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Randomized Face-to-Face vs. Home Exercise Interventions in Pregnant Women with Gestational Diabetes

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Abstract

Objectives—Evaluate effects of a theoretically-based, semi-intensive (Face-to-Face; F2F) exercise intervention and minimum-contact (Home) exercise intervention to the standard care (Control) on exercise, its motivational determinants, blood glucose levels, and insulin use of pregnant women with gestational diabetes mellitus (GDM).

Design—Randomized control trial with two intervention arms and control (standard care).

Method—Participants ($N=65$) were randomized to a Control (standard prenatal care/GDM dietary counseling), Home (standard care + phone education/support + home exercise), or F2F (standard care + on-site education/support + guided exercise with instructor on 2 days/week) group from ~20 weeks gestation to delivery. Assessments of exercise and motivational determinants were obtained at baseline (20-weeks gestation) and follow-up (32-weeks gestation). Blood glucose levels (fasting/postprandial mg/dL) and insulin use were extrapolated from medical records.

Results—At the 32-week follow-up, the F2F group had significantly higher exercise min, pedometer steps/day, and motivational determinants (attitude, subjective norm, perceived control, intention) than controls (p 's < .05) and significantly higher exercise min and subjective norm than

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Disclosure

There is no conflict of interest for any of the authors.

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the Home group (p 's < .05); these effect sizes were medium-large ($\eta^2 = .11-.23$). There was a medium effect ($\eta^2 = .13$) on postprandial blood glucose at 36-weeks gestation with the F2F group having lower values than controls. Although not significant, the F2F group started insulin later (33 weeks gestation) than the Home (27 weeks) and Control (31 weeks) groups.

Conclusion—A theoretically-based, F2F exercise intervention has multiple health benefits and may be the necessary approach for promoting exercise motivation and behavior among GDM women.

1. Introduction

Gestational Diabetes Mellitus (GDM) is a common complication that affects up to 14% of U.S. pregnancies (American Diabetes Association [ADA], 2011; Chasan-Taber, 2015). Maternal hyperglycemia elevates risks for complications such as preeclampsia, hypertension, cesarean section, neonatal macrosomia, and even death (ADA, 2011). GDM prevalence is increasing worldwide (Ignell, Claesson, Anderber, & Berntop, 2014; Sacks, 2014), and is expected to grow even further due to the rise in co-morbid obesity. Thus, there is an important need to develop interventions to treat and prevent GDM. Exercise is one health behavior with good potential to treat and/or prevent GDM (Chasan-Taber, 2015) and it has long been accepted as an adjunct treatment for type 2 diabetes in non-pregnant adults as it improves glucose homeostasis and insulin sensitivity (ADA, 2011). Perinatal exercise is associated with many health benefits without compromising fetal development (American College of Obstetrics and Gynecology [ACOG], 2002; Institute of Medicine [IOM], 2009; Rauff & Symons Downs, 2011; Symons Downs, DiNallo, & Kirner, 2008). However, there has been a lack of guidelines for exercise among GDM women in the literature (Padayachee & Coombes, 2015).

Furthermore, researchers examining the effects of exercise on blood glucose and insulin use in GDM women is limited. Ruchat and Mottola (2013) identified five interventions using varying delivery strategies (supervised/partially supervised) and exercise mode (aerobic, resistance training), duration, and intensity that were successful in controlling GDM. Another study by Halse, Wallman, Newnham, & Guelfi (2014) found a home-based cycling program resulted in lower mean daily postprandial glucose levels among intervention participants compared to controls. Two other partially supervised exercise interventions (e.g., 60% max heart rate exercise prescription, Artal, Catanzaro, Gavard, Mostello, & Friganza, 2007; 70% max heart rate prescription for 30 minutes with 2 sessions supervised and 2 unsupervised per week, Avery, Leon, & Kopher, 1997) were unsuccessful in improving blood glucose and/or limiting insulin use. These differences in outcomes may be due to a lack of supervised exercise sessions to encourage meeting the exercise guidelines of 150 min/week of moderate-intensity exercise; USDHHS, 2008). With less than 25% of pregnant women nationally meeting exercise guidelines (Evenson & Wen, 2010), understanding how to promote perinatal exercise, particularly among women with GDM, is a critical area of research with important public health implications.

To understand how behavior change is occurring and to improve outcome effectiveness, behavioral interventions should be theoretically-driven (Baranowski, Anderson, & Carmack,

1998). One theory that has been used to understand perinatal exercise and its motivational determinants is the Theory of Planned Behavior (TPB; Ajzen, 1991; Hausenblas & Symons Downs, 2004; Symons Downs & Hausenblas, 2003, 2007; Symons Downs & Ulbrecht, 2006). Ajzen (1991) suggested the TPB proposes that people are more likely to engage in a behavior when they are motivated (intention), positively evaluate the behavior (attitude), believe that significant others want them to do the behavior (subjective norm), and see the behavior as within their control (perceived behavioral control). Among pregnant women, the determinants of exercise intention and behavior have shown to vary across the trimesters such that attitude (1st, 2nd trimester) and subjective norm (1st, 3rd trimester) are strong predictors of intention and perceived behavioral control (1st trimester) and intention (2nd, 3rd trimester) are main determinants of exercise behavior (Hausenblas & Symons Downs, 2004; Symons Downs & Hausenblas, 2003, 2007). While the TPB has been used to effectively change some behaviors (e.g., binge drinking, medication adherence; French & Cooke, 2012; Wu, Corley, Lennie, & Moser, 2012), it has not been utilized to our knowledge to promote exercise in GDM women.

There is also no “gold standard” intervention to promote perinatal exercise. Semi-intensive, face-to-face exercise interventions (e.g., supervised, intensity 50–85% of maximum aerobic power for 20–60 minutes; American College of Sports Medicine [ACSM], 2014) have led to increases in exercise volume among non-pregnant populations (Opdenacker, Boen, Coorevits, & Delecuse, 2008); however, few studies have used this approach with pregnant women (Mottola et al., 2010). Alternatively, minimum-contact, home-based approaches are used more often in perinatal interventions because they require less of a time commitment, provide more flexibility for when women can exercise, and are generally easier to adhere to than more structured programs and therefore tend to be less stressful (Guelinckx, Devlieger, Mullie, & Vansant, 2010; Phelan, Phipps, Abrams, Darroch, & Schaffner, 2011). However, the effectiveness of less intensive approaches for promoting exercise behavior in this population is unclear despite the benefits of self-managed approaches to exercise and glucose regulation. For example, Hans, Middleton, Tran, and Crowther (2016) found that a print lifestyle intervention tool for GDM women was unsuccessful at increasing perinatal exercise behavior. We are aware of no studies to date that have empirically tested the effects of semi-intensive face-to-face and minimum-contact home-based approaches on the exercise behavior and motivation of GDM women. This evidence is necessary to design more effective interventions to promote exercise and improved health outcomes in this population.

Our study purpose was to evaluate the effects of a semi-intensive, face-to-face exercise intervention and a minimum-contact, home-based exercise intervention to the standard of care (control) on exercise behavior, its motivational determinants, blood glucose levels, and insulin use of women with GDM. We hypothesized that women in the exercise interventions would: a) engage in more exercise and have stronger TPB motivational determinants (i.e., attitude, subjective norm, perceived behavioral control, intention), b) have lower fasting and average weekly postprandial blood glucose levels, and c) have a lower incidence of insulin use than controls (Ruchat & Mottola, 2013). Due to the equivocal findings comparing exercise mode in managing GDM (Artal et al., 2007; Avery et al., 1997; Ruchat & Mottola, 2013) and the limited exercise guidelines for GDM women (Padayachee & Coombes, 2015), we did not establish an a priori hypothesis regarding which exercise intervention would be

more effective for increasing exercise motivation and behavior or controlling blood glucose levels and insulin use.

2. Methods

2.1 Study Design and Population

This randomized intervention was conducted upon approval by the University's Institutional Review Board and in accordance with ethical standards of the responsible committee on human experimentation. Participants were eligible for this study if they were pregnant, had been diagnosed with GDM (i.e., clinic protocol screened at 16 weeks, 50g glucola; 2 hr glucose tolerance test if > 130 [100g glucola fasting blood sugar 92, 1 hr 180, 2 hr 153 with one abnormal value]), at least 18 years of age, able to speak and understand English, and residing in communities in and around Central Pennsylvania. Participants signed written informed consent prior to study inclusion and were required to obtain written consent from their healthcare provider to participate in the study (i.e., no evidence of contraindications to exercise; ACOG, 2002).

2.2 Recruitment and Enrollment

Participants were identified through advertisements (e.g., study flyers at clinic and community locations) and clinic referrals; all participants received care from the same local obstetric and gynecology clinic. Women were screened for eligibility over the telephone; eligible women were ready a brief study description and invited to attend a baseline session. Interested women were scheduled for their first appointment and gave their address to receive a packet with written consent documents and self-reported measures to reduce burden at baseline.

