The Treatment of Obese Pregnant Women (TOP) study: a randomized controlled trial of the effect of physical activity intervention assessed by pedometer with or without dietary intervention in obese pregnant women

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OBJECTIVE: The objective of the study was to assess physical activity intervention assessed by a pedometer with or without dietary intervention on gestational weight gain (GWG) in obese pregnant women by comparing with a control group.

STUDY DESIGN: This study was a randomized controlled trial of 425 obese pregnant women comparing 3 groups: (1) PA plus D, physical activity and dietary intervention (n = 142); (2) PA, physical activity intervention (n = 142); and (3) C, a control group receiving standard care (n = 141). All participants routinally in gestational weeks 11-14 had an initial dietary counseling session and were advised to limit GWG to less than 5 kg. Physical activity intervention included encouragement to increase physical activity, aiming at a daily step count of 11,000, monitored by pedometer assessment on 7 consecutive days every 4 weeks. Dietary intervention included follow-up on a hypocaloric Mediterranean-style diet. Instruction was given by a dietitian every 2 weeks. The primary outcome measure was GWG, and the secondary outcome measures were complications of pregnancy and delivery and neonatal outcome.

RESULTS: The study was completed by 389 patients (92%). Median values of GWG (ranges) were lower in each of the intervention groups (PA plus D, 8.6 [−9.6 to 34.1] kg, and group PA, 9.4 [−3.4 to 28.2] kg) compared with the control group (10.9 [−4.4 to 28.7] kg [PA + D vs C]; P = .01; PA vs C; P = .042). No significant difference was found between the 2 intervention groups. In a multivariate analysis, physical activity intervention decreased GWG by a mean of 1.38 kg (P = .040). The Institute of Medicine’s recommendations for GWG were more frequently followed in the intervention groups.

CONCLUSION: Physical activity intervention assessed by pedometer with or without dietary follow-up reduced GWG compared with controls in obese pregnant women.

BACKGROUND AND OBJECTIVE

Obesity and high gestational weight gain (GWG) are predictors of obesity in infancy and adulthood. This study of obese pregnant women was designed to measure the effect on GWG of an inexpensive physical activity intervention assessed by pedometer with or without dietary intervention vs controls.

MATERIALS AND METHODS

A prospective randomized controlled trial was conducted from March 2009 through March 2012 at Hvidovre Hospital, University of Copenhagen. All pregnant women with a prepregnancy body mass index (BMI) of 30 kg/m² or greater were offered one consultation with a dietitian during gestational weeks 11-14. The consultation consisted of an individual recommendation of a hypocaloric low-fat diet of 1200-1675 kcal, corresponding to a Mediterranean-style diet based on Danish national recommendations for a healthy diet. Eligible women were asked to participate in the study. All participants were advised by the dietitian to aim for a GWG less than 5 kg, found safe in other studies.

Women were randomized in equal numbers into 3 groups. The physical activity and dietary intervention (PA plus D) group received mixed intervention with follow-up on dietary advice and encouragement to increase physical activity as assessed by a pedometer. The physical activity (PA) group was encouraged to increase physical activity as assessed by a pedometer. The control group (C) received the usual hospital standard regimen for obese pregnant women.

The women allocated to physical activity were individually advised and encouraged to increase physical activity, aiming at a daily step count of 11,000. Physical activity was monitored by a validated pedometer provided to each participant. Daily step counts were registered on 7 consecutive days every 4 weeks.

Dietary intervention consisted of contact with an experienced dietitian every...
2 weeks, alternating between outpatient visits and phone contact (11-13, depending on length of gestation). Follow-up included measurement of weight, encouragement, and dietary advice if weight gain was greater than aimed for or the participant reported an incorrect diet.

**RESULTS**

Of 758 eligible women, 425 participated and 389 completed the study. Median (range) GWG was 8.6 (−9.6 to 34.1) kg in the PA plus D group, 9.4 (−3.4 to 28.2) kg in the PA group, and 10.9 (−4.4 to 28.7) kg in the C group (P = .024). Each intervention resulted in lower GWG than in controls (PA plus D vs C, P = .01; PA vs C, P = .042).

Pedometer-assessed physical activity intervention minimized GWG by a mean of 1.38 kg compared with women not assigned to pedometer (P = .040). GWG less than 5 kg was obtained by 26% in PA plus D, 22% in PA, and 17% of controls (P = .068). The GWG of a maximal 9 kg was obtained in 55% of PA plus D, 49% of PA, and 37% of controls (P = .013) (Figure). Obstetric and neonatal outcomes in the 3 intervention groups were similar except for a lower rate of emergency cesarean section in PA plus D (P = .015).

We stratified participants into 3 groups according to whether they achieved GWG less than 5 kg (n = 81), followed the Institute of Medicine (IOM) recommendation of a GWG of 5-9 kg (n = 95), or exceeded the IOM recommendation of maximal GWG of 9 kg (n = 200). Birthweight was significantly related to increased maternal weight gain (P = .005).

The risk of having a macrosomic child was lower among mothers with a GWG less than 5 kg than those with higher GWG. The risk of having an infant that was small for gestational age was not significantly related to a GWG less than 5 kg.

**COMMENT**

The pedometer intervention is an inexpensive method for increasing physical activity that is more easily implemented in daily life than attending classes. The reduction in median weight gain in the intervention vs control groups was significant but modest, perhaps because of the wide ranges. Motivation was a challenge; if we had measured only the effect on participants who complied with the prescribed intervention, weight reduction might have been more pronounced. The power may also have been too low to detect an effect on pregnancy complications.

The pedometer, which measured almost all physical activity during the day, was not only a tool to promote increased physical activity in daily life but also an instrument for assessing individual physical activity. In an observational study of physical activity during pregnancy performed in the same department as the present study, women with a BMI of 30 kg/m² or greater performed an average of 6500, 7400, and 4600 steps/d in gestational weeks 13, 21, and 37. In the present interventional study, women performed, on average, 8800, 8500, and 6000 steps/d, revealing an obvious effect on behavior.

A recent metaanalysis concluded that intervention reduced GWG and that diet intervention was more effective than physical activity intervention alone or mixed intervention. In our study, the reduction of GWG was 2.3 kg in the group receiving regular dietary and pedometer intervention and 1.5 kg in the group receiving only pedometer intervention compared with controls. However, the additive effect of the dietary intervention was not significant. All participants had an initial dietary counseling session; we measured only the effect of dietary follow-up.

Large longitudinal prospective studies with detailed descriptions of different dietary interventions and on physical activity are needed. Ideally, studies on interventions or methods such as gastric bypass for prepregnancy weight loss should be performed.

Physical activity intervention assessed by a pedometer with or without dietary follow-up reduced gestational weight gain (GWG) in obese pregnant women and should be recommended.

- The effect of the intervention on median weight gain was modest, but a significantly smaller number in the intervention groups exceeded the Institute of Medicine recommendations of a GWG of 5-9 kg for obese women.

- In obese women, GWG less than 5 kg seemed to result in an appropriate birthweight and to protect against having a macrosomic child.

- Large longitudinal prospective studies with detailed descriptions of various dietary interventions and physical activity are needed.