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Nutrition

EFFECTIVENESS OF A COMBINED MIDWIFE-LED STRUCTURED NUTRITION EDUCATION (SNE) AND THERAPEUTIC NUTRITION SUPPLEMENT (TNS) INTERVENTION AMONG PREGNANT WOMEN WITH ANEMIA, A RANDOMIZED CONTROL TRIAL

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ABSTRACT Anemia during pregnancy remains a significant global health concern impacting maternal and fetal outcomes. The purpose of study was to assess the effect of a midwife-delivered, dietitian-led Structured Nutrition Education (SNE) program combined with Therapeutic Nutrition Supplementation (TNS) on dietary practices and hemoglobin levels among pregnant women with anemia. A six-month randomized controlled trial was conducted at a public hospital in Hyderabad enrolling 80 pregnant women with anemia. Participants who attended childbirth classes as part of the standard of care were randomly assigned to a control or intervention group. Midwives were equipped with SNE educational tools, to support counseling on dietary practices in anemia in pregnancy. The TNS developed by dietitians tailored for specific groups was provided to all participants. Pre- and post-intervention assessments were conducted to assess the dietary intake, supplement compliance, and hemoglobin levels. The intervention group showed a statistically significant change in dietary habits especially, in the consumption of ragi/rice flakes, eggs, green leafy vegetables and fruits from pre - post intervention time ($p<0.05$). Although the intervention group showed significant improvements in hemoglobin levels, the difference between groups was not statistically significant. Hence, combined midwife led structured nutrition education and therapeutic supplement intervention improved maternal dietary practices and hemoglobin status in pregnant women with anemia.

KEYWORDS : Structured Nutrition Education, Therapeutic Nutrition, Diet, Anemia, Maternal Health.

INTRODUCTION

Anemia, characterized by a deficiency in the number or quality of red blood cells, is a prevalent public health concern, especially among pregnant women[1].The World Health Organization (WHO) estimates that approximately 40% of pregnant women globally are anemic, with iron deficiency being the most common cause.[2]Anemia during pregnancy is associated with adverse maternal and fetal outcomes, including preterm birth, low birth weight, and increased maternal mortality.[3] Addressing anemia in this vulnerable population is critical to improve both maternal and child health outcomes.[4]

Nutrition plays a pivotal role in preventing and managing anemia. Adequate intake of nutrient-rich foods is essential for maintaining optimal hemoglobin levels and supporting overall maternal health. A diet diversity, defined as the number of different food groups consumed over a reference period, reflects the quality of diet and serves as a key indicator of nutrient adequacy.[5,6] A diverse balanced diet helps to ensure sufficient intake of folate, vitamin B_{12}, iron and other micronutrients crucial for preventing anemia.[7]

Structured Nutrition Education (SNE), a strategic intervention designed and delivered by a dietitian to healthcare professionals, such as midwives, aimed at improving dietary practices, may significantly influence pregnant women's dietary behaviors and compliance with nutritional recommendations.[8,9]

Midwives, who often have established relationships with pregnant women, are in a unique position to provide personalized nutrition education and support. Their role extends beyond clinical care to encompass health promotion and disease prevention, making them ideal candidates for delivering SNE.[9]

SNE and Therapeutic Nutrition Supplementation (TNS) together may provide a comprehensive strategy for treating anemia during pregnancy. While TNS provides the necessary nutrients to address deficiencies, SNE equips pregnant women with the knowledge and skills to make informed dietary choices, promoting long-term dietary improvements and better health outcomes. Previous studies have highlighted the effectiveness of midwife-led interventions in improving maternal health outcomes. Still there is limited evidence regarding the impact of combining nutrition education (SNE) with supplementation (TNS) for pregnant women with anemia. The purpose of this study was to assess the effect of both SNE and TNS on serum hemoglobin levels, dietary compliance and adherence to iron-folic acid supplementation among pregnant women with anemia.

METHODS

A randomized controlled trial was conducted over six months involving pregnant women with anemia visiting the Outpatient Department (OPD) of Modern Government Maternity Hospital, in Hyderabad. The study participants were allocated into intervention and control groups by stratified block randomization. Random sequences were generated using computer software with allocation concealed from the investigators by the Serially numbered opaque sealed envelopes (SNOSE) method.

Antenatal women with anemia attending OPD who met the inclusion criteria were recruited by the dietitian after taking an informed consent. The calculated sample size was 80 (40 per group), incorporating a 5% anticipated loss to follow-up. Eligible participants were pregnant women with mild to moderate anemia (Hb 9.1–10.0 g/dL), confirmed using the CBC cell counter method. Women with Hb < 9 g/dL were excluded due to severe anemia requiring parenteral iron therapy and those with Hb > 10 g/dL were excluded to maintain a homogeneous mild–moderate anemia sample as per hospital protocol. Women with chronic illnesses (e.g., cancer, HIV/AIDS), those on antiretroviral therapy, thalassemia or hemoglobinopathies were also excluded.

