Physical exercise programme during pregnancy decreases perinatal depression risk: a randomised controlled trial

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ABSTRACT

Introduction The incidence of depression is high during the perinatal period. This mood disorder can have a significant impact on the mother, the child and the family.

Objective To examine the effect of an exercise programme during pregnancy on the risk of perinatal depression.

Methods Healthy women who were <16 weeks pregnant were randomly assigned to two different groups. Women in the intervention group participated in a 60 min exercise programme throughout pregnancy, 3 days per week, which was conducted from October 2014 to December 2016. The Center for Epidemiological Studies-Depression Scale was used to measure the risk of depression at the beginning of the study (12–16 weeks), at gestational week 38 and at 6 weeks postpartum.

Results One hundred and twenty-four pregnant women were allocated to either the intervention (IG=70) or the control (CG=54) group. No differences were found in the percentage of depressed women at baseline (20% vs 18.5%) (χ2=0.043; p=0.836). A smaller percentage of depressed women were identified in the IG compared with the CG at 38 gestational weeks (18.6% vs 35.6%) (χ2=4.190; p=0.041) and at 6 weeks postpartum (14.5% vs 29.8%) (χ2=3.985; p=0.046) using the per-protocol analysis. No significant differences were found using the intention-to-treat analyses, except in the multiple imputation analysis at week 38 (18.6% vs 34.4%) (χ2=4.085; p=0.049).

Conclusion An exercise programme performed during pregnancy may reduce the prevalence of depression in late pregnancy and postpartum.

Trial registration number NCT02420288; Results.

INTRODUCTION

Perinatal depression may be experienced by some women at any time during pregnancy or within 12 months after giving birth.[1] Depressive symptoms are common during pregnancy and can increase the risk of postpartum depression and other poor health outcomes in both the mother and the offspring.[2–4] The prevalence of prenatal depression ranges from 5% to 20%,[1] and the prevalence remains high after giving birth. Postpartum depression affects approximately 10%–19% of women after childbirth.[5 6]

The symptoms of perinatal depression often begin during pregnancy,[1 7] and thus prenatal symptoms are considered a risk factor for postnatal depression.[8 9] Risk factors also include previous depression,[10–12] depression in a prior pregnancy,[9 13] emotional instability,[14] lack of social support,[10 11 15] stressful life events, maternal anxiety and low socioeconomic status.[6 10 11]

When this depressive disorder is diagnosed, pharmacological treatment is one of the most frequently used options. However, balancing the risks and benefits of antidepressant medications with the risk of untreated depression is difficult during pregnancy and lactation.[16] Furthermore, a majority of breastfeeding mothers are reluctant to take antidepressant medications because of concerns of possible harm to their baby.[17 18] For this reason, different types of interventions have been designed to examine the prevention of perinatal depression and alternatives to pharmacological treatment,[19] but little has been studied about the effect of exercise during pregnancy on postpartum depression.[20–23] Several epidemiological data support an association between exercise and a decreased risk of depressive symptoms,[24 25] and some studies have shown that prenatal exercise is associated with less prenatal depressive symptoms.[9 26–33] Even after pregnancy, exercise has been proposed as a non-pharmacological intervention with the potential to alleviate postpartum depression.[34–37] However, it is also important to prevent the onset of this type of disorder, especially in high-risk populations such as pregnant women.[38]

Exercise has many advantages, besides general health benefits. Exercise is low-cost and is readily available,[39] and there is considerable evidence that suggests it has a positive influence on the health of pregnant women.[40–43] Engaging in exercise during pregnancy has shown multiple benefits for the mother and the baby,[44–47] but few clinical trials have been conducted to determine its impact on postpartum depression.[20 21] Therefore, the aim of this study was to evaluate the effect of a structured exercise programme initiated during early pregnancy on mood status during late pregnancy and postpartum. We hypothesised that exercise during pregnancy would reduce the symptoms of depression during late pregnancy and in turn during the postpartum period.

METHODS

Study design and recruitment

The present study was a randomised controlled trial (RCT) (identifier: NCT02420288) conducted from October 2014 to December 2016 in Madrid, Spain.

