Physical activity during pregnancy and depression, anxiety and stress: randomized clinical trials

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BACKGROUND: Pregnancy is not an emotionally stable period; pregnant women could suffer psychological lability influenced by hormonal variation between trimesters of gestation. The COVID-19 pandemic and the lack of social interaction increased this psychological instability, increasing the reported rates of prevalence of depression and anxiety, with its associated maternal and fetal complications. Despite the fact that regular physical activity could help regulate hormonal secretion, during the pandemic, its performance decreased, increasing sedentary rates. Pharmacological treatment could imply potential health risks, so a non-invasive intervention is needed.

OBJECTIVE: To assess the impact of two supervised physical activity programs during pregnancy on prenatal and postnatal depression, anxiety and stress symptoms.

STUDY DESIGN: Two randomized clinical trials were developed, with physical activity programs during pregnancy being carried out, randomizing 564 pregnant women in both the Intervention (n=278) and the Control (n=278) groups, of three different regions (and five health centers) from Spain. Three weekly physical activity sessions, online and in-person were performed until the end of pregnancy, measuring depression (measured with CES-D and EPDS), anxiety (STAI) and stress (PSS) symptoms. SPSS software was used, and independent t tests, U Mann Whitney, Pearson Chi-square and one-way ANOVA analyses were used.

RESULTS: After intervention, results showed a significant reduction in depression symptoms in the Per Protocol (P=.028) analysis, with also fewer cases of symptoms compatible with depression at the end of gestation, in the Intention to Treat (5.9% / 12.4%) and Per Protocol (3.2% / 12.2%) analyses in the intervention group, in comparison with the control group. Additionally, significantly lower scores were found in pregnant women with more than 90% of program attendance in depression (P=.003) and in state anxiety (P=.035) at the end of pregnancy compared with women that not accomplished protocol criteria (<70% attendance). Analysis per trial, revealed significant lower scores in depression (P=.043), state (P=.015), trait (P=.045) anxiety and in the combination of both (P=.021), in IG of the 2nd trial, compared with CG. No significant differences were observed in scores of depression, anxiety or stress during and after pregnancy in the Intention to Treat analysis (P>.05).

CONCLUSION: Supervised physical activity during pregnancy could potentially reduce prenatal depression symptoms at the end of gestation and, comparatively, enhance the effects by greater reducing state anxiety and depression symptoms when adherence is greater than 90%.

Key words: physical activity, supervised exercise, pregnancy, depression, anxiety, stress

Introduction

Pregnancy profoundly impacts the health of both the mother and fetus. Ensuring the optimal functioning of physiological, psychological and emotional mechanisms that facilitate fetal growth is essential. Complications in these areas can lead to disorders affecting maternal and newborn health.[1,2] Pregnancy is a vulnerable period with a high prevalence rate of prenatal stress, anxiety, and depression, being associated with negative outcomes for the newborn.[3]

Depressive symptoms often appear early in pregnancy. Furthermore, prenatal anxiety characteristics often lead to difficulties in decision making and the onset of obsessive thoughts,[4] thus psychological disturbances during pregnancy can affect woman's quality of life.[5,6] These factors are determinants of the overall well-being of pregnant women.

The consequences of these disturbances could imply complications as preterm delivery or delays in physical and cognitive newborn development.[7-9] Additionally, the interaction between personal needs, desires, and societal expectations, along with the motherhood responsibilities, can generate substantial psychological stress, increasing emotional strain.[10,11]

The complications arising from COVID-19 look down, such as lack of group support or reduced mobility, have impacted the pregnant lifestyle[12,13] potentially undermining one of the essential recommendations: to be physically active.[14,15]

Evidence confirms that adopting an unhealthy lifestyle (e.g., sedentary behavior), negatively affects pregnancy and childbirth outcomes, leading to complications during and after pregnancy.[16,17] Unfortunately, the COVID-19 pandemic exacerbated sedentary behavior and its associated risks.[18] Before the pandemic, the prevalence of prenatal mental and emotional disorders was estimated to be between 15-30%.[19] However, the pandemic has significantly worsened it, with 37% and 57% of pregnant women reporting clinically depression and anxiety symptoms, respectively.[20]

The risks associated with pharmacological treatments for mental disorders during pregnancy highlight the need for scientific exploration of non-invasive alternatives, particularly focused on prevention.[21-23]

Recent studies[24] suggest that current lifestyles, compounded by the ongoing

Cite this article as: Sánchez-Polán M, Brik M, Silva-Jose C, et al. Physical activity during pregnancy and depression, anxiety and stress: randomized clinical trials. Am J Obstet Gynecol MFM 2026;8:101835.

2589-9333/$36.00

http://dx.doi.org/10.1016/j.ajogmf.2025.101835

AJOG MFM at a Glance

Why was this study conducted?

This study was developed to help promote physical activity during pregnancy and during and after the COVID-19 pandemic, providing benefits to psychological variables for pregnant women.

Key findings

Symptoms and depression cases were reduced throughout physical activity program, and the greater the adherence to the program, the better the results in terms of depression and anxiety.

What does this add to what is known?

A supervised physical activity program during pregnancy, even combining virtual and in-person sessions, could help reducing symptoms of mental illnesses and beneficing overall pregnant women health.

effects of the COVID-19 pandemic, are increasing the prevalence of mental health disorders during pregnancy. There is a gap of knowledge on interventions during pregnancy that could serve as preventive measures for psychological disturbances.

Scientific evidence supports that physical activity (PA) during pregnancy can help prevent chronic diseases in both the mother and fetus.[25] Although the scientific literature is not conclusive, many studies suggest that a structured PA program during pregnancy positively impacts maternal emotional well-being, showing greater benefits when exercise is supervised.[26,27] Therefore, the objective of this study was to evaluate the effect of supervised PA programs during pregnancy on prenatal and postnatal depression, anxiety, and stress symptoms.

Material and methods

Two parallel and multicentric randomized controlled trials (RCTs) were carried out (registration numbers: NCT04563065; NCT05295264) from 2020 to 2022 (first trial) and from 2022 to 2024 (second).

