

Methodology

The methodology for 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**" is presented as follows.

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3.1. Phase I: Baseline Survey to Study the Current Practices and Protocols in the Management of Gestational Diabetes Mellitus (GDM)

3.1.1. Ethical Approval

The ethical clearance for the study was approved from

- Institutional Human Ethical Committee of Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore, Certificate no: AUW/IHEC/FSMD-19-20/XPD-26 (Appendix I).
- Aster Medicity, Kochi, Kerala, Certificate no: AM/EC/99-2019 (Appendix II)
- Amrita Institute of Medical Sciences, Kochi, Kerala, Certificate no: IRM-AIMS-2019-079 (Appendix III).

3.1.2. Locale of the Study

The locale of the study was Kochi, Kerala. The study was carried out in four multispeciality hospitals and three maternity hospitals which were selected through purposive sampling based on the following inclusion and exclusion criteria

Inclusion Criteria

- Operational for more than 5 years
- Has at least two obstetric units led by senior obstetricians

- Permission granted by the management of hospital
- Has healthcare professionals comprising obstetrician, diabetologist or physician, neonatologist, dietitian, nurse and physiotherapist

Exclusion Criteria

- New hospital
- Has only one obstetric unit or none
- Has no dietitian and physiotherapist

3.1.3. Selection of Healthcare Professionals (HCPs) to Study the Current Practices and Protocols in GDM Management

Definitions

- **Healthcare Professionals (HCPs)**

“A health professional or healthcare professional is a health professional who maintains health in humans through the application of the principles and procedures of evidence-based medicine and caring. They study, diagnose, treat and prevent illness, injury and other physical and mental impairments in accordance with the needs of the populations they server. The healthcare professionals include doctors, nurses, dietitians, physiotherapist, pharmacists and other paramedical practitioners.”(WHO, 2013)

Allied Health Personnel (AHP)

“Allied health personnel are personnel who have specific connections with the art and science of health care and are recognized as members of health team in the national health system. They are educated, at either professional or lower levels, in a recognized or accredited health or health-related or academic institution” (WHO, 2000).

As an initial step, the existing protocols and practices for GDM management, followed in the selected seven hospitals were studied. A multidisciplinary team involving physicians namely obstetricians, diabetologists, neonatologists and AHP comprising diabetes educators, nutritionists, psychologists, midwives have been reported to be effective in the management of GDM as well as reduce adverse foetal outcomes (Ali et al., 2020; Rahmani et al., 2015). Considering these evidences, a similar multidisciplinary team of healthcare professionals (HCPs) in the selected hospitals constituting of physicians namely obstetricians, diabetologists and neonatologists followed by AHP comprising of nurses, dietitians, diabetes educators, physiotherapists, psychologists and biochemists were included in the study.

As the first phase of the study focused on understanding the current practices and protocols for GDM management, quality control managers were also included in the study, as it is the quality control managers who verify protocols and policies for total quality management within the concerned hospitals. A total of 200 healthcare professionals involved in the management of GDM were selected through purposive sampling criteria and were grouped (Table IV) as doctors (obstetricians, diabetologists, neonatologists), AHPs (diabetes educators, nurses, physiotherapists, psychologists, biochemists and quality control managers) and dietitians. Dietitians were not included among the AHP as the study focused on obtaining in-depth information of the medical nutrition therapy practices and protocols as a part of baseline survey. According to Kothari, 2019, purposive sampling is defined “as selecting participants for the study deliberately by the researcher whose choice concerning the selection remains supreme”.

Table IV Details of Selected HCPs

| Healthcare Professionals (N=200) | Specialisation | Maternity hospitals (N=3) | Multispeciality hospitals (N=4) |
|---|--------------------------|----------------------------------|--|
| Doctors (N=70) | Obstetricians | 16 | 19 |
| | Diabetologists | 3 | 11 |
| | Neonatologists | 6 | 15 |
| Dietitians (N=55) | Dietitians | 21 | 34 |
| AHP (N=75) | Nurses | 12 | 23 |
| | Diabetes Educators | 3 | 4 |
| | Physiotherapists | 2 | 12 |
| | Psychologists | 2 | 3 |
| | Biochemists | 3 | 4 |
| | Quality control managers | 3 | 4 |

The study utilised the validated questionnaires of the Women in India with Gestational Diabetes Mellitus Strategy (WINGS-5) study (Mahalakshmi et al., 2016) to gather information on background details of healthcare professionals such as age, gender, educational qualification, clinical experience as well as their views about GDM prevalence, GDM as precursor of Type 2 DM, achievement of normoglycaemia with MNT and exercise, risk factors of GDM namely family history of Type 2 DM, previous history of

GDM, obesity and advanced maternal age, consequences for offspring of GDM women such as glucose intolerance, Type 2 DM in childhood and adolescence, obesity and cardiovascular disorders. Other details included preventive measures namely early diagnosis and detection of GDM, evidence-based treatment strategies, health and nutrition education, regular follow up and evaluation, and the common delivery outcomes and foetal complications seen by them in their clinical practice. Furthermore, open ended questions based on the guidelines outlined in Diagnosis and Management of Gestational Diabetes Mellitus: Technical and Operating Guidelines, Ministry of Health and Family Welfare, Government of India, 2018 were included to obtain in depth information on the current practices and protocols with respect to assessment, intervention, monitoring and evaluation of GDM from all the healthcare professionals based on their area of specialization.

