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BRIEF COMMUNICATION

A randomised controlled trial comparing completeness of responses of three methods of collecting patient-reported outcome measures in men diagnosed with prostate cancer

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Abstract

Purpose The purpose of the study was to compare completeness, timeliness and cost of patient-reported outcome measures (PROMs) collection using telephone, email and post in men with prostate cancer.

Methods A parallel, three-arm randomised controlled equivalence trial. 1168 patients were randomised to telephone ($n=295$), postal ($n=388$) and email ($n=385$) arms. Participants were asked to provide self-reported responses for 26 items of Expanded Prostate Cancer Index Composite. Cost and resource data were collected from a provider perspective.

Results Equivalence tests showed no difference in completeness in the three arms within a 10% equivalence margin. Men diagnosed in public hospitals were less likely to complete the survey compared to those in private hospitals, $OR=0.19$ (95% CI 0.04–0.89) ($p=0.035$). The email survey required significantly less time to complete than telephone and postal methods [median time of 2 min (IQR 1,8) vs. 7 min (IQR 6,9) vs. 10 min (IQR 9,12), respectively ($p<0.001$)]. The incremental cost effectiveness ratio for email compared to telephone was AUD$1.90, cost-effective if users valued an additional 1% improvement in survey completion greater than AUD$1.90.

Conclusion Email method took less time and cost and should be used as the primary PROMs collection, with telephone if men without email or do not respond to email.

Keywords Patient-reported outcomes · Randomised controlled trial · Data collection methods · Intention to treat · Telephone · Postal · Email

Introduction

Patient-reported outcomes (PROs) are designed to measure patients' views of their symptoms' status, physical function, mental health, social function and wellbeing, satisfaction

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with care, medication compliance and health related quality of life in relation to specific diseases or conditions [1, 2]. Patient-reported outcomes measures (PROMs) are the tools or instruments that are used to collect information on PROs [3]. Collection and use of PROMs have been demonstrated to improve patient-provider communication and increases patient satisfaction [4, 5].

Increasingly clinical registries are being used to collect PROMs [6] with outputs that are generally used to make comparisons among colleagues, assess quality assurance and undertake research [7]. The completeness depends on how PROMs data are obtained; data collection mode, method and the setting of administration [8]. Survey completeness is also influenced by number of items in the instrument, the perceived relevance and usefulness of the items, and the perceived ease of understanding the items and response scale [9]. Response rate by telephone is generally found superior to both mail and email [10, 11] but some studies have found Internet/web-based survey responses are superior to mail [12, 13]. To integrate PROMs into routine clinical practices, data collection methods must be easy, rapid, continuous, convenient, low-cost, reliable, clinically feasible and efficient [8, 14].

In this study, we compare three different methods of PROMs data collection using the EPIC-26 survey for patients diagnosed with prostate cancer. Primary hypothesis was that there would be less than 10% difference in survey completeness among the three methods of telephone, postal and email. Efficiency was examined in terms of time and costs required to administer and collect completed surveys from the registry perspective only, and predictors of successful completion of responses.

Methods

The study methodology is described in the published study protocol [15] and summarised below.

Participants and data collection

An equivalence parallel, three-arm randomised controlled trial was conducted. Participants were enrolled between January and November 2016 through the Prostate Cancer Outcome Registry Victoria, Australia. The recruitment process and data collection to the registry have been previously described [15, 16]. PROMs are collected to assess the impact of prostate cancer diagnosis on urinary, bowel, hormonal, and sexual function. Participants aged > 18 years were included, answered call centre staff over telephone 12 months after diagnosis or treatment (henceforth recorded as the "anniversary date") and were excluded if they did not speak in English or identified as hearing or mentally impaired. Men were randomised after they had answered the telephone to one of the three methods. If patient did not have email address were again randomised to telephone or postal. In postal and email methods if the survey was not returned within 14 days post anniversary date, patients were telephoned to collect the data. For each of the three methods, men were considered lost to follow up if the survey was not completed within the 21 days from the anniversary date. 1168 patients were eligible for randomisation. Of these, 395 were randomised to telephone, 388 to postal and 385 to email (Fig. 1).

Measures

Primary outcome of interest was successful completion of the survey. Surveys were regarded as complete if all question items were answered. Even if the patient, decline to answer any question item was considered valid and complete. Secondary outcome measure was determined by efficiency and factors associated with successful completion of the survey from the provider-perspective.

