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

NCT number: NCT ID not yet assigned

ID: 2024-442

Document Date:10.09.2024

The aim of this study is to evaluate the effect of symptom management training given with an artificial intelligence supported mobile application developed for gynaecological cancer patients receiving chemotherapy on supportive care needs, symptom severity and psychological well-being.
The study was planned as a randomised controlled trial. Block randomisation will be used to assign patients to intervention and control groups.

The population of the study will consist of patients who applied to Etlik City Hospital-Oncology Hospital-Day Outpatient Unit for the first time to receive chemotherapy treatment for gynaecological cancer and completed the first course.

The sample of the study will consist of patients who applied to Etlik City Hospital-Oncology Hospital-Day Outpatient Unit to receive chemotherapy treatment for the first time and who meet the following inclusion criteria.

Inclusion Criteria

Women who have received chemotherapy for the first time due to gynecological cancer and have completed their first chemotherapy course

At least 18 years old

No previous cancer diagnosis, First AND ONLY gynecological cancer diagnosis

Literate

Agree to participate in the study

No communication barrier

Eastern Cooperative Oncology Group (ECOG) Performance Scale score below 3

No diagnosed psychiatric illness

Women who have an Android or IOS smartphone and can access the internet

Exclusion Criteria

Researcher leaving treatment unfinished

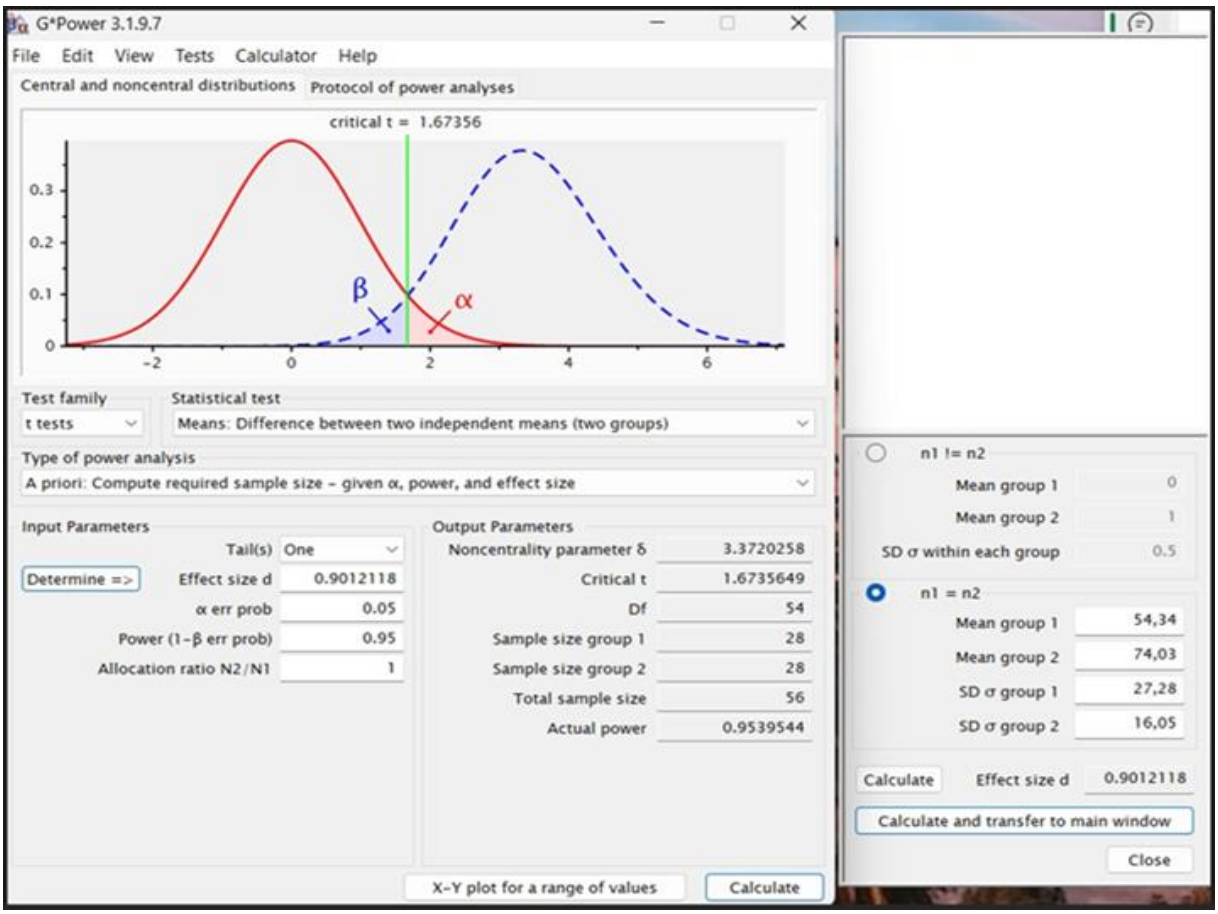
Treatment treatment ended after the study started

Not actively using the mobile application

Not filling out the forms during the use of the mobile application

Another cancer developing during the study period

The study will be conducted with a total of 70 patients, including 35 patients from the intervention group and 35 patients from the control group (The sample number of the study was calculated by using the G Power programme using the data of a study in which mobile application intervention was carried out on cancer patients. Accordingly, the confidence interval was 95%; the margin of error was accepted as 5% and a total of 56 patients were found as 28 intervention and 28 control group. Considering that there may be losses during the mobile application intervention, the sample number was kept 25% higher than the calculated sample number.)



