



# Exploring the impact of providing men with information about potential prostate cancer treatment options prior to receiving biopsy results

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## Abstract

**Purpose** There is little research assessing the impact of providing men with information about prostate cancer (PCa) treatment options at the time of referral for a prostate biopsy. Study objectives were to determine whether receiving an information booklet about PCa treatment options prior to receiving biopsy results was acceptable to patients, and if receiving this information influenced levels of anxiety, depression, distress, and treatment decisional conflict.

**Methods** Between June 2016 and September 2017, a randomised block design was used to allocate patients from an Australian urology practice into the intervention or control group. Patients in the intervention group were provided with written information about treatment options for localised PCa prior to their biopsy. Outcome measures including the Distress Thermometer, Generalised Anxiety Disorder-7, Patient Health Questionnaire-9, and Decisional Conflict Scale were completed pre-biopsy and 2–3 weeks post-biopsy. Ninety-eight patients referred for an initial prostate biopsy for an elevated PSA test or suspicious digital rectal exam participated in the study (response rate = 78%).

**Results** Multimodal repeated-measures analyses showed no significant differences between control and intervention groups in changes in distress, anxiety, or depression from pre- to post-biopsy, and in decisional conflict post-diagnosis (all  $p > .05$ ). Thirty-five (87%) patients believed that the resource made it easier to understand subsequent explanation of treatment options, and 51 patients (98%) who received the intervention preferred to be given information at that time.

**Conclusions** Providing patients with information about treatment options prior to biopsy did not impact on changes in psychological distress and decisional conflict post-biopsy. However, the majority of patients preferred to be given such information at this time point.

**Keywords** Cancer · Oncology · Prostate biopsy · Treatment decision aid · Distress · Decisional conflict

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## Introduction

Prostate cancer (PCa) is one of the most commonly diagnosed cancers in men worldwide [1], with Australia amongst the countries with the highest incidence [1]. Treatment options for PCa may result in significant decrements in quality of life (QoL) [2]. Given that each treatment option results in different types of side effects, receiving a diagnosis of PCa requires men to make a decision regarding the optimal treatment choice, based on their own preferences and medical advice [3]. Men with localised PCa are often provided with several treatment options that are equally viable [3, 4].

Research has suggested that there is a low level of concordance between final treatment choice and side effects that patients reported that they wanted to avoid [4]. In a review of patient decision-making for PCa treatment, the authors concluded that differences in patients' treatment decisions may reflect variation in the content of information delivered and manner/timing of delivery, rather than patients' preferences [5]. This suggests the need to facilitate the treatment decision-making process for patients such that an informed decision is made with minimal decisional regret post-treatment. This is particularly important given research suggesting that higher decisional regret was associated with greater fear of cancer recurrence following treatment [6].

A number of studies have assessed the impact of providing patients with decision aid interventions after a PCa diagnosis. It was anticipated that these interventions would assist men in making an informed decision regarding the appropriate treatment choice. In one study, 240 patients with localised PCa were randomised into two groups. The control group discussed treatment with their specialist as per standard care, whilst the intervention group received a decision aid in addition to the specialist discussion [7]. Results demonstrated that the decision aid led to fewer patients being undecided about treatment choice.

In another study [8], 122 patients were randomised to receive standard information for localised PCa or a decision aid. Decisional conflict scores and satisfaction with the decision improved in the intervention group compared to the control group [8]. Similarly, a qualitative study suggested that a decision aid allowed localised PCa patients to be better prepared for discussions about treatment with doctors and family members, and resulted in improved patient-physician interaction [9].

However, a recent meta-analysis of randomised controlled trials of decision aids for localised PCa [10] demonstrated a wide variation in results for the impact of decisional aids on decisional conflict, knowledge of treatment options, and satisfaction with the decision. There was also minimal evidence demonstrating that decision aids reduced levels of anxiety and depression [10].