Since the study focused on improving MNT practices for GDM, all questions in the Gestational Diabetes Dietetic Practice Survey (Morrison et al., 2011) were incorporated in the questionnaire used for dietitians such as role and importance of MNT and a score card to assess the confidence level of dietitians to follow SSOP based MNT and their understanding of evidence-based guidelines of GDM. The scores ranged from 1 to 4 where '1' represented 'not confident' and '4' represented 'very confident'. Further details such as MNT components discussed for diet counseling of GDM women, MNT practices such as type, duration and frequency of diet counseling were elicited along with additional open ended questions based on the MNT guidelines outlined in GDM Guidelines (Academy of Nutrition and Dietetics, 2016), in order to assess how MNT planning is done as well as the use of NCP model in MNT practice.

NCP according to AND is "an organised group of activities allowing the identification of nutritional needs and the provision of care to meet these needs. It consists of assessing nutritional status (Nutrition assessment) and analysing data to identify nutrition-related problems (Nutrition diagnosis), planning and prioritising nutrition intervention to meet these needs (Nutrition intervention) and monitoring and evaluating the nutritional care outcomes (Nutrition monitoring and evaluation)". MNT involves the specific application of the NCP for the management of diseases. The NCP "articulates the consistent and specific steps a dietetics professional would use when delivering MNT, but it will also be used to guide nutrition education and other preventative nutrition care services" (Lacey and Pritchett, 2003).

The questionnaires were pilot tested among 10 medical and paramedical professionals, suggestions incorporated, questionnaire validated and used as a survey tool. (Appendix IVa-j).

3.1.4. Selection of Pregnant Women to Study the GDM Management and MNT Practices received by them

As the end users in the maternal health care are pregnant women, pregnant women were identified to study the efficacy of the practices and protocols followed in the management of GDM. Non-GDM women were also included in the study to identify the similarities and/or differences which may exist in the practices and protocols followed for them in these hospitals. A total of 160 pregnant women attending the department of obstetrics and gynaecology of the selected hospitals were recruited into the study (Table V) following the inclusion and exclusion criteria.

Inclusion Criteria

- Both GDM and Non-GDM women
- Age group 18-45 years
- Singleton pregnancy
- Viable pregnancy (after ultrasound guided confirmation)

Exclusion Criteria

- Pre-gestational diabetes
- Multifoetal pregnancy
- Severe Infections like Herpes Zoster during pregnancy
- Comorbidities like gestational hypertension, epilepsy, severe anaemia, thalasemia

A bilingual informed consent (Appendix V) was taken from all the pregnant women who participated in the study.

Table V
Details of Selected Pregnant Women

| Pregnant women (N=160) | Maternity hospitals (N=3) | Multispeciality hospitals (N=4) |
|-------------------------------|----------------------------------|--|
| GDM women (N=106) | 46 | 60 |
| Non-GDM women (N=54) | 23 | 31 |

The interview schedule and case report form of Women in India with Gestational Diabetes Mellitus Strategy (WINGS-5) study (Mahalakshmi et.al 2016) was utilized to gather information of background details of pregnant women such as age, education, employment, gravidity. Other details such as anthropometric measurements and biochemical investigations, clinical details with respect to antenatal ultrasound scan results such as foetal defects, foeto-placental anomalies and maternal abnormalities reported by doctor (detailed description mentioned in Glossary), medical treatment received, medical nutrition therapy received, delivery details, maternal and foetal outcomes were obtained from electronic medical record (EMR) of the hospitals. Further details of pregnant women such dietary assessment based on 24-hour dietary recall, physical activity patterns, presence of risk factors for GDM, their understanding of consequences of GDM and a score card based assessment of their perception towards managing pregnancy with scores ranging from 0 to 10, where ‘0’ represented the least score and ‘10’ represented the highest score, MNT practices received from hospital were drawn from the Gestational Diabetes Questionnaire, Foetal Diagnostic Institute of the Pacific, Honolulu, Hawaii, 2014 and integrated into the interview schedule (Appendix VI) and further used for data collection.

Besides collecting patient information through the interview schedule, patient education activities (such as out-patient group sessions on pregnancy, nutrition education, antenatal yoga or physiotherapy led by respective HCPs namely an obstetrician, a dietitian, a yoga instructor or a physiotherapist) were also captured by the investigator through non-participant observation method to understand the holistic care and supportive interventions given to pregnant women in the selected hospitals. According to Kumar, 2011, “non-participant observation is when a researcher does not get involved in the activities of the group but remain a passive observer watching and listening to its activities and drawing conclusions from it”.

3.1.5. Gap Analysis of Existing Practices/Protocols in GDM Management

Gap analysis “is either a tool or a process to identify where gaps are and what differences exist between an organization’s current situation and “what ought to be” in place” (Kim et al., 2018).

The gap identification of the existing practices and protocols in the hospitals compared to national guidelines for GDM management was performed to understand the

gaps in (i) medical management practices and (ii) MNT practices in GDM and reason out the cause of their occurrence.