Research Hypotheses:

Gynaecological cancer patients receiving chemotherapyBetween the intervention group receiving symptom management training with a mobile application and the control group receiving standard care;

1. H1: There is a difference in terms of the severity of symptoms experienced.
2. H2: There is a difference in terms of supportive care needs.
3. H3: There is a difference in terms of psychological well-being levels. Data Collection Tools 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.
    - Data collection tools will be sent to patients via the application and will be asked to be filled in.

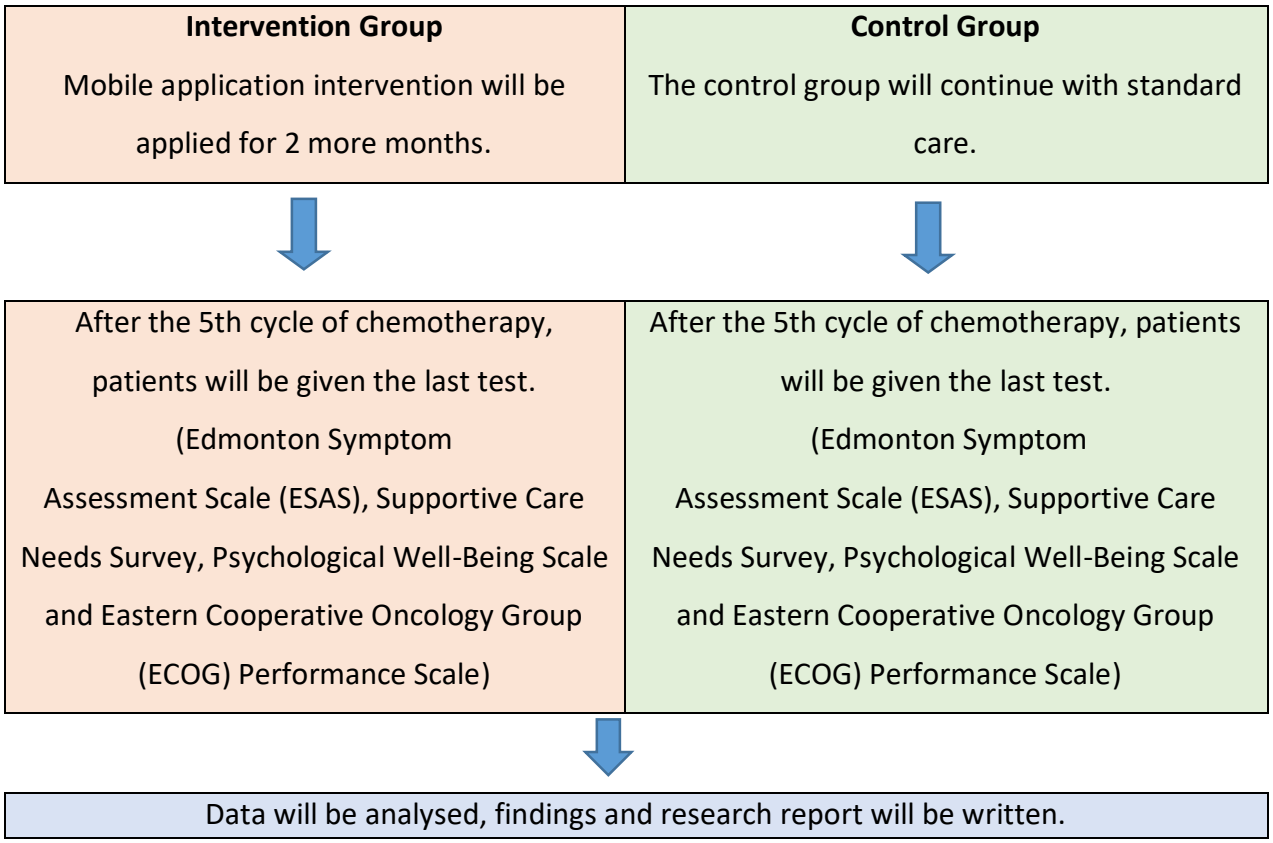
STUDY PROTOCOL

The research was planned as a randomised controlled study.

All participants will fill in the Introductory Information Form.

Randomisation

Intervention Group	Control Group
The mobile application will be downloaded to all groups and the patients will be Pre-tested after the first course of chemotherapy (Edmonton Symptom Assessment Scale (ESAS), Supportive Care Needs Survey, Psychological Well-Being Scale and Eastern Cooperative Oncology Group (ECOG) Performance Scale).	
Intervention Group 2 months mobile application intervention will be applied.	**Control Group** The control group will continue with standard care.
Kemoterapi 3. kür sonrası testler tekrarlanacaktır. (Edmonton Symptom Assessment Scale (ESAS), Supportive Care Needs Survey, Psychological Well-Being Scale and Eastern Cooperative Oncology Group (ECOG) Performance Scale)	Kemoterapi 3. kür sonrası testler tekrarlanacaktır. (Edmonton Symptom Assessment Scale (ESAS), Supportive Care Needs Survey, Psychological Well-Being Scale and Eastern Cooperative Oncology Group (ECOG) Performance Scale)


Intervention Group
Mobile application intervention will be applied for 2 more months.
Control Group
The control group will continue with standard care.
After the 5th cycle of chemotherapy, patients will be given the last test. (Edmonton Symptom Assessment Scale (ESAS), Supportive Care Needs Survey, Psychological Well-Being Scale and Eastern Cooperative Oncology Group (ECOG) Performance Scale)
After the 5th cycle of chemotherapy, patients will be given the last test. (Edmonton Symptom Assessment Scale (ESAS), Supportive Care Needs Survey, Psychological Well-Being Scale and Eastern Cooperative Oncology Group (ECOG) Performance Scale)
Data will be analysed, findings and research report will be written.