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A Supervised Hybrid Prenatal Exercise Program Reduces the Incidence of Macrosomia: A Randomized Controlled Trial

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Running Title: PRENATAL EXERCISE AND MACROSOMIA: RCT

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ABSTRACT

Purpose: To examine the effects of a supervised hybrid prenatal exercise program (combined in-person and online sessions) on the incidence of macrosomia and excessive gestational weight gain (EGWG). **Methods:** A randomized clinical trial (NCT04563065) was conducted. A total of 260 pregnant women were assessed for eligibility and randomized (1:1). This manuscript reports results from a per-protocol analysis including 138 participants (exercise group [EG] n=62; control group [CG] n=76). The EG participated in a supervised moderate-intensity exercise program delivered in a hybrid format (1 in-person session/week at the hospital and 2 online sessions/week via Zoom), from 11 weeks' gestation until delivery. The CG received usual obstetric care, printed lifestyle education materials, and a brief phone-based physical activity interview once per trimester. Macrosomia (>4000 g) and EGWG (Institute of Medicine criteria) were extracted from hospital records and compared between groups. **Results:** The incidence of macrosomia was lower in the EG (0%) than in the CG (7.3%; χ^2=6.70, p=0.01). The incidence of EGWG did not differ between groups (9.6% vs. 19.4%, *p*=0.13). Apgar score at 5 minutes was slightly higher in the EG than in the CG (9.91±0.34 vs. 9.82±0.56, *p*=0.03). **Conclusions:** A supervised hybrid prenatal exercise program was associated with a lower incidence of macrosomia and slightly higher 5-minute Apgar scores compared with usual care. These findings support hybrid delivery as a feasible strategy for implementing supervised prenatal exercise.

Key Words: PHYSICAL EXERCISE, PREGNANCY, EXCESSIVE GESTATIONAL WEIGHT GAIN, MACROSOMIA, BIRTH WEIGHT

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INTRODUCTION

Macrosomia is defined as a birth weight exceeding 4,000 g, and has been noted as an important proxy measure that may be associated with later life risk of chronic illnesses such as obesity and type 2 diabetes (1). The prevalence of macrosomia differs across regions, being reported at approximately 5% to 20% in developed countries and about 0.5% to 14.9% in developing countries (2). Macrosomia is also associated with an increased risk of labor complications, such as shoulder dystocia, cesarean delivery, postpartum hemorrhage, and neonatal hypoglycaemia (2–5). Macrosomia may be prevented with behavioural interventions during pregnancy that can facilitate maternal and neonatal health, including physical activity. Further, gestational weight gain is closely associated with risk of macrosomia and supporting pregnant women with meeting Institute of Medicine (IOM) weight gain guidelines through healthy behaviours like physical activity is an important public health initiative.

Globally, almost half of pregnant women gain weight above the IOM gestational weight gain guidelines (6). Excessive gestational weight gain (EGWG) is defined as gaining above thresholds of 0.58, 0.50, 0.33, and 0.27 kg per week during the second and third trimesters for women who would have a body mass index (BMI) categorized as underweight, normal weight, overweight, and obesity, respectively (6). EGWG has been linked to a higher incidence of pre-eclampsia, gestational diabetes mellitus, and large gestational age infants or macrosomia (7, 8). Accumulating evidence supports lifestyle interventions particularly those incorporating structured physical exercise as effective strategies to reduce the risk for EGWG and related complications (9, 10).

Previous studies have demonstrated that participating in a structured prenatal exercise program with at least 80% adherence can effectively reduce the risk of macrosomia (10).

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Notably though, the global coronavirus (COVID-19) pandemic significantly changed the delivery of in-person supervised exercise sessions for all populations, and virtual or at-home programs gained significant traction. Post-pandemic, there is still a slow return to in person physical activity opportunities while virtual modalities are utilized especially for their convenience. Moving forward, the physical activity environment for supervised exercise training in pregnancy will likely include both in-person and virtual options and therefore it is important to assess adherence to these options and implications on essential health outcomes, including macrosomia and EGWG. Therefore, the present study aimed to examine whether a supervised hybrid prenatal exercise program (combined online and in-person sessions) reduces the incidence of macrosomia and EGWG compared with usual care. We hypothesized that participants allocated to the exercise group would show a lower incidence of macrosomia and EGWG compared with the control group.

