

# Effect of health-promoting behaviors and menopausal symptoms of urban women of Hyderabad: A randomized controlled trial

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## Abstract

**Background:** Menopause, characterized by cessation of menstruation, is accompanied by various physiological and psychological changes. This randomized controlled trial (RCT) investigated the efficacy of a multi-domain lifestyle modification program in alleviating menopausal symptoms and promoting health behaviors among postmenopausal women residing in urban slums of Hyderabad, India. **Methods:** Eighty-two women aged 45–60 years experiencing menopausal symptoms were recruited. Participants were randomly assigned to either a 45-day lifestyle intervention group or a control group receiving standard care. The intervention program addressed six domains: health responsibility, physical activity, nutrition, spiritual growth, interpersonal relations, and stress management. The menopause rating scale (MRS) and a modified health-promoting lifestyle II (HPBII) questionnaire assessed menopausal symptoms and health behaviors at baseline and during follow-up. **Results:** The intervention group showed significant improvements ( $P < 0.05$ ) in terms of overall HPBII scores compared to baseline, with the most notable changes observed in health responsibility, nutrition, and stress management domains. In addition, MRS scores indicating menopausal symptoms were significantly lowered ( $P < 0.05$ ) in the intervention group. No significant changes were found in the control group in either health behaviors or menopausal symptoms. After the intervention, the experimental group showed a significant improvement in HPBII scores compared to the control group, particularly in health responsibility, nutrition, interpersonal relationships, and stress management sub-domains. **Conclusion:** This RCT suggested that a comprehensive lifestyle modification program could effectively improve health behaviors and alleviate menopausal symptoms in postmenopausal women residing in under-resourced settings. Further research is warranted to explore the program's long-term sustainability and generalizability.

**Keywords:** Lifestyle, Menopause, Randomized controlled trial, Health-promoting behavior, Menopause rating scale

## 1. INTRODUCTION

Menopause represents a unique milestone of a woman's life and marks a profound physiological shift in her life. Women experience estrogen deficiency for a significant part of their lives, especially as they age (It may exert a negative effect on her over a third of her life). This shift may usher in a chain of bodily changes and its implication goes far beyond menstrual cessation. In worst cases, episodes of hot flashes might disrupt sleep and normal biological rhythms, even leading to insomnia [1]. The hormonal fluctuation may disturb the menstrual cycle. These changes can impact women physical and mental well-being of the menopausal women. The impact of menopause goes far beyond vasomotor symptoms. For instance, it might pose risk of cardiovascular disorders [2]. It also affects musculoskeletal system, resulting in creaking joints and aching muscles. The insidious osteoporosis, a slow weakening of bones, will substantially impair their physical

strength. When these conditions persist, the quality of life of their later years will suffer greatly. Initially, hormone alternative therapy (HRT) seems to work, effectively relieving their discomforts.

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However, research found that HRT might cause some serious side effect [3] and was found to be linked to the development of malignancies and cardiovascular conditions, which necessitates a shift to a holistic approach [3]. Dietary changes, for example, shift to food rich in calcium and fiber, have become a crucial measure that strengthens the body and promotes the well-being of menopausal women. Stress management also can ease their mental burden [4,5]. This holistic approach recognizes the effect of non-medical interventions, empowering women to actively improve their personal fitness at some stage in their menopause. Integrating menopausal health-promoting measures into family medicine is essential to the complete care to women as they go through this transition. Family medicine practitioners often serve as the primary mediator for women searching for health-care services, helping them address menopause-related health concerns.

This can be achieved through education, attention, and lifestyle changes, including weight-reduction, exercising, symptom control, preventive care, and counseling. Recognizing this, our examination delved into the impact of specific health advertising behaviors on menopausal symptoms. We hypothesized that focused lifestyle interventions could correctly and carefully alleviate the bodily and emotional burden of menopause women. We evaluated the effects of actively engaging in healthy practices, and fulfilling their lives with healthy behaviors, and compared them with other women receiving preferred care. Our objective was to demonstrate whether or not intentional lifestyle adjustments could be an effective countermeasure to address the challenges of menopause and empower them to navigate the substantial life change with grace and resilience.

