# **Original Study**



# Effectiveness of the Continuous Care Model on Quality of Life, Sexual Satisfaction and Function in Bladder Cancer Patients Undergoing Tumor Resection Surgery: A Randomized Control Trial

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## **Abstract**

Bladder cancer can significantly impact patients' quality of life (QoL) and sexual well-being. This randomized controlled trial examined the effects of a Continuous Care Model (CCM) intervention, including sexual health education, on 54 patients undergoing tumor resection. Results indicated notable improvements in QoL and sexual satisfaction in the CCM group, with enhanced sexual function observed in male patients. However, no significant changes were found in female sexual function. These findings suggest that CCM can be beneficial in postsurgical care, while further research is needed to address the specific needs of female patients.

Background: Bladder cancer is a global health concern, and while surgery is vital, it often diminishes patient quality of life, notably sexual function. Existing self-care education is insufficient, necessitating a more holistic approach. The Continuous Care Model (CCM), which emphasizes patient empowerment, shows promise. This study investigates a CCM intervention that includes sexual health education to improve quality of life (QoL) and sexual satisfaction in bladder cancer patients. Methods: This randomized controlled trial enrolled 54 bladder cancer patients undergoing tumor resection surgery in Tehran, Iran (April-September 2024). Participants were randomly assigned to either a CCM intervention group (n = 26) and a control group (n = 28). QoL was assessed using the EORTC QLQ-C30; sexual function and satisfaction were measured using the Larson Sexual Satisfaction Questionnaire, IIEF, and FSFI at baseline and at 1 and 3 months postintervention. Results: The CCM group demonstrated significantly improved overall QoL (P < .001) and several subscales (physical, emotional, cognitive, fatigue) compared to controls. Sexual satisfaction also improved significantly in the CCM group (P < .001). Sexual function enhanced particularly for males (enhanced orgasm and sexual desire, P = .049, P = .020, respectively). No significant changes in female sexual function were observed, although past medical history (P = .019) and partner's job (P = .017) were significantly associated with female sexual function. Conclusions: The CCM intervention effectively enhanced QoL, sexual satisfaction, and sexual function particularly in males. Further research is needed to address the unique challenges impacting female patients' sexual function postbladder cancer surgery.

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Keywords: Postoperative care, Quality of life, Sexual satisfaction, Sexual health, Urinary bladder neoplasms

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#### Introduction

Bladder cancer is a growing concern globally.<sup>1,2</sup> causing significant challenges for healthcare systems, especially in developing countries, where the disease's impact is particularly severe.<sup>3</sup> Although surgeries such as transurethral resection (TUR), partial and radical cystectomy are crucial for treatment,<sup>4</sup> they frequently lead to significant declines in patients' quality of life (QoL), affecting their physical and emotional health as well as their relationships.<sup>5,6</sup>

The negative impact on QoL is particularly pronounced in the context of sexual function. For male patients, radical cystectomy, a procedure often necessary for advanced disease, carries a high

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likelihood of inducing erectile dysfunction, significantly impacting intimate relationships and self-esteem. The implications for female patients are equally significant, although often less explicitly addressed in the literature. Addical cystectomy can lead to impairments in arousal, libido, and overall sexual satisfaction These sexual dysfunctions contribute substantially to the overall decline in health-related QoL, underscoring the need for targeted interventions to address this critical aspect of postsurgical care.

Despite advancements in bladder cancer surgery, psychosocial consequences remain a significant concern.<sup>12</sup> Although self-care education plays a role, the physical, emotional, and sexual difficulties faced by bladder cancer patients after surgery demand a more holistic approach than information alone. 13,14 The Continuous Care Model (CCM), initially developed by Ahmadi for chronic disease management, positions the patient as an active agent in their health process.<sup>15</sup> This is a systematic process that helps to communicate between patients and those in the medical field by letting them discuss their needs, highlighting the health behaviors, and helping them maintain their health. The CCM consists of 4 iterative phases: orientation, sensitization, control, and evaluation. The first step is becoming oriented, which involves the introduction of the model; sensitivity means that patients and families understand the disease and its consequences; control focuses on the implementation of health-promoting behaviors; and evaluation assesses the care process and outcomes. 16 The nature of CCM dynamic and continuous mode of operation makes it well suited for the management of chronic conditions such as bladder cancer. Previous research has shown the positive effects of such follow-up care models in improving the quality of life of hemodialysis and heart failure patients, as well as the promotion of self-care in colon cancer patients, thus making its potential utility in bladder cancer management very likely. 17-19

