



Research Article

A CLINICAL STUDY TO EVALUATE THE EFFECT OF GUDUCHYADI RASAYANA AS A RASAYANA

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ABSTRACT

Now a days reprehensive food habits, erroneous life style, stress, environmental pollution etc are exerting awful effects on human beings. Stress has become an inevitable and most unwanted companion of civilization. It can be induced by several factors like an environmental changes extremes of temperature, fear, anxiety, shock, grief, pain and so on. When the individual is unable to cope with it, it induces a number of clinical manifestations like hypertension, coronary artery disease, peptic ulcer, asthma, migraine, irritable bowel syndrome, fatigue, muscles pain, sleeping problem, behavioural disorders like anxiety and depression. Thus they are susceptible to develop premature aging and various disorders. Ayurvedic text describes *Rasayana* therapy to rejuvenate and nourish the body and mind. Ayurveda emphasizes on the importance of preventive medicine by boosting an individual's own immune system. *Rasayana* therapy rejuvenates and prevents the effect of aging and improves the quality of life. *Rasayana* is useful in treating the disease as well as in maintaining the health of individuals. *Rasayana* drugs are having *Balya*, *Medhya*, *Agnivardhaka*, *Ojovardhaka*, *Vyasthapna* properties. It has been proved that these drugs are immunomodulator, adaptogenic, anti-stress, anti-anxiety and anti-depressant and hepatoprotective. So, *Rasayana* may be helpful to cope up with all the problems occurring due to modern lifestyle.

INTRODUCTION

The main objective of Ayurveda is to maintain the health of a healthy person, to treat the disease and give relief to sick person [1]. These two aspects reflect the unique approach of Ayurveda. The *Rasayana* is the process or way of attaining the *Ahara rasa*[2] of good quality for the body. It is one of the eight branches of Ayurveda that focuses on health and longevity[3]. *Rasayana* is concerned with the conservation, transformation and revitalization of energy. *Rasayana* therapy rejuvenates and prevents the effect of aging and improves the quality of life.

Rasayana nourishes each and every cell of the body and hence contributes to the integrity and replenishment of *Sapta dhatus*. *Rasayana* is the broad spectrum science and covers many aspects of healing and treating individuals. It is predominantly preventive medicine and a curative aspect of *Rasayana* is also well documented. It is included under '*Swasthasya urjasakra*'[4] type of *Bheshaja* (medicine) i.e. drugs which help in maintenance of health of an already healthy individual. On the other hand, *Rasayana* is also curative in nature i.e., *Rasayana* being a *Bheshaj* is both preventive and curative in nature.[5] By strengthening the *Dhatu* and enhancing the immunity, *Rasayana* helps in preventing as well as curing many ailments. *Rasayana* enhances the qualities of *Rasadi dhatu* enriches them with nutrients. *Rasayana* therapy has got a vast scope and covers the wide horizon of medical science. By adopting it man can attain a long life full of vigor and free from diseases.

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AIMS AND OBJECTIVE

To evaluate the efficacy of *Guduchyadi Rasayana* in healthy individuals.

To assess the clinical safety of *Guduchyadi Rasayana*^[6] in healthy individuals.

Patients and Method

15 healthy individuals were registered for the study between the age group 55–60 who fulfilled the criteria of selection from the OPD/IPD of R.G.G.P.G. Ayurvedic College and Hospital Paprola (H.P.)

To fulfill the aims and objectives, the research work was done in the following phases:

Conceptual Study

Detailed review of conceptual study was done on *Rasayana* from available ancient and modern literature. Detailed review of trial drug was reviewed and compiled.

Clinical Study

This was the main part of proposed research work. The present study was carried out to evaluate the *Rasayana* effect of *Guduchyadi Rasayana* in healthy individuals. Total 15 volunteers were screened and registered for the study and all of them completed the trial.

Selection criteria

Inclusion criteria

- Individuals willing and able to participate in trial for 60 days.
- Individuals within age group 55 to 60 years of either sex.
- Individuals not having any serious chronic ailments.
- Individuals not having any state mentioned in exclusion criteria.

