

Type of delivery and gestational age is not affected by pregnant Latin-American women engaging in vigorous exercise. A secondary analysis of data from a controlled randomized trial¹

El tipo de parto y la edad gestacional no se afectan por el ejercicio aeróbico vigoroso en mujeres gestantes latinas. Análisis secundario de un ensayo clínico

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ABSTRACT

Objective There is controversy concerning whether exercise during pregnancy may increase preterm delivery risk and type of delivery. The effect of pregnant Latin-American women engaging in vigorous exercise during the second and third trimester was examined regarding type of delivery and gestational age.

Materials and Methods This was a secondary analysis of data from a controlled randomized trial for determining the influence of physical exercise on pregnant women's endothelial function. The study included 35 nulliparous women, gestational week 16-20 attending prenatal care at three tertiary hospitals in Colombia, who were randomly assigned to one of two groups. The experimental group engaged in aerobic exercise involving 55 % - 75 % maximum heart rate for 60 min, three times a week for 12 weeks. The control group engaged in their usual physical activity. Maternal weight, height, weight gain, blood pressure and type of delivery were recorded; gender, abdominal and head circumference (cm), weight (g), height (cm), vitality (Apgar score at 1 and 5 min) and gestational age at the time of delivery (in weeks, days) were recorded for the newborn.

Results There was no difference in type of delivery by the end of the 12-week

¹(NCT00741312)

program ($p>0.05$), nor regarding newborn anthropometric variables, Apgar score, or maternal variables concerning weight, height, relative weight gain, blood pressure or weeks of gestation ($p>0.05$).

Conclusion The potential public health benefits of vigorous exercise were enormous. This study supported existing guidelines indicating that Latin-American women may begin or maintain an on-going exercise program during pregnancy.

Key Words: Gestational age, exercise, pregnancy, clinical trial (*source: MeSH, NLM*).

RESUMEN

Objetivo Existe controversia acerca del efecto del ejercicio físico vigoroso (EFV) durante el embarazo por sus posibles consecuencias en el tipo de parto y la edad gestacional. El objetivo de este estudio fue evaluar el efecto del EFV durante el segundo y tercer trimestre, en mujeres gestantes latinas sobre el tipo de parto y la edad gestacional.

Materiales y Métodos Se trata de un análisis secundario de un ensayo clínico controlado en 35 gestantes, asignadas al azar en dos grupos. Grupo experimental ($n=18$): EFV entre el 55 % y 75 % de la FC max, por 60 min, 3 veces por sem. Por 12 sem. Grupo Control ($n=17$): actividad física cotidiana y control prenatal habitual. Se registraron en las maternas: peso, talla, ganancia de peso, presión arterial y tipo de parto. En el recién nacido se registró: género, perímetro cefálico y abdominal (cm), peso (g), talla (cm), semanas de gestación, vitalidad (score Apgar al 1 y 5 min), y semanas de gestación.

Resultados No se encontraron diferencias estadísticamente significativas respecto al tipo de parto ($p>0,05$). Tampoco en las variables antropométricas del recién nacido, ni en las variables maternas: peso, talla, ganancia de peso, presión arterial o semanas de gestación ($p>0,05$).

Conclusión Los beneficios potenciales en salud pública del efecto EFV durante la gestación son importantes y este estudio favorece que mujeres latinas puedan comenzar o mantener un programa de ejercicios durante el embarazo.

Palabras Clave: Edad gestacional, ejercicio, embarazo, ensayo clínico (*fuentes: DeCS, BIREME*).

Several publications over the last decade have reported few negative effects on a healthy pregnant woman's pregnancy regarding her engaging in physical activity (1). Physical exercise during pregnancy could be beneficial to the maternal-fetal unit and prevent maternal disorders occurring, such as hypertension and gestational Diabetes mellitus (2,3). Recent American College of Obstetricians and Gynecologists' guidelines (4) promote vigorous exercise/training for pregnant women (including sedentary ones) due to for its overall health benefits, including decreased risk of gestational diabetes mellitus and improving well-being and quality of life (2).

