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The Effect of Isoflavones in Iraqi Postmenopausal Women

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ABSTRACT

Background: Isoflavones are plant-derived phytoestrogens that have garnered interest for their potential to alleviate menopausal symptoms through mild estrogenic activity. This study aimed to evaluate the clinical effects of isoflavone supplementation in postmenopausal women over a six-month period. **Methods:** A single-arm, prospective interventional study was conducted involving 60 postmenopausal women, of whom 53 completed the trial. Participants received a daily dose of *Active-Meno*®, a supplement containing 50 mg of soy isoflavones along with additional micronutrients. Menopausal symptoms were assessed using the validated Menopause Rating Scale (MRS), and serum estradiol and progesterone levels were measured at baseline and after six months. **Results:** Isoflavone supplementation led to a significant reduction in total MRS scores (from 20.8 ± 4.6 to 13.2 ± 3.9 ; $p < 0.001$), with improvements observed across somatic, psychological, and urogenital domains. Estradiol levels increased from 17.4 ± 5.2 pg/mL to 25.6 ± 6.1 pg/mL ($p < 0.01$), and progesterone levels rose from 0.3 ± 0.1 ng/mL to 0.5 ± 0.2 ng/mL ($p < 0.05$). No adverse events necessitated discontinuation, and the supplement was well tolerated. **Conclusion:** These findings support the potential of isoflavones as a safe and effective non-hormonal option for the management of menopausal symptoms.

Keywords: Isoflavones, Menopause, Estrogen, Progesterone, Iraqi women

INTRODUCTION

Isoflavones, naturally occurring compounds found in soy products and other plants, have garnered substantial attention for their potential health benefits, particularly in postmenopausal women. These phytoestrogens exert estrogen-like effects in the body, which can be especially beneficial when endogenous estrogen levels decline during menopause¹.

These phytoestrogens exhibit structural similarity to 17β -estradiol, allowing them to bind selectively to estrogen receptors, particularly estrogen receptor beta (ER- β). Through this interaction, isoflavones can exert weak estrogenic effects, which helps compensate for declining endogenous estrogen during menopause².

One of the most notable benefits of isoflavones is their potential to alleviate menopausal symptoms.

Studies have suggested that the consumption of isoflavones can reduce the frequency and severity of hot flashes, a common concern among postmenopausal women. This could be attributed to their ability to bind to estrogen receptors and mimic the effect of natural estrogen, thus helping to balance hormone levels³.

Isoflavones may also play a role in maintaining bone health. Postmenopausal women are at an increased risk of osteoporosis due to the decline in estrogen, which is crucial for bone density maintenance. Research indicates that isoflavones may help in reducing bone loss and improving bone mineral density, which can significantly lower the risk of fractures⁴.

Furthermore, isoflavones have been linked to cardiovascular health. They are known to improve lipid profiles by lowering LDL cholesterol and increasing HDL cholesterol levels. This is especially important for postmenopausal women who face a higher risk of cardiovascular diseases due to hormonal changes⁵.

In summary, the incorporation of isoflavones into the diet of postmenopausal women can offer a range of health benefits, including alleviation of menopausal symptoms, maintenance of bone health, and improvement in cardiovascular health. These effects make isoflavones a valuable dietary consideration for enhancing the quality of life in postmenopausal women⁶.

Despite promising evidence, current findings on isoflavones remain mixed due to differences in study design, participant characteristics, and dosing regimens. Furthermore, the long-term safety and hormonal impact of isoflavones are not yet fully established. To address this gap, the present study aims to investigate the clinical effects of isoflavones on menopausal symptoms and hormone levels in postmenopausal women through a six-month intervention, using both hormonal assays and the Menopause Rating Scale (MRS) to assess efficacy.

MATERIAL AND METHODS

Study Design

This study was designed as a single-arm, prospective interventional clinical trial aimed at evaluating the effects of isoflavone supplementation in 60 postmenopausal women over a period of six months. The primary focus was to assess changes in the severity of menopausal symptoms and hormonal levels following daily isoflavone intake. Participants served as their own controls, with baseline data compared to post-treatment results. The study was conducted at Dr. Reem M. Badea's Private clinic in AlAdhamiya neighbourhood, Baghdad.

Intervention: Isoflavone Supplementation

Participants were instructed to take one tablet daily of *Active-Meno*® (Doppelherz, Germany), a commercially available dietary supplement formulated for menopausal support. Each tablet contains 50 mg of soy isoflavones, in addition to other active ingredients

including 500 mg of calcium, 5 µg of vitamin D₃, 1.1 mg of vitamin B₁, 1.4 mg of vitamin B₂, 1.4 mg of vitamin B₆, 200 µg of folic acid, 1.25 µg of vitamin B₁₂, 150 µg of biotin, and 3 mg of hyaluronic acid. The supplement was administered orally once daily after a meal for a continuous period of six months.

