4

Results and Discussion

The results of the study, entitled **"Development and Optimisation of a Sustainable Standard Operating Protocol for Medical Nutrition Therapy to Improve Maternal and Foetal Outcomes among Gestational Diabetes Mellitus women"** are discussed under the following headings.

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4.1. Phase I: Details on Current Practices and Protocols in the Management of Gestational Diabetes Mellitus (GDM) among HCPs

4.1.1. Demographic Profile of HCPs

The background information of the 200 healthcare professionals selected to obtain details on the current practices in the management of GDM are shown in Table VIII and Table IX.

Table VIII Details of Age and Gender of HCPs

Demographic Details	Healthcare professionals (N=200)			P value
	Doctors (N=70)	Dietitians (N=55)	AHP (N=75)	
Gender				
Male	24	nil	8	<.001*
Female	46	55	67	
Age (years)				
20-30	1	19	23	<.001*
30-40	24	24	32	
40-50	30	9	17	
>50	15	3	3	
Comparison of Mean Age of HCPs using ANOVA				
Healthcare professionals	**Mean ±SD**	**P Value**	**Sub group difference**	
Doctors[a] (N=70)	43.73±8.56	<.001*	a>b, P <.001	
Dietitians[b] (N=55)	33.87±7.63		a> c, P<.001	
AHP[c] (N=75)	34.92±8.17		b< c, P= 0.750	

* Significant at 1% level

Females outnumbered males in all the three categories of HCPs namely doctors, dietitians and AHP. It was interesting to note that all dietitians, as a category were females. The comparison of mean ages of HCPs done showed significant difference between groups (F=29.465, P<.001). A Tukey post hoc test revealed that the mean ages of doctors (43.73±8.56**,** P <.001) was significantly greater compared to dietitians (33.87±7.63, P<.001) and allied health personnel (34.92±8.17, P<.001). However, there was no significant difference seen between the mean ages of dietitians and allied health personnel (P =0.750) indicating that compared to dietitians and AHP, doctors were seniors with respect to age.

Table IX Details of Educational Qualification and Clinical experience of HCPs

Healthcare professionals (N=200)	Educational qualification				P value	Clinical experience			P value
	N	Graduate	Graduate with Dip./MBBS[1] with Dip.	Post Graduate /MD/DNB[2]		<10 years	10-20 years	>20 years	
Doctors (N=70)									
Obstetricians	35	nil	13	22		12	14	9	
Diabetologists	14	nil	nil	14		5	8	1	
Neonatologists	21	nil	nil	18		4	14	3	
Dietitians (N=55)	55	Nil	8	47		40	12	3	
AHP (N=75)									
Nurses	35	29	5	1	<.001*	26	9	nil	<.001*
Diabetes Educator	7	nil	nil	7		5	2	nil	
Physiotherapists	14	7	1	6		7	1	6	
Psychologists	5	nil	nil	5		2	3	nil	
Biochemist	7	nil	nil	7		2	5	nil	
Quality Control Managers	7	nil	nil	7		4	3	nil	

Comparison of Mean Clinical Experience of HCPs using ANOVA

Healthcare professionals	Mean ±SD	P Value	Sub group difference
Doctors[a] (N=70)	13.91±8.38	<.001*	a>b, P <.001
Dietitians[b] (N=55)	8.58±6.85		a> c, P<.001
AHP[c] (N=75)	7.80±5.62		b> c, P= 0.805

*Significant at 1% level, Dip – Diploma, [1]MBBS – Bachelor of Medicine, Bachelor of Surgery with Diploma, [2]MD – Doctor of Medicine, DNB – Diplomate of National Board

The educational qualification among the HCPs was significantly different at one percent level. All diabetologists and neonatologists held an MD or DNB with specialisation in their respective field compared to 22 obstetricians. Notably, none of the doctors held only MBBS as their highest educational qualification. Among other HCPs, 47 of 55 (85.5%) dietitians and all diabetes educators, psychologists, biochemists and quality control

managers held a higher qualification of post graduation in their respective fields compared to 29 of 35 (82.9%) nurses and 7 of 14 (50%) physiotherapists with only graduation.

The mean years of clinical experience among HCPs compared using ANOVA showed significant difference at one percent level (F=15.628, P<.001). A Tukey post hoc test revealed the mean years of clinical experience of doctors (13.91±8.38, P<.001) to be significantly greater compared to dietitians (8.58±6.85, P<.001) and AHP (7.80±5.62, P<.001). However, there was no significant difference seen in the years of clinical experience between dietitians and AHP (P=0.805). Ajmi & Aase, (2021) rightly pointed out that the clinical experience of physicians is proportional to safer care especially in surgical fields. These findings demonstrated that doctors had greater clinical experience compared to dietitians and AHP with more knowledge on the strategies for GDM management.

4.1.2. Concepts and Perceptions of HCPs about GDM and Practices and Protocols for GDM Management

4.1.2.1. Responses of HCPs on GDM

The responses of HCPs with respect to the concepts about GDM such as prevalence of GDM, risk factors for GDM, future health consequences for children of GDM women and preventive measures for GDM are discussed in Table X.

Table X Responses of HCPs on GDM

Details	Doctors (N=70)		Dietitians (N=55)		AHP (N=75)		P value
	N	%	N	%	N	%	
Prevalence, GDM as precursor of Type 2 DM, Achievement of Normoglycaemia	57	81.4	49	89.1	53	70.7	0.032*
Risk factors for GDM	59	84.3	38	69.1	48	64	0.019*
Consequences for offspring of GDM women	43	61.4	24	43.6	29	38.6	0.017*
Preventive measures for GDM	53	75.7	35	63.6	49	65.3	0.267^{NS}

*Significant at 5% level, ^{NS} Not Significant

The views of HCPs on the concepts such as prevalence of GDM being more in urban than rural areas, GDM as a precursor of Type 2 DM and achievement of normoglycaemia with MNT and exercise was statistically significant at five percent level. Furthermore, a significant difference was seen in the perception of HCPs with 84.3 percent doctors, 69.1 percent dietitians and 64 percent AHP, regarding risk factors for GDM namely family history of Type 2 DM, GDM in previous pregnancy, obesity and advanced maternal age as the risk factors for GDM. Similarly, the HCPs had notable differences in their agreement with 61.4 percent doctors, 43.6 percent dietitians and 38.6 percent AHP on the consequences for offspring of GDM women such as future risk for glucose intolerance, Type 2 DM in childhood and adolescence, obesity and cardiovascular disorders. These views of HCPs about GDM deviate with respect to national guidelines and can create barriers in adherence of guidelines or protocols towards proper GDM management practices.

However, the responses of doctors, dietitians and AHP did not show significant difference on their perception about preventive measures for GDM such as early diagnosis and detection of GDM, evidence-based treatment strategies, health and nutrition education, and regular follow up and evaluation as preventive measures indicating that all HCPs had a positive outlook towards implementation of preventive measures for GDM.

4.1.2.2. Delivery Outcomes commonly seen by HCPs among GDM women

The responses of HCPs regarding the delivery outcomes among GDM women are presented in Figure 7.

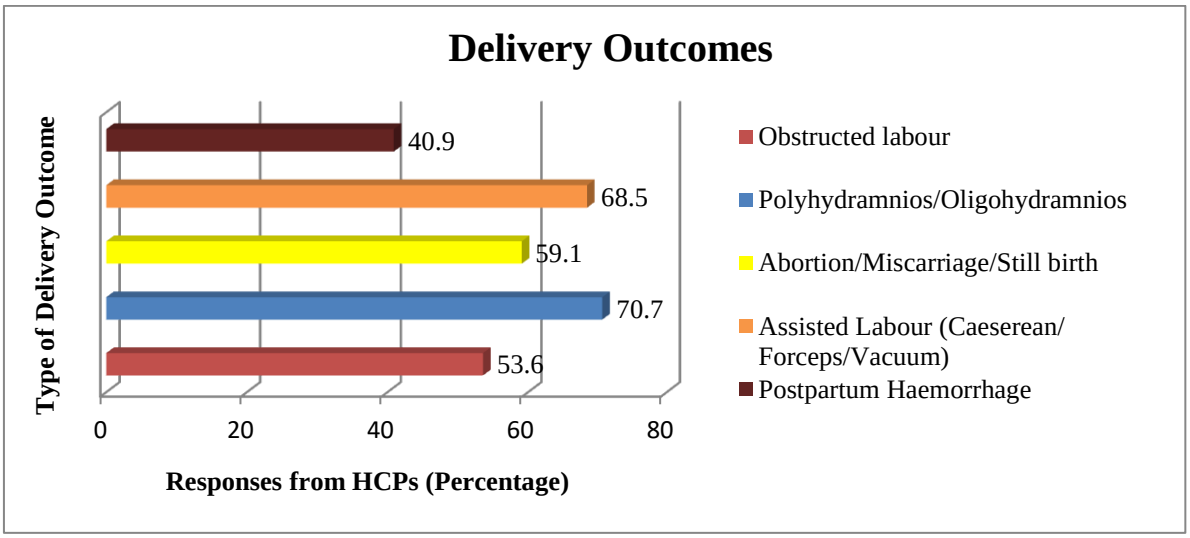

Figure 7 Delivery Outcomes Commonly seen by HCPs among GDM Women

Polyhydramnios / oligohydramnios (polyhydramnios referred as the increase in the amniotic fluid and oligohydramnios as the decrease in amniotic fluid that occurs due to complications during pregnancy) was reported by 70.7 percent HCPs as the frequently seen delivery outcome followed by assisted labour (caesarean/ forceps/vacuum) which was 68.5 percent. Pregnancies complicated with idiopathic polyhydramnios are reported to be at increased risk for adverse outcomes (Pagan et al., 2023). The other delivery outcomes such as obstructed labour, miscarriage, stillbirth and postpartum haemorrhage were reported within a range of 40.9 percent to 59.1 percent by the HCPs suggesting these were not frequently seen compared to assisted labour and polyhydramnios/oligohydramnios. GDM is associated increased chances for elective or emergency caesarean section and instrumental births (Brown et al., 2018, Ye et al., 2022). These results recommend early screening and intervention for GDM preferably at first trimester to prevent the occurrence of such maternal complications. It is recommended to conduct early screening and initiate interventions for GDM high risk women for better maternal outcomes (Ryan et al., 2018).

4.1.2.3. Foetal Complications Commonly seen by HCPs among Infants of GDM Women

The responses of HCPs were collected for the frequently seen foetal complications in infants of GDM women and depicted in Figure 8.

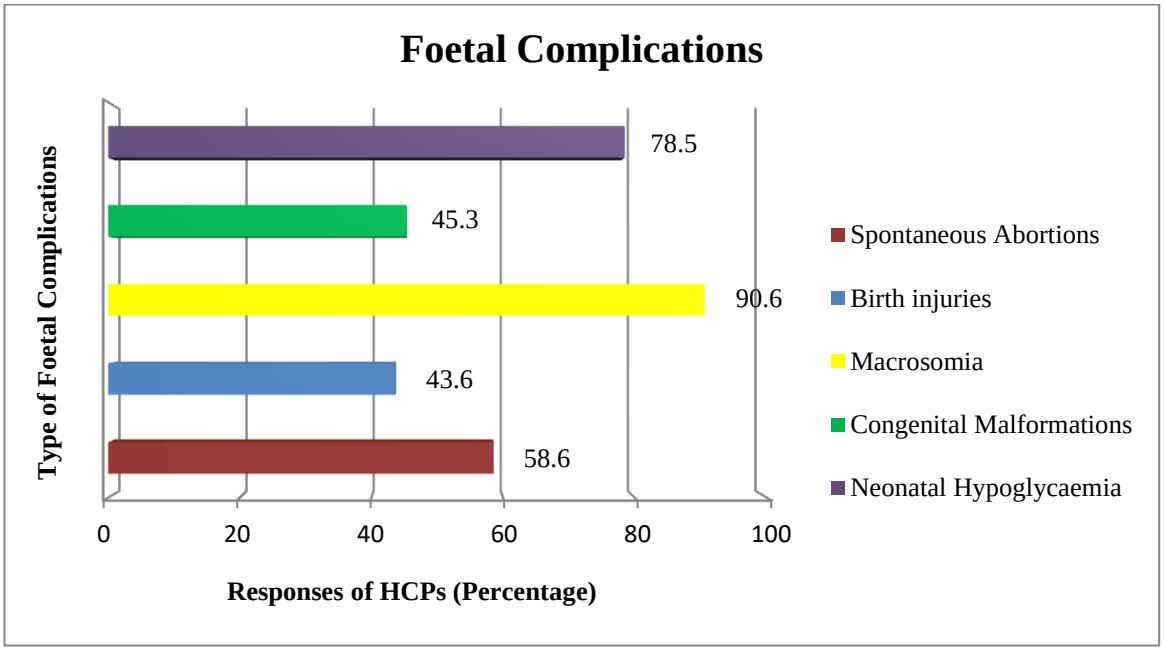

Figure 8 Foetal Complications Commonly seen by HCPs among Infants of GDM Women

Macrosomia was reported as the frequently seen foetal complication among infants of GDM women by 90.6 percent of the HCPs and it is essential that early interventions are taken as macrosomic children and infants of GDM women have been reported to be at increased risk for future cardio vascular diseases, Type 2 DM and obesity (Yapicioglu et al., 2022; Yu et al., 2019; Catalano, 2010). Neonatal hypoglycaemia with 78.5 percent was found to be the next frequently seen foetal complication among infants born to GDM women. Neonatal hypoglycaemia has been reported to alter proper motor and mental development (Stomnaroska et al., 2020) leading to severe consequences like mental retardation and epilepsy. All other foetal complications such as birth injuries, congenital malformations and spontaneous abortions were reported by HCPs in the range 43.6 percent to 58.6 percent indicating these complications to be not frequently seen compared to neonatal hypoglycaemia and macrosomia.Undertaking early screening, early intervention and early preventive measures should be considered to improve the prognosis and outcome of mother and infant (Zhuang et al., 2020).

4.1.2.4. Responses of HCPs on Protocols in GDM Management

The perceptions of HCPs on the need for protocols in their clinical practice for improved quality of care in GDM management were obtained and depicted in Table XI.

Table XI Perception of HCPs on Protocols in GDM Management

Protocols in GDM management	Doctors (N=70)		Dietitians (N=55)		AHP (N=75)		P value
	N	%	N	%	N	%	
Integrated approach	47	67.1	40	72.7	33	44	0.001**
Following evidence-based national guidelines	70	100	52	94.5	61	81.3	0.010**
Using standard operating protocols	69	98.6	52	94.5	68	90.7	0.110^{NS}
Documenting effectively	70	100	55	100	73	97.3	0.335^{NS}
Training of HCPs	69	98.6	54	98.2	73	97.3	1.00^{NS}
Conducting MDR*	66	94.3	51	92.7	62	82.7	0.055^{NS}

** Significant at 1% level, ^{NS} Not Significant,*MDR- Multidisciplinary Rounds

The perception of HCPs significantly differed with respect to integrated approach which is to treat the overall aspects of patient by involvement of a team of specialists comprising doctors, dietitians, nurses and physiotherapist as stated by 67.1 percent doctors,

72.7 percent dietitians and 44 percent allied HCPs respectively. Their perception on the use of evidence-based national guidelines also was significantly different at one percent level with all doctors showing a positive response compared to 94.5 percent responses from dietitians and 81.3 percent responses from AHP. These findings indicate that there are deficiencies in the management strategies for GDM existing in the selected hospitals. This highlights the need for developing a multidisciplinary approach and adopting evidence-based guidelines for provision of optimum care and treatment for such populations. All other management strategies such as use of standard operating protocols, documenting effectively so that GDM management practices are clear to all HCPs, training of HCPs and conducting MDR (which is conducting patient-focused treatment plan with the involvement of HCPs from different specialities and they collate their interventions and provide the best suitable treatment plan for patients) did not show any significant difference among the groups suggesting that all HCPs considered these strategies as important in the management of GDM. Multidisciplinary team led GDM management is effective not only in maintenance of glucose levels and regulation of lipid metabolism but also improve pregnancy outcomes and neonatal immune function (Qi and Dong, 2022).

4.1.3. Gap Analysis of Current Practices and Protocols with National Guidelines regarding Medical Management of GDM

The gaps identified in the current practices and protocols in GDM management are revealed in Table XII, Table XIII and Table XIV.

Table XII Gap Analysis in Screening, Assessment and Diagnosis Procedures

National Guidelines*	Current Practices and Protocols				Gaps Identified	Probable Reasons
	Maternity hospitals (N=3)	N	Multispeciality hospitals (N=4)	N		
Screening for GDM (i) Oral Glucose Tolerance Test (OGTT) at first trimester (National guidelines: 3, 4.4)	• OGTT at second trimester	3	• OGTT at second trimester	4	• OGTT not performed in the first trimester	Lack of protocol
(ii)Use of operating guidelines for GDM management (National guidelines:3)	• International guidelines used • National guidelines used	1 2	• International guidelines used • National guidelines used	3 1	• National guidelines available is not used	No updation of practices based on national guidelines

National Guidelines*	Current Practices and Protocols				Gaps Identified	Probable Reasons
	Maternity hospitals (N=3)	N	Multispeciality hospitals (N=4)	N		
Assessment for GDM (i) Body Mass Index (BMI) based on pre-pregnancy weight (ii) Gestational Weight Gain (GWG) assessment (National guidelines: 4.7)	• Only current weight is recorded	3	• Only current weight is recorded	4	• BMI based pre-pregnancy weight and GWG not done	Lack of awareness
(ii) Ultrasound Scans (National guidelines: 4.8)	• Followed as per national guidelines	3	• Followed as per national guidelines	4	• No Gaps	Nil
Diagnosis for GDM (i)GDM diagnostic criteria: PPBS≥140mg/dl (National guidelines: 4.5)	• International guidelines (FBS≥92mg/dl, PPBS 1hr ≥ 180mg/dl, PPBS 2hrs ≥ 153mg/dl) • National guidelines (PPBS 2hrs ≥ 140mg/dl)	1 2	• International guidelines (FBS≥92mg/dl, PPBS 1hr ≥180mg/dl, PPBS 2hrs ≥ 153mg/dl) • National guidelines (PPBS 2hrs ≥ 140mg/dl) :1	3 1	• PPBS 2hrs ≥140mg/dl is not the diagnostic cut-off used	Lack of awareness on national guidelines
(ii) Time of OGTT First test: At first antenatal visit Second test: Between 24-28 weeks of gestation (National guidelines: 4.4)	• Second test done between 24-28 weeks	3	• Second test done between 24-28 weeks	4	OGTT not done at first antenatal visit and 24-28 weeks of gestation	Lack of protocol

*Diagnosis and Management of Gestational Diabetes Mellitus: Technical and Operational Guidelines, 2018, Ministry of Health and Family Welfare, Government of India

Table XIII Gap Analysis in Intervention Procedures

National Guidelines*	Current Practices and Protocols				Gaps Identified	Reasons
	Maternity hospitals (N=3)	N	Multispeciality hospitals (N=4)	N		
Interventions for GDM (i) MNT and exercise as first line of treatment (National guidelines: 4.7)	• MNT with exercise prescribed by doctors • Dietitian referrals based on doctor's judgement	3 3	• MNT with exercise prescribed by doctors • Dietitian referrals based on doctor's judgement	4 4	• All GDM women are not referred to dietitians for MNT	Lack of protocol.
(ii) Choice of medication Insulin: First choice of medication. (National guidelines: 4.7)	• OHA and/ or insulin used as first choice of medication	3	• OHA and/ or insulin used as first choice of medication	4	• Choice of medication differs between obstetricians and diabetologists	Lack of protocol in choice of medication
(iii) Referrals to higher centres or specialists for GDM management (to co-	• Interdepartmental referrals based on doctor's	3	• Interdepartmental referrals based on doctor's	4	• All GDM women are not referred to other specialists like	Integrated or multidisciplinary approach is not