Both control and intervention groups received standard of care (iron-folic acid tablets) and childbirth classes, which provided education on balanced nutrition during pregnancy, physiological changes in pregnancy and antenatal exercises. Initial dietary assessment was conducted by a dietitian using a validated nutritional assessment method, including a 24-hour dietary recall before the childbirth class. After the class, all the recruited participants received ready-to-eat Therapeutic Nutrition Supplements (TNS) as 'laddus' (small, sweet balls), which were formulated and standardized by the Department of Clinical Nutrition and Dietetics of Fernandez Hospital. They were appropriately packed and labeled as TNS-1 (Fennel seed laddu) and TNS-2 (curry leaves laddu). Each participant received a daily 30 g serving (2 laddus) for four weeks. A 30 g serving of TNS-1 provided 1.5 mg of iron, whereas the same quantity of TNS-2 supplied 3.3 mg of iron.

The control group received TNS-1 and the intervention group received TNS-2. The subjects and midwives were blinded to the different laddu formulations as they looked almost similar. Additionally, the intervention group received reinforced nutrition counselling from the midwife during antenatal visits using the SNE module on the subsequent antenatal visits. The SNE module was developed by the Department of Clinical Nutrition and Dietetics at Fernandez Hospital [10] and all midwives were trained in dietary management of anemia by a dietitian. The module comprises counseling tools such as flip charts, a short movie, and recipes emphasizing iron rich foods (dark green leafy vegetables, pulses and legumes, and vitamin C rich fruits) to facilitate effective patient counseling. The intervention group was followed up for three months with 2-3 regular antenatal visits and an additional 2-3 telephone follow-ups by the dietitian while the control group women came attended standard antenatal visits ranging from 1to 3 visits.

Statistical analyses included descriptive statistics for categorical and continuous variables, independent t-tests, paired t-tests, McNemar tests for paired categorical variables, and Cochran's Q test for paired categorical variables with multiple categories. Significance was set at $p < 0.05$, and all statistical analyses were performed using RStudio Desktop (RStudio Team, 2024). Ethical approval was obtained from the Ethics Committee.

RESULTS

Baseline Characteristics of Participants:

The study was conducted as a randomized control trail at the maternity hospital in Hyderabad. Participants in both intervention and control groups had a mean age of 23.7 ± 2.5years, representing a relatively young cohort of pregnant women. The participants in intervention group had a mean pre-pregnancy Body Mass Index (BMI) of 22.9 ± 2.9 kg/m² and those in the control group had 23 ± 2.96 kg/m².Most participants had completed secondary education or higher, and were predominantly housewives .Family structure was similar amongst the groups, with 55% of participants residing in nuclear families and 45% in joint families.(Table 1).

Table 1: Comparison of background characteristics between intervention and control groups

Variables	Interventio n(n=40)	Control (n=40)	P-value
Age (years), Mean ± SD	23.73 ± 2.52	23.73 ± 2.52	1.000
BMI (kg/m^2), Mean ± SD	22.9 ± 2.98	23.01 ± 2.96	0.866
Education, n (%)			
SSC	11 (27.5%)	13 (32.5%)	0.583
Inter	17 (42.5%)	19 (47.5%)	
Graduate	12 (30%)	8 (20%)	
Occupation, n (%)			
Housewife	26 (65%)	29 (72.5%)	0.469
Others	14 (35%)	11 (27.5%)	
Family type, n (%)			
Nuclear	22 (55%)	22 (55%)	1.000
Joint	18 (45%)	18 (45%)	

Overall, the baseline characteristics demonstrated a well-matched study population, enhancing the validity of the trial findings.

Diet Diversity in the Intervention Group

In the intervention group, the diet diversity improved significantly following the intervention (Fig 1)

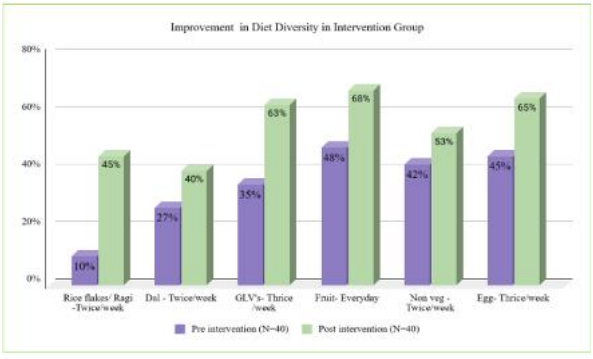

Figure 1 Improvement in Diet Diversity in Intervention Group

The consumption of rice flakes/ragi at least twice weekly increased significantly from 10% to 45% post-intervention ($p<0.001$). Significant improvements were also observed in the intake of green leafy vegetables (three times per week: 35% to 63%), and daily fresh fruit consumption (48% to 68%)($p<0.05$). Furthermore, the proportion of participants consuming eggs three times per week increased from 45% to 65%. ($p<0.05$) (Fig 1).