While the CCM has proven effective in improving quality of life and self-care management for patients with other chronic conditions, <sup>19–21</sup> its application to the specific challenges of sexual dysfunction following bladder cancer surgery remains under-researched. This study addresses this gap by investigating the impact of a CCM intervention that explicitly incorporates sexual health education. The aim is to determine the efficacy of a Continuous Care Model (CCM) in enhancing quality of life (QoL), sexual satisfaction and function in bladder cancer patients.

## **Methods**

This study (registered with the Iranian Registry of Clinical Trials, IRCT20240221061076N1) compared 2 groups of bladder cancer patients after surgery: one receiving a comprehensive care program (CCM), and one receiving standard care. We followed established guidelines (CONSORT) to ensure the reliability of our comparison.

We conducted this research at the hospitals of Shahid Beheshti University of Medical Sciences in Tehran, Iran. Recruitment happened between April 1st and May 29st, 2024. All patients undergoing tumor removal surgery for bladder cancer during this period were initially screened for eligibility. Participants in this study were randomly assigned to either the intervention or control group using block randomization with varying block sizes to ensure unpre-

dictability. The randomization table determined each participant's group assignment and corresponding intervention.

The researcher spoke with potential participants about the study before surgery. She explained everything clearly, using both written materials and a verbal explanation, to make sure they understood their rights and what would be involved.

The inclusion criteria had been very strictly defined to ensure homogeneity within the study population. Patients were considered eligible if they met all of the following criteria: the patient is aged  $\geq 18$  years; diagnosis of bladder cancer and need for a surgical intervention of tumor removal is proven; at the time of diagnosis, the patient reports having a sexual partner; ability to understand and sign the informed consent; no other surgery during the time of current surgery; to be able to answer questionnaires in Farsi (local language); not to have a history of pre-existing major neurological or psychiatric disorders that severely hinder completing the questionnaires and participating in the present study.

Exclusion criteria include: predefined sexual dysfunction based on a physician's assessment using uniform diagnostic criteria, and withdrawal by patients for whatever reason throughout the whole study.

Sample size calculation was performed by G\*Power software version 3.1.9.4 based on a priori power analysis. We aimed for 80% power  $(1-\beta)$  to detect a medium effect size (f = 0.25) at a significance level of 0.05  $(\alpha)$ . Assuming that there is a possibility of a 10% attrition rate, for adequate statistical power of the primary outcome measures, sample size calculation yielded a total of 54 participants (26 in intervention and 28 in control group).

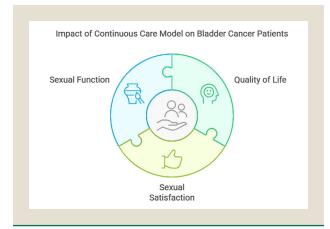
After screening and informed consent, eligible participants were randomly assigned to either the intervention (CCM) group or the control group in a permuted block randomization with varying block sizes of 4, 6, and 8 to maintain allocation concealment. The randomization schedule was developed from a computer-generated random number sequence by an independent researcher who was not involved in patient care or data collection. Blinding of participants to their group assignment was not possible due to the nature of the intervention. However, during the actual collection and analysis of data, outcome assessors were blinded. The outcome assessors were blinded until all participants had been assessed.

The conceptual framework of this study is based on CCM model (Figure 1).

The intervention consisted of 4 different phases of interventions at 4 specific times after the patient's treatment and recovery procedure:

- Preoperative orientation: Day before surgery, for 30 to 45 minutes. Contemplated surgery with possible complications, postoperative care and rehabilitation expectations, detailed explanation about the CCM model and components, reinforcement of informed consent, and administration of questionnaires at baseline. The interventions included family involvement.
- Sensitization postsurgery-Day 2 postsurgery: The session lasted for 90 to 120 minutes, and the researcher gave detailed information regarding bladder cancer, coping with physical symptoms such as pain, problems with urination and

Figure 1 Conceptual framework of this study is based on CCM model.



bowel function, medication adherence, and lifestyle changes in diet and exercise and sleep hygiene. Specific education about sexual function will include etiology of sexual dysfunction after cystectomy, maintaining intimacy, and resources tailored to patient specific needs and preference.

