European Review for Medical and Pharmacological Sciences 2024; 28: 2750-2759

Effect of Nutrition and Behavior Modification Program (NBMP) on maternal and neonatal outcomes among hyperglycemic mothers

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Abstract. – OBJECTIVE: Hyperglycemic mothers and their offspring are at increased risk of various maternal and neonatal complications such as macrosomia, future type 2 diabetes, and metabolic abnormalities. Early diagnosis and individualized dietary management, exercise, and emotional well-being are expected to reduce these risks. The study aims to identify the effect of the Nutrition and Behavior Modification Program (NBMP) on maternal and neonatal outcomes of hyperglycemic mothers.

PATIENTS AND METHODS: A pre-experimental study was performed among 89 hyperglycemic mothers. Glycemic control at 28 and 36 weeks, weight gain during pregnancy, pre-eclampsia, pregnancy-induced hypertension (PIH), mode of delivery, duration of exercise, emotional well-being, neonates' birth weight, incidence of hypoglycemia, and NICU admission were compared among the study and control groups. The intervention group received an individualized NBMP from their diagnosis of hyperglycemia until delivery.

RESULTS: The results showed a significant difference in blood glucose between the study periods and groups at $p<0.05$ as per repeated ANOVA. Also, diet scores had a significant influence on BMI and glycemic control at $p<0.05$. Logistic regression models, adjusted for potential confounders including baseline blood glucose, age, economic status, previous GDM, family history of DM as well as baseline BMI, diet score, physical activity, and maternal well-being score, indicated that the NBMP reduced the blood glucose and BMI significantly at $p<0.05$ in the study group. NBMP also reduced the risk of SGA/LGA and preterm/post-mature birth, as well as increased the exercise duration and emotional well-being of mothers.

CONCLUSIONS: The study's conclusions draw attention to the possible roles that maternal wellness, physical activity, and diet may

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have in reducing risks for both hyperglycemic mothers and their newborns. The NBMP resulted in higher adherence to lifestyle changes. Further research on a larger sample of hyperglycemic mothers is recommended to expand the generalizability of the findings

Key Words:
Hyperglycemia in pregnancy, Maternal outcomes, Neonate, Low birth weight, Preterm, Large for gestational age, Nutritional and behavior modification, Lifestyle modification.

Introduction

Globally, the prevalence of diabetes is rising, especially in developing nations like China and India, where they account for most of the rising burden. By 2030, India is expected to have the largest number of diabetics worldwide, which raises grave concerns[1]. Beyond the inherent susceptibility of South Asians to diabetes, factors contributing to the increased prevalence include aging populations, urbanization, rising rates of obesity, energy-dense foods, and sedentary lifestyles[2]. Additionally, obesity increases the risk of hyperglycemia in pregnancy (HIP), which affects up to 1 in 5 of all pregnancies[3]. The increased demands of the fetus in the second and third trimesters of pregnancy, along with hormonal alterations (hormones generated by the placenta that resist insulin), cause pregnant women to require two to three times the usual dose of insulin[4]. From week 20, there is a substantial increase in insulin requirements because of a marked decrease in insulin sensitivity until week 33[5].

Hyperglycemia during pregnancy presents concerns for both the mother and the fetus in both the immediate and distant future. The International Diabetes Federation (IDF) reports[3] that pregnant women with some kind of hyperglycemia account for 16.8% of live births globally. Pre-existing type 1 or type 2 diabetes that either developed before pregnancy or was discovered during prenatal testing accounts for 16% of cases of gestational diabetes mellitus (GDM), which causes the majority (84%) of cases.

Hyperglycemia may interfere with regular metabolic processes that take place throughout pregnancy[4], impacting fetal growth and development. Due to the mother's altered glucose metabolism and possible vascular complications, the fetus may not receive enough nutrients, which might impede the fetus' growth and raise the risk of SGA[6]. In addition, other adverse neonatal outcomes include hypoglycemia, hypocalcemia, hyperbilirubinemia, polycythemia[7], respiratory distress syndrome (RDS), neonatal mortality, and stillbirth[8].

One of the most important aspects of managing HIP is diet. In addition to keeping the mother's blood sugar levels within a normal limit, a sufficient and well-balanced diet is crucial for promoting ideal fetal development. As the main dietary factor affecting postprandial blood sugar levels, carbohydrates are the focus of nutritional interventions for HIP. Maternal glucose regulation may be impacted by the kind (complex *vs.* simple), quantity, and distribution of carbohydrates during the day. For example, it has been proposed that diets high in dietary fiber with a low glycemic index can help pregnant women with HIP better control their postprandial glucose levels[9].

