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Research

Sequential application of non-pharmacological interventions reduces the severity of labour pain, delays use of pharmacological analgesia, and improves some obstetric outcomes: a randomised trial

Rubneide Barreto Silva Gallo, Licia Santos Santana, Alessandra Cristina Marcolin, Geraldo Duarte, Silvana Maria Quintana

Department of Gynecology and Obstetrics, Ribeirão Preto Medical School, University of São Paulo, Brazil

KEY WORDS

Randomized controlled trial
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ABSTRACT

Question: Among women in labour, does sequential application of non-pharmacological interventions relieve labour pain, shorten labour, and delay pharmacological analgesia use? **Design**: Randomised trial with concealed allocation, assessor blinding, and intention-to-treat analysis. **Participants**: Eighty women admitted in labour at the end of a low-risk pregnancy. **Intervention**: Participants in the experimental group received three interventions for up to 40 minutes each in particular stages of labour: exercise on a Swiss ball at 4 to 5 cm of cervical dilation; lumbosacral massage at 5 to 6 cm dilation; and a warm shower at >7 cm dilation. Participants in the control group received usual maternity unit care. Participants in both groups were encouraged to try not to avoid or delay use of pharmacological analgesia. **Outcome measures**: Pain severity was reported on a visual analogue scale. Maternal and neonatal data were collected from official birth records. Satisfaction with care was recorded with a questionnaire. **Results**: Some participants took analgesic medication before the study was complete, so pain was analysed with a last observation carried forward approach. In this analysis, the experimental group had significantly lower pain severity immediately after: exercises (MD 24 mm, 95% CI 15 to 34), massage (14 mm, 95% CI 4 to 25), and showering (17 mm, 95% CI 5 to 29), which allowed delayed and reduced use of analgesic medication. Other significant benefits included: faster expulsion (MD 18 minutes, 95% CI 5 to 30), improved neonatal status, and higher maternal satisfaction. No adverse effects were identified. **Conclusion**: This sequence of non-pharmacological interventions significantly reduced labour pain from 4 cm to beyond 7 cm of cervical dilation, as reflected in decreased and delayed use of analgesic medication. Women in labour could be encouraged to use these interventions, especially if they seek to minimise or delay use of analgesic medication. **Trial registration**: NCT01389128. **[Gallo RBS, Santana LS, Marcolin AC, Duarte G, Quintana SM (2018) Sequential application of non-pharmacological interventions reduces the severity of labour pain, delays use of pharmacological analgesia, and improves some obstetric outcomes: a randomised trial. *Journal of Physiotherapy* XX: XX–XX]**

Introduction

The strong persistent pain associated with labour may negatively affect both mother and foetus, often changing the course of childbirth.[1] The precepts of healthcare humanisation recommend that women in labour should have the opportunity to relieve their pain with pharmacological and non-pharmacological resources.[2]

Current models of childbirth assistance prioritise the quality of care, specifically in relation to: technology; knowledge; dialogue among professionals and patients; and individual choice of resources considered adequate for a safe delivery.[3] Thus, programs for the humanisation of childbirth and delivery were created. In Brazil, a new initiative started in 2000 with the formal institution of the Program for the Humanization of Pre-Natal Care and Childbirth by ordinance number 569 by the Ministry of Health. This program attempts to implement best practice during childbirth based on evidence, especially in relation to reducing surgical intervention and creating incentives for vaginal delivery.[2]

Some non-pharmacological interventions have been shown to assist with the relief of labour pain and/or the progression of labour. Several studies indicate that exercises with a Swiss ball aid in the efficient evolution of dilation, pain relief and facilitating foetal descent.[4–6] The effectiveness of massage in reducing pain intensity has been demonstrated in several individual randomised trials.[7–9] A Cochrane systematic review with six studies contributing data on 326 women confirmed that massage significantly reduces labour pain and also showed that it improves the

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emotional experience of labour.[10] Another systematic review[11] with data on 3243 women showed that showering reduces pain severity in women with 8 to 9 cm of cervical dilation, reduces the need for pharmacological analgesia, and shortens the duration of the first phase of labour.

In Brazil, epidural analgesia and the combination technique of epidural and spinal analgesia represent the most frequently used pharmacological procedures for pain relief during labour. Non-pharmacological interventions (including pelvic motion sitting on a ball, massage, and showers) have been described as beneficial with few side effects or contraindications.[12] Moreover, these non-pharmacological interventions, when used in conjunction with continuous support, favour the active participation of the woman and her partner during childbirth.[2,12]

The scientific evidence that supports the use of non-pharmacological interventions is derived from trials where one of the interventions was applied in isolation at a particular stage of labour. None of the studies examined the sequential or combined use of these interventions. If a single non-pharmacological intervention applied is effective, then a combination of different non-pharmacological interventions may yield better results.

