The Effects of a Pre-surgical Stress Management Intervention for Men with Prostate Cancer Undergoing Radical Prostatectomy

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Running Head: Pre-surgical stress management intervention and prostate cancer

Abstract

Purpose: This study assessed the short-term and long-term efficacy of a pre-surgical stress management intervention at reducing mood disturbance and improving quality of life (QOL) in men undergoing radical prostatectomy (RP) for prostate cancer.

Patients and Methods: One hundred fifty-nine men were randomly assigned to a 2-session (+2 boosters) pre-surgical stress management intervention (SM), a 2-session (+2 boosters) supportive attention group (SA), or a standard care group (SC). Assessments occurred 1 month before surgery; 1 week before surgery; the morning of surgery; and 6 weeks and 6 and 12 months post-surgery.

Results: Results indicated significant group differences in mood disturbance prior to surgery ($p=0.02$), such that men in the SM group had significantly less mood disturbance than men in the SC group ($p=0.006$), with no significant differences between the SM and SA or SA and SC groups. In the year post-surgery, there were significant group differences on SF-36 physical component summary (PCS) scores ($p=0.004$); men in the SM group had significantly higher PCS scores than men in the SC group ($p=0.0009$) and there were no significant differences between the SM and SA or SA and SC groups. There were no group effects on prostate-specific QOL or SF-36 mental health scores.

Conclusion: These findings demonstrate the efficacy of a brief pre-surgical stress management intervention in improving some short-term and long-term outcomes. If these results are replicated, it may a useful adjunct to standard care for men with prostate cancer undergoing surgery.

Key Words: Prostate Cancer, Stress Management, Psychosocial Intervention, Quality of Life

A cancer diagnosis is a particularly potent stressor.[1] For men with early-stage prostate cancer, treatment often involves radical prostatectomy (RP), which frequently produces short- and sometimes long-term erectile dysfunction and incontinence which may increase patients' distress and negatively affect their QOL.[2-10]

Growing evidence suggests that psychosocial interventions are valuable for cancer patients and may enhance QOL.[8,11-17] Several interventions have been developed for men with prostate cancer and have shown beneficial effects including improved physical functioning and QOL, finding positive meaning in the illness experience, and decreased distress.[8,9,12,15,18,19]

Most psychosocial interventions in cancer patients have been administered after the termination of adjuvant treatment. However, the pre-surgery period is often a period of high stress for cancer patients, and patients may derive significant benefit from interventions at this time. Although some research has suggested that pre-surgical interventions can be useful for women with breast cancer, no studies have been conducted in prostate cancer patients awaiting surgery.[20-22]

Existing studies of pre-surgical interventions in non-cancer patients support the possible benefits of delivering interventions at this time point.[23-25] Additionally, when patients were provided with stress management techniques before surgery, they reported less pain and distress and improved QOL; used less analgesic medication; and had lower systolic blood pressure.[26-28]

The primary aim of the current study was to assess the short-term (pre-operative and peri-operative) effects of the intervention and the secondary aim was to assess the long-term (6 weeks and 6 and 12 months post-surgery) effects of the intervention. Specifically, we hypothesized that men in the stress management (SM) group would have

less mood disturbance (primary outcome) and distress before the surgery than those in the supportive attention (SA) group and standard care (SC) control group and the SA group would in turn have lower mood disturbance and distress than men in the SC control group. In the long-term recovery period (secondary exploratory endpoints), we hypothesized that men in the SM group would have better QOL outcomes in both physical and mental domains than those in the SA and SC groups and the SA group would in turn have better QOL outcomes than men in the SC control group.

METHODS

Participants:

Participants were men with early-stage prostate cancer who were undergoing RP at one of three hospitals within the Texas Medical Center**.** Eligible participants were older than 18 years, undergoing a RP, able to speak and write in English, and able to come to the medical center four times before surgery or live within 100 miles of the medical center. Exclusion criteria included having had other major surgery in the preceding year, having a major psychiatric diagnosis, or currently undergoing psychiatric care or psychological counseling.

Procedure:

Participants attended a baseline assessment approximately 1 month before their surgery. Figure 1 outlines the study timeline. Following the baseline assessment, patients were randomized to one of three groups—SM, SA, or SC using an adaptive randomization procedure called minimization. Minimization results in better group balance than stratification.[29] Characteristics used for study assignment were age (<60 years or 60 years

or older), partner status (living with partner or not), hospital, and type of surgical procedure (nerve sparing, non-nerve sparing, nerve graft).