The U.S. Department of Health and Human Services issued comprehensive guidelines on physical activity and pregnant women in 2008 (5). Healthy women (non-exercisers and moderate exercisers) should begin or continue moderate-intensity aerobic activity during pregnancy, accumulating at least 150 minutes per week (6). Physical activity may reduce the risk of maternal disorders during pregnancy; however, little data is available concerning pregnant Latin-American women's physical activity. For example, Latin-American women have two to four times the risk of developing gestational diabetes mellitus, chronic hypertension, preeclampsia and caesarean delivery compared to non-obese women and non-Latin white women (7).

Obstetricians are hesitant to advise sedentary women to initiate exercise during pregnancy, and nearly half counsel exercisers to reduce their current activity level (8). It has been speculated that obstetricians have not encouraged exercise during pregnancy, partly as a result of a paucity of data regarding fetal safety. Such lack of counseling may have emerged from pregnant Latin-American women's health benefits from exercise and pregnancy-specific benefits such as decreased risk of being overweight and obese, pre-eclampsia, gestational diabetes (9,10) and reduced depressive symptoms (2).

Relevant data from randomized controlled (1,3) trials and controlled pilot training studies (11) (sample size <15 women) and prospective reports on large population samples have suggested no association between vigorous exercise/training during pregnancy and pregnancy outcome (gestational age, risk of preterm delivery, intrauterine growth) (12) in previously physically-active (and thus fit) and usually middle-high-socioeconomic class women (7, 13,14). This randomized, controlled pilot trial was thus undertaken to examine the effect of vigorous exercise/training (during the second and third trimesters of pregnancy) on 35 pregnant Latin-American women regarding the type of delivery and gestational age.

METHOD

Design

This was a secondary analysis of data from a controlled randomized trial designed to determine the influence of physical exercise on endothelial function in pregnant women; its methods have been described in detail elsewhere (9,15). Interested women eligible for the

present study were invited to a pre-test including semi-structured interview and assessment at the Cañaveralejo Hospital and Universidad del Valle Biochemistry Laboratory in Cali, Colombia. The first visit was between 12 and 20 weeks' gestation; secondary measures were recorded from a prenatal interview (in the aforementioned primary care centre) or from the clinical history (in the aforementioned hospital's Obstetrics Department by a nurse and a gynecologist). The study was approved by the local institutional review board, prior to initiation (Resolution-022/29-UV). All participants provided written informed consent before entering the study, in accordance with Declaration of Helsinki guidelines (last modified in 2004). A conservative approach was used to estimating sample size (trial registration: NCT00741312) (9, 15). Power calculations were made for primary outcome measures of gestational age, Apgar score, birth weight and length. It was determined that adequate power (>0.80) would be achieved with 24 pregnant women in the training group and 24 pregnant women in the control group. All power computations assumed that comparing baseline to 16-week scores would be tested at the 5 % significance level. All power computations allowed for 10 % dropout over a 26-week period.

Participants

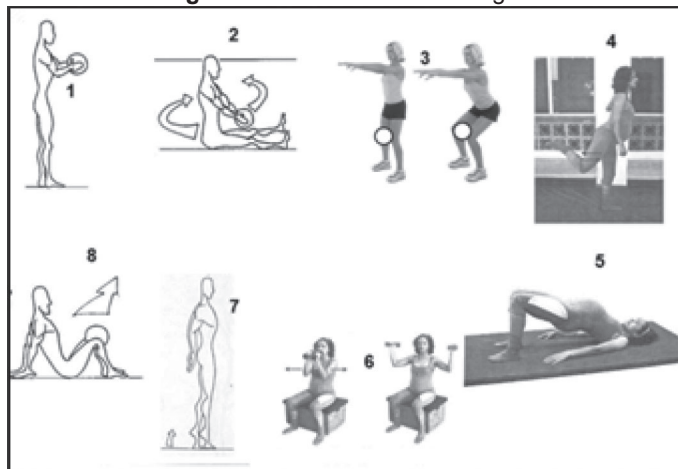
The volunteers were randomly allocated to one of two groups, according to admission order, following a computer-generated randomization list. To guarantee concealment for randomization, each sequential number corresponded to a sealed opaque envelope containing the questionnaires and information regarding the randomization group: experimental group involving supervised vigorous exercise/training (controlled by a physical therapist and a medical doctor) and a control group involving the usual prenatal care. Pregnant women were included if they were nulliparous and had not participated in a structured exercise program beforehand, aged 16-30 years, having a live fetus in routine ultrasound scan, a normal pregnancy and 16 to 20 weeks' gestational age. They were excluded if they had a history of high blood pressure, chronic medical illnesses (cancer or renal, endocrinology, psychiatric, neurological, infectious and/or cardiovascular disease), persistent bleeding after week 12 of gestation, poorly-controlled thyroid disease, placenta praevia, an incompetent cervix, polyhydramnios, oligohydramnios, a history of miscarriage during the last twelve months and diseases which could interfere with participation [following ACSM 2000 (16) and ACOG 2002 recommendations (17)].

