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A RANDOMIZED CLINICAL STUDY TO EVALUATE THE EFFICACY OF ASHWAGANDHA RASAYANA ON KARSHYA W.S.R. TO UNDERWEIGHT.

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ABSTRACT

Background: A majority of the population in the developing countries suffer from malnutrition and under nutrition. In the global campaign of health for all, promotion of proper nutrition is one of the 8 elements of primary health care. *Ayurveda* with its holistic approach can help in this condition with its unique way of lifestyle management and the drug therapy. **Aim:** Evaluation of efficacy of *Ashwagandha Rasayana* overcome the problem of low body weight (*Karshya*). **Material and Methods:** An open clinical trial was conducted at Government Ayurveda college Hospital, Tripunithura on 30 patients of *Karshya* on the basis of body weight, BMI and Haemoglobin. Follow up was done before and after treatment. The results were statistically analyzed.

Result: The study shows statistically significant increase in Body weight, BMI and Haemoglobin. The mean value of Body weight was increased from 38.66 to 39.11 after treatment with statistically significant p-value of ($P<0.0042$). The mean value of BMI

increased from 15.89 to 16.08 after treatment with statistically significant p-value of (P<0.0044). The mean value of Haemoglobin was increased from 11.85 to 12.76 after treatment with statistically significant p-value of (P<0.001). **Conclusion:** *Ashwagandha Rasayana* is effective in management of Under Weight; which promotes the strength of body and has rejuvenating action, it provides nutrition to all the cyclic process of origin, maturation and degeneration of the body fulfilling the principle of rejuvenation. *Ashwagandha Rasayana* was found to have significant effect on increasing body weight, BMI and Haemoglobin.

KEYWORDS: *Ashwagandha Rasayana*, *Karshya*, Body weight and Body Mass Index (BMI), Haemoglobin.

INTRODUCTION

Health and diseases lie along a continuum. It is obvious that health fluctuates within a range of optimum well being to various levels of dysfunction. Nearly half of all deaths in children under 5 are attributable to under nutrition. This translates into the unnecessary loss of about 3 million young lives a year.[1] Several reports from Asia population[2-5] suggested the need for population-specific cut-off points for BMI. Polynesians have a lower percentage of body fat than do white people, for the same age, sex and BMI.[6] Studies in India have shown that nutritional deficiencies are widely persistent among adolescent population due to which they become under weight (*Krusha*) and weak (*Durbala*) both physically and mentally. It is the ill effect of life style modification, which affects the adolescent population because of excessive social stress (*Atichinta*). The same is responsible for improper consumption of food. About a third of Indian's are believed to be malnourished and over 40% of children receive less food than they should. The Government of India is increasing food subsidies to address this situation, but the rapidly rising population of much of Northern India poses continuing challenges.[7] In *Ayurveda*, ample scope is present for incorporating compounds to improve nutritional status. The assessment of the nutritional status involves various techniques, i.e., clinical examination, anthropometric measurements, laboratory and biochemical evaluation.

Under weight (*Krusha*) is one of the eight condemn men (*Asthanindita Purusha*) explained in various texts of *Ayurveda*. Low body weight (*Karshya*) is present alone or it may be present as associated symptom to other illness. Apart from this, the availability of ingredients in abundance, easy mode of preparation and good palatability lead to select the Ayurvedic drug for this study. Indications of *Ashwagandha* (Withania Somnifera) in underweight patient (*Krusha Rogi*) are mentioned in *Astanga Sangraha*.[8]

Low body weight (*Karshya*) is the condition of being excessively lean. These people are also termed as underweight and are characterized by having poor weight, less muscle mass leading to poor development of chest, limbs, and buttocks. In terms this excessive leanness is also known as emaciation. Many factors contribute for the cause of low body weight like feeding habits in younger days, poor eating habits, disease and psychological factors contribute to it.

Rejuvenation (*Rasayana*) therapies contribute to the benefit of both physical and psychological entities of a person thus bestowing him with good health and strength both physically and mentally. *Ashwagandha* (Withania Somnifera) is mentioned as rejuvenator (*Rasayana*) drug in text and is well known for promoting the strength of body which provides nutrition to all the metabolic processes (*Dhatus*) fulfilling the principle of rejuvenation (*Rasayana*).