## 2. MATERIALS AND METHODS

The study was approved by the Institutional Ethical Committee (ESIC/SNR/IEC-F518/03/2023 version no.V01). All procedures were conducted according to the Declaration of Helsinki and ICMR 2019 ethical guidelines. This open-label, parallel-arm, and randomized controlled trial (RCT) used a 1:1 allocation ratio. The participants were invited from the slums of the city, with minimal affordability and access to private health-care facility and resources in the vicinity of a urban health-care setting of the ESIC Medical College and Hospital, Sanath Nagar, Hyderabad, India. The urban health-care setting of the institution was used as a point of referral for further interventions among the women, when necessary. The eligible participants were women aged 45–60 years who experienced menopausal symptoms for at least 1 year, had no menstrual cycles for >1 year, and were willing to participate and provide written informed consent. The exclusion criteria included (1) having a history of chronic illness (e.g., diabetes,

hypertension, and cardiovascular disease), HIV infection, malignancies, or (2) having received hormone therapy within the past 6 months. The study spanned 3 months, with baseline assessments conducted at day 0 and follow-up assessments at days 15 and day 45. The primary outcome was the reduction in menopausal symptoms and was assessed using the menopause rating scale (MRS), a validated 11-item scale measuring psychological, somatic, and urogenital symptoms [6]. The secondary outcome was any improvement in health-promoting behaviors and was evaluated by employing the modified Health-promoting lifestyle profile II (HPBII) questionnaire [7].

Sample size was calculated by utilizing the formula –

$$N = [(Z\alpha/2 + Z\beta)^2 \times \{(p_1(1-p_1) + p_2(1-p_2))\} / (p_1 - p_2)^2,$$

where N = sample size required in each group,

p<sub>1</sub> = proportion of subjects in experimental group (0.31),

p<sub>2</sub> = proportion of subjects cured in control (0.5),

p<sub>1</sub>–p<sub>2</sub> = clinically significant difference (0.26), Z $\alpha$ /2 was 1.96 for 5%;

Z $\beta$  was 0.84 for 80%.

The calculation yielded a sample size required in each group (N) was 41 and, therefore, the total sample size was 82 [8]. The participants were randomly assigned to either the experimental group or control group according to computer-generated random numbers by independent researchers not involved in the study. Allocation was concealed until participant enrolment was complete.

The interventions for the experimental group lasted for 3 months. They were put on a lifestyle modification program designed to address six domains. Domain 1 was health responsibility, for which the participants were educated regarding common menopausal symptoms, early cancer detection, and where they can seek medical help further utilization. Domain 2 was physical activity, for which guidances on engaging in moderate-intensity exercise for at least 30 min, 5 days a week, including options such as walking and yoga postures, were given. Domain 3 was nutrition, for which education on balanced dietary choices was provided, with emphasis on “Each meal plate should include four portions: fruits, vegetables, whole grains, and foods rich in calcium, Vitamin D, and iron.” Domain 4 was spiritual growth, for which guided visualization and mindfulness practices through video demonstrations and WhatsApp group support were carried out. Domain 5 was interpersonal relations, for which skill-building workshops on stress management and communication techniques were carried out by mental health professionals. Domain 6 was stress management, for which training in relaxation techniques such as meditation (heartfulness practice) and pranayama (breathing exercises) was given by trained yoga instructors, including practicing

their hobbies, listening to music, or relaxing in whatever ways that made participants happy. The control group participants received standard care available within the community setting, with no specific lifestyle-modifying intervention provided. They were given a referral to the tertiary care center for further treatment.

## 2.1. Intervention method

The intervention is detailed as follows (Figure 1).

On day 1, both groups underwent baseline assessments using the MRS and HPBII questionnaires. Informed consent was obtained, and detailed explanations regarding the study and intervention (or standard care) were provided. On days 1–2, orientation and training sessions on the specific techniques for each domain of the lifestyle modification program were provided as mentioned above. On day 15, reinforcement and group discussions to address any challenges faced with implementation of the program were carried out. Throughout the study period, ongoing support and monitoring were provided through individual and group interactions, WhatsApp group communication, and phone calls. On day 45, both groups were re-assessed using the MRS and HPBII questionnaires to evaluate changes in menopausal symptoms and health-promoting behaviors.

## 2.2. Data analysis

The data were coded and entered into Microsoft Excel 2019 and analyzed using the Statistical Package for the Social Sciences (22.0, IBM Analytics, USA). Descriptive statistics (frequency, mean, and standard deviation) were used to summarize participant characteristics and outcomes. Shapiro–Wilk test was conducted for checking the normality of data distribution, which was found to be normal. Hence, parametric tests were used for inferential statistics. Paired *t*-test was employed for comparing pre- and post-intervention scores within each group, and independent *t*-tests were used to compare changes between the experimental and control

groups. Cronbach's alpha was calculated to assess the internal consistency of the scales.