Given that the benefits of providing patients with decision aids following diagnosis have not been consistently demonstrated, it is important to explore different means of delivery of such information, including timing of intervention. As patients often experience anxiety immediately following a cancer diagnosis, this anxiety may hamper their ability to make treatment decisions at that point [5]. Research has also demonstrated that patients make a treatment choice almost immediately after a cancer diagnosis, with a majority considering only one treatment option [11, 12]. Thus, introducing patients to a decision aid (for the first time) immediately following diagnosis may not be of maximal benefit in assisting them to make a treatment choice.

To our knowledge, only one study has explored the feasibility of providing men with information about PCa treatment options prior to biopsy [13]. Twenty-nine patients were randomly assigned to receive a usual care biopsy instruction sheet or an education pack explaining treatment options for PCa. Patients who received the intervention reported increased knowledge about PCa treatment options, higher QoL, and a trend towards lower anxiety compared to the control group [13].

Given the dearth of research in this area, this study aims to examine whether patients found it acceptable to receive written information about PCa treatment options at the time of biopsy referral. Another aim was to determine whether receiving information at this time point influenced changes in anxiety, depression, and distress experienced from baseline (pre-biopsy) to follow-up (post-biopsy). A final aim was to examine if patients in the intervention group who received a PCa diagnosis experienced lower treatment decisional conflict at follow-up compared to the control group. It was hypothesised that patients who receive information about treatment options prior to biopsy would have improved or stable levels of psychological symptoms from pre- to post-biopsy compared to those who did not receive the information.

## Methods

### Participants

This study was approved by the institution's ethics committee (714-15). Between June 2016 and September 2017, 126 consecutive patients referred for an initial prostate biopsy for an elevated PSA test or suspicious digital rectal exam in a urology private practice were invited to participate in the study. Exclusion criteria included patients with a prior history of PCa and those suspected of metastatic cancer. Twelve patients declined participation; ninety-eight returned their baseline questionnaire (response rate = 78%). Patients who did not respond did not differ significantly in terms of age, group, or urologist.

## Measures

Demographic data were collected from participants including age, marital status, ethnic background, comorbidities, educational level, and income range. Information regarding patients' biopsy result was also collected.

### The Distress Thermometer

The distress thermometer (DT) is a widely used single-item visual analogue scale measuring self-reported distress. This measure has been validated for use with men with PCa [14].

### The Generalised Anxiety Disorder-7

The Generalised Anxiety Disorder-7 (GAD-7) was used to assess anxiety [15]. The GAD-7 was developed to assess the diagnostic criteria for Generalised Anxiety Disorder and has specificity and sensitivity of .80.

### The Patient Health Questionnaire-9

The Patient Health Questionnaire-9 (PHQ-9) [16] was developed from the diagnostic criteria for Major Depressive Disorder and used to assess depression. The PHQ-9 has been shown to possess excellent validity for patients with severe, moderate, and mild depression.

Both the GAD-7 and PHQ-9 have been used in previous studies to assess depression and anxiety respectively in men with prostate cancer [17, 18].

### Decisional Conflict Scale

Treatment decisional conflict was measured using the Decisional Conflict Scale (DCS) which has 16 items, with 5 response options (score range per item: 0–4) [19]. The scale measures personal perceptions of (a) uncertainty in choosing options, (b) modifiable factors contributing to uncertainty (e.g. feeling uninformed in decision-making), and (c) effective decision-making such as feeling the choice is informed, value-based, and likely to be implemented.

### Use of educational information provided

Patients were asked about their use of the information provided prior to biopsy and whether they would have preferred not to have been given information about treatment options pre-biopsy (for the intervention group).

### Acceptability of the intervention

Acceptability of the intervention was determined by asking about patient preferences in receiving information prior to

biopsy. Patients were also asked about the usefulness of the booklet in improving their understanding of their urologist's explanation of treatment options.

## Intervention

The intervention booklet ("Treating localised prostate cancer") used in this study is second in a series of 4 booklets developed by the Prostate Cancer Foundation Australia for men with localised PCa. The booklet can be read as a standalone booklet. Treatment options covered in the booklet included active surveillance, surgery, radiotherapy, and hormone therapy. Given that men were given this booklet prior to diagnosis, a cover letter was included to inform patients that this booklet was provided purely for informational purposes and that receiving this booklet did not imply that they would be diagnosed with cancer or require treatment.