Intervention

Experimental group

The program's vigorous exercise/training included a total of three (Monday, Wednesday, Friday) 60-minute weekly sessions from the start of the second trimester (weeks 16-20) to the end of the third trimester (weeks 32-36). Thus, an average of ~32 training sessions was originally planned for each participant in the event of no preterm delivery. All subjects wore a heart-rate (HR) monitor (Polar Electro OY, Finland) during the training sessions to ensure that exercise intensity was light-to-moderate. Each session included regular vigorous exercise/training, involving walking (10 min), aerobic exercise (30 min) (Figure 1), stretching (10 min) (Figure 2) and relaxation exercise (10 min) for 12 weeks (15). All sessions were supervised by a physical therapist, doctor and a physical educator. The exercise-program followed ACSM (16) and ACOG (17) exercise prescription. Adherence to the exercise program was addressed by a physical therapy who supervised the presence of each woman for at least 75 % of the exercise sessions. All sessions were supervised by a qualified physical therapy specialist (working with groups of 3-5 subjects), accompanied by music and held in a spacious, well-lit room in favorable environmental conditions (~900m altitude, 22-28°C, 50-60 % humidity) to maximize adherence to the training program and its efficacy.

Figure 1. Aerobic circuit training 2

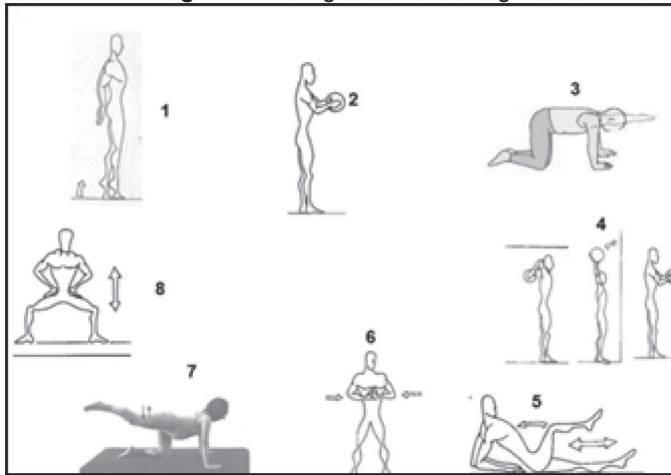


Aerobic exercises included one set of 10–12 repetitions of abdominal curls, bicep curls, arm extensions, arm side lifts, shoulder lifts, seated bench press, seated lateral rowing, lateral leg lifts, leg circles, knee extensions, knee (hamstring) curls and ankle flexing and extension. The women used weight racks and balls (3 lb per exercise) or low-to-medium resistance bands (Thera-bands). Exercises involving extreme stretching and joint overextension, ballistic movements, jumps, and the type of exercise performed on the back were specifically avoided. Supine postures were also avoided.

Control group

This consisted of women who would not (usually) carry out any physical exercise during pregnancy and daily-living activities, who would engage in basic daily-living activities (bathing, dressing, eating, walking) without counseling by a physical therapist, 6 sessions, one month (18).

Figure 2. Strength circuit training 1



Strength exercises consisted of toning and joint mobilization exercises involving major muscle and joint groups. Toning and joint mobilization exercises included shoulder shrugs and rotation, arm lifts, lateral leg lifts, pelvic tilt and rocking.

