Clinical Evaluation of Sukumara Ghritam and Brahmi Churnam in the Management of Menopausal Syndrome: A Prospective Open-Label Study

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ABSTRACT

Introduction: Menopause (Rajonivritti) is one of the most significant events in a woman’s life and brings a lot of physiological changes that affect the life of a woman permanently. Ayurveda consider it as a normal physiological process and hence have not included it as a gynecological disorder.

Objective: To evaluate the clinical efficacy and safety of Sukumara Ghritam and Brahmi Churnam in the management of menopausal syndrome in women.

Materials and methods: This trial was a single-center, single arm study conducted on 49 women aged between 40 years and 55 years having amenorrhea ≥12 months; Kupperman menopausal index score ≥15; follicle-stimulating hormone (FSH) level ≥20 IU/L; and endometrial thickness ≤5 mm. Ayurvedic classical formulations, Sukumara Ghritam (6 g) 1 hour before food and Brahmi Churnam (3 g) after food were administered orally twice a day with lukewarm water for 84 days, and subsequent 28 days follow-up was without intervention. Outcome, i.e., changes in the score of menopause rating scale (MRS) and improvement in the quality of life using menopause-specific quality of life (MENQOL) questionnaire, were assessed at baseline, 84th day, and 112th day. Paired sample t test was used to compare mean change from baseline to 84th day and 112th day. p value < 0.05 was considered significant.

Results: The results reveal that the effect of therapy in decreasing MRS total score was statistically significant (p value < 0.001). The mean score at the baseline was 7.14 (7.47), at 84th day 4.55 (2.67), and 3.33 (2.53) at 112th day (follow-up period without trial interventions). The improvements in MENQOL in four domains, namely, vasomotor, psychosocial, sexual, and physical, were also significant (p value < 0.001) at 84th day and 112th day in comparison to the baseline. All the safety laboratory parameters such as liver and renal function tests remained within the normal limits throughout the trial period, and no adverse events/adverse drug reaction were reported.

Conclusion: Sukumara Ghritam and Brahmi Churnam are found to be safe and effective in the management of menopausal syndrome.

Keywords: Artavakshaya, Brahmi Churnam, Menopausal syndrome, Rajonivritti, Sukumara Ghritam.

INTRODUCTION

India has a large population, which has already crossed 1 billion mark with 71 million people over 60 years of age, and the number of menopausal women about 43 million.1 Menopausal symptoms affect about 70% of the women approaching menopause. Menopause is the permanent cessation of menstruation for more than 12 months resulting in the loss of ovarian follicle development. The age at menopause appears to be genetically determined. Average age of menopause is 47 years in Indian women with an average life expectancy of 71 years.1 As per Indian Menopause Society, average age of menopause is around 48 years, but Indian women could attain menopause at the ages of 30–35 years.2 Different stages, i.e., peri-menopause, menopause, and post-menopause, comprise a half or a third of a woman’s life.3 It is characterized by an altered hormonal status and a subsequent decrease in quality of life, affecting each woman differently. During the menopausal transition, estrogen levels decline and levels of follicle-stimulating hormone (FSH) and luteinizing hormone (LH) increase. Specifically, the decline and eventual cessation of estrogen production are associated with the appearance of uncomfortable symptoms like hot flushes, night sweats, breast tenderness, vaginal dryness, irregular menses, mood changes, and urogenital atrophy as well as pathologies, such as osteoporosis, heart disease, hypercholesterolemia, endothelial dysfunction, vascular inflammation, hyperglycemia, sleep disturbances, depression, and sexual dysfunction.4 Clinical studies indicate that the use of hormone replacement therapy (HRT) in menopause needs to be carefully assessed, and risks and benefits of the therapy should be evaluated by the clinician for each individual woman. Herbal preparations, food supplements, healthy living, and healthy mental
status were mentioned as possible alternatives for management of menopausal symptoms.