The PA programs were conducted by the Universidad Politécnica de Madrid, in collaboration with five healthcare centers in Spain: Hospital Universitario Severo Ochoa de Leganés (Madrid), Hospital Universitario Puerta de Hierro de Majadahonda (Madrid), Hospital Universitario de Torrejón (Madrid), Hospital Universitario Vall d'Hebrón (Barcelona) and Clínica Zuatzu (San Sebastián).

The Research Ethics Committee of the Universidad Politécnica de Madrid provided approval for both RCTs, as well as each recruiting health center. The CONSORT (Consolidated Standards of Reporting Trials) guidelines were followed in both RCTs.

Participants

Pregnant women having antenatal care in the recruiting healthcare centers, meeting the following inclusion criteria, were eligible: over 18 years, between 12 and 16 weeks of gestation, without absolute (e.g., multiple gestation) or relative (e.g., anemia) contraindications[14,15,28] for physical activity, evaluated by the medical team and non-participating in another supervised PA program. Participants had to sign an informed consent prior inclusion.

Clinical outcomes of mother, fetus and newborn were collected at each healthcare center, and primary outcomes were reported through a REDCap (Research Electronic Data Capture) project hosted at the Universidad Politécnica de Madrid.[29,30]

Intervention

Women randomly assigned to the Intervention Group (IG) were involved in a supervised PA program during pregnancy until weeks 38-40 (delivery). The program followed the structure of the Barakat model[31] with the following sections: warm-up; aerobic exercises (focused movements with moderate intensity); mild muscle strengthening (with 1-3 kg dumbbells or TheraBand's, focusing on the lower and upper limbs); coordination and balance exercises; pelvic floor muscle strengthening (Kegel slow and fast contractions exercises); cool-down; final talk.

Sessions were developed in group, lasting 60 minutes, and each component was adjusted to the specific requirements of pregnancy trimester.[31] Three weekly sessions were held, and due to COVID-pandemic settings, the program started (in the first trial) with a virtual design of two sessions developed via Zoom software in live, supervised. The third session was recorded to be watched individually, through videoclips uploaded to a private list on YouTube, making available the advices to safely develop them.

As the pandemic progressed, the second trial program was designed as a semi-virtual setting that involved a mandatory weekly and in-person group session at the hospital facilities and two online (using Zoom). In both settings, different schedules were offered, always supervised by PA professionals (PhD students and an undergraduate student, highly experienced). Attendance was monitored per session. Following protocol criteria, women had to attend at least 70% of the sessions performed during pregnancy (60−65 sessions).

PA intensity was set from light to moderate (55−60% of maximum heart rate). Women measured their heart rate with the Karvonen formula (55−65% of reserve heart rate), and the researchers used the Borg scale to perceive exertion (aimed from 12 to 14 levels). Women were constantly advised to maintain adequate hydration, avoid high body temperatures and impact exercises during sessions.

Participants randomized to the Control Group (CG) received regular antenatal care in a collaborator healthcare center, without involving them in the PA program. They received evidence-based monthly materials that promoted healthy habits with information on the regular course of pregnancy. To measure the development of PA in CG, a decision algorithm was administered

quarterly through REDCap.[32] Participants in CG shouldn't exceed the minimum considered physically active.[14]

For both groups, data from women with a medical diagnosis of prenatal mental disease were discarded for analysis following the protocol criteria.

Outcomes

Clinical and sociodemographic information on maternal and fetal health was provided by the team medical doctors. Primary outcomes were evaluated via e-mail, through REDCap, directly sent to the participant who self-answered.

Primary outcomes: retrieved immediately after randomization, at week 37, and at week 6 postpartum (except EPDS, which was evaluated at week 28 during pregnancy and at the sixth week after pregnancy). All questionnaires indicate the higher the score, the greater the depression, anxiety or stress symptoms.

- Depression questionnaires: Center for Epidemiological Studies Depression Scale (CES-D) was assessed with 20 questions, scored from 0 to 60. When result was ≥16, could be related to depression symptoms.[33] Edinburgh Postnatal Depression Scale (EPDS) was also used, with 10 questions and scored from 0 to 30 (≥10 were considered 'symptoms of depression').[34] An EPDS ≥10 and/or CES-D ≥16 score was considered as diagnosis of depression for study purposes.
- Anxiety: State-Trait Anxiety Inventory (STAI) questionnaire (40 items) was used to measure anxiety. This questionnaire divided into two subscales (trait and state anxiety), thus having three different results. The anxiety disorder was considered when: state anxiety (STAI-S) (≥41); trait anxiety (STAI-T) (≥44); total sum (STAI-TOTAL) (≥85).[35]
- Stress: Perceived Stress Scale (PSS) with 10 items was used, dividing the score into three different cut-offs: 0−13 considered as low stress; 14−26 as moderate stress; 27−40 as high perceived stress.[36]

Secondary outcomes: maternal age, height, weight and BMI (baseline and end on intervention measured), ethnicity, job occupation, parity, history of previous miscarriages, gestational week of delivery, weight gain and excessive weight gain during pregnancy, type of delivery, episiotomy or perineal tear (and degree). Infant outcomes were birth weight, length, head circumference, and measures of the APGAR score at minutes one and five.

Sample size

Recent studies have reported a prevalence of maternal prenatal depression of approximately 30%.[20] To detect a reduction of about 10−12% in the IG, with a confidence level of 95% and statistical power of 80—while accounting for a maximum attrition rate of 15%—the required sample size was estimated to be approximately 95 per group at baseline.

Randomization

A computer-based block randomization sequence was performed, with a 1:1 ratio allocation.

Then, the healthcare providers in each center randomized the participants. As PA was only developed in IG, blinding of participants was not possible. After randomization, the PA instructors contacted them to assign each participant to IG or CG. Clinicians were blinded to randomization sequence and participants were blinded to study design and development.

Statistical methods

IBM SPSS (25.0 version) for Windows (IBM Corporation, Armonk, NY, USA) was used to perform statistical analyses. To report the results, an intention-to-treat (ITT) analysis was performed including any information recorded after randomization (if the participants didn't abandon the study just after it). Results when protocol criteria were achieved, were included in a Per Protocol (PP) analysis.