Statistical analysis

For the primary outcome measure, individual proportions with 95% CI were estimated for each arm. Pooled sample proportions for each pair and the standard error of the difference were calculated. Equivalence between methods was demonstrated when the 95% CI of the differences in completeness fell within the equivalence margin of 10%.

Intention to treat (ITT) and per protocol (PP) analysis were conducted to evaluate the effect of each intervention and univariable and multivariable logistic regression to determine factors associated with successful completion of the survey using Stata V13.0.

Cost-effectiveness analysis

Variable costs were collected for three survey methods, including the costs for phone, sending postal mail and emails. Fixed costs were not considered as these would be marginal once shared across sample respondents. The average time and personnel costs required for preparation and distribution of postal mail, sending emails, and entering survey information were measured (Online Supplement-1). Total administrative costs and the completion rate for each method were calculated for measuring incremental cost-effectiveness ratio (ICER). Sensitivity analysis was conducted to understand the varying effect of variable costs on the ICER.

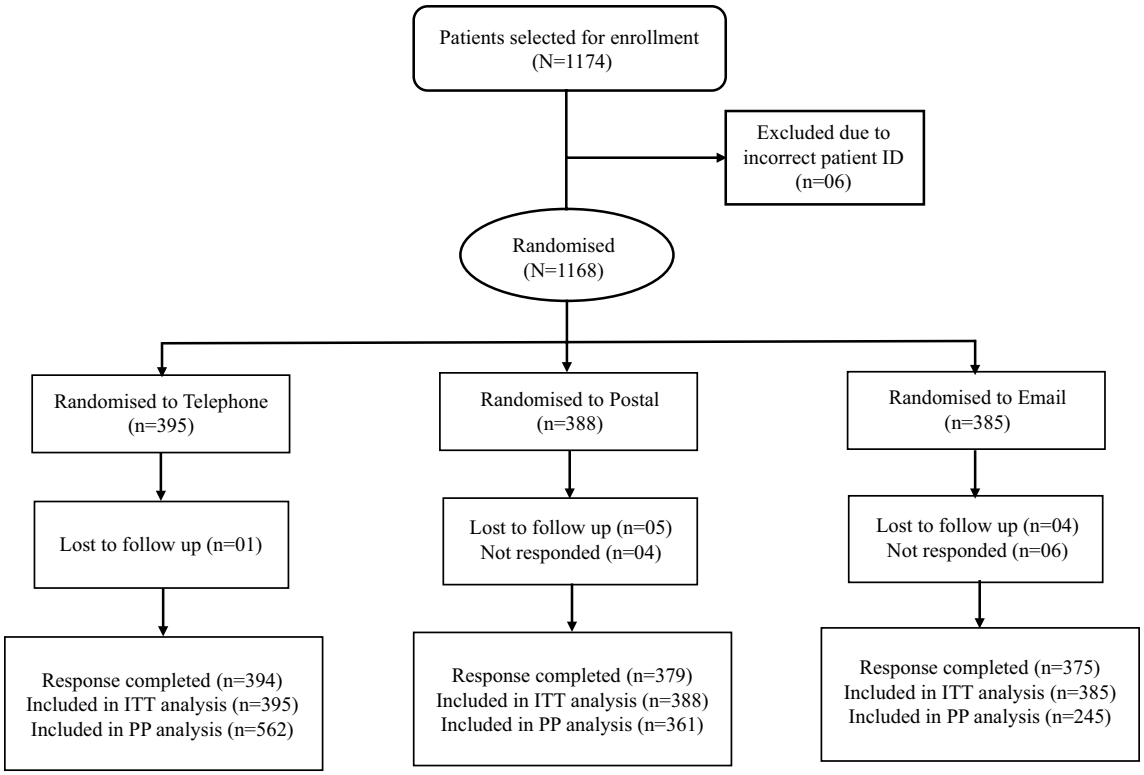

Fig. 1 Recruitment and inclusion of patients in the study

Results

Characteristics of the participants did not differ between the three groups in the ITT analysis (Table 1) but in the PP analysis significant difference was observed in email between public and private hospitals attended for the latest treatment (Online Supplement-2).