- 3. Ongoing monitoring and support (for 3 months): This phase of the intervention involved follow-up with the participants regularly through scheduled in-person virtual visits and by phone at 1- and 3-months postsurgery. These virtual visits also allowed physical assessments and provided an avenue for the participant to discuss any concerns or questions about their physical and psychological status. Reinforcement of previously given education and emotional support were key components in this phase. The research nurse was an active problem solver, adding resources when needed and providing emotional support.
- 4. Follow-up Evaluation (3 months postsurgery): The final 30-minute session was conducted at the 3-month follow-up to assess the effectiveness of the CCM, reinforce key education points, provide final closure, and address any remaining questions. All questionnaires were administered at 1 month and 3 months after surgery during virtual visit.

Patients in the control group received routine postsurgical care per the standard protocols of the hospital. This included routine nursing care, monitoring of vital signs, medication, and discharge planning. The patients received educational materials commonly used in the department. They did not receive the structured CCM intervention, however. The postoperative assessments consisted of routine clinical checks and questionnaires administered at 1 and 3 months postsurgery.

QoL, sexual satisfaction and function were assessed by the following validated self-report questionnaires:

 EORTC QLQ-C30: This is the well-established instrument for basic measurement of QoL in cancer patients, encompassing physical, role, emotional cognitive, and social functioning items, as well as special symptom scales, such as fatigue, pain, and nausea. The reliability of this questionnaire was obtained by Arneson et al.<sup>24</sup> using Cronbach's alpha > 0.70. Pearson's correlation coefficient (convergent and discriminant validity) was also used to determine validity (r > 0.4).<sup>22</sup> In Iran, in the study by Safaei et al.,<sup>25</sup> Cronbach's alpha was estimated to be above 0.70. Pearson's correlation coefficient (convergent and discriminant validity) was also used to determine validity (r > 0.4).<sup>23</sup>

- Larson Sexual Satisfaction Questionnaire: It measures sexual satisfaction, emotional closeness during sexual relations, frequency of love-making, and overall current relationship quality. The reliability of this questionnaire was obtained by Larson et al. 26 using Cronbach's alpha of 0.91. In Iran the reliability of the questionnaire was determined using the test-retest method, which was confirmed with 98% confidence. The face and content methods were also used to determine validity, which was confirmed by ten professors of the psychology and midwifery departments. 27
- International Index of Erectile Function; IIEF-5 is utilized to explore erectile function via 5 domains: erectile function, orgasm function, sex desire, intercourse satisfaction, and total satisfaction. The reliability of this questionnaire was obtained by Rosen et al.<sup>28</sup> using Cronbach's alpha of 0.91. To determine the validity, discriminant validity was used, which had sufficient validity. In Iran, Cronbach's alpha was estimated to be above 0.70. Convergent validity was also used to determine the validity.<sup>29</sup>
- Female Sexual Function Index (FSFI): This questionnaire assesses female sexual function by means of 6 domains of desire, arousal, lubrication, orgasm, satisfaction, and pain. The reliability of this questionnaire was obtained by Rosen et al.<sup>30</sup> using Cronbach's alpha of 0.82. Factor analysis was also used to determine validity. In Iran, Cronbach's alpha was estimated to be 0.86. The opinions of the supervisor and several other professors, and experts were also used to determine validity.<sup>31</sup>

All questionnaires were administered at baseline (prior to surgery), at 1 month, and 3 months postsurgery.

Data were analyzed using IBM SPSS Statistics (version 26). Descriptive statistics (means, standard deviations, frequencies) summarize baseline characteristics. Independent samples t-tests were used to compare baseline characteristics between groups. Repeated Measures with covariate (baseline) was employed to compare changes in QoL, sexual satisfaction and function scores between groups over time, controlling for baseline scores. Multiple linear regression was employed to adjust for potential confounding variables, including age, marital status, pre-existing health conditions, and preoperative QoL and sexual function scores. A significance level of P < .05 (2-tailed) was adopted for all statistical tests. Missing data were handled using multiple imputation techniques.

The study protocol was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences (Ethics Approval Number: IR.SBMU.PHARMACY.REC.1402.264). Informed written consent was obtained from all participants prior to enrollment. All data were anonymized to protect participant confidentiality.

