

ORIGINAL ARTICLE

Feasibility and acceptability of couple counselling and pelvic floor muscle training after operation for prostate cancer

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ABSTRACT

Background: Radical prostatectomy is often followed by long-lasting erectile dysfunction and urinary incontinence, with adverse effects on the quality of life and intimate relationship of patients and partners. We developed the ProCan intervention to ameliorate sexual and urological dysfunction after radical prostatectomy and examined its feasibility, acceptability and changes in sexual function.

Material and methods: Between May 2014 and October 2014, seven couples attending the Department of Urology, Rigshospitalet, were included 3–4 weeks after radical prostatectomy in the ProCan intervention, which consists of up to six couple counselling sessions, group instruction in pelvic floor muscle training (PFMT), up to three individual PFMT sessions and a DVD home training program. We examined its feasibility on the basis of the recruitment rate, adherence to and acceptability of the intervention, the response rate and changes in erectile and sexual functioning measured on the International Index of Erectile Function at baseline and at eight and 12 months.

Results: The recruitment rate was 14%. One couple withdrew, six couples attended 1–4 counselling sessions, and all patients attended PFMT until continence was achieved. The response rate on outcomes was 85% for patients and 71% for partners. The couples reported that counselling improved their sex life but it did not improve their ability to talk openly about sex. Most patients found that the physiotherapist improved their motivation and the quality and intensity of PFMT. Erectile dysfunction improved from severe at baseline to moderate at eight months' follow-up, and mean sexual functioning improved from 18.4 to 37.1 points at eight months' follow-up, but decreased slightly to 31.4 at 12 months.

Conclusion: Our results suggest that the recruitment procedure should be adapted and minor revisions are needed in the intervention. The key components, couple counselling and PFMT, were well accepted and achievable for the patients.

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Curative treatment of prostate cancer is primarily radical prostatectomy, which, despite the introduction of nerve-sparing and robot-assisted surgery, may still be associated with urinary incontinence [1], erectile dysfunction, penile shortening, dry and sometimes painful orgasms, and leakage of urine with orgasm (climacturia) [2]. These physical late effects of treatment may reduce the health-related quality of life and cause psychological distress [3]. It has been suggested that increasing arterial flow during restoration of the cavernous nerves is important for early recovery of erectile function and that early pelvic floor muscle training (PFMT) after radical prostatectomy with biofeedback improves erectile functioning and reduces climacturia [4]. The predominant medical treatment for erectile dysfunction is phosphodiesterase (PDE-5) inhibitors; however, men treated with non-nerve-sparing surgery often require more potent treatment, with alopstadil, or use vacuum erectile devices to achieve erection [5]. While counselling may increase the use of and

compliance with medical treatment for erectile dysfunction [5], many men are reluctant to seek medical help [6], and non-compliance with treatment is common [5]. Other factors in compliance with medical treatment are good female sexual function and a satisfactory relationship [5].

The effect of psychosocial interventions on sexual or relationship functioning in men treated for prostate cancer was evaluated in a review of 16 studies [7], of which eight included [8–13] or recommended inclusion [13–15] of the partner. Different educational and supportive interventions were tested [8,9,11,12,15], with various ways to improve couple communication and intimacy [8–11,14] and the provision of information on medical treatment for erectile dysfunction and counselling to increase use and compliance with treatment [8,9,14]. The considerable variation in the interventions, sample characteristics and in the timing and duration of the interventions limited comparisons [7]. Interventions delivered face-to-face and more complex strategies to target male

sexuality and relationships [8,14] seemed to improve sexual functioning; however, the samples were small, and only one study included a control group [14].

To our knowledge, only two previous randomized clinical trials have used complex strategies to target sexuality in couples after an operation for prostate cancer [16,17], and none included PFMT. Previous studies of interventions for couples after cancer have found it difficult to both recruit and retain couples [8,18]. The aim of this study was to examine the feasibility and acceptability of the ProCan (Prostate Cancer) intervention, which consists of specialist sexual counselling for couples and specialist PFMT. Feasibility as examined with regard to: (1) recruitment of couples to the study; (2) participation in and adherence to the intervention; (3) acceptability of the timing and content of the intervention; (4) response rates on selected outcomes; and (5) changes in erectile and sexual function between baseline and 12-month follow-up.

