *Vata Pitta Kapha Prakruti*. A total of 15(13.15%) belonged to *Pitta Vata Kapha Prakruti*, 02 (1.75%) each

of *Pitta Vata Kapha*, *Pitta Kapha Vata*, *Vata Pitta Kapha* and 15(13.15%) were belonged to *Vata Kapha Pitta Prakruti* (Table no. 14).

**Table 14:** Prakruti Distribution of the Subjects

Prakruti	Frequency	Percent
VPK	78	68.40
PVK	15	13.15
PVK	2	1.75

PKV	2	1.75
VPK	2	1.75
VKP	15	13.15
Total	114	100

**The two subjective questions of WHO QOL**

**1. Rating the quality of life-**

**Group 1 (Control Group)-**Among the 54 subjects maximum of 54 (100%) were good with their quality of life before intervention. After intervention 52

(96.2%) subjects were good with their quality of life and 2 (3.8%) were very good with their quality of life. At follow up 52 (96.2%) subjects were good with their quality of life and 2 (3.8%) were very good with their quality of life. (Table no. 15).

**Table 15:** Rating the quality of life (n=54) Group A

Option	Frequency Before Intervention	Percentage	Frequency After Intervention	Percentage	Frequency At Follow Up	Percentage
Very Poor	00	00	00	00	00	00
Poor	00	00	00	00	00	00
Neither Poor Nor Good	00	00	00	00	00	00
Good	54	100	52	96.2	52	96.2
Very Good	00	00	02	3.8	02	3.8

**Group 2 (study Group)-**Among the 54 subjects maximum of 52 (100%) were good with their quality of life before intervention. After intervention 52 (96.2%) subjects were very good with their quality of life and

2 (3.8%) were good with their quality of life. At follow up 52 (96.2%) subjects were very good with their quality of life and 2 (3.8%) were good with their quality of life. (Table no. 16).

**Table 16:** Rating the quality of life (n=54) Group B

Option	Frequency Before intervention	Percentage	Frequency after intervention	Percentage	Frequency at follow up	Percentage
Very poor	00	00	00	00	00	00
Poor	00	00	00	00	00	00
Neither poor nor good	02	3.8	00	00	00	00
Good	52	96.2	02	3.8	02	3.8
Very good	02	3.8	52	96.2	52	96.2

**2. Health satisfaction-**

**Group 1 (Control Group)-**Among the 54 subjects maximum of 54 (100%) were satisfied with their health satisfaction before intervention. After intervention 52 (96.2%) subjects weresatisfied with their

health satisfaction and 2(3.8%) were very satisfied with their health satisfaction. At follow up 52 (96.2%) subjects were satisfied with their health satisfaction and 2 (3.8%) were very satisfied with their health satisfaction. (Table no. 17).



**Table 17:** Health satisfaction (n=54) Group A

Option	Frequency Before intervention	Percentage	Frequency after intervention	Percentage	Frequency at follow up	Percentage
Very dissatisfied	00	00	00	00	00	00
Dissatisfied	00	00	00	00	00	00
Moderate	00	00	00	00	00	00
Satisfied	54	100	52	96.2	52	96.2
Very satisfied	00	00	02	3.8	02	3.8

**Group 2 (study Group)**-Among the 54 subjects maximum of 53 (100%) were satisfied and 1(1.85%) were very satisfied with their health satisfaction before intervention. After intervention 38 (70.33%) subjects were satisfied with their health satisfaction and 16

(29.61%) were very satisfied with their health satisfaction. At follow up 38 (70.33%) subjects were satisfied with their health satisfaction and 16 (29.61%) were very satisfied with their health satisfaction. (Table no. 18).

