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Araştırma Makalesi/Research Article *2023 - 5(3)*

The Effect of Clean Intermittent Catheterization-Based Nursing Interventions on the Knowledge, Skill, Coping, Adaptation, Anxiety in Caregivers and Infection in Children: A Randomized Controlled Study Protocol*

Temiz Aralıklı Kateterizasyona Dayalı Hemşirelik Müdahalelerinin Bakım vericilerin Bilgi, Beceri, Başa Çıkma, Adaptasyon, Anksiyete ve Çocuklarda Enfeksiyon Üzerindeki Etkisi: Randomize Kontrollü Çalışma Protokolü

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Abstract

Objective: To explore the effect of clean intermittent catheterization training based on android application-supported Roy Adaptation Model (RAMTAKE) given by nurses to caregivers on their knowledge, skills, coping, adaptation and anxiety levels and the development of infection in the child.

Methods: The study is a single-center, single-blind, prospective, randomized controlled trial. This randomized controlled trial was reported according to SPRIT. The sample of the study consisted of 42 patients and their caregivers who underwent clean intermittent catheterization in a university hospital. Participants were divided into two separate groups, experimental and control, by simple random sampling method. Participants in the experimental group will be given RAMTAKE, and after being discharged from the hospital, home visits and telephone counseling will be applied by the researchers. The caregivers in the control group will not be subjected to any intervention by the researchers and will be provided with routine clean intermittent catheterization training in the hospital. Study data will be collected using the knowledge, skill level of the caregiver, The Roy Adaptation Model (RAM) psychosocial adaptation areas scale, Coping and Adaptation Scale, The State/Trait Anxiety Scale and UTI development in children. Knowledge, skills, coping, adaptation and anxiety levels of caregivers in both groups will be measured three times. In addition, after discharge from the hospital, children in both groups will be tested for urine culture three times with an interval of one month. Researchers will not interfere with caregivers during the data collection and urine culture analysis phase of the study.

Results: How beneficial clean intermittent catheterization is for children who cannot urinate on their own is quite clear. However, the effect of RAMTAKE knowledge/skills, anxiety level and coping/adaptation of the caregivers and the development of infection in children is yet unknown. Within the scope of the study, it is aimed that the knowledge/skills, coping and adaptation levels of the caregivers who receive RAMTAKE will increase and their anxiety level will decrease. In addition, it is thought that the frequency of urinary tract infection will decrease in the children of caregivers who receive RAMTAKE.

Conclusion: This study is expected to provide reliable evidence to increase the knowledge, skill, coping, adherence level of caregivers who apply clean intermittent catheterization to their children, and to reduce the anxiety level of caregivers with urinary tract infections in children.

Keywords: Smartphone, caregivers, child, urinary tract infections, intermittent urethral catheterization

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Öz

Amaç: Bu çalışmada hemşireler tarafından bakım vericilere verilen Roy Adaptasyon Modeli'ne dayalı android uygulama destekli temiz aralıklı kateterizasyon eğitiminin (RAMTAKE) bakım vericilerin bilgi, beceri, baş etme, uyum, kaygı düzeyleri ve çocukta enfeksiyon gelişimine etkisinin araştırılması amaçlanmıştır.

Gereç ve Yöntem: Çalışma, tek merkezli, tek kör, prospektif, randomize kontrollü bir araştırmadır. Bu randomize kontrollü çalışma SPRIT'e göre rapor edilmiştir. Araştırmanın örneklemini bir üniversite hastanesinde temiz aralıklı kateterizasyon uygulanan 42 hasta ve bakım vericisi oluşturdu. Katılımcılar basit rastgele örneklem yöntemiyle deney ve kontrol iki ayrı gruba ayrıldı. Deney grubundaki katılımcılara RAMTAKE verilecek, hastaneden taburcu edildikten sonra araştırmacılar tarafından ev ziyareti ve telefon danışmanlığı uygulanacaktır. Kontrol grubundaki bakım vericilere ise araştırmacılar tarafından herhangi bir müdahale yapılmayacak, hastanedeki rutin temiz aralıklı kateterizasyon eğitimi alması sağlanacaktır. Her iki grup için çalışma verileri bakım vericinin bilgi, beceri düzeyi soru formu, Roy Adaptasyon Modeli (RAM) psikososyal uyum alanı soru formu, Başetme ve Uyum Ölçeği, Süreksiz Durumluk/Sürekli Kaygı Envanteri ve çocukta idrar yolu enfeksiyonu gelişim formu kullanılarak toplanacaktır. Her iki gruptaki bakım vericilerin bilgi, beceri, başa çıkma, uyum ve kaygı düzeyleri üçer kez ölçülecektir. Ayrıca her iki gruptaki çocuklara hastaneden taburcu olduktan sonra birer ay ara ile üç kez idrar kültürü tetkiki yapılacaktır. Araştırmacılar, çalışmanın veri toplama ve idrar kültürü analizi aşamasında bakıcılara müdahale etmeyecektir.

