EFFECT OF LIPID-BASED NUTRITIONAL SUPPLEMENTS DURING PREGNANCY ON MATERNAL ANTHROPOMETRY AND HEMATOLOGICAL INDICES; A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Supplementation with macro & micronutrients during pregnancy is crucial to support maternal health and fetal development. Key nutrients like folic acid, iron, and calcium help prevent birth defects, anemia, and strengthen bones. Ensuring adequate intake through supplements promotes a healthy pregnancy and reduces complications.

Objective: To investigate the effect of using lipid based supplements during pregnancy on body composition, BMI and hematological profile.

Material & Methods: A randomized controlled trial was undertaken from 2018 to 2019 to find out the effect of lipid based nutritional supplement (LNS) MAAMTA, on body composition, BMI and hematological findings. Forty underweight primigravidas from different tertiary care hospitals of Khyber Pakhtunkhwa were randomized into two groups of; Supplement: receiving MAAMTA plus antenatal treatment and Placebo: receiving placebo plus antenatal treatment. They continued taking these (MAAMTA/Placebo) from first antenatal visit till one week postnatal. Fasting blood samples were collected and anthropometric measurements taken at three different time points i.e; baseline visit, 16 weeks of gestation and post natal visit. After dropouts and one sample being hemolysed, data of thirty six participants was analyzed.

Results: The analysis of variance (ANOVA) indicated that the effect of time (i.e., the three measurement points: baseline, second trimester, and postnatally) on the BMI of participants was statistically significant, with results showing $F(2, 68) = 44.8$, $P < 0.01$, and a partial eta squared (ηp^2) of 0.57. In a similar manner, time had a strong effect on participants' body weight, $F(2, 68) = 36.32$, $P < 0.01$, $\eta p^2 = 0.51$. Furthermore, the intervention group demonstrated a significant within-group effect of supplementation on weight, $F(2, 68) = 3.18$, $P = 0.048$, $\eta p^2 = 0.086$. For body mass, the within-group analysis revealed a notable effect of supplementation, $F(1.37, 46.7) = 3.63$, $P = 0.050$, $\eta p^2 = 0.096$. A highly significant effect of time on mid-upper arm circumference (MUAC) was also evident, $F(2, 68) = 9.70$, $P < 0.001$, $\eta p^2 = 0.222$. However, no notable impact was seen in case of hematological profile.

Conclusion: This study shows that antenatal supplementation with LNS has a beneficial effect on BMI, weight, and MUAC, indicating improvement in anthropometric measures.

Keywords: Primigravida, supplement, Body mass index, Randomized controlled trial

Trial Registry: ClinicalTrials.gov Identifier: ISRCTN 10088578. Registered on 27 March 2018. https://www.isrctn.com/ISRCTN10088578.

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INTRODUCTION

A healthy diet and supplements are essential throughout pregnancy to support both the health of the mother and the growth of the fetus. Pregnant women in low & middle income nations like Pakistan frequently deal with a number of issues linked to malnutrition and restricted availability to vital nutrients, which can have a negative impact on the health of the mother and the unborn child[1]. Primigravidas are the most susceptible of these; they frequently have worse rates of malnutrition than multigravidas, which is closely linked to negative pregnancy results like premature delivery & low birth weight [2,3]. Maternal malnutrition is a common problem, and socioeconomic limitations make nutritional inequities worse [4].

Preeclampsia, a dangerous hypertension condition that can harm important organs like the liver and kidneys, has been associated with maternal under nutrition, particularly in underweight primigravidas. The possibility of these issues emphasizes the necessity of comprehensive approaches to improve maternal nutrition and health outcomes [5].

The usage of dietary supplements is one of the most important therapies during pregnancy. Lipid-based nutritional supplements (LNS) are one of these that has shown promise in treating maternal malnutrition. LNS formulations are made to provide a variety of minerals, protein, energy, and vital fatty acids in a way that is both tasty and bioavailable [6]. Lipids serve a vital physiological role, including participation in hormone synthesis, maintenance of cell membrane integrity, and facilitating the absorption of fat-soluble vitamins [7] . LNS have also shown promise in improving pregnancy-related outcomes. For instance, a study by N Sher *et al.* in Pakistan demonstrated that LNS supplementation significantly improved maternal anthropometric and hematological indices compared to standard iron–folic acid regimens [8].

