

CERTIFICATE

This is to certify that the thesis 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**” submitted to Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for the award of degree of **Doctor of Philosophy in Food Service Management and Dietetics** is a record of original work done by **Sindhu S.** during the period of her study in the Department of Food Service Management and Dietetics, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore under my supervision and guidance and the thesis has not formed the basis for the award of any Degree/ Diploma/ Associateship/ Fellowship or other similar title to any candidate of any University or Institute.



**Signature of the
Head of the Department**



Signature of the Guide



Signature of the Dean

DECLARATION

I hereby declare that the matter embodied in this thesis 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 the result of investigation carried out by me in the **Department of Food Service Management and Dietetics**, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore under the supervision and guidance of **Dr. S. Uma Mageshwari**, Former HOD and Dean, Student Affairs, Professor, Department of Food Service Management and Dietetics, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore and it has not been submitted for the award of any Degree/ Diploma/ Associateship/ Fellowship etc., of any other University or Institute.


Signature of the Guide


Signature of the Candidate

ACKNOWLEDGEMENT

First and foremost, praises and thanks to the **God Almighty** for giving me strength, wisdom, health, courage and for showering his blessings throughout my research work to complete the thesis successfully.

I take this opportunity to sincerely acknowledge and pay reverential homage to Late **Dr. T. S. Avinashilingam, The Founder** and respectful homage to the Doyen of Nutrition Late Hon, **Padmashri, Dr. Rajammal. P. Devadas, Former Chancellor**, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for providing education in this temple of learning.

I express my profound sense of gratitude and sincere thanks to **Padmashri Dr. P. R. Krishnakumar** and **Prof. S. P. Thyagarajan, Former Chancellors**, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for the successful completion of the study

I express my deep sense of gratitude to **Sri. T.S.K. Meenakshi Sundaram, Managing Trustee and Chancellor**, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for having provided the infrastructure and all amenities to conduct this study.

I express my sincere thanks and gratitude to **Dr. Premavathy Vijayan, Former Vice Chancellor**, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for the relentless support extended for the study..

I record my gratitude and heartfelt thanks to **Dr. V. Bharathi Harishakar, Ph.D, Vice Chancellor**, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for facilitating to complete the study.

I express my deep sense of gratitude to **Dr. S. Kowsalya, Former Registrar**, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for providing all the support towards the smooth conduct of the study.

I am profoundly grateful and express my sincere thanks to **Dr. H. Indu, Registrar**, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for providing the amenities for carrying out the study.

I remain extremely grateful to **Dr. K. Manimozhi, Controller of Examination,** Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for extending her encouragement and support towards the submission of this work.

I express my deepest sense of gratitude to **Dr. G. P. Jayanthi, Former Director, Research and Development Cell,** Avinashilingam Institute for Home science and Higher Education for Women University, for Women, Coimbatore for providing the timely support and necessary guidance in doing this work.

I express my sincere thanks to **Dr. P. Lalitha, Director, Research and Development Cell,** Avinashilingam Institute for Home science and Higher Education for Women University, for Women, Coimbatore for her valuable suggestions and guidance during the tenure of my research work.

I am greatly indebted and thankful to **Dr. N. Vasugi Raja, Former Dean,** School of Home Science for her support and encouragement extended throughout the study.

I am extremely grateful to **Dr. S. Amsamani, Dean,** School of Home Science, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for her continued interest and constant support in the conduct of thesis work.

I extend my profound gratitude for **Dr. G. Vimal Kumar, Subject Expert, Professor and NABH Assessor,** Department of Surgery, PSG Institute of Medical Sciences and Research for all his valuable suggestions and constant support extended throughout the study.

I express my deep sense of gratitude and respect to **Dr. Sarada Ramadas, Former Professor and Head,** Department of Food Service Management and Dietetics, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for her words of encouragement and support towards completion of this work.

I place on record my sincere gratitude and humble note of thanks to **Dr. Premala Priyadarshini, Professor and Head,** Department of Food Service Management and Dietetics, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for her constant support, guidance and encouragement throughout the study.

Words fall short to express my deepest sense of gratitude to my Supervisor **Dr. S. Uma Mageshwari, Former HOD, Dean Student Affairs and Professor,**

Department of Food Service Management and Dietetics, Avinashilingam Institute for Home science and Higher Education for Women University, Coimbatore, for her eminent guidance, untiring effort, patience, valuable and timely suggestions. I am forever indebted to her for taking the time and effort for guiding me throughout my research journey and motivating me to constructive criticism at every stage in my research. I thank her for being the inspiration, motivating me to do my best throughout the study period.