The nutritional intervention for pregnant women with hyperglycemia is like working with a double-edged sword. An increased chance of macrosomia or Large for Gestational age (LGA) babies results from inadequate management of the mother's blood glucose levels. However, if dietary guidelines are overly rigid or calorie consumption is low, there may be a chance that the fetus will not get enough nutrients, which could result in SGA[10]. These results highlight the complex interplay among fetal development outcomes, gestational diabetes mellitus, and mother nutrition. Therefore, encouraging broad dietary patterns rather than individualized nutrient supplementation may be necessary to maximize mother and baby health outcomes, particularly in pregnancies complicated by GDM[11].

In a Spanish randomized trial[12], the impact of dietary patterns on the incidence of SGA was investigated. Following a Mediterranean diet was found to dramatically lower the incidence of SGA when compared with usual care. Gestational weight gain and a lower BMI before conception have been linked to the prevalence of SGA[13].

According to a study performed in India[14], gestational glucose intolerance (GGI) and DM during pregnancy were found to be 16.8% and 11.6% prevalent, correspondingly. Gestational age, pre-pregnancy BMI, gestational weight gain, history of diabetes in the family, PCOS, large for gestational age, and GDM in earlier pregnancies were found to be correlated with HIP.

GDM nutrition management is essentially a careful balancing approach. Although keeping the mother's blood glucose within a target range is the major goal, caution must be used to make sure that dietary recommendations do not unintentionally result in reduced fetal growth. Preventing complications such as SGA in pregnancies complicated by GDM requires close observation, individualized food regimens, and a thorough understanding of nutritional requirements during pregnancy. Numerous studies have been done on the prevalence of GDM and its impact on maternal and newborn health. Studies on the effect of a comprehensive intervention of HIP on maternal and newborn outcomes are scarce in Tamil Nadu, India.

Hence, this study examined the comprehensive "Nutrition and Behavior Modification Program" for hyperglycemic pregnant women, which included tailored recommendations for low-glycemic index diet and exercise, supported by behavior change theories and reinforced by customized follow-up. Following the International Association of Diabetes and Pregnancy Study Group's diagnostic guidelines[15], we hypothesized that this life course approach would lead to a higher incidence of glycemic control.

Patients and Methods

Design

A pre-experimental study was conducted between January 2021 and June 2022 to assess the effect of the Nutrition and Behavior Modification Program (NBMP) on maternal and newborn health among mothers with hyperglycemia. The study focused on pregnant women who visited the antenatal outpatient departments of secondary-level health institutions/Urban Primary Health Centers in Chennai.

Participants and Study Procedures

A total of 186 mothers were approached during their first diagnosis of hyperglycemia (14±2.4 weeks). The selected mothers' blood glucose was monitored after 2 weeks of diet plan to confirm glycemic control. Only those mothers who had achieved glycemic control with dietary recommendations were included in the study. From the initial number of 186 pregnant women, 89 mothers finally completed the study (Figure 1).