Material and methods

Population

We included prostate cancer patients and their female partners. Patients were eligible if they were proficient in Danish, aged ≥ 18 years, in a sexual relationship with a female partner and had undergone surgery within the past 3–4 weeks between May and October 2014 for primary prostate cancer with open or robot-assisted, nerve-sparing or non-nerve-sparing surgery at the Department of Urology, Rigshospitalet. The exclusion criteria were: another cancer diagnosis (except non-melanoma skin cancer) within five years, a major psychiatric disorder, abuse of alcohol or drugs or dementia. The inclusion criteria for the partners were: female, aged ≥ 18 years and proficient in Danish.

Recruitment

Although we planned to randomize patients, because of slow inclusion, we randomized only the first four couples, all of which were allocated to the intervention. We then decided to examine the feasibility and acceptability of the ProCan intervention in a single-arm trial. Initially, eligible patients were handed written information material and were invited to participate in an interview with the project leader. Later, the information material was posted to all patients who had been operated for prostate cancer. If the patient agreed to receive more information, a meeting was arranged with the eligible patient, his partner and the project leader at the urological department, where informed consent and completed baseline questionnaires were collected.

Evaluation of feasibility, acceptability, and changes in erectile and sexual functioning

To evaluate recruitment of couples, we registered the daily number of eligible patients in the department during the first seven weeks of the inclusion period. Adherence to the intervention was registered as part of the study tracking

procedure. Participants themselves evaluated the timing and content of the intervention in questionnaires (Tables 2 and 3). At baseline, participants answered questions on sociodemographic variables and evaluated selected outcomes and changes in sexual functioning. The participants filled in questionnaires at the time of study inclusion and at eight and 12 months. The primary outcome was erectile functioning in patients, and secondary outcomes were sexual functioning scores for both patients and their partners. All patients completed the International Index of Erectile Function [19], a validated 15-item measure of male sexual function within the past four weeks. It measures five subscales: erectile functioning (six items), orgasmic functioning (two items), sexual desire (two items), intercourse satisfaction (three items), and overall satisfaction (two items). In the original study, the total mean score for a volunteer sample was 60.8, and that for men with known sexual dysfunction was 35.2 [19]. All partners provided information for the Female Sexual Function Index [20], which is a validated 19-item measure of six dimensions of female sexual functioning within the past four weeks, including: desire, arousal, lubrication, orgasm, satisfaction, and pain [20]. Higher scores indicate a higher symptom burden, and a total score ≤ 26.55 indicates sexual dysfunction.

Standard care

All patients received standard care, including preoperative instruction in PFMT, regular outpatient visits with a physician, referral for municipal rehabilitation, and medical treatment for erectile dysfunction based on the physician's advice. Three types of medical treatment were offered, if not contraindicated: daily treatment with PDE-5-inhibitor or on demand before sexual activity, or alprostadil as either a urethral pin or penile injection.

ProCan intervention

In addition to standard care, the participants were offered the ProCan intervention, consisting of: up to six one-hour couple counselling sessions with a nurse certified in sexual counselling, one group instruction in PFMT, up to three individual PFMT sessions with a physiotherapist and a DVD containing PFMT programs for home training. Both the couple counselling and the PFMT were offered on a need basis. The theoretical framework for couple counselling and PFMT was social cognitive theory; the methods applied were active learning, adjustment of outcome expectations, and modeling guided practice [21] (Table 1). The project leader prepared manuals for the intervention in collaboration with a consultant in clinical sexology, a trial sexual Counsellor, a specialist in PFMT, and the trial physiotherapists.

Couple counselling

To promote early erectile and sexual functioning, counselling was initiated as soon as the couple felt ready. The counselling was semi-structured, explorative, and informing (Table 1).

Table 1. Intervention content: issues and objectives for couple counselling and pelvic floor muscle training.