## Procedure

Urologists introduced the study to patients and provided them with a participant information and consent form at the time they were booked for biopsy. After providing consent, patients completed a baseline questionnaire and were randomised into either the intervention or control group. All patients received a standard biopsy instruction sheet. Patients in the intervention group were also provided with an information booklet about treatment options. Participants were mailed the follow-up questionnaire 2–3 weeks post-biopsy and a reply-paid envelope was included to facilitate return. Amongst the validated measures, the DT, GAD-7, and PHQ-9 were administered at baseline and at follow-up, approximately 2–3 weeks post-biopsy. The DCS was administered at follow-up only for patients with a positive biopsy result. Men who exhibited high levels of distress were given information about seeking psychological support and potential referral options.

## Statistical analysis

### A priori power analysis

A power analysis was conducted assuming a medium effect size, 5% significance, and 80% power. Based on the results commonly recorded by this institution, it was expected that there would be a 10% attrition rate and that 60% of the men volunteering for the trial would receive a positive biopsy result. This suggested a sample size of 60 for men with a positive biopsy result and 40 for men with a negative biopsy result.

At baseline, distributions of the DT, PHQ-9, and GAD-7 measures showed positive skewness. For post-biopsy measures, outliers were detected for the DCS. Therefore, non-parametric Mann-Whitney tests were used to compare the groups on this measure. Demographic data for the intervention

and control groups were also compared at baseline using chi-squared tests of association.

Demographic and baseline factors associated with attrition were then identified. Controlling for significant baseline differences and attrition propensity, changes from baseline to follow-up in anxiety, depression, and distress scores were compared for the two groups using an intention-to-treat mixed model repeated measures (MMRM) analysis assuming AR(1) dependence. Appropriate transformations were applied to the DT, PHQ-9, and GAD-7. These analyses were repeated for all participants and then separately for men who received positive and negative biopsy results. Finally, paired *t* tests were used to assess if there were significant changes in outcome measures in intervention and control groups, and separately for those who received negative and positive biopsy results. Chi-squared tests of association were used to compare the intervention and control groups in regard to information accessed. A frequency analysis of booklet acceptability was conducted for the intervention group.

## Results

Average participant age was 64.6(SD = 7.1) years. Table 1 displays demographic and medical characteristics of participants. There were no significant differences between the control ( $n = 40$ ) and intervention ( $n = 58$ ) groups across demographic characteristics and distress, anxiety, and depression scores at baseline. There were also no significant differences for patients receiving positive and negative biopsy results, and there was no significant interaction effect for biopsy result with group in the case of distress, anxiety, and depression. However, patients receiving a positive biopsy result were on average significantly older ( $M(SD) = 66.2(5.5)$ ) than patients receiving a negative biopsy result ( $M(SD) = 61.6(9.0)$ ). Similar percentages of men received positive biopsy results in the control (67%) and intervention (72%) groups.

Baseline scores were not related to attrition nor was there a relationship between these scores and any demographic factors or group variable.

For the control group, there were no significant baseline differences for patients receiving positive and negative biopsy results in terms of distress, anxiety, or depression, and there were no significant interaction effects for the group with the biopsy result. However, for the intervention group, there was a significant baseline difference for patients receiving positive and negative biopsy results in the case of distress ( $p = .015$ ,  $d = .783$ ). Baseline distress levels for the intervention group were significantly higher for patients who received a positive biopsy result than patients who received a negative biopsy result as shown in Table 2. Attrition was significantly more likely for patients with a pre-existing depression diagnosis

(Fisher exact test  $p = .008$ ); thus, this was controlled for in the MMRM analyses below.

## Changes in psychological symptoms from pre- to post-biopsy

MMRM analyses showed no significant differences between control and intervention groups in changes in distress ( $F(1,75) = 0.090$ ,  $p = .765$ ), anxiety ( $F(1,83) = 1.748$ ,  $p = .190$ ), or depression ( $F(1,84) = 1.027$ ,  $p = .314$ ) from pre- to post-biopsy. Similarly, there were no significant differences between groups in changes on these measures when patients with positive and negative biopsy results were studied independently.

