IT'S NOT ALL ABOUT THE ERECTION: EXAMINING SEXUAL FUNCTIONING AND PATTERNS OF SEXUAL ACTIVITY AFTER RADICAL PROSTATECTOMY

by

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ABSTRACT

This study examined the process of sexual recovery after surgical treatment for prostate cancer in a sample of 527 men in relationships, both in the context of their broadly measured Expanded Prostate Cancer Index Composite (EPIC) sexual functioning summary scores (Aim 1) and in frequencies of sexual activity (Aim 2). Across a period of 5 years, men submitted data up to 10 times about a variety of factors related to sexual quality of life (e.g., levels of sexual desire). Hierarchical linear growth modeling was used to estimate individual growth trajectories for each outcome, allowing for simultaneous examination of intraindividual and interindividual variability. Although everyone experienced a decrement to both outcomes immediately after surgery, results suggested that younger age, higher pretreatment sexual functioning and frequencies of sexual activity, and receiving nerve-sparing procedures were associated with better sexual functioning and higher frequency of sexual activity several months after surgery. Most men's levels of sexual functioning improved over time, though those with higher pretreatment sexual functioning increased at a faster rate. Although on average there was a slight, steady improvement over time in frequencies of sexual activity, individual men also varied from month-to-month around their own average levels of sexual activity depending on changes in sexual desire, confidence in satisfying a partner, perceived erectile ability, perceived orgasm ability, and whether or not they used sexual aids that

month. These findings are discussed in the context of methodological and clinical implications in order to guide future research targets and improve clinical interventions.

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INTRODUCTION

Prostate cancer is one of the most common cancers in men (CDC, 2011) and is typically characterized as slow-growing, initially asymptomatic, and often still localized at the time of detection (Howlader et al., 2012). This is a cancer with impressive survivorship rates: nearly 100% of men are still alive at 5 years and 91% at 10 years (Galbraith et al., 2011) from detection. Though prostate cancer has traditionally been identified primarily in older men (e.g., Ahmedin et al., 2004), the age of survivors is trending younger, with a recent study finding the mean age of new diagnoses to be 63.6 (Glass et al., 2013). Further, most men are in a romantic relationship at the time of diagnosis (e.g., Davison & Breckon, 2012). Thus, men are now likely to be diagnosed with prostate cancer at a period when they still expect to have many years of high quality of life remaining to spend with their partners.

Approaches for screening and treating prostate cancer have evolved rapidly over the past few decades, which have influenced the complexity of navigating the disease. As the medical model has shifted towards a patient-centered approach, patients have become increasingly involved in treatment decision making (Kon, 2010; Maliski et al., 2002) and a greater emphasis has been placed on measuring and improving psychosocial outcomes (Weber & Sherwill-Navarro, 2005). For some, increased agency for complex health conditions like prostate cancer can be overwhelming, due to the need to simultaneously balance emotionally processing the diagnosis with the logistical challenges of

information gathering and attending numerous medical appointments before making a decision (Holmboe & Concato, 2000). Further complicating this process, advancements in the number, efficacy, and safety of treatment options have resulted in many treatments from which to choose (National Cancer Institute, 2014).

The treatment of focus in the current study, radical prostatectomy (RP), involves removing the prostate gland during a surgical procedure, and recent options for minimally invasive, nerve-sparing approaches to attempt to decrease complications have resulted in this treatment remaining a common choice (e.g., O'Shaughnessy et al., 2013). Unfortunately, each of the available options, including RP, have been shown to cause at least temporary side effects (i.e., sexual, urinary, and bowel problems), which can significantly impact quality of life for both partners and may linger for years or become permanent for some men (e.g., Beck et al., 2009; Song et al., 2011). Considering the common consequences of treating this illness, it is important that doctors and their patients understand both the risks of each treatment option and how various factors influence quality of life after treatment, in order to ensure an educated treatment decision.

Existing Literature on Sexual Quality of Life After Treatment for Prostate Cancer

The side effect that has garnered the most research interest is sexual dysfunction. This is the most common long-term side effect and considered by most men and their partners to be the most distressing (Bokhour et al., 2001; Clark et al., 1999; O'Shaughnessy et al., 2013), particularly when they are surprised by the severity and time course of sexual problems after treatment (Mohamed et al., 2012). Research suggests that sexual problems after surgery may negatively affect multiple types of health-related quality of life, including significant emotional distress (e.g., Davison et al., 2007); overall health and general physical functioning (e.g., Brassel et al., 2013); relationship satisfaction (Yoo, Bartle-Haring, Day, & Gangamma, 2014); and depression and anxiety (e.g., Nelson et al., 2007; 2011). Research further suggests that unrealistic expectations about sexual functioning after treatment may contribute to treatment regret (e.g., Clark et al., 2003).

Thus, it is critical to find ways to improve men's sexual quality of life after prostate cancer, particularly by identifying interventions to resolve sexual problems or cope with treatment-related changes (Reese et al., 2010). It would also be valuable to increase our understanding of the typical recovery process in order to provide couples with more accurate postsurgery expectations when making treatment decisions (Paisch et al., 2016; Wittmann et al., 2015). If there are individual differences and/or treatment factors that affect the rate of recovery, couples could use that information to inform their treatment decision. For example, if a subset of men is unlikely to experience any significant recovery for as long as a year after treatment, it is important they be prepared for such an outcome. This information would also be useful for health care providers, both in helping patients make a treatment decision and in evaluating their recovery.

Although there are a multitude of published findings on sexual and erectile functioning after surgical treatment for prostate cancer, significant variability has been found within and across studies that has limited their use in providing men with guidance related to the recovery process (Brassel et al., 2013; Lubeck et al., 1999; Mulhall, 2009). Overwhelmingly, the existing research has examined sexual functioning at a single point in time after treatment (e.g., 12 months) and compared it with functioning immediately after treatment. These studies demonstrate clearly that most men experience some decrement in functioning immediately after surgery (see Mulhall, 2009); however, research on other points in time after treatment have demonstrated the substantial individual differences between men. Although some studies have concluded that men's levels of sexual functioning early after treatment are predictive of sexual functioning several years later, studies in this area rarely measure men far enough into the recovery period to accurately characterize that process over time (e.g., Stensvold et al., 2013). The few recent studies that have included several points of follow-up (e.g., 1 year and 2 years) are consistent with conclusions that many men may continue to change over time (e.g., Bokhour et al., 2001; Brassel et al., 2013).

Without following and repeatedly measuring the same men's sexual functioning across numerous points of follow-up, it would be challenging to statistically characterize their trajectories of recovery, make conclusions about the moderating effect of individual difference variables on those trajectories, and predict with any accuracy what newly diagnosed men might expect after treatment in terms of functioning. Using longitudinal data analytic approaches for research in this area would allow a robust examination of the recovery process over time, including variations in rates of recovery based on the influence of within-individual and between-men variables. Additionally, given that fully understanding the process of recovery after treatment would involve multiple observations for each man and then comparing groups, the data are considered to be nested. Failing to account for dependency in nested data can have consequences for the accuracy of the estimates and for the interpretation of the results (Raudenbush & Bryk, 2011). Longitudinal analytic procedures, such as hierarchical linear growth modeling, have the ability to account for the dependency in nested data, and can use each individual man's points of follow-up to generate a trajectory for his data that can then be used to identify trends in the data.

In considering the individual difference variables to include in longitudinal studies, the existing research provides some evidence of factors that appeared to influence sexual functioning at certain points after surgery (e.g., a benefit of younger age found at 24 months; Moskovic et al., 2011). For the influence of patient age, others have found this same result at different points in time after treatment (e.g., Rabbani et al., 2000). It is possible that these studies have identified uniquely relevant points in time when age influences sexual functioning, but age may also be influential in a more global way not yet examined, such as in men's trajectory of recovery (i.e., rates of recovery). Including these influential factors in more sophisticated analyses may help us better understand the duration or timing of their influence after surgery, as well as clarify other discrepancies in the existing research. So, although prostate cancer studies have not examined whether older men may recover at a different rate than younger men, it is well established in other health research that older men, due to various health factors (e.g., decreased blood flow, comorbidities), experience a slower return to functioning after illnesses and medical procedures (Sigler et al., 2003). This suggests that we might find that older men would recover their sexual functioning after RP at a slower rate than younger men.

Relatedly, sexual functioning prior to treatment likely influences the rate of recovery. Since previous research has found that men with lower pretreatment functioning continue to be lower functioning at different points after surgery than those with higher pretreatment functioning (Moskovic et al., 2011; Rabbani et al., 2000; Song

et al., 2011), it may be that low pretreatment functioning predicts a flatter trajectory of recovery after surgery than would be observed in those with higher pretreatment functioning. Finally, surgical treatment characteristics may play a role in the rate of recovery of sexual functioning. When medically appropriate, most men undergo at least partial nerve-sparing procedures (also called unilateral and modified nerve-sparing), with a recent study (Stensvold et al., 2013) reporting only 11% received no nerve-sparing while 37% received unilateral nerve-sparing and 52% bilateral nerve-sparing. Several studies have found that degree of nerve-sparing is positively related to men's sexual functioning at various points after treatment (e.g., Moskovic et al., 2011; Rabbani et al., 2000; Stensvold et al., 2013). It is unclear from existing research how sparing the nerves may specifically influence posttreatment functioning, such as whether it may result in more rapid recovery of their sexual functioning. However, one study found that bilateral nerve sparing resulted in more rapid recovery of urinary control than did non-nervesparing procedures, likely due to sparing nerves also implicated in sexual functioning (e.g., inferior hypogastric plexus, Hollabaugh et al., 1998). Thus, it would be expected that an increased degree of nerve sparing would result in a faster rate of recovery.

There is conflicting evidence regarding the presumed superiority of roboticassisted procedures in producing better posttreatment sexual functioning when compared to traditional open procedures (e.g., Ball et al., 2006; Menon et al., 2007; Mulhall, 2009). The argument is that robotic-assisted procedures improve surgeon visibility and precision, while decreasing error, resulting in decreased blood loss and more rapid physical recovery overall (Menon et al., 2002), but it is not clear how or if that would translate to better long-term sexual functioning. Even if robotic-assisted techniques are not reliably more effective in maintaining sexual function, they may result in quicker return to function than open surgical approaches. Therefore, it would be important to examine whether robotic procedures result in a faster rate of sexual functioning recovery after treatment than traditional procedures.