Exclusion Criteria

- Individuals not willing to participate in trial.
- Individuals below age of 55 years and above 60 years.
- Individuals suffering from major systemic illness like cardiac ailment, diabetes mellitus, grade-II hypertension, CA of any organ.
- Individuals having hypothyroidism and hyperthyroidism.
- Mentally unstable and substance abuse Individuals.
- Alcoholic and drug abuse.
- Any other Individuals considered unfit for inclusion in trial.

Protocol of Research

(i) Consent- Written and informed consent of study objects were taken before inclusion in the trial.

(ii) IEC Approval- Approval of synopsis for human trial was obtained from institutional ethical committee

of R.G.G.P.G. Ayurvedic College Paprola (H.P.), Vide Letter No. Ayu / IEC / 2015 /1065.

(iii) Proforma- Proforma incorporating detail profile of study subjects complaints, history, sign & symptoms and assessment was prepared

Laboratory Investigation

- **Haematological-** Hbgm%, TLC, DLC, ESR
- **Biochemical-** FBS, B. Urea, S. Creatinine, TSB, DSB, SGOT, SGPT, Lipid Profile
- **Urine-** Routine and microscopic examination
- **Chest x-ray (if required)-** To rule out any lung or cardiac pathology.
- **ECG (if required)-** To rule out any cardiac pathology.

Preparation of Drug

Guduchyadi Rasayana was prepared as per standard of GMP in the *Charaka* Pharmacy of college with Batch No. R-8/70 and 12-5-2017 as date of manufacturing. Chemical analysis of trial formulation was done at DTL Jogindernagar with letter no. DTL/PP/15/17.

Drug and Dosage

Guduchyadi Rasayana

Dose	5 gm. twice a day
Dosage form	<i>Churna</i>
Route of administration	Oral
<i>Anupana</i>	<i>Ghrita</i>
Duration of Trial	60 days

Haritkayadi Yoga

Dose - 2 gm at bed time
 Dosage form- *Churna*
Anupana - Lukewarm water

Koshtha Shudhi was done by administering *Hritakayadi Yoga*^[7] It was given in the dose of 5 to 10 gm. to all study subjects with lukewarm water at bed time for 3 to 7 days according to *Koshtha*. This drug was also prepared as per standard of GMP in *Charaka* Pharmacy of college with Batch No. R-9/17 and 12 May, 2017 as date of manufacturing.

Total duration of trial- 60 days

Follow up period- After every 15 days

Grouping- There was only single trial group

Criteria for Assessment

Subjective Criteria

1. VAS of general well being
2. Sleep
3. Appetite
4. Exertional capacity
5. Difficulty in daily routine as a memory related problem
6. Mood
7. Will power

Grading of Subjective Criteria

A special proforma was designed for clinical assessment. For this purpose grading of symptoms was done according to their severity. Grading of subjective criteria is done in negative direction i.e., higher score denotes greater severity of the symptoms and low score indicate lesser severity.

1. Visual Analogue Scale of Well Being

Above 60%	G0
Between 50 – 60%	G1
Between 40 – 50%	G2
Below 40%	G3

2. Sleep Pattern

Sound sleep 6 – 8 hr	G0
Sound sleep but < 6 hr	G1
Disturbed sleep 6 - 4 hrs	G2
Sleep < 4 hrs	G3
No Sleep	G4

3. Appetite

Normal appetite	G0
Occasionally decreased appetite	G1
Decreased appetite	G2
Loss of appetite	G3

4. Exertional Capacity

Does not feel tired at all	G0
Feels tired on heavy exertion	G1
Feels tired on mild exertion	G2
No capacity to exert	G3

5. Mood

Changes in circumstance which really affect the life in one or other way	G0
Changes immediately with every minor event which does not affect life indeed	G1
Frequent changes without any reason	G2
Always depressive/ anxious	G3
Opposite moods (sad during happy events)	G4

