Official Title: The Effect of Symptom Management Training Given to Gynaecological Cancer Patients Receiving Chemotherapy with Artificial Intelligence Supported Mobile Application on Supportive Care Needs, Symptom Severity and Psychological Well-Being

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Informed Consent Form (ICF)

Research Project Name: The Effect of Symptom Management Training Given to Gynaecological Cancer Patients Receiving Chemotherapy with Artificial Intelligence Supported Mobile Application on Supportive Care Needs, Symptom Severity and Psychological Well-Being

You have been invited to participate in a research project.

You have been invited to take part in this study because you are being treated with chemotherapy for gynaecological cancer.

It is very important that you understand why and how the research will be carried out before you decide to take part.

Participation in the study is entirely voluntary and refusal to participate will not result in any penalty or loss of any benefit.

Likewise, after agreeing to participate in the research, you can withdraw from the research at any point in the research without giving any reason without causing any harm or loss of any expected benefit to be obtained.

This research is under the responsibility of Prof. Dr. Gülten GÜVENÇ, Research Assistant (PhD Student) Esra Nur ERDOĞAN and Medical Oncologist Tülay EREN working at the Department of Obstetrics and Gynaecology Nursing, Gülhane Faculty of Nursing, University of Health Sciences. D. Student Esra Nur ERDOĞAN and Medical Oncologist Tülay EREN working at Etlik City Hospital Medical Oncology Department.

The financial expenses of the procedures performed within the scope of the research will be covered by the researchers Prof. Dr. Gülten GÜVENÇ, PhD Student Esra Nur ERDOĞAN and Assoc. Prof. Dr. Tulay EREN and will not bring any financial burden to you or your social security institution.

Please read the following information carefully and take some time to decide whether you would like to participate in the study.

After you have been fully informed about the study and your questions have been answered, you will be asked to sign this form if you wish to participate.

This study was planned to evaluate the effect of symptom management training given with an artificial intelligence supported mobile application developed for patients with gynaecological cancer receiving chemotherapy on supportive care needs, symptom severity and psychological well-being.

The study was planned as a single-centre study and will consist of cancer patients who applied to receive chemotherapy for the first time due to gynaecological cancer at Etlik City Hospital-Oncology Hospital-Day Outpatient Unit and who agreed to participate in the study. The research will be carried out with a total of 70 patients by including 35 patients from the intervention group and 35 patients from the control group.

It is entirely up to you whether or not to take part in this study. Even if you sign this form now, you are free to leave the study at any time without giving a reason. If you do not want to take part or if you leave the study, your doctor will apply the most appropriate treatment plan for you. Likewise, the doctor conducting the study may decide that it would not be beneficial for you to continue the study and may exclude you from the study, in which case the most appropriate treatment will be chosen for you.

The study was developed for the first time for symptom management training given with an artificial intelligence supported mobile application developed for gynaecological cancer patients receiving chemotherapy and consists of six modules. These modules are: Module 1 (Let's Meet Module), Module 2 (Application Usage Guidelines Module), Module 3 (Let's Know the Disease Module), Module 4 (Frequently Encountered Symptoms and Suggestions Module during Chemotherapy Treatment), Module 5 (Let's Fight Symptoms Together Module) and Module 6 (Ask Anything on Your Mind-Counselling Module). Apart from the modules, the application will include registration, login and profile creation sections. At the end of the study, the mobile application will also be open to the control group and the control group will also benefit from the content. Descriptive Information Form, Edmonton Symptom Diagnostic Scale, Supportive Care Needs Scale, Psychological Well-Being Scale and Eastern Cooperative Oncology Group (ECOG) Performance Scale will be used as data collection tools in the study. Data collection tools will be sent via the application and asked to be filled in. The forms will be administered three times in total, at the beginning, at the end of the 3rd and 5th cycles.

There will be no harm or risk due to the research.

