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Couple-Based Psychosexual Support Following Prostate Cancer Surgery: Results of a Feasibility Pilot Randomized Control Trial

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ABSTRACT

Introduction: Surgery for prostate cancer can result in distressing side effects such as sexual difficulties, which are associated with lower levels of dyadic functioning. The study developed and tested an intervention to address sexual, relational, *and* emotional aspects of the relationship after prostate cancer by incorporating elements of family systems theory and sex therapy.

Aims: To develop and test the feasibility and acceptability of relational psychosexual treatment for couples with prostate cancer, determine whether a relational-psychosexual intervention is feasible and acceptable for couples affected by prostate cancer, and determine the parameters for a full-scale trial.

Methods: Forty-three couples were recruited for this pilot randomized controlled trial and received a six-session manual-based psychosexual intervention or usual care. Outcomes were measured before, after, and 6 months after the intervention. Acceptability and feasibility were established from recruitment and retention rates and adherence to the manual.

Main Outcome Measures: The primary outcome measurement was the sexual bother subdomain of the Expanded Prostate Cancer Index Composite. The Hospital Anxiety and Depression Scale and the 15-item Systemic Clinical Outcome and Routine Evaluation (SCORE-15) were used to measure emotional and relational functioning, respectively.

Results: The intervention was feasible and acceptable. The trial achieved adequate recruitment (38%) and retention (74%) rates. The intervention had a clinically and statistically significant effect on sexual bother immediately after the intervention. Small decreases in anxiety and depression were observed for the intervention couples, although these were not statistically significant. Practitioners reported high levels of adherence to the manual.

Conclusion: The clinically significant impact on sexual bother and positive feedback on the study's feasibility and acceptability indicate that the intervention should be tested in a multicenter trial. The SCORE-15 lacked specificity for this intervention, and future trials would benefit from a couple-focused measurement.

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Key Words: Couple Therapy; Family Systems; Intimacy; Prostate Cancer; Psychosexual Support; Relationships; Sex Therapy; Sexual Function; Treatment

INTRODUCTION

Prostate cancer is the most common form of cancer in men in developed countries.[1] More men are surviving prostate cancer owing to earlier detection and improved treatment.[2] Removing the prostate gland (radical prostatectomy) is a dominant treatment approach[3]; however, this surgery has a range of side effects, with long-lasting sexual and urinary difficulties being the most common.[4] These effects can result in decreased quality of life, anxiety, and depression[5–7] and are enduring, because most men have not returned to baseline sexual function 2 years after surgery.[8] Partners also can experience significant psychological distress,[9–11] with sexual dysfunction negatively affecting

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partners' views of their relationship and self.[12,13] Rates of psychological distress, including depressive symptoms, in partners of men with prostate cancer are often found to be as high, or even higher, than those of the patient.[14]

Couple cohesion is an important predictor of adjustment in men after a diagnosis of prostate cancer. Erectile dysfunction is associated with lower levels of dyadic adjustment after surgery,[15] which can lead to severe disruption in relationships[16] and decreased well-being owing to the impact on couple intimacy and communication.[17] Therefore, viewing the couple as a relational system is important, with dyads who communicate openly adjusting better to illness and disability.[18] Understanding wider family relationships can be important in supporting sexual functioning in couples,[19] and to address sexual issues it is critical to support the relationship more generally.[20]

A systemic approach is supported by evidence demonstrating that lack of couple communication, relationship problems, and psychological distress are the psychosocial sequelae most amenable to intervention in couples affected by cancer.[21] Other investigators have evaluated the efficacy of psychosocial interventions addressing sexual and relationship functioning in men with prostate cancer.[22] The most successful interventions have been established as driven by a psychologist or a therapist, delivered face to face, and containing the explicit use of sex therapy techniques.[23,24]

Therefore, the present study developed a relational psychosexual treatment for couples with prostate cancer (RiPSToP) that combined a systems approach with elements of sex therapy to enable the intervention to address broader relational issues that affect specific problems concerning sex and intimacy.

AIMS

The primary aim of the study was to determine whether a relational-psychosexual intervention is feasible and acceptable for couples affected by prostate cancer. Subsidiary to this, the study aimed to determine the parameters for a full-scale trial.

METHODS

Full methods have been reported elsewhere.[25] Patients with prostate cancer and their partners were recruited from a single site in Edinburgh, Scotland, United Kingdom.

Participant Eligibility Criteria

Eligible patients were men who (i) were 11 weeks to 4 years since surgery for prostate cancer (to recruit men who had recovered from the surgery); (ii) had a partner who was willing to take part in the trial (in an established same- or different-sex relationship); (iii) scored no higher than 60 (the clinical threshold for potency) on the sexual function domain of the Expanded Prostate Cancer Index Composite (EPIC)[26]; (iv) had a prognosis longer than 1 year based on clinical risk of dying of prostate cancer drawing on the Scottish Cancer Taskforce (2014) guidelines[27]; (v) could provide informed consent; (vi) could communicate in English; and (vii) lived within traveling distance of the intervention site (owing to the catchment area of the clinic, patients who lived in the south-west of Scotland were excluded from the study because it would not have been feasible to travel).

Recruitment and Randomization

Patients attending follow-up completed a screening questionnaire (EPIC) to assess eligibility on site or by postal invitation from the clinical team. All eligible patients were invited to complete this screening questionnaire. Consent was gained by the researcher from eligible couples and baseline data collected before the intervention (outcome measurements and demographics) were returned by post. Subsequently, patients and their partners were randomly assigned using block randomization with a 1:1 allocation ratio. The allocation sequence was computer generated in blocks of four. Randomization was carried out by a research administrator who had no involvement in the study. After randomization, participants were enrolled in the study by the research team and advised of their allocation to the intervention group or to standard care (usual follow-up hospital appointments, without specific attention to psychosexual or relational function). Figure 1 shows the flow of patients through the study.