Information about the study was given by the attending obstetrician to women with a singleton pregnancy who were <16 weeks pregnant. Women interested in participating contacted the investigators

by email or phone, and an information meeting was arranged. According to the exclusion criteria, women with a maternal age <18 or >45 years and those not under medical follow-up throughout their pregnancy at the referral hospital were not included in the study. Women were also excluded if they had any of the following serious medical conditions: cardiovascular, respiratory or systemic serious disorders, persistent second or third trimester bleeding, placenta previa, ruptured membranes, risk of premature labour, pregnancy-induced hypertension or pre-eclampsia, and an incompetent cervix. All participants provided signed written informed consent prior to participating in the study.

A simple randomisation was performed with the Epidat V.3.1 program to allocate the participants into two groups in order of entry: intervention group (IG) and control group (CG). For this, a computer-generated list of random numbers (n=200) was created through the Epidat option of balanced groups (similar but not of equal size).

Characteristics of the participants

The participants had an initial meeting before gestational week 16, where they provided data about parity, prepregnancy and current physical activity (frequency, intensity, time and type (FITT)), smoking status, educational level, occupational activity, and previous prenatal depression. The medical records were provided by the hospital.

Between weeks 37 and 39, all women were interviewed regarding the level of physical activity performed during pregnancy (FITT) and if they had any pregnancy complications. At 6 weeks postdelivery, the women were asked if they had any postpartum complications.

Body mass index (BMI) and maternal gestational weight gain (GWG) were used for a complementary stratified analysis. BMI was calculated by dividing the prepregnancy weight (kg) by height (m^2), and women were classified as underweight (BMI <18.5 kg/m^2), normal weight (BMI ≥18.5 to 24.9 kg/m^2), overweight (BMI ≥25 to 29.9 kg/m^2) or obese (BMI ≥30 kg/m^2). GWG from the beginning to the end of the pregnancy was provided by the hospital and categorised using prepregnancy BMI as excessive or adequate. Excessive GWG was defined as a weight gain of >18.0 kg for underweight, >16.0 kg for normal weight, >11.5 kg for overweight and >9.0 kg for obese women, according to the Institute of Medicine recommendations.[48]

All women who participated in the study received usual care from health professionals of the hospital and the general recommendations of nutrition and exercise. In addition, women who were randomly allocated to the IG participated in a specific exercise programme designed for healthy pregnant women.

Exercise intervention (IG)

The exercise intervention programme took place in a fitness room inside the hospital and consisted of three sessions per week from 12 to 16 gestational weeks to the end of the third trimester (weeks 38–40). In the event of no preterm delivery, between 66 and 78 sessions were planned for each participant. To facilitate compliance with the programme, two to three daily sessions were offered four weekdays a week between 17:00 and 20:00. The exercise programme was designed according to the standards of the American College of Obstetricians and Gynecologists[40] and was similar to our other studies.[28 29 46 47]

Women used the Polar FT7 heart rate monitor (Polar, Kempele, Finland) to maintain a heart rate intensity of 55%–60% of heart rate reserve using the Karvonen formula in the aerobic part of the session.[49] In addition, the Borg Rate of Perceived Exertion (RPE) scale was used.[50]

Each session lasted 60 min, distributed as follows: a 10 min warm-up consisting of 5 min walking and 5 min light static stretching of most muscle groups and joint mobility exercises; 25 min aerobic exercise developed at a moderate intensity through different choreographies; 10 min muscle strengthening exercises; 5 min of coordination and balance; 5 min pelvic floor exercises; and at the end of each session, 5–10 min were devoted to stretching and relaxation. The sessions were conducted in groups of 10–12 participants and were supervised by a qualified fitness specialist.

Exercises where there were extreme stretches, Valsalva manoeuvre, ballistic movements and jumps were avoided. The exercises performed in the supine position did not exceed 2 min in duration.

Adherence to the exercise programme was measured by registering the attendance of the participants at each of the sessions.

Participant involvement

Interviews were carried out with the participants from previous studies[46 47] to know the personal contributions of and experiences in the exercise programme, among which psychological well-being was mentioned. The burden of the intervention was assessed by participants through the RPE scale every session in order to make individual adaptations. Participants were not involved in the design, recruitment and conduct of the study. The results will be disseminated to study participants through a summary of the results, an abstract in Spanish and a link to the publication on the journal's website.