Bulgular: Kendi kendine idrar yapamayan çocuklar için temiz aralıklı kateterizasyonun ne kadar faydalı olduğu çok açıktır. Ancak bakım verenlerin RAMTAKE bilgi, becerileri, baş etme, uyum sağlama ve kaygı düzeylerinin çocuklarda enfeksiyon gelişimine etkisi henüz bilinmemektedir. Çalışma kapsamında RAMTAKE alan bakım vericilerin bilgi, beceri, başetme ve uyum düzeyinin artacağı, anksiyete düzeyinin azalacağı hedeflenmektedir. Buna ilaveten RAMTAKE alan bakım vericilerin çocuklarında idrar yolu enfeksiyonu gelişim sıklığının azalacağı düşünülmektedir.

Sonuç ve Öneriler: Bu çalışma ile çocuklarına temiz aralıklı kateterizasyon uygulayan bakım vericilerin bilgi, beceri, başetme, uyum düzeyinin artırılması ve çocuklarda idrar yolu enfeksiyonu ile bakım vericilerin anksiyete düzeyinin azaltılmasına yönelik güvenilir kanıt sağlaması beklenmektedir.

Anahtar Kelimeler: Akıllı telefon, bakım verici, çocuk, idrar yolu enfeksiyonu, temiz aralıklı kateterizasyon

INTRODUCTION

Clean intermittent catheterization (CIC) is a way of draining urine with a catheter inserted into the bladder neurogenic or non-neurogenic bladder disorders in a hygienic condition, and afterward, the catheter is removed (Akpınar Balcı, 2014). Used for the first time in soldiers with spinal cord trauma treated in rehabilitation centers during the Second World War, CIC was introduced by urologist Lapides after 1972 for the treatment of patients who could not completely empty their bladder (Bloom, 2017; Lapides et al., 1976). CIC is the most effective method used to protect the urinary system by patients with mainly spina bifida (SB), neurogenic bladder and bladder obstruction, and their caregivers (Cobussen Boekhorst et al., 2016; Le Danseur et al., 2016; Svihra et al., 2018). The literature cites that CIC used in individuals who cannot completely empty their bladder enables them to live without being dependent on the bladder, protects bladder and kidney functions, improves the quality of life and body image of the patients, and decreases the morbidity and mortality rate (Gray et al., 2019; Faleiros et al., 2018; Lamin & Newman, 2016). Despite the advantages of CIC, caregivers who perform this procedure face some difficulties. Recurrent infections, hematuria, and urethral stricture can develop in children because of caregivers not being adequately adapted to the CIC procedure, not paying attention to the time intervals of CIC application and hygienic rules and insufficient CIC training (Gould, 2010; Wyndaele, 2012; Zegers, 2011). The most common complication in people using CIC is urinary tract infection (UTI) (Wyndaele, 2012). UTI leads to permanent damage to the kidney and requires renal replacement therapy (Han et al., 2017). Previous studies have emphasized the significance of patient training to prevent infection and it was stated that caregivers should be trained by nurses who have received sufficient training on this subject (Załęska-Ponganis & Jackowska, 2014; Falerios et al., 2018).

The use of nurse theorists' models or theories while applying the role of caregiver, educator and consultant regarding illness/health to their patients is considered as a guiding guide in the creation of the scientific content of the profession. Pathological changes that occur as a result of chronic diseases that require long-term treatment and care affect caregivers as well as patients, causing psychosocial deterioration in both children and families. For this reason, nurses should benefit from theories and models when applying qualified nursing care to patients and caregivers, supporting their adaptation to the new process they experience, and explaining the data they have obtained scientifically (Pektekin, 2013). The Roy Adaptation Model (RAM), which was developed by Sister Callista Roy and started to be implemented in 1970, is one of the nursing models used in the field of adaptation of patients and caregivers to the new process they live. Studies have shown that the use of RAM increases the level of coping and adaptation in the adaptation of caregivers who apply CIC to their child, and reduces the complications that may develop in the child (Lima et al., 2017).

