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RESEARCH ARTICLE

Clinical Efficacy and Safety of *Brahma Rasayana* in Apparently Healthy Elderly Persons: A Prospective Multicenter Open-label Study

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ABSTRACT

Background: *Rasayana* therapy is one of the branches of Ayurveda, which aims at promoting the excellence of *Dhatu*, improving inherent defense mechanisms in our body, and improving general health.

Aim: To assess the clinical efficacy and safety of *Brahma Rasayana* in apparently healthy elderly persons.

Materials and methods: The clinical study was undertaken at three peripheral institutes in different geographical areas. One hundred and eighty apparently healthy elderly persons fulfilling the inclusion criteria were enrolled in the study. *Brahma Rasayana* was administered orally in the dose of 15 grams twice a day on empty stomach with lukewarm milk for a period of 12 weeks (84th day). Parameters, like the Hamilton depression rating scale, PGI Memory Scale, WHO Quality of Life-BREF Scale, hematological parameters, lipid profile, liver function tests, renal function tests, thyroid stimulating hormone (TSH), serum calcium, and serum vitamin D3 level, were assessed before and after the administration of therapy. The paired *t* test was applied to compare mean changes from baseline to the 84th day.

Results: A statistically significant effect ($p < 0.0001$) was observed at the end of the 84th day on all the four domains of the WHOQOL-BREF score, PGI Memory Scale, Hamilton depression rating scale, and chief complaints at the end of 12 weeks, compared with the baseline. Nonsignificant changes in blood parameters were obtained, proving the safety of the test drug. Also, the significant increase in the serum vitamin D3 level and decrease in the fasting blood sugar level were observed.

Conclusion: *Brahma Rasayana* was found to be effective, safe, and tolerable in apparently healthy elderly volunteers.

Keywords: *Brahma Rasayana*, *Dhatu Poshana*, Hamilton depression rating scale, *Rasa Dhatu*

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INTRODUCTION

The word *Rasayana* is defined as *"Rasasya Ayanam Rasayanam."*[1] *Rasa* means the absorbable end product of digestion or the nutrient obtained from food that gets assimilated into the circulation model and spreads throughout the body, providing nourishment to the individual as a whole. *Ayana* means *Marga,*[2] i.e., the channels of circulation. Thus, the word *Rasayana* refers to providing essential nourishment and vital essence to all *Dhatus* in the body, thereby revitalizing and promoting their functional excellence.

Ayurveda conceives a unique concept of *Ojas*, which is the quintessence of all the *Dhatus* and is responsible for the vital strength of the body and resistance against diseases, i.e., immunity.[3,4] *Rasayana* is believed to promote the process of *Dhatu Poshana* by *Srotosodhana* and *Agni Deepana* and enrich *Ojas*, leading to *Vyadhikshamatva*. The defense mechanism or immune mechanism present in our body allows us to survive in the potentially hostile world of infectious agents. Use of *Rasayana* enhances the immunity and reduces the susceptibility to diseases.

Rasayana therapy is one of the branches of *Ashtanga* Ayurveda. *Rasayana* therapy has been classified by *Charaka* into two groups: (a) *Kutipraveshika Rasayana Vidhi* (*Rasayana* therapy done indoors with a strict regimen)

and (b) *Vatatapika Rasayana Vidhi* (*Rasayana* that can be done without resorting to a stringent regimen). According to the requirement of an individual, the *Rasayana* drugs are divided into three groups, viz. *Kamya Rasayana* (which is aimed at the promotion of normal health and often done with a specific purpose), *Naimittika Rasayana* (which is used for a short and specific period and also in disease treatment), and *Ajasrika Rasayana* (substances that can be used regularly for the improvement of health). Ayurveda has mentioned a set of behavioral and regimental modalities, such as the daily intake of *Kshira* (milk) and *Ghrita* (ghee), which promotes mental and social well-being of an individual, namely, *Achara Rasayana* which provides the effect of *Rasayana* without medication.

The concept of strengthening the inherent defense mechanism in our body can be done in a better way by means of *Rasayana* therapy. *Brahma Rasayana* is mentioned in the *Abhayamalakeeya Rasayana Pada* of *Charaka Samhita*, *Chikitsa Sthana*.[5] The effects of *Brahma Rasayana* is said to be many fold; like rejuvenation of the body, enhancing immunity, delaying the ageing process, augmenting vitality, and preventing the early onset of graying of hair and wrinkling of skin.