A person having proportionate musculature and compactness of the body can withstand physical and mental exercises due to his strong sensory and motor organs. So this study is intended to evaluate scientifically the efficacy of *Ashwagandha Rasayana* on underweight (*karshya),* mentioned in *Astanghridaya.*[9]

AIMS AND OBJECTIVES

A majority of the population in the developing countries suffer from malnutrition and under nutrition. In the global campaign of health for all, promotion of proper nutrition is one of the eight elements of primary health care. Ayurveda with its holistic approach can help in this condition with its unique way of lifestyle management and the drug therapy. The incidences of malnutrition, PEM are common complications associated with low body weight (*Karshya).* *Ashwagandha Rasayana* is ideal for underweight (*Karshya*) persons. So far no scientific researchers have been carrd out to document its efficacy. So this study was planned to evaluate the efficacy of the *Ashwagandha Rasayana* in underweight *(Karshya)* patients.

MATERIAL AND METHODS

Trial drug is selected on the traditional as well as modern knowledge of herbs. The study is carried out as per the International Conference Harmonization – Good Clinical Practices Guidelines. Trial drug is prepared according to the method explained in the classical text *Astanghridaya.*[9]

Table no. 1.

S.no.	Name of ingredients	Part used	Botanical name	Form	Ratio
1.	Ashwagandha	Wh.Pl.	*Withania somnifera*	Powder	1
2.	Clarified butter	-	-	-	1
3.	Cow milk	-	-	-	Q.S

Selection of subject - A total of 30 patients were selected for the present study from O.P.D. and I.P.D. of *Swasthavritha* Department, Government Ayurveda College, Tripunithura irrespective of their sex, religion and socio economic status etc. Written & informed consent of patients was taken before trial. The duration of the study was 18 months from the date of beginning of trial.

Criteria for diagnosis

Subjective criteria – Classical sign and symptoms of underweight person i.e. *Karshya* as mentioned in Ayurvedic texts as well as in modern literature.

Objective criteria- Body mass index < 18.5.

Inclusion criteria

- Male and female of age 15 to 50 years.
- Having B.M.I less than 18.5.

Exclusion criteria

- Person aged below 15 and above 50 years.
- B.M.I more than 18.5.
- Persons having any systemic disease.

Laboratory analysis

- Blood – Hb gm%.

Method of study

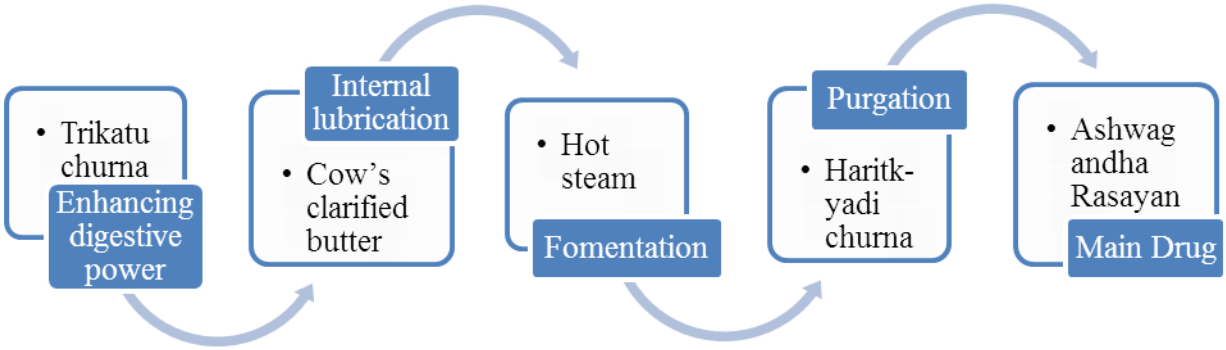
IEC & Consent: - Approval from the *Institutional Ethics Committee (IEC)* was taken prior to begin with this study vide IEC/125/2011 dated 11.04.2011. Written & informed consent of the patients was taken before their registration for the study.

Patient Information Sheet & CRF: - All the patients were given an information sheet stating all the details of the study protocol, benefits of the trial & any expected side effects. A

clinical research Performa was prepared to note down all the details of the patients and their disease.