For normality analysis, the Kolmogorov-Smirnov test was used. Logarithmic and square root transformations were applied when cases of non-normality were found. Independent *t* tests were used to measure the differences between study groups in secondary and descriptive maternal outcomes at baseline and birth, infant outcomes, and any of the main variable's scores. Effect sizes were reported with Cohen's d.[37]

Categorical secondary and descriptive maternal variables were compared between groups using Chi-square ($\chi 2$) of Pearson test at baseline and at the end of the pregnancy, also comparing cases of excessive weight gain during pregnancy,[38] and using cutoff points of the primary outcomes. With significant results, the absolute value of the odds ratio (OR) and the confidence interval (CI) were reported.

An adherence stratification (< 70%; 70-80%; 80-90%; >90%) was performed to compare scores of the questionnaires measured, subsequently including the CG and the adherence groups with better performance. To compare them, a one-way analysis of variance (ANOVA) was used, and in cases of variance heterogeneity (assessed with Levene test), Welch's correction was used. With significant results, post hoc analyses with Scheffé test were performed. Effect sizes were reported using eta-squared (η^2).[39] To compare postpartum results of main outcomes in both study groups in the 2nd trial performed, the non-parametric U Mann-Whitney test was carried out.

Categorical variables were expressed as sample size and percentage, and continuous variables as mean and standard deviation. Statistical power was set at 95%.

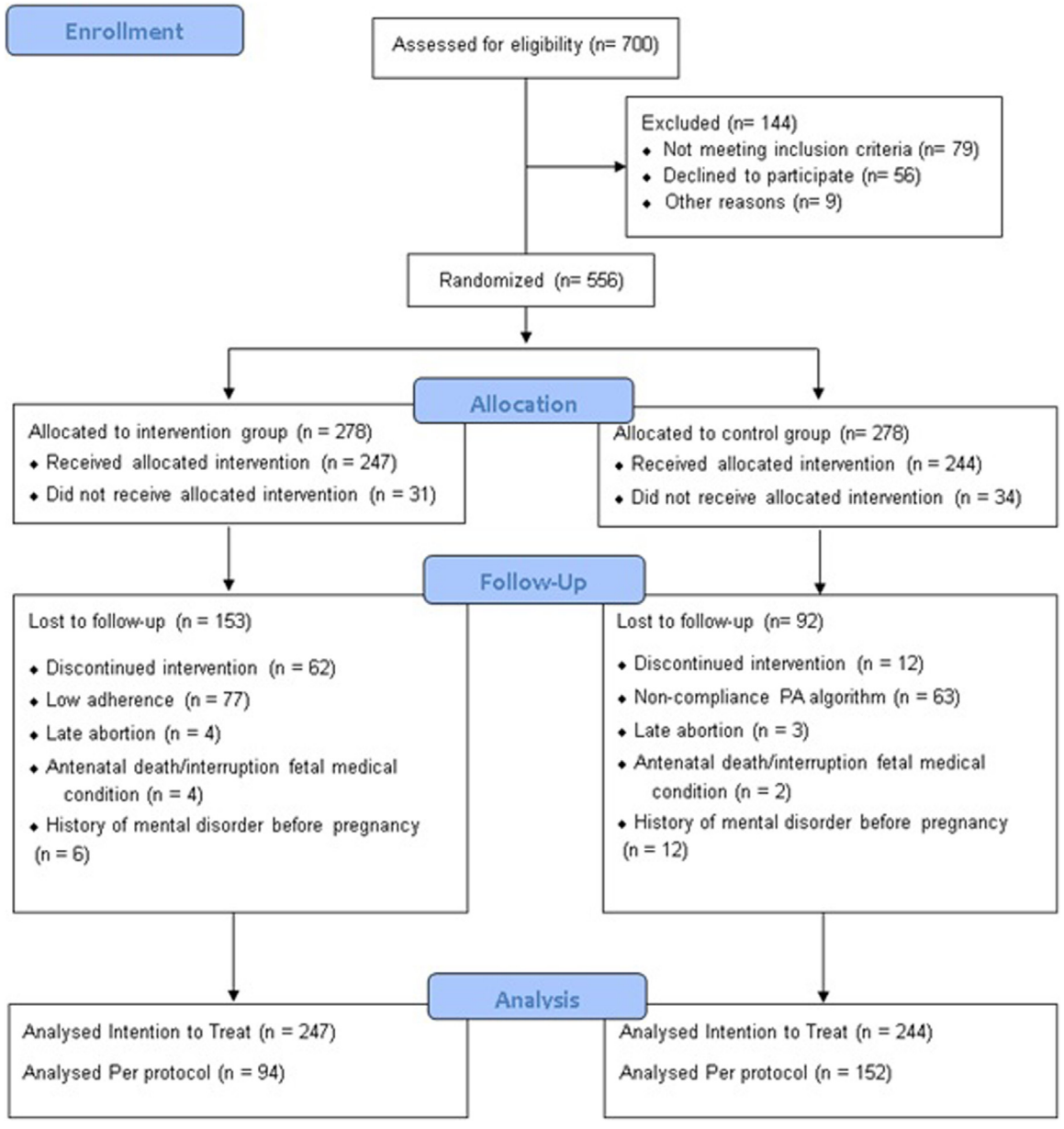
Results

700 pregnant women were assessed for eligibility, excluding 144 because inclusion criteria were not met (n=79), decline to participate in the study (n=56) or due to other reasons (n=9). Therefore, 564 women were randomized into IG (n=278) or CG (n=278), analyzing 491 women in ITT and 246 in the PP analyses (Figure 1).

Sample description

Characteristics of pregnant women who ended the intervention are shown in Table 1, with significant differences between groups in height (P=.019) after performing an ITT analysis. Table 1 However, these differences were not shown in participants in the PP analysis (P>.05).

