



## EFFECT OF STANDARDIZED EXTRACT OF SHATAYUSHI GRANULES ON SHORT STATURE CHILDREN: A CLINICAL STUDY

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(Published Online: April 2023)

Open Access

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Article Received: 16/03/2023 - Peer Reviewed: 27/03/2023 - Accepted for Publication: 09/04/2023.

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## ABSTRACT

**Content-** Height and weight are the most important factors in human growth and development. Poor nutrition and hormonal imbalances lead to stunted growth in children. Using hormone therapy to increase height in allopathy has many side effects, which is why it is important to find solutions that promote rapid growth with no side effects. *Shatayushi* Granules are a homemade Ayurvedic herbal medicine formulation containing Shatavari, Ashwagandha, Shankhpushpi, and Brahmi are known as *Rasayana* and *Bruhana Dravya* in classical Ayurvedic texts. These drugs promote rapid growth in growing children, also act as brain tonics, and have a sedative effect that promotes sound sleep, thereby stabilizing their mental health. **Aim and Objectives-** The aim of this study was to analyze the effect of a self-made Ayurvedic Product (*Shatayushi* Granules) on height gain in children. **Material and Method- Design and Participants:** - A double-blind randomized controlled trial was conducted on 70 children from the department of Kaumarbhritya tantra. **Intervention:** - A group of 70 children aged 1 to 15 years, regardless of gender, with less height according to the child's standard growth, were randomly selected into two groups, i.e. Group A (*Shatayushi*/Experimental group) and Group B (control group), each group containing 35 children. Group A received 5-10 gm of *Shatayushi* Granules with 1 cup of warm cow's milk twice a day for three months while Group B children received 1 cup of warm cow's milk twice a day. **Results-**Group A, which used *Shatayushi* granules along with their daily diet, showed rapid height gain compared to Group B. The maxi-

imum increase in height was 2.5 cm in 3 months. The intragroup comparison in the experimental group was statistically more significant than in the control group ( $P < 0.05$ ). **Conclusion-** *Shatayushi Granules* appears to be the most suitable, convenient, safer, and economical option for height gain in growing children.

**Keywords:** Height Growth, Children, *Shatayushi granules, Rasayana, Bruhana.*

## INTRODUCTION

Growth and development are determined by height and weight. Body growth is rapid during pregnancy, the first year or two years after birth, and also during puberty. Growth accelerates again after puberty, also known as a pubertal growth spurt<sup>(1)</sup>. Normal growth is controlled by various hormones such as growth hormones, thyroid hormones, sex hormones, etc. However, it is also influenced by that person's socioeconomic status and the quality of that person's cumulative net diet<sup>(2)</sup>. In modern times, a sedentary lifestyle, lack of exercise, excessive use of electronic digital devices, increased stress, and socioeconomic status, all these factors greatly affect children's growth. It leads to slower growth than the normal growth rate in children<sup>(3)</sup>. Helping growing children to reach their optimum height is often a concern for parents. Children who are comparatively shorter are ridiculed at school. It makes them anxious, creates psychosocial peer pressure, and affects their self-confidence. To increase height, it is not easy to change the child's genetic makeup. However, the other factors that affect height, such as diet and lifestyle, can be modified. In Charaka Samhita, a person with a shorter height than average is considered *Ash-toninditiya*, also known as *Atirashwa*<sup>(4)</sup>. The baby measures 50 cm at birth, 60 cm at 3 months, 70 cm at 9 months, and 75 cm at 1 year. The average height of a 2-year-old is 90 cm. The Indian child gains about 5 cm in height every year until he is 10 years old<sup>(5)</sup>.

