



Programa de Pós-Graduação  
em Epidemiologia

# Pelotas Birth Cohort Study



STUDY PROTOCOL

Open Access

# Physical activity during pregnancy and maternal-child health (PAMELA): study protocol for a randomized controlled trial

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## Abstract

**Background:** Preterm birth is associated with most cases of neonatal deaths and negative health outcomes, and hypertensive disorders. Hypertension is influenced by maternal behavior, such as physical activity. Physical activity is associated with better outcomes for mother and fetus, besides healthier weight gains during pregnancy. Few women are physically active during pregnancy and few clinical trials have been carried out with pregnant women. The aim of this paper is to describe the protocol of a controlled trial evaluating whether regular exercise during pregnancy may result in improved maternal-child health and neonatal outcomes.

**Methods/Design:** The PAMELA (Physical Activity for Mothers Enrolled in Longitudinal Analysis) trial is a randomized controlled trial nested in a birth cohort study. Eligible women belonging to the birth cohort will be invited (between the 16th and 20th week of gestation) to enroll in the trial. Baseline data (blood and urine samples, anthropometry and pulmonary function) will be collected at enrollment. The same assessments will be repeated eight and 16 weeks after baseline. After randomization, women will be allocated into either one of these groups: control, 426 women who will be advised to keep their usual daily activities; and intervention, 213 women who will engage in an exercise program, three sessions a week. At least 70 % attendance over 16 weeks will be required to be considered compliant to the intervention. Exercise protocol will include aerobics, strength and flexibility training. Maternal and child outcomes will be measured at the 36th week of gestation, at birth and at three, 12, 24 and 48 months postpartum. An intention-to-treat analysis will be performed.

**Discussion:** Few women are active during pregnancy and a vast majority decrease their activities or even quit exercising. We present a population-based regular exercise intervention focused on the prevention of hypertension, pre-eclampsia and preterm birth. Data on the underlying cohort will allow future analysis using different outcomes with low probability of recall bias or misclassification of exposure status. Results will potentially influence prenatal care counseling in regards to physical activity.

**Trial registration:** Clinicaltrials.gov identifier: NCT02148965, registered on 22 May 2014.

**Keywords:** Exercise, Motor activity, Randomized controlled trial, Pregnancy, Infant premature, Cohort studies, Newborn, Gestational diabetes, Pre-eclampsia, Postpartum depression

# PAMELA

Physical Activity for Mothers Enrolled in Longitudinal Analysis

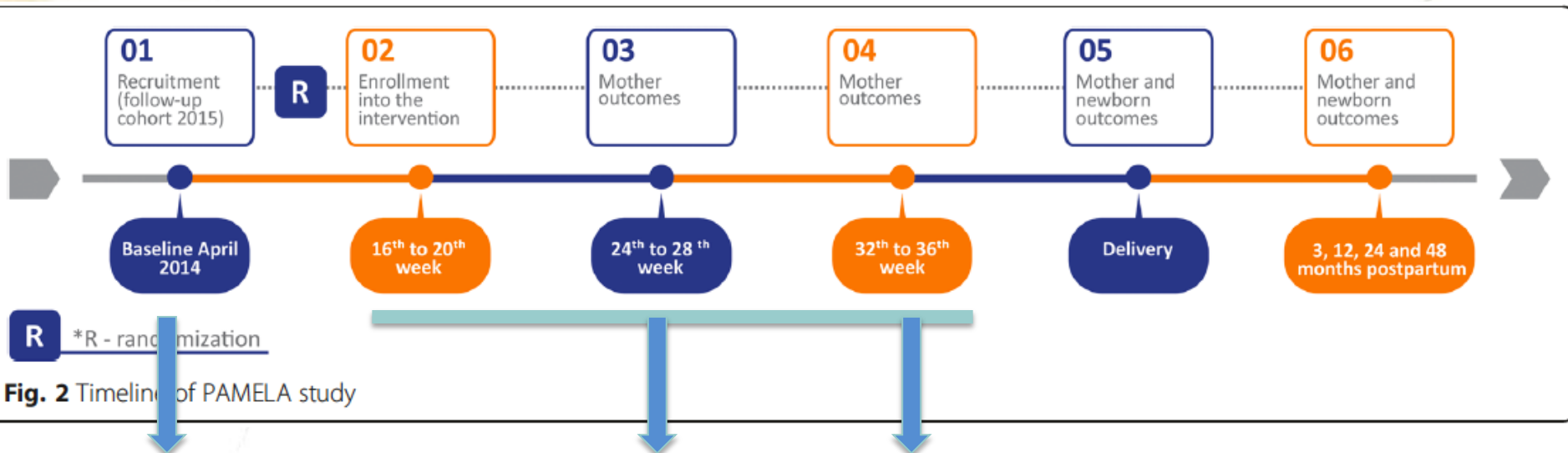


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- **Randomized controlled trial – nested to the 2015 Birth Cohort**
  
- **Exclusion criteria**
  - Under 18 years
  - Hypertension, diabetes or heart disease
  - History of previous miscarriage or preterm birth
  - Women presenting persistent bleeding
  - Fertilization in the current pregnancy
  - Twin pregnancy
  - BMI > 35 kg/m<sup>2</sup>
  - Smoking > 20 cigarettes a day
  - Weekly leisure-time physical activity > 150 min



