STUDY PROTOCOL

Innovations in the treatment of sexual dysfunction and couple intimacy after prostate cancer: A randomized clinical trial of mindfulness versus cognitive behavioural therapy

Study nickname: The INTROSPPECT Study (Innovations in the Treatment of Sexual Health Post Prostate Cancer Treatment)

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BACKGROUND/RATIONALE

SUPPORTIVE CARE NEEDS OF PROSTATE CANCER SURVIVORS

One in every 8 men[1] are affected by prostate cancer (PC). As a result of advances in PC treatments, the 5-, 10-, and 15-year relative survival rates are 100%, 98%, and 95% respectively[2]. However, despite advances in PC treatments, up to 90% of these men will experience significant side effects[1,3]. These side effects negatively impact patient and partner QoL[4-6], and for some men will impact their decision to undergo treatment at all[7-9]. With an aging population, numbers of men treated for and surviving PC are expected to rise[10], and as this number grows, so does the number of men needing supportive care.

The top unmet supportive care need of PC survivors is around sexual health and intimacy[11-13]. All of the side effects of PC treatments are known to impact the sexual lives of men and their partners, including erectile dysfunction, climacturia (loss of urine with ejaculation), anorgasmia (inability to reach orgasm), urinary or fecal incontinence, penile shortening, and/or loss of sexual desire[1,3-6,8,12]. Following PC treatments, sexual functioning and satisfaction sharply decline[1,2,14]. The loss of sexual intimacy can be devastating for partners, relationship satisfaction, health outcomes, mental-health outcomes, and overall QoL[4-6].

To date, research has largely focused on improving erectile functioning in PC survivors, specifically, restoration of an erection sufficient for penetrative intercourse. Current guidelines recommend oral medication (i.e., PDE5 inhibitors) as front-line treatment[15]. However, PDE5i's have variable effectiveness for PC survivors[1, 16], effectiveness decreases over time in 50% of men[17], failure rates have been noted as high as 80%, and the significant financial burden is a barrier for many men[18]. Across medical interventions for erectile function (PDE5i's, penile injections, vacuum erection device[19]), uptake rates are low (50%)[19.20], and discontinuation rates are exceedingly high (50-61%) irrespective of treatment effectiveness[21-26]. Inconsistent efficacy and low adherence suggests that medical interventions aimed at erectile function alone are insufficient in meeting the needs of PC survivors, perhaps because they do not address psychosocial sequelae. Indeed, sexuality is a complex interplay of biological, psychological, and social factors, and current front-line interventions fail to address the broader scope of contributing factors.

Over the past 10 years, psychosocial interventions aimed at improving sexual outcomes following PC treatments have been developed and tested. However, the efficacy of these interventions has fallen short of expectations: sexual functioning, intimacy, and relationship satisfaction are minimally improved[27,28]. We hypothesize that poor outcomes are due, at least in part, to the lack of evidence-based practices in existent psychosocial interventions for PC survivors.

MEETING PSYCHOSOCIAL NEEDS WITH EVIDENCE-BASED PRACTICE

This research program focuses on an important gap in the field of PC, namely improving supportive care for sexual health, intimacy, and overall QoL for men and their partners following PC treatment. This study utilizes a randomized clinical trial (RCT) design to develop, assess, and compare two treatment groups using evidence-based psychological principles that have been shown to improve people's sexual lives, and their ability to cope with a cancer diagnosis: mindfulness and cognitive behavioural therapy (CBT), as well as a control group.

MINDFULNESS

Mindfulness refers to non-judgemental present-moment awareness[30]. Efficacy of this treatment modality has been demonstrated in individuals with a variety of health-related problems[31,32]. In samples of men with PC, mindfulness training improves psychological outcomes such as mood, QoL[33,34], and physiological variables, like immunological parameters[33]. Recent advances in sexual health research supports the benefits of mindfulness for women with a variety of sexual dysfunction, including low sexual desire, genital pain, and sexual dysfunction secondary to gynaecological cancer[30,35-37]. Mindfulness has also been used with couples who do not have cancer to improve intimacy[38]. Presently, members of our research team have developed a mindfulness-based treatment group to improve couples' intimacy after PC. Preliminary data supports the feasibility of mindfulness for this population. Mindfulness is hypothesized to improve attentional focus, thus reducing distractions related to poor erectile functioning, body image, or distress from a cancer diagnosis/treatments, and in turn improve sexual and relationship outcomes.

