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The ProCare Trial: a phase II randomised controlled trial of shared care for follow-up of men with prostate cancer.

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The ProCare Trial: a phase II randomised controlled trial of shared care for follow-up of men with prostate cancer.

Abstract

Objectives

To test the feasibility and efficacy of a multifaceted model of shared care for men after completion of treatment for prostate cancer.

Patients and Methods

Men who had completed treatment for low to moderate risk prostate cancer within the previous eight weeks were eligible. Participants were randomised to usual care or shared care. Shared care entailed substituting two hospital visits with three visits in primary care, a survivorship care plan, recall and reminders, and screening for distress and unmet needs. Outcome measures included psychological distress, prostate cancer-specific quality of life (PCSQoL), satisfaction and preferences for care and health care resource use.

Results

88 men were randomised (Shared Care n=45; Usual Care n=43). There were no clinically important or statistically significant differences between groups on distress, PCSQoL, or satisfaction with care. At the end of the trial men in the intervention group were significantly more likely to prefer a shared care model to hospital follow-up than those in the control group Intervention 63% vs Control 24% p=0.0007). There was high compliance with PSA monitoring in both groups. The shared care

model was cheaper than usual care (Shared care AUS$1,411; Usual Care AUS$1,728; difference AUS$323 (plausible range AUS$91-554)).

Conclusion

Well-structured shared care for men with low to moderate risk prostate cancer is feasible and appears to produce clinically comparable outcomes to standard care at lower cost.

Keywords

Prostate cancer. Primary care. Survivorship. Randomised controlled trial. Follow-up. Health services research.

Introduction

Increases in cancer incidence and improved survival for many common cancers are placing a growing burden on health care systems. International policy is recognising that the strengths of primary care, and its model of continuous, comprehensive and coordinated care, could be critical to providing affordable cancer care.(Rubin et al., 2015) While this will of course place new burdens on primary care, especially in the context of an ageing population, many countries recognise that primary care offers a more holistic and cost-effective approach to chronic disease management. The challenges facing health care systems are well demonstrated by the growing incidence and prevalence of prostate cancer, the most common non-cutaneous cancer among men worldwide.(Center et al., 2012) The incidence of prostate cancer is projected to rise in many developed countries, largely due to the ageing population and the growing use of PSA as a screening test.(Australian Institute of Health and Welfare 2012) In the United Kingdom by 2030 it is estimated 61,000 men will be diagnosed with prostate cancer each year and by 2040 there will be 830,000 prostate cancer survivors.(Maddams et al., 2012) The vast majority of men diagnosed with prostate cancer will survive at least ten years leading to very large numbers of prostate cancer survivors.(Yip et al., 2015)

Men who have completed treatment for prostate cancer require long term follow-up, to detect disease progression, to monitor any adverse effects of treatment, and to

identify and address psychosocial needs. Observational studies have demonstrated that men treated for prostate cancer frequently experience distressing and ongoing side-effects, most notably urinary and bowel incontinence, sexual dysfunction, and significant psychological issues.(Resnick et al., 2013, Smith et al., 2009, Watson et al., 2015) These men have significant levels of unmet need, suggesting that current models of follow-up may be sub-optimal.(Boberg et al., 2003, Smith et al., 2007)

Previous trials of follow-up for breast and colon cancer survivors have found no statistically significant differences between primary and secondary care in terms of disease outcomes, psychological morbidity and patient satisfaction.(Emery et al., 2014b, Lewis et al., 2009b) Trials of care shared between primary and secondary care in cancer have mostly focused on increasing the primary care team's involvement in managing symptoms during or immediately following treatment for cancer.(Jefford et al., 2008) These trials have shown that shared care models can improve patient and provider experience of the care process, including patient and provider satisfaction, provider confidence and knowledge, and patient perceptions of care. No trials of shared care have tested a structured approach to sharing cancer surveillance, management of treatment-related effects and psychosocial support between hospital and primary care after completion of treatment. Furthermore, there are no randomised controlled trials reported to date of prostate cancer follow-up in primary care.

