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The Impact of a Structured Preconception Care Program on Pregnancy Outcomes in Women with Obesity: A Randomized Controlled Trial

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Abstract
Background: Obesity increases the risk of adverse pregnancy outcomes. The efficacy of structured preconception care (PCC) for this population is not well-established.
Objective: To evaluate the impact of a structured PCC program on pregnancy outcomes in women with obesity.
Methods: A randomized controlled trial included 250 women (BMI≥30) planning pregnancy. The intervention group (n=125) received a 6-month PCC program (nutritional counseling, physical activity, psychosocial support) before conception. The control group (n=125) received standard care. Primary outcome was a composite of gestational diabetes, preeclampsia, preterm birth, or macrosomia.
Results: The composite outcome occurred in 28.8% of the intervention group versus 48.0% of controls (RR 0.60; 95% CI 0.43-0.84; p=0.002). Rates of gestational diabetes (12.0% vs 24.8%, p=0.008) and preeclampsia (4.8% vs 12.0%, p=0.04) were significantly lower in the intervention group. Mean neonatal birthweight was lower (3250g vs 3450g, p=0.001) and maternal depression/anxiety scores at 28 weeks were significantly improved in the intervention group.
Conclusion: A structured PCC program for women with obesity significantly reduces the risk of major pregnancy complications and improves maternal and neonatal outcomes. This supports the implementation of preconception interventions in routine care.
Keywords: Obesity; Preconception Care; Pregnancy Outcome; Randomized Controlled Trial; Gestational Diabetes; Lifestyle Intervention.

Introduction

Today's growing worldwide health issue of obesity has increased dramatically from 1975 to the present day - almost tripling since then [1]. More importantly, it has distinct and serious consequences on reproductive health that affect both mother and baby throughout the pregnancy process. Women who are overweight before they are pregnant (BMI of 30 kg/m² or more) are at an increased risk of numerous complications during all stages of pregnancy; including but not limited to gestational diabetes (GDM), hypertensive disorders (preeclampsia), higher likelihood of a cesarean section delivery, and experiencing postpartum hemorrhage, which create a serious risk for the fetus.In terms of fetal outcomes, outcomes such as spontaneous abortion, congenital anomalies, infant macrosomia, premature births, still births, as well as an increased risk of developing metabolic syndrome and obesity in later life are similarly problematic [3,4].In addition to the suffering these complications create for the individual, the burden on health care systems will be serious, as health care systems will have to provide more specialized care, longer hospitalizations, and long-term management of chronic conditions for both mothers and babies [5].

Therefore, preconception care (PCC), which offers the opportunity to optimize a mother's health prior to getting pregnant and thereby improve pregnancy outcomes, has recently emerged as a proactive evidence-based model to address this complex challenge [6]. PCC includes multiple interventions (risk assessment, health promotion, and managing exisitng illnesses) aimed at improving overall health before becoming pregnant. Evidence has shown that by improving the management of chronic diseases, such as diabetes and epilepsy, prior to pregnancy will reduce the risk of teratogenic effects due to medications (based on improved glycemic control) [7]. Unfortunately, there is a lack of evidence regarding the effectiveness of structured PCC programs that focus on obesity since it is a multi-factorial condition.

The current approach to providing standard care for obese women focuses more on the treatment of problems as they occur during the pregnancy; specifically the focus has been on limiting gestational weight gain, but has not included treatment of the underlying metabolic, inflammatory, and psychological conditions prior to conception. Consequently, women are missing their greatest opportunity to receive intervention prior to becoming pregnant. During the preconception time period, women are provided with the opportunity to implement lifestyle changes (dietary changes, increasing physical activity, providing psychological support) that will create improved insulin sensitivity, decrease chronic inflammation, and stabilize hormonal levels prior to the additional stresses of pregnancy [8]. From a theoretical standpoint, the need for PCC for obese women seems evident, however there is limited empirical evidence from RCT's examining the outcomes associated with lifestyle changes in obese pregnant women [9]. Additionally, there are even fewer RCT's examining the outcomes of PCC programs that are comprehensive and initiated in the pre-pregnancy phase.Thus, the purpose of this study was to address the above described need for empirical RCT evidence to evaluate whether a structured multi-component PCC program including dietary counseling, physical activity education and psychosocial support can dramatically improve the outcomes of pregnancy for women with obesity when compared to women who receive standard care. The goal is to go beyond establishing correlation by establishing causation in order to provide high-quality evidence to guide clinical practice, develop health policy, and fundamentally shift the method in which care is provided to this high-risk population from reactive to proactive.