COGNITIVE BEHAVIOURAL THERAPY

Cognitive behavioural therapy (CBT) is an evidence-based practice in which negative thought patterns are recognized and challenged in order to improve emotional or behavioural outcomes[39]. There is a great deal of empirical support for CBT as an effective intervention for mood, anxiety, and health concerns[40]. Some studies have demonstrated improvements in coping and pain[41] in cancer patients following CBT. Similar to mindfulness, there is evidence to suggest that CBT is effective in improving sexual outcomes for individuals[42,43] and couples[44] who do not have cancer. CBT is believed to be effective for sexual dysfunction as it teaches patients the tools to acknowledge and change maladaptive thoughts that can negatively impact sexual functioning and intimacy.

CONTROL GROUP

Participants who are randomized to the control group will not receive mindfulness or CBT treatment. They will proceed with whatever course of treatment they were receiving prior to enrollment in the study. As resources for couples dealing with changes to their sexual lives after prostate cancer are limited, we anticipate that the majority of

these patients will have no treatment targeting sexual intimacy during the 6-week period between completing the first and second questionnaire.

ROLE OF PARTNERS IN PROSTATE CANCER

Partners play a critical role in coping and QoL for men with PC[45-48], thus PC is widely considered a couple's issue, and psychosocial interventions should treat it as such[45]. Partners improve PC survivors' adherence to psychosocial interventions[49,50], which can otherwise be low[28]. Further, partners' response to a PC diagnosis is predictive of patient's outcomes, including relationship and sexual satisfaction[52]. This is important, as a patients' cancer diagnosis produces higher levels of stress in female partners than the patient themselves[51], including significant concerns about patients' post-treatment sexual functioning and how it might impact their relationship/intimacy[53]. Following PC treatment, post-treatment sexual dysfunction is related to worse sexual outcomes in female partners[55,56], which is tied to poorer relationship outcomes[56-58], and worse overall adaptation chronic/life threatening disease for the patient[59-61]. Including partners in this treatment study will maximize outcomes for both men and their partners. It should be noted, that we will specifically target same-sex couples in our recruitment process, as no research exists on the potentially unique needs of these couples in the context of psychosocial interventions.

AIMS

This project builds on an already established multi-step research program with the long-term goal of optimizing the standards of care for the treatment of sexual dysfunction and sexual intimacy in couples post-prostate cancer treatment. The aim of this study is to adapt an existing and effective treatment found to improve women's sexual functioning now to the couple context for survivors of PCa and their partners. We will evaluate the comparative efficacy of each treatment to one another and to "usual care" that patients receive within the Prostate Cancer Supportive Care (PCSC) Program at VPC. We will also identify which treatment works best for whom. The long-term aim is to disseminate this information as treatment manuals to other centres that treat PC nation-wide in order to expand the program. Helping men and their partners reclaim intimacy after PC will improve the recovery process and quality of life.

OBJECTIVES

OBJECTIVE 1. Evaluate two evidence-based psychological treatments (mindfulness-based therapy and cognitive behavioural therapy; CBT) for PC survivors and their partners, compared to controls in the short- (immediately post-treatment) and long-term (6-months follow up).

OBJECTIVE 2: Explore moderators of improvement in outcomes of intimacy and QoL with treatment.

HYPOTHESES

HYPOTHESIS 1a: Compared to controls, we predict that couples who undergo mindfulness-based therapy or CBT will show improvements at follow-up (immediately and 6-months post-treatment) in:

a. **Primary endpoints** of self-reported **intimacy outcomes** (i.e., relationship satisfaction, sexual satisfaction/distress, sexual function, frequency/range of sexual activities).
b. **Secondary endpoints** of self-reported **QoL outcome**s (i.e., psychological well-being (depression, anxiety), distress, overall QoL).

