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Seasonal Preventive effect of *Samshamani vati* over *Ritu-Haritaki* on disorders of *Varsha Ritu* (monsoon) w.s.r. to Quality of Life (QoL) - a Comparative Clinical Study

Research Article

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Abstract

Introduction: Seasonal changes can lead to dosha imbalances, increasing illness vulnerability. *Samshamani Vati* (SV), containing *Guduchi Satva*, is a monsoon-specific prophylactic that enhances *Agni* and reduces the occurrence of common colds, coughs, and fever. This study was designed to compare the effects of *Samshamani Vati* over *Ritu-Haritaki* in preventing diseases during *Varsha Ritu* (monsoon). Aim: To study the effect of S*amshamani vati* over *Ritu-Haritaki* in preventing diseases of *Varsha Ritu* in the participants. Materials & Method: A randomised controlled trial was conducted with 60 healthy volunteers prone to monsoon-related illnesses. Participants were divided into two groups: Group A received *Haritaki Churna* (3g) with *Saindhava Lavana* (1g) & Group B received *Samshamani Vati*. Both groups took their respective formulations once daily on an empty stomach with warm water for 60 days. Baseline and post-treatment evaluations were performed on days 0 and 60, measuring Total Leukocyte Count (TLC), Differential Leukocyte Count (DLC), Erythrocyte Sedimentation Rate (ESR), and WHO Quality of Life (WHO-QOL) scores. Results: Group B (SV) demonstrated a significant reduction in seasonal disorders and symptoms in 60% of participants, with improved WHO-QOL scores ($p<0.05$). Conclusion: *Samshamani Vati* showed significant efficacy over *Ritu-Haritaki* in reducing disease incidence during *Varsha Ritu.*

Keywords: *Samshamani vati, Ritu Haritaki, Varsha Ritu,* WHO-QOL, *Ritucharya*.

Introduction

Ayurveda, an ancient life science, prioritises health maintenance and disease prevention over treatment, focusing on the "*Swasthasya Swaasthya Rakshanam*" principle, emphasising prevention over cure. (1) Various regulations and guidelines have been described to prevent diseases and maintain health. (2) *Ritucharya* is a routine that helps the body adapt to seasonal changes without compromising equilibrium. (3) It involves implementing *samanya* (similarity) and *vishesha* (dissimilarity) *to* maintain *dosha* balance, which can lead to imbalances and illness manifestations. (4) *Ritucharya* guides understanding *Kriya-Kala,* which explains disease development based on *Vata, Pitta,* and *Kapha doshas.* (5) Adopting *Ritucharya* can promote and prevent disease-free life. *Haritaki,* a seasonal *Rasayana,* is a proven preventive drug due to its *Tridosha shamana* (supressing) properties. (6,7)

As a primary management for asthma, cold, fever cough and various respiratory-related conditions, *Samshamani vati* (8) is classically used. Manufactured from *Guduchi* (Tinospora cordifolia) *Ghana*, a proven immune-modulatory drug (9) which is efficacious against a wide range of viral ailments. (10,11,12) According to an analysis of Hippocrates, Individuals who intend to fully comprehend medicine ought to commence the influence of each season of the year.

Keeping all these factors in mind, the present study has been planned to evaluate the effect of *Samshamani vati* in comparison with *Rutu-Haritaki prayoga* for preventing diseases in *Varsha ritu* w.s.r.t in the monsoon period.

Materials & Methods

Haritaki Churna, Saindhava Lavana, and *Samshamani vati* were procured from GMP-certified KLE Ayurveda Pharmacy in Khasbhag, Belagavi. They were authenticated at the AYUSH-certified ASU drug testing Central Research Facility unit of KAHER's Shri B.M.K Ayurveda Mahavidyalaya. An automated machine was used for packaging and storage. The drugs were packed in 2000 packets of *Samshamani vati*, 2000 packets of *Saindhava Lavana*, and 2000 packets of *Haritaki Churna*.

