

THE EFFECT OF SIMULATION-BASED TRAINING ON THE PREPAREDNESS FOR CARE AND THE CAREGIVING BURDEN OF THE CAREGIVERS OF BURN PATIENTS: STUDY PROTOCOL FOR A RANDOMISED CONTROLLED TRIAL

SİMÜLASYON TEMELLİ EĞİTİMİN YANIK HASTALARINA BAKIM VERENLERİN BAKIMA HAZIR OLMA DURUMLARINA VE BAKIM YÜKÜNE ETKİSİ: RANDOMİZE KONTROLLÜ ÇALIŞMANIN PROTOKOLÜ

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ABSTRACT

Background: The care of patients who are discharged after burn treatment is carried out by home caregivers. Preparing the family member will aid the burn patient's recovery process and lessen the caregiver's challenges.

Aim: This research was planned to determine the effect of the discharge training given by scenario-based simulation method on the caregiver's preparedness for care and the caregiving burden of caregivers of burn patients.

Method: This study is a multicenter randomized controlled trial. Relatives of burn patients treated in two burn centers will be added to the study. Selection bias will be controlled by making random assignments and hiding the randomization. Participants will be assigned by an external observer by the block randomization method. In the implementation of the study, standard discharge training will be given to the caregivers in the control group before discharge. Simulation-based training will be given to the experimental group after the standard training. The Preparedness for Caregiving Scale will be applied to all participants before and after the training. The Burden Scale for Family Caregivers will be administered to both groups one month and three months after discharge. In addition, the problems experienced by burn patients at the end of the 3rd month will be evaluated.

Conclusion: Expected results; 1) Caregivers who receive simulation-based discharge training will have a better readiness for care than the group that receives standard training. 2) The caregivers who receive simulation-based discharge training will have less burden of caregiving in the first month and third month during home care compared to the group receiving standard training.

Trial registration: Clinical Trials No: NCT04745208.

Key Words: Burn, simulation, caregiver, preparedness for care, caregiving burden, randomised controlled trial

ÖZET

Giriş: Yanık tedavisi sonrası taburcu edilen hastaların bakımı evde bakıcılar tarafından gerçekleştiriliyor. Aile üyesinin hazırlanması, yanık hastasının iyileşme sürecine yardımcı olacak ve bakıcının zorluklarını azaltacaktır.

Amaç: Bu araştırma senaryo temelli simülasyon yöntemi ile verilen taburculuk eğitiminin yanık hastalarına evde bakım veren bakım vericilerin bakıma hazır oluşluk durumuna ve bakım verme yüküne etkisinin belirlenmesi amacıyla planlanmıştır.

Yöntem: Bu çalışma çok merkezli randomize kontrollü bir çalışmadır. Araştırmaya Ankara'da bulunan iki hastanenin yanık merkezinde tedavi gören yanık hastalarının yakınları dahil edilecektir. Çalışmada randomize atama ve randomizasyonun gizlenmesi yapılarak seçim yanlılığı kontrol altına alınacaktır. Çalışmada müdahale grubuna ve kontrol grubuna katılımcılar blok randomizasyon yöntemi ile bir dış gözlemci tarafından atanacaktır. Araştırmanın uygulanmasında kontrol grubunda yer alan bakım vericilere taburculuktan önce standart taburculuk eğitimi verilecektir. Simülasyon grubuna ise standart eğitimden sonra simülasyon temelli eğitim verilecektir. Tüm katılımcılara eğitim öncesi ve sonrası Bakıma Hazır Oluşluk Ölçeği uygulanacaktır. Her iki gruba taburculuktan bir ay ve üç ay sonra Bakım Verme Yükü Ölçeği uygulanacaktır. Ayrıca 3.cü ayın sonunda yanık hastalarının yaşadıkları sorunlar değerlendirilecektir.

Sonuç: Beklenen sonuçlar; 1) Simülasyon temelli taburculuk eğitimi alan bakım vericilerin standart eğitim alan gruba göre bakıma hazır olma durumlarının daha iyi olacaktır. 2) Simülasyon temelli taburculuk eğitimi alan bakım vericilerin standart eğitim alan gruba göre evde bakım verme esnasında birinci ay ve üçüncü bakım verme yüklerinin daha az olacaktır.

