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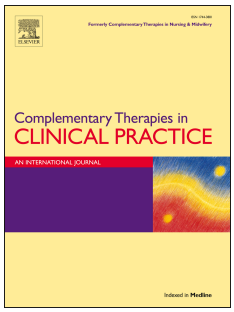

The effects of training and the use of cranberry capsule in preventing urinary tract infections after urostomy

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TITLE: The Effects of Training and the Use of Cranberry Capsule in Preventing Urinary Tract Infections After Urostomy

RUNNİNG TITLE: The Effect of Cranberry on Urınary Tract Infectıons

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We have no conflicts of interest on the subject and during the process of the paper.

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The authors have nothing to disclose.

1.Introduction

Urinary diversion is a surgical procedure that reroutes the normal flow of urine out of the body when urine flow is blocked. Urine flow may be blocked because of an enlarged prostate, injury to the urethra, birth defects of the urinary tract, kidney, or ureter, bladder stones, tumours of the genitourinary tract (i.e., the urinary tract and reproductive organs) or adjacent tissues and organs, and conditions causing external pressure to the urethra or one or both ureters. Parts of the gastrointestinal tract are frequently used in these interventions [1, 2]. However, when a part of the gastrointestinal tract is used for the urinary diversion, one not only encounters problems related to the part's involvement with the urinary system, but also problems related to the part's separation from the gastrointestinal system. There are many methods for diversion that have been tested to minimise these problems. Today, the most common parts of the gastrointestinal tract used for urinary diversions are the terminal ileum and ileocolonic region [3,4].

The principal methods of urinary diversion entail fashioning a segment of intestine into a conduit or reservoir to which the ureters are anastomosed. Cutaneous ureterostomy is performed only in patients who undergo total cystectomy and only when the use of intestinal segments is not possible. The procedure is performed by anastomosing the ureters directly to the anterior abdominal wall. Stomal stenosis, subsequent urinary tract infection, and compromise of renal function are the most frequent complications and limit the use of this technique [5].

Ileal conduit diversion, in this commonly performed procedure, a 15- to 20-cm-long ileal segment is isolated, and the ureters are implanted at its proximal end. A 10- to 15-cm-long ileal segment proximal to the ileocecal junction is preserved to maintain adequate absorption of bile salts, vitamin B12, and fat-soluble vitamins [6].

The most important cause of morbidity and mortality in patients in whom a urostomy was created is complications related to bacterial contamination [7]. When the intestine is anastomosed to the urinary tract, local bacterial growth is facilitated, and these bacteria serve as a source for systemic spread [2].

Nazmy et al. assessed the early and late term complications after urinary diversions and found that 16.4% of the patients with ileal conduits develop urinary tract infections [8]. In their prospective study, Madersbacher et al. reported urinary tract infections including pyelonephritis in 23% of the 423 patients with ileal conduit [9].

Cranberry is called “red gold” by the natives of North America, and it has been used in herbology as a medicine for urinary tract infections, and as a food for many years. The antibacterial effect of cranberries on the urinary system was first reported in 1923 by Blatherwick and Long, and this effect was attributed the increased urinary acidification [10]. With the anthocyanidins and proanthocyanidin it contains, the cranberry blocks the type 1 and p-fimbriae of the urinary pathogens to attach to the uroepithelium in the bladder wall. Also, it maintains the acidification of urine by increasing hippuric acid excretion [11] and has a bacteriostatic effect [12]. In vitro and ex vivo studies supported that cranberry products prevented urinary tract infections by blocking the microorganisms from attaching to the walls of the urinary tract [13,14].

There are many studies in the literature regarding the subject of the use of cranberry products in the prevention of urinary tract infections in middle aged women, young adults, patients with recurrent urinary tract infections, and patients with neurogenic bladder [15-18]. However, studies regarding the use of cranberry to treat upper urinary tract infections are limited.

Despite the prevalent studies about preventing and treating hospital-related or catheter-related urinary tract infections, the number of studies regarding the prevention of late term urinary tract infections in patients who were discharged after a urological intervention is quite small, if any.

In the light of these data, the present study was conducted to investigate the effects of training provided by researcher and the use of cranberry capsule in preventing late term urinary tract infections after urostomy.