Recruitment ran from June 2013 to September 2014. Follow-up ceased in June 2015, when the pilot study was completed.

Intervention: Relational Psychosexual Treatment for Couples With Prostate Cancer

The intervention was comprised of assistance with emotional disclosure,[28,29] psychoeducation,[14,23] relational and sexual needs,[23,24,30] and dyadic adjustment and coping.[31,32] The appropriate dose (six 50-minute sessions) was determined from the literature.[33,34] A treatment manual was developed to guide and promote consistency in delivering the intervention[35] and is available from the corresponding author. The manual was comprised of information about prostate cancer and its effects, principles of therapeutic change, guidance on using the manual, and a detailed session structure plan. The session structure is presented in Table 1.

The manual was based on systemic principles[18,36,37] combined with techniques from sex therapy (ie, sensate focus).[38] The manual offered an intermediate level of specificity, enabling practitioners to use their own therapeutic style and take some lead from the couple, while meeting the objectives of the intervention. Specialist training in delivery of the intervention was provided to practitioners holding accredited counseling or psychotherapy qualifications. Practitioners engaged in routine clinical supervision throughout intervention delivery. The intervention was delivered in the premises of a third-sector

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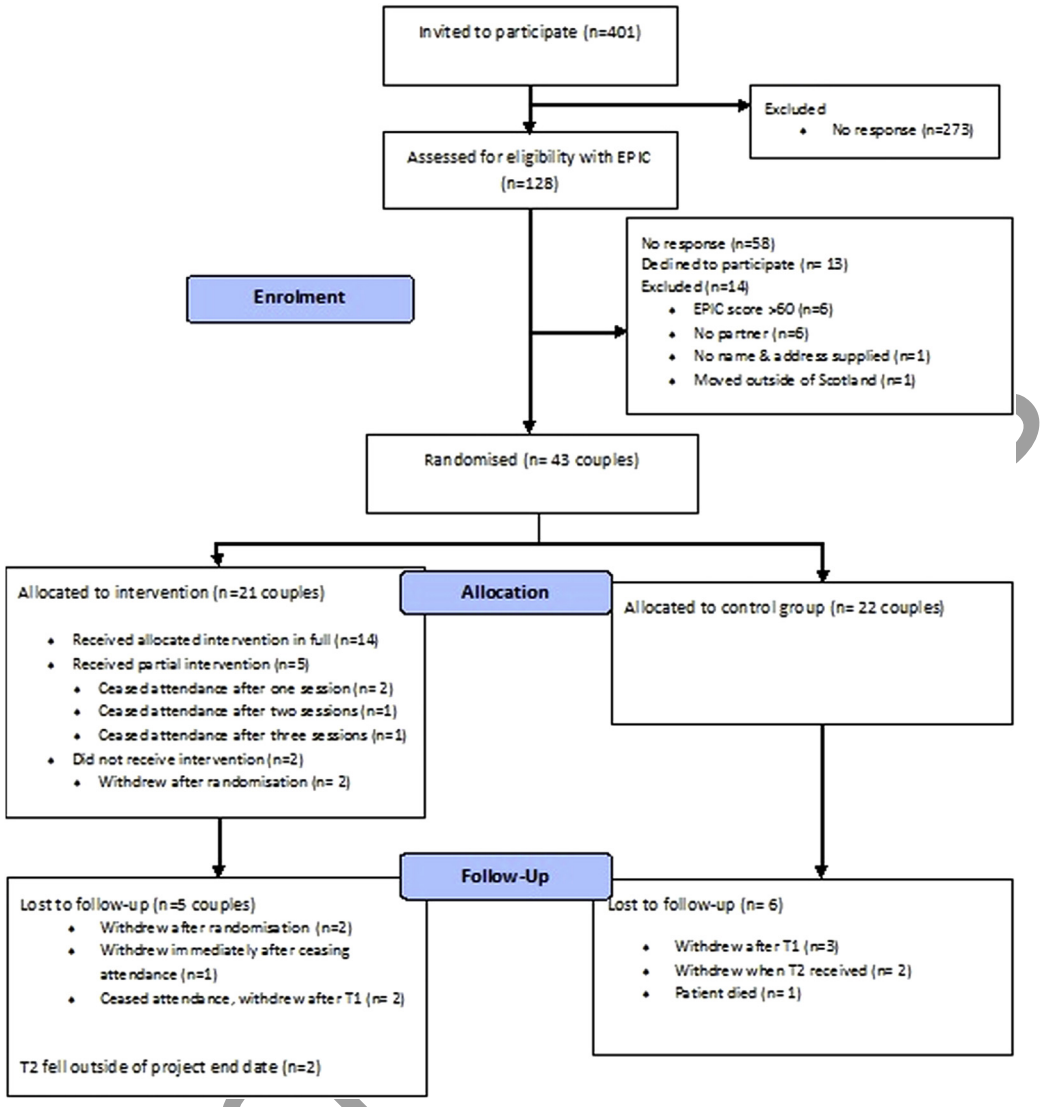

Figure 1. Recruitment flow diagram. EPIC = Expanded Prostate Cancer Index Composite; T1 = end of intervention (or 4 months after baseline for controls); T2 = 6 months after end of intervention.

organization, rather than the clinical setting, and commenced as soon as possible after recruitment.