Controlled Trials No: NCT04745208.

Anahtar Kelimeler: Yanık, simülasyon, bakım verici, bakıma hazır oluşluk, bakım verme yükü, randomize kontrollü çalışma

BACKGROUND

Non-fatal burns are one of the primary causes of morbidity worldwide (WHO, 2020). With advancements in burn treatment, the number of deaths has dropped, and long-term care has become more important both in the hospital and at home. The care of a patient who has been discharged from the hospital with a burn wound continues at home during the rehabilitation phase, and care activities are carried out by those who care for the patient at home (Faydali & Bayraktar, 2011; Jones et al., 2021).

Due to the physiological and psychological changes that occur in the burnt individual, important duties fall on the individual who takes care of the burn patient during the home care process. These duties include important responsibilities such as helping to feed, wound care-follow-up, assisting or performing personal care, arranging household chores, and providing economic, medical and psychological support (Deshpande et al., 2012; Faydali & Bayraktar, 2011; Hartford, 2012; Rencken et al., 2021). In the study of Faydali and Bayraktar (2011), it was determined that burn patients and their relatives lack information about the use of medication, dressing, exercise, position, bathing, clothing requirement, protection from infection and signs of infection after discharge, and they want to get more information on these issues. Another study discovered that carers felt a need for assistance, particularly considering the long-term repercussions of burns (Jones et al., 2021). The factors determining the rehospitalisation of burn patients were explored in the Liberio et al. (2020) study, and it was found that insufficient assistance from the family at home was an important risk factor for readmission.

The nurse's understanding of the carers' challenges, appraisal of the load of caring, and

judgement of the effect on the patient's quality of life can all guide the nurse in patient care (Inci & Erdem, 2008). Considering the holistic care principle, it is stated that home caregivers (including the family) should be included in the discharge training. Considering this situation, nurses should try to integrate family and patient education and include the family in discharge education. The nurse should also evaluate the individual who will care for the burn patient at home in terms of readiness for care (Hartford, 2012).

The primary purpose of discharge education is to assist individuals in developing behaviours that allow them to manage current illness-related problems as well as anticipated future problems that may arise. Nurses play an important role in discharge education and seek to keep education effective through diverse techniques by reacting to changes over time (Han et al., 2009). The educational environment, which is enhanced with various technical instruments and equipment used in the field of education, promotes the learner's behaviour change in the desired direction. Computer-based education, telehealth, and simulation applications are some of the latest technical methods employed in education. (Göriş et al., 2014; Terzioğlu et al., 2012).

Simulation is defined as a method that enables a real-life situation to be created close to reality (TDK, 2021). In the 1950s, the simulation method was used in nursing education to teach physical diagnosis to students (Mıdık & Kartal, 2010). Simulation-based teaching in the field of health is commonly used in laboratories similar to clinical settings for trainee students and clinical staff (Aebersold, 2016; Blum & Parcells, 2012; Cardoza & Hood, 2012; Onarıcı & Karadağ, 2021). Nurses who are in charge of the holistic care of burn patients should strive to be effective in safeguarding the health of

patients' families while also helping the healing process of patients by educating their relatives. Studies utilising the simulation method in the education of patient relatives have demonstrated the efficacy of this method, and it has been stated that family members who maintain home care experience less stress, have less difficulty maintaining care, and see positive developments in the health status of patients (Arnold & Diaz, 2016; Brooks et al., 2021; Jütten et al., 2017; Raines, 2017; Sigalet et al., 2014; Sullivan-Bolyai et al., 2012; Thrasher et al., 2018; Tofil et al., 2013; Wooldridge & Carter, 2021; Yuen et al., 2021).

As a result of the studies examined, it is seen that it is necessary to prepare the relatives of burn patients for home care (Bond et al., 2017; Faydali & Bayraktar, 2011; Jones et al., 2021; Liberio et al., 2020). When the training for family members who will care for burn patients at home are examined, it is seen that there are initiatives such as video-assisted training and home follow-up (Dualan, 2020; Lotfi et al., 2020). However, when the literature on ensuring that individuals who care for burn patients are ready for care by meeting their information needs and thus reducing the burden of caregiving is examined, no study was found that evaluated simulation-based education for family members who care for burn patients at home.