MATERIALS AND METHODS

Study Design

A Randomized Clinical Trial (registered on "ClinicalTrials.gov", registration number: NCT04563065) was conducted by the Universidad Politécnica de Madrid in collaboration with Hospital Universitario Severo Ochoa, Hospital Universitario Puerta de Hierro, and Hospital Universitario Vall de Hebrón, Spain. Ethical approval for the present study was obtained from the Research Ethical Committee of the Universidad Politécnica de Madrid. Participants' personal and medical data were collected from hospital clinical records. Pregnant women were randomly assigned to either the exercise group (EG, Intervention) or the control group (CG). This program was conducted from September 24, 2022, to January 31, 2024. All participants signed informed consent forms before beginning.

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Equity, Diversity, and Inclusion (EDI) Statement

We screened all pregnant women receiving routine care at our collaborating center who had no contraindications to engaging in physical exercise. The study was conducted by a multidisciplinary team, including nine professionals with expertise in gynecology, obstetrics, midwifery, and exercise science. Team members work across different countries and healthcare systems, which broadens our perspectives and strengthens the study approach.

Our team includes six women and three men and brings together complementary expertise in obstetrics, gynecology, physical education, sports nutrition, and research. No participant was excluded on the basis of sociodemographic characteristics. We focused on healthy pregnant women irrespective of ethnicity, socioeconomic status, or educational background. This equity, diversity, and inclusion-oriented approach supports the inclusiveness and representativeness of our research for the populations we aim to benefit.

Participants and Randomization

A total of 260 pregnant women who spoke Spanish and resided in Madrid were recruited and assessed for eligibility during hospital obstetric visits. Inclusion criteria were: singleton pregnancy, Spanish-speaking women residing in Madrid, age between 21 and 46 years, and enrollment prior to 11 weeks' gestation to allow initiation of the intervention at week 11. Women were excluded if they: had multiple or complicated pregnancies, had contraindications to exercise according to international guidelines (11–13), were participating in another trial or structured exercise program, were not planning to give birth in the study hospital, or were not expected to complete routine obstetric follow-up at the recruiting hospital.

The randomization procedure was conducted using REDCap software (14). Participants were randomly assigned to either the EG or CG in a 1:1 allocation ratio. A computer-generated

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randomization sequence was uploaded to the REDCap database. A hospital healthcare provider managed access to the REDCap system for randomization and ensured that all assignments remained confidential from hospital staff. Due to the nature of the intervention, participants and instructors who conducted the exercise sessions were not blinded, however, outcome assessors were blinded to allocation. Participants were not involved in the development of the research.

Exercise Group

Women in the EG, similar to those in the CG, received standard care and healthy lifestyle recommendations at their respective hospitals. Participants followed a supervised exercise program throughout pregnancy; the exercise intervention lasted ~29 weeks, sessions started at 11 weeks gestation until delivery at ~40 weeks gestation. This program entailed three weekly sessions, each lasting 60 minutes and comprising of complementary and interrelated activities based on the Barakat model (15). The program was divided into seven parts: 5 min warm-up, 20 min aerobic exercises, 10 min strength training, 10 min balance and coordination exercises, 5 min stretching and relaxation, 7 min pelvic floor muscle training (coordinated with breath, including 10 sets of slow contractions for 8-12 seconds each and 3 sets of rapid contractions for 25-30 seconds each), and 3 min post-session communication or wrap-up debrief. The exercise structure is tailored according to gestational progression (Table 1)