In Ayurveda, Rajonivritti Kala (the period of permanent cessation of menstrual cycle) is considered as 50 years. It is a consequence of Jara-Awastha (senility) and Vata remains dominant during this period. Menopausal syndrome vis-à-vis Rajonivritti Lakshana is a Jarakaleena Vyadhi (geriatric disorders) as per Ayurveda. Rajokshaya is the main phenomenon of this syndrome. In Ayurveda, Rasayana (rejuvenation) therapy is indicated for Jarakaleena Vyadhi (old age diseases), and it gives Prashrasta Dhatu (excellence to tissues) and hence improves the status of Rajodhatu. Rasayana therapy also is adopted in this study to relieve the psycho-neurotic symptoms like insomnia, anxiety, irritability, and depression. The drugs Sukumara Ghritam and Brahmi Churnam were selected in this study for their Rasayana effect after thorough review of literature.

OBJECTIVES
The primary objective was to assess the clinical efficacy of Sukumara Ghritam and Brahmi Churnam in the management of menopausal syndrome, and secondary objectives were to assess the clinical safety and changes in the quality of life of the women with menopausal syndrome.

MATERIALS AND METHODS
Study Design and Setting
This was a single-center, single-arm study conducted per the existing guidelines of Good Clinical Practices (GCP) of India and Declaration of Helsinki. The study was approved by the Institutional Ethics Committee (IEC), and the study was also registered in Clinical Trial Registry of India (CTRI/2017/11/010312). The study participants were recruited from the OPD of Dr Achanta Lakshmi Research Centre for Ayurveda (ALRCA), Chennai, Tamil Nadu. A total of 50 menopausal women were recruited for the trial after obtaining written informed consent. Patients were selected in accordance with inclusion and exclusion criteria mentioned in the protocol.

Inclusion Criteria
Women between the age of 40 and 55 years; with amenorrhea for ≥12 months; Kupperman menopausal index score ≥15; levels of FSH ≥20 IU/L; endometrial thickness ≤5 mm; and who were willing to provide signed informed consent to participate in the trial were included in the study.

Exclusion Criteria
Women with evidence of malignancy, who had surgical menopause, or those who were diagnosed with mental illness were excluded. Moreover, women suffering from systemic diseases such as diabetes mellitus (DM) with HbA1c >8.0%, hypertension, rheumatoid arthritis (RA), coronary heart disease (CHD), with concurrent serious hepatic disorder (defined as aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT), total bilirubin, alkaline phosphatase (ALP) >2 times upper normal limit) or renal disorders (defined as serum creatinine >1.2 mg/dL), chronic obstructive pulmonary disease (COPD), hypothyroidism, and any other major illness were also excluded from the study. The women on prolonged (>6 weeks) medication with corticosteroids, antidepressants, anticholinergics, or any other drugs that may have an influence on the outcome of the study; alcoholics and/or drug abusers; and those who had participated in any other clinical trial in the past 6 months of screening were also excluded.

Withdrawal Criteria
If the participant became ineligible to continue in the study or developed any serious adverse effect (necessitating hospitalization) or noncompliance of the treatment regimen (minimum 80% compliance is essential to analyze the data) were withdrawn from the trial. The participants were free to withdraw anytime from the study. Further, those who were not formally withdrawn from the study but cease to take medicine and came for examination were also withdrawn from the study.

Outcome Measures
The primary outcome measure was change in menopausal symptoms using menopausal rating scale (MRS) score was assessed at the baseline, at 84th day (last day of treatment), and 112th day of follow-up (without any interventions). The MRS has 11 symptoms, and each was rated on a 5-point scale of severity. It is also divided into three subscales: somatic, psychological, and urogenital.

The secondary outcome measures were clinical safety and changes in the quality of life (QoL) of the study participants from the baseline and assessed at the end of 84th day and at the end of 112th day follow-up by using MENQOL questionnaire. It contains 29 items with four domains: vasomotor, psychosocial, physical, and sexual scores that range from 0 to 6. Lower scores that indicate better quality of life.

