

EMPIRICAL STUDIES

PEER REVIEWED

The Development and Effectiveness of a Care Protocol Using the Stevens Star Model of Knowledge Transformation in Female Patients With Stress Incontinence: An Experimental Study

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Abstract

BACKGROUND: Nurse-led pelvic floor muscle exercise and lifestyle education programs are effective first-line interventions for women with stress incontinence (SI). **PURPOSE:** To develop an evidence-based stress incontinence care protocol (SICP) using the Stevens Star Model of Knowledge Transformation and evaluate its effect on the frequency and quantity of urinary incontinence, quality of life, pelvic muscle self-efficacy levels, and lifestyle variables of women with SI. **METHODS:** An SICP was developed on the basis of the Star model. The views of an expert were consulted for testing the content validity of the protocol. Using a pretest-posttest experimental design, 68 women with SI who visited an outpatient clinical at a hospital in Turkey were prospectively enrolled in the intervention (n = 34) and control (n = 34) groups. After obtaining baseline demographic and health history information, participants completed the King’s Health Questionnaire, the Broome Pelvic Muscle Exercise Self-Efficacy Scale, a 3-day voiding diary, and a 1-hour pad test. The intervention group received an 8-week program of care according to the Star model-derived SICP, and follow-up assessments were completed by both groups after 8 and 12 weeks. **RESULTS:** The content validity index for the SICP was 91.9%. The intervention group had a reduced quantity and frequency of urinary leakage, reduced King’s Health Questionnaire scores, and increased Broome Pelvic Muscle Exercise Self-Efficacy Scale scores ($P < .05$). **CONCLUSION:** Care provided according to the Star model-derived SICP reduced the quantity and frequency of SI and improved the perceived pelvic muscle exercise self-efficacy and quality of life of the participants.

Introduction

Stress incontinence (SI) is involuntary urinary incontinence (UI) experienced during physical activities that increase intra-abdominal pressure.¹ SI is most commonly seen in women and is known to have an adverse effect on quality of life.^{2,3} It is not a life-threatening disorder. Patients can be treated with cost-effective conservative methods that do not have side effects. Pelvic floor muscle (PFM) exercises and lifestyle changes (eg, liquid intake, pad usage, and participating in sports) are conservative interventions that are used as first-line treatments.^{4,5}

Nurses play an essential role on the health care team in evaluating and treating SI.⁶ Care should be provided on the basis of evidence-based guidelines and protocols.⁷ A prospective formative evaluation study by Sampsel et al⁸ to test an evidence-based care protocol for 132 female patients with UI reported reductions in the frequency/quantity of incontinence and in the habit of avoiding activities due to incontinence. The authors concluded that working with the protocol had a beneficial effect on participants’ health.

The purpose of SI treatment is to alleviate SI symptoms without harming the patient and to improve quality of life by encouraging the adoption of a healthy lifestyle.⁶ To provide effective treatment along these lines, nurses need to have evidence about the impact of PFM exercise and lifestyle changes on SI. It is also important that nurses become specialized

in providing care for incontinence. In some countries (such as the UK, Canada, and the United States), certification programs in incontinence care are available.⁹ However, there are no such certification programs in Turkey. Akinci et al¹⁰ reported that nurses do not engage in interventions that educate patients about SI and, furthermore, that they are unable to play an active role in the health efforts that are spent to prevent UI and achieve continence. This information, however, relies on nonsystematic and nonscientific investigations.¹¹ Improving the quality of care and outcomes, standardizing care, and increasing patient satisfaction are made possible through evidence-based approaches.¹² Making use of the best evidence that can be obtained through evidence-based research in the creation of protocols ensures standardization of practices.¹² This approach also prevents the occurrence of substandard and unwanted outcomes.¹¹