Benefits, such as the improvement of intellect, memory, and body glow, prevention of diseases, and slowing down of the ageing process leading to increased lifespan, are described for *Rasayana* in Ayurveda classics.[6] Numerous medicines are described in Ayurveda classics as having *Rasayana* properties. The use of such medicines can help in improving the general health of the population and thus reducing the burden of diseases. Even though many of these medicines have been in use since centuries, scientific data on the clinical safety of these medicines are not available. Thus, the study aims to assess the safety and effectiveness of *Brahma Rasayana* in healthy elderly people, reducing the symptoms related to ageing and various other objective parameters by means of a clinical study.

MATERIALS AND METHODS

The study was a prospective multicenter open-label clinical trial, conducted at three peripheral institutes of Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of AYUSH (a. Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar; b. Central Ayurveda Research Institute for Drug Development, Kolkata; and c. Regional Ayurveda Research Institute for Metabolic Disorders, Bengaluru) and approved by the Institutional Ethical Committees (IEC) of the respective institutes. A total of 180 participants (60 from each Institute) were enrolled in the trial after obtaining the written informed consent. The trial was registered in the Clinical Trial Registry of India vide registration no. CTRI/2015/03/005659.

Inclusion Criteria

Apparently healthy individuals of either sex, with age ranging between 50 and 75 years, who had complaints of general weakness, but without involvement of any particular system and willing to provide informed consent.