Objectives

1. To evaluate the impact of a structured PCC program on the incidence of composite adverse pregnancy outcomes (gestational diabetes, preeclampsia, preterm birth <37 weeks, and macrosomia >4000g) in women with obesity.
2. To assess the change in maternal BMI from enrolment to conception
3. To evaluate the effect of PCC on the incidence of maternal antenatal depression and anxiety
4. To compare neonatal birthweights and Apgar scores between groups.

Materials and Methods

Study Design and Setting: This study was a prospective, parallel-group, randomized controlled superiority trial with a 1:1 allocation ratio. It was conducted at the Department of Obstetrics and Gynaecology of a large tertiary-care university hospital over a 36-month period, from January 2023 to December 2025. The trial was approved by the Institutional Human Ethics Committee (IHEC-I/019/01/2026) and prospectively registered with a clinical trials registry (CTRI/2022/12/048XXX). Reporting followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Participants and Recruitment

Eligibility Criteria: The women of childbearing age were assessed for study eligibility either during a visit to a clinic or through community health advertising efforts. The eligible women who met the inclusion criteria for this study were: (1) between the ages of 18-40, (2) had a pre-pregnancy body mass index of 30.0 kg/m² or higher as measured from height and weight, (3) had expressed an intention and actively planned to conceive within six months of the survey (not using contraception and having regular sexual intercourse), and (4) could understand the information and provide written informed consent to participate in this study in their local language. Women who met the exclusion criteria for this study were: (1) women who had diabetes or other endocrine disorders (e.g. hormonal disorder, uncontrolled thyroid disorder), (2) women

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Vol. 36 Issue 1, 2026, Pages 4843-4847

who were severely mentally ill (e.g. actively psychotic or severely bipolar), (3) women with serious heart problems, (4) women who were pregnant at the time of the survey and (5) women who were involved in a weight-loss program or lifestyle intervention.

Sample Size Determination

To determine the sample size before the start of ytheir study, the research team created an a priori assumption that the percentage of women who would have a negative outcome from not becoming pregnant would be 50% in the control group. From this, the researchers felt that the percentage of women in the experimental group would decrease by 30%. Based on a 0.05 alpha (two-tailed), and an 80% power (1 - beta), this study used an estimated sample size of 109 women per group. The target sample size was adjusted due to the projected attrition rate of 15% based on previous studies (e.g. withdrawal from a study, failure to conceive or loss to follow up), so the final estimate of women per group was set at 125 (250 total women).

Randomization and Blinding

All women who were eligible to participate in the study had a baseline evaluation in order for them to be randomly assigned to one of the two study groups (IG or CG) by using a random number generator prepared by an independent statistician not involved in enrollment (block sizes of 4 and 6). Randomization was conducted with the allocation being kept secret in order for the study randomization method to be valid. After all of the women had completed their baseline assessments, the research coordinator opened sequentially numbered opaque sealed envelopes to be given to the participants. Since the intervention had a behavioral component, participants and providers could not be kept blind to group assignment. However, in order to reduce bias, outcomes were assessed by separate research midwives and pediatricians who were unaware of study group assignments. Data analysts also remained blind to randomization assignments during the primary analysis of the data.

