An online psychological intervention can improve the sexual satisfaction of men following treatment for localised prostate cancer: Outcomes of an RCT evaluating My Road Ahead

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Keywords: prostate cancer, psychological intervention, sexual outcomes, online intervention.
Abstract

Background: Prostate cancer treatment often results in significant psycho-sexual challenges for men following treatment, however many men report difficulty in accessing appropriate care.

Methods: A randomised controlled trial was undertaken to assess the efficacy of a 10-week self-guided online psychological intervention called My Road Ahead (MRA) for men with localised prostate cancer in improving sexual satisfaction. Participants were randomised to one of three conditions My Road Ahead alone or My Road Ahead plus online forum, or forum access alone. Pre, post and follow-up assessments of overall sexual satisfaction were conducted. Mixed models and structural equation modelling were used to analyse the data.

Results: 142 participants (mean age 61 years; SD=7) participated. The majority of participants had undergone radical prostatectomy (88%) and all men had received treatment for localised prostate cancer. Significant differences were obtained for the three groups (p=.026) and a significant improvement in total sexual satisfaction was observed only for participants who were allocated to MRA+Forum with a large effect size (p=.004, partial $\eta^2=.256$). Structural equation modelling indicated that increases in sexual function, masculine self esteem and sexual confidence contributed significantly to overall sexual satisfaction for the MRA+Forum plus forum condition.

Conclusions: This study is the first, to our knowledge, that has evaluated a self-guided online psychological intervention tailored to the specific needs of men with prostate cancer. The findings indicate the potential for MRA to deliver support that men may not otherwise receive and also highlight the importance of psychological intervention to facilitate improved sexual outcomes.
Background

Prostate cancer treatments can have a significant impact on patient quality of life (QoL) [1]. Common side effects include erectile dysfunction (ED) and urinary incontinence (1-4). The support needs of men with prostate cancer are well documented (5). Many men report high levels of unmet supportive care needs (5), particularly in the area of psychological support and sexual support (5-7). Adjustment to sexual dysfunction following treatment for localised prostate cancer, as well as the impact on masculine self esteem and the marital relationship can be challenging (6, 8-10). Unfortunately, access to evidence-based and timely psycho-social and psycho-sexual support is often limited, particularly in rural and remote regions (6). Two recent systematic reviews evaluating psychosocial interventions for prostate cancer patients have indicated that only a limited evidence-base exists for psycho-social and psycho-sexual interventions in prostate cancer and that further research is required (11, 12).

There is a growing interest in delivery of psycho-social or psycho-sexual interventions remotely or using self-directed approaches in order to increase access (13, 14). These approaches appear to show promise in delivering much needed psycho-social or psycho-sexual care and overcoming difficulties faced in the context of limited clinical services. One randomized controlled trial comparing the delivery of a psychotherapeutic intervention for men following treatment for prostate cancer in an online or face to face format with a psychologist found equal benefit across these two modalities (14). The relative anonymity and ease of accessing information and support appears to hold appeal for men, particularly in relation to accessing support in regards to sexual issues (14-16) and there is growing interest in, and support of, the delivery of internet-based interventions to augment the limited face-to-face psycho-social or psycho-sexual specialist services available in cancer care (17, 18). In addition to this there is also growing evidence that peer-based support in addition to, or in combination with, structured psychological support can also facilitate improved outcomes for men with prostate cancer (19, 20).

To date, no prostate cancer specific self-guided online interventions, with minimal therapist support, have been developed and evaluated for localised prostate cancer patients. Our online psychological intervention, My Road Ahead (MRA), is the first, to our knowledge. We have previously reported preliminary evaluation outcomes of this program in which we reported that this online intervention provided significant benefit to participants in terms of reductions in psychological distress (21). The aim of this secondary outcome analysis was to determine whether this intervention also provided benefit for participants in terms of their sexual satisfaction. It was hypothesised that participants randomised to receive MRA, with or without access to a forum, as compared to those who received access to the forum-only condition, would demonstrate significantly greater improvements in sexual satisfaction from pre- to post-intervention. Furthermore it was hypothesised that participants randomised to receive access to the moderated forum in addition to MRA, as compared to those who received access only to MRA, would demonstrate significantly greater improvements in sexual satisfaction from pre- to post-intervention. An examination of the factors that predicted improvements in sexual satisfaction was also planned.