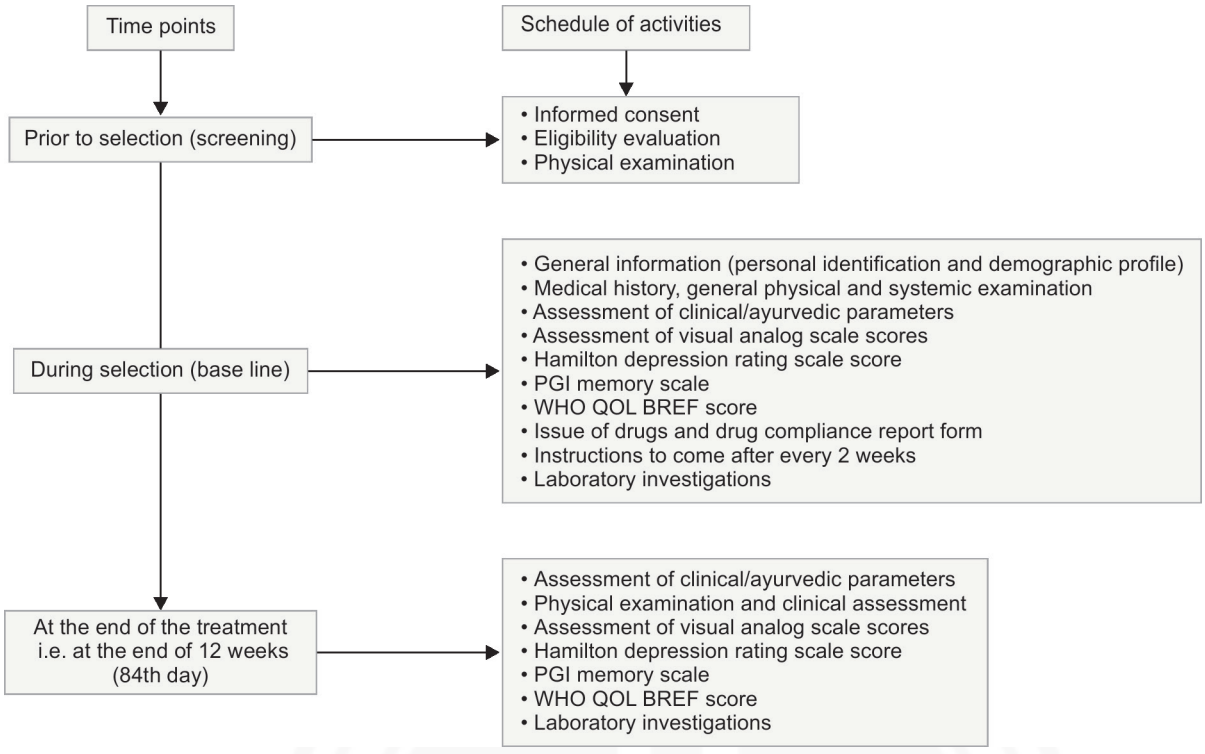
Exclusion Criteria

Patients with evidence of malignancy, suffering from major systemic illness necessitating long-term drug treatment (rheumatoid arthritis, psycho-neuro-endocrine disorders, etc.), who had a past history of atrial fibrillation, coronary artery disease (CAD), acute coronary syndrome, myocardial infarction, and stroke or severe arrhythmia in the last 6 months; symptomatic patients with clinical evidence of heart failure; patients with poorly controlled hypertension; and participants on prolonged (>6 weeks) medication with corticosteroids, antidepressants, anticholinergics, etc., or any other drugs that may have an influence on the outcome of the study. Participants with concurrent serious hepatic disorder (defined as aspartate amino transferase (AST) and/or alanine amino transferase (ALT), total bilirubin, alkaline phosphatase (ALP) >2 times the upper normal limit) or renal disorders (defined as serum creatinine >1.2 mg/dL); participants with severe pulmonary dysfunction (uncontrolled bronchial asthma and/or chronic obstructive pulmonary disease [COPD]), inflammatory bowel disease (IBD), severe dementia, and severe infection(s); nonambulatory patients or any other conditions that would have jeopardized the study, prostate specific antigen (PSA) levels > 4 ng/mL, alcoholics and/or drug abusers; patients suffering from diabetes mellitus; HIV positive subjects; participants with a history of hypersensitivity to the trial drug or any of its ingredients; and participants who had completed participation in any other clinical trial during the past six (6) months or any other condition which the investigator thought may jeopardize the study were excluded from the study.

Posology

Brahma Rasayana was administered as *Vatatapika Rasayana Vidhi* in a dose of 15 grams twice daily on empty stomach with lukewarm milk as *Anupana* for a period of 12 weeks orally. The drug *Brahma Rasayana*[7] was procured from a good manufacturing practice (GMP)-certified Ayurvedic pharmaceutical industry, i.e., M/s Indian Medicines Pharmaceutical Corporation Limited (IMPCL), Mohan, Uttarakhand, and Standardized

Flowchart 1: Study schedule



following the standards mentioned in the Ayurvedic Pharmacopeia of India (API).

Assessment Criteria

On the day of enrolment, i.e., at baseline visit, personal identification, demographic profile, medical history, and general physical and systemic examination were done.

Assessment of chief complaints, such as dizziness, constipation, urge incontinence, muscle ache, joint pain, and stiffness in joints; and generalized symptoms, such as disturbed sleep, loss of appetite, fatigue, generalized weakness, and a generalized sense of ill-being by the visual analog scale (VAS) scores, was done at baseline and after treatment, i.e., on the 84th day visit.

The Hamilton depression rating scale[8] score (to assess the presence of symptoms of depression in old-age individuals), PGI Memory scale, and WHO QOL BREF[9] Score were also recorded. Laboratory parameters, such as hemoglobin (Hb), total leukocyte count (TLC), absolute eosinophil count (AEC), erythrocyte sedimentation rate (ESR), lipid profile, liver function test (LFT), renal function test (RFT), C-reactive protein (CRP), thyroid stimulating hormone (TSH), serum vitamin D3 levels, and serum calcium levels, were assessed at baseline and after the treatment (84th day).

Subsequent visits were planned at intervals of 2 weeks [14th day (visit 2), 28th day (visit 3), 42nd day (visit 4), 56th day (visit 5), 70th day (visit 6), and 84th day (visit 7)]. Volunteers were assessed and given study medication at each subsequent visit till the 84th day (Flowchart 1).

