

Exploring Non-Hormonal Strategies for Improving Hemoglobin Levels in Women During the Perimenopausal Transition

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Abstract

This research aims to investigate the efficacy of non-hormonal interventions in ameliorating hemoglobin levels among perimenopausal women. Specifically, the study examines the impact of incorporating soya supplementation alongside structured health education on hemoglobin levels among perimenopausal women exhibiting altered Hb levels. Conducted in a rural locale in southern India, this single-blinded quasi-experimental study enrolled 54 perimenopausal women aged between 40 and 55 years. The participants were divided into two groups: Group A received structured health education alone, while Group B received both structured health education and a dietary intervention comprising 50 grams of soya meal curry every other day for three days a week over 16 weeks. The primary outcome measure assessed was blood hemoglobin levels. Analysis of inter-group hemoglobin values at various intervals elucidated the comparative efficacy of interventions. Group B, which received both education and the dietary intervention, exhibited significantly superior improvements in hemoglobin levels compared to Group A. Within each group, significant enhancements were noted in various biomarkers, particularly in Group B, indicating the effectiveness of the combined intervention. Although the improvements in Group B were most pronounced initially, a sustained, overall highly significant improvement was observed throughout the study period. The findings underscore the potential of non-hormonal interventions, specifically incorporating soya meals alongside structured health education, as a viable approach to enhancing hemoglobin levels among perimenopausal women. This suggests a promising avenue for addressing altered Hb levels in this demographic.

Keywords: Anemia, Hemoglobin, Non-Hormonal Therapy, Perimenopausal Women, Soya Chunk, Soya Diet.

Introduction

A lack of healthy red blood cells, such as iron deficiency, frequently consequences to anemia [28]. Hemoglobin (Hb) levels play a vital role in oxygen transport within the body, but they can fluctuate significantly among perimenopausal women due to the physiological changes occurring during this transitional phase [1, 5, 15]. Perimenopause, the period leading to menopause, is characterized by hormonal shifts, particularly a decline in estrogen levels. Estrogen, essential for erythropoiesis, stimulates erythropoietin production and enhances iron absorption [6, 7,

8, 25]. Consequently, decreasing estrogen levels may lead to reduced erythropoiesis and, subsequently, lower hemoglobin levels [19]. Besides hormonal changes, perimenopausal women may face pathological variations in hemoglobin levels. Conditions like iron deficiency anemia, exacerbated during perimenopause due to menstrual irregularities and decreased iron absorption, are common [2, 21]. Additionally, chronic diseases such as renal insufficiency or inflammatory conditions can impact erythropoiesis and lead to anemia [22-24]. Altered hemoglobin levels in perimenopausal women can have profound

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health implications. Anaemia resulting from low hemoglobin levels may cause fatigue, weakness, and reduced exercise tolerance, of life. Moreover, decreased oxygen-carrying capacity due to low hemoglobin levels can compromise tissue oxygenation, potentially worsening existing health conditions [10].

Several interventions have been established to manage hemoglobin variations among perimenopausal women. These include iron supplementation for iron deficiency anemia to improve erythropoiesis, and dietary adjustments to enhance iron absorption and overall nutrition [11]. However, hormonal therapy poses risks such as increased breast cancer risk and cardiovascular events [4], necessitating caution, particularly in women with predispositions to these complications.

Given the limitations and risks associated with hormonal therapy, there's a growing need for non-hormonal interventions to address hemoglobin variations among perimenopausal women [3]. Non-hormonal approaches offer alternative strategies to manage symptoms and improve hemoglobin levels without the potential adverse effects of hormonal therapy. [12, 13]. Nevertheless, administering non-hormonal interventions to perimenopausal women poses challenges, including limited awareness among healthcare providers and patients about non-hormonal options, treatment availability and affordability, and individual variability in treatment response [14]. In light of these considerations, this study aims to explore the effect of soya supplementation as a non-hormonal solution to perimenopausal changes in hemoglobin levels [18, 20,]. Restoring this shortage by regular iron supplementation has been the main goal of anemia prevention and control efforts. However, iron supplementation efforts have often had poor results [29]. These menopausal symptoms lead to a compromised quality of life [30].

Methodology

Study Setting

Quasi-experimental study was conducted within a rural community situated in southern India. To facilitate participant recruitment, all perimenopausal women residing in Kuthambakkam village underwent screening for eligibility. With approval from local administrative authorities, the village was segmented into sections, and the survey was systematically conducted. Kuthambakkam village was selected as the study site due to its close proximity to our hospital and the expected higher concentration of the target population, as observed during prior community engagements.