Hypotheses of the Study

H1: The rate of urinary tract infections will be significantly lower in the group that uses cranberry capsules than in the control group.

H2: The rate of urinary tract infections will be significantly lower in the group that received training than in the control group.

H3: The rate of urinary tract infections will be significantly lower in the group that uses cranberry capsules than in the group that received training.

2. Methods

2.1. Study design and subjects

The study was conducted as a randomised controlled experimental study to investigate the effects of training provided by the researcher and the use of cranberry capsules in preventing late term urinary tract infections after urostomy. Five percent of Type 1 errors and 20% of Type 2 errors were assumed in order to find a meaningful two-unit difference between the effects of both cranberry capsule and training on urinary tract infection on a scale of four-unit standard deviation. The sample size was found to be 20 for each group using power analysis. During data collection, a total of 87 patients were reached; however, 13 patients left the use of a cranberry capsule, 14 patients did not agree to participate in the study. The study included 60 patients with urostomy who underwent ileal conduit diversion in the urology clinic of a training and research hospital in Istanbul between June 2013 and November 2014. Patients who were 18 years or older, underwent ileal conduit diversion, and were conscious, cooperative, and fully oriented were included in the study. Patients who had a urinary tract infection, pregnant women, patients with irritable bowel syndrome (due to possible diarrhea), diabetes (due to high sugar content of cranberry capsule), rheumatoid arthritis (acidic cranberry may intensify joint pain), and patients who were taking antibiotics or on warfarin treatment (due to the possible interaction with cranberry capsule) were excluded.

The two most common forms of cranberry that have been studied are juice and capsules/tablets containing concentrated amounts of proanthocyanidins. Commercially available cranberry beverages should include a product that contains 100% pure cranberry juice with no additives or other ingredients. The other form of cranberry that may be used to prevent UTI is non-prescription cranberry capsules/tablets, which contain concentrated proanthocyanidins. Jepson, Williams and Craig reported that most studies of other cranberry products (tablets and capsules) did not report how much of the 'active' ingredient the product contained, and therefore the products may not have had enough potency to be effective. In addition, they reported that many studies reported low compliance and high

withdrawal/dropout problems which they attributed to palatability/acceptability of the products, primarily the cranberry juice [19]. Cranberry beverages should include a product that contains 100% pure cranberry juice are not sold in Turkey. In this study, cranberry capsule was used. A capsule contains 400 mg cranberry, with 1.8% proanthocyanidins (9 mg).

In the literature, it is reported that withdrawal rates have been quite high (up to 55%), suggesting that these products may not be acceptable over long periods. Adverse events include gastrointestinal intolerance, weight gain and drug-cranberry interactions [20]. In addition, patients reported that they did not want to use the cranberry capsule for a long time. For these reasons, the study was conducted for 3 months.

Urine (pH, leukocyte-WBC and culture) and blood (C Reactive Protein) samples were taken from the patients. A urine culture was considered to be positive when there were 10^5 CFU/mL or more bacteria, with no more than two species of organisms present. Laboratory analysis results were evaluated by the same urologist for each patient.

2.2. Interventions

Patients who fulfilled the inclusion criteria were sorted into three groups: the group that used cranberry capsule (20 patients), the group that received training about preventing urinary tract infections (20 patients), and the control group (20 patients). To avoid bias while grouping, a randomisation list was generated using a software program (https://www.random.org/lists/).

The group that used cranberry capsules (Experiment 1): Patients were given three boxes of cranberry capsules, and were instructed to use one box of capsules each month starting from 1 month after discharge to prevent urinary tract infections. Patients used the cranberry capsule twice (before breakfast and dinner) a day for 3 months. Starting from 1 month after discharge, patients received a phone call from the researcher once a week and were questioned about any possible side effects of the cranberry capsule and the presence of signs of urinary tract infection. The confidence of the patients in the experimental group to use the cranberry capsule is based on the verbal expressions of the patients. The patients were assessed for a urinary tract infections by laboratory analysis at 2, 3, and 4 months after discharge.