HYPOTHESIS 1b: The two active treatments (mindfulness and CBT) will not significantly differ from one another with respect to patient outcomes.

HYPOTHESIS 2: Improvements in either treatment arm will be moderated by:

a. **Treatment adherence factors** (e.g., motivation at baseline, (greater) expectations for change, participant's expectations for treatment, amount participants practice the therapeutic skills taught in session).
b. **Individual factors** (e.g., personality variables, state/trait mindfulness, pre-treatment relationship satisfaction, pre-treatment sexual health, previous experience with mindfulness or CBT). Improvements in mindfulness are predicted to will mediate improvements in the mindfulness group only.
c. **Secondary endpoints.** That is, the role of secondary quality of life endpoints (mentioned above) as moderators to primary endpoints of intimacy outcomes will also be assessed.

RESEARCH METHODS

STUDY DESIGN. This is a randomized clinical trial study designed to assess and compare efficacy of two treatment manuals for couples with sexual difficulties secondary to PC treatment: mindfulness-based therapy and CBT. A third arm, where couples receive no intervention will act as a control group. N = 141, with 47 in each arm. Couples will be invited to participate through the VPC's PCSC Program at Vancouver General Hospital. Recruitment is also open to interested couples from the community.

Eligible couples will be randomized to either 4 consecutive weeks of mindfulness-based therapy, CBT, or no intervention (4-6 couples per group). All couples will complete an online questionnaire package to assess primary, secondary, and tertiary endpoints at the time of study enrolment (Time 1). All couples will be invited to complete a Time 2 questionnaire once approximately 6 weeks after they complete the pre-treatment questionnaire (for couples randomized to the treatment arms, this will be immediately after the end of treatment). All participants will be invited to complete the Time 3 follow up questionnaire 6 months after they complete the Time 2 (post-treatment) questionnaire.

For couples randomized to a treatment arm, treatment will consist of a 4-week group lead by a trained clinician. Sessions are 2hrs in length and take place in consecutive weeks, with daily homework recommended between sessions. The therapeutic content presented in each treatment arm is manualized. The mindfulness-based treatment was developed based on pre-existing mindfulness-based cognitive therapy treatment groups for sexual dysfunction developed by Dr. Lori Brotto at the UBC Sexual Health Laboratory, mindfulness in Sex therapy and Intimate Relationships (MSIR) treatment group developed by Kocsis and Newbury-Helps (2016), and expert input. The CBT treatment was adapted from the mindfulness-based treatment, but all mentions of mindfulness have been replaced with CBT principles. Sessions consist of either mindfulness-based training or CBT tools, as well as sex therapy techniques and education.

In order to improve our understanding of the lived experience of patients who take part in the treatment groups or control arm, we will invite all participants to take part in an exit interview after their Time 2 (post-treatment) questionnaire is completed. An individual who was not a treatment facilitator will conduct the exit interviews. This information will then be transcribed and used for qualitative data analyses.

The doctor or healthcare provider referring their patient to the study, be it from Vancouver Prostate Centre/PCSC program or from the broader community, will be notified if their patient chose to enroll in the study (i.e., signed the consent form) in order to follow standard clinical practice. If the healthcare provider is within Vancouver Prostate Centre or PCSC Program, notification will be done internally through the secure and confidential EMR system. If the healthcare provider is external to our program, a confidential fax will be sent to their office. These notifications will be kept brief, secure, and follow patient-provider confidentiality. Please see box 9.7 for a template.

RANDOMIZATION. Once consent has been received from both members of the participating couple, they will be assigned a study ID and then be randomized to their group (CBT, mindfulness, or control). Time 1 baseline measures will then be administered to start data collection.

