Angle Labor Pain Questionnaire Turkish Version: Validity and Reliability Study and Evaluation of Efficacy With a Non-pharmacological Method

04 February 2021

ID: ALPQT_NONFARMA

NCT number: Not available

STUDY PROTOCOL

Study design and participants

The randomized experimental study was conducted with two parallel groups consisting of 60 pregnant women (administration group n:30; control group n:30) who met the inclusion criteria (Figure 2). The inclusion criteria of the study were similar to the first stage; in addition, pregnant women who had any contraindications for applying a back massage were excluded from the study. The sample size in the study group and control group was determined by power analysis in the PASS 11 package program. The sample calculation was made as per the pain score averages of the experimental and control groups in the study conducted by Karami et al. (2007) evaluating the effectiveness of massage practice in managing labor pain (Karami, Safarzadeh, & Fathizadeh, 2007). The calculation set forth that at least 28 pregnant women should be available for each group with a power level of 0.80 and a confidence level of 95% (Type 1 margin of error 0.05).

-Randomization and blinding

For the assignment of the participants to the groups, two separate number sequences were formed by defining the range of numbers 1—80 in the "Research Randomizer" in the computer environment, despite possible data loss. Considering their order of participation in the study, the pregnant women were assigned to the groups (study group and control) in accordance with the randomization sequence. Pregnant women assigned to the study group were also informed about the lower back massage application.

Assignment of the participants to the groups, applications, pain evaluations, and data analysis were performed by the researchers because of the nature of the study (thesis). Therefore, blinding was not performed in the study.

-Instruments and Interventions

"Pregnant Information Form," "Labor Follow-up Form," and "VAS" were used in the first stage, and the Turkish version of the A-LPQ. Basic information for the pregnant women was obtained from patient files. The "Pregnant Identification Form" and "Labor Follow-up Form" (Angle et al., 2017; Hamlacı & Yazıcı, 2017), which were prepared based on the literature, were used for the collection of the study data. The Visual Analog questionnaire and A-LPQ Turkish draft were used for the evaluation of the labor pain.

*-Pregnant Identification Form***:** This form was composed of 23 questions regarding socio-demographic characteristics (age, education, occupation, social security, and family type) of the pregnant women and their obstetric history and characteristics (number of births, delivery method, complaints about current pregnancy, receiving antenatal care, etc.) (Angle et al., 2017, 2016; I. M. Gönenç & Terzioğlu, 2020; Hamlacı & Yazıcı, 2017).

-*Labor Follow-Up Form:* This form consisted of information about the week of pregnancy, the onset of labor and interventions performed in the first stage of labor (amniotomy, showering, oral feeding, etc.), maternal health, and the progression of labor (blood pressure, arterial pulse, body temperature, cervical dilation and effusion, condition of membranes, fetal head level, and heart rate) (Angle et al., 2017; Hamlacı & Yazıcı, 2017; Türkmen, 2017).

-*Visual analog scale (VAS):* VAS is a one-dimensional questionnaire used to evaluate perceived pain. VAS was first developed by Price et al. (1983) (Price et al., 1983). Cline et al. (1992) stated that the vertical use of the VAS was better understood by the patients in their study to ensure standardization in the VAS (Cline et al., 1992). VAS was used in the vertical form in the present study.

-Angle Labor Pain Questionnaire (A-LPQ): It is the first measurement tool developed by Angle et al. to measure labor pain. The original questionnaire consists of 22 items and five sub-dimensions (Angle, 2013; Angle et al., 2017, 2016). Each item in the questionnaire is scored between 0 and 10. Two of the sub-dimensions of the questionnaire are scored 0-50 and the other three sub-dimensions are scored 0-40. A total of 220 points is obtained from the questionnaire, and an increase in the total score is interpreted as an increase in labor pain with no cut-off point. ***A-LPQ was used in this study with its Turkish translation and cultural adaptation.*** Language and content validity was performed to obtain the Turkish draft version of the A-LPQ. Relevant permissions were obtained from the authors who developed the questionnaire via e-mail on 02.05.2017, and a contract was signed with Mapi Thrust, the research company holding the copyright of the questionnaire, on 22.01.2018. Turkish translation and cultural adaptation of the A-LPQ was performed in six stages (Figure 1); *(1)* The questionnaire was translated from English, its original language, to Turkish by an obstetrician, who was an expert in the field, and another person who was not a healthcare professional, both native Turkish speakers. (*2)* The Turkish draft version of the questionnaire was formed by analyzing the two different Turkish translations. *(3)* The Turkish draft version of the questionnaire was translated back into English by another independent translator whose native language was Turkish, who had a good command of English, and did not

