The ProCare Trial of shared care for men with prostate cancer

Jon Emery

Herman Professor of Primary Care Cancer Research

NHMRC Practitioner Fellow

Director of PC4

Open Access Protocol

BMJ Open

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

Jon Emery,[1,2] Juanita Doorey,[2] Michael Jefford,[3] Madeleine King,[4] Marie Pirotta,[1] Dickon Hayne,[5,6] Andrew Martin,[7] Lyndal Trevena,[8] Tee Lim,[9] Roger Constable,[10] Cynthia Hawks,[6] Amelia Hyatt,[11] Akhlil Hamid,[12] John Violet,[13] Suki Gill,[13] Mark Frydenberg,[14] Penelope Schofield[11]

To cite: Emery J, Doorey J, Jefford M, *et al*. Protocol for the ProCare Trial: a phase II randomised controlled trial of shared care for follow-up of men with prostate cancer. *BMJ Open* 2014;**4**:e004972. doi:10.1136/bmjopen-2014-004972

► Prepublication history for this paper is available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2014-004972).

ABSTRACT

Introduction: Men with prostate cancer require long-term follow-up to monitor disease progression and manage common adverse physical and psychosocial consequences of treatment. There is growing recognition of the potential role of primary care in cancer follow-up. This paper describes the protocol for a phase II multisite randomised controlled trial of a novel model of shared care for the follow-up of men after completing treatment for low-moderate risk prostate cancer.

Methods and analysis: The intervention is a shared care model of follow-up visits in the first 12 months after completing treatment for prostate cancer with the following specific components: a survivorship care plan, general practitioner (GP)

Strengths and limitations of study

- This is the first randomised controlled trial of a model of shared care for men with prostate cancer.
- It is also the first trial to use the distress thermometer in primary care and the first to test a specific checklist to identify unmet needs of cancer survivors in primary care.
- As a phase II trial of a complex intervention it is designed to provide preliminary estimates of the feasibility and the efficacy of the shared care intervention for phase III planning purposes.

ProCare trial hypotheses

- A shared care model of follow-up for prostate cancer is feasible, demonstrates the potential to reduce rates of psychological distress and unmet psychosocial and psychosexual needs, and improve satisfaction with care at lower cost compared to usual care.

The Procare Intervention

Communication

- Tailored care plan
  - Disease summary
  - Adverse effects of treatment
  - Treatment team
  - Evidence-based guidance on:
    - Recurrence detection
    - Urinary and bowel symptoms
    - Psychosexual problems
  - Local services
- Faxed to practice within 1 week and given to patient
- Added to GP patient records

Register and recall

- Letter to patient and GP
- Prompts for areas to discuss

Screening for distress and unmet needs

- Distress Thermometer
- Problem prompt list

Patient information resources

Follow-up schedule

	End Rx	2 w	6 w	3 m	6 m	9 m	12 m
'Usual care'		---------	Hosp	Hosp	Hosp	Hosp	Hosp
Trial shared care		GP	Hosp	Hosp	GP	GP	Hosp
Pt Recruitment	√						
PSA testing and examination				√	√	√	√
Outcome measures	√			√	√		√

