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Physical Activity Interventions During Pregnancy: A Registry-Based Analysis of Completed Phase 4 Trials and Gaps in Maternal Functioning and Related Outcomes

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ABSTRACT: Physical activity during pregnancy is associated with numerous benefits for maternal and fetal health, yet its integration into routine prenatal care remains inconsistent. Understanding the current research landscape is essential to identify gaps and guide future interventions. This cross-sectional study aimed to characterize completed Phase 4 clinical trials registered on ClinicalTrials.gov that investigated physical activity as a primary intervention in pregnancy. Methods: A registry-based cross-sectional analysis was conducted using ClinicalTrials.gov. On March 20, 2025, a structured search was performed using the terms “pregnancy” and “exercise,” with filters applied to identify completed, interventional, Phase 4 trials. Trials were included if they involved physical activity interventions in pregnant populations. Extracted data included study design, sample size, intervention characteristics, and primary outcomes, which were summarized descriptively. Results: Of the 531,504 records screened, 1,667 trials involved both pregnancy and exercise. After applying the eligibility criteria, five completed Phase 4 trials were identified. Three trials focused on women with polycystic ovary syndrome, examining outcomes such as ovulation rates, pregnancy rates, insulin sensitivity, and cardiovascular health. The remaining two trials investigated gestational weight gain and maternal-fetal outcomes, including gestational diabetes, anemia, and birth weight. Interventions ranged from structured exercise programs to combined behavioral and pharmacologic strategies. Conclusion: The number of completed Phase 4 trials evaluating prenatal physical activity is limited and primarily concentrated on reproductive and metabolic outcomes in women with polycystic ovary syndrome. Research addressing broader maternal and neonatal outcomes, such as mental health, postpartum recovery, and infant development, remains sparse. Expanding clinical research in this area is essential to inform evidence-based prenatal care practices.

1. INTRODUCTION

Pregnancy is associated with many physiological, metabolic, and psychological changes in women [1]. While these changes are essential for supporting fetal development, they also increase susceptibility to adverse health outcomes such as gestational diabetes mellitus (GDM), preeclampsia, and excessive gestational weight gain [2-4]. Recently, there has been growing focus on physical activity as a non-pharmacological intervention to reduce these risks and support a healthy pregnancy [5-7]. Despite accumulating evidence supporting its benefits, physical activity remains underutilized and inconsistently integrated into prenatal care.

Moreover, pregnant women with elevated BMI or metabolic risk factors are more likely to experience complications [8, 9]. Therefore, several reports have suggested physical activity as an effective approach for these women [10-12]. Adding physical activity to maternal health behaviors could also improve pregnancy outcomes for both mother and offspring [13]. Several studies have shown that physical activity is associated with improved placental function, healthier birth weights, reduced risks

of adverse maternal effects, and greater overall benefits for both mother and offspring [14-16]. Therefore, promoting physical activity during pregnancy represents a practical approach to healthier maternal health.

Recently, researchers have been focusing on how physical activity interventions affect prenatal and maternal care. Clinical trials can assess outcomes by examining how interventions perform across diverse populations and healthcare settings [17]. Clinical trials also provide evidence on clinical outcomes, long-term effects, and practical challenges such as barriers and patient engagement [18, 19]. Therefore, this study aimed to explore Phase 4 clinical trials and the effects of physical activity on pregnancy. Physical activity was evaluated as a means of improving maternal and pregnancy outcomes. Clinical trials were categorized by the conditions studied, the types of interventions used, and the outcomes measured. Thus, this study highlighted key findings, identified knowledge gaps, outlined directions for future research, and helped bridge the gap between developing evidence and clinical application.

2. MATERIALS AND METHODS

2.1 Study Design and Unit of Analysis

This registry-based cross-sectional descriptive study evaluated completed Phase 4 interventional trials of exercise or physical activity related to pregnancy, fertility, or maternal-fetal outcomes. The clinical trial registry record was the unit of analysis; no individual participant-level data were collected or analyzed. A structured protocol was used to define the search strategy, eligibility criteria, variables, and descriptive analysis before final data verification.