Patients in the SM and SA groups then participated in two intervention sessions approximately 1-2 weeks prior to surgery. The same psychologists administered both the SM and SA sessions. Patients in all groups completed another assessment approximately 1 week before surgery. Another brief assessment was then completed while patients were in the holding area the morning of surgery. Patients in the SM and SA groups then had a brief booster session (approximately 5 minutes) in the holding area before going for surgery. Men in the SM and SA groups had another booster session 48 hours after surgery that lasted 10-15 minutes. Additional follow-up assessments were completed 6 weeks, 6 months, and 12 months post-surgery. A dedicated research assistant who was blinded to group assignment collected all measures and all procedures were the same in the three groups except for the additional psychologist contact in the SM and SA groups. The study was approved by the Institutional Review Boards of each hospital.

Study Groups:

Stress Management: The SM intervention consisted of two 60- to 90-minute individual sessions with a clinical psychologist and a Stress Management Guide that expanded on the material covered in the sessions (i.e., relaxation and coping skills and information about prostate cancer and RP including management of side effects). The sessions were cognitive-behavioral in nature, with approximately 60% of the time focused on relaxation skills including diaphragmatic breathing and guided imagery.[30] Men were given audiotapes of the techniques for practice on their own. During the second session, patients did an imaginal exposure of the day of surgery to prepare for what they might expect the morning of surgery and during hospitalization. During the rest of the sessions, men discussed their concerns or fears about the cancer and surgery and learned problem-

focused coping strategies such as activity pacing, seeking out social support, and having realistic expectations about recovery. Patients also had two brief booster sessions with the clinical psychologist on the morning of surgery (before the assessment) and 48 hours after surgery to reinforce the use of relaxation strategies and the problem-focused coping strategies.

Supportive Attention: The SA group consisted of two 60- to 90-minute individual sessions with a clinical psychologist. The sessions were supportive in nature and consisted of a detailed psychosocial and medical history in a semi-structured interview format. Psychologists provided empathy and used reflective listening skills. These sessions gave the patient extra attention from the medical community and provided an encouraging environment to discuss their concerns. Patients also had brief boosters with the psychologist the morning of surgery (before the assessment) and 48 hours after surgery in which they discussed their experiences leading up to the surgery and during their hospital stay.

Standard Care: Patients in the SC group had no meetings with a clinical psychologist and received routine medical care.

Measures:

A number of measures were completed in this study, including self-report measures of psychosocial adjustment and QOL; urine samples were collected to measure cortisol and catecholamine levels; and blood samples were drawn to measure immune function. In the current article, we report on the psychosocial adjustment and QOL measures.

Background and Medical Measures

Patients completed a background questionnaire that assessed age, ethnicity, employment status, marital status, and education. Medical variables were abstracted from patients' charts and

included date of diagnosis, stage of disease, surgical technique, and prostate-specific antigen (PSA) levels.

Adjustment and QOL Measures

Mood disturbance was assessed using a brief version of the Profile of Mood States (POMS).[31] This 18-item measure consisted of an 11-item shortened measure that was developed for cancer patients[32] that assessed total mood disturbance as well as the additional 7 items that make up the original POMS anxiety subscale. We chose this measure because we wanted to assess mood disturbance with an emphasis on the anxiety component. The measure had good internal consistency reliability (α's=0.92-0.94). Higher scores indicated worse mood disturbance. It was administered at baseline, 1 week before surgery, the morning of surgery, and at the 6–week and 6- and 12-month follow-ups. Due to time limitations, the POMS was the only measure assessed the morning of surgery.

The Impact of Event Scale (IES) is a 15-item, self-report scale that assesses intrusive thoughts (intrusively experienced ideas or feelings) and avoidance behaviors (avoidance of certain feelings or situations).[33] It has adequate reliability and validity.[33] Patients rated the items in relation to their cancer, and the scales were combined into a total score with higher scores indicating more distress. It was administered at baseline, 1 week before surgery, and at the 6-week and 6- and 12-month follow-ups.

