

Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

Canadian Journal of Diabetes

journal homepage:
www.canadianjournalofdiabetes.com


Original Research

The Avoiding Diabetes After Pregnancy Trial in Moms Program: Feasibility of a Diabetes Prevention Program for Women With Recent Gestational Diabetes Mellitus

Lorraine L. Lipscombe MD, MSc^{a,b,c,*}; Faith Delos-Reyes R. Kin, BPHE^{a,1};
 Andrea J. Glenn MSc RD^{d,e}; Stephanie de Sequeira MPH^a; Xinyun Liang BSc^b;
 Shannan Grant PDT/RD, MSc, PhD^{f,g}; Kevin E. Thorpe MMath^{h,i}; Jennifer A.D. Price PhD^{a,j}

^a Women's College Research Institute, Women's College Hospital, Toronto, Ontario, Canada^b Department of Medicine, University of Toronto, Toronto, Ontario, Canada^c Institute for Health Policy, Management, and Evaluation, University of Toronto, Toronto, Ontario, Canada^d Clinical Nutrition and Risk Factor Modification Centre, St Michael's Hospital, Toronto, Ontario, Canada^e Department of Nutritional Sciences, University of Toronto, Toronto, Ontario, Canada^f Department of Applied Human Nutrition, Mount St Vincent's University, Halifax, Nova Scotia, Canada^g Department of Obstetrics and Gynaecology, IWK Health Centre, Halifax, Nova Scotia, Canada^h Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canadaⁱ Applied Health Research Centre, Li Ka Shing Knowledge Institute, St Michael's Hospital, Toronto, Ontario, Canada^j Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Toronto, Ontario, Canada

Key Messages

- Women with gestational diabetes (GDM) are at elevated risk of subsequent type 2 diabetes, which can be prevented with health behaviour interventions.
- Health behaviour interventions in women with recent GDM have shown limited effectiveness due to low participation and adherence.
- A customized health behaviour program that accommodates parenting barriers may be more feasible for women with recent GDM.
- A home-based coaching program customized for women with gestational diabetes mellitus is associated with >70% participation, adherence and satisfaction.
- This postpartum program can be feasibly delivered by trained diabetes educators without additional health-care resources.

ARTICLE INFO

Article history:

Received 22 March 2019

Received in revised form

12 August 2019

Accepted 29 August 2019

Keywords:

behaviour
coaching
diabetes prevention
gestational diabetes
lifestyle intervention

ABSTRACT

Objective: Our aim in this study was to evaluate the feasibility of a home-based diabetes prevention program, delivered by interdisciplinary certified diabetes educators (CDEs), and customized for postpartum women with recent gestational diabetes mellitus (GDM).

Methods: This pilot randomized trial recruited women with GDM from 24 to 40 weeks gestation from 4 centres, and trained 10 CDEs in behaviour coaching, physical activity (PA) and low glycemic index education. Women were randomized after 3 months postpartum to standard care (1 visit) or 1 of 3 24-week coaching interventions (1 visit and 12 telephone calls): i) PA and diet, ii) PA only or iii) diet only. Feasibility outcomes included recruitment, retention, adherence and satisfaction.

Results: Of 1,342 eligible patients, 392 were actively invited (29.3%) and 227 (16.9%) consented. Of these, 149 (65.6%) were randomized postpartum, of whom 131 (87.9%) started the program and 105 (70.5%) attended the final assessment. Intervention arm participants completed a median 75% (interquartile range, 50% to 92%) of telephone calls. Visit and call duration were a mean 71.4 (standard deviation, 13.8) and 18.1 (standard deviation, 6.5) minutes, respectively. Participants reported excellent/very good satisfaction 73% of the time, and 87% would recommend the program to others.

* Address for correspondence: Lorraine L. Lipscombe MD, MSc, Women's College Hospital, Women's College Research Institute, 76 Grenville Street, Toronto, Ontario M5S 1B2, Canada.

E-mail address: lorraine.lipscombe@wchospital.ca

¹ Co-first authors, on behalf of the Avoiding Diabetes After Pregnancy Trial in Moms (ADAPT-M) Study Group (Howard Berger, Denice Feig, Karen Fleming, Enza Gucciardi, Ilana Halperin, Paula Harvey, Geetha Mukerji, Joel Ray, Ravi Retnakaran, Diana Sherifali, Jacob A. Udell).

1499-2671/© 2019 Canadian Diabetes Association.

The Canadian Diabetes Association is the registered owner of the name Diabetes Canada.

<https://doi.org/10.1016/j.cjcd.2019.08.019>

Conclusions: A home-based diabetes prevention program customized for postpartum women with GDM can be feasibly delivered by CDEs, and it is associated with >70% retention, adherence and satisfaction.

© 2019 Canadian Diabetes Association.

Mots clés:
comportement
accompagnement
prévention du diabète
diabète gestationnel
intervention sur les habitudes de vie

R É S U M É

Objectif : L'objectif dans notre étude était d'évaluer la faisabilité d'un programme de prévention du diabète réalisé à domicile, offert par des éducateurs interdisciplinaires agréés en diabète (EAD), et adapté aux femmes durant la période post-partum ayant récemment souffert de diabète sucré gestationnel (DSG).

Méthodes : Cet essai pilote randomisé a recruté dans 4 centres des femmes enceintes de 24 à 40 semaines atteintes de DSG et a formé 10 EAD à l'accompagnement comportemental, à l'activité physique (AP) et à la sensibilisation au faible indice glycémique. Les femmes ont été réparties aléatoirement 3 mois après l'accouchement pour suivre des soins standards (1 visite) ou suivre 1 de ces 3 interventions d'accompagnement de 24 semaines (1 visite et 12 appels téléphoniques) : i) AP et alimentation, ii) AP seulement ou iii) alimentation seulement. Les résultats de cette étude de faisabilité comprenaient l'évaluation du recrutement, du maintien dans le programme, de l'adhésion et du niveau de satisfaction.