2.2 Data Source and Search Strategy

ClinicalTrials.gov, maintained by the U.S. National Library of Medicine (RRID: SCR_002309), was searched on March 20, 2025. The broad search combined the terms “pregnancy,” “exercise,” and “physical activity.” Registry filters were then applied for study type (interventional), study phase (Phase 4), and recruitment status (completed). At the time of access, ClinicalTrials.gov contained 531,504 records, of which 1,667 matched the broad pregnancy and exercise search before the application of all eligibility criteria and registry filters. The search date, keywords, filters, and included National Clinical Trial (NCT) identifiers are reported to support reproducibility. Registry information was analyzed as displayed on the date of access because ClinicalTrials.gov records may be updated after their initial registration.

2.3 Eligibility Criteria

Trials were eligible when they met all the following criteria:

1. The study was registered as an interventional Phase 4 trial.
2. The overall recruitment status was reported as completed.
3. The study included pregnant women or women with a reproductive condition in which fertility, pregnancy, or maternal-fetal outcomes were evaluated.
4. Exercise, structured physical activity, or a lifestyle intervention containing a defined physical activity component was included as an intervention or co-intervention.
5. The registry record provided sufficient information on the study design, intervention, and outcomes for data extraction.

Trials were excluded if they were observational, were not classified as Phase 4, were not completed, did not evaluate physical activity as an intervention, were unrelated to pregnancy or reproductive outcomes, or duplicated an existing NCT record. No restrictions were applied according to country, publication status, study start date, or language of the registry record.

2.4 Study Selection and Record Flow

Titles and brief summaries returned by the broad search were screened, followed by a review of the complete ClinicalTrials.gov records for potentially eligible trials. Duplicate records were identified using the unique NCT registration number. Reasons for exclusion were applied consistently according to the predefined eligibility criteria.

Record-level exclusion, rather than participant attrition, determined the final analytical sample. Participant withdrawal and loss to follow-up were not independently reanalyzed because individual participant-level datasets were unavailable. Such information was recorded only when reported in the registry.

2.5 Data Extraction and Verification

Data were manually extracted into a structured extraction form. The extracted variables included the NCT number, study title, condition, country or study location when available, enrolment, participant sex and age eligibility, allocation or randomization method, intervention model, masking, number and description of study arms, exercise type, frequency, intensity, duration, comparator, primary outcomes, availability of results, and linked publications. Exercise interventions were classified as structured exercise, resistance training, general physical activity counseling, or multicomponent lifestyle intervention. Outcome domains were classified as reproductive, metabolic, gestational weight, cardiovascular, or maternal-fetal outcomes. Information not provided in a registry record was coded as “not reported,” and no missing values were imputed. Each included record underwent a second verification against the source registry. Any discrepancy was resolved using the ClinicalTrials.gov record as the source of truth.

2.6 Bias Control, Randomization, and Blinding

Selection and extraction bias were reduced by applying the same eligibility criteria and data-extraction fields to all retrieved records. Eligible trials were included regardless of whether study results or linked publications were available. No participants were assigned, randomized, or blinded in the present registry analysis. Randomization, allocation, and masking were characteristics of the original clinical trials and were extracted exactly as reported in their registry records. Blinding of the reviewer was not feasible because the NCT identifiers, study titles, and intervention descriptions were required for eligibility assessment and data extraction.

2.7 Sex as a Biological Variable

The research question focused on pregnancy and female reproductive health; therefore, eligible study populations were biologically female. Participant sex and gender eligibility were extracted from each registry record. No sex-stratified analysis was conducted because the included trials did not provide a comparable male population.

2.8 Sample Size and Statistical Analysis

All registry records meeting the predefined eligibility criteria were included. Therefore, the analytical sample represented a census of eligible records rather than a sample selected from a larger eligible population. An a priori sample-size calculation and statistical power analysis were not applicable because the study did not test a hypothesis or compare individual participant-level outcomes. Categorical variables were summarised using frequencies and proportions. Continuous variables, including enrolment and intervention duration, were summarised using ranges when data were available. No inferential statistical tests, P values, confidence intervals, effect-size estimates, or meta-analysis were performed because only five trials met the eligibility criteria and their populations, interventions, comparators, and outcomes were heterogeneous. The descriptive analysis required no custom algorithms, computer code, or specialized statistical software.