The American Cancer Society has published consensus guidelines about comprehensive survivorship care following treatment for prostate cancer, which have been endorsed by the American Society of Clinical Oncology.(Resnick et al., 2015, Skolarus et al., 2014) These guidelines cover health promotion, cancer surveillance, psychosocial care and management of treatment side-effects and were produced in recognition of the growing role of primary care clinicians and their need for guidance in the care of prostate cancer survivors. In the United Kingdom, the National Cancer Survivorship Initiative aimed to provide risk-stratified survivorship care and support primary care to manage a large proportion of cancer survivors, including men with prostate cancer. (Department of Health, MacMillan Cancer Support and NHS Improvement 2013)

The objective of the ProCare Trial was to test the feasibility and efficacy of a multifaceted model of shared care for men after completion of treatment for prostate cancer. The model was designed to: identify individual patient needs; tailor information and multidisciplinary referrals; support holistic care coordination by a patient's general practitioner (GP, primary care family physician); improve timeliness and content of communication between hospital and primary care, and reduce burden on hospital clinics. The trial was set within the Medical Research Council framework for the development and evaluation of complex interventions.(Medical Research Council 2008, Campbell et al., 2007) We therefore aimed to test the feasibility and acceptability of the model of shared care, exclude the potential to cause clinically significant harm, and estimate its efficacy and costs to inform decisions about a potential multi-site phase III trial.

Patients and Methods

As the protocol for the ProCare trial has been published,(Emery et al., 2014a) here we report the methods in brief. (Australian New Zealand Clinical Trial Registry ACTRN12610000938000)

Study design

We conducted a multisite randomised controlled trial of two models of follow-up care after men had completed treatment for low to moderate risk prostate cancer. Men were recruited from two rural and four urban treatment centres in Victoria and Western Australia (WA) between November 2011 and July 2013. The two rural centres in Victoria were 150-280 kilometres from the urban centres in Melbourne. The three treatment centres in WA managed patients from across the whole State with some people travelling over 2,000 kilometres. Treatment centre was a stratifier in the randomisation to ensure balance of rural and urban patients between trial groups. Ethics approval was granted from the University of Western Australia's Human Research Ethics Committee (RA/4/1/4447) and from all recruitment sites.

Study population

Eligible men had completed surgery and/or radiotherapy with curative intent for prostate cancer within the previous eight weeks, were able to read and write English and had a GP who agreed to participate. Exclusion criteria were: prostate cancer

with high risk features (cT3; PSA ≥20 or Gleason score ≥8); patients on androgen deprivation therapy (ADT) following completion of radiotherapy; metastatic disease or treatment with palliative intent; or severe cognitive or psychiatric disorder. Men receiving neo-adjuvant ADT with radiation treatment were eligible.

Study procedures

After each participant and his GP had provided informed consent, they were randomly allocated 1:1 to either usual care (control arm) or to trial shared care (intervention arm). Randomisation was performed using a centralised independent tele-randomisation system at the National Health and Medical Research Council (NHMRC) Clinical Trials Centre, stratified by hospital site and treatment type.

Men in the control group received clinical care according to current hospital practice with visits every three months to the treating urologist or radiation oncologist team, consistent with international guidelines.(Heidenreich et al., 2009) These visits included a PSA test, review of any symptoms and clinical examination where indicated.

The intervention was based on a shared care model where two of the routine hospital visits during the first 12 months of follow-up were replaced by GP visits (at 6 and 9 months). An additional GP visit shortly after the completion of their treatment for prostate cancer was intended to re-engage the patient with his GP. In addition to the altered schedule of follow-up, the following five components were designed to facilitate shared care: 1) structured systematic communication, using a survivorship care plan (specific versions for the GP and the patient); 2) GP clinical management guidelines and local resources; 3) a register and recall system to prompt the patient and his GP about follow-up appointments; 4) screening for distress using the Distress Thermometer(Jacobsen et al., 2005) and unmet needs using a prostate cancer-specific problem checklist;(Dimoska et al., 2008) and 5) patient information resources about prostate cancer and treatment side-effects. We include in the Appendices a checklist according to the Template for Intervention Description and Replication (TIDieR) recommendations (Hoffmann et al., 2014) and examples of the Survivorship Care Plans and Distress Thermometer.