Résultats : Des 1 342 patientes admissibles, 392 ont été activement sollicitées (29.3%) et 227 (16.9%) ont donné leur consentement. De ce nombre, 149 (65.6%) étaient des femmes en période post-partum sélectionnées aléatoirement, dont 131 (87.9%) ont commencé le programme et 105 (70.5%) ont participé à l'évaluation finale. Les participantes du groupe d'intervention ont répondu en moyenne à 75% des appels téléphoniques (écart interquartile, de 50% à 92%). La durée moyenne de la visite et de l'appel était respectivement de 71.4 minutes (écart-type, 13.8) et 18.1 minutes (écart-type, 6.5). Les participantes se sont dites extrêmement satisfaites/très satisfaites 73% du temps, et 87% recommanderaient le programme à d'autres personnes.

Conclusions : Un programme personnalisé de prévention du diabète à domicile pour les femmes post-partum atteintes de DSG peut facilement être proposé par les EAD, sachant qu'il est associé à un taux de rétention, d'adhésion et de satisfaction >70%.

© 2019 Canadian Diabetes Association.

Introduction

Gestational diabetes mellitus (GDM) affects approximately 6% of Canadian women (1,2). Although GDM is characterized as a transient condition, which resolves after the infant is born, women who have been diagnosed with GDM have a 7-fold higher risk of type 2 diabetes mellitus (T2DM) after pregnancy (3–6). Behaviour modification, including nutrition and physical activity (PA) education, has been proven to reduce diabetes diagnosis by up to 58% in high-risk groups (7,8), including in women with a remote history of GDM (9). The Diabetes Canada Clinical Practice Guidelines recommend that all women with GDM receive counselling and support for risk-reduction-oriented behaviour (2).

As 20% of women with GDM are diagnosed with T2DM by 10 years of delivery (4), early intervention with a suitable T2DM prevention program is essential to improve health outcomes. However, this population may be difficult to engage in postpartum education due to transitions in care and competing demands of motherhood. To date, behaviour-based clinical trials in women with recent GDM have yielded mixed results and most were limited by low participation and insufficient ability to show meaningful behaviour change (10–12). New mothers report many barriers to healthy behaviours, including fatigue, time and childcare (13,14), making them vulnerable to unhealthy habits and weight gain during the postpartum period (15). Thus, although behaviour interventions are effective at reducing T2DM in other populations, novel approaches are needed in women with recent GDM to accommodate their unique circumstances and maximize participation.

In that context, we sought to create an intervention that integrates evidence-based customized nutrition and PA education with proven behaviour change techniques, while optimizing feasibility and accessibility for new mothers. The Avoiding

Diabetes After Pregnancy Trial in Moms (ADAPT-M) is a 6-month T2DM prevention program specifically designed for women with recent GDM that embodies principles of women's health, including accessibility, empowerment and collaborative planning (16), and applies coaching strategies to optimize behaviour change (17). The ADAPT-M program was modelled after the Women's Cardiovascular Health Initiative (WCHI) at Women's College Hospital, a 6-month cardiac rehabilitation and primary prevention program for high-risk women (16,18), and informed by Diabetes Canada Clinical Practice Guidelines (2,19), the Stanford Patient Education Research Centre Self-management Program (18) and Health Coaching Australia (20). The program was developed collaboratively with input from patients and a range of educators, health-care providers, scientists and other stakeholders.

ADAPT-M uses a home-based approach with telephone-based sessions to enhance flexibility and convenience, and to support women in their efforts to make sustainable health behaviour changes within their home or community. Regular scheduled phone calls with an assigned coach are used to promote behaviour change using Motivational Interviewing (MI) (21), goal-setting and action planning (22). As an initial step, we conducted an earlier study of the WCHI cardiac rehabilitation program in 18 postpartum patients with recent GDM. Women were coached via telephone to meet a minimum 150 minutes per week of moderate aerobic activity through resources within their home or community. We found that 79% were adherent to coaching sessions and 71% achieved the recommended physical activity goal by 6 months. The program was also associated with high satisfaction and significantly improved exercise capacity (23).

Several adaptations were made to the WCHI cardiac rehabilitation program to enhance its applicability to postpartum women with recent GDM. First, the physical activity education incorporates exercises and resources for new mothers (postnatal activities,

stroller walking, mom with baby exercises, etc) and modified abdominal exercises to accommodate postpartum changes. Second, we added nutrition education. To enable expansion and sustainability of program delivery, existing resources within community diabetes education programs (DEPs) were leveraged. Certified diabetes educators (CDEs) within community DEPs were trained to deliver the program as ADAPT-M coaches. The objective of this pilot phase of a larger randomized, controlled trial (RCT) was to evaluate the feasibility of the ADAPT-M program to recruit and retain women with GDM and to be delivered by trained CDEs within existing community DEPs. Furthermore, as we found high adherence and satisfaction in our preliminary cardiac rehabilitation study that focused on physical activity, we were interested in further testing the feasibility of interventions focused on PA only compared to those combined with nutrition education or those focused only on nutrition.

Methods

Study design

This 2×2 factorial prospective, randomized, open-label, pilot study grouped participants into 1 of 4 study arms: 1) coaching with PA education, either by a i) registered kinesiologist or ii) CDE; 2) coaching with low glycemic index (GI) education by a CDE; 3) coaching with combined PA and low-GI diet education by a CDE; and 4) diabetes prevention counselling by a CDE (standard care) (24). Women in the PA arm were randomized to receive PA coaching from a kinesiologist or CDE, to determine whether coaching by a trained CDE nurse or dietitian is as effective for PA behaviour change compared with delivery by a kinesiologist.

Study population

The study population included postpartum women with a recent history of GDM recruited from 4 hospital sites in Toronto. Patients' inclusion criteria were age ≥18 years, ability to speak and understand English, a GDM diagnosis during the most recent pregnancy according to the Diabetes Canada diagnostic criteria (a 1-hour plasma glucose [PG] ≥11.1 mmol/L after a 50-g glucose challenge test, or a fasting PG of ≥5.3 mmol/L, a 1-hour PG of ≥10.6 mmol/L and/or a 2-hour PG of ≥9.0 mmol/L after a 75-g oral glucose tolerance test after 24 weeks gestation) (2) and willingness to provide informed consent and comply with the study protocol. The exclusion criteria were T1DM or T2DM diagnosis prior to pregnancy, any obstetrical/perinatal complications or major illnesses that may interfere with participation, simultaneous participation in clinical drug trials, history of cardiovascular disease or electrocardiogram abnormalities, new pregnancy during the study period, any illnesses affecting carbohydrate digestion or metabolism, treatment with antihyperglycemic medication postpartum and any other factors that may limit participant adherence in the opinion of the principal investigator.