Based on the data collected from the HCPs and pregnant women the investigator collated the information and mapped the existing practices followed in the selected multispeciality hospitals and maternity hospitals. Figure 6 illustrates the flow of operations/processes in GDM management.

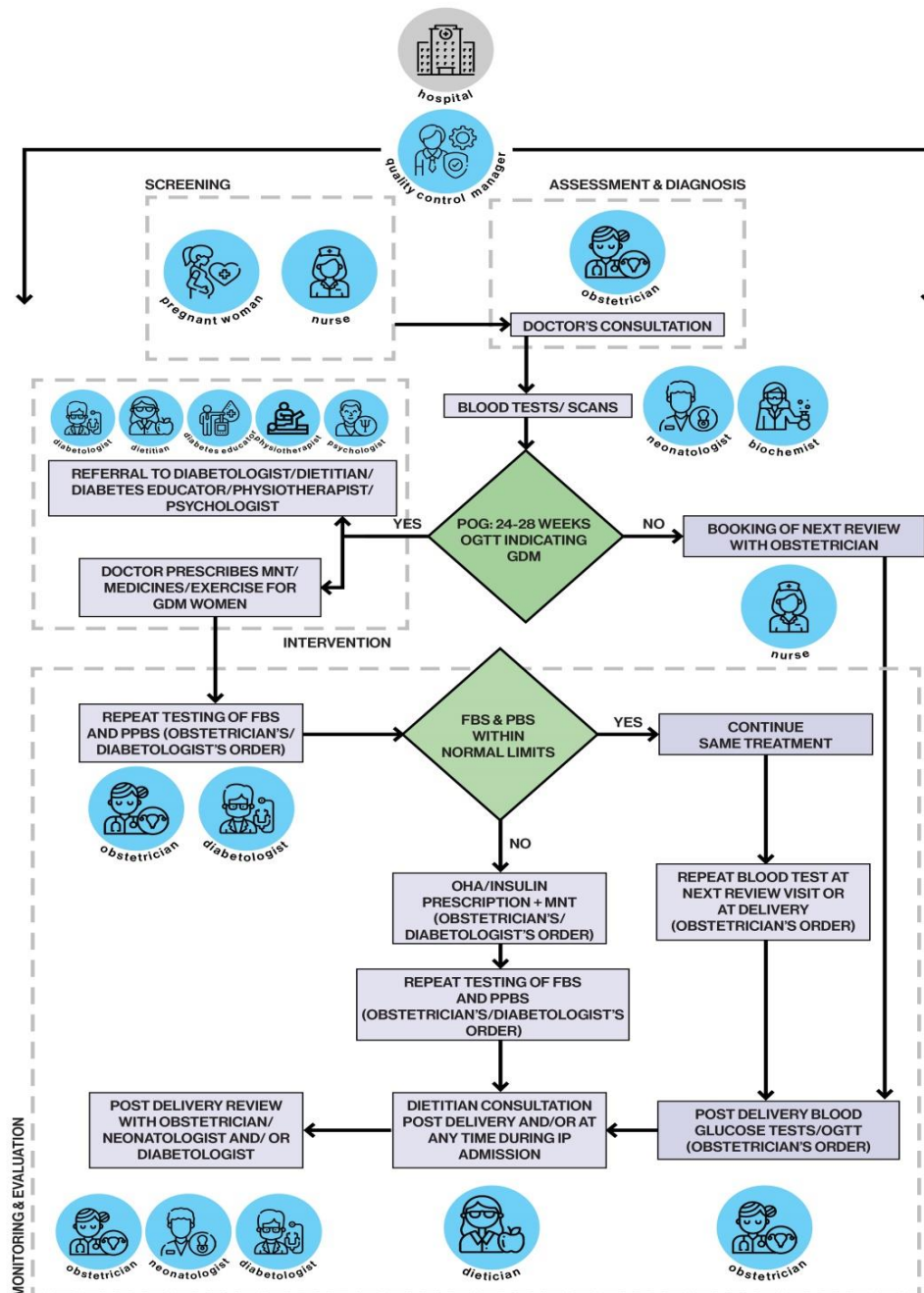


Figure 6- Existing Practices in GDM Management

3.2. Phase II: Augmentation, Validation and Optimisation of a Sustainable Standard Operating Protocol (SSOP) for Medical Nutrition Therapy (MNT) of GDM Women

3.2.1. Augmentation of SSOP

The lacunae observed in the existing SOPs showed that MNT practices followed were not optimum when compared with the national guidelines and thus the setting up of a protocol to facilitate consistency and improvement in MNT practices was found to be essential.

3.2.1.1. Framing the Term “Sustainable Standard Operating Protocol”

According to the Britannica Dictionary the meaning of protocol and procedure are as follows. “A protocol can have different meanings, all connected to the idea of guidelines or procedures to follow. The most common meaning of protocol is a system of rules that explain the correct conduct and procedures to be followed in formal situations.”

A Standard Operating Procedure (SOP) is defined as “a set of written instructions that document a routine or repetitive activity followed by an organization”. The term “SOP may not always be appropriate and terms such as protocols, instructions, worksheets may also be used” (United States Environmental Protective Agency, 2007).

