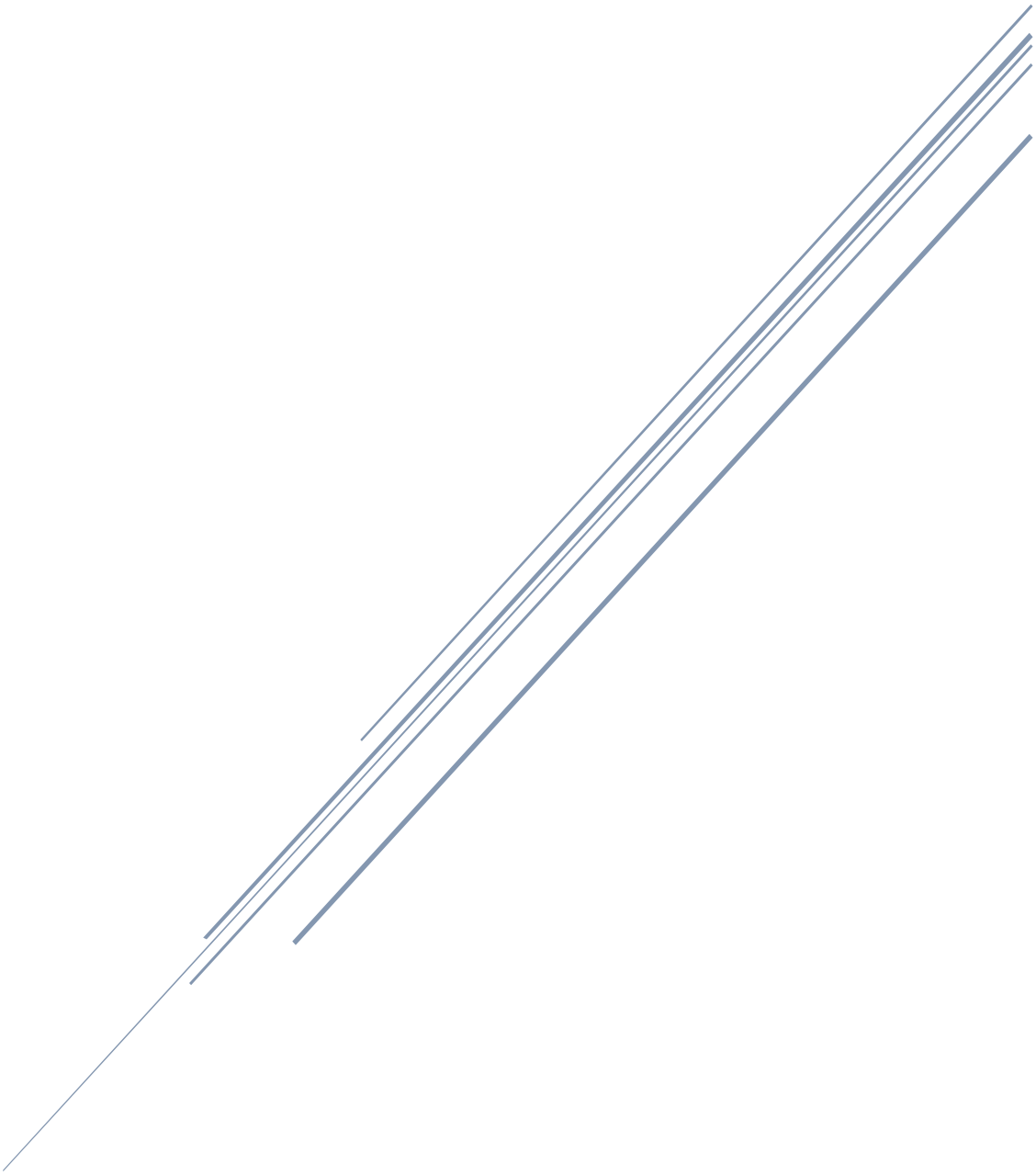
STUDY PROTOCOL

NAME OF THE STUDY: THE EFFECT OF VİDEO EDUCATİON ON ADAPTATİON TO THE PROCEDURE OF PATİENTS AND CAREGİVERS WHO UNDERWENT GASTROSTOMY.HALİÇ UNİVERSİTY MELİKE YAZAR 04/07/2024



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T.C.