Study Interventions
Sukumara Ghritam and Brahmi Churnam the trial formulations were procured from Good Manufacturing Practice (GMP)-certified Indian Medicines Pharmaceutical Corporation Ltd. (IMPCL), Mohan, Uttarakhand, India, with the Certificate of Analysis complying to the standards laid in Ayurvedic Pharmacopoeia of India (API). All the safety parameters like heavy metals, pesticide residue, and aflatoxin were within the permissible limit. Sukumara Ghritam (Mfg. Date: May 2017; Batch no.: AYU-01) was administered orally in a dose of 6 g twice a day with warm water 1 hour before food. Brahmi Churnam (Mfg. Date: November 2016; Batch No.: 04) was administered 3 g orally twice a day with lukewarm water after food. These treatment schedules were continued for 84 days followed by subsequent 28 days follow-up without any trial intervention to observe the impact on the participants after medicine is withdrawn.

Laboratory Investigations
Hematological investigations, lipid profile, thyroid profile, blood sugar, liver function tests, kidney function tests and urine tests, hormonal assay like FSH, LH, and estradiol were carried out at baseline and after the treatment period. PAP smear test was carried out in all participants to exclude malignancy and ultrasonography of abdomen and pelvis to find out any organ and reproductive abnormalities at baseline.

Statistical Analysis
The efficacy and safety parameters were analyzed according to the intention-to-treat analysis. Missing values were imputed by the Last Observation Carry Forward (LOCF) technique. Statistical analysis was performed using Statistical Packages for Social Sciences version 15.0. Statistical significance was defined as p value < 0.05. Primary and secondary outcome measures: changes in the scores of MRS
and MENQOL questionnaire from the baseline to follow-up at the end of 112th day were analyzed by using paired t-test.

**Study Procedure**

On the enrollment day at baseline (visit 1), patients' demographic profile, medical history, general physical and systemic examination, assessment of clinical/Ayurvedic parameters, and scoring of menopause rating scale (MRS) and menopause-specific quality of life (MENQOL) questionnaire were recorded. Trial drugs and drug compliance report form was also given to the participants, and the subsequent visits were planned at an interval of 02 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). Participants were assessed and study medications were given at each subsequent visit till 84th day. In addition to the 84-day intervention period, a without intervention follow-up at 112th day was also scheduled. The details of study procedure at each visit is given in Flowchart 1.

Data of all the participants were recorded in predesigned case report forms (CRFs) and were also entered in 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 scorings and laboratory investigation reports of each participant were sent to the CCRAS headquarters on a weekly basis for the purpose of clinical trial monitoring.

**Observations**

Out of the total 50 research participants enrolled in the study, 6 dropped out during the course of the study for various reasons like health issues of family members, due to unavoidable domestic issues, and issues related with palatability. Intention-to-treat analysis was done, and the data of all those participants who have completed at least 14th day visit were imputed by LOCF technique. Participants who dropped out after baseline visit only were excluded from the analysis. Hence, data of a total 49 participants were used for statistical analysis (Flowchart 2).

**Demographic Profile of Study Participants**

Out of 50 participants, maximum participants, 32 (65.3%), were in the age group of 51–55 years, 38 (77.6%) of the participants were married; 32 (65.3%) were housewives; and 37 (75.5%) were literate enough to read and write. Under socioeconomic status, 38 (77.6%) were below poverty line and 11 (22.4%) were above poverty line; 35 (71.4%) were residing in urban area; addiction to tobacco chewing were observed in 04 (8.2%); and 32 (65.3%) participants reported sleep disturbances (Table 1).

**Results**

**Effect of the Trial Interventions on MRS Score**

At baseline, the mean MRS total score was 7.14 which was reduced to 4.55 at the end of 84th day and to 3.33 at the end of 112th day. The trial interventions on MRS total score have shown statistically significant effect ($p$ value $< 0.001$).