FIGURE 1
Flow diagram with participants included



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Depression scores

Depression scores (CES-D and EPDS) did not show differences between the groups in all measures (P=.05) in ITT analysis. After the PP analysis, significant differences were observed in the EPDS questionnaire at the end of pregnancy in IG in comparison with CG ($t_{238.3=}$−1.92; d=−0.233; P=.028) (Table 2).

Anxiety and stress scores

No significant differences were observed in the anxiety measures in the ITT analysis (P>.05). Regarding protocol analysis, significant differences were observed in STAI-S ($t_{226.06=}$-3.12; d=−0.383; P=.002) and STAI-TOTAL measures ($t_{232.46=}$−2.43; d=−0.302; P=.016) at baseline, with no other differences between the groups at the end of gestation (P>.05).

Stress did not reflect statistical differences between the study groups (Table 3) along the study measures in both analyses (P>.05).

Cut-off of symptoms of mental disorders (depression and anxiety)

After performing a cut-off analysis of the mental disorders mentioned previously (Table 4), a significantly lower number of

TABLE 1
Characteristics of participants at baseline

	Intention to Treat			Per protocol		
Outc/groups	IG (n=247)	CG (n=244)	*P*	IG (n=94)	CG (n=152)	*P*
Age (y)	34.36±4.68	33.83±4.47	.195	34.77±4.57	34.13±4.20	.262
Gestational age (w)	13.61±1.91	13.46±1.64	.332	13.31±1.63	13.42±1.69	.610
Weight (kg)	66.60±15.00	65.38±13.16	.371	65.32±15.31	64.76±11.63	.754
Height (cm)	162.97±5.79	164.34±6.49	**.019***	163.18±5.86	164.49±6.24	.111
BMI	24.89±5.16	24.04±4.60	.069	24.40±5.45	23.69±3.90	.254
BMI Categ (n/%)						
Underweight	7/3.5%	9/4.1%	.197	2/2.4%	8/5.6%	.511
Normal weight	107/54.1%	139/63.5%		54/63.5%	89/62.2%	
Overweight	55/27.8%	49/22.4%		17/20%	32/22.4%	
Obese	29/14.6%	22/10%		12/14.1%	14/9.8%	
Ethnicity (n/%)						
Caucasian	188/90.8%	211/92.5%	.878	81/90%	159/94.1%	.302
Latin American	16/7.6%	15/6.6%		8/8.9%	9/5.3%	
Afro-American	1/.5%	1/0.5%		0/0%	1/0.6%	
Other	2/1%	1/.4%		1/1.1%	0/0%	
Occupation (n/%)						
Housemaker	3/1.5%	1/.5%	.442	0/0%	0/0%	
Passive job	142/70.6%	146/68.2%		62/70.5%	99/71.2%	.901
Active job	56/27.9%	67/31.3%		26/29.5%	40/28.8%	
Parity (n/%)						
Nulliparous	122/57.2%	125/55.8%	.841	51/56%	81/55.5%	.972
One	67/31.5%	76/33.9%		30/33%	50/34.2%	
Two or more	24/11.3%	23/10.3%		10/11%	15/10.3%	
Prev misc (n/%)						
None	133/67.5%	152/71%	.739	65/71.4%	108/74%	.911
One	50/25.4%	48/22.4%		22/24.2%	32/21.9%	
Two or more	14/7.1%	14/6.5%		4/4.4%	6/4.1%	

Outc, Outcomes; IG, Intervention Group; CG, Control Group; y, year; w, weeks; BMI Categ, BMI Categories; Prev misc, Previous miscarriages. Data are expressed as Mean±Standard Deviation or sample size / percentage (n/%).

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women suffering depression symptoms of depression were observed in the IG compared to CG at the end of pregnancy ($\chi 2$ (1)=5.24; *P*=.022) in both the ITT, and the PP analysis ($\chi 2$ (1)=5.91; *P*=.011).

Scores according to the adherence percentage

No differences between groups (Table 5) were found in baseline or postpartum measures (*P*>.05). However, significant differences in CES-D measures were observed at the end of pregnancy ($F_{3,69.2=}$4,37; *P*=.007; $\eta 2$=.052), with higher scores in AG-2 in comparison with the AG-4 (*P*=.036).

Therefore, significant results were observed in STAI-S ($F_{3,69=}$2,79; *P*=.047; $\eta 2$=.042), STAI-T ($F_{3,67.5=}$4,14; *P*=.009; $\eta 2$=.061) and the sum of both questionnaires ($F_{3,69=}$3,50; *P*=.020; $\eta 2$=.051) at the end of pregnancy.

Significant differences were found in the CES-D scale at the end of pregnancy between the groups ($F_{2,84.1=}$6,29; *P*=.003; $\eta 2$=.030) with a significantly lower score (*P*=.037) in AG-4 (7.79±5.53) compared to CG (12.16±9.69).

Furthermore, significant differences were found in the STAI-S questionnaire at the end of gestation ($F_{2,218=}$3,41; *P*=.035; $\eta 2$=.030), reporting a lower score (*P*=.035) in AG-4 (7.79±5.53)

TABLE 2
Results of prenatal and postnatal depression scores

Variable	Gr	Baseline	*P*	End pregnancy	*P*	Postpartum	*P*
ITT (CES-D)	IG	12.63±10.80	.383	11.57±8.98	.912	13.40±10.64	.761
		n=240		n=201		n=133	
	CG	13.49±10.58		11.47±9.55		12.97±11.27	
		n=230		n=190		n=114	
PP (CES-D)	IG	11.18±8.59	.098	10.54±8.15	.164	12.36±10.42	.347
		n=94		n=91		n=69	
	CG	13.20±10.15		11.72±9.43		13.05±11.07	
		n=149		n=139		n=88	
Analysis	Gr.	End pregnancy	*P*	Postpartum	*P*		
ITT (EPDS)	IG	5.50±4.05	.281	6.07±4.89	.692		
		n=205		n=122			
	CG	6.00±5.18		6.35±5.37			
		n=202		n=101			
PP (EPDS)	IG	4.89±3.49	**.028***	5.68±4.93	.284		
		n=94		n=65			
	CG	5.97±5.19		6.16±5.00			
		n=147		n=76			

Gr, Group; *p, p*-value; ITT, Intention to Treat; PP, Per Protocol; IG, Intervention Group; CG, Control Group; CES-D, Center for Epidemiological Studies Depression Scale; EPDS, Edinburgh Postnatal Depression Scale. Data are expressed as Mean±Standard Deviation.