National Guidelines*	Current Practices and Protocols				Gaps Identified	Reasons
	Maternity hospitals (N=3)	N	Multispeciality hospitals (N=4)	N		
ordinate with other experts if needed) (National guidelines: 4.7)	judgement		judgement		diabetologists, dietitians, physiotherapists.	established
(iv) Hyperglycaemia management strategies for GDM women (National guidelines: 4.7)	• Use pre-mixed insulin or short acting insulin	3	• Use pre-mixed insulin or short acting insulin	4	• Start 8 units pre-mixed insulin if 2 hr PPBS ≥ 200mg/dl not done • Sliding scale for insulin not present	Type and dosage of insulin does not have a written protocol
(v) Hypoglycaemia management strategies for GDM women (National guidelines: 4.7)	• Immediate consumption of sugar/ oral glucose/ 25 % dextrose as IV infusion	3	• Immediate consumption of sugar/ oral glucose/ 25 %dextrose as IV infusion	4	• Immediately administer 3 tsp glucose/ 6 tsp sugar in water • Followed by a meal after 15 minutes are not followed	Hypoglycaemia correction differs based on the doctor's order as a protocol does not exist
(vi) Hypoglycaemia strategies in newborns of GDM mothers (National guidelines: 4.9.1)	• Immediate administration of IV bolus infusion of 10% dextrose at 100ml/kg/day and monitor blood sugar levels	3	• Immediate administration of IV bolus infusion of 10% dextrose at 100ml/kg/day and monitor blood sugar levels	4	• Immediate initiation of breast feeding not done • IV bolus injection 10 % dextrose at 2ml/kg/day not done	Immediate correction of hypoglycaemia with IV dextrose infusion than initiation of breastfeeding
(viii) Precautionary treatment plans/procedures for early delivery: IM administration of Inj. Dexamethasone 6mg 12 hourly for 2 days (National guidelines: 4.8)	• Followed as per guidelines (IM administration of Inj. Dexamethasone 6mg 12 hourly for 2 days)	3	• Followed as per guidelines (IM administration of Inj. Dexamethasone 6mg 12 hourly for 2 days)	4	• No Gaps	National guidelines are followed
(ix) Preliminary treatment plans/procedures at the time of delivery: (Protocol based preliminary procedure plans before delivery) (National guidelines: 4.8)	• Stop OHA or insulin on the day of delivery • Monitor GRBS and administer insulin (as per doctor's order)	3	• Stop OHA or insulin on the day of delivery • Monitor GRBS and administer insulin (as per doctor's order)	4	• Stop OHA or insulin on the day of delivery • Monitor GRBS second hourly • IV infusion of normal saline with regular insulin added as per sliding chart not followed	Procedures at the time of delivery differs based on doctor's orders and does not follow any protocol.
(x) Routine time of delivery: Before 39 weeks not recommended (National guidelines: 4.8)	Routine time of delivery:38 weeks	3	Routine time of delivery:38 weeks	4	• Routine time of delivery after 38 weeks not done for all GDM women	Time of delivery is individualised as per doctor's assessment

*Diagnosis and Management of Gestational Diabetes Mellitus: Technical and Operational Guidelines, 2018, Ministry of Health and Family Welfare, Government of India

Table XIV Gap Analysis in Monitoring and Evaluation Procedures

National Guidelines*	Current Practices and Protocols				Gaps Identified	Reasons
	Maternity hospitals (N=3)	N	Multispeciality hospitals (N=4)	N		
Monitoring and evaluation for GDM (i) Postnatal review and pre-conception counselling (National guidelines: 4.11)	• Postnatal reviews with obstetrician	3	• Postnatal reviews with obstetrician	4	• Preconception counselling not done all GDM women	Lack of awareness on national guidelines
(ii) OGTT after 6 weeks post partum (National guidelines: 4.10)	Conducts OGTT after 6 weeks	2	Conducts OGTT after 6 weeks	2	OGTT after 6 weeks is not recommended to all GDM women	Lack of awareness on national guidelines
(iii) Postpartum FBS, PPBS (National guidelines: 4.10)	(i) Conducts postpartum FBS and PPBS (i) Only post partum PPBS	2 1	(i)Postpartum FBS and PPBS (ii) Only post partum PPBS	2 2	Postpartum FBS and PPBS not done for all GDM women	Lack of setting up of protocols based on national guidelines
(iv) Follow up and evaluation every year (National guidelines: 4.10)	Follow up and evaluation done only at first post partum visit	3	Follow up and evaluation done only at first post partum visit	4	Follow up and evaluation every year does not exist	(i) Lack of patient's compliance (ii) Lack of protocols for follow up and evaluation

*Diagnosis and Management of Gestational Diabetes Mellitus: Technical and Operational Guidelines, 2018, Ministry of Health and Family Welfare, Government of India

The gaps identified in screening, assessment, diagnosis, intervention, monitoring and evaluation procedures highlight the need for setting up of standard operating protocols in hospitals for uniformity in GDM management thereby causing improvements in GDM care.

4.1.4. Concepts and Perceptions of Dietitians about MNT Practices and Protocols for GDM Management

4.1.4.1. Role and Importance of MNT

The factors influencing the need for MNT for GDM women were obtained from dietitians and the results depicted in Figure 9.

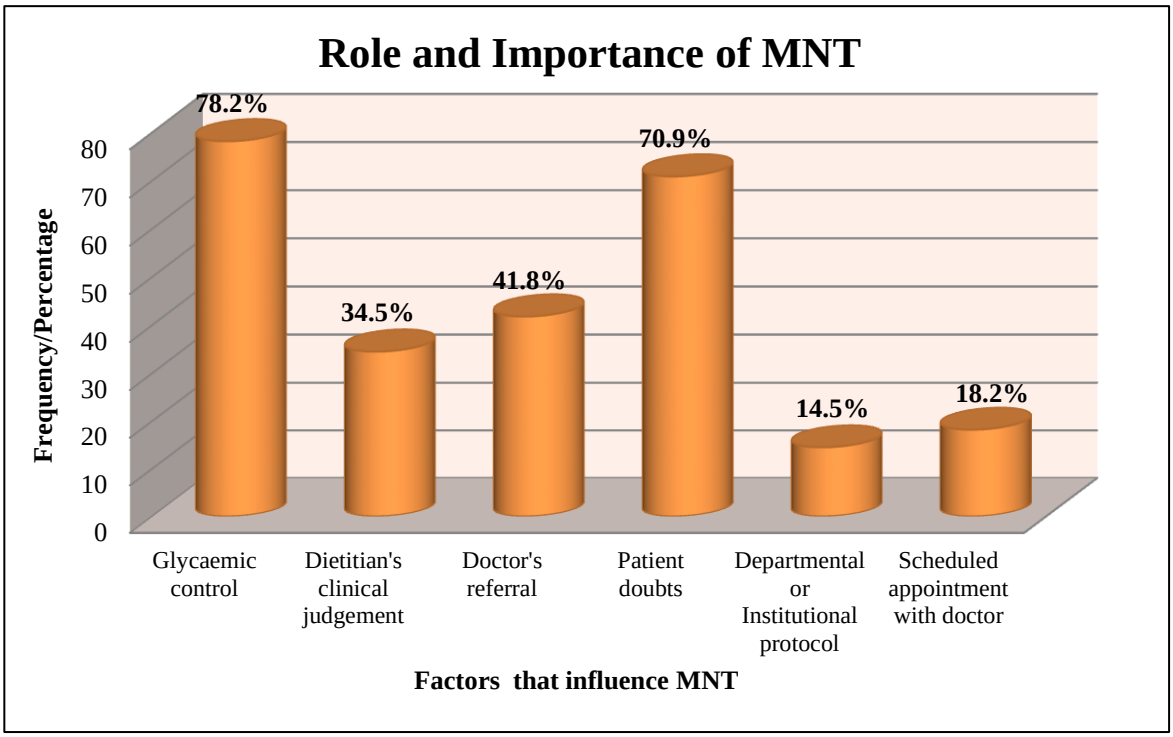

Figure 9 Role and Importance of MNT

It can be noted that 43 (78.2%) dietitians reported glycaemic control as the prominent factor that influenced the need for MNT followed by 39 (70.9%) dietitians stating patient's doubts as the factor influencing the need for MNT. The departmental or institutional protocol with responses only from 8 (14.5%) dietitians was found to be the least influencing factor for the need of MNT. This suggests that patient referrals to dietitians for MNT planning of GDM were not part of a standard operating protocol of the respective multispeciality hospital or maternity hospitals.

4.1.4.2. Confidence Level of Dietitians to Follow SSOP for MNT and their Understanding of Evidence-based MNT Guidelines for GDM

The level of confidence in providing SSOP based MNT to pregnant women and the understanding of evidence-based guidelines in GDM management among dietitians is illustrated in Figure 10.

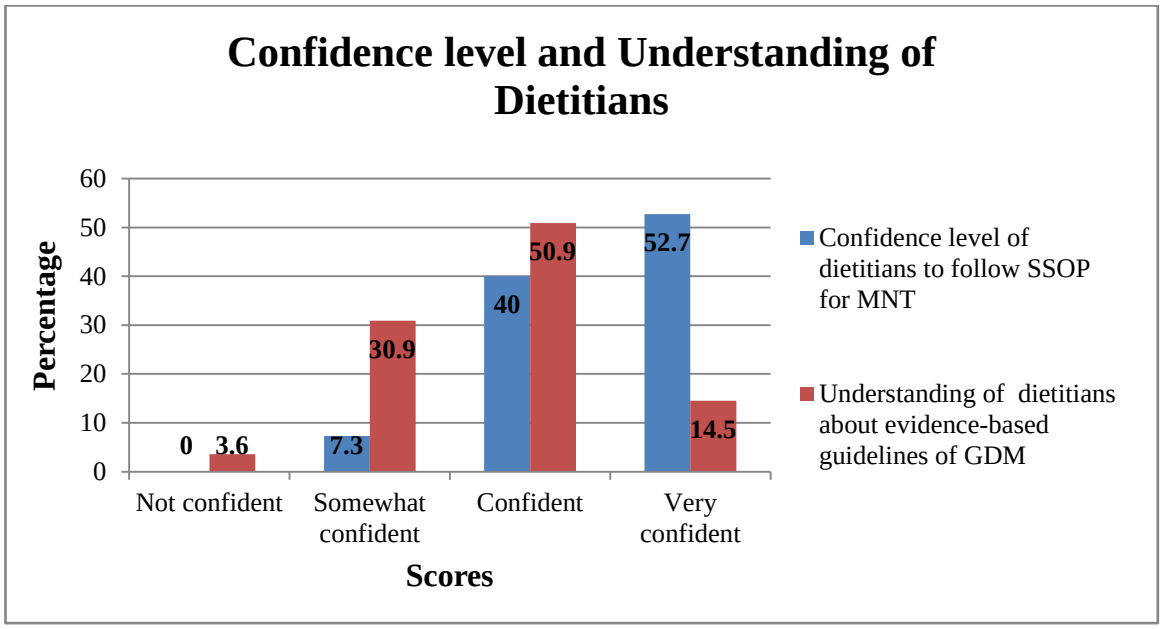

Figure 10 Confidence Level to follow SSOP for MNT and Understanding of Evidence-based Guidelines for GDM among Dietitians

The results shown in Figure 10 indicate that 29 of the total 55 dietitians (52.7%) were in the 'very confident' category indicating their confidence level in following SSOP based MNT planning for GDM. Dietitians' understanding of evidence-based MNT guidelines for GDM was found to be 50.9 percent in the 'confident' category suggestive of their awareness on evidence-based MNT guidelines for GDM. In two surveys conducted among dietitians in Australia (Morrison et.al, 2011) and Malaysia (Farhanah et al., 2014) it was observed that the nutrient recommendations differed among dietitians and need for evidence-based gestational diabetes dietetic practice guidelines were greatly felt for future practice and arriving at a consensus on dietetic practice for GDM.

4.1.4.3. MNT Components Discussed for Diet Counselling of GDM Women

The MNT components found to be most discussed and least discussed by dietitians are depicted in Figure 11 and Figure 12.

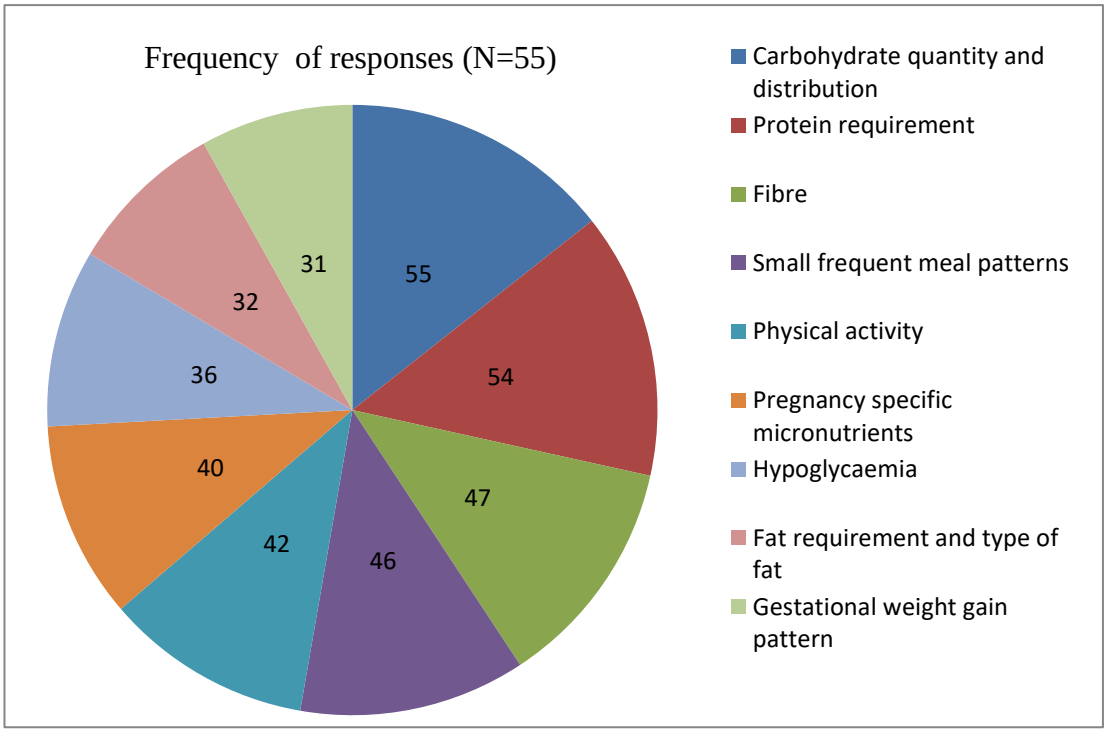

Figure 11 Most Discussed MNT Components by Dietitians

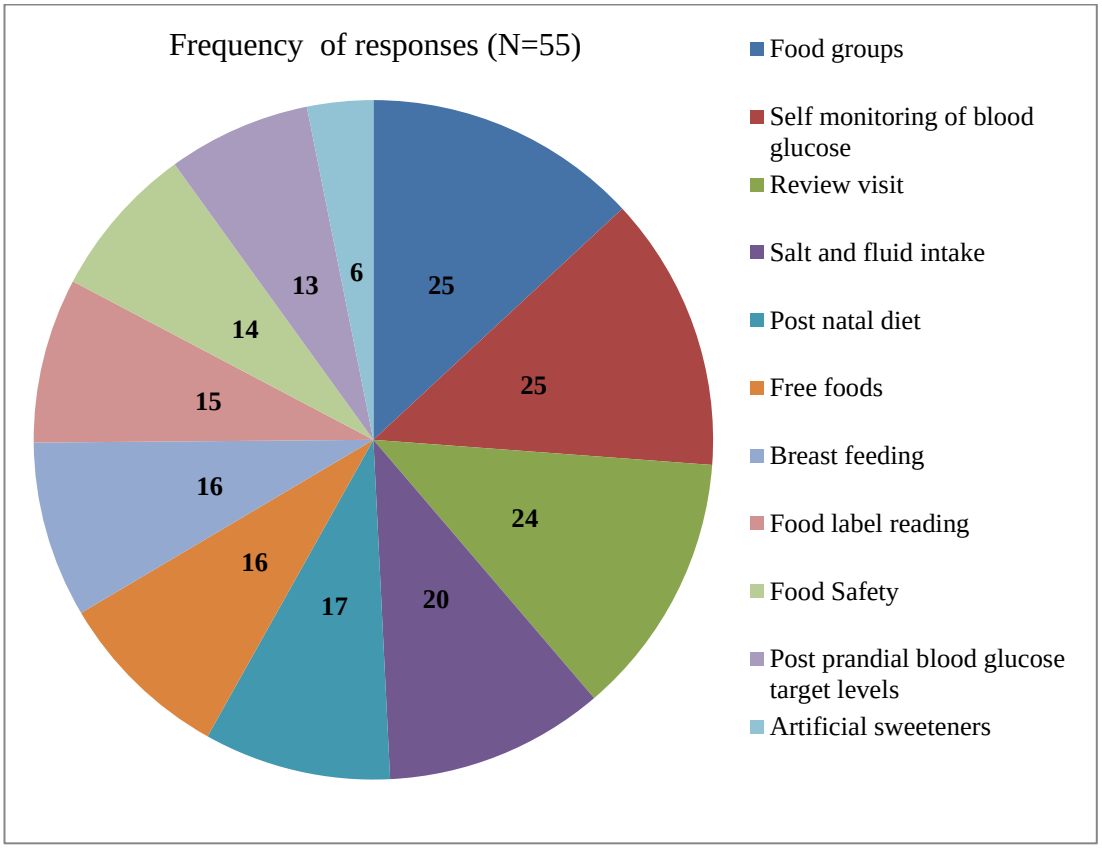

Figure 12 Least Discussed MNT Components by Dietitians

Carbohydrate quantity and distribution was discussed by all dietitians and use of artificial sweeteners was the least discussed topic while providing diet consultation for GDM women. Postprandial blood glucose target levels was found to be the second least discussed topic indicating that the need for achievement of postprandial blood glucose target levels, as described in national guidelines were not part of diet consultation given by majority of the dietitians. These findings recommend training of dietitians to improve the diet consultation provided to GDM women.

4.1.4.4. Type, Duration and Frequency of Diet Counselling for GDM

The type, duration and frequency of diet consultations done for GDM women are presented in Figure 13, Figure 14 and Figure 15.

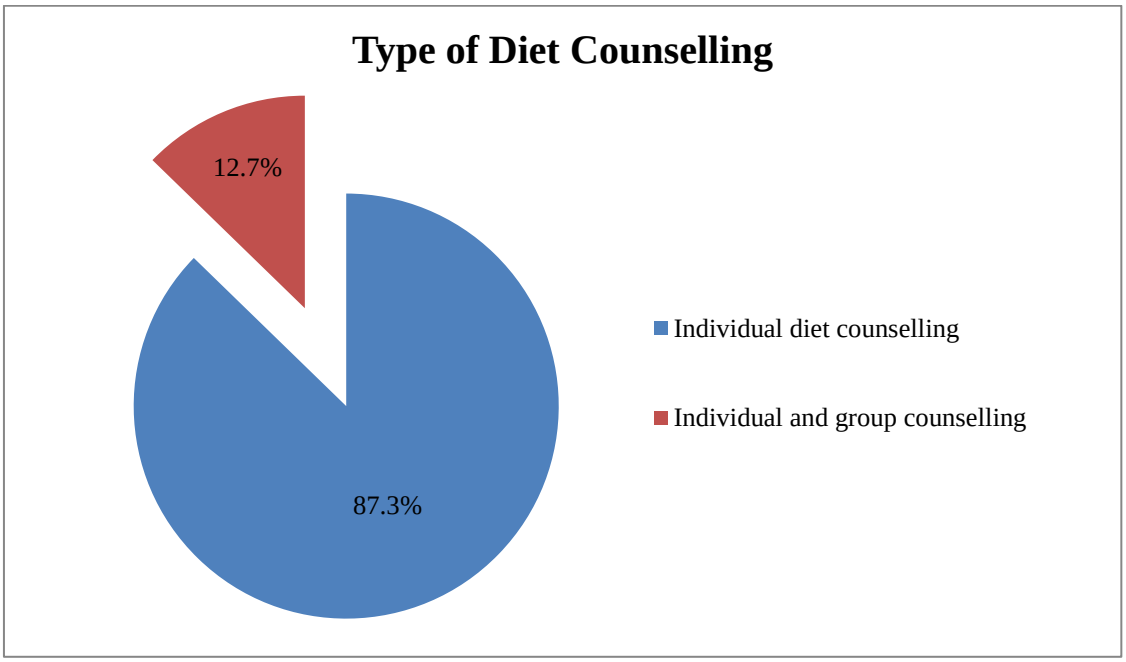

Figure 13 Type of Diet Counselling

It can be seen that individualised diet counselling were provided to GDM women by 87.3 percent dietitians in their practice (Figure 14). A study by Reader et al., (2017) reported reduction in the rates of adverse pregnancy outcomes when individualised dietary advice from a qualified dietitian was provided to women diagnosed with GDM. However group dietary education has also been found to be equally effective in GDM management when it is followed by at least one initial individual diet consultation (Barnes et al., 2018).

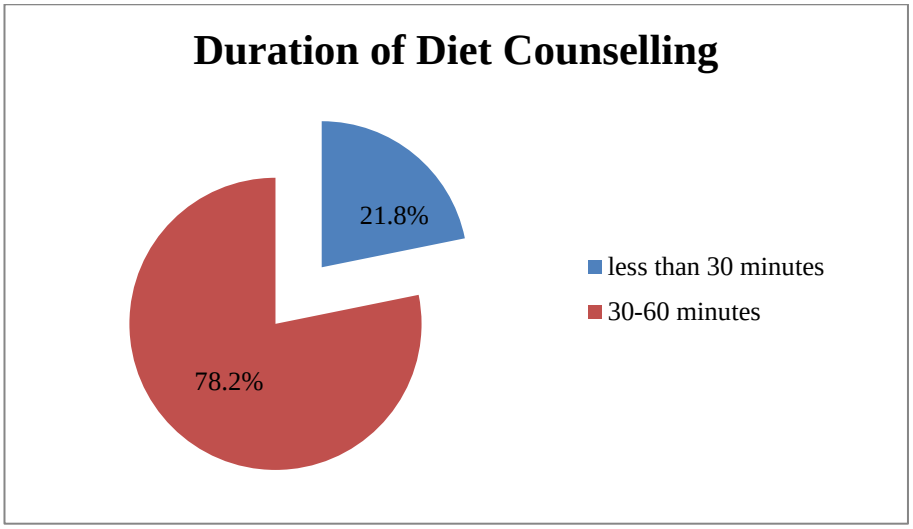

Figure 14 Duration of Diet Counselling

Forty three out of 55 dietitians (78.2 %) reported the duration of diet counselling to be 30 to 60 minutes for every GDM woman. Although MNT is considered as the cornerstone in GDM management there is no specific guidelines on the duration of MNT visit or diet counselling required for GDM except the GDM guidelines of AND (2016) which recommends initial 60 to 90 minutes MNT visit followed by a second MNT visit of 30-45 minutes and a third MNT visit of duration 15 to 45 minutes. The results indicate the need for a systematic procedure for MNT visit or diet counselling provided to GDM women.

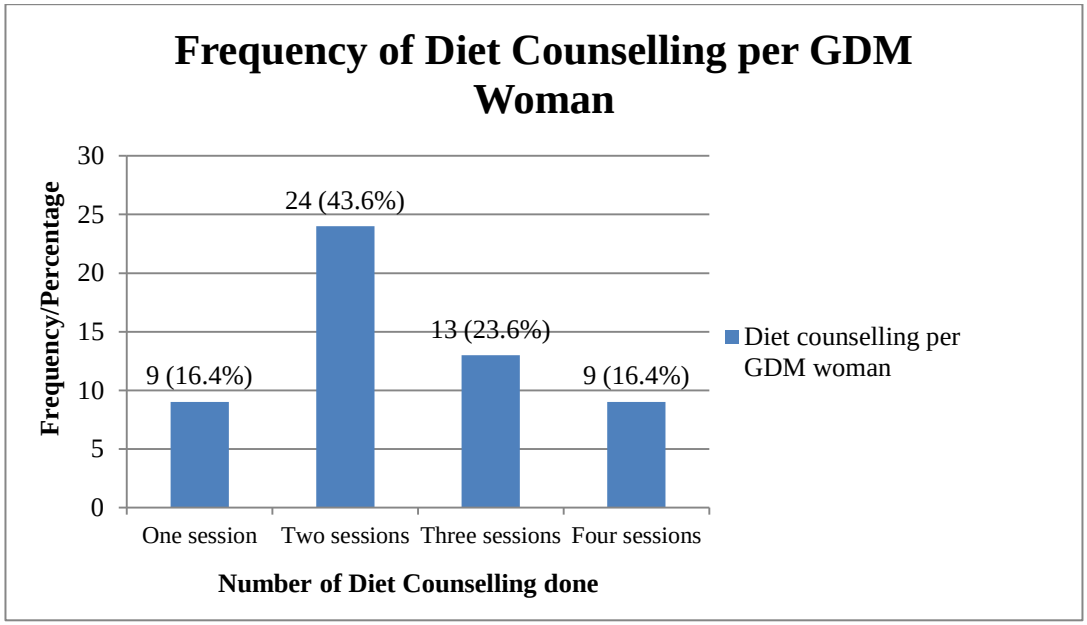

Figure 15 Frequency of Diet Counselling per GDM Woman

From Figure 15, it is evident that the frequency of diet counselling was only two per GDM woman as reported by 24 of 55 (43.6%) dietitians. The GDM guidelines of AND (2016) recommend regular and frequent MNT visits for GDM women to optimise outcomes. The guidelines suggest a second MNT visit within a week after the initial MNT visit, followed by a third MNT visit within two to three weeks. The guideline further suggests scheduling of additional MNT visits every two to three weeks as needed during gestation period. The results indicate lack of proper MNT visit scheduling for GDM women in the selected hospitals further addressing the need for standard operating protocols for MNT visits for GDM women.

4.1.5. Gaps Analysis of Current MNT Practices and Protocols with National Guidelines for GDM Management

Dietitians play a pivotal role in the medical nutrition therapy of GDM. International organizations like ADA, AND, Diabetes UK, Royal College of General Practitioners and Diabetes Australia, Italian Association of Diabetes, etc. recommend MNT interventions done specifically by dietitians in their clinical practice guidelines for GDM (Tsirou et.al, 2019). The gap analysis of the current MNT practices and protocols in GDM management is presented in Table XV.

Table XV Gap Analysis in MNT Practices for GDM

National guidelines*	Current practices and protocols		Gaps identified	Reasons
	Maternal clinics (N=3)	Multispeciality hospitals(N=4)		
Nutrition assessment (i)Individualised nutrition assessment (National guidelines: 3.7)	• Nutrition assessment is individualised.	• Nutrition assessment is individualised.	• No Gaps	Followed as per national guidelines
(ii) Defining BMI and assessing GWG based on pre-pregnancy weight and calculating the nutrients. (National guidelines: 3.7)				No updation of practices

National guidelines*	Current practices and protocols		Gaps identified	Reasons
	Maternal clinics (N=3)	**Multispeciality hospitals(N=4)**		
(ii) Use of operating guidelines for MNT of GDM women (National guidelines: 3.7)	• Use RDA, ICMR-NIN, IDA guidelines	• Use RDA, ICMR-NIN, IDA guidelines	• Guidelines used differ among dietitians	Lack of awareness
Nutrition intervention (i)Individualised nutrition intervention (National guidelines: 3.7)	• Individualised and group diet consultations are done	• Individualised diet consultations are done	• No gaps	Nil
(ii) Composition of meals, snacks and carbohydrate distribution (3 small meals plus 2-3 snacks each day rather than 3 large meal pattern, (National guidelines: 3.7)	• Carbohydrate distribution in meal and snacks are done	• Carbohydrate distribution in meal and snacks are done	• Splitting of meals in diet prescription differs among dietitians	Lack of updation on current guidelines
(iii)Energy, protein calculation based on pre-pregnancy weight, BMI and ICMR equations (National guidelines: 3.7)	• Energy and protein calculation is based on IDA or RDA, ICMR-NIN	• Energy and protein calculation is based on IDA or RDA, ICMR-NIN	• Pre-pregnancy BMI based nutrient calculations are not done for energy and proteins	Lack of awareness and updation on current guidelines

*Diagnosis and Management of Gestational Diabetes Mellitus: Technical and Operational Guidelines, 2018, Ministry of Health and Family Welfare, Government of India

The gaps identified on MNT practices were in pre-pregnancy BMI and gestational weight gain assessment based nutrient calculations and the use of different operating guidelines for MNT planning. These gaps emphasize the need for improving the awareness of dietitians towards the use of protocol-based MNT practices for GDM management. A systematic review of clinical practice guidelines (CPGs) of dietary recommendations for GDM women reported that although most dietary recommendations were strongly made, there was no clarity in evidence base behind the recommendations and research gaps were identified requiring future research to enable development of evidence based CPGs (Mustafa et al., 2021).

Apart from the gaps identified regarding the MNT practices in GDM management in hospitals with respect to national guidelines, the MNT practices identified in GDM Guidelines, 2016, AND are given in Table XVI.

Table XVI MNT Practices Identified in GDM Guidelines, 2016, Academy of Nutrition and Dietetics

S.No.	MNT Practices Nutrition Care Process	Recommendation
1	Nutrition screening and referral	• Screening and Referral to a Registered Dietitian Nutritionist for MNT
2	Nutrition Assessment	• Food and Nutrition-related history inclusive of access to food, food preparation • Knowledge, readiness and willingness to make lifestyle changes • Physical activity • Biochemical data, pertinent client history
3	Nutrition Diagnosis	• Problem. Etiology Signs and Symptoms (PES) statement to formulate nutrition care plan
4	Nutrition Intervention	• Individualised MNT with regular and frequent MNT visits • A minimum of three MNT visits during gestation period • Additional MNT visits scheduled as per need • MNT components such as adequacy of GWG. importance of SMBG, target blood glucose levels, use of artificial sweeteners and avoidance of alcohol and smoking should be discussed during diet counselling
5	Nutrition Monitoring and Evaluation	• Evaluate changes in food patterns, knowledge and beliefs • Post meal glucose levels and compare with required levels • Patient outcomes with respect to nutrition diagnosis and nutrition intervention. • Check scan results and other relevant lab tests • Correct nutritional problems which require further nutrition intervention

4.1.6. Current Practices and Management of GDM as per Responses of Pregnant Women

4.1.6.1. Demographic Profile of Pregnant Women

Table XVII describes the background details of the selected pregnant women both GDM and Non-GDM women to obtain details on the GDM management and MNT practices.

Table XVII – Background Details of Pregnant Women

Demographic details	GDM women (N=106)		Non-GDM women (N=54)		P value
	N	%	N	%	
Age (years)					
18-24	8	7.5	6	11.1	
25-31	60	56.6	32	59.3	0.762 ^{NS}
32-39	31	29.2	14	25.9	
39-45	7	6.6	2	3.7	
Education					
Higher Secondary	15	14.2	7	13	0.336 ^{NS}
Graduate	60	56.6	25	46.3	
Post graduate	31	29.2	22	40.7	
Employment					
Employed	38	35.8	22	40.7	0.546 ^{NS}
Umnemployed	68	64.2	32	59.3	
Gravidity					
Primigravida	46	43.4	23	42.6	0.923 ^{NS}
Multigravida	60	56.6	31	57.4	
Period of Gestation					
Second trimester	66	62.3	8	14.8	<0.001**
Third trimester	40	37.7	46	85.2	
Delivery status at end of study period					
Delivered	36	34	51	94.4	<0.001**
Not delivered	70	66	3	5.6	

** Significant at 1% level, ^{NS} Not Significant

The t test to compare the mean ages of 30.59±4.57 years in GDM women and 29.56±4.13 years in Non-GDM women revealed no significant difference (*t* value -1.403, p=0.163) suggesting the homogeneity in the age of the pregnant women in both groups. The educational qualification of the participants showed 56.6 percent graduates in GDM group

compared to 46.3 percent graduates in Non-GDM group. Whereas post graduates were seen in 40.7 percent Non-GDM women compared to 29.2 percent in GDM women. These findings showed both GDM and Non-GDM women to be well-educated. However, the employment details collected showed that 64.2 percent women in GDM group and 59.3 percent women in Non-GDM women were not working or had quit their job after becoming pregnant. The gravidity of the study participants revealed 56.6 percent GDM women being multigravida compared to 57.4 percent in Non-GDM women. The period of gestation significantly differed between groups with 62.3 percent GDM women in second trimester compared to 85.2 percent Non-GDM women in third trimester respectively. The status of delivery at the end of the study period was found to significantly differ with 94.4 per ent delivered Non-GDM women compared to 34 percent delivered GDM women.

4.1.6.2. Anthropometric Measurements and BMI Categorisation of Pregnant Women

Table XVIII depicts the comparison of anthropometric measurements namely height, pre-pregnancy weight and BMI of the pregnant women.

Table XVIII Comparison of Height, Pre-pregnancy Weight and Body Mass Index (BMI) among Pregnant Women

Anthropometric measurements	GDM women (N=106)		Non-GDM women (N=54)		P value
	Mean	SD	Mean	SD	
Height (cm)	157.82	4.69	157.32	6.26	0.572 ^{NS}
Pre-pregnancy weight (kg)	62.69	11.37	59.50	12.28	0.105 ^{NS}
BMI (kg/m^2)	25.16	4.47	23.97	4.27	0.108 ^{NS}
BMI Categorisation	**N**	**%**	**N**	**%**	
Underweight (<18.5 kg/m^2)	5	4.7	3	5.6	0.286 ^{NS}
Normal (18.5-22.9 kg/m^2)	28	26.4	22	40.7	
Overweight (23-24.9 kg/m^2)	27	25.5	10	18.5	
Obese (≥25 kg/m^2)	46	43.4	19	35.2	

^{NS} Not Significant

The mean height and mean weight were only comparable and did not vary among both groups. The mean BMI of 25.16±4.47kg/m^2 in GDM women and 23.97±4.27 kg/m^2 assessed were not statistically significant among groups and were within the overweight

category as per WHO Asian Classification for BMI. One of the largest studies on pregnant women in Asia reported that higher pre-pregnancy BMI increases maternal risk for GDM, preeclampsia, prolonged labour, post partum haemorrhage and the need for assisted delivery, and foetal outcomes such as macrosomia. It is thus essential to understand the pre-pregnancy BMI and the corresponding expected gestational weight gain as per the guidelines of Institute of Medicine to avoid pregnancy complications.

4.1.6.3. Biochemical Tests and OGTT conducted among Pregnant Women

The biochemical details such as Random Blood Sugar (RBS), Fasting Blood Sugar (FBS), Glycosylated Haemoglobin (HbA1c), Haemoglobin (Hb), Throid Stimulating Hormone (TSH) and Oral Glucose Tolerance Test (OGTT) details are presented in Table XIX and Table XX respectively.

Table XIX Comparison of Biochemical Tests among Pregnant Women

Biochemical investigations	GDM women			Non-GDM women			P value
	N	Mean	SD	N	Mean	SD	
RBS (mg/dl)	65	105.25	22.34	29	88.93	9.94	<.001**
FBS (mg/dl)	19	97.84	20.93	4	85.50	5.32	0.112 ^{NS}
HbA1c (%)	40	5.79	0.94	16	5.25	0.31	0.029*
Hb (g/dl)	89	12.19	0.99	47	11.97	1.35	0.466 ^{NS}
TSH (mIU/l)	75	2.02	1.47	38	1.76	1.17	0.385 ^{NS}

*Significant at 5% ** Significant at 1% level, ^{NS} Not Significant

It can be noted that the RBS and HbA1c were statistically significant between both groups. GDM women had a greater mean RBS of 105.25±22.34g/dl compared to 88.93±9.94mg/dl in Non-GDM women although it is within normal limits for both groups. However, the mean HbA1c value of 5.79% among GDM women clearly indicates the impaired glucose tolerance within this group compared to HbA1c level of 5.25% among Non-GDM women. The mean haemoglobin levels were comparable among groups and were above the cut-off value of 11g/dl which is considered as normal in pregnancy (WHO, 2011). Furthermore the mean TSH levels of both groups were also found to be within the normal range for pregnancy (ITS –FOGSI, 2019).

Table XX Comparison OGTT Values among Pregnant Women

OGTT result	GDM women			Non-GDM women			P value
	N	Mean	SD	N	Mean	SD	
Blood glucose (Fasting)	53	100.53	15.02	29	83.76	6.01	<.001**
Blood glucose (After 1 hour)	35	184.66	30.98	22	124	27.13	<.001**
Blood glucose (After 2 hours)	66	144.47	40.74	43	106.02	17.28	<.001**

** Significant at 1% level

All the mean OGTT values including fasting, after 1 hour value and after 2 hour values were found to be highly significant at one percent level in GDM women compared to Non-GDM women. The evident difference in the mean blood glucose levels between groups underlines diagnostic screening using OGTT to be done for GDM detection.

4.1.6.4. Clinical Details of Pregnant Women

The results of Chi-square analysis done on the clinical problems observed through the ultrasound scans during the antenatal period among GDM and Non-GDM women are presented in table XXI.

Table XXI Antenatal Complications among Pregnant Women

Antenatal complications	GDM women (N=106)		Non-GDM women (N=54)		P value
	N	%	N	%	
Foetal defects (Congenital defects, pelvicalceal dilatation, hydronephrosis, high nuchal transluscency values, dolichocephaly)	4	3.8	5	9.3	0.162 ^{NS}
Foeto-placental anomalies (Oligohydramnios, polyhydramnios, low or high foetal weight, IUGR, organs underdeveloped, circum vallate placenta)	20	18.9	19	35.2	
Maternal abnormalities (Cervical insufficiency, fibroid, pre-eclampsia, anaemia, hypothyroidism, dengue fever, anxiety/depression)	9	8.5	2	3.7	

^{NS} Not Significant

The antenatal complications observed among the GDM and Non-GDM women was not significant indicating that occurrence of antenatal problems among both groups did not vary.

4.1.6.5. Dietary Assessment of Pregnant Women

The nutrient intake of the daily diets of GDM and Non-GDM were compared with the recent Recommended Dietary Allowance of ICMR and shown in Table XXII.

Table XXII Comparison between RDA and Nutrient Intake of Pregnant Women

Nutrients	RDA[#]	GDM women (N=106)			Non-GDM women (N=54)		
	Ref. values	Mean Intake	% Excess/ Deficit	P value	Mean Intake	% Excess/ Deficit	P value
Energy (Kcal)	2010[a]	1998.53	-0.6	0.734 [NS]	2251.59	+12	<0.001**
Carbohydrate (g)	175	255.51	+46	<0.001**	301.13	+72	<0.001**
Protein (g)	75	66.38	-11	<0.001**	73.42	-2	0.464 [NS]
Fat (g) Visible Fat = 30g Total fat (20-35 en%) =78.2g	78.2	77.82	-0.004	0.774 [NS]	84.26	+8	0.004**
Calcium (mg)	1000	659.60	-34	<0.001**	766.56	-23	<0.001**
Iron (mg)	40	11.61	-72	<0.001**	10.08	-75	<0.001**
Fibre (g)	40	35.21	-12	<0.001**	34.02	-15	<0.001**

*Significant at 1% level, [NS] Not Significant, [#]RDA – Recommended Dietary Allowance [a]RDA with added allowance for pregnancy – 350kcal

The energy and fat intake was slightly lower RDA among GDM women with 0.6 percent deficit in energy and .01 percent in fat, whereas among Non-GDM women both energy and fat intake were exceeding RDA with 12 percent excess in energy and eight percent in fat intake respectively. This may be due to the calorie and fat restriction done by GDM women for effective blood glucose control. However, carbohydrate intake was found to be in excess in both groups ranging from 46 to 72 per cent than RDA. Proteins which are one of the important macronutrients required in additional amounts during pregnancy, was deficient in both groups ranging from 2 to 11 percent than RDA for proteins. Similarly, calcium, iron and fibre were deficient among both the groups with the iron intake found to be shockingly deficient by a percent ranging from 72 to 75 percent than RDA. A study on the consumption pattern of GDM and pre-gestational diabetes women found their diets to be containing excess energy, fat and deficient in whole cereals, fibre and minerals like iron

suggesting the need for raising the awareness of women on choosing right foods during pregnancy (Savitha and Mageshwari, 2013). The findings of the present study indicate the need for educating both GDM and Non-GDM women on making the right choices of food, adequate in quantity and quality so as to meet the nutritional requirements for the mother as well as the growing foetus. MNT works better when the diet advice and nutritrion counselling are done by a dietitian making it easier to understand the right food choices, best cooking methods and meal plans towards adapting to healthy eating behaviours (Kapur et al., 2021).

