

The Effect of Education Provided to Children With Type 1 Diabetes Using Gamification Methods on Health Literacy and Quality of Life: A Randomized Controlled Trial

Republic of Turkey

KTO KARATAY UNIVERSITY

ETHICS COMMITTEE FOR NON-PHARMACEUTICAL AND NON-MEDICAL DEVICE
RESEARCH

INFORMED CONSENT FORM

STUDY TITLE: The Effect of Education Provided Using Gamification Methods on Health Literacy and Quality of Life in Children with Type 1 Diabetes: A Randomized Controlled Trial

You are being asked to participate in a research study. The decision to participate or not is entirely yours. Before deciding whether or not to participate, it is important that you understand why the research is being conducted, how your information will be used, what the study involves, and its potential benefits, risks, and discomforts. Please take the time to carefully read the following information. If you decide to participate in the study, you will be given this Informed Consent Form to sign. You are free to withdraw from the study at any time.

SUBJECT AND PURPOSE OF THE STUDY:

This study examines the effect of education provided to children with type 1 diabetes using gamification methods on health literacy and quality of life. The purpose of the study is to reveal the extent to which health literacy and quality of life are affected by diabetes education designed using gamification methods for children with type 1 diabetes.

STUDY PROCEDURES:

If you agree to participate in this study, you will be asked to complete a sociodemographic information form and a questionnaire consisting of two scales with a total of 67 questions. The study is designed to examine the effect of education provided to children with type 1 diabetes using gamification methods on health literacy and quality of life and will be conducted in a randomized controlled manner. Participants will be divided into experimental and control groups, and both groups will undergo pre- and post-tests. Children in the experimental group will be provided with an educational program using gamification methods. Completing the questionnaires will take approximately 15–20 minutes.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING IN THIS STUDY?

The results obtained from this study will contribute to a better understanding of how gamification-based education for children with type 1 diabetes affects health literacy and quality of life. The findings from this study will contribute to the development of diabetes education and future scientific research. There is no risk for participants. The training process is expected to increase children's knowledge and skills related to diabetes management and support their quality of life.

WHAT ARE THE POSSIBLE RISKS OF PARTICIPATING IN THE STUDY?

There are no medical risks associated with participating in this study. As the training process consists of gamification-based activities, there is no physical harm to children. However, some children may experience short-term anxiety or sadness when they remember their responsibilities or difficulties related to diabetes during the training. This situation is not expected to have any negative effects. Participants have the right to withdraw from the study at any time.

HOW WILL MY PERSONAL INFORMATION BE USED?

By signing this form, you will be giving your consent to participate in the study. However, your identity information will not be used explicitly at any stage of the study. The answers you provide in the questionnaires you fill out and any information obtained using visual/auditory devices during the study will be used solely for scientific purposes; your information will not be shared with anyone or for commercial purposes. Research results personal information will be evaluated collectively, will not be shared with third parties under any circumstances, and your privacy will be protected.

ESTIMATED DURATION FOR THE VOLUNTEER TO CONTINUE THE RESEARCH: 8 Weeks

Your participation in the research is voluntary, and you may refuse to participate in the research or withdraw from it at any time without penalty or sanction and without losing any rights. Your participation in the research is voluntary, and you may refuse to participate in the research or withdraw from it at any time without penalty or sanction and without losing any rights.

PERSONS TO CONTACT FOR QUESTIONS AND PROBLEMS:

Dr. Gülfidan BAŞER, Assistant Professor / KTO Karatay University / 05056868687

Çiğdem ANAR, Master's Student / KTO Karatay University / 05056470152

Consent to Participate in the Study

“I have read and understood this informed consent form. I agree to participate in this research and sign this consent form of my own free will. This consent does not invalidate any relevant laws and regulations. The researcher has provided me with a copy of this document, which includes points to note during the study, for my safekeeping.”

Volunteer Name and Surname: Date and Signature:

Address and Phone Number:

Guardian/Legal Representative Name and Surname: Date and Signature:

Address and Phone Number:

Witness 1 Name and Surname: Date and Signature:

Address and Phone Number:

Researcher 2 Name and Surname: Date and Signature:

Address and Phone Number: