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ORIGINAL ARTICLE

Cognitive-behavioral program to control lower urinary tract symptoms after radical prostatectomy: a randomized clinical trial

Programa cognitivo-comportamental para controle de sintomas do trato urinário inferior pós-prostatectomia radical: ensaio clínico randomizado

Programa cognitivo-conductual para el control de los síntomas del tracto urinario inferior después de la prostatectomía radical: un ensayo clínico aleatorizado

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ABSTRACT

Objective: to assess the effectiveness of a cognitive-behavioral program to control lower urinary tract symptoms after radical prostatectomy. **Methods:** a randomized clinical trial study, with 41 participants randomized into intervention (n=20) and control (n=21), for three months. The intervention group received the cognitive-behavioral program, while the control group received routine guidance from the service. Outcome variables were urinary incontinence intensity and lower urinary tract symptoms, assessed by the Pad-Test and Urinary Incontinence Scale of Radical Prostatectomy and King's Health Questionnaire. **Results:** at the end of the study, the intervention group had a lower urinary incontinence intensity (p≤0.001), and there were less chances of presenting changes in urinary frequency (p≤0.001), urinary urgency (p≤0.001), nocturia (p=0.005), stress urinary incontinence (p≤0.001) and urge incontinence (p≤0.045). **Conclusion:** the cognitive-behavioral program was effective in reducing lower urinary tract symptoms after radical prostatectomy. Brazilian Clinical Trial Registry: RBR-3sstqg.

Descriptors: Nursing; Urinary Incontinence; Lower Urinary Tract Symptoms; Prostatectomy; Clinical Trial.

RESUMO

Objetivo: avaliar a efetividade de um programa cognitivo-comportamental para controle de sintomas do trato urinário inferior pós-prostatectomia radical. **Método:** estudo de ensaio clínico randomizado, com 41 participantes aleatorizados em intervenção (n=20) e controle (n=21), durante três meses. O grupo intervenção recebeu o programa cognitivo-comportamental, enquanto o grupo controle recebeu orientações de rotina do serviço. As variáveis desfechos foram intensidade da incontinência urinária e sintomas do trato urinário inferior, avaliados pelo *Pad-Test* e *Urinary Incontinence Scale of Radical Prostatectomy* e *King's Health Questionnaire*. **Resultados:** ao final do estudo, o grupo intervenção apresentou menor intensidade da incontinência urinária (p≤0,001), e houve menos chances de apresentar alterações da frequência urinária (p≤0,001), urgência miccional (p≤0,001), noctúria (p=0,005), incontinência urinária de esforço (p≤0,001) e urge-incontinência (p≤0,045). **Conclusão:** o programa cognitivo-comportamental foi efetivo para a redução de sintomas do trato urinário inferior após a prostatectomia radical. Registro Brasileiro de Ensaios Clínicos: RBR-3sstqg.

Descritores: Enfermagem; Incontinência Urinária; Sintomas do Trato Urinário Inferior; Prostatectomia; Ensaio Clínico.

RESUMEN

Objetivo: evaluar la efectividad de un programa cognitivo-conductual para controlar los síntomas del tracto urinario inferior después de la prostatectomía radical. **Métodos:** estudio de ensayo clínico aleatorizado, con 41 participantes aleatorizados en intervención (n=20) y control (n=21), durante tres meses. El grupo de intervención recibió el programa cognitivo-conductual, mientras que el grupo control recibió orientación rutinaria del servicio. Las variables de resultado fueron la intensidad de la incontinencia urinaria y los síntomas del tracto urinario inferior, evaluados mediante Pad-Test y Urinary Incontinence Scale of Radical Prostatectomy y King's Health Questionnaire. **Resultados:** al final del estudio, el grupo intervención presentó menor intensidad de incontinencia urinaria (p≤0,001), y hubo menos posibilidades de presentar cambios en la frecuencia urinaria (p≤0,001), urgencia urinaria (p≤0,001), nicturia (p=0,005), incontinencia urinaria de esfuerzo (p≤0,001) e incontinencia de urgencia (p≤0,045). **Conclusión:** el programa cognitivo-conductual fue eficaz para reducir los síntomas del tracto urinario inferior después de la prostatectomía radical. Registro Brasileño de Ensayos Clínicos: RBR-3sstqg.

Descriptores: Enfermería; Incontinencia Urinaria; Síntomas del Sistema Urinario Inferior; Prostatectomía; Ensayo Clínico.