Study Procedure

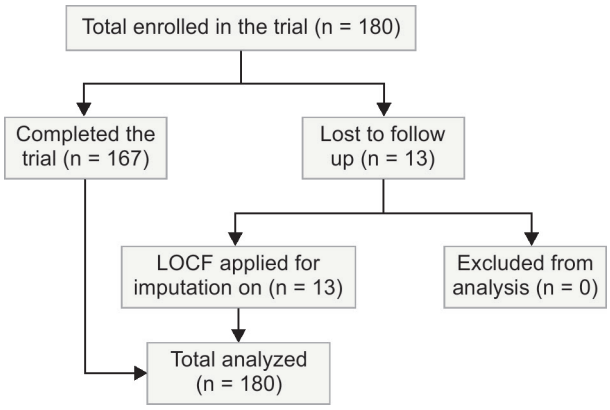
At the study site, data of all the volunteers were recorded in predesigned case report forms (CRFs) and were also entered in the electronic formats (e-formats) designed in MS-Excel with many data validation checks to ensure correct data entry. The e-formats and Xerox of the CRFs along with the laboratory investigation reports of the participants were sent by participating institutes to the Council's headquarters on weekly basis for monitoring purpose.

Out of the total 180 volunteers enrolled in the study, 13 dropped out during the course of the study. The intention-to-treat analysis was done and the data of all those volunteers who have completed at least the 14th day visit were imputed by the last observation carried forward (LOCF) method. Volunteers who dropped out after the baseline visit were only excluded from the analysis. Hence, data of total 180 volunteers were used for statistical analysis. Flowchart 2 shows the outflow of the volunteers in the study.

Statistical Analysis

The outcome measures were analyzed as mean changes in the response from baseline to the 84th day by applying the Student's t test. A p value of <0.05 was considered to be significant. All statistical analyses weres performed using the statistical package for social sciences (SPSS) software.

Flowchart 2: Outflow of the participants in the study



OBSERVATIONS

Out of 180 volunteers who participated in the study, 70.0% were males while the remaining 30% were females. The majority of the volunteers were married (96.7%). About 86.1% were literate enough to read and write, and the remaining 13.9% were illiterate. As per the socioeconomic status of the volunteers, maximum, 84.4%, were from above the poverty line and the remaining were from below the poverty line. About 71% of the patients were from urban area and 93.9% belonged to the Hindu religion. Vegetarians (82.8%) were more in number than nonvegetarians. Addictions in the form of alcohol, smoking, and tobacco chewing were observed in a negligible number of people. About 56.1% volunteers had normal sleep pattern and the remaining (43.9%) had disturbed sleep. About 70.6% volunteers had regular bowel habit and 76.1% had regular urine output (Table 1).

Table 1: Demographic profile of volunteers participated in the study (*n* = 180)

Parameter	*n (%)*
Sex	
Male	126 (70)
Female	54 (30)
Marital status	
Married	174 (96.7)
Unmarried	3 (1.7)
Widow/er	3 (1.7)
Educational status	
Illiterate	25 (13.9)
Read and write	155 (86.1)
Socioeconomic status	
Above poverty line	152 (84.4)
Below poverty line	28 (15.6)
Habitat	
Urban	129 (71.7)
Semiurban	18 (10)
Rural	33 (18.3)
Shareerik Prakriti	
Vataja	12 (6.67)
Pittaja	1 (0.6)
Vata-Pittaja	79 (43.9)
Vata-Kaphaja	9 (5)
Pitta-Kaphaja	78 (43.33)
Sannipataja	1 (0.6)

The level of stress varied in these individuals: a minimal level of stress was observed in 56.7%, moderate in 28.3%, and 15% had too much emotional stress.

Among the 180 volunteers, maximum (43.9%) were of *Vata-Pittaja Prakriti*, followed by 43.3% of *Pitta-Kaphaja Prakriti*. Maximum numbers of patients were having moderate physical parameters in terms of *Samhanana, Pramana*, etc.

RESULTS

Dizziness, constipation, urge incontinence, muscle ache, joint pain, stiffness in joints, disturbed sleep, loss of appetite, fatigue, generalized weakness, and a generalized sense of ill-being were the major subjective complaints that were observed in these participants. It was observed from the study that a change from baseline to the 84th day was statistically highly significant in the cases of dizziness, constipation, urge incontinence, muscle ache, joint pain, and joint stiffness ($p < 0.0001$). The effect of *Brahma Rasayana* on generalized symptoms, such as disturbed sleep, loss of appetite, fatigue, generalized weakness, and a sense of ill-being, was also highly significant with a p value <0.0001 (Table 2).