The increase in the prevalence of smartphone use in the world has also increased the use of health applications on phones. Health applications on smartphones allow individuals with chronic diseases, especially diabetes, multiple sclerosis and heart diseases, to track their own diet, exercise and physical activities. Thus, it is thought that the care and treatment process of people will be supported and the health services of the society will be affected positively. According to a survey study conducted in the United States on the use of health applications on smartphones, 34% of adult individuals download at least one application that supports their health on their smartphones, and 19% download a mobile health application to their smartphones regularly (Lima et al., 2017; Sun et al., 2017). The literature on the use of smartphone applications is very limited in order to support the care process management of caregivers who apply CIC to their children and to increase their adaptation to the new process they live in (De Souza-Junior et al., 2017; Ernsting et al., 2017). The existence of an android

application that caregivers who apply CIC to their children will use on their phones to follow the frequency of CIC application recommended by the physician, the procedure steps and the hospital appointment time determined by the physician will contribute positively to the caregivers' disease process management, skill, coping/adaptation level, In children, we think that it will reduce complications that may occur, especially UTI. The use of the android application, developed for the caregivers to follow the application hours, procedure steps, and hospital appointments, can contribute to managing the disease process, coping with the disease, and adaptation. Studies on patients using CIC frequently focus on the frequency of UTI development, treatment efficiency, patient compliance, quality of life, and nurses' experiences (Akan et al., 2017; Aybek, 2005; Girişgen et al., 2019; Telli et al., 2016). However, starting from the hospital, after discharge, the nursing interventions that need to be done to increase the adaptation of the patient and caregivers to this new situation and reduce their anxiety levels are not implemented, and the guide booklet containing the training given by using the theories of nurse theorists is not delivered to the caregivers after discharge. It is believed that the possible results of this study evaluating the effect of home visits and telephone counseling after discharge from the hospital, the use of the android phone application reminding the CIC application hours, procedure steps, and hospital appointments, on the knowledge/skills, coping/adaptation, and anxiety levels of the caregivers and the development of UTI in the child will make a valuable contribution to the relevant literature. Designed as a randomized controlled study, this protocol aims to evaluate the effects of RAM-based android application-supported CIC training (RAMTAKE) given to caregivers by nurses on the knowledge/skills, anxiety levels and coping/adaptation of caregivers and infection in children.

METHODS

The Aim and Type of the Study: This study protocol includes the design of training, home visits, and telephone counseling for caregivers in the pediatric units of a university hospital in Trabzon with a single-center, single-blind, blinded evaluator, and parallel-group randomly controlled design. The study protocol is arranged according to the standard protocol items, including interventional trials (SPIRIT; Chan et al., 2013). Consort Reporting Trials Standards (CONSORT) process steps were followed in reporting (Moher et al., 2013). The Ecuador network and reporting guidelines of the study are shown in Table 1. Our study was registered at ClinicalTrials.gov (NCT04763382) in February 2021. The study protocol was planned as a two-group randomized controlled pre-test, post-test, and retention test. The participants were randomized to the groups by the statistician according to the simple random sampling method. Caregivers who administer CIC to their children were randomly assigned by a blinded statistician as the first group (the one that will receive RAMTAKE) and the second group (the one that will receive routine CIC training given by the hospital).

Research Hypotheses

$H_{0\text{-}1}$: With caregivers (experimental group) who received RAMTAKE given by the nurse among those who did not receive this training (control group); in terms of knowledge/skills there is no significant difference.

$H_{1\text{-}1}$: With caregivers (experimental group) receiving RAMTAKE given by the nurse among those who did not receive this training (control group); in terms of knowledge/skills there is a significant difference.

$H_{0\text{-}2}$: With caregivers (experimental group) who received RAMTAKE given by the nurse UTI development among children of those who did not receive this training (control group) there is no significant difference in terms of.

H_{1-2}: With caregivers (experimental group) who received RAMTAKE given by the nurse UTI development among children of those who did not receive this training (control group) there is a significant difference in terms of.

H_{0-3}: With caregivers (experimental group) who received RAMTAKE given by the nurse among those who did not receive this training (control group); in terms of anxiety level there is no significant difference.

H_{1-3}: With caregivers (experimental group) who received RAMTAKE given by the nurse among those who did not receive this training (control group); in terms of anxiety level there is a significant difference.

H_{0-4}: With caregivers (experimental group) who received RAMTAKE given by the nurse among those who did not receive this training (control group); coping/adaptation level there is no significant difference in terms of.

H_{1-4}: With caregivers (experimental group) who received RAMTAKE given by the nurse among those who did not receive this training (control group); coping/adaptation level there is a significant difference in terms of.