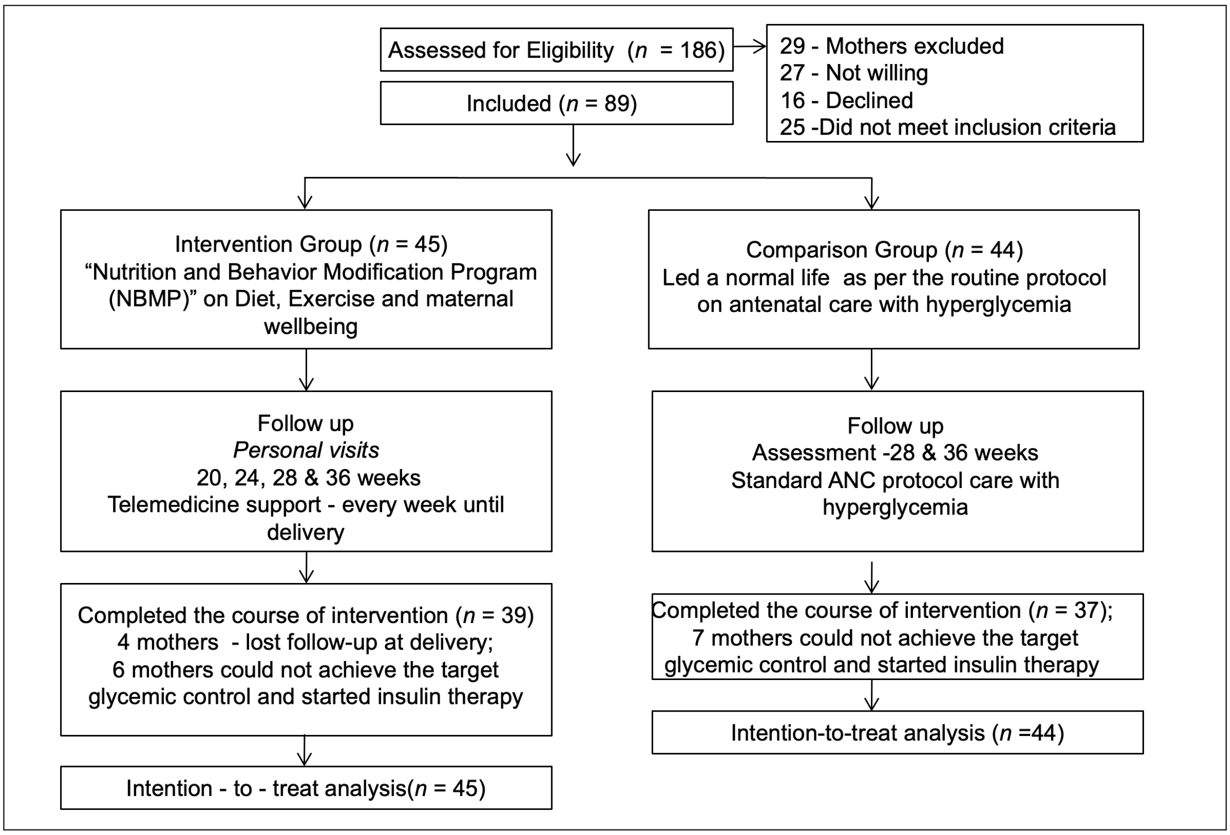

Figure 1. CONSORT flow diagram of the study.

Exclusion criteria included having a history of any chronic condition such as diabetes mellitus before pregnancy, hypertension, heart disease, respiratory issues, hepatic disease, or taking frequent medications like corticosteroids and mothers who had assisted pregnancy. The mothers from two centers were allotted to the study group (45 mothers), and those from two other centers were in the control group (44 mothers). The study centers were selected randomly using a lottery method, and the distance between the study and control group settings was around a 20-24 km radius to avoid contamination.

The incidence of glycemic control with NBMP at 28 and 36 weeks was the predetermined primary outcome. The secondary outcomes for mothers included weight gain during pregnancy, pre-eclampsia, pregnancy-induced hypertension (PIH), mode of delivery, and their self-reported activity levels after 36 weeks. Birth weight, incidence of hypoglycemia, and NICU admission were among the additional outcomes of newborns gathered for exploratory and subgroup analysis. The mothers' weight measurements were recorded to the nearest 0.1 kg on calibrated electronic scales (SECA 374, Scorpia India Medicare Pvt Ltd, Ghaziabad, India) at baseline (GA 14.8±4.2 weeks), GA 28 and 36 (visits 1, 2, and 3). Blood glucose level was assessed using a calibrated glucometer (OneTouch®, LifeScan Inc., India). In addition to this, maternal well-being was assessed using the standardized WHO-5 Well-Being Index questionnaire[16]. It is an easy-to-complete tool for screening psychological symptoms, and emotional well-being during pregnancy is a very important attribute. To determine the final score, the raw score is multiplied by 4, with 0 denoting the lowest possible well-being and 100 the highest possible well-being. The raw score ranges from 0 to 25.

Intervention

After randomization of the study centers, NBMP was given until delivery, along with the standard antenatal care for hyperglycemic mothers. The program began with a single face-to-face education session conducted with 3-4 mothers. The mothers were offered initial one-hour motivational counseling on the benefits of the low glycemic index with a high fiber diet on glycemic control and the importance of moderate exercise for 30 minutes for 5-7 days/week. Personalized WhatsApp messages on NBMP were sent once weekly throughout their pregnancy to motivate them and to bring behavior modifications.