After the end of the 84th day of study, it was observed that *Brahma Rasayana* has provided no significant effect on the laboratory investigations (TLC, Hb%, ESR, AEC, TSH, and serum calcium) of the apparently healthy elderly volunteers. There were statistically significant reduction in fasting blood sugar and also statistically significant rise in vitamin D3 values after the therapy (Table 3).

After the end of the 84th day of study, it was observed that *Brahma Rasayana* has no significant effect on the lipid profile except very-low-density lipoprotein (VLDL). The significant increase was observed in the VLDL level, which is found to be within the physiological limits of apparently healthy volunteers recruited in the study (Table 4).

The effects of *Brahma Rasayana* on safety parameters were assessed through the evaluation of the RFT, LFT, and CRP, at the baseline and after the end of the study, and it was observed that all the parameters were within the physiological limits during the entire trial period and also after the end of the trial with p value >0.05 (Table 5).

It was observed from the study that *Brahma Rasayana* has a highly significant effect ($p < 0.0001$) on the Hamilton depression rating scale after a period of 84 days.

After the administration of therapy for a specific period of time, it was observed that *Brahma Rasayana*

Table 2: Effect of the therapy on chief complaints (*n* = 180)

Chief complaints	*Baseline*	*84th day*	*t value*	*p value*
Dizziness	3.90 (08.30)	11.80 (18.10)	8.784	<0.0001
Constipation	2.69 (10.89)	10.50 (21.30)	6.590	<0.0001
Urge incontinence	2.61 (07.60)	06.94 (16.34)	5.70	<0.0001
Muscle ache	5.40 (15.65)	15.30 (24.82)	4.672	<0.0001
Joint pain	5.61 (15.20)	17.75 (24.75)	9.690	<0.0001
Joint stiffness	4.16 (14.87)	13.63 (22.42)	8.161	<0.0001
Abnormal sleep	4.77 (10.21)	16.11 (21.54)	10.033	<0.0001
Loss of appetite	2.94 (09.36)	07.05 (17.45)	5.423	<0.0001
Fatigue	5.72 (10.42)	20.17 (21.81)	12.409	<0.0001
Generalized weakness	7.18 (26.49)	24.38 (34.16)	9.577	<0.0001
Sense of ill-being	−5.42 (07.65)	−24.72 (16.45)	20.153	<0.0001

Values are expressed as *n* (%)

Table 3: Effect of therapy on laboratory investigations (*n* = 180)

Parameters	*Baseline*	*84th day*	*t value*	*p value*
Hemoglobin (g/dL)	12.63 ± 1.93	12.67 ± 1.99	0.85	0.396
TLC (per mm^3)	7370.78 ± 1654.38	7281 ± 1438.41	0.91	0.364
ESR mm (at the end of 1st hour)	24.04 ± 16.89	23.95 ± 16.02	0.86	0.931
Absolute eosinophil count	367.61 ± 272.16	379.57 ± 331.057	0.718	0.474
Fasting blood sugar (mg/dL)	97.92 ± 13.51	95.71 ± 16.12	2.565	0.011*
TSH (mIU/L)	2.370 ± 1.063	2.46 ± 1.28	1.211	0.227
Serum vitamin D3 (ng/mL)	29.11 ± 14.41	32.84 ± 20.61	4.306	0.000*
Serum calcium (mg/dL)	7.20 ± 2.38	7.19 ± 2.39	0.175	0.862

Data: Mean ± SD; *$p < 0.05$

Table 4: Effect of the therapy on the lipid profile (*n* = 180)

Parameters	*Baseline*	*84th day*	*t value*	*p value*
Serum cholesterol (mg/dL)	187.16 ± 35.40	190.13 ± 34.68	1.353	0.178
Serum triglycerides (mg/dL)	129.96 ± 50.216	137.91 ± 75.815	1.944	0.053
Low-density lipoprotein (LDL) (mg/dL)	120.98 ± 28.86	122.28 ± 29.40	0.830	0.408
High-density lipoprotein (HDL) (mg/dL)	41.68 ± 10.86	41.52 ± 13.33	0.224	0.823
VLDL (mg/dL)	25.36 ± 8.78	27.46 ± 16.63	2.087	0.038*