Table 1. Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Figure With Design and Outcome Evaluations

	Enrolment	**Baseline**	**Intervention**	**Follow-up**		
TIME INTERVAL	After *CIC application decision	Pre-**RAMTAKE (T_0)	Post-RAMTAKE (T_1)	One month after discharge (T_2)	Two months after discharge (T_3)	Three months after discharge (T_4)
ENROLMENT						
Determining the population and sample	X					
Receiving informed consent	X					
Randomization	X					
INTERVENTIONS						
Experimental Group		X	X	X	X	X
Control Group		X		X	X	X
EVALUATIONS						
Sociodemographic		X				
Android phone app installation			X			
Training booklet delivery			X			
Knowledge/skill		X			X	X
***RAM psychosocial adaptation		X			X	X
Coping/Adaptation		X			X	X
Anxiety		X			X	X
Urine culture analysis				X	X	X

Note: After determining a sample from the population following the inclusion criteria of the study, and obtaining informed and signed consent from the participants, randomization made as an experimental and control group. Then, all participants in the experimental and control groups were administered a questionnaire form based on sociodemographic characteristics, knowledge, skills related to CIC application, concepts in the Roy Adaptation Model, stimuli, coping mechanism and psychosocial response areas, and ****NANDA-I nursing diagnoses, a questionnaire created for the Coping/Adaptation and Anxiety scale. RAMTAKE will be given to the people in the experimental group in pediatric units. Measurements will be made before RAMTAKE (T_0) and during follow-up (T_2-T_4).
* **CIC:** Clean intermittent catheterization, ** **RAMTAKE:** Clean intermittent catheterization training based on android application-supported Roy Adaptation Model, *** **RAM**: Roy Adaptation Model, **** **NANDA-I**: North American Nursing Diagnosis Association - International

Settings of the Study: We will conduct our study, registered at ClinicalTrials.gov (NCT04763382) in February 2021, between March 2020 and June 2021 at the Pediatrics Units of the Farabi Hospital Karadeniz Technical University (KTU), providing telephone consultancy and home visits after discharge from the hospital.

Population of the Study: The population of our randomized controlled experimental study consisted of 54 patients who were decided to perform CIC by Farabi Hospital of Pediatric

Nephrology unit. The sample size of the research was calculated with the G*Power 3.1 program. For the sample size of the study, it was aimed to reach a total of 36 people, 18 experiments, 18 controls in each group, with a 95% confidence interval, 5% error margin, and 0.50 effect in power analysis (df=1; F= 4.130). While determining the sample size, a statistician calculated the effect size as 0.50 based on the variance analysis effect size value determined by Cohen (Özçomak & Çebi, 2017). The data collection period of the study was determined as 15 months to reach a sufficient number. During the study, to prevent data loss, it was decided to exceed 20% of the sample size and collect the data from 42 people; 21 the control and the experimental group.

Inclusion Criteria for the Study: Inclusion criteria for the study were established separately for caregivers and children. Inclusion criteria for caregivers; Volunteering to participate in the study, Complete data collection tools, having a smart phone with an android application, being literate, not having received information/training from the nurse about CIC application before. Inclusion criteria for children are being between the ages of 0-17 is the decision to perform CIC application by Farabi Hospital Pediatric Nephrology department and follow up regularly.

Exclusion Criteria: The exclusion criteria for the study were also established separately for caregivers and children. Exclusion criteria for caregivers; hearing, sight and speech impairment, not using a mobile phone with an android application. The exclusion criteria for children are; have complex anatomical anomaly of the urogenital system.

Randomization and Allocation: The participants were randomized to the groups by the statistician according to the simple random sampling method. Caregivers and children who met the inclusion criteria of the study were randomly assigned to the experimental and control groups with equal probability (Kim & Shin, 2014). During randomization, the experimental group was named “1” and the control group “0”. Participants were numbered from 1 to 42 in the order of hospitalization. Randomization results of 42 caregivers were transferred to the Word software, a printout was prepared, and numbers (1-0) were assigned. Envelopes prepared by the researcher were numbered from 1 to 42. A person other than the researcher placed the number of the 1st caregiver drawn during randomization in the 1st envelope and the number of the 2nd caregiver drawn during randomization in the 2nd envelope, and this was repeated for all caregivers until the numbers of all 42 caregivers were enveloped. A randomly selected envelope was opened upon contacting the caregivers who meet the inclusion criteria and whether that participant was in the experimental or control group was determined.

