Impact of Exercise Prescription on Obstetric and Neonatal Outcomes

Coimbra, September 2024

STUDY PROTOCOL

A prospective, longitudinal, single-arm, intervention (prospective cohort) study was conducted in the Obstetric Department of Hospital of Coimbra, Portugal, for a total period of 18 months after a one-year recruitment period between February 2024 and January 2025, with data collection continuing until the final participant had given birth.

Clinical monitoring for high-risk pregnancies takes place solely in a hospital setting. This includes at least monthly visits and standardized trimester ultrasounds, with supplementary scans schedule as needed for fetal development and well-being based on the underlying conditions.

All pregnant patients attending their first obstetric consultation for either Endocrinology/Obstetric (if diagnosis of gestational diabetes or obesity with previous bariatric surgery) or Hypertension/Obstetric (if chronic hypertension) were recruited for the trial.

Inclusion criteria comprised pregnant women aged 16 years or older with a confirmed diagnosis of gestational diabetes (fasting blood glucose greater than 92 mg/dL in first trimester; or values in the oral glucose tolerance test in second trimester greater than 92/180/153 mg/dL, respectively at 0 hours, 1 hour after glucose ingestion, and 2 hours after), chronic hypertension or a history of bariatric surgery and pre-pregnancy Body Mass Index (BMI) above 30Kg/m2. Eligibility further required consistent clinical adherence defined as attending all schedule appointments with the obstetric team without unjustified absences.

Exclusion criteria were defined as follows: multiple gestations, risk of preterm labor or a history of premature delivery due to a non-maternal cause, persistent vaginal bleeding or placenta previa beyond 28 weeks' gestation, cervical insufficiency and any limiting systemic, respiratory or cardiovascular disease.

Study participants were enrolled via screening referrals initiated by both internal or external healthcare providers.

At the first visit, pregnant women were notified of an upcoming telephone contact from the research team. After clinical record verification, a phone interview was conducted to explain the project and collect demographic, anthropometric and obstetric data. After confirming the absence of exercise contraindications, researchers assessed the participants' pre-pregnancy healthy lifestyle habits.

Subsequently, participants received proactive counselling on the exercise modalities most effective for their specific pathologies, including guidance on the intensity, frequency and duration required for optimal health outcomes. This intervention included information on local exercise facilities and access to digital platforms (YouTube Channel – Active Pregnancy) featuring safe, evidence-based activities tailored for pregnancy. Prescriptions were individualized, incorporating patient preferences to determine the most suitable activity types and schedules.

Participants were equipped with a smartwatch to monitor physical activity, specifically tracking heart rate, step count, distance and average speed throughout the pregnancy. They were instructed to activate the device's 'training' mode at the commencement of each exercise session. Subsequently, activity data were synced to a dedicated mobile application for later extraction and analysis from the research team.

Follow-up telephonic consultations were conducted every 3-6 weeks to promote exercise adherence. During these calls, the research team characterized the participants' previous activity levels and adjusted prescriptions based on individual tolerability and evolving interests. These contacts persisted until delivery, the emerge of a medical contraindication or at the participants request.

Informational posters were displayed throughout the institution to highlight the primary advantages of prenatal physical activity. These materials included a link to dedicated social media platform design specifically for this study, intended to educate patients, dispel prevalent myths such as the unsubstantiated link between exercise and miscarriage or preterm birth and provide localized information on community exercise facilities and safe home-based workout routines.

STATISTICAL ANALYSIS PLAN

For statistical analysis, the cohort was categorized into two distinct groups based on adherence levels to physical activity, i.e., <150 min/week versus >150 min/week. The first group (Group 1) consisted of participants who sustained physical activity through or near to deliver; the second group (Group 2) included non-adherence participants and those who initiated the intervention but experienced premature withdrawal (completing only the first assessment).

To prescribe exercise intensity, the Heart Rate Reserve (HRR) framework was selected over traditional age-predicted maximal heart rate equations (e.g., \(220 - \text{age}\)) to ensure greater physiological precision, targeting a training zone of 50–70% of HRR. However, the practical application of this method was constrained by methodological challenges in establishing an accurate resting heart rate (RHR).

Glycemic control was categorized as uncontrolled if pharmacological intervention was required to meet clinical targets typically defined as having more than five weekly blood glucose readings outside the recommended range (fasting plasma glucose ≥ 95 mg/dL and/or 1-hour postprandial glucose ≥ 140 mg/dL) and no association with alimentary mistakes.

Chronic hypertension was categorized as poorly controlled when medication adjustments or new therapies were necessary to achieve blood pressure values below the 140/90 mmHg threshold.

Low birth weight was defined as a birth weight of less than 2500g and macrossomic newborn was defined as a birth weight above 4000g. We considered the fetal growth estimated on the third trimester scan (30-32 weeks), and defined large for gestational age when estimated fetal weight was above the 90 th percentile for the gestational age and small for gestational age when estimated fetal weight was below the 10 th percentile for gestational age. Preterm birth was considered if deliver occurred before 37 weeks of gestational age.

Excessive weight gain was defined according to the Portuguese Directorate General of Health (DGS) guidelines (more than 18kg for women with pre-pregnancy BMI<18.5 kg/m 2 ; more than 16kg if previous BMI between 18.5-24.9 kg/m 2 ; more than 11.5kg if previous BMI between 25-29.9 kg/m 2 ; and more than 9kg if previous BMI above 30 kg/m 2).

Duration of labor was defined as the number of hours required from the onset of the active phase of labor until the moment of birth. Elective cesarean sections were excluded from this calculation.

Statistical analysis was performed using Microsoft Excel ® and IBM *SPSS Statistics* ® 29.0. A descriptive analysis was conducted, followed by statistical analysis. The normality of continuous data was tested via the Shapiro-Wilk method. Accordingly, differences between groups were analyzed using t-student test (for normal distributed data) and Mann-Whitney U test (for non-normal distribution). For categorical data, $\chi 2$ were applied, with Fisher's exact test used whenever expected cell counts fell below 5. A *p* value of 0.05 was considered statistically significant. Logistic regression analysis was employed to estimate the probability of glycemic control occurring, based on the selected predictors. Results were reported as Odds Ratios (OR) with their respective 95% Confidence Intervals (CI).