The program included both face-to-face sessions held once a week at hospital, with approximately 10-15 participants per session, and online sessions held twice a week via Zoom, with approximately 10-30 participants per session. Classes were scheduled on different days to coordinate with participants' calendars. Sessions were implemented by three exercise-qualified PhD students and one exercise-qualified undergraduate student, all trained in prenatal exercise delivery and supervised by senior investigators. Attendance was recorded for each session using

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REDCap. The intensity of the workload was controlled by maintaining values within 55-65% of the maximum maternal heart rate, calculated using the Karvonen formula (16) and using an effort perception of 12-14 (Somewhat Hard) on the Borg's Rating of Perceived Exertion Scale (17) either through a heart rate monitor or manually at the carotid artery.

Control Group

Participants in the CG received usual obstetric care and printed lifestyle education materials. To monitor physical activity, they completed a brief phone-based interview once per trimester using a validated decision algorithm (10). No supervised exercise sessions were provided to the CG.

Outcomes

Data were extracted from hospital obstetric records using the SELENE platform. The primary outcome was macrosomia, defined as birth weight >4000 g. Secondary outcomes included gestational weight gain (GWG, kg; continuous), excessive gestational weight gain (EGWG; categorical, yes/no), birth weight (g; continuous), birth length, head circumference, Apgar score at 1 minute and 5 minutes, gestational length (weeks), mode of delivery, episiotomy, and perineal tear.

Maternal pre-pregnancy BMI was calculated as weight (kg) divided by height squared (m^2). Pre-pregnancy weight was self-reported at baseline and cross-checked against the first prenatal visit record when available. Maternal height was obtained from the clinical record. Weight at delivery was obtained from the last recorded maternal weight prior to delivery in the obstetric record. GWG was calculated as weight at delivery minus pre-pregnancy weight.

EGWG was classified according to Institute of Medicine recommendations based on pre-pregnancy BMI category (18).

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Statistical Analysis

Data analyses were performed using IBM SPSS for Windows, version 27.0 (IBM Corporation, Armonk, NY, United States). Initial assessments included the Kolmogorov-Smirnov test to check for normality violations. Pearson's chi-square test was used to compare the race, parity, type of occupation, miscarriage before delivery, mode of delivery, episiotomy, perineal tear, between the EG and CG. For the primary outcome (macrosomia) and EGWG as secondary, we used Pearson's chi-square test to compare incidence between the EG and CG. We perform a sensitivity analysis, by using Pearson's chi-square test by stratifying sample into potential confounders (baseline parity and occupation) since Logistic regression was not feasible to perform due to it exhibited non-convergence because complete separation of covariates from the main outcome. Risk Ratio (RR) was reported with 95% Confidence Interval (CI). Independent t-tests were used to assess the differences in maternal age, maternal pre-pregnancy weight, maternal height, pre-pregnancy BMI, gestational length, maternal weight at delivery, birth weight, birth length, head circumference, Apgar score at 1minute, and Apgar score at 5 minutes, between the EG and CG.

Continuous variables are reported as mean ± standard deviation, whereas categorical (nominal) variables are reported as counts and percentages. Statistical significance was defined as $p < 0.05$. This manuscript reports results from a per-protocol analysis. Participants allocated to the EG who attended <60% of sessions were excluded from analysis, consistent with prior prenatal exercise trials (19)

Sample Size calculation

Power calculations were conducted for the primary outcome (macrosomia) based on previous prenatal exercise trials reporting an expected incidence of approximately 2% in the

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intervention group and 10% in usual care. Under these assumptions, a two-sample chi-square (χ^2) test (effect size = 0.3), with a two-sided α of 0.05 and 80% power, yielded a required total sample size of 143 participants. Allowing for an anticipated ~5% loss to follow-up, the target enrollment at baseline was increased to approximately 150 women (G*power3.1).

