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Journal Title: Psycho-Oncology
Volume: Volume 26, Number 7
Publisher: Wiley: 12 months | 2017-07-01, Pages 873-913
Type of Work: Article | Final Publisher PDF
Publisher DOI: 10.1002/pon.4431
Permanent URL: https://pid.emory.edu/ark:/25593/s4pfx

Final published version: http://dx.doi.org/10.1002/pon.4431

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INVITED EDITORIAL

New Challenges in Psycho-Oncology Research III: A systematic review of psychological interventions for prostate cancer survivors and their partners: clinical and research implications

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Funding information
National Health and Medical Research Council; NHMRC Centre for Research Excellence in Prostate Cancer Survivorship, Grant/Award Number: APP1116334

1 | BACKGROUND

The medical and social context of prostate cancer (PCa) has changed dramatically since the introduction of PSA testing for early detection in the late 1980s,¹ leading to a peak in incidence in the developed world in the 1990s and again a decade later.² Since that time, novel PCa treatments have rapidly emerged in the radiation and medical oncology field, as well as surgical advances.³ The recent emergence of active surveillance for low-risk disease has further expanded possible treatment approaches.⁴ Market forces from consumers, clinicians, and the therapeutic industry have driven changes in clinical and surgical management and treatment; however, psycho-oncological research and survivorship care arguably has lagged behind. Specifically, although men are surviving longer, they may not be surviving well. In 2012, there were over 1.1 million incident cases of PCa diagnosed and more than 300 000 deaths worldwide.⁵ Five-year prevalence estimates suggest that there are over 3.8 million PCa survivors globally⁶ with this expected to increase rapidly in future.⁷ The challenges we face in meeting the needs of these men and their families into the future are vast.

Up to 75% of men treated for localised PCa report severe and persistent treatment side-effects including sexual dysfunction, poor urinary or bowel function.⁸ Psychosocial concerns are prevalent with 30%-50% of PCa survivors reporting unmet sexuality, psychological, and health system and information needs⁹,¹⁰ and 10%-23% of men clinically distressed.¹¹ Risk of suicide is increased after PCa diagnosis¹²,¹³ and can persist for a decade or more.¹⁴ In the longer term, 30%-40% of PCa survivors report persistent health-related distress,
worry, low mood\textsuperscript{15} and diminished quality of life (QoL).\textsuperscript{16} Partners of PCa survivors also experience ongoing psychological concerns and changes in their intimate relationships\textsuperscript{17}; with these impacts driven in part by the man’s level of distress, sexual concerns and physical QoL.\textsuperscript{18}

In 2011, our group published the first criterion-based systematic review of psychosocial interventions for men with PCa and their partners.\textsuperscript{19} We concluded that group cognitive-behavioural interventions and psycho-education appeared to be helpful in promoting better psychological adjustment and QoL for men with localised PCa, and coping skills training for female partners may improve their QoL. However, data were limited by inconsistent results and low study quality. In response to the increasing burden of PCa, uncertainties about optimal psychosocial care, and additions to the literature, we updated and extended this review with the intent of determining benefit and acceptability, and considering intervention content and format. In brief, we considered the range of psychosocial and psychosexual interventions that may be optimal, and for whom.

2 | METHODS

Two clinical questions guided the review\textsuperscript{20}: In men diagnosed with PCa (Q1) and/or in their partners/carers (Q2), what is the effectiveness of different psychosocial or psychosexual interventions compared with (i) other psychosocial or psychosexual interventions, or (ii) usual care or no intervention, in maintaining or improving QoL or psychological wellbeing? Psychosocial or psychosexual interventions were included if they had one or more of the following components: education (psycho-education, psycho-sexual education, PCa education), cognitive-behavioural (cognitive restructuring, behaviour change, cognitive-behavioural stress management), relaxation (relaxation techniques, meditation), supportive counselling (counselling/psychotherapy, health professional discussion), peer support (peer support, social support including discussion within a group of peers), communication (skill development to encourage communication with partners, health professionals or generally) and decision support (aids or tools to assist decisions about PCa treatment or use of sexual aids). The review and reporting of results were guided by the PRISMA statement.\textsuperscript{21} Ethical approval was not required.

2.1 | Search strategy

Our prior review (until December 1, 2009) identified 195 articles that met criteria for the current study.\textsuperscript{19} Searches were updated from 2009 onwards. Eleven relevant databases were searched (eg, MEDLINE, Embase, PsycINFO, and CINAHL; Figure 1) up to January 9, 2017. Free-text terms and database-specific subject headings for PCa and psychological and QoL outcomes were used (Appendix A shows full search strategies). Reference lists of included articles were also searched. ClinicalTrials.gov (http://clinicaltrials.gov/) (June 2016) and the International Clinical Trials Registry Platform (http://apps.who.int/trialsearch/) (October 2016) were searched for ongoing and completed trials and associated publications.

2.2 | Selection criteria

Studies were included if the following pre-specified criteria were met:

- Randomised controlled trial design.
- ≥80% of participants were men diagnosed with PCa (no restrictions on disease stage or time since diagnosis) and/or partners/carers of men with PCa or results for men with PCa and/or partners/carers were reported separately.
- Intervention(s) were psychosocial or psychosexual.
- Outcome(s) reported were psychosocial (including psychological, relationships, decision-making), health-related QoL, and sexuality outcomes (including sexual function, bother, and use of erectile dysfunction aids or treatments). Mediator outcomes such as cognitive reframing and coping were not included.
- Outcomes were assessed using validated scales or scales adapted from these.
- Intervention(s) were compared with usual care or supportive attention or no intervention, and/or another intervention(s) with different psychosocial or psychosexual components, and/or the same intervention components with a different mode(s) of delivery. Multimodal interventions such as lifestyle interventions were only included if they had a psychosocial or psychosexual component.
- Published in English language.
- Published after December 31, 1999 up to January 9, 2017.

Two authors reviewed titles and abstracts and excluded irrelevant articles and duplicates. Full-text articles that potentially met criteria were then retrieved and reviewed by one author. A random sample of 5% of articles was assessed for inclusion by 2 authors with 100% agreement achieved.

2.3 | Data extraction

One author extracted pre-specified study characteristics (eg, participant demographics, PCa treatments, intervention content, delivery and results) and another checked each extract. To support data extraction, published descriptions of interventions were content analysed to create a framework of common psychosocial or psychosexual intervention components (Appendix B).

2.4 | Risk of bias

The Cochrane Collaboration’s tool was used to assess risk of bias regarding sequence generation, allocation concealment, blinding of participants and personnel collecting outcome data, incomplete outcome data, selective outcome reporting, and other sources (eg, difference in follow-up between arms).\textsuperscript{22} Blinding is difficult to achieve in psychological trials where consent mechanisms require participants to understand differences in treatments, which are often clearly discernible to the participant (eg, therapist-delivered intervention vs self-help materials).\textsuperscript{19} On this basis, blinding was excluded from assessment. Clinical trial registries at https://clinicaltrials.gov/, http://www.isrctn.com/, and http://www.anzctr.org.au/ were searched for protocols of included studies to identify pre-specified outcomes and
determine whether there was a risk of bias from selective outcome reporting. Differences in evaluations were resolved by discussion and where necessary adjudication by a third author.

2.5 | Intervention acceptability

The criteria of Yanez et al\textsuperscript{23} were used to identify and evaluate aspects of interventions that indicate acceptability: ≥40% recruitment rate, ≥70% retention at end of intervention or follow-up (or <30% withdrawal), and ≥70% average intervention attendance.

2.6 | Analyses

It was anticipated that some trials may be underpowered.\textsuperscript{19} Thus, an intervention was considered potentially beneficial compared with usual care or better than another intervention if for at least one reported outcome (at the longest reported follow-up), there was in favour of the intervention(s): (i) a statistically significant difference between arms; (ii) a moderate or large standardised effect size (eg, Cohen’s $d \geq 0.5$, $\eta^2 \geq 0.06$); or (iii) a difference in mean score changes from baseline calculated by ANCOVA or multiple linear regression between arms ≥10% of the scale of the differences in means. For a given measurement scale, results from subscales were only considered in the absence of an overall score.

3 | RESULTS

3.1 | Search results

In all, 6631 citations were identified of which 161 full-text (including 16 identified from reference lists) were retrieved and evaluated.
as well as 195 articles from the prior review. Of the total 356 full-text articles assessed for inclusion, 68 articles met criteria and reported a total of 57 RCTs. Forty-one RCTs reported in 51 articles (2 publications for 10 studies) included only patients (Q1); 1 RCT included only partners (Q2); 15 RCTs reported in 16 articles (2 publications for 1 study) included patients and partners (Q1 and Q2) (Figure 1). Most studies were excluded because of study design or population not meeting criteria, or results for patients or partners/carers were not reported. Clinical trial registry searches identified 47 trials: 25 completed (16 included in the review); 20 ongoing; 2 terminated (slow accrual, funding unavailable).

### 3.2 Risk of bias

Risk of bias from sequence generation (61% Q1: 64% Q2) and allocation concealment (71% Q1: 79% Q2), was unclear, and high for incomplete outcome data (43% Q1: 43% Q2) for most studies. Risk of bias from selective outcome reporting was also high for majority of partner studies (43%) and unclear for patient studies (63%). Most studies were low risk for other sources of bias (70% Q1: 86% Q2) (Appendix C).

### 3.3 Trial characteristics

Included trials randomised 8378 men (range 27-740; 48% of trials had <100 participants), and 1313 partners (range 27-263; 57% of trials had <100 participants; >90% partners were female in 14 trials; >80% partners were spouses in 12 trials). Most (67%) trials were conducted in North America. In 10 trials (4 including partners), participation was determined by socio-demographic background (eg, African-American), emotional state (eg, distress), or QoL (eg, urinary or sexual dysfunction, ADT treatment side-effects, fatigue). When reported, mean or median age was below 65 years in 49% of trials for patients and below 65 years in 100% of trials for partners. In approximately half of trials (57% of patient trials, 40% of partner trials) reporting college/university education, >50% of participants were university/college educated. In 25 trials (45%), men were diagnosed with or treated for localised disease in the previous 6 months (14 trials enrolled men prior to treatment or treatment decision). Men with recurrent or metastatic disease and their partners were included in 16% and 21% of trials, respectively.

The number of relevant outcomes measured by trials varied from 1 to 16 (patient) and 2 to 12 (partner). Most common outcomes for patients were sexual bother and/or function and mental health; and for partners were relationships, general and cancer-specific distress. Trials reported 41 patient, 1 patient and partner, and 1 partner person-focused (targeted and delivered to the individual or person) interventions and 14 couple-focused interventions (targeted and delivered to the couple as a dyad) (Appendix D). Most interventions were compared with usual care or standard care; however, what the comparison group entailed was rarely described. Follow-up ranged from immediately post-intervention to approximately 19 months (person-focused, Median = 3 months) or 12 months (couple-focused, Median = 6 months) post-intervention.

### 3.4 Intervention acceptability

Trials comprising interventions that were person-focused were more acceptable than couple-focused interventions (recruitment: 72% vs 29%; retention: 74% vs 64%). Approximately 40% of person and couple interventions indicated acceptable mean attendance (Table 1).

### 3.5 Intervention effects

Three trials reported couple-focused interventions that, compared with usual care, increased partner distress about sexual function, worsened partner challenge appraisal, and reduced relationship satisfaction and intimacy for partners who had high levels of these constructs at baseline (Appendix D). By contrast, for patients, all intervention effects indicated improvement. Four trials included outcomes of interest but did not report comparative results and were excluded. The remaining 29 trials (21 person-focused: 20 patients, 1 partner and patient; 8 couple-focused) showed a benefit for psychosocial or psychosexual outcomes (Table 2). Most (80%) person-focused interventions were for men with localised disease. Of the effective interventions, most (95% person-focused, 86% couple-focused) significantly impacted patient outcomes. No person-focused trials had a significant effect on relationship outcomes. No couple-focused trials improved decision-making outcomes or fatigue. No trials had a significant effect on partner QoL or sexuality outcomes regardless of intervention focus. Table 3 reports intervention components.

#### 3.5.1 Person-focused

**Decision making**

Six trials improved patient decision-making mostly for men diagnosed with early stage disease and/or recruited prior to treatment. Decision support, aid, or navigation reduced patient uncertainty, conflict, and regret about their treatment decision, and a combined online psycho-educational intervention and moderated peer forum also reduced regret. Patient self-efficacy or confidence in their decision-making was increased by decision navigation and interactive education interventions.