In summary, multilevel longitudinal studies are necessary to (1) increase our understanding of the sexual recovery process after surgery and to (2) more robustly examine the influence of the above individual difference factors on men's recovery rates for sexual functioning. Doing so would improve the accuracy of the information provided to men about what to expect across time after surgery.

Sexual Activity and Health-Related Quality of Life

We now focus on a related topic rarely directly examined in the prostate cancer literature: frequency of sexual activity after treatment. Research suggests that prior to diagnosis many couples are still engaging in sexual activity and view a change to be of significant concern (e.g., Bokhour et al., 2001; Galbraith et al., 2011). For most couples making a treatment decision, considering the potential loss of their sexual activity can be an important aspect of that choice (Holmboe & Concato, 2000). Indeed, continued sexual intimacy into the later stages of life has been shown to be important for emotional wellbeing and physical health for many older adults (Lindau et al., 2007; Willert & Semans, 2000). For many in late adulthood, sexual activity continues to be an important way of expressing love (e.g., Campbell & Huff, 1995; Katz, 2015). Recent work has especially highlighted the importance of learning more about the factors that influence a couple's frequency of sexual activity (including, but not limited to, sexual intercourse) after prostate cancer treatment in order to better understand the quality of life implications of their treatment (e.g., Wittmann et al., 2015). Specifically, some have suggested that nonintercourse sexual activity and intimacy (such as communication about sex and physical affection) with a partner after treatment might serve as a buffer against some of the negative aspects of sexual dysfunction (e.g., Badr & Taylor, 2008; Clark et al., 2003; Manne & Badr, 2008; Reese et al., 2010).

In the prostate cancer literature, the most common sexual quality of life outcome examined after treatment is the broad term sexual functioning. The measures examining this construct usually include multiple indicators, typically focusing on quality of erections and ability to successfully complete penile-vaginal intercourse (e.g., EPIC; Wei, Dunn, Litwin, Sandler, & Sanda, 2000). However, this heavy emphasis on penile-vaginal intercourse and, more often, solely on erectile capacity without measuring actual sexual expression, overlooks the possibility that men could be engaging in frequent, satisfying sexual activity without it being captured by these measures. Currently, only one measure (the long version of the EPIC; Wei et al., 2000) asks about the frequency of any sexual activity, and as a single item contributing to a summary score from nine items, has relatively little impact on that score. Thus, the influence of individual components on that total score are masked, and it is possible that ratings on individual items could fluctuate without an observed change in the overall score. From a clinical standpoint, it is challenging to meaningfully interpret changes in one's overall sexual functioning score over time given that it is a composite of many factors, both physiological and psychological, which may not all be equally related to men's experience of his sexual quality of life. For example, since a man could have an improvement in REM sleep erections that influences the overall score, it might appear as if he is having better

functioning without any meaningful improvements to his reported experience. Unfortunately, it is usually only the total score that gets considered in the research in this area, such that when couples inquire about what the quality of their sex lives will look like after cancer, there is little specific information available (Wittmann et al., 2015).

Further, while men recovering from prostate cancer treatment may have a reduction in erectile capacity, this does not preclude them from engaging in certain sexual activities with their partners, and couples who have adjusted well to a decrement in erectile capacity through alternative types of satisfying sexual intimacy would likely be missed in these types of studies. Intervention research in this area has also commonly relied on these same broad sexual functioning outcomes when their goal is specifically to improve couples' sexual intimacy and satisfaction (Chambers et al., 2015). Examining rates and quality of sexual activity may better capture meaningful changes to sexual expression that couples may experience as a result of surgery, and allow for identifying any moderating factors. Thus far, only a few qualitative studies have directly examined sexual activity after prostate cancer treatment, and have primarily done so by interviewing couples (e.g., Wittmann et al., 2015). While contributing valuable information to the literature, this approach has methodological limitations, is time-consuming, and necessarily results in relatively small samples.

As mentioned above, there are a variety of reasons that patterns of sexual activity after cancer treatment might be an important research target. Considering that couples' concerns are strongly related to minimizing the loss of sexual intimacy (e.g., Bokhour et al., 2001; Clark et al., 2003; Hordern & Street, 2007), there is little available information about the factors that are related to higher frequency of sexual activity after prostate cancer treatment. The return to satisfying rates of sexual activity (irrespective of the degree of coital functionality) is unlikely to be the same for all men. It is likely that men may see an increase in frequency of sexual activity at different rates after surgery, possibly due to some of the same factors as identified in sexual functioning research (e.g., age). Further, research suggests that rates of sexual activity across time are somewhat variable for older men and are related to factors such as sexual desire and sexual self-esteem (e.g., Kontula & Haavio-Mannila, 2009).

There may be other factors than erectile capacity that influence rates of sexual activity after prostate cancer within an individual, since it is quite possible for men to engage in sexual activity with a partner without an erection strong enough for intercourse, such as oral-genital or manual-genital stimulation. It is also possible for men to orgasm without a full erection or even in the absence of an erection (Koeman et al., 1996). In fact, techniques used in some prostate cancer quality of life interventions focus on coping with changes in pleasure and intimacy through alternative sexual activities (e.g., Canada et al., 2005). Investigating the influence of additional factors (other than erectile capacity) that influence men's frequency of sexual activity after treatment would be valuable to men making treatment decisions and to those developing treatment interventions targeting sexual activity after treatment (e.g., Reese et al., 2010).

Objectives for the Current Study

This project examined the longitudinal trajectories of sexual quality of life after surgical treatment of prostate cancer. In particular, an emphasis was placed on two main aims: (1) examining the between-men factors that influence rates of recovery for sexual functioning and (2) examining both between-men (e.g., pretreatment sexual activity) and

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within-men factors (e.g., confidence in ability to satisfy partner) that influence the frequency of sexual activity over time. In combination, the aims were designed to increase the understanding of what accounts for the variability reported across studies in men's sexual quality of life after prostate cancer treatment, with the ultimate goals of helping men and their treatment providers make more informed treatment decisions and guiding posttreatment interventions. This project sought to improve on methodological limitations in previous work by using advanced statistical procedures designed for nested longitudinal data.

Aim 1: Trajectories in Sexual Functioning Recovery

This first aim examined the rate of recovery of men's sexual functioning with two questions. First, do men vary in their rate of recovery for sexual functioning after prostate cancer treatment? As discussed above, research has found wide variation in sexual functioning at various points after treatment, strongly suggesting that men differ in their rates of recovery after treatment. Thus, it was hypothesized that there would be variation in men's trajectories of sexual functioning recovery, such that some men would experience a faster rate of recovery while other men would experience a slower rate of recovery. Second, what factors account for the differences between men in rate of recovery? We hypothesized that the following four between-subjects factors would influence the rate of sexual functioning recovery: age, pretreatment sexual functioning, type of surgical approach (open vs. robotic), and degree of nerve-sparing (none, modified, and bilateral). Specifically, it was hypothesized that those younger men with better pretreatment sexual functioning who received robotic surgery with a greater degree of nerve-sparing would recover sexual functioning at a faster rate than would other men.

Aim 2: Factors That Influence Men's Frequency of Sexual Activity

Sexual activity after prostate cancer treatment has not yet been directly examined through measurement over time in the literature, including identification of factors that might influence sexual activity over time. This study sought to answer the following research questions associated with this. First, is there an association across time between time-varying factors (e.g., levels of sexual desire) and frequency of sexual activity? Qualitative work in prostate cancer (e.g., Bokhour et al., 2001; Chung & Brock, 2013; Clark et al., 2003; O'Shaughnessy et al., 2013; Wittmann et al., 2015; Zaider et al., 2012), as well as other work focusing on sexuality in older adults (Kontula & Haavio-Mannila, 2009), has suggested a number of factors that may relate to couple's frequency of sexual activity over time, including self-image and confidence (especially related to ability to please a partner), perceived erectile ability, levels of sexual desire, and perception of orgasm ability. Further, the use of sexual aids, such as medication and injection, improve the ability to engage in a number of sexual activities (Plym et al., 2014) and are likely related to increased frequency of sexual activity. Thus, it was hypothesized that the monthly fluctuations in these five factors would influence men's frequency of sexual activity across time. Specifically, during those months when men report higher levels of confidence in ability to please a partner, greater orgasm ability, greater sexual desire, greater ability to have an erection, and use of any erectile aids, it was hypothesized that they would engage in sexual activity (included, but not limited to, intercourse) with a greater frequency than other months.

Second, do men differ in their frequency of sexual activity over time after treatment and what between-subjects factors accounts for those differences? It was hypothesized that increases in the frequency of sexual activity over time would vary as a function of age, pretreatment sexual activity, type of surgical approach, and degree of nerve sparing. Specifically, it was anticipated that younger men with greater pretreatment sexual activity who received robotic surgery with a greater degree of nerve sparing would engage in sexual activity with a greater frequency over time than other men.

METHOD

Participants

The current study utilized the data from an ongoing longitudinal project examining health and quality of life outcomes after treatment for prostate cancer. Participants were from the Prostate Disease Oriented Team (PDOT) database, maintained by medical care providers at the Huntsman Cancer Institute in Salt Lake City, Utah since 2002. The data used were a subset of participants from the total database who completed paper versions of the questionnaires containing all variables of interest. Initial eligibility criteria included that men be previously diagnosed with prostate cancer and have completed surgical treatment. Since we were primarily examining sexual functioning and activity, we included only men who reported having some type of partner (excluded 38 cases). Given our interest in change over time, we only included respondents who contributed at least three data points, as well as pretreatment baseline, on the measures and items of interest in this study (excluded 107 cases). The final sample included 527 participants. This study was approved by the Huntsman Cancer Institute IRB, and use of these data falls under that institution's approval.

Participants ranged in age from 43 to 78 (M = 60.81, SD = 6.71). Most were Caucasian (97%), with all other ethnicities each amounting to 1% or less of the sample: Asian/Asian American/Pacific Islander 1%, Latino/Hispanic 0.8%, Black/African American 0.2%, Native American/Alaskan Native 0.2%, and 0.8% identified as "Other." Participants were overall highly educated: 37.6% were educated through graduate school, another 49.1% attended college and 25.6% of those graduated, and only 13.3% endorsed a high school/technical school education or less.