Outcome

Depression levels were assessed using the Center for Epidemiological Studies-Depression (CES-D) Scale at the beginning of the study (weeks 12–16), at the end of pregnancy (week 38–39) and at 6 weeks postdelivery. This questionnaire was developed by the National Institute of Mental Health. It consists of 20 items that assess the different aspects of depressive symptomatology. According to symptom frequency, each response ranges from 0 (never) to 3 (most days). The score is the sum of the 20 weighted items, and the range of scores is 0–60. If more than four items are missing, the test cannot be considered. A score ≥16 indicates depression. This scale is widely used and has been used in pregnant populations.[28 29 31 33 35] The scale has been translated and validated in Spanish, and it has a high correlation with several scales, with a validity of between 0.69 and 0.89, a responsiveness of 0.95, a specificity of 0.66 and a reliability of 0.9.[51]

Statistical analysis

Descriptive statistics, including mean and SD for quantitative variables and percentage for categorical variables, were calculated to examine the maternal characteristics and CES-D scores at baseline. To examine if there were differences between groups at baseline, the χ^2 test and Student's t-test were used for categorical and quantitative variables, respectively.

For comparison between groups, the χ^2 test was also used to analyse the percentage of depressed women at three time points and the level of exercise performed during pregnancy. A repeated-measure analysis of variance was used to assess the CES-D scores between the IG and the CG at three time points, and analysis of covariance was used to adjust for possible baseline confounders (BMI, smoking and exercise before pregnancy).[52]

A per-protocol analysis was performed with the women who completed the questionnaires, with additional stratification according to pregestational BMI and GWG. An analysis