One evidence-based approach consists of creating care protocols designed to improve patient care outcomes when implemented in clinical practice.⁷ Evidence-based study models can provide guidance in developing these protocols. One such model is the Star model, which facilitates the translation of gathered knowledge into a useful and beneficial form for use in patient care. At the same time, the Star model creates a fundamental structure that allows concepts to be better understood and knowledge to be carried over into decision-making processes.¹² In an observational, prospective, quasi-experimental study by Abbott et al¹³ in the United States, researchers employed the Star model to develop a clinical practice guide for ventilator-related pneumonia, and it was found that ventilator-related pneumonia rates decreased in 106 patients on ventilators; this change, however, was not found to be statistically significant. It was reported in a meta-analysis of 1281 cases (experimental n = 665; control n = 616) by Dumoulin et al¹⁴ that women with SI who performed PFM exercises had a lower level of incontinence and a better quality of life than study controls. Although evidence-based studies point to the importance of PFM exercises, nurses often do not make use of this evidence in the care they provide their patients.^{10,15,16} To implement the available knowledge on the use of conservative treatment in SI, nurses must be knowledgeable about the fundamentals of the evidence provided.^{6,17} The Star model, designed to improve patient outcomes by creating a bridge between research and clinical practice,¹⁸ may help nurses implement evidence-based SI care. To the authors' knowledge, there is currently no published stress incontinence care protocol (SICP) based on the Star model. Although there is one published study of a care protocol for UI, this protocol was not created on the basis of an evidence-based model.⁸

The purpose of this study was to develop an SICP using the Star model and evaluate its effect on the frequency and quantity of UI, quality of life and pelvic muscle self-efficacy levels.

Methods

Conceptual framework. The Stevens Star Model of Knowledge Transformation is used to understand the characteristics, type, and quality of information used in various aspects of evidence-based practice. The Star Model depicts a cycle of change in the form of a 5-pointed star, with each corner of the star denoting a different step ([Figure 1](#)).¹⁹

Star point 1: discovery research. New information is uncovered through research. Asking the right questions is the key to producing useful, accurate evidence, and the elements of patient (P), intervention (I), comparison (C), outcome (O), and time (T) are used to this end. The authors specified the current research questions according to the PICOT format. All questions refer to women with a diagnosis of SI.

- How does care based on an 8-week SICP affect UI frequency?
- How does care based on an 8-week SICP affect UI quantity?
- How does care based on an 8-week SICP affect quality of life?
- How does care based on an 8-week SICP affect perceived pelvic muscle self-efficacy?

Star point 2: evidence summary. This stage consists of compiling a useful comparison of findings.⁵ The authors carried out a keyword search of several databases using the search terms “stress urinary incontinence,” “female,” “nurse,” “pelvic floor muscle exercises,” “conservative treatment,” “guidelines,” and “protocol.” The search retrieved a total of 933 studies (PubMed: n = 143; Cochrane Library: n = 8; Google Scholar: n = 291; CINAHL: n = 75; OVID: n = 189; Medline: n = 169; and Science Direct: n = 58). Duplicates (n = 65), publications that were not available in full text (n = 158), publications that were not in English or Turkish (n = 13), and descriptive studies (n = 686) were not included in the review. Guidelines, systematic compilations, and meta-analyses with a high level of evidence published in national and international journals between 2000 and 2016 were included. This left 11 publications: 6 systematic reviews, 1 scoping review, 1 meta-analysis, and 3 sets of guidelines to be used in developing the SICP.

Star point 3: translation to guidelines. This step covers the integration of evidence into practice. In this process, clinical practical guidelines, care standards, clinical paths, protocols, and algorithms can be created.^{18,19} The current study addressed the task of developing the SICP ([Table 1](#)).

Star point 4: practice integration. This stage covers putting evidence into practice.^{18,19} The authors used a panel of 11 experts (3 physicians, 4 faculty members in nursing, 3 nurses with graduate degrees who had specialized in incontinence, and 1 expert in Turkish language and literature) to evaluate the content validity of the SICP. The experts assessed the care protocol on the basis of a 4-point Likert-type of scale where: 1 = not suitable; 2 = a little suitable, needs revisions in the procedural step; 3 = considerably suitable, needs minor changes in the procedural step; and 4 = very suitable. The content validity ratio of each item was calculated in the 11 experts' evaluation. The content validity index was 91.9%.

The content validity of the training booklet ([Table 2](#)) prepared according to the SICP was verified by the 11 experts and its content validity index was 89%. The result of the analysis of the training booklet "Evaluation of Compliance of Printed Materials"²⁵ was 25.61 ± 1.66 , indicating a high level of readability. The form used to assess the suitability of the printed materials was composed of 6 sections and 27 questions. In the assessment, 1 point was given for a "yes" and 0 points for a "no." The total score was assessed as a number between 1 and 27. The higher the score on the form, the higher the readability of the materials.²⁵ The reliability and information quality of the printed training material was evaluated by using the DISCERN instrument.²⁶ The DISCERN total mean score was 67.15 ± 6.98 . DISCERN consists of 3 sections and 16 questions. The scale is a 5-point Likert-type instrument; the first 15 questions were marked as "yes," "partially," and "no." The total score was assessed to be a number between 15 and 75. Lower scores indicate lower quality.²⁶ Finally, the readability of the booklet was evaluated using the Flesch formula, which showed a score of 73, indicating that the booklet was easy to read.²⁷

Star point 5: process, outcome evaluation. The last stage of the Star model is an evaluation of evidence-based practice including patient outcomes, personnel and patient satisfaction, efficiency, effectiveness, economic analysis, and impact on health conditions.¹⁸

Outcomes study methods. The outcomes evaluation was completed using a pretest-posttest control group experimental design. Care was provided according to a protocol developed using the Star model. Study procedures were reviewed and approved by Kirikkale University's Medical Ethics Committee (approval no. 16/01, dated July 6, 2016).

The study was conducted in the urology polyclinic of a university hospital in Turkey from December 2016 to January 2018. Inclusion criteria were being female and 18 years of age or older and literate, having an initial diagnosis of SI and no sensory disorder affecting communication, and agreeing to participate in the research. Patients who were pregnant, had a urinary tract infection, or had a history of SI treatment were excluded from the study. Exclusion criteria were nonadherence to the protocol, being unable to contact the participant for follow-up, and the participant's desire to withdraw from the study.

Participants that matched the sample criteria were recruited into the study. After their consent was obtained, they were randomized into an intervention and a control group. Randomization was achieved by assigning the first participant applying to the polyclinic to the intervention group and the next participant to the control group, continuing alternately in this way.

The researcher provided the intervention group with care according to the SICP. The hospital's routine care protocol was provided to the control group. The intervention group was regularly monitored for the 8-week duration of the study.

At baseline, participants completed the patient characteristics form, the King's Health Questionnaire (KHQ), and the Broome Pelvic Muscle Exercise Self-Efficacy Scale (Broome PMSES) and performed a 1-hour pad test. Participants were then given a 3-day voiding diary and instructions for completion of the diary at home. All participants completed the KHQ, Broome PMSES, 1-hour pad test, and voiding diary again immediately after the 8-week intervention period (postintervention assessment) and then 4 weeks later (follow-up assessment). The participants were given appointments by telephone, and face-to-face interviews were conducted (weeks 8 and 12). The participants (intervention group and control group) were offered counseling services throughout the 8-week period by telephone every week. The control group received standard care (eg, daily routine SI management in the institution) but no other interventions or educational materials during the 8-week study period. After the end of the study, the researcher provided the control group with education and gave them the booklet.

The researcher provided the intervention group with care in accordance with the SICP ([Table 2](#)). One of the researchers gave each participant one-on-one education in line with the SICP as well as the booklet prepared according to the SICP. The participants were interviewed by telephone in each of the first 8 weeks and were offered counseling within the scope of SICP; they were then reevaluated at the end of the 8 weeks (postintervention). No intervention was carried out from the eighth to the twelfth weeks.

Data collection. Research data were collected using paper and pencil. The participants who consented to join the study and fulfilled the inclusion criteria were provided with information about the research. After their written and verbal consent was obtained, they were asked to fill out the data collection tools. The researcher was present to answer any questions the participants had during the data collection. When a participant could not read a particular part of the form, the researcher

read the question aloud. Completion of all forms took approximately 20 to 30 minutes. The data collection procedures were designed to preserve the privacy of the participants. The interviews took place in a quiet and private room. Confidentiality was maintained, and only the researchers had access to the data.

Patient characteristics form. The participants completed the demographic and health questionnaire.^{17,21,28} The descriptive characteristics form contained data on the patient's age body mass index, number of births, type of delivery, episiotomy, menopause, and the duration of incontinence.