Outcome measure

The study investigators were informed when any woman was hospitalized for delivery and were present to follow-up labor and delivery and collect data. Research assistants having no knowledge of group assignment were designated to determine the following variables in all participants from the prenatal interview (in the aforementioned primary-care centre) or from the clinical history (in the aforementioned hospital obstetrics' department).

Maternal and delivery outcomes

Blood pressure was measured by the auscultatory method at the end of each stage of exercise, up to 6 min. following exercise and delivery, using a mercury column sphygmomanometer. Baseline variables were maternal age, body weight and body mass index (BMI), measured by standard methods (17). Gestational age at the time of delivery (in weeks, days) was recorded from a hospital's perinatal records.

Newborn outcomes

Data regarding condition after birth, Apgar score, etc, were recorded at both hospitals by the midwife or doctor following delivery, using the standard hospital form. The results of the classic Apgar (acronym for appearance (skin color), pulse (heart rate), grimace (reflex irritability), activity (muscle tone) and respiration) test (19) were obtained from the delivery room personnel reports (by nurses) at 1 and 5 min after a baby's complete birth (20). A score of one or two was given for each item, depending on whether it were absent or present (total score could thus range from 0 to 10) (20).

Data analysis

Variable distribution was initially evaluated to verify the two groups' comparability using the Kolmogorov-Smirnov test. A bivariate analysis compared qualitative variables using Yates' X² test; quantitative data was analyzed using the Mann-Whitney U test. Multiple comparisons were adjusted for mass significance. Significance was established at 5% using SPSS software (v.14.0, SPSS Inc, Chicago, IL).

RESULTS

Participants

The study started in March 2008 and ended in November 2009; 419 of the 483 pregnant women initially eligible for participation were excluded (did not meet inclusion criteria (n=102), declined (n=8), no contact established (n=150) and other reasons (n=95). Therefore, 64 pregnant women were randomized, 33 to the experimental group and 31 to the control group. By the time of the second evaluation (16 weeks' post-intervention and delivery), 15 women discontinued in the experimental group and 14 in the control group (Figure 3). Table 1 gives the baseline characteristics.

Maternal and delivery outcomes

The women's weight gain was similar in both groups. There were no statistically significant differences between pre-exercise resting values and values after intervention (Table 2). There were no statistically significant differences regarding type of delivery between groups ($p > 0.05$) (Table 3).

New born out comes

Neonatal results were similar in both groups (Table 4). Mean birth weight was $3,013.2 \pm 493.8$ grams and mean gestational age was 38.9 ± 2.2 weeks

for the experimental group and $3,133.3 \pm 406.5$ g and 39.0 ± 1.8 weeks, respectively, for the control group ($p > 0.05$). Most new born obtained ≥ 7 Apgar scores in the first minute in both groups, while all of them obtained ≥ 9 scores at the fifth minute (Table 4).

Table 1. Participants' baseline characteristics

Characteristic	Randomized (n=64)	
	Control [n=33]	Experimental [n=31]
Participants		
Age (yr), mean (SD)	19 (3)	20 (3)
Gestation (wk), mean (SD)	18 (3)	17 (4)
Marital status, n (%)		
Single	11 (33)	8 (26)
Married/living with constant partner	22 (67)	23 (74)
Ethnicity, n (%)		
African Colombian	5 (15)	3 (10)
Indigenous	2 (6)	2 (6)
Mixed race	22 (67)	16 (52)
Caucasian	4 (12)	10 (32)
Socioeconomic level, n (%)		
Stratum 1 (range 1–3)	31 (94)	25 (80)
Stratum 2 (range 4–6)	2 (6)	6 (20)
Education, n (%)		
None	1 (3)	1 (3)
Primary	4 (12)	1 (3)
Secondary	23 (70)	26 (85)
Technical	4 (12)	2 (6)
University	1 (3)	1 (3)
Occupation, n (%)		
Student	7 (21)	8 (26)
Housewife	26 (79)	23 (74)
Location, n (%)		
Urban	16 (49)	18 (58)
Rural	17 (51)	13 (42)

Table 2. Mean values regarding maternal outcomes (baseline and delivery) in the experimental and control groups