The NBMP called for moderate consumption of animal fat and protein (fish, eggs, poultry, and low-fat dairy products were preferred), a restricted intake of processed foods and sweets, and a regular intake of plant-based foods (fruits, vegetables, whole grains, legumes, and nuts) with locally available non-refined oils such as sesame oil as the primary source of fat. In addition, the food choices with locally available fruits, vegetables, legumes, etc., were also discussed on an individual basis. Additionally, the significance of a well-balanced diet, the impact of anemia, and the consequences of vitamin and mineral deficiencies for the mother and the fetus were highlighted. In addition, the necessity of physical activity, the mother's emotional welfare throughout her pregnancy, compliance with additional medicine, and the mix of nutrition supplements were covered. Each mother received a unique, comprehensive menu plan according to weight and moderate activity level of 30 mts for 5 to 7 days a week. At 20, 24, 28, and 36-weeks' gestation, qualified nurses administered individual dietary counseling. To prevent cheating diets, women in the NBMP group were encouraged to remain loyal to the menu plan and physical activity by maintaining a diary, which was monitored by the nurses every week and discussed in their following counseling sessions.

The behavioral goal of NBMP was to keep gestational weight gain (GWG) between 8-10 kg and maintain blood glucose below 120 mg/dl. The mothers were given a helpline number to call whenever they needed any clarification on diet, exercise, food choices, and when they felt low to ventilate their emotions. Under the guidance of an obstetrician and a registered nutritionist, four trained registered nurse midwives continuously monitored the pregnant women across the research. The obstetrician provided a no-harm certificate for the NBMP. Additionally, the mothers in the control group were made sure to adhere to the state government's recommended regimen for prenatal care and control of blood glucose. Throughout the duration of the study, confidentiality and beneficence were guaranteed.

The hospital ethics committee examined and approved the research protocol. In addition to NBMP, a booklet related to exclusive breastfeeding for 6 months, practical advice to improve their diet, and physical exercise to manage their weight effectively postpartum were given as these mothers are prone to develop DM later in life.

Statistical Analysis

SPSS 23 (IBM Corp., Armonk, NY, USA) software was used to handle and analyze data using both descriptive and inferential statistics. Data were analyzed using the intention-to-treat method. Data are presented as standard deviation (SD) for symmetric distributions, frequency, and proportion for categorical data. If the continuous variable had a normal distribution, the student's *t*-test was employed; if not, the Mann-Whitney U test was employed using analysis of covariance (ANCOVA) of repeated data. Differences in body weight changes and glycemic status by gestation week were examined between the intervention and control groups, and $p \leq 0.05$ was considered statistically significant.

Results

Four of the eighty-nine women's birth and neonatal outcome data were absent because they had either preterm delivery or did not attend the last visit. They were distributed within the groups randomly. Six in the study group and 7 in the control group could not achieve glycemic control at various points of the study period. They were referred to the physician, and individualized insulin therapy was started. GWG was calculated by subtracting the measured weight at the time of study enrollment from the weight at the 36-week visit. Proteinuria and consistent high blood pressure (140/90 mmHg) on more than one occasion were considered indicators of preeclampsia. If the blood pressure satisfied the requirements but proteinuria was absent, PIH was diagnosed. The World Health Organization's standards[17] were used to classify overweight and obesity: overweight/pre-obesity (25-29.9 kg/m^2), obesity class I (30.0-34.9 kg/m^2), obesity class II (35.0-39.9 kg/m^2), and obesity class III (those who weigh more than 40 kg/m^2).

Most newborns' birth anthropometry was assessed by skilled nurses within 48 hours of the baby's birth. The sophisticated SECA 374 electronic scale was used to measure birth weight precisely. Using conventional methods, the newborn's crown heel length was measured using locally made, collapsible length boards that were accurate to 1 mm. Periodically, the nurses received refresher training on data collection techniques and anthropometric measuring methodologies. Standard weights were used to calibrate the weighing apparatus.

The baseline data of hyperglycemic mothers showed that the mean age of the mothers in the study and control group was 31.1±4.6 *vs.* 27.9±4.8. The number of primi mothers in the study group was 19, while the control group had 20. The average BMI of both groups was similar (31.7±3.87 *vs.* 32.4±3.1). Eleven mothers in the study group had a previous history of GDM, while only 7 mothers in the control group had GDM. Regarding the family history of DM, 18 and 23 mothers of the control and study group respectively, had a family history of DM. On pre-pregnancy blood sugar status, 27 and 31 mothers of the study and control group had hyperglycemia.