Outcomes

Patient-reported outcome questionnaires comprised four psychometric measures plus a study-specific question to provide a comprehensive assessment of the various psycho-social and quality of life components of this complex intervention.(Campbell et al., 2007) Psychological distress was assessed with the 14-item *Hospital Anxiety and Depression Scale* (HADS).(Zigmond and Snaith, 1983) Unmet needs were assessed with the *Cancer Survivors' Unmet Needs measure (CaSUN),(Hodgkinson et al., 2007)* containing 35-items across five domains (information, patient care, psychosocial, physical, sexual). Prostate cancer-specific quality of life was assessed with the *Expanded Prostate Cancer Index Composite (EPIC);*(Wei et al., 2000) with 32 items across 4 domains (urinary, bowel, sexual and hormonal function). EPIC has greater coverage of key domains and sensitivity to treatment effects than previous prostate-specific quality of life measures.(Wei et al., 2000) Patient satisfaction with care was assessed with the *Short-form Patient Satisfaction Questionnaire (PSQ-18)* (18 items covering access, convenience, continuity, perceived communication between healthcare providers and technical competence).(Marshall and Hays, 1994) A single study-specific question assessed patients' *preference for future follow-up care (PFC)* by asking patients to indicate which of four different options for ongoing follow-up they preferred; we piloted this question prior to using in this trial.

Participants completed the three measures of outcome (HADs, CaSUN and EPIC) at four times points: prior to randomisation and then at 3, 6 and 12 months follow-up. Participants completed the two measures of process (PSQ-18 and PFC) after their 12 month follow-up appointment.

Clinical process measures (adherence to recommended PSA monitoring; referrals to allied health; prescribing prostate-specific medications) and health care resource usage data were obtained by auditing GP medical records and from Medicare Australia national health insurance records, including Medical Benefits Schedule (MBS; clinical care items) and Pharmaceutical Benefits Schedule (PBS; subsidised drug costs). We examined costs from the health system perspective and therefore did not account for differences in patient-incurred costs. Information on medical services obtained via MBS was reviewed blinded to treatment allocation to identify items of relevance to prostate cancer follow-up and the management of common chronic diseases. PBS data and GP records were likewise reviewed to identify medications for the following issues: urinary infection, depression, anxiety, bladder

dysfunction/urinary symptoms and erectile dysfunction. Only those health resource usage items that met the criteria specified above were included in the economic analysis. Unit costs for resource usage items were obtained from MBS, PBS and the Independent Hospital Pricing Authority. The cost of the systems used to manage appointments was assumed to be comparable across arms and not factored into the economic analysis.

Sample size and statistical analysis

As the ProCare Trial was designed to provide preliminary estimates of the feasibility and the efficacy of the shared care intervention, the sample size justification does not employ a statistical hypothesis testing framework. The target sample size of 90 men was calculated to ensure that the 95% confidence intervals for the mean difference between the two groups on the patient reported outcome measures (PROMS i.e. HADS, EPIC, CaSUN and PSQ-18) would extend no further than +/- 0.5 of a standard deviation with 80% probability and allowing for 10% attrition at 12 months (i.e. complete data on n=80 was required). This level of precision corresponds to what has been proposed as a minimal clinically important difference of health-related quality of life measures.(King, 2011)

A statistical analysis plan was prepared prior to analysis. Participants were analysed according to the intervention they were randomised to receive. The principal emphasis of the analysis was estimation of treatment effect size, and interpretation focussed on the confidence intervals of those estimates, using a threshold of +/- 0.5 SDs to define clinically significant benefit and harm.(King, 2011) A mixed model for repeated measures (MMRM) was applied to the longitudinal patient-reported scale scores. These models included fixed effect terms for: treatment allocation, time point, a time point-by-treatment allocation interaction, and the baseline assessment. t-tests were used to compare randomised groups on the PSQ-18 scales, and chi-square tests were used to compare the groups' responses to the PFC.

Results

Study population

A total of 493 men were screened for eligibility, of whom 321 (65.1%) were excluded, predominantly due to high risk or metastatic disease (Figure 1). Of the remaining 172

men who were eligible according to disease criteria, 88 men and their GPs (51.1% accrual rate) consented to participate and were randomised. Two patients in the shared care arm withdrew from the study shortly after randomisation; one man withdrew because he was overwhelmed by the survivorship care plan, and the other by the amount of questionnaires and associated paperwork from being in a trial. One GP, with a patient in the shared care arm, withdrew from the trial after the 6 month GP visit. Table 1 presents the baseline characteristics of participants showing that the two groups were reasonably well balanced.