know the original version of the A-LPQ. Certain language and grammar revisions were made at this stage (*5).* The final Turkish version of the questionnaire was evaluated for content validity by nine experts in the field, in accordance with the Davis method. Experts rated each item in accordance with the Davis method as follows: a: "Appropriate," b: "Should be slightly revised," c: "Should be substantially reviewed," and d: "Not appropriate." Intraclass correlation coefficient (ICC) analysis was performed with the data obtained from the nine experts to evaluate the consistency between the expert opinions given for each item of the A-LPQ. The "Coverage Validity Rate" was obtained for each item and the "Coverage Validity Index"' was obtained for the total questionnaire, and 0.80 was taken as a reference (F. Y. Karakoç & Dönmez, 2014; Yurdugül, 2005). (*6)* A pre-application was made with 20 pregnant women in order to eliminate spelling, expression, and grammar problems of the Turkish version of the questionnaire, and the Turkish form was finalized.

Interventions group: The VAS and A-LPQ forms were administered to evaluate the perceived pain levels of the pregnant women before the application after they were informed about the study and their consent was obtained **(**First measurement**)**. The application was initiated immediately after the pain evaluation (max. 1 min later).

Lower back massage performance: In the study, Linda Kimber's massage protocol was used (Kimber, 1999). The researcher applied the lower region circular hip massage, sacral pressure massage, and lateral lower region circular back massage to the pregnant women in the treatment group as per the Linda Kimber massage protocol (Figure 1). First, the researcher ensured that the patient was holding the bed, squatting, or bent over on the bed, which is suitable for the massage, between two contractions. The pregnant woman was instructed to breathe deeply and exhale

audibly when her contractions began. Gloves were worn during the massage and liquid Vaseline, which does not contain any active substance, was used to provide lubricity. The circular hip massage was applied at the beginning of the contraction, and lower lateral area and sacral pressure massage was applied towards the end of the contraction as per the massage protocol, and simultaneously with the inhaling sound of the pregnant woman (Figure 3). The massage application was continued for an average of 20-25 minutes for at least three contractions. No massage was applied between contractions. After the massage application was finished, the vital signs and fetal heart sounds were checked and the VAS and A-LPQ were administered to the pregnant woman (Second Measurement). Measurements were made between contractions to evaluate the changes in pain level caused by massage application.

Control group: Pregnant women in the control group received standard care in their room and their VAS and A-LPQ score was also evaluated during the same phases (Test 1 and Test 2).

-Data analysis

Data were evaluated in the statistical package program IBM SPSS Statistics Standard Concurrent User V 26 (IBM Corp., Armonk, New York, USA). Shapiro-Wilk test of normality and Q-Q graphs were used to evaluate the distribution of the data. Chi-square test, Mann-Whitney U, and t-test were used in the comparison of groups for socio-demographic, obstetric, and clinical findings. Two-way analysis of covariance was used for repeated measurements in the comparison of VAS score and A-LPQ scores between and within groups in proportion to the measurement times. The partial eta-square calculation was used to evaluate the influence quantity in the comparison of the VAS and A-LPQ scores between the groups. Spearman correlation analysis was used to assess differences between the VAS score of the study group and the total and sub-dimension scores of the A-LPQ to

determine the influence of A-LPQ in the measurement of the perceived pain change. The "Intention-to-Treat" method was not used in the analyses. Statistical significance level was recorded at $\boldsymbol{p<0.05}$.