HALIC UNIVERSITY

NON-INTERVENTIONAL RESEARCH ETHICS BOARD

Date: 04.07.2024

Number: 151

Subject: Ethics Committee Permission

Dear researchers, Prof. Dr. Sibel ERKAL İLHAN, Melike YAZAR

Your application with file number 2024/64 has been reviewed by the Haliç University Non-Interventional Research Ethics Committee. Your research titled "The Effect of Video Education on Adaptation to the Procedure of Patients and Caregivers Who Underwent Gastrostomy" was found ethically appropriate in the meeting of our committee dated 04.07.2024 and the minutes are attached.

I would like your information please.

Prof. Dr. EcSALİHOĞLU

Haliç University Board

Chairman

Annex: Ethics Committee Decision

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HALİÇ UNIVERSITY

REPUBLIC OF TURKEY HALIC UNIVERSITY
NON-INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE

Publication Date: 10.12.2015
Revision Date: 16.09.2020
Revision No: 02
Page Number: 1/1

Date: 04.07.2024
(File 09)

Ethical evaluation of the research titled "Effect of Video Education on Adaptation of Patients and Caregivers to the Procedure Who Underwent Gastrostomy" planned by " Prof. Dr. Sibel ERKAL İLHAN, Melike YAZAR

Number of Meetings:

Name-Surname	area	institution	with research relationship	to the meeting Participation	signature
Prof. Dr. Ece SALIHOGLU (President)	Cardiovascular Surgery	Haliç University Faculty of Medicine	Yes ○ No ⊗	Yes ⊗ No ○	
Assoc. Prof. Dr. Hatice İlhan ODABAS	Sports Management	Haliç University Physical Education and Sports College Haliç	Yes or No ⊗	Evet ⊗ Hayır ○	
Assoc. Prof. Dr. Nevris ALKANLI	Biophysics	University Faculty of Medicine	Var ○ Yok ○	Yes No ○ ○	
Assistant Professor Burcu TÜRK	Psychology	Haliç University Science and Literature Faculty	Yes or No ⊗	Yes ⊗ No ○	
Dr. Lecturer Gülcan KENDİRKIRAN	Nursing	Haliç University Health Sciences Faculty	Yes ○ No ⊗	Yes ⊗ Hayır ○	
Assistant Professor Seda SAKA	Physiotherapy and Rehabilitation	Haliç University Health Sciences Faculty	There is It Yok ⊗	Yes ⊗ Hayır ○	
Assistant Professor Çiğdem YILDIRIM MAVİŞ	Food Engineering	Haliç University Faculty of Health Sciences	There is It Yok ⊗	Yes ⊗ Hayer ○	
Assistant Professor Pınar KÖROGLU AYDIN	Histology - Embryology	Haliç University Faculty of	There is It None ⊗	Yes ⊗ No ○	
Assistant Professor Dilek ŞAHİNOĞLU	Physiotherapy ve Rehabilitation	Medicine Haliç University Faculty of Health Sciences	Var ○ None ⊗	Evet ⊗ No ○	
Assistant Professor Sevim YAĞIZ	Type Date and	Haliç University Faculty of Medicine	Yes or No ⊗	Evet ⊗ No ○	
Assistant Professor Fatih SİRİN	Ethical Mathematics	Haliç University Faculty of Arts and Sciences	Yes ○ No ⊗	Yes ⊗ Hayır ○	
Dr. Lecturer Maral TÖRENLİ	Law	Haliç University Faculty of Business Administration	There is It Yok ○	Yes ○ No ○	

ETKU:10

Summary of the Study

This study will be conducted to investigate the effect of video training given to caregivers of patients who underwent percutaneous endoscopic gastrostomy on the compliance of patients and caregivers to gastrostomy. It was planned as a single-group quasi-experimental study to determine the effect of training on the compliance of patients and caregivers to gastrostomy and the caregiver's gastrostomy care skills. The universe of the study will consist of patients and caregivers who met the inclusion criteria for the study in which gastrostomy procedure was performed for the first time at Beykoz State Hospital between the dates of September 1, 2024 and March 31, 2026. G*Power power analysis was performed to determine the sample size. According to Cohen's effect size coefficients; according to the calculation made assuming that it will have a large effect size (d=0.8), it was decided that there should be at least 20 people with α=0.05 level, 95% power; considering the losses, it was decided to include 25 people in the study. The data of the study; Patient Information Form, Caregiver Information Form, Caregiver Gastrostomy Adaptation Form, Caregiver Gastrostomy Adaptation Monthly Follow-up Form, Caregiver Skills Assessment Form, Patient Gastrostomy Adaptation Form, Patient Gastrostomy Adaptation Monthly Follow-up Form, Caregiver Feedback Form will be collected. SPSS 26 program will be used for statistical analyses. Descriptive statistical methods for data and Shapiro Wilks test and Box Plot graphics will be used in the evaluation of distribution. Student t test, Oneway Anova test, Bonferroni test and Paired Samples t test will be used for variables showing normal distribution, and Mann Whitney U test, Kruskal Wallis test, Dunn test and Wilcoxon Signed Rank test will be used for variables not showing normal distribution. Pearson or Spearman's correlation analysis, linear regression modeling will be done. Chi-Square test and Fisher's Exact test will be used for qualitative data. The results will be evaluated at a 95% confidence interval and significance at $p<0.05$.