Benefits of taking part in the study;

Chemotherapy, which is a common and basic method in the treatment of gynaecological cancer, can cause many physical and psychological side effects while treating the disease. However, side effects may not occur at the same time and some may develop after discharge. Therefore, it is very important to identify, evaluate and control the symptoms experienced and to provide professional health counselling. Patients may not always have access to a nurse or health professional. Training artificial intelligence by the researcher and integrating it into the application will help patients reach the right information without wasting time. At the same time, the content of the Let's fight together with the symptoms module will be created by experts in the field. The aim of the application is to evaluate the effect on patients' supportive care needs, symptom severity and psychological well-being. It is thought that our study will be a resource in terms of contributing to a more harmonious and healthy treatment process and raising awareness on this issue.

By participating in this study, you will not be under any financial burden and no payment will be made to you.

Responsibilities of volunteers,

Your participation in the study is voluntary and you can refuse to participate or withdraw from the study at any time, without penalty or sanction and without losing any of your rights. Your study doctor will use your personal information to conduct the study and statistical analyses, but your identity information will be kept confidential. The study results may be published in the medical literature at the end of the study, but your identity will not be disclosed and will remain confidential. The audience, polling persons, ethics committee, institution and other relevant health authorities will have direct access to your original medical records, but this information will be kept confidential, and by signing the written informed consent form, the volunteer or his/her legal representative will have authorised such access. You or your legal representative will be informed in a timely manner when new information is obtained that is relevant to the subject of the study and may affect your willingness to continue to participate in the study.

If you need additional information about the study, please contact the person below.

Name: Esra Nur ERDOĞAN

Duties PhD Student (Research Assist.)

Telephone:

(Declaration of the Participant/Patient)

Prof. Dr. Gülten GÜVENÇ, PhD Student (Research Assist.) Esra Nur ERDOĞAN and Medical Oncologist Tülay EREN stated that a medical research would be conducted in the Department of Obstetrics and Gynecology Nursing of Gülhane Faculty of Nursing, University of Health Sciences, and I was informed about the above information about this research and read the relevant text. After this information, I was invited as a 'participant' to such a research. I have not encountered any coercive behaviour about my participation in the research. I am also aware that if I refuse to participate, this will not harm my medical care and my relationship with the physician. I can withdraw from the research without giving any reason during the conduct of the project. (However, I am aware that it would be appropriate to inform the researchers in advance that I will withdraw from the research in order not to leave them in a difficult situation). I may also be excluded from the research by the researcher, provided that no harm is caused to my medical condition.

I do not assume any financial responsibility for the expenses to be incurred for the research. I will also not be paid. I am aware that the confidentiality of personal information about me obtained from the research will be protected.

In case of any health problem that may arise due to reasons arising from the research application, I have been given the necessary assurance that all kinds of medical interventions will be provided (I will not be under any financial burden regarding these medical interventions).

If I encounter a health problem during the research, I know that I can call Prof. Dr. Gülten GÜVENÇ, PhD Student (Research Assist.) Esra Nur ERDOĞAN and Medical Oncologist Tülay EREN at the address of Health Sciences University, Etlik / ANKARA and by phone at ……I have read the above-mentioned Informed Voluntary Consent Form, which shows the information that should be given to the volunteer before the research, in my native language and it is written in a plain and simple language that I can understand. I was given the opportunity to ask all the questions I could think of and received satisfactory answers to my questions.

The written and verbal explanation about the above-mentioned research was made by the researcher named below. Under these conditions, I voluntarily agree to participate in this research without any pressure or coercion.

I hereby give permission for the questionnaire responses received within the scope of the research “The Effect of Symptom Management Training Given to Gynaecological Cancer Patients Receiving Chemotherapy with Artificial Intelligence Supported Mobile Application on Supportive Care Needs, Symptom Severity and Psychological Well-Being” to be used in the aforementioned research and all future researches.

I have received a fully signed copy of the Informed Volunteer Consent Form.

Volunteer

Name-Surname:

Signature:

Address (telephone and/or fax number if available):

Date:

The researcher who made the explanations;

Title, Name-Surname:

Department and (telephone number):

Signature:

Date: