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Effect of aerobic water exercise during pregnancy on epidural use and pain: A multi-centre, randomised, controlled trial

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ABSTRACT

Objective: The physical and psychological benefits of exercise during pregnancy are well established. However, the impact of exercise on pain during labour and the use of epidural analgesia has been less explored. The main aim of this study was to analyse the effectiveness and safety of moderate aerobic water exercise by pregnant women on the subsequent use of epidural analgesia during labour, induction of labour, mode of delivery, and pain perception.

Design: A multi-centre, parallel, randomised, evaluator blinded, controlled trial in a primary care setting.

Setting: Primary care centres in a health district of a tertiary obstetric metropolitan hospital in Mallorca, Spain.

Participants: Pregnant women (14 to 20 weeks' gestation) who had low risk of complications.

Methods: Three hundred and twenty pregnant women were randomly assigned to two groups: women who practiced moderate aquatic aerobic exercise with usual antenatal care, and those who received usual prenatal care alone. The gynaecologist, anaesthesiologist and midwife who assisted the women during labour were blinded to group allocations. Principal outcome: use of epidural analgesia during labour. Other outcomes: use of epidural analgesia before 6 cm cervical dilation, labour pain, type of delivery, time of active labour, episiotomy or perineal tear, and induction of labour.

Results: The exercise program did not affect the use of epidural analgesia (OR = 0.79, 95% CI = 0.44 to 1.40), vaginal delivery (OR = 1.35, 95% CI = 0.73 to 2.41), or caesarean section (OR = 0.94, 95% CI = 0.47 to 1.89). However, women in the exercise group reported less pain during labour (mean difference: –0.6, 95% CI = –1.11 to –0.09). The two groups (moderate aquatic aerobic exercise versus usual antenatal care) showed no significant differences in maternal or newborn adverse events.

Conclusion: Aquatic aerobic exercise during pregnancy had no effect on the use of epidural analgesia during labour, whereas pain perception was lower after aquatic exercise compared to usual care in pregnancy. The intervention was safe for pregnant women and their newborns.

Background

Childbirth is a painful experience for most women, and many women worry about the pain they will feel during childbirth (Van der Gucht and Lewis, 2015). Epidural analgesia is the most effective and most commonly used medication-based method of pain relief during labour (Anim-Somuah et al., 2018). This technique is used by 25% of women in the UK (Khor et al., 2000), 58% of women in the US (Declercq et al., 2007), and 58% to 61% of women in Spain (Llobera et al., 2016). However, there is increasing evidence that epidural analgesia increases the duration of the second stage of labour (Walker et al., 2018) and increases the need for instrumental vaginal delivery (Bannister-Tyrrell et al.,

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2014; Walker et al., 2018). A prolonged second stage of labour is associated with increased risk of foetal respiratory acidosis, postpartum haemorrhage, chorioamnionitis, and third- and fourth-degree perineal and vaginal tears (Laughon et al., 2014; Zipori et al., 2019). Furthermore, several studies, including a recent meta-analysis, found that prolonging the second stage of labour was associated with adverse neonatal events (birth asphyxia, low 5-min Apgar score, sepsis, birth trauma, risk of admission to neonatal intensive care unit or perinatal mortality) (Altman et al., 2015; Laughon et al., 2014; Pergialiotis et al., 2020; Sandstrom et al., 2017).

Epidural analgesia, the direct injection of drugs into the nerves that transmit pain, is effective but increases the risk of adverse events and complications. Postdural puncture headache is a common complication that affects up to 17% of women having epidural analgesia. Furthermore, the risk of accidental dural puncture from insertion of the epidural catheter is 1.5% (Choi et al., 2003). Intravascular injection is a serious complication that can cause compression or ischemia of the spinal cord and subsequent paralysis. The toxicity of the local anaesthetic when inadvertently injected into an intravascular region can cause respiratory and cardiac arrest, with an incidence of 1 in 5000 (Simmons et al., 2012). Complications of central neuraxial blockade (maternal hypotension, respiratory arrest, and loss of consciousness) and epidural-induced spinal hematoma have an incidence of 1 in 168,000 (Ruppen et al., 2006).

Most pregnant women are interested in non-pharmacological methods of pain relief during childbirth (Madden et al., 2013; Van der Gucht and Lewis, 2015). Thus, water immersion, perineal exercises, breathing and relaxation techniques, and massage are important parts of antenatal education. Although non-pharmacological methods are unlikely to be harmful, there is limited evidence of their efficacy (Jones et al., 2012). There is some evidence that physical exercise during pregnancy reduces pain during childbirth (Baciuk et al., 2008; Cavalcante et al., 2009; Varrassi et al., 1989). In addition, practicing moderate exercise during pregnancy is associated with an increased level of endorphins, and this provides pain relief during labour and decreases the need for analgesia (Baciuk et al., 2008; Cavalcante et al., 2009; Varrassi et al., 1989). Some studies found that physical exercise was associated with reduced pain sensitivity, and there is evidence that physical exercise increases pain tolerance, but not pain threshold (Ord and Gijsbers, 2003).

The benefits of exercise during pregnancy are widely known, with many clinical practice guidelines recommending exercise for women with low-risk pregnancies (Artal and O'Toole, 2003; Mottola et al., 2018). More specifically, there is evidence that exercise-only interventions during pregnancy prevent gestational diabetes (Ming et al., 2018), improve glycemic control, and reduce weight gain during pregnancy (Davenport et al., 2018). Exercise during pregnancy can also reduce the risks of hypertension (Magro-Malosso et al., 2017a, 2017b) and preeclampsia (Davenport et al., 2018; Dempsey et al., 2005). Aerobic exercise is also associated with a significant lowering of the risk of gestational diabetes in overweight and obese pregnant women (Magro-Malosso et al., 2017, 2017b). However high-impact aerobic exercises should be avoided during the first few months of pregnancy, because there is some evidence from observational studies that performing more than 7 h per week of this type of exercise (racketball, jogging, etc.) increases the risk of miscarriage (Bo et al., 2016). Some studies have found that performance of moderate exercise by pregnant women decreases the number of instrumental deliveries (Davenport et al., 2019; Mottola et al., 2018) and caesarean deliveries (Mottola et al., 2018), while others found no difference in mode of delivery (Salvesen et al., 2014; Sanda et al., 2018).

Water-based exercise during pregnancy is a low-impact form of exercise that is less harmful than weight-bearing exercise on land (Sichani et al., 2019; Soultanakis, 2016). These exercises provide women with a sense of weightlessness and ease of movement, better thermoregulation because of their immersion in water, hydrostatic pressure that alleviates pregnancy-induced edema, and prevention and treatment of low back pain (Artal and O'Toole, 2003).

Despite the growing evidence that exercise provides relief from chronic pain (Geneen et al., 2017), the effect of aerobic training on acute pain sensitivity in healthy individuals is largely unknown. A recent study indicated that physical exercise increased pain tolerance in healthy individuals (Jones et al., 2014). As muscles begin to ache during an exercise session, the body releases beta endorphins that reduce the discomfort, and this exercise-induced hypoalgesia could alter the body's response to pain and decrease pain during childbirth (Cavalcante et al., 2009; Varrassi et al., 1989). Thus, there is some evidence that physical exercise during pregnancy improves maternal outcome, as well as reducing the risk of diabetes, preeclampsia, and low back pain. However, there is little evidence of the effect of aquatic aerobic exercise on labour pain and the reduction of the use of epidural analgesia during childbirth (Rodriguez-Blanque et al., 2019).

The main aim of this randomised controlled trial (RCT) of women with uncomplicated pregnancies was to analyse the effectiveness and safety of aerobic water exercise of moderate intensity in relation to the subsequent use of epidural analgesia during labour, induction of labour, mode of delivery, and pain perception. The secondary aim was to assess neonatal outcomes (signs of intrapartum foetal distress, low birth weight, low gestational age and Apgar score) and safety in the aquatic-exercise program.

Methods

Study design

A phase III, multi-centre, parallel, randomised, evaluator-blinded, controlled clinical trial was designed. The study was carried out in primary care centres in the Spanish National Health System. The trial was conducted from November 2014 to March 2017. A full description of the research protocol was published previously (Navas et al., 2018).

Participants

Pregnant women aged 18 to 40 years having a fetus with a gestational age of 14 to 20 weeks, singleton pregnancy, and low obstetric risk were eligible. All eligible pregnant women from 5 primary care centres in a health district of a tertiary obstetric metropolitan hospital (Son Llatzer Hospital, Mallorca, Spain) were invited to participate.

Women were excluded from the study if they (i) had a complicated obstetric history with a history of stillbirth or neonatal death, multiparity (≥6 pregnancies), 3 or more consecutive miscarriages, previous foetal death *in utero*, previous mid-trimester loss/cervical incompetence/known uterine anomaly, previous early onset of pre-eclampsia (<32 weeks' gestation), rhesus iso-immunisation, or complications during the current pregnancy (such as multiple pregnancy or foetal abnormality); (ii) precluding medical conditions, such as cardiac disease, essential hypertension, renal disease, pre-existing diabetes, severe anaemia (haemoglobin <9 mg/dL), epilepsy, severe asthma, substance abuse or smoking more than 20 cigarettes/day, significant psychiatric disorders, obesity (body mass index [BMI] >35 kg/m^2) or significantly underweight (BMI <17 kg/m^2), recurrent urinary tract or vaginal infection; or (iii) inability to swim.

