Prevention of gestational diabetes

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Running title: Exercise intervention in obese pregnant women

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Objective: To examine the feasibility of an individualized exercise program to prevent gestational diabetes (GDM) in obese pregnant women.

Research Design and Methods: A pilot randomized, controlled trial, with obese pregnant women [Intervention group, individualized exercise program (n = 25); Control group, usual care (n= 25)]. Average weekly energy expenditure (MET-hrs/week & kcal/week) of exercise-specific activity was assessed during pregnancy using the Pregnancy Physical Activity Questionnaire (PPAQ). Fasting glucose and insulin and insulin resistance (HOMA-IR) were assessed at baseline, 20, 28 and 36 weeks gestation.

Results: 16/22 (73%) women in the intervention group achieved more than 900 kcal/week at 28 weeks compared to 8/19 women in the control group (42%), p = 0.047. However, insulin resistance (HOMA-IR) did not differ between the groups.

Conclusion: This intervention was feasible and prompted a modest increase in physical activity. However, we are not confident that this intervention would be sufficient to prevent GDM.

Gestational diabetes mellitus (GDM) is increasing in parallel with overweight and obesity in the obstetric population increasing (1), yet evidence on effective approaches to prevent GDM is lacking. A recent randomized controlled trial (RCT) aimed at modifying nutrition, weight gain, and physical activity in obese pregnant women was not effective in increasing physical activity (2). Based on successful trials in the non-pregnant population (3; 4), we aimed to assess the feasibility of individualized, goal-directed exercise intervention in obese pregnant women. Feasibility issues that we address here include: *implementing* the intervention; the *efficacy* of the intervention and the *acceptability* of the intervention (5).

RESEARCH DESIGN AND METHODS

Obese pregnant women were recruited at 12 weeks gestation and followed to delivery with data collection at 12, 20, 28 and 36 weeks gestation. The intervention group received an individualized exercise program with an energy expenditure (EE) goal of 900 kilocalories (Kcal) per week, whilst the control group received routine obstetric care. The primary outcome EE is expressed in this paper as 1) Weekly Metabolic Equivalent (MET) hours and 2) kCal per week, measured using the Pregnancy Physical Activity Questionnaire (PPAQ) (6). Fasting insulin and glucose were assessed at each time point, and insulin resistance was estimated using the "Homeostasis model" (HOMA-IR) (7). A 2 hour 75 gram oral glucose tolerance test was performed at baseline and 28 weeks. Australian Diabetes in Pregnancy Society criteria were used for the diagnosis and management of gestational diabetes (8). This study was approved by the Royal Brisbane and Women's Hospital (RBWH) Ethics Committee, and registered with the Australian Clinical Trials Registry (ACTRN012606000271505). Further details of the methodology of this study are available in the online appendix at http://care.diabetesjournals.org).

RESULTS

Implementation - During the 7 month recruitment period, 50 obese women were randomised to either the intervention group (n=25) or control group (n=25), representing a recruitment rate of 12% of all eligible women presenting for maternity care at RBWH (Supplemental Figure 1 online). There were no statistically significant differences between intervention and control groups in any baseline variable (Supplemental Table 1 online), although there was a trend towards more frequent early diagnosis of GDM in the intervention group (Table 1). Women in the intervention group were scheduled for 6 face to face visits during the trial and on average attended for 4. Further support was provided by email and telephone.

Efficacy - Exercise duration and intensity varied considerably, with a trend towards weekly energy expenditure (MET-hrs/wk) being greater for women in the intervention group at 28 and 36 weeks gestation (Table 1). In the intervention group, 16/22 (73%) women achieved the pre-defined exercise target of greater than 900kcal/wk at 28 weeks compared to 8/19 (42%) in the control group (42%), $p = 0.047$. The groups did not differ at baseline, 20 or 36 weeks. There was no difference in HOMA-IR between the intervention and control groups (Table 1). At 28 weeks, fasting glucose was lower in the intervention group compared to control (Table 1), and at 36 weeks, insulin was lower in the intervention group.

Acceptability - Feedback was obtained from women in the intervention (n=20) and control groups (n=16). All women in the intervention group provided positive comments (e.g. useful nutritional advice, extra care during

pregnancy). Women reported difficulty incorporating exercise into their daily routine due to pregnancy symptoms, childcare, and work commitments (Supplemental Table 2 online).