KHQ. This 32-item tool measures quality of life. Scores range from zero to 100, with low scores indicating good quality of life.²⁹ Cronbach's alpha for the subscale ranges from 0.72 to 0.89.³⁰ In the current sample, Cronbach's alpha for the subscales ranged from 0.72 to 0.82.

Broome PMSES. This instrument was developed to measure perceived self-efficacy in PFM exercises. It consists of 23 items organized in 2 subscales. The total score ranges from zero to 100, and scores are classified as follows: ≤ 32 points, low self-efficacy; 33 to 55 points, medium self-efficacy; and ≥ 56 points, high self-efficacy.³¹ The scale has a Cronbach's alpha of 0.95.³² In the current sample, the Cronbach's alpha was 0.94.

Three-day voiding diary. This is a semi-objective tool used to record voiding frequency, amount of urine, amount and type of liquid intake, incontinence frequency, and frequency of pad-changing.²¹

One-hour pad test. This test provides an objective measure of the quantity of urine leakage in a 1-hour period. Before the test, the dry pad is weighed using precision scales; this weight is deducted from the wet weight to give the weight of leaked urine.³³ The participant is given the pre-weighed pad, asked to drink 500 mL water, and to rest in a seated position for 30 minutes. During the following 30 minutes, the participant stands up and sits down 10 times, coughs 10 times, runs in place for 1 minute, bends to pick something up from the floor 5 times, and then climbs a flight of stairs. The pad is taken from the participant and re-weighed on the same precision scales. The weight of the dry pad is deducted from the weight of the wet pad, and the weight of urine is recorded.

Data analysis. Data were analyzed using the SPSS Statistics Standard Pack v21 (IBM). The databases and the analysis were checked by 2 researchers. Descriptive statistics (means, standard deviations, frequencies, and percentages) were calculated. Group differences (intervention group and control group) were assessed with the chi-square test, Fisher's exact test, Friedman's 2-way analysis of variance, and the Mann-Whitney test. The statistical significance level was accepted as $P < .05$.

Results

A total of 83 participants were enrolled in the study ([Figure 2](#)). Of those, 4 did not meet the inclusion criteria and 3 declined to participate. During the implementation of the study, 4 patients were excluded from the intervention group (1 had a change of address, 2 missed the follow-up visits, and 1 could not be reached by telephone). Four (4) control group participants were excluded from the study (3 because they missed their follow-up appointments and 1 because of being unavailable by telephone). The Power Analysis and Sample Size (PASS) program revealed a total of 68 participants in the final sample (34 in the intervention and 34 in the control groups), sample size at a power of 0.90, and margin of error of 0.05.

There was no statistical difference between the groups with respect to level of education level, marital status, and body mass index, and the groups were distributed with homogeneity of variance ($P > .05$) ([Table 3](#)).

The diary data indicated a reduction in the number of incontinence episodes per day in the intervention group at baseline, 8 weeks, and 12 weeks (4.38 ± 1.86 , 1.15 ± 1.16 , and 1.21 ± 0.64 , respectively) compared with the control group (3.76 ± 1.71 , 3.59 ± 1.33 , and 3.35 ± 1.41 , respectively) ($P = .001$; [Table 4](#)). Quantity of urine leakage (as measured by the pad test) also decreased in the intervention group at baseline, 8 weeks, and 12 weeks (9.87 ± 4.0 , 1.23 ± 0.94 , and 1.49 ± 0.91) compared with the control group (8.79 ± 3.42 , 8.96 ± 3.32 , and 8.93 ± 3.4 , respectively) ($P = .001$; [Table 4](#)).

There was a significant increase in the efficacy expectation mean scores in the intervention group at baseline, 8 weeks, and 12 weeks (50.84 ± 9.08 , 67.88 ± 7.28 , and 60.29 ± 5.48 , respectively) ($P = .001$; [Table 5](#)). A significant increase also was seen in the outcome expectation mean scores of the intervention group at baseline, 8 weeks, and 12 weeks (54.41 ± 10.12 , 76.11 ± 5.31 , and 72.42 ± 5.37 , respectively) ($P = .001$; [Table 5](#)). In the evaluation of the Broome PMSES mean scores, a significant increase also was seen in the intervention group (52.24 ± 8.71 , 71.1 ± 5.83 , and 65.04 ± 4.69 , respectively) ($P = .001$; [Table 5](#)).