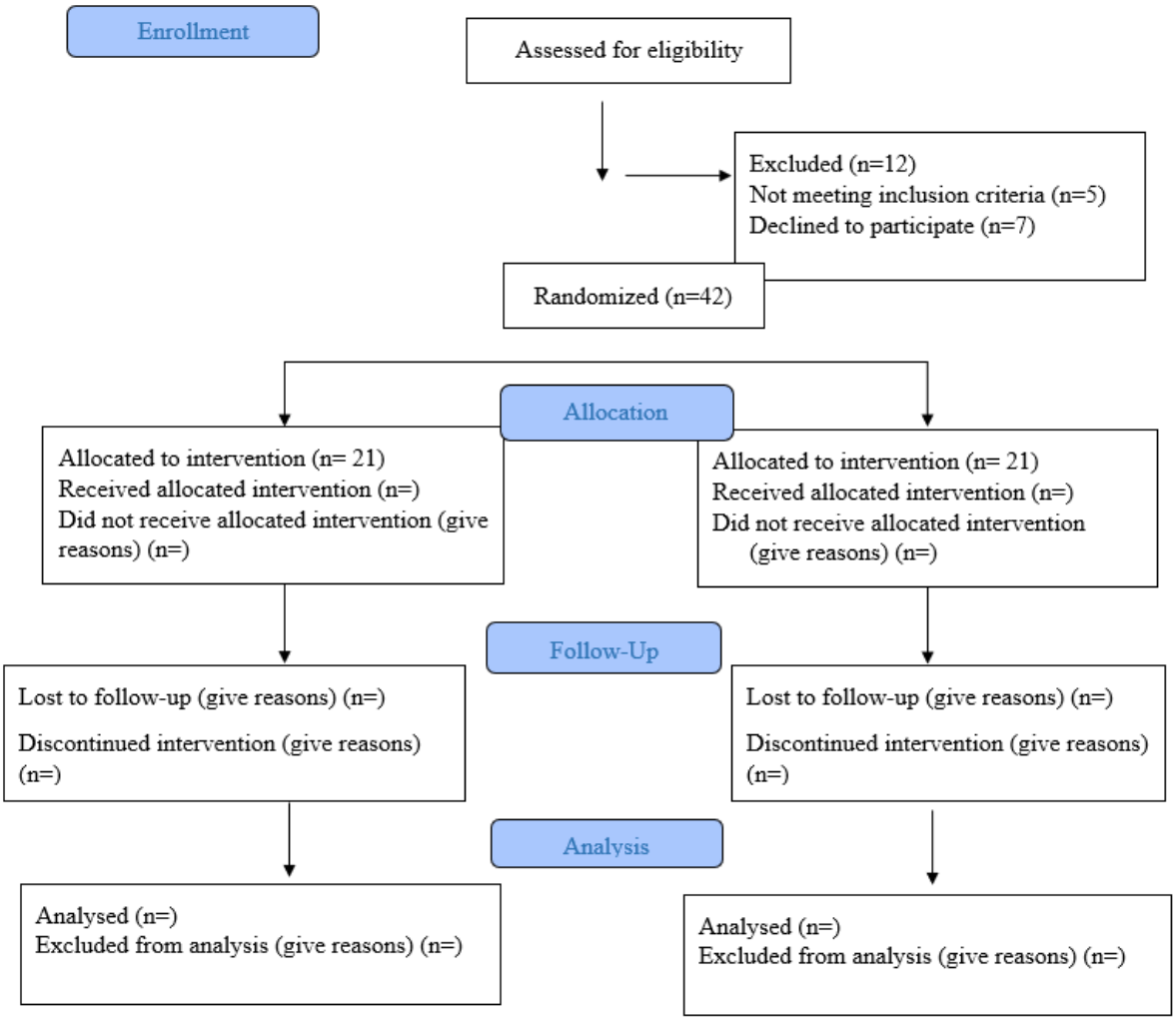
The research consisted of two groups:

1. RAMTAKE training (experimental) group: RAMTAKE was given by researchers.

2. Group receiving routine hospital-provided CIC training (control): Received routine hospital-provided CIC training.

The caregiver group is known only to the researcher. The data collection tools of the research will be filled by the caregivers and the researcher will not intervene. The CONSORT flowchart of study participants is shown in Figure 1.

Figure 1. CONSORT 2010 Flow Diagram



Blinding Design: In our study, caregivers were randomly assigned to the groups. A single blinding method was used for the participants; thus, the participants do not know to which group (experiment or control) they were included. In order to prevent bias that may occur during the data collection phase, the caregiver was provided to read and answer the scales in the data collection tools of the research. Statistical analysis of the data of the study will be carried out by a blinded statistician other than the researchers.

Experimental Group: During the 16-week implementation period for caregivers, all data collection tools were first applied as a pre-test. The caregivers in the experimental group were given RAMTAKE with face-to-face training model in four separate sessions by making an appointment at appropriate time intervals (15:00-18:00) in the patient room using a face-to-face training model and a powerpoint presentation. 45 minutes were allocated for each training. This training was based on the psychosocial adaptation modes of RAM, namely physiologic needs, self-concept, role function and interdependence.