**TABLE 1** Acceptability of included trials comprising person- (n = 43) and couple- (n = 14) focused interventions

| Acceptability category | Person* N (%) | Couple N (%) |
|------------------------|---------------|--------------|
| 1. Recruitment         |               |              |
| No: <40%               | 8 (19%)       | 6 (43%)      |
| Yes: ≥40%              | 31 (72%)      | 4 (29%)      |
| Unclear: Not reported  | 4 (9%)        | 4 (29%)      |
| 2. Retention/Withdrawal|               |              |
| No: Retention <70%; Withdrawal > 30% | 2 (5%) | 1 (7%) |
| Yes: Retention ≥70%; Withdrawal ≤ 30% | 32 (74%) | 9 (64%) |
| Unclear: Not reported  | 9 (21%)       | 4 (29%)      |
| 3. Attendance          |               |              |
| No: <70%               | 7 (16%)       | 2 (14%)      |
| Yes: ≥70%              | 18 (42%)      | 6 (43%)      |
| Unclear: Not reported  | 18 (42%)      | 6 (43%)      |

*Includes 2 person-focused trials for partners both rated acceptable on recruitment, retention, and attendance.
TABLE 2  Person - (N = 21) and couple - (N = 8) focused trials that significantly (or moderate-large effect size) and positively impacted psychosocial or psychosexual outcomes

| Study            | N   | Intervention(s) that had an effect | Comparison | Components | Deliverer | Follow-up | Outcomes impacted | Sig level or effect size * |
|------------------|-----|-----------------------------------|------------|------------|-----------|-----------|------------------|---------------------------|
| **Person-focused interventions**                                                                                       |
| Badger 2011,2013 | 71  | 1. Interpersonal psychotherapy + cancer education: patient and partner | 2. Health education attention: patient and partner | 1. E, SC, PS, C 2. E | 1. Nurse or social worker 2. Research assistants | 8 weeks post-intervention | Depression  
• Patient  
• Partner | P < 0.001 P < 0.05 |
| Patients + partners | 8 (patients) or 4 (partners) individual telephone sessions over 8 weeks | | | | | | Negative affect  
• Patient | P < 0.001 |
| Bailey 2004      | 39  | Uncertainty management: cognitive reframing tailored to patient needs | UC | E, CB, C, DS | Nurse | ~5 weeks post-intervention | QoL | P = 0.01 |
| Berry 2012,2013  | 494 | Decision support                  | UC | E, C, DS | Self-admin | 6 months post-intervention | Decisional uncertainty | P = 0.04 |
| Campo 2014       | 40  | Qigong                            | Stretch control | R | Qigong master and instructors | 1 week post-intervention | Fatigue | P = 0.02 |
| Carmack-Taylor 2006,2007 | 134 | 1. 30 minutes expert speaker or facilitated discussion | UC | 1. E, PS | Facilitator supervised by clinical psychologist | 6 months post-intervention | Anxiety | Sub-group P = 0.02 |
|                  |     | 2. 90 minutes expert speaker or facilitated discussion | | 2. E, PS | |
|                  |     | Both interventions 21 group face-to-face sessions over 6 months | | | | | Depression | Sub-group P = 0.002 |

(Continues)
| Study               | N     | Intervention(s) that had an effect                                                                 | Comparison | Components | Deliverer     | Follow-up          | Outcomes impacted          | Sig level or effect size * |
|---------------------|-------|----------------------------------------------------------------------------------------------------|------------|------------|---------------|--------------------|----------------------------|---------------------------|
| Chabrera 2015       | 142   | Decision aid                                                                                       | UC         | E, C, DS   | Self-admin    | 3 months post-baseline | Decisional conflict        | \( P < 0.001 \)           |
| Chambers 2013       | 740   | Telephone psycho-educational                                                                        | UC         | E, CB, R, DS | Nurse Counsellor | 24 months post-tx | Cancer-specific distress | Sub-group                | \( P < 0.008 \)           |
|                     |       | 5 individual sessions; 2 pre-tx, and 3 weeks, 7 weeks and 5 months post-tx                         |            |            |               |                    | Mental health               | Sub-group                | \( P = 0.04 \)            |
| Diefenbach 2012     | 91    | 1. Prostate Interactive Educational System with or without tailoring to patient’s information seeking style (combined results from arms) | 1. E, DS   |            | Self-admin    | Immediately post-intervention | Confident about tx choice | \( P = 0.02 \)           |
|                     |       | 2. Control Read Standard National Cancer Institute booklets on PCa for 45 minutes                 | 2. E       |            |               |                    | Prefer more information   | \( P = 0.02 \)            |
|                     |       | 1 individual internet/CD-ROM session                                                               |            |            |               |                    |                           |                           |
|                     |       | 1 individual booklet                                                                               |            |            |               |                    |                           |                           |
| Hacking 2013        | 123   | Decision navigation                                                                               | UC         | DS         | Research assistants | 6 months post-consult | Decisional self-efficacy | \( P = 0.009 \)           |
|                     |       | 1 individual face-to-face or telephone session, audiotape and written notes                        |            |            |               |                    | Decisional regret          | \( P = 0.04 \)            |
|                     |       | 2. Education                                                                                      |            |            |               |                    |                           |                           |
|                     |       | Both 6 weekly face-to-face group sessions                                                          |            |            |               |                    |                           |                           |
| Lepore 2003; Helgeson 2006 | 250 | 1. Education + group discussion (with family member/friend)                                         | Standard medical care | 1. E, PS   | Multiple health professionals | 12 months post-intervention | Mental health | Sub-group                | \( P < 0.05 \)           |
|                     |       | 2. Education                                                                                      |            | 2. E       |               |                    | Depression                | Sub-group                | \( P < 0.05 \)           |
|                     |       | Both 6 weekly face-to-face group sessions                                                          |            |            |               |                    | Sexual bother             | \( P < 0.01 \)            |
| Mishel 2009         | 252   | 1. Decision navigation: Patient only                                                                | Control    | 1. E, SC, C, DS | Nurse, Self-admin | 3 months post-baseline | Decisional regret          | \( P = 0.01 \)           |
|                     |       | 2. Decision navigation: Patient and support person                                                 |            | 2. E, SC, C, DS |               |                    |                           |                           |
|                     |       | Both information + telephone calls to review content, identify/formulate questions and practise skills delivered to patient and/or support person individually (not dyad) |            |            |               |                    |                           |                           |
|                     |       | Both individual/couple booklet, DVD and 4 telephone calls over 7-10 days                           |            |            |               |                    |                           |                           |

(Continues)
| Study (Year) | N   | Intervention(s) that had an effect | Comparison | Components | Deliverer | Follow-up | Outcomes impacted | Sig level or effect size * |
|-------------|-----|----------------------------------|------------|------------|-----------|-----------|-------------------|---------------------------|
| Penedo 2006; Molton 2008 | 191 | 1. 10-week group CB stress management techniques + relaxation training 10 weekly group face-to-face sessions | 2. Half-day stress management seminar (same content) 1 group face-to-face session | 1. E, CB, R, SC, PS, C 2. E | Therapist | 12-13 weeks post-baseline | Cancer-related QoL | P < 0.05 Sexual function | Sub-group P < 0.05 |
| Penedo 2007 | 93  | 1. 10-week group CB stress management techniques + relaxation training 10 weekly group face-to-face sessions | 2. Half-day stress management seminar (same content) 1 group face-to-face session | 1. E, CB, R, SC, PS, C 2. E | Therapist | 12-13 weeks post-baseline | Cancer-related QoL | P = 0.006 |
| Petersson 2002 | 118 | Group rehabilitation programme (only or + individual support) including psychosocial components + physical activity 8 group face-to-face sessions over 8 weeks + booster group session after 2 months + written information | No group intervention 1 group face-to-face session | E, CB, R Multiple health professionals | 3 months post-intervention start | Cancer-related distress (Avoidance) | Sub-group P < 0.01 |
| Schofield 2016 | 331 | Nurse-led group psycho-educational consultation 4 x group face-to-face sessions (beginning, mid, completion, and 6 weeks post-radiotherapy) + 1 individual session after 1st group consultation | UC E, PS, C | Uro-oncology nurse | 6 months post-tx | Depression | P = 0.0009 |
| Siddons 2013 | 60  | CB group intervention 8 group face-to-face sessions over 8 weeks | Wait-list E, CB, R, C | Psychologist | 8 weeks (end of intervention) | Masculine self-esteem | P = 0.037 Sexual confidence | P = 0.001 Sexual QoL | P = 0.046 Orgasm satisfaction | P = 0.047 |
| Traeger 2013 | 257 | 1. 10-week group CB stress management techniques + relaxation training 10 weekly group face-to-face sessions | 2. Half-day stress management seminar (same content) 1 group face-to-face session | 1. E, CB, R, SC, PS, C 2. E | Therapist | 12-13 weeks post-baseline | Emotional well-being | P < 0.05 |
| Study     | N    | Intervention(s) that had an effect | Comparison | Components          | Deliverer            | Follow-up            | Outcomes impacted                          | Sig level or effect size * |
|-----------|------|-----------------------------------|------------|---------------------|----------------------|----------------------|--------------------------------------------|----------------------------|
| Weber 2004 | 30   | Peer support                       | UC         | PS                  | Peer (>3 years PCa survivor) | 8 weeks post-baseline | Sexual bother                           | P = 0.014                  |
| Weber 2007 a,b | 72   | Peer support                       | UC         | PS                  | Peer (>3 years PCa survivor) | 8 weeks post-baseline | Depression                       | P = 0.03                  |
| Wootten 2015, 2016 | 142  | 1. Online psycho-education + moderated peer online forum (PsychE + F) | 2. Moderated peer online forum (F) | 1. E, CB, PS, C, 2. PS | Self-admin | 6 months post-baseline | Distress                          | P = 0.02                  |
|           |      | 6 individual sessions over 10 weeks | Individually accessed over 10 weeks |                     |                      |                      | Decisional regret                      | P = 0.046                 |
|           |      |                                   |            |                     |                      |                      | Sexual satisfaction                     | Sig level NR, Difference 1.24 (95%CI 0.25-2.22) |
| Yanez 2015 | 74   | 1. CB stress management + relaxation/stress reduction techniques | 2. Health promotion attention-control | 1. E, CB, R, PS, C, 2. E | Therapist | 6 months post-baseline | Depression                       | Cohen's d 0.5               |
|           |      | 10 weekly group online sessions    | 10 weekly group online sessions |                     |                      |                      |                              |                           |
| Couple-focused interventions |       |                                   |            |                     |                      |                      |                              |                           |
| Campbell 2007 | 30   | Partner assisted coping skills training | UC         | E, CB, R, C | Therapist | ~6 weeks post-baseline | Sexual bother • Patient | Cohen's d 0.5               |
|           |      | 6-weekly dyadic telephone sessions |            |                     |                      |                      |                              |                           |
| Chambers 2015 | 189  | 1. Peer-delivered telephone support | UC         | 1. E, CB, PS, C    | PCa Nurse counsellor | 12 months post-recruitment | Use of ED tx Patient | p < 0.01                  |
|           |      | 2. Nurse-delivered telephone counselling |                     | 2. E, CB, SC, C, DS |                      |                      |                              |                           |
|           |      | 8 (recruited pre-surgery) or 6 (recruited post-surgery) dyadic telephone sessions: 2 pre-surgery and/or 6 post-surgery over 22 weeks |                     |                      |                      |                      |                              |                           |
| Couper 2015 | 62   | Cognitive-existential couple therapy | UC         | CB, SC             | Mental health professional | 9 months post-baseline | Relationship function Partner | P = 0.009                |
|           |      | 6 weekly dyadic face-to-face sessions |            |                     |                      |                      |                              |                           |

(Continues)
| Study       | N        | Intervention(s) that had an effect                                                                 | Comparison | Components | Deliverer          | Follow-up               | Outcomes impacted                  | Sig level or effect size * |
|------------|----------|---------------------------------------------------------------------------------------------------|------------|------------|--------------------|--------------------------|-------------------------------------|--------------------------|
| Giesler 2005 | 99       | Post-tx nursing support 6 monthly dyadic sessions; 2 face-to-face and 4 telephone sessions       | UC         | E, C       | Oncology nurse     | 12 months post-tx       | Sexual limitation               | $P = 0.02$               |
|            |          |                                                                                                   |            |            |                    |                          | Cancer worry                   | $P = 0.03$               |
| Manne 2011 | 71       | Intimacy-Enhancing Therapy 5 dyadic face-to-face sessions over 8 weeks                             | UC         | E, CB, SC, C | Therapist          | 8 weeks post-baseline   | Cancer concern                  | Sub-group $P = 0.02$     |
|            |          |                                                                                                   |            |            |                    |                          | Cancer-related distress          | Sub-group $P = 0.02$     |
|            |          |                                                                                                   |            |            |                    |                          | Relationship satisfaction        | Sub-group $P = 0.0002$   |
|            |          |                                                                                                   |            |            |                    |                          | Intimacy                         | Sub-group $P = 0.001$    |
|            |          |                                                                                                   |            |            |                    |                          | Partner                          |                          |
| Thornton 2004 | 80 patients, 65 partners | Pre-surgical communication enhancement 1 dyadic face-to-face session | UC delivered by a nurse | SC, C | Trained counsellor | 1 year post-surgery | Stress Partner | partial $\eta^2 = 0.12$ |
| Titta 2006 | 57       | Intracavernous injection-focused sexual counselling for couples following patient training in PGE1-intracavernous injections Six 3-monthly dyadic face-to-face sessions | Control (partner invited to follow-up visits every 3 months) | E, SC, C | NR | 18 months post-surgery | Erectile function | $P < 0.05$ |
|            |          |                                                                                                   |            |            |                    |                          | Sexual satisfaction             | $P < 0.05$               |
|            |          |                                                                                                   |            |            |                    |                          | Sexual desire                   | $P < 0.05$               |
| Walker 2013 | 27       | Educational intervention for couples to maintain intimacy 1 dyadic face-to-face session + booklet | UC         | E          | Researcher familiar with ADT | 6 months post-enrolment | Intimacy                      | Cohen's d |
|            |          |                                                                                                   |            |            |                    |                          | Patient                        | 0.6                      |
|            |          |                                                                                                   |            |            |                    |                          | Dyadic adjustment               | 1.0                      |
|            |          |                                                                                                   |            |            |                    |                          | Partner                         | 0.5                      |

*Precision of effect and size of effect correspond to longest reported follow-up; size of effect only reported if not significant. C, Communication; CB, Cognitive-behavioural; DS, Decision Support; E, Education; ED, Erectile dysfunction; NS, Not significant; PCa, Prostate cancer; PS, Peer Support; QoL, Quality of Life; R, Relaxation; SC, Supportive Care; Tx, treatment; UC, Usual or standard care
Quality of life

An uncertainty management intervention improved QoL for patients on watchful waiting. In 2 trials, a 10-week cognitive-behavioural stress management intervention improved cancer-specific QoL for patients with early stage disease.

Fatigue

Participants who received Qigong or a health education intervention experienced reduced fatigue.