Dynamic changes in body composition occur throughout pregnancy, including an increase in fat reserves to support the growing fetus. In order to make sure that maternal weight increase stays within a healthy range, it is essential to monitor these changes, especially using indicators like body mass index (BMI) & mid-upper arm circumference (MUAC)[9]. Problems including gestational diabetes, hypertension, and cesarean birth are linked to abnormal weight patterns, whether they are caused by under nutrition or excessive weight gain [10].

Hematological measures, including red blood cell indices, hemoglobin (Hb) levels, mean corpuscular volume (MCV) & hematocrit (hct) are also important markers of maternal health. Significant increases in these markers have been linked to nutritional therapies, particularly those that include iron and many micronutrients, which lower the risk of anemia and enhance the fetus's ability to receive oxygen[11],[12].

Given the high burden of maternal malnutrition in Pakistan and the promising evidence for LNS, this study aimed to look into the impact of lipid-based supplementation during pregnancy on BMI, body composition, and hematological indices among primigravidas. By understanding the physiological impact of these supplements, we can inform public health strategies aimed at improving maternal and neonatal outcomes in resource-limited settings.

MATERIAL & METHODS

This study was designed as a single-blind, randomized controlled trial (**Trial registry:** ClinicalTrials.gov Identifier: ISRCTN 10088578. Registered on 27 March 2018. https://www.isrctn.com/ISRCTN10088578) conducted in major tertiary care hospitals (including Hayatabad medical complex, Khyber teaching hospital & Saidu teaching hospital) across Khyber Pakhtunkhwa (KPK), Pakistan. The study population consisted of pregnant women aged 15 to 45 years, all experiencing their first pregnancy. Ethical approval was obtained from the Khyber Medical University Ethical Board (DIR/KMU-EB/EH/000453) as well as from the respective hospital administrations prior to participant enrollment, which was carried out based on predefined inclusion criteria. The recruitment process is outlined in Figure I.

Underweight primigravida women with a body mass index (BMI) below 18.5 kg/m² were eligible for participation. All participants were otherwise healthy and free of clinical conditions. Exclusion criteria included the presence of chronic diseases, diagnosed eating disorders, known supplement allergies, gastrointestinal abnormalities, or any history of GI surgery.

The study protocol, objectives, and participant responsibilities (like they were required to make three visits and utilize the supplement/placebo on daily basis from their first antenatal visit till a week postnatally) were thoroughly explained to both the hospital authorities and the women enrolled. Each participant's medical background and socio-economic information were recorded in detail. Random allocation to either the supplementation or placebo group was performed using computerized software (Research Randomiser, version 3.0). MAAMTA, a validated WFP supplement distributed in Pakistan for pregnant and lactating mothers. It is a peanut butter based paste, which can be consumed as such or as a spread. It is high in healthy fats & proteins with a moderate amount of carbohydrates. These are calorie dense and provide a moderate amount of sustained energy.

Supplements or placebo sachets (i.e; 75 gm/day)were distributed weekly by the principal investigator, and compliance was monitored through the collection of used sachets packets.

Participants were required to attend three scheduled visits: an initial (baseline) visit, a follow-up at 16 weeks of gestation, and a final postnatal assessment. Routine antenatal records, any treatments received, and the occurrence of complications if any like pre eclampsia, miscarriage etc.were meticulously documented. Alongside the intervention, nutritional counseling regarding the type of diet that should be taken during pregnancy was provided. During each visit, fasting blood samples were collected, and anthropometric measurements (BMI, weight, MUAC, bone mass, body fat & hydration) were recorded.

Anthropometric measurements (weight, bone mass, bodyfat & hydration) were measured using a bio electrical impedence digital scale (Beurer GmbH, Soflinger str.218 89077 Ulm, Germany Art.-Nr.748.13, TypeBF220). Height was measured to the nearest 0.1 cm using a standiometer seca Leicester 214. The Strip used was a validated World Food Programme strip for MUAC measurement.The following formula was used to compute the BMI

BMI = weight (kg) / height ^{2} (m^2)

To minimize confounding, participants were recruited with similar baseline characteristics and followed under the same protocol. Potential confounders such as age and baseline BMI were checked for comparability between groups.

Statistical Analysis: Data were analyzed using SPSS version 20. Normality was checked using the Shapiro–Wilk test. Repeated measures ANOVA was applied to assess changes in anthropometric measurements and hematological indices across the three time points. Chi- square test was used for categorical data. A P-value < 0.05 was considered statistically significant."