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compared to CG (12.16±9.69). Significant differences in STAI-TOTAL score at the end of the intervention ($F_{2,218=}$3,10; *P*=.047; η2=.028) with a lower but not significant (*P*>.05) mean in the AG-4 than in the CG.

Comparison between trials

After performing two trials, results of main outcomes separated by each one (i.e., Trial 1 or Trial 2) are displayed in Table 6.

No significant differences were found in the results these variables in Trial 1 at the end or after pregnancy (*P*>.05). However, significant lower scores were observed in symptoms of depression measured with EPDS questionnaire ($t_{112.6=}$−1.734; d=−0.305; *P*=.043), in state anxiety ($t_{104=}$−2.207; d=−0.407; *P*=.015), trait anxiety ($t_{100.9=}$−1.778; d=−0.338; *P*=.045) and the total sum of both types of anxiety recorded with STAI scale ($t_{103.7=}$−2.05; d=−0.382; *P*=.021) in the second Trial. Comparing mean of IG in both Trials, no significant differences were observed (*P*>.05).

Maternal and infant outcomes at delivery

A significantly higher weight gain at delivery ($t_{379=}$−1.936; d=0.199; *P*=.027) and a larger head circumference ($t_{355=}$−2.124; d=0.225; *P*=.034) was reported in the CG compared to the IG, in the ITT analysis (Table 7).

Comment

Principal findings

To ensure transparency, we opted to present intention-to-treat analysis results, even though the research team achieved a high protocol adherence (mean adherence to the PA sessions of 86.2±7.34).

The results indicate that moderate intensity PA programs could suppose a positive trend in reducing the symptoms of prenatal depression, anxiety, and stress, and postnatal depression and stress, despite the non-significative results observed (*P*>.05). However, significantly lower results with small effect sizes were observed on the measure of depression symptoms at 28th week in the IG compared to CG in the PP analysis. In this line, significantly less pregnant women who suffered depression symptoms were observed in IG compared to CG in the ITT analysis showing that women without physical activity during pregnancy could be twice as likely to suffer depression than physically active women, but also in the PP analysis becoming 4 times.

After stratifying IG according to adherence rates, significant differences were observed between attendance ratios, with small to moderate effect sizes, in women with the highest attendance rate obtaining significantly fewer depression scores than the 70-80% adherence group. However, lower scores with small effect sizes were found in the >90% of the adherence group in depression and state anxiety compared to CG.

TABLE 3
Anxiety scores during and after pregnancy

Analysis	Gr	Baseline	*P*	End pregnancy	*P*	Postpartum	*P*
ITT (STAI-S)	IG	38.99±11.10	.343	38.78±10.62	.656	39.69±11.18	.772
		n=238		n=198		n=126	
	CG	40.00±11.89		39.28±11.41		39.25±12.04	
		n=226		n=186		n=105	
ITT (STAI-T)	IG	39.67±10.41	.763	38.94±9.88	.821	39.29±9.92	.506
		n=238		n=198		n=126	
	CG	39.96±10.43		38.71±10.39		38.39±10.46	
		n=226		n=186		n=105	
ITT (STAI-TOTAL)	IG	78.66±20.80	.509	77.72±19.95	.899	78.98±20.44	.632
		n=238		n=198		n=126	
	CG	79.96±21.73		77.99±21.25		77.64±21.96	
		n=226		n=186		n=105	
PP (STAI-S)	IG	36.23±8.71	**.002***	37.77±9.15	.126	39.75±11.27	.439
		n=94		n=91		n=67	
	CG	40.36±11.85		39.41±11.38		39.46±11.16	
		n=149		n=136		n=80	
PP (STAI-T)	IG	38.13±8.75	.122	37.98±8.85	.203	39.31±9.99	.319
		n=94		n=91		n=67	
	CG	40.09±10.78		39.10±10.64		38.53±10.17	
		n=149		n=136		n=80	
PP (STAI-TOTAL)	IG	74.36±16.77	**.016***	75.75±17.29	.154	79.06±20.58	.378
		n=94		n=91		n=67	
	CG	80.44±22.02		78.51±21.59		77.99±20.82	
		n=149		n=136		n=80	

(continued)

TABLE 3
Anxiety scores during and after pregnancy *(continued)*

Analysis	Gr	Baseline	*P*	End pregnancy	*P*	Postpartum	*P*
ITT (PSS)	IG	14.75±6.70	.768	12.45±6.12	.520	12.96±7.25	.816
		n=228		n=195		n=118	
	CG	14.57±6.15		12.88±6.83		13.19±7.24	
		n=216		n=179		n=94	
PP (PSS)	IG	13.95±5.94	.341	12.58±5.67	.269	13.31±7.71	.441
		n=94		n=91		n=65	
	CG	14.71±6.15		13.12±6.91		13.49±6.88	
		n=148		n=130		n=71	

Gr, Group; *p*, *p*-value; ITT, Intention to Treat; PP, Per Protocol; IG, Intervention Group; CG, Control Group; STAI, State-Trait Anxiety Inventory; PSS, Perceived Stress Scale. Data are expressed as Mean±Standard Deviation.

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Interestingly, dividing the sample per performed trials into results of Trial 1 (full virtual PA program) and Trial 2 (semi-virtual setting), significant differences were observed through the second, with small effect sizes and lower scores in depression measured with the EPDS questionnaire, state, trait and the total sum of both dimensions of the STAI questionnaire in the IG compared with the CG. However, no significant differences were observed between IGs.

Results in the content of what is known

Firstly, our program achieved a mean adherence consistent with previously reported adherences to this model.[40] Therefore, recent studies have reported the benefits of physical activity during pregnancy on depressive symptoms, with different methodological designs,[26,41-44] highlighting the strength of our supervised physical activity during the pregnancy program even during one of the most restrictive periods to perform physical activity, the COVID-19 pandemic.