Sexuality

Five trials reported better sexuality outcomes (80% of trials included majority of men who had radical prostatectomy). Combined education and group discussion, and peer support decreased sexual bother. A 10-week group cognitive-behavioural stress management intervention improved sexual function for men treated with prostatectomy (88% erectile dysfunction (ED)) who had high interpersonal sensitivity. Sexual satisfaction improved for patients in a combined online psycho-educational intervention and moderated peer forum had less distress. Qigong also decreased distress; and a nurse-led psycho-education intervention and peer support reduced depression. In 2 trials, a 10-week cognitive-behavioural stress management intervention improved emotional well-being and depression.

Mental health and cancer-specific distress improved in younger, more highly educated patients who received a tele-based psycho-educational intervention. A multi-modal intervention including cognitive-behavioural therapy also reduced cancer-related distress (avoidance) in patients with a monitor (cognitive scanning) coping style. Patients with high-baseline depression or anxiety showed improvement in these constructs if they were allocated to either a multi-modal intervention including either 30 or 90 minutes of an expert speaker/facilitated discussion. In another trial, patients with lower baseline depression were less depressed if they received a combined education and group discussion intervention. In this same study, patients with lower self-esteem at baseline had less depression and better mental health if they participated in either a combined education and group discussion or education only intervention.

One trial improved patient and partner mental health outcomes. Patients in the health education attention intervention had less depression, negative affect, stress, and greater spiritual well-being. Effects on stress were more pronounced for men who were less educated, and greater reductions in depression were experienced if men were older, had lower Ca-specific QoL, active chemotherapy, less social support or cancer knowledge. Patients receiving combined psychotherapy and education had more positive affect if they were more highly educated, had higher Ca-specific QoL, or more social support. Partners in the health education intervention had improved depression, social, and spiritual well-being.

### TABLE 3

| Components | Person-focused interventions* | Couple-focused interventions* |
|------------|-------------------------------|-------------------------------|
|            | % (n)                          | % (n)                          |
| Education (psycho-education, psycho-sexual education, PCa education) | 85% (29) | 78% (7) |
| Communication (partner, sexual, health professional, general or type not specified) | 44% (15) | 78% (7) |
| Peer support (peer discussion, social support) | 41% (14) | 11% (1) |
| Cognitive-behavioural (cognitive restructuring, behaviour change, cognitive-behavioural stress management) | 29% (10) | 56% (5) |
| Decision support (PCa treatment, sexual aids) | 24% (8) | 11% (1) |
| Relaxation (meditation, relaxation techniques) | 24% (8) | 11% (1) |
| Supportive counselling (counselling/psychotherapy, health professional discussion) | 12% (4) | 56% (5) |

*Note that some trials had multiple arms and more than one effective intervention.

Social support may include general group discussion with peers.

NB. Total percentages may exceed 100% because of multiple intervention components.

PCa, prostate cancer.
3.5.2 | Couple-focused

Quality of life

Intimacy-enhancing therapy increased cancer-specific QOL for patients with early stage disease and higher symptom-related concerns at baseline.26

Sexuality

Four trials improved sexuality outcomes for patients only. Coping skills training reduced sexual bother,58 and intracavernous injection-focused sexual counselling increased patient sexual function, sexual satisfaction, and desire.59 Post-treatment nursing support lessened the extent to which sexual dysfunction interfered with spousal role activities.60 Prostate cancer nurse-delivered and peer-delivered telephone counselling interventions uniquely reported increased use of ED treatment at 12-month post-recruitment follow-up for men with localised disease who had prostatectomy.51

Mental health

Mental health was improved in 5 trials, predominantly for partners. Coping skills training reduced partner’s depressed mood.58 Pre-surgical communication enhancement intervention reduced partner stress.62 Cancer-related distress lessened in younger women receiving cognitive-existential couple therapy,63 and partners with high levels of baseline distress receiving intimacy enhancing therapy.26 Cancer-related worry also reduced for patients receiving post-treatment nursing support.60

Relationships

Three trials improved relationship outcomes, mostly for partners. Cognitive-existential couple therapy enhanced relationship function for female spouses.63 Intimacy enhancing therapy was associated with improved partner relationship satisfaction and intimacy for partners with lower baseline scores on these variables.26 Education to maintain intimacy also improved intimacy for patients starting ADT, and dyadic adjustment for patients and their female partners.64

3.6 | Intervention delivery

Effective person-focused interventions were most commonly delivered in an individual (53%) or group (47%) setting; face-to-face (50%), via telephone (26%) or online (26%); by a psychologist/counsellor (41%), nurse (29%) or self-administered (26%). Couple-focused interventions were delivered to dyads most commonly face-to-face (67%) or by telephone (44%); by a psychologist/counsellor (44%) or nurse (22%).

4 | DISCUSSION

Psychosocial and psychosexual intervention can improve decision-related distress, mental health, domain-specific, and health-related QOL in men with PCa. Combinations of educational, cognitive behavioural, communication, and peer support have been most commonly applied and found effective; followed by decision support and relaxation; and to a much lesser extent supportive counselling. These components were often used in a multi-modal approach, and delivered through both face-to-face and remote technologies, with therapist, nurse or peer support. In sum, multi-modal psychosocial and psychosexual care for men with PCa, particularly localised disease, is both acceptable and effective.

The evidence is less clear for the female partners of these men and couples as a dyadic unit. Couple-focused interventions were the least acceptable approach and almost half of the couple interventions produced poorer outcomes for partners. When couple interventions were effective, they improved relationship outcomes for the partner but not the man; had a positive effect on the partner’s mental health but conversely; improved sexuality outcomes for the man but not the partner. No interventions improved sexuality outcomes for female partners. Based on these results, effective and acceptable interventions for female partners and couples remain an area of uncertainty. It may be that couples interventions have been primarily focused on the PCa survivor’s needs, leaving the partner’s concerns poorly managed. This is an area where significant further work is required to understand the needs and preferences of couples, and to determine approaches to improve sexual and relationship satisfaction for both partners.

Limitations of the research to date include small sample sizes; low statistical power; suboptimal statistical methods in some studies; inconsistency in measurement approaches; a lack of diversity in participants—particularly with regards to gay and bisexual men; men with advanced PCa; and men from socio-economically deprived; and non-Anglo-Saxon backgrounds. Long-term survivorship outcomes (>2 years) are yet to be addressed. In addition, intervention components were often described in a vague way such that it was not always clear what was actually delivered; and treatment fidelity and therapist adherence was in most studies not well described. Strengths of the current review by comparison with previous reviews include a departure from a narrow focus on specific intervention type(s), single outcomes, or sub-groups; a consideration of acceptability as well as statistical significance; and examination of not only intervention effectiveness but also who benefits by considering the influences of socio-demographic and medical characteristics of men and their partners; intervention format and delivery; and acceptability.

4.1 | Clinical implications

Standards for psychosocial care with regards to screening for distress are now widely accepted.65 and the validity of the distress thermometer for men with PCa is well established with clear cut-offs for caseness.31 In this review, approximately one-quarter of interventions reported effects moderated by socio-demographic or psychosocial variables; with age, educational level, domain-specific QOL, baseline mental health, and social support important considerations in designing care. Hence, as well as taking into account levels of distress, it is also important to consider factors that both moderate intervention effectiveness and place men at risk of greater psychosocial distress and poorer QOL (such as age, domain-specific QOL, socio-economic deprivation) over the longer term.15 Survivorship care plans for PCa will need to be stepped according to the type and depth of need.66,67 In conclusion, there is sufficient evidence to recommend multi-modal psychosocial and psychosexual interventions for men with PCa; with
distress screening and risk and need assessment built in to tailor support to the individual. As yet, there is insufficient evidence to confirm the optimal approach for female partners and couples.

We note that in this review education and communication support was commonly applied effectively across both person and couples-focused interventions. By contrast, supportive counselling was often used for couples, whereas for patients peer support was more common. This may reflect in part what support methods are acceptable to men. Care approaches also need to consider the impact of PCA on men’s masculine identities and embed sensitivity to these masculinities in psychosocial and psychosocial interventions in a way that extends beyond a reductionist focus on erectile dysfunction.

4.2 Future research

There is a need for improvement in the field in study quality, especially with regard to treatment fidelity. Where interventions are multimodal better clarity about therapy components would assist application by clinicians. There remain gaps in knowledge about effective interventions for men with advanced cancer and how to best help couples and partners warrants further investigation. Finally, expanded research is needed targeting the needs of gay and bisexual men and those from non-Anglo-Saxon and socio-economically deprived backgrounds.

ACKNOWLEDGEMENTS

This study is supported by a National Health and Medical Research Council Centre for Research Excellence in Prostate Cancer Survivorship (APP1116334).

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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APPENDIX A
SEARCH STRATEGIES USED
For Cochrane Central Register of Controlled Trials, Embase, MEDLINE,
PREMEDLINE and PsycINFO, and MEDLINE Epub Ahead of Print
databases (OVID):

| #  | Searches                                      |
|----|----------------------------------------------|
| 1  | exp Prostatic Neoplasms/                     |
| 2  | (prost* adj3 (cancer* or carcinoma* or malig* or tumo?r* or neoplas* or metastas* or adeno*)).mp. |
| 3  | exp Neoplasms/                               |
| 4  | exp Prostate/                                |
| 5  | 3 and 4                                      |
| 6  | 1 or 2 or 5                                  |
| 7  | exp Affective Symptoms/                      |
| 8  | exp affective disorders/                     |
| 9  | affective disorders.mp.                     |
| 10 | exp Mood Disorders/                          |
| 11 | mood*.mp.                                    |
| 12 | exp Depression/                              |
| 13 | depress*.mp.                                 |
| 14 | exp Anxiety Disorders/                       |
| 15 | exp Anxiety/                                 |
| 16 | anxiet*.mp.                                  |
| 17 | anxious.mp.                                  |
| 18 | exp Psychosomatic Medicine/                  |
| 19 | exp Stress, Psychological/                   |
| 20 | psycholog*.mp.                               |
| 21 | psychosoci*.mp.                             |
| 22 | (psycho adj soci*).mp.                      |
| 23 | (intrusive adj (thinking or thoughts)).mp.   |
| 24 | intrusiveness.mp.                           |
| 25 | exp Mental Fatigue/                          |
| 26 | exp "Conflict (Psychology)"/                |
| 27 | exp Emotions/                                |
| 28 | emotion*.mp.                                 |
| 29 | unhapp*.mp.                                  |
| 30 | happiness*.mp.                              |
| 31 | sad.mp.                                      |
| 32 | sadness.mp.                                  |
| 33 | (anhedon* or melanchol* or bear* or worr*).mp. |
| 34 | (stress* or distres* or nervous* or nervos*).mp. |
| 35 | (uncertainty or hope or wellbeing).mp.       |
| 36 | well being*.mp.                             |
| 37 | exp Adaptation, Psychological/               |
| 38 | exp Adjustment/                              |
| 39 | (cognitive adj3 adjustment).mp.              |
| 40 | exp Decision Making/                         |
| 41 | decision making.mp.                         |
| 42 | decisional uncertainty.mp.                  |
| 43 | decisional regret.mp.                       |
| 44 | (decision* adj3 satisf*).mp.                |
| 45 | exp Mental Health/                           |
| 46 | Behavioral Symptoms/                        |
| 47 | exp Attitude to Health/                     |
| 48 | exp Patient Satisfaction/                   |
| 49 | exp Personal Satisfaction/                  |
| 50 | (relationship or sexual) adj3 satisfaction).mp. |
| 51 | self efficacy.mp.                           |
| 52 | conflict*.mp.                               |
| 53 | (quality adj4 (life or living)).mp.          |
| 54 | exp "Quality of Life"/                      |
| 55 | quality of life.mp.                         |
| 56 | (QOL or HRQOL).mp.                          |
| 57 | exp Social Support/                          |
| 58 | social support.mp.                          |
| 59 | Interpersonal Relations/                    |
| 60 | exp interpersonal relationships/             |
| 61 | exp interpersonal interaction/               |
| 62 | social interaction.mp.                      |
| 63 | exp Personal Autonomy/                      |
| 64 | autonomy.mp.                                 |
| 65 | exp "independence (personality)"/           |
| 66 | exp Fatigue/                                 |
| 67 | (fatigue* or tiredness or libido* or impot*).mp. |

(Continues)
# Searches

| # | Searches |
|---|---|
| 68 | exp Libido/ |
| 69 | sex drive.mp. |
| 70 | erectile dysfunction.mp. |
| 71 | exp Sexual Dysfunction, Physiological/ |
| 72 | exp Sexual Dysfunctions, Psychological/ |
| 73 | exp Sexual Function Disturbances/ |
| 74 | sexual dysfunction.mp. |
| 75 | exp Sexuality/ |
| 76 | sexuality.mp. |
| 77 | exp Self Concept/ |
| 78 | self image.mp. |
| 79 | (intimacy or wife or wives or dyad* or spous* or partner* or carer* or caregiv* or relational).mp. |
| 80 | exp marital relations/ |
| 81 | or/7-80 |
| 82 | 6 and 81 |
| 83 | Randomized Controlled Trial.pt. |
| 84 | Pragmatic Clinical Trial.pt. |
| 85 | exp Randomized Controlled Trials as Topic/ |
| 86 | "Randomized Controlled Trial (topic)"/ |
| 87 | Randomized Controlled Trial/ |
| 88 | Randomization/ |
| 89 | Random Allocation/ |
| 90 | Double-Blind Method/ |
| 91 | Double Blind Procedure/ |
| 92 | Double-Blind Studies/ |
| 93 | Single-Blind Method/ |
| 94 | Single Blind Procedure/ |
| 95 | Single-Blind Studies/ |
| 96 | Placebos/ |
| 97 | Placebo/ |
| 98 | (random* or sham or placebo*).ti,ab,hw. |
| 99 | ((singl* or doubl*) adj (blind* or dummy* or mask*)).ti,ab,hw. |
| 100 | ((tripl* or trebl*) adj (blind* or dummy* or mask*)).ti,ab,hw. |
| 101 | 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 |
| 102 | 82 and 101 |
| 103 | limit 102 to English language |
| 104 | limit 103 to yr = "2000-current" |

Used Canadian Agency for Drugs and Technologies in Health filter for identifying randomised controlled trials (https://www.cadth.ca/resources/finding-evidence accessed 17/02/2016)

For Health Technology Assessments (HTA) and Database of Abstracts of Reviews of Effects (DARE) databases (Ovid):

| # | Searches |
|---|---|
| 1 | exp Prostatic Neoplasms/ |
| 2 | (prostat* adj3 (cancer* or carcinoma* or malig* or tumo?r* or neoplas* or metastas* or adeno*)).mp. |
| 3 | exp Neoplasms/ |

(Continues)
APPENDIX B

FRAMEWORK FOR CATEGORISING PSYCHOSOCIAL INTERVENTION COMPONENTS

Education

- Psycho-education: information or education about emotional impact of PCa and stress management; excludes cognitive-behavioural approaches.
- Psycho-sexual education: information or education about sexuality or psycho-sexual impact of PCa or treatment.
- PCa education: information or education about PCa, treatment, and/or physical side effects.