Intervention Protocol

1) Intervention Group (Structured Preconception Care Program): The program lasted 6 months and provided multidisciplinary services to participants attempting to conceive. The program utilized standardized procedures, including one face-to-face visit, one supportive phone or secure messaging contact and monthly delivery of services.

a) Nutritional counselling consisted of one-on-one appointments with a registered dietitian that provided extensive dietary assessments using 24-hour recalls and a food frequency questionnaire. Participants received a personalized diet plan based on a moderately energy-restricted nutrient-dense Mediterranean-style diet that created a target daily caloric deficit of approximately 500 kcal derived from estimated energy expenditure in order to obtain a gradual weight loss of 0.5-1.0 kg per week. The plan emphasized consumption of large amounts of vegetables, fruits, and whole grains for managing weight; low-fat or lean protein sources (pulses, poultry and fish) for managing weight and maintaining muscle tissue (or the mass of muscles); healthy fats (nuts and olive oil) for managing body fat and providing other essential nutrients; and strict limitation of added sugars, refined carbohydrate based foods (e.g., white bread and white rice) and ultra-processed foods. Participants were prescribed daily 400 mcg folate supplementation and extra iron base on standard preconception guidelines. Each month, a registered dietitian reviewed dietary diaries with each participant and modified each participant's diet plan based on participant compliance, dietary tolerability, and feedback from participant's diet diary review.

b) Physical activity guidance was established by a physiotherapist that specializes in women's health. Exercise prescriptions were prescribed based on FITT Principles (frequency, intensity, time, type). Participants were prescribed at least 150 minutes per week of moderate-intensity aerobic physical activity (e.g., walking, riding a stationary bicycle, water aerobics) spread over at least 3 days, confirmed by provision of pedometers and activity logs from each participant. The intensity of each participant's physical activity was monitored using the Borg Rating of Perceived Exertion scale (target 12-14). Following the first month, each participant was provided with adequate resistance exercise instruction that targeted all major muscle groups two times per week. Exercise safety and joint protection were considered for all participants due to their obesity prior to prescribing specific exercises for each participant.

c) Psychosocial support was provided through cognitive-behavioral therapy (CBT) from a licensed clinical psychologist. To assess psychological readiness for change, stress levels (the Perceived Stress Scale) and body image issues were assessed to determine the psychology needs of each participant. Cognitive-behavioral therapy (CBT) sessions were held once per month during each participant's initial 6month period where each participant would develop goals for making health-related lifestyle changes, strategies for overcoming barriers to making health-related lifestyle changes, strategies for coping with emotional eating and developing resiliency. Group support meetings (containing 6-8 participants each meeting) were held every other month to help provide emotional and social peer support for making healthier lifestyle changes, share similar experiences and remove stigma related to making healthier lifestyle changes. Mindfulness and stress management techniques were also taught at the meetings.

d) Every month, participants from the intervention group will have their study physician determine their participant's weight (using a calibrated scale), blood pressure and symptoms. Once each participant completed the preconception program, the study physician will complete a fasting blood glucose (FBG) and fasting lipids at baseline (first visit) and at the end of the third month of participation in the study.

2) Control Group (Standard Care): The control group will receive one counselling session related to general healthy lifestyle (i.e., healthy eating, why should use folate as a vitamin supplement for good prenatal health and why it is important to be physically active) at their initial visit to the preconception program. Control participants will receive a pamphlet of general information regarding healthy pregnancies. Control participants will not receive structured, repeated and/or supervised intervention during the preconception program. Control participants are encouraged to seek routine prenatal care from their primary care provider as soon as they are informed of their pregnancy.

Follow-up and Outcome Measurement

For all participants (IG and CG), a positive urinary pregnancy test (confirmed by serum beta-hCG) triggered an exit from the preconception phase of the study. They were then followed through pregnancy as per standard antenatal care protocols, with additional research-specific data collection at key timepoints.

- **Baseline Data:** Demographic details, medical and obstetric history, anthropometry (height, weight, waist circumference), blood pressure, and fasting blood samples.
- **Preconception Phase Data (IG only):** Monthly adherence logs (diet diary, activity log), session attendance, and weight change.
- **Pregnancy Follow-up Data (All participants):** Research staff, blinded to allocation, extracted data from medical records at 28 weeks gestation and after delivery. At 28 weeks, participants completed the Edinburgh Postnatal Depression Scale (EPDS) and the Generalized Anxiety Disorder-7 (GAD-7) questionnaire.
- **Delivery and Neonatal Data:** Extracted from delivery and pediatric records included: gestational age at delivery, mode of delivery, maternal complications (GDM diagnosed via 75g OGTT using IADPSG criteria, preeclampsia defined by ISSHP criteria), birth weight, birth length, head circumference, Apgar scores at 1 and 5 minutes, and admission to the neonatal intensive care unit (NICU).