Study outcomes

Patient-reported measures

Table 2 presents the HADS and EPIC scores, Table 3 the PSQ-18 scores and Table 4 the PFC results. There were no statistically significant differences between groups for distress, prostate-specific quality of life, patient satisfaction or unmet needs. Figure 2 presents the point estimates and 95% confidence intervals for the effect size for each measure relative to the threshold of +/- 0.5 SDs reflecting clinically significant benefit and harm. Of the 37 confidence intervals produced, all but four excluded values indicative of clinically significant harm due to the shared care model, and 12 suggested the possibility of benefit (Figure 2).

There was a statistically significant difference in preference for model of care (p=0.007); men in the shared care arm demonstrated a stronger preference for shared care (63%), whilst those in the standard care arm distributed their preferences between shared care (24%), follow-up with treating specialist (34%), and follow-up with available specialist (24%) (Table 4).

Clinical process measures and health care resource use

Adherence to PSA testing recommendations in the usual care arm was 98% at month 3, 93% at month 6, 74% at month 9 and 91% at month 12. For the shared care arm, compliance was 98% at months 3, 6 and 12, and 91% at month 9. Two men had biochemical recurrence of their prostate cancer. Both were in the shared care group and were referred and seen by a hospital specialist within one week of the GP detecting recurrence.

Relative to standard care, shared care was associated with an overall reduction of $323 per patient in direct health care costs. This reduction was based on a saving of $590 for two hospital outpatient visits (point estimate only; based on $295 for Medical Oncology consultation from National Efficient Price Determination 2013-2014); which was offset to some degree by an average $18 increase for medications (95% CI: -$31 to $67); a $121 increase for medical services (95% CI: -$61 to $304); an extra $128 to develop and discuss the survivorship care plan (point estimate only; based on award rate + 20% for 2 hours oncology nurse work). The plausible range for the overall reduction in cost was $91 to $554 per patient. The lower end of this range was obtained by summing the lowest estimates for each component, and the upper end by summing the highest estimates for each component.

Discussion

ProCare is the first randomised controlled trial to test a model of shared care for the follow-up of men after completion of treatment for low to moderate risk prostate cancer. The results suggest that this model of care is feasible to implement, acceptable to participating men and their GPs, broadly comparable to standard care in terms of levels of participants' psychological distress, quality of life, unmet needs and satisfaction with care and clinical process measures, and likely to be cheaper than standard care.

Sixty-five per cent of eligible men who were approached and 90% of their GPs agreed to participate. At the end of the trial, those men who had experienced shared care were significantly more likely to prefer a model of care which involved their GP. We acknowledge that there may have been some selection bias, whereby patients who did not like their specialist might be more likely to take part in the study (and

more likely to prefer shared care), whereas patients who did not like their GP would be more likely to refuse to take part. The former group of patients though should theoretically have been randomised equally between groups. We believe our trial demonstrates that shared care is acceptable for a large proportion of men following treatment for prostate cancer because of convenience, greater involvement of their GP and limited perceived value of short hospital consultations.(Emery et al., 2014, Watson et al., 2015)

This was a phase II trial designed to provide estimates of efficacy on a range of measures and recruitment rates to inform decisions about a larger phase III trial. As described in the protocol paper,(Emery et al., 2014a) our original proposed sample size was larger, but this was adjusted based on more accurate estimates of eligible patients and consent rates. The major issue with recruitment was the higher than expected prevalence of men with high risk prostate cancer, who were ineligible. Also, during the trial accrual period there was a significant increase in the use of active surveillance for men with low or moderate risk disease thus reducing our pool of eligible men.(Weerakoon et al., 2015). The hospital specialists involved in this trial were concerned about including men at higher risk of recurrence in this trial. This was the first trial of shared care in prostate cancer, and it was felt that we needed to demonstrate the safety of this model in men at lower risk of recurrence before including men with high risk disease. On the basis of our results, we believe that future such models of care would be suitable for men with high risk disease.