Rationale and Purpose of the Study :

Adequate and balanced nutrition is defined as the adequate intake of all nutrients necessary for growth, renewal and maintenance of organ functions, and modulating immune responses (McClave et al., 2016; Özbaş, 2018). However, failure to provide nutrition for various reasons, i.e. nutritional deficiency, can negatively affect the functioning of many organ systems (Çelebi and Yılmaz, 2019).

Malnutrition damages the patient's muscle strength and immune function, making the patient more vulnerable to infections; resulting in prolonged hospital stays, higher rates of hospital readmission, and increased healthcare costs (Çelebi and Yılmaz, 2019; Van den Berg et al., 2021). In order to avoid malnutrition in the patient, nutrition can be administered orally, enterally, and parenterally according to the patient's medical condition and needs (Boullata et al., 2017; Duzenli et al., 2021).

Among the enteral feeding types, ‘‘Percutaneous Endoscopic Gastrostomy (PEG)’’ is a more accepted and less invasive method for placing a feeding tube in patients with difficulty swallowing (Adachi et al., 2018; Arvanitakis et al., 2021). If enteral feeding will be for more than 4-6 weeks, the procedure defined as percutaneous endoscopic gastrostomy, which is frequently preferred, is the surgical insertion of a tube by directly entering the stomach through the abdominal wall (McClave et al., 2016; Kahveci and Çelik, 2020). Patients who undergo this procedure need a lot of information on the subject when they are discharged (Kahveci and Çelik; 2020). The guideline prepared by the European Society for Clinical Nutrition and Metabolism

(ESPEN) provides information about the application to professionals and home enteral nutrition providers (Bischoff et al., 2020; Karaca et al., 2020). Enteral nutrition is an important clinical intervention for patients of all ages in various care settings (Boullata et al., 2017). It is also very important that this intervention is performed correctly (Kahveci et al.; 2020).

The most common indications for gastrostomy are head and neck cancer, motor neuron disease, other neurological disorders, multiple trauma, and malnutrition (due to postoperative recovery, mental retardation, gastrointestinal motility disorders) (Strijbos et al., 2018; Kahveci and Çelik, 2020). It is known that nutritional support reduces the risk of mortality, pain, and improves functional quality of life outcomes in cancer patients (Barbosa et al., 2016; Bargetzi et al., 2021; Davies et al., 2021).

However, if patients are not given sufficient information about percutaneous endoscopic gastrostomy care and dressing, the complications that occur or are seen due to the procedure are divided into two groups as minor and major complications (Kahveci et al., 2020).

Minor complications; periostomal infection, periostomal leakage, pneumoperitoneum, bleeding and ulceration in the gastrointestinal system, tube obstruction (Friginal-Ruiz and Lucendo, 2015; Kahveci et al., 2020; Chan et al., 2023).

Major complications are necrotizing fasciitis, buried bumper syndrome, colocutaneous fistula, pulmonary aspiration (Kahveci et al., 2020; Yoshida et al., 2023). In order to prevent complications, planned discharge education, home monitoring and home tube care education can be given to patients who have undergone gastrostomy and their relatives (Kahveci et al., 2020; Lima et al., 2023).

Tube care after percutaneous endoscopic gastrostomy is quite difficult for the patient and their relatives (Kahveci et al., 2020; Saka et al., 2021). Continuous education and guidance should be provided to patients and their relatives who have undergone percutaneous endoscopic gastrostomy procedures regarding device or stoma care, medication administration, monitoring of nutritional status, coordination with expert teams for the diagnosis and treatment of complications including nutritional problems, assessment of the need for tube change or removal, and appropriate continuation of enteral nutrition (Farrah, 2019; Chan et al., 2023). It has been demonstrated that the need for information affects the care burden of patients' caregivers and increases their anxiety and depression levels (Burgos et al., 2018; Aydar et al., 2023).