Change score analyses of the data shown in Table 2 indicated no significant changes from pre- to post-biopsy for the control or intervention group (all  $p > .05$ ), when the whole group was evaluated (regardless of biopsy result). Change score analyses were also performed separately for intervention and control groups, according to positive or negative biopsy results in Table 2. Control group patients receiving a positive result experienced significant increases in distress, and there was a trend towards greater anxiety symptoms from pre- to post-biopsy. Conversely, control group patients who received a negative result, experienced a significant decrease in depressive symptoms. In the intervention group, there were no significant changes from pre- to post-biopsy on any of the measures. The effect sizes and power to detect a difference between the groups are also displayed in Table 2.

Treatment decisional conflict did not differ significantly between the control ( $M(SD) = 23.36(18.73)$ ) and intervention groups ( $M(SD) = 17.95(13.78)$ ).

## Information accessed and acceptability of intervention

There was no significant difference between the groups in regard to whether patients searched for information regarding PCa treatment options before receipt of biopsy results (chi-square = .072,  $p = .788$ ). Fifty-six percent of the control group and 59% of the intervention group looked for information about PCa treatment options whilst awaiting their biopsy results.

In the intervention group, 52 (90%) of the 58 patients who received the information booklet read the information booklet, and 6 (10%) did not respond to this question. Of those who read the material, 2 (4%) spent less than 5 min doing so, 19 (36%) spent 5 to 15 min, 25 (48%) spent 15 to 30 min, and 6 (12%) more than 30 min. 11 (21%) patients found it somewhat useful, 31 (60%) found it very useful, and 10 (19%) found it extremely useful. Fifty-one (98%) of the 52 patients who read the booklet said they preferred to be given such information, with only one person saying not.

Of the 37 who read the booklet and received a positive biopsy result, 2 (5%) stated that it had no impact on being able

**Table 1** Demographic and medical characteristics

	Count (%)			Chi-squared	<i>p</i> value
	Control group ( <i>N</i> = 40)	Treatment group ( <i>N</i> = 58)	Overall ( <i>N</i> = 98)		
Biopsy result				$\chi^2(1) = .304$	.581
Negative	13(33)	16(28)	29(30)		
Positive	26(67)	41(72)	67(70)		
Missing	1	1	2		
Anxiety disorder <sup>a</sup>				$\chi^2(1) = .215$	.643
No	35(90)	45(87)	80(88)		
Yes	4(10)	7(14)	11(12)		
Missing	1	6	7		
Prior cancer diagnosis <sup>b</sup>				$\chi^2(1) = .430$	.512
No	33(85)	42(79)	75(81)		
Yes	6(15)	11(21)	17(19)		
Missing	1	5	6		
Depression diagnosis <sup>c</sup>				$\chi^2(1) = .012$	.911*
No	37(95)	50(94)	87(95)		
Yes	2(5)	3(6)	5(5)		
Missing	1	5	6		
English first language				$\chi^2(1) = .004$	.947*
No	3(7)	4(7)	7(7)		
Yes	37(93)	52(93)	89(93)		
Missing	0	2	2		
Ethnicity				$\chi^2(1) = .233$	.629
Caucasian	36(92)	54(95)	90(94)		
Other	3(8)	3(5)	6(6)		
Missing	1	1	2		
Income				$\chi^2(1) = .080$	.777
< \$100,000	18(45)	24(42)	42(43)		
> \$100,000	22(55)	33(58)	55(57)		
Missing	0	1	1		
Marital status				$\chi^2(1) = .691$	.406
Not married	7(18)	14(25)	21(22)		
Married	33(82)	43(75)	76(78)		
Missing	0	1	1		

\*Fisher exact *p* value = .631

a,b,c Based on patient self-report

to understand the post-biopsy explanation, 7 (19%) said it made it somewhat easier, 10 (27%) said it made it moderately easier, and 15 (41%) said it made it much easier. Three patients (8%) were unable to respond as they had not yet had a consultation with their urologist.

