Desi-GDM Trial Protocol Version 6.0

# A culturally-tailored personalizeD nutrition intErvention in South ASIan women at risk of Gestational Diabetes Mellitus (DESI-GDM) – a randomized trial

Principal Investigator:
Russell de Souza, ScD, RD

Co-Investigators:
Kristi Adamo, Sonia Anand, Harpreet Bajaj, Shrikant Bangdiwala, Hertzel Gerstein, Scott Lear, Sarah McDonald, Paul Ritvo, Diana Sherifali, Jennifer Stearns, Gita Wahi, Michael Zulyniak,

Funded by: Canadian Institutes of Health Research (Project Grant)

Table of Contents

## 1.0 Introduction

Gestational diabetes mellitus (GDM) is a condition in which a woman without existing diabetes develops high blood sugar levels during pregnancy[1]. Complications for the baby include neonatal hypoglycemia and intensive-care admission[2], and GDM is a strong risk factor for future type 2 diabetes (T2DM): up to 50% of women with GDM develop T2DM within 5 y of giving birth[3,4], and face up to seven-fold higher lifetime risk of T2DM compared with women who have a non-GDM pregnancy[3,5]. GDM is associated with future atherosclerosis and cardiovascular disease (CVD) in the mother and increases the risk of T2DM in offspring up to eight-fold.[5-8] South Asians (SA), people whose ancestors are from India, Pakistan, Bangladesh, or Sri Lanka, are the largest non-white ethnic group in Canada, and are at high risk of T2DM and early CVD. SA women have at least double the risk of GDM of white European women, and risk factors for future T2DM in the offspring including higher birthweight, more adipose tissue, and reduced insulin sensitivity, are more common in SA infants of mothers with GDM than infants born to mothers without GDM.[9]

Building upon our findings in START[9], which identified diet as a key modifiable risk factor for GDM, and a qualitative study of barriers and facilitators to healthy eating encountered by pregnant and recently pregnant South Asian women and health care providers living and working in the Peel Region[11], a region of Ontario where 20.9% of residents are South Asian[10,12], we have developed a dietary intervention. Our conversations with women likely to benefit from this study and health care providers in the field have informed the development and delivery of our intervention.[11] South Asian women voiced several facilitators to healthy eating such as: ***i)*** knowledge of culturally appropriate healthy foods, and ***ii)*** access to a health care provider able to provide resources and support in a timely fashion. They also identified barriers to healthy eating including: ***i)*** changing long-held cultural diet practices; ***ii)*** difficulty adapting standard dietary advice to personal health beliefs; ***iii)*** navigating food choices at family gatherings; and ***iv)*** accommodating meal needs of others in the household. The women we spoke with expressed a desire to learn more about healthy eating to prevent diabetes during pregnancy and were keen to use mobile health technology. Health care providers we spoke with identified two major challenges to providing appropriate advice to members of this community: ***i)*** insufficient time for counseling; and ***ii)*** lack of familiarity with South Asian foods. These findings are consistent with other studies of sociocultural influences on the behaviour of diabetic South Asian women in pregnancy[12,13].

A report from our partners at Peel Public Health[12] emphasize that South Asian with diabetes living in Peel: ***i)*** report a lack of knowledge of "what to eat" that is healthy and culturally-appropriate, ***ii)*** face challenges accessing healthy foods, ***iii)*** have difficulty navigating social interactions that are food-focused, and ***iv)*** often lack control over food intake. Service providers, including family physicians, echoed these concerns and reported ***i)*** difficulty modifying the "unhealthy diet pattern, rich in fats, sweets, and carbohydrates", with tools that are "Euro-centric" (*Canada's Food Guide*), and ***ii)*** dietary guidelines that "can be confusing" to teach. Our dietary intervention will focus on: ***i)*** providing personalized food recommendations that consider a woman's current dietary habits by identifying food choices and substitutions that will optimize the diet; ***ii)*** providing dietary advice that is sensitive to religious (e.g., vegetarian for *Hindu*, *Buddhists*, *Jainists*; inclusion of meat for *Sikhs*, *Christians*) and regional (e.g., Northern vs. Southern India, Sri Lanka, Bangladesh, Pakistan) culinary practices; ***iii)*** involving the household meal preparer, if this is not the participant herself, in the coaching contacts; and ***iv)*** use mobile health technology to reduce the amount of in-office time a health care practitioner spends on dietary counseling.