In the present study, the SOP is termed as ‘Sustainable Standard Operating Protocol (SSOP)’ with the aim that such a SOP for MNT practices for vulnerable groups like pregnant women in particular would ultimately lead to sustainable nutrition and better management of GDM.

3.2.1.2. Development of SSOP

The investigator developed the SSOP based MNT (Appendix VII) focused on five important components comprising “GDM risk screening, nutrition assessment, nutrition intervention, nutrition monitoring and evaluation” which were outlined on the guidelines in Table VI. Structuring of the SSOP was done based on the guidelines for making SOPs described in the quality control operation manuals mentioned in Table VI.

**Table VI Guidelines and Quality Control Operation Manuals referred for
Development of SSOP for MNT for GDM**

| Guidelines | Year |
|--|-------------|
| GDM Risk Screening (i) <i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development, US Department of Health and Human Services, National Institutes of Health | 2012 |
| Nutrition Assessment (i) Diagnosis and Management of Gestational Diabetes Mellitus: Technical and Operating Guidelines, Ministry of Health and Family Welfare, Government of India | 2018 |
| (ii) GDM guidelines, Academy of Nutrition and Dietetics | 2016 |
| (iii) Gestational weight recommendations, Institute of Medicine and National Council Report | 2009 |
| (iv) Nutrition Intervention Standards of Medical Care in Diabetes, American Diabetes Association | 2007 |
| Nutrition Diagnosis (i) GDM guidelines, Academy of Nutrition and Dietetics | 2016 |
| Nutrition Intervention (i) Diagnosis and Management of Gestational Diabetes Mellitus: Technical and Operating Guidelines, Ministry of Health and Family Welfare, Government of India | 2018 |
| (ii) GDM guidelines, Academy of Nutrition and Dietetics | 2016 |
| (iii) Gestational weight recommendations, Institute of Medicine and National Council Report | 2009 |
| (iv) Standards of Medical Care in Diabetes, American Diabetes Association | 2007 |
| (v) Recommended Dietary Allowances ICMR-NIN | 2020 |
| Nutrition Monitoring and Evaluation (i) Diagnosis and Management of Gestational Diabetes Mellitus: Technical and Operating Guidelines, Ministry of Health and Family Welfare, Government of India | 2018 |
| (ii) GDM guidelines, Academy of Nutrition and Dietetics | 2016 |
| (iii) Standards of Medical Care in Diabetes, American Diabetes Association | 2007 |
| Quality Control Operation Manuals | Year |
| Structuring the SSOP (i) United States Environmental Protection Agency: Guidance for preparing standard operating procedures (SOPs), EPA QA/G-6, 2007, Office of Environmental Information, Washington DC | 2007 |
| (ii) National Accreditation Board for Hospitals and Healthcare Providers (NABH), Accreditation standards for Hospitals, 5 th Edn., National Accreditation Board for Hospitals and Healthcare Providers (NABH), New Delhi. | 2020 |

A stepwise, standardised flow of operations and procedures were developed for MNT of in-patients and out-patients. It is essential to have SOPs for workflow or processes that need to be reproduced repeatedly and/or maintain compliance to guidelines (Hollmann et al., 2020). GDM risk screening was the initial step to identify pregnant women at risk of GDM. GDM risk screening should be an important component of GDM management strategy as it is helpful in early risk assessment of GDM and studies have recommended the need for early diagnosis and intervention of GDM as preventive measures for GDM (Herath et al., 2017; Sahu et al., 2021) This is followed by nutrition assessment which involves assessment of anthropometric, biochemical, clinical and dietary assessment of pregnant women. Nutrition diagnosis is the third step which involves deriving problem-etiology-signs and symptoms (PES) statement. Nutrition intervention is done by prescribing customised diets (Appendix VIII) based on nutrition assessment and nutrition diagnosis and providing diet counselling. The last step is the nutrition monitoring and evaluation where the impact of nutrition intervention is assessed in terms of food and nutrition based knowledge, glycaemic control, gestational weight gain, maternal and foetal outcomes.

3.2.2. Validation of SSOP

Validation, according to the WHO Expert Committee 2019, “is the action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results”.

Content validation of the SSOP was done using the Content Validity Index (CVI) calculation (Yusoff, 2019). Content validity is defined as “the degree to which elements of an assessment instrument are relevant to and representative of the targeted construct for a particular assessment purpose” (Cook, et.al 2006; Haynes, et.al 1995). CVI assessed relevance and representativeness of each item to a specific domain by a panel of experts. Obstetricians, diabetologists and dietitians were selected as the panel members for content validation of the SSOP as they were the key players to initiate MNT as the first line of treatment for GDM upon detection. The content validation was done by a ten-member medical and paramedical team consisting of two obstetricians, three diabetologists and five dietitians through a Google form questionnaire (Appendix IX). The criteria for content validation states that the total number of experts should be at least 6 and should not exceed 10 and the expert should be having individual expertise in the field being studied (Yusoff, 2019; Polit and Beck, 2006; Davis, 1992; Lynn, 1986).