The Medical Outcomes Study 36-item short form survey (SF-36)[34,35] assessed general health-related QOL. The SF-36 assesses several domains: physical functioning, role-physical, bodily pain, general health perceptions, vitality, social functioning, role-emotional, and mental health. The RAND scoring method was used [0 (worst) to 100 (best)] and Physical Component Summary (PCS) and Mental Component Summary (MCS)

scores were computed. It has good reliability and validity. It was completed at baseline and at the 6-week and 6- and 12-month follow-ups.

The UCLA Prostate Cancer Index (PCI)[36] assessed prostate cancer-specific QOL including function and bother in the urinary, bowel, and sexual domains and cancer worry. Scores range from 0 to 100, with higher scores indicating better functioning. The psychometric properties of this measure are good.[36] It was administered at baseline and at the 6-week and 6- and 12-month follow-ups.

Statistical Analyses

Descriptive statistics were computed. We examined whether there were any differences in demographic (age, ethnicity, marital status, education) and clinical (PSA at baseline, stage of disease) variables in the three groups using ANOVA or Chi-square tests and whether there were differences in the psychosocial measures at baseline. Group comparisons of the psychosocial adjustment and QOL measures were performed by regressing the follow-up assessments for each measure on time, group assignment, the group by time interaction, the respective baseline measure, and covariates (age, ethnicity, baseline PSA, and stage of disease) using general linear mixed model regression analyses. Mixed model analyses include all patients in the analyses who contribute at least one assessment in addition to baseline, which supports an intent to treat approach. We used PROC MIXED procedure in SAS V9.1.3 to run these analyses; the intercept was treated as random and the covariance structure was variance components. The group effect was treated as a classification variable using class statement in PROC MIXED procedure and the standard care group was the reference group. Instead of modeling “time” as a continuous effect, we treated time as a classified

variable using class statement and the last time point in each model was the reference time point. The covariates in each model were grand-mean centered. We examined the short-term preoperative and peri-operative effects of the intervention on mood disturbance (POMS) and distress (IES) separately from the long-term effects of the intervention (6 weeks and 6 and 12 months post-surgery) on mood disturbance, distress and QOL (SF-36, PCI). None of the mixed model analyses yielded significant group by time interactions, therefore we did not examine group differences at each time point but instead present the group means collapsed over time in the text and the means at each time point in Tables 2-4. The t test was used for all post-hoc group comparisons. The study had 80% power to detect a 0.55 standard deviation unit change between any two groups at a single time point.

Results

Sample Characteristics

Two hundred twenty-one men were approached. Fifteen men were ineligible (5 had surgery elsewhere, 5 did not have surgery or surgery was too soon, 2 had history of another cancer, 1 was visually impaired, and 2 were on antidepressants); 42 men refused (32 indicated they were too busy, 1 did not like to read, and 9 men gave no reason). There were no differences between men who refused and those who agreed to participate on demographic characteristics (ethnicity, marital status, education, employment status, age). One hundred sixty-four men agreed to participate in the study and completed the baseline assessment (Figure 1). Five men dropped out of the study because they did not have time to participate, so 159 men were randomized to one of the three groups (53 SM; 54 SA; 52 SC).

The demographic and medical characteristics are summarized in Table 1. The three groups were similar on all medical or demographic variables except ethnicity (significantly more minorities were in the SC group than in the SM and SA groups) and on baseline medical comorbidities. The groups were well-balanced on the factors used in the minimization procedure. There were no statistically significant differences among the groups on any of the psychosocial variables at baseline (see Table 2).

Evaluation of Intervention

Short-Term Effects (1 week before surgery and morning of surgery)

Mixed model analyses indicated significant group differences for mood disturbance (least square means[standard error], p value from type 3 test: SM = 8.2[0.92], SA = 9.8[0.91], SC = 11.9[0.99], p=0.02), a significant change in mood over time with the highest levels of mood disturbance 1 week before surgery (1 week before surgery = 11.0[0.81], morning of surgery = 9.4[0.81], p=0.04), and no group by time interaction (p=0.22) (Table 2). Post-hoc analyses showed that men in the SM group had significantly less mood disturbance than did the men in the SC group (p=0.006). No other group comparisons reached significance.

There were no statistically significant group differences or changes over time for IES scores (Table 2).

Long-Term Effects (6 weeks and 6 and 12 months post-surgery)

Mixed model analyses yielded no significant group differences or changes over time for mood disturbance or IES scores during the longer-term recovery period (all ps >0.05; data not shown).