The comparative clinical study was conducted on healthy volunteers during the Varsha Rutu who had a history of illnesses related to the monsoon period for at least two consecutive years. Before the commencement of the study, a newspaper announcement was given, and

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participants were screened. From those screened (62 subjects), based on predefined inclusion and exclusion criteria, 60 participants were selected and randomly allocated into two groups of 30 each using a computer-generated random number table. On the first day, the initial assessment of parameters of the subjects in both groups was carried out.

Study Type: Interventional

Study Design: Open label Randomised Comparative Clinical Trial

Sample size: 60 (30 in each group)

Groupings: Group-A and Group-B

Study period: 2 months (*Shravana (Nabha) & Bhadrapada (Nabhasya):* Mid-July to Mid-September)

Study site: Swastharakshan OPD, KLE Shri BMK Ayurveda Hospital and Research Centre, Belagavi, Shahpur, Karnataka

The Institutional Ethics Committee approved the study, and a clearance certificate was given, with **Ethical Clearance No.-** BMK/21/PG/SW/3

This study was carried out for two months of *Varsha Ritu* as mentioned in Ayurveda classics (*Shravana (Nabha) & Bhadrapada (Nabhasya):* Mid-July to Mid-September) with follow-up days on the 0th, 15th, 30th, 45th and 60th days (No such differences were observed or reported by the subjects, as stated in the inclusion criteria, which says that the subjects must be healthy persons. The purpose of the assessment days was to monitor any adverse effects that the drugs might have on any individual).

The control group (Group A) received 3gms *Haritaki Churna* + 1gm *Saindhava Lavana* (Ref.- *Bhava Prakasha, Haritakyaadi Varga*) dissolved in warm water, while the trial group (Group B) received 1 *Samshamani Vati* (250mg) (Ref.- single drug formulation of *Siddha Sara Yoga*) with warm water, both of which were administered orally for 60 days on an empty stomach.

Randomization of participants was done by a computer-generated random number table.

The study used dependent and independent t-tests for statistical analysis.

Inclusion Criteria

The study requires healthy individuals aged 20-55 years, with normal physical and bio-chemical parameters (TLC, DLC, ESR profile) and those willing to give informed consent, to participate.

Exclusion Criteria

Participants with systemic illnesses, those contra-indicated for *Haritaki* administration, and those with known cases of hypertension were excluded.

Withdrawal Criteria

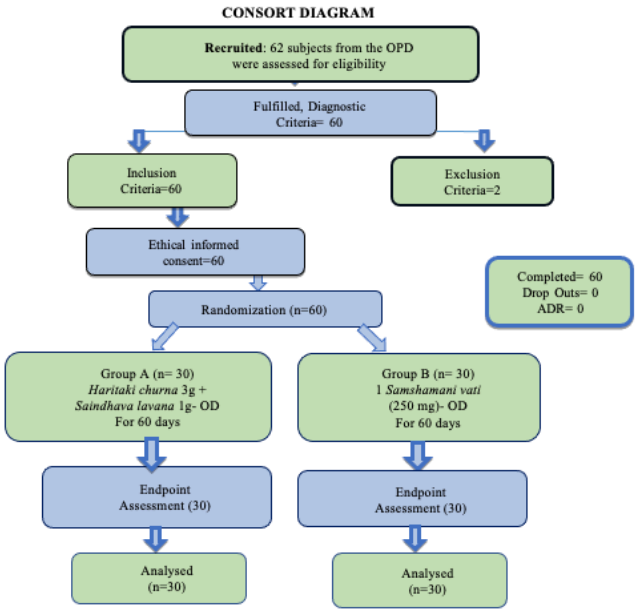
The Principal Investigator can withdraw the subject from the study at any time due to severe side effects, negative medication effects, potential health risks, subjects' disregard for directions or additional administrative justifications & depending on the nature of the complaint, patients were treated using the conventional method.

Assessments & Outcomes

The Objective assessment criteria include ESR, TLC, and DLC before and after intervention on the 0th & 60th days.