Univariable and multivariable regression results of Table 2 demonstrated that men diagnosed in public hospitals had significantly lower odds of successful completion of the survey compared to those who were in private hospitals. In multivariable odds ratio [OR]: 0.19; 95% confidence interval [95% CI] 0.04–0.89, $p = 0.035$. Postal and email methods for univariable and multivariable analysis showed significantly lower odds of successful completion rate compared to telephone method. In multivariable analysis, for postal *OR*: 0.09; 95% CI 0.01–0.76, $p = 0.027$ and for email *OR*: 0.11; 95% CI, 0.01–0.91, $p = 0.04$.

Equivalence testing to assess PROMs completion demonstrated no significant differences among three methods either in ITT or PP analysis (Fig. 2). ITT analysis revealed that the email group took significantly less administrative time than other two methods and cost per entered survey for each method presented in Table 3.

The ICER for email compared to telephone was AUD$1.90 (AUD$6.76, PP analysis), cost-effective if users valued an additional 1% improvement in survey completion greater than AUD$1.90 (Online Supplement-3). Sensitivity analysis also showed similar trend (Online Supplement-4).

Discussion

Our findings revealed that there was less than a 10% difference in the three methods, demonstrating equivalence in the completion of the survey both in ITT and PP analysis. In both the analyses, assessing factors associated with completion of surveys, in postal and email method, significantly lower odds of successful completion rates were observed compared to the telephone. Across each of the three study groups' completion rates were more than 95% in both analyses. Because telephone contact was made with the participants prior to randomisation to validate information and obtain an email address and most of the time telephone survey occurred immediately after the randomisation. Postal and email groups were high because a multi-modal approach was taken to follow up men who did not return their postal survey or complete the email survey. Each of these two methods was reverted to telephone to avoid being lost to follow up.

Men diagnosed in public hospitals were significantly less likely to complete the PROMs compared to those diagnosed

Table 1 Characteristics and outcome by randomised group at enrolment time (ITT analysis)

Characteristics	Group			Total ($n=1168$)
	Telephone ($n=395$)	Postal ($n=388$)	Email ($n=385$)	
	n (%)	*n* (%)	*n* (%)	*n* (%)
Age (years)				
Mean (SD)	67.6 (8.1)	67.0 (8.0)	67.5 (8.4)	67.4 (8.1)
Median (IQR)	68 (63,73)	67 (61, 73)	68 (62, 73)	67 (62, 73)
Age (years)				
< 60	56 (14.2)	66 (17.0)	66 (17.1)	188 (16.1)
60–69	181 (45.8)	184 (47.4)	169 (43.9)	534 (45.7)
≥ 70	158 (40.0)	138 (35.6)	150 (39.0)	446 (38.2)
Residential location based on post code				
Urban	381 (96.5)	368 (94.8)	364 (94.5)	1113 (95.3)
Rural	14 (3.5)	19 (4.9)	21 (5.5)	54 (4.6)
Missing	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.1)
Index of relative socio-economic advantage and disadvantage (IRSAD) [17][a]				
Mean (SD) (IRSAD score)[a]	1017.7 (69.3)	1018.6 (69.2)	1017.6 (72.3)	1018.0 (70.2)
Median (IQR) IRSAD score	1025.8 (963.8, 1073.3)	1029.2 (964.8, 1073.3)	1029.2 (963.8, 1074.4)	1027.8 (963.8, 1073.6)
Quintile (Q1)	73 (18.5)	71 (18.3)	91 (23.6)	235 (20.1)
Q2	91 (23.0)	84 (21.6)	59 (15.3)	234 (20.0)
Q3	78 (19.7)	81 (20.9)	71 (18.4)	230 (19.7)
Q4	76 (19.2)	72 (18.6)	85 (22.1)	233 (19.9)
Q5	76 (19.2)	79 (20.4)	77 (20.0)	232 (19.9)
Missing	1 (0.3)	1 (0.3)	2 (0.5)	4 (0.3)
Diagnosing institutes (metropolitan/regional)				
Metropolitan	267 (67.6)	280 (72.2)	265 (68.8)	812 (69.5)
Regional	107 (27.1)	82 (21.1)	103 (26.8)	292 (25.0)
Missing/unknown	21 (5.3)	26 (6.7)	17 (4.4)	64 (5.5)
Diagnosing institutes (public/private)				
Public	127 (32.2)	100 (25.8)	124 (32.2)	351 (30.1)
Private	247 (62.5)	262 (67.5)	244 (63.4)	753 (64.5)
Missing/unknown	21 (5.3)	26 (6.7)	17 (4.4)	64 (5.5)
Treating hospitals for latest treatment (metropolitan/regional)				
Metropolitan	309 (78.2)	313 (80.7)	299 (77.7)	921 (78.9)
Regional	81 (20.5)	70 (18.0)	80 (20.8)	231 (19.8)
Missing/unknown	5 (1.3)	5 (1.3)	6 (1.6)	16 (1.4)
Treating hospitals for latest treatment (public/private)				
Public	139 (35.2)	113 (29.1)	109 (28.3)	361 (30.9)
Private	251(63.5)	270 (69.6)	270 (70.1)	791 (67.7)
Missing/unknown	5 (1.3)	5 (1.3)	6 (1.6)	16 (1.4)
National Comprehensive Cancer Network (NCCN) risk of disease progression at diagnosis [18]				
Low risk disease	99 (25.1)	90 (23.2)	92 (23.9)	281 (24.1)
Intermediate risk disease	192 (48.6)	187 (48.2)	173 (44.9)	552 (47.3)
High risk/very high risk and metastatic disease	99 (25.1)	106 (27.3)	119 (30.9)	324 (27.7)
Missing	5 (1.3)	5 (1.3)	1 (0.3)	11 (0.9)
Initial treatment received (to 12 months post diagnosis)				
Surgery	208 (52.7)	209 (53.9)	199 (51.7)	616 (52.7)
External beam radiotherapy (EBRT)	48 (12.2)	46 (11.9)	50 (13.0)	144 (12.3)
EBRT + surgery	14 (3.5)	10 (2.6)	11 (2.9)	35 (3.0)
Low dose rate (LDR) brachytherapy	9 (2.3)	11 (2.8)	7 (1.8)	27 (2.3)