### 1.1 Results of Pilot Study

We have conducted a pilot trial of 20 pregnant South Asian pregnant women living in Peel Region to understand the feasibility of our proposed intervention. The results of the pilot study have informed the design and operations plan of the DESI-GDM trial.

***Recruitment:*** Between March 1 and July 31, 2019, one research coordinator working 2 days/week screened 30 women, enrolling 20 participants. All participants completed the study (retention = 100%). Based on these early data, with our proposed full staffing, we will be able to screen 15 participants per month, and randomize 10, reaching the desired 190 participants in 1.5 years, as projected.

***Feasibility and Adherence:*** We randomized 11 participants to the intervention, and 9 to control. Control group participants received a median of 8 (1 per week), and intervention group participants received a median of 10 text messages (1 per week) to encourage walking. Intervention participants received a median of 20 text messages (2 per week) tailored to her nutrition goals. Intervention participants received a median of 5 coaching calls (1 every 2 weeks), each lasting approximately 10-15 minutes. Participants typically set 2-3 initial goals, modifying at least 2 goals during the intervention. Over 60% of participants met >80% of their goals.

***Acceptability:*** Nine participants agreed to participate in a short interview about their study experience, following completion of their OGTT visit. All 9 (100%) found the study useful, would recommend participation in this study to a friend, and would participate in future studies with our group. Reasons participants gave for participating in the study included a desire to receive health advice, and a desire to help the South Asian community. Knowing that someone was reviewing their data and supporting them helped them stay motivated, and the regular feedback from the health coach or text messages helped them stay on track with their goals. Women found the visit location convenient, and the staff communicative and respectful of their time. Of the 9 participants, 7 felt the style and frequency of messages was acceptable, and 7 felt the frequency of health coach contact was adequate. Two control participants desired more messages and two participants wished for more frequent contact with the coach. Therefore, we have demonstrated that we can recruit and retain participants, and that the intervention is feasible to deliver and acceptable to participants.

## 2.0 Research Questions

This trial will assess the impact of a culturally tailored, personalized nutrition intervention on glycemic response to an oral glucose load (as measured by the area-under-the curve glucose) in high-risk pregnancies of South Asian women. The intervention targets two at-risk individuals: mother and infant, "breaking the cycle" of maternal gestational dysglycemia, excess infant adiposity and insulin resistance, and CVD in both mother and baby. The findings of this study will be important in guiding future evidence-based recommendations and public health policies to manage gestational glycemia in pregnant women at risk of GDM.

### 2.1 Primary Research Question

In pregnant South Asian women living in Peel Region, Ontario, does a culturally tailored, personalized nutrition intervention delivered by a trained health coach improve blood sugar levels in South Asian women to a greater extent than usual dietary advice?

### 2.2 Secondary Research Question

In pregnant South Asian women living in the Peel Region, Ontario, does a culturally tailored, personalized nutrition intervention delivered by a trained health coach to pregnant South Asian women reduces the incidence of gestational diabetes mellitus to a greater extent than usual dietary advice?

## 3.0 Research Design

### 3.1 Randomization

Women will be randomized 1:1 to intervention or control using a centralized integrated web response system (IWRS) at the Population Health Research Institute (PHRI) in Hamilton. A statistician will generate a randomization list using a permuted blocks algorithm with randomly chosen block sizes to ensure balance in numbers and avoid predictability.[15] At the baseline visit, the research assistant/health coach will confirm eligibility and obtain consent, either in person, verbally via telephone or web conferencing, or electronically via REDCap. After collecting baseline physical measures, the study personnel completing the visit will activate the IWRS to randomly allocate participants to control or intervention in a concealed fashion using a computer-generated random sequence.

### 3.2 Blinding

Randomization allocations will be determined by a statistician at the Population Health Research Institute (PHRI, Hamilton, ON) not involved in participant recruitment, assessment or study intervention, to ensure participant allocation concealment. In this complex intervention, one arm of the study will receive an intensive behavioural intervention, and the other arm will receive usual care. Therefore, the participants will not be blinded to treatment assignment. For administrative and logistical reasons, the staff revealing the randomization to the health coach will not be blinded. Because the health coach will be delivering the intervention s/he will also be aware of treatment assignment. Blinding will occur at outcome assessment (75 g, 2h OGTT). The staff who administer the OGTT will be unaware of treatment assignment, and they will assess the primary clinical endpoint (area-under-the curve of glucose [AUC] by 75-g oral glucose tolerance test [OGTT]). Data analysts will have no contact with study participants and will be unaware of treatment assignment.