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INTRODUCTION

After radical prostatectomy (RP), transient or prolonged voiding dysfunctions may be experienced, with emphasis on urinary incontinence (UI) and other lower urinary tract symptoms (LUTS). LUTS refer to a set of clinical manifestations present when any of the components of the physiological process of urination are altered. According to the International Continence Society (ICS), LUTS can be classified into symptoms of storage, voiding and/or post-voiding changes. UI, in turn, is characterized as any involuntary loss of urine, and, when investigated in detail, is characterized as a complex clinical condition and not just a symptom[1].

Men undergoing RP may experience more LUTS compared to the preoperative period, including six months after surgery[2]. As for UI, about 57% of men report involuntary urinary leakage after one month of RP. Spontaneous reduction of UI over time is expected, however, about 44% of men may still complain of urinary leakage associated with exertion and need one or more pads a day[1,3].

Nursing interventions (NI) based on the control of UI and other LUTS should be considered in a timely manner, with a view to improving the prognosis after surgery. These interventions should involve behavioral measures, including pelvic floor muscle (PFM) exercises, in addition to the acquisition of habits and behaviors, such as adequate fluid intake, smoking cessation, caffeine and capsaicin (pepper) intake, presenting treatment compliance with one of its limitations[1].

In this sense, the use of a cognitive-behavioral approach as a strategy for implementing NI tends to help increase compliance with treatment, promoting greater chances of therapeutic success. The cognitive-behavioral approach described in the Social Cognitive Theory (SCT)[4] aims to integrate guidelines into patientss routine using mechanisms of positive reinforcement of the therapeutic process, such as social persuasion, positive feedback and vicarious reinforcement. It is noteworthy that there are few studies in the literature on behavioral measures to control post-radical prostatectomy urinary incontinence (PRPUI) based on this theoretical framework. Thus, it is believed that the results of this study may contribute to the incorporation into clinical practice of low-cost and potentially successful interventions for controlling post-RP LUTS, providing control knowledge and self-management.

OBJECTIVE

To assess the effectiveness of a cognitive-behavioral program to control LUTS after RP.

METHODS

Ethical aspects

In the development of this study, ethical recommendations referring to research with human beings were adopted. The project was approved by the Research Ethics Committee, and registered in the Brazilian Clinical Trials Registry Platform, under Universal Trial identification number: RBR-3sstqg.

Study design, period, and place

This is a randomized, single-blind clinical trial study with 1:1 randomization, using an intervention group (IG) and a control group (CG), developed between November 2019 and December 2020 in an outpatient unit linked to a philanthropic Oncology Care Center (CACON) in the Midwest Brazil.

In the study preparation and execution, the Consolidated Standards of Reporting Trials (CONSORT) recommendations were considered[5].

Sample; inclusion and exclusion criteria

The sample corresponded to all eligible participants in the data collection period, totaling 41 men with post-RP UI. Men aged over 18 years, with mild, moderate or severe UI, assessed using the Pad-Test[1], with preserved cognitive capacity, assessed using the Mini-Mental State Examination[6], with preserved locomotor capacity, telephone contact available and availability for fortnightly face-to-face visits were included. Men with a history of diseases that influence voiding control or use of medications with a diuretic effect, in addition to prolonged use (> 21 days) of an indwelling urinary catheter (IUC) were excluded.

Recruitment was performed through the institution's surgical and outpatient schedule. Patients were approached after IUC withdrawal and introduced to the study objectives. Upon interest in participating, they were invited to return between 15 and 20 days to read and sign the Informed Consent Form, clinical assessments and randomization between IG and CG.

Study protocol

Participants were randomized into five "chunks" of ten subjects. In this way, five lists of ten random numbers associated with the letter "I" (intervention) or "C" (control) were generated on Randomizer.org by an external researcher. This same researcher made opaque envelopes for the generated numbers. After the application of all data collection instruments and immediately before the first intervention session, the envelope was opened by participants to identify which group it would be allocated to.

At the first moment of data collection, a form was applied to characterize the sample by the main researcher, who did not know, a priori, to which group (CG and IG) participants had been allocated. Subsequent assessments were performed by other previously trained researchers, which characterized the blinding of data collection stages.