Statistical Analysis

All analyses were conducted using version 27.0 of SPSS software according to the intention-to-treat principle, which included all participants randomized into their assigned groups. Continuous variables with a normal distribution were reported with descriptive statistics as the mean and standard deviation, while skewed continuous variables were reported as the median and interquartile range and categorical variables were reported by frequency and percentage. Independent t-test or Mann-Whitney U test comparing two groups were done to compare continuous variables; chi-square or Fisher's exact test were used to compare categorical variables. The relative risk (RR) and a 95% confidence interval (CI) were calculated for the primary outcome and primary key secondary outcome of interest. A two-sided p-value of < 0.05 was interpreted as

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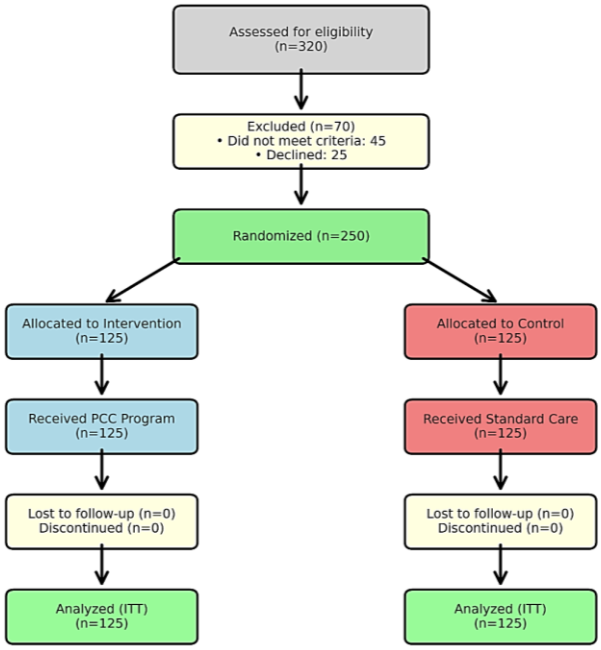
Vol. 36 Issue 1, 2026, Pages 4843-4847

statistically significant. An additional analysis was pre-planned as a per-protocol analysis, which included only those individuals who attended at least 80% of the sessions in the intervention and got pregnant within 12 months post-randomization. No interim analyses have been completed during this study.

Figure 1: CONSORT Flow chart



Results: Of 320 women assessed, 250 were randomized (IG=125, CG=125). Baseline characteristics were comparable (Table 1).

Table 1: Baseline Characteristics of Participants

Characteristic	Intervention Group (n=125)	Control Group (n=125)	p-value
Age (years), mean (SD)	29.4 (4.1)	30.1 (3.8)	0.15
BMI (kg/m²), mean (SD)	34.2 (3.5)	33.9 (3.7)	0.52
Nulliparous, n (%)	78 (62.4)	75 (60.0)	0.69
Family history of diabetes, n (%)	45 (36.0)	48 (38.4)	0.69

The primary composite outcome occurred in 28.8% (36/125) of the IG versus 48.0% (60/125) of the CG (Relative Risk [RR] 0.60, 95% CI 0.43-0.84; p=0.002). Significant differences were observed in rates of GDM (IG: 12.0% vs CG: 24.8%, p=0.008) and preeclampsia (IG: 4.8% vs CG: 12.0%, p=0.04). Rates of preterm birth and macrosomia were lower in the IG but did not reach statistical significance (Table 2).