CONCLUSIONS

This individualized goal-directed exercise intervention in obese pregnant women met several criteria of feasibility. Recruitment rates were acceptable, implementation was achieved and women found participation in the intervention acceptable.

There was some evidence of efficacy, with increased physical activity in the intervention group at some time points during pregnancy. Women in the intervention group were achieving sufficient activity at 20 weeks to fall within the exercise guidelines for weekly moderate to vigorous intensity activities (9). At 28 weeks, women in the intervention group were significantly more likely to achieve greater than 900kcal/wk of exercise-based activity. However, while the intervention group showed some improvement in fasting glucose at 28 weeks, and fasting insulin at 36 weeks compared to the control group, there was no definitive between group differences in HOMA-IR. The study was not powered to examine GDM prevalence as an outcome.

There are a number of potential explanations as to why there was no difference seen in insulin resistance, despite some improvement in physical activity. The difference in physical activity between the two groups might not have been sufficient to result in differences in insulin resistance. Randomization was not concealed from the women due to the need for informed consent. Women in the control group voluntarily undertook far more physical activity than predicted (or seen in clinical practice), which resulted in smaller differences between groups than expected. This issue needs careful consideration for future studies. Exercise alone might not be sufficient during pregnancy to impact on insulin resistance. It is also possible that HOMA-IR is not the most sensitive way of assessing the impact of exercise on insulin resistance. Although HOMA-IR is regarded as a good measure of overall insulin resistance in pregnancy, it may provide a better reflection of liver rather than peripheral insulin resistance (7), whilst exercise is likely to preferentially reduce peripheral (muscle) insulin resistance.

Given our data, we believe a combined dietary and exercise intervention might have a stronger impact on insulin resistance, and subsequently on the prevention of GDM. This would be supported by a recent study which has shown the success of a dietary intervention in reducing the deterioration in glucose metabolism in obese pregnant women (10).

While pregnancy may represent an ideal opportunity to initiate lifestyle changes (11), most interventions in pregnancy have not been overly successful (12). Barriers to physical activity (i.e. pregnancy symptoms, childcare responsibilities, work commitments) (13) are difficult to address. While this intervention was feasible and prompted a modest increase in physical activity, there is no evidence to suggest that it would be sufficient to prevent GDM.

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Conflict of interest.

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Outcome	**12 weeks**		**20 weeks**		**28 weeks**		**36 weeks**	
	n=25	**n=25**	**n=19**	**n=21**	**n=19**	**n=22**	**n=16**	**n=19**
	Control	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**
MET-h.week								
Median (IQR[1])	6.7(7.5[2])	9.7(10.12)	9.9(22.5)	16.9(22.2)	7.5(14.1)	15.0(11.2)	2.8(9.0)	9.6(11.0)
p value	0.23		0.16		0.067		0.05	
kcal/wk								
>900 kcal/wk n(%)	7(28%)	10(40%)	9(47%)	15(71%)	8(42%)	16(73%)	5(31%)	10(53%)
p value	0.37		0.12		0.047		0.2	
HOMA IR[3]								
Mean (SD)	2.49(1.04)	2.74(1.72)	2.21(1.0)	2.13(1.68)	3.53(1.96)	2.89(1.27)	3.82(3.0)	3.04(1.84)
p value	0.73		0.4		0.11		0.18	
Fasting Insulin								
Mean (SD)	12.42(5.06)	13.76(8.94)	11.42(4.68)	10.95(4.52)	16.78(7.85)	14.67(5.85)	20.28(10.8)	14.59(8.51)
p value	0.74		0.37		0.17		0.05	
Fasting Glucose								
Mean (SD)	4.46(0.47)	4.47(0.39)	4.33(0.40)	4.28(0.44)	4.67(0.54)	4.38(0.48)	4.29(0.66)	4.18(0.47)
p value	0.55		0.35		0.03		0.29	
GDM								
n(%)	0 (0%)	3(12%)			3(16%)	5(23%)		
p value	0.07				0.57			

Note. It is recommended that an individual achieves at least between 7.5-12.5 MET-hrs/wk to meet current exercise guidelines for weekly moderate to vigorous intensity activities (15).

[1]Interquartile range; [2]Mean (SD)

[3]Analyses were repeated by excluding all women with GDM, and then by excluding all women with insulin treated GDM. Results did not materially differ from those presented here.