MATERIALS AND METHODS
Ethical approval to conduct the study was obtained from Melbourne Health, Swinburne University of Technology, Deakin University and Peter MacCallum Cancer Centre Human Research Ethics Committees.

**Eligibility and Recruitment**

Participants were eligible to participate in the study if they had been diagnosed with localised prostate cancer and had received, or were currently receiving, treatment with curative intent within the last five years. They were not eligible to participate if they had a diagnosis of advanced or metastatic disease. Participants were recruited using a variety of methods (invitations from urologists and advertisements in newsletters, website and via postcards). All methods relied on self-referral following invitation to participate in the study.

**Study Design**

Participants were required to complete the consent process online and create a personalised account on the MRA program website (www.myroadahead.org). After consenting to participate in the study, participants completed the baseline questionnaires and were randomised to one of the three intervention conditions using a computer generated sequential 1:1:1 allocation across the three (3) conditions. Group 1 participant’s received access to My Road Ahead (MRA-Only). Group 2 participants received access to My Road Ahead plus the moderated forum (MRA+Forum). Group 3 participants received access to the moderated forum only (Forum-Only). Participants in all groups received a weekly email reminder to return to the program and/or forum. Participants in all conditions were required to complete the online assessment at five time points; baseline, week 5, post-intervention (week 10 for group 3), 3-month and 6-month follow-up (see online supplemental Figure 1).

To power the study at the 80% level, based on an alpha level of .05 with an estimated medium effect size ($\eta^2=.06$) and with three groups completing five assessment points, 125 complete responses were required. To account for an estimated 20% drop-out rate a total of 150 participants was required; 50 per group.

**Outcome Measure**

Overall sexual satisfaction was measured using International Index of Erectile Function (IIEF) (22). The IIEF yields 5 subscale scores of erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall sexual satisfaction, as well as a total score. The range for overall sexual satisfaction scores was 0-10 and the range for erectile function was 0-30. Higher scores indicate better functioning. High internal consistency has been reported for these scales ($\alpha=0.91$), as well as high test-retest reliability ($r=0.82$) (22).
Independent Measures

Psychological distress was measured using the Depression Anxiety and Stress Scales (DASS-21) short version designed to measure the negative emotional states of depression, anxiety and stress as well as total distress (23). The Prostate Cancer related Quality of Life scale (PCa-QoL), was used to assess quality of life (24). The scale contains 84 Likert type items that fall into 11 scales including: 1. Urinary control 2. Sexual ability - sexual intimacy 3. Sexual confidence; 4. Spouse affection; 5. Masculine self-esteem; 6. Health worry; 7. Prostate Specific Antigen (PSA) concern; 8. Cancer control; 9. Informed decision; 10. Regret; and, 11. Positive outlook (24). Use of sexual aids were also collected at each time point via self report.

The online psychological intervention: My Road Ahead

My Road Ahead is a self-guided cognitive behavioural therapy (CBT) based intervention that provides psycho-education (through text, video, audio and graphics) as well as psychotherapeutic interventions delivered through a series of interactive exercises and regular automated feedback as participants’ progress through the program.

The intervention is a six (6) module online program that offers a range of topics to work through at an individual pace for ten (10) weeks. The six modules focus on 1) The emotional impact of prostate cancer; 2) Cognitive strategies and effective communication; 3) Coping with the physical challenges related to prostate cancer; 4) Sexuality and masculinity; 5) Sexuality and intimacy; 6) Planning for the future. We have previously published extensive detail about the program (16, 25).

Moderated forum

Two moderated forum facilities are hosted within the website. The forums used a simple topic based discussion system where participants could post comments and start discussions. To avoid contamination across conditions two separate forums were implemented for the MRA+Form and Forum Only conditions.