Diet Diversity in the Control Group

Despite slightly better baseline dietary practices in the control group compared to the intervention group, only minimal improvements were observed over time, with pre- and post-intervention comparisons showing no statistically significant changes in the intake of rice flakes/ragi, dal, green leafy vegetables, fresh fruits, non-vegetarian foods, or eggs ($p>0.05$) .

Adherence to Iron and Folic Acid Supplements:

In both the intervention and control groups, the adherence to iron and folic acid supplementation did not show a statistically significant change from pre-intervention to post-intervention (Table 2).

Table 2: Adherence to Iron and Folic Acid Supplements Between Intervention and Control Groups Pre- and Post-Intervention

Adherence to iron and folic supplements	Pre-intervention (N=40)	Post-intervention (N=40)	P-value
Intervention Group	23 (57.5%)	29 (72.5%)	0.129
Control Group	15 (37.5%)	20 (50%)	**0.063**

Although the adherence marginally increased in both groups, these improvements were not statistically significant.

Comparison of Hemoglobin Levels Between Intervention and Control Groups Pre- and Post-Intervention

The mean hemoglobin levels did not differ significantly between the intervention and control groups ($p = 0.971$) .(Table 3).

Table 3: Comparison of Hemoglobin Levels Between Intervention and Control Groups Pre- and Post-Intervention

Hemoglobin	Intervention Group (n=40)	Control Group (N=40)	P-value between groups
Pre-intervention	9.54 ± 0.3	9.54 ± 0.3	0.971
Post- intervention	9.63 ± 0.32	9.57 ± 0.31	0.422
	<0.001	0.001	

However, following the Structured Nutrition Education + TNS 2, the intervention group showed an increase in mean hemoglobin to 9.63 ± 0.32 g/dL. Though a small increase, but statistically significant rise in mean (±SD) hemoglobin from pre-intervention to post-intervention was noticed in both the groups ($p<0.05$).

DISCUSSION

In the current study, the intervention group showed significant improvements in dietary practices, particularly the increased consumption of rice flakes, ragi, green leafy vegetables, fresh fruits, and eggs that demonstrated the effectiveness of SNE in enhancing diet diversity. These findings are consistent with those of Dewidar et al.[11]who reported that focused nutrition education dramatically improved dietary patterns among pregnant women, especially those at risk of anemia. In contrast, the control group demonstrated no significant changes in dietary patterns, highlighting the importance of structured educational interventions and frequent follow–up in altering nutritional behavior. This observation aligns with Ponnambalam et al.[12] who emphasized that tailored nutrition education is more effective than generic recommendations in achieving substantial and long-term dietary improvements.

Although compliance with iron and folic acid supplementation improved in both groups, the intervention group showed a more pronounced, but not statistically significant, increase, possibly attributable to reinforcement during antenatal care childbirth education class.

This trend suggests that the SNE intervention may have positively influenced adherence to supplementation protocols. This finding is consistent with findings, by Siabani et al. [13] who reported that multifaceted approaches, integrating education with support mechanisms, are often required to improve supplementation compliance.

Hemoglobin (Hb) levels improved significantly from pre- to post-

intervention in both the intervention and control groups. This may be owing to good compliance with iron–folic acid supplementation. However, no significant differences between the groups were observed. Similar results by Moorthy et al. [14] who reported that while nutrition interventions may improve dietary behaviors; changes in hemoglobin levels are often influenced by standard care and supplementation in both groups. Additionally, the study duration and sample size may have been insufficient to detect clinical hematological change.

Conclusion and Future Directions The combined intervention improved dietary practices among pregnant women with anemia indicating its potential to strengthen nutrition behaviors within antenatal care. It appears feasible for implementation by midwives or trained health care workers as part of routine antenatal care processes, supporting its practicality and integration in real-world settings. Larger studies with extended follow-up are needed to determine its effect on hemoglobin and clinical anemia outcomes.

Study Limitations

Despite promising results, the short follow-up period may have limited the assessment of long-term effects on dietary behaviors and hemoglobin levels, indicating the need for future studies with longer intervention period. Additionally, although the sample size was adequate to detect changes in dietary practices and hemoglobin, it may have limited the statistical power to detect significant differences in supplementation, compliance between the groups, highlighting the need for larger samples in future research.

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Conflict of Interest

There are no conflicts of Interest.

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