ADAPT-M training

A total of 10 CDEs (8 registered dietitians and 2 registered nurses) and 1 registered kinesiologist were trained as coaches to deliver the ADAPT-M program. Coaches attended 2 half-day sessions that covered behaviour change strategies, home-based telephone coaching, PA and low-GI education. All coaches in this study had received training in MI. For ADAPT-M, they attended a workshop with a certified MI trainer and a standardized patient to practice MI and other behaviour coaching strategies. Workshops also addressed issues specific to postpartum women, such as sleep, breastfeeding, pelvic floor health and diastasis rectus abdominis, which can be a common barrier to exercise in postpartum women;

that is, some abdominal core and resistance training exercises should be avoided as this may worsen the condition, and diastasis rectus abdominis may be corrected via referral to community physiotherapy (25). Coaches were trained with novel education tools on low-GI nutrition counselling and received ongoing support from a registered dietitian. As evidence indicates low self-efficacy among CDEs in providing exercise counselling (26), CDEs received training and ongoing support for PA from a registered kinesiologist. All coaches received a detailed ADAPT-M coach training manual.

Trial procedures

Recruitment: Eligible women were invited to participate and provided informed consent during pregnancy. We used active and passive recruitment strategies. Active recruitment involved clinic staff identifying potential participants at weekly "Diabetes in Pregnancy" clinics at 4 Toronto hospitals, who were then invited by a research assistant to participate in the trial and provide informed consent. Passive recruitment strategies included presentations by study staff at weekly group GDM classes, and study brochures were given to all GDM patients. Women were considered passively recruited if they contacted us via e-mail or telephone during pregnancy or within the first 12 weeks postpartum and were consented to participate in the study.

Randomization and study procedures: After a run-in period until 4 to 6 weeks after delivery, consented participants were contacted for rescreening and were invited to attend a baseline assessment within 12 to 24 weeks postpartum. They were randomized using a web-based automated randomization system in a 2:1:1:1 allocation to 1 of 3 intervention arms (coaching with PA education only [CDE or kinesiologist], with low-GI education only [CDE] or with combined PA and low-GI diet education [CDE]) or were given standard care. The baseline assessment included an interviewer-administered survey for demographic and clinical history and the Edinburgh Postpartum Depression Scale to screen for depression (27), physical measures (blood pressure, weight, height, waist circumference, percent body fat using a handheld body fat analyzer), a venous fasting oral glucose tolerance test (OGTT) and glycated hemoglobin to test for dysglycemia (T2DM or prediabetes) (2) and a graded exercise treadmill test using the standard Bruce protocol to test for fitness (estimated peak oxygen consumption in metabolic equivalents [METs]).

Intervention period: During the 24-week intervention period, all participants attended 1 in-person education visit with their ADAPT-M coach (week 1). Women randomized to an intervention arm then received 12 scheduled telephone sessions to cover arm-specific educational topics and coaching. The telephone sessions occurred weekly on weeks 2 through 8, then on a tapering schedule on weeks 10, 12, 16, 20 and 24. Women randomized to standard care received education and a handout regarding post-GDM guidelines (2), but did not receive coaching or telephone follow up. After completion of the intervention period, participants attended a final health assessment to assess effectiveness of the program, which will be evaluated and reported separately as part of a larger effectiveness trial. All participants completed regular diet and PA records and questionnaires to evaluate behavioural outcomes at baseline, 12 weeks and final assessment. Strategies to optimize retention of participants included child-minding services during study visits; flexible scheduling of coaching calls; a gift card after study completion; and a midstudy phone call by study staff to complete diet and physical activity questionnaires, review their study progress and satisfaction and schedule their final assessment.

ADAPT-M education

PA education: Currently, there are no specific exercise guidelines for postpartum women with recent GDM. The 2018 Diabetes Canada Guidelines continue to promote an “over-the-counter” prescription using the Canadian Physical Activity Guidelines (28), and the Society of Gynecologists of Canada also promotes PA during pregnancy and in the postpartum period (25). Participants were given PA education based on Canadian guidelines to reach a minimum of 150 minutes of moderate aerobic activity (or 75 minutes of vigorous aerobic activity) and 2 days of strength training per week (28), incorporating the FITT principle (frequency, intensity, time, type) (29), and goals were customized for their preferences, resources and baseline fitness. Women were provided with exercise instructional photos using body weight and/or resistance bands focused on exercises for major muscle groups (29), and also included modified exercises while holding their baby.

Low-GI diet education: Although standard low-calorie diets have been associated with prevention of T2DM, evidence suggests that a low-GI dietary pattern may be more effective for glycemic control and is associated with greater dietary adherence and increased feelings of self-efficacy in T2DM (30,31). For persons without diabetes, low-GI diets are associated with better insulin sensitivity, beta-cell function and weight loss than conventional diets (32,33), including in postpartum women with recent GDM (34). A low-GI diet approach may also be easier to adopt and sustain than a low-calorie diet for postpartum women who are breastfeeding, due to their higher caloric needs. Novel evidence-based low-GI education tools and materials developed by members of our team (31,35) were adapted for study participants. Participants in the study were counselled to layer low-GI education on top of general nutrition recommendations, which includes recommendations for Canadians on healthy eating using Canada’s Food Guide (36), Diabetes Canada Clinical Practice Guidelines (2,19) and the Plate Method (37). Participants were advised to substitute at least one high-GI food with a low-GI food option at each meal and snack, and food choices were customized to their preferences, dietary restrictions and resources. Other weekly topics included heart-healthy eating, healthy protein sources, healthy snack ideas, eating for pre- and postexercise and fibre intake.

