

# Couples-based interventions following prostate cancer treatment: a narrative review

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**Background:** Sexual dysfunction following prostate cancer (PC) treatment often results in sexual avoidance and a loss of sexual intimacy, which can lead to relationship distress. This review aims to evaluate six studies intended to address relational and sexual intimacy following PC treatment and discuss methodological concerns which may help produce more effective interventions.

**Methods:** Electronic databases used to conduct literature searches included Medline, PsychINFO, and Web of Science. Studies were included if they were: randomized controlled trials (RCTs) using samples of men diagnosed with PC of any stage, had a psychosocial intervention, and addressed at least one sexual and relational outcome.

**Results:** As a whole, the literature has produced mixed results. While significant findings were reported, many of the primary hypotheses were not achieved. The six studies show that men with PC may benefit from education and support related to treatment options for erectile dysfunction (ED), whereas their partners may benefit more from interventions focused on relational issues. Important methodological limitations included: selection of general outcome measures as opposed to measures specific to sexuality or intimacy outcomes, lack of assessing distress or bother of the patient/couples as study entry criteria, heterogeneity of study populations, and lack of innovative intervention content as the current studies tested standard educational interventions, sex therapies techniques, and couples therapy strategies with only marginal success.

**Conclusions:** Interventions based on innovative theoretical approaches as well as study designs that address the outlined methodological limitations are needed in this area.

**Keywords:** Prostate cancer (PC); erectile dysfunction (ED); sexual function; erectile rehabilitation

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## Introduction

In the U.S., over 200,000 new cases of prostate cancer (PC) will be diagnosed in 2015 (1,2), making it the most commonly diagnosed cancer in men. Of these cases, 90% will be diagnosed in the early stage due to effective screening and early detection (3). With early detection, survival rates continue to increase and close to 100% of cases diagnosed in the U.S. will survive five years post-diagnosis (4).

The combination of the large number of men diagnosed with PC, early detection, and effective treatment, has led to an increased focus on survivorship-related concerns

following treatment for PC, of particular importance, erectile dysfunction (ED) (5). Data suggest that only 16% of men will return to their baseline erectile function following PC surgery (6). Importantly, ED can have a significant negative psychological effect; men with ED report frustration and shame, an increase in depressive symptoms, and lower general life happiness (6). The impact of ED can also extend to the couple. The psychological burden related to difficulties with erections often results in a loss of sexual and non-sexual intimacy, which, in turn, can lead to relationship distress (7). Additionally, while men with PC may experience psychological distress, psychosocial research has emerged

suggesting that female partners may experience equal, if not more distress than their male partners with PC (8,9).

These findings suggest that high levels of distress may be present in both men with PC and their partners, and that this distress can have a negative impact on their relationship. Thus, there is a significant need for interventions that help the PC patient and his partner to manage and cope with the impact cancer treatment can have on their intimacy and relationship. The purpose of this paper is to review and to critically evaluate important intervention studies that intended to address relational and sexual intimacy following PC treatment. Possible methodological concerns are discussed in order to determine what is needed to produce more effective interventions in this area.

## Methods

Identification of relevant studies occurred by a two stage process: (I) database search: electronic databases used to conduct literature searches included Medline, PsychINFO, and Web of Science (January 1, 2005-January 1, 2015). Key words used to search titles and abstracts included *prostate, AND randomized-controlled trial, AND psychosocial intervention OR psychological intervention\* OR psychosocial support\* OR psychological support\* OR psychosexual\* OR psychosexual support\* OR intimacy enhancing intervention \*OR education OR counseling\**; (II) inclusion screening: abstracts were screened for relevance according to the inclusion criteria. Retrieved studies were included if they were randomized-controlled trials (RCTs) using samples of men diagnosed with PC of any stage. Studies were required to have a psychosocial intervention in at least one arm of the study design, which had to address at least one sexual and one relational outcome. Following this search, and through group consensus with the authors, six RCTs intended to increase intimacy and sexual functioning in couples following PC treatment were identified. We review these studies below.