## **Results**

Of 70 initially enrolled patients, 12 were excluded (7 for unmet inclusion criteria, 5 due to noncompliance), leaving 58 participants

Figure 2 Comparison of sexual satisfaction in patients with bladder cancer during the study.

70

60

50

40

10

0 before 1 month 3 month time

who were randomized equally into control and intervention groups (n=29 each). During the 3-month intervention, 4 participants withdrew (1 control, 3 intervention) due to nonadherence to the study protocol.

Finding from the group comparisons reveal the intervention group's average age was  $53.46 \pm 8.59$  with 69.2% (n = 18) being male, compared to the control group's  $50.03 \pm 9.14$  average age and 57.1% (n=16) male representation. Most patients underwent TUR surgery (intervention: 57.7%, n = 15; control: 60.7%, n = 17), though radical cystectomy was performed in 34.6% (n = 9) of the intervention group and 28.6% (n = 8) of the control group. Partial cystectomy was 2 (7.7%) in CCM compared to 3 (10.7%) in control group. Smoking was prevalent in both groups (intervention: 50%, n = 13; control: 57.1%, n = 16), whereas drug use was less common (intervention: 15.4%, n = 4; control: 35.7%, n = 10). The majority in both groups had 3 or more past medical issues. There was no significant difference between the 2 groups in terms of the baseline characteristic

Table 1 demonstrates that the mean changes in physical, emotional, fatigue, overall quality of life, and sleep disturbance domain scores during the study are statistically significant as repeated measures using baseline scores as covariates.

Figure 2 presents a comparison of the mean sexual satisfaction scores. In the control group: at baseline, it was  $47.60 \pm 5.57$ , after 1 month  $48.35 \pm 4.40$ , and 3 months later  $48.10 \pm 4.48$ ; in the experimental group at baseline, it was  $46.61 \pm 6.25$ , after 1 month  $61.11 \pm 7.86$ , and 3 months later  $56.61 \pm 5.89$  between groups, with P = .007. Also, preintervention scores significantly influenced changes in sexual satisfaction during the study period, P < .001.

Table 2 shows in males, significant differences were found in orgasm function and sexual desire over the study period. In females

there was no significant differences in domain scores throughout the experimental period. This result is demonstrated by repeated measures, which adjusts for initial differences in the baseline scores.

Table 3 shows the result of multiple linear regression analyses that is a statistically significant positive association between intervention group assignment and sexual function scores in both male and female participants. In females, a significant negative association was also observed between the number of past medical conditions and partner's job, suggesting that 5 or more pre-existing medical conditions, and the partner's role as a housekeeper, were associated with the lowest sexual function scores.

Table 4 presents multiple linear regression results examining the associations between demographic factors and both QoL and Sexual Satisfaction scores. The intervention group showed a significant negative association with QoL, indicating lower QoL scores in the intervention group compared to the control group. Conversely, the intervention group showed a significant positive association with sexual satisfaction, suggesting higher sexual satisfaction scores in the intervention group. Further analysis reveals a significant negative association between the number of PMH and QoL, while other demographic factors such as partner's job and patient's education showed some association with QoL. The "Total before" variable also showed a significant positive association with sexual satisfaction. These findings suggest complex relationships between demographic factors, QoL, and sexual satisfaction, with the intervention exhibiting contrasting effects on these 2 outcomes.

#### **Discussion**

This study explored the impact of a CCM on the QoL, sexual satisfaction and function of bladder cancer survivors after tumor removal surgery. Our findings showed significant positive effects for