Trial Groups: - Total 30 underweight (*Karshya)* patient were selected for the present clinical study. After diagnosis all subjected gone through complete clinical intervention i.e. purgation (*Virechana karma*) followed by the administration of main trial drug.

(Figure 1)



Purgation (*Virechana karma*) was done in all the patients as per classical method in the following manner. The patients were first subjected to increase the digestive power (*Deepana and Pachana*) by an Ayurvedic formulation i.e. *Trikatu Curna*.

After *Deepana* and *Pachana*, cow's clarified butter (*Go-Ghrit*) was administered for the purpose of internal body lubrication (*Snehan*). It was given at 7.00 am with hot water (*Anupana*). The dose of cow's clarified butter (*Go-Ghrit*) was calculated according to the patient. The initial dose of cow's clarified butter (test dose) on the first day was 30-50 ml. Then according to the symptoms presenting in the individual, the duration taken to digest the given dose of cow's clarified butter, the time of appearance of appetite in the patient, the dose of the next day was decided. It was generally increased by 30 ml or 50 ml or according to the symptoms presenting in the patient. Maximum emphasis was given on the presence of complete digestion (*Samyaka Snigdha*) symptoms and was recorded accordingly. Individual was advised to avoid excessive wind, sunlight, emotional exacerbations, exercise, heavy work, excessive talking-laughing-standing and journey. The patient was advised not to take any type of diet till he got the strong sensation of hunger. One was just allowed to have lukewarm water till then.

After complete digestion of cow's clarified butter (*Samyak Snehana Laksanas*), full body hot fomentation (*Sarvanga Bashpa Svedna*) was given for one day. Then purgation (*Virechana Karma*) was performed by an *Ayurvedic formulation* i.e. *Haritakyadi Churna* used to clear the faecal material and empting of the intestine (*Mala Shudhi*).

After completion of the whole process main drug i.e. *Ashwagandha Churna* is administered along with milk and cow's clarified butter. Dose of *Ashwagandha Rasayana* was 12 g in two divided dose morning and evening.

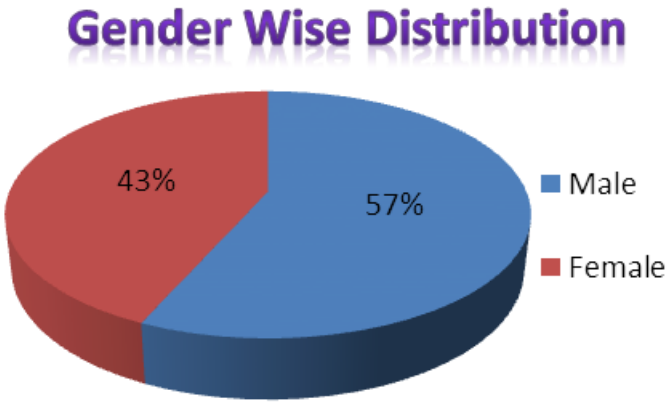
Duration of trial - Duration of trial was of 90 days
Follow up - Follow up will be done 30 days after therapy period and second follow up on 90th day.

Assessment: - Patients were thoroughly assessed for any improvement in the subjective and objective criteria after completion of trial and on each follow up. Haematological parameters, body weight and BMI were evaluated both before and after the therapy.

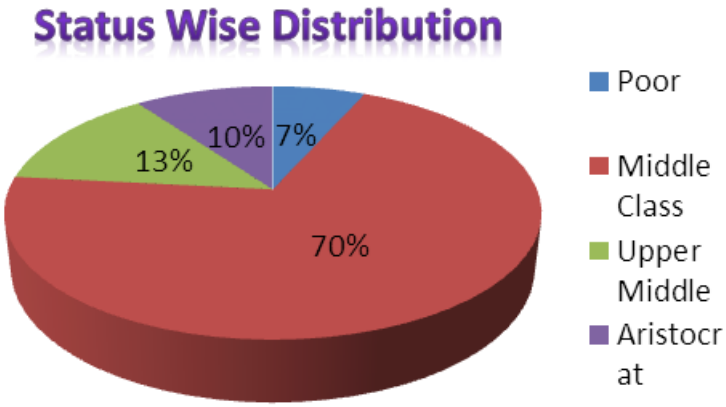
Statistical Analysis:-The obtained data was analyzed statistically and expressed in terms of mean, standard deviation (± SD) and standard error (± SE). Appropriate statistical test i.e. "t" test was applied to observe the significance of results obtained after treatment. The results obtained were interpreted accordingly.