## 4.0 Trial Population

### 4.1 Inclusion Criteria

a) pregnant women;
b) South Asian ancestry;
c) gestational weeks 12-18;
d) singleton pregnancy; and

e) ≥2 of the following GDM risk factors: age>29, low diet quality (assessed with a short diet screener17), family history of DM, GDM during a previous pregnancy, or a pre-pregnancy BMI ≥23.17

**4.2 Exclusion Criteria**

a) type 1 or type 2 diabetes;
b) high blood pressure (≥140 mmgHg systolic or ≥90 mmHg diastolic);
c) poor understanding of English (93% of Canadian South Asian women in the National Household Survey could conduct a conversation in one or both official languages[10]);
d) unwilling to modify diet, based on a screening question;
e) at high risk of adverse pregnancy outcomes other than GDM (e.g., twins or higher-order multiples, use of fertility treatment, preexisting hypertension, history of placenta previa or pre-term delivery);
f) enrolment in another study;
g) does not have a smartphone;
h) not willing to walk; or
i) excessive nausea and/or vomitting

**5.0 Study Interventions**

**5.1 Intervention Group**

A personalized nutrition plan will be developed for each woman by a culturally congruent dietitian (**de Souza**). This plan will respect faith-based food choices (e.g., vegetarian for Hindu, Buddhists, Jainists; inclusion of meat for Sikhs, Christians), and regional preferences (e.g., North Indian diet: vegetarian, rich in yogurt, cream, starch from naan, chapatti, roti, and sweets vs. South Indian diet: non-vegetarian, rich in coconut curries, ghee, and starch from rice). The plan will be delivered by a culturally congruent health coach, and consider baseline dietary intake, energy balance for recommended gestational weight gain, personal values and preferences, through setting 2-4 "SMART" goals. Participants assigned to the intervention group will receive text messages that support 11 categories of nutrition goals, targeted to address eating behaviours identified by participants in our qualitative study, designed to optimize energy balance for weight gain, and improve dietary quality. Participants assigned to the intervention group will be given a Fitbit to track their steps**.**

**5.2 Both Groups**

Participants in both groups receive simple text messages weekly, aimed at increasing walking. Both groups will be given PDF resources that provide advice on healthy eating, physical activity, and other lifestyle factors during pregnancy plus additional materials adapted specifically for the South Asian community. Health care providers in Peel Region use these tools routinely (Diabetes Canada: https://bit.ly/2m8r2tT; or Heart & Stroke: https://bit.ly/2lDubl7).

**6.0 Study Measurements and Schedule**

Treatment duration will be between 6 and 16 weeks, depending on time of enrolment. In-person or Zoom study visit contact will occur 2 times: once for the baseline visit and once for the OGTT. Duration of follow-up ranges from 6 to 16 weeks, depending on gestational week of enrollment and OGTT timing. Between these visits, all participants receive weekly text

messages, and intervention participants will also have bi-weekly telephone or video conferencing (Zoom/*Skype/Facetime*).

At the baseline visit, a member of the study team will screen eligible participants. After an informed consent discussion, study personnel will complete the baseline visit, which includes physical measures (height, weight, blood pressure, skinfold thickness and mid upper arm circumference), finger stick for glucose, fasting urine sample collection, fasting blood sample collection, questionnaires to assess sociodemographic characteristics, medical, obstetric and lifestyle histories, an Ayurvedic assessment, COVID-19 and vaccine questionnaires, and INTEHEART food frequency questionnaire. COVID-19 and vaccine questionnaires will be completed to provide context to the sociodemographic characteristics, medical, obstetric and lifestyle histories of participants. The COVID-19 pandemic has impacted all aspects of day-to-day life, and these questionnaires will be available for analysis if needed to provide context to our findings. Health card numbers will be recorded for future linkage with administrative data sources from Ontario such as the Institute for Clinical Evaluative Sciences (ICES) for health economic evaluation and potential for long-term follow-up of mother and her child.

Study personnel meet with all participants, and reviews their usual diet. Once baseline measures are collected, randomization takes place as described (section 3.1). Following group allocation, intervention participants develop a personalized nutrition plan with the health coach and will be provided training on how to use the *Bitesnap* application for food recording. Both intervention or control participants receive PDF or paper-based resources and web links to standard resources. The baseline visit will be approximately 1 hour.