The intervention group showed decreases in pad usage at baseline, 8 weeks, and 12 weeks (73.5%, 38.2%, and 41.2%, respectively) compared with the control groups (82.4% for all 3 measurements) (both $P < .05$, [Table 6](#)). A significant increase was observed in the intervention group in terms of sports activity (26.5%, 52.9%, and 50%, respectively) and daily liquid

intake (1.71 ± 0.9 , 1.75 ± 0.7 , and 1.66 ± 0.7 , respectively) ($P < .05$, [Table 6](#)). These data show that the SICP was effective in decreasing pad usage while increasing exercising and daily liquid intake.

Finally, at baseline, 8 weeks, and 12 weeks, the intervention group showed reductions in KHQ scores for perceived impact of incontinence (51.47 ± 17.34 , 47.79 ± 12.86 , and 49.26 ± 7.50 , respectively), role limitations (58.82 ± 14.35 , 31.37 ± 7.96 , and 34.31 ± 5.72 , respectively), physical limitations (53.43 ± 12.83 , 29.41 ± 9.23 , and 34.31 ± 10 , respectively), social limitations (52.61 ± 15.79 , 29.41 ± 13.08 , and 34.31 ± 12.94 , respectively), relationships (20.11 ± 24.95 , 14.94 ± 14.33 , and 13.89 ± 9.87 , respectively), emotions (58.17 ± 13.14 , 36.93 ± 12.75 , and 40.2 ± 12.54 , respectively), sleep/energy (35.29 ± 23.49 , 17.65 ± 3.98 , and 18.63 ± 6.82 , respectively), and severity measures (59.8 ± 11.14 , 37.99 ± 7.45 , and 37.99 ± 7.16 , respectively) at the postintervention assessment (all $P < .001$; [Figure 3](#)). The perceived general health score was similar in the intervention group and in the control group ($P = .958$; [Figure 3](#)).

Discussion

Providing standard nursing care is important in the conservative treatment of SI. The purpose of this study was to develop an SICP based on the Star model and to determine the effect of this on the frequency of incontinence and amount of urine voided, quality of life, and pelvic muscle self-efficacy levels. Next, a pretest-posttest study was carried out to examine the effect of the care protocol based on the Star model on UI frequency, UI quantity, quality of life, and pelvic muscle self-efficacy levels in 34 women with SI. The control group also included 34 women, and there were no significant demographic characteristics or medical history differences between the 2 groups. In the intervention group, but not in the control group, there was a statistically significant difference between UI quantity and frequency after postintervention and follow-up assessments. This was similar to the prospective formative evaluation study by Sampsel et al,⁸ which tested an evidence-based protocol for UI in 132 women and showed that conservative treatment reduced incontinence frequency and quantity by the end of the fourth month of training. After training, participants reported that their incontinence was less disruptive and they were able to perform their everyday activities more easily, thus demonstrating the efficacy of the evidence-based care protocol.⁸ Similarly, a randomized controlled pilot study in Brazil (group treatment = 17; individual treatment $n = 17$; control group $n = 15$) by Pereira et al³⁴ reported reduced incontinence quantity at the end of the sixth week in 2 treatment groups relative to the control group.

Although no significant difference was seen between the quality of life subscales and general health ($P < .05$) in the current study, it was noted that in the postintervention and follow-up assessments, there were significant decreases in the intervention group compared with the control group in terms of perceived impact of incontinence, role limitations, physical limitations, social limitations, relationships, emotions, sleep/energy, and severity of symptoms mean scores according to the SICP ($P < .05$) ([Figure 3](#)). This is similar to what was found in a randomized controlled study by Pereira et al³⁴ that compared a control group ($n = 15$) with group ($n = 17$) and individual ($n = 15$) PFM training. Those authors found that quality of life improved in both intervention groups relative to the control group, but there was no group difference in perceived general health. A randomized controlled study in which PFM exercises were offered to females with SI in group ($n = 20$) or individual ($n = 20$) formats also reported that quality of life improved in both intervention groups.³⁵ It is also reported in the literature that regular PFM exercise leads to improvement in PFM function and has a positive impact on continence.⁴