Data: Mean ± SD, * *p* value of <0.05

Table 5: Effect of the therapy on liver and renal function test (*n* = 180)

Parameters	*Baseline*	*84th day*	*t value*	*p value*
Blood urea (mg/dL)	22.58 ± 6.54	22.03 ± 5.71	1.226	0.222
Serum uric acid (mg/dL)	5.687 ± 1.09	5.693 ± 1.06	0.123	0.903
Serum creatinine (mg/dL)	0.847 ± 0.159	0.847 ± 0.161	0.076	0.940
Aspartate aminotransferase (AST or SGOT) (IU/L)	22.10 ± 8.26	22.35 ± 8.80	1.113	0.716
Alanine aminotransferase (ALT or SGPT) (IU/L)	22.25 ± 11.14	22.37 ± 9.65	1.277	0.863
Total protein (g/dL)	7.043 ± 0.609	7.516 ± 5.475	1.176	0.241
Serum albumin (g/dL)	4.533 ± 0.399	4.5280 ± 0.390	0.190	0.850
Conjugated bilirubin (mg/dL)	0.453 ± 0.322	0.454 ± 0.340	0.094	0.925
Unconjugated bilirubin (mg/dL)	0.290 ± 0.298	0.330 ± 0.532	1.073	0.285
Serum alkaline phosphatase (IU/L)	121.44 ± 57.84	123.43 ± 62.32	0.928	0.355
Serum CRP (mg/L)	1.034 ± 1.522	2.354 ± 19.932	0.892	0.374

Data: Mean ± SD

provided a highly significant effect ($p < 0.0001$) on the individual domains of the PGI Memory Scale, viz. recent memory, mental balance, attention and concentration, delayed recall, immediate recall, verbal retention for dissimilar pairs, visual retention, visual recognition, and also in PGI memory total score. In the domain verbal retention for similar pairs, it was highly significant in the level of $p < 0.001$.

A statistically significant effect ($p < 0.0001$) was obtained at the end of the 84th day on all the four domains

Table 6: Effect of the therapy on outcome parameters

Parameters	*Baseline*	*84th day*	*t value*	*p value*
Hamilton depression rating scale	15.71 ± 7.35	6.22 ± 4.59	18.906	<0.001
PGI memory scale				
Remote memory	5.35 ± 0.855	5.86 ± 0.474	8.682	<0.001
Recent memory	4.61 ± 0.655	4.94 ± 0.253	7.250	<0.001
Mental balance	6.59 ± 1.687	7.91 ± 1.443	12.082	<0.001
Attention and concentration	11.11 ± 3.88	12.58 ± 3.608	8.857	<0.001
Delayed recall	7.96 ± 1.767	9.05 ± 1.183	9.632	<0.001
Immediate recall	8.59 ± 2.62	10.58 ± 1.87	12.453	<0.001
Verbal retention for similar pairs	4.41 ± 0.738	4.82 ± 0.398	7.622	<0.001
Verbal retention for dissimilar pairs	9.71 ± 3.14	12.41 ± 2.842	11.935	<0.001
Visual retention	10.28 ± 8.69	10.77 ± 2.315	0.790	0.431
Visual recognition	8.39 ± 1.669	9.27 ± 0.966	9.964	<0.001
PGI memory total score	76.04 ± 13.85	88.16 ± 11.29	15.883	<0.001
WHOQOL-BREF score				
Domain 1 (physical health)	21.89 ± 3.82	26.45 ± 3.476	16.390	<0.001
Domain 2 (psychological)	20.38 ± 3.14	23.54 ± 2.70	15.948	<0.001
Domain 3 (social relationships)	10.31 ± 1.701	11.01 ± 1.791	8.464	<0.001

Data: Mean ± SD

of the WHO QOL BREF Score after administration of *Brahma Rasayana* (Table 6).