## Discussion

In this study, we assessed whether providing patients with an information booklet about PCa treatment options prior to their prostate biopsy was acceptable to patients. Another aim was to

examine if patients' anxiety, depression, distress, and treatment decisional conflict were impacted by the intervention. Although several studies have examined the influence of treatment decisional aids on PCa treatment selection [7], satisfaction with decision, and decisional conflict [8], there are few studies assessing whether there is an additional benefit of providing information about treatments before receiving biopsy results.

In the present study, patients in the control and intervention groups did not differ in levels of anxiety, depression, distress, or decisional conflict at post-biopsy follow-up. In examining change in psychological symptoms from pre- to post-biopsy,



**Table 2** Time 1 and time 2 scores and change score analyses (time 2 minus time 1) for control and intervention groups with appropriate transformations

Measures <sup>a</sup>	Control group			Intervention group			p value	d	Power
	N	Mean (SD) <sub>Time 1</sub>	Mean (SD) <sub>Time 2</sub>	N	Mean (SD) <sub>Time 1</sub>	Mean (SD) <sub>Time 2</sub>			
<b>Positive biopsy result</b>									
LN(DT+1)	22	0.908(.636)	1.191(.607)	32	1.097(.704)	1.304(.745)	.161	.110	.067
-1/(GAD+1)	25	-0.665(.394)	-0.509(.338)	35	-0.504(.361)	-0.510(.376)	.903	.346	.218
-1/(PHQ+1)	25	-0.660(.353)	-0.525(.357)	34	-0.606(.367)	-0.594(.365)	.856	.339	.213
<b>Negative biopsy result</b>									
LN(DT)	9	0.953(.995)	0.584(.662)	12	0.530(.513)	0.472(.531)	.783	.482	.170
-1/GAD-7	11	-0.577(.418)	-0.642(.357)	15	-0.678(.363)	-0.719(.371)	.730	.110	.056
-1/PHQ-9	11	-0.513(.402)	-0.690(.375)	15	-0.688(.356)	-0.802(.299)	.390	.168	.063
<b>Combined biopsy result</b>									
LN(DT)	31	0.921(.740)	1.015(.673)	44	0.942(.700)	1.077(.783)	.263	.314	.254
-1/GAD-7	36	-0.638(.398)	-0.550(.345)	50	-0.556(.367)	-0.573(.383)	.739	.247	.177
-1/PHQ-9	36	-0.615(.369)	-0.576(.365)	49	-0.631(.362)	-0.657(.356)	.658	.238	.165

DT, Distress Thermometer; GAD-7, General Anxiety Disorder Scale-7; PHQ-9, Patient Health Questionnaire-9

<sup>a</sup>Higher scores indicate higher distress, anxiety and depression, \*p value < .05

results similarly indicated that there were no differences between control and intervention groups in patterns of change in symptoms experienced over time. The provision of information about PCa treatment options prior to a definitive diagnosis did not unduly increase the level of anxiety, depression, or distress experienced. Our findings were in line with those reported by Zeliadt et al. [13] who found no significant differences in anxiety or depression from pre- to post-biopsy, although they noted a trend towards reduced anxiety in the intervention group. It is important to note that baseline assessment was conducted following the provision of the intervention, unlike the present study which assessed patients prior to them perusing the information. Hence, interpretations of results may differ between the studies.

Present findings demonstrated that the intervention did not improve the psychological symptoms experienced by patients, nor impact upon levels of decisional conflict when patients made treatment decisions. It is likely that changes in patients' psychological symptoms and decisional conflict are influenced by a range of factors. One would expect that physician-patient communication and management of patient expectations about potential outcomes prior to undergoing biopsy would impact upon psychological reactions post-biopsy. In a recent study assessing patients with localised PCa, it was demonstrated that patients who felt well informed and better supported by their physicians reported higher QoL and emotional functioning respectively [20]. Furthermore, written feedback provided by patients in the current study suggested that discussion with their urologist about biopsy results was a key factor that mitigated their anxiety and reduced decisional conflict post-biopsy. Nevertheless, given that this study did not set out to explicitly assess physician factors, such hypotheses remain speculations.