Issue	Objective
Couple counselling	
Definition of the sexual problem	The couple was supported in articulating the sexual problem and the counsellor helped to adjust and correct misunderstandings
Adjustment of mutual expectations	The couple was supported in setting realistic goals of counselling
General information on sexuality	To provide knowledge about the physical and psychological consequences of prostatectomy and sexual changes related to menopause and aging
Information on medical treatment for erectile dysfunction	To provide knowledge about medical and mechanical treatments for erectile dysfunction and treatment for lubrication problems related to menopause
Loss and grief with regard to a changed sex life	The couple was supported to start a process of acceptance of the loss of the usual practice for their sex life and to put focus on the intimacy that remained
Couple communication	The couple was supported in mutual, clear communication, with a focus on the influence of behavior, body language and tone of voice
Sensuality training	Couples that were interested were introduced to sensuality training in order to increase intimacy and sexual desire
Agreement on future sexual activity	The couple was supported in the use of mutual constructive communication about sexual activity in order to define and agree upon future frequency and practice
Group PFMT	
Normal functioning of pelvic floor muscles and consequences of radical prostatectomy	To provide information about the normal functioning of pelvic floor muscles, including on the lower urinary tract and the consequences of radical prostatectomy on urinary and sexual function
Lifestyle advice	To provide information on the influence of lifestyle factors on urinary incontinence
Aids for incontinence	To provide information on pads and 'uridoms' and how to acquire these aids
Instructions in PFMT	To instruct patients in exercising the pelvic floor muscles and to hand out a DVD with a home training program
Prolonged incontinence	To provide information on operational alternatives if incontinence continues beyond 6–12 months
Individual PFMT follow-up	
Subjective examination of urinary function	To design an exercise program, the physiotherapist obtains patients' subjective experience of urinary frequency and incontinence, fluid intake, obstipation, pain, erectile function, use of aids, limitations to daily activities, other diseases, medication, and personal factors related to motivation and coping
Objective examination of pelvic floor muscle function	To assess the function of the pelvic floor muscles by manual palpation to determine muscle strength and endurance, and compensation by activation of other muscles and relaxation after exercise

PFMT: pelvic floor muscle training.

Elements of sexual therapy in which sexuality is defined as a multidimensional construct involving biological, psychological, and social aspects were included. Counselling was structured according to the first three levels of the PLISSIT model [22]: permission to discuss sexual problems, limited information about the sexual problem, and specific solutions for resolving the problem. The counsellor provided assistance in self-management by encouraging couples to take responsibility for their situation and acted mainly as a mediator for personal reflection and couple communication. Sexual counselling focused on establishing safe communication about feelings, intimacy, sex, and the relationship, and was completed eight months after study inclusion.

Pelvic floor muscle training

PFMT was adapted to patients' needs and followed the recommendations for treatment of urinary incontinence of the Professional Association of Danish Physiotherapists [23], adjusted for men operated for prostate cancer. Certified physiotherapists qualified to perform examination and treatment of pelvic floor muscle dysfunction provided the training. Ability to contract and relax the muscles properly was assessed by digital examination, and individual manual facilitating techniques were used when necessary. Once voluntary control had been achieved, the therapist designed an

individual PFMT program to the patient in accordance with his dysfunction (Table 1). Individual physiotherapy was completed within 3–4 months of inclusion in the study.

Analyses

All measures of feasibility and acceptability are descriptive. Between 15 May and 4 July 2015, we evaluated the feasibility of recruitment and estimated the number of eligible patients to be included in the study. The feasibility of adherence to the intervention was estimated from participation in the different components. To measure the acceptability of the content and timing of the intervention, we counted the responses to the evaluation form (Tables 2 and 3). The feasibility of collecting outcomes was evaluated by estimating the response rates to the outcome measures at baseline and at eight and 12 months. We performed descriptive analyses of sociodemographic and clinical characteristics and calculated individual and mean scores for erectile and sexual functioning among patients (Table 4) and sexual functioning in female partners at baseline and at eight and 12 months' follow-up. We examined only female sexual desire, which is the only domain that is independent of sexual activity, as not all the female partners had been sexually active within the past month. Changes in scores for individual items and mean total scores for sexual functioning among patients and partners

between baseline and 12 months follow-up were plotted for patients (Figure 1) and partners (Figure 2) separately.