4.1.7. Concepts, Perceptions about GDM among Pregnant Women

4.1.7.1. Risk Factors of GDM

The risk factors of GDM were analysed among GDM and Non-GDM women and presented in Table XXIII.

Table XXIII – Risk Factors of GDM among Pregnant Women

Risk factors of GDM	GDM women (N=106)		Non-GDM women (N=54)		P value
	N	%	N	%	
Family history of Type 2 DM	68	64.2	18	33.3	<.001**
Previous history of PCOS	27	25.5	10	18.5	0.324 ^{NS}
Previous history of Hypothyroidism	27	25.2	13	24.1	0.847 ^{NS}
GDM in previous pregnancy	23	21.7	6	11.1	0.100 ^{NS}
Previous history of delivering large baby	2	1.9	nil	nil	0.310 ^{NS}
Maternal age > 25yrs	95	89.6	46	85.2	0.412 ^{NS}

**Significant at 1% level, ^{NS} Not Significant, Type 2 DM –Type 2 Diabetes Mellitus, PCOS- Polycystic Ovarian Syndrome

Family history of Type 2 DM among GDM and Non-GDM significantly differed at 1 per cent level with 64.2 percent in GDM women compared to 33.3 percent in Non-GDM women indicating that family history of Type 2 DM can be considered as a risk factor for GDM. All other risk factors such as previous history of PCOS, hypothyroidism and GDM in previous pregnancy, previous history of delivering large baby and maternal age greater than

25 years did not show any significant difference although the presence of these factors were greater in GDM women compared to Non-GDM women.

4.1.7.2. Understanding the Consequences of GDM among Pregnant Women

The understanding the consequences of GDM were analysed among GDM and Non-GDM women and presented in Table XXIV.

Table XXIV Understanding the Consequences of GDM among Pregnant Women

Variables	GDM women (N=106)		Non-GDM women (N=54)		P value
	N	%	N	%	
Awareness on consequences of GDM	57	53.8	18	33.3	0.014**
Readiness for current pregnancy	95	92.6	50	89.6	0.542^{NS}

** Significant at 1% level, ^{NS} Not Significant

From Table XXIV it is evident that the awareness of GDM and Non-GDM women on the consequences of GDM on pregnancy significantly differed with 57 (53.8%) GDM women showing an understanding of the impact of GDM on pregnancy compared to 18 (33.3%) in Non-GDM women. Bhavadharini B. et.al, (2017) evaluated the knowledge about GDM among pregnant women and found that most participants were unaware of the possible effects of GDM on the mother or the baby suggesting that HCPs should ensure that pregnant women are counselled about GDM and its adverse consequences.

The responses of GDM and Non-GDM women recorded to assess their current pregnancy as planned or unplanned was not statistically significant (p=0.542) between groups. In both groups 50 (92.6%) Non-GDM women and 95(89.6%) GDM women positively stated that their current pregnancy was planned, suggesting their readiness for motherhood.

4.1.7.3. Perception towards Managing Pregnancy among Pregnant Women

Table XXV shows the t-test results between GDM and Non-GDM women concerning their perception of making lifestyle changes to manage pregnancy and their confidence level in adopting lifestyle changes in pregnancy.

Table XXV Perception towards Managing Pregnancy among Pregnant Women

Variables	GDM Women (N=106)	Non- GDM Women (N=54)	t value	P value
	Mean score±SD	Mean score±SD		
Importance of making changes in lifestyle to manage pregnancy	9.08±.68	8.72±.81	-2.992	0.003*
Confidence level in adopting lifestyle changes in pregnancy	8.40±.90	7.76±.99	-4.088	<0.001*

* Significant at 1% level

The mean scores for the importance of making changes in lifestyle to manage pregnancy were significantly different among both groups with 9.08±.68 in GDM women compared to 8.72±.81in Non-GDM women. Similarly, the mean score for confidence level in adopting lifestyles in pregnancy also significantly differed with 8.40±.90 in GDM women compared to 7.76±.99 in Non-GDM women indicating that GDM women had good perception towards making changes to manage pregnancy as well as greater confidence to adopt these changes compared to their counterparts, which may be as a result of their need to keep their blood glucose within the target levels.

4.1.8. Details of MNT practices and Physical Activity among Pregnant Women

4.1.8.1. MNT Practices received among Pregnant Women

The MNT practices received by GDM and Non-GDM women are presented in Table XXVI.

Table XXVI MNT Practices received among Pregnant Women

MNT practices	GDM Women (N=106)		Non- GDM Women (N=54)		P value
	N	%	N	%	
MNT plan received	82	77.4	26	48.1	<0.001**
MNT received during					
In patient (IP) admission /	68	64.2	6	11.1	<0.001**
GDM detection /					
After delivery	14	13.2	20	37	
MNT given by					
Treating doctor	10	9.4	nil	nil	

MNT practices	GDM Women (N=106)		Non- GDM Women (N=54)		P value
	N	%	N	%	
Dietitian	72	67.9	26	48.1	
Self-made	24	22.6	28	51.9	<0.001**
Duration of MNT					
Two weeks or up to 3 months	24	22.6	nil	nil	
<2 weeks or MNT with medicines	51	48.1	nil	nil	nil
MNT only	31	29.2	nil	nil	nil
					nil
Reasons for noncompliance of MNT					
Loss of appetite	12	11.3	5	9.3	
Uncontrolled hunger	43	40.6	15	27.8	0.689 NS
Adequacy in quantity and quality of diets difficult to maintain	63	59.4	10	18.5	0.112 NS
					<0.001**

* Significant at 1% level, NS Not Significant

The medical nutrition therapy received among GDM and Non-GDM women was statistically significant at 1 per cent level showing that 77.4 percent GDM women received MNT compared to 48.1 percent Non-GDM women. The time of receiving MNT also significantly differed among both groups with 64.2 percent GDM women receiving MNT at the time of detection of GDM and 13.2 percent receiving MNT after delivery compared to 11.1 percent Non-GDM receiving upon IP admission and 37 percent Non-GDM women receiving it after delivery. The duration of MNT of less than two weeks or initiation of MNT along with medicines was found in 48.1 per cent of the GDM women suggesting that the MNT duration as per national guidelines are not followed in the selected hospitals. The comparison of factors affecting compliance to MNT among both groups showed significant difference in the inability to maintain adequacy of diet quality and quantity with 59.4 percent in GDM women compared to 18.5 percent in Non-GDM women indicating that such issues were prominent among GDM women than their counterparts. All these indicate deficiencies in the MNT practices followed in the surveyed hospitals recommending the need for protocol based MNT practices.

4.1.8.2. Physical Activity Patterns among Pregnant women

The physical activity patterns of GDM and Non-GDM women are shown in Table XXVII.

Table XXVII – Physical Activity Patterns among Pregnant Women

Details of Physical activity	GDM Women (N=106)		Non-GDM Women (N=54)		P value
	N	%	N	%	
Exercise					
Walking	60	56.6	30	33.6	0.899[NS]
Duration of walking (15-30min)	31	51.7	17	56.7	0.654 [NS]
Frequency of walking(>5times/wk)	44	72.1	26	83.9	0.212 [NS]
Rest					
Hours inactive day time (5-6 hours)	45	42.5	22	40.7	0.884 [NS]
Rest advised by doctor	18	17.0	9	16.7	0.960 [NS]

[NS] Not Significant

The physical activity patterns in GDM and Non-GDM women did not show any significant difference for type, duration and frequency of exercise as evidenced by walking being done by 56.6 percent GDM women compared to 33.6 percent Non-GDM women. The duration of walking of 15-30 minutes was stated by 56.7 percent Non-GDM compared to 51.7 percent GDM women and a frequency of greater than five times per week was reported by 83.9 percent Non-GDM women compared to 72.1 percent GDM women. The rest recommendation advised by doctor and the hours of inactivity also did not show any marked difference indicated by 5-6 hours of inactivity during the day among 42.5 percent GDM women and 40.7 percent Non-GDM women respectively. The Asia-Pacific consensus on physical activity needed in pregnancy and the postnatal period recommends 150 minutes of moderate intensity exercise every week during pregnancy for those with no contraindication (Lee et al., 2021). In the present study although 56.6 percent GDM women were engaged in walking as the form of exercise, it cannot be considered to be as per guidelines as it was not brisk walking and did not come under moderate intensity physical activity. It has been reported that pregnant women in India are less physically active compared to pregnant women in western countries (Anjana et al., 2016).

4.1.9. Details of Delivery Outcomes among Pregnant Women

Results of mode of labour, type of delivery, birth weight of new born, birth outcomes, maternal and foetal outcomes among GDM and Non-GDM women are presented in Table XXVIII.

Table XXVIII Delivery Details, Maternal and Foetal Outcomes among Pregnant Women

Delivery Details	GDM Women (N=106)		Non-GDM Women (N=54)		P value
	N	%	N	%	
Mode of labour					
Spontaneous	5	13.9	18	35.3	0.026*
Induced/emergency	31	86.1	33	64.7	
Mode of delivery					
Vaginal delivery	12	33.3	21	41.2	0.822 ^{NS}
Caesarean delivery	22	61.1	27	52.9	
Others (vacuum, forceps)	2	5.6	3	5.9	
Birth weight of new born					
Less than 2.5kg	8	22.2	8	15.7	0.438 ^{NS}
2.5kg-4kg	28	77.8	43	84.3	
Birth outcome					
Preterm	10	27.8	3	5.9	0.006**
Term	26	72.2	48	94.1	
Presence of adverse maternal outcomes	8	22.2	8	15.7	0.438 ^{NS}
Presence of adverse foetal outcomes	22	61.1	20	39.2	0.044*

*5% level of significance, ** 1% level of significance, ^{NS} Not Significant

The mode of labour, birth outcome and adverse foetal outcomes were the parameters found to show significant difference among groups. The results of the mode of labour among both groups was statistically significant at five percent level with spontaneous labour in 35.3 percent Non-GDM women compared to 13.9 percent in GDM women and emergency or induced labour in 86.1 percent GDM women compared to 64.7 percent in Non-GDM women respectively.

The mode of delivery was comparable among groups with 41.2 percent vaginal deliveries in Non-GDM women compared to 33.3 percent in GDM women. Whereas, 61.1 percent caesarean deliveries were noted in GDM women compared to 52.9 percent in Non-GDM women. Other modes of delivery namely vacuum and forcep assisted deliveries were negligible with 5.6 percent in GDM and 5.9 percent in Non-GDM women respectively. In a large retrospective cohort study (N=4033) it was observed that GDM women had greater risk for induced delivery and caesarean section compared to the controls without GDM (Koivunen et al., 2020).

In the present study, birth outcomes namely preterm birth significantly differed with 27.8 percent in GDM women compared to 5.9 per cent in Non-GDM women and term births of 94.1 percent in Non-GDM women compared to 72.2 percent in GDM women respectively. The birth weight of infants born to GDM and Non-GDM women was comparable with 15.7 percent Non-GDM with low birth weight babies compared to 22.2 percent in Non-GDM group. Similarly 84.3 percent Non-GDM women delivered babies with normal weight compared to 77.8 percent of GDM women. There was no difference in the adverse maternal outcomes observed among both the groups. However, the presence of adverse foetal outcomes was statistically significantly with 61.1 percent in GDM women compared to 30.2 percent in Non-GDM women. These results indicate GDM women being susceptible for induced labour, preterm delivery and adverse foetal outcomes compared to Non-GDM women and the SSOP based MNT should focus on these lines towards betterment of maternal and foetal outcomes.

4.1.10. Patient Education Activities for GDM Management

The investigator observed that four out of seven hospitals conducted patient education activities such as out-patient group sessions on topics such as what to expect during pregnancy, need for proper diet and antenatal yoga led by the respective HCPs namely a obstetrician, a dietitian and a yoga instructor once a month. It is beneficial to include patient education activities as group sessions during pregnancy as it positively influences the psychosocial condition of pregnant women leading to favourable perinatal outcomes (Salvador-Moysén et al., 2021).

4.1.11. Mapping of Lacunae Identified in Current Practices and Protocols in GDM Management

The existing practices in GDM management were mapped and lacunae represented in Figure 16 as follows.

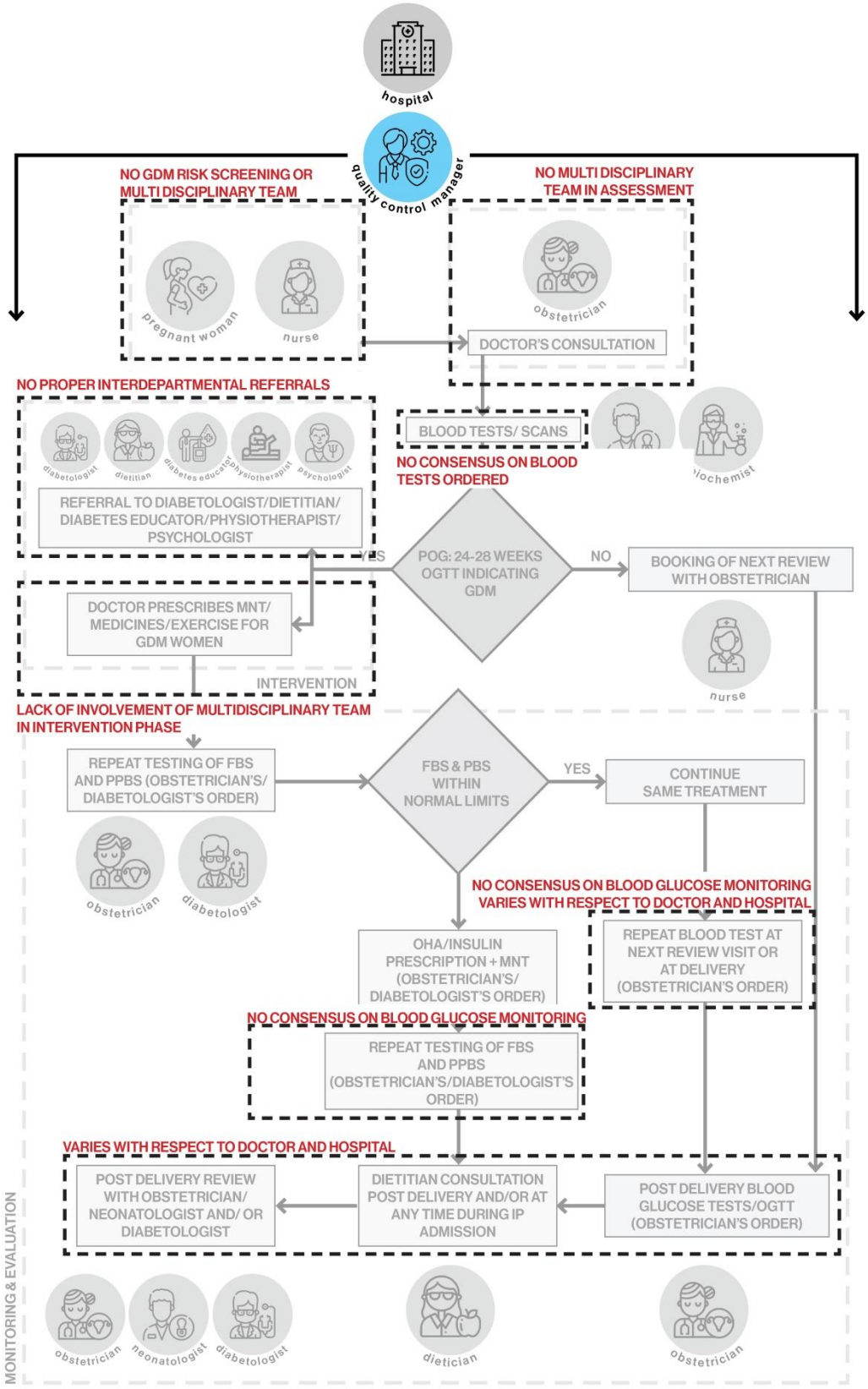

Figure 16 Lacunae Identified in Existing Practices in GDM management

Figure 16 illustrates the flow of operations/processes in GDM management. It was observed that all pregnant women visiting the hospital underwent initial screening. However, GDM risk screening and Oral Glucose Tolerance Test (OGTT) were not conducted at first antenatal visit. Lack of screening due to the absence of a protocol based initial assessment and not keeping any registry for GDM prevalence and postpartum follow were reported as barriers for effective GDM management (Nwose et al., 2019). Assessment processes such as blood investigations suggested and the diagnosis criteria used for detection of GDM was found to vary among the surveyed hospitals. Intervention strategies such as immediate MNT referral to dietitian upon GDM detection, multidisciplinary approach, use of SOP based MNT etc. and monitoring and evaluation procedures namely self monitoring of blood glucose, review visits with dietitians, modification of diet plans based on SMBG, monitoring of GWG, blood investigations done at peri-natal and post-natal periods were found to differ compared to standard guidelines and are highlighted with red text in Figure 17.Lack of adequate scheduling of dietitian consultations and referrals and use of guidelines for GDM management have been reported as barriers to effective GDM management (Wilkinson et al., 2014). Although the national guidelines for diagnosis and management of GDM in India was formulated in 2014 by the Maternal Health Division of the Ministry of Health and Family Welfare, Government of India and later updated in 2018, the actual implementation is still in the trial phase in many parts of India (Mishra et al., 2020).

4.2. Phase II: Development, Validation and Optimisation of a SSOP for MNT of GDM women

4.2.1. Development of SSOP

As the study focused on improvement in MNT followed for GDM management, based on the limitations observed in Phase I of the study, a Sustainable Standard Operating Protocol (SSOP) was developed based on the "Nutrition Care Process (nutrition assessment, diagnosis, intervention, monitoring and evaluation) for GDM" was developed (Appendix VII). The components of the SSOP for MNT of GDM are described as follows.

4.2.1.1. Segment I - GDM Risk Screening

The initial step in SSOP involves GDM risk screening which aims to identify pregnant women at risk of developing GDM. The GDM risk screening tool (Appendix XII) helps to identify pregnant women at risk for GDM and classify as GDM high risk women, GDM average risk women and GDM low risk women respectively.

4.2.1.2. Segment II - Nutrition Assessment

Nutrition Assessment involves collecting and assessing anthropometric details, relevant biochemical investigations, clinical data, nutrition and lifestyle patterns of pregnant women, previous medical and obstetric history. The anthropometric details such as height, pre-pregnancy weight, and current weight are useful to assess the pre-pregnancy body mass index, expected gestational weight gain and total weight gain needed at the particular period of gestation. The biochemical investigations help to assess the presence of nutritional deficiencies and co-morbidities. The clinical data such as ultrasound scan reports, previous medical and obstetric histories are verified and the dietary assessment pertaining to food preferences, dietary recall and nutrient intake completes the nutrition assessment.

4.2.1.3. Segment III - Nutrition Diagnosis

Nutrition Diagnosis is a statement written based on the nutrition assessment of the pregnant women. “The nutrition diagnosis is written in a format called the Problem-Etiology-Signs and Symptoms (PES)” statement, which describes the patient’s nutritional problem, the related factors contributing to the nutritional problem and the specific characteristics of the nutritional problem. The nutrition diagnosis of all pregnant women in all three GDM risk categories would be derived and noted.

4.2.1.4. Segment IV – Nutrition Intervention

Nutrition Intervention involves three unique nutrition interventions based on the severity of the GDM risk assessed. Nutrition intervention encompasses prescription of diet plan, diet counselling, nutrition education through webinars and group contact and provision of e-booklet on lactation and complementary feeding (Appendix XVIII) after delivery. The three nutrition interventions based on GDM risk are described below in Table XXIX.