Variable*	Control (n=17)		Experimental (n=18)		p value (between groups)	
	Baseline (n=31)	Delivery (n=17)	Baseline (n=33)	Delivery (n=18)	Baseline	Delivery
Age in years (mean \pm SD)	19.5 \pm 3.4	NA	19.2 \pm 2.6	NA	0.690	NA
Gestational age (w \pm days)	17.0 \pm 4.5	39.0 \pm 1.8	17.5 \pm 3.4	38.9 \pm 2.2	0.268	0.36
Weight (kg)	56.7 \pm 7.9†	63.5 \pm 8.4	53.6 \pm 6.1†	60.7 \pm 6.0	0.131	0.19
Height (m)	1.54 \pm 0.06	1.54 \pm 0.06	1.57 \pm 0.08	1.56 \pm 0.06	0.136	0.23
BMI (kg/m ²)	22.4 \pm 3.8	24.1 \pm 4.5	21.4 \pm 2.4	23.4 \pm 4.5	0.456	0.57

* Data in mean \pm standard deviation (SD); W: weeks; WG: weight gain; BMI: body mass index; NA: Not applicable; † Intra-group differences between measurements at baseline and intervention/delivery ($p < 0.05$); ** significance value ($p < 0.05$), Mann-Whitney U test

Figure 3. Study design and flow-chart for participants involved in the study

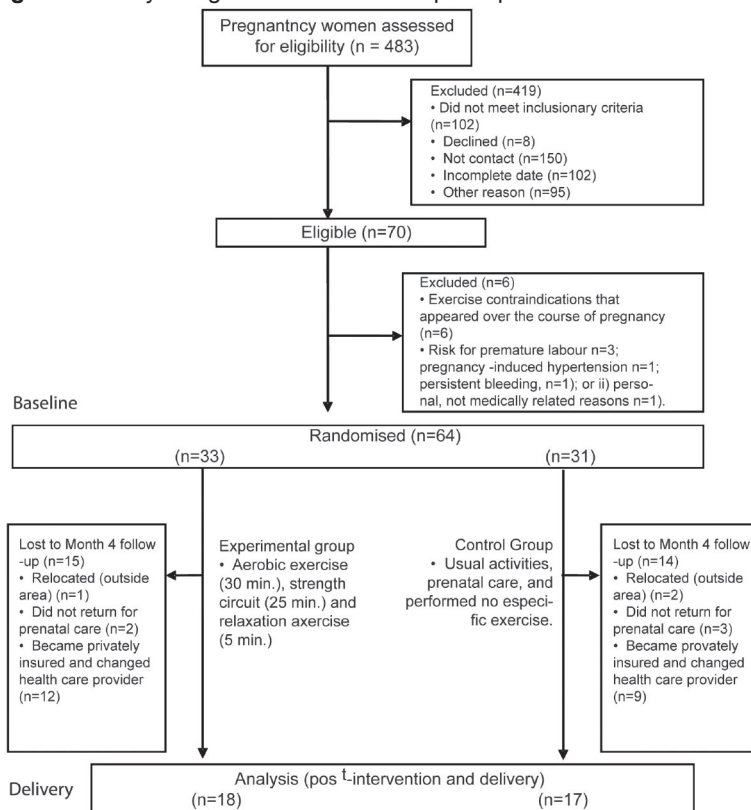


Table 3. Type of delivery, maternal and newborn complications in the experimental and control groups

Variable	Groups		p value
	Control n (%)	Experimental n (%)	
	n=17	n=18	
Male	11 (64.7)	11 (61.1)	0.65
Female	6 (35.3)	7 (38.9)	0.82
Type of delivery*			
Elective caesarean	1 (5.9)	4 (22.2)	0.92
Emergency caesarean	2 (11.8)	3 (16.7)	0.89
Spontaneous delivery	13 (76.5)	11 (61.1)	0.79
Induced labor	1 (5.9)	0	0.99
Newborn complications *			
None	5 (29.4)	13 (72.2)	0.54
Meconium	6 (35.3)	1 (5.6)	0.91
Other complications (δ)	6 (34.3)	4 (22.2)	0.67

*Significance value, YatesX² test; (δ) cyanosis, macrosomic foetus, respiratory distress and cephalopelvic disproportion