## Randomized clinical trial of a family intervention for prostate cancer (PC) patients and their spouses

### Methods

The objective of the Northouse *et al.* [2007] study was to test if a family-based intervention could improve coping resources, appraisal variables, quality of life (QOL), and symptom distress in patients with PC and their spouses. Three groups of PC patients were recruited: those newly

diagnosed with PC after completion of their primary treatment, those in biochemical recurrence who had two consecutive rises in their PSA score, and those with advanced stage PC after the diagnosis of metastatic disease (10). Two hundred and thirty-five dyads (PC patients and their spouses or live-in partners) in total participated in either the control (n=123 for 4-month assessment, n=114 for 12-month assessment) or experimental conditions (n=112 for 4-month assessment, n=104 for 12-month assessment). The control condition was standard clinic care, whereas the experimental condition was standard care plus the FOCUS program, an intervention adapted from the stress-coping framework of Lazarus and Folkman. The participants all received assessments at baseline, four months, eight months, and 12 months. Northouse *et al.* hypothesized that couples who received the FOCUS program would report fewer negative appraisal variables, more positive outcomes on coping resources, and higher QOL than couples in the control group (10).

### Intervention

The FOCUS Program, based off of Lazarus and Folkman's cognitive appraisal framework, consisted of three 90-minute home visits and two 30-minute telephone sessions spaced out between the baseline assessment and the four month assessment. FOCUS stands for the sessions of family involvement, wherein couples are encouraged to work as a team, communicate openly about the illness and be supportive of one another; optimistic attitude, in which couples are told to maintain hope and focus on short-term, attainable goals; coping effectiveness, wherein couples are taught techniques for stress reduction as well as active coping strategies and healthy lifestyle choices; uncertainty reduction, the focus of which is on how to obtain information, and how to live with uncertainty; and symptom management, which teaches couples how to cope with symptoms. The trained nurses who delivered this intervention also tailored the intervention to the individual couple's needs.

### Results

While the patients received only minimal benefit from the FOCUS program, the partners in the intervention group demonstrated moderate advantages. The most robust result for the partners was the reporting of better communication with the patients across all three assessment points compared to control partners. The partners in the

intervention condition also demonstrated less negative appraisal of caregiving, including less uncertainty on the Mishel Uncertainty Illness Scale (11) and reduced hopelessness on the Beck Hopelessness Scale (12) than the control partners at 4 months. However, only the result for uncertainty remained significant at a later time point. Additionally, the partners in the intervention condition demonstrated benefit in general well-being or QOL when compared to controls. At four months, the partners in the intervention group reported significantly better scores on the Medical Outcomes Study 12-item short form (MOS SF-12) mental health QOL subscale (13) and better overall Functional Assessment of Cancer Treatment (FACT-G) QOL (14) scores compared to controls. For later time points, the intervention partners reported better physical QOL on the MOS SF-12 (13) at eight and 12 months compared to control partners. On the measures of coping resources, the partners in the intervention had higher self-efficacy to manage the illness at four and 12 months on the Lewis Cancer Self-Efficacy Scale (15) and more active coping at 12 months than those in the control condition on the Lewis Mutuality and Interpersonal Sensitivity Scale (15). Additionally, partners who had undergone the FOCUS program had significantly less general symptom distress than control spouses on the Symptom Scale of the Omega Clinical Screening Questionnaire (OSQ) (16) and fewer problems related to husband's urinary incontinence at four months and eight months.

The patient results stand in contrast to these partner results. The intervention patients only significantly differed from control patients on the measures of communication and uncertainty about their illness at four months. The patients in the intervention did not differ from those in the control condition on any QOL variables and the patients saw no significant differences in general symptom distress or PC specific symptoms, including patients' urinary, bowel, sexual, and hormone symptoms, as measured by the 50-item Expanded Prostate Cancer Index Composite (EPIC) (17). Therefore, the spousal benefit from the family-based intervention, FOCUS, proved to be far better than the benefit for the patients.

### **Pilot intervention to enhance sexual rehabilitation for couples after treatment for localized prostate carcinoma**

#### **Methods**

A study by Canada *et al.* [2005] focused specifically on the

sexual rehabilitation aspect for couples where the man had either undergone surgery or radiation therapy (RT) for PC. Canada and colleagues developed an intervention that was either given to the patient alone or to the patient and his female partner (18). Eligible patients included those who had been treated for localized PC within three months to five years of starting the intervention, were unable to achieve and maintain an erection for sexual intercourse during  $\geq 50\%$  of attempts within the past three months, and had not been successful in using medical treatment for ED. A total of 26 men received the intervention without their partners and 25 men received the intervention with their partners. The purpose of this intervention was to enhance levels of sexual satisfaction and help men achieve successful utilization of medical treatments for ED. Assessments were given at baseline, after the last session of the intervention (after one month), and at three-month and six-month follow-ups.