A randomization list will be created using the random number generator at www.researchrandomizer.org (Urbaniak, & Plous, 2013). A value of 1 indicates randomization to the mindfulness-based intervention, a value of 2 indicates the CBT intervention, and a value of 3 indicates the no treatment control group.

The random number generator will be run after the study has opened to recruitment and before the first potential participant is approached for the study. The randomization list will be stored electronically, in a password-protected document on the secure Vancouver Prostate Centre network by a person independent of the study with a nominated back-up in case they are absent.

At the time of randomization, the Study Coordinator/Assistant will contact the randomization list holder to request the treatment allocation and then inform the participants by phone.

RECRUITMENT.

Interested couples with sexual complaints secondary to prostate cancer treatments (*N* = 141, based on anticipated small effect size, α = .05, power = 0.8) will be recruited from existing waitlists at VPC and the PCSC Program and outside sources. This is 47 couples per study arm.

Note that, as this is a study evaluating group treatment for couples, both members of the couple are required to consent in order to be eligible to participate. If one member of the couple decides with withdrawal their consent at any point during the study, then both members of the couple with be removed from the treatment group (if applicable). However, if one member of the couple still wishes to take part in the study, they will be given the option to arrange individual sessions with a group facilitator to ensure that they receive the full treatment intervention. This individual will not be invited to complete follow up questionnaires or the optional follow up interview.

The following recruitment pathways will be followed:

1. Prospective recruitment in Person at the PCSC Program

During a scheduled Sexual Health Service (SHS) appointment, patients who are identified by the Sexual Health Clinician as being possibly eligible to participate in the study will be provided with a study advertisement (see Section 9.4). At this point, one of two recruitment pathways may be taken:

(a) The patient will have the option to contact the Study Coordinator (contact information is included in the study advertisement) at a later date.

(b) If the patient expresses interest in the study to the clinician, or would like additional information, they have the option to speak with a trained member of the study team (e.g., the Study Coordinator or Research Assistant) in person at that time following conclusion of their appointment. At this meeting, the patient will be fully informed about the study protocols and provided with a consent form. They are under no obligation to consent to participate during that initial meeting.

If the patient has read the study information, had an opportunity to ask any questions, and is willing to participate, they and their partner will be asked to complete the screening interview. If they are deemed eligible to participate, they will be given the option to sign the study consent form, or, if the patient prefers or perhaps if their partner is not present at the clinic, they have the option to take the information home and have decide later whether they'd like to participate. They have the option to be followed-up by a telephone call later (up to two weeks) at an agreed time. If the patient is willing to take part in the study, consent will be obtained either electronically (signed and scanned) or

through the mail (they will be provided a pre-addressed stamped envelope upon request).

For participants who complete the screening interview but indicate that they are not interested in providing consent to participate, or if it deemed that the study is not a good fit for them, the information they provided during the screening interview will be destroyed.

Note that all email correspondence between the researcher and participants is done using the researcher's Prostate Centre email, which is a secure emailing service hosted through the Vancouver Prostate Centre network. Electronic versions of the signed consent forms are stored on the secure Prostate Centre Network. Original hard copies are stored in a secure, locked cabinet housed in the UBC Sexual Research Lab.

We have also created a study recruitment poster (see section 9.4) to be displayed in the clinic rooms at the Diamond Health Care Centre and to be used in the Prostate Cancer Supportive Care (PCSC) program and other suitable advertising spaces. For instance, the PCSC has a quarterly newsletter that is disseminated to patients, loved-ones, and staff, in which the approved recruitment poster or information can be appended. In addition, the PCSC facilitates educational modules for diagnosed patients and their partners to learn skills and information in coping with prostate cancer, for example workshops on intimacy, sexual rehabilitation, exercise, nutrition etc. We will leave the same recruitment materials (section 9.4) at these module workshops and make quick announcements about the study when appropriate (see section 9.7 for a sample script). It is important to note that, because of the personal and sensitive nature of topics, these PCSC education modules are kept confidential not only between the facilitators and attendees but also between attendees. Thus, these modules serve as a safe place for potential participants to learn more about the study and ask questions.