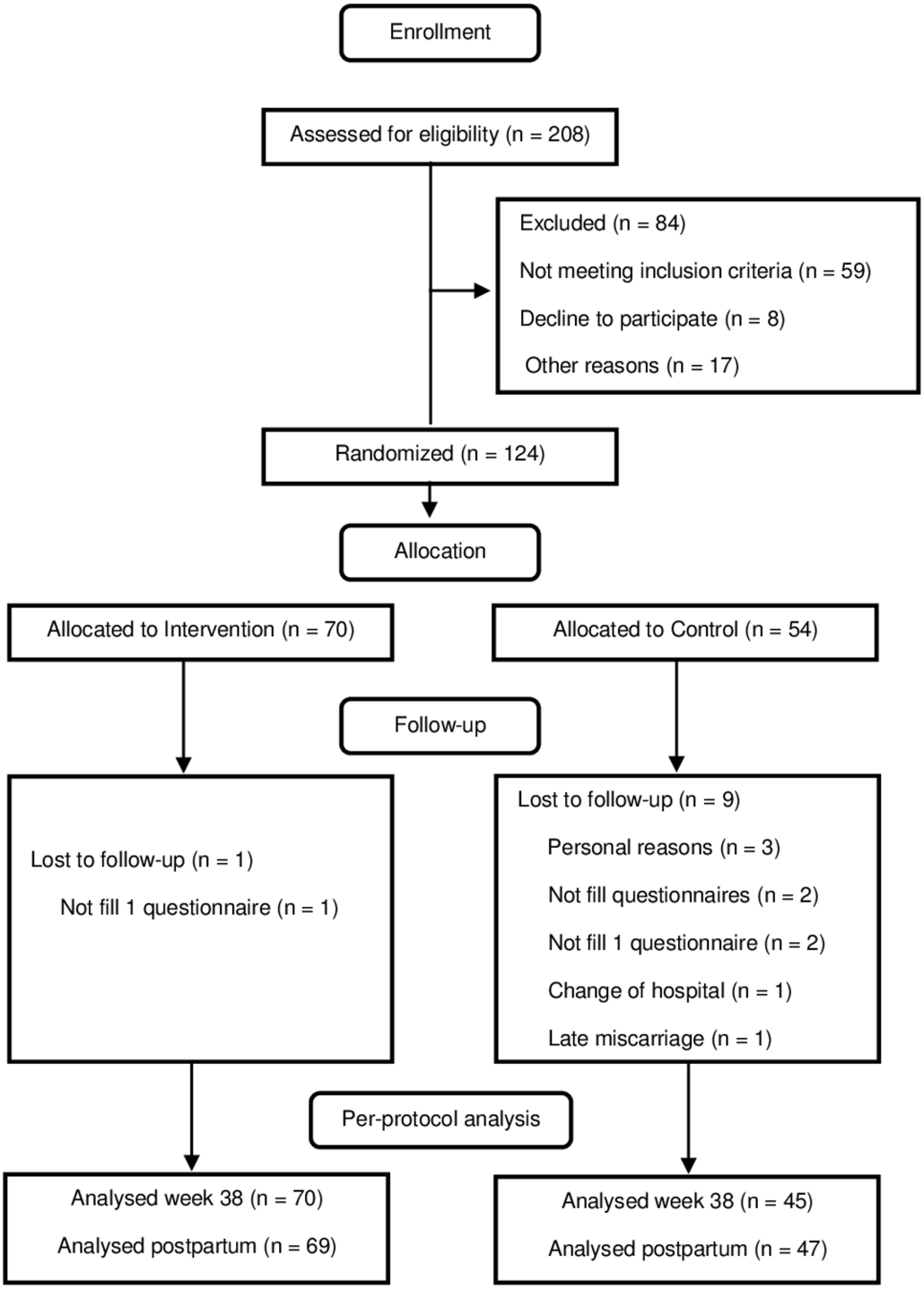

Figure 1 Flow diagram.

by intention-to-treat was also performed using two different methods.[53] In the first method (simple imputation), the mean of the outcome of the entire group was inserted for missing values in the quantitative variables (CES-D score), and the percentage of the entire group was followed to assign new values in the categorical variables (CES-D result). In the second method, the statistical technique of multiple imputation was conducted to impute lost data values automatically (five imputations) and calculate the average of the five files.

Study analyses were performed using the Statistical Package for Social Sciences (SPSS) V.20.0 data software.

Sample size calculation

To detect a 25% reduction in the percentage of depressed women in the IG compared with the CG during the postpartum period, with a two-sided 5% significance level and a power of 80%, a sample size of 50 pregnant women per group was necessary given an anticipated dropout rate of 15%.[54]

RESULTS

A total of 208 women contacted the investigators. One hundred and twenty-four pregnant women met the inclusion criteria and were randomly allocated into IG (n=70) and CG (n=54).

Table 1 Maternal characteristics of intervention and control groups at the beginning of the study

	Intervention (n=70)	Control (n=54)
Maternal characteristics		
Maternal age (years)	33.3±2.9	32.3±5.0
BMI (kg/m^2)	23.0±3.7	23.9±5.0
Walk (min/week)	414.4±401.7	418.0±461.1
Standing (min/day)	242.6±144.0	216.9±137.9
CES-D score	11.0±7.7	10.06±6.8
Depression (CES-D), n (%)		
Yes	14 (20.0)	10 (18.5)
No	56 (80.0)	44 (81.5)
BMI categories, n (%)		
Underweight	5 (7.1)	4 (7.4)
Normal weight	50 (71.4)	35 (64.8)
Overweight	9 (12.9)	8 (14.8)
Obese	6 (8.6)	7 (13.0)
Occupational activity, n (%)		
Unemployed/Home maker	16 (22.9)	12 (22.2)
Sedentary job	32 (45.7)	22 (40.7)
Active job	22 (31.4)	20 (37.0)
Level of education, n (%)		
Elementary school	6 (8.6)	3 (5.6)
High school/College	30 (42.9)	22 (40.7)
University	34 (48.6)	29 (53.8)
Previous physical activity habits, n (%)		
Sedentary	30 (42.8)	32 (59.3)
2 days/week	22 (31.4)	16 (29.6)
3–4 days/week	18 (25.7)	6 (11.1)
Parity, n (%)		
None	49 (70.0)	40 (74.1)
1	21 (30.0)	14 (25.9)
Previous postnatal depression, n (%)	0 (0)	0 (0)
Smoking before pregnancy, n (%)		
Yes	18 (25.7)	22 (40.7)
No	52 (74.3)	32 (59.3)
Smoking during pregnancy, n (%)		
Yes	5 (7.1)	8 (14.8)
No	64 (91.4)	45 (83.8)
Previous miscarriage, n (%)		
None	55 (78.6)	42 (77.8)
1	8 (11.4)	10 (18.5)
2	7 (10.0)	2 (3.7)

There are no statistical differences between groups at baseline (p>0.05). Data are expressed as mean±SD unless otherwise indicated.
BMI, body mass index; CES-D, Center for Epidemiological Studies-Depression Scale.