DISCUSSION

Rasayana[6] is a specialized treatment aimed at providing the overall improvement in an individual by prevention of ageing, promoting resistance against diseases, enhancing bodily strength, and improving mental faculties. The *Rasayana* drugs can act on the body by qualitative enhancement of the nutritional value of the *Asthayee Rasa Dhatu*, which in turn acts by improving *Dhatu Poshana*, e.g., *Dugdha, Ghruta, Shatavaree,* etc. *Rasayana* drugs have an important role in improving *Agni Vyapara*, i.e., proper digestion and metabolic transformation in the body, thereby regulating proper *Dhatu Nirmana* in the body (*Chitraka, Bhallataka,* etc., are few drugs capable of promoting *Agni* in *Koshta* and *Dhatu* levels). Certain drugs, such as *Guggulu* with *Rasayana* effect, have the ability to produce *Srota Shodhana* (cleansing the macro and macro channels in the body), which ultimately improves *Dhatu Poshana Kriya*.

Previous studies have also proven the efficacy of *Brahma Rasayana* for its antioxidant and tissue-regeneration capacity.[10] Oral administration of *Brahma Rasayana* (50 mg/dose/animal) is found to have free oxygen radical-scavenging activity in *in vitro* and *in vivo* models.[11] Another clinical study mentions an unexpected finding that the administration of *Brahma Rasayana* did not produce any significant increase in the total leukocyte or absolute counts of various WBCs or other hematological parameters, but there was a significant functional enhancement of lymphocytes in healthy volunteers. There was also a marginal increase in the serum granulocyte macrophage-colony stimulating factor (GM-CSF) in volunteers after ten days of *Brahma Rasayana* treatment when compared to the day prior to the start of *Brahma Rasayana* treatment.[12]

Brahma Rasayana rejuvenates the body, improves intelligence, boosts memory, and augments the immune mechanism. This is a very good tonic for enhancing youthfulness, luster, complexion, and efficiency of individuals. It is beneficial for promoting mental clarity and improved cognition whilst improving resilience to mentally demanding lifestyles. Its unique blend of herbs helps improving focus and concentration. It also increases sperm count and enhances libido.

It was noticed from the study that maximum volunteers were married and male, as the inclusion criteria included age ranging from 50 to 75 years. Maximum were literate and from urban area, which may be due to the fact that the study was conducted in an urban populated area where the provision for education is better. Maximum were having past occupational history of field work with physical labor. The majority of the participants were from above the poverty line, since most were from urban area where the livelihood is better. Maximum were from the Hindu community, since the study was conducted in areas where Hindu predominance in population is seen. The majority was observed to be nonvegetarians and was devoid of any addiction. The maximum number of volunteers had normal sleep pattern, regular bowel habit, and regular urine output, which may be due to the fact that apparently healthy volunteers were considered for the study. Quite a large number had average emotional stress, which may be due to the present lifestyle. Maximum were having average body built and were

moderately nourished, which might be due to their regular physical labor. The majority were of *Vata-Pitta Prakriti* followed by *Pitta-Kapha Prakriti* and belonged to *Mamsa Sara* followed by *Tvak Sara*. All other criteria, such as *Satva, Samhanana, Satmya*, and *Vyayama*, were observed to be in the *Madhyama* category in majority of the participants.

In the present study, *Brahma Rasayana* showed a highly significant effect on most of the parameters viz. in subjective complaints like dizziness, constipation, urge incontinence, aching muscle, pain in joints, stiffness in joints, abnormal sleep, loss of appetite, fatigue, generalized weakness, and a sense of well-being, with p values <0.001. It also had shown a highly significant effect on the PGI Memory scale, Hamilton depression rating scale, and WHOQOL-BREF scale. *Brahma Rasayana* can be believed to have antioxidant, nootropic, immune stimulant, and revitalizing properties. The generalized symptoms are reflection of functional deterioration of *Dhatu* secondary to free radical- and age-induced damage. *Brahma Rasayana* has promoted excellence of *Dhatus* by nourishing, replenishing, and regenerating them. Statistically significant reduction in fasting blood sugar and statistically significant rise in vitamin D3 values were also observed after the therapy. It was also observed that *Brahma Rasayana* improved the mental and psychosomatic attributes. No adverse events (AE) or adverse reactions (ADR) were noticed during the entire trial period. The values of LFT and RFT were within stipulated limits during the entire period.