There is a need for clinical guidelines to assess and protect the health of caregivers, and culture-specific programs and long-term clinical studies to ensure that caregivers can cope with daily life stressors (Ay et al., 2017; Farrag et al., 2019).

Nurses should collaborate with the patient and their family to alleviate their fears and concerns, and include them in the care process (Kahveci et al., 2020). It has been shown that the education provided improves outcomes such as caregiver burden, depression, anxiety, and satisfaction with care (Davies et al., 2021).

It has been shown that education given to patients undergoing percutaneous enteral gastrostomy via instant messaging increases the patient's self-care ability, improves the social aspects of quality of life, and can reduce complications (Hill et al., 2021; Chen et al., 2023). The active

participation of the patient and caregivers in the training program and the implementation of the training make the learning permanent (Ay et al., 2017; Kahveci et al., 2020).

It is important for the patient's nutritional status and the caregiver's care burden that healthcare professionals working in hospitals can provide support to caregivers, plan appropriate interventions and evaluate the results of the interventions (Kahveci et al., 2019).

This study will reveal the necessity of the caregiver participating in the care along with the patient and that trainings requiring psychomotor skills should be carried out in a way that supports this skill. It is also thought that this training will increase the compliance of caregivers. While there are studies in the literature focusing on the care burden and anxiety level of this patient group of caregivers, no study focusing on the compliance of the caregiver and the patient has been found (Burgos et al., 2018; Davies et al., 2021; Aydar et al., 2023). In this respect, it is thought that it will fill the gap in the literature.

This study will be conducted to investigate the effect of video training given to caregivers of patients undergoing percutaneous endoscopic gastrostomy on the compliance of patients and caregivers to gastrostomy. It was planned as a single-group quasi-experimental study to determine the effect of training on the compliance of patients and caregivers to gastrostomy and the caregiver's gastrostomy care skills.

Method, Tools/Materials to be Used

Purpose and Type of Study: This study will be conducted to examine the effect of video education given to caregivers of patients who underwent percutaneous endoscopic gastrostomy on the compliance of patients and caregivers to gastrostomy. It was planned as a single-group quasi-experimental study to determine the effect of education on the compliance of patients and caregivers to gastrostomy and the caregiver's gastrostomy care skills.

H0: Video education given to caregivers does not increase the compliance of the caregiver and patient and the caregiver's gastrostomy care skills.

H1a: Video education given to caregivers ensures the caregiver's compliance with the procedure.

H1b: Video education given to caregivers increases the caregiver's care skill level.

H1c: Video education given to caregivers ensures the patient's compliance with the gastrostomy tube.

Place and Time of the Study: This study was planned to be conducted with caregivers who met the inclusion criteria for the study and underwent percutaneous endoscopic gastrostomy for the first time at the Beykoz State Hospital endoscopy unit between September 1, 2024 and March 31, 2026.

Universe and Sample of the Study: The universe of the study will consist of caregivers who met the inclusion criteria for the study and underwent percutaneous endoscopic gastrostomy for the first time at the Beykoz State Hospital between the dates of the study. Power analysis was performed using the G*Power (v3.1.7) program to determine the sample size. The power of the study is expressed as 1-β (β = Type II error probability). According to Cohen's effect size coefficients; Assuming that the evaluations after the video training to be conducted with patients who underwent percutaneous endoscopic gastrostomy at Beykoz State Hospital would have a large effect size (d=0.8), it was found that at least 20 people were needed at α=0.05 level with 95% power. Considering the losses, it was decided to include 25 people in the study.

Patient Inclusion Criteria:

Not having cancer,

Having had a percutaneous endoscopic gastrostomy procedure for the first time.

Caregiver Inclusion Criteria:

Being willing to participate in the study,

Being over 18 years of age,

Being able to communicate in Turkish,

Being able to read and write,

The caregiver will be involved in the percutaneous endoscopic gastrostomy care of their patient.

Not being a healthcare professional.