Sample size

The initial power calculation was based on the use of obstetric epidural analgesia in vaginal deliveries in Spain, which was reported as 61% (Bernis et al., 2013). To detect a total reduction of at least 20% in the use of obstetric epidural analgesia in the exercise group with 80% power, an estimated follow-up loss of 15%, and a two-sided α-value of 0.05, a total of 272 women were needed. However, women in the usual care group might also decide to practice physical activity during pregnancy,

and this could include supervised or unsupervised aquatic aerobic exercises; we therefore increased the sample size by 15% to account for increased physical activity by women in the usual care group. Thus, the final sample size was 160 for each group (320 women total).

Randomisation and blinding

Pregnant women were randomly allocated to a group that underwent moderate aquatic-aerobic exercise with usual antenatal care or to a group that received usual antenatal care alone.

A computer-generated randomisation list in blocks of 6 was used to randomly allocate women to each group. The details of the 1:1 randomisation and centralised allocation process were described in a previous publication (Navas et al., 2018). All assessments of the primary outcome were blinded, external personnel blinded to the group allocation review hospital clinical record. The gynaecologist and midwife that assist the women during labour were also blinded. The statistician and data entry staff were also blinded to allocations. However, primary care midwives (recruitment of patients, follow-up visits and delivering of the intervention) were not blinded to the allocations.

Intervention

Women in the exercise group participated in 45 min of water aerobics classes 3 times per week in an indoor pool (28 to 30 ˚C) for 5 months (Appendix 1). This procedure was based on recommendations of the American College of Sports Medicine (Artal and O'Toole, 2003; Pescatello, 2014), which proposes 3 to 5 classes per week, a training zone of 55% to 65% of the maximum heart rate, class duration of 20 to 60 min, maximum heart rate of 140 bpm, and maintenance of body temperature below 38 ˚C.

Aquatic aerobic exercise program

- Warm-up out of water (5 to 7 min). These exercises consisted of stretching and warming up the neck, pectoral muscles, shoulders, back, quadriceps, and calves, and mobility training of pelvic girdle, feet, ankles, and knees.
- Warm-up in water (5 to 10 min). These exercises consisted of walking in the water, taking big steps and then small jumps, walking sideways, and walking forward and backward.
- Moderate aquatic exercise (20 min). These 4 different sets of exercises and compound exercises included coordinating breathing. Each set consisted of exercises of the arms, legs, lower back, and pelvic floor.
- Breathing and relaxation exercises (5 min).
- Playful exercises (5 min).

Women were asked to discontinue the intervention if any of the following events occurred: vaginal bleeding, placenta previa, premature rupture of membranes, intrauterine growth retardation, severe anaemia, regular painful contractions, amniotic fluid leakage, dyspnea before exertion, dizziness, headache, chest pain, muscle weakness affecting balance, calf pain or swelling, preterm labour, decreased foetal movement or any contraindications to being physically active (ACOG Committee, 2015).

Women in the exercise group also received standard antenatal care by their primary care midwives. Women in the usual care group only received standard antenatal care, but this could include advice regarding physical activity.

Patient recruitment

There was at least one midwife from the research team in each participating primary care centre. Midwives invited eligible women to participate in the clinical trial. Women willing to participate and who met the eligibility criteria were enrolled after reading and signing an informed consent document. Randomisation and allocation concealment were centralised at a single coordinating centre, midwives telephoned the research unit of the Mallorca primary care and women were assigned to the exercise group or the usual care group by a prespecified random allocation sequence by blocks of 4 and 6.

Study outcomes

The primary outcome measure was the use of epidural analgesia during labour, determined by review of the clinical history. The secondary outcome measures were use of epidural analgesia before 6 cm cervical dilation, mode of delivery (vaginal delivery, instrumental delivery, caesarean section), time of active labour (first and second stage of labour), episiotomy or perineal tear, induction of labour and labour pain. Labour pain was assessed using a visual analogue scale (VAS), with women asked to rate their pain (0 = no pain to 10 = worst pain) retrospectively at the final visit.

Neonatal medical outcomes

The neonatal medical outcomes were signs of intrapartum foetal distress, including foetal heart rate abnormalities, low birth weight (<2500 kg), low gestational age (<37 weeks of gestation), Apgar score at 1 and 5 min from delivery, and pH of umbilical cord blood.

Safety

Women were asked to report any adverse events that could be related to physical activity at each medical visit and exercise class. The women were also asked to consider a list of adverse events that included back pain, urinary tract infection, bleeding, and uterus contractions.