Main Outcome Measures

All outcome measurements were self-reported and completed at three time points: at baseline before the intervention (T0), at the end of the intervention (or 4 months after baseline for controls; T1), and 6 months after the end of the intervention (T2).

The EPIC, a 36-item measurement of health-related quality of life in men with prostate cancer, was used.[39] The primary outcome measurement was the "sexual bother" subdomain score. This subdomain of the EPIC asks the patient to rate the extent of difficulty (from "no problem" to "big problem") associated with his level of sexual desire, ability to have an erection, ability to achieve orgasm, and overall sexual function (see Supplemental Materials).

Two secondary outcome measurements were the Hospital Anxiety and Depression Scale (HADS)[40] and the 15-item Systemic Clinical Outcome and Routine Evaluation (SCORE-15), a validated systemic therapy outcome measurement to assess family functioning within therapy.[41,42] The SCORE-15 includes positive and negative items concerning strength and adaptability (eg, "we trust each other"), disrupted communication (eg, "it feels risky to disagree in our family"), and whether the family is overwhelmed with difficulties (eg, "we find it hard to deal with everyday problems"). Patients and partners independently reported on family interactions, indicating the level of difficulty within their family and the level of similarity or difference in perceptions within the couple.

A bespoke self-report questionnaire collected demographic information.

Practitioner Fidelity to the Manual

Practitioners reported their adherence to the manual by completing a scale of 0 to 10 for each sub-objective within each

Table 1. Summary of the six-session intervention

Session number—main focus	Content
Session 1—getting to know the couple: orientation and engagement	This first session outlined the support on offer. Topics for discussion included:
	Couple's definition of current issues, concerns and problems
	Cancer diagnosis and treatment(s)
	Partner's role in the context of diagnosis and treatment mapping the support network and wider family system
Session 2—couple's communication style and relationship	This session was focused primarily on understanding the patient and his partner as a couple, to explore how they convey love, support, understanding, companionship and affection.
Session 3—intergenerational patterns of illness, coping, and affection	Focusing on intergenerational patterns, discussion centered on the role and meaning of illness in the couple relationship in the context of:
	Family resilience
	Dyadic adjustment in ill health
	Role of partners and family when someone is ill
	How people in the family express intimacy
Session 4—couple intimacy before and after cancer	The couple's sexual relationship before and after cancer was explored. A psychoeducational approach was used to promote closeness and express intimacy after treatment. The place of medical treatments was considered and techniques from sex therapy were applied if appropriate for the couple.
Session 5—further exploration of emerging areas	This session focused on areas that emerged in previous sessions in which the practitioner and couple wished to give more time. This included more work on increasing levels of intimacy and improving satisfaction with sexual activity, with discussion of successes or challenges therein.
Session 6—summarizing couple's accomplishments and future planning	The final session summarized the work to date, with discussion of relapse prevention and how to take forward progress that has been made, including the setting of short- and long-term goals. This included a specific focus on maintaining intimacy and dyadic adjustment.

session, thereby capturing the competence and depth of each element of the intervention rather than purely whether the issue had been discussed. Adherence was stressed in the preparatory training session and in a further question-and-answer session with the practitioners approximately midway through the intervention to emphasize the importance of manual fidelity.

Acceptability and Feasibility

A priori criteria[43] were set to ensure there was a rationale for concluding that the intervention was feasible and acceptable. These criteria included establishing adequate recruitment and retention rates of 29% and 72%, respectively (based on other couple psychosexual interventions[44]); effective randomization processes with comparable groups at baseline (T0); and clinically significant improvement on the primary outcome measurement.

Qualitative data also were gathered on trial procedures and intervention content regarding their acceptability to participants. These findings will be published elsewhere.

Data Analysis

This article reports clinical and statistical significance. Meaningful clinical change for the EPIC is considered 0.5 of SD from each of the domain-specific scores of the validation cohort.[30] For sexual bother, this required a 15-point change (based on the validation cohort having a mean score of 41.1, SD = 30.1). Therefore, observed differences between time points are reported (in units of measurement) to give a preliminary estimate of the clinical significance of the intervention. The statistical significance level was set at an α level of 0.05. Repeated-measures analysis of variance (two-way) was performed to identify trends in outcome measurements and the effect size of the intervention (partial η^2). Fidelity to the manual was analyzed with descriptive statistics. Data were managed and analyzed using SPSS 19 (SPSS, Inc, Chicago, IL, USA).

Ethics

The U.K. National Health Service research ethics committee granted the study a favorable opinion by the NHS West of Scotland Research Ethics Committee (Reference: 12/WS/0255). Written consent was gained from all study participants.

RESULTS

Figure 1 shows the flow of participants through this trial. Of the 401 men invited to participate in the study, 128 (32%) returned the screening questionnaire and were assessed for eligibility to the study. One hundred fourteen men met the

Table 2. Participant characteristics*

	Intervention			Control		
	Couples (n = 21)	Patients (n = 21)	Partners (n = 21)	Couples (n = 22)	Patients (n = 22)	Partners (n = 22)
Age (y) at baseline, range (mean)		55–76 (64.15)	—		44–77 (63.27)	—
Deprivation quintile						
1 (highest)	1			1		
2	2			2		
3	5			3		
4	3			4		
5 (lowest)	10			11		
Mean	3.90			4.05		
Median	4			5		
Mode	5			5		
Time since surgery (mo), range (mean)		2–23 (10.67)	—		2–46 (12.82)	—
Length of relationship (y), range (mean)	10–51 (35.62)			1–52 (28.64)		
Clinical risk						
Low		6	—		5	—
Intermediate		13	—		13	—
High		2	—		3	—
White ethnicity, %		100	100		100	100

*P values are reported in Table 3.

eligibility criteria. Forty-three couples were subsequently recruited to the study, comprising 44 men and 42 women, because there was one same-sex couple. This represents a recruitment rate of 38% of eligible men who returned screening questionnaires.