Whilst ProCare was not undertaken as a formal non-inferiority trial, the revised sample size of 90 was designed to ensure estimates for patient-reported measures were obtained with a level of precision that corresponded to the smallest clinically important effect recommended for patient-reported measures (i.e. 0.5 SDs).(King, 2011) Nevertheless, the target sample size still provided 65% power to detect differences of at least 0.5 SDs and 80% power to detect differences of at least 0.6 SDs at the two-sided 5% level of significance. No statistically significant differences were detected between groups on any patient-reported measures but, more importantly, clinically important harms were found to be implausible for 33 of the 37 comparisons performed (based on the width of the 95% confidence intervals). The uncertainty for these remaining four measures (i.e. HADS depression score at 6 months; EPIC hormonal scores at 6 and 12 months; EPIC sexual score at 12

months) is unlikely to be sufficiently of concern about safety to warrant a subsequent phase III non-inferiority trial.

The ProCare shared care intervention was complex and incorporated several components which were carefully designed based on existing evidence from survivorship care and chronic disease models.(Barlow et al., 2002, Hewitt et al., 2006) To improve communication among providers and between providers and patients, we developed a prostate cancer-specific survivorship care plan. There were patient-oriented and GP-oriented versions, the latter providing more detailed clinical practice guidelines and referral information about local allied health providers. Survivorship care plans (SCP) are increasingly being promoted as a standard of care internationally but there remain significant challenges in their implementation.(Mayer et al., 2014) A recent national survey in the US found that oncologists provide a SCP for less than 5% of their patients even though their provision is associated with greater involvement of primary care physicians in survivorship care.(Blanch-Hartigan et al., 2014) In our trial, the SCP required up to two hours of research-nurse time to produce, principally because the required information was not easily accessible or extractable from hospital records. Our SCP was a static paper-based document so did not support ongoing communication between healthcare providers, for example in relation to results of PSA monitoring tests. There have been very few randomised clinical trials of SCPs in primary care; the largest trial of SCPs for women with breast cancer followed up in primary care also found no differences in a range of patient-reported measures.(Grunfeld et al., 2011)

Our intervention included patient and GP reminders aimed to promote compliance with the follow-up schedule. This was effective with very high compliance rates for PSA monitoring and attendance for follow-up visits. Another important component of effective shared care is the ability to access specialist care rapidly when required.(Lewis et al., 2009a) Both men in our trial with biochemical recurrence were seen promptly in specialist care. We believe reminder systems and rapid access to specialist care are key aspects of effective shared care for people with cancer but their ease of implementation into routine practice will vary in different healthcare settings.

For the first time in a trial of cancer follow-up, we incorporated the Distress Thermometer and a prostate cancer-specific problem prompt list as part of the primary care package of care delivery.(Dimoska et al., 2008, Jacobsen et al., 2005) Based on the audit of GP records there was some limited evidence of use of the tool in general practice and subsequent referrals to psychologists, physiotherapists and prescribing specific drugs (detailed results not shown but incorporated in health care resource use analysis). However, we did not show any statistically significant difference in our measure of unmet needs. Previous trials in hospital care of screening for distress and unmet needs have had, at best, small or equivocal results.(Carlson et al., 2012, Hollingworth et al., 2013) Although based on limited process measures, our results do not add any weight to support use of this aspect of the intervention.

There are alternative models of care which have been examined to manage the growing number of cancer survivors. These include, for example, hospital nurse-led models (Lewis et al., 2009) and telemedicine approaches.(Viers et al., 2015) While both of these are potentially effective, either in reducing demand on hospital specialists or minimising travel burden for patients, they fail to engage primary care. In the United Kingdom, models of self-directed care for men at low risk of prostate cancer recurrence are also being deployed to reduce medical visits and associated costs.(Dept of Health 2013)

In summary, our novel trial of shared care for men with treated prostate cancer has demonstrated this is an acceptable and feasible model of care that appears to deliver comparable outcomes to current practice at lower cost. This is consistent with findings from trials of primary care follow-up for breast and colorectal cancer.(Emery et al., 2014b, Lewis et al., 2009b) The core elements of the care model included a survivorship care plan, recall and reminders for patients and GPs and rapid access to specialist care when required. Whether a larger phase III trial is required to justify a change in practice requires further consideration. Future trials of shared care for prostate cancer should consider broadening the population to include men with high risk disease or those on active surveillance.