2.9 Reproducibility, Protocol, and Data Availability

The analysis can be reproduced using the reported search date, keywords, registry filters, eligibility criteria, and NCT identifiers. The study protocol was not prospectively registered. All source records are publicly available through ClinicalTrials.gov under the NCT numbers reported in Tables 1 and 2. The extracted variables used in the analysis are presented in Tables 1–3. No restricted datasets or individual participant-level data were accessed.

3. RESULTS AND DISCUSSION

3.1 General Characteristics of Included Trials

The included trials were conducted across various regions and from the early 2000s to 2012. The sample sizes ranged from 40 to 150 participants. Three trials primarily addressed Polycystic Ovary Syndrome, while two focused on general pregnancy-related outcomes. Two trials were linked to published publications (Table 1). The trials varied in designs, with most being

randomized controlled trials, and one marked as non-randomized. The interventions were primarily categorized under behavioral modifications, often combining physical activity with nutritional counseling or pharmacologic treatment.

Table 1: Summary of Included Phase 4 Trials on Physical Activity in Pregnancy

NCT Number	Study Title	Enrolments	Conditions	Related publications
NCT00813657	Resistance Exercise Training During Pregnancy: A Randomized Controlled Trial	80	Gestational Age	NA
			Birth Weight Anemia	
			Gestational Diabetes Mellitus	
NCT01084941	Lifestyle Intervention to Limit Excessive Weight Gain During Pregnancy in Minority Women	57	Pregnancy	NA
			Weight Gain	
NCT00593294	Oral Contraceptive and Cardiovascular Risk in Polycystic Ovary Syndrome	150	Polycystic Ovary Syndrome	[20]
NCT00473538	Structured Exercise Training Program Versus Hypocaloric Hyperproteic Diet in Obese Anovulatory Infertile Patients With Polycystic Ovary Syndrome	40	Polycystic Ovary Syndrome	[21-24]
			Anovulation	
			Infertility	
NCT01004068	Short-term Structured Exercise Training Program Plus Diet Intervention in Patients With Polycystic Ovary Syndrome	96	Polycystic Ovary Syndrome Anovulation	[21, 24, 25]

3.2 Interventions

Intervention protocols across the five trials varied in type, intensity, and duration. As shown in Table 2, one trial implemented a supervised resistance exercise training regimen throughout the second and third trimesters of pregnancy. At the same time, another performed a lifestyle program initiated early in gestation. In trials focusing on Polycystic Ovary Syndrome, interventions included structured exercise training, hypocaloric diets, and combinations of exercise with clomiphene citrate or oral contraceptive pills. Physical activity frequency ranged from 3 sessions per week to daily exercise, and intervention durations ranged from 6 weeks to 6 months. Control groups varied by study and included standard care, pharmacological-only regimens, or dietary-only interventions.

Table 2: Intervention and Exercise Protocols in Included Trials

NCT Number	Participant Group/Arm	Detailed Interventions
NCT00813657	Experimental: Lifestyle counseling	Behavioral: Exercise Women in the intervention group were enrolled in three sessions/week of individually supervised, resistance exercise training performed over the second and third trimester of pregnancy (in total 26 weeks, ~80 training sessions). Heart rate (HR) was carefully and individually controlled ($\leq 80\%$ of age-predicted maximum HR value, $220 - \text{age}$) through a heart rate monitor during the training sessions. In brief, each session consisted of 35-40