Results

Recruitment

During the first seven weeks, of the 32 patients who underwent surgery, 11 did not fulfill the inclusion criteria. All 21 eligible patients were handed the project material and three of the potentially eligible patients (14%) and their partners agreed to participate. Between July and October 2014, we included seven couples. Six patients had undergone nerve-sparing surgery and one non-nerve-sparing surgery. Five couples had medium to long education and two couples had short education.

Participation in and adherence to the intervention

Of the seven couples, two attended four couple counselling sessions, two couples attended two sessions, and two attended one session. One female partner withdrew after

one session and one couple withdrew from the study and did not attend any counselling. All seven patients attended the group instruction in PFMT and two patients had three follow-up sessions; two patients were followed up twice, one patient was followed up once, and two patients had no individual follow-up.

Acceptability of timing and content of the intervention

The couples responded that counselling should be offered within three months of the operation (Table 2). Most participants reported that the counselling lived up to their expectations: they found the topics discussed relevant and considered that the counselling had helped or could help to improve their sex life (Table 2). Two of 11 participants responded that specific advice should have been provided, three reported that the counselling might have improved their ability to talk openly about sex, and about half reported that the counselling might have brought the couples closer. Five of six patients would have preferred that PFMT be offered within one month of the operation (Table 3). Most patients found the topics discussed during PFMT relevant,

Table 2. Evaluation of content and timing of couple counselling. We would like to know your opinion of the content and timing of counselling. Please answer the questions in the table below.

	Yes (N)	Maybe (N)	No (N)
Do you consider the topics discussed during counselling relevant for you?	9	1	1
Did you learn anything new about yourself and your partner?	2	5	4
Did you receive any specific advice that might help you to handle the changes in your sex life?	1	1	9
Has your ability to talk openly about your sex life with your partner improved?	2	1	8
Did the counselling bring you and your partner closer?	4	2	5
Did the counselling live up to your expectations?	9		2
Did you talk with the nurse about topics other than sexual problems related to the disease and treatment?	7		4
Did you feel a need for counselling?	5	5	1
Do you consider that the counselling will help to improve your sex life?	6	2	3
In general, when do you consider that counselling should be offered?	Within the first month of the operation 4	Within 2–3 months of the operation 7	More than 3 months after the operation

Responses are based on patients (N = 6) and partners (N = 5) who attended the couple counselling.

Table 3. Evaluation of the content and timing of pelvic floor muscle training. We would like to know your opinion on the content and timing of pelvic floor muscle training. Please answer the questions in the table below.

	Yes (N)	Maybe (N)	No (N)
Were the topics discussed in the group relevant for you?	5		1
Did you learn anything new (something you did not know already)?	3	1	2
Was it beneficial for you to meet others who had a similar experience?	5		1
Did the instructions increase your motivation to train your pelvic floor muscles?	4	1	1
Did you receive any specific advice that you can use in your training?	4	1	1
Did you prefer individual follow-up with a physiotherapist?	2		4
Did the individual follow-up with a physiotherapist improve the quality of your training?	4	1	1
Have you used the DVD?	4		2
Was the DVD useful?	3		3
Was the contact with the physiotherapist important for how much you trained?	4	1	1
In general, when do you consider that pelvic floor muscle training should be offered?	Within the first month of the operation 5	Within 2–3 months of the operation 1	More than 3 months after the operation

Responses are based on patients (N = 6) who attended the pelvic floor muscle training.

that they had learnt something new and had been given specific advice, and that PFMT might have improved their motivation and the quality and intensity of training. Most preferred group training to individual training, and three of six patients found the DVD useful.

Response rates and changes in erectile and sexual functioning over time

The response rate on primary outcome measures was 85% for patients and 71% for partners. Five patients and partners who attended both the counselling and PFMT filled in all three questionnaires. The score for erectile functioning increased from a mean of 2.8 (range 1–5) at baseline to 11.4 (range 5–29) at eight months’ follow-up and slightly decreased to 10.6 (range 1–19) at 12 months’ follow-up (Table 4). The scores for the domains sexual desire, orgasmic function, intercourse satisfaction, and overall satisfaction improved from baseline to eight months’ follow-up and then decreased at the 12-month follow-up (Table 4). The mean score for sexual functioning at baseline was 18.4 (range 5–34), improved over time to 37.1 (range 22–66) at eight

months and decreased slightly to 31.4 (range 9–50) at 12 months’ follow-up (Figure 1). At baseline, five partners reported a mean desire score of 2.9 (range 2.4–3.6), which improved slightly to 3.7 at eight months’ follow-up (range 3.0–4.8), then decreased to baseline levels at the 12-month follow-up. Two partners reported improved sexual functioning from below to above 26.55, the cutoff score for probable sexual dysfunction (Figure 2).