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Table 1: Baseline characteristics

Characteristic*	Standard Care (*n*=43)	Shared Care (*n*=45)
Treatment Type		
Surgery	15	16
ADT + radiotherapy	12	11
Radiotherapy + surgery	16	18
Age (mean; (SD) and median)	65.8 (8.2); 68.3	67.4 (7.0) 68.3
Level of Education		
Year 11 or below	17 (40%)	19 (43%)
Year 12 or equivalent	4 (9%)	3 (7%)
Trade apprenticeship	7 (16%)	10 (23%)
Tertiary certificate diploma	7 (16%)	5 (11%)
University degree	7 (16%)	7 (16%)
Other	1 (2%)	0 (0%)
Stage of Disease		
T1c	7 (16%)	12 (27%)
T2	5 (12%)	1 (2%)
T2a	4 (9%)	3 (7%)
T2b	4 (9%)	3 (7%)
T2c	10 (23%)	15 (34%)
pT2a	2 (5%)	6 (14%)
pT2c	11 (26%)	4 (9%)

** 1 participant missing baseline questionnaire in Shared care; stage T2c.*

Table 2: Hospital Anxiety and Depression and Expanded Prostate Cancer Index Composite (EPIC) Scores at each time point and by intervention.

Scale	Month	Randomisation	N	Mean	SD	Min	Max	Mean	Mean Difference	Lower 95%CL	Upper 95%CL	p-value
Anxiety	0	Standard Care	42	4.0	3.1	0.0	11.0					
	0	Shared Care	44	4.0	3.6	0.0	17.0					
	3	Standard Care	42	3.5	2.8	0.0	10.0	3.7				
	3	Shared Care	42	3.6	3.0	0.0	12.0	3.5	-0.2	-1.3	0.8	0.6718

Scale	Month	Randomisation	N	Mean	SD	Min	Max	Mean	Mean Difference	Lower 95%CL	Upper 95%CL	p-value
	6	Standard Care	43	3.3	2.7	0.0	9.0	3.3				
	6	Shared Care	39	3.7	3.5	0.0	14.0	3.8	0.5	-0.6	1.5	0.3813
	12	Standard Care	43	3.7	3.2	0.0	13.0	3.7				
	12	Shared Care	39	3.5	3.5	0.0	14.0	3.6	-0.2	-1.2	0.9	0.7445
Depression	0	Standard Care	42	3.9	3.4	0.0	15.0					
	0	Shared Care	44	3.7	3.8	0.0	20.0					
	3	Standard Care	42	3.0	3.0	0.0	10.0	3.2				
	3	Shared Care	42	3.8	3.6	0.0	17.0	3.6	0.4	-0.7	1.5	0.4632
	6	Standard Care	43	3.0	2.8	0.0	10.0	2.9				
	6	Shared Care	39	3.4	3.4	0.0	12.0	3.7	0.9	-0.2	1.9	0.1081
	12	Standard Care	43	3.7	3.5	0.0	15.0	3.6				
	12	Shared Care	39	3.3	3.6	0.0	17.0	3.5	-0.1	-1.2	1.0	0.8423

EPIC

Scale	Month	Randomisation	N	Mean	SD	Min	Max	Mean	Mean Difference	Lower 95%CL	Upper 95%CL	p-value
Bowel	0	Standard Care	42	82.3	15.0	37.5	100.0					
	0	Shared Care	44	85.7	12.3	51.8	100.0					
	3	Standard Care	42	89.7	12.8	41.1	100.0	89.7				
	3	Shared Care	43	91.4	9.1	64.3	100.0	90.9	1.2	-3.9	6.3	0.6538
	6	Standard Care	43	87.7	15.6	23.2	100.0	88.4				
	6	Shared Care	40	89.8	10.8	60.7	100.0	88.7	0.2	-4.9	5.4	0.9257
	12	Standard Care	43	87.3	15.4	48.2	100.0	88.0				
	12	Shared Care	39	90.4	10.0	64.3	100.0	89.7	1.7	-3.4	6.9	0.5090
Hormonal	0	Standard Care	41	80.1	13.5	40.9	100.0					
	0	Shared Care	43	82.9	15.4	27.3	100.0					
	3	Standard Care	40	85.2	13.7	52.3	100.0	85.4				
	3	Shared Care	42	86.6	13.3	52.3	100.0	86.0	0.6	-3.8	5.0	0.7780
	6	Standard Care	42	89.3	11.3	61.4	100.0	90.3				
	6	Shared Care	39	88.1	11.2	65.9	100.0	86.1	-4.2	-8.7	0.2	0.0631
	12	Standard Care	41	87.8	14.0	40.9	100.0	88.9				
	12	Shared Care	39	86.6	15.0	40.9	100.0	85.2	-3.7	-8.2	0.7	0.0990
Sexual	0	Standard Care	38	24.2	23.0	0.0	82.7					
	0	Shared Care	43	24.6	23.6	0.0	85.4					
	3	Standard Care	38	28.1	23.3	0.0	88.5	28.6				
	3	Shared Care	43	28.7	20.1	0.0	84.6	28.4	-0.2	-7.9	7.6	0.9671