#### **Intervention**

A trained interventionist administered four counseling sessions to the patient alone or to him and his partner. The sessions included education surrounding the sexual impact of surgery or RT for PC, medical and surgical treatments for ED, coping strategies to use during sexual activity for patients experiencing urinary incontinence or partners with postmenopausal vaginal atrophy. Additionally, couples were given skill training to enhance general communication of feelings, open expression of affection, and sexual communication. Cognitive behavioral techniques were also used to decrease negative beliefs about cancer and sexuality. As homework assignments, the patients and partners were asked to do a variety of behavioral exercises, and to make action plans for their use of medical treatments for ED.

#### **Results**

There were no significant differences between the two treatment groups (the participant attending the sessions alone compared to the couple attending together). Therefore, the data from both groups were combined and repeated measures analyses were conducted using the subjects as their own controls. There was no intervention impact on marital adjustment, as measured by the dyadic adjustment scale (A-DAS) (19), perhaps due to the fact that many couples already had high marital adjustment scores at baseline. The patients' scores on emotional distress did

significantly improve from baseline on the Brief Symptom Inventory (20) as did male sexual functioning/satisfaction in general as measured by the International Index of Erectile Functioning (IIEF) (21). The subscales of the IIEF of erectile function (mean score at baseline  $7.6 \pm 8.7$ , mean score at 3-mos  $15.3 \pm 11.2$ ), orgasmic function, intercourse satisfaction, and overall satisfaction all were significantly improved at three months, however only overall sexual satisfaction remained significant at six months. The partners' scores on sexual functioning/satisfaction as measured by the Female Sexual Function Index (FSFI) (22) significantly improved on the global score as well as on all of the FSFI subscales for the post treatment time point. As with men, only overall sexual satisfaction remained significant at six months. Importantly, the use of medical treatments for ED improved from the 31% of men using them at baseline, to 52% at post treatment, and to 55% at three-month follow-up. At six months, the significant improvement in the use of ED treatment remained with 49% continuing to use the treatment.

### **A randomized trial of internet-based versus traditional sexual counseling for couples after localized prostate cancer (PC) treatment**

#### **Methods**

A study by Schover *et al.* [2011] built upon Canada *et al.*'s [2005] study. Schover and colleagues compare a face-to-face format to an internet-based format of a revised version of the Canada *et al.* intervention entitled Counseling About Regaining Erections and Sexual Satisfaction (CAREss) (23). The study also included a three month wait list control condition. A second internet-based group was added to examine the relationship between website use and outcomes. The internet-based intervention was created with the hopes to be more convenient, to minimize the drop-out rate, and to play to the fact that many men already seek sexual content on the internet. Males who were married or living with a partner for over a year with localized PC who had either definitive surgery or RT three months to seven years previously were included in this study. The men had to be unable to achieve and maintain an erection for sexual intercourse for  $\geq 50\%$  of attempts within the past three months. The 112 couples (waitlist  $n=43$  (waitlist randomized after three-month period to FF  $n=20$  and WEB1  $n=22$ ), FF  $n=40$ , WEB1  $n=41$ , WEB2  $n=43$ ) were given assessments at baseline, posttreatment (after 12 weeks), and at three-

months, six-months, and 12-months follow-up.

#### **Intervention**

The content of these interventions were based on the Canada *et al.* [2005] intervention described above. The face-to-face and internet-based formats of CAREss had the same content and homework and both were three sessions in length. For participants in the WEB condition, their therapists were available through email and to give feedback on homework. For participants in the FF condition, therapists discussed the homework in the next session. The exercises were designed to boost expression of affection and comfort in initiating sexual activity, enhance sexual communication, and aid in resuming sex without performance anxiety. The education provided gave suggestions regarding coping with postmenopausal vaginal atrophy and coping with male urinary incontinence. Participants learned cognitive reframing techniques to identify negative beliefs about sexuality, and received a decision aid for choosing ED treatment together.