At the second clinic visit (24-28 weeks' gestation), baseline physical measures, INTERHEART food frequency questionnaire, fasting urine sample collection and fasting blood sample collection are repeated and the 75-g OGTT is performed. Optional additional blood samples may be collected at multiple time points during the OGTT for future analysis if funding is obtained. Any future analysis will be relevant to DESI-GDM and will be submitted in a separate HiREB submission.

Participants in both control and intervention groups receive at least 1 text message every week, sent by automated outbound messaging system, *MemoTEXT*.

The intervention group only will be sent weekly text messages to reinforce individual nutrition goals. The intervention group will receive at least 2 text messages/week at times of day requested by the participant: one or more tailored diet text messages, and a message that provides 1 of the 6 walking tips. Participants assigned to the intervention group will be given a Fitbit to track their steps and will track food in *Bitesnap*, a photo food journal app that integrates with the *MemoTEXT* dashboard, for 2 weekdays and 1 weekend day bi-weekly (up to 8 assessments). Health coaches will be able to view activity from the participants Fitbit via the Health Coaching Platform. Coaching calls to the intervention group will be made post-baseline weeks 2, 4, 6, 8, 10, 12, 14, and 16 (bi-weekly up to OGTT). These coaching calls will be recorded using an audio recording device. At each scheduled contact, intervention participants review agreed-upon diet goals, and assess, on a Likert scale, how often they were able to meet them (ranging from "never" through "all of the time"); the coach works with the participant to overcome barriers

using our Brief Action Planning Guide. After each coaching call, participants and Health Coaches will complete a Visit Reflection questionnaire.

The control group will receive 1 text message weekly up to OGTT with 1 of the 6 walking tips reviewed at baseline. The central coordinator will review data regularly for completion, and *ad hoc* calls may be made to clarify items, but no counseling is provided to control group participants.

At the completion of their OGTT, each woman will be asked to complete the DESI-GDM exit survey (see attached). This is a 9-item questionnaire based on previous tools created and used by our group. Responses to each question are provided using a 5-item Likert scale (Strongly Disagree through Strongly Agree).

Study participants will be contacted after delivering their baby to self-report the birth weight and length of their baby. Participants will also be asked to provide details of any complications during delivery.

**7.0 Study Outcomes**

The primary clinical outcome of this trial is the ***glucose area under the curve (glucose AUC).*** A measure of glycemic response, glucose AUC is a continuous measure of the response to a 75-g OGTT that accounts for variations in fasting plasma glucose levels between individuals. It is calculated by the trapezoidal method using the fasting, 1-h, and 2-h glucose[10]. The AUC is superior to a single measure, which, though convenient for diagnosis and treatment, may not provide complete information regarding the processing of plasma glucose after a load[11].

The secondary outcome is ***GDM,*** classified using the cut-offs derived in the *BiB* cohort: fasting glucose ≥ 5.2 mmol/L, or 2-hour post-load ≥7.2 mmol/L[12]. These cut-offs were associated with infant birth weight >90th percentile for gestational age and adiposity (sum of skinfold measurements [SSF] >90$^{th}$ percentile for gestational age) in this cohort[12]. Current clinical cutoffs for the 75-g OGTT used to diagnose GDM in the general population are: fasting glucose ≥ 5.3 mmol/L, 1-hour ≥ 10.6 mmol/L, or 2-hour ≥9.0 mmol/L[13]. In Peel, pregnant women usually undergo a 50-g glucose challenge at 24-28 weeks, with a 1-h value ≥7.8 mmol/L being an indication for a 75-g OGTT[14]. We have selected the 75-g OGTT because: 1) it was used to establish South Asian-specific diagnostic criteria for GDM, and thus our outcomes will be directly comparable[12], 2) it avoids the high false negative rate of the 50-g GCT among South Asians[15,16], 3) one-step screening has potential for long-term cost savings[17-19] , and 4) Diabetes Canada recognizes that the one-step strategy can identify a subset of women who would not otherwise be identified as having GDM and who may benefit with regards to certain perinatal outcomes.[13] We will co-ordinate with the health care provider (**section 2.13**) to ensure participants receive the 75-g OGTT between 24-28 weeks, avoiding the two-step screen. A study endocrinologist (Bajaj) will review the OGTT results and send a letter to the participant's provider communicating the result, to ensure continuity of care and appropriate management. We will assess the sensitivity and specificity of the BiB definition against the IASPSG or WHO criteria.