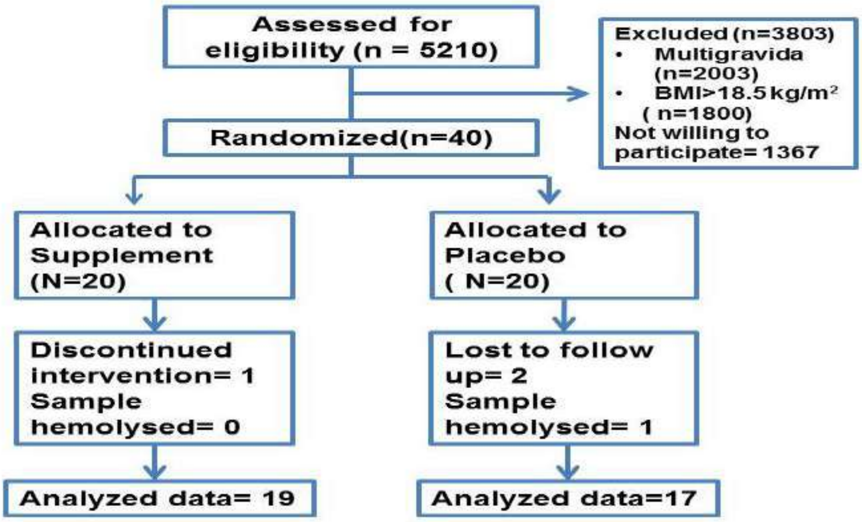

Figure I: CONSORT diagram showing the recruitment of participants.

RESULTS

The two-way repeated measures ANOVA revealed that time exerted a highly significant effect on participants' BMI, with $F(2, 68) = 44.8$, $P < 0.01$, and a partial eta squared of 0.57. However, the within-group comparison showed that supplementation did not significantly influence BMI, as indicated by $F(2, 68) = 0.45$, $P = 0.634$, $\eta p^2 = 0.013$. Additionally, the between-subjects analysis demonstrated that supplementation accounted for only 3.9% of the variation in BMI ($P = 0.250$).

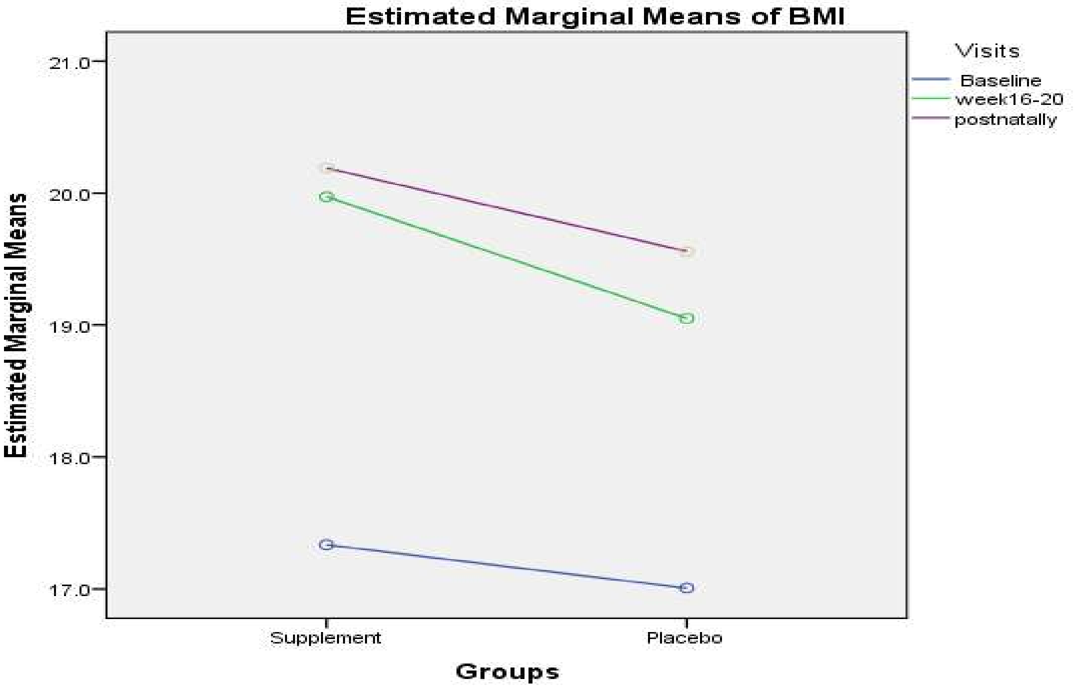

Figure II: Comparison of BMI of the Participants of the study at different timepoints

According to the two-way repeated measures ANOVA, a borderline significant within-group effect of supplementation on body weight was observed ($F(2, 68) = 3.180$, $P = 0.048$, $\eta p^2 = 0.086$). Additionally, time was found to have a highly significant effect on participant weight, $F(2, 68) = 36.32$, $P < 0.01$, with an effect size of $\eta p^2 = 0.51$. The between-subjects analysis showed that supplementation contributed to 9.5% of the variation in weight ($P = 0.067$).