This reinforces the demonstrated fact that a supervised physical activity program, when adherence is high, could be related with better benefits in psychological and physiological factors.[45-47] Being relevant, our results could imply that supervised physical activity of moderate intensity during pregnancy, performed in person and in groups, could improve mental health.

Clinical implications

The findings of this study suggest that supervised PA during pregnancy can significantly reduce depression and anxiety symptoms in pregnant women. This could be related to the positive effect that regular PA could have on hormone regulation and social interaction, improving emotional well-being.[14,48,49] These results praise the need to promote PA as a regular part of regular prenatal care. However, while the results are promising, large RCTs are needed in different regions to confirm them.

TABLE 4
Percentage of women with suitable symptoms to suffer mental illnesses

Outcome	Timepoint	IG (n/%)	CG (n, %)	$\chi 2$	OR (95% CI)	*P*
ITT CES-D	Baseline	70/29.2%	72/31.3%	.255	1.11 (.75, 1.64)	.614
	End Preg	53/26.4%	46/24.2%	.240	.89 (.57, 1.41)	.624
	Postpartum	48/36.1%	38/33.3%	.206	.89 (.52, 1.50)	.650
PP CES-D	Baseline	21/22.3%	45/30.2%	1.80	1.50 (.83, 2.74)	.180
	End Preg	19/20.9%	34/24.5%	.40	1.23 (.65, 2.32)	.321
	Postpartum	21/30.4%	30/34.1%	.24	1.18 (.60, 2.33)	.378
ITT EPDS	End Preg	12/5.9%	25/12.4%	5.24	2.27 (1.11, 4.66)	**.022***
	Postpartum	11/10%	15/14.9%	1.15	1.57 (.69, 3.6)	.284
PP EPDS	End Preg	3/3.2%	18/12.2%	5.91	4.23 (1.21, 14.79)	**.011***
	Postpartum	6/9.2%	10/13.2%	.537	1.49 (.51, 4.35)	.323
ITT STAI-S	Baseline	84/35.3%	94/41.6%	1.95	1.31 (.90, 1.90)	.163
	End Preg	74/37.4%	76/40.9%	.490	1.16 (.77, 1.75)	.484
	Postpartum	54/42.9%	43/41%	.085	.93 (.55, 1.56)	.770
PP STAI-S	Baseline	28/29.8%	61/40.9%	3.09	1.63 (.94, 2.83)	.079
	End Preg	31/34.1%	52/38.2%	.409	1.20 (.69, 2.09)	.310
	Postpartum	29/43.3%	33/41.3%	.062	.92 (.48, 1.78)	.804
ITT STAI-T	Baseline	71/29.8%	68/30.1%	.004	1.02 (.68, 1.51)	.952
	End Preg	59/29.8%	58/31.2%	.087	1.07 (.69, 1.65)	.768
	Postpartum	37/29.4%	30/28.6%	.018	.96 (.54, 1.70)	.895
PP STAI-T	Baseline	21/22.3%	42/28.2%	1.03	1.36 (.75, 2.49)	.311
	End Preg	23/25.3%	43/31.6%	1.06	1.37 (.75, 2.48)	.189
	Postpartum	20/29.9%	22/27.5%	.099	.89 (.44, 1.83)	.753
ITT STAI-TOTAL	Baseline	76/31.9%	80/35.4%	.624	1.17 (.79, 1.72)	.430
	End Preg	66/33.3%	65/34.9%	.111	1.07 (.70, 1.64)	.739
	Postpartum	47/37.3%	36/34.3%	.226	.88 (.51, 1.51)	.634
PP STAI-TOTAL	Baseline	24/25.5%	51/34.2%	2.04	1.52 (.86, 2.70)	.153
	End Preg	28/30.8%	48/35.3%	.501	1.23 (.70, 2.16)	.287
	Postpartum	24/35.8%	27/33.8%	.069	.91 (.46, 1.80)	.793
Outcome	Timepoint	IG (n/%)	CG (n, %)	$\chi 2$		*P*
ITT PSS	Baseline	114/50%; 11/4.8%	103/47.7%; 9/4.2%	.438		.803
	End Preg	70/35.9%; 2/1%	70/39.1%; 7/3.9%	4.06		.131
	Postpartum	44/37.3%; 6/5.1%	38/40.4%; 4/4.3%	.259		.879
PP PSS	Baseline	46/48.9%; 2/2.1%	72/48.6%; 6/4.1%	.68		.712
	End Preg	36/39.6%; 0/0%	53/40.8%; 5/3.8%	3.76		.153
	Postpartum	21/32.3%; 6/9.2%	28/39.4%; 4/5.6%	1.15		.563

IG, Intervention Group; CG, Control Group; OR, Odds Ratio; CI, Confidence Interval; ITT, Intention to Treat; PP, Per Protocol; Preg, Pregnancy; CES-D, Center for Epidemiological Studies Depression Scale; EPDS, Edinburgh Postnatal Depression Scale; STAI, State-Trait Anxiety Inventory; PSS, Perceived Stress Scale. Data are expressed as sample size / percentage of women who have compatible symptoms to suffer each disease (CES-D ≥16; EPDS ≥10; STAI-S ≥41: STAI-T ≥44; STAI-TOTAL ≥85). In the case of the PSS questionnaire, the first measure is related to moderate stress and the second to severe stress (14-26, and ≥27, respectively).