Children's height also depends on getting enough nutrients like vitamins, minerals, proteins, carbohydrates, omega-3 fatty acids, etc. in your diet. Vitamin A is essential for the proper growth and functioning of the body<sup>(6)</sup>. Vitamin D helps in the absorption of calcium from food<sup>(7)</sup>. It also regulates body growth. Minerals such as calcium, phosphorus, zinc, and magnesium are essential for bone growth. Proteins

help in the growth and repair of body tissues<sup>(8)</sup>. But an improper diet and more fast food slower the rate of growth<sup>(9)</sup>. Ayurveda offers preventive and supportive measures for children to improve their quality of life. Therefore, the best likely intervention is to use herbal medicines for normal growth and development, which are economical, palatable, and readily available. There are several herbal medicines that are known to affect normal physiological and biochemical processes. All these drugs are mentioned in Charaka Samhita as *Rasayana Dravya*<sup>(10)</sup>, as well as in *Vajikaran Dravya*<sup>(11)</sup>. In Charaka Samhita, there is a brief description of *Rasayana*<sup>(12)</sup> and *Bruhana*<sup>(13)</sup>. *Shatayushi Granules* is a unique combination containing four Ayurvedic medicines i.e., *Shatavari*, *Ashwagandha*, *Shankhpushpi*, and *Brahmi*. Research has shown more percentage of vitamins and minerals. It is rich in copper, manganese, zinc, cobalt, and minerals like calcium, magnesium, selenium, potassium, and various vitamins<sup>(14,15,16,17)</sup>. Therefore, homemade Ayurvedic *Shatayushi granules* are a good source of vitamins and minerals. According to Ayurveda, proper sleep offers many advantages like *Sukh* (happiness), *Pushti* (nourishment), *Bala* (strength), *Vrushata* (fertility), *Dnyana* (cognition), and *Jiveeta* (life)<sup>(18)</sup>. A night of adequate sleep can improve concentration, increase productivity, and promote the healing and repairing of body tissues. And sound sleep can be achieved by *Shatayushi granules* as all its ingredients are *Medhya* and sedative in nature.

The combined effect of *Shatayushi granules* i.e. *Rasayana, Bruhana, Medhya*, and *Pachana* in our body helps in improving mental and physical strength as well as increasing height in growing children. Hence the significant pharmacological properties of herbal drugs as described in ancient Ayurvedic literature can

be useful, which may boost body height in growing children.

The present study was undertaken to study the efficacy of *Shatayushi* granules in children during their developmental stage to increase body height. This study also attempted to study the individual effects of a balanced diet along with *Shatayushi* granules in normal healthy children.

#### Material and Methods

**Study Design:** This is a randomized, double-blind, placebo-controlled study.

#### Study Population:-

70 children were selected randomly from the OPD of the Kaumarbhrityantra Department after obtaining permission from the Institutional Ethical Committee and written consent from their parents. A general examination of each child is performed to exclude any systemic disorder and only children who met the inclusion criteria was selected. This clinical study included two main groups, viz. the drug intervention group (*Shatayushi* group/Experimental group/Group A) and the standard group (control group/Group B).

#### Inclusion Criteria:

1. Age range 1 to 15 years.
2. Children with a low height based on a standard growth chart<sup>(19)</sup>.
3. Symptom-free child during a first general clinical examination.
4. Voluntary participation with the written consent of parents.

#### Exclusion Criteria:

1. Children over 15 years of age.
2. Subjects with any other systemic disease.
3. Subjects suffering from any developmental disease such as dwarfism, or growth hormone deficiency.

#### Method of preparation of drug formulation:

All raw materials such as Shatavari, Ashwagandha, Shankpushpi, and Brahmi were sourced from established suppliers. Identification and authentication were done in a government-approved laboratory. The ingredients were powder and decoctions were prepared according to the reference of Sharangdhara Samhita<sup>(20)</sup>. *Shatayushi* granules were made from the decoction of the above raw ingredients with sugar

(50%) as given in Khanda Kalpana in Sharangdhara Samhita<sup>(21)</sup>. Nutritional analysis and chemical testing of *Shatayushi* granules were performed in a NABL-accredited laboratory. (Table 1, 2).

#### Pharmacological properties / activity of the component drugs:

- Ashwagandha (*Withaniasomnifera*): Immunomodulatory, anti-stress, anti-anxiety, CNS inhibitory, Analgesic, Anti-tumor, anti-microbial, and GABA inhibitory property<sup>(22)</sup>.
- Shatavari (*Asparagus racemosus*): Anti-dysenteric, antifungal, gastric sedative, anti-bacterial, anti-toxic, anti-viral, diuretic, and anticancer property<sup>(12)</sup>.
- Shankpushpi (*Convolvulus pluri*): It has significant action on CNS and Cardiovascular activities. It is Brain and Nerve tonic, in addition, it is anti-epileptic and purgative<sup>(23)</sup>.
- Brahmi (*Bacopa monnieri*): It is a tranquillizer, smooth muscular relaxant, anti-spasmodic, anti-cancer, anti-rheumatic, analgesic, anti-anxiety, and sedative<sup>(24)</sup>.