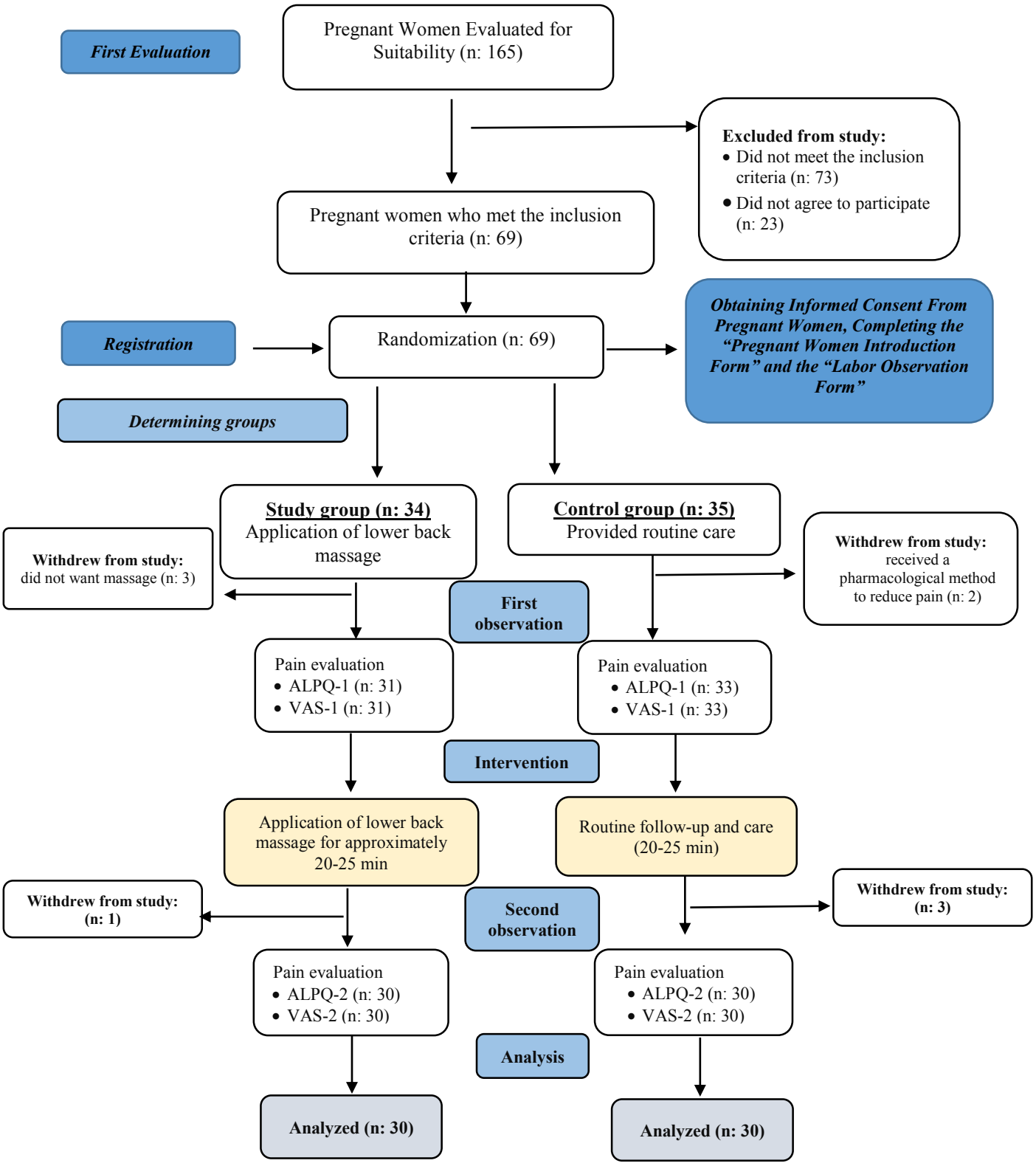

Figure 1. CONSORT flow chart of the randomized controlled experimental study (Grant et al., 2018)