The current study showed that in the baseline measurements of perceived self-efficacy in PFM exercises in the control and intervention groups, the mean scores of the intervention group were higher than in the control group and the difference was significant ($P < .05$) ([Table 5](#)). This result indicates that the pelvic muscle self-efficacy levels of the intervention group was higher. The measurement of perceived self-efficacy in PFM exercises is important in that it provides significant information on the motivation and belief of the individual regarding the effectiveness of this intervention. A randomized controlled trial in Japan with 48 females with SI by Kim³⁶ reported that PFM training and telephone counseling increased self-efficacy. The same study also reported that telephone counseling encouraged patients to continue with PFM exercises and thus reduces symptoms.³⁶ In a single-group efficacy trial of quasi-experimental design by Cera et al,³⁷ it was reported that a nurse practitioner-led continence education program with 28 women resulted in an increase in the Broome PMSES score. The same study also demonstrated that self-efficacy increased when a strong focus was placed on variable risk factors and behavioral therapy and when the anatomy of FMSs were explained in detail.³⁷ In this study, participants were called once a week during the 8-week intervention period to encourage them to perform the exercises as recommended; this improved compliance with the protocol and increased self-efficacy, demonstrating the utility of the education provided in line with the SICP.

A lifestyle change related to incontinence involves identifying habits, changing negative behaviors, and recovering PFM control.²² Participants in the current study achieved changes in lifestyle (smoking, pad usage, participation in sports, liquid intake) through the training offered under the SICP ([Table 6](#)). In smokers, severe coughing may be detrimental to the urethral sphincter mechanism and to supporting pelvic structures.²³ In a cross-sectional study by Danforth et al³⁸ ($n = 83$ 355 women), it was reported that the risk of urinary leakage increased in those who smoked compared with those who did not smoke. In a randomized controlled study in Canada (intervention group = 210; control group = 211), Borrie et

al²⁸ determined that when interventions related to lifestyle were carried out, a statistically significant decrease was seen in the use of pads at the end of 25 weeks. This study is consistent with our own research. Danforth et al³⁹ reported in their prospective analysis (n = 2355 older women) that low-impact physical activity was correlated with a decrease in urinary incontinence. Women who tend to avoid exercise due to urinary incontinence should be informed that low-impact exercise does not raise the risk of developing incontinence and should be supported in their exercising efforts.³⁹

The results presented in this article show that a nurse-led SICP treatment protocol for women that was based on the Star model reduced incontinence frequency and quantity, improved PFM self-efficacy, and enhanced quality of life, thus demonstrating the effectiveness of the SICP. These results also confirm previous reports about the effectiveness of PFM exercises and changes in lifestyle and that they should be recommended as first-line treatment for women with urinary incontinence.

Limitations

This study has several limitations. First, the study was conducted at the urology polyclinic of only 1 university hospital in Turkey. Second, it was carried out with a small sample size and there was no follow-up after the 12-week assessment. Third, the study included only women with SI; mixed and urge incontinence were not assessed.

Conclusions

An SICP was developed based on the Star model and was submitted to 11 experts for their views in terms of content validity; the content validity index was determined to be 91.9%. Next, a pretest-posttest controlled clinical study was conducted to examine the effect of the care protocol on UI frequency, UI quantity, quality of life, and pelvic muscle self-efficacy levels in 68 women with SI. After 8 weeks, incontinence frequency and quantity significantly decreased in the intervention group (n = 34). Although no statistically significant difference was found between the quality of life subscales and the perception of general health in the intervention group, significant improvements were seen in the impact of incontinence, role limitations, physical limitations, social limitations, personal relationships, emotional status, sleep/energy levels, and severity of symptoms. The nurse-led SICP also led to positive changes in the lifestyles of the participants (eg, pad usage, participation in sports, and liquid intake). The results of this study show that a care protocol based on the Star model was effective as a first-line treatment for women with UI and confirm the effectiveness of nurse-led interventions in the care of women with stress UI.

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Potential Conflicts of Interest

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