The intervention was based on a cognitive-behavioral program (CBP) composed of NI to control UI and LUTS post-RP. Verbal and written NI were implemented through educational material (booklet) entitled *"Manual de orientações sobre incontinência urinária pós-prostatectomia radical"*[7]. The booklet contains guidance on voiding complaints, including structures and processes involved in etiology, lifestyle habits associated with control, such as adequate fluid intake, smoking cessation, reduced intake of caffeine-containing beverages, bladder irritant foods in the diet[1,8]. Information about the practice of PFM exercises was also included[9].

The PFM training regimen proposed in the booklet is based on guidelines and recommendations from protocols already

implemented and validated in other studies[9], with the aim of promoting strength and voiding control. It is a six-step program to be carried out over twelve weeks, with rapid maximum or sub-maximal voluntary contractions, sustained and performed in lying, sitting, standing and walking positions. Progress in the stages occurred each week, according to participants' success in the previous stage. In the present study, face-to-face training was carried out (weekly, fortnightly or monthly, according to proprioception), in addition to weekly telephone contacts with all IG participants, for monitoring and reinforcing the importance of continuing the exercises at home.

In order to encourage and verify compliance with the guidelines received in person, regular individual telephone contacts were made with IG participants throughout the time provided for in the program. This follow-up consisted of text messages via mobile device and weekly telephone contacts guided by a guiding script offering positive feedback in case of compliance with habits and behaviors or reinforcing the importance of compliance. In addition to educational aspects, personal motivation, using social persuasion and vicarious experience (video presentation on a patient's success with therapy), and the provision of a telephone number for any needs were part of CBP, with a view to favoring the role of nurses as motivators and supervisors of the entire process.

Men allocated to CG received usual care, including verbal instructions on caffeine restriction and performance of pelvic muscle contractions after IUC withdrawal.

Data collection took place in individual structured interviews, whose average duration was 60 minutes. They were carried out by the main researcher and a previously trained team, in a private environment. Data were collected at five times during pre-scheduled outpatient visits: 15 to 20 days after IUC removal (baseline - T_0); thirty days after baseline (T_1); sixty days after baseline (T_2); and ninety days after baseline (T_3).

This study assessed the positive effects of CBP in controlling PRPUI intensity (primary outcome) as well as LUTS (secondary outcomes). PRPUI intensity was assessed by the Pad-Test, a validated method frequently used in clinical research to quantify the volume of urinary loss through the weight of a sanitary pad[10]. The test was performed in five steps: 1) weighing the pad on a high sensitivity scale (e-LABShop); 2) ingestion of 500 ml of water; 3) 15 minutes of rest; 4) performing a series of physical exercises to provoke urinary loss; and 5) reweighing the pad. The results obtained in the weighing classify urinary loss as mild (1.1 to 9.9 g), moderate (10 to 50 g) or severe (above 50 g)[11].

The Urinary Incontinence Scale of Radical Prostatectomy (UISRP) was also used to assess the primary outcome. It is the only specific instrument for prostatectomized patients and validated for the Brazilian population. It consists of seven items with five-point Likert scales, in which zero indicates "never" and four indicates "always". The score ranges from 0 to 32, and higher scores indicate greater UI intensity[12].

LUTS (secondary outcomes) were assessed using an independent scale of King's Health Questionnaire (KHQ), which assesses the presence and intensity of urinary symptoms. There is no total score for this scale, and the items are analyzed independently[13].

At baseline (T_0), participants answered a form for sociodemographic and clinical characterization, and then were assessed for urinary leakage intensity (Pad-Test). Then, they were submitted to UI intensity assessment by UISRP and LUTS by the KHQ. At this time, participants were randomized into CG and IG. Those allocated to IG were introduced to the CBP for early UI rehabilitation and received guidance on performing the exercises and lifestyle changes. Areturn was scheduled within 15 days to receive reinforcement of the guidelines in person, and others, after 30 (T_1), 60 (T_2) and 90 (T_3) days, for subsequent assessments. Those allocated in CG continued in routine care at the institution, and a new assessment was scheduled within 30 days. At all outpatient visits for clinical follow-up (T_1, T_2, and T_3), men in both groups were assessed for urinary leakage intensity (Pad-Test and UISRP) and subsequently assessed for the presence of other LUTS.