Study Design and Duration

This study employed a quasi-experimental design involving two groups and was conducted from October 2019 to February 2021. Participants were recruited from the target population residing in Kuthambakkam village. The quasi-experimental nature of the study arose from the use of a non-random sampling technique (consecutive sampling). A six-month pause occurred due to the prevalence of the COVID-19 pandemic in India, spanning from April 2020 to July 2020.

Study Population and Inclusion Criteria

The study targeted women aged 40-55 experiencing frequent menstrual irregularities, with initial menstrual cycles lasting longer than 60 days and low hemoglobin (less than 12) within the preceding three months. All selected participants from Kuthambakkam village were required to be literate in Tamil and willing to participate. Before inclusion, participants underwent screening for a history of hemoglobin deficiency, with enrollment limited to those exhibiting abnormalities in hemoglobin levels or reporting anemia. Exclusion criteria included individuals undergoing hormone replacement therapy (HRT), those with chronic systemic diseases,

bleeding disorders, and individuals with obesity, defined as having a body mass index (BMI) exceeding 30.

Sampling

The required sample size for the study was determined based on the effect size obtained from a similar previous study (effect size 0.21) using G-power software version 3.1.1.2. Initially, a sample size of 48 was calculated. To account for potential dropouts, the sample size was increased by 10%, resulting in a final sample size of approximately 54. Randomization of the samples into two groups, Group A and Group B, was performed in a 1:1 ratio using the random table method.

Group Intervention

Group A received structured health education covering topics such as the meaning of perimenopause, associated signs and symptoms, causes of early perimenopausal issues, specific health concerns like weight gain, osteoporosis, and anemia, and corresponding preventive measures such as a balanced diet, recommended daily allowances of calcium and iron, supplemented with dietary examples, and the importance of physical activity and exercise. Continuous educational support and dietary recommendations were provided throughout the study duration. In contrast, Group B received the same structured health education initially, followed by a soya diet plan consisting of 50 grams of soya meal curry on alternate days (Monday, Wednesday, and Friday) for a duration of 16 weeks.

Data Collection

The study's primary outcome was hemoglobin, which was analyzed at three different time points: baseline analysis before the intervention (Pre-test), after 8 weeks of intervention (Post-test 1), and at the 16th week following the intervention (Post-test 2). The evaluator and the individual responsible for allocating and generating random numbers

were blinded to the samples and group allocations.

Blood Sampling

Participants provided fasting blood specimens for hemoglobin analysis between 8:00 a.m. and 10:00 a.m. in a supine position, without the use of a tourniquet. Blood was drawn using Terumo Venoject VT-100PZ vacuum tubes. The primary researcher managed the collection and organization of these outcomes.

Ethical Considerations

All study participants provided informed consent after receiving a concise orientation about the study procedures and the necessity of blood draws, considering it an invasive procedure. This study received approval from the institutional ethical committee at Saveetha Institute of Medical and Technical Sciences, Chennai, Tamil Nadu, India (IEC NO-001/09/2019/IEC/SMCH).

Statistical Analysis

The data collected from the study underwent analysis using SPSS software version 26. A significance level of $p < 0.005$ was set with a confidence level of 95%. Initially, the data were examined for baseline homogeneity concerning demographic variables using chi-square and independent t-tests. Distribution analysis was conducted through the Kolmogorov-Smirnov test. For analysing outcome measures, within-group variations were assessed using ANOVA, while between-group differences were evaluated using independent t-tests. Post-hoc analysis was performed using the Bonferroni test.

Results

The results demonstrate that Group B showed better improvement in the early stage, and although there was no significant improvement from post-test 1 to post-test 2, there was an overall highly significant improvement. Post-hoc analysis for Group A

was not performed as there was no significant difference in the ANOVA analysis.