Table XXIX Nutrition Intervention based on GDM Risk

GDM High Risk Women **Nutrition Intervention 1**	Customised diet plan for first trimester	BMI, expected gestational weight gain, total weight gain needed, current period of gestation (Appendix XIX)
	Customised diet plan for second and third trimester	Modify the customised diet plan in second and third trimester as per the increment in energy and protein requirements for pregnancy (AppendixVIII)
	Diet counselling	First antenatal visit followed by MNT review every month
	Duration of diet counselling	20 minutes
	Physical activity (after fitness clearance from doctor)	Walking for 30 minutes, 3-5 times per week
	Nutrition education sessions	Two webinars of one hour duration on topics such as nutrient adequacy of diets, importance of gestational weight gain and physical activity
	Group contact	Reminders for attending webinars and improving adherence to MNT guidelines (Appendix XV)
	Healthy recipe videos	Three healthy recipe videos were shared through group contact (Appendix XVI)
	E-booklet on lactation and complementary feeding	After delivery an e-booklet on lactation and complementary feeding was provided along with diet counselling (Appendix XVIII)
GDM Average Risk Women **Nutrition Intervention 2**	No customised diet plan	Nil
	Diet counselling	First antenatal visit followed by MNT review every trimester
	Duration of diet counselling	20 minutes
	Physical activity (after fitness clearance from doctor)	Walking for 30 minutes, 3-5 times per week
	Nutrition education sessions	Two webinars of one hour duration on topics such as nutrient adequacy of diets, importance of gestational weight gain and physical activity
	Group contact	Reminders for attending webinars only, No reminders for adherence to MNT guidelines
	No healthy recipe videos	Nil
	E-booklet on lactation and complementary	After delivery an e-booklet on lactation and complementary feeding was provided along with

	feeding	diet counselling (Appendix XVIII)
GDM Low Risk Women **Nutrition Intervention 3**	No customised diet plan	Nil
	Diet counselling	First antenatal visit only
	Duration of diet counselling	20 minutes
	No physical activity recommendations	Nil
	Nutrition education sessions (Webinars)	Two webinars of one hour duration on topics such as nutrient adequacy of diets, importance of gestational weight gain and physical activity
	No group contact	Nil
	No healthy recipe	Nil
	E-booklet on lactation and complementary feeding	After delivery an e-booklet on lactation and complementary feeding was provided along with diet counselling (Appendix XVIII)

4.2.1.5. Segment V – Nutrition Monitoring and Evaluation

Nutrition monitoring and evaluation was the last segment in the SSOP. Nutrition monitoring involved monitoring of anthropometric details, biochemical investigations, clinical data, and MNT reviews.

- Nutrition monitoring for GDM high risk women was conducted every month for all the described parameters as well as for clarifying diet-related queries. Dissemination of dietary guidelines and monitoring of gestational weight gain was done by sending reminders through group contacts using social media.
- Nutrition monitoring for GDM average risk women was done once every trimester for clarifying diet-related queries during their scheduled antenatal reviews with the obstetrician. No reminders were sent through group contacts for dissemination of dietary guidelines and monitoring of gestational weight gain.
- No face to face interview or use of social media for nutrition monitoring was done for GDM low risk women. However, these women were monitored through the Electronic Medical Record (EMR) of the selected hospital.
- Nutrition evaluation comprising maternal and foetal outcomes among pregnant women, impact of nutrition education, adequacy of total gestational weight gain at delivery, detection of GDM among participants and effect of SSOP on maternal and foetal outcomes was done for all GDM risk groups.

A flowchart of the SSOP for MNT of GDM is illustrated in Figure 17.

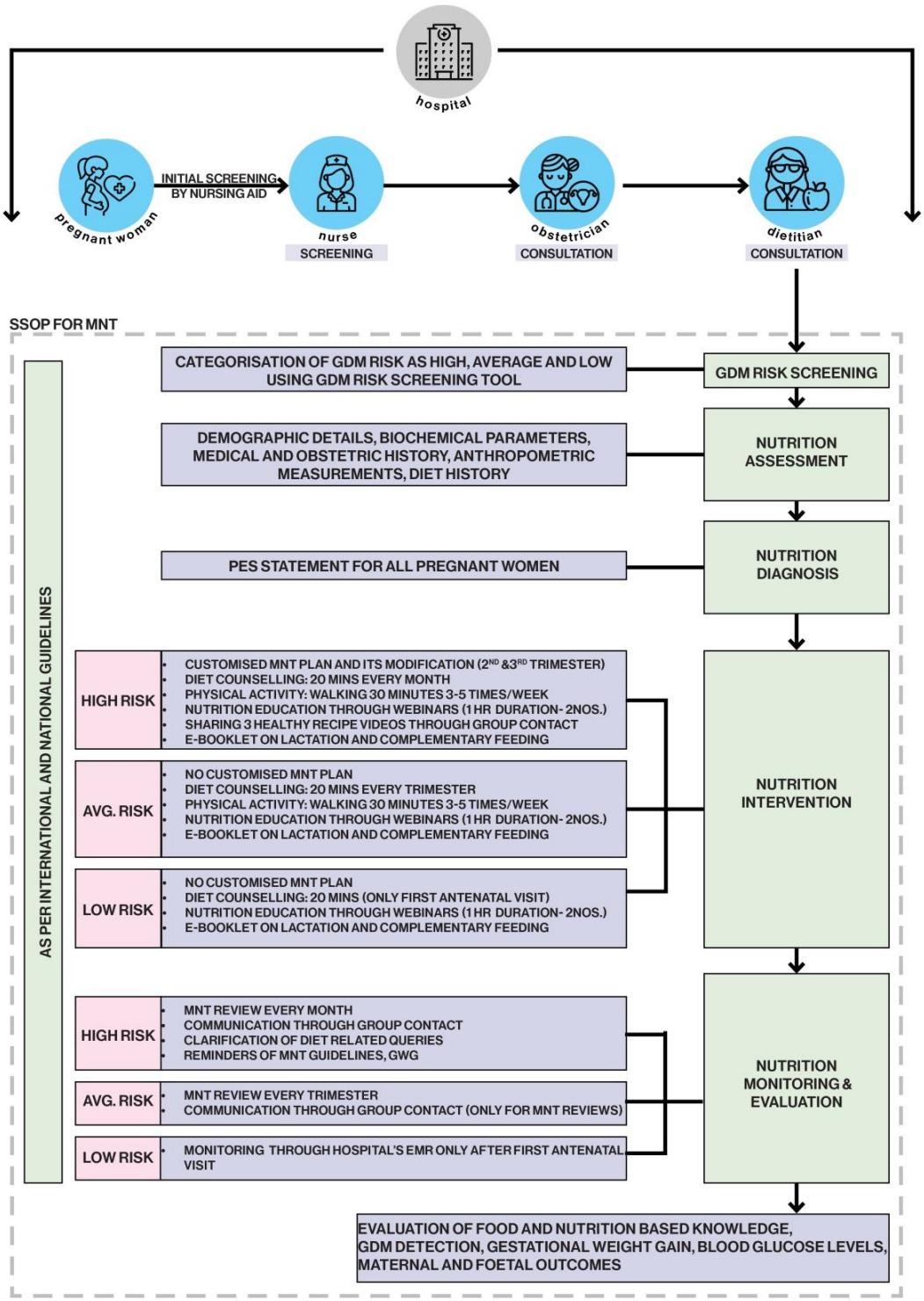

Figure 17 Flowchart of SSOP for MNT of GDM

The flowchart of SSOP for MNT of GDM depicts the "nutrition care processes namely nutrition assessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation from the first antenatal visit of pregnant women till delivery".

4.2.2 Validation of SSOP

The results of the content validation of the SSOP done by the target group of 10 HCPs namely obstetricians, diabetologists and dietitians using the Content Validity Index (CVI) calculation (Yusoff, 2019) is described below in Table XXX.

.Table XXX Relevance Ratings on the SSOP for MNT of GDM by HCPs

SSOP guidelines	OB 1	OB 2	OB 3	DM 4	DM 5	DM 6	DN 7	DN 8	DN 9	DN 10	Experts in agreement	I-CVI
Q1GDM risk screening	1	1	1	1	1	1	1	1	1	1	10	1
Q2 Need for an App for SSOP	1	1	1	1	1	1	1	1	1	1	10	1
Q3.Categorisation of GDM risk	1	1	1	1	1	1	1	1	1	1	10	1
Q4Nutrition diagnosis generation	1	1	1	1	1	1	1	1	1	1	10	1
Q5Nutrition intervention for High risk group	1	1	1	1	1	1	1	1	1	1	10	1
Q6 Nutrition intervention for Average risk	1	1	1	1	1	1	1	1	1	1	10	1
Q7 Nutrition intervention for Low risk	1	1	1	1	1	1	1	1	1	1	10	1
Q8 Nutrition education sessions	1	1	1	1	1	1	1	1	1	1	10	1
Q9 Nutrition monitoring and evaluation	1	0	1	1	1	1	1	1	1	1	9	0.9
Q10 Need for pre-conception counselling	1	1	1	1	1	1	1	1	1	1	10	1
Proportion relevance	1	0.9	1	1	1	1	1	1	1	1	S-CVI/Ave S-CVI/Ave	0.99 0.99

OB- Obstetrician, DM- Diabetologist, DN- Dietitian/Nutritionist

The content validity was evaluated based on the CVI values for the satisfactory level of content validation (Lynn et. al, 1986). The accepted CVI value for a panel of 9 to 10 experts is 0.78. The CVI values derived from the HCPs of the present study for SSOP for MNT of GDM are shown in Table XXX. The S-CVI/Ave value of 0.99 for average of total scores of all items and average of proportion relevance by all experts were found to be acceptable indicating that the developed SSOP for MNT of GDM achieved satisfactory level of content validity.

4.2.3. Optimisation of SSOP

Optimisation of SSOP for MNT was done by implementing the SSOP among ten selected pregnant women throughout their gestation period. The GDM risk screening done resulted in two pregnant women from control group and three pregnant women from experimental group being in GDM high risk category.

Nutritional assessment conducted revealed that there were three pregnant women with greater BMI (BMI>25kg/m^2) in experimental group compared to their counter parts. Dietary assessment showed the mean energy intake to be significantly exceeding than RDA in control group whereas it met RDA requirements in the experimental group. However, the mean protein, calcium and iron intakes were significantly lower than RDA for both groups.

Nutrition diagnosis related to knowledge deficit in following healthy diet during pregnancy was found among three pregnant women in control group compared to two in experimental group. However, inadequate oral intake related nutrition diagnosis was found in two pregnant women in experimental group compared to none in the control group.

Nutrition intervention as per SSOP was given to the experimental group, while the control group received nutrition intervention as per the existing MNT practices of the selected hospital.

Nutrition monitoring and evaluation indicated equal number of pregnant women in both groups getting diagnosed with GDM. The mean postprandial blood sugar (PPBS) was significantly different with 115.25mg/dl in control group compared to 100.75mg/dl in the experimental group. No adverse maternal outcome was observed in the experimental group compared to one adverse maternal outcome in control group. Similarly three women had adverse foetal outcomes in the control group compared to one adverse foetal outcome in the

experimental group. These results recommend the SSOP for MNT of GDM women to be implemented on a larger sample size to evaluate the impact of SSOP implementation on maternal and foetal outcomes.

4.3. Phase III: Development, Validation and Optimisation of a Mobile App for SSOP of MNT for HCPs

4.3.1. Development of a Mobile App

The developed Mobile App for SSOP consisted of a total of 8 screens comprising of Home screen, Login screen, Add/Update/Delete patient screen, Patient's personal details screen, Medical details screen, Laboratory details screen, Medicine details screen and the Result details screen. Plate 7 and Plate 8 shows the details of the Home screen and the Login details screen of the App.

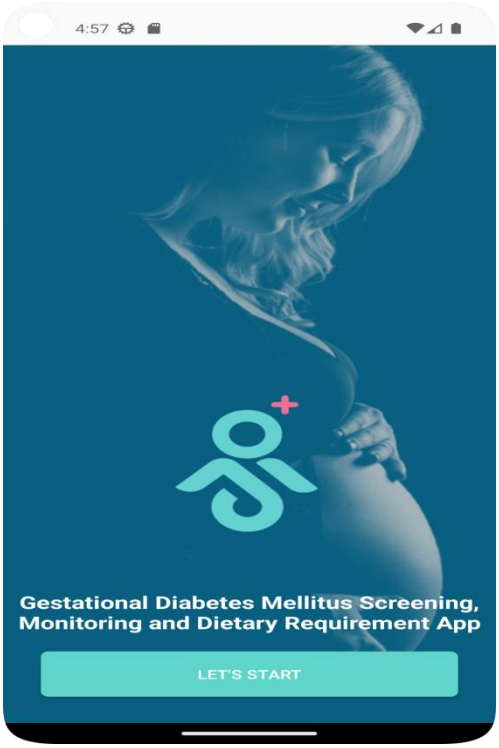

Plate 7: Home Screen

- ❖ The first screen that opens up on the user's phone on clicking the App icon.
- ❖ The "Let's Start" field encourages the user to begin using the App
- ❖ A short text of GDM describes main functionality of the App.

Plate 8: Login Screen

- Promps the user is to create an acccount or sign in based on the accoount's status (already created or new account).
- Consists of only two mandatory fields which are creation of a username and a password.
- Enables change of password in case the user has forgotten his/her password.

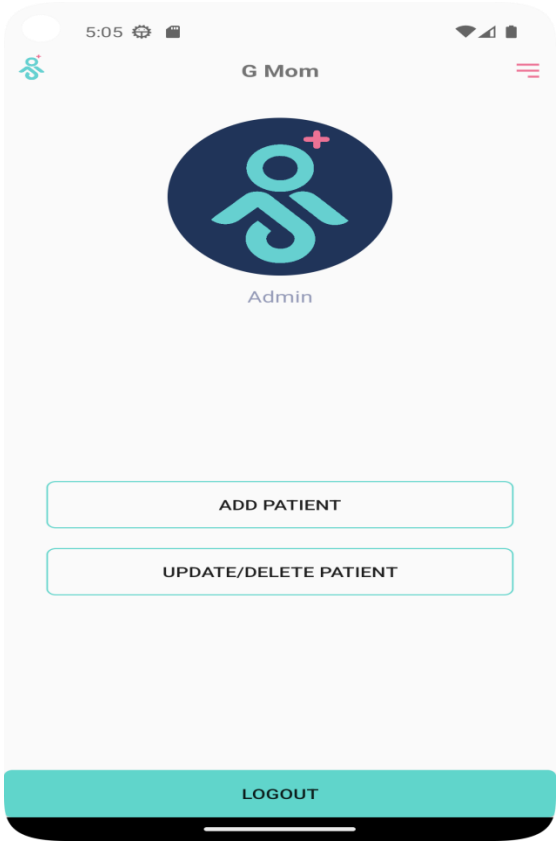

Plate 9: Add/Update/ Delete Patient Screen

- Enables entry of new patient details, updation or deletion of already exiting patient
- 'Add' function helps in adding new patients
- 'Update/Delete' function activates upon entering the unique patient registration number
- Functions also as a Search Screen
- After fetching patient details, updation in respective screens can be done
- Allows the user to log out from the App any time

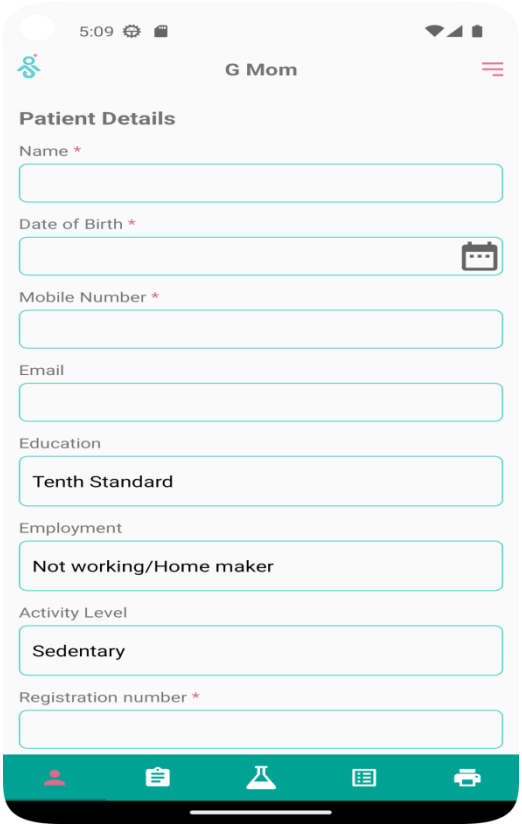

Plate 10: Patient's Personal Details Screen

- ❖ Enables entering personal details such as name, date of birth, mobile number, email id, education, employment, activity level and hospital registration number
- ❖ Mandatory fields include name, date of birth, mobile number and hospital registration number which are highlighted with a * mark.
- ❖ Name, phone number and hospital registration number are needed for patient identification and communication purposes
- ❖ Date of birth required for GDM risk screening analysis.

Plate 11: Medical Details

- ❖ Captures anthropometric details such as height, pre-pregnancy weight, and current weight for calculating pre-pregnancy BMI and ideal body weight.
- ❖ Current period of gestation is used for calculation of expected gestation weight and for total gestational weight gain
- ❖ Risk factors for GDM with Yes/No radio buttons functions as tool for GDM risk screening.

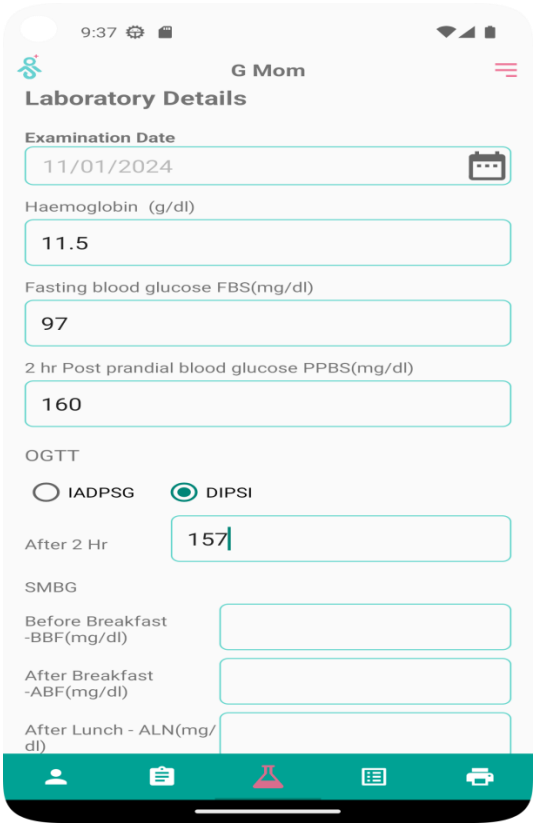

Plate 12: Laboratory Details

- ❖ Allows data entry of blood test results such as haemoglobin, FBS, PPBS, RBS, HbA1c, TSH, OGTT, self monitoring of blood glucose (SMBG) values and blood pressure
- ❖ Enables date wise entry based on the date of investigation
- ❖ Has a pop-up message (Yes/No) feature which prompts user to verify if all blood tests are duly entered.
- ❖ Permits moving to next screen only after pop-up message is answered.