2.3 Baseline Assessment

The baseline assessment (20-weeks gestation) was conducted at the University's Clinical Research Center (CRC) and lasted about 60-min. Participants were escorted to a clinic room where the project manager explained the study, obtained written consent, verified the signed provider consent form, and collected self-reported measures. Height, weight, blood pressure, urine, and medical history were recorded in addition to an activity readiness screening to rule-out any exercise contraindications (ACOG, 2002). Women who did not pass the medical screen were referred to their healthcare provider ($n=2$). Participants then completed a treadmill walking protocol (i.e., warm-up + 5-min walk intervals at 2.0, 2.5, 3.0, 3.5 miles/hr speed at level grade + cool down; Pivarnik, Lee, & Miller, 1991) to assess baseline oxygen consumption (VO_2) and heart rate for an estimate of fitness. The project manager and CRC nurse conducted the protocol and assessed negative symptoms (e.g., dizziness) and blood pressure during and after the protocol. None of the participants reported negative symptoms. Participants were given an activity monitor and written instructions for wearing it over the next seven days to obtain a free-living assessment of activity.

2.4 Randomization and Initial Consultation

Participants who successfully completed baseline assessments were randomized using variable-size, random permuted blocks using 1:1 allocation with equal probability into the

semi-intensive, face-to-face (F2F) exercise intervention, minimum-contact, home-based (Home) exercise intervention, or standard care (Control) group. Participants randomized to the Control group were scheduled for the 32-week follow-up assessment while participants randomized to the F2F and Home groups were scheduled for an in-person consultation to explain the interventions and give them study materials (i.e., education binder, schedules, parking/childcare instructions). They were also scheduled for the 32-week follow-up assessment. This visit took about 30-min.

2.5 Interventions

The Control group received standard prenatal care delivered by their healthcare provider (not informed by the research team of the randomization assignment) including dietary guidance for GDM and encouragement to exercise on own to meet guidelines (USDHHS, 2008). The F2F exercise intervention group received standard care + F2F exercise education, motivational support/self-efficacy enhancement, and engaged in moderate intensity exercise (e.g., treadmill walking/jogging, cycle ergometer, low-impact aerobics) on 2 days/week delivered in a 70-min session (e.g., 10-min warm-up, 30–40 min exercise, 10-min cool-down, 10–15 min stretching; ACOG, 2002; Padayachee & Coombes, 2015) and led by a certified fitness instructor. Educational curriculum was based on the Diabetes Prevention Program (Rubin et al., 2002) and included content on exercise as a way of life, committing to lifestyle change, eating for exercise, managing stress, and staying motivated, The TPB (Ajzen, 1991) content was developed by the first author (e.g., benefits/positive attitude characteristics of exercise; sources of and strategies to improve normative/social support, perceived control, and self-regulation; overcoming barriers to exercise such as goal-setting, exercise self-monitoring, and overcoming negative self-talk; motivational tools including positive affirmations/encouraging quotes; and interactive discussions with the instructor on these topics). A registered nurse was present during sessions to monitor negative symptoms and evaluate blood glucose values (i.e., women self-checked blood glucose before/after exercise sessions; ADA, 2011). The Home group received standard care + the same education/motivational support/self-efficacy enhancement as the F2F group but it was delivered every two weeks in a 45-min phone session led by a certified fitness instructor. Participants were encouraged to exercise on their own to meet guidelines (ACOG, 2002; USDHHS, 2008). Education curriculum was mailed to participants the week before the call.

2.6 Follow-up Assessment

This assessment included the same self-report measures and activity monitor protocol as baseline. Although the intervention continued through delivery, the follow-up was conducted at 32-weeks gestation to reduce the likelihood of a woman going into labor before the follow-up assessments were complete.

2.7 Incentives

Participants completing the assessments received a \$50 check at each visit. The intervention groups (F2F, Home) were also compensated with a \$25 gift card (25-weeks gestation); this incentive amount was chosen to compensate for the women's time but was not large enough to influence study outcomes in a meaningful way (Gneezy, Meier, & Rey-Biel, 2011). All participants had free parking and childcare during study visits.