For body mass, a significant within-group effect of supplementation was detected ($F(1.37, 46.7) = 3.63$, $P = 0.050$, $\eta p^2 = 0.096$), while time had no significant influence ($F(1.3, 46.7) = 2.59$, $P = 0.103$, $\eta p^2 = 0.071$). Between-subject effects of supplementation accounted for only 5.6% of the difference in bone mass ($P = 0.166$).

Time had no notable effect on participants' body fat levels ($F(1.62, 55.1) = 0.85$, $P = 0.112$, $\eta p^2 = 0.025$), nor did supplementation show any within-group significance ($F(1.62, 55.1) = 0.083$, $P = 0.88$, $\eta p^2 = 0.002$). The between-subject comparison revealed that supplementation explained just 4.6% of the variance in body fat ($P = 0.210$). Furthermore, the ANOVA results indicated no significant within-group effect of supplementation ($F(2, 68) = 0.66$, $P = 0.51$, $\eta p^2 = 0.019$), and time likewise had no significant impact ($F(2, 68) = 1.53$, $P = 0.22$, $\eta p^2 = 0.043$). The test of the between-subjects effect of supplementation on hydration showed a minimal contribution of 3.8% ($P = 0.252$).

Finally, time significantly affected mid-upper arm circumference (MUAC), with results showing $F(2, 68) = 9.70$, $P < 0.001$, and $\eta p^2 = 0.222$. However, no significant within-group effect of supplementation on MUAC was found ($F(2, 68) = 0.42$, $P = 0.65$, $\eta p^2 = 0.012$). Between-subject analysis indicated that supplementation explained 11.6% of the variation in MUAC ($P = 0.043$).

Table 1: Anthropometric measurements of study participants

s.no	Parameters	Groups	Visit -1	Visit- 2	Visit- 3	P=value (Within group effect)	P=value (Time)
1.	Weight (kg)	Placebo	42.29±4.27	47.67±3.75	48.33±4.28	**0.048***	**<0.001*** **
		Supplement	41.68±3.25	46.33±2.91	44.61±3.72		
2.	BMI (kg/m^2)	Placebo	17.0±1.25	19.09±2.19	19.55±2.26	0.634	**<0.001*** **
		Supplement	17.33±1.20	19.97±2.26	20.19±2.09		
3.	Bone mass (%)	Placebo	30.44±4.32	30.72±5.30	31.98±6.59	**0.05***	0.103
		Supplement	31.96±5.98	35.52±5.66	32.42±5.42		
4.	Body fat (%)	Placebo	24.02±5.53	24.67±4.29	23.88±4.14	0.920	0.409
		Supplement	25.66±5.40	26.77±5.53	25.25±5.55		
5.	Hydration (%)	Placebo	53.97±6.15	50.79±5.02	52.64±5.84	0.51	0.22
		Supplement	50.81±7.06	50.18±6.33	50.81±6.25		
6.	MUAC (cm)	Placebo	20.37±1.32	20.35±1.29	20.52±1.24	0.65	**<0.001*** **
		Supplement	21.35±1.44	21.24±1.36	21.47±1.42		

The two-way repeated measures ANOVA showed that time did not significantly affect participants' hemoglobin (Hb) levels, F(2, 68) = 0.489, P = 0.615, ηp² = 0.014. Likewise, there was no notable within-group effect of supplementation on Hb, F(2, 68) = 0.363, P = 0.697, ηp² = 0.011. The between-subjects analysis indicated that supplementation explained only 2.1% of the variation in hemoglobin levels (P = 0.400).

In the case of hematocrit (Hct), no significant within-group effect of supplementation was found, as shown by F(2, 60) = 0.329, P = 0.721, ηp² = 0.011. Time also had no significant impact on Hct, with F(2, 60) = 0.076, P = 0.927, ηp² = 0.003. However, supplementation contributed to 13.3% of the variation in hematocrit levels in the between-subjects test (P = 0.040).