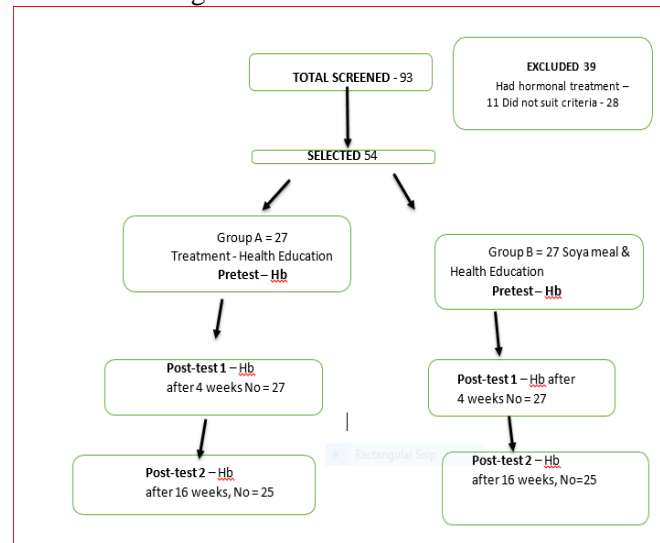


Figure 1. Demonstrates total of 93 Subjects were screened for the Study, out of which 54 Samples were selected. The Flow Chart is Depicted in Figure 1. Both Groups Comprised 27 Subjects, all of Whom Underwent Baseline Analysis before receiving the Intervention based on their Group Assignment

Criteria	Control	Experimental	Significance
Age (years)			
40-45	5	4	Chi square = 0.587
46-50	12	11	P= 0.745
51-55	10	13	
BMI	28 (1.2)	27 (1.8)	t = 1.223, p=0.821
Education	Illiterate - 2	Illiterate - 1	Chi square = 0.247
	Higher secondary - 14	Higher secondary - 11	P= 0.507
	Graduate or more - 11	Graduate or more - 15	
Employment	Employed - 8	Employed - 5	Chi square = 0.621
	Unemployed - 19	Unemployed - 22	P= 0.527
Number of hospital visits	1.8 (1.2)	2.1 (0.9)	t = 6.32 p=0.141
Diet preference	Vegetarian - 7	Vegetarian - 12	Chi square = 0.921
	Non-vegetarian - 20	Non-vegetarian - 15	P= 0.02

Figure 2. Demographic Data of Both Group Participants

BMI – Basal Metabolic Index

Figure 2 demonstrates that the demographic characteristics collected before the intervention

were comparable between both groups, suggesting these variables are unlikely to confound the research findings.

Table 1. Outcome Measure Analysis

Outcomes	Tests	Group A	Group B	P value
Hb	Pre test	12.5714	12.4286	0.937
	Post test 1	12.5000	13.3571	0.001*
	Post test 2	12.4286	14.7143	0.001*

* Significant difference. Hb – haemoglobin

The demographic details of both groups are presented in Table 1. All 27 subjects Between group (Independent t-test) underwent post-test 1, but there were two dropouts in each group

after the 6th week. These dropouts were not considered for final data analysis as they were accounted for during sample size estimation.

Table 2. Outcome Measure Analysis - within Group (ANOVA)

Group	PAIRS	Mean Difference (I-J)	Sig.
Group B (Hb)	Pre vs Post 1	-0.928*	0.018
	Post 1 Vs Post 2	-0.571	0.209
	Pre vs Post 2	-2.285*	0.001

* Significant difference, Hb – haemoglobin

In Table 2, the between-group analysis compares haemoglobin (Hb) values across different time points for Group A and Group B, indicating whether the observed differences are

statistically significant. The findings reveal a notably superior improvement in Hb levels for Group B.

Table 3. Post Hoc Analysis – Bonferroni Test

Outcome	Group	Pre test	Post test 1	Post test 2	P value
Hb	A	12.5714	12.5000	12.4286	0.774
	B	12.4286	13.3571	14.7143	0.001*

* Significant difference, Hb – hemoglobin

Table 3 provides a within-group analysis of Hb effectiveness for each intervention, showcasing the extent of improvement in biomarkers within each group. Results indicate

that the intervention in Group B significantly enhanced all biomarkers, while Group A exhibited only marginal improvement in total cholesterol (TCL).