RESULTS

A total of 260 pregnant women were assessed for eligibility, and 160 were randomized (80 to the exercise group [EG] and 80 to the control group [CG]). In the EG, 18 participants were excluded from the per-protocol analysis: 14 due to attendance <60%, 3 due to change of hospital, and 1 for other reasons. In the CG, 4 participants were excluded due to missing follow-up data and 2 due to change of hospital. The final per-protocol sample included 62 participants in the EG and 76 in the CG (Figure 1).

Maternal characteristics at baseline

Baseline maternal characteristics are presented in Table 2. There were no statistically significant differences between groups in age, pre-pregnancy weight, BMI, race, parity, or type of occupation (p>0.05). Maternal height was slightly higher in the CG compared with the EG (164.70±6.93 cm vs. 163.08±5.23 cm, p=0.04).

Maternal delivery outcomes

Maternal delivery outcomes are presented in Table 3. There were no statistically significant differences between groups in gestational length, weight at delivery, mode of delivery, episiotomy, or perineal tear (p>0.05). Although not statistically significant, weight at delivery was 3.2 kg lower in the EG than in the CG, and the proportion of women classified with EGWG was lower in the EG (9.6%) compared with the CG (19.4%). No miscarriages occurred in either group.

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Due to missing data in hospital records, sample sizes vary slightly across outcomes.

Newborn outcomes

Newborn outcomes are presented in Table 4. There were no statistically significant differences between groups in mean birth weight, birth length, or head circumference ($p>0.05$). However, the incidence of macrosomia was significantly lower in the EG, with no cases observed (0%) compared with 7.3% in the CG ($\chi^2=6.70$, $p=0.01$). Apgar scores were high in both groups; Apgar at 5 minutes was slightly higher in the EG compared with the CG (9.91±0.34 vs. 9.82±0.56, $p=0.03$).

Perhaps no significant differences were observed in the baseline report of occupation and parity outcomes, it was opted to perform a sensitivity analysis with the main outcome by stratifying the sample into these two possible confounders. A significant greater percentage of newborns with macrosomia was observed in CG women with sedentary work (0 / 0% vs 5 / 11.6%; $p = 0.030$), but also in CG nulliparous women (0 / 0% vs 4 / 10.4%; $p = 0.048$) in comparison with IG women (Supplemental Table 1, Supplemental Digital Content, http://links.lww.com/MSS/D427). There were not observed other differences in the rest of categories of these two variables, EG continued having less cases of macrosomia in comparison with CG.

Intervention adherence

Among participants included in the per-protocol analysis, adherence to the exercise intervention was high. Mean attendance across all scheduled sessions was 80.32% (SD: 11.28), with a median attendance of 80.89%. Attendance for the in-person sessions averaged 79.09%(SD:11.50), and attendance for the online sessions averaged 82.24% (SD: 10.43).

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DISCUSSION

In this randomized clinical trial, participation in a supervised hybrid prenatal exercise program was associated with a lower incidence of macrosomia and slightly higher 5-minute Apgar scores compared with usual care. No statistically significant differences were observed in other maternal or newborn outcomes; however, the trial was powered for macrosomia and may have been underpowered to detect group differences in secondary outcomes.

The absence of macrosomia in the EG despite comparable mean newborn anthropometrics suggests that prenatal exercise may reduce the upper tail of the birth weight distribution without adversely affecting typical fetal growth. Potential mechanisms include improved maternal glucose homeostasis (20), placental vascular function (21), and fetal nutrient partitioning, which may reduce the likelihood of fetal overgrowth. These findings are consistent with previous prenatal exercise trials and meta-analyses showing that structured exercise reduces macrosomia incidence (19, 22, 23).

Apgar scores were high in both groups. Although the between-group differences were numerically small, the higher 5-minute Apgar score in the EG may reflect slightly improved neonatal adaptation at birth. Importantly, the clinical interpretation of this finding should be considered alongside the very high Apgar scores observed in both groups (21).