The CVI was calculated based on item-level content validity index (I-CVI) and scale-level content validity index (S-CVI) as shown in Table VII where the panelists' rate each item on the questionnaire based on a Likert scale ranging from 0 (not relevant) to 4 (highly relevant). The content validity was scored based on the CVI values described by Lynn, (1986) for the satisfactory level of content validity.

Table VII Definition and formula for I-CVI and S-CVI/Ave

| CVI indices | Definition | Formula | Accepted CVI value for 10 experts |
|--------------------|---|---|--|
| I-CVI | The proportion of experts giving items a relevance rating of 3 or 4 | I-CVI = (agreed item) / (number of expert) | 0.78 |
| S-CVI/Ave | The average of the I-CVI scores for all items on the scale or the average of proportion relevance judged by all experts. The proportion relevant is the average of relevance rating by individual expert. | S-CVI/Ave = (sum of I-CVI scores)/(number of item) S-CVI/Ave = (sum of proportion relevance rating)/(number of expert) | |

3.2.3. Optimisation of SSOP

According to Wolfenden et al. (2019), optimization is “a deliberate, iterative and data-driven process to improve a health intervention and /or its implementation to meet stakeholder-defined public health impacts within resource constraints.”

The optimisation of the SSOP based MNT was done by implementing the SSOP among 10 pregnant women throughout their gestation period so as to make the SSOP optimum for use.

3.3. Phase III: Development, Validation and Optimisation of a Mobile Application (Mobile App) for SSOP

3.3.1. Development of the Mobile App

GDM risk screening, the foundation for early identification of GDM high risk women was found to be lacking in the selected hospitals and the need to integrate GDM risk screening effectively through a mobile application was greatly felt. Use of technology in the healthcare sector offers numerous benefits like work simplification, improved patient care, boosting efficiency, reducing costs and facilitating better communication among healthcare professionals. As a result, a mobile application was developed for the SSOP based MNT to enable healthcare professionals, particularly obstetricians and dietitians to conduct GDM risk screening as well as the subsequent steps in SSOP with ease. Although there are several pregnancy apps available such as Gestational Diabetes Tracker, Pregnant with Diabetes, Ob-Wheel Pregnancy Calculator, these apps lacked features like GDM risk screening, calculation of nutrient intake and percentage distribution of macronutrients based on pre-pregnancy BMI and expected gestational weight gain which were incorporated in the mobile application developed for SSOP based MNT.

3.3.1.1. Technical details of the Mobile App

3.3.1.1.1. Integrated Development Environment

The App for this study was developed using the Integrated Development Environment, Android Studio which can work in both mobile and tablets with an Android Operating System. According to Chaubey and Sharma, (2023), Android Studio not only aids in software development but it also provides tools and framework to enhance the speed of the creation process. The programming language used for the App development was Kotlin.

3.3.1.1.2. Back-End Development

The back end to store all patient details was developed using a programming language called PHP. All the storage of information/data was done using MySQL database. MySQL database was used as it has the best overall performance in terms of speed, reliability, scalability, ease of use, wide application support and has an open-source code (Vasvani, 2010). The communication between the mobile/Android App with the back end server was established using Application Programming Interface (API).

3.3.1.1.3. Domain

The App was hosted with a popular domain register called GoDaddy with domain name www.gmoms.com which was purchased and used only for the Apps' application calling interface and not as a website. This domain register was taken up as it was more economical and user friendly and was thus taken up for the study purpose.

3.3.1.1.4. UI (User Interface) and Logo Design

The User Interface or UI for the App was developed taking into consideration of such similar existing applications. Designing of the user interface in terms of the colour, font style was done using Adobe Photoshop. The Logo Design of the App was done using Adobe Illustrator. Both Adobe Illustrator and Photoshop are part of Adobe Creative Cloud which includes both graphic software to create new vector designs and editing tools to make changes to contents like photos and videos to make them more refined (Adobe, 2024). Descriptions for template, use of radio buttons, scroll down features etc. were extensively worked on before finalising on the current design (Plate 1).

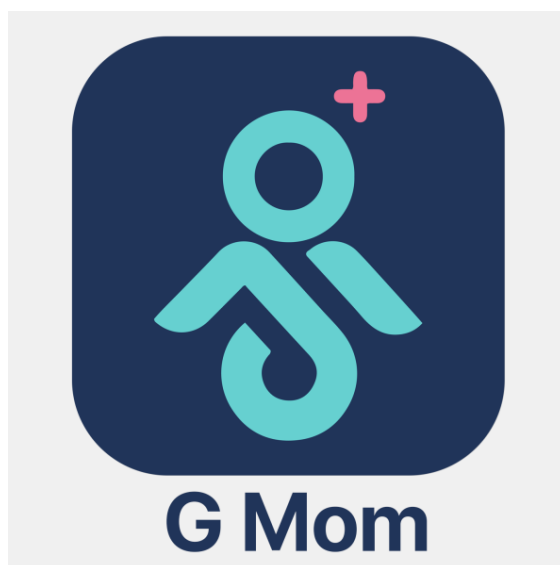


Plate 1 - Logo and Name of the Mobile App

3.3.1.1.5. Testing and Deployment

Once the prototype of the App was ready, the researcher and the software developer tested the App extensively and all bugs were fixed. The App was finally deployed as APK (Android Package Kit) files which are the installation files used specifically for Android devices. An APK file contains all the data an app needs, such as codes of software program, assets and resources (Gillis, 2023).