The test formulations also showed statistically significant ($p$ value $< 0.001$) improvement in all three MRS subscale scores (somatic, psychological, and urogenital symptoms) at all time intervals when compared to their respective baseline score. In somatic subscale, at baseline the Mean score was 6.61 and at 84th day it reduced to 2.06; the mean psychological subscale scores at baseline was 6.57 which was reduced to 1.57 at 84th day and
urogenital subscales score at base line was 2.53 and on 84th day was 0.92 (Table 2).

**Effects of Trial Drugs on Total MENQOL Score and on its Different Domains**

A statistical significant reduction in different domains of MENQOL scores, i.e. vasomotor ($p$ value $< 0.001$), psychosocial ($p$ value $< 0.001$), physical ($p$ value $< 0.001$), and sexual scores ($p$ value $< 0.001$), was observed after the treatment of 84 days and also at the end of 112 day in comparison to the baseline. Further, in vasomotor domain, the mean reduction in the symptoms at 84th day was 0.71 and at the end of 112th day was 0.39 in comparison to baseline score, i.e. 2.63; on psychosocial domain, the reduction in the symptoms at the end of 84 days was 3.18 in comparison with baseline score, i.e., 9.9. Similarly, in physical domain, the reduction in the symptoms at the end of 84 days was 7.29 and at the end of 112 day was 5.22 in comparison to baseline, i.e. 22.2. In sexual domain, the reduction of symptoms from baseline score was 2.22 to 1.29 at the end of 84 days and 0.94 at the end of 112 days (Table 3).

**Effect of the Trial Interventions on Vital Parameters**

The value of vital parameters at baseline and each follow-up have been depicted at Table 4. Statistically significant decrease was observed in weight ($p$ value $< 0.05$) at 84th and 112th day in comparison to baseline. Whereas in systolic blood pressure, statistically significant decrease ($p$ value $< 0.05$) was noted after 112th day. The changes observed in all the parameters were within physiological limit at each follow-up. It is observed that there is no adverse effect of the drug on these parameters.

**Effect of the Interventions on Hormonal Parameters**

The effect of the trial interventions on hormonal parameters has been depicted in Table 5 and found that there is no significant change ($p$ value $> 0.05$) observed after the completion of treatment period when compared with baseline in serum FSH, LH and estradiol.

**Effect of the Interventions on Laboratory Parameters for Safety Evaluation**

The effect of these treatments on hematological parameters, liver function tests, and renal function tests was assessed at baseline and at 84th day. Despite the intervention (*Sukumara Ghritam*) being a Ghee base, even after 84th day the cholesterol levels were within normal limits. This result can be interpreted that medicated Ghrita can be used safely in patients for a longer period without fear of dyslipidemia. The values of all the laboratory parameters were within range during the entire period (Tables 6 and 7). These observations validate that these classical drugs are safe for human use. Further, no adverse drug effect or adverse events were also reported during the treatment period.
Clinical Evaluation of Sukumara Ghritam and Brahmi Churnam in the Management of Menopausal Syndrome

Menopause is a natural process in women’s life and is signaled by cessation of normal cyclic ovarian activity resulting in permanent amenorrhea. Due to onset of menopause, majority of gynecological and systemic diseases occur because of deficiency of hormones, especially estrogen and Progesterone. The menopausal age in Indian women is approximately 4–5 years lower than Western women.13

The early symptoms of menopause due to continuous diminution of hormones and ovarian estrogen deficiency include sweating, hot flushes, sleep disorders, menstrual disorders, and mental changes.14 Late consequences of menopause are cardiovascular diseases, urogenital atrophic changes and related sexual dysfunctions, musculo-articular complaints, and osteoporosis.

Rajonivritti is not described separately as a pathological condition or severe health problem in Ayurvedic classics. The ancient Acharya’s termed it as a normal physiology. It occurs due to Kshaya of Artava which is the Upadatu of Rasa Dhathu and Kshaya of Artava manifest as cessation of menstruation. Due to aging process, properties of Vata increases in the body and manifests various symptoms that are classified as menopausal symptoms, such as joint pain, hot flushes, night sweats, mood swings, sleeplessness, weakness, giddiness, loss of sexual desire, etc.