Procedures

Participants were initially recruited to the study by their nurse and their medical specialist at the "treatment options consultation" after diagnosis, who provided them with information about the purpose of the study and asked if they were interested in participating. They were told that as part of participation in a longitudinal study through HCI, they would be asked to complete a set of questionnaires about their experiences with prostate cancer treatment and quality of life. They were told they would be contacted at approximately the following points to complete the questionnaires: prior to treatment, every 3 months for the 1st year posttreatment (3, 6, 9, and 12 months), every 6 months during year 2 (18 and 24 months), and then yearly through up to 5 years (36, 48, and 60 months). Note that although these were the approximate points at which patients were contacted, patients varied in when they returned the packets. They were informed that they would not be financially compensated for their participation and that they could refuse to participate or drop out at any time without negatively impacting their access to medical care. After consenting to participate in the study, men were provided with a questionnaire packet, either in person or via mail depending on the patient's preference, to complete and return by the time they proceeded with treatment. The specific date on which the patient returned the questionnaire packet was recorded.

At the time of each point of follow-up, a member of the Huntsman Cancer Institute staff contacted them, reminded them of the value of their participation, and either asked them to fill out the packet at their follow-up appointment or mailed them the questionnaire packet after urging them to return it promptly. As much as possible, patients were prompted to fill out packets around the time of regularly scheduled follow-up appointments, which usually closely followed the targeted schedule for the study. If they did not return the packet within a week, they were reminded via phone. The date they returned the questionnaire packets was recorded. If they missed a given point of follow-up, they were asked again at the next point unless they asked to be removed from the study. Participant data were entered by members of the research team into a computerized database, which was de-identified prior to use for research purposes.

Measures

The full questionnaire packet, which included the same items at baseline and all follow-up points, consisted of a number of measures designed to gain information about men's demographics, quality of life, and physical functioning following treatment. From the battery given to participants, the following was used for this study.

Functioning and Quality of Life

The Sexual Functioning subscale of the long version of the Expanded Prostate Cancer Index Composite (EPIC; Wei, Dunn, Litwin, Sandler, & Sanda, 2000) included such questions as "How would you describe the usual QUALITY of your erections during the past four weeks" on a 1 (*very poor to none*) to 5 (*very good*) scale. This measure has been shown to have adequate reliability and validity across multiple treatment types, including surgery (Wei, Dunn, Litwin, Sandler, & Sanda, 2000), and is one of the most commonly used measures to evaluate sexuality quality of life in the literature (Punnen et al., 2013).

The score from the Sexual Functioning domain was used for Aim 1, in order to be comparable with previous research. In order to study this construct independent of the frequency of sexual activity (examined in Aim 2), the EPIC Sexual Functioning score was calculated without the inclusion of the frequency of sexual activity item. Thus, this score was made up of eight items, and was calculated as follows: each item was converted to 0-100 scale and then averaged for a total score. For Aim 2, the outcome variable was the frequency of sexual activity item, i.e., item 5: "During the last 4 weeks, how often did you have <u>any</u> sexual activity?" on a 1 (*none at all*) to 5 (*daily*) scale. The predictors included the following items from this measure: "How would you rate each of the following during the last 4 weeks? a. your level of sexual desire, b. your ability to have an erection, and c. your ability to reach orgasm" on a 1 (*very poor to none*) to 5 (*very good*) scale (Appendix A).

Additionally, physicians included questions asking about sexual aid use ("Which of the following, if any, have you used in the past 4 weeks to improve your erections?" offering five options, i.e., medication, penile injection therapy, vacuum erection device, MUSE, and the option to write in "other" sex aid), which was scored dichotomously to indicate no use or use in the previous month, and confidence in ability to satisfy partner ("How would you rate...during the past 4 weeks your ability to satisfy your spouse or partner sexually" on a 1 (*very poor to none*) to 5 (*very good*) scale). This item was asked both with and without using medication, and the highest score was taken to indicate greatest confidence (Appendix A).

Finally, some information about the patient and their treatment characteristics was

recorded by the patient's medical team rather than asked directly of the patient. This included patient's date of birth, type of surgical treatment (i.e., open vs. robotic), and degree of nerve-sparing (e.g., none, modified, and bilateral). All open procedures used a retropubic abdominal incision, while robotic-assisted procedures used laparoscopic abdominal incisions. For the purpose of this study, the degree of nerve sparing was determined by the patient's surgeon and was based on the estimated percentage of nerves spared during surgery.

RESULTS

Multilevel modeling procedures (via HLM version 7 software; Raudenbush, Bryk, & Congdon, 2011) were used to address study aims, which allowed the examination of effects at multiple levels of the data. Specifically, the purpose was to analyze a data structure where lower-level time observations (level-1) were nested within men (level-2). Models are described using the common terminology for multilevel modeling (Raudenbush et al., 2011). HLM utilizes restricted maximum likelihood, which robustly handles missing data at level-1 when modeling individual trajectories. Missing data at level-2 amounted to less than 5% of the data, and listwise deletion was used to handle this. This software program is particularly beneficial in its handling of unbalanced data, which in this study included men varying both in their number of time points and the date on which they returned each questionnaire packet relative to the target month. For each point of follow-up, time was calculated as the number of months since the individual's baseline. A predicted trajectory, with intercept and slope, was then created for each individual. Models for both Aims were primarily set up and analyzed the same way, with the exception of the addition of five time-varying covariates (TVCs) at level-1 in Aim 2 (i.e., level of desire, perceived erectile ability, perceived orgasm ability, confidence in ability to satisfy one's partner, and use of sexual aids). In addition to the advantage of HLM in simultaneously estimating level-1 and level-2 nested data, it also allows for examination of monthly associations between variables of interest (TVCs) and the

outcome.

Descriptives

First, study variables were examined in their raw state to obtain descriptive information, test for multicollinearity and meeting assumptions of normality, and to ensure that a linear model was an appropriate fit for the data, prior to running models. Descriptions of data transformations (e.g., centering decisions) are listed below by the appropriate Aim. Given that men were allowed to vary in the number of follow-up points completed at the time of the study, as well as the exact timing relative to the study targets in which they submitted data for each point of follow-up, we examined these patterns in our sample. Although participants had to contribute pretreatment data plus three points of follow-up at the time of the study in order to be included, most had participated at a higher rate (Range: 4-11 time points; M = 7.26, SD = 2.02; Median = 7). The median number of days prior to surgery that men supplied pretreatment data was 6, though the modal time was the day before surgery. Most men attended their first follow-up appointment between 1 and 3 months after surgery, at which time they submitted posttreatment baseline data (M = 2.03, SD = 1.45). More participants in the study received robotic assisted laparoscopic procedure (62.2%) than an open retropubic one (37.7%). Participants also varied in the degree to which the nerves around the prostate were spared (i.e., None: 14.4%, Modified/Unilateral: 40.1%, Bilateral: 45.3%). Participants in our sample were more likely to have had at least some nerves spared if they had a robotic procedure (96%), than if they had an open one (68%), $X^2(1) = 74.68$, p < .001. Those variables unique to a given Aim (i.e., pretreatment sexual functioning, pretreatment sexual activity, the five TVCs) are described below in the appropriate Aim.

Aim 1: Trajectories in Sexual Functioning Recovery

Preliminary analyses on sexual functioning suggested that, on average, men experience a significant decrement from pretreatment (M = 59.23, SD = 24.48) to posttreatment baseline (M = 25.18, SD = 20.80), t(498) = 34.94, p < .001. In order to examine whether there was sufficient within-individual and between-subjects variance in the outcome to test our hypotheses, an unconditional model was run first with no predictors (see Appendix B). This model revealed an intraclass correlation coefficient (ICC) of .64, indicating that 64% of the total variance in sexual functioning scores after surgery was between men. This significant variance component also justified testing both level-1 and level-2 predictors, as hypothesized. Next, in order to address the first research question for this aim (i.e., Do men vary in their rate of recovery for sexual functioning after prostate cancer treatment?), the unconditional random growth model added linear time (in months) as the only predictor to determine whether it accounted for variance in sexual functioning. Significant variance components were present both on the intercept, i.e., men's initial sexual functioning scores at posttreatment baseline, and on the slope, in linear change over time (see results of preliminary analyses in Appendix B). This suggests that men differed both in their level of sexual functioning early after surgery, as well as in overall rate of improvement over time, or trajectories. Thus, even though hypotheses were not offered about differences at baseline, we decided to explore the possible factors that might explain this variance by including the same level-2 predictors on the intercept as were planned for the slope. The significant slope of the baseline model, B = .27, SE = .02, p < .001 (for every 1-month change) suggested that the average man improved approximately 3.24 points on the sexual functioning scale each year from

baseline (scored 0-100). Further analyses found that linear time accounted for 29% of the within-man variance, and that the model was significantly improved by the inclusion of the level-1 predictor time, as well as by random effects on the intercept and time. Thus, all further models included these.

Next, to address the second research question (i.e., what between-subjects factors account for differences in sexual functioning after surgery), the following hypothesized predictors were examined: age, pretreatment sexual functioning, surgery type, and degree of nerve-sparing. Initially, each predictor was added independently as the sole level-2 predictor on the intercept and slope, with time as the level-one predictor. Thus, there were four 2-level models, where measures for each time point (level-1 time in months variable) was nested within-person (level-2 between-subjects variables).

In the basic level-1 equation,

$$Y_{ti}=\pi_{0i}+\pi_{1i}a_{ti}+e_{ti}$$

where π_{01} = sexual function at posttreatment baseline (a_{ti} = 0) for person *i*, π_{1i} = growth rate for person *i* over the data-collection period in months, and represents the expected change across months when a_{ti} = months since posttreatment baseline.

The level-2 equation for each model introduced a between-subjects factor and tested whether it accounted for variance in men's posttreatment baseline and/or recovery rates, e.g.,

$$\pi_{0i} = \beta_{00} + \beta_{01}(AGE) + r_{0i}$$
$$\pi_{1i} = \beta_{10} + \beta_{11}(AGE) + r_{1i}$$

where for the fixed effects, β_{00} = mean initial sexual functioning for the average-aged man at baseline posttreatment and β_{10} = mean rate of recovery across men. In this

example, age is centered at the grand mean, such that a significant effect on the intercept with a negative coefficient would indicate that older men had lower sexual functioning scores at baseline posttreatment than younger men, and a significant effect on the slope with a negative coefficient would indicate that older men had a slower rate of recovery over time than younger men.