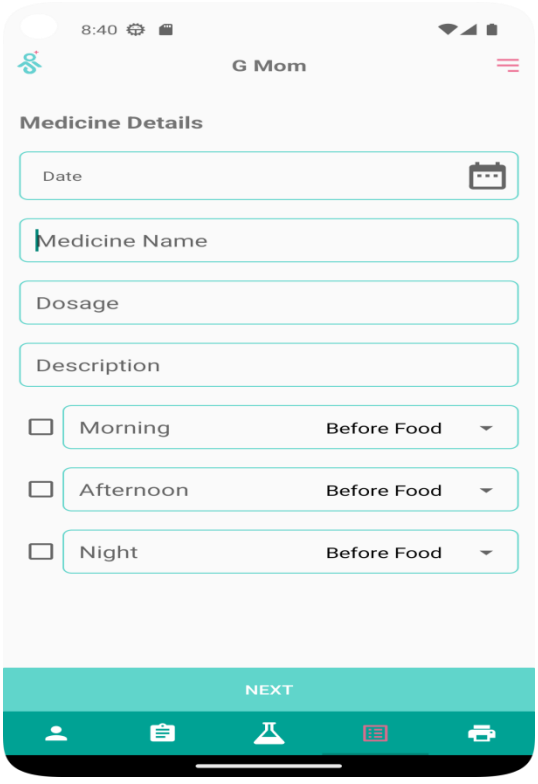

Plate 13: Medicine Details Screen

- ❖ Entering of all the prescribed medications is possible
- ❖ Separate fields are provided for the name, dosage and description of medications
- ❖ Check box design to select time of medication, aids in easy prescription of medicines
- ❖ Has a pop-up message (Yes/No) feature which prompts user to verify that no medications are missed out.
- ❖ Permits moving to next screen only after pop-up message is answered.

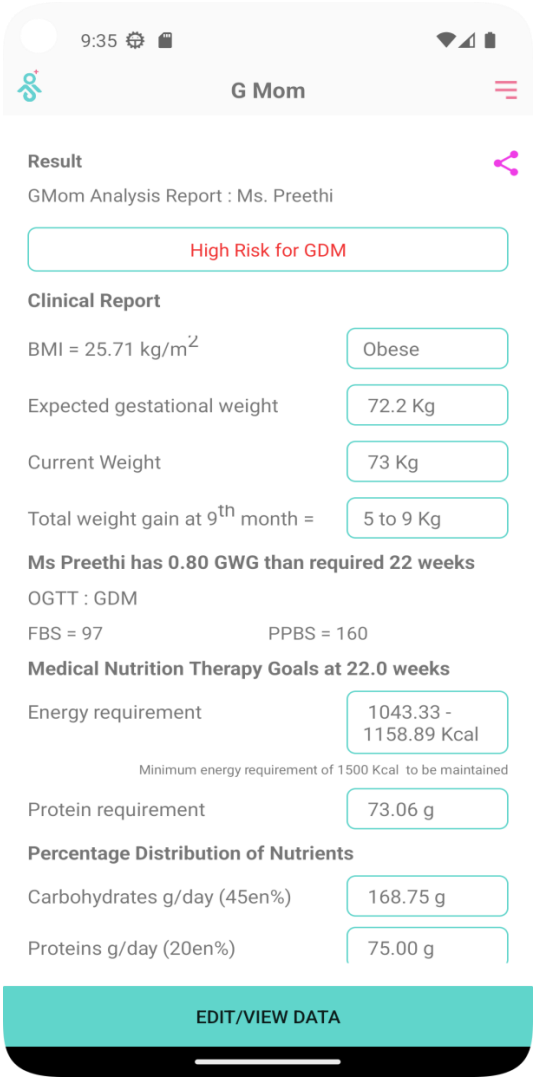

Plate 14: Result screen/ MNT Planning Screen

- ❖ Most important screen of the App which displays SSOP based MNT Goals for prescription of Customised Diet Plan
- ❖ Displays the following results
- ❖ GDM Risk Screening: High/Average/Low risk
- ❖ Nutrition Assessment :
  - ○ BMI category
  - ○ Expected Gestational Weight Gain
  - ○ Total Weight Gain needed
  - ○ Excess or Deficit in GWG
  - ○ OGTT/ Other Blood results if lower or higher than cut-off values
- ❖ Nutrition Diagnosis
  - ○ Additional field for recording PES statement
- ❖ Nutrition Intervention
  - ○ Estimates energy and protein requirement based on pre-pregnancy BMI and GWG
  - ○ Percentage distribution of nutrients namely carbohydrates, proteins and fat.
- ❖ Nutrition Monitoring and Evaluation
  - ○ Additional field for recording review date, blood glucose values, maternal and foetal outcomes and any special instructions for patients etc.
- ❖ Enables sharing of this screen to other android phones

4.3.2. Validation of Mobile App

The results of the content validation of the Mobile App was done by the target group of 10 HCPs namely obstetricians, diabetologists and dietitians using the Content Validity Index (CVI) calculation (Yusoff, 2019) is described below in Table XXXI.

Table XXXI Relevance ratings on the Mobile App by HCPs

Mobile App features	OB 1	OB 2	OB 3	DM 4	DM 5	DM 6	DN 7	DN 8	DN 9	DN 10	Experts in agreement	I-CVI
Q1 GDM risk screening in App	1	1	1	1	0	1	1	1	1	1	9	0.9
Q2BMI classification of Asians in App	1	1	1	1	1	1	1	1	1	1	10	1
Q3 Macronutrient requirements	1	1	1	0	1	1	1	1	1	1	9	0.9
Q4 Micronutrient requirements	1	1	1	1	1	1	1	1	1	1	9	0.9
Q5 Demographic details in App	1	1	1	1	1	1	0	1	0	1	7	0.7
Q6 Medical details in App	1	1	1	1	0	1	0	1	1	1	8	0.8
Q7Lab details in App	1	1	1	0	0	1	1	1	1	1	9	0.9
Q8 Result details in App	1	1	1	1	1	1	1	1	1	1	9	0.9
Proportion relevance	1	1	1	0.625	0.625	1	0.75	1	0.875	1	S-CVI/Ave S-CVI/Ave	0.88 0.89

OB- Obstetrician, DM- Diabetologist, DN- Dietitian/Nutritionist

The content validity was evaluated based on the CVI values for the satisfactory level of content validation (Lynn et al., 1986). The accepted CVI value for a panel of 9 to 10 experts is 0.78. The CVI values derived from the HCPs of the present study are shown in Table XXX. The S-CVI/Ave value of 0.88 for average of total scores of all items and 0.89 for average of proportion relevance by all experts were found to be acceptable indicating that the developed Mobile App achieved satisfactory level of content validity.

4.3.3. Optimisation of Mobile App

4.3.3.1. Assessment of Usability of Mobile App among Selected HCPs

Optimisation of the Mobile App in terms of its usability was assessed among 50 HCPs comprising 25 doctors and 25 dietitians using the System Usability Scale Grade (Setemen et al., 2019) and the results are represented in Figure 18.

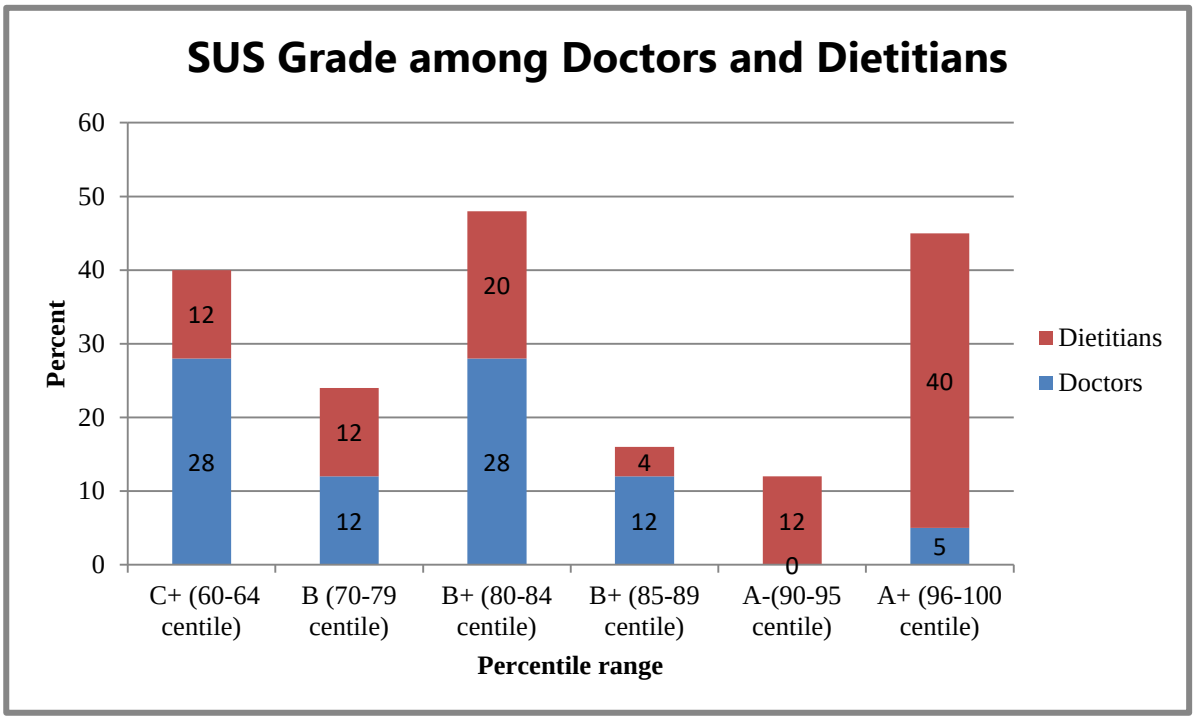

Figure 18 SUS Grade among Doctors and Dietitians

The mean SUS scores of the Mobile App was not statistically significant (p=0.128) with a mean score of 78.90±7.18 among doctors and 82.20±7.85 among dietitians respectively. The calculated mean from both groups separately corresponded to grades A- and A respectively indicating that the Mobile App was highly acceptable in terms of its usability. Figure 18 demonstrates the SUS grade based on percentile range which shows 40 percent of the scores of dietitians to be under A+ grade scale whereas 28 percent of scores of doctors came under B+ and C+ grade scale respectively. The mean of SUS scores of 50 HCPs taken together corresponded to 80.55 which further confirm the App to be acceptable. A study on Smartphone application for GDM reported mobile app to be highly useful in managing GDM (Jo et al, 2016).

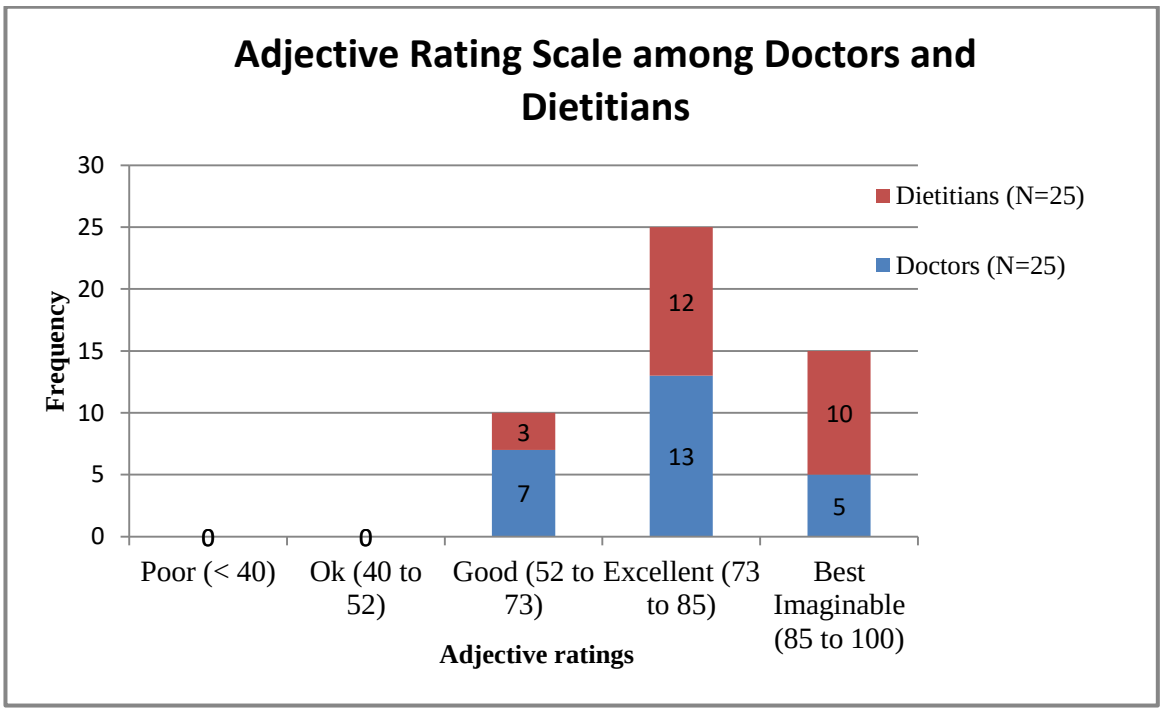

Figure 19 Adjective Rating Scale among Doctors and Dietitians

The SUS score calculated in the current study was also subjected to the SUS score based adjective rating scale by Bangor (2009). It was observed that SUS scores ranging from 73 to 85 given by 12 doctors and 13 dietitians came under the "excellent" category and SUS scores ranging from 85 to 100 given by 10 dietitians and five doctors came under the "best imaginable" category confirming that the Mobile App was highly rated as suitable as per the adjective rating scale.

4.4. Phase IV: Implementation and Evaluation of SSOP for MNT among Pregnant Women

4.4.1.1. Demographic Profile of Pregnant Women

The background details of the selected 364 patients who participated in Phase IV of the study are shown in Table XXXII.

Table XXXII Background Details of Pregnant Women

Demographic details	Experimental Group (N=178)		Control Group (N=186)		P value
	N	%	N	%	
Age (yrs)					
18-26	76	42.7	45	24.2	<0.001**
27-35	102	57.3	141	75.8	
Mean ±SD	**27.42±3.80**		**29.01±3.37**		
Education					
School	6	3.4	8	4.3	0.849 NS
Graduate	116	65.2	117	62.9	
Post Graduate	56	31.5	61	32.6	
Employment					
Working	75	42.1	89	47.8	0.273 NS
Not working	103	57.9	97	52.2	
Occupation					
Home maker	90	50.6	82	44.1	0.583 NS
Academician/Student	15	8.4	18	9.7	
IT Professional/Engineer	24	13.5	36	19.4	
Health Care Professional	18	10.1	18	9.7	
Entrepreneur/Pvt firm	21	11.8	18	9.7	
Other professionals	10	5.6	14	7.5	
Gravidity					
Primigravida	92	51.7	77	41.4	0.049*
Multigravida	86	48.3	109	58.6	

*5% level of significance, ** 1% level of significance, NS Not Significant

Mean age of 27.42±3.80years in experimental group and 29.01±3.37years in control group was found to be significantly different at 1 per cent level and the pregnant women in both groups largely belonged to the age group of 27-35 years. Ninety two out of 178 (51.7%) pregnant women in experimental group were primigravida whereas 109 (58.6%) pregnant women in the control group were multigravida. Although 65.2 percent graduates and 31.5 percent post graduates comprised in experimental group and 62.9 percent graduates and 32.6 percent post graduates in control group respectively, only 47.8 percent in control group and 42.1 percent in experimental group were working. Pregnant women in both groups were homemakers with 50.6 percent in experimental group and 44.1 percent in control group, which could be associated with women stopping to go for work upon confirmation of their pregnancy.

4.4.2. SSOP based GDM Risk Screening of Pregnant Women

4.4.2.1. GDM Risk Screening

The results of GDM risk screening among both experimental and control group using the GDM risk screening tool (Appendix XII) obtained during the first antenatal visit are presented in Table XXXIII.

Table XXXIII - GDM Risk Screening among Pregnant Women

GDM risk screening factors	Experimental Group (N=178)		Control Group (N=186)		P value
	N	%	N	%	
Age >25 yrs	123	69.1	155	83.3	0.001**
BMI status ≥25	80	44.9	85	45.7	0.885 ^{NS}
Family H/o Type 2 DM	83	52.2	110	59.1	0.186 ^{NS}
H/o PCOS or Hypothyroidism	49	27.5	39	21	0.144 ^{NS}
H/o Impaired glucose tolerance	2	1.1	1	0.5	0.616 ^{NS}
H/o GDM	9	5.1	16	8.6	0.181 ^{NS}
H/o Still birth or Macrosomia	2	1.1	nil	nil	0.238 ^{NS}

** 1% level of significance, ^{NS} Not significant

The GDM Risk screening showed significant difference among experimental and control group only for age with 83.3 percent pregnant women in the control group having age greater than 25 years compared to 69.1 percent in the experimental group. Other GDM risk factors such as BMI greater than 25 kg/m^2, family history of Type 2 DM and previous history of GDM, previous history of PCOS or hypothyroidism, previous history of still birth or macrosomia were only comparable and did not show any significant difference among groups. A prospective cohort study by Koukhan et al. (2021) reported advanced maternal age, obesity, family history of diabetes mellitus, previous history of gestational diabetes mellitus and previous history of macrosomia as the major risk factors for GDM. The study found significant correlation between adverse pregnancy outcomes and GDM, calling attention for early GDM risk screening and intervention of GDM.

4.4.2.2 Categorisation of GDM risk

The GDM risk categorisation derived based on the GDM risk screening tool (Appendix XII) is shown in Table XXXIV.

Table XXXIV – GDM Risk Categorization based on GDM Risk Screening

GDM risk categorisation	Experimental Group (N=178)		Control Group (N=186)		P value
	N	%	N	%	
High risk	122	68.5	127	68.3	0.072 ^{NS}
Average risk	36	20.2	49	26.3	
Low risk	20	11.2	10	5.4	

^{NS} Not significant

The GDM risk categorisation estimated among both groups did not show significant difference suggesting the homogeneity in the distribution of GDM high risk, average risk and low risk pregnant women within the study groups.

4.4.2.3. GDM Risk Screening and Diagnosis of GDM

The diagnosis of GDM among high risk, average risk and low risk pregnant women belonging to groups is shown in Table XXXV.

Table XXXV- Detection of GDM based on GDM Risk Screening

Group	GDM Risk score	OGTT Result Indication				P value
		Non GDM		GDM		
		N	%	N	%	
Experimental group (N=178)	High risk	75	61.5	47	38.5	0.040*
	Average risk	25	69.4	11	30.6	
	Low risk	18	90	2	10	
Control group (N=186)	High risk	53	41.7	74	58.3	0.005**
	Average risk	31	63.3	18	36.7	
	Low risk	8	80	2	20	

*Significant at 5%, **Significant at 1%

GDM risk screening and GDM diagnosis assessed resulted in 58.3 percent GDM high risk women of control group being detected with GDM which was statistically significant compared to 38.5 percent in experimental group. Similarly, compared to 36.7

percent of GDM average risk women becoming detected with GDM in the control group, only 30.6 percent GDM average risk women of experimental group got detected with GDM. Even in the GDM low risk category, significant difference was seen with only 10 percent GDM low risk women of experimental group getting detected with GDM compared to 20 percent in the control group. These findings suggest that GDM risk screening can be a useful tool in identifying pregnant women at risk of developing GDM as GDM diagnosis was largely seen in the high risk category followed by average risk category and least in the low risk category in both groups. Additionally, the SSOP based MNT has facilitated in reduction in the number of pregnant women in experimental group becoming detected with GDM compared to the control group.

The results of GDM risk screening conducted in this study highlights the need for early GDM risk screening and identification of severity of GDM risk, followed by early initiation of a SSOP based MNT from first antenatal visit to delivery as a preventive measure for GDM.

4.4.2.4. Detection of GDM in Pregnant Women

Detection of GDM among pregnant women is shown in Table XXXVI.

Table XXXVI – Comparison of detection of GDM among Pregnant Women

OGTT result	Experimental Group (N=178)		Control Group (N=186)		P value
	N	%	N	%	
GDM women	60	33.7	94	50.5	0.001**
Non-GDM women	118	66.3	92	49.5	

**Significant at 1%

The OGTT results reveal that 94 of 186 (50.5%) pregnant women were detected with GDM in the control group compared to 60 of 178 (33.7%) in experimental group which was highly significant at 1 percent level. This indicates that the SSOP based MNT initiated from the first trimester was effective in reducing the number of pregnant women becoming diagnosed with GDM. A study on the impact of MNT alone and MNT with metformin led intervention started among pregnant women between 10 to 15 weeks of gestation demonstrated a lower incidence of GDM in the MNT alone group compared to the MNT with Metformin group (Perichart-Perera et al., 2022).