The Subjective Criteria consists of a pre-designed validated questionnaire (face validity taken) that was used to assess the following common symptoms seen in *Varsha Ritu* before the intervention only on the 0th day to note the incidence of disorders, including *Kshavathu, Shirashoola, Peenasa / dushta-peenasa, Swarasaada* (Hoarseness of voice), *Gala-shotha* (sore throat), *Sa-shabda-shwasa* (wheezing), *Jwara, Kasa*, Nasal obstruction, *Nasa-sraava* (Rhinorrhoea), *Aruchi, Jarana Shakti, Abhyavarana Shakti, Bala, Ajeerna* & *Malabaddhata* recorded in terms of *Pravara, Madhyama* & *Avara*; & WHO QOL BREF (Hong Kong version)- A 26-item questionnaire was used for evaluation of QOL before and after intervention on the 0th & 60th day. It consists of- 24 items to assess perception of quality of life in four domains, including physical health, psychological, social relationships and environment; and 2 items on overall QOL and general health. The domain scores were transformed into a linear scale between 0 and 100 following the scoring guidelines. A higher score indicated a better QOL.

Follow-up days 15th, 30th and 45th were kept to check the compliance of the subject and to assess any adverse effects of the drugs.



Observations & Results

The study focused on observing demographic profiles, history, and local examination while results reveal Haematological parameters and WHO Quality of Life BREF and its components.

Local Examination includes *Kshavathu* (67%) & *Nasa Srava* (47%) falls into *Pravara*; *Shirashoola* (45%), *Kasa* (52%), *Jarana Shakti* (80%), *Abhyavarana Shakti* (88%), *Bala*, (98%) comes in *Madhyama; Peenasa/ dushta peenasa* (60%), *Swarasaada* (78%), *Gala Shotha* (70%), *Sa-shabada Swasa* (93%), *Jwara* (97%), Nasal Obstruction (86%), *Aruchi* (65%), *Ajeerna* (63%), *Malabaddhata* (93%) comes in *avara* column.

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Parameters Result:

Table 1: Paired t-test of parameters within Group A

PAIRED T-TEST- Within the Groups		Group A						
Parameters		**ESR**	**TLC**	**DLC-N**	**DLC-E**	**DLC-L**	**DLC-M**	**WEIGHT**
P- value		< 0.0001	< 0.0001	0.5325	0.0007	0.0015	0.7450	0.7623
T- value		6.724	8.068	0.6317	3.808	3.509	0.3283	0.3054
Mean difference		4.400	1093	0.4333	2.000	-2.533	0.03333	0.06667
Mean	**BT**	15.57	8807	58.67	4.900	35.23	1.267	63.61
	AT	11.17	7713	58.23	2.900	37.77	1.233	63.54
Std. Deviation	**BT**	5.923	1560	5.573	2.708	4.717	0.4498	10.20
	AT	3.983	1078	3.766	1.062	3.720	0.4302	9.485
Std. Error	**BT**	1.081	284.8	1.017	0.4945	0.8613	0.08212	1.863
	AT	0.7273	196.7	0.6876	0.1939	0.6792	0.07854	1.732
Summary		***	***	ns	**	**	ns	ns

Table 2: Paired t-test of parameters within Group B

PAIRED T-TEST- Within the Groups		Group B						
Parameters		**ESR**	**TLC**	**DLC-N**	**DLC-E**	**DLC-L**	**DLC-M**	**WEIGHT**
P- value		< 0.0001	< 0.0001	0.9563	< 0.0001	0.0721	0.0299	0.0989
T- value		6.661	5.775	0.05522	5.348	1.832	2.283	1.705
Mean difference		4.233	863.7	0.03333	2.400	-2.833	0.2667	0.4067
Mean	**BT**	14.73	7930	58.10	5.567	34.80	1.467	62.90
	AT	10.50	7066	58.07	3.167	37.63	1.200	62.49
Std. Deviation	**BT**	5.595	1567	6.713	2.909	5.762	0.5074	10.28
	AT	3.608	1182	6.231	1.642	6.212	0.4842	9.778
Std. Error	**BT**	1.022	286.1	1.226	0.5311	1.052	0.09264	1.878
	AT	0.6587	215.9	1.138	0.2997	1.134	0.08841	1.785
Summary		***	***	ns	**	**	*	ns