The input data in the Mobile App is mentioned in Appendix VII.

3.3.2 Validation of the Mobile App

A Google questionnaire was prepared for content validation of the App and a panel of 10 medical and para medical staff comprising two obstetricians, three diabetologists and five dietitians rated each item on a Google form questionnaire (Appendix X) based on a Likert scale ranging from 0 (not relevant) to 4 (highly relevant). Content Validity Index (CVI) calculation described above for SSOP was done to validate the mobile App also.

3.3.3 Optimisation of Mobile App

The trial version of the mobile App was created and shared to 50 healthcare professionals comprising of 25 doctors and 25 dietitians for usage. The System Usability Scale (SUS) was adapted into a Google questionnaire (Appendix XI) and all healthcare professionals rated the questions and the responses were analysed to estimate the usability of the mobile App. All suggestions regarding the usability of the App were taken up and modifications done accordingly. The App was taken up by the investigator and used in the SSOP for MNT of pregnant women in Phase IV.

3.4. Phase IV: Implementation and Evaluation of the SSOP on Maternal and Foetal Outcomes

Although the SSOP was developed for MNT of GDM women, the SSOP also took into consideration identification of pregnant women at risk of developing GDM with the intent of preventing the occurrence of GDM among such women. Hence, for Phase IV of the study a new target group of pregnant women was selected and the SSOP implemented and evaluation of the SSOP on the maternal and foetal outcomes carried out. The developed SSOP was used at every antenatal visit of the pregnant women for periodic recording of all elements of the nutrition care process namely “nutrition assessment, nutrition diagnosis, nutrition intervention, nutrition monitoring and nutrition evaluation” by the investigator. Phase IV of the study was carried out after taking due permission and consent from the management at only one multispeciality hospital located in Kochi, Kerala through convenience sampling, as the COVID-19 pandemic restricted conducting research at many hospitals. The interview schedule used in Phase I (Appendix VI) was used in Phase IV of the study to collect details such as background information, as well as SSOP for MNT based GDM risk screening and categorisation, detection of GDM based on GDM risk assessed and

nutrition assessment namely anthropometric measurements, biochemical investigations, clinical assessment and dietary assessment. Further details such as nutrition diagnosis comprising PES statement, nutrition intervention such as assessment of nutrition education sessions through knowledge attitude practice (KAP) study, need for medical and nutritional interventions to manage GDM, nutrition monitoring namely blood glucose levels, gestational weight gain, gestational age at delivery and nutrition evaluation consisting of adequacy of gestational weight gain, delivery details, maternal and foetal outcomes were also obtained from the participants and analysed.

3.4.1. Selection of Sample Size and Sampling technique

The sample size was calculated as per the GDM estimated prevalence range of 0 to 41.9 percent, reported in a “systematic review and meta-analysis study” conducted in India (Li et.al, 2018). Using the formula given below calculation of sample size was done using the upper limit of the estimated prevalence as follows.

$$n \geq \frac{Z_{1-\alpha/2}^2 * p * (1 - p)}{d^2}$$

Let $\alpha=0.05$, $Z_{1-\alpha/2} = 1.96$

Estimated prevalence of GDM, (p) =0.419

Precision (d) =6%

Substituting these values in the above formula

$n \geq 259.78$ Therefore the minimum sample size required for this study was 260

3.4.2 Identification of Pregnant Women

Based on the sample size calculated and considering the chances of drop outs in the study, 372 pregnant women who came for antenatal checkups at the outpatient unit of the department of obstetrics and gynaecology of selected hospital were selected through purposive sampling method. The calculated sample size was attained only after four months of continuous screening of pregnant women based on the following inclusion and exclusion criteria.

Inclusion Criteria

- Pregnant women in their first trimester
- Willingness to participate
- Age group 18-35 years
- Singleton pregnancy
- Viable pregnancy (after ultrasound guided confirmation)

Exclusion Criteria

- Pre-gestational diabetes
- Infertility treatment
- Multifoetal pregnancy
- Severe Infections (Herpes Zoster)
- Comorbidities (gestational hypertension, epilepsy, severe anaemia, thalasemia)

A bilingual informed consent (Appendix V) was taken from all the pregnant women who participated in the study.

3.4.3 Categorisation of Pregnant Women as Experimental and Control Groups

The selected sample of 372 pregnant women initially underwent GDM risk screening using the validated GDM risk screening tool (Appendix XII). The GDM risk screening tool consisted of eight questions with binary Yes or No responses for answers. A high risk for GDM was indentified if two or more ‘Yes’ responses were present, an average risk if only one ‘Yes’ response was recorded and a low risk if all responses were ‘No’.