The group that received training and written information about urinary tract infections (Experiment 2): Patients received verbal information from the researcher at the appropriate time and place about urinary tract infections, and they were also given informational brochures that could be taken home and used later. Starting from 1 month after discharge, the patients received a phone call from the researcher once a week and were questioned about the presence of signs of urinary tract infections. The state of urinary tract infections was assessed by the researcher using laboratory analysis at 2, 3, and 4 months after discharge.

The control group: No intervention was made for the patients in the control group. Starting from 1 month after discharge, the patients received a phone call from the researcher once a week and were questioned about the presence of signs of urinary tract infections. The state of urinary tract infections was assessed by the researcher using laboratory analysis at 2, 3, and 4 months after discharge.

The data acquired were recorded by the researcher on the data collection form, which is composed of three sections. Descriptive characteristics of the patients were acquired from the patient, the patient's relative, the patient file, and healthcare workers and recorded in the first section. Data about the patient's history of urinary tract infections were recorded in the second section. Laboratory findings that assist in the diagnosis of urinary tract infection and physical signs of urinary tract infection were recorded in the third section.

2.3. Statistical Analysis

Data were analysed using the Statistical Package for the Social Sciences for Windows 11.5 (SPSS, Chicago, IL). Number, percentage, mean, and standard deviation were used for descriptive statistics. Chi-square analysis *(Pearson)* was used to compare the similarity/homogeneity of the groups in terms of descriptive statistics. The differences in pain scores and body temperature scores, which are the signs of urinary tract infection, between groups were assessed using Kruskal-Wallis analysis. The differences between the distributions of other signs of urinary tract infection were assessed with chi-square analysis *(Pearson)*, whereas repetitive measurements were assessed by variance analysis. The effect of intervention on the prevention of urinary tract infections was assessed with Kaplan-Meier analysis. The results were evaluated within a 95% confidence interval, and $p<0.05$ was considered statistically significant.

2.4. Ethical considerations

The study was approved by the Istanbul University Cerrahpasa Medical faculty ethical board (reference no. 83045809/14490). Participants were informed about the study, and oral consent was obtained.

2.5. Limitations

The technique applied by the surgeon performing the surgical procedure with his or her individual skill and experience can affect the development of urinary tract infections after opening the urostomy. The confidence of the patients in the experimental group to use the cranberry capsule is based on the verbal expressions of the patients.

3. Results

The mean age of the patients participating in this study was 63.83±4.72. Of these, 68.3% were men and 60% were married. An education level of primary school degree was achieved by 48.3%. In the group, 66.7% were unemployed or retired. Seventy-five percent of patients had a diagnosis of either bladder or prostate cancer, and 68.3% of the patients had a history of urinary tract infection before the urostomy operation. The groups were similar when compared in terms of descriptive characteristics.

When the distributions of changes in the mean body temperatures according to evaluation periods in experiment and control groups were analysed, there was no statistically significant difference between the three groups ($p>0.05$, Table 1).

When the distributions of changes in the mean flank pain scores according to evaluation periods in the experiment and control groups were analysed, there was no significant difference between the groups at 5 to 8 weeks and at 9 to 12 weeks ($p>0.05$, Figure 2). On the other hand, there was a statistically significant difference between the groups at 13to -16 weeks ($p<0.05$, Figure 2). Further analysis was performed to determine the source of the difference. The pain score of the patients in the control group at 13 to16 weeks was significantly higher than for patients in the experiment groups ($p<0.05$, Figure 2).

When the distributions of changes in the mean urine pH according to evaluation periods in the experiment and control groups were analysed, there were no significant differences between the groups at 2 and 4 months ($p>0.05$); whereas, a statistically significant difference was observed at 3 months ($p<0.05$, Figure 3). Further analysis aimed at finding the cause of the difference showed that the urine pH of the patients in the control group was significantly higher than the subjects at 3 months. The urine pH of the patients who received training was also significantly higher than that of the patients who used cranberry capsules ($p<0.05$, Figure 3).

When the distributions of changes in the mean white blood cell count and C-reactive protein (CRP) values according to evaluation periods in the experiment and control groups were analysed, no significant difference was observed between the groups at 2, 3, or 4 months ($p>0.05$. Table 2).

As a result of the log rank analysis, the interventions (cranberry/training/control) were found to have a significant impact on the period of time passed without a urinary tract infection ($p= 0.03$, Table 3). To find the source of the significance, the interventions were compared in pairs. The use of cranberry capsules was the only intervention found to significantly affect the period of time passed without a urinary tract infection ($p= 0.01$).