6. Difficult in daily routine as a result of memory related problems

Not at all	G0
A bit but it doesn't affect self daily schedule	G1
Affect daily routine mildly	G2

Affect daily routine moderately	G3
Affect daily routine severely	G4

7. Will Power

Cope up all the problems of life without any help	G0
Cope up all the problems of life but sometimes need help	G1
Cope up all the problems of life with the help of other	G2
Unable to cope up the problems with or without help	G3

OBJECTIVE CRITERIA FOR ASSESSMENT

- 1 Body weight
- 2 Body temperature
- 3 Pulse rate
- 4 HB gm%
- 5 Systolic blood pressure (mm Hg)
- 6 Diastolic blood pressure (mm Hg)
- 7 6 min. walk capacity (6 MWT)
- 8 Foot Thrust
- 9 Grip Power

WHO Quality of Life-BREF Score

PGI Memory Scale

Statistical Analysis

The information collected on the basis of observation was subjected to statistical analysis in terms of mean score of before treatment (BT) and after treatment (AT) difference of mean (BT – AT), Standard Deviation (SD) and Standard Error (SE) and paired 't' test were carried out at $p \leq 0.001$, $p < 0.01$, $p < 0.05$, $p > 0.05$. The obtained results were interpreted as:-

- Highly significant - $p \leq 0.001$
- Moderately significant - $p < 0.01$
- Significant - $p < 0.05$
- Insignificant - $p > 0.05$

OBSERVATION AND RESULTS

15 healthy individuals were registered for the study between the age group 55–60 who fulfilled the criteria of selection from the OPD/IPD of R.G.G.P.G. Ayurvedic College and Hospital Paprola (H.P.). All the 15 individuals completed the course of therapy.

Demographic Profile

Table 1: Status of 15 registered volunteers

Status	No. of Volunteer
Completed the trial	15
Dropped out	0
Total	15

Table 2: Effect of therapy on Subjective Criteria

S. No.	Criteria	Mean Score		Mean Diff.	% Change	SD±	SE±	't'	'p'
		BT	AT						
1.	VAS	1.46	1.26	0.20	13.69%	0.414	0.107	1.871	0.050
2.	Appetite	1.7	1.2	0.5	29%	0.737	0.190	7.359	0.001
3.	Sleep	2.13	0.867	1.267	59.14%	0.799	0.20	6.141	0.001
4.	Exertional capacity	1.33	1.00	0.33	25%	0.4	0.126	2.646	0.01
5.	Mood	2.53	2.13	0.40	16%	0.50	0.13	3.055	0.009
6.	Difficulty in daily routine as a result of memory related problem	2.46	2.26	0.200	8%	0.414	0.107	1.871	0.082
7.	Will power	1.6	1.5	0.06	3.75%	0.458	0.118	0.564	0.582