Midwives recorded all adverse events on case report forms and investigated the potential causal relationship of the study intervention with adverse events. All serious adverse outcomes of the infant or the mother during the course of this study were reported to the ethics committee.

Resource utilisation outcomes

Use of the following resources was recorded: oxytocin/prostaglandin induction, oxytocin augmentation, amniotomy, pharmacological and non-pharmacological methods of labour pain relief, antibiotic use, continuous electronic foetal monitor, maternal blood transfer, maternal length of stay (48 h *vs.* more than 48 h),admission to a neonatal intensive care unit, need for positive pressure ventilation, sepsis work-up and treatment, neonatal readmission (<28 days-old), non-delivery admissions and emergency room admission, antepartum hospital admission, emergency room without admission, postpartum maternal readmission (30 days post-partum), use of comprehensive perinatal services program, and non-planned visits to a primary care centre.

Data analyses

All statistical analyses were performed using IBM SPSS Statistics version 23 (SPSS/IBM, Chicago, Illinois, USA) according to a predefined analysis plan (Navas et al., 2018). We tested for the significance of differences in baseline characteristics of the control and intervention groups. An intention to treat (ITT) analysis was used for all clinical outcomes, and results are reported in accordance with the Consolidated Standards of Reporting Trials guidelines extension for cluster trials. The effectiveness of the exercise program on the use of epidural analgesia during labour was examined using logistic regression models. Logistic regression models were also used to analyse the effectiveness of the exercise program on the use of epidural analgesia before 6-cm cervical dilation, and delivery outcomes (operative vaginal delivery, instrumental delivery, caesarean section, episiotomy, perineal tear, and induction of labour).