		minutes of exercise divided into a light intensity ($\leq 60\%$ maximal heart rate) warm-up period (~8 minutes), followed by toning and very light resistance exercises (~20 minutes) and a light intensity cool-down (~8 minutes) period. Resistance exercises were performed with barbells (<3 kg per exercise) or low-to-medium resistance bands (Therabands).
NCT01084941	Experimental: Lifestyle intervention	Behavioral: Lifestyle Intervention group Women in the intervention group will participate in a lifestyle program based on diet and moderate physical activity implemented shortly after the first recognition of pregnancy. These women will attend monthly nutrition and physical activity educational sessions, and receive a booster every 2 weeks.
	Active Comparator: Standard of care group	Behavioral: Standard of Care Patients randomized to the standard-of-care group will receive counseling routinely provided to all pregnant women, as recommended by the Institute of Medicine for appropriate nutrition and weight gain, and by ACOG guidelines for appropriate physical activity during pregnancy.
NCT00593294	Experimental: A,1, I	Behavioral: Physical exercise 45 minutes each day three times/week for 6 months
	Active Comparator: B, 2, II	Drug: OC - Drospirenone plus Ethynylestradiol 1 cp for 21 days each month for 6 months of OC (Drospirenone 3 mg plus Ethynylestradiol 30 microgram = Yasmin, Schering, Milan, Italy)
	Placebo Comparator: C,3, III	Dietary Supplement: Vitamin, polyvitamin tablets Tablet of vitamin 1cp for 21 days each month for 6 months
NCT00473538	Behavioral: Structured exercise training	Pregnancy rate
	Behavioral: Hypocaloric hyperproteic diet	
NCT01004068	Experimental: SET-diet plus clomiphene Structured exercise program plus hypocaloric diet for two months, and received one-cycle of clomiphene citrate for one cycle	Other: SET-diet plus clomiphene - Two months of a structured exercise program plus hypocaloric diet followed by 150 mg daily of clomiphene citrate - Other Names: - Lifestyle modification
	Active Comparator: Clomiphene citrate	Drug: Clomiphene citrate Clomiphene citrate at 150 mg daily for one cycle

	One month of observation followed by one-cycle of clomiphene citrate therapy	
	Experimental: SET plus diet Lifestyle modifications for two months.	Behavioral: Structured exercise program plus hypocaloric diet • SET plus diet • Other Names: ○ Lifestyle modifications

3.3 Conditions Studied and Primary Outcomes

As summarized in Table 3, three of the five trials investigated Polycystic Ovary Syndrome, focusing on reproductive and metabolic outcomes such as ovulatory rate, pregnancy rate, and insulin sensitivity. One trial evaluated maternal weight gain during pregnancy, and another assessed maternal-fetal outcomes, including gestational age, anemia, and birth weight. In addition, one Polycystic Ovary Syndrome-focused trial included cardiovascular health outcomes, such as carotid intima-media thickness.

Table 3: Conditions and Outcome Domains Studied

Conditions	No. of Trials	Common Primary Outcomes
Polycystic Ovary Syndrome	3	Ovulation rate, pregnancy rate, insulin sensitivity
General Pregnancy / Weight Gain	1	Weight gain control, lifestyle modification
Maternal-Fetal Outcomes (Anemia, Birth Weight, Gestational Age)	1	Birth weight, anemia status, gestational duration

3.4 DISCUSSION

This study evaluated clinical trials examining the effects of physical activity on prenatal and maternal health. Of the five eligible trials, the majority focused on women with polycystic ovary syndrome, with primary outcomes related to ovulation and pregnancy rates. One trial addressed gestational weight gain in the general pregnancy population, and another investigated maternal-fetal outcomes, including GDM, anemia, and birth weight. However, none of the trials incorporated mental health or postpartum recovery outcomes. The interventions varied in type and delivery, ranging from structured exercise and lifestyle counseling to combined behavioral and pharmacologic strategies. These findings underscore a narrow concentration of clinical research and highlight key opportunities for expansion.

The trials in this study that investigated polycystic ovary syndrome showed that exercise improves ovulatory frequency, insulin sensitivity, and fertility outcomes. In Addition, confirming that lifestyle modification, including physical activity, can be as effective as pharmacotherapy in improving ovulation in women with polycystic ovary syndrome. In fact, several studies have reported that physical activity is beneficial for reproductive and metabolic health, particularly in women with Polycystic Ovary Syndrome, with insulin resistance, hyperandrogenism, and ovulatory dysfunction [26-28]. The emphasis on reproductive endpoints, such as ovulation and pregnancy rates, reflects the high clinical need for non-pharmacological solutions to improve fertility in this population.

