IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 1, September 2026
Impact Factor: 8.2

A Randomized Open Controlled Clinical Trial to Evaluate the Add-On Effect of Shishushoshnashak Ghrita Matra Basti & Prinana Modak in Underweight Children

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Abstract: ***Background:*** *Karshya (underweight) is a global problem resulting from malnutrition, affecting millions of children and stunting both physical and mental development.* ***Aim:*** *To evaluate the add-on effect of Shishushoshnashak Ghrita Matra Basti and Prinana Modak in underweight children compared to Prinana Modak alone.* ***Methods:*** *A randomized, open controlled clinical trial was designed involving 140 children aged 5 to 10 years, divided into a trial group and a control group (70 patients each). The trial group receives Shishushoshnashak Ghrita Matra Basti rectally and Prinana Modak orally, while the control group receives only Prinana Modak orally. The treatment duration is 15 days with follow-ups up to 60 days. Objective parameters (weight, height, BMI) and subjective parameters (activity, recurrent infections, fatigability, appetite) are assessed.* ***Conclusion:*** *The study aims to establish a safe, palatable, and cost-effective Ayurvedic therapy for underweight children to achieve high growth potential.*

Keywords: *Karshya*

I. INTRODUCTION

Karshya is a common problem which is affected to millions of people. It is a condition, which arise due to malnutrition. Malnutrition is one of the most serious problem facing the world today. India is one of the leading country this respect, where about 212 million people are registered as Malnutrition. In the world, approximately 62 million people die each year. Where all the causes of death are combined, one in twelve people worldwide is malnourished according to 2012 report.

In Kashyapa, the reference of Sandashi Jataharini is similar to Parigarbhika and Karshya found as an early symptom of Parigarbhika. Karshya as a symptom of Kshudita person has been mentioned in Kashyap. In Bhojanakalpa chapter, Karshya has been described as a prestage of KshirajaPhakka. KshinaMamsa has been described as a Symptoms of Vyadhija Phakka. Aachrya Charaka in Sutrasthana 21st chapter has described 8 types of undesirable persons from treatment point of view, Atikrisha is one of them.

Importance of study of Kaumarbhritya is to achieve high potential for growth and development. Similarly, morbidity and mortality of growing children due to malnutrition are maximum, hence attention is paid towards this area to control it from the dietic as well as therapeutic point of view. Balanced nutrition plays a crucial role in the normal growth and development of an individual. Children are most vulnerable to the effects of malnutrition. In childhood poor nutrition only does not stunt physical growth but it also affect development of brain.

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Need of Study

1. Underweight in children has become global problem affecting the growth of children. The cases of underweight children are more found in the developing country.
2. In modern science, many hypothesis have been put forth on this subject but still there is need of more safe, easily available, palatable, cost effective therapy which could be explored from Ayurveda.
3. The recent information is that about 47% of children are underweight in India, along with this in developing world 146 million children are underweight, so need of this study is imp.

AIM & OBJECTIVES

Primary Objective

To assess the effect of Shishu Shoshnashak Ghrita Matra Basti on weight gain and nutritional status in children suffering from underweight.

Secondary Objectives

1. To evaluate changes in Agni (digestive power) and appetite.
2. To assess improvements in physical strength, energy level, and mental alertness.
3. To compare the overall clinical improvement between the trial and control groups.
4. To compare clinical signs and symptoms of underweight before and after intervention.
5. To observe any adverse effects during the course of therapy.
6. To compare clinical signs and symptoms of Bal Karshya before and after intervention.

II. MATERIALS & METHODS

Study Design: A randomized, open clinical trial. Patients will be selected from the OPD/IPD of Balarog Department based on inclusion and exclusion criteria after informed consent.

Sample Size & Population: 140 underweight children aged 5 to 10 years, divided randomly into two groups of 70 patients each (Adjusted for a 10% dropout rate).

Inclusion Criteria: Children aged 5-10 years; willing to participate with informed consent; having underweight Grade 1 & Grade 2 (Gomez Classification).

Exclusion Criteria: Congenital disorders (e.g., congenital heart disease); allergic to ghrita or basti ingredients; chronic diseases (tuberculosis, developmental disorders); systemic illness; severe underweight Grade 3 & Grade 4.

Grouping & Treatment:

• Group A (Trial Group): Treated by Matra basti of Shishushoshnashak ghrita (once a day, rectal) & Prinana Modak (twice a day, oral with Godugdha).
• Group B (Control Group): Treated by Prinana Modak (twice a day, oral with Godugdha).

Duration & Follow-up: Duration of treatment is 15 days. Total duration of trial is 60 days with follow-ups on the 15th, 30th, 45th, and 60th days.

Assessment Criteria:

• Objective: Weight, Height, Head circumference, Chest circumference, Mid-arm circumference, BMI.
• Subjective: Child's general activity, frequency of recurrent infections, easy fatigability, and appetite.

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III. DETAILED LITERATURE REVIEW

Karshya in Samhita

- Kashyap Samhita: Mentioned as a symptom of kshudita person (Bhojanakalpa); pre-stage of kshirajaphakka.
- Charak Samhita: Child becomes krusha due to intake of Vatadushta milk (Chikitsa Sthana 30/239).
- Asthang Sangraha: Maharshi Vagbhata mentioned krusha as early symptom of parigarbhika (Balshosha 2/34-35).
- Ashtang Hridaya: Krusha is described in Sutrasthana 14/31.
- Bhavprakasha: Described in karshyadhikar in Madhyama khanda 40/1-1c.
- Sharangdhara: Mentioned as one of the types of vatroga in purvakhanda 7/112.
- Madhav Nidana: Child becomes krusha due to intake of vatadushta (68/1).