Feasibility outcomes

For the pilot phase of this randomized, controlled trial, we identified feasibility outcomes of the intervention based on the first 3 components of the PIPE (penetration, implementation, participation, effectiveness) framework to evaluate effectiveness of health improvement programs (38). Feasibility outcomes include recruitment (penetration [invited/target population] and participation [enrolled/invited]), retention (completed/enrolled), program implementation metrics, program adherence and program satisfaction. Program implementation and adherence data were abstracted from coach logs and participant charts (program duration, length of visits and telephone sessions, number of sessions completed). Program satisfaction was also evaluated based on surveys administered to participants at study end, including questions regarding their overall satisfaction and the most and least liked components of the intervention.

Statistical analysis

Implementation data and baseline characteristics of participants are summarized using descriptive statistics. Categorical variables are reported as frequency and percent, whereas continuous variables are reported as mean and standard deviation (SD) or median

and interquartile range (IQR) for non-normally distributed variables. Recruitment and retention rates were calculated as a proportion of eligible patients recruited, proportion of recruited participants randomized, proportion of participants who completed the trial and mean \pm SD monthly recruitment rate (overall and per site). The proportion of calls completed (out of 12) was calculated for each active arm participant and summarized with descriptive statistics, and adherence was defined as completing at $\geq 80\%$ (10 of 12) of session calls. Multiple imputation was used to adjust for missing visit and call duration data.

Research ethics

The study was approved by the research ethics board of Women’s College Hospital and the institutional board at each study site.

Results

Trial recruitment and retention

Trial recruitment and retention data are presented in [Figure 1](#). We identified 1,342 pregnant women who met eligibility criteria at the 4 Toronto sites during the 26-month recruitment period. Of these women, 396 (penetration 29.5%) were actively invited for recruitment by study staff during GDM clinic visits. The remainder were invited via passive recruitment involving ADAPT-M presentations during GDM education classes and distribution of study brochures. Of the women actively invited, 169 (participation 42.6%) were enrolled and provided informed consent; 58 (participation 4.3%) were enrolled through passive recruitment. A total of 227 (16.9%) were recruited from the eligible population at a mean \pm SD recruitment rate of 8.7 ± 6.9 women (2.37 ± 1.67 per site) per month. Of the women recruited during pregnancy, we were unable to contact 32 (14.1%) of them for postpartum rescreening, 46 (20.3%) were excluded or no longer interested and 149 (65.6%) were randomized. Reasons for exclusion were T2DM diagnosis before the rescreen, abnormalities on cardiac stress testing, health issues preventing physical activity and dietary changes and a new pregnancy. After being randomized, 131 (87.9%) participants attended their first ADAPT-M program visit (106 active arm participants, 25 standard care) and 105 (70.5%) participants were retained until the final study visit. The most common reasons for dropout were loss to follow up or competing demands (e.g. childcare, return to work).

Baseline data of randomized participants

Baseline characteristics of participants are presented in [Table 1](#); data are not presented by study arm due to the small numbers. There were 149 women who completed a baseline assessment at 16.5 ± 4.3 weeks postpartum. They were 36.7 ± 4.6 years of age, 70.5% were non-Caucasian, 20.1% had a prior history of GDM, 79.2% were breastfeeding, 22.1% screened positive for postpartum depression based on an Edinburgh Postnatal Depression Scale score > 10 (27) and 40.3% had dysglycemia (2.0% T2DM). Participants had a mean body mass index (BMI) of 29.7 ± 6.8 kg/m², waist circumference of 90.6 ± 12.4 cm and METs of 9.7 ± 1.9 mL/kg/min, representing an average fitness of 98% predicted exercise capacity for mean age and sex (39).

Program implementation and participation

The program duration for all participants was 29.7 ± 7.3 weeks. For the 106 active arm participants who attended the first program visit, the mean duration of the first visit was 71.4 ± 13.8 minutes and the telephone sessions each lasted a mean of 18.1 ± 6.5 minutes