All the screened pregnant women were further categorised into two groups, namely experimental group and control group each comprising of 186 participants. Pregnant women who agreed to continue with their participation during the entire course of the study with regular nutrition reviews and avail treatment in the selected hospital itself until delivery formed the experimental group and the others formed the control group. The pregnant women were then followed for the entire period of pregnancy from first trimester till delivery spanning a period of nine months to one year as delivery dates differed among the pregnant women. During the first trimester, eight pregnant women were dropped out of the experimental group due to miscarriage, abortion or did not want to continue in the study. Hence the total sample size reduced to a total of 364 pregnant women comprising 178 participants in experimental group and 186 participants in control group

3.4.4. Intervention with SSOP based MNT

Face to face discussions and Power point presentations about the SSOP for MNT for GDM management were done by the investigator with the medical, paramedical and administrative team of the selected hospital prior to implementation of the SSOP. Each step of SSOP for MNT such as “screening and nutrition assessment, nutrition diagnosis, nutrition intervention, nutrition monitoring and nutrition evaluation” were elaborated for

establishing the smooth flow of operations described in the SSOP. The investigator underwent training in certified diabetes educator programme for advanced patient education.



Plate 2 Face to Face Discussions with HCPs

The SSOP based MNT (Appendix VII) intervention was given to all the pregnant women in the experimental group, based on the GDM risk category in which they belonged by the investigator.



Plate 3 Diet Counselling at OPD

The GDM high risk women were provided Nutrition Intervention 1, the GDM average risk women Nutrition Intervention 2 and the GDM low risk women Nutrition Intervention 3 as per the developed SSOP for MNT. The control group followed the existing MNT practices followed in the selected hospital.

The investigator also conducted daily checks of the entire process flow of the SSOP based MNT including scheduling of review/follow up MNT visits of recruited participants at dietitian's OP, sending reminders of review/follow up MNT visits to recruited patients, monitoring of real-time meal plate checks, undertaking IP (in patient) MNT visits of recruited participants and rectification of problems encountered while implementing the SSOP.



Plate 4 Real-time Plate Checks of Participants

The investigator followed all the recruited patients from the time of recruitment into the study until their delivery extending to a span of 9 to 11 months. Direct face to face diet counselling and online nutrition education sessions on topics such as nutrition during pregnancy, gestational weight gain, GDM and its prevention etc. were taken by the investigator for the participants in the experimental group using educational tools such as Power point presentations (Appendix XIII).

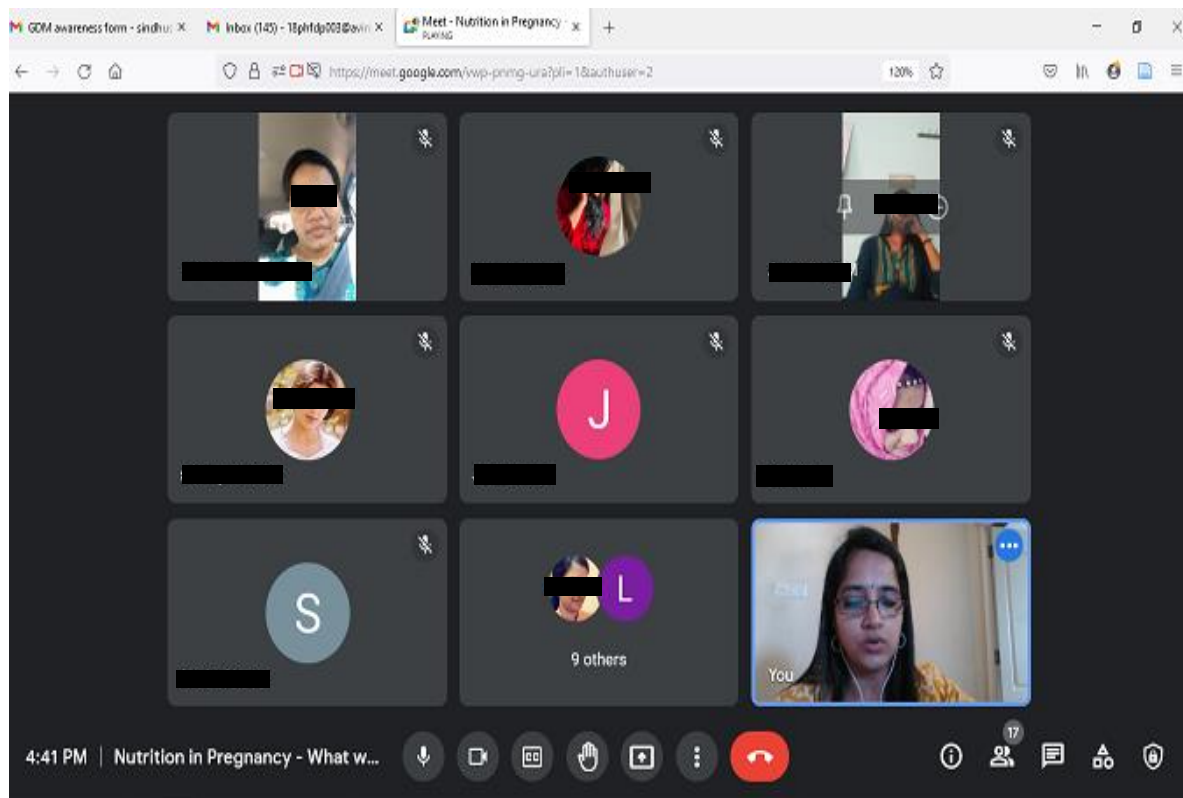


Plate 5 Online Nutrition Education Sessions for Participants

A group contact (Appendix XIV) was formed among the participants in the experimental group to clear doubts regarding diet, send reminders of nutrition reviews, MNT guidelines (Appendix XV) to meet nutrient requirements and maintenance of adequate gestational weight gain. Three healthy recipe videos (Appendix XVI) were done by the investigator to motivate and educate the pregnant women in experimental group to follow healthy eating patterns throughout their gestational period.