#### **Results**

There were no differences for any of the variables compared to the wait list controls. Additionally, there were no differences between the face-to-face CAREss group and the internet-based CAREss group. Therefore, these two groups were combined for repeated measures analyses. Men who received the CAREss intervention had significant gains on the subscale of erectile functioning (EF) on the IIEF between baseline and six-month follow-up as well as between baseline and one-year follow-up, with 16% having near-normal function (a score of  $\geq 22$  on the EF subscale of the IIEF) at baseline increasing to 39% at six months, and slightly declining again to 35% at one year follow-up. Men in the intervention conditions also improved significantly on the subscales of orgasmic function, intercourse satisfaction, and overall sexual satisfaction from baseline to one year. The rates of ED treatment use did not change significantly within any group. However, men who intensified their ED treatment [the use was defined as (I) none; (II) using oral medication only; and (III) using invasive ED treatment] had large, significant increases in IIEF scores across time. There were no significant differences in marital happiness, as measured by the A-DAS, or overall distress, as measured by the Brief Symptom Inventory (BSI-18) (24), for men in either of the intervention conditions. However, the sample



of men was not particularly distressed at baseline, which could have been the reason for the lack of change. Women as a whole in the intervention conditions did not improve significantly on sexual functioning/satisfaction, but when divided into the categories of those who had abnormal versus normal scores at baseline, the women who had abnormal scores at baseline in the intervention conditions did have significant improvement over time. Interestingly, normal FSFI scoring women in the intervention conditions at baseline actually declined and then recovered to baseline by one year. The baseline sexual functioning of women predicted the efficacy of CAREss in improving men's IIEF scores.

### **Intimacy-enhancing psychological intervention for men diagnosed with prostate cancer (PC) and their partners: a pilot study**

#### **Methods**

Manne *et al.* [2011] conducted a pilot evaluation of an intimacy enhancing therapy for men diagnosed with PC and their partners. The aim of this study was twofold; to determine whether IET proved efficacious in a small sample and to identify couples for whom IET would be most beneficial (25). To achieve both aims, the impact of IET versus usual care (UC) on survivor and partner psychological outcomes was evaluated, as was the impact of IET on dyadic communication. The participants were men diagnosed with localized PC within the past year, who were married or living with a significant other of either gender. Seventy-one couples were randomized to receive either five sessions of IET (n=37) or UC (n=34), which consisted of standard psychosocial care, such as social work consultations. Couples were assessed at two time points; baseline, and at eight weeks following baseline assessments (IET patients n=31, partners n=30; UC patients n=29, partners n=26).

#### **Intervention**

Utilizing the Relationship Intimacy Model of Cancer adaption (26), a 90 minute, five session intervention coined IET was developed to improve communication amongst PC survivors and their partners. The ultimate goal of IET is to address the effects of cancer and its treatments on relational intimacy. Each session of IET focuses on didactic content, and includes in-session skill practice as well as homework practice assignments. IET aims to

enhance couples' emotional intimacy by promoting the use of techniques that focus on the maintenance of mutual understanding and support, as well as reciprocal disclosure. By providing techniques that facilitate constructive discussions regarding patients' and partners' concerns of the experience and impact of cancer, IET sessions aim to provide greater overall relationship satisfaction. To achieve improved communication skills and enhance emotional intimacy, couples utilize a variety of techniques derived from cognitive-behavioral and behavioral marital therapy. Rudimentary communication skills techniques were adapted to the context of PC from the Prevention and Relationship Enhancement Program, and from Gottman and colleagues' communication skills intervention (27).

#### **Results**

The significant results for this study were found following moderator analyses. When comparing the groups without moderation analyses, no significant effects were found for couples general distress on the Psychological Distress scale of Mental Health Inventory (28), cancer-specific distress on the Impact of Events Scale (29), cancer concerns, relationship satisfaction on the Dyadic Adjustment Scale (30), and relationship intimacy on the Personal Assessment of Intimacy in Relationships scale (30). Similarly, no treatment differences were observed for patients or partners on relationship communication outcomes. For patients, there were marginally significant treatment effects following IET on psychological well-being on the Psychological Well-Being Scale of Mental Health Inventory (28), while no significant treatment differences for partners were observed.

Moderator analyses of baseline variables revealed that patients with greater cancer concerns and poorer communication showed an increase in self-disclosure, perceived partner disclosure and perceived responsiveness following IET compared to UC, using scales adapted from Laurenceau and colleagues (31). While no significant effects following IET were found for mutual constructive communication on The Mutual Constructive Communication subscale of the communication Pattern Questionnaire (32) and demand-withdraw communication on The Demand-Withdraw subscale of the CPQ (32) for patients, significant effects were found for partners. Interestingly, patients who reported high levels of self-disclosure at baseline showed a reduction in self-disclosure at the eight-week follow-up after IET. Partners who reported greater cancer-specific distress, higher relationship

satisfaction and intimacy, and poorer communication benefited more from IET than UC, specifically with cancer-specific distress, relationship satisfaction, and relationship intimacy. Partners who reported low levels of pre-intervention cancer-specific distress and high levels of relationship satisfaction and intimacy at baseline reported an increase in cancer-specific distress, and lower levels of relationship satisfaction and intimacy following IET.