OBSERVATIONS AND RESULTS

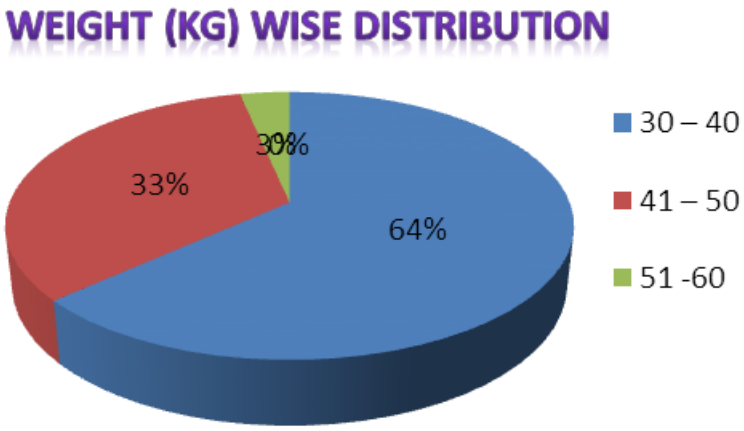
Total 36 patients were enrolled in the study in which 30 patients completed the study. Maximum patients i.e. 39% were from the age group of 39-50 years, followed by 35% from 15-26 years of age. The different surveys also say about the maximum number of persons having low body weight (*Karshya)* belongs to teen age group. The reason may be the food habits and stressful lifestyle during this age group. Maximum patients in the present study i.e. 57% were males and 43% were females (Figure 2).



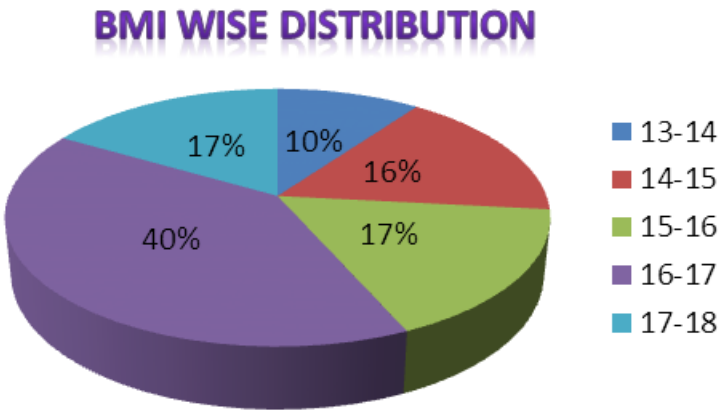
Lack of nutrition knowledge may be the causative factor. Majority of patients belong to middle class 68%, where as 13% were in upper middle class, 10% were in Aristocrat and the remaining 7% were poor patient (Figure 3).



Among the sample 87% patients were non-vegetarians but a small population of patients 13% were pure-vegetarians. This may be due to the sample residing area containing maximum number of non-vegetarians. And also, it shows that the foods they take are not properly assimilated. Disturbed digestion power (*Agni Vishamata*) was observed in 43% patients and low digestion power (*Mandata*) in 23%. This indicates the more underweight (*Karshya)* subjects are having disturbed digestion power (*Vishamagni*) followed by low digestion power (*Mandagni*). In this study 60% patients were constipated. Constipation is the one of the associated complaint of underweight patients. It is due to the *Vata Prakruti*, and *Rooksha Anna Pana*. In this study 60% subjects were having reduced sleep. Disturbed sleep is mainly due to the *Vata Dosha* dominance. In this study Maximum i.e. 63% patients were having weight in the category of 30-40 kg followed by 33% patients in 41-40 kg category (Figure 4).



Maximum i.e. 39% patients were having BMI in the category of 16-17 followed by 17% patients in 14-15, 15-16 and 17-18 each (Figure 5).