Discussion

As in previous studies on interventions for couples after cancer, we found recruitment difficult, with a participation rate of 14%. Nevertheless, the couples that participated had acceptable adherence to the intervention, and most reported high satisfaction with the counselling and PFMT. As only one couple considered that the counselling had provided specific advice and only two couples reported that the counselling had improved their ability to talk openly about sex, these are areas for improvement. Data collection was extensive, and we observed improvements in erectile and sexual functioning over time, indicating that the outcome measures are sensitive and relevant for detecting changes.

On average, 16–20 patients are operated on at the urological department each month, and we had expected to include five or six couples a month during the six-month inclusion period. Potentially eligible patients were invited either by post or in person; however, we do not know whether all eligible patients were invited. Difficulties in recruitment of participants to psychosocial interventions for couples were reported in a large review [18]. In addition, many men are reluctant to consult health professionals for sexual problems [8] and health professionals find it difficult to bring up sexual problems with patients [24]. Our inclusion criteria may have been too strict, as we intended to

Table 4. Mean erectile and sexual functioning at baseline, eight, and 12 months.

Outcome measure (score range)	Mean (range)		
	Baseline	8 months	12 months
Age	64.1 (58–72)		
International Index of Erectile Function			
Erectile function (1–30)	2.8 (1–5)	11.4 (5–29)	10.6 (1–19)
Sexual desire (2–10)	4.2 (2–8)	7.0 (4–9)	4.6 (2–6)
Orgasmic function (0–10)	2.8 (0–10)	7.4 (5–10)	6.0 (0–10)
Intercourse satisfaction (0–15)	2.0 (0–10)	6.0 (0–11)	3.8 (0–9)
Overall satisfaction (2–10)	6.6 (4–8)	5.6 (3–8)	6.4 (5–8)
Total score	18.4 (5–34)	37.4 (22–66)	31.4 (9–50)

Results are based on responses from five patients who attended the intervention and answered all three questionnaires.