The aim of this study was to assess the efficacy of trial interventions Sukumara Ghritam and Brahmi Churnam in a combination on various signs and symptoms of menopausal syndrome and assessed by using MRS. The result shows significant efficacy of these interventions to reduce the total MRS score as well as the score of three subscales in study participants. Further, there was significant improvement in all the domains of MENQOL scales at the end of 84 days treatment in comparison to initial values. The trial interventions decreased the FSH level to a minimal level while

**Table 2: Effect of trial drugs on MRS score (n=49)**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Baseline</th>
<th>84th day</th>
<th>t value</th>
<th>p value</th>
<th>Baseline</th>
<th>112nd day</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatic sub scale</td>
<td>6.61 (1.94)</td>
<td>2.06 (1.38)</td>
<td>17.66</td>
<td>&lt;0.001</td>
<td>1.49 (1.16)</td>
<td>18.76</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Psychological sub scale</td>
<td>6.57 (3.05)</td>
<td>1.57 (1.32)</td>
<td>14.14</td>
<td>&lt;0.001</td>
<td>1.16 (1.16)</td>
<td>14.27</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Urogenital subscale</td>
<td>2.53 (2.001)</td>
<td>0.92 (1.27)</td>
<td>7.03</td>
<td>&lt;0.001</td>
<td>0.67 (1.44)</td>
<td>7.40</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Total MRS score</td>
<td>7.14 (7.47)</td>
<td>4.55 (2.67)</td>
<td>2.56</td>
<td>0.014</td>
<td>3.33 (2.53)</td>
<td>3.77</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

Values are expressed as mean (SD)

**Table 3: Effect of trial drugs on MENQOL score (n = 49)**

<table>
<thead>
<tr>
<th>Domains</th>
<th>Baseline</th>
<th>84th day</th>
<th>t value</th>
<th>p value</th>
<th>Baseline</th>
<th>112nd day</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vasomotor</td>
<td>2.63 (2.49)</td>
<td>0.71 (1.04)</td>
<td>5.71</td>
<td>&lt;0.001</td>
<td>1.24 (7.9)</td>
<td>6.45</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Psychological</td>
<td>9.9 (5.61)</td>
<td>3.18 (3.2)</td>
<td>9.59</td>
<td>&lt;0.001</td>
<td>2.24 (2.67)</td>
<td>9.89</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td>22.2 (9.39)</td>
<td>7.29 (5.65)</td>
<td>11.22</td>
<td>&lt;0.001</td>
<td>5.22 (5.29)</td>
<td>11.59</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Sexual</td>
<td>2.22 (2.82)</td>
<td>1.29 (2.28)</td>
<td>3.42</td>
<td>&lt;0.001</td>
<td>0.94 (2.18)</td>
<td>4.26</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

Values are expressed as mean (SD)

**Table 4: Effect of trial drugs on vital parameters (n = 49)**

<table>
<thead>
<tr>
<th>Vital parameters</th>
<th>Baseline</th>
<th>84th day</th>
<th>t value</th>
<th>p value</th>
<th>Baseline</th>
<th>112nd day</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>60.06 (11.13)</td>
<td>59.45 (10.72)</td>
<td>3.03</td>
<td>0.004</td>
<td>59.34 (10.7)</td>
<td>3.55</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>Blood pressure: systolic (mm Hg)</td>
<td>123.1 (15.01)</td>
<td>121.43 (15.14)</td>
<td>1.18</td>
<td>0.24</td>
<td>118.37 (14.2)</td>
<td>2.90</td>
<td>0.006</td>
<td></td>
</tr>
<tr>
<td>Blood pressure: diastolic (mm Hg)</td>
<td>78.9 (8.72)</td>
<td>77.55 (9.02)</td>
<td>0.808</td>
<td>0.42</td>
<td>77.55 (9.02)</td>
<td>1.01</td>
<td>0.316</td>
<td></td>
</tr>
</tbody>
</table>

Values are expressed as mean (SD)