Table 4. Anthropometric neonatal outcomes and Apgar score

Variable*	Group		p value
	Control n=17	Experimental n=18	
Head circumference (cm)	33.7 ± 1.6	32.8 ± 2.7	0.47
Chest circumference (cm)	32.6 ± 1.8	32.4 ± 2.0	0.98
Birth weight (g)	3 133.3 ± 406.5	3 013.2 ± 493.8	0.34
Crown heel length (cm)	50.5 ± 2.4	50.1 ± 2.2	0.63
Apgar score (1 min)	7.5 ± 1.3	8.0 ± 0.8	0.31
Apgar score (5 min)	9.4 ± 0.6	9.6 ± 0.4	0.08

* Data in mean ± standard deviation (SD). Significance value, Mann-Whitney U test

DISCUSSION

Secondary analysis of data from a controlled, randomized trial showed that supervised vigorous exercise/training performed during the second and third trimester of pregnancy did not affect the type of delivery and/or gestational age in pregnant Latin-American women. Supervised aerobic exercises, such as those performed by our experimental group, would thus be recommended for improving public health by major medical organizations (4,5,16,17). Other potential benefits of vigorous exercise/training during pregnancy would include a decreased risk of insulin dependence in overweight women having gestational diabetes mellitus and also better posture, prevention of gestational lower back pain and diastasis recti and strengthening the pelvic floor (1,3,21,22).

Comparing studies, however, was hampered difficult by differences in several variables which could have affected delivery type and gestational age, such as age, BMI, gestational weight gain according to age, previous parity history, smoking habits and alcohol intake. Previous studies' cross-sectional (23) or non-randomized (24) nature precluded a true cause-effect relationship from being established between exercise and type of delivery. Only one study (24) showed an association between physical activity and mode of delivery, suggesting a considerably increased risk of caesarean amongst sedentary pregnant women. A etiological mechanisms behind this reported association have yet to be elucidated.

The neonatal results from the present study confirmed the wellbeing of newborn infants born to mothers who initiated vigorous exercise/training during their pregnancy. This kind of exercise could therefore be recommended for mothers willing to practice some form of physical activity during their pregnancy (25). Babies having suitable weight, gestational age and vitality at birth confirmed the trend reported in the pertinent literature

that moderate, vigorous exercise/training has no influence on prematurity or the weight of a newborn infant (26). However, the adequacy of such exercise has to be assured, since engaging in physical activity which is rigorous in terms of its intensity, duration or frequency is associated with low neonatal birth weight (27-29).

The results of this study showed that vigorous exercise/training during pregnancy by low-risk women who were previously sedentary was not detrimental to the health of the mother or the child. Clap et al., (30) observed similar results when studying women who engaged in physical activity and either continued or spontaneously stopped exercising (control group) during the first trimester of pregnancy. Regarding birth weight, many studies (1,3, 30) have shown that there is no increased risk of low birth weight for pregnant women who practice leisure-time physical activities. Among the studies which have analyzed vigorous exercise/training as a predictive factor for low birth weight, some (26-30) have shown a subtle association; however newborn mean weight was not inadequate in any of the groups studied. However, other studies (1,3,26-30) have identified some specific activities (e.g. doing laundry standing on one's feet for hours on end) but not regular physical activity in general, as risk factors for inadequate birth weight.

The same has been observed in studies in which the main outcome has been gestational age at delivery (1,3). Many articles either found no association or reported a protective effect for vigorous exercise/training during pregnancy related to premature birth (23-25). Again, some specific activities, like climbing stairs and occupational activities requiring standing for prolonged periods or causing fatigue and requiring agility, have been identified as being risk factors for premature birth (21, 23).

Some of the current study's limitations could be pointed out. The most important one would refer to the practical difficulty of maintaining high compliance with the supervised exercise program, plus the cost of transport three times per week. Around a third of the participants discontinued the program during pregnancy due to logistical and family constraints, including job restrictions, taking care of children and home affairs.

Vigorous exercise or training performed during the second and third trimester of pregnancy did not affect pregnant Latin-American women's delivery type and gestational age in this study. The research adds further

evidence to support the overall health benefits of supervised, vigorous regular exercise for healthy pregnant women, involving very few (if any) complications ♣

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