2. Recruitment by Invitation at the PCSC Program, Vancouver Prostate Centre/Prostate Clinic, and BC Cancer Agency

For PCSC and Vancouver Prostate Centre, patients who may be eligible to participate will be identified from SHS clinic lists held in the electronic medical record (EMR) by the SHS clinician or the Study Coordinator/Research Assistant, who all have access to the EMR database. Patients active in the SHS (i.e. seen in clinic in the past 12 months) will be contacted. There are two extensive databases of patients who have provided permission to contact (PTC) for prostate cancer research; one is termed SPIRIT Databank (H16-02295) for patients enrolled into the PCSC program and the other is the Prostate Clinic at Vancouver General Hospital patient database. Patients identified on EMR will be cross-referenced with the research consent databases, and those who have provided PTC will be contacted via telephone, email, or mail see box 9.7 for example dialogue/text. Members of the research team have access to both EMR and the PTC databases. To minimize participant burden, we will not contact patients who are currently participating in other Prostate Centre projects that have high time commitment as noted in the database.

For those patients from either the PCSC or Prostate Clinic database who have not yet provided PTC, they will be sent an invitation letter in the mail (see section 9.6). This letter is signed by Dr. Larry Goldenberg, the head of the Vancouver Prostate Centre. The patient will be provided with the reasons why the study is being carried out, a description of the study, reasons why the patient is being invited to participate, and what the study involves, in compliance with the Initial Letter of Contact template designed by the Vancouver Coastal Health Privacy Office. This letter may also be sent out to patients who have consented for future contact and who have not been reached by phone or email as another recruitment method. An approved study brochure will also be included in the envelope for further information. The Study Coordinator will follow up with the potentially eligible participant by phone in approximately two weeks' time after the letter was sent to ensure that it was received, and to inquire as to whether the patient is interested in participating in the study. Telephone contact will only be attempted during typical office hours on weekdays. No voicemail will be left if the patient does not answer the phone.

Lastly for Recruitment by Invitation, we will recruit by mail invitation through the BC Cancer Agency Registry database in the same manner as the step described above. We will request data from this registry through the BC Cancer Agency's stringent Data Access Request process. A list of names and addresses of patients who have a confirmed prostate cancer diagnoses and permission to contact for research will be exported through approved BC Cancer Agency protocol and staff (e.g., data will be transferred using a password encrypted file and network, stored in an institutional computer, and will be destroyed at the earliest possibility). Only the principal investigator, the designated study lead, and the study coordinator will have access to this list to perform the mail out. Similar to above, the letter sent to BC Cancer Agency Registry patients is signed by Dr. Larry Goldenberg. The patient will be provided with the reasons why the study is being carried out, a description of the study, reasons why the patient is being invited to participate, and what the study involves, in compliance with the Initial Letter of Contact template designed by the Vancouver Coastal Health Privacy Office (see section 9.6). An approved study brochure will also be included in the envelope for further information. The Study Coordinator will follow up with the potentially eligible participant by phone in approximately two weeks' time after the letter was sent to ensure that it was received, and to inquire as to whether the patient is interested in participating in the study. Telephone contact will only be attempted during typical office hours on weekdays. No voicemail will be left if the patient does not answer the phone.

3. Community Outreach

We intend to recruit participants from the Greater Vancouver Area to participate in this study. One method in which we will do so is via outreach to General Practitioners (GPs) and Urologists in the community. In contacting physicians, we will send a letter to their offices with information about the current study (see section 9.7) and copies of the study advertisements either by email, fax, or regular mail and ask permission to display the advertisements in their office. The advertisement material informs potential

participants about the current study, and provides contact information for the study team (see section 9.4, same advertisement as above). Offices are free to decline our request if they do not wish to display the materials, at that point they may disregard our package. We will follow up with the office by phone approximately 2 weeks later to ensure that they received the letter and to confirm whether they would like more advertisement material sent to their office. After the agreeing physician's office has received the advertisement material, the healthcare providers are free to share the information about the study to any patients whom might be a fit for the study. No patient contact information will be sent from the GP offices to the research team. Rather, interested patients must contact our research team through the provided phone or email.

In addition to physician offices, the approved study ads (box 9.4) will be posted in relevant health settings with permission from the authorizing administrator(s). These include but are not limited to: Vancouver General Hospital, UBC Hospital, St. Paul's Hospital, Men's Health Initiative, community health outreach events (e.g., Movember) etc.

We will also post advertisements throughout community center bulletin boards and gathering spaces with permission from the respective administrator. We will place advertisements in community newspapers such as the Vancouver Courier through an agency called Glacier Media, see box 9.4 for sample newspaper advertisement.

4. Online Recruitment

We will post advertisements online through social media, email, and websites relevant to the prostate cancer population. In addition, we will post advertisements through Glacier Media which will display online content (box 9.4) throughout the web and on social media such as Facebook and Instagram. All online advertisements will be passive, meaning interested individuals will need to click on web links to find our contact information and the advertisements will be posted on public domains. These ads can be shared and disseminated by any community member. Where possible, comments will be disabled in order to protect the privacy of potential participants i.e., to prevent names and information from being inadvertently posted.

Examples include but are not limited to:

Twitter: @UBCSexualHealthLab, @VCHRI, @PCSC_Program

Facebook pages: UBC Sexual Health Lab, Vancouver Coastal Health Research Institute PCSC Program

Websites (box 9.4 for draft of sample material):

- www.prostatecentre.com
- www.prostatecancer.ca
- www.clinicaltrials.gov

- www.pcscprogram.ca
- http://brottolab.med.ubc.ca/

The Vancouver Coastal Health Research Institute (VCHRI) provides a webpage for all approved studies. The same information as the advertisement in box 9.4 in VCHRI formatting will be posted on their registry https://www.vchri.ca/participate. This is for ease of access and can be forwarded by word-of-mouth and email among interested individuals.

VCHRI E-Blast is a free service which emails all VCH staff about research studies. The approved materials (VCHRI Format Ad) will be forwarded to all interested individuals who have opted to be part of this mailing list. Moreover, we will also be sending E-Blasts to subscribers of other relevant email lists, for example prostate cancer survivors or family members of survivors, with the permission of the respective list administrator. Examples of email lists include but are not limited to: Prostate Cancer Canada, Ride to Conquer Cancer, and BC Cancer Agency. Emails will be sent directly to the individuals' inboxes with no identifying link to the information of others. It is important to note that these emails are sent to subscribers of these lists who have expressed previous interest in knowing up-to-date information on prostate cancer resources rather than uninterested individuals. The frequency of emails will be limited to once every three months at minimum as per VCHRI guidelines. Uninterested individuals may also unsubscribe from these lists at any point. Please see "INTROSPPECT Study E-Blast Sample Text" in box 9.4 for sample text that will be sent via E-Blasts. Other approved materials (e.g., brochure or poster) in box 9.4 may also be attached in the emails for reference.

Potential participants who contact the lab will then be given more information about the study. Those who are interested in participating will be provided with the option to complete a screening interview over the phone or in person. In the event that they choose to undergo the screening interview over the phone, an electronic copy of the consent form will be sent to them, which they can either (a) print, sign, and scan, or (b) sign electronically and send back to the Study Coordinator/Research Assistant via email. In the event that a participant prefers a hard copy of the consent form, one will be sent to them, along with a self-addressed stamped envelope for their convenience. Participants from outside sources will have the opportunity to consider the study with their partner before signing the consent form in the same manner as the other recruitment avenues above.

The utmost sensitivity will be used during the recruitment processes, and all contact will comply with Vancouver Coastal Health Privacy Office standards. Given the high number of men diagnosed and treated for prostate cancer, the exceedingly high numbers of men who go on to experience distress related to treatment side effects, and the limited community access to sexual health experts with training in prostate cancer in British Columbia, we believe that many patients will appreciate learning about the study via the abovementioned means.