able 1 Compariso	on of QoL in Patients W	ith Bladder Cancer B	etween Groups in 3 Pe	eriods	
Scale	Time	Intervention	Control	<i>P</i> -Value Group <sup>a</sup>	<i>P</i> -Value Before <sup>b</sup>
Physical	Before	$10.19 \pm 2.05$	11.10 ± 1.44	< .001	< .001
	After 1 mo	8.15 ± 1.18	$10.50 \pm 2.13$		
	After 3 mo	9.42 ± 1.85	$10.67 \pm 2.22$		
Role	Before	$3.88 \pm 1.27$	4.28 ± 1.18	.877	.207
	After 1 mo	4.23 ± 1.24	$3.96 \pm 1.50$		
	After 3 mo	3.84 ± 1.22	3.89 ± 1.13		
Cognitive	Before	4.42 ± 1.10	4.17 ± 1.02	.004	.087
	After 1 mo	$3.30 \pm 1.22$	4.25 ± 1.77		
	After 3 mo	$3.07 \pm 1.09$	$3.96 \pm 1.03$		
Social	Before	4.34 ± 1.09	$4.53 \pm 0.99$	.069	.707
	After 1 mo	$3.96 \pm 0.95$	$4.42 \pm 0.99$		
	After 3 mo	3.76 ± 1.10	4.32 ± 1.05		
Emotional	Before	$12.15 \pm 1.93$	$11.46 \pm 2.30$	< .001	.002
	After 1 mo	9.03 ± 1.39	11.60 ± 2.13		
	After 3 mo	$9.30 \pm 1.66$	11.64 ± 2.04		
Pain	Before	4.92 ± 1.05	4.32 ± 1.54	.079	.001
	After 1 mo	4.03 ± 1.45	4.67 ± 1.05		
	After 3 mo	$3.96 \pm 1.48$	4.67 ± 1.15		
Fatigue	Before	$7.92 \pm 1.44$	$7.32 \pm 1.54$	< .001	.514
	After 1 mo	$5.76 \pm 1.39$	$7.71 \pm 1.08$		
	After 3 mo	$5.76 \pm 1.39$	$7.71 \pm 1.08$		
Nausea and vomiting	Before	$4.00 \pm 1.05$	4.14 ± 1.07	.211	.153
	After 1 mo	$3.73 \pm 1.21$	3.92 ± 1.05		
	After 3 mo	$3.57 \pm 1.30$	4.10 ± 1.10		
overall quality of life	Before	$6.42 \pm 1.52$	$6.17 \pm 2.31$	< .001	.965
. ,	After 1 mo	$8.46 \pm 2.40$	5.71 ± 1.01		
	After 3 mo	$7.96 \pm 2.57$	$6.00 \pm 1.05$		
Dyspnea	Before	$1.80 \pm 0.96$	$2.17 \pm 0.87$	.328	.667
	After 1 mo	2.00 ± 1.05	$1.97 \pm 0.90$		
	After 3 mo	1.96 ± 1.07	$1.82 \pm 0.94$		
Constipation	before	$2.00 \pm 0.74$	$2.28 \pm 0.89$	.130	.493
·	After 1 mo	$2.34 \pm 0.97$	$2.10 \pm 0.68$		
	After 3 mo	$2.34 \pm 0.97$	$2.10 \pm 0.68$		
Diarrhea	before	$2.0 \pm 0.93$	$2.42 \pm 0.79$	.289	.041
	After 1 mo	$2.28 \pm 0.94$	$1.89 \pm 0.91$		
	After 3 mo	$2.30 \pm 0.97$	$1.89 \pm 0.91$		
Sleep disturbance	before	$2.46 \pm 0.64$	$2.78 \pm 0.62$	< .001	.850
	After 1 mo	$1.34 \pm 0.48$	2.28 ± 0.71		
	After 3 mo	$1.73 \pm 0.87$	$2.5 \pm 0.74$		
Financial impact	before	$2.65 \pm 0.62$	$2.39 \pm 0.62$	.073	.659
•	After 1 mo	$2.65 \pm 0.79$	2.92 ± 0.46		
	After 3 mo	$2.57 \pm 0.64$	2.92 ± 0.71		
Total (1-28)	before	$64.65 \pm 4.53$	$65.60 \pm 5.82$	.001	.001
,	After 1 mo	$54.70 \pm 4.87$	$64.25 \pm 4.81$		
	After 3 mo	$54.76 \pm 5.54$	$64.17 \pm 4.94$		

<sup>&</sup>lt;sup>a</sup> Adj. for baseline value (before intervention).
<sup>b</sup> The effect of baseline value on the mean change of outcomes during the study.