For Allied and Complementary Medicine (AMED) database (OVID):

| #  | Searches                                                                 |
|----|--------------------------------------------------------------------------|
| 54 | decisional uncertainty.mp.                                               |
| 55 | decisional regret.mp.                                                    |
| 56 | (decision$ adj3 satisf$).mp.                                            |
| 57 | exp Mental Health/                                                       |
| 58 | Behavioral Symptoms/                                                     |
| 59 | exp Attitude to Health/                                                  |
| 60 | exp Patient Satisfaction/                                                |
| 61 | exp Personal Satisfaction/                                               |
| 62 | (relationship or sexual) adj3 satisfaction).mp.                         |
| 63 | self efficacy.mp.                                                        |
| 64 | (quality adj4 (life or living))).mp.                                     |
| 65 | exp "Quality of Life"/                                                  |
| 66 | quality of life.mp.                                                      |
| 67 | QOL.mp.                                                                  |
| 68 | HRQOL.mp.                                                                |
| 69 | exp Social Support/                                                      |
| 70 | social support.mp.                                                       |
| 71 | Interpersonal Relations/                                                 |
| 72 | exp interpersonal relationships/                                          |
| 73 | exp interpersonal interaction/                                            |
| 74 | social interaction.mp.                                                  |
| 75 | exp Personal Autonomy/                                                   |
| 76 | autonomy.mp.                                                             |
| 77 | exp "independence (personality)"/                                       |
| 78 | exp Fatigue/                                                             |
| 79 | fatigue.mp.                                                              |
| 80 | tiredness.mp.                                                            |
| 81 | exp Libido/                                                              |
| 82 | libido.mp.                                                               |
| 83 | sex drive.mp.                                                            |
| 84 | erectile dysfunction.mp.                                                |
| 85 | impotence.mp.                                                            |
| 86 | exp Sexual Dysfunction, Physiological/                                  |
| 87 | exp Sexual Dysfunctions, Psychological/                                  |
| 88 | exp Sexual Function Disturbances/                                       |
| 89 | sexual dysfunction.mp.                                                  |
| 90 | exp Sexuality/                                                           |
| 91 | sexuality.mp.                                                            |
| 92 | exp Self Concept/                                                        |
| 93 | self image.mp.                                                           |
| 94 | relational*.mp.                                                         |
| 95 | intimacy*.mp.                                                           |
| 96 | wife.mp.                                                                |
| 97 | wives.mp.                                                               |
| 98 | dyad*.mp.                                                               |
| 99 | spous*.mp.                                                              |
| 100| partner*.mp.                                                            |
| 101| exp marital relations/                                                  |
| 102| carer*.mp.                                                              |
| 103| caregiv*.mp.                                                            |
| 104| or/7-103                                                                |
| 105| 6 and 104                                                               |

For CINAHL database (EBSCO):

| #  | Searches                                                                 |
|----|--------------------------------------------------------------------------|
| S17| S3 AND S15 Published date: 2009-2016; English language: Exclude MEDLINE records |
| S16| S3 AND S15                                                               |
| S15| S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 |
| S14| TX allocat* random*                                                     |
| S13| (MH "Quantitative Studies")                                             |
| S12| (MH "Placebos")                                                        |
| S11| TX placebo*                                                             |
| S10| TX random* allocat*                                                     |
| S9 | (MH "Random Assignment")                                               |
| S8 | TX randomi* control* trial*                                             |
| S7 | TX ((singl* n1 blind*) or (singl* n1 mask*)) or TX ((doubl* n1 blind*) or (doubl* n1 mask*)) or TX ((tripl* n1 blind*) or (tripl* n1 mask*)) or TX ((trebl* n1 blind*) or (trebl* n1 mask*)) |
| S6 | TX clinic* n1 trial*                                                    |
| S5 | PT Clinical trial                                                       |
| S4 | (MH "Clinical Trials+")                                               |
| S3 | S1 OR S2                                                               |
| S2 | TX (prostat* N3 (cancer* OR carcinoma* OR malignan* or tumo#r* OR neoplas* OR metast* OR adeno*)) |
| S1 | (MM "Prostatic Neoplasms")                                            |

Used SIGN filter for identifying randomised controlled trials (http://www.sign.ac.uk/methodology/filters.html#top accessed 17/02/2016)
Cognitive-behavioural

- Cognitive restructuring: working with cognitions, challenging negative thoughts, refocusing thoughts onto positives.
- Behaviour change: Goal setting and problem solving or behavioural maintenance.
- Cognitive behavioural stress management: intervention identified as CBSM.

Relaxation

- Relaxation: meditation or relaxation techniques (e.g., progressive muscle relaxation, Qigong, breathing exercises).

Supportive counselling

- Counselling/psychotherapy (as identified by the study author): counselling or therapy offered as part of the intervention including sexual therapy, excludes cognitive-behavioural approaches.
- Health professional discussion: discussion with a health professional (excludes counselling/psychotherapy, routine/standard care).

Peer support

- Peer support: shared experience with a peer who also has PCa (includes support groups, social support).
- Social support: mentions social support generally and may also include informal peer support in a group setting, or does not specify type.

Communication

- Partner: information or skill development to promote partners/couples communication (e.g., treatment side-effects, intimacy), excludes communication about sex.
- Sexual: information or skill development to enable communication with partner about sex.
- Health professional: information or skill development to encourage communication with health professional regarding treatment or post-treatment concerns (e.g., side-effects).
- Communication: general interpersonal communication or communication unspecified.

Decision support

- PCa treatment: decision aid, tool or navigator to support PCa treatment decision.
- Sexual aids: decision aid, tool or navigator to support decision to use erectile or other sexual aid or treatment.

APPENDIX C

RISK OF BIAS ASSESSMENT OF TRIALS ADDRESSING QUESTION 1 (PATIENTS N = 56 TRIALS) AND QUESTION 2 (PARTNERS N = 14 TRIALS)

| Risk of bias category | Q1 N (%) | Q2 N (%) |
|-----------------------|----------|----------|
| 1. What was the risk of bias from the random sequence generation? | | |
| Low: Adequate (e.g., computer random number generator) | 20 (36) | 5 (36) |
| High: Inadequate | 2 (4) | 0 (0) |
| Unclear: Not reported | 34 (61) | 9 (64) |
| 2. What was the risk of bias from the allocation concealment? | | |
| Low: Adequately concealed (e.g., central randomisation) | 16 (29) | 3 (21) |
| High: Inadequately concealed (e.g., sealed envelopes) | 0 (0) | 0 (0) |
| Unclear: Concealment not reported or insufficient information to permit judgement | 40 (71) | 11 (79) |
| 3. What was the risk of bias from incomplete outcome dataa? | | |
| Low: Loss to follow-up less than 50% and balanced across arms (<5% difference) | 19 (34) | 4 (29) |
| High: Loss to follow-up greater than 50% or not balanced between arms or non ITT analyses | 24 (43) | 6 (43) |
| Unclear: Insufficient information to permit judgement | 13 (23) | 4 (29) |
| 4. What was the risk of bias from selective outcome reporting? | | |
| Low: Study protocol available and all pre-specified outcomes reported | 7 (13) | 3 (21) |
| High: Study protocol available and not all pre-specified outcomes reported | 14 (25) | 6 (43) |
| Unclear: Insufficient information to permit judgement (e.g., study protocol not found) | 35 (63) | 5 (36) |
| 5. What was the risk of bias from other sources**a? | | |
| Low: Study appears free of other sources of bias | 39 (70) | 12 (86) |
| High: There is at least one important risk of bias from other sources | 14 (25) | 2 (14) |
| Unclear: Insufficient information to assess whether there is a risk of bias from other sources | 3 (5) | 0 (0) |

*a For primary outcome
** Including differences in disease stage or follow-up between arms, and analyses that did not consider baseline measures
ITT, intention-to-treat
### APPENDIX D

**ELIGIBLE TRIALS INCLUDED IN THE REVIEW ADDRESSING QUESTION 1 (PATIENTS) AND QUESTION 2 (PARTNERS)**

**TABLE A1**  Trials comprising person-focused interventions \( N = 43: 41 \) patient only, 1 partner only, 1 patient and partner