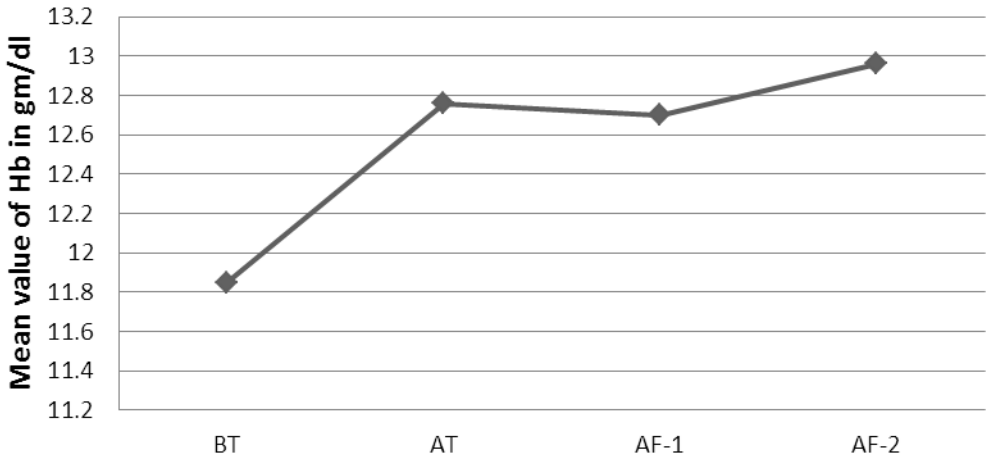


The effect of trial drug on Haematological values was evaluated, as the mean value of Haemoglobin increased from 11.85 to 12.76 after treatment, it shows statically highly significant ($p<0.001$).

Table no. 2: Analysis regarding effect of treatment on Haemoglobin.

State	Mean	SD	N	Group	Mean Difference	"t" Value	P-Value
BT	11.85	2.03	30	BT vs. AT	-0.91	-11.58	<0.001
AT	12.76	1.95	30	BT vs. AF-1	-0.86	-9.31	<0.001
AF-1	12.70	1.91	30	BT vs. AF-2	-1.11	-11.60	<0.001
AF-2	12.96	1.82	30				

(Figure 6)

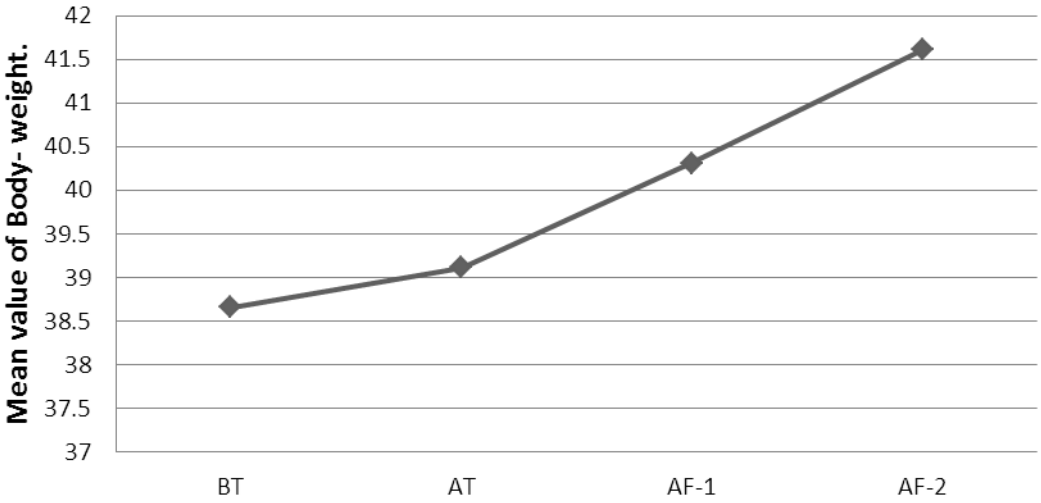


Effect of trial drug on body weight was evaluated as, the mean value of Body weight increased from 38.66 to 39.11 after treatment. It shows statistically significant p value (P<0.0042) and after the 3 months treatment with *Ashwagandha Rasayana* body weight increased from 38.66 to 41.61. It shows statistically extremely significant (P<0.0001).

