Effects of ambulation during the first stage of labour on maternal and neonatal outcomes: A randomized controlled trial

Study Protocol with SAP

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Introduction

There is clear and important evidence that walking and upright positions in the first stage of labour reduces the duration of labour, the risk of caesarean birth, the need for epidural, (Lawrence, Lewis et al. 2013). In addition, ambulation and upright position have not been found to be associated with increased intervention or negative effects on mothers' and babies' wellbeing (Lawrence, Lewis et al. 2013). Women, particularly who have low risk labour, are highly advised to follow upright positions, and encouraged and assisted to assume whatever positions they choose (Lawrence, Lewis et al. 2013; Ondeck 2014).

Research confirms that movement is a safe and healthy coping strategy for pain, and confining labouring women to bed increases pain and decreases women's satisfaction with their birth experience (Romano and Lothian 2008; Ondeck 2014). An experimental study was conducted in Mangalore to examine the effect of ambulation during the first stage of labour on the intensity of labour pain, length of the first stage of labour, and use of analgesia, the study comprised of 40 primigravid mothers and they were grouped as experimental and control through randomization, experimental group received ambulation, the other group did not. Pain was assessed through Visual Analog Pain Scale and observational checklist was used to assess the outcome of labour there was a significant difference in duration of first stage of labour between the experimental and control group but no significant difference in overall outcome of labour. The mean pain

score for experimental group was (6.8) which was less than the main pain score of control group. The findings of the study revealed that ambulation was effective to reduce the intensity of labour pain among primigravid mothers (Savitha, Nayak et al. 2013).

Another experimental study was conducted to evaluate the effectiveness of back massage versus ambulation during first stage of labour among primigravid mothers in terms of pain and anxiety, an experimental research approach with pre-test post test control group design was undertaken on 90 primigravid mothers (30 in each experimental group1, experimental group 2 and control group). Purposive sampling technique was used to select the primigravid mothers. There was a significant difference in mean pre-test and post-test labour pain scores and anxiety scores during first stage of labour among primigravid mothers .It was concluded that back massage and ambulation was effective to reduce the level of labour pain and anxiety among primigravid mother during first stage of labour(Bala, Babu et al. 2017).

Ambulation and upright position were found to positively affect the progress of labour and a woman's behavioural response to childbirth. An updated systematic review of 25 studies with a total of 5218 women, done to assess the effects of upright positions(walking, sitting, standing, kneeling) versus recumbent positions (supine, semi recumbent, lateral) for women in the first stage of labour on the length of labour, and other outcomes. Results showed that the duration of labour was approximately one hour

shorter for women randomized to upright as opposed to recumbent positions(Lawrence, Lewis et al. 2013).

A quasi experimental study conducted to determine the effectiveness of ambulation during first stage of labour, on the outcome of labour. A post test only control group design was used in 60 samples. Results revealed that ambulation during first stage of labour was effective in reducing duration of labour (t value = -2.27 and p value <0.05) also in bringing positive behavioural response (Mann-Whitney U test, p value< 0.05). Authors concluded that ambulation during first stage of labour was effective in reducing the duration of labour and to bring out good behavioural response in primigravid women. Also ambulation did not have any adverse effect on neonatal outcome. It was observed by the investigator that, having the choice to ambulate is well accepted by women when they were told the potential benefits of ambulation. Also it is a cost effective intervention which the nurse can implement independently (Prabhakar, George et al. 2015).

A systematic review of the effect of ambulation and maternal position during the first stage of labour on duration of this stage was done. All randomized controlled trials carried out to assess this effect were taken into consideration in this review. Authors concluded that adoption of the upright position or ambulation during first stage of labour may be safe, but considering the available evidence and its consistency, it cannot be recommended as an effective intervention to reduce duration of the first stage of labour(Souza, Miquelutti et al. 2006) .

A randomized controlled trial was conducted to evaluate the vertical position adopted by nulliparous women during labour in terms of pain and satisfaction with the position. The study was based on a secondary efficacy analysis of data from 107 nulliparous women enrolled in which the vertical position adopted during the dilation phase of labour was evaluated. The analysis involved comparing the median percentages of the duration for which women remained in the vertical position for each of the variables studied. Results revealed that at 4 cm of dilation, the women with a pain score < 5 remained longer in the vertical position during labor compared to those with a score >7 ($p=0.02$). At 4 and 6 cm of dilation, the women who reported greater satisfaction remained more than 50% of the time in the vertical position ($p=0.02$ and $p=0.03$, respectively). Authors concluded that vertical position helped relieve labour pain and increased comfort and patient satisfaction (Miquelutti, Cecatti et al. 2009).