To evaluate safety outcomes, we measure maternal blood pressure at baseline and the OGTT visit, and note any pregnancy complications at coaching contacts. We will conduct comparisons of primary and secondary outcome data at the end of the trial, unless advised otherwise by our data safety monitoring committee (DSMC).

**8.0 Safety Measurements**

To evaluate safety outcomes, maternal blood pressure is measured at baseline and the OGTT visit, any pregnancy complications are noted at coaching contacts. Potential adverse events that may be experienced by the woman include induced labour, anemia, urinary tract infection, fall, low mood, or high blood pressure (minor); and miscarriage, pre-eclampsia, Cesarean section delivery, Hyperemesis gravidarum, post-partum hemorrhage (>500 ml). Potential adverse events for the baby include pre-term delivery (<36 w) or shoulder dystocia; and mortality or stillbirth (major).

**8.1 Serious Adverse Events**

Any untoward medical occurrence that: results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect will be reported to the Coordinating Centre within 1 business day of its discovery. A narrative summary will be prepared.

**9.0 Sample Size and Statistical Power**

With 95 participants per group, and an expected 10% loss-to-follow-up, we will have ≈86 participants per group, which will provide 90% power to detect at least a 15% between group differences in AUC glucose, assuming 70% adherence to the intervention (i.e. goal setting, health coach contacts, tracking) and SD of AUC glucose = 173 mmol/min17. A change of at least this magnitude has been observed in trials of fibre supplements[20] high-protein[21] or high fat diets[22]. We will have 80% power to detect a 61% relative risk reduction in GDM. An effect of this magnitude is unlikely, so we will look to see if GDM is lower in the intervention. Failure to observe substantial impact on AUC glucose (i.e., <10% reduction) with no signal of benefit for GDM (i.e., an OR between 0.9 and 1.1), or a signal of harm (OR > 1.1) with high intervention fidelity will suggest that a larger trial primarily powered to detect differences in GDM is not warranted.

**10.0 Statistical Analysis**

We will assess the main effect of the diet intervention ($\beta_1$) on the primary outcome of AUC glucose with a linear regression model with **intervention** as the main effect (a dummy variable, where 1=treatment; 0=control)

***a) Primary clinical outcome:*** We will assess the main effect of the diet intervention ($\beta_1$) on the primary outcome of glucose AUC with a linear regression model with ***intervention*** as the main effect (a dummy variable, where 1=treatment; 0=control):

$$\widehat{[glucose\ AUC]} = \beta_0 + \boldsymbol{\beta_1}\ \boldsymbol{intervention} + \varepsilon$$

***b) Secondary clinical outcome:*** We will assess the main effect of the diet intervention ($\beta_1$) on the secondary outcome of GDM by fitting a logistic regression model with ***intervention*** as the main effect (a dummy variable, where 1=treatment; 0=control):

$$logit\ (Pr|GDM = 1) = \beta_0 + \boldsymbol{\beta_1 intervention} + \ \varepsilon$$

***c) Process and acceptability assessments:*** These data will be presented descriptively, and include monthly process feedback (e.g. recruitment, retention, adherence), which the team discusses on an ongoing basis (e.g. poor adherence, unmet goals). The study team review qualitative and quantitative data to refine processes and calibrate expectations. Acceptability will include a 9-item, Likert scale survey, administered after the OGTT visit (***Supplementary Information "C"***), which allow each participant a voice in the research experience, and convey what they liked and disliked about the study, and if they would recommend the program to a friend, as we have in 3 previous studies of similar design[20-22].

## 11.0 Ethical Requirements

Participants will provide written, verbal or electronic informed consent. If providing verbal consent, participants will be sent the full consent via email or paper mail, to read and refer to while being consented. If providing electronic consent via REDCap, participants will be sent a link that contains the full consent and will review the consent over telephone or web-conferencing with study staff. The participant will select whether they agree to participate at the bottom of the consent page. Participant data will be deidentified to protect confidentiality, and will only be reported and published in aggregate.