Gestational weight gain

We did not observe statistically significant differences in EGWG or total GWG between groups. Although prenatal exercise is often associated with lower gestational weight gain in the literature, GWG is a limited proxy for metabolic health and does not capture changes in body composition that may occur with interventions that include strength training, such as the Barakat model (15, 24). It is plausible that exercise contributed to beneficial metabolic or compositional

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adaptations without translating into statistically significant differences in GWG classification in this sample. Emerging research has emphasized that maternal metabolic health is critical to understanding the intrauterine environment and is not comprehensively captured through weight measurements alone (25, 26).

Adherence and hybrid delivery

This study was designed as a hybrid intervention, combining weekly in-person supervision with twice-weekly online sessions. Adherence in the per-protocol sample was high (mean attendance 80.32%, median 80.89%), supporting the feasibility of hybrid delivery for prenatal exercise. Attendance was similar across modalities (79.09% for in-person sessions and 82.24% for online sessions), suggesting that hybrid formats may help address common barriers to prenatal physical activity, including time constraints, transportation, and childcare responsibilities (27), while still maintaining key benefits of in-person supervision such as exercise technique correction, social support, and motivation (28, 29). The COVID-19 pandemic saw a significant increase in virtual delivery of exercise interventions for many populations, including pregnancy (30). Post-pandemic, pregnant individuals have continued to express interest in home-based options for physical activity (31). Previous research in pregnant populations has shown that virtual and hybrid physical activity programs are well-accepted, enjoyable, and can achieve high adherence and positive outcomes (31–34). Low adherence reduces the efficacy of exercise programs and complicates interpretation of outcomes (35). Future research should directly compare adherence and outcomes across fully in-person, fully online, and hybrid delivery models, and examine whether hybrid programs support adherence among participants at higher risk of poor engagement.

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Strengths and limitations

Strengths of this study include the randomized design, blinded outcome assessment, and the structured exercise protocol spanning approximately 29 weeks. Limitations include the per-protocol design with an adherence threshold and differential attrition between groups, which may affect generalizability. In addition, the control group received substantially less contact with the research team than the exercise group (one phone interview per trimester vs. three supervised sessions per week), which may have influenced engagement in healthy behaviors beyond exercise. Physical activity in the control group was monitored qualitatively but not quantified for analysis. Nutrition and other lifestyle behaviors were not systematically assessed. Exercise intensity partly relied on self-monitoring methods (e.g., perceived exertion), which may introduce measurement variability. Finally, the trial was powered for macrosomia, and secondary outcomes should be interpreted cautiously as potentially underpowered. We decided to perform a sensitivity analysis stratifying by potential confounders to ensure the richness of the results, finally observing the same trend in this additional analysis. The study was also not powered to detect rare adverse outcomes.

Overall, these findings support hybrid supervised prenatal exercise as a feasible and potentially effective strategy for reducing macrosomia incidence. The intervention frequency and intensity are consistent with current recommendations encouraging pregnant individuals without contraindications to engage in moderate-intensity physical activity throughout pregnancy (11, 12).

CONCLUSIONS

A supervised moderate-intensity prenatal exercise program delivered in a hybrid format (one in-person and two online sessions per week) was associated with a lower incidence of

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macrosomia and slightly higher 5-minute Apgar scores compared with usual care. No statistically significant differences were observed for gestational weight gain or maternal delivery outcomes. These findings support hybrid delivery as a feasible approach for implementing supervised prenatal exercise programs in routine antenatal care.

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Authors' Contribution: Dingfeng Zhang: Led the implementation of the intervention trial for pregnant women; data collection and statistical analysis; drafted the initial manuscript and revised it accordingly. Miguel Sánchez-Polán: Led the implementation of the intervention trial for pregnant women; data collection. Ángeles Díaz-Blanco: Recruited participants, performed group allocation, and collected data. Maia Brik: Recruited participants, performed group allocation, and collected data. Paloma Hernando: Recruited participants, performed group allocation, and collected data. Taniya S. Nagpal: The main contributor responsible for manuscript review. Duan Rui: review the manuscript. Hongyou Liu: review the manuscript. Rubén Barakat: Study design and oversight, interpretation of the findings, manuscript editing and critical revision, and final approval of the submitted version. We would like to express our appreciation to all participants and the involved hospitals for their valuable support. The results of the study are presented clearly, honestly, and without fabrication, falsification, or inappropriate data manipulation. The results of the present study do not constitute endorsement by the American College of Sports Medicine. The authors declare no potential competing interests. Due to privacy and confidentiality considerations involving participants' personal information, the dataset is not publicly available. Data supporting the findings of this study may be obtained from the corresponding author upon reasonable request.