Each model with a separate level-2 predictor revealed significant effects on both the intercept and the slope, indicating the appropriateness of including all four predictors in the final model. Additionally, interaction terms were initially included in models to test for a qualifying relationship of the degree of nerve sparing by surgery type, and then were subsequently removed when no effect was present.

Thus, the final 2-level model was as follows:

Level 1 SEXUAL FUNCTIONING_{ti} = $\pi_{0i} + \pi_{1i}^{*}(TIME_{ti}) + e_{ti}$

Level 2

 $\begin{aligned} \pi_{0i} &= \beta_{00} + \beta_{01}(AGE) + \beta_{02}(PRETREATMENT\ SEXUAL\ FUNCTIONING) + \\ \beta_{03}(SURGERY\ TYPE) + \beta_{04}(DEGREE\ NERVE\ SPARING_1) + \beta_{05}(DEGREE\ NERVE\ SPARING_2) + r_{oi} \\ \\ \pi_{1i} &= \beta_{10} + \beta_{11}(AGE) + \beta_{12}(PRETREATMENT\ SEXUAL\ FUNCTIONING) + \end{aligned}$

 $\beta_{13}(SURGERY TYPE) + \beta_{14}(DEGREE NERVE SPARING_1) + \beta_{15}(DEGREE NERVE SPARING_2) + r_{1i}$

where age and pretreatment sexual functioning are grand-centered, surgery type is dummy-coded (0 = open and 1 = robotic), degree of nerve sparing_1 is coded 0 = no nerve sparing and 1 = modified, and degree of nerve sparing_2 is coded 0 = no nerve

sparing and 1 = bilateral nerve sparing).

Results for the intercept suggested that the average posttreatment baseline level of sexual functioning after surgery was 10.98 for men of average age, who received open surgery, no nerve sparing, and with average pretreatment sexual functioning. For the intercept, there were significant main effects of age, degree of nerve sparing, and pretreatment sexual functioning (see Table 2 for all results). Of the level-2 fixed effects, the degree of nerve sparing had the greatest impact on baseline postsurgery sexual functioning, particularly for those who had bilateral nerve-sparing procedures (B = 18.61, SE = 2.22, p<.001). Indeed, post hoc analyses indicated a significant difference between modified and bilateral nerve sparing, with bilateral nerve-sparing procedures resulting in a higher baseline posttreatment level of sexual functioning (Estimate = 7.54, SE = 1.92), $\chi^2(1) = 1.95$, p < .001. As hypothesized, there was a significant fixed effect of pretreatment sexual functioning on the slope, which is illustrated in Figure 1. Post-hoc simple slopes indicated effects of pretreatment sexual functioning on posttreatment rates of recovery over time for men with both high pretreatment functioning (Estimate = 0.53, SE = 0.14), $\gamma^2(1) = 15.29$, p < .001), and low pretreatment functioning (Estimate = 0.33, SE = 0.13, $\gamma^2(1) = 6.24$, p<.05). It was also hypothesized that age, degree of nerve sparing, and surgery type would vary between men, which would influence their sexual functioning recovery rates; however, this was not supported in our models.

Thus, overall, Aim 1 results suggested that men differed in their levels of sexual functioning after treatment, as measured by the EPIC questionnaire, both in terms of levels early after surgery and in their rates of recovery over time. Younger men who received any amount of nerve sparing and who had higher pretreatment sexual

functioning, started higher than other men at postsurgery baseline. Bilateral nerve sparing had the most significant impact on levels of sexual functioning at baseline after surgery. From that early level of posttreatment functioning, there was improvement over time for most men, but the rate of that improvement depended on pretreatment sexual functioning, with higher functioning men experiencing a faster rate of recovery over time. In other words, having higher pretreatment sexual functioning resulted in men both starting off higher postsurgery and increasing faster over time.

Aim 2: Factors That Influence Men's Frequency of Sexual Activity

Descriptives for the scale-type TVCs and Aim 2 outcome are listed in Table 1, including means, standard deviations, and frequencies at pretreatment and baseline posttreatment. For the dichotomous TVC, sexual aids, more men reported use in the early period after surgery (63.7%) than endorsed them prior to surgery (16.1%; χ^2 (1) = 12.67, p < .001). Of the men who noted erectile aid use prior to surgery or early after surgery, medication (i.e., PDE-5 inhibitors, such as Viagra) was by far the most common, with less than 10% of men endorsing any other option (e.g., at baseline postsurgery: medication 96.5%, penile injection therapy 2.5%, 0.3% vacuum erection device, and other 0.6%). Preliminary analyses suggested that, on average, men experienced a significant decrease in rates of sexual activity from before surgery (M = 2.67, SD = 1.06) to the early period (i.e., first few months) after surgery (M = 2.03, SD = 1.05), t(498) =34.94, p<.001. Notably, even if there was a decrease in frequency compared to before surgery, over half (57.6%) of men at baseline posttreatment endorsed at least some sexual activity in the previous month.

In order to determine the appropriateness of testing research question one and two

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(i.e., whether there were within-person and between-men differences in the frequency of sexual activity after surgery), unconditional models first tested for variance components (see Appendix B). Results of the unconditional baseline model suggested significant variance within- and between-men in frequency of sexual activity (ICC: .59), which justified testing both level-1 and level-2 predictors. The unconditional random growth model further found significant variance components both on the intercept (men's initial frequency of sexual activity posttreatment) and on the slope (linear change over time). Thus, similar to Aim 1, we included the same level-2 predictors on the intercept as were planned for the slope. For the slope in the unconditional growth model, the coefficient was quite small (B= .001 average monthly increase, SE = .04, p<.001), suggesting that the average man would have to wait several years to experience much meaningful change solely from time, without considering other contributors (e.g., TVCs). Additional analyses demonstrated that 12% of the within-person variation over time in the frequency of sexual activity was explained by linear time.

Next, a series of models tested the five level-1 within-person TVCs of interest (i.e., confidence in ability to satisfy partner, sexual desire, perceived erectile ability, perceived orgasm ability, and use of sexual aids) to determine their appropriateness for inclusion in the final model. Initially, these models separately examined the effects of each TVC, including each of their relationships with time and their unique contribution. Including time separately in each model allowed an examination of whether there was a distinct effect of linear time on sexual activity (i.e., if improvement is steady and directly due to their temporal distance from the surgery date) or whether the within-men effect may have been fully accounted for by the monthly association between the TVCs and the outcome. In all growth models, random effects for the intercept and time, but not for the TVCs, were included. Also, in all growth models with TVCs, sexual aids was dummy coded 0 = no use, 1 = use. The remaining four TVCs were detrended (i.e., removing any linear growth over time) in SPSS software prior to their inclusion in models, as is the current recommendation for the use of TVCs in linear growth models (Curran & Bower, 2011). Detrending is a type of data transformation appropriate in longitudinal analyses with TVCs when person-centering is desired but growth in the TVC over time would violate those assumptions. The following describes an example of these preliminary analyses, where for the level-1 equation:

SEXUAL ACTIVITY_{ti} =
$$\pi_{0i} + \pi_{1i}a_{ti} + \pi_{2i}(ERECTILE \ ABILITY) + \pi_{3i}a_{ti}(ERECTILE \ ABILITY) + e_{ti}$$

where π_{01} = frequency of sexual activity at posttreatment baseline ($a_{ti} = 0$) for person *i* at his average level of erectile ability, π_{1i} = rate of sexual activity for person *i* over the datacollection period, and represents the expected change across months when a_{ti} (time) = months since treatment, π_{2i} = expected monthly change in rate of sexual activity for person *i* as he deviates from his average levels of erectile ability, and π_{3i} = expected change across months as qualified by the monthly association between erectile ability and time.

In these models, all five TVCs were found to significantly relate to frequency of sexual activity on a monthly basis, such that on months when a given TVC deviated from an individual's overall average level of that TVC, there was a corresponding change in frequency of sexual activity in the same direction (e.g., as a man's level of desire increased from his own average desire in a given month, his frequency of sexual activity

also increased during that same month). None of the TVCs interacted with time. Thus, time and all five TVCs were included in the final level-1 model.

In preparing the level-2 portion of the model, we first tested separate models with each of the four between-subjects factors on the intercept and on the slope as was discussed in Aim 1. The only differences between these models and those in Aim 1 were the outcome (i.e., frequency of sexual activity vs. sexual functioning) and the predictor measuring pretreatment levels of the outcome (i.e., pretreatment sexual activity vs. pretreatment sexual functioning). For all level-2 analyses, the four predictors were centered as listed above in Aim 1 (e.g., pretreatment sexual activity was grand-centered). Each of these four models showed a significant effect of the predictor on the intercept (i.e., men's level of sexual activity at baseline postsurgery), and thus were all included in the final model. None individually had an effect on the slope, but were included in the final model in case adding in the five TVCs at level-1 would influence the effect of the level-2 predictors on the slope. Additionally, interaction terms were initially included in models to test for a qualifying relationship of the degree of nerve sparing by surgery type, and then were subsequently removed when no effect was present.