I am grateful to all the **Faculty members**, Department of Food Service Management and Dietetics, Avinashilingam Institute for Home science and Higher Education for Women University, Coimbatore for their concern, constant encouragement, timely support, valuable suggestions, guidance and motivation given throughout the study.

I express my sincere gratitude to the **Management** of the seven hospitals for granting permission and providing all the required help for conducting the study. I would also like to sincerely thank all the doctors, dietitians, allied healthcare personnel and pregnant women for their unwavering support and co-operation and it is their participation that made this the study possible.

A special note of thanks and gratitude to **Dr. V. Mohan, Chairman, Dr. Ranjit Unnikrishnan, Vice Chairman and Dr. Balaji Bhavadharini, Scientist**, Madras Diabetes Research Foundation for providing the survey tools for the study.

I express my thank to Mr. Selvakumar, Euro Informatics for the thesis documentation work and to Dr Joshy C.G., Senior Scientist, ICAR-CIFT, Kochi, Dr. Soubhagya S. Prabhu, Assistant Professor, Dept. of Statistics, Rajagiri College of Social Sciences, Kochi, Mr. Abish Sudhakar, Research Co-ordinator, Amrita Institute of Medical Sciences, Kochi, Dr. Sunanda C., Statistical Consultant and Biostatistician, Vaidhyaratanam Ayurveda College, Thrissur, Dr. Neha Sanwalka Rungta, Associate Professor, Jehangir Hospital, Pune, Dr. Nikhil Jain, Maastricht University, Netherlands and the Research Team at CoGuide Research Services, Bengaluru for their support and help rendered in the statistical interpretation of the study.

I am deeply thankful to the Dr. T.V. Ravi, Managing Director and Dr. C. G. Raghu, Medical Director and Ms. Anu Zachariah, Head, Department of Nutrition and Dietetics, and my colleague, Ms. Saro Rose Sebastian, Dietitian, Ernakulam Medical Centre, for their continued support and constant encouragement which helped me complete this thesis on time.

I sincerely thank all my **fellow Research Scholars** of Department of Food Service Management and Dietetics in Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore for their constant help and support during my research work.

A special note of thanks to my friends and seniors for their constant encouragement and continuous support throughout the study.

Words cannot express how much grateful I am for the everlasting love and selfless support of my beloved husband, daughter, parents, brother, in-laws and all other family members. I thank my family for their patience, wishes and prayers for the successful completion of this research work within the stipulated time.

LIST OF TABLES

TABLE NO	TITLE	PAGE NO
1.	Current Guidelines for Screening and Diagnosis of GDM	19
2.	Monitoring and Evaluation Goals from Various Organisations	25
3.	Maternal and Neonatal Complications of Gestational Diabetes Mellitus	28
4.	Details of Selected HCPs	47
5.	Details of Selected Pregnant Women	49
6.	Guidelines and Quality Control Operation Manuals referred for Development of SSOP for MNT for GDM	53
7.	Definition and Formula for I-CVI and S-CVI/Ave	55
8.	Details of Age and Gender of HCPs	69
9.	Details of Educational Qualification and Clinical experience of HCPs	70
10.	Responses of HCPs on GDM	71
11.	Perception of HCPs on protocols in GDM management	74
12.	Gaps Analysis in Screening, Assessment and Diagnosis Procedures	75
13.	Gap Analysis in Intervention Procedures	76
14.	Gap analysis in Monitoring and Evaluation Procedures	78
15.	Gap analysis in MNT practices for GDM	84
16.	MNT practices identified in GDM Guidelines, 2016, Academy of Nutrition and Dietetics	86
17.	Background details of Pregnant Women	87
18.	Comparison of Height, Pre-pregnancy Weight and Body Mass Index (BMI) among Pregnant Women	88
19.	Comparison of Biochemical Tests among Pregnant Women	89
20.	Comparison OGTT Values among Pregnant Women	90
21.	Antenatal Complications among Pregnant Women	90
22.	Comparison of Nutrient Intake of Pregnant Women with RDA	91
23.	Risk factors of GDM among Pregnant Women	92
24.	Understanding the Consequences of GDM among Pregnant Women	93
25.	Perception towards managing Pregnancy among Pregnant Women	94