| Study          | Participants # | Intervention                                                                 | Comparator       | Relevant outcomes                | Precision of effect * | Size of effect * | Key findings                                                                                                                                  | Acceptability |
|----------------|----------------|-------------------------------------------------------------------------------|------------------|----------------------------------|-----------------------|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| **Ames 2011 USA** |
| 57 men with biochemical recurrence Median age 76 years | Multi-modal intervention which included psychosocial components Delivered by clinical psychologist, medical oncologist, dietician and physiatrist 8 group face-to-face sessions over 8 weeks | E, CB, R, PS Wait-list control | Mental health NR | -0.0 | The multi-modal intervention did not significantly (or with a moderate or large effect size) improve outcomes | 100% retention at end of intervention 97% participants attended \( \geq 6 \) of 8 intervention sessions 80% rated on a 5-point scale helpfulness of intervention as 4 (very much) or 5 (extremely) | |
| **Badger 2011, 2013 USA Patients + partners** |
| 71 men and social network members (93% female; 83% partner, 13% family member, 4% friend) Men \( \leq 6 \) months since tx Minimum 11% stage IV Patient M age 67 years; Partner M age 61 years | 1. Interpersonal psychotherapy + cancer education for patient and partner Delivered by nurse or social worker Patients: 8 individual telephone sessions over 8 weeks Partners: 4 individual telephone sessions over 8 weeks Follow-up 8 weeks post-intervention | 1. E, SC, PS, C 2. E | 1. Health education attention condition for patient and partner Delivered by research assistants Patients: 8 individual telephone sessions over 8 weeks Partners: 4 individual telephone sessions over 8 weeks | Patients Depression \( P < 0.001 \) NR | | The health education attention intervention significantly improved depression, negative affect, stress, fatigue, and spiritual well-being when compared with psychotherapy + education intervention Men in the psychotherapy + education intervention had significantly greater improvement in positive affect if they were more highly educated, had higher PCa-specific QoL or had more social support from friends Men in the psychotherapy + education intervention had significantly greater reduction in stress if they were less educated 40% recruitment rate 6% withdrew from psychotherapy + education intervention and 9% withdrew from education attention intervention 86% attendance in psychotherapy + education arm 89% attendance in education attention intervention | 40% recruitment rate | 6% withdrew from psychotherapy + education intervention and 9% withdrew from education attention intervention | 86% attendance in psychotherapy + education arm 89% attendance in education attention intervention |
| Study | Participants # | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect * | Size of effect * | Key findings | Acceptability |
|-------|----------------|--------------|-------------------------|------------|------------------|-----------------------|-------------------|--------------|---------------|
| Bailey 2004 USA | 39 men ≤10.3 years post-tx decision on watchful waiting | Uncertainty management: cognitive reframing tailored to patient needs | E, CB, C, DS | Usual care | QoL (Cantrill's ladder) | $P < 0.05$ | NR | The health education intervention significantly improved depression, fatigue, social, and spiritual well-being when compared with psychotherapy + education intervention | Uncertainty management intervention significantly improved QoL when compared with usual care | 76% recruitment rate |
| | | Delivered by a nurse | 5 weekly individual telephone sessions | | | | | | 5% withdrew from intervention |
| | | Follow-up ~5 weeks post-intervention | | | | | | 95% follow-up in both arms |
| Beard 2011 USA | 54 men undergoing radiotherapy 91% ADT | Relaxation response therapy with cognitive restructuring (RRT) | CB, R | 1. Wait-list control 2. Reiki therapy | Anxiety | NS | NR | No significant improvements in outcomes were found when all 3 arms were compared | 73% recruitment rate |
| | | Delivered by psychologist | | | Depression | NS | NR | 100% in Reiki and RRT arms completed study |
| | | 8 weekly individual face-to-face sessions during radiotherapy period | | | Cancer-related QoL | NS | NR | 89% in RRT arm attended all 8 sessions |
| | | Follow-up 8-12 weeks post-intervention | | | Emotional well-being subscale | NS | NR | |
| Berglund 2007 Sweden | 211 men ≤6 months since dx | 1. Physical training + relaxation 2. Information sessions 3. Physical training + information sessions + relaxation | 1. R 2. E, PS 3. E, R, PS | Standard care | Anxiety | NS | NR | The multi-modal interventions did not significantly improve outcomes | 50% recruitment rate |
| | | Psychosocial components for all interventions delivered by physiotherapist (1, 3), nurse and urologist/oncologist (2, 3) | | | Depression | NS | NR | 8% withdrew from physical training and information arms; 7% withdrew from information only arm—primarily because of transport issues | |
| Study                          | Participants # | Intervention components | Comparator | Relevant outcomes | Precision of effect * | Size of effect * | Key findings | Acceptability |
|-------------------------------|----------------|-------------------------|------------|-------------------|-----------------------|-------------------|--------------|---------------|
| Berry 2012, 2013 USA         | 494 men recently dx and pre-tx (50% had tx preference at baseline) | Decision support system Self-administered 1 individual internet session Follow-up 6 months post-intervention | E, C, DS + Clinic's usual educational resources (eg, pamphlets and links to reputable websites) Usual care | Decisional uncertainty (100 unit scale) Decisional satisfaction Decisional regret Subgroup of men who made decision by 6 months Total decisional conflict (100 unit scale) | P = 0.04, P = 0.04, NS, NS, NS | Coefficient -3.61 units, NS, NS, -1.75 units | Internet decision support significantly reduced decisional uncertainty when compared with usual care | 68% recruitment rate 100% compliance Authors identified good acceptability (M 25.1 on scale of 6-30) |
| Campo 2014 USA               | 40 men <26 years since dx with significant fatigue and sedentary 48% ADT 61% Stage III-IV | Qigong Delivered by qigong Master and his certified instructors 24 twice weekly group face-to-face sessions Follow-up 1 week post-intervention | R Stretch control (24 twice weekly group face-to-face sessions) | Fatigue (scale 0-52) Distress | P = 0.02 | Cohen's d NR ≥ 3-point improvement in fatigue score for 69% qigong vs 38% controls | Qigong significantly improved fatigue and reduced distress when compared with stretch control however 47% had advanced disease in qigong arm compared with 82% in stretch control arm | 18% consented to eligibility assessment 20% withdrew from qigong arm; 35% withdrew from stretch control arm 85% median rate of attendance for qigong arm; 43% for stretch control |
| Carmack-Taylor 2006, 2007 USA| 134 men on ADT for next 12 months M age 69 years 12% depressed requiring clinical evaluation | 1. CB training to increase physical activity +30 minutes of expert speaker or facilitated discussion 2. 90 minutes of expert speaker or facilitated discussion | 1. E, PS 2. E, PS | Standard care Mental health Anxiety Depression Self-esteem | NS, NS, NS, NS | NS, NS, NS, NS | For the outcomes of depression and anxiety, there were significant group x baseline level interactions indicating that men with high rather than low baseline levels of depression (P = 0.02) or anxiety (P = 0.002) were more likely to benefit from either of the 2 interventions | 64% recruitment rate 4% 90 minutes E + PS and 3% controls withdrew 70% mean attendance rate for 90 minutes E + PS; ~82% attended at least 50% of sessions |
| Study | Participants # | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect | Size of effect | Key findings | Acceptability |
|-------|----------------|--------------|-------------------------|------------|------------------|---------------------|---------------|--------------|---------------|
|       |                |              |                         |            |                  |                     |               |              |               |
| Chabrera 2015 Spain | 142 men with localised disease pre-tx | Follow-up 6 months post-intervention | Decision aid | E, C, DS | Usual care | Decisional conflict | $P < 0.001$ | Difference in change from baseline score $-24.4$ (100-point scale) | Decision aid significantly reduced decisional conflict when compared with usual care | 100% recruitment of eligible men |
|       | M age 69 years |              | Self-administered | Individual printed | Follow-up 3 months post-baseline | | | | 84% intervention and 82% control had follow-up |
|       |                |              |                         |            |                  |                     |               |              |               |
| Chambers 2013 Australia | 740 men with localised disease pre-tx | Follow-up 24 months post-tx | Telephone psycho-educational intervention | E, CB, R, DS | Usual care | Cancer-specific distress | NS | NR | For a subgroup of participants who were younger with higher education levels, the psycho-educational intervention significantly improved mental health ($P = 0.04$) and cancer-specific distress ($P < 0.008$) | 82% recruitment rate |
|       | M age 63 years |              | Delivered by nurse counsellors | 5 individual telephone sessions: 2 pre-tx, and at 3 weeks, 7 weeks and 5 months post-tx | | | | | At 6 months post-tx, 7% withdrawn in intervention arm; 5% withdrawn in control arm |
|       |                |              |                         |            |                  |                     |               |              |               |
| Chambers 2017 Australia | 189 men with metastatic disease and/or castration-resistant biochemical progression | Follow-up 9 months post-baseline | 1. Mindfulness-based cognitive therapy (MBCT) Delivered by health professionals with oncology experience and professional training in MBCT 8 weekly group teleconference sessions | 1. E, CB, R, PS 2. E | 2. Minimally enhanced usual care | Psychological distress | NS | NR | MBCT did not significantly improve outcomes compared with minimally enhanced usual care | 46% recruitment rate |
|       | M age 71 years |              | 99% had received ADT | 40% significant baseline distress | | | | | 14% withdrew from MBCT arm and 6% withdrew from minimally enhanced usual care arm |
|       |                |              |                         |            |                  |                     |               |              |               |
| Daubenmier 2006; Frattaroli 2008 USA | 93 men on active surveillance Stage T1-T2 | | Multi-modal lifestyle intervention including 1 hour/day stress management practice | R, PS | Usual care | Mental health | NS | NR | The multi-modal intervention did not significantly improve outcomes | 51% recruitment rate |
|       | M age 66 years |              | Deliverer of intervention NR | Introduced at 1-week residential retreat | | Stress | NS | NR | Mean self-reported programme adherence 95% at 24 months |
|       |                |              |                         |            |                  |                     |               |              |               |

(Continues)
| Study                  | Participants # | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect | Size of effect | Key findings                                                                 | Acceptability |
|-----------------------|----------------|--------------|-------------------------|------------|-------------------|---------------------|------------------|-----------------------------------------------------------------------------|---------------|
| Davison 2007 Canada   | 324 men recently dx and considering bx T1-T2 M age 62 years | Weekly group face-to-face sessions ongoing Follow-up 24 months post-baseline | 1. Individualised decision support Self-administered 1 individual interactive computer session | 1. E, DS 2. E | Decisional conflict | NS                  | NR               | Individualised decision support intervention did not significantly improve decisional conflict when compared with generic decision support | 86% recruitment rate 100% compliance 91% individualised intervention and 90% generic intervention post-intervention follow-up |
|                      |                |              |                         |            |                   |                     |                  | Mean total rating of satisfaction with preparation in decision making was 2.80 for individualised arm and 2.67 for generic arm. The individualised intervention was rated higher in helping considering pros and cons and communicating opinions |               |
| Diedrich 2012 USA     | 91 men 4-6 weeks since dx who had not made a tx decision T1-T2 M age 62 years | 1. Prostate Interactive Educational System (PIES) with or without tailoring to patient's information seeking style (combined results from both PIES arms) | 1. E, DS 2. E | Control Asked to read Standard National Cancer Institute booklets on PCa for 45 minutes Self-administered 1 individual internet/CD-ROM session | Confident about tx choice Prefer more time to decide Prefer more information Feel informed | $P = 0.02$              | NR               | The interactive education intervention improved confidence about tx choice and reduced preference for more information when compared with printed information (however, baseline levels of confidence about tx choice were not measured) | 75% recruitment rate 100% compliance 82% PIES with tailoring, 75% PIES without tailoring and 79% controls had post-intervention follow-up |
|                      |                |              |                         |            |                   |                     |                  | Mean rating of helpfulness in decision making was 4.29 for tailored PIES, 4.10 for non-tailored arm and 1.79 for control, scored 1 (not at all) to 5 (very much) |               |
| Dieperink 2013 Denmark| 161 men 4 weeks since radiotherapy T1-T3 (46% T3) M age 68-69 years | Individualised psychosocial (2 sessions) and physical therapy (2 sessions) counselling | SC Usual care | Mental health Sexual QoL | | | | The multi-modal intervention did not significantly improve outcomes | 77% recruitment rate 3% withdrew from intervention; 2% withdrew from control 90% had 100% attendance rate |
| Study | Participants # | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect * | Size of effect * | Key findings | Acceptability |
|-------|----------------|--------------|-------------------------|------------|------------------|----------------------|-------------------|--------------|---------------|
| Feldman-Stewart 2012 Canada | 156 men with a new dx and making a tx decision Stage T1-T2 60% ≥ 60 years | 1. Decision aid—Information + explicit values clarification exercises Self-administered 1 individual computerised session | 1. E, DS 2. E | Decision regret NS NR | Including values clarification exercises in a decision aid did not significantly improve decision regret when compared with a decision aid providing information only | 37% recruitment rate (refusal because of: knowing what tx preferred or not needing further resources/help) 100% intervention completion and immediate post-intervention follow-up |
| Hack 2007 Canada | 425 men attending primary tx consultation with radiation oncologist Stage T1-4 (15% T3-4) | Audiotape of tx consultation with radiation oncologist Individual audiotape | E, DS No audio-tape of tx consultation | PCA-related QoL Mood | An audiotape of radiotherapy tx consultation did not significantly improve outcomes | 96% recruitment rate 35% of those who received tape did not listen to it M 83.0 for patients who listened to the tape (0 extreme dislike–100 extreme like); 47% rated it ≥75 |
| Hacking 2013 UK | 123 men newly dx with localised or early stage disease considering tx options and referred to urologist M age 65-67 years | Decision navigation Delivered by research assistants 1 individual face-to-face or phone session, audiotape and written notes | DS Usual care | Decisional self-efficacy Decisional conflict Decisional regret Anxiety Depression Mental adjustment to cancer: Fighting spirit Anxiety Fatalism | Decision navigation significantly increased decisional self-efficacy and reduced decision regret when compared with usual care | 43% recruitment rate 2% withdrew from intervention prior to medical consultation At 6 months, men in the intervention arm used the consultation plan M 3.3 times, the consultation summary M 3.1 times and listened to the audiotape M 2.4 times 92% of respondents rated the intervention as very helpful before the urologist consultation |
| Huber 2013 Germany | 203 men attending pre-prostatectomy consultation M age 63 – 64 years | Multimedia-supported pre-operative education Delivered by physician 1 individual computer-based session | E Standard pre-operative education | Anxiety Decisional confidence | The addition of multimedia-support to standard pre-operative education did not significantly improve outcomes | 96% recruitment rate 100% compliance Complete satisfaction with pre-operative education reported by 69% intervention and 52% control (P = 0.016) |
| Study          | Participants # | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect * | Size of effect * | Key findings                                                                 | Acceptability |
|---------------|----------------|--------------|-------------------------|------------|-------------------|----------------------|--------------------|-----------------------------------------------------------------------------|---------------|
| Follow-up 6-10 hours after pre-operative education |
| Kim 2002 USA | 152 men undergoing radiotherapy | Specific information about radiotherapy procedures and side effects | E | General information about radiotherapy | Negative affect | NS | NR | Providing specific information did not significantly improve outcomes when compared with providing general information | Cannot assess |
| Stage A-C (21% stage C) | | Self-administered | Individual audiocassettes of 2 information sessions | | | | | | |
| M age 71 years | | Follow-up at end of radiotherapy tx | | | | | | | |
| Follow-up 6-10 hours after pre-operative education |
| Lepore 2003; Helgeson 2006 USA | 250 men ≤1 month since tx started | 1. Education + group discussion (attended with a family member or friend) | 1. E, PS | Standard medical care | Mental health | NS | NR | Education and group discussion intervention significantly reduced sexual bother when compared with standard care | 85% consented to assessment for eligibility; 77% of those eligible agreed to participate |
| Stage T1-3 (12.8% T3) | | Education delivered by urologist, oncologist, dietician, oncology nurse and clinical psychologist | 2. E | | Depression | NS | NR | For depression, there was a significant group x self-esteem interaction indicating that men with lower self-esteem were more likely to benefit from either intervention and a significant group x baseline depression interaction indicating that men with lower baseline depression levels were likely to benefit from education + group discussion intervention (P < 0.05) | |
| M age 65-66 years | | Group discussion delivered by male clinical psychologist to patients and by female oncology nurse to female family members | | | Sexual function | NS | NR | For mental health, there was a significant group x self-esteem interaction indicating that men with lower self-esteem were more likely to benefit from either intervention (P < 0.05) | |
| | | 6 weekly group face-to-face sessions | | | Sexual bother | P < 0.01 | NR | | 67% mean attendance rate in both intervention arms |
| | | 2. Education only | | | | | | Helpfulness M 4.22 (scored 1 not at all to 5 very) | |
| Study                  | Participants # | Intervention components | Comparator | Relevant outcomes | Precision of effect | Size of effect | Key findings | Acceptability |
|-----------------------|----------------|-------------------------|------------|-------------------|---------------------|---------------|--------------|---------------|
| Manne 2004 USA        | 60 female partners of men dx with any stage of PCA (5% Stage IV) M age 60 years 18% clinically significant distress (MHI score = 1.5 SD > normative mean) 49% had IES score > 19, ie, high cancer-related distress | Psychosocial educational groups for wives/partners Delivered by radiation oncologist, nutritionist, clinical psychologists and social worker | E, CB, R, C | Standard psychosocial care Support from a social worker and referral to a community mental health professional | NS NR | NS NR | Psychosocial education groups did not significantly improve outcomes when compared with standard psychosocial care | 57% recruitment rate (refusal because of: distance from centre, time and health problems) |
| McQuade 2016 USA      | 66 men scheduled to undergo radiotherapy Stage I-III (21% ≥ T3a) M age 65 years | Qigong/Tai chi Delivered by trained qigong master 3 individual or group face-to-face sessions per week during radiotherapy (6-8 weeks) Follow-up 3 months post-radiotherapy | R | 1. Light exercise Delivered by exercise physiologist 3 individual or group face-to-face sessions per week during radiotherapy (6-8 weeks) | Fatigue NS NR A qigong and tai chi programme during radiotherapy did not significantly improve fatigue when compared with a light exercise programme or usual care | 38% recruitment rate 81% intervention, 73% light exercise control and 92% wait-list control had follow-up at end of intervention |
| Mishel 2002 USA        | 252 couples (% female partner unclear) Men ≤ 2 weeks since catheter removal following surgery or ≤3 weeks since radiotherapy start Stage T1-3 (27% T3) | 1. Uncertainty management—Patient only Delivered by nurse 8 weekly individual phone calls 2. Uncertainty management—Patient and support person | 1. E, CB, C 2. E, CB, C | Usual care Illness appraisal/uncertainty | Symptom intensity Symptom number Sexual function Sexual satisfaction | NS NR NS NR NS NR | For patients, sexual satisfaction was significantly different between arms over time however actual effects of uncertainty management intervention were unclear | 77% recruitment rate |
| Study | Participants # | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect * | Size of effect * | Key findings | Acceptability |
|-------|----------------|--------------|-------------------------|------------|------------------|----------------------|-------------------|--------------|---------------|
| Mishel 2009 USA | 252 couples (~80% married or partnered) | 1. Decision navigation—Patient only | Information + telephone calls to review content, identify/formulate questions and practice skills | Control | Mood | NS | NR | Patients in both decision navigation interventions had significantly lower decision regret scores than controls | 75% recruitment rate |
| | | 2. E, SC, C, DS | Handout on staying healthy during tx | | Well-being | NS | NR | | |
| | | 2. E, SC, C, DS | Phone calls delivered by nurse | | Decisional regret | $P = 0.01$ | NR | | |
| | | Individual self-administered booklet, DVD and 4 phone calls over 7-10 days | | | | | | | |
| | | 2. Decision navigation—Patient and primary support person | | | | | | | |
| | | Intervention as for patient only intervention delivered to both patient and their support person individually (not dyad) | | | | | | | |
| | | Phone calls delivered by nurse | | | | | | | |
| | | Individual/couple self-administered booklet, DVD and 4 phone calls over 7-10 days | | | | | | | |
| | | Follow-up 3 months post-baseline | | | | | | | |
| Osei 2013 USA | 40 men ≤5 years since dx | 1. Online support | Us TOO International website | 1. E, PS | Mental health | NS | NR | Online support and information did not significantly improve outcomes when compared with printed information | 5% of patients who received invitation were interested and eligible |
| | | | Self-administered | 2. E | Sexual QoL | NS | NR | | |
| | | | 3 times per week individual internet sessions over 6 weeks | | Life satisfaction (Well-being) | NS | NR | | |
| | | | | | Relationship satisfaction | NS | NR | | |
| | | | | | Positive | NS | NR | | |
| | | | | | Negative | NS | NR | | |
| | | 2. Resource kit | US TOO International pamphlets | | | | | | 58% said online support community met all or most of their needs M satisfaction 3.01 (scale 1-4) | | |
| | | | Self-administered | | | | | | | |
| | | | Individual booklet over 6 weeks | | | | | | | |
| | | | | | | | | | | |