#### Study Intervention:

Group A children received 5-10 gm of *Shatayushi* granules twice a day with 1 cup of warm cow's milk, and Group B children received 1 cup of warm milk twice a day. This schedule continued uniformly for three months. Observations for a total of three months with follow-up visits every 30 days were noted (i.e., first visit at 30 days, second visit at 60 days, and third visit at 90 days)<sup>(20)</sup>.

#### Study Outcome:

A simple proforma was developed for collecting demographic and anthropometric data from the recruited subjects. In OPD, details about the subjects were recorded on day 1. Height was measured in centimeters and weight in kilograms.

Height in children older than 2 years of age was measured with the Stadiometer in a standing erect posture. The parents of the children were advised to administer the drug orally along with warm cow's milk two times a day, in the morning and the evening. They were asked to report back within 30 days in OPD for a checkup. The height and weight of chil-

dren were again measured by the same method and instruments and recorded in the proforma sheet.

#### Data processing and Statistical methods:

The generated raw data was processed and classified by age and gender. The mean and standard deviation values were based on the sample estimated. Unpaired t-test/Independent student t-test was used to determine statistical significance in equality of means of small samples for intergroup comparison. Comparison between the first day and third visit of the patient was calculated using One-way ANNOVA. The results were considered statistically significant if the p-value < 0.05.

#### Results:

Ayurvedic supplementary products i.e. *Shatayushi* granules were given to children to measure their effect on height. The results were expressed as a mean  $\pm$  standard deviation (SD) of both the experimental group and control group. Results showed that there was an increase in height of children after giving *Shatayushi* granules at the second and third visits as compared to the control group. The mean value at the second visit was 114.77 and at the third visit, were 116.01 as compared to the first visit 113.57, and the first day was 112.80 in the experimental group (children consuming *Shatayushi* granules). The mean value at the second visit was 110.24 and at the third visit was 110.87 as compared to the first visit 110.04 and the first day 109.82 in children in the control group (without consuming *Shatayushi* granules). (Table 3). The intergroup comparison between the first day and first visit in the experimental group who were given *Shatayushi* granules and a control group without *Shatayushi* granules showed an increase in height which was statistically insignificant ( $P>0.05$ ). The first visit comparison between the experimental group and control group showed an increase in height which was statistically insignificant  $P= 0.325$ . The comparison between the second and third visit in cases who were given *Shatayushi* granules i.e., the experimental group and control group without *Shatayushi* granules showed an increase in height which was statistically significant ( $P<0.05$ ). The second-day visit showed an increase in height between the experi-

mental and control group ( $P= 0.05$ ) and a similar was found between the third visit ( $P=0.014$ ) (Table 4). The intragroup comparison between different time intervals (i.e., comparison between the first day of a patient visit to the third visit for a 3-month follow-up period) was statistically significant ( $P<0.05$ ) in the experimental group, while it was not statistically significant in the control group (Table 5).

## DISCUSSION

Growth and development are the physiological process that begins from conception to adulthood of the child. Nutritional status is the factor responsible for children's physical and mental growth. Nutritional deficiency shows various side effects such as weight loss, short stature, increased susceptibility to infections, anemia, wasting, impaired immune system, etc. Other factors affecting growth are physical hyperactivity, lack of adequate rest, and physical and emotional illness leading to decreased appetite and improper absorption. One of the traditional medicines known as Ayurveda follows holistic principles that focus on the proper growth and development of the individual for a better quality of life<sup>(25, 26)</sup>. In Ayurveda, the imbalance of the doshas is considered to be the root cause of all ailments, including hormonal imbalances, since the endocrine system is not addressed directly. Human growth hormone is secreted by the pituitary gland, located in the brain, in the Sella turica of the sphenoid bone, and connected to the hypothalamus. According to Ayurveda *Prana Vata*, *Sadhaka Pitta*, and *Tarpaka Kapha* are also located in the brain. Co-ordinated functions of these three *dosha* sub-types can be compared to functions of the pituitary gland. Alternatively, we can tell that the pituitary gland and its functions are influenced and monitored by mentioned *doshas* sub-types.