### **A randomized controlled trial (RCT) of a couples-based sexuality intervention for men with localized prostate cancer (PC) and their female partners**

#### **Methods**

While support for patients with PC and their partners include nurses, social workers, psychologists and sex counselors, research emerging from the PC community has highlighted the benefits of peer support (33). To date, no research has been done to examine whether peer support is equally, if not more beneficial, than current professional care. With this in mind, Chambers and colleagues (2014) conducted a study that compared the efficacy of a couples-based, peer-delivered telephone support (n=63) versus couples-based, nurse delivered telephone counseling (n=62) versus UC (n=64) in improving patients' and their partners' psychosexual adjustment after the diagnosis and treatment of PC (33). In total, 189 couples were randomized to one of the three arms. The couples who received UC received standard medical management and a set of published educational materials. The participants were men who were scheduled for, or who had undergone surgery for PC within the last 12 months and their female partners. Assessments were conducted at four time points: baseline and at 3 (peer-delivered n=53, nurse delivered n=54, UC n=54), 6 (peer-delivered n=53, nurse delivered n=54, UC n=52), and 12 months follow-up (peer-delivered n=52, nurse delivered n=53, UC n=54).

#### **Intervention**

The couples-based, peer-delivered telephone intervention was oriented to empathic mutual support and education, which is consistent with a peer support framework in which couples bolster support based on shared personal experiences. Content included psycho-education about PC diagnosis, treatment and recovery, ED management, and maintaining intimacy and constructive communication

between couples. Managing and reviewing goals was also specifically focused on, and in doing so, couples were able to move beyond any setbacks experienced during the intervention. The couples-based, nurse-delivered telephone counseling followed theoretical principles and techniques of cognitive-behavioral sex and couples therapy, in which couples self-selected goals. Intervention content included education about PC, menopause, and sexuality. Behavioral homework consisted of aiming to increase the expression of affection and non-demanding sexual touch, challenging negative beliefs, and helping the couple collectively choose a medical treatment for ED that each would feel comfortable incorporating into their intimate relationship. It is important to note that for both intervention arms, couples recruited post-surgery received six sessions, while couples recruited pre-surgery received eight.

#### **Results**

No significant treatment effects were found for patients or partners for either intervention arm on sexual function on the IIEF (21) and the FSFI (22), sexuality needs on the sexuality needs subscale of the Supportive Care Needs Survey (34), sexual self-confidence on The Psychological Impact of Erectile Dysfunction-Sexual Experience scale (35), masculine self-esteem on The Masculine Self-Esteem Scale (36), marital satisfaction or intimacy on The Revised Dyadic Adjustment Scale (37). To examine whether beginning the intervention pre-or post-operatively had a significant effect, longitudinal analyses were run for all continuous variables. While no significant effects were found for partners, significant effects were found for patients for sexual function and sexual self-confidence. At 12-month follow-up, there were significant differences among intervention arms for overall use of medical treatments for ED. Patients in the peer intervention were 3.14 times more likely to use medical treatments for ED than those in UC, and patients in the nurse-delivered intervention were 3.67 times more likely to use medical treatments for ED than those in UC.

### **Androgen deprivation therapy (ADT) and maintenance of intimacy: a randomized controlled pilot study of an educational intervention for patients and their partners**

#### **Overview**

Walker *et al.* [2013] conducted this pilot study to evaluate an

educational intervention designed to help couples anticipate and manage ADT generated changes, and to investigate whether such intervention impacts couple's relationships favorably. The participants were Caucasian men with PC who had either just started, or were scheduled to begin ADT, and showed no evidence of metastatic disease (18). Partners of any age were permitted to participate as long as they had English fluency and were either married or common-law female partners to the patient. Following consent, couples were given their own baseline questionnaire packets and instructed to complete each questionnaire and seal them in individual envelopes. Upon completion, 20 couples were randomized as a unit to either a treatment arm or UC (number of participants in experimental and control arms were not listed). Couples were assessed at two time points: baseline and at six months following baseline assessments.