**Table 5: Effect of trial drugs on serum hormones (n = 49)**

<table>
<thead>
<tr>
<th>Hormonal assay</th>
<th>Baseline</th>
<th>84th day</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSH</td>
<td>74.89 (29.8)</td>
<td>73.6 (28.8)</td>
<td>0.89</td>
<td>0.38</td>
</tr>
<tr>
<td>LH</td>
<td>37.7 (13.6)</td>
<td>38.38 (12.6)</td>
<td>0.68</td>
<td>0.55</td>
</tr>
<tr>
<td>Estradiol</td>
<td>21.05 (31.1)</td>
<td>28.87 (85.8)</td>
<td>0.98</td>
<td>0.33</td>
</tr>
</tbody>
</table>

Values are expressed as mean (SD)

**Table 6: Effect of trial drugs on safety parameters (n = 49)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>84th day</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood urea (mg/dL)</td>
<td>21.74 (6.72)</td>
<td>20.34 (5.69)</td>
<td>1.99</td>
<td>0.05</td>
</tr>
<tr>
<td>Serum uric acid (mg/dL)</td>
<td>4.33 (1.04)</td>
<td>4.45 (1.2)</td>
<td>1.52</td>
<td>0.13</td>
</tr>
<tr>
<td>Serum creatinine (mg/dL)</td>
<td>0.64 (0.13)</td>
<td>0.62 (0.16)</td>
<td>0.72</td>
<td>0.47</td>
</tr>
<tr>
<td>SGOT (IU/L)</td>
<td>25.33 (9.87)</td>
<td>24.8 (7.78)</td>
<td>0.61</td>
<td>0.54</td>
</tr>
<tr>
<td>SGPT (IU/L)</td>
<td>22.5 (12.65)</td>
<td>22.1 (10.17)</td>
<td>0.35</td>
<td>0.73</td>
</tr>
<tr>
<td>Total protein (g/dL)</td>
<td>7.3 (0.4)</td>
<td>7.22 (0.6)</td>
<td>0.97</td>
<td>0.34</td>
</tr>
<tr>
<td>Serum albumin (g/dL)</td>
<td>4.22 (0.24)</td>
<td>4.18 (0.39)</td>
<td>0.850</td>
<td>0.4</td>
</tr>
<tr>
<td>Serum globulin (g/dL)</td>
<td>3.06 (0.38)</td>
<td>3.03 (0.38)</td>
<td>0.581</td>
<td>0.56</td>
</tr>
<tr>
<td>Conjugated bilirubin (mg/dL)</td>
<td>0.17 (0.1)</td>
<td>0.15 (0.1)</td>
<td>2.21</td>
<td>0.03</td>
</tr>
<tr>
<td>Unconjugated bilirubin (mg/dL)</td>
<td>0.36 (0.2)</td>
<td>0.39 (0.21)</td>
<td>1.47</td>
<td>0.15</td>
</tr>
<tr>
<td>Serum alkaline phosphatase (U/L)</td>
<td>90.6 (27.3)</td>
<td>85.9 (31.74)</td>
<td>1.8</td>
<td>0.29</td>
</tr>
</tbody>
</table>

Values are expressed as mean (SD); SGOT, serum glutamic oxaloacetic transaminase; SGPT, serum glutamic pyruvic transaminase

**DISCUSSION**

Menopause is a natural process in women’s life and is signaled by cessation of normal cyclic ovarian activity resulting in permanent amenorrhea. Due to onset of menopause, majority of gynecological and systemic diseases occur because of deficiency of hormones, especially estrogen and Progesterone. The menopausal age in Indian women is approximately 4–5 years lower than Western women.13

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The aim of this study was to assess the efficacy of trial interventions Sukumara Ghritam and Brahmi Churnam in a combination on various signs and symptoms of menopausal syndrome and assessed by using MRS. The result shows significant efficacy of these interventions to reduce the total MRS score as well as the score of three subscales in study participants. Further, there was significant improvement in all the domains of MENQOL scales at the end of 84 days treatment in comparison to initial values. The trial interventions decreased the FSH level to a minimal level while
showing insignificant increase in estradiol content as compared with the baseline values.