Therefore, the research question for this randomised trial was:

Among women in labour at the end of a low-risk pregnancy, does the sequential application of non-pharmacological interventions relieve labour pain, shorten the duration of labour, and delay the need for pharmacological analgesia?

Method

Design

This was a randomised, controlled trial with concealed allocation, assessor blinding, and intention-to-treat analysis. After confirmation of which patients met the eligibility criteria for the study, the primary researcher randomised willing participants to an experimental group or a control group, according to computer-generated random assignments.

The primary researcher applied a series of three non-pharmacological interventions (exercises with a Swiss ball, massage and a warm shower) to the participants allocated to the experimental group. Each intervention was applied for up to 40 minutes in accordance with the degree of cervical dilation, as detailed below. Another researcher, who remained blinded to the participants' group allocation, measured the pain intensity before and immediately after each intervention. Participants in the control group received routine maternity care and were evaluated by the blinded researcher at the same times as the participants in the experimental group, as determined by cervical dilation. Maternal and neonatal outcome data were also collected by the blinded researcher before the participant was discharged from the maternity unit.

Pharmacological analgesia was available to the participants when they requested it and it was prescribed by medical staff. This form of analgesia was available to women in both groups. The doctors were blinded throughout the study and prescribed the medication to be 'given as needed' before the study interventions started, so that they were effectively blinded and it was just the women's request that triggered the nurse to deliver the pharmacological analgesia.

Participants, therapists and centre

All participants were recruited from among the women admitted to the Reference Centre of Women's Health of Ribeirão Preto-MATER, state of São Paulo, Brazil, from October 2011 to July 2012. This is a 40-bed unit that serves approximately 3600 low-risk pregnant women per year in Brazil's public health system. The aim and methods of the study were explained to all eligible patients and voluntary participation was requested.

The inclusion criteria were: primigravida parturients with a low-risk pregnancy; a gestational age $>$ 37 weeks; a single foetus in the cephalic position; spontaneous onset of labour; cervical dilation of 4 to 5 cm and appropriate uterine contractions for this phase; intact ovular membranes; and literacy, including the ability to understand the study. The exclusion criteria were: use of analgesic medications or other drugs that interfere with uterine motility from hospital admission until randomisation; cognitive or psychiatric problems; admission for induction of labour; premature rupture of chorioamniotic membranes; or other risk factors.

Participants were requested to not use analgesic medications or other drugs that interfere with uterine motility during the study period, if possible. The experimental interventions were ceased if: pain increased to a level that prevented the application of the non-pharmacological interventions, the participant wished to end the treatment, acute foetal distress was suspected, or medical management progressed to a caesarean section. Participants were free to withdraw from the study if they declined further participation at any stage.

There were only two therapists involved in the study. The primary researcher was a physiotherapist with 4 years of clinical experience. Although standardisation of the methods for evaluating labour pain should minimise the interference of the researcher and could be performed by anyone, the therapists undertook the same role (ie, the primary researcher performed randomisation and application of the procedures (sequential non-phamacological interventions or routine care), while the blinded researcher measured the outcomes listed in the study protocol).

Intervention

Experimental group

The experimental group received three non-pharmacological interventions: exercises on a Swiss ball, lumbosacral massage, and a warm shower. Each intervention was administered at a different stage of labour, as detailed below. Each intervention was intended to be delivered for a 40-minute period, but if a participant progressed to the next level of cervical dilation in less than 40 minutes, she was progressed to the next intervention.

The first intervention was administered at the beginning of the active phase of labour, during the period of 4 to 5 cm of cervical dilation. The primary researcher instructed the participant to perform pelvic motion exercises while sitting on a Swiss exercise ball. The exercises were performed during uterine contractions for a period of 40 minutes. The exercises on the Swiss ball were meant to increase pelvic girdle movement, with active anteversion and retroversion, lateral tilting, circumduction and propulsion of the pelvis.

The second intervention was administered when the participant reached 5 to 6 cm of cervical dilation. The primary researcher (a physiotherapist) massaged the participant for 40 minutes, using rhythmic ascending kneading hand movements and a return with sliding through the lateral region of the trunk in association with sacral pressure. The technique was applied between T10 and S4. This region corresponds to the path of the hypogastric plexus and the pudendal nerve, which innervate the paravertebral ganglia, delivery canal and perineum. The participant determined the intensity of the massage by requesting greater or less force during execution of the movements. The participant also chose their preferred position for receiving the massage (sitting, lateral decubitus or standing with the trunk bending forward).

When cervical dilation was at $\geq$ 7 cm, the third intervention was applied. The primary investigator led the participant to take a warm shower for 40 minutes, with the water at 37 °C and supervision of the primary researcher.

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