The final model was as follows:

Level 1

 $SEXUAL \ ACTIVITY_{ti} = \pi_{0i} + \pi_{1i}^{*}(\text{TIME}_{ti}) + \pi_{2i}^{*}(DESIRE_{ti}) + \pi_{3i}^{*}(ERECTILE \ ABILITY_{ti})$ $+ \pi_{4i}^{*}(ORGASM \ ABILITY_{ti}) + \pi_{5i}^{*}(SATISFY \ PARTNER_{ti}) + \pi_{6i}^{*}(SEXUAL \ AIDS_{ti}) + e_{ti}$

Level 2

 $\pi_{0i} = \beta_{00} + \beta_{01}(AGE) + \beta_{02}(PRETREATMENT SEXUAL ACTIVITY) + \beta_{03}(SURGERY TYPE) + \beta_{04}(DEGREE NERVE SPARING_1) + \beta_{05}(DEGREE NERVE$

$SPARING_2 + r_{oi}$

 $\pi_{1i} = \beta_{10} + \beta_{11}(AGE) + \beta_{12}(PRETREATMENT SEXUAL ACTIVITY) + \beta_{13}(SURGERY TYPE) + \beta_{14}(DEGREE NERVE SPARING_1) + \beta_{15}(DEGREE NERVE SPARING_2) + r_{1i}$

For Research Question 1, it was hypothesized that variations across men in the trajectory of sexual activity frequency over time would be influenced by the same factors as identified to be relevant in sexual functioning research (i.e., age, pretreatment sexual activity, type of surgical approach, and degree of nerve sparing), such that younger men with greater pretreatment sexual activity who received robotic surgery with a greater degree of nerve sparing would be expected to have a steeper slope in their trajectory. However, none of the predictors were significant on the slope (rate of change across time), indicating that these variables did not influence the trajectory of men's rate of sexual activity across time. Although a priori hypotheses were not offered related to the intercept, our analyses indicated that age (B = -.02, SE = .005, p < .001), pretreatment sexual activity (B = .43, SE = .04, p<.001), and nerve sparing (for both: B = .38, .10, p < .001) were all significantly associated with baseline posttreatment sexual activity (see Table 2). This indicates that these variables were associated with men's frequency of sexual activity in the first couple of months after surgery, rather than the rate of change in activity across time. There was not a significant difference between unilateral and bilateral nerve sparing, $\chi^2(1) = 0.30$, p > 500. Given the coefficient of the intercept (B =1.96 for the average aged man with average pretreatment sexual activity who had open surgery with no nerve sparing at time = 0, who was at his average for TVCs), results indicated that on average, those who had at least some degree of nerve sparing, a onepoint increase over average levels of pretreatment sexual activity, and were 6 years younger than average (i.e., 1 *SD*) had a score of 2.89, or almost a full one-unit increase on a 5-point scale in frequency of sexual activity that month.

For Research Question 2, it was hypothesized that the within-person monthly variation of the TVCs (e.g., erectile ability) would be associated with a similar monthly change in the frequency of sexual activity. Indeed, each of the TVCs were significant in the final model, suggesting that on those months when a given man used sexual aids and/or had a 1-unit increase above his average levels of desire, confidence in satisfying his partner, perceived orgasm ability, and/or perceived erectile ability, he had a corresponding increase in frequency of sexual activity (see Table 2 for all model coefficients and standard errors and Figure 3 for an example of the association between a TVC and frequency of sexual activity). The scaled TVC with the highest regression coefficient was perception of orgasm ability (B = .22). Further, the slope of time in months was significant, suggesting that in addition to the monthly varying association between the TVCs and sexual activity, there was a steady, slight improvement over time in men's frequency of sexual activity (see Figure 2).

Taken together, the results of the analyses in Aim 2 suggested a complex pattern regarding the frequency of sexual activity after prostatectomy. It appears that men did not greatly improve over time in their frequency of sexual activity, regardless of their treatment characteristics, age, or pretreatment sexual activity. Rather, men differed from each other in their initial levels of sexual activity after treatment, and this benefitted younger men, those with greater frequencies of pretreatment sexual activity, and those with greater degrees of nerve sparing. By including the five varying factors (e.g., desire) that were measured at the same points as the outcome, we learned that much of the within-individual variation in frequency of sexual activity across time was related to corresponding fluctuations in those factors (TVCs). In other words, those factors and the frequency of sexual activity tended to fluctuate from month-to-month together around a man's average. Thus, there were between-group differences in baseline levels of sexual activity after surgery, and then from month-to-month individual men varied around their own average levels of sexual activity depending on changes in desire, confidence in satisfying a partner, perceived erectile ability, perceived orgasm ability, and whether or not they used erectile aids that month.

Table 1Means and Standard Deviations for Aim 2 Raw (Not Transformed) Scale Variables

	Pretreatment		Baseline		Answer Choice 1		Answer Choice 2	
					Pre	Post	Pre	Post
	M(SD)	Ν	M(SD)	Ν	N(%)	N(%)	N(%)	N(%)
Sexual	2.67(1.06)	522	2.03(1.05)	524	90(17.2)	222(42.4)	130(4.9)	119(22.7)
Activity								
Desire	3.48(1.45)	520	2.86(1.21)	522	35(6.7)	91(17.4)	68(13.1)	114(21.8)
Erectile	3.53(1.24)	511	1.60(.96)	517	42(8.2)	<u>332(64.2)</u>	71(13.9)	106(20.5)
Ability								
Orgasm	3.82(1.20)	508	2.19(1.32)	511	35(6.9)	<u>233(46.2)</u>	41(8.1)	76(14.9)
Ability								
Satisfy	3.66(1.31)	509	2.00(1.32)	502	57(11.2)	<u>283(56.4)</u>	44(8.6)	60(12.0)
Partner								

	Answer Choice 3		Answer Choice 4		Answer Choice 5	
	Pre	Pre	Post	Post	Pre	Post
	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)
Sexual	174(33.3)	130(24.8)	120(23.0)	50(9.5)	8(1.5)	3(0.6)
Activity						
Desire	136(26.2)	130(24.9)	176(33.8)	<u>151(28.9)</u>	105(20.2)	36(6.9)
Erectile	107(20.9)	42(8.1)	158(30.9)	29(5.6)	133(26)	8(1.5)
Ability						
Orgasm	87(17.1)	95(18.6)	162(31.9)	73(14.3)	183(36)	31(6.1)
Ability						
Satisfy	77(15.1)	64(12.7)	170(33.4)	65(12.9)	161(31.6)	30(6.0)
Partner						

Table 1 Continued

Note. All scale variables were scored 1-5, with higher values indicating higher levels of the measured variables. See Appendix A for labels. For each variable, most frequent response for pretreatment in bold type and posttreatment underlined. "Baseline" refers to baseline posttreatment, the first time measured point after surgery.

	Aim 1	Aim 2
	Sexual Functioning	Sexual Activity
For INTERCEPT, π_0	B(SE)	B(SE)
Intercept, β_{00}	10.97(2.05)***	1.96(.17)***
Surgery Type, β_{01}	3.23(1.83)	-0.11(.18)
Age, β_{02}	-0.28(.14)*	-0.02(.005)***
Degree Nerve Sparing 1, β_{03}	11.07(1.93)***	0.38(.10)***
Degree Nerve Sparing 2, β_{04}	18.61(2.21)***	0.38(.11)***
Pre-Trtmt Sexual Functioning ₁ /Activity ₂ , β_{05}	0.32(.03)***	0.42(.04)***
For TIME (MONTHS) slope, π_l		
Intercept, β_{10}	0.32(.07)***	0.003(.001)*
Surgery Type, β_{11}	-0.10(.05)	0.004 (.008)
Age, β_{12}	-0.004(.004)	0.000(.0000)
Degree Nerve Sparing 1, β_{13}	-0.04(.06)	0.004(.007)
Degree Nerve Sparing 1, β_{14}	-0.01(.07)	0.007(.008)
Pre-Trtmt Sexual Functioning ₁ /Activity ₂ , β_{15}	0.004(.001)**	0.001(.001)
For ERECTILE AIDS slope, π_2		
Intercept, β_{20}	NA	0.20(.14)***
For DESIRE slope, π_3		
Intercept, β_{30}	NA	0.15(.21)***
For SATISFY PARTNER slope, π_4		
Intercept, β_{40}	NA	0.05(.02)*

Table 2Final Estimation of Fixed Effects (with Robust Standard Errors) for Aim 1 and Aim 2.

Table 2 Continued

	Aim 1	Aim 2
	Sexual Functioning	
For ERECTILE ABILITY	slope, $\pi 5$	
Intercept, β_{50}	NA	0.11(.04)**
For ORGASM ABILITY		
slope, $\pi 6$		
510pe, 20		

Note. Sexual Functioning is scaled 0-100, Sexual Activity is scaled 1-5. For *p* values: *p < .05, **p < .01, ***p < .001.

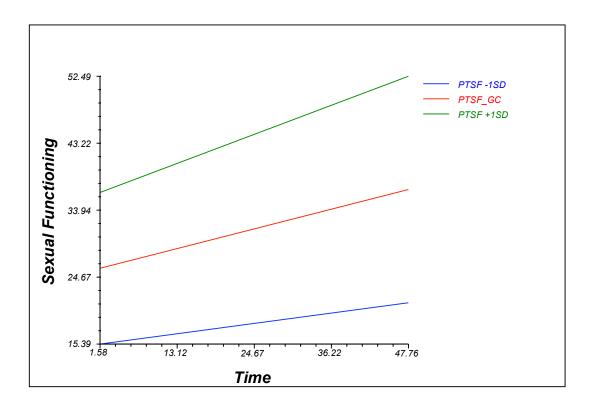


Figure 1. The effect of the Aim 1 interaction between time, in months since baseline, and pretreatment sexual functioning, grand-centered, on sexual functioning scores. The z-axis depicts pretreatment sexual functioning at the grand mean ($PTSF_GC$, red line) and at two levels found to be significant in post-hoc analyses: at one standard deviation above the grand mean (PTSF + ISD, green line), and at 1 standard deviation below the grand mean (PTSF - ISD, blue line). Those with higher pretreatment sexual functioning have steeper trajectories than men with average pretreatment sexual functioning, and those with lower pretreatment sexual functioning have flatter trajectories than men with average pretreatment sexual functioning.

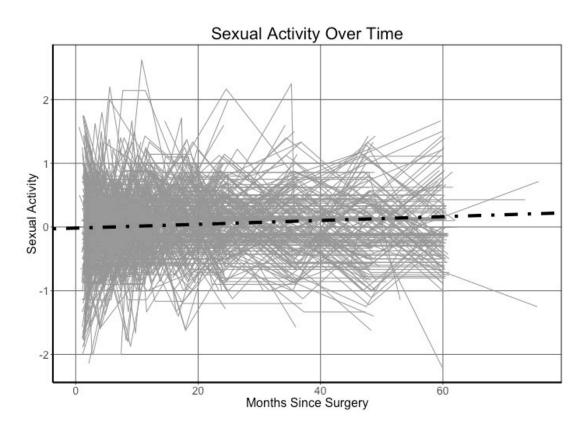


Figure 2. The pattern of the Aim 2 outcome (frequency of sexual activity) across time in months after surgery when the outcome is centered at the individual's mean, such that each gray line illustrates a man's variations around his average across time and the black dashed-dotted line represents the best fit linear trend, demonstrating the significant, yet small, increase in sexual activity over time after surgery.