Statistical Analyses

Descriptive statistics for overall sexual satisfaction were generated from the pre- and post-intervention questionnaires, the 3 months and 6 month follow-up questionnaires. The three conditions were compared in terms of demographics, the number of erectile aids used and baseline outcome measures. All assumptions were met for conducting a mixed model analysis and this was conducted using an intention to treat approach. First, Mixed Models were used to confirm that there were significant group differences in changes in overall sexual satisfaction after treatment, allowing for correlation between consecutive outcome measures (AR(1) dependence) and assuming normality. Pre-planned analysis of variance (ANOVA) were then used to determine which intervention group had experienced significant changes and what condition differences were
significant. Effect sizes were reported using $\eta^2$ with values of .06 associated with medium effect sizes and values above .14 associated with large effect sizes. Pre-planned correlation analyses were then conducted to examine likely causes of the changes in overall sexual satisfaction for each group. On the basis of these results a structural model was fitted for the MRA+Forum group.

RESULTS

Participants

Of the 152 participants recruited, 10 were excluded because they reported treatment for advanced disease. The remaining 142 participants had received treatment only for localised disease and were randomly allocated to the three intervention conditions. The mean age was 61 years (SD=7; range 42-82) and the mean time since diagnosis was 3.5 years (SD=1.8; Range=6mths-5years). Sixty-five percent of participants reported their ethnicity as anglo-celtic and 35% as European. Online supplemental table 1 provides a summary of the demographic details of the sample. Baseline erectile functioning scores indicated that all participants across all three groups were experiencing significant erectile dysfunction (22). Average baseline sexual satisfaction scores indicated a very low level of sexual satisfaction and average erectile function scores indicated severe dysfunction across the three intervention arms (22). (See online supplemental table 2).

[insert link to online supplemental table 1 about here]

No significant differences in the sexual measures were found between the conditions at baseline ($F(10,270)=1.31, p=.226$) and in particular there were no significant difference for total sexual satisfaction ($F(2,139)=.777, p=.402$). Significant demographic differences were found only in the case of country of birth. Australian born patients were disproportionately represented in the MRA-Only condition (85%), compared to 79% in the Forum-Only condition and 63% in the MRA+Forum condition. Assuming a Negative Binomial distribution for the number of sexual aids used, no significant difference was found between the groups at Baseline (Chi-Square = 1.061, df=2, $p=.588$) or post-treatment (Chi-Square = 2.138, df=2, $p=.343$). However, for both the MRA+Forum and the Forum-Only groups a significant reduction in the number of sexual aids was observed from a related samples Wilcoxon Signed Rank tests ($p=.003$ in both cases), with near significance for the MRA Only group ($p=.056$) from baseline to post-intervention follow-up.

Intervention completion rates

The rate of intervention completion by participants who received access to the MRA modules was calculated using page view data. The mean percentage of content completed by participants was 59%. Participants in the MRA-Only condition completed on average 60% of the content while participants in the MRA+forum completed 57% of the content. Content completion rates reduced as participants moved through the modules. Forum participation for participants who had access to the forum alone (Forum-Only) was higher (average 2-3 posts per user) than forum participation by participants who had access to both the forum and the modules (MRA+forum) (average 1-2 posts per user). On average the majority of participants (62%) reported spending less than 30 mins per
week on the forum. This indicates that forum ‘lurking’, the process of reading but not actively participating, was most likely occurring for the majority of participants with access to the forums.

**Questionnaire Completion Rates**

There were similar rates of questionnaire completion for all three conditions with an overall completion rate of 87% at week 5 of treatment and 73% at post-treatment. Completion rates for 3 months and 6 months were 66% and 51% respectively.

**Group comparison analyses**

A Mixed Model Analysis for pre- and post- intervention assessments of sexual and masculine self esteem outcomes showed that only in the case of overall sexual satisfaction was there a significant difference between the groups in terms of the change from baseline to post-treatment (F(2, 100) = 5.26, p=.007). The only significant improvement for the MRA-Only group occurred in the case of masculine self esteem (t(32)=2.21, p=.034) and the improvements for the Forum-Only group occurred in the case of masculine self esteem (t(35) = 2.505, p=.017) and erectile function (t(35)=2.135, p=.040). The MRA+Forum group exhibited a significant improvement in overall sexual function (t(34) = 3.605, p=.001), and relatively large, although not significant improvements in erectile function and intercourse satisfaction. This group did also experience a significant improvement in masculine self esteem (t(33)=3.206, p=.003) and sexual confidence (t(34) = 2.093, p=.044). The detailed results can be found in supplemental table 2. These findings justify the model proposed in Figure 1.