After randomisation, seven participants in the CG were lost, and two participants who finished the study did not complete the questionnaire at week 38. A participant in the IG did not complete the questionnaire at week 6 postpartum (figure 1). For the intention-to-treat analysis, these participants were taken into account following the procedure mentioned in the Methods section.

Maternal characteristics

Personal data were collected from all the participants at the beginning of the study (table 1), and no statistical differences were found between groups (p>0.05). No significant differences were identified in the percentage of women who started the study with prenatal depression according to the CES-D questionnaire (20% vs 18.5%) (χ^2=0.043; p=0.836). Likewise, both groups started the study without significant differences in CES-D scores (t_{122}=0.724; p=0.470).

At the end of the study no significant differences were found in the level of daily physical activity during pregnancy between groups (χ^2=2.214; p=0.529), excluding the exercise developed in the intervention programme.

Table 2 Incidence of depression throughout the perinatal period according to CES-D

	Intervention	Control	P values
Depressed women in the per-protocol analysis, n (%)			
Baseline (n=124)	14 (20.0)	10 (18.5)	0.836
Gestational week 38 (n=115)	13 (18.6)	16 (35.6)	0.041
Week 6 postpartum (n=116)	10 (14.5)	14 (29.8)	0.046
Depressed women in the intention-to-treat analysis (n=124), n (%)			
Simple imputation analysis			
Baseline	14 (20.0)	10 (18.5)	0.836
Gestational week 38	13 (18.6)	18 (33.3)	0.060
Week 6 postpartum	11 (15.7)	16 (29.6)	0.063
Multiple imputation analysis			
Baseline	14 (20.0)	10 (18.5)	0.836
Gestational week 38	13 (18.6)	19* (34.4)	0.049
Week 6 postpartum	12 (17.1)	17* (30.7)	0.079

*These values reflect the average of 5 files; the real values are 18.6 and 16.6.
CES-D, Center for Epidemiological Studies-Depression Scale.

Adherence and dropout

Among the 70 participants of the IG, the average of attendance to the programme was 69.3% (around 50 sessions). Individually, 65.7% (n=46) of the participants attended more than 70% of the sessions, 22.8% (n=16) attended 30%–55%, and 11.4% (n=8) attended less than 30%.

Significant differences were found in the percentage of participants who dropped out of the study (χ^2=6.72; p=0.01), being 13% (n=7) in the CG compared with 1.4% (n=1) in the IG, based on the data available at 6 weeks postpartum.

Level of depression

The percentage of depressed women was significantly lower in the IG compared with the CG at week 38 (18.6% vs 35.6%) (χ^2=4.190; p=0.041) and at 6 weeks postpartum (14.5% vs 29.8%) (χ^2=3.985; p=0.046) in the per-protocol analysis. However, different results were found in the intention-to-treat analysis according to the method used: no significant differences were found in the simple imputation analysis at week 38 (18.6% vs 33.3%) (χ^2=3.543; p=0.060) and at 6 weeks postpartum (15.7% vs 29.6%) (χ^2=3.465; p=0.063). However, significant differences were found in the multiple imputation analysis at week 38 (18.6% vs 34.4%) (χ^2=4.085; p=0.049), but no differences were found at 6 weeks postpartum (17.1% vs 30.72%) (χ^2=3.202; p=0.079) (table 2).