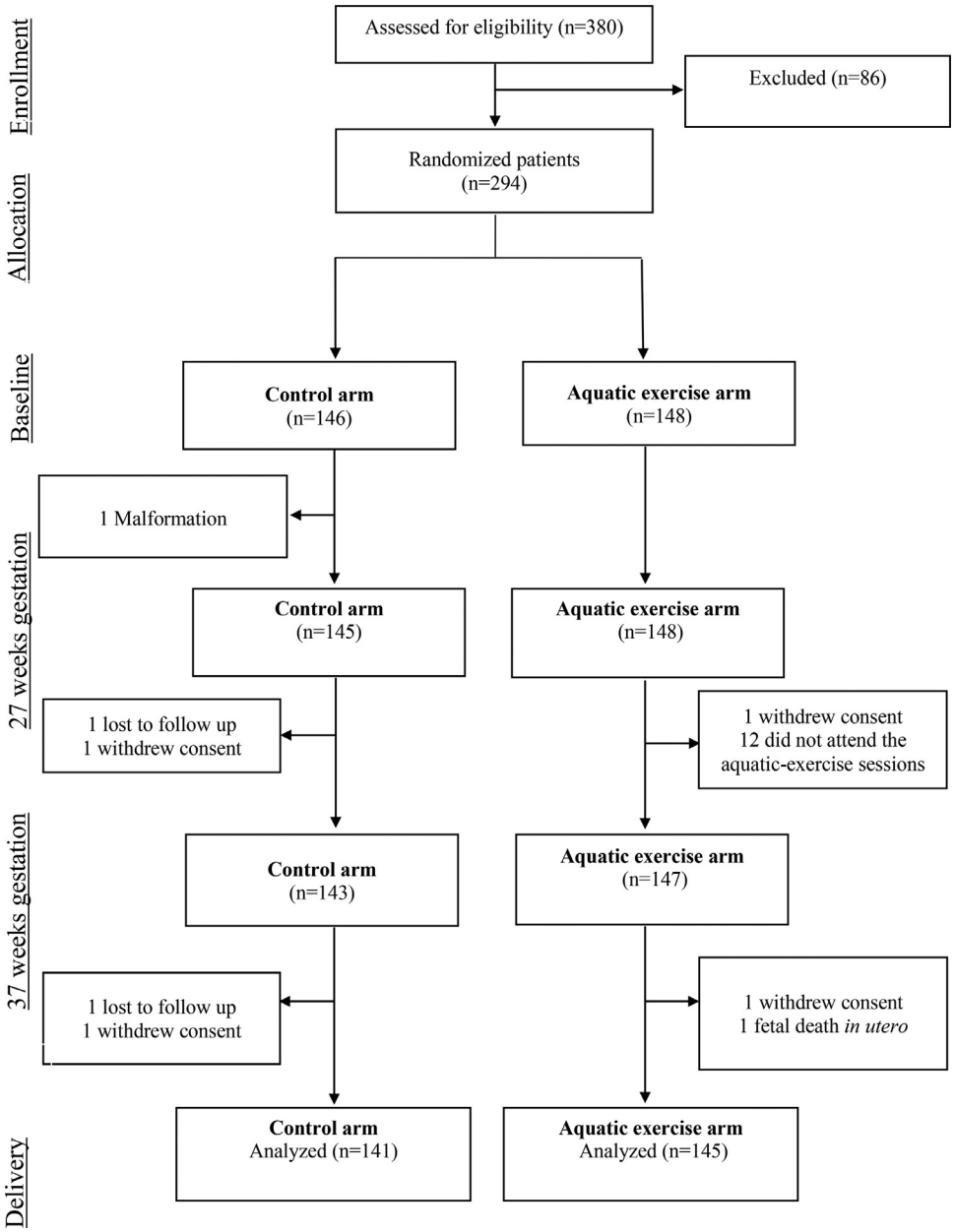

Fig. 1. Flow chart of recruitment procedure.

Ordinal logistic regression models were used to analyse the effect of the aerobic water exercise on vaginal tear grade. Between-group comparisons of labour pain (measured by a VAS), time of active labour, neonatal weight, pH of umbilical cord blood, and Apgar score at 1 and 5 min were analysed by Student's *t*-test. Crude estimates of the proportion of infants with intrapartum distress, weeks of gestation over 41, and analyses of adverse events were determined using the chi-squared test. All estimates included 95% confidence intervals, and all treatment effects were considered significant if the two-sided *p*-value was below 0.05. Multiple imputation was used for the main analysis because this generally provides less biased estimates of effect compared with a complete cases analysis.

Ethical considerations

This study followed the principles outlined in the Declaration of Helsinki (World Medical, 2001). The study protocol was approved by the Primary Care Research Committee and the Balearic Ethical Committee of Clinical Research (registered CEI-IB Ref. No: 2358/14). All participants provided written informed consent and they were told participation was voluntary and they could withdraw at any time without any negative consequences concerning medical treatments.

Validity and reliability

The study was registered with www.isrctn.com (ISRCTN14097513) on September 04, 2017. ~~The results of the study are presented clearly, honestly, and without fabrication, falsification, or inappropriate data manipulation.~~ There are no restrictions on publicly sharing the dataset; however, as a result of the informed consent given by the study participants, we made available only an anonymous minimal dataset (https://doi.org/10.5281/zenodo.3580637).

Results

We assessed 380 women for eligibility, and excluded 5 women based on the exclusion criteria, 10 women who could not be contacted to sign the informed consent document, and 71 women who refused to participate. Thus, we randomised 294 women to the exercise group ($n = 148$) or the usual care group ($n = 146$). Only 8 women were lost during follow

Table 1
Baseline characteristics of patients in the aquatic exercise (intervention) group and the control (usual care) group.

	Group Intervention (n = 148)	Control (n = 146)
Age (years), mean ± SD	31.1 ± 4.1	31.5 ± 4.2
BMI (kg/m^2), mean ± SD	23.5 ± 3.2	23.4 ± 3.1
Obstetric characteristics, n/N (%) Nulligravid Preterm Spontaneous abortion One previous child Two or more previous children	98/145 (67.6) 1/145 (0.7) 39/145 (26.9) 45/145 (21.0) 3/145 (2.1)	98/141 (69.5) 1/141 (0.7) 39/141 (27.6) 38/141 (27.0) 4/141 (2.8)
Smoking, n/N (%) Smoker Quit smoking prior to pregnancy	11/143 (17.9) 12/143 (8.4)	25/140 (7.7) 24/140 (17.1)
Social Class, n/N (%) I and II (high) III IV and V (low)	49/124 (39.5) 42/124 (33.9) 33/124 (26.6)	47/126 (37.3) 33/126 (26.2) 46/126 (36.5)
Educational level, n/N (%) Primary school Secondary school University	8/147 (5.4) 61/147 (41.5) 78/147 (51.7)	14/143 (9.8) 54/143 (37.8) 74/143 (51.7)
IPAQ (MET-min/week), mean ± SD	1,008.0 ± 14,033.3	1,047 ± 10,33.3
IPAQ category score, n/N (%) Low Moderate High	63/145 (43.4) 76/145 (52.4) 6/145 (4.1)	75/141 (53.2) 60/141 (42.6) 6/141 (4.3)

SD=standard deviation; BMI=body mass index; IPAQ=international physical activity questionnaire; MET=metabolic equivalent.

Table 2
Primary and secondary outcomes in the intervention group and the control group.