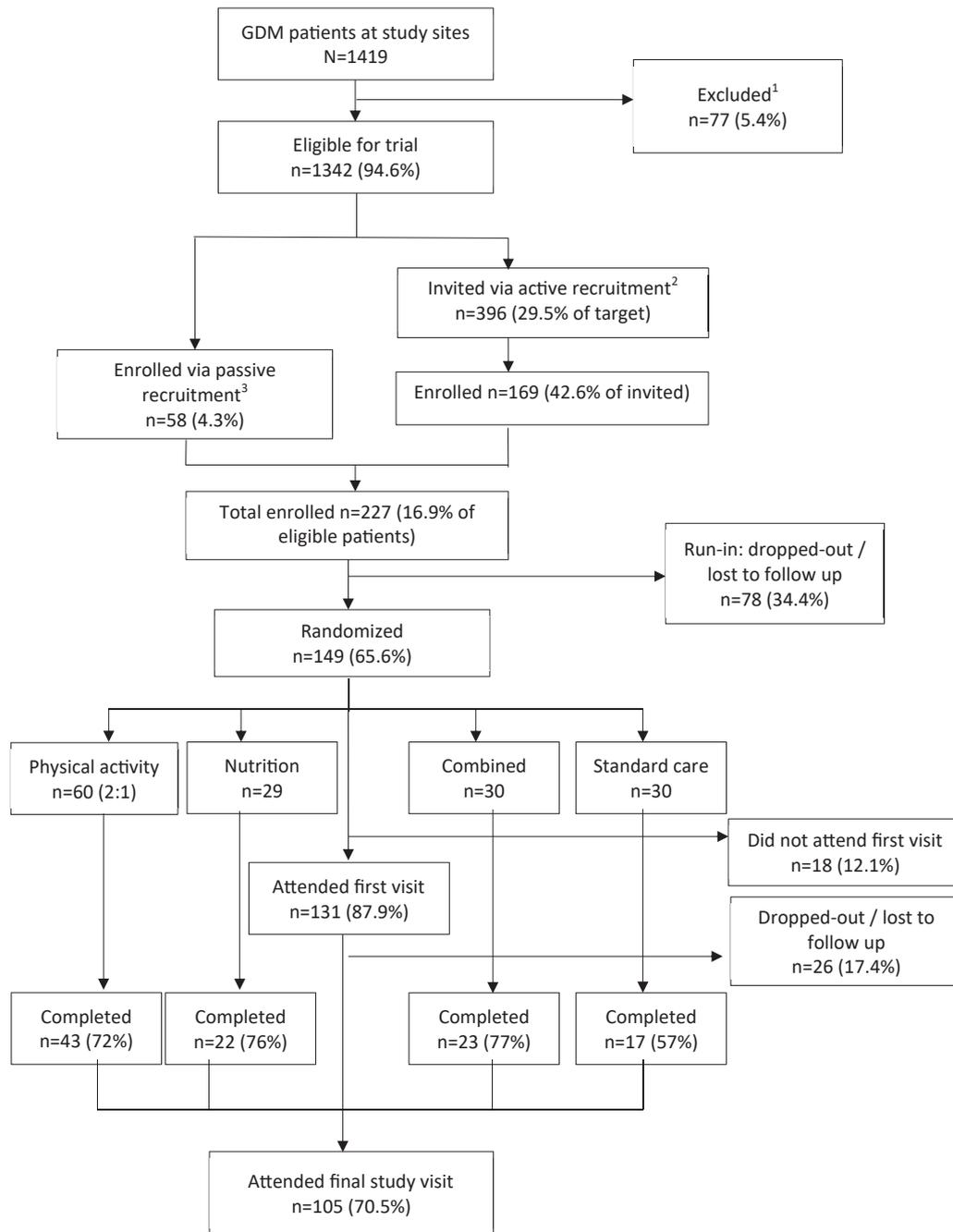


Figure 1. Consort diagram. Trial recruitment and retention data: ¹Pregestational diabetes, non-English speaking; ²researcher invited patients in GDM clinic; and ³patients contacted research team. *GDM*, gestational diabetes mellitus.

(median, 17.6; IQR, 13.8 to 20.6). Participants completed a mean 8.1±3.5 or 67±30% of the 12 telephone sessions (median, 75%; IQR, 50% to 92%). There were 50 (47.2%) participants who adhered to at least 80% of the scheduled sessions. Table 2 shows these data by study arm; results were similar for the PA program delivered by CDEs vs a kinesiologist (data not shown).

Intervention program satisfaction

Among active intervention participants who completed the final assessment (N=88), 73% reported satisfaction with the program as excellent/very good, 22% as good and 5% as fair/poor. Of these, 97% reported that they would definitely (87%) or maybe (10%) recommend the program to others. The most commonly cited components that were most liked by participants were the knowledge/

resources (39%) and working with a coach (29%); the least liked components were completing diet and physical activity records (27%) and blood tests (10%).

Discussion

This pilot study demonstrated that a 6-month T2DM prevention program customized for postpartum women with recent GDM and delivered by trained community CDEs, proved feasible with high participation and retention. Although penetration of the target population was modest at 17%, we successfully recruited almost half of the eligible women who were actively invited, and >70% of those randomized were retained in the study. Postpartum women assigned to an intervention arm were able to complete a mean two-thirds of the planned telephone sessions, and almost half

Table 1
Baseline characteristics of the 149 randomized trial participants

	Mean (SD) [*] or N (%)
Demographic and clinical characteristics	
Gestational age at delivery (weeks)	38.3 (2.0)
Parity >1	81 (54.36%)
Time of study enrolment (weeks postpartum), median (IQR)	15.6 (13.7–17.7)
Age at study enrolment (years)	36.7 (4.6)
Non-Caucasian ethnicity	105 (70.5%)
South Asian	35 (23.5%)
East/Southeast Asian	27 (18.1%)
African/Caribbean	15 (10.1%)
Filipino	7 (4.7%)
Middle Eastern	6 (4.0%)
Other [†]	15 (10.1%)
Household income >CAN\$60,000	94 (63.1%)
University education	116 (77.9%)
Family history of type 2 diabetes	82 (55.0%)
Personal history of GDM	30 (20.1%)
Breastfeeding	118 (79.2%)
Postpartum depression (EPDS >10 points)	33 (22.1%)
Physical and metabolic measures	
Body mass index (kg/m ²)	29.7 (6.8)
Waist circumference (cm)	90.6 (12.4)
Body fat (%)	36.2 (5.6)
Systolic blood pressure (mmHg)	108.7 (12.1)
Fasting BG (mmol/L)	5.0 (1.0)
OGTT 2-hour BG (mmol/L)	7.1 (2.6)
A1C (%)	0.054 (0.006)
Dysglycemia (diabetes or prediabetes)	60 (40.3%)
METs (mL/kg/min)	9.7 (1.9)
Age-predicted fitness (%)	98 (19.2)

A1C, glycated hemoglobin; BG, blood glucose; EPDS, Edinburgh Postpartum Depression Scale; GDM, gestational diabetes mellitus; IQR, interquartile range; MET, metabolic equivalent; OGTT, oral glucose tolerance test; SD, standard deviation.

^{*} Unless stated otherwise.

[†] Hispanic, Aboriginal, Pacific Islander or mixed race.

completed $\geq 80\%$ of the sessions. Over 90% of participants rated satisfaction with the program as good to excellent and would recommend it to others. These findings suggest that this telephone-based T2DM prevention program can successfully engage women with recent GDM during a demanding life period, and can be feasibly delivered within usual care.