The microorganism causing the urinary tract infection was *E. coli* in 1 patient in the experiment group that used cranberry capsules, two patients in the training group, and 4 patients in the control group (Table 4).

4. Discussion

There are many studies investigating the use of cranberry on the prevention of urinary tract infection, which cause serious discomfort and perception of losing kidney function in patients, lowering their quality of life [21-23]. Despite numerous studies, the Cochrane meta-analysis reports that due to the heterogeneity of cranberry and lack of consensus on the dosage and type to be used, cranberries are not recommended in routine use in either the prevention or the treatment of urinary tract infection [24].

In their study, Foxman et al. found that 64% of the patients in the cranberry group and 63% of the control patients had a history of urinary tract infections [23]. Another study reported that 70.7% of the patients in the cranberry group and 68.2% of the patients in the

control group had no history of urinary tract infections [25]. In the current study, 75% of the patients in the experiment who used cranberry capsules, 70% of the patients in the experiment group that received training, and 60% of the control patients had a history of urinary tract infection before the surgical intervention. The difference was statistically significant ($p>0.05$).

Increased body temperature, flank pain, lumbar pain, leukocytosis, and increased CRP and erythrocyte sedimentation rate accompanies uncomplicated urinary tract infection. However, the results of the urine culture are significant for the urinary tract infection diagnosis in patients with urinary diversion as well as these parameters [26].

Mano et al. conducted their study with 79 patients who had orthotopic neobladder and found that the estimated cumulative incidence of symptomatic urinary tract infection at 3, 6, and 12 months was 34%, 40%, and 43%, respectively. The rate of symptomatic urinary tract infection was 36% in the first 3 months, 10% in months 3 to -6, and 8% in months 6 to 12 [27]. Nazmy et al. reported that 16.4% of the 62 patients with ileal conduit developed urinary tract infection [8]. In their study regarding the effect of cranberry on preventing urinary tract infection, Mathison et al. found that blood parameters of the patients in the cranberry group were lower than those of the control group, but the difference was not statistically significant [28]. Cowan et al. investigated the effect of cranberry on preventing urinary tract infection in patients receiving radiation therapy for bladder cancer. The researchers followed the patients for 9 weeks and stated that the signs and symptoms of urinary tract infections were less frequently observed in the group that used cranberry [29].

When we analysed the signs and symptoms of urinary tract infections in the experiment and control groups, there was no statistically significant difference between groups (experiment and control) in terms of body temperature, white blood cell count, and CRP levels ($p>0.05$) (Tables 1 and 2). However, flank pain and urine pH levels showed significant difference ($p<0.05$). The pain score of the control patients at 13 to 16 weeks was significantly higher than the pain scores of the patients in the experiment groups (cranberry capsule and training) ($p<0.05$, Figure 1). Urine pH levels of the control patients at 3 months was significantly higher than the patients in the experiment groups (cranberry capsule and training); and the urine pH of the patients who received training was significantly higher than that of the patients who used cranberry capsules ($p<0.05$, Figure 2). The urine pH of the patients who used cranberry capsules was lower than those of the remaining two groups.

Quinic acid, which is a component of cranberry, has a bacteriostatic effect. It transforms in to hippuric acid, which makes the urine acidic, and is excreted with urine. This metabolism underlies the effect of cranberries on preventing urinary tract infections. Our results show that lower urine pH with cranberry supports this literature fact.

A meta-analysis recommends the use of cranberry products for preventing recurrent urinary tract infections in middle-aged women and young adults. However, due to the heterogeneity of cranberry and lack of consensus on the dosage and type to be used, cranberries are not recommended in routine use for urinary tract infections [24].

In a 2008 double-blind, placebo-controlled study that included 47 patients with spinal cord injury, the use of cranberry tablets was found to have an important preventive effect on urinary tract infections, and it decreased the incidence of urinary tract infections from 1 per year to 0.3 per year [30]. In their study with women aged 50 years or older who had acute uncomplicated cystitis, Takashi et al. found a 29.1% urinary tract infection rate in the cranberry group and a 49.2% rate in the placebo group. The difference was statistically significant [31].