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FIGURE LEGEND

Figure 1. Study population flow chart

SUPPLEMENTAL DIGITAL CONTENT

SDC 1: Supplementary Table 1.pdf

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Table 1. Distribution of program components (15)

Exercise domains	- 20 weeks	21- 30 weeks	31- delivery
AE	40%	30%	25%
MS	30%	25%	25%
C-E	10%	15%	15%
SR	10%	15%	15%
PF	10%	15%	20%

AE: Aerobic Endurance; MS: Muscle Strengthening; C-E: Coordination/postural, Equilibrium(balance); SR: Stretching/Relaxation; PF: Pelvic Floor.

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Table 2. Maternal characteristics at baseline

	Exercise group (n = 62)	Control group (n = 76)	P-value
Age (years)	36.32 ± 4.22	33.71 ± 4.41	0.63
Weight (kg)	64.41 ± 14.25	64.47 ± 12.16	0.99
Height (cm)	163.08 ± 5.23	164.70 ± 6.93	0.04
BMI ($kg \cdot m^{-2}$)	24.04 ± 5.05	23.65 ± 4.72	0.89
Race (n/%)			
Caucasian	56/91.8	69/92	
Hispanic American	4/6.6	5/6.7	0.99
South American	1/1.6	1/1.3	
Parity (n/%)			
None	37/61.7	38/52.8	
One	15/25.0	27/37.5	0.30
Two or more	8/13.3	7/9.7	
Type of occupation (n/%)			
Sedentary work	40/70.2	43/59.7	0.22
Active work	17/29.8	29/40.3	

Data are expressed as mean ± standard deviation, non-continuous variables are reported as number/percentage.

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Table 3. Maternal delivery outcomes

	Exercise group (n = 61)	Control group (n = 76)	χ^2/F	P-value
Gestational length (weeks)	39.21 ± 1.62	39.31 ± 1.49	1.99	0.16
Weight at delivery (kg)	71.88 ± 13.20	75.08 ± 11.94	0.21	0.65
Excessive weight gain (n/%)				
Yes	5/9.6	14/19.4	2.25	0.13
No	47/90.4	58/80.6		
Mode of delivery				
Vaginal delivery	45/73.8	57/75	0.03	0.87
Cesarean section	16/26.2	19/25		
Episiotomy (n/%)				
Yes	12/19.7	16/21.3	0.06	0.81
No	49/80.3	59/78.7		
Perineal tear (n/%)				
Yes	32/52.5	34/45.3	0.68	0.41
No	29/47.5	41/54.7		
Miscarriage (n/%)				
Yes	0	0	-	-
No	61	76		

Data are expressed as mean ± standard deviation, non-continuous variables are reported as n/percentage. Excessive gestational weight gain was defined as total gestational weight gain exceeding the upper limit of the recommended range for the corresponding pre-pregnancy BMI category(18).