### Intervention

The educational intervention involved reading a 70-page booklet entitled "Androgen Deprivation Therapy: a Guide for Prostate Cancer Patients and their Partners," which discussed different ways to manage the side effects of ADT that directly affect patients (e.g., hot flashes and fatigue), as well as those that impact the couple (e.g., reduced libido and emotional lability). Each couple had two weeks to read the booklet, and subsequently received a one-hour private educational review session. The educational review session was headed by a male and female team to ensure that couples' individual needs were adequately met. The educational review session served as an opportunity for couples to address any remaining concerns that may have come up while reading the booklet, and to address any issues that may have not been brought up in the booklet. By providing a combination of an educational booklet as well as a review session, Walker and colleagues [2013] intended to help couples maintain a co-supportive bond that includes emotional and sexual intimacy.

### Results

With the small sample size in each group, the authors focused on reporting effect sizes as opposed to statistical significance. A medium effect size ( $d=0.58$ ) for patients' changes in the Personal Assessment of Intimacy in Relationships (PAIRS) (30) was observed favoring the treatment group, while partners in the treatment group scored lower ( $d=0.04$ ) on PAIRS than the controls at

follow-up. Thus, patients in the educational intervention demonstrated gains in intimacy, while partners in the intervention evidenced no important change. For patients, a large effect size ( $d=1.02$ ) was seen in DAS (38) scores at the six month follow-up, indicating that patients in the intervention arm had better dyadic adjustment following the educational intervention. A medium effect size ( $d=0.50$ ) was observed for partners' scores on DAS at six months follow-up, indicating that partners in the intervention group also had more improvements on dyadic adjustment. While both patients and partners experienced improvements in dyadic adjustment, partner's scores following the intervention eventually attenuated. Secondary analyses of sexual activity revealed that controls had a 42% decline in sexual activity from baseline, while couples in the intervention group reported only a 32% decrease in sexual activity at six months follow-up. Taken collectively, couples who did not receive the educational intervention experienced greater losses in intimacy, dyadic adjustment and sexual activity following ADT.

### Discussion

Taken as a group, these studies have produced mixed results. While there are clearly significant findings reported, many of the primary hypotheses were not achieved, and at times mediator or moderator analyses were needed to demonstrate effectiveness. Additionally, only two of the six studies (Northouse and Chambers) were large randomized controlled studies (10,33). To organize the summary of results, the manuscripts can be grouped loosely into two types of studies. First, the Canada, Schover, Chambers and Walker studies all focused on sexuality and ED treatments (18,23,33,39). These studies addressed: (I) educating participants about ED treatments; (II) educating participants about how to initiate sexual activity; or (III) managing side effects of PC treatment, with a focus on engaging in sexual relations (18,23,33,39). Although the results from these studies indicated an increase in the utilization of ED treatments, the primary aim of improved EF was generally not sustained. When significant results were reported, the effect of the intervention was not encouraging as the mean Erectile Function Domain of the IIEF improved but stayed within the "moderate" ED range. Additionally, these studies generally did not find significant outcomes for the partners. The second group of studies utilized couple's interventions that primarily addressed relationship aspects. The Manne and Northouse studies addressed a variety of concerns

regarding relationship variables such as communication and intimacy (10,25). The results from these studies were mixed but suggest better relationship outcomes and reduced distress for the partners. There were not many significant outcomes for the patients, suggesting that partners benefit more from relational aspects of interventions (10,25).

When this literature is considered as a whole, it is clear that future studies are needed. Since no one study stood out, using the lessons learned from these studies, and assessing their strengths and limitations, can provide valuable guidance for the next generation of interventions in this area. We outline what we believe to be important methodological and intervention considerations that when addressed, may help to produce more effective interventions for these men and their partners.

First, innovative theoretical approaches are needed to continue to push this literature forward. While the above literature has provided a sound foundation of intervention content and techniques, the studies have tested standard educational interventions, sex therapies techniques, and couples therapy strategies with only marginal success. According to the Complex Intervention Framework outlined by the Medical Research Council, in order to produce an effective intervention, the intervention must be grounded by a strong theoretical base (40). Therefore, changes that are expected, or changes that are likely to be achieved will have been tailored by the specific needs of the population. For example, in a recent qualitative study, Nelson *et al.* (in press) develop a theoretical argument that avoidance of sexual situations is an important construct to address with new interventions (6). The authors outline a theoretical justification to using Acceptance and Commitment Therapy techniques as the main intervention component to help men utilize ED treatments. A similar approach related to preventing avoidance of sexual situations is also being tested by Wooten and colleagues (41). Developing more specific interventions, based on sound theoretical foundations, would also have the benefit of helping us understand which components of the interventions are most effective for both the patients and the partners. Conducting qualitative research prior to intervention development is one way to understand which theoretical framework may be most useful. The studies reviewed above relied on previous research to guide their interventions; however, they did not conduct their own qualitative research before running their RCTs. Interviewing men with PC and their partners would have given the authors an opportunity to explore theoretical frameworks, develop a better understanding of the needs

of men and their partners, and address any potential study barriers (40).