Table 2: Primary and Secondary Pregnancy Outcomes

Outcome	Intervention Group (n=125)	Control Group (n=125)	RR (95% CI)	p-value
Composite Outcome	36 (28.8%)	60 (48.0%)	0.60 (0.43-0.84)	**0.002**
Gestational Diabetes	15 (12.0%)	31 (24.8%)	0.48 (0.28-0.84)	**0.008**
Preeclampsia	6 (4.8%)	15 (12.0%)	0.40 (0.16-1.00)	**0.04**
Preterm Birth	8 (6.4%)	13 (10.4%)	0.62 (0.26-1.44)	0.26
Macrosomia	10 (8.0%)	16 (12.8%)	0.63 (0.30-1.32)	0.22
Mean Birthweight (g), (SD)	3250 (420)	3450 (510)	-	**0.001**
Apgar <7 at 5 min, n (%)	3 (2.4%)	7 (5.6%)	0.43 (0.11-1.62)	0.20

Women in the IG achieved a significant reduction in pre-conception BMI (-1.8 kg/m², SD 1.2) compared to the CG (-0.3 kg/m², SD 0.8; p<0.001). At 28 weeks gestation, the IG also had significantly lower median scores for depression (EPDS: 6 vs 9, p=0.003) and anxiety (GAD-7: 5 vs 8, p=0.001).

Figure 2: Comparison of Pregnancy outcomes

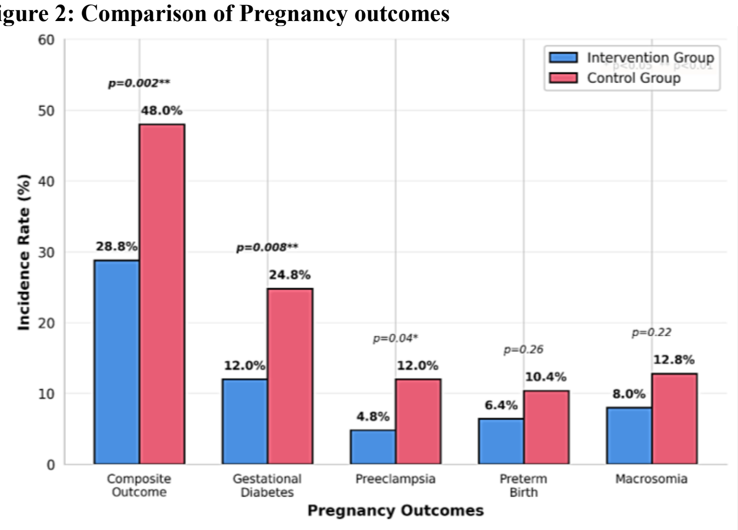


Figure 3: Change in BMI from Baseline to Conception

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Vol. 36 Issue 1, 2026, Pages 4843-4847

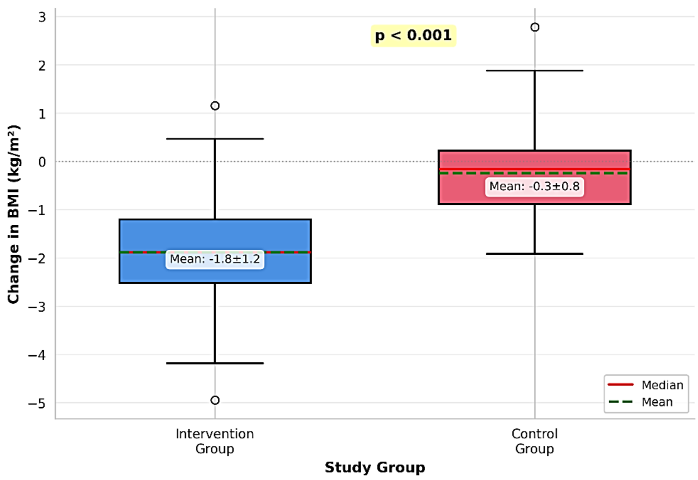
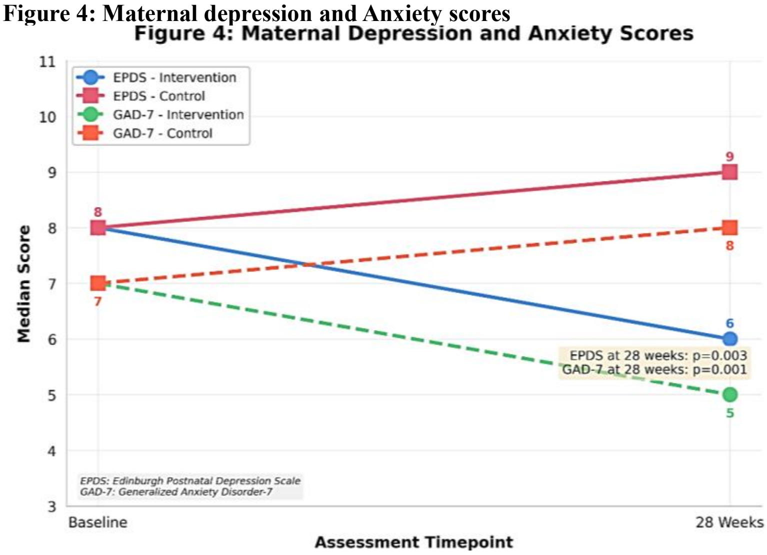