**Table 18:** Health satisfaction (n=54) Group B

Option	Frequency Before intervention	Percentage	Frequency after intervention	Percentage	Frequency at follow up	Percentage
Very dissatisfied	00	00	00	00	00	00
Dissatisfied	00	00	00	00	00	00
Moderate	00	00	00	00	00	00
Satisfied	53	98.10	38	70.33	38	70.33
Very satisfied	01	1.85	16	29.61	16	29.61

**Total WHO QOL health status- Group 1 (Control Group)-**

Among the 54 subjects, Physical health status (Domain 1) was 81% before intervention, 88.22 % after intervention and 88 % follow up.

Among the 54 subjects, Psychological health status (Domain 2) was 69% before intervention, 69.22 % after intervention and 69.22 % follow up.

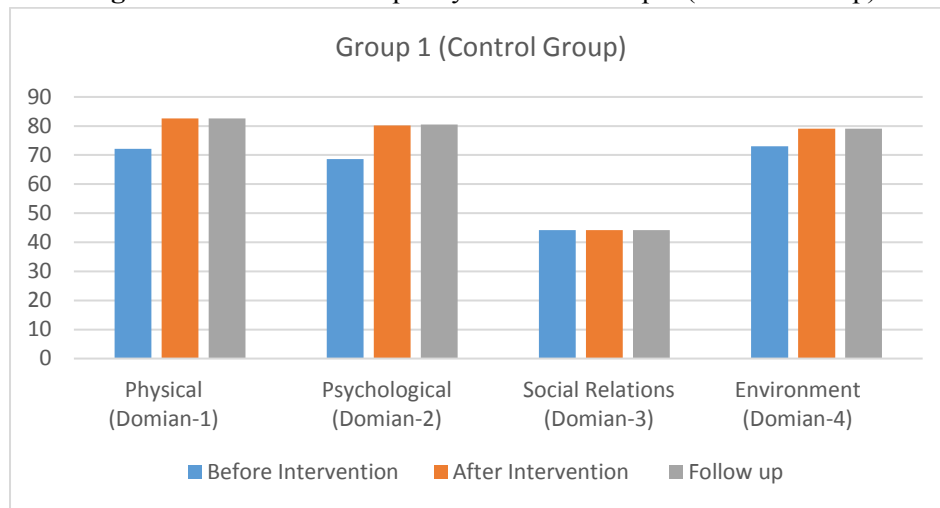
Among the 54 subjects, Social Relations status (Domain 3) was 44% before intervention, 44 % after intervention and 44 % follow up.

Among the 54 subjects, Environment factors status (Domain 4) was 69% before intervention, 69.22 % after intervention and 69 % follow up. (Table no. 19).

**Table 19:** Assessment of quality of life in Group 1 (Control Group)

	N	Before Intervention	After Intervention	Follow up
Physical health (Domian-1)	54	81	88.22	88
Psychological health (Domian-2)	54	69	69.22	69.22
Social Relations (Domian-3)	54	44	44	44
Environment factors (Domian-4)	54	69	69.22	69
Overall	54	65.75	67.65	67.55