Scale	Month	Randomisation	N	Mean	SD	Min	Max	Mean	Mean Difference	Lower 95%CL	Upper 95%CL	p-value
	6	Standard Care	39	25.9	24.0	0.0	84.6	26.4				
	6	Shared Care	40	26.2	21.1	0.0	84.6	25.5	-0.9	-8.7	6.9	0.8292
	12	Standard Care	40	29.8	23.8	0.0	82.7	30.4				
	12	Shared Care	39	26.1	19.1	0.0	82.7	25.1	-5.3	-13.1	2.6	0.1869
Urinary	0	Standard Care	42	66.2	18.7	31.3	97.9					
	0	Shared Care	44	68.6	15.4	28.4	95.8					
	3	Standard Care	42	80.2	17.0	38.3	100.0	79.5				
	3	Shared Care	40	80.7	12.3	55.6	100.0	81.6	2.1	-3.8	7.9	0.4820
	6	Standard Care	43	83.1	16.5	35.4	100.0	83.5				
	6	Shared Care	38	84.7	9.8	64.6	100.0	84.1	0.6	-5.3	6.5	0.8466
	12	Standard Care	42	81.6	16.0	47.9	100.0	82.4				
	12	Shared Care	39	85.2	13.3	49.3	100.0	84.5	2.1	-3.8	8.0	0.4755

Table 3: Patient satisfaction (PSQ-18)