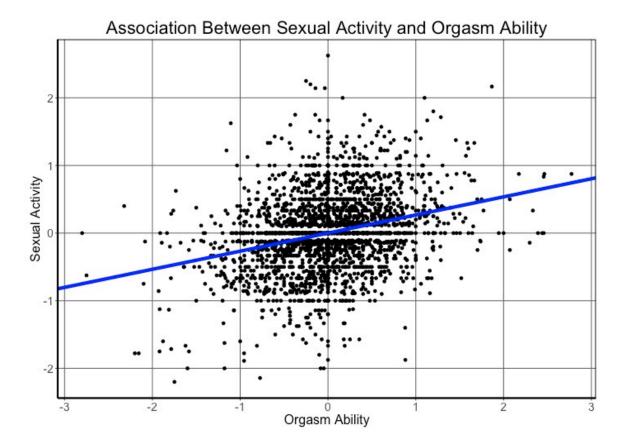


Figure 3. The association of within-person ratings (on five-point scales) between one of the five time-varying covariates (i.e., Perception of Orgasm Ability) and the Aim 2 outcome (Frequency of Sexual Activity) when such ratings are centered at the individual's average. Positive values on both axes (i.e., a dot in the upper right quadrant) suggest a month when a man was both above his average level of orgasm ability and above his average frequency of sexual activity. The blue line indicates the best fit linear relationship between ratings of orgasm ability and sexual activity within-men, and is illustrating an effect of corresponding monthly associations between ratings in the same direction.

DISCUSSION

This study examined sexual quality of life outcomes after surgical treatment of prostate cancer utilizing several novel methodological approaches, including (1) the use of statistical approaches that account for dependence in nested data structures, (2) a more thorough examination of the influence of time on the outcome through longitudinal analyses, and (3) proposing the value of a more specific construct, sexual activity, in order to increase the clinical utility of the research in this area. The potential value and implications of this study are thus both methodological and clinical, and are discussed separately.

Methodological Improvements in Examining Sexual Quality of Life

Previous research has approached the examination of sexual quality of life after prostate cancer by comparing broad sexual functioning immediately following prostate cancer surgery with some point in time in the recovery process. This existing work has been valuable in identifying factors (e.g., patient age) that appear to relate to postsurgery quality of life, and in demonstrating that many men do experience some degree of change in their sexual functioning after surgery. The challenge has been in identifying, with cross-study consistency, the specific influence of individual difference variables while simultaneously capturing the unique degree of improvement, if any, from natural recovery across time. In other words, we have thus far been unable to provide men or their treating clinicians with accurate expectations regarding the timeline and degree of recovery they might experience, and what might improve or worsen those odds. Multilevel linear growth modeling allows us to observe the intra- and interindividual pattern of change, improving the accuracy of our results and isolating unique contributions of predictors. Particularly, the ability to parse effects due to variables that change over time (i.e., time-varying covariates) from effects that distinguish between individuals should provide a more complete picture of men's experiences after surgery. By using linear growth modeling techniques, it is theoretically possible to more accurately estimate a man's expected long-term sexual quality of life given enough pretreatment and posttreatment data. Using such an approach for this study, we were able to use data on men's demographics and pretreatment functioning/frequency of sexual activity, baseline posttreatment functioning/sexual activity, and multiple points of followup to estimate the expected rate of change for a given man, as well as the unique influence of individual difference variables on groups of men.

Of particular value to our understanding of the long-term period after surgery, using linear growth modeling allowed for a more thorough examination of the effects of time, which are often masked in typical methodological approaches in this area (e.g., pretest vs. posttest). This study was able to identify influences of time on the outcomes in numerous ways. We captured a pattern of natural recovery (e.g., the natural healing process) by including a main effect of change over time for each man, while simultaneously controlling for the effects of other predictors. The use of trajectories in a multilevel model allowed us to separately track the patterns of any observed change within-men and between-men, in order to investigate the effects on the outcome of predictors as a function of time. We were also able to identify individual differences in levels of sexual functioning within the first few months after surgery based on pretreatment and surgery characteristics. This suggested that these factors (e.g., greater degree of nerve sparing) either encouraged rapid recovery immediately after surgery or protected in some way against greater surgery-related loss of functioning. Further, with the ability to separate out the between-men predictors on both initial status (baseline postsurgery) and rate of change over time, we identified a particularly strong influence of pretreatment sexual functioning on functioning after surgery: men with higher pretreatment sexual functioning both started with higher functioning after surgery and improved faster than those with lower pretreatment functioning. Finally, by including predictors with time at level one in Aim 2 models with sexual activity as the outcome, we could identify monthly associations between time-varying factors (e.g., levels desire) and the frequency of sexual activity to illustrate that deviations from an individual man's average level of these factors in a given month resulted in similar changes in the outcome during that same month.

Comparisons With the Existing Sexual Functioning Literature

In order to compare our findings with those reported in the existing literature, we first examined the most commonly used outcome construct: broadly measured sexual functioning. We were able to replicate previous findings and provide clarification for effects that appear inconsistent throughout the literature. For example, similar to others (Moskovic et al., 2011; Rabbani et al., 2000), our findings supported that younger men have better sexual functioning after surgery than older men, but the effect was found at baseline after surgery rather than on the rate at which men recover over time. This may suggest that any benefit from younger age occurs very early on, such as influencing the

speed at which men physically recover in the first few months before their first follow-up appointment (i.e., our first measurement occasion). Alternatively, instead of indicating greater early recovery, it may actually be that younger men experience less decrements to functioning from surgery. Parsing this effect would require a closer examination of the period in the first few months after surgery.

Next, the effect of surgery type on broad sexual functioning has been inconsistent in the literature, particularly in whether the introduction of robotic technology has had a positive impact on sexual functioning due to increased precision (e.g., Menon et al., 2007). Our findings indicated that there is no unique effect of surgery type on initial postsurgery levels of sexual functioning or on rate of improvement over time. Rather, it is likely that any effect of surgery type is being captured by nerve sparing, which was highly impactful on men's initial levels of sexual functioning after surgery, particularly if they received bilateral nerve-sparing. The preservation of nerves likely lessens the damage to smooth muscles and nerves needed for erectile capacity (Chung & Brock, 2013), which may have resulted in less negative impact of surgery on sexual functioning scores. Although a robotic procedure may in fact result in less overall tissue damage than open procedures, perhaps the nerve bundles are the most important parts of the tissue in the area surrounding the prostate for erectile capacity. Our findings also suggest that nerve sparing does not directly influence rates of recovery of functioning over time, further supporting that men with greater nerve preservation may retain more of their pretreatment sexual functioning after surgery than other men.

We also found that men with higher pretreatment sexual functioning recovered their sexual functioning at a faster rate over time than did men with lower pretreatment sexual

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functioning. Lower pretreatment sexual functioning could be the result of non-cancerrelated contributors, such as heart disease or diabetes (Turek et al., 2013). While treatment can stop the spread of the cancer, it is unlikely to restore losses to sexual functioning that were already present, which may be why these men experience lower rates of recovery over time. Thus, even though we did not follow men for the rest of their lives, our models indicate that that those younger men with higher pretreatment sexual functioning scores who were candidates for nerve-sparing procedures will enjoy the highest levels of broadly measured sexual functioning scores at all points in time after surgery compared to other men with prostate cancer.

Introducing an Alternative Construct

The final methodological approach used in this study was to examine a different construct than in previous work: frequency of sexual activity. Using the same methodologically advantageous approach as in our analyses on sexual functioning, we investigated men's frequencies of sexual activity after surgery. We examined the same individual difference variables as we did in sexual functioning analyses (i.e., age, degree of nerve-sparing, surgery type, and pretreatment sexual activity), and found similar effects on the frequency of sexual activity (Aim 2) at baseline postsurgery as in our earlier sexual functioning analyses (Aim 1). For example, younger men engaged in more frequent sexual activity in the first several months after surgery than did older men. Further, there was no effect of surgery type on baseline frequency of sexual activity or on trajectories. There was an effect of nerve sparing on baseline postsurgery rates of sexual activity, but unlike in earlier sexual functioning analyses, we observed no greater rates in sexual activity for those who had bilateral nerve sparing over those with modified nerve

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sparing.

Finally, even though most men's rates of sexual activity decreased from pretreatment to baseline postsurgery, those with higher presurgery rates also evidenced higher postsurgery rates of sexual activity. Perhaps those couples who were used to more frequent sexual activity sought it out again early after surgery as a way to maintain intimacy, even if it was not the identical experience as before surgery. This would be similar to findings on the effect of other life challenges on sexual activity, like pregnancy (Leeman et al., 2012). Unlike in our sexual functioning analyses, pretreatment sexual activity did not influence men's trajectories of sexual activity over time. In fact, we did not find any effect of individual difference variables on growth trajectories.

Arguably, the most clinically and methodologically valuable information gained from using frequency of sexual activity as an outcome, as opposed to sexual functioning scores, was our finding that monthly rates of sexual activity varied as a function of its associations with one's level of desire, perception of erectile ability, confidence in ability to satisfy partner, perception of orgasm ability, and use of sexual aids, such as PDE-5 inhibitors. This illustrated that the frequency with which couples engage in sexual activity after surgical treatment of prostate cancer is fluid and dynamic. In other words, we demonstrated that unlike the pattern of sexual functioning scores after surgery, the frequency of sexual activity is more variable from month-to-month and depends on a man's current attitudes and predictions about how the sexual experience might go were he to engage in it.

These findings offer a number of clinical implications, which are elaborated upon in the next section. From a methodological perspective, though, our results suggest that researchers in this area may want to consider the use of more sophisticated statistical techniques in their longitudinal studies and more clinically useful constructs, like the frequency of sexual activity, in order to gain new, valuable insights into men's sexual quality of life. This is not to say that there is not value in using broad constructs, like sexual functioning, as an outcome. Rather, the choice of construct depends on the questions one hopes to answer, and by using advanced statistical methods, we gain substantial flexibility to answer a variety of questions in novel ways.

