



## Efficacy of Ashwagandha (*Withania somnifera*) in improving cardiorespiratory endurance (Harvard step test) in healthy subjects

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### ABSTRACT

*Ayurveda is widely used in India as a primary health care system and is flourishing in the promotion of health worldwide. Ayurveda aims at maintaining the health of healthy and treating the individuals with diseases. Chakrapani defines Swasthavritta as the regimens followed to keep oneself healthy and thus, it includes promotion of health and prevention of diseases. Ashwagandha is one of Ayurveda's most essential herbs, used as Rasayana for its wide range of health benefits for centuries. Ashwagandha roots are a constituent of over 200 formulations in Ayurveda, Siddha and Unani medicine, which are used in the treatment of various physiological disorders. Ashwagandha has been used to promote youthful vigor, strength and health, nurture the body's time elements and increase the production of vital fluids, muscle fat, blood, lymph, semen and cells. Chronic exhaustion, debility, dehydration, bone weakness, loose teeth, hunger, impotence, premature ageing, emaciation, weakness and stress of the muscles can also be counteracted. It is also used for constipation, senile debility, rheumatism, general weakness, nervous exhaustion, memory loss, muscle energy loss and spermatorrhoea (excessive ejaculation). The study evaluated the efficacy of Ashwagandha (WS) to improve cardiorespiratory endurance (Harvard step test) in healthy subjects. Study group received Ashwagandha 12gm with milk (200ml) empty stomach in morning and control group only milk (200 ml). Harvard step test of both study and control group before intervention (0<sup>th</sup> day), after intervention (60<sup>th</sup> day) and follow up (90<sup>th</sup> day). A significant improvement in the Harvard step test after intervention in between the group ( $F=7.996$   $p=0.003$ ) and follow up ( $F=7.304$   $p=0.030$ ). Supplementation of Ashwagandha (*Withania somnifera*) improve cardiorespiratory endurance (Harvard step test).*

**Keywords:** Ashwagandha, *Withania somnifera*, Health, Harvard step test

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### INTRODUCTION

Ayurvedic medicine is holistic, which means viewing the whole of the body and mind. Not only does Ayurveda treat the physical ailments of a patient, but it also changes lifestyle practices to help preserve or improve health.[1] To maintain health, reduce stress, and improve flexibility, strength and endurance, people use Ayurvedic medicines. Ashwagandha (*W. Somnifera*) has the property of Rasayana as mentioned in literature.[2] It not only maintains the equilibrium of Dosha and Dhatu of the body but also promotes the health. Vatakaphahara, Jara Vyadhi Nashaka, Balya, and Dhatu Vriddhikara are all properties of Ashwagandha. Because of these qualities, it has not only preventive, but also promotive and curative effects, as well as the ability to slow down Jara by delaying the pathogenesis.[3] Ashwagandha (WS) promotes good health, improves quality of life, treats insomnia, drowsiness, physical and mental fatigue, weakness, and prolongs youth. In Ayurveda, Unani and Siddha, this plant is used in more than 100 formulations. One of Ashwagandha most important useful drug is Medica Ayurveda Material.[4] Ashwagandha (*Withania somnifera*) chemical constituents such as flavonoids, alkaloids, and steroidal lactones (withanolides) or antioxidants (superoxide dismutase, catalase, and glutathione peroxidase) may be behind Harvard step test improvement.[5] In healthy adults and also in athletes, Ashwagandha also enhances cardiovascular fitness, providing an additional alternative as a dietary supplement to boost the cardiorespiratory endurance (Harvard step test) and improve the quality of life.[6] Physical fitness is

defined as the ability to perform a physical activity in a variety of environments. Aerobic capacity, muscular endurance, flexibility, and body composition are the five components. The Harvard Step Test is regarded the gold standard of cardiovascular and muscle cell fitness.[7] Study the efficacy of Ashwagandha to improve cardiorespiratory endurance (Harvard step test) in healthy subjects.