Table 1 (continued)

Characteristics	Group			Total ($n=1168$)
	Telephone ($n=395$)	Postal ($n=388$)	Email ($n=385$)	
	n (%)	*n* (%)	*n* (%)	*n* (%)
Androgen deprivation therapy (ADT)	18 (4.6)	12 (3.1)	21 (5.5)	51 (4.4)
Watchful waiting (WW)/active surveillance (AS)	89 (22.5)	94 (24.2)	87 (22.6)	270 (23.1)
Others	7(1.8)	4 (1.0)	7 (1.8)	18 (1.5)
Unknown treatment	2(0.5)	2 (0.5)	3 (0.8)	7 (0.6)

Except mean and median, all are expressed in percentage

ITT intention to treat analysis, *SD* standard deviation, *IQR* interquartile range

[a]The Index of Relative Socio–economic Advantage and Disadvantage (IRSAD) summarises information about the economic and social conditions of people and households within an area, including both relative advantage and disadvantage measures, and is one of the four indexes created from social and economic census information. A low score indicates relatively greater disadvantage and a lack of advantage in general. A high score indicates a relative lack of disadvantage and greater advantage in general

in private hospitals. This may reflect a lower level of engagement with their treating clinician or hospital, or uncertainty as to who would act the results. Similar to our findings, a higher response rate was found when electronic data collection had been compared to paper mode [19–21] and postal surveys [21, 22]. Telephone administration of PROMs has been repeatedly found to result in higher response rates when compared to postal [10, 11] and email [10, 11]. With regard to completion rates for surveys, our study, like others [10, 23], have shown that telephone interviews resulted in a high completion rate of PROMs data compared to postal survey.

We, like others, have identified that having a multi-modal data collection approach provides an effective means of improving PROMs response rates compared to single mode approaches [23, 24]. Mixed mode methods offer opportunity to reduce survey costs by using the least expensive mode initially before switching to a more expensive mode [25]. The cost-effectiveness of the email method was superior to telephone and postal because it required very little staff time to enter data, and no additional costs for incidentals such as postage, printing, envelopes and label.

The main strength of our study is the randomly selected relatively large sample size representing 30 hospitals across Victoria. We conducted both ITT and PP analysis. This study compared three different methods of data collection including incremental cost-effective analysis, supported by sensitivity analysis. This study is particularly important as one of the major barriers are PROMs data collection cost, which requires innovative and cost-effective method.