Eleven couples withdrew during the course of the study. This represents a retention rate of 74%. Another two couples did not return their T2 scores within the project timeframe.

Participant Characteristics

Participant characteristics and demographics are presented in Table 2. The average age of the sample was 63.7 years and all participants were white. The range of time since surgery was 2 to 46 months (mean = 11.51 months). The duration of the couple relationship ranged from 1 to 52 years (mean = 35.62 years for intervention couples, mean = 28.64 years for control couples). Couples tended to be from the least deprived areas of Scotland.[45] Clinical risk of prostate-specific mortality was calculated drawing on the Scottish Cancer Taskforce (2014) guidelines.[27] Most men (60%) were in the medium-risk category, with only 12% of men being at high risk.

Analysis of the baseline data (independent-sample t-tests and χ^2 tests) indicated that randomization was successful, with no significant differences observed between the control and intervention groups (Table 3).

Outcomes

Means, SDs, and ranges of scores are presented in Table 4 for the primary and secondary outcome measurements (and relevant subscales) at the three time points.

Results of the two-way analysis of variance showed significant variation in the primary outcome of sexual bother ($F_{2,50} = 3.461$, $P = .033$). Therefore, pairwise comparisons were conducted, and data between baseline and first follow-up (T1) were found to be significantly different for men in the intervention group (mean difference = −12.27, 95% CI = −24.09 to −0.46, $P = .04$). Comparisons between T0 and T1 for men in the control group were statistically insignificant. This result means that there was a significant difference on sexual bother for men randomized to the psychosexual intervention group compared with men in the usual-care group; this difference was not maintained at second follow-up (T2). Further, those men assigned to the intervention had an average increase in sexual bother score of 19.98 from T0 to T1. This exceeded the 15-point increase criteria for minimally significant change on the EPIC. Men in the control group had an average increase of only 5.94. However, this improvement for men who received the intervention was not maintained; 6 months after the intervention, sexual bother had returned to levels similar to those at baseline. No differences between the intervention and control groups were observed for anxiety, depression, emotional functioning, and relational functioning.

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Table 3. Baseline equivalence of patients

Test	Intervention	Control	*P* values
t			
Patient age (y), mean	64.15	63.27	.723
SIMD quintile, mean	3.90	4.05	.714
Years with partner, mean	35.62	28.77	.104
Months since surgery, mean	10.67	12.82	.456
χ^2			
Risk categorization, %			.865
Low	28.6	23.8	
Medium	61.9	61.9	
High	9.5	14.3	
Education, %			.258
School	38.1	31.8	
College	23.8	36.4	
University	38.1	31.8	

SIMD = Scottish Index of Multiple Deprivation.

Acceptability and Feasibility

The trial processes were feasible, reflected in adequate recruitment and retention rates of 38% and 74%, respectively.[44,46] Randomization worked well, with comparable groups at baseline (Table 3). Clinically meaningful improvement in outcome measurements was achieved for the EPIC (sexual bother domain). A more sensitive and specific measurement of couple relationship would be beneficial to replace the SCORE-15 to assess couple communication and relational functioning.

An average of 4.43 sessions was attended (range = 1−6, mode = 6). Although the manual stated that sessions should be scheduled every 2 to 3 weeks, every 3 to 4 weeks was a more acceptable timeframe for couples and practitioners. For the 14 couples who attended all six sessions of the support, the average time it took to complete the intervention was 135.43 days (~19 weeks, range = 60−254 days).

Completed adherence checklists demonstrated a good level of fidelity to the manual (Table 5), and practitioners reported that the training on delivery of the intervention was acceptable.

The first and final sessions had the highest adherence ratings (mean adherence = 8.87 and 8.78, respectively); session 4 had the lowest overall rating of adherence (mean = 7.38). Two components of the intervention were less well addressed: role of orgasm in sexual activity and sensate focus, which was covered in session 4. Mean adherence ratings for role of orgasm (4.71) and sensate focus (5.14) were significantly below the mean adherence rating (8.18). Postintervention interviews with practitioners indicated that some couples were unwilling to have sexually focused discussion owing to an absence of sexual activity before the cancer treatment. Despite these reported challenges, the adherence ratings for role of orgasm and sensate focus ranged from 0 to 10, showing that the difficulty in delivering and discussing these topics was not universal. These results suggest that the content and number of intervention sessions should be guided by existing relational dynamics, including the level and type of sexual activity before cancer treatment. Accordingly, the manual would benefit from further nuanced guidance on how and when to engage and explore such issues with couples.

The integrated process evaluation did not identify any other implementation problems of note. Hence, the study design and content appear to have met predefined feasibility criteria as described in the Methods section subject to more detailed guidance in the manual on how to explore pre-existing sexual activity to determine the appropriate level of sexually focused discussion with the couple.

Sample Size Calculation for a Definitive Trial

Preliminary statistical analysis suggests a future definitive trial of a refined intervention should assume a small effect size ($f = 0.10$) on the primary outcome at follow-up. Using the between-within interaction in a repeated-measures analysis of variance with two groups, three points of measurement and a 0.50 correlation between repeated measures, a total sample size of 214 would be required to have 90% power to detect this small effect ($f = 0.10$) at an α level of 0.05.