STUDY OUTCOMES

As part of baseline measures, participants will be asked for basic demographic variables such as age, gender-identification, marital status etc. for basic reporting purposes. They will also be asked about information regarding sex including orientation, circumcision status, time since prostate cancer treatment etc. Full demographic questionnaire can be found in section 9.5 of the application. As we are aware of participant burden, the questionnaire packages will take no longer than 30 minutes to complete at each time point.

The **primary endpoint**s of the current study are **self-reported intimacy correlates**. They will be assessed using the following measures:

Relationship satisfaction	Adapted dyadic adjustment scale (A-DAS[66]). The A-DAS is a validated, 7-item measure that assesses relationship adjustment.
Sexual satisfaction/distress	Female sexual distress scale (FSDS[67]). The FSDS is a 13-item measure that assesses sexual distress. Although named for it's use with women, this measure has been validated as a measure of sexual distress in women and men.
Sexual functioning	International Index of Erectile Functioning (IIEF[68]). The IIEF is a 15-item validated measure of men's self-reported sexual functioning; it is considered the gold-standard measure in the sexual-dysfunction literature. OR International Index of Erectile Functioning for Men who have sex with men (IIEF-MSM[69]). The IIEF-MSM is a 22-item measure of sexual dysfunction that has been adapted from the IIEF for use with men who have sex with men (MSM). OR Female Sexual Functioning Index (FSFI[70]). The FSFI is a 19-item measure of self-reported sexual dysfunction in women.
Sexual behaviours	Sexual activity scale. This is a questionnaire developed by the study lead that asks individuals to rate the frequency of times that they engaged in a range of sexual activities over 3 time-periods: (a) ever, (b) since their/their partner's prostate cancer surgery, and (c) in the past 4 weeks.

The **secondary endpoints** of the current study are mental and health-related quality of life indices. They will be assessed using the following measures:

Psychological well-being	Hospital Anxiety and Depression Scale (HADS[71]). The HADS is a validated, 14-item measure of depression and anxiety.

Distress	Distress Thermometer[72]. The distress thermometer is a single-item distress screening scale, which has been shown to be a valid measure of cancer-specific distress among prostate cancer patients and their partners. Participants indicate their current level of distress on an 11-point scale.
Overall quality of life	World Health Organization Quality of Life – BREF (WHOQOL-BREF[73]). This is a 26-item measure that assesses overall quality of life in the domains of physical health, psychological well-being, social relationships, and environmental well-being.

The **tertiary endpoints** of the current study are treatment mechanisms factors. These will be assessed using the following measures:

Treatment adherence	Expectations for treatment. A 4-item questionnaire, designed for and used in our approved mindfulness-based treatment study for women with provoked vestibulodynia (H12-02358)
	Therapeutic Skills Practice. This is a questionnaire designed by the experimenters to assess the amount that participants practice the skills taught in treatment. Participants will indicate the skills practices each day, and number of minutes they spent practicing each skill. This log will be completed as a separate, online questionnaire that participants will access daily. Participants have the option of completing a paper-version of this log, which they will give to the Study Coordinator each week.
Individual factors	Five Facets of Mindfulness questionnaire; Short form (FFMQ-SF[74]). The FFMQ-SF is a validated, 24-item measure of different aspects of mindfulness..
	Big Five Inventory - 10 (BFI-10[75]). An adapted, brief 10-item measure of personality characteristics.
	Pre-treatment sexual functioning. This is an experimenter derived questions asking participants to indicate if they have a history of sexual dysfunction that preceded their own/their partner's prostate cancer treatments.
	Treatment and Medical History This measure will review date of diagnosis, disease severity, any treatments, treatment duration, and the time elapsed from prostate cancer treatment to enrollment. This will take place at time 1 and reviewed at time 3 to capture changes.

The **qualitative data analyses** will explore meaningful treatment outcomes from the perspective of men and their partners. This will be assessed using a semi-structured interview. The interview contains a series of investigator-derived questions about participant experience in the study, including questions about participation in treatment groups (for those randomized to the treatment arm), or the experience of not taking part in a treatment group (i.e., the control arm). The interviewer will follow up on responses as needed to ensure all meaningful information is discussed. See section 9.5 for interview questions.

