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A Clinical Study to Evaluate the Efficacy of *Triphala* as *Rasayana* in Healthy Individuals

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ABSTRACT

The word *Rasayana* is composed of two words *Ras+Ayan*, the means by which one gets the excellence of *Rasa dhatu*. *Rasa* means the essence of the end product of digestion and "*Ayanam*" means the opening, door or the process by which *Rasa* reaches the targeted body tissues. The process that facilitate optimum acquisition, assimilation and circulation of the essence of food or medicine is *Rasayana*. A person undergoing *Rasayana* or rejuvenation therapy attains longevity, memory, intellect, freedom from diseases, lustre of skin, good strength and improved functioning of sense organs**.**Present study has been designed to evaluate the efficacy of *Triphala* as *Rasayana* in healthy individuals. 30 individuals fulfilling the inclusion criteria were randomly selected. Individuals were given *Triphala Rasayana* for the duration of 8 weeks. Individuals were thoroughly assessed on various subjective and objective parameters during the trial period. Statistically significant improvement was observed on various parameters like Visual Analogue Scale, Foot thrust, Hand grip power, Six-minute walking capacity, WHO QOL BREF scale. It can be concluded from the study that the trial drug has a potential to improve physical as well as mental health of an individual. No untoward effect of therapy was observed in study subjects during the entire trial period.

Key Words *Rasayana, Ojas, Triphala, Dhatu, Madhu, Ghrita, Rejuvenation Immunomodulator, Antioxidants*

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INTRODUCTION

Ayurveda, deals with physical, psychological as well as spiritual wellbeing of an individual. The desire to live long, one of the basic instincts, has been common to all living creatures. Today everyone aspires to enjoy a luxurious life. Physical inactivity has become a major public health concern in developing as well as in developed countries. Sedentary life style super added with faulty eating patterns has resulted in a very high incidence of various non communicable diseases. In spite of advancement in medical science with invention of investigative tools and deep knowledge of human physiology and its structure, there has been no significant control over diseases, rather new health issues are emerging. Hence it is the time to reanalyse the system of health management and look back at the philosophy of prevention and preservation as the first step to the treatment. "*Swasthasya*

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Swasthya Rakshanam"[1] means maintaining the health of a healthy person had been the prime aim of *Ayurveda* that is why the emphasis is given to preventive aspect considering physical, mental, and social aspects rather than treating a disease. To achieve this goal, daily regimen, seasonal regimen, code of conduct, diet and social behaviour has been mentioned in *Ayurveda* along with implication of *Rasayana*. *Rasayana Tantra* represents the basic approach of *Ayurveda* which comprises preventive, promotive and curative aspects of health through its measures as the *Rasayana Chikitsa*[2].The process that facilitate optimum acquisition, assimilation and circulation of the essence of food or medicine is *Rasayana*[3]. *Rasayana* nourishes each and every cell of the body and hence contributes to the integrity and replenishment of *Sapta Dhatus*. *Rasayana* alleviates exertion, lassitude, exhaustion and debility. Generally, most of the *Rasayana* are micro-molecular nutrient having *Balya, Medhya, Agnivardhaka, Ojovardhaka* and *Vayasthapana* properties like immunomodulatory, adaptogenic, anti-stress, anti-anxiety, anti-depressant and anti-oxidant effect[4]. Looking at the multifaceted approach of *Rasayana,* it can be said that *Rasayana* therapy includes all such activities in the form of diet, lifestyle, or medicines which target at achieving homeostasis (*Dhatu Samya*) thus retarding the process of aging, thus helpful in prolongation of healthy life.

AIMS AND OBJECTIVES

To evaluate the efficacy and safety of *Triphala* as *Rasayana* in healthy individuals.

Protocol of research:

IEC Approval – Approval of Institutional Ethical Committee was obtained before commencement of research work vide Letter No.-***AYU*/IEC/2018/1179 dated 27/09/2019.**

CTRI Registration – Before starting the trial, registration in Clinical Trial Registry of India (CTRI) was obtained vide CTRI No.– **CTRI/2020/07/026483 dated 10/07/2020.**

MATERIALS & METHODS

Source of Data:

Total 30 healthy individuals were registered from the campus of R.G.G.P.G. Ayurvedic College and Hospital, Paprola, between the age group between 30-60 years irrespective of gender, caste, race and religion. A detailed history was obtained, physical examination was done and relevant investigations were carried out before the commencement and after the completion of trial.