According to the CES-D scores, a significant treatment effect was found in the per-protocol ($F_{2,220}$=3.798; p=0.024) and in the simple imputation ($F_{2,244}$=3.351; p=0.037) analyses. Significant differences were found in the group–time interaction between gestational weeks 12–16 (baseline) and 6 weeks postdelivery (p=0.014) in the per-protocol analysis, but no significant differences were found between baseline and gestational week

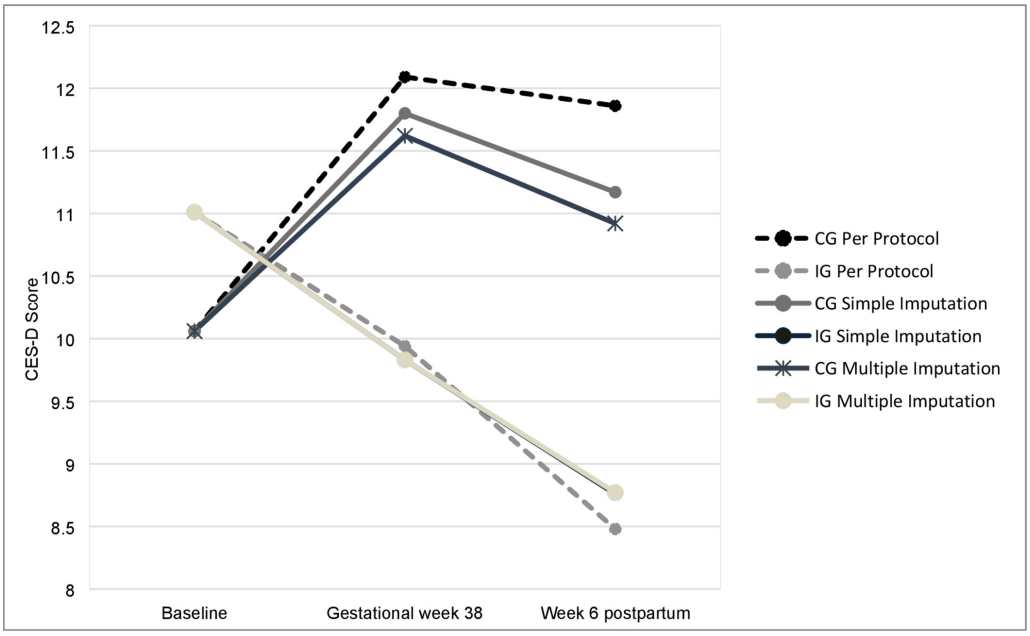

Figure 2 CES-D score at the three time points. CESD-D, Center for Epidemiological Studies-Depression Scale; CG, control group; IG, intervention group.

38 (p=0.066). In the simple imputation analysis, significant differences were found in the group–time interaction between CES-D scores at baseline and gestational week 38 (p=0.046), and between baseline and 6 weeks postdelivery (p=0.025), with a lower CES-D score in the IG than in the CG. No differences were found in the multiple imputation analysis ($F_{2,244}$=2.828; p=0.067) (figure 2).

After adjusting for baseline confounders, the covariables BMI, smoking and physical exercise before pregnancy did not modify the effect of the exposure factor in any of the analyses: per-protocol ($F_{2,214}$=3.654; p=0.028); simple imputation ($F_{2,238}$=3.422; p=0.034); and multiple imputation ($F_{2,238}$=3.007; p=0.0538).

Among women who gained excessive gestational weight, the CG had a significantly higher percentage of women with depression at week 38 (χ^2=9.489; p=0.002) and at 6 weeks postpartum (χ^2=5.202; p=0.023). No differences were found among women with an adequate GWG (p>0.05).

The percentage of depressed women was significantly lower in the IG than in the CG at week 38 among women with prepregnancy normal-weight BMI (χ^2=4,688; p=0.030). No other differences in the percentage of depressed women were found according to prepregnancy BMI at week 38 and at 6 weeks postdelivery (p>0.05).

DISCUSSION

This RCT examined the effects of physical training during pregnancy on the incidence of perinatal depression according to the CES-D Scale. Since the pregnant population has a higher risk of depression, this study aimed to reduce the incidence of depression through prenatal exercise. Indeed, the prevalence of women with postpartum depression was lower in those who attended the exercise programme. Furthermore, as some RCTs have already shown,[28 29 31] the results confirm that an exercise intervention decreases the probability of prenatal depression. Whereas the percentage of depressed women tended to increase among the CG from the beginning to the end of the study, this percentage decreased among women who participated in the exercise programme, and the same trend occurred with the CES-D score.