Oxidative stress plays an integral part of the aging process and results from the overproduction of free radicals, which overwhelm the body’s antioxidant defense mechanisms. The decline in antioxidant level combined with a gradual loss of estrogens in the female body is highly associated with the various sequel of menopausal syndrome.15,16

Sukumara Ghritam is indicated in Vibandha (constipation), Udara Roga (diseases of abdomen/enlargement of abdomen), Gulma (abdominal lump), Pleeha Roga (spleen disease), Vidradhi (abscess), Shopha (oedema), Yonishula (pain in female genital tract), Arsha (haemorrhoids), Vridhi (hydrocele), Vatavyadhi (diseases due to Vata Dosha), Vatarakta (gout) and also as a drug for Snehapana (oleation therapy) in Purvakarma (preceding procedure) for Shodhana Karma. Sukumara Ghritam is one of the examples for Yamaka (combination of two Sneha) type of Sneha which contains Ghrita (ghee) and Eranda Taila (castor oil) as ingredients.

The ingredients of Sukumara Ghrita, such as Shatavari (Asparagus racemosus Willd.) and Punarnava (Boerhavia diffusa L.), might act as phyto-estrogen and help in relieving the menopausal symptoms. The ingredients like Dashamoola and Aswagandha (Withania somnifera (L.) Dunal) and Eranda Taila (seed oil of Ricinus communis L.) have best Vata-Shamana property that might be helpful in relieving inflammation, pain, and other associated symptoms during menopause. In an experimental study on Kantakari (Solotum xanthocarpum) Schrad. & H. Wendl., which is one of the ingredient of Dashamoola, in ovarectomized rats showed increase in estradiol level and uterine weight and also improved bone strength and density. Further, it contains Trinapanchamoola like Darbha (Desmostachya bipinnta (L.) Staff), Kusha (Imperata cylindrica (L.) Rauesch.), Sara (Saccharum munja Roxb.), Ikshu (Saccharum officinarum L.), Kasha (Saccharum spontaneum L.) which are Mootrala (diuretic); helps in checking physiological edema; and helps in reducing water retention which occurs during menopausal period due to hormonal imbalance. Drugs like Khseera Kakoli (Lilium polyphylum D.Don.), Ashwagandha, Shatavari, Durgda (milk), Guda (jaggery) have Brimhana property and thus provide nutrition.

Punarnava, Gokshura (Tribulus terrestris L.) also prevents urinary tract infection that is common in this phase. Being Ghrita based intervention it is Pittashamaka (pacifying Pitta) so useful to treat hot flushes. Due to presence of Erand Taila and Goghritha in Sukumara Ghritam, Anulomana of Apanata is maintained as the vitiation of Apana is the major cause for menopausal disturbances that occur in menopause. Looking to its Rasayana (rejuvenation) property, it helps in nourishing the Rasa, Rakta like Pooorvadhatu, Asthi like Uttoratara Dhatus and helps in preventing Asthisoshas (Osteoporosis) and act as rejuvenator. Brahmi (Bacopa monnieri (L.) Wettst.) Churna has Medhya property and is indicated in Manasavikara and is useful in reducing anxiety, insomnia, etc. As these drugs have nootropic activity it is useful for managing the psychological disturbances during the menopause.

Further, it is observed that all the trial interventions were clinically safe to use as no significant changes were seen in any of the safety parameters, i.e., kidney function and liver function. No adverse drug reaction (ADR) or events were also reported during the treatment period. Hence, it is suggested that Sukumara Ghritam and Brahmi Churnam are clinically safe to use.

**CONCLUSION**

From the present study, it is concluded that Sukumara Ghritam and Brahmi Churnam are effective in the treatment of menopause-associated symptoms and promoting the quality of life of menopausal woman while being safe for use. Hence, these Ayurvedic formulations can be used effectively and safely for the management of menopausal syndrome. Further, it is suggested that a Randomized Clinical Trial (RCT) may be conducted to corroborate the result of this study.

