TİTLE: Vaginal Breech Birth Management Educational Mobile Game Design and Evaluation for Midwifery Students

NCT05551611

01/28/2022

INFORMED CONSENT FORM

Dear Volunteer

We invite you to participate in the research titled "Design and Evaluation of Vaginal Breech Birth Management Educational Mobile Game for Midwifery Students" conducted at Kocaeli University Research and Application Hospital. Before deciding whether or not to participate in this research, you should know the purpose and how the research will be conducted, the possible benefits, risks and discomforts that this research will bring to the volunteer participants, and you should make your decision freely within the framework of this information. Therefore, reading and understanding this form is of great importance. This form contains the written form of the information given to you verbally by us as the research officer. Before signing the form, please take the time to read the following information, which has also been explained to you verbally, carefully once. If there is anything that you do not understand or that is not clear to you, or if you would like more information, please ask us. If you agree to take part, you will be given a copy of this signed form to keep.

Participation in the research is completely voluntary. You have the right not to participate in the research or to withdraw from the research at any time after participation. In both cases, we would like to inform you that you will not be subject to any sanctions and loss of rights.

Research Officers
Prof. Dr. Lecturer Prof. Dr. Özlem ÇAĞAN
Uzm. Midwife Research Assistant. Assist. Suzi ÖZDEMİR

This "Informed Consent Form" consists of 2 parts;

1) BİLGİLENDİRME
2) RIZA

INFORMATION

PURPOSE OF THE RESEARCH: The study we are asking you to volunteer for is a research project. This research project has two objectives. The primary aim of the study is to design an educational mobile game on vaginal breech birth management for midwifery students. The secondary aim of the study is to evaluate the effect of the educational mobile game-supported teaching activity given to midwifery students about vaginal breech birth within the scope of risky childbirth and postpartum period course on learning.

INFORMATION ABOUT THE RESEARCHER AND PARTICIPANT: The research was conducted by Dr. Assoc. Prof. Dr. Özlem ÇAĞAN and Uzm. Midwife Res. Assist. Suzi ÖZDEMİR will be conducted by Kocaeli University Faculty of Health Sciences, Department of Midwifery 3rd year students. It will continue until 80 participants, which is the sufficient number of participants for the research, are reached. No unnecessary procedure will be applied to you within the scope of the research.

WHY WE INVITE YOU TO PARTICIPATE IN THE RESEARCH: Since the research is planned to be conducted with 3rd year midwifery students, the research institution is the researcher's own institution and you meet the inclusion criteria, we offer you to participate in the study. If you agree to participate in this study, you have the right to withdraw from the study at any time. In such a case, your relationships with the researchers will not be negatively affected and your

education will not be disrupted. The information obtained from the research will be evaluated by the researchers. No information about your identity will be shared either during the research or when it is published. No fee will be charged or paid to you during this research.

WHAT KIND OF APPLICATION WILL BE MADE WITHIN THE SCOPE OF THE RESEARCH? WHAT ARE THE METHODS AND PROCEDURES: No unnecessary procedure will be applied to you within the scope of the research. In our research, theoretical or practical training will be given in accordance with the course content for vaginal breech delivery management. The training method will be specified after random assignment to the research groups. Before and after the training, you will be asked to fill out questionnaires with multiple choice, check boxes and open-ended questions.

WHAT ARE THE POSSIBLE BENEFITS OF THE RESEARCH TO SCIENCE AND TO YOU: As a result of this research, the effectiveness of the training methods given for vaginal breech birth management will be evaluated and midwifery practices will be strengthened by determining how to support and empower pregnant women with breech presentation during vaginal delivery.

WHAT ARE THE ADDITIONAL RISKS AND DISCOMFORTS THAT THE RESEARCH MAY BRING TO YOU: The study is not expected to cause you any risks or discomfort.

YOUR RIGHTS TO PARTICIPATE IN/LEAVE THE RESEARCH AND THE RESEARCHER'S ASSURANCE TO PROTECT YOUR RIGHTS: Taking part in this research is entirely voluntary. You can refuse to take part in the study or you can stop at any time after you have started. The principal investigator may also exclude you from the study if necessary. In cases of non-participation, withdrawal or exclusion from the study, there will be absolutely no penalties or loss of rights in your favor. You will be informed if new information about the research subject is obtained that may affect your willingness to continue the research.
The results of the research will be used for scientific and educational purposes. All information obtained from you will be used entirely for research purposes, will be kept confidential, and the confidentiality of your identity information, if any, will be maintained when the research is published. If you exercise your right to withdraw before the completion of the research or if you are removed, the data about you will not be used.
The research will be completed when training on vaginal breech delivery management is given and data collection forms are collected.

HOW RESEARCH COSTS WILL BE COVERED: You will not be charged for any procedure to be applied to you within the scope of the research. The research budget will be provided by the researcher and from the study grant applied for.

CONTACT PERSON(S): During the research, you can reach the researcher at any time by calling 0554 848 86 74. If you have any complaints about your participation in the research, you can contact Kocaeli University Ethics Committee (Tel: 0 262 303 74 50). All complaints will be confidentially evaluated, investigated and you will be informed about the result.

COMPLAINT SUBMISSIONS: If you have a complaint about the study, you can contact the Kocaeli University Ethics Committee rapporteur. Your complaints will be confidentially evaluated, investigated and you will be informed about the result.

IF YOU HAVE ANY QUESTIONS OTHER THAN THOSE MENTIONED ABOVE, THEY WILL BE ANSWERED BY ADDING THEM TO THIS SECTION.

☐ **Additional questions asked by the volunteer and answers**

☐ **There are no additional questions.**

CONSENT / APPROVAL / ASSENT

I have read the information section on the above-mentioned subject and purpose of the study and have been informed first verbally and then in writing by the undersigned. I fully understand the scope and purpose of the study in which I was asked to participate and my responsibilities as a volunteer. I had the opportunity to ask questions and discuss the study and received satisfactory answers. The possible risks and benefits of the study were also explained to me verbally. I understand that I am participating in the study voluntarily, that I can leave the study at any time with or without justification, that I can be excluded from the study by the researcher regardless of my own will, and that my current treatment will not be adversely affected when I leave the study.

In these circumstances;

1) I voluntarily agree to my child's participation in this Clinical Trial without any pressure or coercion.
2) If necessary, my personal information can be accessed by the persons/institutions specified in the legislation,
3) I consent to the use of the information obtained in the study (provided that my identity information remains confidential) for publication, archiving and, if necessary, transfer outside our country for scientific contribution.

I give my consent to participate in this clinical trial without any further explanation, without being under any pressure and consciously.

Name Surname
Signature:
Address:
Telephone No:
Date (day/month/year): .... /..../....

The volunteer whose name is written above was informed by me about the purpose, content, method, benefits and risks of the research and the rights of the volunteer. The patient's questions were answered. It was also ensured that the volunteer examined this form in detail and signed it.

The Person Who Made the Statements
Name-Surname: Research Assistant Suzi ÖZDEMİR, MSc.
Signature:
Date (day/month/year): ..../..../.....

This Informed Voluntary Consent Form consisting of a total of 3 pages was prepared in 2 copies and one copy was delivered to the volunteer.