A second consideration is the selection of outcome measures. The assessment of sexual function is well defined in the field. The IIEF for men and the FSFI for women are gold standard measures. However, assessing secondary distress variables can be a challenge. Many of these studies used relatively general assessments of “distress”, depression, or relationship functioning, and found no change on these variables. More focused assessments targeting specific constructs related to sexuality may be needed to see beneficial effects. Examples of more specific outcomes are constructs such as sexual bother, sexual self-esteem, or sexual relationships.

These studies also prove that greater attention needs to be paid to assessing the level of distress of the patients/couples prior to entry into the study. Canada *et al.* found no changes in marital adjustment on the A-DAS most likely because the couples were not distressed at baseline (18). Similarly, Schover *et al.* found no change in marital happiness or overall distress because there was high marital happiness and there were low-distress levels at entry into the study (23). Even more discouraging was the outcome that intervening on these low-distress couples can actually have unintended negative effects. Manne *et al.* found couples with low distress levels at baseline, after the intervention to have an increase in distress, lower intimacy levels, and poorer communication (25). The intervention may have been making couples more aware of problems, thus heightening their distress. Additionally, future studies should take into account the individual couples’ needs in order to focus on important issues for that couple. A study protocol by Robertson *et al.* addresses this issue by including a qualitative interview to get an in-depth understanding of the specific challenges of each couple and what they would hope to gain from the intervention (42).

Other patient selection criteria, beyond levels of distress, are also important. It is essential to distinguish eligibility criteria related to such variables, such as: type of treatment for PC, the amount of time following treatment, and stage of disease. The distinction between men who were treated with surgery compared to men treated with RT can be very important for research in this area. These men differ on the trajectory of EF following treatment, types of ED treatments that will be effective at different time points following treatment, and important patient characteristics such as age and co-morbidities. Many of these studies discussed above grouped men who had surgery and men



who had RT together, without addressing the distinct needs between these two groups. This limits the effectiveness of interventions and may dissipate their treatment results. Second, the length of time following treatment should be addressed as patient and partner concerns may differ based on this time frame. In the Canada study, participants were eligible if they had received treatment between three months and five years prior to entry into the study (18). This gap in time is especially important when addressing the individual needs of each participant, as sexual side effects of PC treatment may vary largely depending on the length of time post-treatment. The distress level within a couple may also be related to time following treatment. Clinical observation suggests that couple distress may be lower following the completion of early stage treatment when support related to the diagnosis/treatment is high and the couple is relieved with the completion of treatment, yet there is no current data available tracking the level of the couples' distress following treatment. It may not be until several months following PC treatment that the impact of ED and frustration of loss of intimacy is felt by the couple.

The largest complication of these interventions appears to be that men and women may need different types of interventions to see benefits. The six studies illuminate the fact that men who have undergone treatment for PC may benefit from education about treatment options for ED and avoidance of sexual situations, whereas their partners may gain more from interventions focused on relationship issues. In the interventions where sexual functioning was the main concern—Canada *et al.*, Schover *et al.*, Chambers *et al.*, and Walker *et al.*—patients were more likely to report benefit and sustained increases in ED treatment use (18,23,34,40). However, the partners in these studies did not see many benefits and neither patient nor partner saw gains on measures of marital satisfaction. Conversely, in the interventions focusing on intimacy support for couples after PC treatment—Northouse *et al.*, and Manne *et al.*—the patients reported far fewer benefits, if any, as compared to their partners, while the partners reported gains (10,25). Taken altogether, this suggests that interventions in the future should be developed to target the patient and partner separately, as well as together, so that the couple receives the intervention necessary to improve its sexual functioning and intimacy. Addressing the needs of the partner and the patient as individuals, as well as together, will be vital in successfully giving support to patients and their partners after treatment for PC.

While the six RCTs intended to address relational and

sexual intimacy following PC treatment, the methodological limitations of these studies reduce the effectiveness of these interventions. If the aforementioned areas of concern are considered and individual needs of participants are taken into account, interventions in the future have the potential to be more effective.

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## Footnote

*Conflicts of Interest:* The authors have no conflicts of interest to declare.