Table I shows the comparison of blood glucose status among hyperglycemic mothers at different times of observation. Differences in group means were compared using the *t*-test to compare the NBMP with the conventional program. For the study group, the mean blood glucose was 119.1 with an SD of 3.08 at baseline, 115.7 with an SD of 4.03, and 117.1 with an SD of 2.81 at 28 and 36 weeks of gestation, respectively. A significant difference in the blood glucose status was noted

Table I. Comparison of blood glucose status among hyperglycemic mothers at different periods of observation.

Maternal blood glucose level (mg/dl)	Intervention group mean (SD)	Comparison group mean (SD)	*t*-value *p*-value
Baseline	119.1 -3.08	117.3 -4.91	*t*=0.846 *p*=0.037*
28 weeks	115.7 -4.03	117.1 -3.99	*t*=0.299 *p*=0.05*
36 weeks	117.1 -2.81	118.5 -5.05	*t*=0.913 *p*=0.05*
Repeated ANOVA	F=19.305, *p*=0.0471*	F=0.633, *p*=0.532 (NS)	

p-value ≤0.05; *Significant.

Table II. Effect of the dietary score on the blood glucose and BMI of the hyperglycemic mothers.

Diet score	≤5	6-7	8	9	≥10	*p*
Women (n)	6	3	19	21	27	
BMI (kg/m^2)	33.98 (7.2)	32.08 (4.4)	31.81 (3.87)	30.81 (3.03)	29.7 (2.61)	0.033*
Maternal blood glucose (mg/dl)	126.1 (4.1)	125.8 (3.61)	124.1 (3.37)	122.8 (3.19)	117.0 (2.71)	0.051*

p-value ≤0.05; BMI: body mass index; *Significant.

between the study periods and the study and control groups at $p \leq 0.05$, as per repeated ANOVA.

An analysis of variance was used to investigate the primary effects of the dietary scores of the two groups on the mothers' blood sugar levels and BMI. The data in Table II shows that there is a significant difference between the mothers' blood sugar level and BMI according to the diet score, i.e., when the diet score is high, the BMI and blood glucose level were reduced.

The blood sugar level, adjusted for confounders such as baseline blood glucose, age, economic status, previous GDM, and family H/o of DM, reduced by 4.17 mg/dl in the study group in 36 weeks from the baseline value as compared to mothers in the control group. Similarly, the maternal BMI (kg/m^2) was also reduced by 2.67 as compared to controls with adjusted confounders such as baseline BMI, diet score, maternal wellbeing score, and physical activity, which indicated that the NBMP reduced the blood glucose and BMI significantly in the study group (Table III).

The weight gain did not show a significant change among the groups. There was a significant difference between physical activity and maternal well-being between groups at $p<0.01$ (Table IV). The newborn outcomes, such as birth weight and gestational age at birth, showed a significant difference at $p<0.05$. The incidence of hypoglycemia and admission to NICU did not show any significant difference between the groups.

Discussion

A prompt diagnosis and treatment of hyperglycemia can be extremely advantageous for both the mother and the fetus since it is an emerging, silent precursor of poor health outcomes. Pre-eclampsia, postpartum hemorrhage, neonatal hypoglycemia, jaundice, infant respiratory distress syndrome, reductions in abortions, stillbirths, obstructed labor, shoulder dystocia, and pregnancy-induced hypertensive disorders are just a few of the conditions that can be prevented by identifying women with hyperglycemia during pregnancy and putting interventional strategies aimed at controlling glycemic status into practice.

In this study, the hyperglycemic pregnant mothers were the samples, and the effect of the Nutrition and Behavior Modification Program (NBMP) on maternal and newborn health was assessed. The average BMI of both the groups was similar (31.7±3.87 *vs.* 32.4±.3.1). A total of 18 mothers had a previous history of GDM, 41 had a family history of DM, and 27 and 31 mothers of the study and control group had hyperglycemia

Table III. Blood glucose and BMI at baseline and 36 weeks' gestation.

	n	Baseline mean (s.d.)	36 weeks' mean (s.d.)	Adjusted mean diff.	*p*-value
Blood glucose (mg/dl)					
Intervention	45	113.4±3.08	117.1±2.81	-4.17 (7.81-11.67)	0.04[a]
Comparison	44	118.7±2.91	118.5±5.05		
Maternal BMI (kg/m^2)					
Intervention	45	26.7±3.87	32.08±4.4	-2.67 (3.11-7.46)	0.05[b]
Comparison	44	28.7±3.1	34.3±5.17		

[a]Mean group differences adjusted for baseline BG, age, economic status, previous GDM, and family H/o of DM; [b]Mean group differences adjusted for baseline BMI, diet score, physical activity, and maternal well-being score. *p*-value ≤0.05; BMI: body mass index; *Significant.