**Figure 1:** Assessment of quality of life in Group 1 (Control Group)



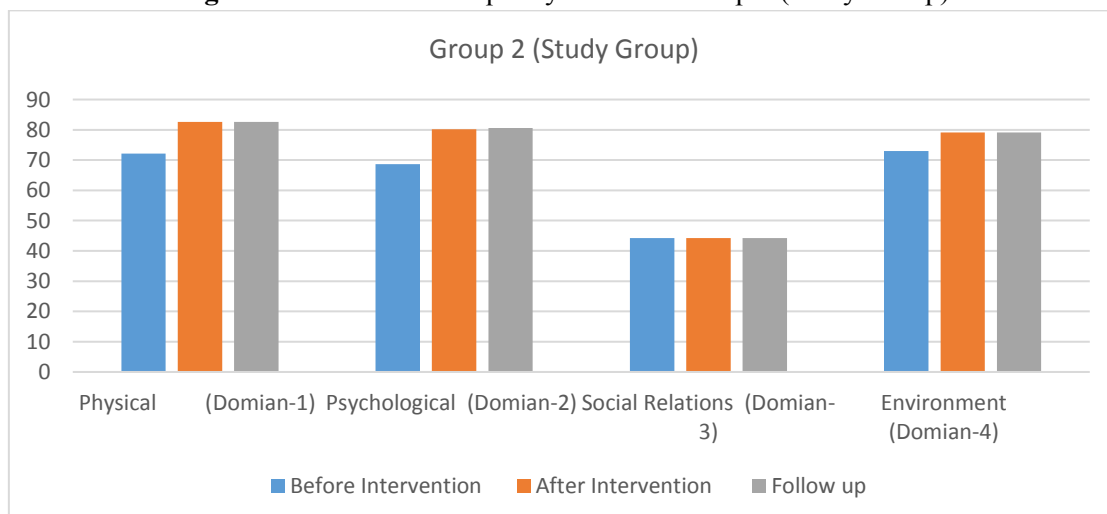
**Group 2 (study Group)-** Among the 54 subjects, Physical health status (Domain 1) was 72.11% before intervention, 82.59 % after intervention and 82.59 % follow up. Among the 54 subjects, Psychological health status (Domain 2) was 68.62% before intervention, 80.22 % after intervention and 80.55 % follow

up. Among the 54 subjects, Social Relations status (Domain 3) was 44.22% before intervention, 44.22 % after intervention and 44.22 % follow up. Among the 54 subjects, Environment factors status (Domain 4) was 73% before intervention, 79.11 % after intervention and 79.11 % follow up. (Table no. 20).

**Table 20:** Assessment of quality of life in Group 2 (Study Group)

	N	Before Intervention	After Intervention	Follow up
Physical health (Domian-1)	54	72.11	82.59	82.59
Psychological health (Domian-2)	54	68.62	80.22	80.55
Social Relations (Domian-3)	54	44.22	44.22	44.22
Environment factors (Domian-4)	54	73	79.11	79.11
Overall	54	64.38	71.53	71.61

**Figure 2:** Assessment of quality of life in Group 2 (Study Group)



## DISCUSSION

This study aimed to assess the effects of Ashwagandha to evaluate the quality of life of these subjects.

**WHO QOL Bref:** The quality of life assessment questionnaire of WHO consisted of 26 questions with two subjective questions likely the rating the quality of life and rating the satisfaction of the health.<sup>13</sup>

**Effect of Ashwagandha-** In Overall results the effect of *Ashwagandha* improve the quality of life compare to control group. *Ashwagandha* effects increase in testosterone, which leads to muscle growth and decrease in the level of cortisol, which as catabolic agent detracts from muscle mass. In the term of energy production. *Ashwagandha* can have beneficial effects on mitochondrial energy level and functioning the reduce activity of the Mg<sup>2</sup> dependent ATPase enzyme responsible for the breakdown of ATP and increase creatine levels can in turn leads to ATP generation. Finally, the effect of Ashwagandha on the nervous system as anti-anxiety agent and in promoting focus and concentration may translate to better coordination and recruitment of muscle.

## CONCLUSION

*Ashwagandha* is one of the rejuvenative and potent supplement to improve the health status. In present study, the subjects had higher scores among the physical, psychological domains compared with the environment and social domains. In comparison with study group and control group the quality of life (WHO BREF) found improved in study group.

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Source of Support: Nil

Conflict of Interest: None Declared

How to cite this URL: Bargale Sushant Sukumar et al: A Clinical Study On Effectiveness Of Ashwagandha (Withania Somnifera) On Quality Of Life (Whoqol-Bref) In Apparently Healthy Subjects. International Ayurvedic Medical Journal {online} 2020 {cited December, 2020} Available from: [http://www.iamj.in/posts/images/upload/5268\\_5278.pdf](http://www.iamj.in/posts/images/upload/5268_5278.pdf)