Graph No. - 1

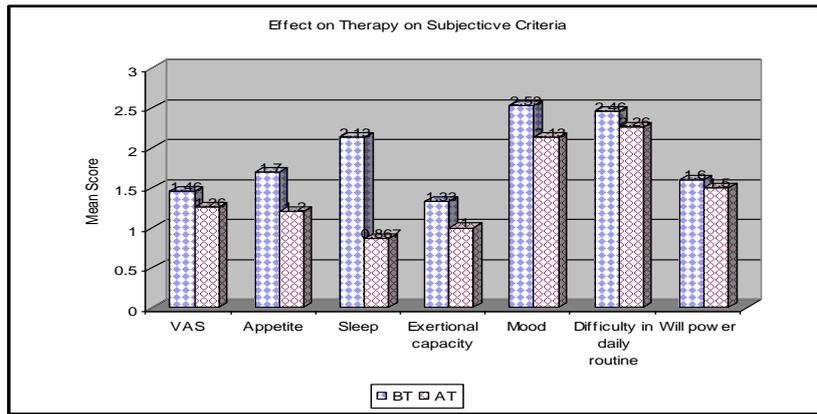


Table 3: Effect of Therapy on Objective Criteria

S. No.	Criteria	Mean Score		Mean Diff.	% Change	SD±	SE±	't'	'p'
		BT	AT						
1.	Body weight (kg.)	57.86	58.6	0.733	1.26%	0.704	0.182	0.036	<0.001
2.	Body Temperature (°F)	97.79	98.10	0.313	0.32%	0.607	0.157	1.999	0.065
3.	Pulse Rate (per min.)	77.33	76.53	0.80	1.03%	3.098	0.800	1.000	0.334
4.	Systolic blood pressure (mm of Hg)	112.13	110.53	1.600	1.426%	11.01	2.843	0.563	0.583
5.	Diastolic blood pressure (mm of Hg)	73.60	73.60	00	00	4.59	1.187	0.00	1.000

Graph No. - 2

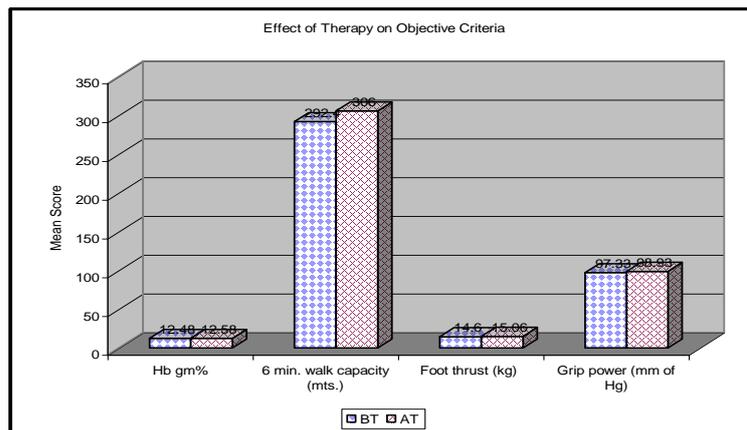


Table 4: Effect of Therapy on Objective Criteria

S. No.	Criteria	Mean Score		Mean Diff.	% Change	SD±	SE±	't'	'p'
		BT	AT						
6.	Hb gm%	12.48	12.58	0.10	0.801%	1.53	0.397	0.252	0.805
7.	6 min. walk capacity (mts.)	292.4	306	14.26	4.87%	8.31	2.146	6.649	0.001
8.	Foot thrust (kg)	14.60	15.06	0.467	3.198%	0.616	0.133	3.500	0.004
9.	Grip power (mm of Hg)	97.33	98.93	1.60	1.64%	0.82	0.214	7.483	0.001

Graph No. - 3

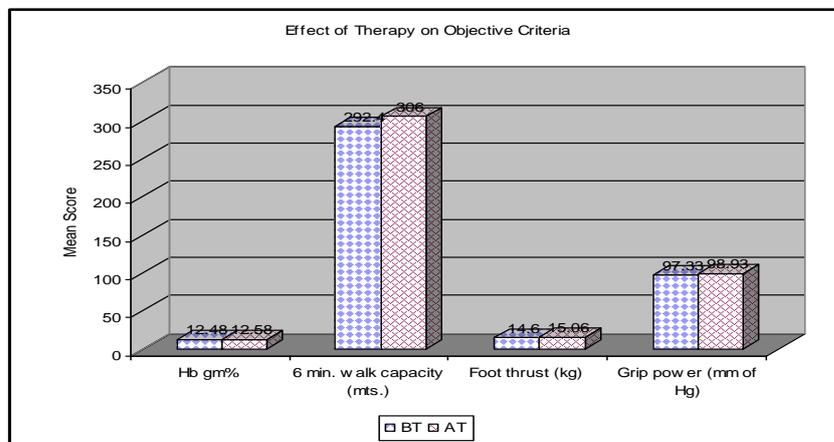


Table 5: Effect of Therapy on WHO QOL Bref Score

S. No.	Criteria	Mean Score		Mean Diff.	% Change	SD±	SE±	't'	'p'
		BT	AT						
1.	Domain-I (Physical health)	22.800	24.800	2.00	8.7%	1.558	0.402	4.971	<0.001
2.	Domain-2 (Psychological health)	15.20	18.26	3.067	20.13%	1.870	0.483	6.353	<0.001
3.	Domain 3 (Social health)	6.067	7.133	1.067	17.58%	0.704	0.182	5.870	<0.001
4.	Domain 4 (environmental health)	25.00	25.93	0.933	3.733%	0.458	0.118	7.897	