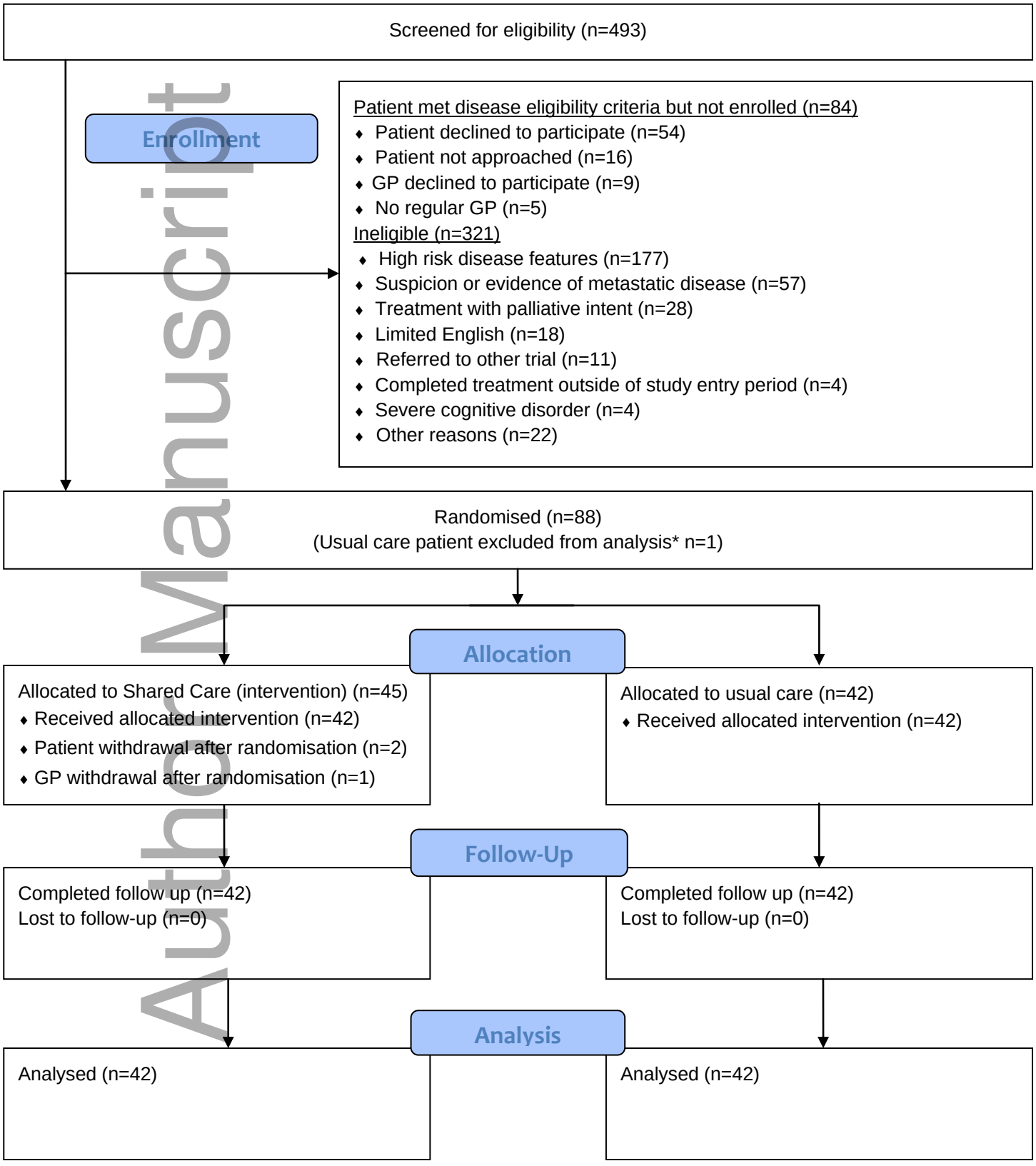
Criterion	Randomisation	N	Mean	SD	Min	Max	Mean	Mean Difference	Lower 95%CL	Upper 95%CL	p-value
General Satisfaction	Standard Care	40	4.3	0.7	2.5	5	4.3				
	Shared Care	35	4.3	0.8	1.5	5	4.3	0	-0.3	0.4	0.9022
Accessibility and Convenience	Standard Care	40	4	0.7	1.7	5	4				
	Shared Care	35	4.2	0.7	1.7	5	4.2	0.2	-0.1	0.6	0.165
Communication	Standard Care	40	4.3	0.6	3	5	4.3				
	Shared Care	35	4.4	0.6	2.5	5	4.4	0.1	-0.2	0.3	0.6584
Financial Aspects	Standard Care	40	4	0.7	2	5	4				
	Shared Care	35	4.1	0.7	2.5	5	4.1	0	-0.3	0.4	0.9068
Interpersonal Manner	Standard Care	40	4.2	0.7	2.5	5	4.2				
	Shared Care	35	4.3	0.6	3	5	4.3	0.1	-0.2	0.4	0.534
Technical Quality	Standard Care	40	4.2	0.7	2.3	5	4.2				
	Shared Care	35	4.3	0.6	2	5	4.3	0.1	-0.2	0.4	0.521
Time Spent	Standard Care	40	4	0.8	2	5	4				
	Shared Care	35	4.1	0.9	2	5	4.1	0	-0.3	0.4	0.8596

Table 4 Preferred model of care

If you could choose one of these four options, which one would you choose?

Care option	Standard Care	Shared Care	p-value
Follow-up care at the hospital where my prostate cancer was treated by the surgeon or radiation oncologist who treated me	14 (34%)	10 (26%)	
Follow-up care at the hospital where my prostate cancer was treated by one of the doctors in the clinic (not necessarily the one who treated me)	10 (24%)	0 (0%)	
Follow-up care shared between my general practitioner and the hospital where I had my prostate cancer treatment	10 (24%)	24 (63%)	
Follow-up care with my general practitioner (instead of attending follow-up appointments at the hospital)	7 (17%)	4 (11%)	
Total	41	38	0.0007

Figure 1 Trial Flow Diagram



*Randomised but did not meet eligibility criteria because of high risk disease features.

Figure 2. Estimates of effect size and associated 95% confidence intervals for PROMS.

Whiskers extending beyond -0.5 SD (in grey) denote measures where clinically significant harm has not been excluded (HADS depression 6 months; EPIC hormonal 6 & 12 months; EPIC sexual 12 months)

Whiskers extending beyond 0.5 SD (in grey) denote measures suggesting benefit (CaSun Emotional & Relationship, Life Perspective and QoL Needs 12 months; EPIC bowel and urinary 3 & 12 months; PSQ-18 general satisfaction; accessibility and convenience; financial aspects; interpersonal manner; technical quality)