For the PCS scores, mixed model analyses revealed significant group differences (SM = 50.9[1.3], SA = 48.8[1.2], SC = 46.1[1.3], p=0.004), a change over time (6-week: 47.2[1.09]; 6-month: 49.6[1.10]; and 12-month: 49.0[1.10], p=0.02), and no group by time interaction (p=0.25) (Table 3). Post-hoc analyses indicated that men in the SM group had significantly higher PCS scores than did men in the SC group (p=0.0009). No other group comparisons reached significance. There were no statistically significant group differences or changes over time for MCS scores (means shown in Table 3).

There were no significant group differences or group by time interactions for the prostate cancer-specific QOL domains (Table 4). There were significant changes over time for urinary function (p<0.0001), urinary limitation (p<0.0001),urinary bother (p<0.0001), sexual function (p<0.0001), and cancer worry (p=0.004). For most scales, prostate-specific QOL declined from baseline to 6 weeks and 6 months post-surgery and then improved by 12 months post-surgery.

There were no group differences in pre-, peri- or post-operative complications, hospitalizations, or other medical complications in the year following surgery.

Discussion

Our results are consistent with other studies that have shown beneficial effects of pre-surgical psychosocial interventions on mood and aspects of QOL in patients with cancer and other medical conditions.[20-22,37-43] An important observation of our study was that the SM group, which was taught specific stress management skills, had better outcomes than did the SA group in terms of mood and QOL in that the SM group was significantly different than the SC group but the SA group was not significantly different from either group in the post-hoc comparisons.

Our results suggest modest effects for the primary outcome of mood disturbance prior to surgery. Although the group differences in POMS scores were in the hypothesized direction and

were statistically significant, they were small and not likely clinically significant. The POMS, however, is not typically used as a clinical measure of mental health. The full clinical implications of reducing patients' mood disturbance pre-surgically needs further investigation as there is a link between distress, immune function, and wound healing time.[22,45]

The finding that such a brief intervention in the perioperative period was associated with better physical functioning one year later is intriguing and suggests the possibility that skills taught prior to surgery might have a lasting effect on patients' recovery and QOL. Although there were no significant differences in post-operative complications and hospitalizations, these were not controlled for in the analyses, nor were other comorbid conditions. In addition to showing statistically significant effects of the intervention on SF-36 PCS scores, the post-hoc differences between the SM and SC groups were greater than half a standard deviation and likely clinically meaningful.[44] As it is not exactly clear why such a brief intervention could lead to such a lasting effect on physical aspects of QOL, the findings need to be interpreted with caution. Future studies are needed to replicate these findings and explore potential meditators for the effects of the intervention.

Our hypothesis of detecting both short- and long-term group differences was supported, however, group differences were not apparent for all outcome variables. For example, the intervention had an effect on general physical aspects of QOL but not prostate cancer-specific QOL. It may be that the intervention was not powerful enough to affect the specific physical side effects of surgery, but improves overall QOL. In addition, this may also be due to the limited nature of the intervention and that the focus was on the peri-operative period with no intervention sessions focusing on side effects management once men were discharged from the hospital. There were also no group differences on mental health, as assessed by the SF-36 MCS and the IES, or long-term effects on mood. However, it is important to note that men in the study had high

levels of mental health at study entry compared with normative data, and there were no statistically significant changes in these measures over time.

Some limitations should be noted. Participants were primarily white, non-Hispanic, married, and highly educated. Additional studies are needed with more diverse populations. The study was also conducted in men with early-stage disease, and the findings might be different in patients with more advanced disease. Additionally, this study did not target men at risk for distress prior to surgery. In fact, we excluded men with psychiatric diagnoses or who were undergoing psychotherapy. A targeted recruitment strategy focusing on highly distressed individuals might yield significant long-term effects on the mental health variables since including men who were more distressed at study entry may leave more room for improvement on mental health outcomes, although caution should be taken due to the brief nature of this intervention. Future research should examine whether there are subgroups of men for whom the intervention is most beneficial and whether the intervention could be adapted to other cancer populations. Our results suggest that providing prostate cancer patients with a brief stress management intervention before surgery reduces mood disturbance prior to surgery and may enhance general physical aspects of QOL up to a year following surgery. There is a need to replicate these findings to determine whether or not this is a useful adjunct to standard care for men with prostate cancer undergoing surgery.