Previous Work Done

Various clinical studies have evaluated the brimhana effect of Ayurvedic compounds like Ashwagandha Granules, Ashwagandha Sidha Kshir Basti, Ashwagandhadilehya, Vidari Churna, Chaturjatadi Churna, Shatgandha Granules, and Bala Ghrita on underweight children (Balkrusha/Karshya) by scholars including Dr. K.S. Patel, Dr. Rushikesh Tikole, Dr. Bangale Swapnil Devdas, Dr. Patil Amit Tukaram, Dr. Lokhande Amruta Rajendra, and Dr. Palash Vinod Pande.

Disease Review

The term Balkarhsya is derived from "Bal" (children up to 16 years) and "Karshya" (condition in which the person becomes thin and lean/emaciated). According to WHO, underweight in children is defined using Weight-for-Age Z-scores (WAZ), where a score < -2 SD is considered underweight.

NIDANA PANCHAKA

Hetu (Causes): Intake of Vata-aggravating diet (Vatalahar sevan), excessive exercise (ativyayama), excessive sexual activity (vyavaya), study (adhyayana), fear (bhaya), grief (shoka), night awakening (ratri jagarana), excessive thirst, hunger, and intake of astringent/less food (kashayalpasana).

Purvaroopa (Premonitory Symptoms): Described as a pre-stage of kshirajaphakka in Kashyapa.

Roopa (Symptoms): Shushka Sphig Udara Greeva Dhamani Jala Darshana, Twagasthishesho Atikrusha Sthula Parva Naro Matah (Charak Sutra 21/15). The main features include dryness and emaciation of buttocks, abdomen, and neck; prominent vascular network; only skin and bones remaining visible; prominent joints; and overall weight for age between 60-80% of normal (Gomez classification Grade I & II).

Samprapti (Pathogenesis): Vata-aggravating factors lead to Vataprakopa. This causes Shoshita Rasa Dhatu (depleted nutrient fluid). The shushka rasa dhatu circulates (anukramati) in the whole sharira. Because of the alpa/ shushka rasa dhatu, all other dhatus do not get proper nourishment, leading to the origin of Karshya (Karshya Uttpati).

SAMPRAPTI GHATAKA

- Dosha: Vata
- Dushya: Rasa
- Srotas: Rasavaha
- Srotodushti: Sang (Obstruction/Depletion)
- Adhisthana: Pakvashaya
- Vyaktisthana: Whole body

CHIKITSA

Principle: Satatam chopacharyau hi karshanairbrimhanairapi (Charak Sutra 21/16). Emaciated individuals should always be treated with Brimhana (nourishing) therapy. Krushanam brimhanarthacha laghu santarpanacha yat (Charak Sutra 21/20) For emaciated persons, light (laghu) but nourishing (santarpaka) substances are beneficial.

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Treatment Modules:

• Shishushoshnashak Ghrita (Trial Drug): Prepared with Kalka of Kateri, Ashwagandha, Tulsi, and Pippali siddha with ghrita. Administered rectally via Matra Basti (Dose according to age: e.g., 5 yrs 15ml, up to 10 yrs - 30ml).

• Prinana Modak: Prepared by combining majja of Priyala, Yashtimadhu, honey, Laja, and Sitopala. Administered orally (Dose: 3-5yr 3gm; >5-8yr 5gm; >8-12yr 8gm) twice a day with Godugdha (cow's milk).

PHARMACOLOGICAL ACTION

Drug Properties

Dravya	Latine Name	Gana	Rasa	Virya	Doshakarma
Ashwagandha	Withania somnifera	Balya, Bruhaniya	Tikta, Katu, Madhura	Ushna	Kapha, Vata shamak
Pippali	Piper longum	Dipaniya, Kasahara	Katu	Anushnasheet	Vata shamak
Tulasi	Ocimum sanctum	Shwashara, krimighna	Katu, Tikta	Ushna	Kapha, Vata shamak
Kantakari	Solanum xanthocarpum	Shwasahara, kasahara	Katu, Tikta	Ushna	Kapha, Vata shamak
Yashtimadhu	Glycyrrhiza glabra	Jeevaniya, Rasayana	Madhura	Sheet	Vata, Pitta shamak
Priyal	Buchanani lanzan	Udhardprashman	Madhura	Sheet	Vata, Pitta shamak
Laja	Oryza sativa		Madhura, Kashaya	Sheet	Kapha, Pitta shamak

Probable Mode of Action of Matra Basti

By absorption mechanism: In the rectum, there is an abundant supply of blood as well as lymph, and drugs can penetrate the mucosa, just like any other layer of lipid. So, it quickly absorbs unionized and lipid-soluble substances. Matra Basti is a safe and effective treatment modality for Vata disorders and can be effectively used among children, resolving strotavarodha (mainly through Kaphaghna action of the drugs).

IV. DISCUSSION

Clinical importance and application of the material will be discussed in the concerned subject after the completion of the clinical trial and data analysis.

V. CONCLUSION

All experimental work shall be summarized step by step. The study is anticipated to provide substantial clinical evidence on the efficacy of Matra Basti with Shishushoshnashak Ghrita and oral Prinana Modak in improving the physical and nutritional parameters of underweight children.

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