DISCUSSION

Results from this feasibility and pilot trial suggest that this novel intervention has clinical benefits in lessening distress related to sexual function in the short term. This improvement is particularly notable when evidence indicates that sexual bother after prostatectomy tends to level off only at 36 months after surgery.[47] The improvement was not maintained at 6 months, so couples might need continuing support to maintain the benefits gained by the end of intervention. Other psychosexual interventions in prostate cancer have similarly lacked sustained effects,[23,34] although there have been promising results for breast and gynecologic cancers.[48] With many men exhibiting difficulty adjusting to long-term functional loss,[7] ongoing psychosocial support might be required to support the emotional consequences of erectile dysfunction. Although recruitment focused on postsurgical patients, men receiving other treatments affecting psychosexual and relational functioning, such as radiotherapy or brachytherapy, also could benefit from this approach.[49]

The study sought to match, or exceed, published recruitment and retention rates as cited in the literature of couple psychosexual interventions, which are 29% and 72%, respectively.[44,46] The study surpassed this expectation with 38% couples recruited and 74% retained in the study. The retention rate (74%) is comparable to those reported in a systematic review of dyadic (although not psychosexual) health interventions (77.5%).[50] This good retention rate might be resultant from the communication the research team maintained through the study with patients and partners. The process aimed to check ongoing consent and, as a consequence of the personal contact, establish positive relationships between participants and the project team. The low rate of enrollment for those 2 to 4 years after surgery

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Table 4. Mean scores, SD, and ranges of scores on primary and secondary outcome measurements at study time points

	Intervention, mean (SD) [range]						Control, mean (SD) [range]					
	Patient			Partner			Patient			Partner		
Time points	T0 (n = 21)	T1 (n = 18)	T2 (n = 14)	T0 (n = 21)	T1 (n = 18)	T2 (n = 14)	T0 (n = 22)	T1 (n = 18)	T2 (n = 16)	T0 (n = 22)	T1 (n = 18)	T2 (n = 16)
EPIC												
Sexual bother subscale	24.11 (20.38) [0–62.50]	44.09 (30.42) [0–100]	30.77 (32.12) [0–87.50]	–	–	–	20.45 (21.14) [0–62.50]	26.39 (23.24) [0–75]	29.91 (31.41) [0–75]	–	–	–
HADS												
Total	10.67 (6.87) [0–23]	7.22 (5.93) [0–18]	8.54 (5.75) [1–19]	11.14 (5.84) [1–21]	6.89 (4.95) [1–21]	5.92 (4.57) [0–18]	9.77 (6.40) [0–28]	8.94 (6.21) [1–20]	10.44 (7.62) [1–25]	8.55 (6.69) [0–24]	8.72 (6.58) [1–21]	9.67 (7.24) [2–24]
Anxiety subscale	6.24 (4.15) [0–15]	4.06 (3.42) [0–11]	4.62 (3.07) [0–10]	7.71 (3.59) [0–14]	5.17 (3.60) [0–12]	4.31 (2.63) [0–8]	6.32 (4.12) [0–17]	5.72 (4.11) [1–14]	6.69 (5.89) [1–20]	5.82 (4.57) [0–20]	6.33 (4.99) [1–18]	6.60 (5.58) [2–20]
Depression subscale	4.43 (3.56) [0–12]	3.17 (3.22) [0–9]	3.92 (3.33) [0–9]	3.43 (2.84) [0–9]	1.72 (2.02) [0–9]	1.62 (3.18) [0–12]	3.45 (2.72) [0–11]	3.22 (2.46) [0–7]	3.75 (2.65) [0–8]	2.73 (2.95) [0–10]	2.39 (2.64) [0–9]	3.07 (3.35) [0–12]
SCORE-15	1.47 (0.39) [1–2.73]	1.49 (0.48) [1–2.67]	1.60 (0.63) [1–2.73]	1.63 (0.62) [1–3.47]	1.51 (0.41) [1–2.40]	1.44 (0.46) [1–2.13]	1.83 (0.73) [1–3.40]	1.83 (0.76) [1.13–3.93]	1.95 (0.83) [1–4]	1.72 (0.53) [1.07–2.93]	1.47 (0.45) [1–2.93]	1.65 (0.69) [1–3.33]

EPIC = Expanded Prostate Cancer Index Composite; HADS = Hospital and Anxiety and Depression Scale; SCORE = Systemic Clinical Outcome and Routine Evaluation; T0 = baseline; T1 = end of intervention (or 4 months after baseline for controls); T2 = 6 months after end of intervention.

indicates that limiting the timeframe to less than 2 years after surgery would be more suitable, while making efforts to recruit couples as soon as possible after they have recovered from the immediate effects of surgery. Although addressing psychosexual needs might not be an immediate priority for couples, the results of this pilot study indicate that the intervention should be delivered within a limited period before long-term adaptation has commenced. The importance of offering support soon after surgery reflects evidence that the sexual side effects of surgery are immediate and troublesome[51] and men express a desire for early treatment to tackle these effects.[52] Time since surgery has not been reported in other studies that have been successful in delivering short-term benefits after a couple-focused psychosexual intervention.[23,24,34] However, this aspect of participant characteristics is an important variable that should be analyzed in future trials to improve recruitment and retention and to understand how the efficacy of interventions might be enhanced, particularly to extend benefits longer term.