Graph No - 4

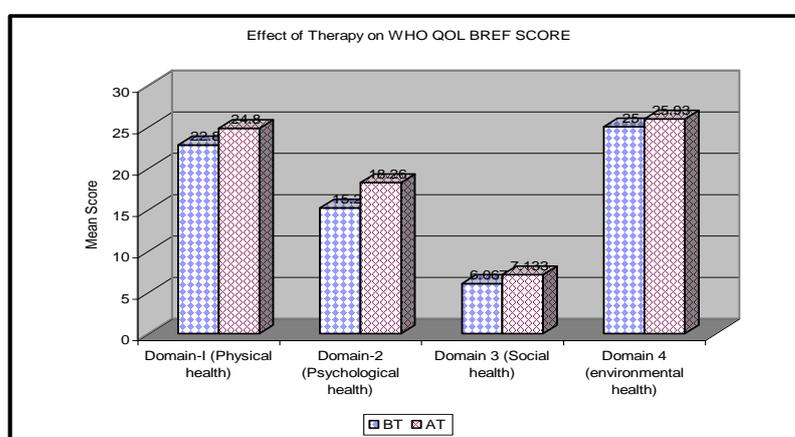
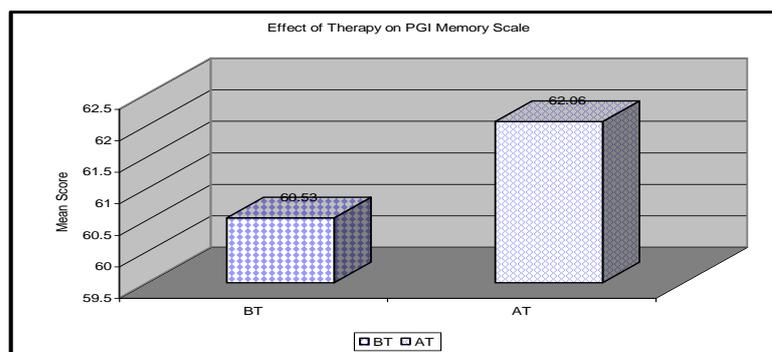


Table 6: Effect of Therapy on PGI Memory Scale

S. No.	Criteria	Mean Score		Mean Diff.	% Change	SD±	SE±	't'	'p'
		BT	AT						
1.	PGI Memory Scale	60.53	62.06	1.533	2.53	1.302	0.336	4.561	<0.001

Graph No. - 5



DISCUSSION

As per Visual Analogue Scale of Well Being

Pre-therapy mean score of VAS of 15 volunteers was 1.46 which reduced to 1.26 after the completion of trial. The improvement in the score of VAS was 13.69% which was significant. Out of 15 patients, 60% were having sense of well being between 40-50% and rest 40% had score above 60%. This shows that quality of life as experienced by elderly person is not satisfactory as age related health problems may cause dissatisfaction in elderly age.

Appetite

In the present trial 73.33% individuals had complaint related to appetite (either reduced or loss of appetite or occasionally reduced). In elderly persons due to *Vata Prokopa* and disturbed *Agni* i.e., *Mandagni* and *Vishamagni* occurs, which causes the formation of *Ama* and in turn leads to disturbances related to appetite. The improvement in the score of appetite was 29% which was statistically highly significant ($p < 0.001$). Pre therapy mean score was 1.7 which reduced to 1.2 after treatment.

Sleep

In the present study 73.3% people had either reduced or disturbed sleep or both.