Primary outcome	Intervention	Control	OR (95% CI)	p	ITT analysis: Imputed OR*(95% CI)	p
Epidural analgesia, n/N (%)	113/145 (77.9)	116/141 (81.7)	0.79 (0.44-1.41)	0.791	0.79 (0.44-1.40)	0.418
Secondary outcomes						
Epidural analgesia / vaginal dilation > 6 cm	14/113 (12.4)	15/114 (13.2)	0.93 (0.43-2.04)	0.862	0.93 (0.43-2.03)	0.672
			Beta (95% CI)**		Imputed Beta*** (95% CI)	
Labour pain, mean ± SD	7.55 ± 2.20	8.15 ± 1.95	-0.60 (-1.11;-0.09)	0.021	-0.54 (-1.10;-0.03)	0.039

*Imputed by age, BMI, and group.
**Adjusted for epidural analgesia.
***Imputed by age, BMI, group, and adjusted by epidural analgesia.

up, and there were two severe adverse events (1 foetal malformation in the control group and 1 foetal death in the intervention group). At 12 months we had complete data from 141 women in the usual care group and 145 women in the exercise group. All women who were randomised at baseline (148 in the exercise group and 146 in the usual care group) were analysed in the ITT analysis. The study flow diagram is shown in Fig. 1.

The baseline characteristics of the two groups (Table 1) were similar in terms of age, BMI, obstetric characteristics (nulligravid, preterm, spontaneous abortion, one previous child, or two or more previous children) and physical activity. Women in the intervention group were more physically inactive and were more frequently smokers; however, the control group showed a higher proportion of women in social class IV/V.

Primary outcome measure

Analysis of epidural use (Table 2), defined as the use of any epidural analgesic by catheter or injection during childbirth, indicated that 113 women (80%) in the exercise group and 116 women (82%) in the usual care group used an epidural (OR = 0.79, 95% CI = 0.44 to 1.40).

A total of 12.4% of women exercise group and 13.2% of women in the usual care group used an epidural before vaginal dilation was more than 6 cm (OR = 0.93, 95% CI = 0.43 to 2.03). The mean vaginal dilation upon use of an epidural was 3.6 ± 1.7 cm in the exercise group and 3.7 ± 1.6 cm in the usual care group. Labour pain, measured using a VAS scale, was significantly lower in the exercise group than in the usual care group (mean difference: –0.6, 95% CI = –1.11 to –0.09). Measurement of attendance at the exercise sessions indicated the mean adherence was 45%, 1% of women did not attend any classes and only 12.2% of women attended 70% or more of the sessions. Women in the intervention group attended an average of 27 classes during the study.

Secondary outcomes

Analysis of delivery outcomes (Table 3) indicated that vaginal births occurred in 110 women (80%) in the exercise group and 106 women (75%) in the usual care group (OR = 1.35, 95% CI = 0.73 to 2.41), instrumental births occurred in 10 women (7%) in the exercise group and 16 women (11%) in the usual care group (OR = 0.59, 95% CI = 0.26 to 1.36), and caesarean births occurred in 18 women (13%) in the exercise group and 19 women (14%) in the usual care group (OR = 0.94, 95% CI = 0.47 to 1.89). The incidence of labour induction was 30.6% in the exercise group and 38.2% the usual care group (OR = 0.71, 95% CI = 0.43 to 1.19).

Vaginal tears occurred in 68 women (51%) in the exercise group and 69 women (53%) in the usual care group, and episiotomy was performed in 35 women (28%) in the exercise group and 36 women (30%) in the usual care group.

There was one abortion due to malformation in the usual care group and one case of foetal death in the exercise group. The foetal death was caused by chorioamnionitis, and the mother only attended four classes and her last session was 2 months before the foetal death. The foetal death occurred at 40 weeks of gestation and probably not related to the intervention.

Fifteen newborns were admitted to an intensive care unit, 10 in the exercise group and 5 in the usual care group. The causes of neonatal admission were respiratory distress, sepsis, neutropenia, hypothyroidism and probably not related to the intervention. The attribution of these adverse events was made by the midwives.

The two groups had no significant differences in maternal adverse events, such as urinary tract infection, back pain, and bleeding (Table 4) or newborn adverse events, such as gestational age weight, intrapartum foetal distress, Apgar score, and pH of umbilical cord blood (Table 5).

~~Any serious adverse event, inpatient hospitalisation or death related to the intervention was reported by the midwives and obstetricians during the study. There was one foetal death in the exercise group and one abortion in the control group (congenital malformation). The foetal death in the intervention group was caused by chorioamnionitis probably not related to the intervention. The mother only attended four classes and her last session was 2 months before the foetal death. The foetal death occurred at 40 weeks of gestation.~~

Table 3
Delivery outcomes in the intervention group and the control group.