4.4.3. SSOP based Assessment of Pregnant Women

4.4.3.1. Anthropometric Measurements and Body Mass Index (BMI)

The t test conducted between experimental and control group on variables such as height, pre-pregnancy weight and BMI is displayed in Table XXXVII.

Table XXXVII – Comparison of Height, Pre-pregnancy weight and BMI among Pregnant Women

Anthropometric measurements	Experimental Group (N=178)		Control Group (N=186)		P value
	Mean	SD	Mean	SD	
Height (cm)	157.70	5.04	159.08	6.45	0.023*
Pre-pregnancy weight (kg)	61.51	10.54	63.01	11.04	0.186 ^{NS}
BMI (kg/m^2)	24.68	3.74	24.84	3.75	0.687 ^{NS}
Underweight	6	3.4	6	3.2	0.966 ^{NS}
Normal	53	29.8	51	27.4	
Overweight	39	21.9	42	22.6	
Obese	80	44.9	87	46.8	

* Significant at 5%, ^{NS} Not significant

Table XXXVII reveals that mean height was the only variable showing significant difference between the groups with the control group having a mean height of 159.08±6.45cm compared to 157.70±5.04cm of experimental group. However, the mean BMI estimated using height and pre-pregnancy weight of 24.68±3.74kg/m^2 in experimental group and 24.84±3.75kg/m^2 in control group did not significantly differ and were under the overweight category as per the WHO Asian Classification for BMI. Assessing the pre-pregnancy BMI is important as higher risk for adverse maternal and foetal outcomes have been reported with elevated pre-pregnancy BMI (Vats et al., 2021). Also, while overweight and obese pregnant women have higher chances of complications during pregnancy and adverse perinatal outcomes, underweight women are at higher risk for preterm birth outcomes and delivering low birth weight babies (Vince et al., 2021).

4.4.3.2. Biochemical Investigations (First Trimester)

Biochemical investigations recorded among both groups at first trimester were compared using t test and results represented in Table XXXVIII.

Table XXXVIII Comparison of RBS, FBS, HbA1c, Hb and TSH among Pregnant Women

Biochemical investigations	Experimental Group			Control Group			P value
	N[1]	Mean	SD	N[1]	Mean	SD	
RBS (mg/dl)	178	92.95	13.53	175	95.30	15.32	0.128 [NS]
FBS (mg/dl)	61	88.05	5.78	46	89.98	7.82	0.145 [NS]
HbA1c (%)	177	5.10	0.29	132	5.19	0.36	0.019**
Hb (g/dl)	178	12.48	0.97	186	12.30	0.97	0.080 [NS]
TSH (mIU/l)	177	1.93	1.42	180	2.14	1.76	0.202 [NS]

*Significant at 5%, [NS] Not significant, [1]indicates the actual number of test results obtained

The biochemical investigations compared between groups at first trimester showed significant difference only in glycosylated haemoglobin (HbA1c). However, these values were within normal limits indicating that both groups maintained euglycaemia during the first trimester. The mean value of all other biochemical markers namely RBS, FBS, Hb and TSH levels did not show any marked difference among groups and were also found to be within the normal limits. These results indicate maintenance of homeostasis in both groups.

4.4.3.3. Oral Glucose Tolerance Test (OGTT)

The blood glucose values of OGTT conducted among pregnant women is presented in Table XXXIX.

Table XXXIX Comparison of Oral Glucose Tolerance Test among Pregnant Women

OGTT result	Experimental Group			Control Group			P value
	N[1]	Mean	SD	N[1]	Mean	SD	
Blood glucose (Fasting)	162	88.44	8.89	169	90.04	10.60	0.193 [NS]
Blood glucose (After 1 hour)	160	144.27	32.26	160	150.23	37.24	0.127 [NS]
Blood glucose (After 2 hours)	166	116.79	24.92	182	122.82	30.35	0.099 [NS]
OGTT criteria	**N[1]**	**Percent**		**N[1]**	**Percent**		**P value**
IADPSG	164	92.1		160	86.0		0.075 [NS]
National guidelines / DIPSI	12	6.7		17	9.1		
FBS and PPBS	2	1.1		9	4.8		

[NS] Not Significant, [1]indicates the actual number of test results obtained

The results revealed no significant difference among the both groups with respect to fasting, other blood sugar levels. The mean values blood glucose at fasting of 88.44± 8.89 mg/dl, after 1 hour of 144.27±32.26mg/dl and after 2 hours of 116.79±92mg/dl in

experimental group were only comparable with the mean values of blood glucose at fasting of 90.04±10.06mg/dl, after 1 hour of 150.23±37.24mg/dl and after 2 hours of 122.82±30.35mg/dl in control group. The OGTT criteria used between groups also did not show any notable difference with 92.1 percent in experimental group and 86 percent in control group stating IADPSG as the commonly used diagnostic criteria for GDM detection.

4.4.3.4. Clinical Assessment (Antenatal Period)

The clinical problems observed observed through the ultrasound scans during the antenatal period among both groups were grouped and Chi-square analysis conducted between the groups (Table XL).

Table XL– Antenatal Complications seen among Pregnant Women

Antenatal complications	Experimental Group (N=40)		Control Group (N=86)		P value
	N	%	N	%	
Foetal defects (Congenital defects, pelvicalceal dilatation, hydronephrosis, high nuchal transluscency values, dolichocephaly)	2	1.1	25	13.4	<0.001*
Foeto-placental anomalies (Oligohydramnios, polyhydramnios, low or high foetal weight, IUGR, organs underdeveloped, circum vallate placenta)	27	15.2	33	17.7	
Maternal abnormalities (Cervical insufficiency, fibroid, pre-eclampsia, anaemia, hypothyroidism, dengue fever, anxiety/depression)	11	6.2	28	15.1	

* Significant at 1% level

It is evident from the Table XL that antenatal complications were not seen in 77.5 percent of experimental group compared to 53.8 percent in control group which was found to be highly significant at 1 per cent level. The Chi square analysis of antenatal complications among groups were statistically significant with the control group having 13.4 percent foetal defects, 17.7 percent foeto-placental anomalies and 15.1 per cent maternal complications compared to 1.1 percent foetal defects, 15.2 percent foeto-placental anomalies and 6.2 percent maternal complications in the experimental group respectively. These results suggest that early GDM risk screening and initiation of SSOP based MNT

intervention including nutrition education sessions has helped in reducing the antenatal complications among experimental group compared to the control group.

4.4.3.5. Dietary assessment

The 24-hour dietary recall of all participants taken during the first antenatal visit were compared with the recommended dietary allowance (RDA) of nutrients for pregnant women, ICMR-NIN guidelines and results shown in Table XLI.

Table XLI – Nutrient Intake of Pregnant Women and RDA

Nutrients	RDA[a]	Experimental group (N=178)			Control group (N=186)		
		Mean Intake	% Excess/ Deficit	P value	Mean Intake	% Excess/ Deficit	P value
Energy (Kcal)	1600	1783.60	+11	<0.001**	1977.18	+24	<0.001**
Carbohydrate (g)	175	241.46	+38	<0.001**	250.20**	+43	<0.001**
Protein (g)	65	48.70	-25	<0.001**	64.95	-0.08	0.964 [NS]
Fat (g)	Visible Fat = 30g Total fat (20-35 en%) =62g	71.20	+15	<0.001**	76.23**	+23	<0.001**
Calcium (mg)	1000	393.34	-61	<0.001**	579.99**	-42	<0.001**
Iron (mg)	40	8.37	-79	<0.001**	9.60**	-76	<0.001**
Fibre (g)	40	22.34	-44	<0.001**	26.72**	-33	<0.001**

**Significant at 1% level, [NS] Not Significant, [a]Recommended Dietary Allowance

Energy, fat and carbohydrate intake was found to be in excess for both the groups ranging from 11 to 24 percent than the RDA for energy, 38 to 43 percent for carbohydrates and 15 to 23 percent for fat; but discouragingly protein intake was less than the RDA among both the groups (0.08 to 25 % deficit). Similarly, calcium, iron and fibre intake were deficient among both the groups. Among all the nutrients, iron which is the most important mineral to prevent anaemia was shockingly deficient by a percent ranging from 76 to 79 percent when compared with the RDA. Additionally, anaemia during pregnancy is indeed a notable concern as it is associated with increased risk for severe acute maternal morbidity, post partum haemmorhage and psychiatric disorders after delivery (Guignard et al., 2021) in the mother and adverse foetal outcomes such as low birth weight, preterm birth, small for gestational age, foetal malformations, lower Apgar scores amd perinatal mortality (Karami et al., 2022)

4.4.4. SSOP based Diagnosis of Pregnant Women

4.4.4.1. Derivation of Nutrition Diagnosis

The nutritional diagnosies derived from the nutrition assessment of both groups are displayed in Table XLII.

Table XLII Nutrition Diagnosis derived after Nutrition Assessment of Pregnant Women

Problem-Etiology-Signs and Symptoms (PES) statement	Experimental Group (N=178)		Control Group (N=186)		P value
	N	%	N	%	
No Nutrition Diagnosis	37	20.8	57	30.6	0.154^{NS}
Related to Knowledge deficit	63	35.4	62	33.3	
Related to Excess energy intake	46	24.7	41	22	
Related to Inadequate oral intake	34	19.1	26	14	

^{NS} Not significant

The nutrition diagnosis derived as a PES statement based on knowledge deficit related to poor awareness on healthy and proper food choices both in quantity and quality in pregnancy, excess energy intake related to excess consumption of calorie dense and high carbohydrate foods and inadequate oral intake related to nausea and vomiting was seen as 35.4 percent, 24.7 percent and 19.1 percent in experimental compared to 33.3 percent, 22 percent and 14 percent respectively in control group. This emphasizes the need for providing proper nutrition education to pregnant women on the need for meeting the nutrition requirements, proper food choice both in quantity and quality during pregnancy.

4.4.5. SSOP based Intervention of Pregnant Women

4.4.5.1. Assessment of Nutrition Education Sessions using Knowledge, Attitude and Practice (KAP) Study in a Selected Sample of Pregnant Women

The results of the pre-intervention and post-intervention KAP study conducted among 45 selected participants of the experimental group who attended the nutrition education sessions on nutrition during pregnancy, gestational weight gain, gestational diabetes mellitus and its prevention are presented in Table XLIII.

Table XLIII KAP Study to Assess the Impact of Nutrition Education Session given to a Selected Sample of Pregnant Women

KAP Study among a Selected Sample of Experimental Group (N=45)						
Parameters	**Pre -test**		**Post-test**		**t value**	**P value**
	Mean	**SD**	**Mean**	**SD**		
Knowledge	13.18	2.08	20	0.00	-21.990	<0.001**
Attitude	7.09	1.61	10	0.00	-12.151	<0.001**
Practice	14.11	3.24	20	0.00	-12.185	<0.001**
Total Scores	34.38	5.01	50	0.00	-20.916	<0.001**

** Significant at 1% level

The KAP pre and post test scores for knowledge, attitude and practice among experimental group shows significant difference indicating that the nutrition education sessions were effective in improving their knowledge on topics such as nutrition during pregnancy, gestational weight gain, gestational diabetes mellitus and its prevention. A KAP study on pre and post counselling scores on women with GDM and women with normal glucose tolerance resulted in higher scores post counselling in both groups and effective control of the maternal blood glucose levels in GDM women highlighting the importance of nutrition education in pregnancy (Savitha and Mageshwari, 2013). It is thus suggested to provide nutrition education sessions at every trimester of pregnancy for improving the awareness of pregnant women about proper nutrition during pregnancy.

4.4.5.2. Requirement of Medical and Nutritional Interventions among Pregnant Women

Table XLIV shows the interventions such as MNT, OHA and Insulin that were provided to the pregnant women who were detected with GDM in the study.

Table XLIV MNT, Oral Hypoglycaemic Agents and Insulin among Pregnant Women

MNT, OHA and Insulin among GDM women	**Experimental group[1] (N=60)**	**Control group[2] (N=94)**	**P value**
	Frequency	**Frequency**	
MNT and exercise only	50	71	0.557^{NS}
MNT and OHA	73	12	
MNT and Insulin	Nil	2	
MNT, OHA and Insulin	3	9	

[1]Experimental group followed SSOP based MNT, [2]Control group followed existing MNT practice in the selected hospital, ^{NS} Not Significant

MNT along with exercise, OHA and insulin-related interventions received by pregnant women who were detected with GDM in both groups was only comparable for effective blood glucose control. This indicates that the SSOP based MNT along with exercise alone was not found to be sufficient in achieving glycaemic control among GDM women and wherever MNT fails, OHA or insulin should be initiated for treatment. GDM should be initially managed with MNT and physical exercise and if it is not controlled with MNT and lifestyle changes, OHA or Insulin should be added to the MNT (GDM Technical Guidelines, Government of India, 2018).

4.4.6. SSOP based Monitoring of Pregnant Women

4.4.6.1. Blood Glucose Monitoring among Pregnant Women

The fasting and after meal values of blood glucose of GDM women who followed SSOP based MNT in experimental group and the GDM women who followed usual MNT in the control group were compared using t test and results shown in Table XLV.

Table XLV Comparison of FBS and PPBS among Pregnant Women

Variable	GDM Women				P value
	Experimental group (N=60)		Control group (N=94)		
	SSOP based MNT		Existing MNT		
	Mean	SD	Mean	SD	
FBS	90.13	8.82	91.37	13.87	0.751 ^{NS}
PPBS	106.77	15.10	114.96	20.60	0.005*

*Significant at 5%, ^{NS} Not Significant, FBS- Fasting Blood Sugar, PPBS- Post Prandial Blood Sugar

The mean PPBS of 106.77±15.10 mg/dl in the experimental group receiving SSOP based MNT and 114.96±20.60 mg/dl in the control group following existing MNT showed significant difference indicating that the SSOP based MNT facilitated in control of postprandial blood glucose levels among GDM women in experimental group compared to control group. A similar result of significant reduction in postprandial blood glucose was reported in a study after intervention with alimentary control and nutrition guidance in the observation group compared to control group receiving conventional dietary education (Chao et al., 2019).

4.4.6.2. Gestational Age at Delivery and Total Weight Gained among Pregnant Women

The week's completed at delivery and weight gain achieved at delivery among the experimental and control group are shown in Table XLVI.

Table XLVI Comparison of Gestational age and Total Weight Gained among Pregnant Women

Variables	Experimental Group			Control Group			P value
	N	Mean	SD	N	Mean	SD	
Gestational age at delivery	178	38.25	1.42	184	38	1.68	0.130 ^{NS}
Total weight gain during pregnancy	178	10.65	4.40	186	11.08	4.28	0.342 ^{NS}

^{NS} Not significant

The mean gestational age at delivery and the total weight gained after delivery did not show any significant difference between the target groups. Nutrition Practice Guidelines (NPG) based care provided to GDM women in the intervention group showed no difference in the gestational age at delivery and the total weight gained during pregnancy compared to the usual care GDM control group in a study conducted to validate nutrition practice guidelines for GDM in hospitals and maternal clinics across the United States (Reader et al., 2006). The Women in Indian with GDM Strategy (WINGS) project- developed model of care for standardised approach to GDM management, implemented on 1124 pregnant women showed significant difference only in the maternal gestational weight gained with lesser total weight gain in GDM women compared to Non-GDM women whereas no difference was observed in the gestational age at delivery among both groups (Uma et al., 2017).

4.4.6.3. Adequacy of Gestational Weight Gain (GWG) among Pregnant Women

The results of the GWG among both groups compared with the GWG guidelines of Institute of Medicine are presented in Table XLVII.

Table XLVII Comparison of GWG among Pregnant Women with Recommended GWG of Institute of Medicine

Target groups	Lower total weight gain		Adequate total weight gain		Higher total weight gain		P value
	N	%	N	%	N	%	
Experimental group (N=178)	42	23.6	78	43.8	58	32.6	0.031*
Control group (N=186)	42	22.6	60	32.2	84	45.2	

*Significant at 5%

Low gestational weight gain of 42 cases in experimental group and 42 cases in control group indicated that the number of pregnant women with low GWG did not vary among groups. However, significant difference was seen between groups with 78 (43.8%) pregnant women in experimental group achieving adequate GWG compared to 60 (32.2%) pregnant women in the control group. A higher GWG was found in 84 (45.2%) pregnant women belonging to the control group compared to 58 (32.6%) pregnant women in the experimental group.

The results revealed that the SSOP based MNT was effective in achieving adequate GWG and reducing high GWG among the pregnant women in the experimental group compared to those pregnant women who received the existing MNT in the control group. The SSOP based MNT thus helped in maintenance of ideal GWG as GWG below recommendations have been reported to increase risk for infants to be born as small for gestation period or born early and GWG above recommendations heightens the chances of cesarean delivery, large for gestation period and birth weight above 4 kg (Goldstein et al., 2017). A telehealth lifestyle intervention study to reduce GWG among overweight or obese pregnant women resulted in the lifestyle intervention group having significant reduction in GWG compared to the group following usual care (Ferrara, et al., 2020).

4.4.7. SSOP based Evaluation of Pregnant Women

4.4.7.1. Delivery Details among Pregnant Women

The mode of delivery, birth outcome, induction of labour and birth weight and birth details of newborn among experimental and control groups are presented in Table XLVIII.

Table XLVIII – Comparison of Delivery, Birth Outcome, Labour and Birth weight and Birth Details of Newborns of Pregnant Women

Variables	Experimental Group (N= 178)		Control Group (N=186)		P value
	N	%	N	%	
Mode of delivery					
Vaginal delivery	109	61.2	130	69.9	0.016 *
Caesarean surgery (LSCS)	60	33.7	55.0	29.6	
Others	9	5.1	1	0.5	
Birth outcome					
Preterm	11	6.2	22	11.8	0.089 NS
Early term	62	34.8	71	38.2	
Full term	105	59	93	50	
Induction of labour					
Induced	108	60.7	119	64.	0.738 NS
Spontaneous	34	19.1	35	18.8	
Not induced (elective/emergency LSCS)	36	20.2	32	17.2	
Birth weight					
Birth weight less than 2.5kg	13	7.3	23	12.4	0.106 NS
Birth weight greater than 4kg	1	0.6	3	1.6	0.336 NS
Birth details of new born	**Mean**	**SD**	**Mean**	**SD**	**P value**
Mean birth weight	3.02	0.42	2.98	0.49	0.526 NS
Apgar score (1 min)	7.94	0.44	7.90	0.46	0.393 NS
Apgar score (5 min)	8.98	0.25	8.97	0.19	0.667 NS

*Significant at 5%, NS Not Significant

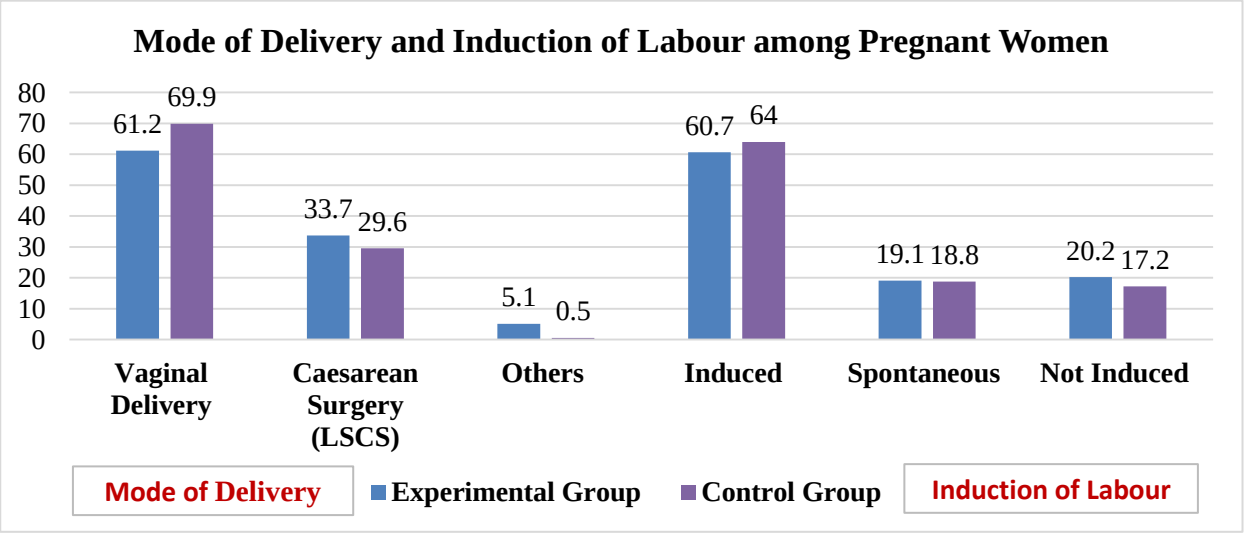

Figure 20 Mode of Delivery and Induction of Labour among Pregnant Women

From Table XLVIII and Figure 20, it can be seen that there was significant difference in the mode of delivery with 69.9 percent vaginal deliveries in control group compared to 61.2 percent in experimental group. On the contrary, caesarean deliveries were significantly greater in experimental group with 33.7 percent compared to 29.6 percent in control group29.6 caesarean deliveries in control group. Similar results were seen in a study were after multifaceted intervention no significant reduction in the rate was observed in the intervention group compared to control group (Zhang et al., 2020). The induction of labour observed among both groups was comparable with 64 percent of case of induced labour in control group compared to 60.7 percent in experimental group.

