Effectiveness of breathing exercises, foot reflexology and back massage (BRM) on labour pain, anxiety, duration, satisfaction, stress hormones and newborn outcomes among primigravidae during the first stage of labour in Saudi Arabia: a study protocol for a randomised controlled trial

ABSTRACT

Introduction Labour pain is among the severest pains primigravidae may experience during pregnancy. Failure to address labour pain and anxiety may lead to abnormal labour. Despite the many complementary non-pharmacological approaches to coping with labour pain, the quality of evidence is low and best approaches are not established. This study protocol describes a proposed investigation of the effects of a combination of breathing exercises, foot reflexology and back massage (BRM) on the labour experiences of primigravidae. Methods and analysis This randomised controlled trial will involve an intervention group receiving BRM and standard labour care, and a control group receiving only standard labour care. Primigravidae of 26–34 weeks of gestation without chronic diseases or pregnancy-related complications will be recruited from antenatal clinics. Eligible and consenting patients will be randomly allocated to the intervention or the control group stratified by intramuscular pethidine use. The BRM intervention will be delivered by a trained massage therapist. The primary outcomes of labour pain and anxiety will be measured during and after uterine contractions at baseline (cervical dilatation 6 cm) and post BRM hourly for 2 hours. The secondary outcomes include maternal stress hormone (adrenocorticotropic hormone, cortisol and oxytocin) levels, maternal vital signs (V/S), fetal heart rate, labour duration, Apgar scores and maternal satisfaction. The sample size is estimated based on the between-group difference of 0.6 in anxiety scores, 95% power and 5% α error, which yields a required sample size of 154 (77 in each group) accounting for a 20% attrition rate. The between-group and within-group outcome measures will be examined with mixed-effect regression models, time series analyses and paired t-test or equivalent non-parametric tests, respectively. Ethics and dissemination Ethical approval was obtained from the Ethical Committee for Research Involving Human Subjects of the Ministry of Health in the Saudi Arabia (H-02-K-076-0319-109) on 14 April 2019, and from the Ethics Committee for Research Involving Human Subjects (JKEUPM) Universiti Putra Malaysia on 23 October 2019, reference number: JKEUPM-2019–169. Written informed consent will be obtained from all participants. Results from this trial will be presented at regional, national and international conferences and published in indexed journals.