Secondary outcomes	Intervention	Control	Beta (95% CI)	P	ITT analysis:Imputed Beta (95% CI)*	p
Time of active labour, min ± SD	57.1 ± 56.6	62.3 ± 71.6	-5.60 (-29.55-18.37) OR (95% CI)	0.646	-6.9 (-30.75-16.93) ITT analysis:Imputed OR (95% CI)*	0.570
Operative vaginal delivery, *n* (%)	110/138 (79.7)	104/139 (74.8)	1.32 (0.75-2.32)	0.332	1.35 (0.76-2.41)	0.304
Instrumental delivery, *n* (%)	10/141 (7.1)	16/141 (11.3)	0.59 (0.26-1.36)	0.221	0.59 (0.26-1.35)	0.209
Cesarean delivery, *n* (%)	18/138 (13.0)	19/139 (13.7)	0.95 (0.47-1.89)	0.878	0.94 (0.47-1.89)	0.861
Induced labour, *n* (%)	41/134 (30.6)	50/131 (38.2)	0.71 (0.43-1.19)	0.195	0.69 (0.41-1.17)	0.172
Episiotomy, *n* (%)	35/124 (28.2)	36/123 (29.3)	0.95 (0.55-1.65)	0.856	0.94 (0.52-1.71)	0.846
Vaginal tear, *n* (%)	68/133 (51.1)	69/130 (53.1)	0.92 (0.57-1.50)	0.925	0.94 (0.58-1.51)	0.794
Vaginal tear grade, *n* (%) 1 2 3	34/66 (51.5) 28/66 (42.4) 4/66 (6.1)	34/68 (50.0) 31/68 (45.6) 3/68 (4.4)	0.97 (0.50-1.89)	0.944	0.98 (0.50-1.93)	0.959

*Imputed by age, BMI, and group.

Table 4
Adverse events in the intervention group and the control group.

Adverse event, n/N (%)	Intervention	Control	P
Urinary tract infection Back pain Bleeding Contractions Abortion/Fetal death Fetal admission to intensive care Mother admission to intensive care	7/139 (5.0) 3/139 (2.2) 3/139 (2.2) 3/139 (2.2) 1/139 (0.7) 10/139 (7.2) 1/139 (0.7)	11/132 (8.3) 1/132 (0) 2/132 (1.5) 0/132 (0) 1/132 (0.8) 5/132 (3.8) 0/132 (0)	0.276 0.623 1.000 0.248 1.000 0.288 1.000

Table 5
Neonatal outcomes in the intervention group and the control group.

Secondary outcomes	Intervention	Control	P
Weight, *g* ± SD	3367 ± 799.7	3281 ± 497.1	0.283
Intrapartum fetal distress, *n* (%)	25/120 (20.8)	28/119 (23.5)	0.365
Weeks of gestation At least 41 weeks' gestation	39.9 ± 2.0 20/139 (14.4)	39.8 ± 2.0 17/132 (12.9)	0.739 0.725
Apgar score 1 min 5 min	8.7 ± 1.3 9.8 ± 0.99	8.7 ± 0.9 9.8 ± 0.4	0.813 0.398
pH of umbilical cord blood	7.27 ± 0.09	7.26 ± 0.07	0.420

Discussion

Our results indicated that the exercise group and usual care group showed similar use of epidural analgesia during labour. The incidence of induced or stimulated labour and epidural use in our study population was higher than in other studies (Geneen et al., 2017; Sanda et al., 2018), and was higher than the average reported for the Balearic Islands and Spain (Llobera et al., 2016). It is important to mention that this study was conducted in one hospital only, therefore findings may not be generalisable to different settings.

Our results are in line with two large clinical trials which also found that moderate exercise by pregnant women had no impact on the subsequent use of epidural analgesia (Salvesen et al., 2014; Sanda et al., 2018). However, a recent RCT with a relatively small sample reported decreased use of epidural anaesthesia by pregnant women who exercised (Rodriguez-Blanque et al., 2019).

Women in our exercise group reported less pain during labour, in agreement with another study that assessed pain levels during labour (Musa and Daniel, 2011), although the sample size was smaller in this previous study. We found no evidence that aquatic aerobic exercise influences mode of delivery. Although there was a higher percentage of normal vaginal delivery and a lower percentage of operative vaginal delivery in the exercise group, these differences were not statistically significant. Many previous RCTs found no effect of aquatic aerobic exercise on dystocia (Coll et al., 2019; Sanda et al., 2018). However, a recent meta-analysis of 26 trials (9650 women) found that exercise by pregnant women significantly reduced the incidence of operative vaginal delivery (Davenport et al., 2019), although the included studies had a high risk of bias (Barakat et al., 2012). Our two groups showed no difference in the use of caesarean section. However, two previous trials found significantly fewer caesarean sections in women who exercised (Barakat et al., 2012; Price et al., 2012), but a large clinical trial of 856 women and a meta-analysis of RCTs found no effect of physical activity on caesarean section (Davenport et al., 2019; Salvesen et al., 2014; Sanda et al., 2018). We also found no difference in the duration of labour between the two groups. A recent meta-analysis of 17 trials (3,123 women) reported similar results (Davenport et al., 2019), and a large clinical trial found an inverse association with a shorter active second stage labour among nulliparous women in the control group (Salvesen et al., 2014). However, two trials found a positive association between physical activity and shorter first phase of labour (Barakat et al., 2018; Perales et al., 2016).