Main topics and content of RAMTAKE

Training Topics in the Physiological Mode: The definition of CIC is hand hygiene, use of gloves, the organs that make up the urogenital system, the characteristics of normal urine, the position to be given to the child during CIC and perineal cleaning according to gender, the

materials to be used, the procedure steps and discharge training (Akpınar Balcı, 2014; Şenturan, 2015).

Training Topics in the Self-Concept Mode: Self-esteem, characteristics of individuals with high self-esteem, how to raise self-esteem, the definition of stress and methods of coping with stress (Velioğlu, 2012).

Training Topics in the Role-Function Mode: Primary, secondary, and tertiary roles of caregivers, occurrence of role change, maintaining role sharing within the family, taking responsibility and problem solving (Pektekin, 2013; Velioğlu, 2012).

Training Topics in the Interdependence Mode: Creating a support system and communicating through support the systems (Pektekin, 2013; Velioğlu, 2012).

In the pre- and post-education period, a practical application of the CIC application was made on a model suitable for the gender of the child, and then with the caregivers on the child. During the CIC application, aseptic techniques will be followed to prevent the development of infection and a disposable CIC catheter was used in each application. On the last day of the training, a guidebook containing the entire training was distributed to the caregivers. Before being discharged from the hospital, an android phone application reminding the CIC hours, procedure steps and hospital appointments was installed on the phones of the caregivers and the application was applied together with the caregivers. After discharge, home visits and three phone calls were made at certain time intervals to evaluate the knowledge/skills of the caregivers regarding the CIC application, to identify the problems related to the android phone application and to propose solutions. The caregivers in the control group did not receive any intervention by the researchers, only the routine CIC training program in the hospital was applied to these caregivers.

Control Group: During the 16-week implementation period for caregivers, all data collection tools were first applied as a pre-test. The caregivers received the CIC training provided routinely by the institution during the hospital stay. The training was given by the clinic physician or the representative of the company that sells the CIC catheter. The training, lasting approximately 30 minutes, included verbal instructions for the application and practical application performed several times. Data collection tools were reapplied to the caregivers after discharge as a post-test and retention test. After discharge, urine culture tests were performed three times with an interval of one month. The participants were thanked for their contributions to the study and said goodbye.

Outcome Measures: North American Nursing Diagnosis Association - International (NANDA-I), which is one of the data collection tools of the study, was created by the researchers based on the Sociodemographic Characteristics Question Form of the participants, the Knowledge and Skill Level Assessment Form regarding the CIC Application, Concepts in the Roy Adaptation Model, Stimuli, Coping Mechanism, and Psychosocial Response Adaptation Areas. Coping and Adaptation Scale and Trait/State Anxiety Inventory are the scales used in data collection. In addition, three urine culture tests will be performed at one-month intervals to determine the development of UTI in the children included in the study. Data will be collected by the researcher and a nurse trained by the researcher. Statistical evaluation of the data will be done by a blind statistician other than the researcher.

Primary Outcome Measure: The primary outcome measure of the study is to evaluate the knowledge/skill level of caregivers and UTIs in the children.

UTI development in children: UTI development in children will be evaluated with urine culture analysis. Growth of 105 colonies or more microorganisms per milliliter in the urine taken by caregivers using a mid-stream urine sample will mean the presence of UTI (Telli et

al., 2016). Urine culture analysis results of children will be obtained through the patient's file numbers on the hospital information system. The type of bacteria that grows in the urine will also be evaluated through urine culture analysis.

The knowledge, skill level of the caregiver: It is a questionnaire consisting of two parts created by the researcher following the literature (Akpınar Balcı, 2014; Telli et al., 2016; Şenturan, 2015). In the first part, the knowledge levels of caregivers about the use of CIC will be evaluated. The content validity of the form consisting of 26 questions was performed according to the Lawshe technique, and the content validity index was determined as 0.897. In the second part, the skill levels of caregivers in using CIC will be evaluated. The content validity index of the form consisting of 17 questions was determined as 0.877.

Secondary Outcome Measure: The secondary outcome measure of the study involves the response, coping, adaptation, and anxiety levels of caregivers to the RAM psychosocial adaptation areas scale.

Data Collection Tools

The RAM Psychosocial Adaptation Areas Scale: The level of caregivers' responses to RAM psychosocial adjustment was evaluated with the NANDA-I Questionnaire based on RAM and Nursing Diagnoses, created by the researchers in line with the literature. The form was developed created according to the adaptation areas of the model and consists of a total of 39 questions; 14 on the Physiological area, 9 on the Self-Concept Area, 8 on the Role Function Area, and 8 on the Inter-Dependence Area. Eight experts were consulted about the scale, and the content validity of the test was performed based on the Lawshe technique. The content validity index was determined as 0.873. The scoring of the scale is as follows: Disagree (1), Partially Disagree (2), Undecided (3), Partly Agree (4), Agree (5). The score to be taken from the form is between 39 and 195 (Çatal & Dicle, 2011; Ocakçı, 2013; Pektekin, 2013).