## 12.0 Study Coordination and Management

Dr. Russell de Souza will take responsibility for the oversight of the study. The coordinating centre for the trial will be Population Health Research Institute (PHRI) in Hamilton, ON. The coordinating centre, under the direction of Dr. Shrikant Bangdiwala in collaboration with Ted Scott, will receive all data, and take process steps to reduce missing data. Senior project manager, Ms. Dipika Desai, along with a student (TBD) who will oversee logistics of recruitment of participants, will handle central trial coordination. At weekly meetings, we will review recruitment, minor adverse events, study inventories, and review any expressed concerns by participants or the team.

### 12.1 Data and Safety Monitoring

The steering committee will direct operational/process (de Souza, Anand, Gerstein), nutrition (de Souza), coaching (Sherifali), and statistical (Bangdiwala) aspects of the trial. For our previous pilot study, we had convened a DSMC, consisting of an experienced endocrinologist, biostatistician, and internal medicine specialist. Our committee advised that a DSMC was not required for the pilot, voting for a safety officer, and disbanded

During our pilot study, we convened a meeting with senior investigators (3 of which are also involved in this study- Anand, Bangdiwala, and Gerstein) on May 2, 2019. At this meeting, the senior members of the investigative team advised that a DSMB was not necessary for this trial. They instead advised that a safety officer be appointed to review data monthly (or more

frequently as indicated). Dr. Sonia Anand was appointed as the safety officer. She will retain this role for the study under submission herein. At each monthly meeting, she will review data, noting any of the 5 minor (premature labour, anemia, urinary tract infection, fall/injury/accident related to study, or high blood pressure), or 3 major maternal events (miscarriage, pre-eclampsia, or hyperemesis gravidarum); or 2 minor (pre-term delivery <36 weeks, or shoulder dystocia) or 2 major (mortality or stillbirth) infant events. She will determine whether they are related to study participation.

An interim data analysis, comparing 1) mean AUC glucose; and 2) GDM incidence between treatment and control (blinded) after the first 25 participants have completed their OGTT visit. Thereafter, we will have the committee review the data following each additional 50 participants. There is no early stopping rule for this study. We will only collect data at baseline and the OGTT visit.

**Table 1. Schedule of visit procedures**

| | **Baseline** | **Weekly** | **Health Coach Visits** | **OGTT Visit** | **Post-Birth Visit** |
|---|---|---|---|---|---|
| Screening | x | | | | |
| Informed Consent | x | | | | |
| Randomization | x | | | | |
| Physical Measures (height, weight, blood pressure, skinfold thickness, mid upper arm circumference) | x | | | x | |
| INTERHEART Food Frequency Questionnaire | x | | | x | |
| COVID-19 and Vaccine Questionnaires | x | | | | |
| Finger Stick for Glucose | x | | | | |
| 75-g OGTT | | | | x | |
| Urine Sample Collection | x | | | x | |
| Blood Sample Collection | x | | | x | |
| Sociodemographic Questionnaire | x | | | | |
| Medical History Questionnaire | x | | | | |
| Obstetrics Questionnaire | x | | | | |
| Lifestyle Questionnaire | x | | | | |
| Ayurvedic Assessment | x | | | | |
| Device Identification* | x | | | | |
| *FitBit* Distribution* | x | | | | |
| *Bitesnap* Downloaded* | x | | | | |
| Resource Handouts | x | | | | |
| Walking tips via *MemoTEXT* | | x | | | |
| Diet reinforcement via *MemoTEXT** | | x | | | |

| | | | | | |
|---|---|---|---|---|---|
| Calls With Health Coach (set and review SMART goals, Brief Action Planning Guide) * | | | x | | |
| Visit Reflection* | | | x | | |
| *Bitesnap* Food Journal* | | x | | | |
| *FitBit* Return* | | | | x | |
| Exit Questionnaire | | | | x | |
| Mother-reported Infant Physical Measures | | | | | x |