2.8 Outcome Measures

The primary outcome was exercise behavior. To obtain scale correspondence (i.e., equivalence in measures for target, action, context, time of behavior) with the theory measures (Courneya, 1994), the Leisure-Time Exercise Questionnaire (Godin & Shephard, 1985) was used to assess frequency of moderate and strenuous exercise done for at least 15 min in the past 7 days. Consistent with methods of past researchers (Andrykowski, Beacham, & Jacobsen, 2007; Amireault, Godin, Lacombe, & Sabiston, 2015; Plotnikoff, Lubans, Penfold, & Courneya, 2014) and research with pregnant women (Symons Downs et al., 2008), the LTEQ was modified to generate total scores in minutes (min) of moderate-vigorous exercise for prepregnancy and at 20- and 32-weeks gestation (mild was not included). This format has been easier for pregnant women to recall activity than the traditional use of the scale in bouts of activity (Symons Downs et al., 2008). Women also wore the piezoelectric NL1000 pedometer (New Lifestyles, Inc., Lee's Summit, MO, USA) and recorded their steps on a log (Plotnikoff et al., 2010; Plotnikoff et al., 2014). The pedometer and step log were also used as a strategy to promote exercise (Plotnikoff et al., 2010). We assessed average pedometer steps/day for 7 days at 20- and 32-weeks gestation. The NL1000 has been shown to accurately assess steps in free-living conditions (Clemes, O'Connell, Rogan, & Griffiths, 2010; Schneider, Crouter, & Bassett, 2004).

2.9.1—Exercise Motivational Determinants were assessed with items based on the TPB guidelines (Ajzen, 1991) and prior research with pregnant women (Hausenblas & Symons Downs, 2004; Symons Downs & Hausenblas, 2003, 2007). Attitude was assessed with 7 semantic differential pairs (e.g., useless-useful) following the statement "Exercise during my ___ (2nd/3rd trimester) will be". Subjective norm was assessed with 4 items (e.g., "Most people who are important to me think that I should exercise during my ___ (2nd/3rd trimester)," ranging from 1=strongly disagree to 7=strongly agree. Perceived behavioral control was measured with 3 items (e.g., "If I wanted to, I could easily exercise during my ___ (2nd/3rd trimester)," ranging from 1=strongly disagree to 7=strongly agree. Intention was assessed with 4 items (e.g., "I intend to exercise during my ___ (2nd/3rd trimester)," ranging from 1=strongly disagree to 7=strongly agree. Internal consistency scores for all measures at baseline and follow-up had alphas > .85.

2.9.2—Blood Glucose Levels were measured with standard care procedures (ADA, 2011). Women reported fasting and postprandial blood glucose values (mg/dL) to the clinic dietician by email and these values were then entered into the medical records. Recent data showed a correlation of .96 between self-reported and clinical measurement of glucose levels (Thomas, Paulet, & Rajpura, 2016). Mean weekly fasting (morning value) and postprandial values (within an hour post-meal averaged over the day) were extracted from medical charts and calculated at 4-week cycles consistent with prenatal care visits at 20, 24, 28, 32, and 36 weeks gestation.

2.9.3 Insulin Use—Clinic medical records documented whether a participant was prescribed insulin to treat her GDM (yes/no) and at what gestational week insulin use began (once insulin was initiated, it was continued through delivery with adjustments to dosage as necessary).

2.9.4—Sample Characteristics assessed included demographic information (e.g., age, weight, race/ethnicity, pregnancy history, complications). Prepregnancy weight was defined as the weight self-reported at the last menstrual cycle (ACSM, 2014).

2.10 Data Analyses

Analyses were performed with SPSS (v. 22) software. Descriptive statistics were used to examine means/standard deviations for variables with normal distribution and percentages for categorical variables. Assumptions were met (e.g., no outliers, normal distribution, homogeneity of regression slopes and variance) and ANCOVA were used with condition (F2F, Home, Control) as the independent variable (IV), baseline (20 week gestation pre-test) measure as the covariate, and follow-up (32-week gestation post-test) as the dependent variable (DV) to examine exercise behavior (LTEQ min, pedometer steps) and its motivational determinants. Repeated measures ANOVAs were used to examine mean fasting and weekly postprandial blood glucose levels (mg/dL) at 20, 24, 28, 32, and 36 weeks gestation. Chi square analysis was used to examine insulin use (yes, no) and a univariate ANOVA was used to examine group differences for gestational week insulin was initiated. Effect sizes were calculated using eta squared (η^2) with .01, .06, and .14 representing small, medium, and large effects (Cohen, 1988).

2.11 Sample Size Calculation

Power calculations were based on the primary outcome, exercise behavior (LTEQ min), using estimates from the literature (Duvall, Dinger, Taylor, & Bembien, 2004) and our pilot work with a sample size of 20 per group (total of 60). This sample with level of significance of .05 had 80% power to detect expected maximum differences for the primary (LTEQ min) and secondary outcomes (pedometer steps, motivational determinants, blood glucose). We also expected drop-out as pregnant women are a difficult population to retain for studies, thus, target recruitment was 70.