Lifestyle modification programs have been associated with T2DM prevention in high-risk groups (7,8), including in the subgroup of women with a prior history of GDM in the Diabetes Prevention Program (DPP) trial (9). It is unclear whether these results can be applied to postpartum women with recent GDM, as women in the DPP were older, already had impaired glucose tolerance and were an average 12 years since their GDM pregnancy. A meta-analysis of 15 lifestyle intervention trials in women with recent GDM showed more limited effectiveness, with a modest 1.07-kg weight difference and no significant decrease in T2DM (11). Insufficient participation and retention of patients and low adherence to behavioural goals were cited as key barriers to effectiveness (10,11). For instance, the Mothers After Gestational Diabetes in Australia (MADGA) trial randomized over 500 Australian women at a mean 8 months since their GDM pregnancy to a group-based behaviour program or usual care (40). Although they found a small significant effect on weight loss, they noted poor adherence to sessions and behaviour goals despite a retention rate of >70% (40). The GEM trial embedded a DPP intervention within usual care and used telephone coaching, and showed higher adherence rates than the MAGDA trial and significant changes in weight and physical activity after 12 months (41). We have shown that our low-intensity telephone-based program is associated with comparable retention and adherence rates in postpartum women with recent GDM as the

GEM trial. We note that adherence to telephone sessions was greater in our study than in the MAGDA trial, which may be due to their higher number of in-person visits (40). Our findings suggest that virtual or telephone-based sessions may be more accessible for busy new mothers, with the potential to target a wider range of patients. Although the translation of these results into effective behaviour change remains to be confirmed, evidence indicates that adherence to diabetes prevention programs is highly correlated with effectiveness in reducing diabetes (42).

Women with recent GDM may be more difficult to reach and enroll in diabetes prevention studies than other populations, due to more competing priorities and changing life circumstances. This may limit the generalizability of research findings, as women who participate may be more motivated and have fewer barriers than the target population. Although we had a high proportion of non-Caucasian women, most of our participants reported a university education and a household income >CAN\$60,000. A recent review noted that penetration and participation in postpartum diabetes prevention programs is highest when women are invited during pregnancy, ideally within GDM care settings (43). Consistent with those findings, we showed that 43% of those invited to participate during a GDM clinic visit were successfully enrolled in our trial. In contrast, only 4% of those who attended a study presentation and received a study brochure were enrolled. Despite good participation rates, we were only able to approach and invite 30% of our eligible patients. This was primarily due to challenges in connecting with women during busy clinic visits and competing studies. Greater accessibility of resources and better integration of research within prenatal and postpartum GDM care may improve engagement, particularly for women of lower socioeconomic status and health literacy. Involvement of spouses and other family members in behavioural interventions may also promote recruitment and retention in diabetes prevention programs (44,45).

Lifestyle programs can be costly and resource intense within current Canadian health-care models, which can pose barriers to implementation and sustainability. As the incidence of women with GDM continues to rise (3), more efficient resources will be needed to meet the growing demand for T2DM prevention services. We have shown “real-world” feasibility of the ADAPT-M program, by leveraging existing diabetes education resources and capitalizing on the skill set and practice scope of CDEs with training by experts in MI, low GI and exercise. Our home-based telephone approach is also associated with a low intervention burden for health systems and patients. Home-based cardiac rehabilitation programs have been shown to be as effective (46) and less costly than centre-based programs and are associated with greater adherence and long-term benefits (47). In our study, telephone sessions were <20 minutes each and were easily incorporated into existing schedules. In addition to providing customized evidence-based lifestyle education and behaviour change strategies, our program can feasibly be integrated within the health-care system to optimize its scalability, efficiency and generalizability across diverse settings.

This study has several strengths. First, participants in our study were from diverse ethnic backgrounds, with 70.5% reported as non-Caucasian. This demonstrates our ability to engage a wide range of minority groups, many of whom are at elevated risk of T2DM (5), and enhances the applicability of our findings to the multicultural Canadian population. Second, we were able to reach a large proportion of the target population through access to dedicated prenatal GDM classes and clinics. Finally, the pilot and feasibility phase has provided an opportunity to optimize the intervention and protocol prior to the full-scale effectiveness trial. There are, however, limitations that merit mention. First, our intervention consisted of 12 sessions over 6 months, which is suggested as the minimum exposure for behaviour change (48). Although adherence and retention were comparable to other more intensive programs

Table 2

ADAPT-M program implementation data for the active arm participants who attended the first program visit (N=106)

	Nutrition (N=25)		Physical activity (N=53)		Combined nutrition and physical activity (N=28)	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Adherence to telephone coaching sessions						
Sessions completed (of 12) (N)	8.2 (3.4)	10 (7–11)	9.2 (2.9)	10 (8–11)	6.0 (3.8)	6 (3–10)
>80% adherence [*] , N (%)	13 (52.0%)	—	29 (54.7%)	—	8 (28.6%)	—
Duration of trial and program components						
Program duration (weeks) [†]	29.2 (6.3)	27.0 (25.3–30.1)	29.3 (5.7)	27.9 (25.6–32.6)	31.1 (10.3)	28.1 (26.0–32.2)
Duration of first coaching visit (minutes)	77.8 (14.2)	71.4 (71–85)	70.6 (12.5)	71.4 (60–72)	73.2 (11.6)	71.4 (71–75)
Duration of telephone sessions (minutes)	18.3 (7.3)	18.2 (11.8–22.9)	16.7 (5.2)	16.6 (14.2–19.4)	20.6 (7.5)	20.6 (15.4–22.4)

ADAPT-M, Avoiding Diabetes After Pregnancy Trial in Moms; IQR, interquartile range; SD, standard deviation.

^{*} Number of participants who completed ≥ 10 (>80%) telephone sessions.[†] Time from first coaching visit to final health assessment.

(41,42), longer duration and more frequent sessions may be required to achieve optimal effectiveness. Second, evidence indicates combined diet and PA programs are more effective than individual components (49), yet adherence was substantially lower for the combined group in our study. The combined intervention was initially designed to target one diet and PA goal for each session, which may have been too overwhelming and less manageable for some women during this demanding period. To mitigate this, we have adapted the combined program to allow for one goal at a time in our ongoing effectiveness phase. Third, only 57% of standard care participants returned for their final visit compared with >70% of active arm participants. To address this imbalance, we now offer the WCHI primary prevention program to standard-care participants upon completion of the study to increase motivation for follow up. Finally, although consistent with other studies, penetration of the target population and postpartum retention remained suboptimal for scientific validity and the study participants may not be fully representative of the target population. Recruitment of women at a later stage as in the DPP trial, when baseline risk is higher and parental challenges are lower, may also be more effective at promoting behaviour change (9). However, access to the target population may be more difficult (43), and it may be too late to intervene for the 20% of women who progress to T2DM within the first decade after delivery. Indeed, lifestyle interventions offered in the first year after delivery may be more effective at reducing T2DM risk in women with GDM than those offered later (11). A strategy to identify and prioritize those women with GDM at highest risk of early T2DM for postpartum interventions may maximize engagement and effectiveness of T2DM prevention programs.