## **MATERIAL AND METHODS**

This randomized controlled comparative study with pretest and post test design was approved by IEC Sri Dharmasthala Manjunatheshwara college of Ayurveda and Hospital Hassan, Karnataka, India (IEC No.\; SDM/IEC/92/2016-2017 date 25 June 2016) and the 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** -The subjects were screened and selected from OPD of Sri Dharmasthala Manjunatheshwara college of Ayurveda and Hospital Hassan, Karnataka.

**Method of collection of Data**- The selected healthy subjects was done as per the criteria inclusion and exclusion. Apparently healthy volunteers within the age group 18-40 years ready to give written consent irrespective of gender were included in the study. The subjects (108) included in study were alternatively divided into control group (N1=54) and study group (N2=54). In study group administration of Ashwagandha Choorna (*Withania somnifera*) given in the dose of 12 grams with 200ml milk in daily morning empty stomach for a period of 60 days. The control group administration of milk 200ml in daily morning empty stomach a period of 60 days. The blood, urine routine and lipid profile was analyzed before, after intervention and follow up (0<sup>th</sup>, 60<sup>th</sup> and 90<sup>th</sup> day); the Cardiorespiratory endurance test (Harvard test) were assessed through a pre-structured, pre validated questionnaire based on Ayurvedic description of health. Data analyze was done by SPSS 20 version.

### **Inclusion criteria:**

1. Apparently Healthy subjects who are interested and willing to take Ashwagandha Churna.
2. Subjects of age group 18-40 yrs.

### **Exclusion Criteria-**

1. Pregnant women, lactating women etc.
2. Those on other supplements.

**Duration of the study:** For both groups 60 days.

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

### **Operational definitions/Techniques employed:**

**Method of sample selection** – Healthy Volunteers

**Study design**- Controlled comparative clinical study with pre-test and post-test design wherein 108 apparently healthy subjects were selected.

**Method of Sampling**- Convenient sampling method.

**Method of group allocation**- Simple random sampling technique viz., alternate group distribution.

### **Interventions-**

**Medicine Name:** Ashwagandha Choorna

**Authentication of Drugs** - Ashwagandha Choorna purchased from SDM pharmacy Udipi, Karnataka.

**Packaging and labeling**- 12 gm of Ashwagandha Churna were measures each dose packed separately in small Ziploc plastic covers and placed in a big size bottles.

**Route of Drug administration**- Oral

**Form of drug** - Choorna (powder)

**Dosage of the drug**-12gm

**Anupana**- Milk

**Sample Size**- 108 persons were screened and selected from OPD of SDM Ayurveda College and Hospital, Hassan.

**Grouping**- Control Group 1 - 54 subjects and Study Group 2- 54 subjects

### **Intervention-**

The included subjects are divided under two groups Control Group 1 and Study group 2.

**GROUP 1** - 54 persons were given 2 Haritaki tablets for KosthaShuddhi with hot water for days and 200 ml Dugdha (milk) for 60 days in empty stomach early in the morning kept as a control.

**GROUP 2** - 54 persons were given 2 Haritaki tablets for KosthaShuddhi with hot water for 3 days and 12gm of Ashwagandha Choorna with 200 ml Dugdha (milk) for 60 days in empty stomach early in the morning.

### **Harvard Step Test-**

**Equipment required:** The height of the platform is about 50 cm (20 inches) for men and 40 cm (16 inches) for women, stop watch, pulse oxy meter.

**Procedure:**

1. The athlete steps up and down on the platform at a rate of 30 steps per minute (every two seconds) for 5 minutes or until exhaustion. Exhaustion is defined as the athlete's inability to maintain a 15-second stepping rate.
2. The athlete immediately sits down on completion of the test, and the total number of heart beats are counted between 1 to 1.5 minutes after finishing.
3. This is the only measure required if using the *short form* of the test.
4. If the *long form* of the test is being conducted, there is an additional heart rate measures at between 2 to 2.5 minutes, and between 3 to 3.5 minutes.

**Scoring:** the Fitness Index score is determined by the following equations. For example, if the total test time was 300 seconds (if completed the whole 5 minutes), and the number of heart beats between 1-1.5 minutes was 90, between 2-2.5 it was 80 and between 3-3.5 it was 70, then the long form Fitness Index score would be:  $(100 \times 300) / (240 \times 2) = 62.5$ . Note: you are using the total number of heart beats in the 30 second period, not the rate (beats per minute) during that time.