(Continues)
| Study | Participants # | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect | Size of effect | Key findings | Acceptability |
|-------|----------------|-------------|------------------------|------------|------------------|-------------------|----------------|-------------|---------------|
| Parker 2009; Gilts 2013 USA | 159 men scheduled for prostatectomy Stage I-III (12.6% stage III) M age 60-61 years | 1. Pre-surgical stress management sessions Delivered by clinical psychologist 4 individual face-to-face sessions (3 prior to surgery and 1 at 48 hours post-surgery + printed materials + audiotape 2. Supportive attention Delivered by clinical psychologist 4 individual face-to-face sessions | 1. E, CB, R, SC, PS 2. SC | No meetings with a clinical psychologist | Mood | NS | NR | Stress-management and supportive care interventions did not significantly improve outcomes when compared with controls | 77% recruitment rate |
| | | | | | Cancer-related distress | NS | NR | | 58% stress management arm, 72% supportive attention arm and 69% controls had 6 weeks post-surgery follow-up |
| | Follow-up 8 weeks post-baseline | | | | Mental health | NS | NR | | |
| | | | | | Sexual function | NS | NR | | |
| | | | | | Sexual bother | NS | NR | | |
| | | | | | Subgroup with all measures at baseline and 12 months Distress | NS | NR | | |
| | | | | | Marital relationship satisfaction | NS | NR | | |
| Penedo 2006; Molton 2008 USA | 191 men <18 months since tx Stage T1-T2 M age 65 years | 1. 10-week group CB stress management techniques + relaxation training Co-delivered by licenced clinical psychologist and/or master's level clinical psychology students 10 weekly group face-to-face sessions | 1. E, CB, R, PS, C 2. E | | Cancer-related QoL | P < 0.05 | NR | Stress management training delivered as 10 weekly sessions significantly improved cancer-related QoL compared with a single half-day intervention | 56% recruitment rate for eligible men |
| | | | | | Follow-up 12-13 weeks post-baseline Subgroup + additional participants 121 men who had undergone prostatectomy 88% significant ED M age 60 years Sexual function | P < 0.05 | NR | For men who had undergone a prostatectomy, the 10-week intervention significantly improved sexual function compared with the half-day intervention particularly for men with high interpersonal sensitivity | 8% withdrew from 10-week intervention 6% withdrew from half-day intervention 79% 10-week arm and 84% half-day arm completed post-intervention follow-up |
| | | | | | 2. Half-day seminar on stress management techniques Same content as 10-week intervention Co-delivered by licenced clinical psychologist and/or master's level clinical psychology students 1 group face-to-face session | | | However, there was a difference in assessment for the 10-week intervention (assessed 2-3 weeks post-intervention) and the half-day seminar (assessed 7-8 weeks post-seminar) |
| | | | | | Cancer-related QoL | P = 0.006 | NR | | |
| | | | | | Sexual QoL | NS | NR | | |
| Penedo 2007 USA | 93 monolingual Spanish speaking men <21 months since tx | 1. 10-week culturally sensitive group CB stress management techniques + relaxation training Co-delivered in Spanish by licenced clinical | 1. E, CB, R, PS, C 2. E | | Cancer-related QoL | P = 0.006 | NR | Stress management training delivered as 10 weekly sessions significantly improved cancer-related QoL when compared with the half-day stress management training session | 37% recruitment rate for eligible men |
| | | | | | Sexual QoL | NS | NR | 9% withdrew from 10-week intervention | (Continues) |
| Study | Participants # | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect * | Size of effect * | Key findings | Acceptability |
|-------|----------------|--------------|------------------------|------------|------------------|----------------------|-------------------|--------------|---------------|
| Stage T1-T2 | M age 66 years | psychologist and clinical health psychology graduate student | 10 weekly group face-to-face sessions | Co-delivered in Spanish by licenced clinical psychologist and clinical health psychology graduate student | Same content as 10-week intervention | | | | 3% withdrew from half-day intervention |
| | | | Follow-up 12-13 weeks post-baseline | | | | | | | 77% 10-week arm and 75% half-day arm completed post-intervention follow-up |
| Petersson 2002 Sweden | 118 men (~ 50% on watchful waiting) ≤ 3 months since dx | Randomly assigned to +/- individualised intervention including CB therapy | Group rehabilitation programme (only or + individual support) which included psychosocial components + physical activity | Psychosocial components delivered by oncologist, urologist/surgeon and dietician (education), psychologist and oncology nurse (CBT) and physiotherapist (relaxation) | 8 group face-to-face sessions over 8 weeks + booster group session after 2 months + written information | | | | 61% in group arm and 68% in no group arm had post-intervention follow-up |
| | M age 71 years | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

E, CB, R No group intervention Anxiety NS NR For the outcome of avoidance there was a significant group x coping style interaction indicating that men with monitor (cognitive scanning) rather than blunter (cognitive avoidance) coping style were more likely to benefit from the multi-modal intervention ($P < 0.01$) | 61% in group arm and 68% in no group arm had post-intervention follow-up |