TABLE NO	TITLE	PAGE NO
26.	MNT practices received among Pregnant Women	94
27.	Physical Activity Patterns among Pregnant Women	96
28.	Delivery Details, Maternal and Foetal Outcomes among Pregnant Women	97
29.	Nutrition Intervention based on GDM Risk	102
30.	Relevance ratings on the SSOP for MNT of GDM by HCPs	105
31.	Relevance ratings on the Mobile App by HCPs	112
32.	Background Details of Pregnant Women	115
33.	GDM Risk Screening among Pregnant Women	116
34.	GDM Risk Categorisation based on GDM Risk Screening	117
35.	Detection of GDM based on GDM Risk screening	117
36.	Comparison of Detection of GDM among Pregnant Women	118
37.	Comparison of Height, Pre-pregnancy weight and BMI among Pregnant Women	119
38.	Comparison of RBS, FBS, HbA1c, Hb and TSH among Pregnant Women	120
39.	Comparison of Oral Glucose Tolerance Test among Pregnant Women	120
40.	Antenatal Complications seen among Pregnant Women	121
41.	Nutrient Intake of Pregnant Women and RDA	122
42.	Nutrition Diagnosis derived after Nutrition Assessment of Pregnant Women	123
43.	KAP Study to Assess the Impact of Nutrition Education Session given to a Selected Sample of Pregnant Women	124
44.	MNT, Oral Hypoglycaemic Agents and Insulin among Pregnant Women	124
45.	Comparison of FBS and PPBS among Pregnant Women	125
46.	Comparison of Gestational age and Total Weight Gained among Pregnant Women	126
47.	Comparison of GWG among Pregnant Women with Recommended GWG of Institute of Medicine	127
48.	Comparison of Delivery, Birth Outcome, Labour and Birth weight and Birth Details of Newborns of Pregnant Women	128

TABLE NO	TITLE	PAGE NO
49.	Comparison of Maternal Outcomes among Pregnant Women	130
50.	Comparison of the Presence of Adverse Maternal Outcomes among Pregnant Women	130
51.	Logistic Regression for Identifying the Risk Factors of Adverse Maternal Outcome	131
52.	Comparison of Foetal Outcomes among Newborns of Pregnant Women	132
53.	Comparison of Presence of Adverse Foetal Outcomes	133
54.	Logistic Regression to Identify Risk Factors of Adverse Foetal Outcomes	133
55.	Logistic Regression for Identifying the Risk Factors of GDM	134
56.	Comparison of Delivery, Birth weight of Newborns, Adverse Maternal and Foetal Outcomes among Pregnant Women of Phase I and Pregnant Women of Phase IV	135

LIST OF FIGURES

FIGURE NO	TITLE	PAGE NO
1.	Hyperglycaemia in Pregnancy (20-49 years) ranked by age-adjusted comparative prevalence estimates (Figure generated from IDF Atlas, 2021)	11
2.	Median (interquartile range) prevalence (%) of GDM by WHO region, 2005–2015	12
3.	Prevalence of GDM in Five Different Zones in India	15
4.	Transgenerational Transmission of Diabetes – The Vicious Cycle	31
5.	Nutrition Care Process Model	35
6.	Existing Practices in GDM management	51
7.	Delivery Outcomes Commonly seen by HCPs among GDM women	72
8.	Foetal Complications commonly seen by HCPs among Infants of GDM women	73
9.	Role and Importance of MNT	79
10.	Confidence level to follow SSOP for MNT and Understanding of Evidence-based Guidelines for GDM among Dietitians	80
11.	Most Discussed MNT Components by Dietitians	81
12.	Least Discussed MNT Components by Dietitians	81
13.	Type of Diet Counselling	82
14.	Duration of Diet Counselling	83
15.	Frequency of Diet Counselling per GDM Woman	83
16.	Lacunae Identified in Existing Practices in GDM management	99
17.	Flowchart of SSOP for MNT of GDM	104
18.	SUS Grade among Doctors and Dietitians	113
19.	Adjective Rating Scale among Doctors and Dietitians	114
20.	Mode of Delivery and Induction of Labour among Pregnant Women	128
21.	Birth Outcomes and Birth Weight of Newborns	129
22.	Delivery Details, Maternal and Foetal Outcomes among Phase I and Phase IV Pregnant Women	136