Table 3: Unpaired t-test of parameters Between the Groups

UNPAIRED T-TEST- Between the Groups (Calculated by AT mean)							
Parameters	**ESR**	**TLC**	**DLC-N**	**DLC-E**	**DLC-L**	**DLC-M**	**WEIGHT**
P- value	0.4996	0.0307	0.9007	0.4581	0.9200	0.7790	0.6754
T- value	0.6794	2.215	0.1254	0.7470	0.1333	0.2819	0.4208
Summary	ns	***	ns	ns	ns	ns	ns

ESR Results

In the present study, when we compare the ESR within the groups before and after the treatment, significant results are seen i.e., the P value of Group A & Group B is < 0.0001. However, when we compare between the groups after treatment by using unpaired t-test, statistically significant results are not seen (P value= 0.4996).

TLC Results

In TLC, within and between the groups, before and after the treatment, significant results are seen. Within the groups, P value of Group A & Group B is < 0.0001. It shows the P value= 0.03 between the groups which is statistically significant.

DLC-Neutrophils Results

In Neutrophils results, there are no statistically significant results seen in between the groups and within the groups.

DLC-Eosinophils Results

When we compare the Eosinophil in between the groups before and after the treatment, significant results are seen. P value Group A= 0.0007 & Group B < 0.0001.

DLC- Lymphocytes Results

Both are significant within the groups. P value of Group A= 0.0015 & Group B= 0.0721. When we compare between the groups it is seen statistically non-significant but clinically efficacious. P value= 0.9200.

DLC- Monocytes Results

Within the group, Group A don't show any significant results. P value= 0.7450. However, in Group B, an appreciable amount of significance is seen statistically. P value= 0.0299.

Weight Results

In any of the groups, there is no statistical results are seen either within the group or between the groups. (P value= 0.6754).

QOL Results

Table 4: Paired t-test of QOL Results within Group A

PAIRED T-TEST- Within the Groups		Group A				
WHO-QOL Domains		Total	Physical	Psychological	Social	Environmental
P- value		0.0224	0.0951	0.0332	0.1608	0.1340
T- value		2.412	1.725	2.236	1.439	1.542
Mean difference		-1.400	-0.3000	-0.5000	-0.06667	-0.1667
Mean	BT	91.10	24.53	19.43	8.433	31.27
	AT	92.50	24.83	19.93	8.500	31.43
Std. Deviation	BT	4.088	1.634	1.716	1.251	1.112
	AT	3.127	1.487	1.507	1.306	0.8584
Std. Error	BT	0.7464	0.2984	0.3132	0.2284	0.2030
	AT	0.5708	0.2716	0.2752	0.2385	0.1567
Summary		*	ns	*	ns	ns

Table 5: Paired t-test of QOL Results within Group B

PAIRED T-TEST- Within the Groups		Group B				
WHO-QOL Domains		Total	Physical	Psychological	Social	Environmental
P- value		<0.0001	0.0121	<0.0001	0.3256	0.0629
T- value		6.801	2.677	5.194	1.000	1.934
Mean difference		-4.767	-0.7667	-1.400	-0.06667	-0.4000
Mean	BT	87.80	23.57	19.23	9.767	29.83
	AT	92.57	24.33	20.63	9.833	30.23
Std. Deviation	BT	3.800	1.888	1.813	2.029	1.783
	AT	2.112	1.213	1.033	2.069	1.223
Std. Error	BT	0.6938	0.3447	0.3311	0.3704	0.3255
	AT	0.3856	0.2215	0.1887	0.3778	0.2233
Summary		***	*	***	ns	ns

Table 6: Unpaired t-test of QOL Results Between the Groups

UNPAIRED T-TEST- Between the Groups					
WHO-QOL Domains	Total	Physical	Psychological	Social	Environmental
P- value	0.9232	0.1590	0.0403	0.0042	< 0.0001
T- value	0.09677	1.427	2.098	2.984	1.200
Summary	ns	ns	*	**	***

Total QOL

Assessment of QOL before and after the treatment, reveals significant results towards Group B. P value of Group A is 0.0224 & Group B is < 0.0001.