[Insert link to supplemental table 2 about here]

The results for the intention to treat analysis that showed significant differences in overall sexual satisfaction between the conditions for pre-, post-, 3-month and 6 month follow-up (F(6,411)=2.39, p=.028) can be found in Table 1. In this analysis the most recent previous values were carried forward in order to replace missing data for participants who failed to complete an assessment.

[Insert table 1 about here]

The use of sexual function aids was also measured at each assessment time point and presented in the online supplemental table 3.

[Insert link to online supplemental table 3 about here]

McNemar tests were used to determine for each group whether the reduction in participant use of medication and erectile dysfunction aids was significant. In the case of the MRA-Only groups there was a non-significant reduction from 24 to 22 (p = .625). For the Forum Only group there was a non-significant reduction from 22 to 18 (p=.289). However, in the case of the MRA+Forum group the reduction from 23 to 15 was significant (p=.021).
Change scores were calculated for overall sexual satisfaction for each group condition over time and this data is presented in Table 2. Only in the case of the MRA+Forum group was there a significant improvement in overall sexual satisfaction with the large effect size ($\eta^2=.356$) suggesting a clinically meaningful improvement. However, mean scores indicate that participants did not reach a ‘normal’, non-patient population score. Table 3 shows the difference between the three conditions for each of these changes. Significant condition differences were observed for comparisons between the MRA+Forum group and the Forum-Only group changes between pre-treatment and post-treatment, and this significant difference was sustained for the 3-month and 6-month follow-up. There were also significant group condition differences between the MRA-Only and MRA+Forum groups from pre- to post-treatment and the three-month follow up, but not the six-month follow-up.

The above results suggest that the MRA+Forum group produced significantly better results than the MRA-Only group as well as the Forum-Only group. In order to understand why the MRA+Forum arm of the study was so successful in improving overall sexual satisfaction correlation and structural model analyses were then undertaken.

**Structural Equation Model for Overall Sexual Satisfaction**

Pre-specified pre-intervention to post-intervention change scores were calculated and entered into a correlation analysis to examine the relationship of the independent variables with changes in overall sexual satisfaction for each intervention condition. The results of the correlation analysis suggest that the important reasons for the success of the MRA+Forum condition, in terms of the improvement of overall sexual satisfaction after treatment, relate to improvements in sexual function (erectile function, orgasm function, intercourse satisfaction), sexual confidence and masculine self-esteem. Figure 1 shows the structural model capturing these relationships. The model of fit was excellent with 62% of the variance explained by the included variables.

**DISCUSSION**

The MRA online intervention in combination with access to a peer discussion forum provided the greatest improvements in sexual satisfaction. Participants who received access to this combined condition showed significantly greater improvements in sexual satisfaction than those participants who received access to the MRA intervention alone, or the forum alone and these benefits were sustained at the three- and six-month follow up assessments. Structural equation modelling indicated that improvements in overall sexual satisfaction were largely associated with improvements in sexual functioning but were also related to improvements in sexual confidence and masculine self-esteem for those participants who had access to the combined intervention and...
These findings support our hypotheses and previous findings in relation to this combined condition resulting in the greatest reductions in psychological distress (21).

A large component of the MRA intervention focussed on facilitating adjustment to the changes in sexual functioning experienced by men following treatment for localised prostate cancer. Participants were encouraged to explore their beliefs and attitudes towards sexual functioning and intimacy and to consider broadening their approach to sexual intimacy. This approach was not intended to minimise the loss associated with erectile dysfunction and participants were also encouraged to acknowledge and explore this loss as part of the program. My Road Ahead also directly focussed on beliefs and attitudes associated with masculinity, masculine ideals and expectations and the ways in which these beliefs impact on self-judgement and self-esteem. The findings of the current study are interesting in that participants who received the combined MRA and forum condition appeared to benefit from both improvements in physical sexual functioning as well as psychological components of sexuality and both these areas significantly contributed to overall improvements in sexual satisfaction. Interestingly use of erectile dysfunction aids actually decreased over the course of the intervention for the combined MRA plus Forum group indicating that this improvement in sexual functioning was not related to increased use of physical agents or devices. These findings indicate that the combination of the structured intervention in addition to the peer-led discussion forum resulted in the most significant improvements for participants, greater than the intervention or forum alone. The rates of program completion were very similar across both groups and sexuality, intimacy and masculinity were the main topics of discussion in both the forum conditions. These findings suggest that men treated for localised prostate cancer benefit the most in adjusting to the sexual dysfunction experienced as a result of treatment when provided with the opportunity to discuss, and possibly normalise, their experience with peers whilst at the same time learning new skills that provide a structured framework to personally process the loss and explore psychological responses to their new sexual identity.