The lower adherence ratings for the sexually focused aspects of the treatment suggest that the intervention could be strengthened with more detailed information about ways to engage couples in sex-focused discussions, including techniques from sex therapy. Practitioners reported that some couples were unwilling to engage in sex-focused discussion, particularly if sexual activity had been absent before cancer treatment. These data suggest that further training and more specific guidance in the manual would be beneficial to strengthen the intervention's focus on the sexual relationship. This might include grieving the loss of the sexual relationship and the physical sequelae of cancer treatment.[53] In intimacy-enhancing interventions for couples affected by prostate cancer, Manne et al[28] found that treatment effects were moderated by baseline levels of individual distress and relational characteristics, whereas Schover et al[54] established that a partner's baseline level of sexual function influenced the efficacy of the intervention for men. Such evidence would suggest that future trials should measure pre-existing levels of relational intimacy, including sexual intimacy, within the couple, and partners' baseline level of sexual function, first, to assist practitioners in framing sex-focused discussions and, second, to establish whether this aspect of the couple's relationship mediates intervention outcomes in addition to therapeutic processes. Assessments such as the Personal Assessment of Intimacy in Relationships[55] complemented by the Dyadic Adjustment Scale,[56] as used by Manne et al[28] to compare levels of intimacy and relational satisfaction before and after treatment, could be an alternative to the SCORE-15 given its lack of sensitivity for measuring relational functioning in the present study. In addition, the International Index of Erectile Function,[57] as adopted by Canada et al[23] and Titta et al[24] in their intervention studies, could be used in addition to the EPIC to understand levels of bother and distress in the context of sexual intercourse to provide a fuller picture of baseline sexual functioning in the couple. The Female Sexual Function Index[58] could be used to understand the efficacy of the intervention in relation to the partner's sexual function before the intervention.

Table 5. Average adherence of practitioners to treatment manual across intervention sessions

Practitioner (couples seen)	Session 1 (n = 19)	Session 2 (n = 16)	Session 3 (n = 15)	Session 4 (n = 14)	Session 5 (n = 14)	Session 6 (n = 14)	Total
Practitioner 1 (n = 1)	8.43	7.86	8.17	7.45	8	8.67	8
Practitioner 2 (n = 2)	10	10	8	8.60	8.17	9.17	9
Practitioner 3 (n = 5)	9	8.71	8.83	8.23	7.62	9	8.8
Practitioner 4 (n = 6)	8.04	7.83	8.2	6.67	7.37	8.3	7.3
Practitioner 5 (n = 1)	10	7.29	8.5	10	10	10	9.4
Practitioner 6 (n = 4)	9.21	8.48	8.56	6.15	7.52	8.89	8.4
Total	8.87	8.41	8.39	7.38	7.77	8.78	8.5

LIMITATIONS

This was a small-scale single-site study. The intervention was delivered by clinicians with a mixture of modalities, rather than solely systemic and/or psychosexual. Use of a mixed therapist cohort reflected an innovative approach on the team's part to meet the demand of increasing numbers of men diagnosed with prostate cancer and the existing pressure on existing psychosexual services in the United Kingdom. Because most of these practitioners were not familiar with sex therapy techniques before the intervention, this might have influenced adherence to the sex-focused part of the manual. Given the benefits associated with interventions that have sexual functioning as a major focus,[23,24] recruiting clinicians with experience of sex therapy could have improved the intervention's efficacy.

Participants varied considerably in time since surgery. Compliance and motivation are likely to be moderated by time since treatment. However, with a small sample it was not possible to analyze any such effect on outcomes. The limited number of same-sex couples and racial diversity in this sample also must be acknowledged and a future trial should attempt to recruit a broader and more proportionate sample of participants to test aspects of social difference (eg, sexuality, age, cultural background, or socioeconomic status) that might affect the process or outcome of the intervention.

Future larger trials would benefit from objective assessment of manual fidelity through audio recording of sessions assessed by independent raters. Moreover, although blinded randomization was not possible in the present study—and is challenging in principle for psychosocial interventions[59]—a definitive trial would benefit from an attention placebo control to understand the effects of the psychosexual components more clearly.

Administering the EPIC in its entirety might not be methodologically or ethically sound in future studies, because there was very little change on global scores, with participants reporting relatively high functioning on the three other summary domains (urinary, bowel, and hormonal). Future studies should consider administering only the sexual domain of this outcome measurement and complementing the measurement with the International Index of Erectile Function. The SCORE-15 lacked specificity for this intervention, so a couple-focused outcome measurement such as the Personal Assessment of Intimacy in Relationships and the Dyadic Adjustment Scale would be appropriate for future studies.

CONCLUSIONS

This novel feasibility study of a psychosexual intervention shows promise in lessening distress associated with changes in sexual function after surgery for prostate cancer. These findings indicate the value of combining a family-systems approach with elements of sex therapy to address broader relational issues that affect sexual function. The clinically significant impact on sexual bother immediately after couple therapy indicates that the intervention would benefit from further development to extend benefits.

Because improvements in sexual bother were not maintained at longer-term follow-up, the intervention should be adapted to provide more extended support for couples. More sensitive and specific measurements of couple communication and relational functioning should replace the SCORE-15 in future trials. With a low recruitment rate of men 2 to 4 years after surgery, a definitive trial should be targeted at men who have recovered from the immediate side effects of surgery but who are no more than 2 years past surgery.

Future trials should aim to recruit more same-sex couples and a more ethnically and socially diverse participant group to increase the generalizability of any results. The manual could be enhanced with further information about how and when to engage couples in discussing techniques from sex therapy, particularly when there has been an absence of sexual activity before cancer treatment.

Overall, the study adds to the literature on psychosexual interventions for men with prostate cancer by demonstrating the efficacy of a manual-based intervention for minimizing sexual bother, particularly for men within 2 years of surgery, and highlighting the importance of understanding the couple's levels of sexual activity before surgery to contextualize and deliver the sexually focused aspects of treatment within a broader family-systems model.