Table IV. The maternal and newborn outcomes of the study population.

Maternal outcome variables	*Intervention*	*Comparison*	*p*
Gestational weight gain	11.19±3.62	12.3±5.08	NS
Overall average physical activity (mts/wk)			
Before intervention	71±11	77±14	
After intervention	131±12	103±17	0.01*
Maternal well-being score			
Before intervention	54±13	59±18	0.01*
After intervention	81±19	67±11	
Pregnancy induced hypertension	4	7	NS
Preeclampsia	1	0	
Mode of delivery			
Normal	11	17	NS
Assisted with episiotomy	13	9	
Cesarean	15	11	
Newborn outcome variables			
Birth weight	2.620±0.560	2.560±0.490	0.01
Gestational age at birth	36.1 (3.3)	34.3 (3.9)	0.04
Incidence of hypoglycemia	9	11	NS
Admission to NICU	7	5	NS

p-value ≤ 0.05; NS: not significant; *Significant.

before pregnancy. As per a study[14] done in India, pre-pregnancy weight and BMI, weight gain during the pregnancy, family history of diabetes, PCOS, macrosomia, and GDM in prior pregnancies were found to be significant with GDM, which aligns with our findings.

In the present study, the differences in group means were compared using the *t*-test and the repeated ANOVA, which showed a significant difference between the study and control group values. Similarly, some clinical research[18,19] showed that tailored nutritional intervention had a positive effect on regulating and stabilizing blood sugar levels, suggesting that tailored nutritional intervention has a great deal of potential for stabilizing plasma glucose in individuals with GDM. According to a meta-analysis, nutrition therapy that modifies daily dietary intake of carbohydrates, fats, energy, and low Glycemic Index foods can reduce pregnancy weight gain in mothers, reduce the incidence of macrosomia, and possibly even lower the risk of cesarean sections in GDM mothers[20]. Hence, for GDM mothers, a tailored food plan can help minimize the risk of excess weight gain and large for gestational age newborns[21].

GDM can be classified as A1GDM and A2GDM. The classification of gestational diabetes managed without medication and responsive to nutritional therapy is diet-controlled gestational diabetes (GDM) or A1GDM. In the present study, the diet score has influenced the BMI and blood glucose levels of hyperglycemic mothers significantly. Elevated levels of adiposity or BMI in infancy, childhood, and adulthood have been associated with excess gestational weight gain (GWG), and this has also been connected to an increased risk of obesity in offspring[22-24]. According to recent research[25-28], higher GWG increases postpartum weight retention[25,26] and has longer-term consequences on the risk of obesity[27,28]. Our findings were consistent with the results of another study by Ferrari et al[29] that the women participating in the lifestyle intervention experienced a weekly rate of GWG that was lower than that of usual care [mean 0.26 kg (SD=0.15) *vs.* 0.32 kg (0.13); mean between-group difference -0.07 kg per week, 95% CI -0.09 to -0.04].

The present study findings also show that after the following factors were considered as confounders, baseline blood glucose, age, economic status, previous GDM, and family H/o of DM, the NBMP had significantly reduced the BMI and blood glucose level among the hyperglycemic mothers. Also, the NBMP increased the physical activity and maternal well-being of the mothers. This finding was also suggested by Skouteris et al[30], who affirmed that future behavioral therapies should focus on psychological elements such as motivation, self-esteem, body image issues, and mood to affect behavior, which may influence the maternal and newborn outcomes of the hyperglycemic mothers. Newborn outcomes, such as birth weight and gestational age at birth, have been significantly influenced by the NBMP, while others were not. A meta-analysis revealed significant variation in results, but diet and exercise modifications were successful in lowering gestational weight gain[31] overall. Depending on gestational weight gain, a recent study[32] found that being overweight or obese before being pregnant was linked to a higher risk of SGA in people with GDM.