In conclusion, we have demonstrated that a home-based T2DM prevention program customized for postpartum women with recent GDM can be feasibly integrated within community diabetes education programs and is associated with high patient engagement and satisfaction. These findings support a larger trial to evaluate the effectiveness of this intervention to reduce T2DM risk factors in this population and their families.

Acknowledgments

The authors thank Susan Jackson, Christina Yu, Sarah McTavish, Lauren McNicol, Peter Anderson, Leigh Caplan, Amina Chaudary, Anuisa Ranjan, Wei Wu and participating coaches for their assistance with coach training, program development, trial management, patient recruitment, patient assessment, data collection, entry and analysis, manuscript preparation and provision of the coaching program. Funding for this study was provided by a Lawson Foundation research grant and an operating grant from Diabetes Canada. The funders had no role in data collection and analysis or

writing of the report. L.L. holds a Diabetes Investigator Award from Diabetes Canada.

Author Disclosures

Conflicts of interest: None

Author Contributions

L.L. codesigned the intervention, designed the study, provided funding and oversight, contributed to data interpretation and cowrote the manuscript. F.D.R. codesigned the intervention, provided coaching, collected data and cowrote the manuscript. A.G. codesigned the intervention, contributed to study design, participant recruitment and data collection and edited the manuscript. S.d.S. contributed to study design, participant recruitment and data collection, and edited the manuscript. X.L. contributed to data collection and analysis and edited the manuscript. K.T. codesigned the study, designed the analytical plan and edited the manuscript. J.P. codesigned the intervention, contributed to participant assessments and data collection and edited the manuscript.

References

- Feig DS, Hwee J, Shah BR, Booth GL, Bierman AS, Lipscombe LL. Trends in incidence of diabetes in pregnancy and serious perinatal outcomes: A large, population-based study in Ontario, Canada, 1996–2010. *Diabetes Care* 2014;37:1590–6.
- Diabetes Canada Clinical Practice Guidelines Expert Committee, Feig DS, Berger H, Donovan L, et al. Diabetes and pregnancy. *Can J Diabetes* 2018; 42(Suppl. 1):S255–82.
- 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.
- Feig DS, Zinman B, Wang X, Hux JE. Risk of development of diabetes mellitus after diagnosis of gestational diabetes. *CMAJ* 2008;179:229–34.
- Mukerji G, Chiu M, Shah BR. Impact of gestational diabetes on the risk of diabetes following pregnancy among Chinese and South Asian women. *Diabetologia* 2012;55:2148–53.
- Xiang AH, Li BH, Black MH, et al. Racial and ethnic disparities in diabetes risk after gestational diabetes mellitus. *Diabetologia* 2011;54:3016–21.
- Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002; 346:393–403.
- Tuomilehto J, Lindstrom J, Eriksson JG, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med* 2001;344:1343–50.
- Ratner RE, Christophi CA, Metzger BE, et al. Prevention of diabetes in women with a history of gestational diabetes: Effects of metformin and lifestyle interventions. *J Clin Endocrinol Metab* 2008;93:4774–9.
- Gilinsky A, Kirk A, Hughes A, Lindsay R. Lifestyle interventions for type 2 diabetes prevention in women with prior gestational diabetes: A systematic review and meta-analysis of behavioural, anthropometric and metabolic outcomes. *Prev Med Rep* 2015;2:448–61.
- Goveia P, Canon-Montanez W, Santos DP, et al. Lifestyle intervention for the prevention of diabetes in women with previous gestational diabetes mellitus: A systematic review and meta-analysis. *Front Endocrinol (Lausanne)* 2018;9:583.