Analysis of results, and statistics

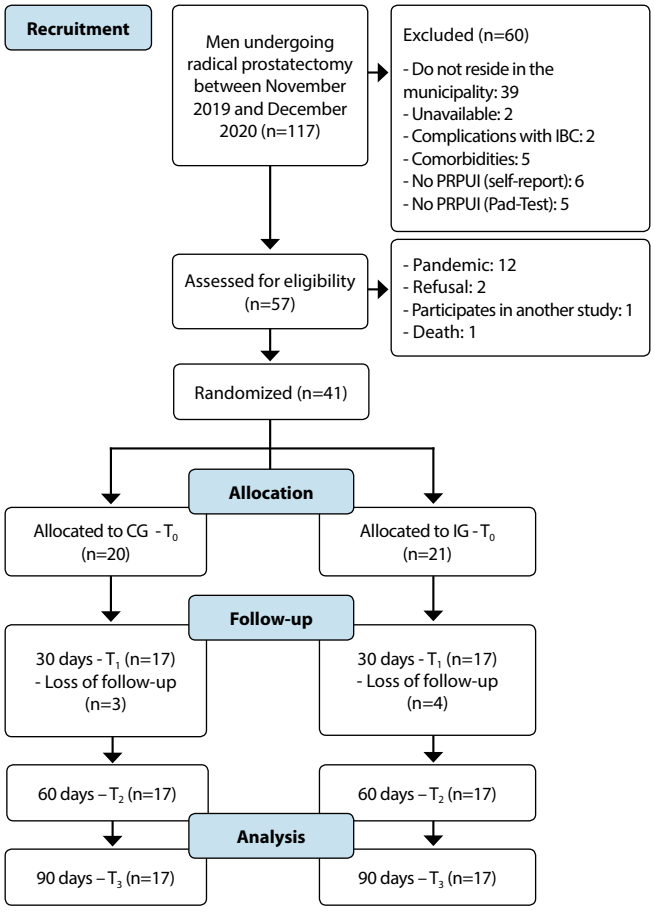
Data were entered into an Excel spreadsheet for Windows®, in double entry, to verify equivalence. Analysis was performed using statistical software Statistical Package for the Social Sciences (SPSS) for Windows®, version 23. The Shapiro-Wilk test was performed to test whether the variables studied followed normal distribution. The explanatory variables of the nominal type were described by frequency distribution and by tables, and the quantitative variables, depending on normality, were described by measures of central tendency and dispersion (mean/standard deviation, in case of normal distribution, and median/percentiles, in case of non-normal distribution). Equivalence between groups regarding sociodemographic and clinical characteristics in the pre-test was verified by Student's t and Mann-Whitney tests. The chi-square or Fisher's exact test was used for categorical variables.

Regarding the comparison between IG and CG at different moments of the post-test and of each group over time, the primary outcome variables (UI intensity) at different time intervals were analyzed by the longitudinal model using generalized estimating equations (GEE), in order to assess the effect of group allocation, time and the interaction between the effect of the group and time (group*time). For significant effects at 5%, the comparison of means was obtained through the post-hoc t test, protected by Bonferroni, which aims to adjust the test significance value based on the number of comparisons, in order to reduce the chance of type I error.

RESULTS

Of the 117 men undergoing RP, 57 were assessed for eligibility, and 41 were eligible and randomized, of which 21 were allocated to IG and 20 to CG. However, during follow-up, four participants from IG and three from CG were discontinued as a result of the impediment to face-to-face returns due to the COVID-19 pandemic. Thus, there were 17 participants in IG and 17 in CG, who composed the sample for analysis of outcomes (Figure 1).

According to sociodemographic and clinical characterization data, there was no significant difference between CG and IG in terms of age, skin color, education, income, marital status, coffee/tea intake, smoking, physical activity, number of diapers, Body Mass Index, time after surgery and days of permanence with the IUC ($p>0.05$). Such results demonstrate homogeneity between the groups.



Note: T_0 - pre-test; T_1 - 30 days after surgery; T_2 - 60 days after surgery; T_3 - 90 days after surgery; CG - control group; IG - intervention group; IBC - indwelling urinary catheter; PRPUI - post-radical prostatectomy urinary incontinence.

Figure 1 - Flowchart of recruitment and inclusion of participants in the study, in accordance with the Consolidated Standards of Reporting Trials (CONSORT), Goiânia, Goiás, Brazil

Comparing the primary outcome (Table 1), there was a statistically significant effect on the group*time interaction for IG. There was a reduction in PRPUI intensity, with a statistical difference only in the first month of follow-up (T_1) ($p \leq 0.001$) for IG participants, when assessed by the Pad-Test. On the other hand, when assessed using the UISRP, UI intensity also reduced significantly, but this difference remained at all follow-up times from the study to IG (T_1 – $p=0.003$; T_2 – $p \leq 0.001$ and T_3 – $p \leq 0.001$), as shown in Table 1.