A controlled and safe simulation environment allows the training to be tailored to the needs of the trainee (Evgeniou & Loizou, 2013). A simulation environment, built by increasing the reality based on the established needs, allows families to be taught about care, to be included in traditional family education, and to manage this education (Sigalet et al., 2014). This study was needed because it was thought that simulation training with a computer-based simulator mannequin, whose high reality is

provided by moulage, would help the patient's relatives better understand the burn, feel more prepared to care for themselves, make it easier to be involved in care practises, and thus reduce the burden of caregiving.

METHODS

Study Design

The study will be conducted as a randomised controlled experimental study to determine the effect of discharge training provided using the scenario-based simulation method on carer preparedness for care and the caregiving burden of carers who provide home care to burn patients (Clinical Trials Number: NCT04745208).

Settings

The research will be conducted in the burn unit of one university hospital and the burn center of another university. In both institutions, burn patients are informed by nurses when they are discharged. However, no written or visual document is used during these notifications.

Sample

The study will include caregivers of adult burn patients receiving inpatient treatment in the burn unit and burn center. In the literature review, no similar research evaluating the impact of simulation-based discharge education provided to caregivers of burn patients on the caregiver's readiness for caregiving and caregiving burden was found. Therefore, during the ongoing study, power analysis will be conducted using the "G Power 3.1.9.2" software based on the participants' Preparedness for Caregiving Scale (PCS) and Burden Scale for Family Caregivers (BSFC) data.

Inclusion- Exclusion criteria

Inclusion Criteria for Caregivers

- 1) Caring for the burn patient after discharge,
- 2) Be over 18 years old,
- 3) Ability to communicate with the researcher,
- 4) Not having a diagnosed mental problem,
- 5) The burn patient to be cared for is older than 18 years of age, receiving inpatient treatment in the burn facility, no communication problems, no diagnosed mental problems, no additional problems (fractures, paralysis, etc.) other than burns,
- 6) It is at least 5 days until the discharge of the burn patient.

Exclusion Criteria for Caregivers:

- 1) Refusal to voluntarily participate in the study,
- 2) Being a health professional,
- 3) Caring for another family member, including the burn patient.

Reasons for exclusion during research for patient relatives

- 1) Death of the burn patient and/or caregiver,
- 2) The participant declares that he/she wishes to leave at any stage of the study,
- 3) Not participating in the implementation of the data collection tools to be applied in the first and third months.

Randomization

In the study, selection bias will be controlled by making random assignment and hiding the randomization. Participants in the experimental group and control group in the study will be assigned by a faculty member who does not know the characteristics of the participants with the block randomization method. The faculty member has created 15 blocks on the Randomizer.org site, each block containing 4

individuals, and those who is in the experimental and control groups will be hidden from the researcher until the initiative begins.

Blinding

The experimental and control groups are not possibly blinded in the study. The statistics and report writing procedure will be blinded. The study data will be coded as 'A' and 'B' without defining the experimental and control groups. The biostatistics expert will analyse the data that has been coded in terms of groups. The coding for the experimental and control groups will be clarified after the statistical analyses are completed and the research report is written. This blind strategy will control statistical and reporting bias.

Experimental Group: Simulation-Based Discharge Education

The simulation training will be carried out in the simulation laboratory of a university's Faculty of Nursing. The following are the learning objectives for caregivers of burn patients in the simulation-based discharge training.

At the end of this training, caregivers;

- Will be able to evaluate the wound of the burn patient,
- Will unwrap the burn wound area and ensure proper cleaning,
- Will be able to offer appropriate nutritional recommendations to the burn patient,
- Will recognize the infection in the burn area, know the symptoms,
- Will be able to give a bath,
- Will be able to provide appropriate pressure garments for the burn patient.

The researcher develops a scenario for the simulation training based on the literature, expert opinion, and the challenges experienced by these folks in caring for the burn patient at home for carers who would care for the burn patient at home. Furthermore, the International

Nursing Association for Clinical Simulation and Learning-(INACSL Standards 2021) recommendations were considered when developing the simulation training (Watts 2021).