12. Pedersen ALW, Terkildsen Maindal H, Juul L. How to prevent type 2 diabetes in women with previous gestational diabetes? A systematic review of behavioural interventions. *Prim Care Diabetes* 2017;11:403–13.
13. Smith BJ, Cheung NW, Bauman AE, Zehle K, McLean M. Postpartum physical activity and related psychosocial factors among women with recent gestational diabetes mellitus. *Diabetes Care* 2005;28:2650–4.
14. Graco M, Garrard J, Jasper AE. Participation in physical activity: Perceptions of women with a previous history of gestational diabetes mellitus. *Health Promot J Austr* 2009;20:20–5.
15. Williamson DF, Madans J, Pamuk E, Flegal KM, Kendrick JS, Serdula MK. A prospective study of childbearing and 10-year weight gain in US white women 25 to 45 years of age. *Int J Obes Rel Metab Disord* 1994;18:561–9.
16. Price J, Landry M, Rolfe D, Delos-Reyes F, Groff L, Sternberg L. Women's cardiac rehabilitation: Improving access using principles of women's health. *Can J Cardiovasc Nurs* 2005;15:32–41.
17. Huffman M. Health coaching: A new and exciting technique to enhance patient self-management and improve outcomes. *Home Healthc Nurse* 2007;25:271–4; quiz 5–6.
18. Stanford School of Medicine. Chronic disease self-management program 2014, <http://patienteducation.stanford.edu/programs/cdsmtp.html>. Accessed December 11, 2019.
19. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee, Thompson D, Berger H, Feig D, et al. Diabetes and pregnancy. *Can J Diabetes* 2013;37(Suppl. 1):S168–83.
20. Gale J, Linder H. Health coaching model for CCPSM. https://cscs.qld.edu.au/sdc/Provectus/Diabetic_Foot/Patient%20self-management%20education%20theory/files/HCA_Model_Self_Management_June_2007.pdf. Accessed March 1, 2019.
21. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. *Am J Health Promot* 1997;12:38–48.
22. Sutton K, Logue E, Jarjoura D, Baughman K, Smucker W, Capers C. Assessing dietary and exercise stage of change to optimize weight loss interventions. *Obes Res* 2003;11:641–52.
23. Mukerji G, McTavish S, Glenn A, et al. An innovative home-based cardiovascular lifestyle prevention program for women with recent gestational diabetes: A pilot feasibility study. *Can J Diabetes* 2015;39:445–50.
24. ClinicalTrials.gov. Avoiding Diabetes After Pregnancy Trial in Moms (ADAPT-M). National Library of Medicine. 2016. Updated March 21, 2019. <https://clinicaltrials.gov/ct2/show/NCT01918345>. Accessed February 27, 2019.
25. Mottola MF, Davenport MH, Ruchat SM, et al. 2019 Canadian guideline for physical activity throughout pregnancy. *Br J Sports Med* 2018;52:1339–46.
26. Shields CA, Fowles JR, Dunbar P, Barron B, McQuaid S, Dillman CJ. Increasing diabetes educators' confidence in physical activity and exercise counselling: The effectiveness of the "physical activity and exercise toolkit" training intervention. *Can J Diabetes* 2013;37:381–7.
27. Vincenti GE. Edinburgh Postnatal Depression Scale. *Br J Psychiatry* 1987;151:865.
28. Canadian physical activity guidelines. http://csep.ca/CMFiles/Guidelines/CSEP_PAGuidelines_0-0-65plus_en.pdf. Accessed February 11, 2019.
29. American College of Sports Medicine. In: Franklin BA, editor. ACSM's Guidelines for Exercise Testing and Prescription. 6th edn. Philadelphia: Lippincott, Williams & Wilkins, 2000.
30. Brand-Miller J, Hayne S, Petocz P, Colagiuri S. Low-glycemic index diets in the management of diabetes: A meta-analysis of randomized controlled trials. *Diabetes Care* 2003;26:2261–7.
31. Grant SM, Wolever TM, O'Connor DL, Nisenbaum R, Josse RG. Effect of a low glycaemic index diet on blood glucose in women with gestational hyperglycaemia. *Diabetes Res Clin Pract* 2011;91:15–22.
32. Larsen TM, Dalskov SM, van Baak M, et al. Diets with high or low protein content and glycemic index for weight-loss maintenance. *N Engl J Med* 2010;363:2102–13.
33. Juanola-Falgarona M, Salas-Salvado J, Ibarrola-Jurado N, et al. Effect of the glycemic index of the diet on weight loss, modulation of satiety, inflammation, and other metabolic risk factors: a randomized controlled trial. *Am J Clin Nutr* 2014;100:27–35.
34. Shyam S, Arshad F, Abdul Ghani R, et al. Low glycaemic index diets improve glucose tolerance and body weight in women with previous history of gestational diabetes: A six months randomized trial. *Nutr J* 2013;12:68.
35. Wolever TMS. The glycaemic index: A physiological classification of dietary carbohydrate 2006.
36. Government of Canada. Canada's food guide 2019. <http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/index-eng.php>. Accessed February 24, 2019.
37. Diabetes Canada Clinical Practice Guidelines Expert Committee. Diabetes Canada 2018 clinical practice guidelines for the prevention and management of diabetes in Canada. *Can J Diabetes* 2018;42(Suppl. 1):S1–325.
38. Aziz Z, Absetz P, Oldroyd J, Pronk NP, Oldenburg B. A systematic review of real-world diabetes prevention programs: Learnings from the last 15 years. *Implement Sci* 2015;10:172.
39. Gulati M, Black HR, Shaw LJ, et al. The prognostic value of a nomogram for exercise capacity in women. *N Engl J Med* 2005;353:468–75.
40. O'Reilly SL, Dunbar JA, Versace V, et al. Mothers after Gestational Diabetes in Australia (MAGDA): A randomised controlled trial of a postnatal diabetes prevention program. *PLoS Med* 2016;13:e1002092.
41. Ferrara A, Hedderston MM, Brown SD, et al. The comparative effectiveness of diabetes prevention strategies to reduce postpartum weight retention in women with gestational diabetes mellitus: The Gestational Diabetes' Effects on Moms (GEM) Cluster Randomized Controlled Trial. *Diabetes Care* 2016;39:65–74.
42. Aziz Z, Absetz P, Oldroyd J, Pronk NP, Oldenburg B. A systematic review of real-world diabetes prevention programs: Learnings from the last 15 years. *Implement Sci* 2015;10:172.
43. Dasgupta K, Terkildsen Maindal H, Kragelund Nielsen K, O'Reilly S. Achieving penetration and participation in diabetes after pregnancy prevention interventions following gestational diabetes: A health promotion challenge. *Diabet Res Clin Pract* 2018;145:200–13.
44. Kragelund Nielsen K, Groth Grunnet L, Terkildsen Maindal H, et al. Prevention of Type 2 diabetes after gestational diabetes directed at the family context: A narrative review from the Danish Diabetes Academy symposium. *Diabet Med* 2018;35:714–20.
45. Dasgupta K, Da Costa D, Pillay S, et al. Strategies to optimize participation in diabetes prevention programs following gestational diabetes: A focus group study. *PLoS One* 2013;8:e67878.
46. Taylor RS, Dalal H, Jolly K, Moxham T, Zawada A. Home-based versus centre-based cardiac rehabilitation. *Cochrane Database Syst Rev*; 2010:CD007130.
47. Dalal HM, Zawada A, Jolly K, Moxham T, Taylor RS. Home based versus centre based cardiac rehabilitation: Cochrane systematic review and meta-analysis. *BMJ* 2010;340:b5631.
48. Eakin EG, Lawler SP, Vandelanotte C, Owen N. Telephone interventions for physical activity and dietary behavior change: A systematic review. *Am J Prev Med* 2007;32:419–34.
49. Amorim AR, Linne YM, Lourenco PM. Diet or exercise, or both, for weight reduction in women after childbirth. *Cochrane Database Syst Rev*; 2007:CD005627.