## 3. RESULTS

Our study employed a balanced, two-arm design, and enrolled 41 postmenopausal women in both experimental and control groups. Participants were carefully matched for socioeconomic background within urban slums to ensure baseline comparability, with characteristics detailed in Table 1.

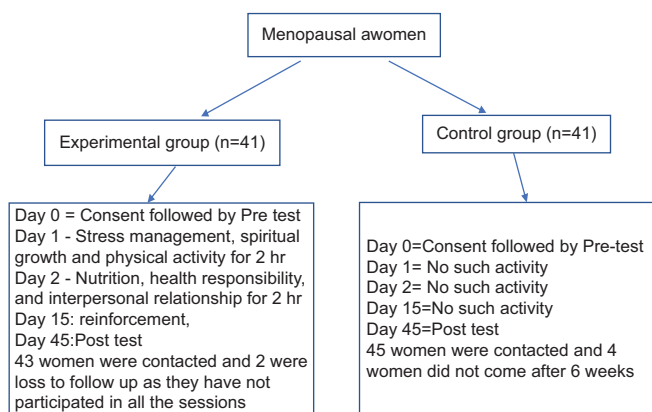
Statistical analysis revealed a minimal impact of the intervention on the control group. While slight increases in mean scores for physical activity, nutrition, and stress were observed at 6 weeks compared to baseline. These changes did not reach statistical significance. Similarly, the spiritual and interpersonal relationships domains remained unaffected (Table 2).

This result suggests the observed changes might be ascribed to natural fluctuations rather than a direct consequence of the intervention. Further research with better-controlled groups and interventions may be needed to elucidate the specific effects of this approach. The intervention group exhibited statistically significant improvements in overall health-promoting behavior scores compared to baseline ( $P < 0.05$ , Table 3).

Notably, the domain of health responsibility demonstrated the highest mean difference, followed by nutrition and stress. The experimental group showed significant improvement in menopause symptoms and health-promoting behaviors compared to the control group, with particularly notable changes in the scores on the MRS and various domains, such as health responsibility, nutrition, interpersonal relations, and stress management (all with  $P < 0.05$ ). However,

**Table 1.** General characteristics of the postmenopausal women in the experimental group and control group

General characteristics	Experimental group (n=41)	Control group (n=41)
Mean age	47.17±3.48	50.95±10.31
Marital status	Married=33 (82.5%) Separated=17 (17.5%)	All were married
Occupation	Housewives=32 (78%) Semi-skilled workers=9 (22%)	Housewives=30 (73%) Semi-skilled workers=11 (27%)
Mean per capita income	10.250±4539	Rs. 13425±611
Number of children	2.05±0.677	2.44±1.51
Any gynecological history	Yes=12 (30%) No=29 (70%)	Yes=10 (20%) No=31 (80%)
Mean body mass index	27±1.25	28±0.146



**Figure 1.** Flow chart of the study methodology.

improvements in physical activity and spiritual domains were not statistically significant (Table 4).

#### 4. DISCUSSION

Open-label randomized control trial was conducted in 82 postmenopausal women in an urban slum of Hyderabad and they were followed up for 6 weeks (45 days). In the experimental group, a statistically significant association was found between the reduction of menopause rating scores and healthy lifestyle-promoting behaviors. Domains showing the highest mean difference after intervention were

health responsibility, followed by nutrition and stress. In the control group, even though there was an increase in the mean scores of physical activity, nutrition, and stress domains, no statistically significant association was observed between the scores of symptom reduction and lifestyle-promoting behaviors. Spiritual domain and interpersonal relationship domain remained unaltered. Similarly, a quasi-experimental study in Srilankan postmenopausal women found the robustness of the structured health education program in this study was high, showing a significant strength that contributed to the overall success of the intervention [9]. The incorporation of diverse strategies, specifically tailored to the

**Table 2.** Comparison between mean scores of health-promoting behaviors and their domains and menopausal symptom scores in control group ( $n=41$ )

Variables	Pre-test (Baseline)	Post-test (After 6 weeks)	P-value
Menopause rating scale	12.95±7.86	12.85±7.76	0.936
Health-promoting behavior score	73.45±23.17	73.47±22.18	0.786
Various domains of health-promoting behavior	Pre-test	Post-test	P-value
Health responsibility domain	12.27±4.53	12.56±4.33	0.779
Physical activity domain	6.72±6.32	7.17±6.30	0.984
Nutrition domain	12.77±4.00	13.87±4.10	0.878
Spiritual domain	14.60±5.58	14.80±5.48	0.910
Interpersonal relations domain	15.22±4.22	15.22±4.22	1.022
Stress domain	11.85±4.11	12.01±4.11	0.183

Note: P-value after performing the *t*-test.