Clinical Implications

The findings in this study provide potentially valuable clinical information to medical providers and their patients as they make a treatment decision and search for ways to improve patients' sexual quality of life after surgery. The current literature suggests that most couples strongly want to be sexually intimate after surgery, and thus are seeking guidance and reassurance (Chung & Brock, 2013). Unfortunately, it has been challenging to accurately prepare couples for what to expect and to reassure them that there is hope in returning to an active sex life. These results provide important insights into men's experiences of sexual activity after prostate cancer, something that is not typically addressed in this body of research. Even though we cannot translate our scaletype measure into an exact count of sexual encounters, we can confidently say that, on average, most men reported some monthly sexual activity across time. Many couples are engaging in some type of sexual activity within a few months after surgery (57.6%). Of course, given the impact of the within-men and between-men factors, there were variations observed, and in this information lies much of the clinical utility of these findings. There are several ways providers could use these findings to help their patients

navigate the cancer survivorship process, such as fostering realistic expectations of what to expect and when to seek help, encouraging couples to shift their focus to a broader conceptualization of sexuality and sexual satisfaction, and targeting the five influencing factors found to vary from month-to-month in order to optimize the frequency of sexual activity.

Setting Realistic Expectations

The findings on sexual activity in this study, combined with other sex research, could be used prior to surgery to provide couples with information that encourages realistic expectations. For example, they can be informed that levels of sexual activity after surgery will be variable depending on multiple factors (e.g., level of desire) rather than just depending on their erectile capacity, which was also variable. Additionally, one study found that if men maintained the unrealistic expectation that they would completely regain their pretreatment erectile capacity, they were more likely to have poorer emotional outcomes (Katz, 2015). Thus, in addition to instilling hope with findings from this study, it would be important to also inform patients that they may never return to their pretreatment erectile capacity.

They can also be provided with individually tailored expectations for their frequency of sexual activity in the first few months after treatment based on the man's age, the likelihood of nerve preservation in his surgery, and the couple's previous pattern of sexual activity. Although they should expect a decrease in the frequency immediately following surgery, rates did not go to zero after surgery for most patients. Instead, many men who engaged in a relatively higher frequency of sexual activity prior to treatment still reported sexual activity immediately following surgery, just at a lower frequency than they had prior to surgery. For all men, there was a slight increase in sexual activity over time as they recovered from surgery. The better predictor of increased sexual activity, though, was the month-by-month levels of desire, perceived orgasm ability, confidence in satisfying one's partner, perceived erectile capacity, and the use of erectile aids. This is encouraging because these are factors that fluctuated over time and can be targeted in clinical interventions. Therefore, sexual activity posttreatment is much more fluid than perhaps originally thought, and men (and their partners) can take an active role in increasing their levels of sexual activity.

Having an open conversation with their provider about what to expect after surgery might serve to increase couples' comfort with bringing up sexual concerns after surgery. Research has found that patients tend not to bring up sexual issues with medical providers unless that provider has appeared open and willing to discuss them (Wittmann et al., 2009), and that patients often feel there are no options when sexual issues present after surgical treatment of prostate cancer (Walker & Robinson, 2011). This approach to setting realistic expectations might serve to increase patients' perceptions of having made an informed treatment decision, protect against postsurgery surprise and disappointment, and encourage the couple to bring up sexual issues after treatment (Paisch et al., 2016).

Shifting to a Broader Conceptualization of Sex

Discussion in the literature has proliferated in recent years about the need to identify interventions that could be used to improve sexual quality of life after prostate surgery, particularly targeting couples' sexual intimacy and sexual satisfaction (see Chung & Brock, 2013; Wittmann et al., 2015). With the goal of understanding more about couples' sexual encounters after surgery, this study focused on measuring sexual activity defined broadly, rather than being limited to only intercourse. Findings highlighted that even if they are not able to engage in intercourse, most couples continue to be engaged in some type of sexual activity across time. Although this study did not identify the specific sexual behaviors in which couples engaged, their endorsement of the item indicates that they perceived the behaviors to be sexual in nature. Sex researchers have posited that the ways in which individuals conceptualize constructs like "having sex" and "sexual activity" might influence how well they adapt to a change in functioning that impacts their ability to engage in certain sexual behaviors, like intercourse (e.g., Sewell & Strassberg, 2015).

Within the field of prostate cancer research, some have called for finding ways to help couples increase satisfaction within their current sexual capabilities when there are unlikely to be additional improvements in erectile capacity (Galbraith et al., 2011; Reese et al., 2010). To that end, interventions are needed to help couples shift to a less intercourse-focused view of sexuality, such that their emphasis is on maintaining sexual intimacy even in the absence of significant erectile ability. Indeed, some heterosexual couples have reportedly come to appreciate the value in broadening their sexual experiences after surgery because of the increased focus on activities more stimulating to the female partner (see Katz, 2015). Further, a related study examining men with prostate cancer on androgen deprivation therapy (ADT) found that couples who expanded their view of sexual satisfaction to include nonintercourse behaviors were better able to cope with symptoms (Hamilton et al., 2015). Thus, interventions in this area might have two components: psychoeducation to teach the couple about alternative ways to express their sexuality, and cognitive approaches to increase sexual flexibility and challenge rigid thinking patterns (Reese et al., 2010).

Exploring New Interventions

Findings in this study of five factors that are related to monthly sexual activity may guide clinicians and researchers in efficacious interventions. In addition to helping couples set realistic expectations and shift their focus to a broader set of sexual behaviors and experiences, clinicians can directly target those five factors in order to help couples increase the frequency with which they are engaging in sexual behaviors. Since several of those factors measure cognitions (i.e., perceptions about orgasm and erectile ability; confidence in ability to satisfy partner), interventions might focus on helping couples process their appraisals of physical changes and self-image, reframe perceptions of "failed" sexual experiences more accurately and positively, and set up positive expectations for the future (Brock & Chung, 2013).

The couple might also benefit from exploring ways of expressing sexual intimacy that increase their pleasure and satisfaction during sexual encounters, which may increase the likelihood of having an orgasm. Research shows that although most men experience orgasm and ejaculation as paired, neither the postsurgery loss of ejaculatory fluid nor impaired erectile capacity necessarily precludes orgasm ability (Koeman et al., 1996). Given our finding of the strong influence of perceived orgasm ability on the frequency of sexual activity, helping couples in their efforts to reach orgasm despite incomplete erectile capacity should be highly beneficial to their level of satisfaction. Sex therapy techniques might be utilized that have been shown to be effective, such as sensate focus (Wincze, 2015). Also, existing research indicates that pelvic floor training (e.g., kegel exercises) can help increase orgasm strength (see Chung & Brock, 2013). Finally, couples can be encouraged to increase engagement in nonintercourse sexual behaviors that are linked to orgasm, such as manual-genital stimulation and oralgenital stimulation. Since women rarely report PVI as their most sexually pleasurable behavior due to the greatest concentration of nerve-endings in the genitals being external (e.g., clitoris) and near the entrance of the vaginal canal (Hite, 2004), encouraging heterosexual couples to focus on other sexual behaviors might increase her likelihood to orgasm and her overall sexual satisfaction. Furthermore, engaging in other pleasurable behaviors may increase the man's perceived ability to satisfy his partner, which can increase relationship satisfaction (Yoo, Bartle-Haring, Day, & Gangamma, 2014) and, as we found, the couple's frequency of sexual activity.

There are interventions that have shown some efficacy in improving men's erectile abilities, such as sexual aids. The most common aids used by our sample included PDE-5 inhibitors (e.g., Viagra), vacuum erection devices, and penile injection therapy. Previous research finds that some couples are disappointed with erectile aids, mainly due to insufficient training, suggesting that psychoeduation may help couples increase their willingness and effectiveness with these aids (Walker et al., 2015). Particularly, Walker, Wassersug, and Robinson (2015) suggested that early dissatisfaction with erectile aids resulted in discontinuation and reluctance to consider future interventions. On the other hand, studies on the use of erectile aids has also found a relationship with increased frequency of sexual activity (Lee, Nazroo, & Pendleton, 2015). Towards that end, the findings in this study were promising: On the months that our sample used aids, they engaged in more sexual activity than on months they did not use them. We are unable to say whether they found the sexual activity with aids to be more or less satisfying than

without, but research in other areas indicates that erectile aids can also be used to enhance couples' sexual satisfaction and even their orgasm ability (Paduch, Bolyakov, Polzer, & Watts, 2013).

Finally, engaging in sexual activity within the first few months after surgery might confer additional benefits to couples who hope to return to presurgery rates of sexual activity. It could help them manage disappointment and begin the process of adjustment at a time when they have the lowest expectations about erectile capacity. Next, research suggests a potential bidirectional relationship between desire and sexual activity, such that engaging in sexual activity may result in increased desire through increased testosterone, influencing future sexual activity (e.g., Dabbs & Mohammed, 1992). Thus, if low desire is a problem, encouraging the couple to engage in sexual activity anyway might serve as an effective intervention. Finally, providers might encourage couples to specifically use sexual activity during the period early after surgery as a time to focus on the intimacy gained from touching, kissing, and communicating, without the expectation of optimal erectile and orgasmic functioning. Research suggests that these types of physical affection can release oxytocin and dopamine, which can be self-reinforcing for future sexual activity and increased perceptions of intimacy (Veening et al., 2015).

Thus, there are many factors that can be targeted through clinical interventions in order to help couples recover their sexual activity after prostate cancer treatment. In all of these, the intervention is likely to be more successful if it includes the partner (e.g., Hamilton et al., 2015; Katz, 2015; Nelson et al., 2015). Not only will this allow for a focus on building intimacy and enhancing sexual communication, but the dyad may also be more engaged in the treatment if approached jointly and considered "our" problem. Research suggests that men may be more open to treatment for sexual problems after prostate cancer if a partner is involved (e.g., Chung & Brock, 2013). Further, interventions that target couples encourage dyadic coping, or approaching a problem as a shared experience to manage, which can allow for additional support, greater availability of resources, and better application of the skills (Berg, Wiebe, & Butner, 2008; Bodenmann, 2005).