Perineal damage, grade of laceration, and incidence of episiotomy were similar in our two groups. Similar results were reported in 4 previous RCTs (Ghodsi and Asltoghiri, 2014; Price et al., 2012; Salvesen et al., 2014; Sanda et al., 2018) and in a meta-analysis (Davenport et al., 2019). However, a recent RCT found that pregnant women who exercised had an increased incidence of intact perineum (Rodriguez-Blanque et al., 2019). We found that the two groups were also similar in terms of spontaneous miscarriage, foetal malformations, foetal death, neonatal death, preterm labour, pre-labour rupture of membranes, Apgar score, umbilical artery pH, low weight at birth, and neonatal complications. These results are in line with previous research (Di Mascio et al., 2016). A previous meta-analysis reported an inverse association between physical activity and newborn macrosomia (Davenport et al., 2019).

Strengths and limitations

The strengths of this study are the ~~that it was a large and multisite RCT with significant~~ internal validity; the exercise and usual practice groups were homogenous and well balanced, although there were some differences in smoking status and social class between

groups; data were analysed by ITT analyses; and there were blinded analyses of outcomes. In addition, the intervention was delivered by midwives, who provided integral care during pregnancy and childbirth.

A limitation of our study is the low external validity. In particular, we only included women who delivered at one hospital, only examined women younger than 40 years-old, and excluded women with diabetes, hypertension, or a BMI above 35 kg/m^2. Another limitation is the low adherence to the exercise program. More than 50% of the women attended fewer than half of the exercise sessions, and only 17 women attended more than 70% of the sessions. We believe this low adherence could have influenced the results. Further studies of this topic are needed in which additional strategies are used to achieve higher rates of adherence to the exercise program. A qualitative study would be appropriate to evaluate the barriers, motivations and attitudes of pregnant women with low adherence to the intervention.

Implications for practice

We found that aquatic aerobic exercise during pregnancy did not influence the use of epidural analgesia during childbirth but did reduce pain during childbirth. Based on our study results, we do not recommend aquatic aerobic exercise for reducing the use of epidural analgesia, but it could be effective for pain relief management. The use of analgesia during childbirth could be influenced by a woman's expectations and knowledge of alternative methods for pain relief. The use of analgesia is also associated with the mode of delivery, with induced or stimulated labour being associated with greater pain (NICE, 2008) and greater use of analgesia (Spanish Ministry of Health, 2012; Sutton et al., 2017).

Conclusion

We found no evidence that aquatic aerobic exercise during pregnancy reduced the use of epidural analgesia, or the incidence of instrumental or caesarean delivery. However, we found that pregnant women who were in a physical exercise program reported less pain during labour, and that aquatic aerobic exercise was safe for women and their newborns. Further confirmatory studies are needed to analyse the association between exercise and pain perception during childbirth, and qualitative studies are needed to determine the expectations and knowledge of pregnant women regarding pain relief during childbirth.

Declaration of Competing Interest

None.

CRediT authorship contribution statement

María del Carmen Carrascosa: Conceptualization, Investigation, Writing – original draft, Writing – review & editing, Supervision, Project administration, Funding acquisition. **Araceli Navas:** Conceptualization, Investigation, Writing – original draft, Writing – review & editing. **Catalina Artigues:** Conceptualization, Investigation, Funding acquisition, Writing – review & editing. **Silvia Ortas:** Investigation, Writing – review & editing. **Elena Portells:** Investigation, Funding acquisition, Writing – review & editing. **Aina Soler:** Data curation, Methodology, Writing – review & editing. **Miquel Bennasar-Veny:** Writing – original draft, Writing – review & editing. **Alfonso Leiva:** Conceptualization, Methodology, Investigation, Funding acquisition, Validation, Formal analysis, Data curation, Writing – original draft, Writing – review & editing.

Ethical approval

The study protocol was approved by the Primary Care Research Committee and the Balearic Ethical Committee of Clinical Research (registered CEI-IB Ref. No: 2358/14).

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.midw.2021.103105.

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