The simulation training will be conducted in three stages:

Stage 1: Preparation of the simulation environment and pre-briefing:

- The pre-prepared burn wound model was used for the simulation.
- The researcher prepared the simulation environment to resemble a room in a house where the burn patient's bed is located.
- The "Simulation Application Guide," developed specifically for the simulation, will be provided to the participants before the simulation session.
- The training team involved in the study will receive training on the scenario's topic and the roles of team members as described in the scenario.
- After the Standard Discharge Education, participants will be given a pre-briefing about the simulation session and its potential gains, introducing them to the simulation area.
- Following the briefing, the caregiver will be given 5-10 minutes to examine the simulation environment. Once the caregiver expresses readiness, the simulation training will begin.

Stage 2: Conducting the simulation:

- The simulation will be carried out using a scenario developed by the researcher based on the caregiver's needs.
- As per the "Simulation Application Guide," any tasks that the participant cannot perform or performs incorrectly

will be explained again, and the participant will be asked to redo them. Two individuals will be assigned to monitor the adherence to the "Simulation Application Guide."

- Camera recording will be conducted throughout the simulation scenario.
- The duration of the scenario implementation is expected to be 35-45 minutes.

Stage 3: Debriefing session:

- After the completion of the simulation scenario, a debriefing session will take place with the burn patient's family member and the researcher, utilizing the camera recording captured during the scenario and following the guidelines provided in the "Simulation Application Guide."
- The debriefing session is expected to last for 30-40 minutes.

Control Group: Standard Discharge Education

Standard discharge training was prepared by the researcher in line with the needs of caregivers based on the literature (Faydali & Bayraktar, 2011; Karahan, 2016). Suggestions were received from experts in the creation of standard training booklets. Ateşman's (1997) formula was applied to determine the readability level of written material, and the result was found to be between 90-100, with a very easy readability level.

The content of the standard training is as follows.

- General information about the burn
- Evaluation of the burn wound
- Conditions that may develop in burn wounds after discharge
- Home care of the burn wound
- Infection diagnosis-importance

- Interventions to prevent infection
- Signs of infection in the burn wound
- Importance of nutrition
- Things to consider during the bath
- Considerations in dressing (pressure garments)

Standard discharge training will be given in the burn center and training rooms in the burn unit. The training, which will be held in the form of a PowerPoint presentation, is expected to take approximately 30 minutes. The booklet version of the PowerPoint presentation will be given to the participants at the end of the training. Participants will be allowed to ask questions during and after the presentation.

Data Collection Tools

The data collection tools, "Information Form for the Caregiver", which questions the socio-demographic data of caregivers, "The Preparedness for Caregiving Scale (PCS)" to assess readiness for care, and "Burden Scale for Family Caregivers (BSFC)" to assess caregiver burden will be used.

"Information Form for Burns Patients" will be used to obtain information about burns from burn patients, and the "Post Discharge Evaluation Form" for problems experienced after discharge will be used.

Information Form for the Caregiver

It was developed by the researcher using the literature. The form includes 16 questions evaluating the socio-demographic characteristics and caregiving data of the individual caring for the burn patient. Scope evaluation was carried out in line with the opinions of four experts.

The Preparedness for Caregiving Scale

The Preparedness for Caregiving Scale (PCS) is an assessment tool in which informal caregivers

self-assess and demonstrate their readiness for care. There are 8 questions in the scale to determine the caregiver's state of care. The average of all answers to each question is calculated using a 5-point Likert-type evaluation starting from 0 to 4. The total score is between a minimum of 0 and a maximum of 32. The higher the score, the more the caregiver feels ready to care (Archbold et al., 1990; Zwicker, 2010). The scale developed by Archbold et al. (1990) was re-evaluated by Pucciarelli et al. (2014) and the Cronbach alpha value was found to be 0.94 and test-retest reliability as 0.92. The Turkish adaptation, validity and reliability of the scale were performed by Karaman and Karadakovan (2015) and the Cronbach alpha value was found to be 0.92.

Burden Scale for Family Caregivers

The Burden Scale for Family Caregivers (BSFC) is a scale developed by Grasel et al. (2003) to assess the difficulties experienced by caregivers of individuals in need of care. The scale, which consists of 28 questions, has a Likert-type evaluation ranging from 0 to 3 as completely correct (3 points), mostly correct (2 points), slightly correct (1 point), and not correct (0 points). The scale score is calculated by summing the scores obtained from each question one by one. The score obtained from the scale can be at most 84 and at least 0. A high score on the scale indicates a high level of distress experienced by the caregiver. The Turkish adaptation, validity and reliability of the scale were performed by Ulusoy and Graessel (2017) and the Cronbach alpha value was found to be 0.89.