Moreover, according to a recent meta-analysis[33], women with GDM are more likely to acquire T2DM (RR=7.43, 95% CI=4.79-11.51). Women had a relative risk of 4.69 within 5 years of an index pregnancy complicated by GDM; this risk more than quadrupled to 9.34 in those studied beyond 5 years postpartum. According to an Indian study[34], 16 years after the index pregnancy, pregnant women with GDM had a 3-fold higher lifetime risk of developing T2DM than pregnant women without GDM. According to research, by the age of 17, one-third of children born to women with GDM exhibit signs of impaired glucose tolerance (IGT) or type 2 diabetes[35]. Thus, while managing hyperglycemia during pregnancy, it is imperative to ensure that the mother's diet is not only balanced in macronutrients, but adequate physical activity and psychological well-being are also essential to safeguard against potential complications for the mother and the fetus. This will also reduce the complications of T2DM, obesity, and other related complications among the mothers and their offspring in their later life.

Strengths and Limitations

This study has strengths and limitations. To our knowledge, this is the first study assessing the impact of NBMP on the hyperglycemic mothers in the selected population. The methodology used was proper and thorough and the questionnaire used was validated. For ethical reasons, both study and control group mothers were carefully monitored throughout the pregnancy for any deviations in health by the trained healthcare professionals though only the study group underwent the intervention. However, the sample size was not large, and therefore, any generalization of the results needs to be made with caution.

Conclusions

In a presentation on the strategy of "primordial prevention" of diabetes, the present study has tried to shed light on various aspects of NBMP to reduce the risk factors in hyperglycemic pregnant mothers. It emphasized the possible impact of dietary components, exercise, and the emotional well-being of mothers during pregnancy on the decrease of risk factors in mothers and their offspring. Determining the socio-demographic characteristics such as blood glucose, BMI, and level of physical activity, as well as the emotional well-being of the mothers throughout pregnancy, provides crucial information for behavioral and nutritional therapy, as well as perinatal care. Preventing the complications of GDM depends on preventing obesity, effective nutrition, and physical activity intervention that produces weight loss. Preventive strategies aimed at both individual and societal levels are needed to control the growing epidemic of diabetes. We also suggest that behavior-based interventions must be more systematically designed, evaluated, and reported with a larger sample size to advance our knowledge and clear the path for the best possible pregnancy and neonatal outcomes.

Conflict of Interest

The authors declare that they have no conflicts of interest.

Data Availability

The data presented in this study are available upon request to the corresponding author.

Authors' Contributions

Conceptualization, P.P., H.M.A.M., H.A.S., V.K., and K.P.; Methodology, P.P., H.A.S., V.K., N.T.M.M., V.V.P., P.B., and R.M.M.; Software, G.K., E.L.S., V.K., A.A.Z.M., and M.A.M.; Validation, P.P., H.A.S., and K.P.; formal analysis, P.P., H.A.S., V.K., N.T.M.M., V.V.P., P.B., A.A.Z.M., and R.M.M; resources, P.P., H.M.A.M., H.A.S., V.K., and K.P.; data curation, P.P., H.A.S., V.K., N.T.M.M., V.V.P., P.B., R.A., and R.M.M.; writing-original draft preparation, P.P., H.M.A.M., H.A.S., V.K., and K.P.; writing-review and editing, R N.T.M.M., V.V.P., P.B., A.A.Z.M., R.A., and R.M.M.; visualization, G.K., E.L.S., V.K., R.A., and M.A.M.; supervision, P.P., V.K., and G.K.: project administration, P.P., V.K., H.M.A.M., and E.L.S. All authors have read and agreed to the published version of the manuscript.

Informed Consent

Written informed consent was obtained from the study participants.

Ethics Approval

The Ethics Committee of Vee Care Hospitals, Chennai, gave an ethical clearance with IEC/2020-26, dated 29.11.2020.

Funding

This research was funded by the Deanship of Scientific Research at King Khalid University, K.S.A, Grant number: RGP 2/92/44.

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Acknowledgments

The authors extend their sincere appreciation to the Deanship of Scientific Research at King Khalid University for funding this study through the Large Research Group Project under grant number RGP 2/92/44. We also extend gratitude to the mothers and their families of both the study and control groups and the research assistants.

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