Significance of the study

Despite evidence in the literature that ambulation and upright positioning during labour does not harm mother, fetus, or newborn, there is evidence that women are still largely confined to bed during the first stage of labour(Simkin and Bolding 2004). The increased use of medical interventions such as epidural analgesia, continuous electronic fetal monitoring, intravenous infusions for fluids and electrolytes, and a restrictive birthing environment limits women's instinctive responses to labour pain and contractions rather than assisting the woman to cope with the pain and anxiety of labour (Simkin and Bolding 2004)

In Jordan practices in maternity wards are not based on best evidence(Shaban, Hatamleh et al. 2011). The majority of health facilities restrict movement during labour, women were confined to bed in the lithotomy position and most of these facilities strap women in the delivery position, women have no choice to assume the position they prefer during labour and delivery (Khresheh, Homer et al. 2007; Sweidan, Mahfoud et al. 2008; Shaban, Hatamleh et al. 2011). The practice of restricting women's movement in labour is contrary to the statements and recommendations of professional organizations advocate for women to move about during the first stage of labour, as long as they remain low-risk (WHO 1996; Ondeck 2014).

Implementing evidence-based maternity care in developing countries with limited resources such as Jordan is particularly challenging, and requires commitment to applying the most up to date evidence to clinical decisions.

Purpose of the study

The purpose of this study is to begin investigation that could help provide a better quality of care during birth and improve maternity outcomes in one Jordanian hospital. The process was introducing an evidence-based practice of encouraging women to ambulate and assume the upright position during the first stage of labour and observing if results would suggest low cost modifications for the maternity health service environment, especially the labour ward. This is the first study that has attempted to implement and evaluate such an intervention in Jordan.

Aim

To examine the effect of ambulation (walking) during first stage of labour on maternal and neonatal outcomes.

Methods

Design

A randomised controlled study will be conducted with primiparous women who come to give birth at Al- Karak Hospital in Jordan. In the intervention group women will be encouraged to ambulate and women in the control group will receive usual maternity care. Women will be subsequently randomised into the groups using a table of random numbers. "Ambulation during labour" here will refer to moving from place to place during the first stage of labour that reduces the amount of time a woman spends laying down during this stage (measured by recording the number of minutes spend on walking).

Setting

The setting for this study will be the maternity ward at Al-Karak hospital, the main governmental and teaching hospital in the southern region of Jordan. In 2016 2,808 births occurred in this hospital, 59% were caesarean births (Ministry of Health 2017).

In this hospital, the woman usually labours in 26- bed ward with restrictions on movement. This is consistent practice nationally. Certified midwives, resident physicians, and obstetricians provide care. Midwives in this hospital work with uncomplicated labours and help obstetricians with complicated cases.

Sample and sampling

We will recruit consecutive eligible women interested in participating in the study, for a period of one year. All primiparous women with uncomplicated singleton pregnancies between 37 and 41 weeks gestation, cephalic, with cervical dilatation 3 to 5cm who come to give birth at Al-Karak hospital, between the 1st of January and the 30th of December 2018 will be approached for participation.

Sample size

The sample size was calculated using the G power version 3.1. Based on difference between two independent groups, alpha= 0.05, median effect size 0.3, power =95%, sample size required for each group is 88 women. To overcome attrition, 25% of the calculated sample will be added, the final sample size will be 110 women in each group.

Data collection process

Data will be collected using structured tool developed by the researchers based on literature review of research related to the current topic (appendix 1). The tool composed of section collecting the socio-demographic data and another section collecting maternal and neonatal outcomes. The research tool was reviewed by a panel (n=3) of experts in maternity health field. Before starting the study, the final version of the tool will be tested in a pilot study to evaluate its feasibility, clarity, and reliability. Assistant researcher (midwife) will complete the first section of the tool, which related to socio-demographic data, and will allocate participants to control and intervention group according to the randomization list.

The principal researcher will be kept blind for those participants who are in the intervention and control groups. Completing the second part of the study tool, which is related to maternal and infant health outcomes, will be in maternal ward and by the primary investigators 24 to 48 hours after birth.

Outcomes Measurement

The study outcomes have two main aspects; related to maternal outcomes and neonatal outcomes. The maternal outcomes will include 1. Duration of the first stage of labour (defined as the time from the onset of regular contractions to the time of full cervical dilatation of 10 cm as documented by the midwife) 2. Intensity of labour pain (measured by the Visual Analogue pain Scale rating from 0 to 10 in which the woman registers the pain perception, considering 0 no pain and 10 the worst pain imaginable.) 3. Use of analgesics (defined as used or not used), 3. Mode of birth (defined as normal, vacuum extraction, forceps delivery, or cesarean section) 4. Woman satisfaction with the birth experience (measured by research-based birth satisfaction and dissatisfaction items from literature. Women will respond on a five-point Likert scale with agreements with the statement).

The new neonatal outcomes will include: 1. Apgar scores at 5 minutes

Data analysis

Data will be analysed using SPSS version 22. Descriptive statistics will be used to describe the sample characteristic. According to the level of measurement, independent *t*-test, and ANOVA will be used to examine the differences between study groups (intervention and control) based on baseline socio-demographic date and health

outcomes. Statistical assumptions will be checked and ensured, and results will be considered significant if *P* values were < 0.05.

Ethical consideration

Approval to conduct the study will be obtained from the ethics committee at faculty of nursing / Mutah University and the Ministry of Health (MOH). Women will be informed about the study and verbal and written consent for agreement will be obtained from each woman (appendix 2). Women will be assured that participation is voluntary and they have the right to withdraw from the study at any time without giving any reason. Women will be assured that their information will not be recognized in any products of this research.

References