Pharmaceutical companies are paying increasingly more attention to medicinal plants since they serve as sources for the identification of novel bioactive chemicals. Natural items have been used as medicines for a long time since they have less adverse effects than synthetic pharmaceuticals. Since ancient times, natural medicinal plants like Ashwagandha,

Shatavari, Brahmi, and Shankpushpi have been known to have a variety of benefits for children's healthy growth and development with no side effects. This study formulated *Shatayushi* granules using the most widely accessible botanicals, including Ashwagandha, Shatavari, Brahmi, and Shankpushpi. In order to enhance children's general physical and mental health, *Shatayushi* granules are created to measure physical growth parameters including height. Ashwagandha is referred to in Ayurveda as *Madhura*, *Tikta*, *Kashaya Rasatamaka*, and *Ushana Virya*, which function as *Vataghana* and *Kaphaghana*<sup>(27)</sup>. Similarly, Brahmi is described as *Tikta*, *Kashaya*, *Madhur Rasa*, and *Sheeta Vipaka*, who serve as *Tridoshagana*<sup>(28)</sup>. Other ingredients, such as Shankpushpi, act as *Medhaya*<sup>(29)</sup> by its Prabhava, while Shatavari possesses qualities that make it act as *Vataghana* and *Pittaghana* as well as *Madhura*, *Tikta*, and *Sheeta Virya* properties<sup>(30)</sup>. The unique combination of *Shatayushi* granules aids in the appropriate operation of the pituitary gland for healthy body growth and development. Similarly, Ashwagandha, Brahmi, Shankpushpi, and Shatavari are also part of *Rasayana*, and *Rasayana* therapy in Ayurveda bestows the strength of all tissues. It helps to improve the physical and mental development of the body thereby promoting height as well. *Rasayana*, *Balya*, *Medhya*, and *Vayasthapana* are some herbal ingredients in *Shatayushi* granules. According to a food analysis report, the product also has good levels of protein, and minerals including potassium, calcium, and magnesium, as well as high levels of energy. So, we may conclude that these medications help in a person's proper growth and development as well as the sleep of individuals. Additionally, these medications have immunomodulatory and antioxidant effects on children's overall growth. Due to the lack of heavy metals, according to chemical testing results, it is not only efficient but also safe for children.

The purpose of the current clinical trial was to examine the impact of *Shatayushi* granules on children's physical growth variables, such as height. The children were divided into two groups experimental and control groups. The experimental group received

warm cow's milk with *Shatayushi* granules while the control group received warm cow's milk. The findings of our study revealed that children who received *Shatayushi* granules experienced a considerable rise in height, particularly during the second and third visits. The *Shatayushi* granules have shown statistically significant outcomes on the parameters, i.e., height, by increasing height as well as displaying a favorable reaction in all the children's general physical health without causing any negative side effects. The present study on children treated with *Shatayushi* granules showed significant results in height growth in the experimental group children as compared to the control group in the age group of 1-15 years. The maximum height gain was 2.5 cm in 3 months in growing children. Height growth was not influenced by gender. Also, there was no sector in the age group of 1-15 years of the children that demonstrated a greater spurt in height. It is found that *Shatayushi* granules appear to be the most suitable, convenient, safer, and economical option for height growth in growing children. Further studies are needed to evaluate the direct effects of *Shatayushi* granules on growth hormones. More elaborate studies are warranted to demonstrate the actions of the major pharmacologically active components or phytochemicals of the herbal formulation on normal growth in children.

**Limitations:** Larger group, longer duration of the study, control of dietary factors (qualitative).

## CONCLUSION

The Short stature children in the study showed an effective increased in height after taking *Shatayushi* granules as compared to controls. For growing children, the use of *Shatayushi* granules is particularly advantageous as it improves metabolism, and hormonal imbalance, strengthens muscles and bones, and overall improvement in physical and mental health. *Shatayushi* granules are a 100% natural and organic food supplement that has been shown to boost children's overall physical development and height in stunted children. *Shatayushi* granule is a unique herbal product containing four valuable ayurvedic herbs.