When performing a new comparison between the groups, after correction by Bonferroni's post-hoc test, there was a statistically significant difference at the end of the study both for the assessment performed by the Pad-Test ($p=0.016$) and by the UISRP ($p \leq 0.001$). In the comparison between the baseline and the different assessment moments in the follow-up, CG shows a significant difference only after sixty days of follow-up (T_2). In IG, this difference was observed in the first assessment (T_1), remaining at all times for both assessment strategies (Table 2).

The result related to the comparison of the means of urinary losses (in grams) by the Pad-Test at T_1, T_2 and T_3 showed a significant improvement when compared to the means of urinary losses (in grams), obtained at baseline (T_0), both in CG and IG. However, CG started the study with a mean of 53.6±12.8 g and reached 15.1±3.9 g at the end of follow-up. IG started with a mean of 50.9±7.8 g, ending the ninety days of follow-up with 3.4±2.8 g of urinary loss.

The same occurred when the average scores obtained in the UISRP at T_1, T_2 and T_3 were compared. CG started the study with a mean of 18.4±1.1, reaching 13.0±1.2 at the end of follow-up. IG started with a mean of 18.5±1.2, ending the ninety days of follow-up with 3.0±1.1.

Table 3 shows that, when comparing the proportion of participants with urinary symptoms (KHQ), there was an effect over time (baseline and follow-up), regardless of the groups, for symptoms of nocturia ($p=0.020$) and urge incontinence ($p=0.009$).

Table 1 - Generalized estimating equation model to assess the effectiveness of the intervention on urinary incontinence intensity, Goiânia, Goiás, Brazil, 2021 (n=34)

	Mean (SD)		Effect: group[a]		Effect: time[b]		Group*time[c]	
	IG	CG	β (95% CI)	*p* value	β (95% CI)	*p* value	β (95% CI)	*p* value
Pad-Test								
T_0	50.9(7.8)	53.6(12.8)			-	-	-	-
T_1	12.5(3.0)	32.2(9.0)			-0.508 (-0.934;-0.081)	0.020	-0.895 (-1.427;-0.363)	≤**0.001**
T_2	7.2(4.7)	20.9(4.9)	-0.051 (-0.611;0.508)	0.858	-0.941 (-1.286;-0.586)	≤**0.001**	-1.006 (-2.277; 0.265)	0.121
T_3	3.4(2.8)	15.1(3.9)			-1.266 (-1.709;-0.824)	≤**0.001**	-1.413 (-3.023;0.197)	0.085
UISRP								
T_0	18.5(1.2)	18.4(1.1)			-	-	-	-
T_1	11.8(1.0)	15.8(1.4)			-0.151 (-0.242;-0.060)	≤**0.001**	-0.293 (-0.487;-0.098)	0.003
T_2	5.3(0.9)	13.6(1.5)	0.006 (-0.179;0.192)	0.946	-0.299 (-0.457;-0.141)	≤**0.001**	-0.952 (-1.292;-0.611)	≤**0.001**
T_3	3.0(1.1)	13.0(1.2)			-0.343 (-0.563;-0.123)	0.002	-1.447 (-2.166;-0.729)	≤**0.001**

Note: T_0 - pre-test; T_1 - 30 days after surgery; T_2 - 60 days after surgery; T_3 - 90 days after surgery; CG - control group; IG - intervention group; UISRP - Urinary Incontinence Scale of Radical Prostatectomy; 95% CI - 95% confidence interval; [a]statistical difference between the two groups in T_0 (reference: CG); [b] statistical difference between the assessment times (reference: T_0); [c]statistical difference in IG in relation to CG in the different post-test moments (reference: T_0).