**Fitness Index (long form)** =  $(100 \times \text{test duration in seconds})$  divided by  $(2 \times \text{sum of heart beats in the recovery periods})$ . [8,9,10]

**Grading assessment of Harvard step test.**

Grade	Rating	Fitness index (long form)
1	Excellent	> 96
2	Good	83 - 96
3	Average	68 - 82
4	low average	54 - 67
5	Poor	< 54
(norms from: Fox et al. 1973)		

**RESULT**

Total 408 subjects were screened, 114 subjects were enrolled for the study, 108 subjects completed the clinical trial and there was 6 subjects was drop out.

**Age distribution-** Among 114 subjects, majority of 102 (89.45%) had completed the schooling till PUC and 12 (10.52%) subjects were graduates.

**Educational Status-** Among 114 subjects, majority of 102 (89.45%) had completed the schooling till PUC and 12 (10.52%) subjects were graduates.

**Type of family-** Among 114 subjects, majority of 84 (73.67%) subjects having joint family and 30 (26.33%) subjects having nuclear family.

**Housing condition-** Among 114 subjects, majority of 70 (61.39%) subjects having poor housing condition, 32 (28.09%) subjects having moderate housing condition, 10 (8.77%) subjects having good housing condition and 02 (1.75%) having very good housing condition.

**Food Habits (Vegetarian or Mixed)-** Among 114 subjects, all the subject having mixed food (vegetarian and non-vegetarian).

**Food consumption (Timely consumption / Untimely consumption / frequent food intake)-** Among 114 subjects, majority 86 (75.44%) consume the food timely and 28 (24.56) consume untimely.

The Friedman test is non parametric alternative alternate to the one way ANOVA with repeated measures. It is used to test for differences between groups when the dependent variable being measures is ordinal. It can also be used to analyze continuous data that deviates from the assumptions required for one-way ANOVA with repeated measures. Friedman's test followed by post hoc analysis with Wilcoxon signed rank test was applied for subjective parameters. In the parameters N was fixed to 54 in each group. The study's initial significance level was set at 0.05. The subjects were analyzed at interval of BT (Before Intervention- i.e. on baseline or 0<sup>th</sup> day), AT (After Intervention i.e. on 60<sup>th</sup> day) and FU (Follow up i.e. 90 day).

**Table No 01- Descriptive Statistics for Friedman test in Harvard step test**

Harvard step test	Control Group			Study Group		
	N	Mean	SD	N	Mean	SD
<b>BT (0<sup>th</sup> day)</b>	54	2.759	.5472	54	2.9259	.26435
<b>AT (60<sup>th</sup> day)</b>	54	2.537	.5734	54	2.2222	.50157
<b>FU (90<sup>th</sup> day)</b>	54	2.555	.5718	54	2.3333	.47583

**Table No 02- Descriptive Statistics for Friedman test in Harvard step test**

Harvard step test	Control Group			Study Group		
	N	Mean	SD	N	Mean	SD
BT (0 <sup>th</sup> day)	54	79.6808	5.25325	54	77.5206	5.21865
AT (60 <sup>th</sup> day)	54	81.4401	5.01079	54	83.3287	5.03840
FU (90 <sup>th</sup> day)	54	81.6658	5.40752	54	82.7652	5.09379

**Control Group-** The mean physical fitness index (Harvard step test) in the control group was 79±5.25 which increased to 81.44±5.01 after intervention and after the follow up 81.66±5.40. Physical fitness index (Harvard step test) showed statistically significant change with  $p < 0.001$ .

**Study Group-** The mean physical fitness index (Harvard step test) in the Study group was 77.52±5.21 which increased to 83.32±5.03 after intervention and after the follow up 82.76±5.09. Physical fitness index (Harvard step test) showed statistically significant change with  $p < 0.0001$ .