While the primary focus of the study was on the effects of isoflavones, it is acknowledged that the additional components present in the supplement may have contributed to the observed outcomes. These factors will be considered in the interpretation of results and discussed accordingly in the limitations section.

Participants

Inclusion Criteria

Participants were eligible for inclusion if they met the following criteria:

Women aged 45 to 60 years. At least 12 consecutive months of amenorrhea (natural menopause). Reporting moderate to severe menopausal symptoms, particularly vasomotor symptoms such as hot flashes, as assessed by the Menopause Rating Scale (MRS). Willingness to comply with the study protocol, including supplementation for six months. Ability to provide informed consent.

Exclusion Criteria

Participants were excluded if they met any of the following conditions:

History of hormone replacement therapy (HRT) or use of other phytoestrogen supplements within the last 3 months. Current use of medications known to affect estrogen or bone metabolism (e.g., bisphosphonates, corticosteroids). Diagnosis of breast cancer, endometrial cancer, or any estrogen-sensitive malignancy. History of liver or kidney dysfunction, uncontrolled hypertension, or cardiovascular disease. Known allergy or hypersensitivity to soy or any components of the supplement. Participation in another clinical trial within the past 3 months.

Outcome Measures

Primary Outcomes

The primary outcomes of this study were:

Severity of Menopausal Symptoms assessed using the Menopause Rating Scale (MRS)⁷

The MRS is a validated self-report questionnaire that evaluates the intensity of menopausal symptoms across three domains: somatic, psychological, and urogenital. Participants completed the MRS at baseline (pre-intervention) and again at the end of the 6-month supplementation period. Changes in total and subscale MRS scores were used to determine symptom improvement.

Table 1. Menopausal Rating Scale (MRS) Questionnaire

Domain	Item	Score Range (0–4)
Somatic	1. Hot flashes, sweating	0–4
	2. Heart discomfort	0–4
	3. Sleep problems	0–4
	4. Joint and muscle discomfort	0–4
Psychological	5. Depressive mood	0–4
	6. Irritability	0–4
	7. Anxiety	0–4
	8. Physical and mental exhaustion	0–4
Urogenital	9. Sexual problems	0–4
	10. Bladder problems	0–4
	11. Vaginal dryness	0–4

Scoring: Each item is scored by the participant on a scale from 0 (no symptoms) to 4 (very severe symptoms).

Total Score Range: 0–44. Higher scores indicate greater overall symptom severity.

Table 2. Interpretation of MRS Score

Total MRS Score	Severity Interpretation
0–4	No or little complaints
5–8	Mild symptoms
9–15	Moderate symptoms
≥16	Severe symptoms

Serum Hormone Levels, specifically:

Estradiol (E2), Progesterone, Blood samples were collected in the morning following an overnight fast at **baseline** and **after 6 months** of intervention, Hormone concentrations were analyzed using **standard ELISA kits** at a certified clinical laboratory.

Secondary Outcomes

Participant adherence and tolerability of the supplement were monitored through monthly follow-up phone calls and capsule counts.

Adverse events or side effects were recorded and evaluated throughout the study period.

RESULTS and DISCUSSION

Participant Flow

A total of 60 postmenopausal women were enrolled in the study. During the six-month intervention period, 7 participants discontinued due to personal reasons or loss to follow-up, resulting in a final analysis sample of 53 participants.

Baseline Characteristics:

The baseline characteristics of the participants are summarized in **Table 3**. The mean age was **[56.2 ± 3.8]** years, and the average duration since menopause

was **[6.1 ± 2.2]** years. All participants reported moderate to severe menopausal symptoms at baseline based on MRS scores.

Table 3. Baseline Characteristic and Observations

Characteristic	Mean ± SD / n (%)
Age (years)	56.2 ± 3.8
Years since menopause	6.1 ± 2.2
Body Mass Index (BMI, kg/m ²)	28.5 ± 3.1
MRS Total Score at baseline	20.8 ± 4.6
- Somatic domain score	9.3 ± 2.0
- Psychological domain score	6.7 ± 1.8
- Urogenital domain score	4.8 ± 1.5
Estradiol Level	17.4 ± 5.2 pg/mL
Progesterone level	0.3 ± 0.1 ng/mL
Married	45 (84.9%)
Non-smoker	50 (94.3%)
On other medications	12 (22.6%)
Family history of menopausal symptoms	28 (52.8%)