LIST OF PLATES

PLATE NO	TITLE	PAGE NO
1.	Logo and Name of the Mobile App	57
2.	Face to Face Discussions with HCPs	61
3.	Diet Consultation at OPD	61
4.	Real-Time Plate Checks of Participants	62
5.	Online Nutrition Education Sessions for Participants	63
6.	Direct and Online Training Sessions for Dietitians	64
7.	Home Screen	107
8.	Login Screen	108
9.	Add/Update/ Delete Patient Screen	108
10.	Patient's Personal Details	109
11.	Medical Details Screen	109
12.	Laboratory Details Screen	110
13.	Medicine Details Screen	110
14.	Result screen/MNT Planning Screen	111

ABBREVIATIONS

ACHOIS	-	Australian Carbohydrate Intolerance Study
ACOG	-	American Congress of Obstetricians and Gynecologists
ADA	-	American Diabetes Association
ADIPS	-	Australasian Diabetes in Pregnancy Study Group
AHP	-	Allied Health Personnel
AND	-	Academy of Nutrition and Dietetics
BMI	-	Body Mass Index
CC	-	Carpenter and Coustan
CDA	-	Canadian Diabetes Association
CGM	-	Continuous Glucose Monitoring
CI	-	Confidence Interval
CMS	-	Centers for Medicare and Medicaid Services
CPG	-	Clinical Practice Guidelines
CVI	-	Content Validity Index
DASH	-	Dietary Approaches to Stop Hypertension
DIPSI	-	Diabetes in Pregnancy Study Group India
DNA	-	Deoxy Nucleic Acid
DNB	-	Diplomate of National Board
DPP-4	-	Dipeptidyl Peptidase-4
FBS/FBG	-	Fasting Blood Sugar/Fasting Blood Glucose
FIGO	-	International Federation of Gynecology and Obstetrics
FSI	-	Fasting Serum Insulin
GDM	-	Gestational Diabetes Mellitus
GI	-	Glycaemic Index
GLP-1	-	Glucagon- Like peptide-1
GM	-	Gut Microbiota
HAPO	-	Hyperglycaemia Adverse Pregnancy Outcome

HAPO-FUS	-	Hyperglycaemia and Adverse Pregnancy Outcome Follow Up Study
Hb	-	Haemoglobin
HbA1c	-	Glycosylated Haemoglobin
HCP	-	Healthcare Professional
HIP	-	Hyperglycaemia In Pregnancy
HOMA-IR	-	Homeostatic Model Assessment for Insulin Resistance
hs-CRP	-	High sensitivity C-reactive protein
IADPSG	-	International Association of Diabetes and Pregnancy Study Group
ICMR	-	Indian Council of Medical Research
I-CVI	-	Item-level Content Validity Index
IDF	-	International Diabetes Federation
IDR	-	Interdisciplinary Rounds
IEC	-	Information, Education and Communication
IL-6	-	Interleukin-6
KAP	-	Knowledge Attitude Practice
LGA	-	Large for Gestational Age
LMIC	-	Low and Middle Income Countries
MBBS	-	Bachelor of Medicine Bachelor of Surgery
MD	-	Doctor of Medicine
MNT	-	Medical Nutrition Therapy
NCD	-	Non Communicable Disease
NCP	-	Nutrition Care Process
NDDG	-	National Diabetes Data Group
NFHS	-	National Family and Health Survey
NICE	-	National Institute for Health and Care Excellence
Non-GDM	-	Non-Gestational Diabetes Mellitus
NPG	-	Nutrition Practice Guidelines
OAD	-	Orally Administered Drugs
OGTT	-	Oral Glucose Tolerance Test

OHA	-	Oral Hypoglycaemic Agents
PA	-	Physical Activity
PCOS	-	Polycystic Ovarian Syndrome
PP	-	Post Prandial
PPBS	-	Post Prandial Blood Sugar
PUFA	-	Poly Unsaturated Fatty Acid
RBS	-	Random Blood Sugar
RCT	-	Randomised Controlled Trial
RDA	-	Recommended Dietary Allowance
RDN	-	Registered Dietitian Nutritionist
RR	-	Relative Risk
S-CVI	-	Scale- level Content Validity Index
SD	-	Standard Deviation
SGLT2	-	Sodium Glucose Cotransporter-2
SMBG	-	Self Monitoring of Blood Glucose
SOP	-	Standard Operating Procedure
SSOP	-	Sustainable Standard Operating Protocol
SUS	-	System Usability Scale
TNF- α	-	Tumor Necrosis α
Type 2 DM	-	Type 2 Diabetes Mellitus
UI	-	User Interface
USDHHS	-	US Department of Health and Human Services
UTI	-	Urinary Tract Infection
WHO	-	World Health Organisation
WINGS	-	Women in India with Gestational Diabetes Mellitus Strategy