Table 2 - Analysis of urinary incontinence intensity, verified through the Pad-Test and Urinary Incontinence Scale of Radical Prostatectomy, expressed as mean and standard deviation, according to Bonferroni's post-hoc t test – generalized estimating equations, Goiânia, Goiás, Brazil, 2021 (n=34)

	Mean (SD)				T_0-T_1 (95% CI)† *p* value	T_0-T_2 (95% CI)† *p* value	T_0-T_3 (95% CI)† *p* value
	T_0	T_1	T_2	T_3			
Pad-Test							
IG	50.9(7.8)	12.5(3.0)	7.2 (4.7)	3.4 (2.8)	(23.0;53.8) ≤ **0.001**	(22.5;64.7) ≤**0.001**	(26.9;67.9) ≤**0.001**
CG	53.6(12.8)	32.2(9.0)	20.9(4.9)	15.1(3.9)	(-4.1; 46.8) 0.165	(6.5; 58.8) 0.006	(9.4; 67.5) 0.003
(IC 95%)† *p* value	(-32.2;26.9) 0.859	(-38.5;-0.9) 0.039	(-27.0;-0.2) 0.045	(-21.0;-2.1) 0.016	-	-	-
UISRP							
IG	18.5 (1.2)	11.8 (1.0)	5.3 (0.9)	3.0 (1.1)	(3.2; 10.0) ≤**0.001**	(10.0;16.4) ≤**0.001**	(11.4;19.4) ≤**0.001**
CG	18.4 (1.1)	15.8 (1.4)	13.6 (1.5)	13.0 (1.2)	(0.7;4.4) ≤**0.001**	(1.9;7.6) ≤**0.001**	(0.9;9.7) 0.008
(IC 95%)† *p* value	(-3.3; 3.5) 0.946	(-7.4; -0.4) 0.027	(-11.8; -4.8) ≤**0.001**	(-13.2; -6.6) ≤**0.001**			

*Note: CG - control group; IG - intervention group; SD - standard deviation; †confidence interval for the difference of means in 95%; *p < 0.05 according to Bonferroni's post-hoc test.*

Table 3 - Model of generalized estimating equations to assess the effectiveness of the intervention on the presence of urinary symptoms assessed by King's Health Questionnaire, Goiânia, Goiás, Brazil, 2021 (n=34)

Urinary symptoms	n (%)				Effect: group[a]		Effect: time[b]		Group*time[c]	
	T_0	T_1	T_2	T_3	β (95% CI)	*p* value	β (95% CI)	*p* value	β (95% CI)	*p* value
Frequency										
CG	17 (25.0)	14 (20.6)	12 (17.6)	15 (22.1)	1.000 (1.000;1.000)	**<0.001**	0.941 (0.868;1.021)	0.144	0.625 (0.525;0.744)	**≤0.001**
IG	17 (25.0)	10 (14.7)	2 (2.9)	3 (4.4)						
Nocturia										
CG	16 (23.5)	14 (20.6)	11 (16.2)	10 (14.7)	1.030 (0.973;1.091)	0.310	0.818 (0.691;0.969)	0.020	0.719 (0.572;0.904)	0.005
IG	17 (25.0)	10 (14.7)	2 (2.9)	3 (4.4)						
Urgency										
CG	16 (23.5)	15 (22.1)	13 (19.1)	14 (20.6)	0.879 (0.764;1.010)	0.069	0.939 (0.833;1.060)	0.309	0.661 (0.544;0.802)	**≤0.001**
IG	12 (17.6)	6 (8.8)	1 (1.5)	1 (1.5)						
Urge incontinence										
CG	16 (23.5)	14 (20.6)	10 (14.7)	9 (13.2)	0.879 (0.764;1.010)	0.069	0.788 (0.660;0.941)	0.009	0.788 (0.624;0.995)	0.045
IG	12 (17.6)	5 (7.4)	1 (1.5)	1 (1.5)						
Effort UI										
CG	16 (23.5)	15 (22.1)	15 (22.1)	15 (22.1)	1.030 (0.973;1.091)	0.310	0.970 (0.874;1.076)	0.562	0.728 (0.599;0.885)	**≤0.001**
IG	17 (25.0)	16 (23.5)	13 (19.1)	7 (10.3)						
Nocturnal enuresis										
CG	13 (19.1)	6 (8.8)	7 (10.3)	4 (5.9)	0.933 (0.780;1.116)	0.450	0.700 (0.573;0.856)	≤0.001	0.867 (0.680;1.107)	0.253
IG	11 (16.2)	1 (1.5)	2 (2.9)	0 (0.0)						
Sexual UI										
CG	2 (2.9)	1 (1.5)	2 (2.9)	1 (1.5)	0.947 (0.797;1.126)	0.540	0.947 (0.971;1.135)	0.557	0.997 (0.809;1.229)	0.977
IG	1 (1.5)	0 (0.0)	1 (1.5)	0 (0.0)						
Urinary tract infections										
CG	2 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0.947 (0.797;1.126)	0.540	0.895 (0.780;1.026)	0.112	1.118 (0.909;1.373)	0.290
IG	1 (1.5)	0 (0.0)	1 (1.5)	1 (1.5)						
Bladder pain										
CG	4 (5.9)	2 (2.9)	0 (0.0)	1 (1.5)	0.857 (0.706;1.041)	0.120	0.857 (0.738;0.995)	0.043	1.102 (0.918;1.323)	0.298
IG	1 (1.5)	0 (0.0)	1 (1.5)	0 (0.0)						
Difficulty urinating										
CG	3 (4.4)	2 (2.9)	1 (1.5)	1 (1.5)	0.900 (0.747;1.085)	0.269	0.900 (0.789;1.027)	0.117	1.049 (0.886;1.242)	0.576
IG	1 (1.5)	0 (0.0)	1 (1.5)	0 (0.0)						