DATA ANALYSIS

HYPOTHESIS 1a. Our **primary hypothesis**—that **intimacy** correlates will improve following treatment—will be assessed using repeated-measures multiple analysis of variance (MANOVA), comparing outcomes at three time points [Time 1 (pre-treatment), Time 2 (post-treatment), Time 3 (6-month follow-up)] for the 3 treatment arms (mindfulness, CBT, control). Primary endpoint measures will be used as the dependent variables in a single MANOVA (e.g., dyadic adjustment scale scores, female sexual distress scale scores, IIEF/IIEF-MSM/FSFI scores). Relevant demographic variables (e.g., age) will be included as covariates to control for their effects.

HYPOTHESIS 1a. Our **secondary hypothesis**—that **quality of life** endpoints will improve following treatment—will be assessed using repeated-measures MANOVAs again comparing outcomes at three time points [Time 1 (pre-treatment), Time 2 (post-treatment), Time 3 (6-month follow-up)] for the 3 treatment arms (mindfulness, CBT, control). Secondary endpoint measures will be used as dependant variables in a single MANOVA (e.g., HADS scores, Distress Thermometer score, WHOQOL-BREF score). Again, relevant demographic variables (e.g., age) will be included as covariates to control for their effects.

HYPOTHESIS 1b. The hypothesis that the two active treatments (mindfulness and CBT) will not significantly differ from one another with respect to patient outcomes will be assessed in the abovementioned MANOVAs, as treatment arm (mindfulness, CBT, control) is an independent variable included in the analysis. Main effect of treatment arm will be assessed, and follow-up ANOVAs will be carried out in the event of a significant main effect. We expect mindfulness and CBT will not significantly differ from one another, but both will show significant improvements compared to the control arm.

HYPOTHESIS 2a. The **tertiary hypothesis**—that the couple's outcomes will be moderators by **treatment adherence** factors—will be assessed using moderator analyses. In these moderator analyses, primary endpoint measures will be the dependent variable (i.e., intimacy measures mentioned above), time-point (Time 1, Time 2, Time 3) will be the independent variable, and treatment adherence variables (e.g., expectations for treatment questionnaire scores, amount of therapeutic skills practice) will be entered as moderators.

HYPOTHESIS 2b. The **tertiary hypothesis**—that couple's outcomes will be moderated by **individual factors**—will be assessed using moderator analyses mentioned above with individual factors (e.g., five factors of mindfulness questionnaire scores, big five inventory scores, pre-treatment sexual functioning scores) as moderators.

HYPOTHESIS 2c. The **tertiary hypothesis**—that couple's primary intimacy outcomes will be moderated by **secondary quality of life outcomes** will be assessed using moderator analyses as well, with QOL outcomes (i.e., HASD scores, distress thermometer rating, WHOQOL-BREF scores) included as moderators.

ADDITIONAL EXPLORATORY ANALYSIS OF MODERATORS: We also intend to include multiple regression analyses to determine predictors of treatment efficacy. In these analyses, regression analyses will be conducted with each primary outcome as the independent variable (dyadic adjustment scale scores, female sexual distress scale scores, IIEF/IIEF-MSM/FSFI scores), and secondary quality of life outcomes as well as tertiary treatment factors (e.g., treatment adherence factors, individual factors) included as predictors.

EXPLORATORY ANALYSES: As the current study offers a novel exploration of mindfulness-based and CBT interventions as a treatment for couple's sexual difficulties, we also intend to include hypothesis-generating exploratory analyses with our data analyses. These analyses will be born from the abovementioned core statistical analyses that we propose with this study.

QUALITATIVE ANALYSES: Finally, qualitative data analyses using a Grounded Theory Approach[76] will be conducted on the transcribed qualitative exit interviews. Themes will be identified and extracted by independent reviewers.

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