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TABLE 5
Mental illness questionnaire scores depending on PA program adherence

Out	Time	<70% (AG-1)	70-80% (AG-2)	80-90% (AG-3)	>90% (AG-4)	*p*
CES-D	End	12.95±10.02	11.90±6.73	10.81±7.85	7.79±5.53	**.007***
		n=73	n=20	n=42	n=34	
	Post	15.34±11.36	11.60±9.02	14.97±10.86	9.63±9.14	.111
		n=44	n=15	n=31	n=27	
EPDS	End	6.04±4.00	5.15±3.25	5.24±3.38	4.40±3.84	.187
		n=75	n=20	n=42	n=35	
	Post	6.58±4.88	7.17±4.13	6.48±5.21	4.52±4.97	.278
		n=40	n=12	n=31	n=27	
STAI-S	End	39.96±11.27	40.25±7.47	38.57±9.46	34.64±8.89	**.047***
		n=72	n=20	n=42	n=33	
	Post	39.81±11.45	44.08±11.25	40.19±12.27	36.96±10.19	.320
		n=42	n=13	n=31	n=27	
STAI-T	End	40.29±10.41	42.50±7.40	37.36±8.19	35.30±9.08	**.009***
		n=72	n=20	n=42	n=33	
	Post	40.02±10.13	43.23±9.36	38.48±10.04	37.81±10.19	.398
		n=42	n=13	n=31	n=27	
STAI-TOTAL	End	80.25±21.23	82.75±13.77	75.93±16.99	69.94±17.40	**.020***
		n=72	n=20	n=42	n=33	
	Post	79.83±20.87	87.31±19.53	78.68±21.69	74.78±19.94	.356
		n=42	n=13	n=31	n=27	
PSS	End	12.14±6.19	13.80±4.56	12.71±5.44	11.45±6.35	.528
		n=71	n=20	n=41	n=33	
	Post	12.92±6.77	15.00±6.81	13.45±8.56	12.07±6.93	.702
		n=38	n=12	n=29	n=27	

Out, Outcome; Time, Moment of data capture; End, End of Pregnancy; Post, Postpartum; CES-D, Center for Epidemiological Studies Depression Scale; EPDS, Edinburgh Postnatal Depression Scale; STAI, State-Trait Anxiety Inventory; PSS, Perceived Stress Scale. Data are expressed as Mean±Standard Deviation.

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Research implications

As postnatal main outcomes and prenatal stress did not report significant differences between study groups, a large RCT with only in-person supervised PA sessions (as they better promoted the social interaction) reviewing these variables, shall be carried out.

Strengths and limitations

This study has several limitations. First, a proportion of participants were lost to follow-up due to medical complications related to pregnancy, personal or logistical difficulties in attending follow-up visits, or withdrawal of consent. An intention-to-treat analysis was conducted to minimize potential bias.

Second, the measurement of exercise adherence presents another limitation. Although adherence was tracked through exercise logs and periodic interviews, these methods may not fully capture the actual amount, intensity, or duration of physical activity performed by participants. Consequently, adherence data may not perfectly reflect the intervention, potentially affecting the interpretation of its effectiveness. Future studies could incorporate objective measures, such as accelerometers or wearable devices, to more accurately assess physical activity levels.

Despite the randomization process was balanced per group, the multicenter design could have introduced variability unmeasured and it could potentially influence the self-perception of participants through questionnaires. This, combined with there were simultaneous questionnaires administered to participants, could have affected the responses of them. Additionally, the significant differences observed in the baseline values of state and the sum of both state and treat anxiety between IG and CG, could mean that all pregnant women wanted to participate in our PA program, as CG participants did not have supervised PA sessions, but also this could be related to

TABLE 6
Comparison of main outcomes between interventions

		Trial 1			Trial 2		
Out	Time	IG	CG	*P*	IG	CG	*P*
CES-D	End	10.48±8.20	10.61±8.37	.467	10.60±8.19	12.98±10.42	.094
		n=48	n=74		n=43	n=65	
	Post	11.74±10.11	13.05±10.79	.262	13.68±11.18	13.24±11.68	.753
		n=47	n=60		n=22	n=29	
EPDS	End	4.88±3.42	5.61±5.07	.188	4.91±3.61	6.36±5.33	**.043***
		n=49	n=77		n=45	n=70	
	Post	6.30±5.32	5.98±4.59	.756	4.38±3.78	6.54±5.89	.318
		n=44	n=52		n=21	n=24	
STAI-S	End	38.69±9.60	37.77±9.86	.613	36.74±8.61	41.32±12.72	**.015***
		n=48	n=73		n=43	n=63	
	Post	40.78±11.71	39.19±9.55	.458	37.64±10.22	40.04±14.13	.804
		n=45	n=54		n=22	n=26	
STAI-T	End	38.54±8.56	37.53±9.76	.561	37.35±9.22	40.92±11.39	**.045***
		n=48	n=73		n=43	n=63	
	Post	40.56±10.47	38.06±9.03	.205	36.77±8.62	39.50±12.36	.605
		n=45	n=54		n=22	n=26	
STAI-TOTAL	End	77.23±17.49	75.30±19.09	.575	74.09±17.11	82.24±23.77	**.021***
		n=48	n=73		n=43	n=63	
	Post	81.33±21.61	77.24±17.94	.306	74.41±17.88	79.54±26.16	.764
		n=45	n=54		n=22	n=26	
PSS	End	13.08±5.58	13.01±6.53	.952	12.02±5.78	13.25±7.37	.173
		n=48	n=70		n=43	n=60	
	Post	13.88±8.16	13.29±5.50	.690	12.18±6.77	13.91±9.26	.865
		n=43	n=48		n=22	n=23	

Out, Outcome; Time, Moment of data capture; End, End of Pregnancy; Post, Postpartum; CES-D, Center for Epidemiological Studies Depression Scale; EPDS, Edinburgh Postnatal Depression Scale; STAI, State-Trait Anxiety Inventory; PSS, Perceived Stress Scale. Data are expressed as Mean±Standard Deviation.