Information Form for Burn Patients

This form was prepared by the researcher in line with the literature and includes 17 questions that determine the sociodemographic characteristics

This form was prepared by the researcher in line with the literature and includes 5 questions evaluating the post-discharge status of burn patients, the problems they experienced, and their readmission.

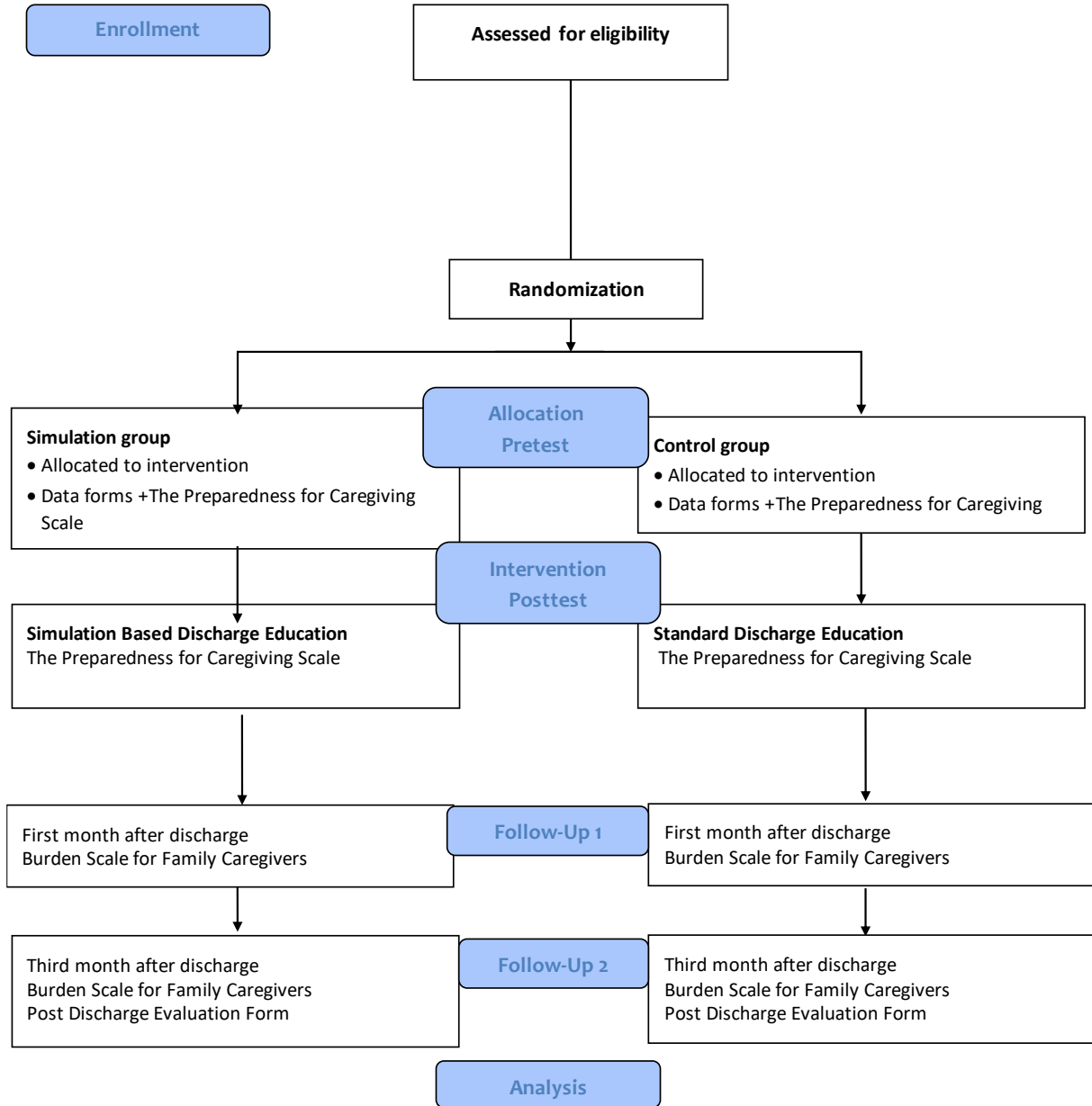
of the burn patient and the burn experience. Scope evaluation was carried out in line with the opinions of four experts.