Limitations of the study are that we surveyed an older population of men and excluded non-native English speaker; therefore generalising to other populations should be done with caution. We assessed time of completing tasks from the perspective of the registry funder, which does not value the time to complete the survey by patient. If an economic evaluation was to be conducted considering overall costs, this information should be considered.

In summary, collecting PROMs from prostate cancer patients by telephone, postal or email demonstrates equivalence but from an economic perspective, when assessing efficiency, email was more cost-effective as it required less time and cost than telephone and postal method. It should be used as the primary PROMs collection method, with telephone used if men without email or do not respond to the email invitation.

Table 2 Univariable and multivariable analysis of predictors for successful completion of the survey (ITT)

Variables	Total Completed *n* (%)	Total ($n=1168$)	Univariable model			Multivariable model		
			OR	(95% CI)	*p*-Value	*OR*	(95% CI)	*p*-Value
Age (in years)								
60–69	522(97.8)	534	Ref. group					
< 60	185 (98.4)	188	1.42	(0.40, 5.08)	0.592	1.43	(0.37, 5.63)	0.606
≥ 70	441 (98.9)	446	2.03	(0.71, 5.80)	0.187	1.85	(0.53, 6.51)	0.337
Index of relative socio–economic advantage and disadvantage (IRSAD) (4 missing)								
Quintile 1 (lowest)	229 (97.4)	235	Ref. group					
Q2	229 (98.3)	234	1.51	(0.42, 5.41)	0.530	1.08	(0.25, 4.65)	0.915
Q3	230 (100)	230	1.00					
Q4	227 (97.4)	233	0.99	(0.32, 3.12)	0.988	0.72	(0.17, 3.12)	0.658
Q5 (highest)	229 (98.7)	232	2.00	(0.49, 8.09)	0.331	2.27	(0.35, 14.62)	0.390
Diagnosing institutes (metropolitan/regional) (64 missing)								
Metropolitan	799 (98.4)	812	Ref. group					
Regional	287 (98.3)	292	0.93	(0.33, 2.64)	0.897	0.81	(0.15, 4.43)	0.808
Diagnosing institutes (private/public) (64 missing)								
Private	745 (98.9)	753	Ref. group					
Public	341 (97.2)	351	0.37	(0.14, 0.94)	0.036	0.19	(0.04, 0.89)	0.035
Treating hospitals for latest treatment (metropolitan/regional) (16 missing)								
Metropolitan	905 (98.3)	921	Ref. group					
Regional	228 (98.7)	231	1.34	(0.39, 4.65)	0.641	3.10	(0.40, 24.26)	0.281
Treating hospitals for latest treatment (private/public) (16 missing)								
Private	780 (98.6)	791	Ref. group					
Public	353 (97.8)	361	0.62	(0.25, 1.56)	0.312	1.41	(0.30, 6.49)	0.663
NCCN risk of disease progression at diagnosis (11 missing)								
Intermediate risk disease	545 (98.7)	552	Ref. group					
Low risk disease	273 (97.2)	281	0.44	(0.16, 1.22)	0.115	0.67	(0.19, 2.38)	0.535
High risk/very high risk and metastatic disease	320(98.8)	324	1.03	(0.30, 3.54)	0.966	1.40	(0.31, 6.42)	0.665
Initial treatment received (to 12 months post diagnosis)								
Surgery	608 (98.7)	616	Ref. group					
External beam radiotherapy (EBRT)	143(99.3)	144	1.88	(0.20, 13.46)	0.644	0.78	(0.08, 7.82)	0.830
EBRT + surgery	34 (97.1)	35	0.45	(0.05, 3.31)	0.393	0.17	(0.01, 1.94)	0.153
Low dose rate (LDR) brachytherapy	26 (96.3)	27	0.34	(0.04, 2.55)	0.272	0.37	(0.04, 3.50)	0.383
Androgen deprivation therapy (ADT)	51(100)	51	1.00					
Watchful waiting (WW)/active surveillance (AS)	262 (97.0)	270	0.43	(0.14, 1.06)	0.065	0.39	(0.11, 1.46)	0.163
Others	18 (100)	18	1.00					
Method of survey administration								
Telephone	394 (99.7)	395	Ref. group					
Postal	379 (97.7)	388	0.11	(0.01, 0.85)	0.034	0.09	(0.01, 0.76)	0.027
Email	375 (97.4)	385	0.10	(0.01, 0.75)	0.025	0.11	(0.01, 0.91)	0.041