ACCEPTED

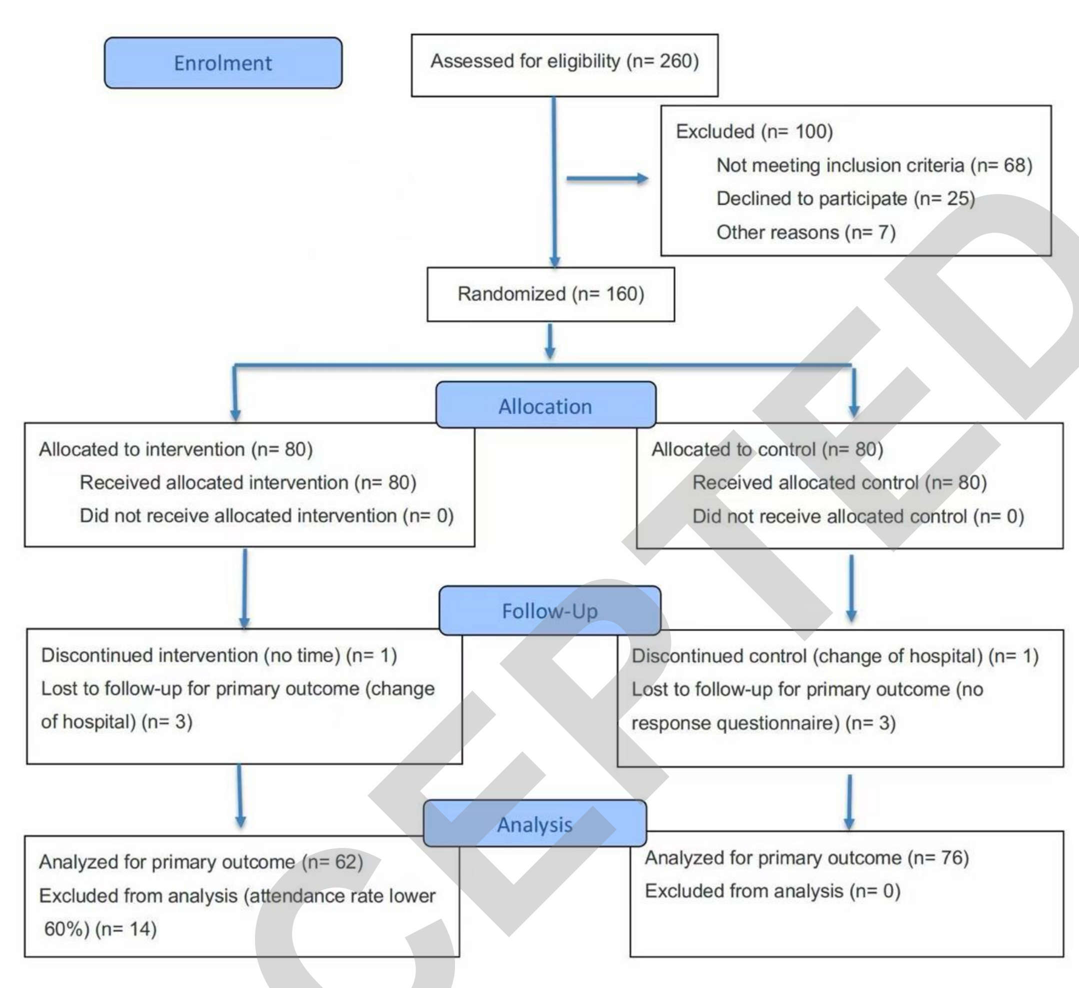
Table 4. Newborn outcomes

	Exercise group (n = 59)	Control group (n = 76)	χ^2/F	P-value
Birth weight (g)	3054.76 ± 439.53	3323.33 ± 493.83	1.05	0.31
Birth length (cm)	49.32 ± 2.07	50.33 ± 2.20	0.06	0.81
Head circumference (cm)	34.55 ± 1.38	35.18 ± 1.61	1.43	0.23
Macrosomia (n/%)				
Yes	0	6/7.3		
No	59/100	76/92.7	6.70	**0.01**
Apgar 1	8.88 ± 0.75	8.76 ± 0.78	0.85	0.36
Apgar 5	9.91 ± 0.34	9.82 ± 0.56	4.81	**0.03**

Data are expressed as mean ± standard deviation, non-continuous variables are reported as n/percentage. Macrosomia is defined as a birth weight over 4,000 grams.

ACCEPTED

Figure 1



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