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REFERENCES

1. Ferlay J, Soerjomataram I, Dikshit R, et al. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. **Int J Cancer 2015;136:E359-E386.**
2. Center MM, Jemal A, Lortet-Tieulent J, et al. International variation in prostate cancer incidence and mortality rates. **Eur Urol 2012;61:1079-1092.**
3. Djavan B, Ravery V, Rocco B, et al. European Study of Radical Prostatectomy: time trends in Europe, 1993—2005. **BJU Int 2007;100:22-25.**
4. Stensvold A, Dahl AA, Brennhovd B, et al. Bother problems in prostate cancer patients after curative treatment. **Urol Oncol 2013;31:1067-1078.**
5. Johansson E, Steineck G, Holmberg L, et al; SPCG-4 Investigators. Long-term quality-of-life outcomes after radical prostatectomy or watchful waiting: the Scandinavian Prostate Cancer Group-4 randomised trial. **Lancet Oncol 2011; 12:891-899.**
6. Smith DP, King MT, Egger S, et al. Quality of life three years after diagnosis of localised prostate cancer: population based cohort study. **BMJ 2010;340:b4817.**
7. Nelson CJ, Mulhall JP, Roth AJ. The association between erectile dysfunction and depressive symptoms in men treated for prostate cancer. **J Sex Med 2011;8:560-566.**
8. Levinson AW, Lavery HJ, Ward NT, et al. Is a return to baseline sexual function possible? An analysis of sexual function outcomes following laparoscopic radical prostatectomy. **World J Urol 2011;29:29-34.**
9. Couper J, Bloch S, Love A, et al. Psychosocial adjustment of female partners of men with prostate cancer: a review of the literature. **Psychooncology 2006;15:937-953.**
10. Northouse LL, Mood DW, Montie JE, et al. Living with prostate cancer: patients' and spouses' psychosocial status and quality of life. **J Clin Oncol 2007;25:4171-4177.**
11. Soloway CT, Soloway MS, Kim SS, et al. Sexual, psychological and dyadic qualities of the prostate cancer 'couple'. **BJU Int 2005;95:780-785.**
12. Tanner T, Galbraith M, Hays L. From a woman's perspective: life as a partner of a prostate cancer survivor. **J Midwifery Womens Health 2011;56:154-160.**
13. Sanders S, Pedro LW, Bantum EO, et al. Couples surviving prostate cancer: long-term intimacy needs and concerns following treatment. **Clin J Oncol Nurs 2006;10:503-508.**
14. McCorkle R, Siefert ML, Dowd MF, et al. Effects of advanced practice nursing on patient and spouse depressive symptoms, sexual function, and marital interaction after radical prostatectomy. **Urol Nurs 2007;27:65-77.**
15. Pereira RF, Daibs YS, Tobias-Machado M, et al. Quality of life, behavioral problems, and marital adjustment in the first year after radical prostatectomy. **Clin Genitourin Cancer 2011;9:53-58.**
16. Zaider T, Manne S, Nelson C, et al. Loss of masculine identity, marital affection, and sexual bother in men with localized prostate cancer. **J Sex Med 2012;9:2724-2732.**
17. Letts C, Tamlyn K, Byers ES. Exploring the impact of prostate cancer on men's sexual well-being. **J Psychosoc Oncol 2010; 28:490-510.**
18. Rolland JS. In sickness and in health: the impact of illness on couple's relationships. **J Marital Fam Ther 1994;20:327-347.**
19. Strait JG, Sandberg JG, Larson JH, et al. The relationship between family-of-origin experiences and sexual satisfaction in married couples. **J Fam Ther 2013;37:385.**
20. Carr A. The effectiveness of family therapy and systemic interventions for adult-focused problems. **J Fam Ther 2009; 31:46-74.**
21. Regan TW, Lambert SD, Girgis A, et al. Do couple-based interventions make a difference for couples affected by cancer? A systematic review. **BMC Cancer 2012;12:279.**
22. Chisholm KE, McCabe MP, Wootten AC, et al. Review: psychosocial interventions addressing sexual or relationship functioning in men with prostate cancer. **J Sex Med 2012;9:1246-1260.**
23. Canada AL, Neese LE, Sui B, et al. Pilot intervention to enhance sexual rehabilitation for couples after treatment for localized prostate carcinoma. **Cancer 2005;104:2689-2700.**
24. Titta M, Tavolini IM, Dal Moro F, et al. Sexual counseling improved erectile rehabilitation after non-nerve-sparing radical retropubic prostatectomy or cystectomy: results of a randomized prospective study. **J Sex Med 2006;3:267-273.**
25. Robertson JM, Molloy G, Bollina PR, et al. Exploring the feasibility and acceptability of couple-based psychosexual support following prostate cancer surgery: study protocol for a pilot randomised controlled trial. **Trials 2014;15:183.**
26. Wei JT, Dunn RL, Litwin MS, et al. Development and validation of the Expanded Prostate Cancer Index Composite (EPIC) for comprehensive assessment of health-related quality of life in men with prostate cancer. **Urology 2000; 56:899-905.**