 Table 2
 Comparison of Sexual Function in Patients With Bladder Cancer Between Groups in 3 Periods

	Scale	Time	Intervention	Control	<i>P</i> -Value Group <sup>a</sup>	<i>P</i> -Value Before <sup>b</sup>
Male	Erectile function	Before	$9.555 \pm 1.756$	$9.062 \pm 2.379$	.503	< .001
		After 1 mo	$6.277 \pm 4.675$	$8.937 \pm 2.205$		
		After 3 mo	$12.00 \pm 1.748$	$9.562 \pm 2.096$		
	Orgasm function	Before	$3.277 \pm 0.826$	$3.187 \pm 1.108$	.049	< .001
		After 1 mo	$2.166 \pm 1.689$	$3.187 \pm 1.108$		
		After 3 mo	3.777 ± 1.165	$3.687 \pm 1.07$		
	Sexual desire	Before	2.777 ± 1.114	$3.062 \pm 1.062$	.020	< .001
		After 1 mo	$1.722 \pm 1.447$	$3.062 \pm 1.062$		
		After 3 mo	$3.388 \pm 1.036$	$3.562 \pm 1.093$		
	Intercourse satisfaction	Before	4.611 ± 1.500	$3.125 \pm 2.502$	.919	< .001
		After 1 mo	$3.00 \pm 2.520$	$4.125 \pm 1.087$		
		After 3 mo	$6.00 \pm 1.37$	$4.125 \pm 1.087$		
	Overall satisfaction	Before	$3.166 \pm 0.923$	$3.125 \pm 0.885$	.245	< .001
		After 1 mo	2.11 ± 1.711	$3.125 \pm 0.885$		
		After 3 mo	$4.055 \pm 1.109$	$3.562 \pm 0.727$		
	Total	Before	$23.388 \pm 2.354$	$22.562 \pm 3.444$	.261	.037
		After 1 mo	15.277 ± 11.265	$22.437 \pm 3.385$		
		After 3 mo	$29.222 \pm 3.352$	$24.50 \pm 2.581$		
Female	Desire	Before	$3.750 \pm 1.707$	$3.500 \pm 1.522$	.904	.10
		After 1 mo	$2.125 \pm 2.642$	$2.333 \pm 2.435$		
		After 3 mo	$4.250 \pm 1.707$	$3.500 \pm 1.522$		
	Arousal	Before	$5.750 \pm 1.832$	$5.250 \pm 0.866$	.500	.248
		After 1 mo	$2.125 \pm 3.136$	$2.500 \pm 2.645$		
		After 3 mo	$6.875 \pm 1.457$	$5.250 \pm 0.866$		
	Lubrication	Before	$5.500 \pm 1.309$	$5.583 \pm 1.083$	.843	.169
		After 1 mo	$1.875 \pm 2.642$	$2.750 \pm 2.988$		
		After 3 mo	$6.125 \pm 1.246$	$5.583 \pm 1.083$		
	Orgasm	Before	$4.125 \pm 1.246$	$4.250 \pm 0.866$	.713	.009
		After 1 mo	$1.500 \pm 2.267$	$2.250 \pm 2.416$		
		After 3 mo	4.375 ± 1.187	$4.250 \pm 0.866$		
	Satisfaction	Before	4.375 ± 1.187	$3.916 \pm 1.083$	.579	.003
		After 1 mo	$1.625 \pm 2.263$	$2.000 \pm 2.256$		
		After 3 mo	$5.625 \pm 1.846$	$3.916 \pm 1.083$		
	pain	Before	4.875 ± 1.642	$4.083 \pm 1.083$	.295	.009
		After 1 mo	$2.000 \pm 2.976$	$1.916 \pm 2.108$		
		After 3 mo	$6.375 \pm 2.263$	4.083 ± 1.083		
	Total	Before	$25.58 \pm 2.234$	27.375 ± 4.307	.649	.429
		After 1 mo	10.250 ± 14.449	12.750 ± 13.430		
		After 3 mo	36.625 ± 1.302	25.583 ± 2.234		

<sup>&</sup>lt;sup>a</sup> Adj. for baseline value (before intervention).

many patients, but also highlighted the complex, individual factors influencing recovery. The discussion will focus on the key outcomes, their implications for patient care, and future research directions.

Patients receiving the CCM reported notable improvements in QoL, including reduced physical and emotional distress, enhanced cognitive function, and decreased fatigue (Table 1). These results align with existing research emphasizing the importance of holistic cancer care.<sup>32,33</sup> The CCM's success can be attributed to its multifaceted approach, which included preoperative education, postoper-

ative self-management strategies, and ongoing monitoring. Preoperative education likely reduced anxiety and improved preparedness, <sup>34,35</sup> while postoperative sensitization empowered patients to manage pain and urinary issues, fostering a sense of control. <sup>19,36</sup> Regular follow-ups provided emotional and practical support, reducing isolation and promoting adherence to treatment plans. <sup>36,37</sup>

The intervention group demonstrated significantly greater improvements in sexual function compared to the control group, underscoring the limitations of standard postoperative care. The

<sup>&</sup>lt;sup>b</sup> The effect of baseline value on the mean change of outcomes during the study.