**Table No03- Friedman Test in Harvard step test**

Harvard step test Control Group	N	MR	X <sup>2</sup>	Df	P	Remarks
BT (0 <sup>th</sup> day)	54	2.21	19.00	2	<0.0001	S
AT (60 <sup>th</sup> day)	54	1.88				
FU (90 <sup>th</sup> day)	54	1.91				
Harvard step test Study Group	N	MR	X <sup>2</sup>	Df	P	Remarks
BT (0 <sup>th</sup> day)	54	2.65	62.600	2	<0.0001	S
AT (60 <sup>th</sup> day)	54	1.59				
FU (90 <sup>th</sup> day)	54	1.76				

**Table No 04- Ranks for Wilcoxon test in Harvard step test**

Harvard step test	Control Group			Study Group		
	N	MR	Sum of Ranks	N	MR	Sum of Ranks
AT - BT	NR	0	.00	0	.00	.00
	PR	12	6.50	38	19.50	741.00
	Ties	42		16		
	Total	54		54		
FU - AT	NR	3	3.00	8	5.50	44.00
	PR	2	3.00	2	5.50	11.00
	Ties	49		44		
	Total	54		54		
FU - BT	NR	0	.00	0	.00	.00
	PR	11	6.00	32	16.50	528.00
	Ties	43		22		
	Total	54		54		

**Table No 05 - Wilcoxon signed rank Test in Harvard step test**

Harvard step test	Control Group			Study Group		
	AT - BT	FU - AT	FU - BT	AT - BT	FU - AT	FU - BT
Z value	-3.464	-.447	-3.317	-6.164	-1.897	-5.657
Asymp. Sig. (2-tailed) (P value)	0.001	.655	0.001	<0.0001	0.058	<0.0001
Remarks	HS	NS	HS	HS	NS	HS

**Control Group-** There was statistically significant difference in Harvard step from BT (0<sup>th</sup> day) to AT (60<sup>th</sup> day) and FU (90<sup>th</sup> day),  $\chi^2 = 19.00$ ,  $p < 0.0001$ . Post hoc analysis with Wilcoxon signed-rank tests was applied resulting and it also significance changes. There was significant differences between BT (0<sup>th</sup> day) to AT (60<sup>th</sup> day) ( $Z = -3.464$ ,  $p < 0.0005$ ), in between AT (60<sup>th</sup> day) to FU (90<sup>th</sup> day) ( $Z = -3.317$ ,  $p = 0.001$ ). There was no significant differences between BT (0<sup>th</sup> day) to FU (90<sup>th</sup> day) ( $Z = -.447$ ,  $p = 0.655$ ).

**Study Group-** There was statistically significant difference in Harvard step from BT (0<sup>th</sup> day) to AT (60<sup>th</sup> day) and FU (90<sup>th</sup> day),  $\chi^2 = 62.600$ ,  $p < 0.0001$ . Post hoc analysis with Wilcoxon signed-rank tests was applied resulting and it also significance changes. There was significant differences between BT (0<sup>th</sup> day) to AT (60<sup>th</sup> day) ( $Z = -6.164$ ,  $p < 0.0005$ ), in between BT (0<sup>th</sup> day) to FU (90<sup>th</sup> day) ( $Z = -2.449$ ,  $p < 0.0005$ ). There was no significant difference in between AT (60<sup>th</sup> day) to FU (90<sup>th</sup> day) ( $Z = -1.897$ ,  $p = 0.058$ ).

#### COMPARE IN CONTROL GROUP AND STUDY GROUP-

Mann-Whitney U test is used to compare differences between two independent groups when the dependent variable is either ordinal or continuous, but not normally distributed.

In the parameter N was fixed to 54 in each group Total 108 subjects. The initial significance level considered in this study is 0.05. The subjects were analyzed at interval of BT (Before Intervention- i.e. on baseline or 0<sup>th</sup> day), AT (After Intervention i.e. on 60<sup>th</sup> day) and FU (Follow up i.e. on 90 day).