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## Outcomes

(Body mass index, Blood pressure, Spirometry,  
Blood lipids, Glycaemia)

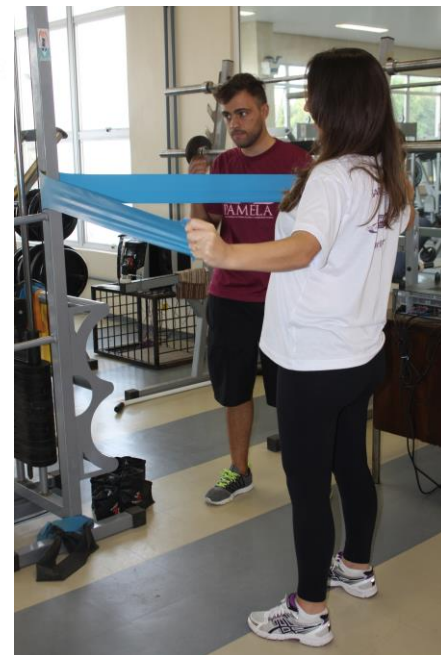


## ○ Intervention:

- 16 weeks
- 3 days/week: 60 minutes

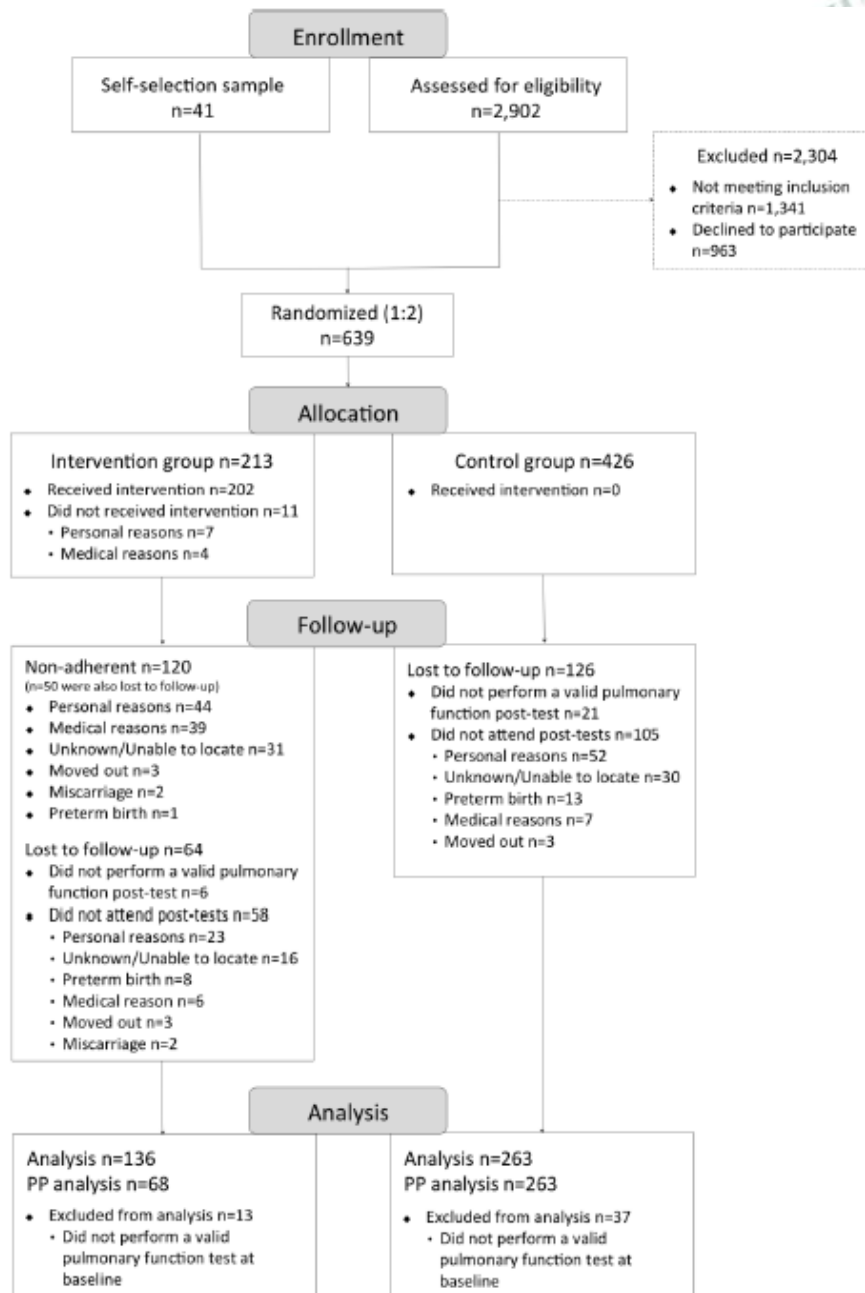
**Table 1.** Exercise program stages according to weeks of intervention – PAMELA trial.

<b>Weeks of intervention</b>	<b>Warm-up</b>	<b>Aerobic exercise</b>	<b>Strength training/ Floor exercises</b>	<b>Cool-down</b>
1 to 4	5 min	15 min	35 min: 3 sets of 12 reps	5 min
5 to 10	5 min	20 min	30 min: 3 sets of 10 reps	5 min
11 to 16	5 min	25 min	25 min: 3 sets of 8 reps	5 min





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**Figure 1.** Flow diagram of the study participants.  
PP: per protocol.