(Continues)
| Study | Participants # | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect * | Size of effect * | Key findings | Acceptability |
|-------|----------------|--------------|-------------------------|------------|------------------|----------------------|-------------------|--------------|---------------|
| Schofield 2016 Australia | 331 men starting radical radiotherapy | Nurse-led group psycho-educational consultation intervention | E, PS, C | Usual care | Anxiety | NS | 0.0 | Psycho-educational intervention significantly reduced rise in depression when compared with control arm | 71% recruitment rate |
| | | Delivered by uro-oncology nurses | 4 x group face-to-face sessions | Sessions at beginning of radiotherapy, mid-radiotherapy, radiotherapy completion, and 6 weeks post-radiotherapy +1 individual session after week 1 group consultation | | | | | 3% withdrew from intervention |
| | | | | Follow-up 6 months post-radiotherapy | | | | 68% attended all 4 intervention group sessions |
| Siddons 2013 Australia | 60 men 6-60 months since prostatectomy, 90% ED | CB group intervention | E, CB, R, C | Wait-list | Masculine self-esteem | P = 0.037 | NR | CB intervention significantly improved masculine self-esteem, sexual confidence, sexual QoL and orgasm satisfaction when compared with wait-list control | 7% recruitment rate |
| | | Delivered by psychologist | 8 group face-to-face sessions over 8 weeks | Follow-up 8 weeks (end of intervention) | | | | (did not participate because of not feeling in need of psychological support, work commitments, difficulties commuting) |
| | | | | | Sexual confidence | P = 0.001 | NR | | 100% intervention and control had follow-up at end of intervention |
| | | | | | Marital satisfaction | NS | NR | | |
| | | | | | Sexual QoL | P = 0.046 | NR | | |
| | | | | | Sexual function | | | | |
| | | | | | Sexual cognition | NS | NR | | |
| | | | | | Sexual arousal | NS | NR | | |
| | | | | | Sexual behaviour | NS | NR | | |
| | | | | | Orgasm satisfaction | NS | NR | | |
| | | | | | Drive/relationship | NS | NR | | |
| | | | | | Depression | NS | −0.52 | CB therapy did not significantly improve outcomes when compared with usual care | 75% recruitment rate |
| | | | | | Anxiety | NS | −0.32 | | |
| | | | | | Cancer-related QoL | NS | −0.97 | | | Compliance: 88% read either all (69%) or more than half of booklet (19%) |
| | | | | | | | | | 79% used relaxation CD and 76% practiced paced breathing at least once a week |
| | | | | | | | | | 97% of both intervention and controls had follow-up at end of intervention |
| Stefanopoulou 2015 UK | 68 men receiving ADT with problematic hot flushes and night sweats (HFNS) | Guided self-help CB therapy | E, CB, R, SC | Usual care | | | | | |
| | | Self-administered | 4-week individual intervention (booklet and CD) with 1 telephone call at 2 weeks for support and guidance delivered by a clinical psychologist | Follow-up 32 weeks post-randomisation | | | | | |
| | | | | | Depression | NS | | | |
| | | | | | Anxiety | NS | | | |
| | | | | | Cancer-related QoL | NS | | | | (Continues) |
| Study          | Participants # | Intervention | Intervention components | Comparator       | Relevant outcomes | Precision of effect * | Size of effect * | Key findings                                                                 | Acceptability |
|---------------|----------------|--------------|-------------------------|------------------|-------------------|----------------------|---------------------|-----------------------------------------------------------------------------|---------------|
| Taylor 2010   | 120 men with a new dx prior to tx decision | 1. Decision aid— Information +3 interactive decision tools | 1. E, DS          | 2. Decision aid— Information only | Mental health      | NS                   | NR                  | Including interactive decision tools in a decision aid did not significantly improve outcomes when compared with a decision aid providing information only | 86% recruitment rate (refusal because of: 9% lack of interest, 3% no need for further information, 2% uncomfortable with computers) |
| Stage T1-T2   | M age 65 years | Self-administered | Individual CD-ROM       | Self-administered | Sexual function    | NS                   | NR                  | 69% information + decision tool intervention used CD – 42% accessed all 3 decision tools |               |
|               |                | Follow-up 1 month post-baseline |                        |                   | Sexual bother       | NS                   | NR                  | 90% information only intervention used CD                                      |               |
|               |                |              |                         |                   | Decisional conflict | NS                   | NR                  | 88% of information + decision tool and 89% of information only had follow-up at end of intervention |               |
|               |                |              |                         |                   |                   |                      |                     | Mean rating of helpfulness of CD-ROM for both arms combined was 60.4 on 0-100 scale (No association found between helpfulness rating and group) |               |
| Templeton 2004| 58 men tx with ADT | Nurse delivered education booklet | E                  | Usual care        | Prostate cancer-related QoL | NR                   | NR                  | (no comparative results reported)                                             | 89% recruitment rate |
| UK            | 42% aged 71-80 years | Participant read booklet with urology nurse |                                          |                   |                   |                      |                     | 100% compliance                                                             |               |
|               |                | Delivered by urology nurse |                                          |                   |                   |                      |                     | 97% intervention and 93% controls had follow-up                                |               |
|               |                | Single individual face-to-face session |                                          |                   |                   |                      |                     |                                                                          |               |
|               |                | Follow-up 1 month post-baseline |                                          |                   |                   |                      |                     |                                                                          |               |
| Traeger 2013  | 257 Spanish speaking men <18 months since tx | 1. 10-week group CB stress management techniques + relaxation training with culturally sensitive seminars | 1. E, CB, R, PS, C | 2. Half-day seminar on stress management techniques with culturally sensitive seminars | Emotional well-being | $P < 0.05$           | NR                  | Stress management training delivered as 10 weekly sessions significantly improved emotional well-being when compared with a single half-day stress management training session | 52% recruitment rate |
| USA           | Stage T1-T2    | Co-delivered by clinical psychologist and clinical psychology graduate | 1. E               | 2. E              |                   |                      |                     | 14% withdrew from 10-week intervention                                       |               |
|               | M age 65 years |              |                         |                   |                   |                      |                     | 8% withdrew from half-day intervention                                       |               |
|               |                |              |                         |                   |                   |                      |                     | 82% 10-week arm and 84% half-day arm completed post-intervention follow-up     |               |
| Study                      | Participants # | Intervention components | Comparator | Relevant outcomes | Precision of effect * | Size of effect * | Key findings                                                                 | Acceptability |
|---------------------------|----------------|-------------------------|------------|------------------|-----------------------|-------------------|-------------------------------------------------------------------------------|---------------|
| Van Tol Geerdink 2013, 2016 Netherlands | 240 men who had not made a tx decision | Decision aid Delivered by a researcher 1 individual face-to-face intervention + printed materials Follow-up 12 months post-tx completion | E, DS Usual care | Decisional regret | NS | NR | Decision aid did not significantly improve outcomes when compared with usual care | 88% recruitment rate |
|                          | Stage T1-T3a (≤12% T3) M age 64 years | Decision aid Delivered by a researcher 1 individual face-to-face intervention + printed materials Follow-up 12 months post-tx completion | E, DS Usual care | Decisional regret | NS | NR | Decision aid did not significantly improve outcomes when compared with usual care | 88% recruitment rate |
|                          | 1. Mindfulness-based stress reduction training Delivered by trained and experienced mindfulness instructor | 8 weekly group face-to-face sessions | | | | | | Compliance 100% |
|                          | M age 69-71 years | 2. Access to a book on mindfulness Self-administered | 1. CB, R 2. E | PCA-related anxiety Mental health | NS | NR | Mindfulness-based stress reduction training did not significantly improve PCA anxiety or mental health when compared with access to a book on mindfulness | 37% recruitment rate (refusal because of distance and lack of time) |
|                          | Follow-up 12 months post-baseline | | | | | | | 88% of mindfulness intervention arm and 89% of mindfulness information arm had follow-up at end of intervention |
| Victorson 2016 USA | 43 men with low-risk localised disease on active surveillance M age 69-71 years | Peer support Delivered by peer—a long term (> 3 years) PCA survivor who had undergone a prostatectomy that resulted in urinary and sexual dysfunction 8 individual face-to-face sessions over 8 weeks Follow-up 8 weeks post-baseline | PS Usual care | Depression | NS | NR | Peer support significantly reduced sexual bother when compared with usual care | 49% recruitment rate (42% non-responders and 9% refused) |
|                          | M age 58 years | Peer support Delivered by peer—a long term (> 3 years) PCA survivor who had undergone a prostatectomy that resulted in urinary and sexual dysfunction 8 individual face-to-face sessions over 8 weeks Follow-up 8 weeks post-baseline | PS Usual care | Depression | NS | NR | Peer support significantly reduced sexual bother when compared with usual care | 49% recruitment rate (42% non-responders and 9% refused) |
|                          | 30 men ≥6 weeks since prostatectomy resulting in urinary and sexual dysfunction | Peer support Delivered by peer—a long term (> 3 years) PCA survivor who had undergone a prostatectomy that resulted in urinary and sexual dysfunction 8 individual face-to-face sessions over 8 weeks Follow-up 8 weeks post-baseline | PS Usual care | Depression | NS | NR | Peer support significantly reduced sexual bother when compared with usual care | 49% recruitment rate (42% non-responders and 9% refused) |
|                          | M age 58 years | Peer support Delivered by peer—a long term (> 3 years) PCA survivor who had undergone a prostatectomy that resulted in urinary and sexual dysfunction 8 individual face-to-face sessions over 8 weeks Follow-up 8 weeks post-baseline | PS Usual care | Depression | NS | NR | Peer support significantly reduced sexual bother when compared with usual care | 49% recruitment rate (42% non-responders and 9% refused) |
| Study | Participants # | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect * | Size of effect * | Key findings | Acceptability |
|-------|----------------|--------------|-------------------------|------------|------------------|----------------------|-------------------|--------------|---------------|
| Weber 2007 a, b USA | 72 men ≤3 months since dx and 6 weeks since prostatectomy | Peer support | Delivered by peer with long-term PCa survivor who had undergone a prostatectomy at least 3 years prior to the study and had experienced similar tx side effects as the participants | Usual care provided by their urologist | Depression | $P = 0.03$ | NR | The peer support intervention significantly reduced depression and increased self-efficacy regarding adjusting after PCa when compared with usual care | 53% recruitment rate (33% refused or did not respond, 14% excluded because of geographic location) |
| Wootten 2015, 2016 Australia | 142 men ≤5 years since tx | 1. Online psycho-educational intervention (PsychE) | Self-administered | Usual care | Distress | $P = 0.02$ | $\eta^2 = 0.07$ | The combined online psycho-educational intervention + moderated peer forum significantly reduced distress and decision regret, and significantly improved sexual satisfaction when compared with moderated peer forum alone | 30% withdrew from PsychE arm, 27% withdrew from PsychE + F arm and 23% withdrew from F only arm |
| | | 2. Online psycho-educational intervention + access to moderated peer online forum (PsychE + F) | Individually accessed over 10 weeks | | | | | Mean 60% of psycho-educational content completed in PsychE arm and mean 57% completed in PsychE + F arm | Mean 1-2 forum posts/user for PsychE + F intervention |
| | | 3. Moderated peer online forum access (F) | Self-administered | | | | | Mean 2-3 forum posts/user for F only intervention | Mean 2-3 forum posts/user for F only intervention |
| Yanez 2015 USA | 74 men with advanced disease at dx who received ADT in last 6 months | 1. CB stress management + relaxation/stress reduction techniques | Delivered by ≥ masters level therapist | | | | | The 10-week CB stress management intervention lowered depression levels with a moderate effect size when compared with health promotion control | 31% recruitment rate (refusal because of: time involved or lack of interest) |
| | | 2. Health promotion attention-control (HP) | Delivered by ≥ masters level therapist | Depression | $P = 0.02$ | Cohen's d 0.5 | | 66% attendance for CB stress management and 82% for HP intervention ($P = 0.04$) | |
| Study | Participants # | Intervention components | Comparator | Relevant outcomes | Precision of effect | Size of effect | Key findings | Acceptability |
|-------|----------------|-------------------------|------------|-------------------|--------------------|-----------------|--------------|---------------|
| Zhang 2006, 2007 USA | 29 men ≥6 months (M 19-22 months) since prostatectomy with post-prostatectomy urinary incontinence Stage I-III M age 61-62 years | Social support group + pelvic floor muscle exercises with biofeedback Delivered by a licenced health psychologist 6 bi-weekly group face-to-face over 3 months | E, PS, C Pelvic floor muscle exercises with biofeedback | Symptom distress Illness intrusiveness Mood | NS NS NS | NR NR NR | Addition of the social support group did not improve outcomes | 57% recruitment rate (3 withdrew because of work schedules) 100% intervention and 87% controls had follow-up at end of intervention |

#Treatment is reported if ≥80% of men received it, with the exception of ADT where the percentage of men currently receiving ADT was reported. *Precision of effect and size of effect correspond to the longest reported follow-up. ADT, Androgen deprivation therapy; C, Communication; CB, Cognitive-behavioural; DS, Decision Support; Dx, Diagnosis; E, Education; EBRT, External beam radiation therapy; ED, Erectile dysfunction; M, Mean; NR, Not reported; NS, Not significant; PCa, Prostate cancer; PS, Peer Support; QoL, Quality of Life; R, Relaxation; SC, Supportive Counselling; Tx, treatment.
## TABLE A2  Trials comprising couple-focused interventions (N = 14)

| Study | Couples# | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect * | Size of effect * | Key findings | Acceptability |
|-------|----------|--------------|-------------------------|------------|-------------------|----------------------|------------------|--------------|---------------|
|       |          |              |                         |            | Patients          | Cohen's d            |                  |              |               |
|       |          |              |                         |            | Mental health     | NS                   | 0.0              |              | 25% recruitment rate |
|       |          |              |                         |            | Sexual QoL        | NS                   | 0.3              |              | 75% of dyads completed intervention |
|       |          |              |                         |            | Sexual function   | NS                   | 0.3              |              | 60% intervention and 90% control had follow-up at end of intervention |
|       |          |              |                         |            | Sexual bother     | NS                   | 0.5              |              | Qualitative assessment only of intervention acceptability |
|       |          |              |                         |            | Self-efficacy     | NS                   | 0.2              |              |               |
|       |          |              |                         |            | Partner           | NS                   | 0.3              |              |               |
|       |          |              |                         |            | Caregiver strain  | NS                   | 0.3              |              |               |
|       |          |              |                         |            | Mood              | NS                   | 0.0              |              |               |
|       |          |              |                         |            | Anger             | NS                   | 0.3              |              |               |
|       |          |              |                         |            | Confusion         | NS                   | 0.3              |              |               |
|       |          |              |                         |            | Depression        | NS                   | 0.5              |              |               |
|       |          |              |                         |            | Fatigue           | NS                   | 0.4              |              |               |
|       |          |              |                         |            | Anxiety           | NS                   | 0.3              |              |               |
|       |          |              |                         |            | Vigour            | NS                   | 0.4              |              |               |
|       |          |              |                         |            | Self-efficacy     | NS                   | 0.1              |              |               |
| Canada | 51 couples | 1. Sexual counselling—couple | 1. E, CB, C | 1. E, CB, C | Patients | NS | NR | Couples sexual counselling did not significantly improve patient outcomes when compared with patient only sexual counselling | 66% completed couple intervention; 57% completed patient only intervention |
|        | (100% female; married/living together) | Delivered by psychologist or counsellor | 2. Sexual counselling—patient only | 2. E, CB, C | Distress | NS | NR | 21% withdrew because of high marital distress, 9% discomfort with explicit sexual topics, 6% scheduling conflicts |
|        |       | 4 dyad face-to-face sessions | 4 individual face-to-face sessions | | Sexual QoL | NS | NR | 61% attended all 4 sessions | |
|        |       | Follow-up 6 months post-intervention | | | Marital satisfaction | NS | NR | | |
|        |        | | | | | | | (Continues) | |
| Study | Couples# | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect | Size of effect | Key findings | Acceptability |
|-------|----------|--------------|-------------------------|------------|------------------|--------------------|-----------------|--------------|---------------|
| Chambers 2015 Australia | 189 couples (100% female partners) | 1. Peer-delivered telephone support Delivered by PCa survivors | 1. E, CB, PS, C | Usual care | Patients Sexual Function | NS | NR | Patients in the peer intervention were 3.14 times more likely to use ED tx when compared with usual care (z = 2.41, P = 0.016) | 47% recruitment rate |
| | | | | | | | | | | At 6-months post-recruitment 8% peer-delivered arm, 5% nurse-delivered arm and 6% controls withdrew because no longer interested |
| | | | | | | | | | | 88% (8 sessions) or 100% (6 sessions) median attendance for both peer- and nurse-delivered interventions |
| | | | | | | | | | | High helpfulness ratings for all interventions (1 not at all to 10 extremely) (Nurse intervention: Patient M 8.67, Partner M 8.35; Peer intervention: Patient M 7.74, Partner M 7.47) |
| | | | | | | | | | | (Continues) |
| Study      | Couples#                  | Intervention                          | Intervention components | Comparator   | Relevant outcomes                  | Precision of effect * | Size of effect * | Key findings                                                                 | Acceptability                       |
|-----------|--------------------------|---------------------------------------|-------------------------|--------------|-----------------------------------|-----------------------|------------------|-----------------------------------------------------------------------------|-------------------------------------|
| Couper 2015 Australia | 62 couples (100% female spouses) | Cognitive existential couple therapy | CB, SC                  | Usual care   | Patients                          | NS                    | NR                | Cognitive existential couple therapy did not significantly improve outcomes for patients | 18% consented to assessment for eligibility |
|           | Men ≤ 12 months post-dx  | Delivered by mental health professionals |                         |              | Cancer-related distress           | NS                    | NR                |                                                                             | 7% dyads withdrew because of unacceptability of programme |
|           | Stage T1-3 (19% T3)     | 6 weekly dyadic face-to-face sessions |                         |              | Distress                          | NS                    | NR                |                                                                             | 100% median attendance rate          |
|           | Median age years: 65 (patient) and 61 (partner) | Follow-up 9 months post-baseline |                         |              | Well-being                        | NS                    | NR                |                                                                             |                                    |
|           |                          |                                       |                         |              | Relationship function             | NS                    | NR                |                                                                             |                                    |
|           |                          |                                       |                         |              | Partner                           | NS                    | NR                |                                                                             |                                    |
|           |                          |                                       |                         |              | Cancer-related distress           | NS                    | NR                | For partners, cognitive existential couple therapy significantly improved relationship function when compared with usual care |                                    |
|           |                          |                                       |                         |              | Distress                          | NS                    | NR                |                                                                             |                                    |
|           |                          |                                       |                         |              | Well-being                        | NS                    | NR                |                                                                             |                                    |
|           |                          |                                       |                         |              | Relationship function             | NS                    | NR                |                                                                             |                                    |
| Giesler 2005 USA | 99 couples (96% female spouses) | Post-tx nursing support | E, C                    | Standard care | Mental health                     | NS                    | Effect size -0.1 | For patients, post-tx nursing support significantly reduced with a moderate effect size cancer worry and the extent to which sexual dysfunction interfered with spousal role activities when compared with standard care | 48% recruitment rate |
| Reported patient data only | Men ≤ 2 weeks post-tx | Delivered by oncology nurse |                         |              | Sexual function                   | NS                    | 0.4               |                                                                             |                                    |
|           | Stage T1a-T2c           | 6 monthly dyadic (with partner) sessions; 2 face-to-face and 4 telephone sessions |                         |              | Sexual limitation                 | P = 0.02              | 0.5               |                                                                             |                                    |
|           | Patient M age 64 years  | Follow-up 12 months post-tx            |                         |              | Sexual bother                     | NS                    | 0.2               |                                                                             |                                    |
|           |                          |                                       |                         |              | Depression                        | NS                    | 0.2               |                                                                             |                                    |
|           |                          |                                       |                         |              | Cancer worry                       | P = 0.03              | 0.5               |                                                                             |                                    |
|           |                          |                                       |                         |              | Dyadic satisfaction               | NS                    | 0.4               |                                                                             |                                    |
|           |                          |                                       |                         |              | Dyadic cohesion                   | NS                    | 0.1               |                                                                             |                                    |
| Study | Couples# | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect * | Size of effect * | Key findings | Acceptability |
|-------|----------|--------------|-------------------------|------------|------------------|----------------------|-------------------|--------------|--------------|
| Lambert 2016 Australia | 42 couples (97% married/defacto) | Coping skills for couples and relaxation | E, R, C | Minimal ethical care | Patient Anxiety | NS | Difference −0.28 | Coping skills and relaxation intervention did not significantly improve patient outcomes when compared with minimal ethical care | 37% recruitment rate; 42% refused or did not respond (24% not interested, 7% too busy) |
| | | | | | Depression | NS | 0.71 | | No withdrawals during intervention in intervention arm |
| | | | | | Self-efficacy | NS | −4.41 | | 100% attendance rate for 91% (maximum) intervention arm and 74% (maximum) control arm |
| | | | | | Mental health | NS | −0.05 | | |
| | | | | | Cancer-specific distress | NS | NR | | |
| | | | | | Uncertainty | NS | 4.60 | | |
| | | | | | Relationship satisfaction | NS | NR | | |
| | | | | | Illness appraisal | Partner Anxiety | NS | NR | | Partners who received coping skills intervention had significantly worse challenge appraisal scores than partners who received minimal ethical care |
| | | | | | | Depression | NS | 1.17 | | |
| | | | | | | Self-efficacy | NS | 2.17 | | |
| | | | | | | Mental health | NS | −0.04 | | |
| | | | | | | Caregiver QoL | NS | NR | | |
| | | | | | | Cancer-specific distress | NS | NR | | |
| | | | | | | Uncertainty | NS | −3.51 | | |
| | | | | | | Relationship satisfaction | NS | NR | | |
| | | | | | | Illness appraisal | Threat | NS | −1.13 | | |
| | | | | | | | Challenge | P < 0.05 | 2.94 | | |
| | | | | | | | Harm/loss | NS | 0.26 | | |
| | | | | | | | Benign | NS | 1.05 | | |