27. Scottish Cancer Taskforce. Prostate cancer: Clinical quality performance indicators (v2.1). Healthcare Improvement Scotland: Edinburgh 2014.
28. Manne SL, Kissane DW, Nelson CJ, et al. Intimacy-enhancing psychological intervention for men diagnosed with prostate cancer and their partners: a pilot study. **J Sex Med 2011; 8:1197-1209.**
29. Porter LS, Keefe FJ, Baucom DH, et al. Partner-assisted emotional disclosure for patients with gastrointestinal cancer: results from a randomized controlled trial. **Cancer 2009; 115:4326-4338.**
30. Bronner G, Shefi S, Raviv G. Sexual dysfunction after radical prostatectomy: treatment failure or treatment delay? **J Sex Marital Ther 2010;36:421-429.**
31. Mishel MH, Belyea M, Germino BB, et al. Helping patients with localized prostate carcinoma manage uncertainty and treatment side effects. **Cancer 2002;94:1854-1866.**
32. Zhou ES, Kim Y, Rasheed M, et al. Marital satisfaction of advanced prostate cancer survivors and their spousal caregivers: the dyadic effects of physical and mental health. **Psychooncology 2011;20:1353-1357.**
33. Campbell LC, Keefe FJ, Scipio C, et al. Facilitating research participation and improving quality of life for African American prostate cancer survivors and their intimate partners. **Cancer 2007;109:414-424.**
34. Giesler RB, Given B, Given CW, et al. Improving the quality of life of patients with prostate carcinoma: a randomized trial testing the efficacy of a nurse-driven intervention. **Cancer 2005;104:752-762.**
35. Carroll KM, Nuro KF. One size cannot fit all: a stage model for psychotherapy manual development. **Clin Psychol Sci Pract 2002;9:396-406.**
36. Burnham J. Family therapy: first steps toward a systemic approach. London: Routledge; 1996.
37. Kissane DW, Bloch S. Family focused grief therapy: a model of family-centred care during palliative care and bereavement. Buckingham: Open University Press; 2002.
38. Reese JB, Keefe FJ, Somers TJ, et al. Coping with sexual concerns after cancer: the use of flexible coping. **Support Care Cancer 2010;18:785-800.**
39. Morris C, Gibbons E, Fitzpatrick R. A structured review of patient reported outcome measures for men with prostate cancer. Oxford: Department of Public Health, University of Oxford; 2009.
40. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. **Acta Psychiatr Scand 1983;67:361-370.**
41. Cahill P, O'Reilly K, Carr A, et al. Validation of a 28-item version of the Systemic Clinical Outcome and Routine Evaluation in an Irish context: the SCORE-28. **J Fam Ther 2010;32:210-231.**
42. Stratton P, Lask J, Bland J, et al. Detecting therapeutic improvement early in therapy: validation of the SCORE-15 index of family functioning and change. **J Fam Ther 2014;36:3-19.**
43. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. **BMC Med Res Methodol 2010;10:1.**
44. Reese JB, Porter LS, Regan KR, et al. A randomized pilot trial of a telephone-based couples intervention for physical intimacy and sexual concerns in colorectal cancer. **Psychooncology 2014;23:1005-1013.**
45. Scottish Government. Scottish Index of Multiple Deprivation. Scottish Government: Edinburgh 2012.
46. Northouse LL, Katapodi MC, Song L, et al. Interventions with family caregivers of cancer patients: meta-analysis of randomized trials. **CA Cancer J Clin 2010;60:317-339.**
47. Parker WR, Wang R, He C, et al. Five year Expanded Prostate Cancer Index Composite-based quality of life outcomes after prostatectomy for localized prostate cancer. **BJU Int 2011; 107:585-590.**
48. Scott JL, Halford WK, Ward BG. United we stand? The effects of a couple-coping intervention on adjustment to early stage breast or gynecological cancer. **J Consult Clin Psychol 2004; 72:1122-1135.**
49. Litwin MS, Gore JL, Kwan L, et al. Quality of life after surgery, external beam irradiation, or brachytherapy for early-stage prostate cancer. **Cancer 2007;109:2239-2247.**
50. Walker LM, Robinson JW. A description of heterosexual couples' sexual adjustment to androgen deprivation therapy for prostate cancer. **Psychooncology 2011;20:880-888.**
51. Nelson CJ, Deveci S, Stasi J, et al. Sexual bother following radical prostatectomy. **J Sex Med 2010;7:129-135.**
52. Chartier-Kastler E, Amar E, Chevallier D, et al. Does management of erectile dysfunction after radical prostatectomy meet patients' expectations? Results of a national survey (REPAIR) by the French Urological Association. **J Sex Med 2008;5:693-704.**
53. Wittmann D, Foley S, Balon R. A biopsychosocial approach to sexual recovery after prostate cancer surgery: the role of grief and mourning. **J Sex Marital Ther 2011;37:130-144.**
54. Schover LR, Canada AL, Yuan Y, et al. A randomized trial of internet-based versus traditional sexual counseling for couples after localized prostate cancer treatment. **Cancer 2012; 118:500-509.**
55. Schaefer MT, Olson DH. Assessing intimacy: the Pair Inventory. **J Marital Fam Ther 1981;7:47-60.**
56. Sharpley CF, Cross DG. A psychometric evaluation of the Spanier Dyadic Adjustment Scale. **J Marriage Fam 1982; 44:739-741.**
57. Rosen RC, Cappelleri JC, Smith MD, et al. Development and evaluation of an abridged, 5-item version of the International Index of Erectile Function (IIEF-5) as a diagnostic tool for erectile dysfunction. **Int J Impot Res 1999;11:319-326.**
58. Rosen CB. The Female Sexual Function Index (FSFI): a multidimensional self-report instrument for the assessment of female sexual function. **J Sex Marital Ther 2000;26:191-208.**
59. Vickers AJ, de Craen AJM. Why use placebos in clinical trials? A narrative review of the methodological literature. **J Clin Epidemiol 2000;53:157-161.**

SUPPLEMENTARY DATA

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.jsxm.2016.05.013.

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