They have drawn the notice of their innovative features because it does not contain preservatives, artificial colors, essence, soy powder, or milk powder.

**Conflict of Interest Statement:** The authors declared that they do not have any conflict of interest.

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Source of Support: Nil

Conflict of Interest: None Declared

How to cite this URL: Rajesh M. Shah et al: Effect of standardized extract of Shatayushi Granules on short stature children: A Clinical study. *International Ayurvedic Medical Journal* (online) 2023 (cited April 2023) Available from: [http://www.iamj.in/posts/images/upload/784\\_792.pdf](http://www.iamj.in/posts/images/upload/784_792.pdf)

**Legends:-**

1. Table 1:- Food Analysis Report of Shatayushi Granules
2. Table 2:- Chemical Testing (Heavy Metal Contains)
3. Table 3:- Descriptive Statistics of the study parameter in the Experimental and Control groups at different visits
4. Table 4:- Intergroup comparison of the study parameter between experimental and control groups at different visits
5. Table 5:- Intragroup comparison of the study parameter between different time intervals in the Experimental and Control group

**Table 1: - Food Analysis Report of Shatayushi Granules**

\*Below analysis is done from a NABL-accredited laboratory (ULR-TCSS092000012984F)

Sr. No.	Parameter (Nutritional Analysis)	Result	Unit
1.	Energy Value	399	Kcal/100g
2.	Protein	5.5	g/100g
3.	Carbohydrates	91.7	g/100g
4.	Sugar	55.7	g/100g
5.	Fat	1.18	g/100g
<b>Minerals</b>			
6.	Potassium	86.7	mg/100g
7.	Calcium	11.9	mg/100g
8.	Magnesium	5.67	mg/100g

**Table 2: - Chemical Testing (Heavy Metal Contains)**

\*Below analysis is done from a NABL-accredited laboratory (ULR-TCSS092000012984F)

Sr. No	Parameters	Results	Units
1.	Lead	<0.05	Max 2.5 Mg/kg (ppm)
2.	Copper	1.81	Max. 30 Mg/kg (ppm)
3.	Arsenic	0.355	Max. 1.1 Mg/kg (ppm)
4.	Cadmium	0.043	Max. 1.5 Mg/kg (ppm)
5.	Mercury	<0.01	Max. 1 Mg/kg (ppm)

**Table 3:** -Descriptive Statistics of the study parameter in the Experimental and Control groups at different visits

	Visit	N	Minimum	Maximum	Mean	Std. Deviation
Experimental group	First day	35	80.00	140.00	112.80	14.81
	First visit	35	81.50	141.00	113.57	14.73
	Second visit	35	83.00	142.50	114.77	14.60
	Third visit	35	85.50	143.50	116.01	14.46
Control group	First day	35	85.00	142.00	109.82	14.91
	First visit	35	85.00	142.00	110.04	15.00
	Second visit	35	86.00	142.00	110.24	14.95
	Third visit	35	86.50	142.50	110.87	14.79

\*p value <0.05 statistically significant

**Table 4:** -Intergroup comparison of the study parameter between experimental and control groups at different visits.

Experimental vs control group	Groups	N	Mean	Std. Deviation	t	df	p-value
First day	Experimental group	35	112.8000	14.81414	.836	68	.406
	Control group	35	109.8286	14.91049			
First visit	Experimental group	35	113.5714	14.73798	.992	68	.325
	Control group	35	110.0429	15.00998			
Second visit	Experimental group	35	114.7714	14.60426	1.282	68	0.05*
	Control group	35	110.2429	14.95157			
Third visit	Experimental group	35	116.0143	14.46115	1.471	68	0.014*
	Control group	35	110.8714	14.79087			

\*p value <0.05 statistically significant

**Table 5:** - Intragroup comparison of the study parameter between different time intervals in the Experimental and Control group.

Comparison	Groups	Sum of Squares	df	Mean Square	F	P value
First day vs the First visit vs Second visit vs Third visit	Experimental group	207.948	3	69.316	.323	0.09*
	Control group	21.234	3	7.078	.032	.992

\*p value <0.05 statistically significant