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## Appendix 1

Author	Intervention	Treatment groups	Delivery method	Outcome measure
Northouse <i>et al.</i> [2007]	The FOCUS program: a family-based intervention using a cognitive appraisal framework to improve coping resources, appraisal variables, quality of life (QOL), and symptom distress	Experimental condition: FOCUS program Control condition: standard of care	Three 90-minute home visits Two 30-minute telephone sessions Over the period of four months	Appraisal of illness scale Appraisal of caregivers scale Mischel uncertainty illness scale Beck hopelessness scale Medical outcomes study 12-item short form (MOS SF-12) Functional assessment of cancer treatment (FACT-G) Brief coping orientations to problems experienced scale Lewis cancer self-efficacy scale Lewis mutuality and interpersonal sensitivity scale Symptom scale of the omega screening questionnaire (OSQ) Expanded prostate cancer (PC) Index composite (EPIC) Omega clinical screening interview (OSQ)
Canada <i>et al.</i> [2005]	An educational intervention designed to target sexual rehabilitation, specifically to enhance levels of sexual satisfaction and to raise levels of successful utilization of medical treatments for erectile dysfunction (ED)	Individual condition: patient alone receives intervention Couple condition: patient and partner receive intervention	Four counseling sessions Homework assignments and behavioral exercises were given following each session	International index of erectile functioning (IIEF) Females sexual function index (FSFI) Utilization of medical treatments for ED scale Brief symptom inventory (BSI) Abbreviated form of the dyadic adjustment scale (A-DAS) UCLS PC Index (UCLA PCI) Breast cancer prevention trial (BCPT) Symptom Checklist SF-36 short form health survey's physical (PCS) and mental (MCS) health components
Shover <i>et al.</i> [2011]	The Counseling About Regaining Erections and Sexual Satisfaction (CAREss) intervention: counseling about regaining erections and sexual satisfaction, an intervention based on Canada <i>et al.</i> 's 2005 intervention designed to target sexual rehabilitation through a face-to-face or internet-based format	Face-to-face (FF) condition: received CAREss in person Internet-based (WEB & WEB2) conditions: received CAREss online Control condition: Waitlist (WL)	Three CAREss sessions either delivered in person or online	International index of erectile functioning (IIEF) Females sexual function index (FSFI) Utilization of medical treatments for ED scale Brief symptom inventory (BSI-18) Abbreviated form of the dyadic adjustment scale (A-DAS)

Appendix 1 (continued)



**Appendix 1** (*continued*)

Author	Intervention	Treatment groups	Delivery method	Outcome measure
Manne <i>et al.</i> [2011]	Intimacy-enhancing therapy; combination of CBT and BMT. Enhances communication skills to improve support exchanges and enhance emotional intimacy	Intimacy-enhancing therapy (IET) condition Usual care (UC) condition: received social work consultations	Delivered in five 90-min sessions	The psychological well-being scale of mental health inventory The impact of events scale Dyadic adjustment scale (DAS) The personal assessment of intimacy relationships scale (PAIRS) Communications pattern questionnaire (CPQ) Self-disclosure, perceived partner disclosure and perceived partner responsiveness were assessed using scales adapted from Laurenceau and colleagues (1998)
Chamber <i>et al.</i> [2014]	Couples-based peer-delivered telephone support; oriented to empathic mutual support and education. Consistent with a peer support framework in which couples bolster support based on shared personal experiences. Couples-based nurse delivered telephone counseling; combination of cognitive-behavioral sex and couples therapy. Couples self-selected goals	Couples-based peer-delivered telephone support condition Couples-based nurse delivered telephone counseling condition UC control condition: received standard medical management and a set of published educational materials	Couples-based peer-delivered telephone support and couples-based nurse delivered telephone counseling both delivered over the telephone in 6 (post-surgery) or 8 (pre-surgery) sessions	International index of erectile function (IIEF) Female sexual function index (FSFI) Sexuality need subscale of the supportive care needs survey Psychological impact of erectile dysfunction-sexual experience scale Masculine self-esteem scale Revised dyadic adjustment scale The miller social intimacy scale Utilization of erectile dysfunction (ED) treatments by couples was measured using a scale created by Schover and colleagues
Walker <i>et al.</i> [2013]	Educational intervention and educational review session; discusses how couples could anticipate and manage androgen deprivation therapy (ADT) generated changes	Educational intervention condition US control condition: received standard care	Participants reviewed educational booklet for 2 weeks and educational review session was delivered in one hour, private sessions	The personal assessment of intimacy in relationships (PAIRS) The dyadic adjustment scale (DAS)