3. Results

3.1 Sample Characteristics

Participants ($N=74$) were identified through recruitment strategies (from an initial pool of 105) of which 70 women were eligible to participate and 65/70 (93%) completed consent and baseline assessment procedures and were randomized to the F2F ($n=22$), Home ($n=22$), or Control ($n=21$) groups (see Figure 1). The drop-out rate was 14%; reasons included no time (F2F $n=3$, Home $n=3$, Control $n=3$), complications (Home $n=1$), and moved (Home $n=1$). Eight participants had < 5% missing data (mean replaced in accordance with Allison, 2001; Cohen, Cohen, West, & Aiken, 2003); 13 women had missing data > 5% and were excluded from analyses. The remaining women had complete data; thus subsequent analyses were conducted on 41 participants (F2F=13, Home=13, Control=15). This sample had 83% power to detect expected maximum difference for the primary outcome (exercise behavior), 80% power for secondary outcome, motivational determinants, and 75% power for secondary outcome, blood glucose. No significant group differences were observed at baseline for age, pre-pregnancy BMI or min/week of exercise, fitness (VO_2 or heart rate), parity, race/ethnicity, marital status, education, family income per year, or occupational

status (see Table 1). Participants (M age=32 years; range 19–41 years) were from communities around Central Pennsylvania and were mostly non-Hispanic White (80%), married (90%), parity >1 (56%), college or graduate/professional educated (95%), worked full-time (61%), and with an annual family income of \$40,000 (68%).

3.2 Adherence

Adherence was calculated based on completion of sessions through delivery; 88% of the participants in the F2F group and 84% of the participants in the Home group adhered to the exercise interventions. Reasons for missing a session included doctor's appointment, feeling nauseous/sick, holiday, and vacation. Two participants (1 in F2F, 1 in Home) were put on bed rest by their physician between 36–37 weeks gestation until delivery (~39 weeks gestation); however, they continued with the study to receive education and motivational support until delivery and remained in the analyses.

3.3 Intervention Effects: Exercise Behavior

Table 2 displays baseline and follow-up findings by group. No significant baseline group differences were observed for LTEQ min of moderate exercise/week or NL1000 pedometer steps/day. At follow-up, significant group differences were observed with the F2F group reporting significantly more min moderate exercise/week than the Home and Control groups and significantly more pedometer steps/day than controls. The effect sizes for both exercise measures were in the large range ($\eta^2 = .15$ steps; $.23$ LTEQ min). No significant differences for LTEQ min or pedometer steps were observed between the Home and Control groups.

3.4 Intervention Effects: Exercise Motivational Determinants

No significant baseline group differences were observed for attitude or subjective norm. The F2F group had significantly higher baseline perceived behavioral control and intention than controls. The Home group also had significantly higher baseline intention than controls. After controlling for baseline values in the analyses, the F2F group had significantly higher attitude, subjective norm, perceived behavioral control, and intention at follow-up compared to controls. The F2F group also had higher motivational determinants than the Home group, however, only the difference for subjective norm was statistically significant. The effect sizes for the motivational determinants were in the medium to large range ($\eta^2 = .11 - .18$).

3.5 Intervention Effects: Blood Glucose Levels

Figure 2 displays the mean fasting and weekly blood glucose values by group. A significant repeated measures effect for fasting blood glucose was observed, *Wilks' Lambda* = .65, $F(4,32) = 4.25$, $p < .01$, but not for fasting glucose X group, *Wilks' Lambda* = .69, $F(8,64) = 1.57$, $p = .14$. No significant group differences were observed at any time points, although examination of the means showed the F2F group had lower levels ($M = 82$, $M = 78$) than the Home ($M = 91$, $M = 83$) and Control ($M = 89$, $M = 85$) groups at week 24 and 36, respectively, and these differences trended toward significance ($p = .10$, $.13$) with effect sizes in the medium range ($\eta^2 = .12$, $.11$), respectively. A significant repeated measures effect for average postprandial blood glucose was observed, *Wilks' Lambda* = .71, $F(4,32) = 3.34$, $p = .02$, but not for postprandial blood glucose X group, *Wilks' Lambda* = .68, $F(8,64) = 1.71$,

$p = .11$. Follow-up analyses showed the F2F ($M = 94$) and Control ($M = 102$) groups had significantly lower baseline (week 20) postprandial blood glucose than the Home ($M = 114$) group. The F2F group also had significantly lower postprandial blood glucose than the other groups at weeks 24, 28, 32, and 36; however, this group difference was significant only at week 36 for the F2F group ($M = 95$) compared to the Control ($M = 103$) group, $p = .03$, $\eta^2 = .13$. The F2F group also had lower mean values than the Home group at all time points although these comparisons were not significant.