* Intervention group only

REFERENCES


1. Gestational diabetes. 2017. (Accessed 5 March, 2018, at https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/gestational.)
2. Hapo Study Cooperative Research Group, Metzger BE, Lowe LP, et al. Hyperglycemia and adverse pregnancy outcomes. N Engl J Med 2008;358:1991-2002.
3. Diabetes in pregnancy: management from preceonception to the postnatal period. 2018. (Accessed 5 March, 2018, at https://www.nice.org.uk/guidance/ng3/chapter/2-research-recommendations#postnatal-treatment-for-women-diagnosed-with-gestational-diabetes.)
4. Lee AJ, Hiscock RJ, Wein P, Walker SP, Permezel M. Gestational diabetes mellitus: clinical predictors and long-term risk of developing type 2 diabetes: a retrospective cohort study using survival analysis. Diabetes Care 2007;30:878-83.
5. Bellamy L, Casas JP, Hingorani AD, Williams D. Type 2 diabetes mellitus after gestational diabetes: a systematic review and meta-analysis. Lancet 2009;373:1773-9.
6. Gunderson EP, Chiang V, Pletcher MJ, et al. History of gestational diabetes mellitus and future risk of atherosclerosis in mid-life: the Coronary Artery Risk Development in Young Adults study. Journal of the American Heart Association 2014;3:e000490.
7. Clausen TD, Mathiesen ER, Hansen T, et al. High prevalence of type 2 diabetes and pre-diabetes in adult offspring of women with gestational diabetes mellitus or type 1 diabetes: the role of intrauterine hyperglycemia. Diabetes Care 2008;31:340-6.
8. Archambault C, Arel R, Filion KB. Gestational diabetes and risk of cardiovascular disease: a scoping review. Open Med 2014;8:e1-9.
9. Anand SS, Gupta M, Teo KK, et al. Causes and consequences of gestational diabetes in South Asians living in Canada: results from a prospective cohort study. CMAJ Open 2017;5:E604-E11.
10. Allison DB, Paultre F, Maggio C, Mezzitis N, Pi-Sunyer FX. The use of areas under curves in diabetes research. Diabetes Care 1995;18:245-50.
11. Sakaguchi K, Takeda K, Maeda M, et al. Glucose area under the curve during oral glucose tolerance test as an index of glucose intolerance. Diabetol Int 2016;7:53-8.
12. Farrar D, Fairley L, Santorelli G, et al. Association between hyperglycaemia and adverse perinatal outcomes in south Asian and white British women: analysis of data from the Born in Bradford cohort. The Lancet Diabetes & Endocrinology;3:795-804.
13. Diabetes Canada Clinical Practice Guidelines Expert C, Feig DS, Berger H, et al. Diabetes and Pregnancy. Canadian journal of diabetes 2018;42 Suppl 1:S255-S82.
14. Thompson D, Berger H, Feig D, et al. Canadian Diabetes Association 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada: Diabetes and Pregnancy. Canadian journal of diabetes 2013;37:S1-S212.
15. Anand SS, Vasudevan A, Gupta M, et al. Rationale and design of south Asian birth cohort (START): a Canada-India collaborative study. BMC public health 2013;13:79.
16. Mohan V, Mahalakshmi MM, Bhavadharini B, et al. Comparison of screening for gestational diabetes mellitus by oral glucose tolerance tests done in the non-fasting (random) and fasting states. Acta Diabetol 2014;51:1007-13.

17. Duran A, Saenz S, Torrejon MJ, et al. Introduction of IADPSG criteria for the screening and diagnosis of gestational diabetes mellitus results in improved pregnancy outcomes at a lower cost in a large cohort of pregnant women: the St. Carlos Gestational Diabetes Study. Diabetes Care 2014;37:2442-50.
18. Lapolla A, Dalfra MG, Ragazzi E, De Cata AP, Fedele D. New International Association of the Diabetes and Pregnancy Study Groups (IADPSG) recommendations for diagnosing gestational diabetes compared with former criteria: a retrospective study on pregnancy outcome. Diabet Med 2011;28:1074-7.
19. Mission JF, Ohno MS, Cheng YW, Caughey AB. Gestational diabetes screening with the new IADPSG guidelines: a cost-effectiveness analysis. Am J Obstet Gynecol 2012;207:326 e1-9.
20. Samaan Z, Schulze KM, Middleton C, et al. South Asian Heart Risk Assessment (SAHARA): Randomized Controlled Trial Design and Pilot Study. JMIR Res Protoc 2013;2:e33.
21. Zulyniak MA, de Souza RJ, Mente A, et al. A randomized controlled trial of the effects of a prudent diet on cardiovascular risk factors, gene expression, and DNA methylation - the Diet and Genetic Intervention (DIGEST) Pilot study. BMC Nutrition 2016;2:1-11.
22. A Culturally-tailored Personalized Nutrition Intervention in South Asian Women at Risk of Gestational Diabetes. 2019. at https://ClinicalTrials.gov/show/NCT03607799.)