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Table 1: Demographic and Medical Characteristics by Study Group

Characteristic	Standard Care	Supportive Attention	Stress Management
Age in years			
Mean (SD)	60.9 (5.9)	60.7 (7.2)	59.8 (6.9)
Ethnicity **			
White	48(92%)	38(70%)	38(71%)
African American	3(6%)	7(13%)	11(21%)
Hispanic/Latino	--	4(7%)	3(6%)
Asian	--	3(6%)	--
Other	1(2%)	2(4%)	1(2%)
Marital Status			
Married/living with partner	44(85%)	49(90%)	42(81%)
Divorced/separated	8(15%)	4(8%)	8(15%)
Widowed	--	--	1(2%)
Never married	--	1(2%)	1(2%)
Education			
High school or less	14(27%)	8(15%)	9(18%)
Some college	9(17%)	12(22%)	15(29%)
College graduate	18(35%)	21(39%)	20(39%)
Graduate degree	11(21%)	13(24%)	7(14%)
PSA			
Mean (SD)	7.0 (7.6)	7.0 (3.9)	6.5 (3.7)
Stage of Disease			
I	7(13%)	7(13%)	6(12%)
II	39(75%)	42(79%)	35(69%)
III	6(12%)	4(8%)	10(19%)
IV	--	--	--
Type of Surgery			
Non nerve-sparing	12(25%)	11(22%)	14(28%)
Nerve-sparing	34(69%)	33(66%)	32(64%)
Nerve graft	3(6%)	6(12%)	4(8%)
Hospital			
M. D. Anderson Cancer Center	43(88%)	41(82%)	39(81%)
Baylor College of Medicine	3(6%)	5(10%)	4(8%)
Veteran's Administration	3(6%)	4(8%)	5(11%)

*Significantly different at $p < 0.05$; **Significantly different at $p < 0.01$

Table 2: Adjusted Means on Outcome Variables by Group at Each Assessment Time Point (Short-Term Effects)

	Group		
Outcome variables	Stress Management Mean (SE)	Supportive Attention Mean (SE)	Standard Care Mean (SE)
POMS-18			
Baseline	10.53 (1.05)	9.61 (1.50)	10.49 (1.40)
1 week pre-Surgery	10.26 (1.17)	9.63 (1.13)	13.13 (1.19)
Morning of Surgery	7.45 (1.16)	9.92 (1.13)	10.71 (1.21)
Impact of Events-Total Score			
Baseline	14.31 (1.67)	12.15 (1.59)	15.17 (1.85)
1 week pre-Surgery	15.51 (1.45)	12.41 (1.43)	16.00 (1.57)

Note: Follow-up means adjusted for: age, ethnicity, baseline PSA, stage of disease, and baseline level of the outcome variable.
Higher scores indicate more mood disturbance/distress.

Table 3: Adjusted Means on Outcome Variables by Group at Each Assessment Time Point (Long-Term Effects)

	Group		
Outcome variables	Stress Management Mean (SE)	Supportive Attention Mean (SE)	Standard Care Mean (SE)
SF36 PCS			
Baseline	52.79 (0.98)	51.32 (1.08)	52.29 (0.98)
6 weeks post-surgery	49.58 (1.56)	47.28 (1.47)	44.63 (1.52)
6 months post-Surgery	51.36 (1.49)	48.86 (1.44)	48.51 (1.68)
12 months post-Surgery	51.76 (1.67)	50.22 (1.39)	45.12 (1.57)
SF36 MCS			
Baseline	54.45 (1.01)	54.50 (1.24)	53.25 (1.19)
6 weeks post-surgery	48.55 (1.5)	51.95 (1.40)	53.27 (1.47)
6 months post-Surgery	52.05 (1.43)	53.60 (1.38)	53.22 (1.60)
12 months post-Surgery	50.97 (1.34)	52.65 (1.34)	53.42 (1.52)

Note: Follow-up means adjusted for: age, ethnicity, baseline PSA, stage of disease, and baseline level of the outcome variable.
Higher scores indicate better QOL.