 Table 3
 Association Between Demographic Variables With Sexual Function

Demographic Variables	Male			Female		
	Coef.	95% CI	<i>P</i> -Value	Coef.	95% CI	<i>P</i> -Value
Group (inter)	6.196	2.570: 5.822	< .001	6.145	4.519: 7.771	< .001
PMH	-0.330	—1.481: 0.820	.559	<b>—1.475</b>	-2.651: -0.298	.019
Smoke (y) <sup>a</sup>	0.410	-1.185: 2.006	.601	0.782	-0.660: 2.224	.258
Age	0.159	-1.806: 2.125	.896	1.145	-0.427: 2.716	.137
Partner's job	0.982	-0.188: 2.152	.096	-1.974	-3.522: -0.425	.017
Patient's job	<b>-1.116</b>	-2.909: 0.677	.212	0.392	-0.667: 1.451	.432
Patient's education	-0.347	-1.419: 0.725	.511	0.409	-0.633: 1.452	.406
Total before	0.768	0.456: 1.079	< .001	0.489	0.247: 0.730	.001

a y means yes.

Table 4 Association between demographic variables With Quality of Life and Sexual Satisfaction
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Demographic Variables	Quality Of Life			Sexual Satisfaction		
	Coef.	95% CI	<i>P</i> -Value	Coef.	95% CI	<i>P</i> -Value
Group (Inter)	-7.799	—10.580: —5.018	< .001	1.090	0.490: 1.720	.003
PMH	-3.613	-5.728: -1.498	.001	-0.076	-0.564: 0.413	.740
Smoke(y)	0.605	-2.154: 3.365	.661	-0.290	-0.891: 0.312	.312
Age	4.330	1.019: 7.642	.12	0.395	-0.272: 1.063	.219
Partner's job	2.621	0.490: 4.752	.017	-0.369	-0.953: 0.214	.191
Patient's job	2.107	-0.036: 4.250	.054	0.129	-0.300: 0.558	.523
Patient's education	2.064	0.169: 3.960	.033	0.144	-0.285: 0.573	.474
Total before	0.123	-0.148: 0.394	.365	1.182	0.944: 1.420	< .001

CCM's inclusion of psychological support, patient education, and partner involvement was particularly effective in addressing sexual health concerns. Partners in the care process can foster open communication and mutual support, which is vital for maintaining intimacy and sexual well-being.<sup>38</sup> Male patients experienced significant improvements in sexual satisfaction, orgasm function, and desire (Table 2), likely due to the tailored sexual health education provided.<sup>39,40</sup> However, female patients did not show statistically significant improvements, highlighting the need for further research into the biological, psychological, and social factors affecting female sexual health postsurgery.<sup>41,42</sup>

The analysis also identified key predictors of sexual function, such as a female's medical history and her partner's employment status (Table 3), emphasizing the complex interplay of factors influencing recovery. Additionally, the CCM's effectiveness varied across different QoL and sexual function domains, indicating the need for personalized care plans that address both physical and emotional well-being (Table 4).

Our analysis controlled for several factors that could affect the results, such as age, marital status, existing health problems, and initial levels of QOL and sexual function. However, it's possible that other unmeasured factors also played a role. Future studies should include a broader range of variables to better understand these complex relationships.

#### Strengths and Limitations

Strengths of this study include explicitly addressing sexual health in male patients, revealing the limitations of standard care, highlighting a gender gap in recovery, and underscoring the need for a more comprehensive, partner-inclusive strategy that also considers mental and social well-being.

This study was limited by the inability to directly monitor patients' adherence to the care program and by cultural barriers to discussing sexual health, which were addressed through the guidance of the urologist consultant, sending educational images and videos and answering questions after posting the videos on social media.