(Continues)
| Study          | Couples#                          | Intervention                                                                 | Intervention components | Comparator   | Relevant outcomes                  | Precision of effect * | Size of effect * | Key findings                                                                 | Acceptability                                                                 |
|---------------|-----------------------------------|------------------------------------------------------------------------------|-------------------------|--------------|-----------------------------------|-----------------------|------------------|--------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| Manne 2011    | 71 couples (97% female; 97% spouses) | Intimacy-Enhancing Therapy (IET)                                            | E, CB, SC, C            | Usual care   | Patients                          | NS                    | NR               | For a subgroup of patients with higher baseline cancer concerns, the IET intervention was predicted to significantly improve cancer concern when compared with usual care ($P = 0.02$) | 21% recruitment rate (did not participate because of time required, or believed would not benefit) |
|               | Men ≤12 months since dx           | Delivered by therapists                                                     |                         |              | Distress                          | NS                    | NR               |                                                                           | 22% did not attend any sessions (unclear if withdrew or not)                |
|               | Stage 1-2                         | 5 dyadic (with partner) face-to-face sessions over 8 weeks                  |                         |              | Well-being                        | NS                    | NR               |                                                                           | 73% attendance ≥80% of sessions                                             |
|               | M age years: 60 (patient) and 56 (partner) | Follow-up 8 weeks post-baseline (end of intervention)                        |                         |              | Cancer-specific distress          | NS                    | NR               |                                                                           | Intervention success M 3.2 (3 quite successful, 4 extremely successful)      |
|               |                                   |                                                                             |                         |              | Cancer concerns                   | NS                    | NR               |                                                                           | Intervention helpfulness M 4.2 (5 strongly agree)                           |
|               |                                   |                                                                             |                         |              | Relationship satisfaction         | NS                    | NR               |                                                                           |                                                                                  |
|               |                                   |                                                                             |                         |              | Intimacy                          | NS                    | NR               |                                                                           |                                                                                  |
|               |                                   |                                                                             |                         |              | Patients                          | NS                    | NR               |                                                                           |                                                                                  |
|               |                                   |                                                                             |                         |              | Distress                          | NS                    | NR               |                                                                           |                                                                                  |
|               |                                   |                                                                             |                         |              | Well-being                        | NS                    | NR               |                                                                           |                                                                                  |
|               |                                   |                                                                             |                         |              | Cancer-specific distress          | NS                    | NR               |                                                                           |                                                                                  |
|               |                                   |                                                                             |                         |              | Cancer concerns                   | NS                    | NR               |                                                                           |                                                                                  |
|               |                                   |                                                                             |                         |              | Relationship satisfaction         | NS                    | NR               |                                                                           |                                                                                  |
|               |                                   |                                                                             |                         |              | Intimacy                          | NS                    | NR               |                                                                           |                                                                                  |
| McCorkle 2007 | 107 couples (100% female spouses) | Post-tx nursing support for patient/partner dyad during an 8-week period immediately following hospital discharge after radical prostatectomy | E, C                    | Usual care   | Patients                          | NS                    | NR               | Post-tx nursing support did not significantly improve patient outcomes when compared with usual care | 7% of eligible dyads withdrew pre-randomisation                             |
|               | Men immediately prior to radical prostatectomy | Delivered by advanced practice nurse                                         |                         |              | Depression                        | NS                    | NR               |                                                                           |                                                                                  |
|               | 30% depressive symptoms (patient); 25% (partner) | 8 weekly dyadic face-to-face sessions and 8 weekly telephone calls (16 contacts over 8 weeks) Follow-up 6 months post-surgery |                         |              | Sexual function                   | NS                    | NR               |                                                                           |                                                                                  |
|               |                                   |                                                                             |                         |              | Partners                          | NS                    | NR               |                                                                           |                                                                                  |
|               |                                   |                                                                             |                         |              | Depression                        | NS                    | NR               |                                                                           |                                                                                  |
|               |                                   |                                                                             |                         |              | Relationship function             | NS                    | NR               |                                                                           |                                                                                  |
|               |                                   |                                                                             |                         |              | Sexual function                   | $P = 0.048$           | NR               |                                                                           |                                                                                  |

(Continues)
### TABLE A2 (Continued)

| Study | Couples# | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect | Size of effect | Key findings | Acceptability |
|-------|-----------|--------------|--------------------------|------------|-------------------|--------------------|-----------------|--------------|---------------|
| Northouse 2007 USA | 235 couples (100% female spouses) | Supportive education for couples | Targeted at disease phase and tailored to the needs of each couple | Standard care | Patients Mental health | NS | Effect size = 0.1 | Supportive education did not significantly improve patient outcomes or result in a moderate or large effect size when compared with standard care | 69% recruitment rate (7% refused intervention assignment; 5% did not complete intervention 1% refused control assignment) |
| | | | Delivered by masters-prepared nurses | | Cancer-related QoL | NS | 0.0 | | |
| | | | 5 bi-weekly dyadic sessions: face-to-face (3) and telephone call (2) | | Illness appraisal | NS | 0.0 | | |
| | | | Follow-up 12 months post-intervention | | Uncertainty | NS | 0.0 | | |
| | | | | | Hopelessness | NS | 0.0 | | |
| | | | | | Self-efficacy | NS | 0.0 | | |
| | | | | | Symptom distress | NS | 0.0 | | |
| | | | | | Sexual QoL | NS | 0.0 | | |
| | | | | | Partners Mental health | NS | 0.0 | | |
| | | | | | Cancer-related QoL | NS | 0.0 | | |
| | | | | | Uncertainty | NS | 0.0 | | |
| | | | | | Hopelessness | NS | 0.0 | | |
| | | | | | Self-efficacy | NS | 0.0 | | |
| | | | | | Symptom distress | NS | 0.0 | | |
| | | | | | Partner’s sexual symptoms causing problems | NS | 0.0 | | |
| Robertson 2016 UK | 43 couples (98% female partners) | Couple-based relational psychosexual treatment | | Usual care usual follow-up hospital appointment | Patient Anxiety | NR | NR | NR (no comparative results reported) | 37% consented to assessment for eligibility; 38% of those eligible agreed to participate |
| | | | Delivered by accredited counselling or psychotherapy practitioners | | Depression | NR | NR | | 24% withdrew from intervention and 23% withdrew from control |
| | | | 6 x 3-4 weekly dyadic face-to-face sessions | | Relationship function | NR | NR | | |
| | | | Follow-up 6 months post-intervention | | Patient Sexual bother | NR | NR | | |

(Continues)
| Study | Couples# | Intervention | Intervention components | Comparator | Relevant outcomes | Precision of effect * | Size of effect * | Key findings | Acceptability |
|-------|----------|--------------|-------------------------|------------|------------------|----------------------|---------------------|--------------|---------------|
| Schover 2012 USA | 100 couples (100% female partners; 97% spouses) | 1. Face-to-face sexual counselling | Delivered by therapist | 1. E, CB, SC, C, DS | Patient and Partner Distress | NR | NR | NR (no comparative results reported) | 28% face-to-face and 13% internet-based arm withdrew during intervention |
| | Men 3 months–7 years since tx | 2. Internet-based sexual counselling | Delivered by therapist | 2. E, CB, SC, C, DS | Relationship satisfaction | NR | NR | | 75% face-to-face, 82% internet-based and 90% controls followed-up at end of intervention |
| | Stage T1-T3 with erectile dysfunction (ED) | 3. Patient M age 64 years | | | Sexual function and satisfaction | NR | NR | | |
| Thornton 2004 USA | 80 patients and 65 partners (100% female spouses) | Pre-surgical communication enhancement | Delivered by trained counsellor | SC, C | Patients | Mental health | NS | NR | Pre-surgical communication enhancement intervention did not significantly improve patient outcomes when compared with standard care | 51% recruitment rate (47% did not participate because they were too busy) |
| | Men scheduled for prostatectomy | 1 dyadic (with partner) | Delivered by a nurse | | PCa-related QoL | NS | NR | | |
| | Stage A-C (17% Stage C) with baseline, 3 weeks post-surgery and 1 year post-surgery data | 2 dyadic (with partner) | face-to-face session | | Sexual function | NS | NR | | |
| | M age years: 61 (patient) and 57 (partner) | 3 dyadic (with partner) | | | Positive affect | NS | NR | | |
| | | 4 dyadic (with partner) | | | Negative affect | NS | NR | | |
| | | 5 dyadic (with partner) | | | Cancer-specific stress | NS | NR | | |
| | | 6 dyadic (with partner) | | | Stress | NS | NR | | |
| | | 7 dyadic (with partner) | | | Relationship satisfaction | NS | NR | | |
| | | 8 dyadic (with partner) | | | Mental health | NS | NR | | For partners, the communication enhancement intervention reduced stress with a moderate effect size when compared with standard care | |
| | | 9 dyadic (with partner) | | | Positive affect | NS | NR | | |
| | | 10 dyadic (with partner) | | | Negative affect | NS | NR | | |
| | | 11 dyadic (with partner) | | | Cancer-specific stress | NS | NR | | |

(Continues)
| Study           | Couples# | Intervention                                                                 | Intervention components                                                                 | Comparator | Relevant outcomes | Precision of effect | Size of effect | Key findings                                                                 | Acceptability |
|----------------|----------|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|------------|-------------------|--------------------|----------------|--------------------------------------------------------------------------------|---------------|
| Titta 2006 Italy | 57 patients and partners (100% female) | Intracavernous injection-focused sexual counselling for couples following patient training in PGE1-intracavernous injections | E, SC, C                                                                                | Control Partner invited to follow-up visits every 3 months | Sexual function | NS                 | NR                | For patients, the intracavernous injection-focused sexual counselling intervention significantly improved erectile function, sexual satisfaction and sexual desire | 100% intervention and 71% controls completed study |
|                | Men 20-41 days since prostatectomy (88%) | Stage I-II or cystectomy (8%) who requested sexual rehabilitation and responsive to and trained to administer PGE1-intracavernous injections | Deliverer of sexual counselling NR                                                      |            |                    |                    |                 |                                                                                |               |
|                |          | Follow-up 18 months post-surgery                                              |                                                                                         |            |                    |                    |                 |                                                                                |               |
|                |          | Patient M age 63.5 years                                                      |                                                                                         |            |                    |                    |                 |                                                                                |               |
| Walker 2013 Canada | 27 couples (100% female married/defacto) | Educational intervention for couples to maintain intimacy | E                                                                                      | Usual care | Patients Intimacy | NS                 | 0.6              | For patients, educational intervention improved intimacy and dyadic adjustment with moderate and large effect sizes when compared with usual care (however, baseline levels of partner dyadic adjustment differed between arms and was not controlled for in analyses) | 30% recruitment rate at main centre (did not participate because of being too busy or not interested) |
|                | Men starting ADT M age 73 years                                                | Delivered by researcher familiar with ADT                                              |                                                                                        |            | Dyadic adjustment | NS                 | 1.0              |                                                                                | 100% compliance—men in intervention arm read at least part of booklet | |
|                |          | 1 dyadic face-to-face session + booklet                                       |                                                                                        |            |                    |                    |                 |                                                                                |               |
|                |          | Follow-up 6 months post-enrolment                                             |                                                                                        |            |                    |                    |                 |                                                                                |               |

#Treatment is reported if ≥80% of men received it, with the exception of ADT where the percentage of men currently receiving ADT was reported. *Precision of effect and size of effect correspond to the longest reported follow-up. ADT, Androgen deprivation therapy; C, Communication; CB, Cognitive-behavioural; DS, Decision Support; Dx, Diagnosis; E, Education; EBRT, External beam radiation therapy; ED, Erectile dysfunction; M, mean; NR, Not reported; NS, Not significant; PCa, Prostate cancer; PS, Peer Support; QoL, Quality of Life; R, Relaxation; SC, Supportive Counselling; Tx, Treatment.