Coping and Adaptation Scale: The scale was developed by Roy in 2004 to evaluate the level of coping and adaptation, and its validity and reliability in Turkish were carried out by Çatal and Dicle in 2015. It is a 4-point Likert-type scale and includes 47 items, five sub-dimensions, and responses as Always (4), Frequently (3), Occasionally (2) and Never (1). The total score to be obtained from the scale varies between 47 and 188. Higher scores indicate effective coping methods (Çatal, 2015).

The State/Trait Anxiety Scale: The scale, which was created by Spielberger and Gorsuch in 1964, was adapted into Turkish by Öner and Le Compte in 1975. The scale consists of two parts; each consisting of 20 items. The first part of the 4-Likert-type scale is scored as 1 (Never), 2 (Sometimes), 3 (Frequently), and 4 (Always), and the second part is scored as 1 (Rarely), 2 (Sometimes), 3 (Frequently), and 4 (almost always). Scores ranging from 20 to 80 are obtained from each scale. Higher scores indicate higher anxiety levels (Öner & Le Compte, 1985).

Data Collection: The data will be collected in 4 different periods (before training, one, two, three months after discharge) in line with the literature. Data collection time and process stages are given in Table 2.

Pre-test Application Before Training: All data collection tools were applied to caregivers. The Sociodemographic Characteristics questionnaire will be administered to the caregivers in the experimental and control groups only during the pre-test of the study. Caregivers will be requested to read and fill in data collection tools themselves. Skill levels of the caregivers will be evaluated by a nurse-observer other than the researcher.

Table 2. Details and Timing of Data Collection

Measurements	Pre-*RAMTAKE (T_0)	One month after discharge (T_2)	Two months after discharge (T_3)	Three months after discharge (T_4)
Sociodemographic characteristics questionnaire	X			
**CIC application knowledge/skills questionnaire	X		X	X
***RAM psychosocial adaptation questionnaire	X		X	X
Coping / Adaptation Scale	X		X	X
State / Trait Anxiety Scale	X		X	X
Evaluation of ****UTI development		X	X	X

Note: The sociodemographic characteristics questionnaire will be administered to the caregivers in the experimental and control groups only before RAMTAKE (T_0). The "skill questionnaire" (T_0, T_3, T_4), evaluating the skill levels of the caregivers while applying CIC, will be administered by a blinded nurse.
RAMTAKE:** Clean intermittent catheterization training based on android application-supported Roy Adaptation Model, ** **CIC:** Clean intermittent catheterization, *** **RAM:** Roy Adaptation Model, * UTI: urinary tract infection

One Month After Discharge: Urine culture analysis will be done to evaluate the development of UTI in the urine of children taken by caregivers. Regular monthly urine culture analysis of patients using CIC is a routine practice for Farabi Hospital. Researchers did not intervene in the caregivers when they are taking urine analysis.

Two Months After Discharge: Data collection tools applied as a pre-test will be re-applied as a post-test after two months in line with the literature. Caregivers will be requested to read and fill in data collection tools themselves. Skill levels of the caregivers will be evaluated by a nurse-observer other than the researcher. Urine culture analysis will be done to evaluate the development of UTI in the urine of the children taken by the caregivers.

Three Months After Discharge: Data collection tools applied as a pre-test will be re-applied as a post-test after three months in line with the literature. Caregivers will be requested to read and fill in data collection tools themselves. Skill levels of the caregivers will be evaluated by a nurse-observer other than the researcher. Urine culture analysis will be done to evaluate the development of UTI in the urine of the children taken by the caregivers.

Variables of the Study: Dependent variable; Caregiver's knowledge and skill level mean score, The RAM Psychosocial Adaptation Areas Scale mean score, Coping and Adaptation Scale mean score, The State/Trait Anxiety Scale mean score and the incidence of UTI. Independent variable; Participants' age, education status, gender.

Data Assessment: Statistical analysis will be performed using SPSS 22.0 and, with statistical significance set at $p < .05$. For participants' characteristics, will be tested with mean, standard deviation, number (n), percentage (%) and chi-square analysis. The difference between numerical measurements, such as the knowledge/skill level, will be evaluated using the Mann Whitney U and t test. Freidman two-way analysis of variance, such as knowledge, skills, coping, adaptation, anxiety and RAM psychosocial adjustment area, will be used to compare the pre-test, post-test and retention tests of the experimental and control groups within the group. Repeated measurement analysis of variance will be applied to within-group differences, followed by the bonferroni, post-hoc test. In case of data loss in the experimental and control groups, Intention-to-treat analysis will be performed.