Table 3: Analysis regarding effect of treatment on Body-Weight.

State	Mean	SD	N	Group	Mean Difference	"t" Value	P- Value
BT	38.66	5.17	30	BT vs. AT	.44	3.10	<0.0042
AT	39.11	5.01	30	BT vs. AF-1	1.64	12	<0.0001
AF-1	40.31	4.94	30	BT vs. AF-2	2.94	14.69	<0.0001
AF-2	41.61	4.92	30				

Figure 7

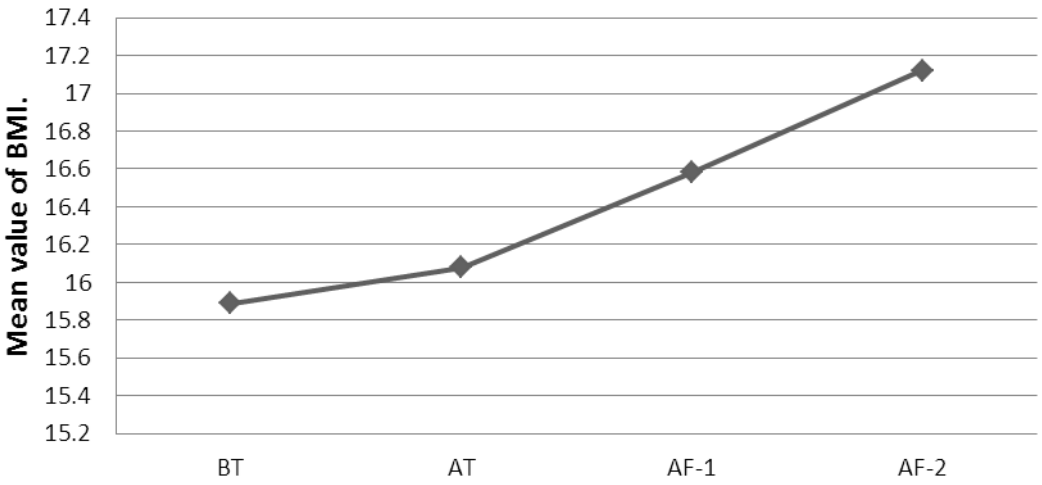


The significant increase in weight might be due to the acceleration of the body growth due various alkaloids present in the formulation. As *Ashwagandha* (Withania Somnifera) is anabolic (*Brimhana*) is nature. After analysing the effect of treatment, the mean value of BMI increased from 15.89 to 16.08 after treatment. It shows statistically extremely significant (P<0.0044) and after the 3 months treatment with *Ashwagandha Rasayana*, BMI increased from 15.89 to 17.12. It shows statistically significant p value (P<0.0001) as increase of the BMI depends on the increased weight. Gradual increase of BMI was attained in this study.

Table no. 4: Analysis regarding effect of treatment on BMI.

State	Mean	SD	N	Group	Mean Difference	"t" Value	P- Value
BT	15.89	1.21	30	BT vs. AT	.19	3.091	<0.0044
AT	16.08	1.14	30	BT vs. AF-1	.69	11.62	<0.0001
AF-1	16.58	1.09	30	BT vs. AF-2	1.22	14.05	<0.0001
AF-2	17.12	1.11	30				

Figure 8



DISCUSSION

In Ayurveda classical text *Karshya* is a *Rasapradoshaja Vikara* i.e. low body weight or underweight condition arises due change in metabolism named as *Dhatupusti*, which is seen in majority of adult population in developing countries. The main cause is found to be inadequate intake of nutritious food and lack of awareness regarding its importance. Poverty and lack of personal hygiene are the other causative factors which contribute to the manifestation of the underweight (*Karshya)*. Since India is a developing country where socio-economic status of the majority of population is low, the quality of life determines under

nutrition. On global scale, kwashiorkor, marasmus and nutritional anaemia are three principle nutritional deficiency diseases that are being recorded the highest priority action.

The present study was completed to evaluate the efficacy of an *Ayurvedic* formulation on improving the condition of low body weight (*Karshya).* The outcome of the study showed ample evidence in regard to the action of the drug. The drug was prepared using fresh ingredients.