In this study, patients with ileal conduit were provided with cranberry capsules to be used twice daily for three months after discharge. Only one patient in the cranberry group (5%) and 8 patients (40%) in the control group developed urinary tract infections, and the difference was significant (Table 3). This result **that supported the H1 hypothesis** is consistent with previous studies and indicates that the use of cranberry capsules prevents urinary tract infections.

Providing training brochures to individuals with stoma to educate and guide regarding urinary tract infection prevention in the post-discharge period is essential and is one of the methods that aids learning [32,33]. In preventing catheter-related urinary tract infections, Wu et al. reported that training programs that include emptying the urine, hygiene, and care skills decrease urinary tract infections [34]. Gonzalez-Chamorro et al. stated that increasing oral fluid intake, cleaning, avoiding complications, and prophylactic antibiotic use are effective in preventing urinary tract infections in the elderly [35]. Fox et al. implemented the hand hygiene protocol to prevent urinary tract infections and found that the infection rates were decreased at the end of 12 months [36]. Different studies concluded that the use of antibiotics

to prevent and treat urinary tract infections decreases with training and the use of clinical guides [37,38]. Howe and Adams reported that training is essential in preventing urinary tract infections in patients with a catheter, but is not sufficient by itself [39].

In the current study, only 3 patients (15%) in the group that received training developed urinary tract infections, and there was no statistically significant difference between this group and the control group ($p>0.05$, Table 3). This result, **refutes the H2 hypothesis**, and supports Howe and Adams' standpoint that training alone is not effective in preventing urinary tract infections [39].

In this study, although there was a slight quantitative difference in favour of the group that used cranberry capsules, this difference was not statistically significant (Table 3). Therefore, the **H3 hypothesis was not reached.**

As a routine practice, antibiotic treatment is administered for the first 10 days after an ileal conduit is created. During this period, the urine and mucus is colonised by gram positive cocci, and as the antibiotic therapy is completed, gram negative microorganisms (*E. coli*, *Pseudomonas*, and *Klebsiella*) indwell the flora [17]. Mano et al. reported that urine cultures of 13% of the patients with urinary diversion were positive for *E. coli* [27]. Foxman et al. also found that *E. coli* caused urinary tract infection [23]. When we assessed the urine culture results in this study, *E. coli* was the infectious agent in all patients who developed urinary tract infections (Table 4). This result is consistent with and supportive of the literature data and previous study findings.

5. Conclusion

In conclusion, we found in this study that unsystematic informing and planned training by themselves are not effective in preventing late-term urinary tract infections after urostomy; whereas, the use of cranberry capsules was effective. Cranberry capsule/juice may be recommended to avoid urinary infections in patients with urostomy. However, since there is no consensus on the dose to be used, further studies with larger sample sizes and longer follow-up should be planned. Protocols related to the form, dosage, and duration of use of cranberry should be constructed inlight of these research findings.

Despite the numerous studies that assess the effect of cranberry on preventing lower urinary tract infections, the number of studies that investigate the effect of cranberry on

preventing upper urinary tract infections is limited. Future studies in this direction are recommended.

Because the number of studies that assess the effect of training on preventing upper urinary tract infections after urostomy is limited, planning novel studies and creating written brochures to be used in clinics in the light of these research findings are recommended.

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Table 1: Comparison of Mean Body Temperatures in Patients in Experiment and Control Groups (n=60)

Mean Body Temperature								
Evaluation period	**Exp 1(n=20)**		**Exp 2 (n=20)**		**Control (n=20)**			
	X	**±SS**	**X**	**±SS**	**X**	**±SS**	**KW***	**p**
Between 5th and 8th weeks[a]	36.50	0.21	36.46	0.22	36.49	0.24	0.215	0.898
Between 9th and 12th weeks[b]	36.59	0.27	36.57	0.29	36.78	0.38	3.004	0.223
Between 13th and 16th weeks[c]	36.47	0.22	36.51	0.36	36.68	0.43	3.261	0.196
***F**/ p (sd:2)*	***3.882***	***p:0.04***	***1.275***	***p:0.30***	***4.795***	***p:0.02***		
Significant difference	**b>c**				**b>a**			

