Preparing for the worst – promoting safety behaviours in antenatal care among Norwegian, Pakistani and Somali pregnant women. A randomised controlled trial

Consent form in English

11.01.2018

Trygt Svangerskap

REQUEST FOR PARTICIPATION IN THE RESEARCH PROJECT

SAFE PREGNANCY

This is a request for you to participate in the research project: Safe Pregnancy. Asking women about factors and events that can affect pregnancy is a part of antenatal care. Research shows that stressful life events and mental health issues can affect the health of mother and child. Norwegian health authorities recommend health personnel to map stressful events in order to help and support women who have experienced, or are currently experiencing stressful events.

WHAT DOES THE STUDY ENTAIL?

The purpose of this research project is to gain more detailed knowledge about pregnant women's experience of their quality of life and stressful events during pregnancy. We would also like to find out more about the consequences stressful life events have for the health of mother and child. In addition, we want to test the effect of short video. Your participation is valuable regardless of how you experience your health or how far you have come in your pregnancy.

All women agreeing to participate will be asked to complete a questionnaire on a tablet and watch a video. Completing the questionnaire takes approximately 20 minutes. The video lasts about 7 minutes. All participants will receive a card with useful quality-assured websites for pregnant women with information on safety in pregnancy. You can watch the video as many times as you want when visiting the health center.

After you have given birth, we wish to collect information about you and your child from the discharge report from the hospital. In addition will we invite about 20% of the participants to fill in a second questionnaire, approximately 3 months after the baby is born. We need your phone number for this follow-up.

In this project we will collect and register the following information: Phone number, background information, information about pregnancy/previous pregnancies, life events, health and quality of life, actions taken to ensure a safe pregnancy, mode of delivery, use of pain relief during delivery, gestational age, weight and length of your baby and if you have had complications during/after birth.

POTENTIAL ADVANTAGES AND DISADVANTAGES

Research and reports show that routine questions concerning stress and stressful life events to all women in antenatal care could help women and their families. As a participant in this study, you will benefit by receiving relevant information about safety in pregnancy. Another benefit of participation is that you will contribute to research, which will benefit other women. This study will guide the

development of a digital tool (questions and video) which if proven useful can be made available to more pregnant women. A slight disadvantage for you is the time it will take you to complete the questionnaire and watch the video. All participants are invited to be included in a lottery of 5 electronic tablets. You will be asked about participation at the end of the questionnaire. The lottery happens when all women have been included in the study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL OF CONSENT

Participation in the study is voluntary. If you agree to participate your signature is required. You can withdraw your consent to participate in the study at any time without giving any particular reason. Withdrawal from the study will not have any consequences for your follow-up at the Community Health Centre. If you choose to withdraw from the study you can demand that all information regarding you and your child is deleted unless this information has already been used for analysis or in scientific publications. If you choose to withdraw later or have questions regarding the project please contact Lena Henriksen, phone number: 900 68 485 or by e-mail: lena.henriksen@hioa.no

WHAT WILL HAPPEN TO THE INFORMATION ABOUT YOU?

All your data will be handled anonymously. This means that your name and ID-number will not be directly connected to the answers you give in the questionnaire. The staff at the Community Health Centre will not have access to the information given in the questionnaires. You will receive a study ID which can be linked to your name for a limited time. The link between your study ID and your name will be kept secure at the Community Health Centre. Only the researchers in the study will have access to the information collected in the questionnaires. The leader of the project is responsible for the everyday running of the project and safe storage of your information. Identifiable information regarding yourself will be deleted at the latest five years after the end of the project. The information registered about you will only be used as described above. You have the right to know what information has been registered about you and the right to correct potential wrong information.

ETHICAL APPROVAL

The project is approved by The Regional Committee for Medical and Health Research [2017/358].

CONSENT FOR PARTICIPATION IN THE STUDY

I AM WILLING TO PARTICIPATE IN THE STUDY

Place and date

Signature of participant

Name of participant in printed letters

I confirm that I have given information about the study

Place and date

Signature

Name in printed letters