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TABLE 7
Maternal and infant outcomes at delivery

	Intention to Treat			Per protocol		
Outc/groups	IG (n=195)	CG (n=213)	*P*	IG (n=89)	CG (n=140)	*P*
Gest age at delivery (w)	39.28±1.53	39.25±1.41	.812	39.20±1.58	39.21±1.46	.958
Weight at delivery (kg)	76.03±14.50	75.76±12.77	.844	75.09±13.85	74.48±11.35	.720
Gest weight gain (kg)	9.66±5.08	10.74±5.77	**.027***	9.23±5.65	9.90±5.74	.203
BMI delivery	28.70±4.90	28.08±4.55	.190	28.21±4.82	27.53±3.82	.244

(continued)

TABLE 7
Maternal and infant outcomes at delivery *(continued)*

Outc/groups	Intention to Treat			Per protocol		
	IG (n=195)	CG (n=213)	*P*	IG (n=89)	CG (n=140)	*P*
BMI Categ (n/%)						
Normal weight	35/19%	52/24.6%	.401	20/23.8%	38/27.1%	.833
Overweight	91/49.5%	96/45.5%		42/50%	65/46.4%	
Obese	58/31.5%	63/29.9%		22/26.2%	37/26.4%	
Excess weight gain (n/%)						
No	140/79.5%	159/78.3%	.772	63/79.7%	117/84.8%	.343
Yes	36/20.5%	44/21.7%		16/20.3%	21/15.2%	
Type of delivery (n/%)						
Eutocic	116/58.6%	137/64.9%	.230	50/57.5%	91/66.4%	.401
Cesarea	45/22.7%	47/22.3%		21/24.1%	26/19%	
Instrumental	37/18.7%	27/12.8%		16/18.4%	20/14.6%	
Episiot (n/%)						
No	156/87.2%	166/88.8%	.634	69/88.5%	106/86.2%	.638
Yes	23/12.8%	21/11.2%		9/11.5%	17/13.8%	
Perineal tear (n/%)						
No	74/41.6%	77/42.3%	.194	32/41.6%	45/36.9%	.510
One	47/26.4%	64/35.2%		23/29.9%	45/36.9%	
Two	54/30.3%	38/20.9%		20/26%	29/23.8%	
Three	2/1.1%	1/.5%		2/2.5%	1/.8%	
Four	1/.6%	2/1.1%		0/0%	2/1.6%	

Outc/groups	Intention to Treat			Per protocol		
	IG (n=177)	CG (n=225)	*P*	IG (n=86)	CG (n=137)	*p*
Birth weight (g)	3137.30±443.71	3211.15±439.62	.051	3097.66±439.64	3186.36±472.94	.081
Birth length (cm)	49.57±2.15	49.91±2.09	.134	49.64±2.32	49.75±2.28	.725
Head circumference (mm)	34.43±1.35	34.75±1.41	**.034***	34.44±1.36	34.76±1.45	.117
APGAR 1 min	8.77±1.06	8.80±.77	.761	8.76±1.12	8.67±.96	.279
APGAR 5 min	9.80±.57	9.85±.47	.305	9.81±.56	9.81±.51	.492

Outc, Outcomes; IG, Intervention Group; CG, Control Group; Gest, Gestational; w, weeks; BMI Categ, BMI Categories; Excess, Excessive; Episiot, Episiotomy. Data are expressed as Mean±Standard Deviation or sample size / percentage (n/%).

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unmeasured confounding variables. Another limitation, due to the nature of these interventions, was that blinding of participants was not possible. However, self-reported mental health questionnaires were used to eliminate the outcome recording unblinding bias. Additionally, our strong protocol, which promotes high adherence to the program in the IG, limited our sample size, and not including a social support outcome measurement.

However, this study had remarkable strengths, such as a large sample size, outstanding that our model, when adherence is close to 100%, could achieve better benefits compared to a low adherence rate. Our program had an essential social impact on the participants enrolled, since our supervised sessions were conducted in groups online and in-person. We could lead at the same time during pregnancy in five different locations in Spain during the COVID-19 pandemic, promoting a better external validation of the results.

Conclusion

Supervised PA program during pregnancy could reduce depression

symptoms and percentage of women with depression symptoms at the end of pregnancy. When the PA program adherence is above 90%, significantly fewer symptoms of depression and state anxiety appeared.

Information of 1st Trial

1. Date of registration: 2020-08-01
2. Date of initial participant enrollment: 2020-09-19
3. Clinical trial identification number: NCT04563065.
4. URL of the registration site: https://clinicaltrials.gov/study/NCT04563065

Information of 2nd trial

1. Date of registration: 2022-03-17
2. Date of initial participant enrollment: 2022-03-24
3. Clinical trial identification number: NCT05295264.
4. URL of the registration site: https://clinicaltrials.gov/study/NCT05295264?term=Active%20pregnancy.%20Mental%20and%20emotional&rank=1

CRediT authorship contribution statement

Miguel Sánchez-Polán: Writing – review & editing, Writing – original draft, Visualization, Software, Methodology, Investigation, Formal analysis, Conceptualization. **Maia Brik:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Data curation, Conceptualization. **Cristina Silva-Jose:** Writing – review & editing, Writing – original draft, Validation, Software, Methodology, Investigation, Data curation. **Dingfeng Zhang:** Writing – original draft, Validation, Software, Methodology, Investigation, Data curation. **María Ángeles Díaz-Blanco:** Resources, Investigation, Formal analysis, Data curation. **Paloma Hernando López de la Manzanara:** Resources, Investigation, Formal analysis, Data curation. **Aránzazu Martín Arias:** Resources, Investigation, Formal analysis, Data curation. **Irune Alzola:** Resources, Investigation, Formal analysis, Data curation. **Rubén Barakat:** Writing – review & editing, Writing – original draft, Validation, Supervision, Resources, Methodology, Investigation, Conceptualization.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.ajogmf.2025.101835.

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Received Sept. 15, 2025; revised Oct. 29, 2025; accepted Oct. 31, 2025.

Data sharing information: Individual participant data will not be shared due to it contain sensitive information for patients.

Tweetable statement: This study, developed during and after the COVID-19 pandemic with online and in-person supervised physical activity group sessions, helps reduce suitable cases and symptoms of depression and anxiety.

Ethics statement: All procedures were performed in compliance with relevant and institutional laws and guidelines, having been approved by the Universidad Politécnica de Madrid (UPM-2020-32/33, on date January 23, 2020).

This work was supported by the Instituto de las Mujeres. Ministerio de Igualdad. Spain (grant numbers 27/1ACT/22, 30-1ACT-24).

The authors declare no conflict of interest.

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