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Clinical Evaluation of Sukumara Ghritam and Brahmi Churnam in the Management of Menopausal Syndrome

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मेनोपोजल सिंड्रोम के उपचार में सुकुमार घूट और ब्राह्मी चूर्ण का नैदानिक मूल्यांकन:
एक प्रोस्पेक्टिव ओपन लेबल अध्ययन

कांचेरला प्रमीला देवी, सारदा ओटा, श्रीनिवास पिटटा, राकेश राणा, रिचा सिंघल, भगवान सहाय शर्मा,
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भूमिका: मेनोपोजल (रजोनिवृति) महिला के जीवन की एक बहुत महत्वपूर्ण घटना है और इसके कारण बहुत से शारीरिक परिवर्तन होते हैं जो महिला के जीवन को स्थायी रूप से प्रभावित करते हैं। आयुर्विद इसे एक सामान्य शारीरिक क्रिया समझता है। अतः, इसमें इसके किसी भी लक्षण का बदला नहीं किया गया है।

लक्षण: महिला में मेनोपोजल सिंड्रोम के उपचार में सुकुमार घूट और ब्राह्मी चूर्ण की प्रभाव-कारता और सुधा का नैदानिक मूल्यांकन करना।

सामग्री और पद्धति: यह एक कंट्रोल, सिंगल आर्म अध्ययन है। जिन महिलाओं का मासिक वजन 12 या उससे अधिक मात्र से बंद हो गया है, कुपेमन मेनोपोजल इंडेक्स स्कोर ≥15, एफएसएफ ≥20 आईयूएल व एंडोमेट्रियल थिक्सस ≤ 5 मिमी तथा जिनकी आयु 40 से 55 वर्ष की बीच थी ऐसे 49 महिलाओं चयन किया गया। पारंपरिक आयुर्विदिक चिकित्सा योग, जैसे की सुकुमार घूट - 6 घंटे भोजन से एक घंटे पहले और ब्राह्मी चूर्ण - 3 घंटे भोजन उपरान्त दिन में दो बार गुणगुण नाटक के साथ 84 दिनों के लिये दिये गये और इसके बाद 28 दिनों तक बिना किसी औषधियाँ के फोलोअप किया गया। मेनोपोजल रिटेंशन फंड (एमआरएफ) में बदलाव, मेनोपोजल बिशिष्ट जीवन गुणवत्ता (एमआरबीएम) प्रशासकी में सुधा का मूल्यांकन वेसलाईन, 84 वें दिन और 112 वें दिन (बिना औषधि के परिक्षन/फोलो-अप अवधि) पर परिणाम मूल्यांकन हेतु किया गया। औसतम परिवर्तन की तुलना करने हेतु स्रोत पेयकूल टेस्ट का उपयोग किया गया।

परिणाम: प्रस्तुत अध्ययन से यह ज्ञात होता है कि एमआरएफ कुल स्कोर को कम करने में आयुर्विदिक योग चिकित्सा का प्रभाव सादृश्यकारी रूप से महत्वपूर्ण है (p < 0.001)। वेसलाईन का औसत स्कोर 84वें दिन 7.14 (7.47) और 112वें दिन पर 3.33 (2.53) रहा। वेसलाईन की तुलना में 84वें दिन और 112वें दिन एमआरबीएम के चारों क्षेत्रों या वासोमेटर, साइकोसेल, सेक्रसेल और फिजिकल में भी महत्वपूर्ण सुधार पाया गया। परीक्षण अवधि के दौरान सभी सुधा प्रकोष्ठ शासन ग्रामपंचात अधिक और रितल फंक्शन टेस्ट सामान्य सीमा में रहे और औषधि प्रतिक्रिया का कोई प्रतिकूल प्रभाव रिपोर्ट नहीं किया गया।

निष्कर्ष: मेनोपोजल सिंड्रोम के उपचार में सुकुमार घूट और ब्राह्मी चूर्ण सुरक्षित और प्रभावीकारी पाए गए।