Time since diagnosis and treatment may also be a factor that should be considered when interpreting these results as the mean time since diagnosis was 3.5 years. Our findings indicate that even at this length of time post diagnosis the intervention did have a significant impact on sexual outcomes. However, our sample size limited our ability to be able to explore whether there were any difference in outcomes between those who participated in the study sooner after treatment compared to those who participated much later after treatment. Further research is required to explore any differential outcomes based on time since diagnosis or treatment.

The ways in which masculinity is impacted by the prostate cancer experience, particularly the sexual impact of prostate cancer treatment, is emerging in the research literature (26). Masculine beliefs have been found to predict negative mood, functional wellbeing and social wellbeing (27). In a recent couple based intervention study Masculine self-esteem was the largest predictor of anxiety, depression, mental quality of life and cancer specific distress in a sample of men with prostate cancer (8). Masculine self-esteem as a concept is relatively unique in that it is based on appraisals of
masculinity and perceptions and judgments of the self in the context of masculine identity or ideals (24). Items that assess this construct include the following; I feel as if I am no longer a whole man, I have lost part of my manhood, I’m not the man I used to be, I feel weak and small, I feel I have been too emotional (24). Whilst masculinity and masculine self-esteem has been reported to be associated with distress more broadly the findings of this study indicate that masculine self-esteem is also implicated in sexual satisfaction. Sexual confidence also plays a role in these factors.

Although this study has found evidence for improvements in sexual satisfaction, which were sustained over time, there are a number of limitations to the current study. The sample size is relatively small and may have resulted in insufficient power to detect moderate treatment effects. Furthermore the sample of participants recruited heavily favoured men who had undergone radical prostatectomy. Whilst every effort was made to recruit men who had undergone a variety of treatments for localised prostate cancer it is evident that this was not overly successful. Future evaluation of the program with a larger sample size, a larger representation of treatment types and enhanced tailoring of the intervention to meet the specific needs of participants would be beneficial.

This is the first self-guided online psychological intervention developed specifically tailored to the needs of men with localised prostate cancer. It is evident that participants engaged well with the program, and those participants who received access to the combined MRA and Forum condition showed significantly better improvements in sexual satisfaction than participants who received the intervention or forum alone. Given the difficulty patients often encounter in accessing appropriate psychological and psycho-sexual support and the high levels of needs reported by men across these domains this program shows promise in improving access using an accessible and user friendly online medium. This study also has wide application for clinical practice. The integration of an e-health system such as this could be easily adopted with low cost. However, more broadly this study supports the need for men with sexual dysfunction as a consequence of prostate cancer treatment to have support to process the emotional impact of such changes in order to be able to regain confidence and the ability to have a satisfying sex life.

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CONFLICT OF INTEREST DISCLOSURES

No conflicts of interest to be declared.
References


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<td>4.33</td>
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Table 2: Mean Changes in Overall Sexual Satisfaction from Pre- to Post-Treatment and 3 and 6-month follow up for each Condition with 95% Confidence Intervals

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<th>MRA Only</th>
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<td>F(3,45)=5.16, p=.004, $\eta^2=0.256$</td>
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LCI = Lower confidence interval; UCI = Upper confidence interval
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<td></td>
<td>-0.86</td>
<td>-1.84</td>
<td>0.13</td>
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LCI = Lower confidence interval; UCI = Upper confidence interval
Author/s:
Wootten, AC; Meyer, D; Abbott, J-AM; Chisholm, K; Austin, DW; Klein, B; McCabe, M; Murphy, DG; Costello, AJ

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