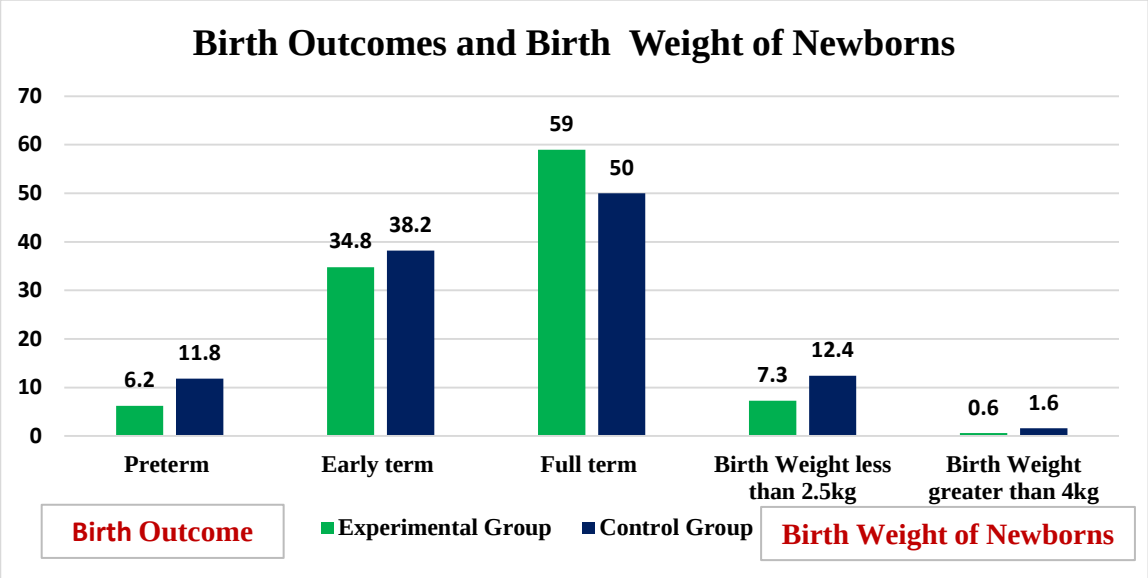

Figure 21 Birth Outcomes and Birth Weight of Newborns

As seen in Table XLVIII and Figure 21, there was no difference in birth outcome, presence of low birth weight (<2.5kg) and higher birth weight (>4kg) among experimental group and control group. Similar results were seen in a clinical trial in which no difference was seen in the maternal and foetal outcomes such as cesarean surgery, preterm births, low birth weight, lower apgar scores at one and five minutes and macrosomia in the nutrition practice guidelines (NPG) based GDM intervention group and the usual care GDM group (Reader et.al, 2006).

4.4.7.2. Maternal Outcomes among Pregnant Women

The details of maternal outcomes seen among both experimental and control groups are shown in Table XLIX.

Table XLIX Comparison of Maternal Outcomes among Pregnant Women

Variable	Experimental group (N=178)		Control group (N=186)		P value
	N	%	N	%	
Perineal tear	15	8.4	28	15.1	0.050*
Post partum haemmorhage	1	0.6	4	2.2	nil
Post partum hypertension, Impaired glucose tolerance	1	0.6	2	1.1	nil
Muscle spasm, low back ache, cholelithiasis, bulky uterus, decreased urine output	1	0.6	1	0.5	nil

* Significant at 5%

Among the various maternal outcomes perineal tear was found in the control group with 28 cases compared to 15 cases in experimental group which was just significant at 5 percent. Contrary to these results, Women in India with GDM Strategy (WINGS) project, using a standardized model of care for GDM, reported that there was no difference in perineal trauma and pre-eclampsia among the study groups comprising of GDM and Non-GDM women (Uma et al., 2017). The SSOP based MNT in this study, initiated from the first antenatal visit till delivery in pregnant women belonging to the experimental group, showed difference in the occurrence of perineal trauma at 5 percent level of significance indicating a favourable effect on maternal outcomes with lesser number of perineal tears.

Table L – Comparison of the Presence of Adverse Maternal Outcomes among Pregnant Women

Group	Presence of adverse foetal outcomes		Chi-square Value	P value
	N	%		
Experimental group (N=178)	18	10.2	5.540	0.019**
Control group (N=186)	35	18.9		

**Significant at 1%

The presence of maternal outcomes among control group was significantly higher at 18.9 percent compared to 10.2 percent in the experimental group (p=.019) indicating that the SSOP based MNT was beneficial in preventing the occurrence of adverse maternal

outcomes in experimental group compared to control group. Significantly lower adverse maternal outcomes were reported among the experimental group compared to the control group in another study which focused on lifestyle intervention to prevent GDM and adverse maternal outcomes (Lin et al., 2020).

4.4.7.3. Multiple Logistic Regression for Identifying Risk Factors Affecting Adverse Maternal Outcomes

Multiple logistic regression was done for identifying the risk factors for the occurrence of adverse maternal outcomes (Table LI).

Table LI Logistic Regression for Identifying Risk Factors of Adverse Maternal Outcomes

Variables	B	S.E.	Wald	df	P-value	Adj. Odds ratio	95% C.I.for EXP(B)	
							Lower	Upper
Experimental group	-0.683	0.331	4.270	1	0.039*	0.505	0.264	0.965
Age >25 yrs	0.853	0.504	2.866	1	0.090^{ns}	2.347	0.874	6.299
BMI status ≥25	0.543	0.320	2.883	1	0.090^{ns}	1.721	0.920	3.222
Family H/o Type 2 DM	-0.276	0.317	0.757	1	0.384^{ns}	0.759	0.408	1.413
H/o PCOS or Hypothyroidism	0.665	0.339	3.847	1	0.050*	1.944	1.000	3.777
H/o GDM	1.360	0.456	8.893	1	0.003**	3.897	1.594	9.529
Constant	-2.648	0.541	23.934	1	<0.001	0.071		
χ^2 value = 27.305**; P-value<0.001; Naelkerke R square = 0.128								

Logistic regression model was statistically significant at the χ^2 value = 27.305 and P-value less than 0.001. The model explained only 12.8 per cent of the variation in the occurrence of adverse maternal outcome and correctly classified 86.3 per cent of the cases. P-value shows that shows that intervention (SSOP based MNT), previous history of PCOS and history of Type 2 DM significantly affecting the outcome of having GDM. Adjusted odds ratio indicates that experimental group has less chance of having adverse maternal outcome compared to control groups. Experimental group exhibits adverse maternal outcome, 0.505 times lower than that of control group. Pregnant women having history of PCOS were 1.944 times more likely to have adverse maternal outcome compared to those not having history

PCOS. Also, those having history of GDM were 3.897 times more likely to have adverse maternal outcome compared to those not having the history of GDM. The overall results of this study outline the positive effect of the SSOP based MNT towards prevention of adverse maternal outcomes A study on lifestyle intervention to prevent gestational diabetes mellitus and adverse maternal outcomes among pregnant women at high risk of for GDM, also revealed similar logistic regression model results with a lower risk for all adverse maternal outcomes such as excessive GWG, pregnancy induced hypertension, post partum haemorrhage, premature rupture of membrane, antepartum haemorrhage and requirement of caesarean surgery in the experimental group receiving the lifestyle intervention compared to the usual care in the control group (Lin et al., 2020).

4.4.7.4. Foetal Outcomes among Newborns of Pregnant Women

The foetal outcomes observed among the experimental and control groups are shown in Table LII.

Table LII Comparison of Foetal Outcomes among Newborns of Pregnant Women

Foetal Outcomes	Experimental Group (N=178)		Control Group (N=186)		P value
	N	%	N	%	
Neonatal hyperbilirubinemia	18	10.1	32	17.2	0.049*
Respiratory distress syndrome	18	10.1	19	10.2	0.974 ^{NS}
Sepsis	6	3.4	6	3.2	0.938 ^{NS}
Low birth weight	13	7.3	23	12.4	0.106 ^{NS}
Macrosomia	-	-	3	1.6	0.248 ^{NS}
Birth injury	3	1.7	3	1.6	1.000 ^{NS}
Congenital malformation	20	11.2	25	13.4	0.523 ^{NS}
Hypernatraemia	5	2.8	19	10.2	0.004**
Hypoglycaemia	2	1.1	1	0.5	0.615 ^{NS}

*Significant at 5%, ^{NS} Not Significant

Hypernatraemia was the adverse foetal outcome showing significant difference among the experimental and control group. The presence of hyperbilirubinemia was just significant at 5 percent level with an occurrence of 17.2 percent in control group compared to 10.1 percent in the experimental group. All other foetal outcomes namely respiratory distress syndrome, sepsis, low birth weight, macrosomia, birth injury, congenital malformation and hypoglycaemia were not significantly different in the experimental group compared to control group. The SSOP based MNT thus aided in lower occurrence of

adverse foetal outcomes such as hypernatraemia and neonatal hyperbilirubinemia. The Women in India with GDM Strategy (WINGS) project, using a standardized model of care for GDM, reported that macrosomia, foetal distress, birth injury and low birth weight were not significantly different in women with GDM compared to Non-GDM women (Uma et al., 2017).

The results of the Chi-square analysis of presence of adverse foetal outcomes among experimental and control group is presented in Table LIII.

Table LIII Comparison of Presence of Adverse Foetal Outcomes

Group	Presence of adverse foetal outcomes		Chi-square Value	P value
	N	%		
Experimental group (N=178)	54	30.3	14.607	<0.001**
Control group (N=186)	93	50.0		

**Significant at 1%

The presence of adverse foetal outcomes revealed was 50 percent in control group which was significantly higher compared to 30.3 percent in experimental group. These results project the desirable effect of SSOP based MNT on the prevention of adverse foetal outcomes.

4.4.7.5. Multiple Logistic Regression for Identifying Risk Factors Affecting Adverse Foetal Outcomes

Table LIV - Logistic Regression to Identify Risk Factors of Adverse Foetal Outcomes

Variables	B	S.E.	Wald	df	P-value	Adj. Odds ratio	95% C.I.for EXP(B)	
							Lower	Upper
Experimental group	-0.850	0.226	14.173	1	0.000	0.428	0.275	0.665
Age >25 yrs	0.113	0.271	0.174	1	0.677	1.120	0.658	1.904
BMI status ≥25	0.203	0.227	0.804	1	0.370	1.226	0.786	1.912
Family H/o Type 2 DM	-0.161	0.225	0.513	1	0.474	0.851	0.547	1.324
H/o PCOS or Hypothyroidism	0.216	0.256	0.707	1	0.400	1.241	0.751	2.050
H/o DM	-0.174	0.435	0.160	1	0.689	0.840	0.358	1.971
Constant	-0.122	0.300	0.166	1	0.683	0.885		
χ^2 value = 17.09**; P-value = 0.009; Naelkerke R square = 0.062								

Logistic regression model was statistically significant at the χ^2 value = 17.09 and P-value less than 0.01. The model explained only 6.28 per cent of the variation in the occurrence of adverse foetal outcome and correctly classified 62.1 per cent of the cases. P-value shows that shows that only intervention (SSOP based MNT) has significance in the model. P-value for all other independent variables were greater than 0.05 indicating that these variables were not influencing the occurrence of adverse foetal outcome. Adjusted odds ratio indicates that experimental group has less chance of having adverse foetal outcome compared to control groups. Experimental group exhibits adverse foetal outcome; 0.428 times lower than that of control group. The SSOP based MNT implemented in the study from the first antenatal visit till delivery, has the potential to lower the occurrence of adverse foetal outcomes.

4.4.7.6. Multiple Logistic Regression for Identifying the Risk Factors of GDM

Presence of GDM is taken the binary response variable and the variables like group, age group, BMI status, family history of type 2 DM, history of PCOS History of DM as independent variable (Table LV).

Table LV Logistic Regression for Identifying Risk Factors of GDM

Variables	B	S.E.	Wald	df	P-value	Adj. Odds ratio	95% C.I.for EXP(B)	
							Lower	Upper
Experimental group	-0.657	0.233	7.969	1	0.005**	0.519	0.329	0.818
Age >25 yrs	0.078	0.279	0.079	1	0.779^{ns}	1.082	0.626	1.870
BMI status ≥25	0.799	0.233	11.770	1	0.001**	2.223	1.408	3.509
Family H/o Type 2 DM	0.623	0.235	7.033	1	0.008**	1.865	1.177	2.955
H/o PCOS or Hypothyroidism	0.015	0.265	0.003	1	0.954^{ns}	1.015	.604	1.706
H/o GDM	1.851	0.533	12.057	1	0.001**	6.368	2.240	18.108
Constant	-0.993	0.547	3.298	1	0.069^{ns}	0.371		
χ^2 value = 49.04**; P-value<0.001; Naelkerke R square = 0.169								

Logistic regression model was statistically significant at the χ^2 value = 49.04 and P-value less than 0.001. The model explained only 16.9 per cent of the variation in GDM and correctly classified 65.7 per cent of the cases. Wald test was used to test the significance of each independent variables. P-value shows that SSOP based MNT, BMI status, family history of Type 2 DM, and history of GDM significantly affecting the outcome of having GDM. Adjusted odds ratio indicates that experimental group has less chance of having

GDM compared to control groups. Experimental group exhibits GDM 0.519 times lower than that of control groups. Pregnant women having BMI greater than or equal to 25 were 2.223 times more likely to have GDM compared to those with BMI less than 25. Also pregnant women having a family history of Type 2 DM were 1.865 times more likely to have GDM compared to those not having the family history of Type 2 DM. Pregnant women having previous history of GDM were 6.368 times more likely to have GDM compared to those not having the previous history of GDM. Overall results showcase the beneficial effect of SSOP based MNT towards prevention of GDM. The incidence of GDM was reported to be significantly lower in the intervention group compared to the control group (14.4% vs 24.6%, P=0.03) in a similar study were a structured lifestyle intervention comprising balanced diet pattern, moderate physical activity and weight control was provided to pregnant women in the intervention group and control group followed usual care (Lin et al., 2020).

4.4.7.7. Comparison of Mode of delivery, Birth weight of Newborns and Presence of Adverse Maternal and Foetal Outcomes among Pregnant Women (Phase I) and Pregnant women (Phase IV)

The mode of delivery, birth weight of baby, presence of adverse maternal and foetal outcomes were compared among pregnant women (Phase I) and pregnant women in experimental group (Phase IV) and results displayed in Table LVI.

Table LVI – Comparison of Delivery, Birth weight of Newborns, Adverse Maternal and Foetal Outcomes among Pregnant Women of Phase I and Pregnant Women of Phase IV

Variables	Delivered women Phase I (N=87)		Delivered women Phase IV experimental group (N=178)		P value
	N	%	N	%	
Mode of delivery					
Vaginal delivery	32	36.8	109	61.2	0.001**
Caesarean surgery	50	57.5	60	33.7	
Others	5	5.7	9	5.1	
Birth weight					
Birth weight < 2.5kg	16	18.4	12	6.7	0.004**
Birth weight ≥ 4kg	nil	nil	1	0.01	1.000^{NS}
Presence of adverse maternal outcomes	16	18.4	17	9.6	0.041*
Presence of adverse Foetal outcomes	41	47.1	54	30.3	0.007**

*Significant at 5%, ^{NS} Not Significant **Significant at 1%

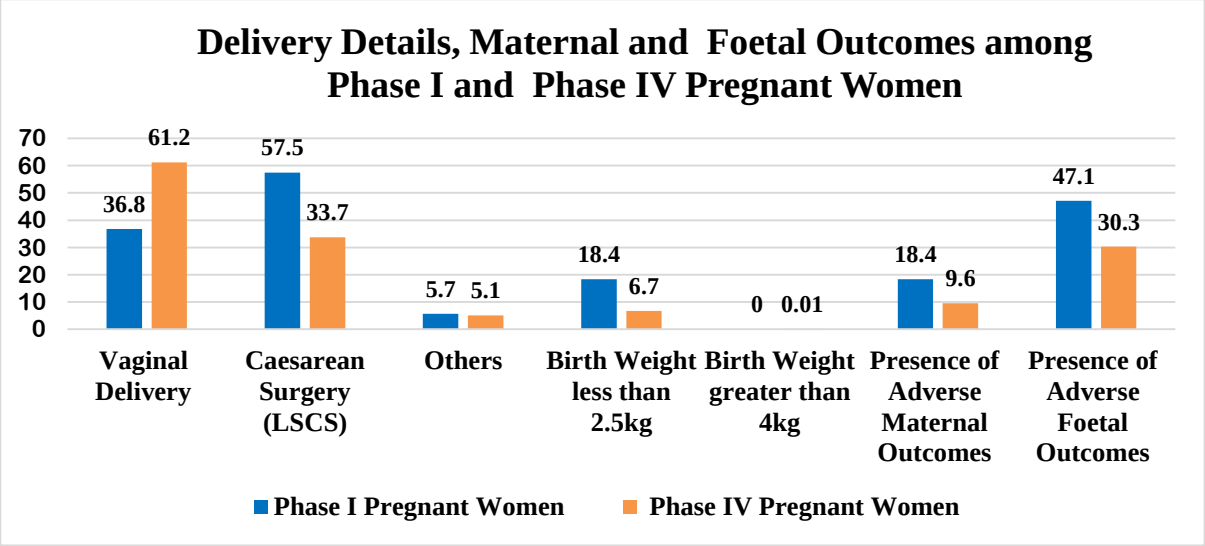

Figure 22 Delivery Details, Maternal and Foetal Outcomes among Phase I and Phase IV Pregnant Women

Table LV and Figure 22 revealed that the mode of delivery compared among pregnant women of Phase I and pregnant women of experimental group in Phase IV showed difference at one percent level of significance with higher cases of vaginal deliveries of 61.2 percent among the experimental group of Phase IV compared to 36.8 percent vaginal deliveries in the pregnant women belonging to Phase I. The birth weight of babies evaluated for underweight (birth weight < 2.5kg) among both groups also showed significant difference of 16 underweight newborns among pregnant women of Phase I compared to 12 underweight newborns in the experimental group of Phase IV. The differences in mode of delivery and presence of underweight among the newborns among both groups indicate that the SSOP based MNT intervention provided to the experimental group of Phase IV has been beneficial in resulting in vaginal deliveries and reduction of low birth weight infants.

The presence of adverse maternal compared among the pregnant women in Phase I and the experimental group in Phase IV also showed significant difference with 18.4 percent adverse maternal outcomes in Phase I compared to 9.6 percent in Phase IV. Additionally, the presence of adverse foetal outcomes compared among the pregnant women in Phase I and the experimental group in Phase IV also showed significant difference with 47.1 percent adverse foetal outcomes in Phase I compared to 30.3 percent in Phase IV respectively.

These results further ascertain the positive effect of the SSOP based MNT intervention towards reducing the occurrence of adverse maternal and foetal outcomes.