Change in patients' scores was examined separately for the positive and negative biopsy result groups and this yielded interesting findings. Patients who did not receive the intervention and later obtained a positive biopsy result experienced an increase in distress and trend towards an increase in anxiety symptoms. This increase in symptoms is not unexpected, given that the patients were recently diagnosed when they completed the follow-up questionnaire and may have been experiencing a process of adjustment. Conversely, patients who did not receive the intervention booklet and later received a negative biopsy result showed a significant decrease in depressive symptoms, potentially indicating a sense of relief that they did not have cancer.

Patients who received the intervention booklet pre-biopsy and were later diagnosed with cancer did not experience an increase in psychological symptoms from pre- to post-biopsy, as was experienced by those in the control group. This could potentially be attributed to patients in the intervention group having more awareness and understanding about future treatment options. It is possible that patients were better placed to

ask questions about their diagnosis and suitable treatment options if primed about this prior to their biopsy. However, it is important to acknowledge that there were a small number of patients in the positive biopsy group, and the study may be underpowered to detect a change in anxiety and depression across time. Furthermore, baseline distress levels for the intervention group were significantly higher for patients who received a positive biopsy result compared to those who received a negative result, and this may affect interpretations of findings. As some patients undergo an MRI scan prior to their biopsy, it is possible that patients in positive biopsy result group may have known about their increased likelihood of being diagnosed with cancer due to the MRI scan results.

Patients were receptive to receiving information about treatment options prior to undergoing their biopsy. Ninety percent of patients read the material and 60% spent at least 15 min perusing the material provided. All patients found the information useful, with 79% of them reporting that it was very or extremely useful. Ninety-eight percent of patients who received the booklet reported that they preferred to be given such information prior to biopsy. This unanimous preference for information at this point was apparent for both the positive and negative biopsy result groups. In addition, patients' written feedback about the intervention booklet suggested that being provided with treatment information at an early stage eliminated the need to search for information from other sources and of having to discern the accuracy of that material.

This study has some limitations. The intervention booklet provided to patients was not validated for use with patients prior to cancer diagnosis. Furthermore, patients who see their urologist for a consultation post-diagnosis of PCa may be provided with both verbal and written information about PCa treatment options, depending on the individual clinician's practice. We were unable to ascertain if patients completed Questionnaire 2 before or after written information was given by their urologist (if any). However, we attempted to account for this by asking patients in Questionnaire 2, about their experience of receiving written information about treatment options *prior* to their biopsy. It is hoped that this would have given some insight into how they experienced the receipt of information at an early stage, regardless of whether they received it a later point. Furthermore, this study was conducted within a single urology practice in Australia; thus, findings may not be applicable to other settings. Finally, the sample sizes were small, especially for patients receiving a negative biopsy result, and this produced little power for the comparison of results for the control and intervention groups. Future research may benefit from examining the applicability of these findings to a broader cohort of patients and assessing the mechanisms through which information provision pre-biopsy may influence psychological outcomes.

## Clinical implications

The findings in this preliminary study suggest that patients undergoing prostate biopsy are receptive to receiving written information about potential treatment options, although there was no impact on changes in psychological symptoms post-biopsy. These findings may be particularly important given that diagnostic and imaging capabilities have improved in the past decade; hence, a larger percentage of prostate biopsies conducted may emerge as positive compared to previous decades [21]. It is important to provide patients with adequate information at an early time point, without unduly increasing distress levels. Nevertheless, we also need to be cognisant of the potential drawbacks of such an intervention before advocating for change in practice. Providing patients with information about treatment options as part of clinical routine may result in higher financial costs for the service and longer clinical consultations [9]. There is also a risk of misinterpretation of information presented in decision aids [22], particularly if information is provided prior to discussion with the physician. It is important that clinicians are aware of these issues before routinely providing patients with written information about treatment options prior to biopsy. This would ensure that patients are well informed and feel empowered about potentially making a treatment decision in the future.

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## Compliance with ethical standards

This study was approved by the institution's ethics committee (714-15).

**Conflict of interest** The authors declare that they have no conflict of interest.

Authors had full access to all of the data (including statistical reports and tables) in the study.

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