#### Conclusion

This study provides significant insights into the potential of the CCM to improve QoL, sexual satisfaction and function in bladder cancer patients following tumor removal surgery. The observed improvements, particularly in several aspects of QoL, sexual satisfaction, and male sexual function, demonstrate the effectiveness of a multifaceted, patient-centered approach to postsurgical care. However, the lack of consistent positive effects across all domains and patient subgroups, especially regarding female sexual function, underscores the complexity of this area and the need for further research. Larger, more diverse studies using rigorous research designs (like randomized controlled trials) are needed to further test and

refine this approach. It's also vital to include patient perspectives through interviews and other qualitative methods to understand how to best meet the specific needs of individuals. This is especially important for tailoring care to men and women, ensuring that everyone benefits fully.

#### Clinical Practice Points

This study showed a Continuous Care Model (CCM) improved quality of life and sexual satisfaction in bladder cancer patients, with significant improvements in male sexual function but limited impact on female patients, highlighting a need for further gender-specific research.

# Declaration of Generative AI and AI-Assisted Technologies in the Writing Process

To enhance readability and grammar, the authors utilized artificial intelligence during the preparation of this manuscript. After using this service, the authors reviewed and edited the content as needed and take full responsibility for the content of the published article.

## **Availability of Data and Materials**

The information obtained from the findings is presented in the table and in the article.

#### **Disclosure**

The authors declare that they have no conflicts of interest.

# **CRediT** authorship contribution statement

Fateme Rezaeeniya: Writing – review & editing, Writing – original draft, Data curation. Fateme Hasandoost: Writing – review & editing, Writing – original draft, Validation, Methodology. Amir Reza Abedi: Writing – review & editing, Writing – original draft, Supervision. Alireza Amanollahi: Writing – original draft, Software, Formal analysis, Data curation. Soolmaz Moosavi: Writing – review & editing, Writing – original draft, Project administration, Methodology, Conceptualization.

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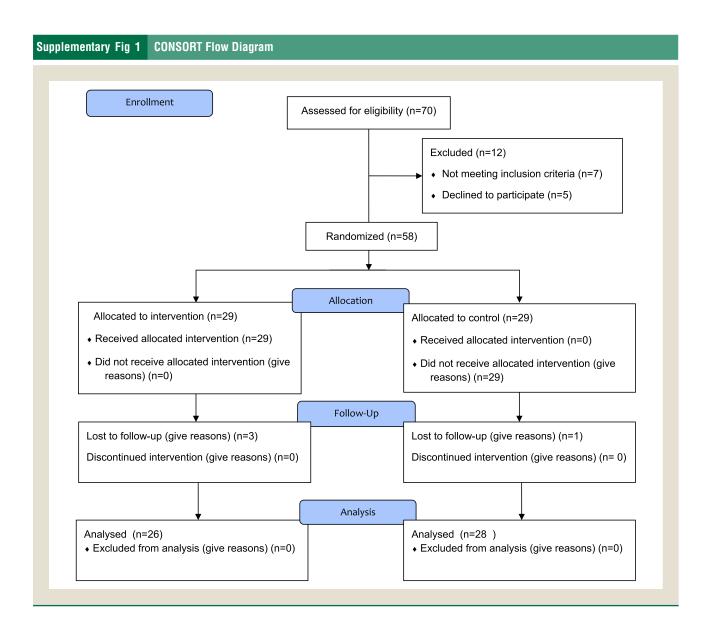
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# **Supplementary material**



#### Supplementary Table 1 CONSORT 2010 Checklist of Information to Include When Reporting a Randomized Trial

Section/Topic	Item No	Checklist Item	Reported on Page No
Title and abstract	10	Identification on a condensited trial in the title	4
	1a 1b	Identification as a randomized trial in the title	1 2
	ID	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			_
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	4
Methods			_
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	6
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomization			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomization; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	5
	11b	If relevant, description of the similarity of interventions	Not applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7,8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	7
	13b	For each group, losses and exclusions after randomization, together with reasons	7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7
	14b	Why the trial ended or was stopped	10
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	10-15
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10-15
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	10-15

 $(continued\ on\ next\ page)$ 

Supplementary Table 1 (continu	ued)		
Section/Topic	Item No	Checklist Item	Reported on Page No
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	10-15
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	10-15
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	15-16
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	16
Other information			
Registration	23	Registration number and name of trial registry	17
Protocol	24	Where the full trial protocol can be accessed, if available	No
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	18