Comparing between the groups shows no statistically significant result (P value= 0.9232). So, the Quality of life is enhanced in both the groups.

Physical domain: Within the group, significant result is seen in group B. (P value= 0.0121). Between the groups, no significant result was seen. (P value= 0.1590).

Psychological domain: It is a very important domain and significant results are seen within the group in both groups, more efficiently in group B (P value Group A= 0.0332 & Group B < 0.0001). In between the group, also it is seen as statistically significant. P Value= 0.0403.

Social domain: There are no statistically significant results seen within the groups, but by using unpaired t test, significance is seen between the groups. P value= 0.0042.

Environmental domain: There is no statistically significant results seen within the groups, but by using unpaired t test, significance is seen between the groups (P value < 0.0001). The WHO QOL-BREF scale was used to calculate quality of life in Healthy subjects.

Discussion

Seasonal fluctuation has an influence on health that goes beyond physical issues to include physiological changes, such as *Tridosha Prakopa* and *Agnimandya*, which are widespread in all *Ritus* (seasons), to pathological levels. (13) New stats suggest

that these variations in immunity contribute to seasonal alterations in illnesses. (14)

External environments significantly influence human behaviour, with exogenous and endogenous rhythms having specific phase relationships. Monsoon can disrupt Ayurveda's *doshas*, with summer being a season for celebration. However, *Varsha Ritu* can exaggerate *Vata dosha*, making it the aggravator of it. (15) There is specificity in the *Rasa* and *Ritu* relationship. By *Kaala-swabhava* only *Rasa, Bala-krama, snigdha* and *ruksha guna* gets manifested. In *Varsha ritu*, *Amla rasa* is very *snigdha* and potent. These characteristics of *Ritu* decide the regimen to be followed to maintain health and to prevent *Kaalaja* disorders.

The findings of this study corroborate the diagnostic utility of erythrocyte sedimentation rate (ESR) and total leucocyte count (TLC) in common infections such as fever, cough, and cold. Elevated ESR was observed consistently among participants with active inflammatory responses, affirming its role as a sensitive though nonspecific indicator of infection, as supported by StatPearls and other clinical reviews. (16,20) Similarly, fluctuations in TLC mirrored the immune system's responsiveness, in agreement with research demonstrating TLC's prognostic relevance in lower respiratory infections. (21)

Applying an Ayurvedic lens, the seasonal concept of Varsha Ritu, which signifies diminished vitality (Avara Bala), was linked to increased susceptibility to infection. This aligns with a randomized controlled trial of Rituharitaki—an Ayurvedic seasonal regimen—which showed statistically significant reductions in ESR, TLC, and incidence of respiratory symptoms during the monsoon ($p < 0.05$). (22) These results provide empirical validation of Ayurveda's traditional assertions regarding immune modulation in monsoon seasons.

Assessment of quality-of-life domains revealed that while physical health scores were high, environmental domain scores remained relatively low—a finding consistent with studies underscoring the persistent influence of sanitation, air quality, and infrastructure on overall health. (23) The author contends that these findings substantiate a holistic evaluation model that synthesizes biomedical parameters with socio-environmental determinants, thus providing a comprehensive framework for seasonal public health strategies.