Post Discharge Evaluation Form

Data Collection Procedure

In the study, the data of the control and experimental groups will be collected as listed below (Consort Flow Diagram). Time frame: expected to last 6 months.

CONSORT Flow Diagram



1. Data collection of the control group

- Written informed consent will be obtained from individuals who agree to participate by providing information about the research.

- Questionnaires prepared by the researcher for the caregiver and the burn patient and “The Preparedness for Caregiving Scale” will be applied only to the caregiver. The application of the scale and the

questionnaires is expected to take approximately 30 minutes. Appropriate training time will be determined by the caregiver.

- “Standard Discharge Training” will be given to the caregiver at the specified time. After the training, “The Preparedness for Caregiving Scale” will be applied again.
- The “Burden Scale for Family Caregivers” will be applied to the caregiver by phone 1 month and 3 months after the patient is discharged, and the “Post Discharge Evaluation Form” will be applied to the burn patient. The application of the scale and the questionnaire is expected to take approximately 30 minutes.

2. Data collection of the experimental group

- Written informed consent will be obtained from individuals who agree to participate by providing information about the research.
- Questionnaires prepared by the researcher for the caregiver and the burn patient and “The Preparedness for Caregiving Scale” will be applied only to the caregiver. The application of the scale and the questionnaires is expected to take approximately 30 minutes. Appropriate training time will be determined by the caregiver.
- “Standard Discharge Training” will be given to the caregiver at the specified time. After the discharge training, the participant will participate in the simulation training. After the simulation training, “The Preparedness for Caregiving Scale” will be applied again. The application of the scale is expected to take approximately 10 minutes.
- The “Burden Scale for Family Caregivers” will be applied to the caregiver by phone 1 month and 3 months

after the patient is discharged, and the “Post Discharge Evaluation Form” will be applied to the burn patient. The application of the scale and the questionnaire is expected to take approximately 30 minutes.

Outcome Measures

Primary Outcome Measure:

1. Caregiving burden

The caregiver burden of those receiving simulation training will be lower than those receiving standard discharge training. [Time Frame: first month-third month]

2. Preparedness for care

The readiness of simulation training people to be ready to provide care will be higher than those who receive standard discharge training. [Time Frame: after education]

Secondary Outcome Measure:

3. Burn Patient Outcome

- a. Burn patients who are cared for by those receiving simulation training will experience fewer complications during the healing process. [Time Frame: 3 months]
- b. Burn patients who are cared for by those receiving simulation training will readmitted less to the hospital. [Time Frame: 3 months]

Analysis

Data will be analysed by using IBM SPSS Statistics 23 (Statistical Package for Social Science) for Windows. While evaluating the study data, frequency distribution (number, percentage) for categorical variables and descriptive statistics (mean, standard deviation) for numerical variables will be given.

While evaluating the study data, the compatibility of scale scores with normal distribution will be evaluated by looking at

Kolmogorov-Smirnov and Shapiro-Wilks tests (McKillup, 2011; Tabachnick et al., 2007; Wilcox, 2017).

Whether there is a difference between the two groups will be evaluated with the independent sample t-test, the chi-square test will be used to examine the relationships between two categorical variables, and if there is a difference between the times in repeated measurements, with the dependent sample t-test. When the data do not show normal distribution, Spearman Correlation and Mann-Whitney U tests will be used to look at the difference between the two groups. $p < 0.05$ was accepted for statistical significance.

Ethic

Before starting the study, approval was obtained from the Clinical Research Ethics Committee of Hacettepe University (Date:04.04.2019 No:2019/06-36-KA19021). The study will be conducted following the Declaration of Helsinki. To carry out the research, necessary permissions were obtained from the hospitals where the burn facilities are located. Written informed consent will also be obtained from burn patients and caregivers in the study.