The individuals who were willing and able to undergo trial for 8 weeks of duration and were ready to give written consent were included in the trial. Individuals having history of hypersensitivity to trial drug or any of its ingredients and any other condition which is considered unfit for inclusion were excluded from the study. Out of 30 registered study subjects 2 individuals couldn't complete the trial,

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they were dropped out from the study and rest 28 completed the full course of therapy.

Haematological investigations include Hb gm%, TLC, DLC, ESR, FBS, Blood Urea, Serum Creatinine, SGOT, SGPT, Serum Lipid Profile, Serum Proteins.

Assessment Criteria:

Subjective criteria

a) Sleep Pattern

b) Appetite

c) Exertional capacity

Objective criteria

a) Body weight

b) Blood pressure

c) Pulse rate

d) Visual Analogue Scale of Well Being

e) Foot thrust

f) Hand grip power

g) 6-minute walk test

h) WHO QOL BREF score

Grouping: Present study was carried out in a single group only.

Composition of Trial Drug: - As described in table no.1

Table 1 *Triphala Rasayana*[5]

Ingredients	Botanical Name	Family	Part used	Quantity
Amalaki	*Emblica officinalis Retz.*	*Euphorbiaceae*	Fruit	1 part
Haritaki	*Terminalia chebula Garten.*	*Combretaceae*	Fruit	1 part
Vibhitak	*Terminalia bellerica Roxb.*	*Euphorbiaceae*	Fruit	1 part

Preparation of Trial drug-

The drug was prepared in *Churan* form as per standards of GMP in the *Charak* Pharmacy of College with batch no. as **R-6/20 date of manufacture 19/2/2020**. Chemical analysis of trial formulation was done at DTL Jogindernagar with letter no. **DTL/PP/15/19-830.**

Administration and Drug Dosage

Triphala Churan - 5 gm twice a day

Anupana - *Madhu&Ghrita* in unequal quantity

Duration of therapy - 8 Weeks

Route of administration – Oral

Follow up - Follow up after every 15 days.

Follow up and assessment of the study subjects:

A thorough assessment of the study subjects was done before commencement of the therapy (day zero) and at the 14th, 28th, 42nd and 56th day i.e. at the time of the completion of therapy. The effects of treatment were assessed on the basis of various subjective and objective parameters. Laboratory investigations were carried out before commencement and after completion of the treatment.

OBSERVATIONS & RESULTS

As seen in table no. 2 to table no.9

Table 2 Effect of therapy on Objective Parameters

Parameters	Mean score		Percent Change	Mean Diff.	SD±	SE±	't' value	'p' Value
	BT	**AT**						
VAS (in percentage)	40.714	72.143	77.19%	31.429	7.559	1.429	22.00	<0.001
Foot Thrust (in kg)	29.654	30.186	1.90%	0.532	0.925	0.175	3.044	0.005
Hand Grip	76.429	78.429	2.61%	2.000	2.776	0.525	3.813	<0.001

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(in mm of Hg)								
Body weight (in kg)	64.00	64.468	1.67%	0.468	1.029	0.195	2.405	0.023
6 min walk test (in Meters)	270.893	290.750	7.33%	19.857	11.853	2.240	8.865	<0.001
Systolic BP (in mm of Hg)	122.571	121.429	0.932%	1.143	4.568	0.863	1.324	0.197
Diastolic BP (in mm of Hg)	79.786	79.357	0.537%	0.429	3.327	0.629	0.682	0.501
Pulse rate (per minute)	78.214	77.036	1.507%	1.179	2.127	0.402	2.933	0.007

Table 3 Effects of therapy on Subjective Parameters

Parameters	Mean score		Percent Change	Mean Diff.	SD±	SE±	't' Value	'p' Value
	BT	**AT**						
Appetite	1.143	0.429	62.464%	0.714	0.460	0.086	8.216	<0.001
Sleep	1.393	0.929	33.309%	0.464	0.508	0.096	4.837	<0.001
Exertional capacity	0.964	0.429	55.601%	0.536	0.508	0.096	5.582	<0.001

Table 4 Effects of therapy on WHO QOL BREF Score

Group	Mean score		Percent Change	Mean Diff.	SD±	SE±	't' Value	'p' Value
	BT	**AT**						
Domain I	23.250	24.107	3.686%	0.857	1.508	0.285	3.007	0.006
Domain II	21.000	22.393	6.63%	1.393	1.618	0.306	4.555	<0.001
Domain III	11.679	12.464	6.73%	0.786	0.568	0.107	7.318	<0.001
Domain IV	29.607	31.321	5.789%	1.714	2.355	0.445	3.852	<0.001