A knowledge attitude practice (KAP) survey was conducted among a subset of 45 participants of the experimental group using a validated KAP questionnaire (Appendix XVII) to evaluate the extensive nutrition education given to the experimental group. According to the United States Agency for International Development, 2011, a Knowledge, Attitude and Practices (KAP) survey “is a quantitative method (predefined questions formatted in standardized questionnaires) that provides access to quantitative and qualitative information”.

Training sessions on the SSOP based MNT planning and practices for GDM were also taken by the investigator for dietitians and nutritionists who participated in the study.

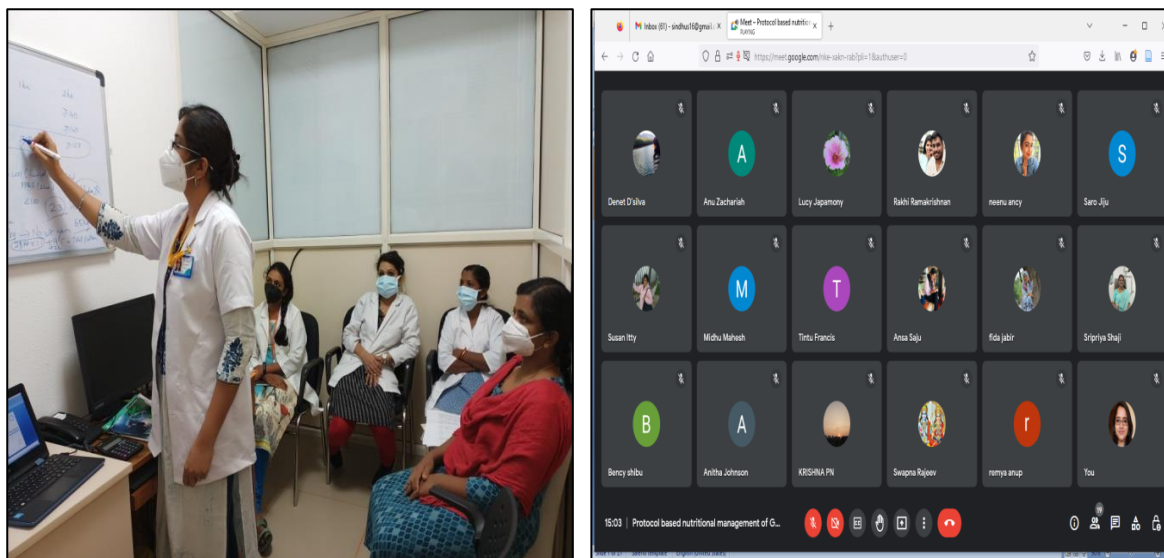


Plate 6 Direct and Online Training Sessions for Dietitians

The KAP questionnaire was used as a pre-test and post-test tool to compare the knowledge, attitude and practice of selected participants of experimental group after conducting the nutrition education sessions by the investigator. KAP surveys are useful to identify the knowledge, myths and misconceptions; attitudes and beliefs; and behaviour in relation to a specific health-related topic, ideally used before implementation of an educational and interventional program and then repeated post-intervention to assess the impact of the intervention (Andrade et al., 2020). An e-nutrition booklet on lactation and initiation of complementary feeding (Appendix XVIII) was prepared and given to all the participants of the study after their delivery during the final MNT visit by the investigator.

3.4.5. Evaluation of SSOP

The evaluation of the SSOP for MNT was done by comparing each component of the SSOP based MNT namely “GDM risk screening, nutrition assessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation” among the experimental and control groups.

Detection of GDM, impact of GDM risk screening, adequacy of gestational weight gain, need for OHA and insulin, presence of adverse maternal and foetal outcomes and identification of the factors that influence adverse maternal and foetal outcomes were also done between the experimental and control groups to understand the impact of the SSOP based MNT.

Finally, a comparison of the mode of delivery, birth weight of baby, maternal and foetal outcomes among pregnant women of Phase 1 and pregnant women of experimental group (Phase IV) was done to assess how effective the SSOP based MNT was compared to existing MNT practices in the hospital.

3.5. Statistical Interpretation

The statistical analysis was conducted using SPSS 21 software version. Descriptive statistics were reported as frequency of total number of responses in numbers and percentages. Chi square and Fisher's exact tests were performed between categorical variables among HCPs, GDM and Non-GDM women. Numerical variables were reported as mean with standard deviation. Comparison of scale variables between GDM and Non-GDM women were done through independent sample t test and paired sample t test. In Phase IV descriptive statistics, parametric and non-parametric tests were conducted among experimental and control groups and logistic regression analysis done to evaluate the possible association between the independent and the dependent variables and to find the impact of SSOP on GDM occurrence as well as the occurrence of adverse maternal and foetal outcomes.