Note: CG – control group; IG - intervention group; T_0 - pre-test; T_1 - 30 days after surgery; T_2 - 60 days after surgery; T_3 - 90 days after surgery; 95% CI - 95% confidence interval; [a]statistical difference between IG and CG at T_0 (reference: CG); [b]statistical difference between pre-test and post-test (reference: T_0); [c] statistical difference in IG compared to CC at post-test (reference: CG at T_0).

As for the group*time interaction (baseline and follow-up), it is noteworthy that there was a statistically significant difference between IG and CG at the end of follow-up with regard to symptoms of increased frequency (p≤0.001), urinary urgency (p≤0.001), nocturia (p≤0.005), stress UI (p≤0.001), and urge incontinence (p< 0.045). At the end of the study, IG was 37.5% less likely (β=0.625) to have increased urinary frequency, 33.9% (β=0.661) to have urinary urgency, 28.1% (β=0.719) of nocturia, 27.2% (β=0.728) of having stress UI and 21.2% (β=0.788) of having urge incontinence, compared to the group that did not receive guidance related to behavioral NI contained in the program under study.

DISCUSSION

The findings found in the present study converge to the finding that, although a reduction in PRPUI intensity is observed for both groups (IG and CG), for IG participants, the reduction in UI intensity (Pad-Test and UISRP) was more expressive and faster, since, with thirty days after surgery, it was already possible to observe clinical results. These findings prove that CBP to control UI and other LUTS accelerates the therapeutic process with regard to the outcomes assessed in this study and in the population studied.

Regardless of the group in which they were allocated, prostatectomized men included in this study showed a reduction in the rate of urinary loss assessed by the Pad-Test and a reduction in scores using UISRP. Based on these results, it can be inferred that participants in both groups tend to obtain a reduction in PRPUI intensity over time. However, it was observed that, even with a significant improvement in PRPUI during follow-up, at the end of the study, participants in CG still had more severe urinary leakage (above 10 g of urinary leakage)[11], compared to IG[1].

In short, PRPUI and other LUTS are clinical conditions that can spontaneously manifest in a transient way or extend for a longer time in an individual's life, especially when associated with factors such as advanced age, sedentary lifestyle and obesity[14]. In general, UI intensity is expected to decrease over time[3]; however, the findings of this study find that, even after ninety days post-surgical, men who do not receive a therapeutic option may experience moderate or severe UI.

These findings corroborate the results presented by other authors, which demonstrate that, after six months postoperatively, approximately 57% of prostatectomized men had involuntary urinary leakage, with 41% mild UI, 14% moderate UI and 2% severe UI[3]. Therefore, it is evident the need to invest in therapeutic options in a timely manner, with the use of strategiesthat promote self-efficacy and positive belief, with a view to increasing compliance with behaviors and, therefore, reducing physical, psychological and social impacts. In this way, stronger attitudes towards compliance with the proposed NI, supported by the belief in self-efficacy obtained through the strategies adopted in the CBP, may have been responsible for the beneficial implications in the increase of compliance and consequent reduction of PRPUI and LUTS intensity, in a more expressive way, in IG participants. For the SCT[4], these strategies are immediate predictors in decision-making for adopting a health behavior. Therefore, it is assumed that the intentions projected through the strategies contained in a cognitive-behavioral approach, sustained by the belief of self-efficacy and constant motivation throughout the therapeutic process, were reverted into concrete actions for the real effectuation of a behavior to control LUTS post-RP. Furthermore, with regard to the assessment of other LUTS in the population studied, it is observed that, in relation to the frequency and urgency of urination, nocturia, stress UI and urge incontinence were the most reported LUTS by patients at baseline for both CG and IG. For men in whom LUTS are clinically more expressive, behavioral therapeutic interventions prove to be significantly more relevant and beneficial in relieving these symptoms[15]. Corroborating this statement, in the present study, men whose LUTS were more expressive at baseline also showed a more expressive and significant improvement after the implementation of a CBP.