Limitations of the Study: Conducting the study in a single-center and not being able to blind the researchers are the limitations of the study.

Ethical Considerations: Written approval was obtained from Karadeniz Technical University Faculty of Medicine Clinical Research Ethics Committee on 13.03.2020 and numbered 24237859-241. Also, written permission was obtained from the chief physician of the relevant hospital with the letter dated 18.02.2020 and numbered E.636 where the research

will be carried out. All caregivers will be informed about the purpose of the study and got their informed consent for the participation of their child in the study.

The Helsinki Declaration: All processes of the study were carried out in line with the principles stated in the Declaration of Helsinki (WTB Helsinki Declaration, 2013). Ethics committee approval was obtained to conduct the study.

Validity and Reliability: Expert opinion was obtained from the questionnaires (knowledge, skills, RAM psychosocial adjustment field) created in line with the literature to collect data for the study, and then Cronbach's alpha internal consistency was determined. Other data collection tools, such as Coping / Adaptation and anxiety level, were made Turkish validity and reliability.

Trial Organization: The Co-ordinating Group: The coordination center and the institution responsible for the design of the study is the department of pediatrics nephrology, Karadeniz Technical University Faculty of Health Sciences. The coordination group is also responsible for preparing reports for the Thesis monitoring committee. Members: CS, BCD.

Steering Committee: The entire process of the study, the evaluation of the data, the safety of the patients, and adherence to the established protocol will be monitored by an independent scientific and administrative Steering Committee. Members: HÖ and MK

Data Monitoring Committee: Training given to caregivers includes non-pharmacological intervention. Therefore, there is no negative impact on people. However, our research is still supervised by a committee. As the study will take approximately 15 months to complete, the results will be monitored by the independent Data Monitoring Committee (DMC). This can be done at least three times a year with all members of the DMC. DMC may discuss specific interim analyzes or suggest specific protocol changes. Members: HÖ and MK.

RESULTS

When the data collection phase is over, the results will be shared. After RAMTAKE, caregivers' knowledge/skills, coping and compliance levels will increase; It is thought that the risk of urinary tract infection development in children and the anxiety level of caregivers will decrease.

DISCUSSION

It is very important that the training of caregivers on the application of CIC is given by the nurses. Relevant literature emphasizes that if caregivers are not adequately trained, the incidence of UTI, the most significant complication of CIC use in children, thus the frequency of hospitalization, permanent damage to the kidney, and renal replacement therapy increases (Cobussen-Boekhorst et al., 2016; Le Danseur et al.,2016; Gray et al., 2019). To prevent complications that may occur in patients using CIC, caregivers should be educated, adapted to the application of CIC to their children, and they should pay attention to the frequency of CIC, procedure steps, and hospital appointments (Telli et al., 2016; Akan et al., 2017; Girişgen et al., 2019). This study involves a single center, randomized controlled trial protocol that investigates the effect of RAMTAKE given to caregivers who administer CIC to their children, using a single blinding method. In line with the results we will achieve, it is planned that the caregivers who apply CIC will receive training according to RAMTAKE. CIC is mandatory for individuals who cannot urinate on their own. With our study, it is planned to give CIC training supported by an android phone application based on nursing models to the caregivers administering CIC to their children. Existing literature on RAMTAKE, created for caregivers who apply CIC to their children, is not sufficient. This study aims to fill the gap in the literature on empirical evidence regarding CIC training for caregivers.

CONCLUSION

Children who are applied CIC are at risk of developing UTIs, and caregivers are also in the risky group in terms of knowledge/skills, coping/adaptation, and anxiety level. This randomized controlled study is valuable as it is expected to increase the knowledge/skills, coping/adaptation level of caregivers, decrease the anxiety level and prevent the incidence of UTI development in children. The results will serve as a resource for further studies for caregivers of children using CIC.

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Conflicts of Interest: *The authors declare that they have no conflict of interest.*

Ethics Committee Approval: *This study was approved by Clinical Research Ethics Committee of Faculty of Medicine, Karadeniz Technical University, (approval date 13.03.202 and number 2019/364).*

Peer-review: *Externally peer-reviewed.*

Author Contributions:

Research idea: CS, BCD

Design of the study: CS, BCD

Acquisition of data for the study: CS, BCD

Analysis of data for the study: CS, BCD

Interpretation of data for the study: CS, BCD

Drafting the manuscript: CS, BCD

Revising it critically for important intellectual content: CS, BCD

Final approval of the version to be published: CS, BCD

Data Availability Statement: *The datasets used and analyzed during the current study are available from corresponding author upon request.*

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