3.6 Intervention Effects: Insulin

Of the total sample, 44% required insulin (12% F2F, 20% Home, 12% Control); no significant group differences were observed for requiring insulin or for gestational week insulin was initiated (p 's $> .05$) although examination of the means showed the F2F group started insulin later (33 weeks gestation) than the Home (27 weeks) and Control (31 weeks) groups.

4. Discussion

We evaluated the effects of a theoretically-driven, semi-intensive, face-to-face exercise intervention (F2F), a minimum-contact, home-based exercise intervention (Home), and standard care only (Control) on exercise behavior, its motivational determinants, blood glucose levels, and insulin use of women with GDM. Our findings suggest the F2F intervention had a large effect on women's exercise behavior (min of moderate-vigorous exercise and pedometer steps), attitude, and intention, and a medium effect on subjective norm and perceived control. There was also a medium effect on postprandial blood glucose at 36-weeks gestation with the F2F group having lower values than controls. Although not significant, the F2F group started insulin later (33 weeks gestation) than the Home (27 weeks) and Control (31 weeks) groups. Also of interest, the Home exercise intervention was no better than the Control in promoting exercise, its motivational determinants, or impacting blood glucose levels and insulin use. These findings illustrate that onsite supervised exercise may have multiple health benefits for women with GDM despite the notion that pregnant women will exercise more in the comfort of their own home. These findings have important implications for developing effective exercise interventions for women with GDM.

In partial support of our hypothesis and consistent with past research (Ruchat & Mottola, 2013), the F2F, but not the Home intervention, resulted in increases of overall exercise. Specifically, the F2F group engaged in significantly more min of moderate-intensity exercise and pedometer steps/day compared to the Home and Control groups. While the F2F group increased exercise min and steps from 20 to 32-weeks gestation, exercise decreased in both the Home (min and steps) and Control (min) groups. Although no group met the threshold for meeting guidelines of 150 min/week (USDHHS, 2008) at follow-up, the F2F group was just below the guidelines at 144 min/week compared to the Home (73 min) and Control (81 min) groups. These findings are particularly important as prior researchers have demonstrated that exercise declines over the course of pregnancy (Evenson & Wen, 2010) and our findings suggest a particular strength of the F2F intervention in maintaining exercise over the course of pregnancy. Onsite supervised exercise maybe obligatory to ensure that

women are sufficiently and consistently active throughout pregnancy to help them overcome barriers and sustain activity levels. This may be particularly important for women with GDM who have the added challenges of regulating blood sugar and for some, delaying the need for insulin.

The Home intervention was also less effective than the Control condition at increasing (or at least maintaining) exercise at follow-up. While the F2F and Home exercise interventions received the same education, goal-setting, and motivational support, the lack of structure/commitment to weekly supervised sessions (or perhaps more “freedom” to exercise on their own) in the Home condition may have been less motivating. That is, the F2F group is the only group that yielded no pre-post test decrease (attitude, intention) and an increase (subjective norm, perceived control) in these determinants whereas the Home and Control conditions resulted in decreases in all motivational determinants from baseline to follow-up. This finding is also consistent with the usually observed decline in exercise over the course of pregnancy (Evenson & Wen, 2010). Moreover, adherence to the interventions was slightly higher in the F2F group (88%) compared to the Home group (84%). One recent study among pregnant women with poorer compliance to a home-based exercise intervention (35%) compared to our study suggested that although women believed a home program would make it easier to incorporate exercise into their daily routine, the unanticipated increased barriers in later pregnancy (e.g., feeling uncomfortable, fatigue) made it difficult to exercise on their own (Seneviratne et al., 2016). In contrast, an onsite exercise program with the support from an exercise specialist may help women to work through many of these barriers, stay motivated, and remain active through delivery.

Also as predicted, the F2F group had significantly higher subjective norm than both the Home and Control conditions. Understanding the relative influence of these theoretical determinants on exercise behavior is especially important and may explain why we observed influences in exercise in the F2F condition. Future studies aiming to promote exercise in GDM women should consider these TPB motivational factors to effectively promote increases (as opposed to observing gradual declines) in exercise. Collectively the exercise and motivational determinants findings are contrary to evidence that home-based interventions in pregnancy are ideal because of convenience (Guelinckx et al., 2010; Phelan, 2011); thus, this aspect of intervention delivery requires future testing to better understand these differences. Given the increased interest in strategies to promote exercise remotely (e.g., Smartphone, Internet, new technologies), future research is needed to understand if a hybrid onsite-home approach can generate similar exercise effects as the F2F only approach while also easing participant burden.

