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ONCOLOGY

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

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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 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