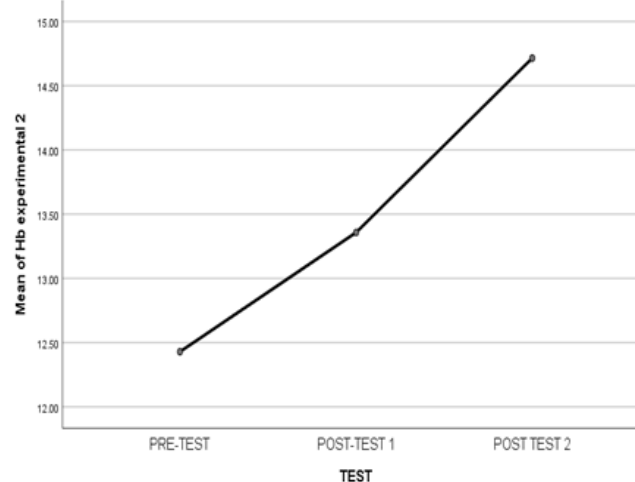


Figure 3. Temporal Differences in Group B for Hb Values

Temporal variations in hemoglobin levels are presented in Figure 3

Soya chunks curry – Ingredients

1. Soya chunks (soaked) -100 grams
2. Onions (medium size) -2
3. Ginger garlic paste - tsp
4. Tomato (grain) medium - 2
5. Green chilli - 1

Preparation;

Heat oil in a pan. Add mustard, curry leaves, onions, and green chilli. Fry till onions turn golden. Add the ginger garlic paste and grained tomatoes. Add gram masala and salt as per taste.

Transfer the soya chunks to add water to make the gravy. Cook for 10 minutes.

Nutritive Value – per 100 grams of soya chunk.

Calories - 244 K. Cal

Carbohydrates - 20 grams

Protein - 20 grams, fat - 8 grams

Sodium - 456 mg

Potassium - 178 mg

Calcium - 15.6%

Iron - 28.8 %

Vitamin -A -3.2%

The above illustrates the ingredients preferably added to the meal with a brief instruction on how to prepare the dish, with the final nutritive value of the dish.

Discussion

During perimenopause, hormonal changes can significantly influence hematopoiesis, the process of blood cell formation, including hemoglobin production. Estrogen, a crucial hormone, stimulates erythropoiesis and enhances iron absorption, essential for hemoglobin synthesis. Therefore, the decline in estrogen levels during perimenopause may lead to alterations in hematological parameters, including hemoglobin levels. Additionally, perimenopausal women in India may encounter challenges related to nutritional factors and health disparities, further impacting haemoglobin levels. Dietary habits, socioeconomic status, access to healthcare, and the prevalence of nutritional deficiencies, particularly iron deficiency anemia, contribute to variations in hemoglobin levels during this phase.

From an Indian perspective, addressing hemoglobin fluctuations during perimenopause requires a comprehensive approach considering hormonal changes, socio-cultural factors, and nutrition. Tailored interventions aimed at optimizing hemoglobin levels and overall health outcomes in perimenopausal women are essential. In this study, 54 perimenopausal women aged 40-55 from rural southern India were divided into two groups. Group A received structured health education, while Group B received the same education along with a soya diet plan. The study aimed to assess the impact of non-hormonal intervention on hemoglobin levels among perimenopausal women with abnormal Hb levels.

The findings align with existing literature on non-hormonal interventions for perimenopausal women, suggesting that dietary modifications and structured health education can positively impact hemoglobin levels. There is substantial research on the health benefits of soya and its isoflavones, especially in improving hemoglobin levels. Non-hormonal therapies, including soya supplementation and structured health education, were found

effective even among cancer survivors with menopausal complications. The observed improvements in hemoglobin levels with soya supplementation and structured health education are consistent with previous research, highlighting the potential benefits of phytoestrogens found in soya in promoting erythropoiesis.

The potential mechanisms underlying these improvements may include the estrogen-like effects of phytoestrogens, stimulating erythropoiesis and enhancing iron absorption. Additionally, structured health education may promote dietary changes and lifestyle modifications supporting optimal hemoglobin levels. Incorporating non-hormonal interventions into the management of perimenopausal women with deficient Hb may be beneficial for improving hemoglobin levels and overall health outcomes. Healthcare providers can utilize these findings to develop personalized interventions aimed at optimizing hemoglobin levels and overall health outcomes in this population.

Future research should focus on investigating the long-term effects and

sustainability of non-hormonal interventions on hemoglobin levels in perimenopausal women, exploring underlying mechanisms, and examining their impact on other health outcomes and quality-of-life measures. Analyzing the perception models of perimenopausal women before offering educational and interventional programs would also be valuable.

Conclusion

This study suggests that non-hormonal therapy with soya meals and structured health education can effectively improve Hb levels among perimenopausal women, with future studies needed to generalize these findings across diverse populations differing in culture, geography, food habits, and physical demands.

Author's Contribution

The author effectively took part in this study. Read and approved the final manuscript.

Conflict of Interest

Nil.

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