Furthermore, we found partial support for the hypothesis that both exercise interventions yielded lower fasting and average weekly postprandial blood glucose levels and a lower incidence of insulin use than controls. Consistent with past researchers (Ruchat & Mottola, 2013), we found that women in the F2F intervention had consistently lower fasting and postprandial blood glucose values across pregnancy compared to the Home and Control conditions; however, these differences reached statistical significance for postprandial values only at 36-weeks gestation. Although this effect size was medium ($\eta^2 = .13$), the study sample was slightly underpowered (75% power) to detect differences in blood glucose

outcomes. Thus, these findings should be interpreted as preliminary. Given that the F2F group was more active at follow-up than the other two groups, this may be a key explanation for why they had better glucose control. However, given the scant research in this area, more research is needed to understand the impact of different exercise interventions on blood glucose levels among GDM women before definitive conclusions can be made.

While no group differences were found for requiring insulin or for gestational week insulin was initiated, it is nevertheless important to note that the F2F group did start insulin later in gestation (33 weeks) compared to the Home (27 weeks) and Control (31 weeks) groups. Even if regular exercise cannot prevent the onset of insulin, it still may delay the onset of use which offers tremendous health benefits to both mother and child. More research examining the impact of exercise on insulin use in light of recent recommendations for aerobic and resistance exercise (Padayachee & Coombes, 2015) is needed to better understand our findings and make future research suggestions.

To our knowledge, this is the first study to use the TPB (Ajzen, 1991) to guide the development of a perinatal exercise intervention and the findings suggest the theory is useful for promoting the motivational determinants of perinatal exercise. A particular strength of this study is that it is also one of the first studies to examine the impact of two exercise interventions compared to standard care on outcomes in GDM women. Despite these strengths, there are still limitations. The homogenous sample (e.g., married, middle to upper class, Caucasian) may limit the dissemination of findings to more diverse samples. The retention rate of <70% (baseline to follow-up) although average, was less than anticipated and led to smaller than desired sample sizes (originally powered with 20 per group for 80% power); thus, the findings are limited in their generalizability to other populations. The study also included questionnaires to assess leisure-time exercise (LTEQ) and the TPB motivational determinants as well as a log to write down pedometer steps. While we used validated surveys and standard recommendations to collect this data, there is nevertheless an inherent bias in self-report data. Future studies may consider using newer technology (e.g., wrist-worn monitors) that provide an objective estimate of steps/day while also providing self-regulatory feedback and motivational tools (e.g., step goals, achievements embedded in the app) for promoting exercise behavior. In conclusion, this study demonstrated that a theoretically-based, onsite supervised exercise intervention resulted in higher exercise behavior and motivational determinants compared to a less intensive, home-based intervention and the standard care condition. Future research is needed to test this F2F exercise intervention in a larger sample to confirm the effects. Healthcare professionals may want to encourage pregnant women with GDM to seek out opportunities for guided F2F exercise (e.g., personal trainer, instructor led activity classes) to achieve sufficient levels of exercise and related improved health outcomes over the course of pregnancy.

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Highlights

- An onsite, structured exercise program for women with gestational diabetes had a large effect on their exercise and medium to large effect on their motivational determinants
- Onsite structured exercise had a medium effect on lowering postprandial blood glucose levels in later pregnancy
- Women who needed to take insulin started in later in gestation in the onsite structured exercise program (33 weeks) compared to the home program (27 weeks) and controls (31 weeks)
- A theoretically-based, onsite structured exercise intervention may be useful for promoting exercise, motivation, and health in women with gestational diabetes

Figure 1.

Flow of participants through the study. Face-to-Face = semi-intensive, face-to-face structured exercise program; Home = minimum-contact, home-based exercise program; GDM = gestational diabetes mellitus; Completed = completed protocol and 32-week follow-up assessment.

Figure 2.

Mean fasting and postprandial blood glucose levels (mg/dL) for each group at 20, 24, 28, 32, and 36 weeks gestation. Differences were tested using repeated measures ANOVA and follow-up ANCOVAs controlling for 20 week levels. F2F = Face-to-Face; ^a = F2F group has significantly lower mean weekly postprandial blood glucose levels than controls at 36 weeks gestation.