Limitations and Future Directions

As with any study, there were several limitations that may affect the generalizability and application of these findings. First, our sample was relatively homogenous, with the majority of participants being Caucasian, well-educated, and likely higher SES. Although participants were not asked the gender of their partner(s), it is likely that most patients were heterosexual. Participants were also slightly younger than average for those with prostate cancer (i.e., 60.81 vs. mid- to upper-60s in most studies, Glass et al., 2013). Thus, our sample may have had greater access to resources, such as sexual aids, and fewer other health-related changes to erectile capacity than typical men with prostate cancer. Next, this study did not have access to the partners of the men surveyed. We cannot hope to fully understand these couples' experiences without having information from the partner. Since we did not have that data or measures of relationship quality, it is unclear how the relationship or the partner's functioning might have influenced frequency of sexual activity. Research suggests that there is often congruence in a couple's sexual functioning, such that when a man reports ED his partner often also reports sexual dysfunction (Shindel et al., 2005). It would be most beneficial for future

studies to measure and address sexual and relationship issues in both individuals, although it is acknowledged how difficult such research can be to conduct.

Further, there were limits to our measurement of sexual activity that could be expanded on in future studies. The scale used to measure the frequency of sexual activity was retrospective, queried only the patient, and did not allow for us to identify specifically how many episodes of sexual activity in which couples were engaging, or the nature of that activity. A more specific weekly diary, completed by both the man and his partner, would have been preferable. Particularly if this had been conducted online, where reminders could be sent easily, it might have reduced the inconsistent timing across participants of returning questionnaires. Future studies might also explore the couples' satisfaction with the specific sexual behaviors in which they engaged so as to better inform interventions. Finally, future research might examine the effectiveness of interventions designed to target the five factors shown in this study to influence the frequency of sexual activity.

Conclusion

With the use of more sophisticated analytic techniques than typically employed in previous research, we found that in the first few months after surgery, men's sexual functioning scores and frequency of sexual activity were related to their presurgery levels of these factors, their age, and the degree of nerve sparing they received, but not to the type of prostatectomy they received. Most experienced as least some improvement in broadly measured sexual functioning over time from posttreatment baseline, with faster rates of recovery observed in those with higher pretreatment functioning. This study also specifically examined couples' frequency of sexual activity after surgery. Findings were

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encouraging, particularly for those with higher levels of sexual activity prior to surgery. Although surgery dampens their frequency of sexual activity, at least initially, many prostate cancer survivors are nonetheless engaging in some type of monthly sexual activity after surgery. Monthly frequencies appear to be influenced by five within-men factors, suggesting multiple targets for intervention for couples who wish to improve their sexual experiences. Further examining the construct "sexual activity" might enhance the outcomes of intervention research, particularly when the goal is to increase sexual intimacy and sexual satisfaction. This study provides additional information for men and their partners in making treatment decisions, setting realistic expectations, and seeking assistance after surgery to improve their sexual quality of life.

APPENDIX A

SEXUAL FUNCTION

The next section is about your **current** sexual function and sexual satisfaction. Many of the questions are very personal, but they will help us understand the important issues that you face every day. Remember, THIS SURVERY IS COMPLETELY **CONFIDENTIAL**. Please answer honestly about **THE LAST 4 WEEKS ONLY**.

1. How would you rate each of the following during the last 4 weeks?

	Very Poor To			
Very	N	D	г.	
(Circle ONE number on each line)	None	<u>Poor</u>	Fair	<u>Good</u>
<u>Good</u>				
a. Your level of sexual desire 5	1	2	3	4
b. Your ability to have an erection 5	1	2	3	4
c. Your ability to reach orgasm 5	1	2	3	4

2. How would you describe the usual QUALITY of your erections **during the last 4** weeks?

(Circle ONE number on each line)	
None at all	1
Not firm enough for sexual activity	2
Firm enough for masturbation and foreplay only	
Firm enough for intercourse	4

3. How would you describe the FREQUENCY of your erections **during the last 4** weeks?

(Circle ONE number on each line)

I NEVER had an erection when I wanted one	1
I had an erection LESS THAN HALF the time I wanted one	2
I had an erection ABOUT HALF the time I wanted one	3

I had an erection MORE THAN HALF the time I wanted one	,.4
I had an erection WHENEVER I wanted one	5

4. How often have you awakened in the morning or night with an erection **during the last 4 weeks?**

(Circle ONE number on each line)	
Never	1
Less than once a week	2
About once a week	3
Several times a week	4
Daily	5

5. During the last 4 weeks, how often did you have any sexual activity?

(Circle ONE number on each line)

None at all	1
Less than once a week	2
About once a week	3
Several times a week	4
Daily	5

6. During the last 4 weeks, how often did you have sexual intercourse?

(Circle ONE number on each line)

	,
None at all	1
Less than once a week	2
About once a week	
Several times a week	4
Daily	

7. Overall, how would you rate your ability to function sexually **during the last 4** weeks?

(Circle ONE number on each line) Very poor. 1 Poor. 2 Fair. 3 Good. 4 Very good. 5

How big a problem during the last 4 weeks, if any, has each of the following been for you?

Big		No	Very Small	Small	Moderate
Dig	(Circle ONE number on each line)	Problem	Problem	Problem	Problem

Problem

<u>a</u> .	Your level of sexual desire	0	1	2	3
b.	Your ability to have an erection 4	0	1	2	3
C.	Your ability to reach orgasm1 4	0	1	2	3

9. Overall, how big a problem has your sexual function or lack of sexual function been for you **during the last 4 weeks?**

(Circle ONE number on each line)
No problem 1
Very small problem
Small problem
Moderate problem
Big problem 5

Questions Used Added by Study Team

1. Which of the following, if any, have you used in the past 4 weeks to improve your erections?

(Circle ALL that apply)
None at all0
Vacuum erection device (Erect-aid) 1
Penile injection therapy 2
Penile prosthesis
Muse (intra-urethral alprostadil) 4
Medication (Viagra, Levitra, or Cialis)5
Other 6

2. How would you rate each of the following during the last 4 weeks?

	Very Poor To			
Very				
(Circle ONE number on each line)	None	Poor	Fair	Good
Good				
e. Your ability to satisfy your spouse or partner sexually				
without using medication	1	2	3	4
5				
with medication (leave blank if you do not use	1	2	3	4
5 such medications				

APPENDIX B

PRELIMINARY ANALYSES FOR AIMS 1 AND 2

Below are the results of the preliminary analyses for Aims 1 and 2: *Aim 1 (Sexual Functioning) Unconditional Baseline Model:*

$\pi_{0i} = \beta_{00} + r_{oi}$

where for the fixed effects, β_{00} = mean overall level of sexual functioning across men. Parameter r_{0i} represents variance in the levels of sexual functioning; therefore, a significant variance component suggests that including level-2 between-subjects factors is justified.

Results suggest that there is significant variance in the outcome variable, $\chi^2(486) = 8430.36$, *p*<.001 (see Table 3).

Aim 1 (Sexual Functioning) Unconditional Random Growth Model:

$$\pi_{0i} = \beta_{00} + r_{0i}$$

 $\pi_{1i} = \beta_{10} + r_{1i}$

where for the fixed effects, β_{00} = mean initial level of sexual functioning across men at baseline posttreatment and β_{10} = mean monthly growth in levels of sexual functioning. Parameter r_{1i} represents variance in the levels of sexual functioning across men over time; therefore, a significant variance component suggests that including level-2 betweensubjects factors is justified. Results suggested significant variance components for the intercept, $\chi^2(486) = 4263.17$, p < .001, and on the slope of time, $\chi^2(486) = 1267.25$, p < .001 (see Table 3). Further, a likelihood ratio test comparing the unconditional random growth model with the unconditional model suggested that the model with the random effect on time was a better fit than the one with only a random effect on the intercept, $\chi^2(2) = 60.57$, p < .001. Finally, 29% of the within-person variance is explained by linear time ($r^2 = .29$). *Aim 2 (Sexual Activity) Unconditional Baseline Model:*

$$\pi_{0i} = \beta_{00} + r_{oi}$$

where for the fixed effect, β_{00} = mean overall rates of sexual activity across men. Parameter r_{0i} represents variance in the rate of sexual activity across men; therefore, a significant variance component suggests that including level-2 between-subjects factors is justified.

Results suggest that there is significant variance in the outcome variable, $\chi^2(486) = 6748.82$, *p*<.001 (see Table 3).

Aim 2 (Sexual Activity) Unconditional Random Growth Model

$$\pi_{0i} = \beta_{00} + r_{oi}$$
$$\pi_{1i} = \beta_{10} + r_{1i}$$

where for the fixed effects, β_{00} = mean initial rates of sexual activity across men at baseline posttreatment and β_{10} = mean monthly growth in sexual activity across men over time. Parameter r_{1i} represents variance in the rate of sexual activity across men over time; therefore, a significant variance component suggests that including level-2 betweensubjects factors is justified.

Results suggested significant variance components for the intercept, $\chi^2(486) =$

3192.18, *p*<.001, and on the slope of time, $\chi^2(486) = 755.70$, *p*<.001 (see Table 3).

Further, a likelihood ratio test comparing the unconditional random growth model with the unconditional model suggested that the model with the random effect on time was a better fit than the one with only a random effect on the intercept, $\chi^2(2) = 60.57$, *p*<.001. Finally, 12% of the within-person variance is explained by linear time ($r^2 = .12$).

Table 3	
Estimation of Fixed Effects (with Robust Standard Errors) and Random Effects	
for Aim 1 and Aim 2 Preliminary Analyses	

	Aim 1	Aim 2
	Sexual Functioning	Sexual Activity
Unconditional Baseline Model	Coefficient(SE)	Coefficient(SE)
For INTERCEPT, π_0		
Intercept, β_{00}	29.29(0.99)***	2.14(.04)***
INTERCEPT, r0	443.83 (21.07)***	0.71(.84)***
level-1, e	165.44(<i>12.86</i>)	0.34(.58)
Unconditional Growth Model	Coefficient(SE)	Coefficient(SE)
For INTERCEPT, π_0		
Intercept, β_{00}	25.18(0.96)***	2.12(.04)***
INTERCEPT, r0	384.12(19.60)***	0.74(.86)***
For TIME (MONTHS) slope, πi		
Intercept, β_{10}	0.26(.02)***	0.001 (.001)
MONTHS slope, r_1	0.14(.37)***	0.001 (.01)***
level-1, e	116.34(<i>10.79</i>)	0.30(.55)

Note. Sexual Functioning is scaled 0-100, Sexual Activity is scaled 1-5. For p values: *p<.05, **p<.01, ***p<.001.

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