For mean corpuscular volume (MCV), no significant within-group effect of supplementation was observed (F(2, 62) = 0.181, P = 0.835, ηp² = 0.006), nor was there any significant time effect (F(2, 62) = 0.007, P = 0.993, ηp² < 0.001). The between-subjects effect of supplementation accounted for approximately 5% of the variance in MCV (P = 0.211).

Table 2: Hematological findings of the participants at three different visits

Groups	Parameters	Visit -1	Visit- 2	Visit- 3	P=value (with in group effect)	P=value (Time effect)
Placebo	**Hemoglobin (gm/dl)**	11.06±1.61	11.15±1.27	10.59±0.99	0.697	0.615
Supplement		10.71±1.45	10.76±1.45	10.70±1.24		
Placebo	**Mean corpuscular volume(fl)**	84.25±5.71	85.32±5.38	84.78±6.08	0.835	0.993
Supplement		86.01±4.09	85.96±4.16	85.32±5.17		
Placebo	**Hematocrit (%)**	32.93±4.58	32.68±4.90	33.61±3.89	0.721	0.927
Supplement		35.32±3.66	34.81±4.03	34.46±2.77		

Table 3: Socio economic characteristics of the study participants

MONTHLY INCOME	Supplement group	P-value	Placebo group	P-value
5000--15,000	5(23.53)	0.996	9(52.94)	0.965
16,000-25,000	5(23.53)		3(17.65)	
26,000-35,000	9(52.94)		5(29.41)	
HOUSEHOLD				
Joint	13 (70.59)	1.000	15 (88.24)	1.000
Separate	6 (29.41)		2 (11.76)	
HOUSE TYPE				
Bungalow	0	1.000	0	1.000
Apartment	1 (5.88)		3 (17.65)	
Town house	15 (88.24)		13 (76.47)	
Village house	3 (5.88)		1 (5.88)	
HOUSE STRUCTURE				
Pakka	13 (76.47)	0.970	14 (82.35)	0.967
Kacha	1 (5.88)		0	
Semi Pakka	3 (17.65)		3 (17.65)	
Others	0		0	
HOUSE STATUS				
Rented	9 (47.06)	1.000	11 (64.71)	0.998
Self	10 (52.94)		5 (29.41)	
Employer/Govt	0		1 (5.88)	
RENT PAYMENT				
Self	17 (94.12)	1.000	14(82.35)	0.990
Govt	0		1 (5.88)	
Other	1 (5.88)		2 (11.76	
NO. OF KITCHEN				
0-3	19 (100.0)	1.000	17 (100.0)	1.000
4—6	0		0	
	0		0	

7—9				
NO. OF ROOMS				
0-3 4—6 7—9	13 (70.59) 6 (29.41) 0	1.000	15 (88.24) 1 (5.88) 1 (5.88)	0.999
NO. OF BATHROOMS				
0-3 4—6 7—9	15(82.35) 4 (17.65) 0	1.000	15 (88.24) 2 (11.76) 0	1.000
RESIDENCE LOCATION				
Rural Urban	7 (28) 12 (72.0)	1.000	10(70) 7 (30.0)	1.000
WATER SUPPLY				
Bore water Community tape water	4 (17.65) 15 (82.35)	1.000	2 (11.76) 15 (88.24)	1.000

DISCUSSION

Regarding maternal outcomes, there was no discernible impact of LNS supplementation on MUAC or maternal weight increase throughout pregnancy. Because the participants only took one sachet of 75g LNS per day, which contains roughly 400kcal per day, the effect of HENS on maternal weight growth was not what was anticipated. Our findings contrast with those of the balanced protein-energy supplement trial, which found that participants gained up to 21 g of weight per week in several trials [13], However, we only noticed a 5k g/visit difference. The explanation was that LNS offered a very small amount of energy in comparison to protein energy supplements. This weight gain was also higher than the findings of our investigation, despite a previous trial in Tanzania on a multivitamin intervention (without any macronutrients) showing a promising outcome of 15 g/week more in the supplement group than the placebo group [14].