The WHO Quality of Life-BREF is a psychometric tool designed to assess an individual's quality of life in clinical settings. It comprises 26 items across four domains: Physical Health, Psychological Health, Social Relationships, and Environment, and includes two global items assessing overall health. The WHOQOL-BREF is a clinical tool used to assess the impact of chronic illnesses, mental health conditions, or disabilities on a patient's quality of life, providing quantitative data for therapeutic decisions and ensuring its cross-cultural applicability across diverse patient populations. The scale's focus on subjective well-being aligns with holistic models of care, recognizing that health is not merely the absence of disease but encompasses physical, psychological, social, and environmental dimensions. In mental health, it is particularly valuable for assessing improvements in depression or anxiety treatment. Similarly, in palliative care, it helps evaluate interventions aiming to improve comfort and emotional well-being. The WHOQOL-BREF is an indispensable instrument for clinical practitioners and researchers seeking to enhance patient care and measure the broader impacts of health conditions on daily life. (14) Moderate satisfaction with the environment increases psychological QOL, partly due to non-smoking habits.

The *Varsha Ritu* in India is associated with respiratory problems and infectious diseases. *Rasayana* medications can slow down the ageing process and help people become more resistant to illness. (17) The *Rasayana* boosts immunity according to *Acharya Sharangadhara*. (18) *Samshamani vati* is categorized as a *Rasayana*, (19) it is a single medication formulation containing *Guduchi* in it. *Rituharitaki* is the seasonal usage of *Haritaki* with different *Prakshepas* (vehicles), i.e., *Vasanta* (Spring)-*Madhu* (Honey), *Grishma* (Summer)-*Guda* (Jaggery), *Varsha* (Rainy)-*Saindhava Lavana* (Rock salt), *Sharad* (Autumn)- *Sharkara* (Sugar), *Hemanta* (Early Winter)-*Shunti* (Dry ginger powder), *Shishira* (Late Winter)-*Pippali* (Long pepper) and the action is said to be as *Swasthasya Urjaskaram* (health promoting). *Haritaki* with its *tri-dosha shamana, agni-vardhana* and *rasayana* action might have reduced the incidence of common cold, cough and fever in the trial group compared to the control group. *Haritaki* is known for its properties such as *lavana rahit pancha rasa, kashya rasa pradhan, laghu* and *rukhsha* in *guna, madhura* in *vipaka*, and *ushna* in *veerya*. This formulation aids in sustaining health and increasing lifespan.

In Ayurveda, mental and physical health varies according to environmental changes, so individuals may need a distinct diet, medications, and adjuvants in different seasons to reap maximum health benefits. In the *Varsha Rutu*, *Haritaki* is mixed with *Saindhava* (rock salt), which is also *tridosha-shamaka* and *Agni-vardhaka* to cure fever, cold, flu, strep throat, and other maladies. The results obtained in the trial group may be due to the combined effect of these two drugs. An illness may begin due to a *vata, pitta,* and *kapha* imbalance at the cellular level. A key factor in preserving this homeostasis is *Rasayana*. (15)

Conclusion

The effect of *Samshamani vati* over *Ritu-haritaki prayoga* on WHO Quality of life BREF and haematological parameters in *Varsha Ritu* in the participants was found with a clinically significant P value of total QOL score. The monitoring of the incidence of diseases in *Varsha Ritu* in both groups was found to be significant. The study found that the environmental domain had the highest mean scores, followed by the psychological, and lastly, the social domain had the lowest QOL index. Changes in the

haematological parameters (TLC, DC, ESR) within the normal limits imply that the intervention has improved overall health, which is also conclusive. *Samshamani vati* effectively reduces the common cold and cough during *Varsha Ritu.* This study aims to identify an affordable, palliative illness prevention strategy during monsoon season, highlighting the dynamic nature of *Doshas.*

Limitation

Rapid seasonal variations disrupt the perfect seasonal patterns to give a note of which *ritu* is going on.

Scope for Further Studies

A similar study can be conducted in the same *Ritu* with a study of specific biomarkers, in different *Ritus*, or with different immunological drugs in the same *Ritu.*

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Conflicts of Interest: There are no conflicts of interest.
CTRI no. – CTRI/2022/10/046856

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