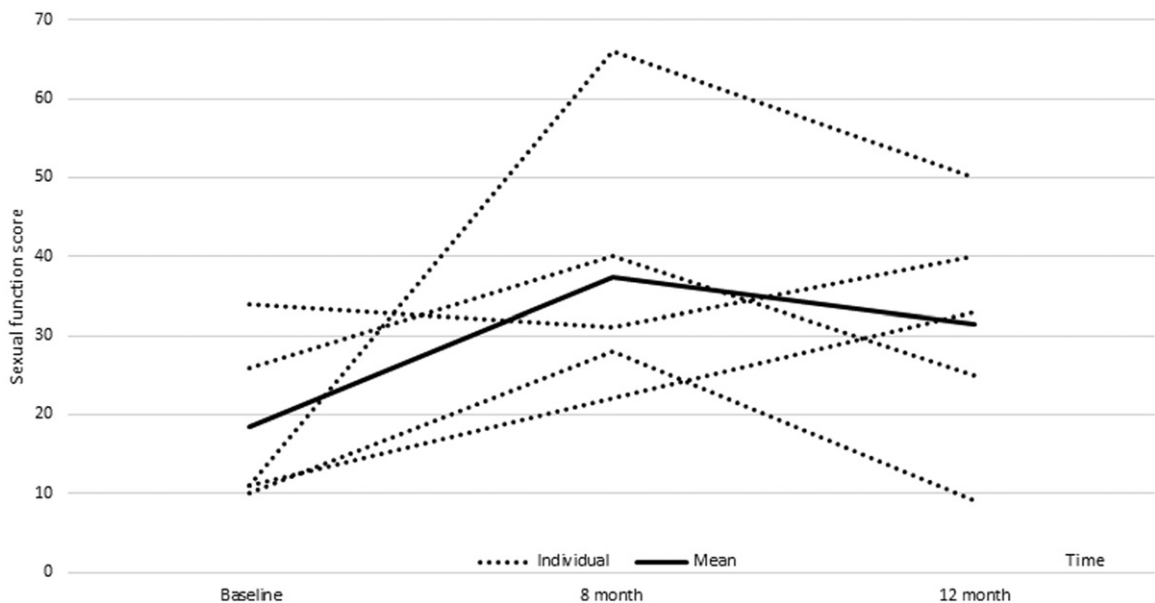


Figure 1. Sexual functioning at baseline, eight, and 12 months of five prostate cancer patients who attended pelvic floor muscle training and couple counselling. Note: Erectile function was measured on the International Index of Erectile Function.

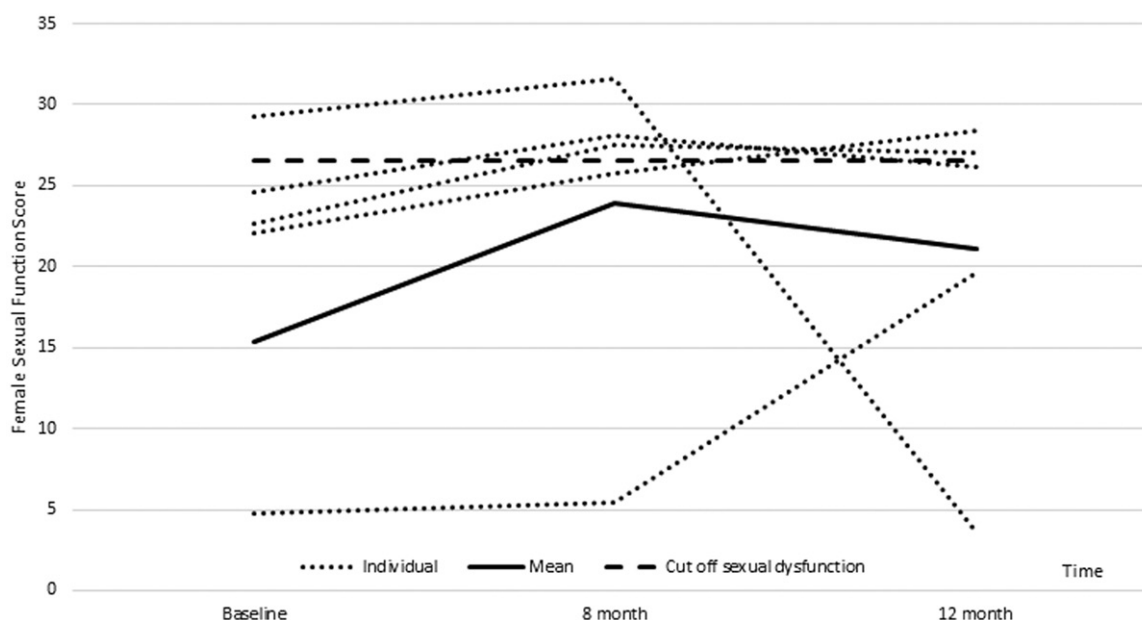


Figure 2. Sexual functioning at baseline, eight, and 12 months of five female partners of prostate cancer patients who attended counselling. Sexual functioning was measured on the Female Sexual Function Index. A score ≤ 5 indicates no sexual activity at baseline or at 12-month follow-up. A cutoff score of ≤ 26.55 indicates sexual dysfunction.

determine the effect of the intervention specifically on sexual and urological problems after radical prostatectomy and therefore included only sexually active men. In similar studies, sexually active men treated with either radiation or surgery were recruited from three months up to 5–7 years after treatment [8,16,17], invited from cancer registries or outpatient clinics, and through public service announcements; however, only one study had a recruitment rate of 47% [16]. Furthermore, these recruitment strategies may introduce self-selection bias and result in a sample of participants who are not representative of the population to be examined. Our experience in the present study does not reveal the exact need for rehabilitation, but we suggest that participation be broadened to several study centers, and also include irradiated patients. Further, to improve the participation rate, we might enlist physicians or clinical staff to introduce the study and answer questions [18].