Table 1Sample Characteristics by Randomization Condition.[†]

	F2F	Home	Control
<i>Group N</i>	13	13	15
Age (<i>M, SD</i>)	31 (5)	33 (5)	32 (3)
Pre-pregnancy BMI (<i>M, SD</i>)	29.7 (9)	30.0 (8)	27.8 (8)
Pre-pregnancy Exercise Minutes/Week [‡]	57.5 (50)	104 (90)	77.5 (56)
Fitness			
Average VO ₂ (ml·kg ⁻¹ ·min ⁻¹) [§]	13.9 (2)	15.1 (5)	12.4 (2)
Average heart rate	172.4 (20)	174.1 (13)	173.5 (16.9)
Parity			
Pregnant with 1 st child	31%	54%	47%
Pregnant with 2 nd child	46%	31%	33%
Pregnant with 3 rd child	15%	8%	13%
Pregnant with 4 th + child	8%	8%	7%
Race/Ethnicity			
Non-Hispanic White	85%	77%	80%
Asian American	15%	23%	13.3%
Hispanic	0%	0%	7%
American Indian	0%	0%	0%
Other	0%	0%	0%
Marital Status			
Married/Common Law	100%	92%	87%
Divorced	0%	0%	7%
Single	0%	8%	0%
Other	0%	0%	7%
Education			
High school	0%	8%	7%
College	77%	38%	67%
Graduate/Professional	23%	54%	27%
Family Income/Year			
< \$9,999	0%	8%	7%
\$10–19,999	0%	0%	6%
\$20–39,999	15%	17%	29%
\$40–99,999	77%	67%	50%
\$100,000 +	0%	8%	14%
Other	8%	0%	0%
Occupational Status			
Full-time	54%	54%	73%
Part-time	23%	8%	13%
Homemaker	15%	23%	7%

	F2F	Home	Control
Self-employed	8%	8%	7%
Unemployed	0%	8%	0%

Note. F2F = semi-intensive, face-to-face exercise program; Home = minimum-contact, home-based exercise program; Control = standard of care control group; *N* = number, *M* = mean, *SD* = standard deviation; BMI = body mass index;

[†]There were no significant differences between groups for any baseline characteristics; Age and percent values were rounded to nearest whole number.

[‡]Leisure-Time Exercise Questionnaire (asked retrospectively to report average time spent in exercise before pregnancy);

[§]VO₂ and heart rate assessed at min 14–15 of treadmill test to ensure steady state.

Table 2

Mean (M), Standard Deviation (SD), and Follow-up (32-Weeks Gestation) Group Differences Controlling for Baseline for Face-to-Face (F2F) and Home-Based (Home) Exercise Interventions and Standard Care (Control) for Study Variables.

Outcome Variable	F2F M (SD)	Home M (SD)	Control M (SD)	Follow-up ANCOVA (controlling for baseline)		
				F (df 3)	p	Effect Size (η^2)
LTEQ Min Exercise/Week				7.51	<.01	.23
20-week Baseline	51 (46)	80 (71)	68 (33)			
32-week Follow-up	144 (51) ^a	73 (69) ^b	81 (66) ^b			
NL1000 Average Steps/Day				3.17	.05	.15
20-week Baseline	5952 (2388)	6961 (2498)	5811 (1415)			
32-week Follow-up	6833 (1720) ^a	5290 (3076)	4955 (2328) ^b			
Exercise Attitude				4.13	.02	.16
20-week Baseline	41 (4)	41 (4)	39 (5)			
32-week Follow-up	41 (5) ^a	33 (11)	31 (10) ^b			
Exercise Subjective Norm				4.95	.01	.11
20-week Baseline	17 (4)	17 (4)	17 (3)			
32-week Follow-up	19 (2) ^a	14 (6) ^b	14 (5) ^b			
Exercise Perceived Behavioral Control				3.60	.03	.12
20-week Baseline	15 (4) ^a	14 (4)	11 (3) ^b			
32-week Follow-up	16 (4) ^a	11 (5)	9 (5) ^b			
Exercise Intention				4.32	.02	.18
20-week Baseline	17 (3) ^a	17 (2) ^a	14 (3) ^b			
32-week Follow-up	17 (3) ^a	14 (5)	10 (6) ^b			

Note. LTEQ = Leisure-Time Exercise Questionnaire (minutes of moderate-vigorous exercise/week); η^2 = Eta squared; Means that do not share superscripts are significantly different at .05 alpha level.