Table 5 Effects of therapy on Laboratory Parameters

Parameter	**Mean BT**	**AT**	**%Change**	**Mean Diff.**	**SD±**	**SE±**	**'t'Value**	**'p'Value**
Hb	12.161	12.511	2.87%	0.35	0.998	0.189	1.875	0.074
TLC	8706.071	8789.286	0.95%	83.21	1902.367	359.51	0.231	0.819
ESR	16.464	15.714	4.55%	0.75	5.365	1.014	0.740	0.466

Table 6 Effect of therapy on Differential Leucocyte Count

Parameter	**Mean**		**Percent Change**	**Mean Diff.**	**SD±**	**SE±**	**'t' Value**	**'p' Value**
	BT	**AT**						
Neutrophils	68.825	65.573	4.716%	3.246	12.854	2.429	1.336	0.193
Lymphocytes	21.400	24.786	15.822%	3.386	8.965	1.694	1.998	0.056
Mixed cells	10.529	10.639	1.054%	0.111	10.218	1.931	0.0573	0.955

Table 7 Effect of therapy on FBS and Renal function test

Parameter	**Mean**		**Percent Change**	**Mean Diff.**	**SD+**	**SE+**	**'t' Value**	**'p' Value**
	BT	AT						
FBS	93.143	92.929	0.229%	0.214	8.350	1.578	0.136	0.893
B. Urea	25.357	21.393	15.632%	3.964	4.443	0.840	4.721	<0.001
S. Creatinine	1.307	1.296	0.765%	0.0107	0.470	0.088	0.121	0.905

Table 8 Effect of therapy on Lipid Profile

Parameter	**Mean**		**Percent Change**	**Mean Diff.**	**SD+**	**SE+**	**'t' Value**	**'p' Value**
	BT	AT						
S. Cholesterol	122.678	121.607	0.873%	1.071	22.428	4.239	0.253	0.802
S. Triglycerides	103.536	102.643	0.862%	0.893	8.381	1.584	0.564	0.578
HDL	52.357	53.714	4.80%	1.357	3.880	0.733	1.851	0.075
LDL	79.250	79.929	0.856%	0.679	8.886	1.679	0.404	0.689
VLDL	26.464	24.143	8.770%	2.321	8.228	1.555	1.493	0.147

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Table 9 Effect of therapy on SGOT, SGPT and Serum Proteins

Parameter	Mean		Percent Change	Mean Diff.	SD+	SE+	't' Value	'p' Value
	BT	AT						
SGOT	42.571	38.250	10.150%	4.321	14.257	2.694	1.604	0.120
SGPT	38.964	35.036	10.083%	3.929	15.724	2.972	1.322	0.197
S. Proteins	6.411	6.561	2.339%	0.150	0.233	0.044	3.402	0.002

DISCUSSION

The present research work was designed to evaluate the efficacy of *Triphala* as Rasayanaand to assess its clinical safety in healthy individuals.

Statistically highly significant results were observed on subjective parameters viz. Sleep pattern, Appetite and Exertional capacity. Mean score of appetite before therapy was 1.143 and after therapy was 0.429 with a change of 62.164%, which is statistically highly significant (p<0.001). Mean score of exertional capacity before therapy was 0.964 and after therapy mean score was 0.429 with a change of 55.601%, which is statistically highly significant (p<0.001). Mean score of sleep before therapy was 1.393 which improved to 0.929 after therapy with a change of 33.309%, which is statistically highly significant (p<0.001).

Statistically highly significant results were observed on various objective parameters. After completion of the therapy 77.19% change was observed in the **Visual analogue score of well-being** with initial mean score of 40.71% which increased to 72.143% after the completion of the therapy, which was statistically highly significant (p<0.001). Before therapy mean score of **Foot thrust** was 29.654 kg which increased to 30.186 kg after therapy with a change of 1.90 %, which is statistically significant (p<0.05). Before therapy mean score of **hand grip power** was 76.429 mm of Hg which increased to 78.429 mm of Hg after therapy with a change of 2.61%, which is statistically highly significant (p <0.001).Initial mean **Body weight** before was 64 Kg which increased to 64.468 Kg after therapy with a change of 1.67% which is statistically significant (p <0.05).Initial mean score of **six-minute walking capacity** before therapy was 270.893 meters which increased to 290.750 meters after therapy with a change of 7.33%, which is statistically highly significant (p<0.001). WHO QOL BREF Score was adapted for the study**,** Initial mean score of WHO QOL BREF**Domain I** (Physical) before therapy was 23.250 which increased to 24.107 after therapy with a change of 3.686%, which is statistically significant (p<0.05).Initial mean score of WHO QOL BREF**Domain II** (mental) before therapy was 21.00 which increased to 22.393 after therapy with a change of 6.63%, which is statistically highly significant (p<0.001).Initial mean score of WHO QOL BREF**Domain III** (social)before therapy was 11.679 which increased to 12.464 after therapy with a change of 6.73%, which is statistically highly significant (p<0.001).Initial mean score of WHO QOL BREF**Domain IV** (environmental) was 29.607 which increased to 31.321 after therapy with a