Ayurvedic pharmacology depends on five principles of *Rasa- Guna- Virya- Vipaka* and *Prabhava.*[10] *Acharya Charak* has mentioned that any *Dravya* can have similar *Rasa, Virya* and *Vipak*a but a different mode of action which can be explained on the basis of *Prabhava.*[11]

Karshya is considered as one of the *Apatarpana Janya Vikara* which needs to be corrected by *Santarpana* measures. Hence the present study is designed to study the efficacy of the *Ashwagandha Rasayana* which is having *Guru, Snigdha Guna, Sheeta Veerya, Kapha Vardhaka* and *Vata Shamaka* properties (i.e. the qualities equalling to that of *Kapha* and *Medas*) in the management of *Karshya* individuals *Ashwagandha Rasayana* produces the anabolic (*Brimhana*) effect on the different tissues of the body. *Ashwagandha Rasayana* is *Madhura* and *Tikta Rasa, Snigdha Guna, Ushna Veerya* and *Madhura Vipaka,* having *Vata Pitta Shamana* and *Kapha Vardhaka* effect. *Laghu Guna* of *Ashwagandha* (Withania Somnifera)helps in kindling the Agni and may help in proper digestion, absorption and assimilation of the drug.

Ashwagandha (Withania Somnifera) powder (*Choorna*) was given with cow's clarified butter (Ghrita) and Milk. Cow's clarified butter used in *Ashwagandha Rasayana* is considered to be the best *Sneha,* which causes *Snehana* to the tissues. Milk is considered as a complete and ideal food. The main sugar present in milk is lactose. Lactose favours the absorption of calcium and phosphorous and the synthesis of some B-complex vitamins in the small intestine. Most of the properties (*Guna*) of milk are similar to *Ojus*. Thus Milk and cow's clarified butter nourishes the body. Both cow's clarified butter and milk add palatability to the drug, which is an important factor to be considered for administration to the patients suffering from underweight.

Thus it can be inferred that *Ashwagandha* (Withania Somnifera) acts both on *Agni* and *Poshaka Rasa*. Being rich in proteins contains essential amino acids and steroids. It is the anabolic to *Mamsa* according to *Charaka*. It has the ability to nourish all the tissues of the body by increasing the *Adya Dhatu* i.e., *Rasadhatu*. The anabolic steroids found to be present in the formulation and the procedure of drug administration might influence protein metabolism. Such anabolic agents if given in conjunction with an adequate diet for conditions characterized by wasting of bones and muscles prove to be beneficial to the patient suffering from *Karshya*. *Ashwagandha* (Withania Somnifera) is also an "adaptogen," as it increases resistance to physical, chemical and biological stressors, builds energy and general vitality.[12-15]

Underweight *(Karshya)* patients are prone to infections; hence treatment should be aimed to fulfil their nutritional requirements. The formulation *Ashwagandha Rasayana* is such a nutritious medicament which possesses *Laghu*, *Snigdha Guna*, *ushna Veerya*, and *Vata Shamaka* properties. *Ashwangandha* (Withania Somnifera) is the ideal drug which helps in the improving the condition of low body weight (*Karshya*). This gives *Sharirika* and also *Manasika Dridhatva*.

CONCLUSION

The present study concluded that *Ashwagandha Rasayana* is effective in improving body weight among lean people. *Rasayana* therapy aims at purifying and nourishing each *Dhatu* right from *Rasa* to *Shukra* and result in the physical and mental quality of individual. The leanness even though mimics a fit person, in most cases it leads to less bodily resistance and is more chance to infections. *Ashwagandha* (Withania Somnifera) is mentioned as rejuvenating drug in text and is well known for promoting the strength of body which provides nutrition to all the *Dhatus* fulfilling the principle of *Rasayana*. *Ashwagandha Rasayana* was found to have significant effect in improving Haemoglobin. *Ashwagandha Rasayana* is found to be significantly effective in improving body weight and BMI among low body weight (*Krusha*) people. Apart from concentrating therapeutic aspects of this disease, it should be considered to improve the socio-economic status and also awareness of nutrition education. The sample size was small and so a pinpoint conclusion cannot be drawn. Even the follow up period was planned only three month keeping in view of study period.

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