**Table 3.** Comparison of mean scores of health-promoting behaviors with their domains and menopausal symptom scores in the experimental group ( $n=41$ )

Variables	Pre-test	Post-test	Difference	P-value
Menopause rating scale	11.30±8.18	6.17±5.94	5.13±2.24	0.048
Health promoting behavior score	66.40±19.92	96.89±23.87	30.49±3.95	0.00001
Various domains of health-promoting behavior	Pre-test	Post-test	Difference	P-value
Health responsibility domain	12.45±4.72	20.32±4.93	7.87±0.21	0.098
Physical activity domain	4.45±4.73	9±5.28	4.55±0.55	0.0001
Nutrition domain	10.95±3.59	18.37±4.44	7.42±0.85	0.00002
Spiritual domain	13.0±6.56	16.65±6.70	3.65±0.14	0.0001
Interpersonal relations domain	14.29±5.09	18.16±5.83	3.87±0.74	0.027
Stress domain	10.10±4.57	15±4.58	4.91±0.01	0.006

**Table 4.** Comparison of mean scores of health-promoting behaviors in terms of their domains and menopausal symptom scores between the control group ( $n=41$ ) and the experimental group ( $n=41$ ) after intervention

Variables	Post-test control group	Post-test experimental group	Difference	P-value
Menopause rating scale	12.85±7.76	6.17±5.94	6.68±1.82	0.00003
Health-promoting behavior score	73.47±22.18	96.89±23.87	23.42±1.69	0.0001
Domains of behavior noted in the study	Post-test (Control group)	Post-test (Experimental Group)	Difference	P-value
Health responsibility domain	12.56±4.33	20.32±4.93	7.76±0.6	0.00001
Physical activity domain	7.17±6.30	9±5.28	1.83±1.02	0.1579
Nutrition domain	13.87±4.10	18.37±4.44	4.5±0.34	0.00008
Spiritual domain	14.80±5.48	16.65±6.70	1.85±1.22	0.1750
Interpersonal relations domain	15.22±4.22	18.16±5.83	2.94±1.66	0.0106
Stress domain	12.01±4.11	15±4.58	2.99±0.47	0.002

sociocultural features of the urban slum setting, underscored a thoughtful and inclusive approach [8]. Interactive sessions not only facilitated the dissemination of information but also created an environment conducive to active engagement and participatory learning. This dynamic aspect of the program was crucial, as it promoted a sense of community and shared responsibility in adopting healthier lifestyles.

The practical skill-building exercises further enhanced the program's effectiveness. By providing participants with hands-on experience and tangible tools, the intervention moved beyond theoretical knowledge, fostering a more in-depth understanding of health-promoting behaviors. This practical focus was particularly pertinent in urban slum contexts, where access to resources and opportunities for healthy living might be limited.

Empowering individuals with practical skills not only addresses immediate health concerns but also equips them with the means to navigate health challenges in the long term. The availability of readily accessible resources is another positive aspect of the program. In resource-constrained urban slums, interventions that rely on easily available materials and methods stand a better chance of being sustainable. This adaptability is crucial for the success of health education initiatives in environments with limited infrastructure. By recognizing and working within these constraints, the program increases its potential for long-term impact, ensuring that the positive changes observed during the study can be extended beyond the intervention period. The focus on health responsibility as a core component of the program is a strategic choice that likely contributed significantly to the observed improvements [8].