Table 4: Adjusted Means on Outcome Variables by Group at Each Assessment Time Point (Long-Term Effects)

	Group		
Outcome variables	Stress Management Mean (SE)	Supportive Attention Mean (SE)	Standard Care Mean (SE)
QOL-Urinary Function Scale			
Baseline	95.85 (1.21)	94.78 (1.63)	94.37 (1.83)
6 weeks post-surgery	46.89 (4.93)	39.16 (4.74)	38.85 (5.01)
6 months post-surgery	68.72 (4.73)	59.00 (4.68)	58.69 (5.27)
12 months post-surgery	73.36 (5.08)	66.37 (4.61)	62.56 (5.13)
QOL-Urinary Limitations Scale			
Baseline	98.16 (0.99)	98.87 (0.57)	98.27 (0.87)
6 weeks post-surgery	80.11 (3.36)	75.76 (3.26)	77.57 (3.41)
6 months post-surgery	90.69 (3.20)	87.84 (3.23)	87.80 (3.64)
12 months post-surgery	91.15 (3.52)	89.81 (3.13)	91.54 (3.23)
QOL-Urinary Bother Scale			
Baseline	91.56 (1.92)	93.14 (1.55)	88.54 (2.16)
6 weeks post-surgery	65.87 (4.37)	62.08 (4.22)	65.72 (4.39)
6 months post-surgery	80.19 (4.09)	74.86 (4.11)	72.77 (4.65)
12 months post-surgery	79.62 (4.47)	80.15 (4.08)	82.01 (4.53)
QOL-Sexual Function Scale			
Baseline	62.08 (4.36)	65.22 (3.62)	64.25 (3.61)
6 weeks post-surgery	20.51 (3.56)	19.90 (3.47)	18.84 (3.60)
6 months post-surgery	29.50 (3.56)	30.32 (3.39)	23.93 (3.87)
12 months post-surgery	32.18 (3.73)	35.65 (3.34)	30.18 (3.74)
QOL-Sexual Limitations Scale			
Baseline	92.55 (1.68)	96.15 (0.97)	94.23 (1.22)
6 weeks post-surgery	79.61 (2.79)	77.07 (2.72)	78.91 (2.80)
6 months post-surgery	80.40 (2.64)	76.53 (2.66)	78.72 (3.02)
12 months post-surgery	81.20 (2.96)	77.85 (2.66)	82.22 (2.89)

Sexual Bother Scale			
Baseline	78.03 (2.82)	81.82 (2.31)	76.74 (2.82)
6 weeks post-surgery	56.09 (4.56)	47.15 (4.51)	49.53 (4.73)
6 months post-surgery	52.55 (4.41)	51.39 (4.49)	48.08 (4.92)
12 months post-surgery	51.94 (4.68)	53.00 (4.42)	55.50 (4.82)
Bowel Function Scale			
Baseline	76.93 (1.17)	76.48 (1.04)	77.59 (0.85)
6 weeks post-surgery	72.06 (1.59)	73.53 (1.56)	73.73 (1.56)
6 months post-surgery	73.02 (1.48)	73.94 (1.51)	75.81 (1.72)
12 months post-surgery	73.00 (1.68)	75.17 (1.48)	75.96 (1.60)
Bowel Limitations Scale			
Baseline	99.90 (0.10)	99.51 (0.35)	99.40 (0.37)
6 weeks post-surgery	97.20 (0.87)	98.13 (0.84)	97.81 (0.85)
6 months post-surgery	97.34 (0.81)	97.35 (0.83)	97.89 (0.93)
12 months post-surgery	96.17 (0.91)	98.35 (0.80)	98.95 (0.87)
Bowel Bother Scale			
Baseline	70.01 (0.93)	70.69 (0.90)	70.01 (0.92)
6 weeks post-surgery	66.85 (1.43)	66.82 (1.43)	66.89 (1.38)
6 months post-surgery	69.92 (1.31)	67.40 (1.32)	69.37 (1.51)
12 months post-surgery	67.38 (1.50)	68.74 (1.29)	69.03 (1.44)
Cancer Worry Scale			
Baseline	58.88 (4.51)	62.43 (4.53)	56.35 (4.37)
6 weeks post-surgery	59.45 (4.55)	70.42 (4.32)	68.51 (4.46)
6 months post-surgery	63.29 (4.24)	70.67 (4.19)	72.36 (4.73)
12 months post-surgery	69.30 (4.60)	75.95 (4.14)	76.02 (4.59)

Note: Follow-up means adjusted for: age, ethnicity, baseline PSA, stage of disease, and baseline level of the outcome variable.
Higher scores indicate better QOL.
There were no statistically significant group or group by time effects.

Figure 1: Recruitment and Participation Rates