The reason no significant differences were found in the incidence of depression in the simple imputation analysis may be due to the fact that the majority of women who did not complete the questionnaire belonged to the CG. Because the percentage of the entire group was followed to assign new values in the lost variables, differences between groups decreased. Although no significant differences were found in most of the intention-to-treat analyses, they all showed a similar trend. Therefore, a larger sample size could result in significant differences.

Similarly, no differences were found between the groups according to the pregestational BMI, except among women of normal weight, and this may be due to the small sample size when data were stratified, particularly in the low and high BMI categories.

In the scientific literature, some RCTs have found that exercise during postpartum may protect against postnatal depression[37] and may even be a feasible treatment in women with postnatal depression.[34 55] However, an exercise intervention given during pregnancy may promote the prevention of prenatal and postpartum depression. This study confirms that prenatal exercise can reduce depressive symptomatology in pregnant women, who are at risk for prenatal and postnatal depression. In contrast, two other RCTs studied the effects of exercise during pregnancy on postpartum depression and found no improvements in depressive symptoms.[20 21] In the Songøygard *et al* study,[20] the intervention was shorter (12 weeks) and was conducted between weeks 20 and 36 of pregnancy. Although there were three weekly sessions, only one was attended, while the other 2 days were home exercises. However, they found high prevalence of depression scores in the subgroup of control women who did not exercise regularly before pregnancy. In the Mohammadi *et al* study,[21] there were three groups: a CG and two IGs. Although one of the groups participated in the intervention during pregnancy and postpartum, they found no differences between groups. This could be because the intervention consisted of a 40 min session

where it was recommended to exercise 3 days a week, but there were no guided or structured sessions, and through phone calls most subjects reported they did not regularly exercise. In addition, both studies used a questionnaire different from the present RCT.

Beyond the physiological effects, the psychological aspects are an important part of physical activity. However, as a limitation of the present study, the sessions were in a group setting, and this could have a preventive impact on depressive symptomatology, since these classes also promote socialisation. Therefore, in future studies it would be advisable that the CG has similar socialisation conditions and number of meetings to ensure that the differences found are due only to the exercise intervention. It would also be interesting to assess the effects of individual exercises and to evaluate the motivation of the pregnant population and to relate these factors to depression.

Another limitation of the present study was the size difference between the groups, which can be explained by the simple randomisation method used.[52] Likewise, there was a difference in dropout between the groups, which could be due to the loss of interest in the study among women in the CG due to lack of follow-up, which was 6 visits compared with 50 of the IG.

Finally, postpartum depression was only measured at 6 weeks postdelivery, so we have no information on the following 11 months in which depression may remain latent. Further research is required to determine whether exercise during pregnancy may prevent long-term postnatal depression. Likewise, there is a need to study exercise during pregnancy as a preventive agent and as a treatment among pregnant women who suffer from depression since the beginning of their pregnancy.

In conclusion, structured exercise during pregnancy reduced late prenatal and early postpartum depression. Consequently, exercise should be an important component to promote women's psychological health during the perinatal period.

What are the findings?

- This study is an important contribution to the growing literature on the benefits of exercise for mental health outcomes, focusing on pregnant women, among whom the risk of depressive symptoms is higher than in the general population.

How might it impact on clinical practice in the future?

- This study provides new scientific evidence on devising new strategies to improve women's psychological health during the perinatal period.

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Contributors MVT: had the major responsibility for the intervention programme and the manuscript writing; supervised the field activities including quality assurance and control. RB: director of the study; designed the study's analytic strategy and helped conduct the statistical analyses. BS: codirector of the study; designed the study and the hospital protocol for organisation and data collection; supervision and monitoring of the participants. IF-B: supervised the field activities including quality assurance and control; responsible for the medical supervision and monitoring of the participants, collection and record of data. MFM: coresponsible for the manuscript writing; helped conduct the literature review, the statistical analyses and the English writing.

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Patient consent Not required.

Ethics approval The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. The research protocol was approved by the Research Ethics Committee of the Torrejon University Hospital.

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