Strengths

In the current study, the relatives of burn patients will be prepared for home care with the simulation method. The use of simulation to educate the relatives of burn patients will be a first in this respect.

In addition, the planning of the study was made in a randomized controlled manner and the randomization groups would be determined by an external observer. An objective design will be provided to prevent the biased selection of the researcher.

The researcher will gain knowledge and experience in developing simulation scenarios and using the moulage technique to increase

reality.

Limitations

This study will only involve carers of adult patients who were hospitalised in the burn units of two Ankara hospitals. It cannot be applied to all carers of patients getting treatment in burn centres. The study's location in Ankara makes it easier for carers to attend health institutions, particularly burn centres. As a result, generalisations about the caregiving burden of those caring for burn patients at home in different provinces are not feasible.

DISCUSSION

Due to the complex nature of the burn and the long recovery period, the special care required after discharge and the need to use pressure garments, it has been shown in studies that individuals who will continue to care at home experience a lack of knowledge and related anxiety (Faydali & Bayraktar, 2011; Rencken et al., 2021). Being discharged from the hospital does not signify the end of treatment for a burn patient, but rather the beginning of a new period of care. The treatment team's responsibility for care is passed to the patient and family in a way that may result in new difficulties (Coleman et al., 2004; Hartford, 2012). For this reason, providing home care support to burn patients after discharge constitutes an important care burden for caregivers (Deshpande et al., 2012; Karahan, 2016; Ozdemir & Saritas, 2018). Bond et al. (2017) showed in their study with the relatives of burn patients that although it was high at the first hospitalization, the depression and anxiety levels of the relatives of the patients were still high even during the discharge period. In the study by Jones et al., (2021) it was determined that caregivers of burn patients did not have enough information about especially

reaching the burn unit and problems that can be seen at home after burns.

As indicated by the aforementioned studies, it is evident that the preparation of burn patients' families for home care is necessary. Therefore, in our study, a scenario according to the needs of burn patients' families will be developed and implemented. The use of simulation in the context of burns is generally observed in training sessions aimed at the burn team, nursing students, and medical students. These studies usually involve case-based training sessions conducted using standardized patients and mannequins, in which realism is enhanced through the application of moulage techniques (D'Asta et al., 2019; Kilickier et al., 2021; Oliveira-Kumakura et al., 2018; Onarıcı & Karadağ, 2021; Reeves et al., 2018; Sadideen et al., 2016; Zheng et al., 2021).

No studies examining the impact of simulation-based training specifically for burn patients' families have been found. However, in studies targeting families of patients requiring home care, the effectiveness of simulation techniques has been demonstrated. It has been reported that family members providing home care experience less stress, face fewer challenges in caregiving, and observe positive developments in the patients' health condition (Arnold & Diaz, 2016; Barsuk et al., 2019; Brooks et al., 2021; Graham et al., 2019; Jütten et al., 2017; Prickett et al., 2019; Raines, 2017; Raphael et al., 2021; Sigalet et al., 2014; Stanley et al., 2019; Sullivan-Bolyai et al., 2012; Thrasher et al., 2018; Tofil et al., 2013; Wooldridge & Carter, 2021; Yuen et al., 2021). When examining studies on preparing burn patients' families for caregiving, Dualan (2020) conducted a pretest-

posttest study with 30 caregivers of burn patients, showing that video-assisted training resulted in better preparedness of family members for caregiving. Additionally, secondary outcomes such as hand hygiene, medication administration, and wound dressing skills were evaluated in this study, and it was determined that there was a significant difference in performing these skills after the training. The simulation method, which has demonstrated effectiveness on family members of other patient groups, is deemed necessary to be applied to burn patients' families who have limited opportunities to participate in treatment and care during their hospital stay. With our study, the use of the simulation method will be a pioneering approach in this field, and its effectiveness in preparing family members for caregiving will be evaluated. Additionally, the simulation laboratory will be prepared to resemble a home environment, providing the opportunity for the family members to practice care procedures they will experience at home in a safe setting.

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Conflicts of Interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

Author Contribution

Study conception and design: Sabri Karahan, Zahide Tunçbilek; **Drafting of the article:** Sabri Karahan, Zahide Tunçbilek; **Critical revision of the article:** Zahide Tunçbilek, Sabri Karahan

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