ITT intention to treat analysis, *CI* confidence interval, *OR* odds ratio, *NCCN* National Comprehensive Cancer Network

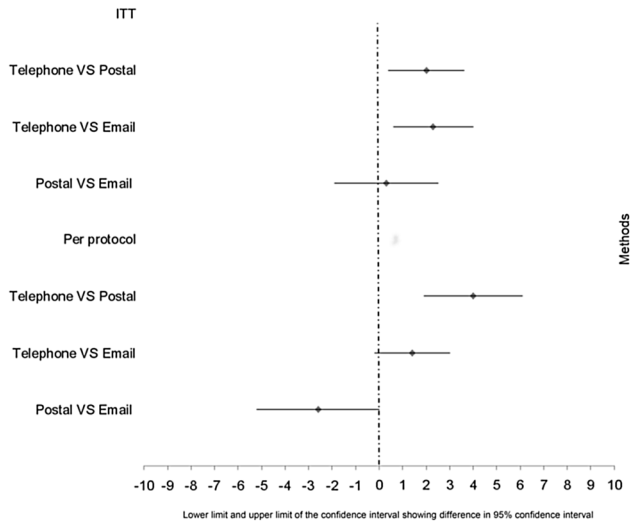

Fig. 2 Equivalence testing showing differences among the three methods with 95% CI within the 10% equivalence margin both in ITT and in PP analysis

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Table 3 Successful response rates, duration and variable costs (AUD $) of the three different methods by randomisation group in ITT and PP analysis [$n = 1168$]

Methods of analysis	ITT				PP			
Data collection methods	Telephone	Postal	Email	*p*-Value	Telephone	Postal	Email	*p*-Value
Randomisation *n* (%)	395 (33.8)	388 (33.2)	385 (33.0)		562 (48.1)	361 (30.9)	245 (21.0)	
Response completed *n* (%)	394 (99.7)	379 (97.7)	375 (97.4)		561 (99.8)	346 (95.8)	241 (98.4)	
Time in minutes taken from approach to completion of follow-up								
Mean (SD) minutes	7.7 (3.6)	10.9 (3.9)	4.5 (4.9)		8.8 (4.5)	10.3 (3.1)	1.5 (1.2)	
Median (IQR) minutes	7 (6, 9)	10 (9, 12)	2 (1, 8)	0.0001[a]	7 (6, 10)	10 (9, 11)	1 (1, 2)	0.0001[a]
Personnel costs (PC) (data collector and study coordination) in AUD	$9.50	$13.44	$5.55		$10.85	$12.70	$1.85	
Telephone cost (TC) (75% mobile phone and 25% land phone) in AUD	$0.47	0.08	0.04		$0.47	N/A	N/A	
Stationery and printing costs (SPC) in AUD	N/A	$0.49	N/A		N/A	$0.49	N/A	
Mailing cost (MC) including return stamp in AUD	N/A	$4.00	N/A		N/A	$4.00	N/A	
Total cost: (PC + TC + SPC + MC) in AUD	$9.97	$18.01	$5.59		$11.32	$17.19	$1.85	

[a]Kruskal–Wallis equality-of-populations rank test: probability

N/A not applicable

Compliance with ethical standards

Conflict of interest None declared except Sue Evans is coordinator of the Prostate Cancer Outcome Registry—Australia and New Zealand (PCOR-ANZ).

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was built on an existing project, which received Ethical approval, by the Monash University Human Research Ethics Committee for enrolment of prostate cancer patients in PCOR VIC (Approval Number CF09/0931–2,009,000,436). We obtained separate approval for our study from the Monash University Human Research Ethics Committee (Approval Number CF15/4157-2015001762).

Informed consent Men who participated in this study were part of the Prostate Cancer Outcomes Registry which has an opt out consent process. Men are sent an explanatory statement, which details the process for opting out and use of data for research purposes. As men are being contacted as part of the registry a waiver of consent for this study was provided to enable men to be randomised to one of the three arms, verbal consent for this was obtained at initial contact with the patient.

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