Moreover, physical activity could promote hormonal normalization, further supporting fertility outcomes. Exercise interacts with fluctuating estradiol and progesterone levels across the menstrual cycle, with higher estradiol/progesterone ratios associated with increased fat oxidation during moderate-intensity exercise [29]. In addition, endurance training can increase the expression of estrogen receptor- α in skeletal muscle, potentially enhancing metabolic responsiveness to circulating estrogen

during exercise [30]. These findings align with the trials studied in this study, in which structured exercise interventions were applied either independently or alongside pharmacological treatments. However, more representative trials are needed to confirm these effects across diverse populations in clinical settings.

One included trial also examined the impact of physical activity on gestational weight gain. Excessive gestational weight gain has been consistently associated with increased risks of cesarean delivery and preeclampsia [31, 32]. Interventions aimed at controlling gestational weight gain have shown positive effects in previous studies, where structured lifestyle programs significantly reduced excessive weight gain [33, 34]. It has been reported that incorporating physical activity into lifestyle interventions for women with gestational diabetes mellitus can significantly reduce gestational weight gain, improve weight management during pregnancy, and lower the risk of delivering macrosomic infants, without adverse effects on maternal or fetal outcomes [35]. However, the absence of follow-up data on postpartum weight retention and longer-term maternal health outcomes highlights a gap that warrants further investigation.

While moderate physical activity is generally beneficial, high-intensity or prolonged exercise may negatively affect reproductive function. It has been reported that high-intensity physical activity could negatively impact fertility, potentially through hormonal disruptions affecting ovulation and menstrual cycle regulation. Although the meta-analysis did not include direct hormonal measurements, it suggests that excessive exercise may interfere with reproductive function, while moderate activity appears to have no adverse effect [36]. Intense physical activity, particularly in energy-deficient states, can also disrupt hypothalamic function and suppress reproductive hormones such as GnRH, LH, and FSH, leading to menstrual irregularities and fertility issues [37]. Strenuous aerobic exercise during pregnancy may reduce uteroplacental blood flow, potentially compromising fetal well-being [38]. However, short-duration strenuous exercise in healthy pregnant women does not compromise fetal well-being; nevertheless, very active women may experience a slight temporary reduction in fetal heart rate and changes in uterine and umbilical artery blood flow after exercise without apparent clinical complications [39]. These findings highlight the need for individualized exercise recommendations during pregnancy that consider intensity, duration, maternal fitness level, and overall health status. Several limitations should be considered in this study's findings. First, the number of eligible Phase 4 clinical trials evaluating physical activity during pregnancy was small, which limits the generalizability of the findings. The included studies varied in study populations, intervention types, durations, and measured outcomes, making direct comparisons challenging. Furthermore, several trials lacked publicly available results or complete datasets on ClinicalTrials.gov, restricting the depth of outcome analysis. Another limitation is the underrepresentation of key outcomes such as mental health, postpartum recovery, and infant development, which affect the understanding of prenatal physical activity impacts. Lastly, the study focused exclusively on trials registered in ClinicalTrials.gov, which may exclude relevant studies from other databases or unpublished trials, introducing potential selection bias.

4. CONCLUSION

This study highlights the limited scope of completed clinical trials investigating the effects of physical activity before and during pregnancy. Most trials focused narrowly on reproductive outcomes in women with polycystic ovary syndrome, with minimal exploration of broader maternal or fetal health outcomes. Despite strong evidence supporting the benefits of prenatal exercise, key areas such as mental health, postpartum recovery, and infant development remain underrepresented. Future trials should aim to include diverse populations, assess a wider range of clinical endpoints, and evaluate long-term maternal and infant outcomes. Expanding the evidence base through well-designed clinical trials is essential to inform clinical guidelines and support the safe, effective integration of physical activity into routine prenatal care.

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AUTHOR CONTRIBUTIONS

Not Applicable

CONFLICT OF INTEREST

The author declare that there is no conflict of interest.

ETHICS STATEMENT

Ethics committee approval and informed consent were not required for this secondary analysis because it used publicly available, non-identifiable clinical trial registry information and involved no participant contact, intervention, or access to protected health information.

DATA AVAILABILITY STATEMENT

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

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