By emphasizing self-management and decision-making skills, the intervention not only imparts knowledge but also cultivates a sense of agency among participants. Yoshany *et al.* conducted a cross-sectional study in Iranian women, reporting a score of  $10.21 \pm 6.55$  (mean  $\pm$  standard deviations [SD]) for severe menopausal symptoms and  $126.44 \pm 79.27$  for women's quality of life. The analysis used multiple hierarchical linear regressions in three models, revealing a significant negative correlation between lifestyle scores and menopausal symptoms according to their severity and medium.  $P < 0.001$  was demonstrated. This indicated that quality of life could reduce menstrual symptoms. However, large SD in social scores raised concerns about intra-sample variability, which may limit the generalizability of findings. Furthermore, the cross-sectional design prevented causal inference, which means it needs a detailed analysis to clarify the direction of this relationship [10]. This psychological aspect is instrumental in promoting sustained behavioral change, as individuals who feel capable are more likely to engage in health-promoting actions. Furthermore, the

program's attention to nutrition and stress management was consistent with established evidence linking these factors to menopausal symptoms [11]. The incorporation of dietary modifications and stress reduction techniques acknowledges the multifaceted nature of health and wellness. By addressing these specific aspects, the intervention provided practical tools for participants to manage common menopausal symptoms such as hot flashes, sleep disturbances, and mood swings. This holistic approach is vital, recognizing that menopausal health goes beyond a singular focus and requires comprehensive strategies. Koçak and Kizilkaya Beji examined 32 postmenopausal women in the intervention group and 32 women in the control group and found that the total MRS scores in the intervention group were significantly reduced, yielding the largest decrease in the cognitive sub-scores, which was comparable to the findings of our study [12]. Similarly, a negative relationship was found between total scores of HLBS and total scores of menopause-specific quality of life, with the lowest mean scores being in physical activity and the highest mean scores in interpersonal support [13]. A RCT conducted in postmenopausal women at health centers in Qazvin included 42 participants in the experimental group and 42 in the control group. The intervention consisted of four sessions of lecture-based group training, incorporating slides, booklets, pamphlets, and six areas from the health-promoting lifestyle questionnaire. The questionnaire was administered to both groups 1 month, 2 months, and 3 months after the intervention, and the results revealed a positive impact, with scores in health-promoting lifestyle behaviors increased [14]. Similarly, Li *et al.* evaluated the effect of multidisciplinary health education based on lifestyle medicine on menopausal syndrome and lifestyle behaviors and found significant improvements in the intervention group compared to the control group ( $P < 0.001$ ). Notably, there was a significant increase in weekly energy expenditure from total physical activity ( $P = 0.001$ ), exercise participation ( $P < 0.001$ ), and improved nutritional status ( $P < 0.001$ ) in the intervention group compared to the control [15]. The effect of spiritual interventions in reducing the severity of depression also played an important role in Iranian postmenopausal women [16]. Despite the positive outcomes, a careful reflection on the study's limitations is crucial for a balanced interpretation of the findings. One notable limitation was the reliance on self-reported data, which introduced the possibility of response bias. Participants might provide socially desirable responses, inflating the observed improvements. In addition, the lack of a control group limited the ability to attribute the changes solely to the intervention, as external factors could have influenced the outcomes. The findings from this study cannot be generalized to other different populations due to the specific socioeconomic and cultural context of the participants.

The unique environmental factors, limited resources, and specific health behaviors of the urban slum population may not reflect those of women in different settings, such as rural areas or more affluent urban communities. In addition, the intervention, which was tailored to the constraints and needs of this particular community, may not be applicable to or effective with other populations, thus limiting the broader applicability of the study's results. Future research could benefit from incorporating objective measures and employing a randomized controlled design to enhance the internal validity of the findings.

## 5. CONCLUSION

The effectiveness of the structured health education program in promoting healthy lifestyles and alleviating menopausal symptoms in urban slum-dwelling postmenopausal women was underscored by the good design of the program. As the gynecologists are not available at grassroots level, these strategies incorporated into primary health care will provide a holistic approach, personalized care to women beyond the menopausal transition, thereby addressing their evolving health needs as they age and ensuring continuity of care throughout their lifespan to improve their quality of life.

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## CONFLICT OF INTEREST

The authors declare no conflicts of interest.

## AUTHOR CONTRIBUTIONS

*Conceptualization:* Sudha Bala, Shrikanth Muralidharan

*Investigation:* Sudha Bala

*Methodology:* Sudha Bala, Shrikanth Muralidharan

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*Writing – review & Editing:* Sudha Bala, Satya Lakshmi K, Sathyanath Dasarathan, Shrikanth Muralidharan

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The ethics approval was obtained from ESIC Medical College and Hospital, Hyderabad (ESIC/SNR/IEC-F518/03/2023 version no.V01).

## CONSENT FOR PUBLICATION

None.

## AVAILABILITY OF DATA

Not applicable.

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