Figure 4: Maternal depression and Anxiety scores



Discussion

The results of this randomized controlled trial support a structured multidisciplinary method to preconception care that provides strong support for improving pregnancy outcomes with women who have high BMI (obese) prior to conception. The 40% relative decrease in the occurrence of the primary composite adverse outcome (RR 0.60) demonstrates that this reduction is more than just statistically significant; it is clinically significant and indicates the opportunity for the prevention of a large amount of future morbidity. The success of the program illustrates that the physiological environment during the moment of conception establishes the foundation for the entire pregnancy. By actively changing the environment (through the stabilization of body weight, improvement of metabolic function and emotional well-being) with the intervention, we may have recalibrated the potential for risk.The most impressive benefit observed in this study was that the incidence of Gestational Diabetes Mellitus (GDM) was cut in half within the intervention group. This finding aligns well with the understanding of how GDM develops according to the natural processes of insulin resistance caused by obesity and exacerbated by the release of the placental hormones during pregnancy, leading to overwhelming the capacity of the beta cells in the pancreas to produce insulin. The preconception care program likely occurred on two levels. The first was through the use of a caloric controlled diet and regular physical activity prior to pregnancy to improve insulin sensitivity in both the skeletal muscle and liver. Second, a modest weight loss (mean -1.8 kg/m²) prior to pregnancy resulted in a decrease in the inflammatory changes in the adipose tissue, a major contributor to insulin resistance. The proactive nature of the metabolic optimization of participants in this study is in stark contrast to the usual standard of care, which does not typically initiate GDM screening until the second trimester of pregnancy, well after many of the metabolic factors have developed. Our findings also support the meta-analysis of Bennett et al.The findings from the written work, as well as information found in previous studies suggest a positive correlation between lifestyle changes among mothers before pregnancy and the risks of developing gestational diabetes during pregnancy [12]. By changing their lifestyle before becoming pregnant, and improving their metabolic reserves, we believe that mothers have put themselves in a better position to adapt to the changes in insulin resistance seen during pregnancy [12].For mothers that have already given birth or have developed gestational diabetes in previous pregnancies, the intervention developed significant reductions in the risk of developing preeclampsia. We believe that through the improvement of vascular health, the intervention has been able to create enough changes so that mothers have developed the resilience of their vascular systems (such as improved endothelial function, reduction of blood pressure and reduction of systemic inflammation) to be able to handle the significant hemodynamic changes and placental needs during pregnancy and thus reduce their risks of developing preeclampsia [13,14].

Neonatal outcomes should be taken into account as well. While the reduction of frank macrosomia (>4000g) did not reach statistical significance, the statistically significant reduction in mean birthweight (3250g vs 3450g) for babies born to mothers who participated in the intervention demonstrates a substantial shift across the entire distribution of birthweight toward birthweights that did not result from excessive fetal growth. [16]. This reduction in birthweight may be explained by the fact that macrosomia is fundamentally caused by hyperglycemic mothers stimulating hyperinsulinemic fetuses thereby promoting an accelerated rate of growth [16]. Our intervention improved maternal glycemic control and, therefore, appears to have normalised the supply of fuel to fetuses, which allowed those growing in mothers participating in this study to grow appropriately. Macrosomia is linked to a host of health issues, including birth trauma, hypoglycaemia in neonates and the likelihood of childhood obesity and metabolic disease, establishing a cycle of risk that extends across generations [17]. The declining number of participants scoring low Apgar ratings at five minutes after birth, although not statistically significant, suggests a possible positive impact on neonatal transition as well.