**Table No 06- Descriptive Statistics in Harvard step test in between group (Control group and study group)**

Harvard step test	Group	N	Mean	Std. Deviation	Std. Error Mean
AT (60 <sup>th</sup> day)	Control Group	54	2.5370	.57340	.07803
	Study Group	54	2.2222	.50157	.06826
FU (90 <sup>th</sup> day)	Control Group	54	2.5556	.57188	.07782
	Study Group	54	2.3333	.47583	.06475

**Table No 07- Independent sample test in Harvard step test in between group (Control group and study group) AFTER INTERVENTION**

Harvard step test	Equal variances assumed	Equal variances not assumed
<b>Levene's Test for Equality of Variances</b>		
F	7.996	
Sig.	.006	
<b>t-test for Equality of Means</b>		
T	3.037	3.037
Df	106	104.156
Sig. (2-tailed)	<b>0.003</b>	<b>0.003</b>
Remarks	S	S
Mean Difference	.31481	.31481
Std. Error Difference	.10367	.10367
<b>95% Confidence Interval of the Difference</b>		
Lower	.10928	.10924
Upper	.52035	.52039

This study found that statistically significantly Harvard step test increase in the (2.22± 0.50) after intervention at the study group compare to control group (2.53±0.57), t(106)= 3.037, p=0.003.

**Table No 08- Independent sample test in Harvard step test in between group (Control group and study group) FOLLOW UP**

Harvard step test	Equal variances assumed	Equal variances not assumed
<b>Levene's Test for Equality of Variances</b>		
F	7.304	
Sig.	.008	
<b>t-test for Equality of Means</b>		
T	2.195	2.195
Df	106	102.608
Sig. (2-tailed)	<b>0.030</b>	<b>0.030</b>
Remarks	S	S
Mean Difference	.22222	.22222
Std. Error Difference	.10124	.10124
<b>95% Confidence Interval of the Difference</b>		
Lower	.02151	.02143
Upper	.42294	.42301

This study found that statistically significantly Harvard step test increase in the (2.33± 0.47) after intervention at the study group compare to control group (2.55±0.57), t(106)= 2.195, p=0.030.

## DISCUSSION

Apparently healthy subjects consumed in 12 grams in Ashwagandha Choorna with 200ml milk on daily basis, it has all possibility to show the effect as Rasayana. In study group shows that improve the cardiorespiratory endurance (Harvard test). Ashwagandha (*Withania somnifera*) reduced oxidative stress, as various oxidants and improve level of diverse anti-oxidants. Harvard step test represent long term aerobic and cardiovascular endurance. Endurance training combined with a favourable genetic disposition, results in series of physiological adaptations, designed to maximize endurance performance by increasing the amount of oxygen, which can be delivered to utilized by working muscle. [11]

Exercises that cause damage to amount of different human body systems are long-term strenuous free radical release. Increased lipid peroxidation may be caused by stress, whereas catalase and glutathione

peroxidase enzymes minimise antioxidant levels. All of the above parameters of free harm are standardised in a dose-dependent manner when researchers administered Ashwagandha (*Withania somnifera*) one hour prior to a daily stress-inducing therapy.[12]

Ashwagandha (*Withania somnifera*) chemical constituents such as flavonoids, alkaloids, and steroidal lactones (withanolides) or antioxidants (superoxide dismutase, catalase, and glutathione peroxidase) may be behind cardiorespiratory endurance (Harvard step test) improvement. In healthy adults and also in athletes, Ashwagandha also enhances cardiovascular fitness, providing an additional alternative as a dietary supplement to boost the Harvard step test measure.[13]

The active principles of Ashwagandha (*Withania somnifera*), VII-X sitonodosides and withaferin A (glycowithanolides) have been evaluated for antioxidant activity using the major free radical scavenging enzymes in the frontal cortex and striatum of the rat brain, superoxide dismutase (SOD), catalase (CAT) and glutathione peroxidase (GPX).[14]

## CONCLUSION

Ashwagandha (*Withania somnifera*) an important drug in Ayurveda in traditional Indian system medicine is conserved to be a Rasayana (rejuvenating). In this clinical study, oral administration of Ashwagandha (WS) with milk enhance aerobic capacity (Harvard step test) in healthy subjects. The finding of this clinical study suggests that Ashwagandha improves cardiovascular dynamics by increasing Harvard step test, thereby enhancing cardiorespiratory endurance in healthy subjects.

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## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest for this study.

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