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change of 5.789%, which is statistically highly significant ($p<0.001$).

Various laboratory investigations including Hb gm%, TLC, DLC, ESR, FBS, Serum creatinine, SGOT, SGPT, S. Lipid profile, S. Proteins were within normal range both before and after the therapy. However, statistically highly significant change in **blood urea** was observed after the therapy with 15.632% reduction ($p<0.001$) and statistically significant change was observed in **S. Proteins** after the therapy with 2.34% increase ($p<0.05$).

As far as overall health is concerned *Triphala, Madhu* and *Ghrita* are well known for their rejuvenating properties. They ensure the best quality of all the *Dhatus* which helps in the formation of *Oja* and this is how they maintain the overall health and boost up the energy[6]. These drugs have scavenging action on the oxidants which further decrease the oxidative stress of the body.

Amalaki possesses *Madhur Rasa, Laghu Guna, Sheeta Veerya* and *Madhura Vipak*[7]. It has *Tridhoshamak* effect. Due to *Amla Ras* it alleviates *Vata Dosha*. Due to *Madhur Vipaka* it alleviates *Pitta Dosha*. Due to *Kashaya Rasa* and *Ruksha Guna* it alleviates *Kapha Dosha*[8]. *Amalaki* has a variety of flavonoids, abundance of Vitamin C, iron, phosphorous which helps in the better functioning of enzymatic reactions and hence *Amalaki* helps in improving overall health and boost up energy[9]. It has tannoids, gallic acid, ellagic acid, corilagin which not only reduce the oxidative stress in the body but also possess cardioprotective activities[10]. It helps in improving the memory and intellect by enhancement of gabaminergic metabolic activity[11].

The *Rasapanchaka* of ***Haritaki***are very useful for *Agnideepan* (stimulating *Agni*), *Aampachan* (digesting toxic waste of metabolism) and *Srotas-shodhana* (clearing the channels of micro circulation), by means of these actions, it normalizes the functions of *Jatharagni*, regularizes digestion and tissue metabolism. Restoration of *Agni* at the *Dhatu* level (*Dhatwagni deepan*), helps in removal of excessive *Kleda* which further results in proper nourishment of *Dhatus* and production of excellence of *Dhatus*[12].

Vibhitakiis *Kashaya Rasa*, it absorbs *Kleda* due to predominance of *Vayu Mahabhoota* and pacifies *Pitta* and *Kapha*, helps in restoration of *Dhatus*[13]. *Madhur Vipaka* pacify *Vata Dosha*, alleviates *Dhatukshaya, Daurbalya*and results in formation of best quality of *Dhatus*[14].

Ghrita possesses *Madhura Rasa, Guru, Snigdha, Sheeta Guna, Sheeta Veerya* and *Madhura Vipaka*. By virtue of these properties it acts as *Medhya, Balya, Ayushya, Ojovardhaka, Rasayana, Vayaasthapna*[15]. ***Madhu*** possesses *Madhura* and *Kashaya Rasa, Guru* and *Ruksha Guna, Sheeta Veerya* which helps in *Tridosha Shamana* and hence balances the pillars of body i.e. *Vata, Pitta, Kapha*[16]. Honey nourishes the body with its *Brihana Guna.*

CONCLUSION

The present study established the overall effect and clinical safety of *Triphala Rasayana* in healthy individuals. It revealed that the trial drug was effective in most of the subjective and objective parameters. Hence, we may conclude that *Triphala Rasayana* is effective in increasing the general physical and mental fitness of an individual. No untoward effect of therapy was seen during the entire trial period. Study has shown remarkable results; it was carried out in small number of patients with short time span because of limited study duration.

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