Lipid-based nutrient supplements (LNS), in addition to various micronutrients, have become a significant tactic to treat energy and micronutrient shortages during pregnancy, especially in areas that are food insecure. These supplements offer a variety of vitamins, energy, and critical fatty acids in a convenient, tiny dose . However, their impact on hematological parameters has varied depending on the context. Red cell indices like MCV and Hct have improved in several trials, including those by Hess *et al.* and Smith *et al.*, among women receiving LNS. This suggests that the extra fat and nutrient matrix may improve nutrient absorption and red blood cell quality [15] . LNS without adequate iron fortification, however, did not significantly enhance Hb or other hematologic indicators, according to other assessments, such as the Cochrane analysis by De-Regil *et al*., particularly in populations where iron insufficiency was not common [16]. These results highlight the significance of customizing supplement formulations to address individuals' unique nutritional gaps and baseline inadequacies.

The effect of supplements on maternal anthropometry has also been studied, in addition to hematological benefits. Gestational weight gain, MUAC & BMI are important measures of maternal nutritional health. Fetal growth and delivery outcomes are closely correlated with appropriate mother nutrition. Positive results in this area have been linked to the use of LNS during pregnancy. For example, Dewey *et al.* found that newborns whose mothers got LNS had lower rates of stunting and low birth weight, indicating a direct benefit on fetal growth [17]. In Pakistan, Tariq *et al.* observed that LNS intake among primigravidas led to significant improvements in BMI and MUAC, further affirming the role of these supplements in improving maternal nutritional reserves [18]. The impact of LNS on anthropometric outcomes, however, may be limited in populations with comparatively better baseline nutritional status, according to studies like Matias *et al.* This suggests that supplementation strategies should be contextualized based on local needs and deficiencies [19].

According to their socioeconomic background, 90% of the participants were from low-income households. This could be the cause of the low BMI during the first prenatal checkup and during pregnancy. Our study's results are consistent with those of Shivanand C *et al*., who found that 27.4% of participants in their study experienced food insecurity and that the bulk of participants (64.8%) came from lower socioeconomic backgrounds. The majority of patients had mild anemia (15.5%) to moderate anemia (78.6%). A third of the population (36.6%) was underweight, indicating inadequate nutrition for pregnant women and a higher likelihood of anemia in those with low socioeconomic status and food insecurity [20]. According to a recent Indian study, socioeconomic challenges leading to anemia and low maternal weight during pregnancy are associated with higher incidences of stillbirths, neonatal deaths, and LBW deliveries [21]. According to a study conducted in India to better understand the intricate relationship between maternal problems and women's features, socioeconomic and demographic factors have a major impact on both pregnancy and delivery issues [22].

When combined, these results show that although LNS have the potential to improve maternal hematological and anthropometric indicators, their efficacy depends on a number of variables, such as adherence, supplement composition, duration of intake, and baseline nutritional status. In situations when energy and micronutrient deficits overlap, LNS can also significantly improve maternal health and fetal growth, especially when combined with balanced diets and fortified with sufficient iron. To find the best supplement formulations, dosages, and timing during pregnancy, more context-specific research is necessary, as seen by the inconsistent results among studies.

CONCLUSION

The findings of this study demonstrated that the intervention group exhibited a notable effect of supplementation on weight and body mass, suggesting that the intervention may have contributed to positive changes in these parameters. However, no significant effects were detected in hematological parameters, indicating that the supplementation and duration of intervention may not have been sufficient to produce measurable changes in these indices.

STRENGTHS AND LIMITATIONS

Strengths of this trial include rigorous randomization, high supplement adherence (≥88 %), and the combined assessment of body composition and haematology. Limitations are its small sample size, lack of biochemical micronutrient assays, and follow-up restricted to a week after delivery. Longer surveillance is needed to examine postpartum sustainability and infant growth trajectories.

FUTURE DIRECTIONS

Overall, the results highlight the potential of targeted nutritional interventions to improve certain aspects of body composition, while also underscoring the need for longer durations or alternative approaches to elicit hematological improvements.

Funding resource: Partial funding by Khyber Medical University.

Conflict of interest: None

Author Contributions

Kalsoom Tariq: Conceptualization, Methodology, Data curation, Formal analysis, Writing – original draft.

Bela Inayat: Methodology, Investigation, Writing – review & editing.

Hashim Khan: Supervision, Resources, Writing – review & editing.

Hafsa Zafar: Revising it critically for important intellectual content

Nabila Sher:Final approval of the version to be published

Sadia Fatima: Substantial contribution to the concept or design of the work,drafting and revising it critically for intellectual content.

Acknowledgments

We thank all individuals who contributed to this study but did not meet the authorship criteria.

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