Education Booklet : An education video will be created with a patient who has a percutaneous endoscopic gastrostomy procedure, for which written and verbal consent has been obtained regarding the subjects specified in the education booklet (ANNEX-9) created by the researcher. The education video is planned to be 30-45 minutes in line with the literature (Kahveci, 2020; Torun, 2023). This education video will be watched by the caregivers and will be sent to their phones via the Whatsupp application by the researcher so that they can review it again when necessary. In addition, the Education Booklet will be given to the caregivers after the training. The booklet will be finalized by obtaining the opinions of 10 experts regarding the education booklet.

Data Collection Method: Percutaneous endoscopic gastrostomy procedure is performed on patients in the endoscopy unit by appointment. After the procedure, the patients' treatments continue in the ward, intensive care unit or at home where they are followed. The appointment list will be followed and the researcher will collect face-to-face data from the patient and caregivers in the ward where the patient who has undergone percutaneous endoscopic gastrostomy for the first time is hospitalized. Patients who are hospitalized in intensive care will be included in the study after they are discharged from intensive care. Data will be collected by face-to-face interviews with patients and caregivers whose percutaneous endoscopic

gastrostomy has been opened for the first time and whose verbal and written consents have been obtained to participate in the study.

Preliminary Application: In order to determine the clarity of the data collection forms to be used in the study, a preliminary application will be carried out by the researcher after obtaining the necessary institutional and ethics committee permissions. Since the preliminary application should be 10% of the sample studied in accordance with the literature, a pilot study will be carried out by applying it to three caregivers (Arlı and Nazik, 2001; Torun, 2023). After the preliminary application, the necessary corrections will be made and the data collection forms and training materials will be finalized.

Application: The first visit will be carried out in the patient room the next morning following the percutaneous endoscopic gastrostomy procedure in accordance with the literature (Kahveci, 2020; Torun, 2023). Percutaneous endoscopic gastrostomy care training will be given to the caregivers of patients who have undergone percutaneous endoscopic gastrostomy for the first time by the researcher via video. The video training will be sent to the caregivers' phones via the Whatsapp application. At the end of the training, the caregivers' questions will be answered and the researcher's contact number will be given to provide consultancy in case of any problems that may occur. After the training, the caregivers will be given the training booklet. At the first visit, the Patient Information Form, Caregiver Information Form, Caregiver Gastrostomy Adaptation Form, and Patient Gastrostomy Adaptation Form will be applied. At the 14th and 30th day follow-ups after the first training, the caregivers' questions will be answered and the Caregiver Gastrostomy Adaptation Form, and Patient Gastrostomy Adaptation Form will be applied by the researcher. The care given to the patients by the caregiver will be observed by the researcher on the 14th and 30th day follow-ups and the Caregiver Skills Assessment Form will be filled out. When the patients are discharged, the Caregiver Skills Assessment Form will be applied during the home visit.

Evaluation of Data: SPSS 26 (Statistical Package for the Social Sciences) program will be used for statistical analysis of the data obtained from the study. While evaluating the study data, descriptive statistical methods (Mean, Standard deviation, median, frequency and ratio) as well as Shapiro Wilks test and Box Plot graphics will be used to evaluate the conformity of the data to normal distribution. Student t test will be used for two-group evaluations of variables showing normal distribution; Oneway Anova test will be used for comparisons of three groups and above and Bonferroni test will be used to determine the group causing the difference. Paired Samples t test will be used for within-group evaluations. In the evaluation of variables that do not show normal distribution according to two groups, Mann Whitney U test; Kruskal Wallis test will be used in comparisons of three groups and above and Dunn test will be used in determining the group causing the difference. Wilcoxon Signed Rank test will be used in within-group evaluations. In the evaluation of relationships between variables, Pearson or Spearman's correlation analysis will be used according to the distribution; Linear regression modeling will be done in advanced evaluations. Chi-Square test and Fisher's Exact test will be used in the comparison of qualitative data. The results will be evaluated at a confidence interval of 95% and significance at the level of $p<0.05$.

Determined Study Period: The study is planned to be conducted between September 1, 2024 and March 31, 2026 and the total duration (1.5 years).

Ethical Direction: The study will be conducted in accordance with the provisions of the Declaration of Helsinki. Ethics committee approval will be obtained from the Haliç University Non-Interventional Clinical Research Ethics Committee. In order for this study, which will use a quantitative research design, to be conducted at Beykoz State Hospital, an institutional permit will be obtained from the Istanbul Provincial Health Directorate. After the ethics committee approval, the study will be initiated by obtaining verbal and written consent from patients and caregivers who meet the inclusion criteria.

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