In the elderly person *Kaphakshaya* and *Vata Vridhi* occurs leading to vitiation of *Manovaha Srotas* thus majority of patients had this type of problem. At the end of trial 57.14% improvement was observed in sleep pattern with mean score reducing from 2.13 to 0.867, which was statistically highly significant. ($p < 0.001$)

Exertional Capacity

In the present study 53.33% people complaint of feeling of tiredness over mild exertion. This is due to the fact that *Dhatu Kshaya* and surge in *Vata Dosha* are responsible for *Oja Kshaya*, which directly affect the exertional capacity of an individual.

Initial means score of exertional capacity was 1.33 which reduced to 1.00 after treatment with 25% increase in exertional capacity which was moderately significant. ($p < 0.01$)

Mood

It was observed that out of 15 volunteers 60% were having mood related problem. Increased *Vata*, *Raja Guna* and decreased *Kapha* in elderly people leads to declination of *Sattva* resulting in mood disorders.

Pre-therapy mean score of mood was 2.53 which reduced to 2.13 with 16% improvement in mood which was statistically moderately significant.

Difficulty in Daily Routine as a result of memory related problem

Vata Dosha is increased and *Kapha Dosha* (*Tarpak Kapha*) is decreased in old age causes impaired memory. Among 15 volunteers mean score of difficulty in daily routine as a result of memory related problem was 2.46 before treatment which reduced to 2.26 after treatment showing a reduction of 8% which was statistically insignificant. ($p > 0.01$)

Will Power

Before treatment mean score of will power was 1.6 which reduced to 1.5 after treatment showing a reduction of 3.75% which was statistically insignificant. ($p > 0.01$)

PROBABLE MODE OF ACTION OF TRIAL DRUGS

According to *Charaka Samhita*, certain drugs act through *rasa*, some through *Veerya*, some through their *Gunas*, some through their *vipaka* and some through their *Prabhava*.^[8]

In the trial formulation (*Guduchyadi Rasayana*) maximum ingredients are having *Tikta* and *Katu Rasa*,^[9] *Laghu*, *Ruksha* and *Teekshana Guna*, *Ushana Veerya*, *Katu & Madhura Vipaka*, *Rasayana* and *Balya* properties.

Action on Dosha

The drug due to its *Ushana Veerya* and *Madhura Vipaka*, pacify *Vata Dosha* and help to alleviate the *Dhatukshaya* and *Daurbalya*.

Action on Agni

It kindles the *Agni* (*Jatharagni*, *Dhatvagni*), due to its *Tikta*, *Katu Rasa*, *Laghu* and *Tikshana Guna* removes *Ama* and consequent *Srotasa* through

increased digestion, assimilation and metabolism by its *Deepana, Pachana* and *Vatanulomana* properties.

Rasayana drug correct the *Agni* which is responsible for *Ayu, Bala, Varna, Ojas* etc. Proper functioning of *Agni* alleviates the state of *Amavastha* and consequently optimum quantity and quality of *Dhatu* formation is ensured.

Action on *Satrotasa*

Due to *Tikta, Katu Rasa* and *Teekshana Guna*, this drug decrease *Strotorodha*, and nourishes the tissue at micro level leading to the proper formation of *Dhatu*.

Action on *Dhatu*

This drug nourishes the *Rasa Dhatu* due to its *Madhura Vipaka*. *Rasa Dhatu* nourishes all of the *Dhatu*s which ultimately leads to formation of *Prashashta Dhatu*.

Action on *Dhatukshaya*

These drugs act on *Dhatukshaya* by their *Rasayana, Balya* and *Brimhana* properties. *Rasayana Dravya* mainly acts at the level of *Dhatvagni* and maintain the disrupted homeostatis thus help in *Pushti* of *Dhatu*s.

CONCLUSION

- The present study established the overall *Rasayana* effect and clinical safety of *Guduchyadi Rasayana* in healthy individuals.
- There were no adverse effects of the trial drug observed during the trial period of 60 days.
- The present study revealed that trial drug was effective in most of the subjective and objective criteria.
- To conclude the trial, it was seen that trial drug has very good efficacy and safety.

The trial study of *Guduchyadi Rasayana* should be carried out further in more number of elderly persons.

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