*Kruskal-Wallis analysis **One-way variance analysis was used for repetitive measurements

Table 2: Comparison of Mean White Blood Cell Count and CRP Values in Patients in Experiment and Control Groups

Measurement time	**Exp1[1](n=20)**		**Exp2[2](n=20)**		**Control[3](n=20)**				
	X	**±SS**	**X**	**±SS**	**X**	**±SS**	**KW***	**P**	**Significant difference**
White blood cell count									
2nd month after discharge[a]	2.55	0.51	2.40	0.50	2.65	0.48	2.502	0.286	
3rd month after discharge[b]	2.70	0.47	3.20	2.04	3.35	1.63	2.663	0.264	
4th month after discharge[c]	3.00	1.52	3.20	1.90	4.50	2.62	4.394	0.111	
***F**/ p (sd:2)*	***1.662***	***p:0.218***	***2.905***	***p:0.08***	***5.567***	***p:0.01***			
Significant difference						**c>a**			
CRP Values									
2nd month after discharge[a]	3.40	0.50	3.60	0.59	3.50	0.51	1.151	0.562	
3rd month after discharge[b]	3.35	0.58	5.26	5.28	5.61	7.49	2.394	0.302	
4th month after discharge[c]	3.72	3.75	4.65	5.17	10.18	10.75	5.129	0.077	
***F**/ p (sd:2)*	***0.246***	***p:0.789***	***1.018***	***p:0.38***	***5.249***	***p:0.01***			
Significant difference						**c>a**			

*Kruskal-Wallis analysis **One-way variance analysis was used for repetitive measurements

Table 3: Results of Nursing Practices on the Prevention of Urinary Tract Infections (Log Rank Analysis)

Variable	**Total**	**Number of subjects**		**Censor**	
	n	**n**	**%**	**n**	**%**
Cranberry	20	1	5.0	19	95.0
Training	20	3	15.0	17	85.0
Control	20	8	40.0	12	60.0
-Group (cranberry/ training/ control)	60	12	20.0	48	80.0
Log rank:6.65 sd:2	**p:0.03**				
-Group(cranberry/control)	40	9	22.5	31	77.5
Log rank:6.07 sd:1	**p:0.01**				
-Group (training/control)	40	11	27.5	29	72.5
Log rank:2.05 sd:1	**p:0.15**				
-Group (cranberry/training)	40	4	10.0	36	90.0
Log rank:1.17 sd:2	**p:0.27**				

Table 4: Comparison of the Distribution of Microorganisms Causing UTIs in Patients in the Experiment and Control Groups[a]

Microorganism	**Exp1(n=1)**		**Exp2(n=3)**		**Control(n=8)**	
	n	**%**	**n**	**%**	**N**	**%**
Escherichia coli	1	100	2	75.0	4	50.0
Pseudomonas	-	-	-	-	2	25.0
Klebsiella	-	-	1	25.0	2	25.0

[a]The analysis was performed on 12 patients, in whom the UTI was proven with urine cultures