CONCLUSION

Brahma Rasayana has provided highly significant improvement in somatic, psychological, and psychosomatic (subjective and objective) parameters including significant reduction in fasting blood sugar and statistically significant rise in vitamin D3 in apparently healthy elderly volunteers with no AE or ADR. Hence, it can be concluded that *Brahma Rasayana* can be acknowledged as an effective medication with *Dhatu Poshaka*, *Balya*, and *Ojo-vardhaka* properties, which is safe and effective to be used in people for revitalization, rejuvenation, and immune-stimulant activities.

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हिंदी सारांश

स्वस्थ प्रौढ व्यक्तियों में ब्रह्म रसायन की सुरक्षा एवं प्रभावकारिता: एक बहुकेंद्रीय चिकित्सीय अध्ययन

बनामली दास, भगवान सहाय शर्मा, रोहित कुमार रावते, जी वेंकटेश्वरलू, पूर्णेन्दु पाण्डा, देबज्योती दास, शशीधर एच दोड्डामणी, प्रदीप दुआ, श्रुति खण्डूड़ी, राकेश राणा, रिचा सिंघल, नारायणम श्रीकांत

पृष्ठभूमि: रसायन का तात्पर्य है, जो शारीरिक उत्तकों तथा शारीरिक प्रणाली की उत्कृष्टता को बढ़ाने के साथ-साथ सभी धातुओं का पोषण करने वाले रस धातु की भी वृद्धि करता है। रसायन सभी धातुओं की गुणवत्ता, मात्रा तथा क्रियात्मक गुण में वृद्धि करता है। रसायन को विवेकपूर्ण प्रयोग करने पर यह प्रतिरक्षण क्षमता को बढ़ाता है, आयु वृद्धि के होंने वाले दुष्प्रभावों को कम करता है तथा उत्तम स्वास्थ प्रदान करता है। रसायन औषधियाँ अस्थायी धातुओं (पाचन क्रिया का अवशोषित होने वाला अंतिम परिणाम है, जो कि स्थायी धातुओं या स्थायी उत्तको और अंगो का पोषण करता है) के पोषक भाव की कोष्ठ और शाखागत स्तर पर वृद्धि करती है तथा स्रोतोदृष्टि को ठीक करता है। रसायन सहज रक्षात्मक प्रतिक्रिया को बढ़ा कर संक्रमण तथा व्याधि उत्पन्न होने की सम्भावना को कम करता है।
उद्देश्य: स्वस्थ प्रौढ/वृद्ध व्यक्तियों में ब्रह्म रसायन के चिकित्सीय प्रभाव तथा सुरक्षित होने का आंकलन करने हेतु।
सामग्री एवं विधि: इस परियोजना को परिषद् के तीन परिधीय संस्थानों में आई. ऍम. आर चिकित्सीय अनुसंधान कार्यक्रम के रूप में चिकित्सीय अध्ययन किया गया। यह चिकित्सीय अध्ययन १८० प्रति-भागियों में पूरा किया गया। ब्रह्म रसायन १५ ग्राम की मात्रा में दिन में दो बार कोष्ण दूध के साथ १२ सप्ताह तक दिया गया। चिकित्सा शुरू करने से पहले तथा बाद में हैमिल्टन डिप्रेशन रेटिंग स्केल, पीजीआई मेमोरी स्केल और डब्ल्यूएचओ क्यूओएल आरईएफ स्केल जैसे मापदंडो का आंकलन किया गया । प्रारंभ से ८४वें दिन तक होने वाले औसतन बदलाव के तुलनात्मक अध्ययन हेतु पेयरड टी टेस्ट किया गया । ०.०५ से कम के पी-वेल्यु को सार्थक माना गया ।
परिणाम: तुलनात्मक अध्ययन के दौरान आरंभ से १२वें सप्ताह (८४वें दिन) तक सभी मापदंडो में सांख्यकीय रूप से सार्थक सुधार पाया गया । स्वस्थ व्यक्तियों में यह चिकित्सा सुरक्षित तथा प्रभावी पाई गई । परीक्षण की अवधि के दौरान कोई प्रतिकूल प्रभाव नहीं पाया गया ।
निष्कर्ष: प्रधानतया स्वस्थ प्रौढ व्यक्तियों में ब्रह्म रसायन सुरक्षित एवं प्रभावी रसायन है ।