The baseline characteristics indicate that participants had a mean age of 56.2 ± 3.8 years and an average of 6.1 ± 2.2 years since menopause onset, aligning with typical postmenopausal demographics⁸. The mean BMI of 28.5 ± 3.1 kg/m² suggests a trend toward overweight, which is common in this population and can influence estrogen metabolism due to increased peripheral conversion of androgens in adipose tissue⁹. The baseline MRS total score of 20.8 ± 4.6 reflects moderate to severe menopausal symptoms, consistent with results of other studies¹⁰. Notably, the mean estradiol level was 17.4 ± 5.2 pg/mL, which is higher than the average for postmenopausal women, potentially attributable to the elevated BMI and associated adipose-derived estrogen production. The progesterone level of 0.3 ± 0.1 ng/mL falls within the expected postmenopausal range. These baseline findings provide a comprehensive context for evaluating the effects of isoflavone supplementation on menopausal symptoms and hormonal profiles¹¹.

Post-Treatment Results

Menopausal Symptom Severity (MRS Scores)

After six months of isoflavone supplementation, participants experienced a statistically significant reduction in total MRS scores:

- Mean MRS score at baseline: 20.8 ± 4.6
- Mean MRS score after 6 months: 13.2 ± 3.9
- Mean reduction: −7.6 points
- p-value: < 0.001

Table 4. MRS Domain Changes pre- and post-Treatment

MRS Domain	Baseline (Mean $\pm$ SD)	6 Months (Mean $\pm$ SD)	p-value
Somatic	9.3 $\pm$ 2.0	5.6 $\pm$ 1.8	< 0.001
Psychological	6.7 $\pm$ 1.8	4.5 $\pm$ 1.6	< 0.01
Urogenital	4.8 $\pm$ 1.5	3.1 $\pm$ 1.3	< 0.05

The observed reduction in MRS scores across all domains suggests a broad improvement in menopausal symptomatology following isoflavone supplementation. The most notable changes occurred in the somatic symptoms, particularly hot flashes and sleep disturbances, which are commonly reported by postmenopausal women. These findings support the potential of isoflavones to provide symptomatic relief through their estrogen-like activity¹².

Table 5. Hormonal Profile Changes pre- and post-Treatment

Hormone	Baseline (Mean $\pm$ SD)	6 Months (Mean $\pm$ SD)	p-value
Estradiol	17.4 $\pm$ 5.2 pg/mL	25.6 $\pm$ 6.1 pg/mL	< 0.01
Progesterone	0.3 $\pm$ 0.1 ng/mL	0.5 $\pm$ 0.2 ng/mL	< 0.05

The observed increases in serum estradiol and progesterone levels, although modest, suggest a potential endocrine-modulating effect of isoflavone supplementation. These changes remained within the expected postmenopausal range¹³, indicating that the intervention did not induce supraphysiological hormone levels. The elevation in estradiol may partly explain the improvement in menopausal symptoms, particularly vasomotor disturbances, through the phytoestrogenic activity of isoflavones. The rise in progesterone, while less pronounced, may reflect an indirect regulatory effect or individual variation in hormonal responsiveness which also align with results revealed from other studies¹⁴.

None of the participants in this study reported adverse effects that required discontinuation of the treatment. Minor complaints such as mild bloating or transient nausea were self-limited and did not impact adherence. This favorable tolerability profile is consistent with previous clinical trials evaluating soy isoflavones, which have generally shown a low incidence of side effects and good safety outcomes in postmenopausal women¹⁵.

Overall, the findings of this study support the use of isoflavone supplementation as a potentially safe and effective strategy for alleviating menopausal symptoms in postmenopausal women. However, the absence of a placebo control, the relatively small sample size, and the reliance on a multi-component supplement limit the ability to attribute the effects solely to isoflavones. Future studies with larger sample sizes and controlled designs are warranted to confirm these findings and to better understand the long-term safety and optimal dosing of phytoestrogen therapies.

CONCLUSION

This study demonstrates that six months of isoflavone supplementation may significantly reduce the severity of menopausal symptoms in postmenopausal women, particularly in the somatic and psychological domains. The intervention was well-tolerated, with no serious adverse events, and associated with modest yet statistically significant increases in estradiol and progesterone levels that remained within postmenopausal physiological ranges. These findings support the potential of isoflavones as a safe and effective non-hormonal option for the management of menopausal symptoms. However, further randomized controlled trials with larger sample sizes and pure isoflavone preparations are warranted to confirm efficacy, isolate the active components, and determine long-term safety.

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