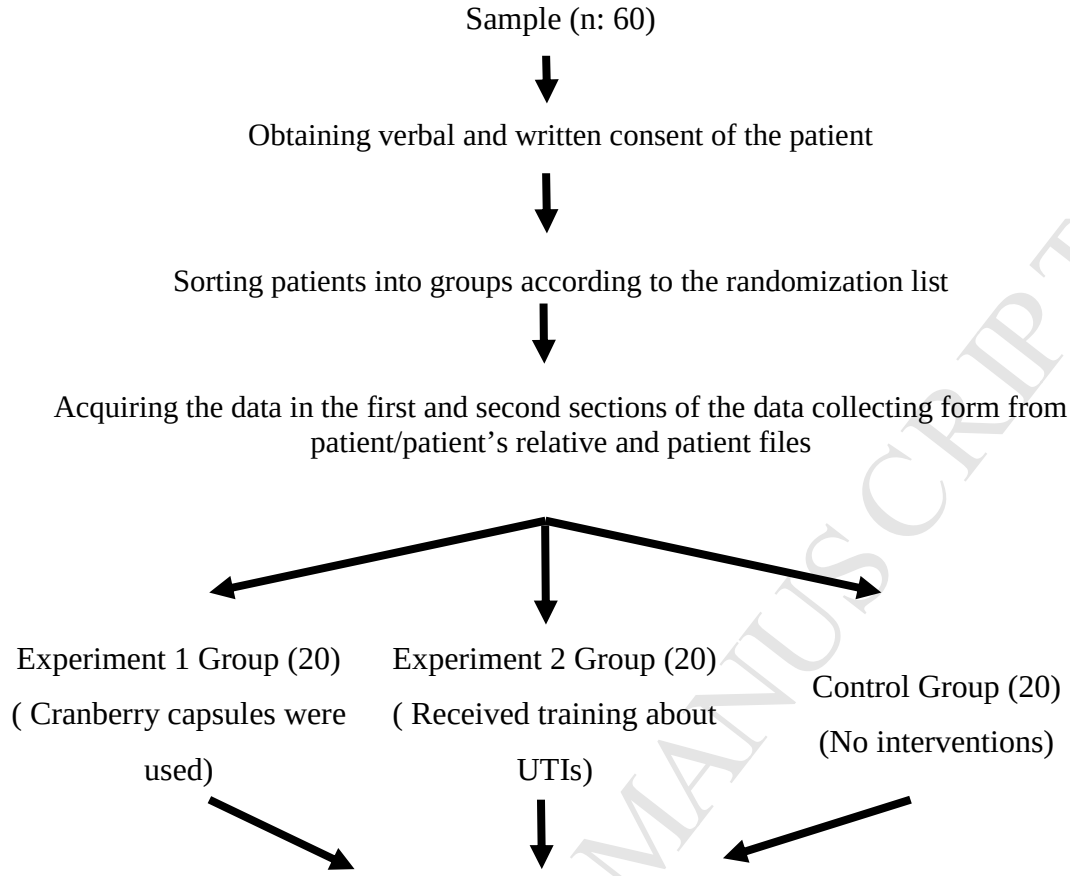

Figure 1. The flowchart of the study

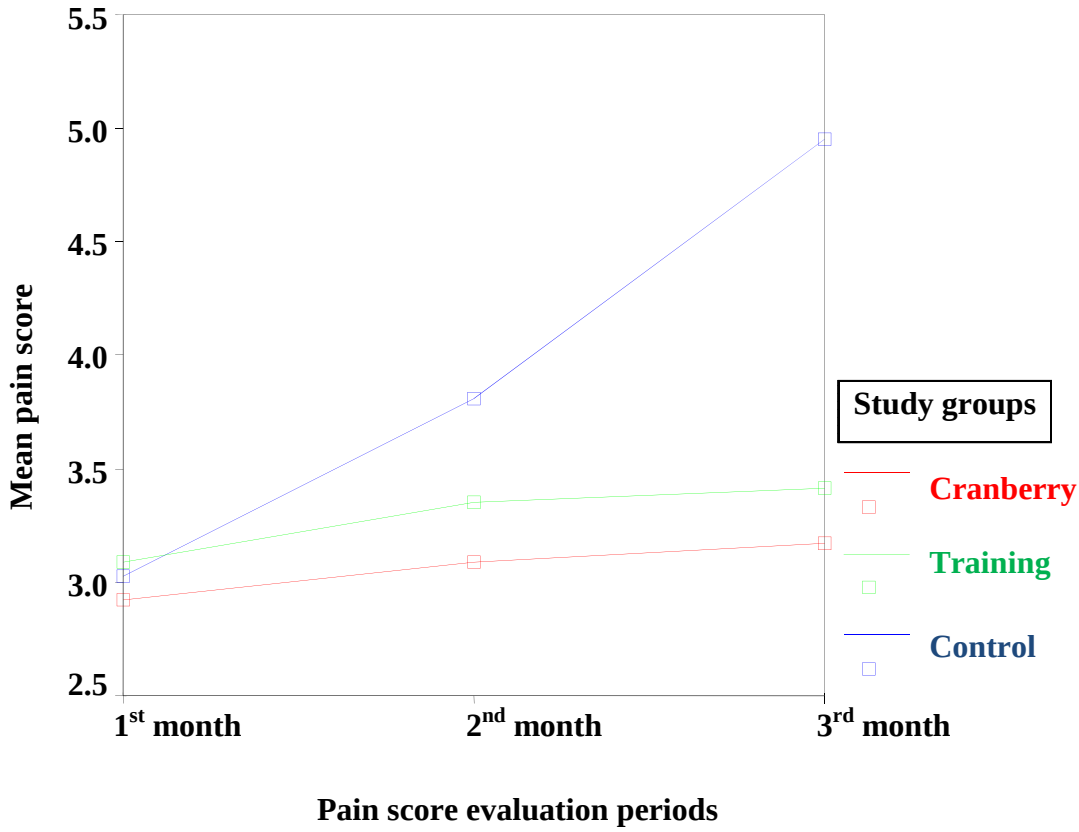

Figure 2: Comparison of Mean Pain Scores in Patients in Experiment and Control Groups

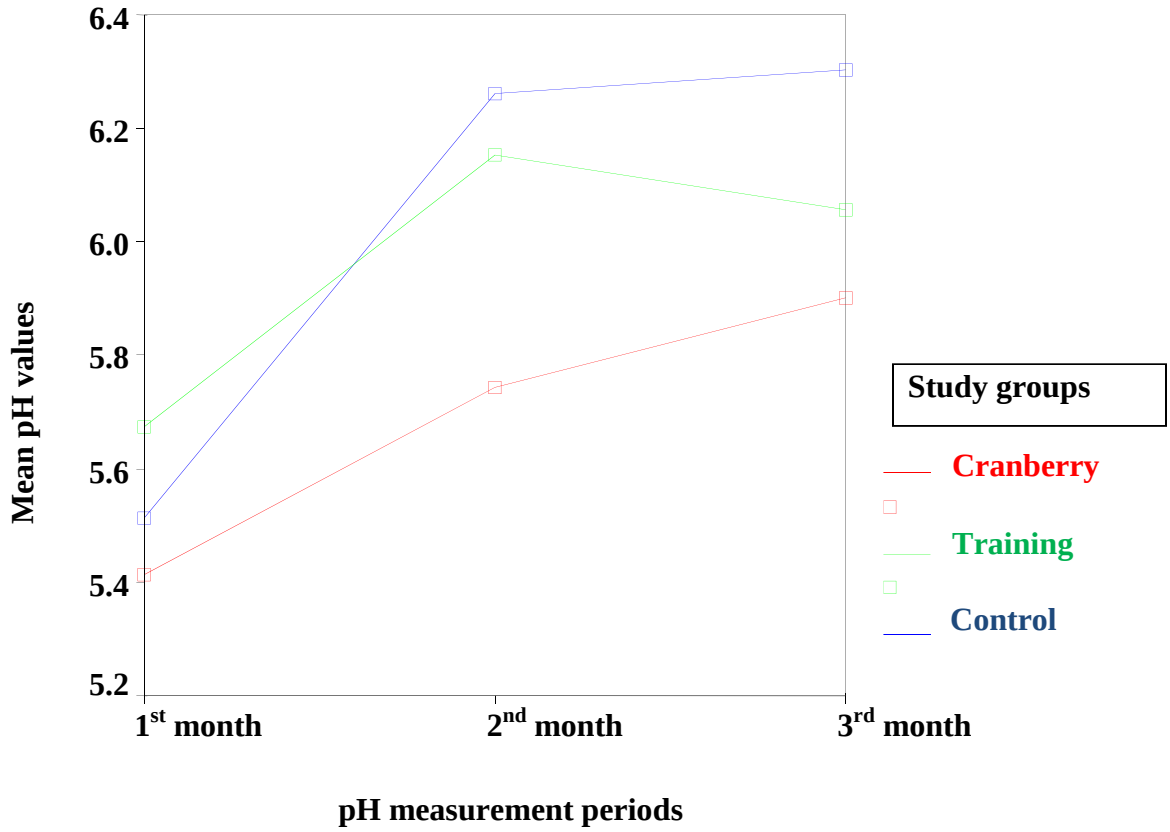

Figure 3: Comparison of Mean Urine pH Values in Patients in Experiment and Control Groups

Highlights

- Unsystematic informing and planned training by themselves are not effective in preventing late-term UTIs after urostomy
- The use of cranberry capsules was effective. However, there is no consensus on the dose to be use