To date, most studies assessing post-RP functional outcomes emphasize PRPUI as a primary outcome of perceived patient dissatisfaction after surgery[1]. However, PRPUI is just one component of a symptom complex[15], and using it as the sole metric can be biased, as these symptoms have a significant effect on overall well-being and are often the reason men seek investigations that culminate in a diagnosis of prostate cancer.

Authors have reported a reduction in LUTS after RP, especially in men with moderate to severe symptoms, however they emphasize that the profile of LUTS changes after surgery. Prior to RP, voiding symptoms are more prevalent and, after prostate removal, these symptoms become less expressive and give way to storage symptoms[17]. These statements corroborate the findings presented in this study, since it was possible to observe a reduction in voiding LUTS and permanence of PRPUI, predominantly of the type of stress and other storage symptoms, such as frequency, urgency and nocturia.

Although both groups showed improvement in LUTS, notably men undergoing the proposed CBP were less likely to remain with storage symptoms, such as stress UI, urge incontinence, nocturia and frequency. NI, including behavioral therapeutic methods, always constitute the first step in the management of LUTS after RP. Therefore, it is important for nurses to be aware of the clinical features of post-prostatectomy LUTS in order to provide healthcare tailored to the needs of these men. Furthermore, NI must be implemented with strategies that provide support and support, in order to promote motivation and belief in self-efficacy[17]. Thus, it reinforces the idea that the CBP structured by NI, which aims to promote self-care through the adoption of health behaviors and habits using motivation strategies and telephone follow-up, proves to be effective for obtaining better clinical results. In this context, authors[17] emphasize that a teaching program associated with telephone follow-up can allow an increase in knowledge and a bond between nurse and patient. Moreover, this strategy may allow, through effective monitoring and communication, men undergoing RP to manifest better clinical results through the adoption of behaviors that will lead to the reduction of PRPUI and other LUTS.

Although progressive improvement is seen in PRPUI and other LUTS over time, for those men in whom these symptoms persist, the social, emotional, physical, and economic impacts can become extremely overwhelming and impactful. Thus, through a therapeutic option with the use of cognitive-behavioral strategies[17], implemented in a timely manner, the chances of returning to full and definitive voiding control will be greater[18]. With this, it is possible to reduce the chance of physical consequences that can impact the lives of

subjects with UI[19], in addition to reducing the economic impact for both patients and health services, with a consequent reduction in the need for more complex, invasive and costly therapeutic measures[20].

Study limitations

As a limitation of this research, the restriction of generalization of its results to different contexts is mentioned. This intervention was proposed in an academic context, in which a team of nurses was exclusively dedicated to the proposed activities. In this way, it is suggested that, for a successful reproduction, a qualified and committed professional is necessary, in addition to the support of the institution where the program will be implemented. Furthermore, as it is a study with a small number of participants, it is possible to mention the restriction of generalization of the results presented. Therefore, it is important to implement the intervention in different contexts and with a significant number of participants.

Contributions to nursing, health, and public policies

The contribution of this study to clinical nursing practice and related areas focuses on enabling a low-cost and feasible therapeutic proposal. Thus, it is expected that the results presented will encourage the performance of new studies with a significant sample size to support the clinical effectiveness results presented in this study.

CONCLUSION

The CBP structured in NI proved to be effective in reducing UI and LUTS intensity. From the program proposed in the present study, greater support and motivation were provided through strategies of social persuasion, positive feedback and vicarious reinforcement. In this way, it is possible to infer that the strategies listed through the SCT contributed to increased compliance with habits and behaviors that helped in the control of LUTS after RP, in addition to providing greater confidence in the nurse-patient relationship and, therefore, increased joining the proposed NI.

SUPPLEMENTARY MATERIAL

Considering open science communication practices, the data are in the SciELO Data repository under DOI: https://doi.org/10.48331/scielodata.WYJ9UX.

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