One of the secondary outcomes of significant interest was the improvement in maternal psychological well-being. Lower scores on the EPDS and GAD-7 within the intervention group indicate a benefit that goes beyond just the physical components of health. Women who are obese during pregnancy typically experience numerous stressors including weight stigma, fear of complications and body image concerns, which contribute to high rates of depression and anxiety during their pregnancies [18]. Our PCC model's integrated psychosocial support provided a safe space to process and address these issues whilst developing coping strategies and increasing self-efficacy pre-pregnancy, thus providing women with psychological preparation for engaging in healthy behaviours and having satisfaction with their pregnancies [19]. Such a holistic approach, whereby we treat the individual as an entire being versus merely her BMI, represents a more compassionate and likely effective model of care.When compared to the existing literature, our results both confirm previously published findings and expand upon them. Our very strong results support the position posited by Stephenson et al. [8] in their landmark series in The Lancet suggest that the pre-pregnancy timeframe is an unrecognized, but very important point at which to intervene in order to increase the chances of long-term health. They also provide confirmation that the Swain et al. [20] proposal for use of PCC in low-resource countries is a viable intervention to achieve the intended results with a control trial. In addition, they help explain the modest results from trials such as UPBEAT [9], which implemented a robust behavioral intervention, but began afterwards when women were already pregnant (an average of 18 weeks into gestation). Our trial provides evidence that the pre-pregnancy or preconception time may be a more potent point of leverage than the pregnancy period for effecting change, as patterns of living are historically set before the exhaustion and physical exertion of being at an advanced stage of pregnancy.

Our study has limitations. A single-site study, generalizability of study findings to other populations/healthcare delivery models through multi-center replication is required for confirmation. Due to the nature of behavioral interventions, our lack of blinding of participants may have introduced performance bias (although the outcome assessors' blinding negated the possibility of detection bias). Our study's assessment of participants concluded at delivery, meaning that we were unable to assess long term postpartum retention of weight, the mother's cardiometabolic health and child's development will be areas of research that warrant further investigations. Moreover, the program's delivery involved considerable resources including dietitians, physiotherapists and counselors; and therefore, additional cost-effectiveness studies are required before the program can be feasibly scaled.In spite of these limitations, there are numerous strengths associated with this study. Specifically, the outcome of this study represents a very high degree of validity due to the fact that the study population was recruited using a prospective design (RCT) ii) I/T/T analysis and iii) endpoint assessment of validity was accomplished with blinding of endpoint assessors' to group assignment of the patients under assessment. The multiple-component program represents the multifaceted cause(s) of obesity and related health issues; thus, it also demonstrates that this is a practical and all-encompassing approach. Further, adherence to the program as evidenced by a minimal dropout rate suggests that the program was both acceptable and feasible for participants.This study illustrates that investing in the health of women with obesity prior to pregnancy provides substantial continued benefits for both mother and child. Specific to this study, participation in a systematic PCC program reduced the estimated odds of suffering from serious complications of pregnancy, facilitated better weight gain for the fetus, and improved the mental well-being of mothers. The findings of this study suggest that the traditional way of defining the first prenatal visit as the starting point for care, should be re-evaluated; instead healthcare systems should emphasize identifying, advising, and assisting obese women of reproductive age through the preconception period. To aid in this effort, healthcare systems will need to improve patient education, referral patterns, and potentially have specific preconception clinics. By redefining the preparing for pregnancy as a positive, therapeutic experience, we may be able to stop the intergenerational cycle of obesity and related health issues and create healthier mothers and children.

Conclusion

The implementation of a multi-component, interdisciplinary pre-conceptual care program including diet, exercise and psycho-social support is associated with reduced risk of adverse pregnancy outcomes among women who are obese. The provision of improved metabolism and psychological health services before conception will result in lower rates of gestational diabetes mellitus, eclampsia, and fetal overgrowth. This evidence is further evidence that formalized, multidisciplinary counseling and intervention for pre-conception care for obese women attempting to conceive should be included in standard of care pathways.

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