We did find some challenges with adherence to the couple counselling in the ProCan intervention. Although the counselling was offered as required, the attendance varied and two-thirds of the couples attended at least two counselling sessions, and one couple withdrew from any kind of counselling. Adherence to the intervention is similar to that reported by Canada et al. [8], and thus suggest that adherence to this kind of intervention targeting sensitive issues such as sexual function should receive more attention. The PFMT appeared to be feasible, as all patients attended the group training and were followed up until continence was achieved.

In general, the counselling lived up to the couples' expectations, but they commented that it provided limited new knowledge or specific advice and limited improvement in their ability to talk openly about sexuality. The counsellor's primary role was to mediate personal reflection and couple communication, and the participants may not have regarded

this as specific advice. Most of the couples were well educated and might already have been well informed and able to talk openly about sexuality with their partner. Nevertheless, the participants' feedback indicates that coping with prostate cancer may challenge couple communication and that counselling should focus even more on how patients and partners communicate to achieve intimacy, which is important for psychological adjustment to prostate cancer [25].

Patients reported that PFMT was acceptable and that the physiotherapist improved their motivation and the quality and intensity of training, as reported by others [26]. The timing of PFMT was considered appropriate; a preference for group instruction was reported, which includes the benefits of meeting others with similar experiences.

The high response rate and few missing data on the outcomes indicate that the outcome measures are feasible, even for questions related to sexual concerns. Recovery of penile erection after radical prostatectomy is often only partial and may take up to two years [27]. We found a positive mean change in patients' erectile function during the 12-month follow-up, with an improvement from severe to moderate dysfunction. Improvements were seen in all domains of sexual functioning; counselling may have contributed to the increases in sexual desire and intercourse satisfaction. The mean changes in erectile functioning observed between baseline and 12 months' follow-up represent a clinically meaningful change according to Rosen et al. [28]. Nevertheless, the range of individual changes was wide, perhaps reflecting differences in erectile functioning before surgery. The improvements appeared to peak soon after the intervention and then leveled out, perhaps indicating an effect of the intervention. Two previous studies of the effect of interventions for couples with manuals and face-to-face or web counselling also found that improvement in sexual

functioning peaked soon after the intervention [8,17]; the only one that included a control group showed a significant effect [17].

As a result of limitations of the Female Sexual Index, we could not include participants who had not been sexually active four weeks before measurement; however, female sexual desire peaked at the eight-month follow-up. It is possible that the couple counselling improved sexual desire by use of techniques from sex therapy for reducing performance anxiety and enhancing skills in sexual communication and stimulation [5].

The strengths of this feasibility study include our multidisciplinary intervention which combines sexual counselling for couples and PFMT to improve sexual functioning. The intervention is based on a theoretical framework, a manual and use of trained health professionals. Inclusion of partners has shown great potential in improving multiple aspects of the quality of life of both patients and partners [18]. Our evaluation of the feasibility of recruitment resulted in concrete adjustments to our randomized clinical trial procedure and participant feedback on the timing indicates the appropriateness of early rehabilitation of erectile functioning. Feedback from the participants on the content of couple counselling has guided us to make minor revisions, which include greater focus on good sexual communication. A further strength of our study is the collection of outcome measures at all follow-up times with standardized scales and confirmation that the measures are feasible to implement and can detect changes.

The limitations of our study include the small sample of participants who may constitute a selected group that might already have been able to discuss sexuality. We had no access to information on the number of eligible patients throughout the study period and whether all eligible patients were actually invited to participate in the study. This weakens generalization of the results to couples in which one partner has prostate cancer. The lack of a control group limits interpretation of the observed improvements in sexual functioning between baseline and 12 months' follow-up, and we can only speculate that the improvements were related to the intervention.

Conclusion

We found that the ProCan intervention is feasible, and it should now be evaluated in a large randomized controlled trial. We recommend that attention should be paid to the inclusion criteria for participants after radical prostatectomy, recruitment procedures optimizing inclusion, procedures ensuring adherence to the intervention, and the provision of specific communication skills as part of the couple counselling.

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Disclosure statement

No potential conflict of interest was reported by the author(s).

Ethical approval

The study was approved by the Danish National Committee for the Capital Region (registration number H-3-2013-206). The trial is registered on ClinicalTrials.gov identifier: NCT02103088.

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