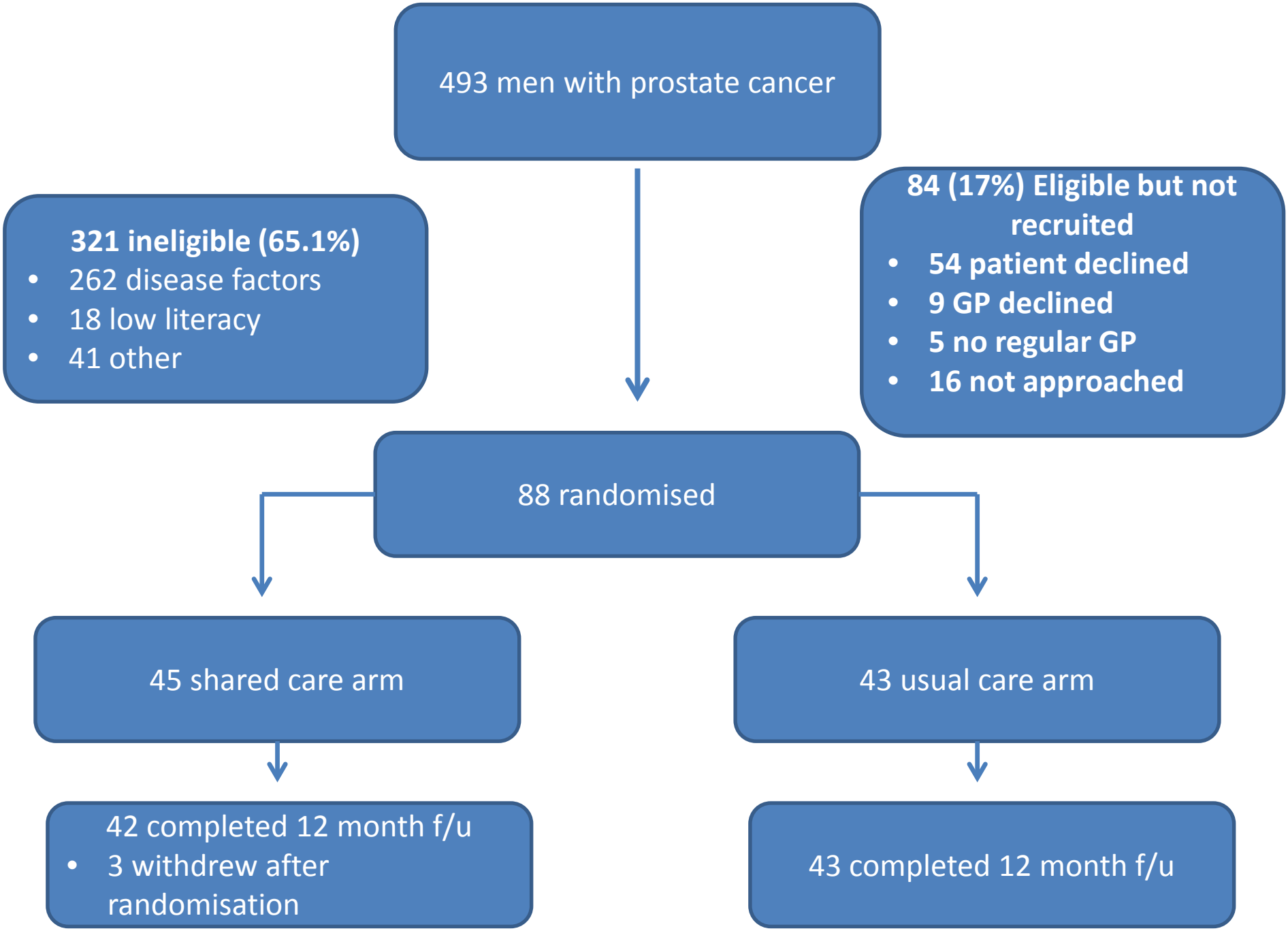
Trial entry criteria

Inclusion criteria

- Pathologically confirmed diagnosis of prostate cancer
- Completed surgery and/ or radiotherapy (+/-neo- adjuvant androgen deprivation therapy) with curative intent within 8 weeks of study entry
- Able to read and write English
- Have a general practitioner who agrees to participate.

Exclusion criteria

- **Suspicion or evidence of metastatic disease**
- **Patients with a pathologically confirmed diagnosis of prostate cancer with any of the following high risk features:**
- **(cT3; PSA > 20 or Gleason score ≥ 8).**
- **Patients having androgen deprivation therapy following radiotherapy**
- Severe psychiatric or cognitive disorder


493 men with prostate cancer
321 ineligible (65.1%)
• 262 disease factors
• 18 low literacy
• 41 other
84 (17%) Eligible but not recruited
• 54 patient declined
• 9 GP declined
• 5 no regular GP
• 16 not approached
88 randomised
45 shared care arm
43 usual care arm
42 completed 12 month f/u
• 3 withdrew after randomisation
43 completed 12 month f/u

HADS anxiety

							Mixed Model Repeated Measures Analysis				
Assessment Number	Randomisation	N	Mean	SD	Min	Max	LS Mean	LS Mean Difference	Lower 95%CL	Upper 95%CL	P-value for Difference
Baseline	Standard Care	42	4.0	3.1	0.0	11.0					
Baseline	Shared Care	44	4.0	3.6	0.0	17.0					
3 Months	Standard Care	42	3.5	2.8	0.0	10.0	3.7				
3 Months	Shared Care	42	3.6	3.0	0.0	12.0	3.5	-0.2	-1.3	0.8	0.6718
6 Months	Standard Care	43	3.3	2.7	0.0	9.0	3.3				
6 Months	Shared Care	39	3.7	3.5	0.0	14.0	3.8	0.5	-0.6	1.5	0.3813
12 Months	Standard Care	43	3.7	3.2	0.0	13.0	3.7				
12 Months	Shared Care	39	3.5	3.5	0.0	14.0	3.6	-0.2	-1.2	0.9	0.7445

HADS depression

Assessment Number	Randomisation	N	Mean	SD	Min	Max	Mixed Model Repeated Measures Analysis: LS Mean	LS Mean Difference	Lower 95%CL	Upper 95%CL	P-value for Difference
Baseline	Standard Care	42	3.9	3.4	0.0	15.0					
Baseline	Shared Care	44	3.7	3.8	0.0	20.0					
3 Months	Standard Care	42	3.0	3.0	0.0	10.0	3.2				
3 Months	Shared Care	42	3.8	3.6	0.0	17.0	3.6	0.4	-0.7	1.5	0.4632
6 Months	Standard Care	43	3.0	2.8	0.0	10.0	2.9				
6 Months	Shared Care	39	3.4	3.4	0.0	12.0	3.7	0.9	-0.2	1.9	0.1081
12 Months	Standard Care	43	3.7	3.5	0.0	15.0	3.6				
12 Months	Shared Care	39	3.3	3.6	0.0	17.0	3.5	-0.1	-1.2	1.0	0.8423

Low levels of distress

EPIC Sexual scales

							Mixed Model Repeated Measures Analysis			
Assessment Number	Randomisation	N	Mean	SD	Min	Max	LS Mean	LS Mean Difference	Lower 95%CL	Upper 95%CL	P-value for Difference
Baseline	Standard Care	38	24.2	23.0	0.0	82.7					
Baseline	Shared Care	43	24.6	23.6	0.0	85.4					
3 Months	Standard Care	38	28.1	23.3	0.0	88.5	28.6				
3 Months	Shared Care	43	28.7	20.1	0.0	84.6	28.4	-0.2	-7.9	7.6	0.9671
6 Months	Standard Care	39	25.9	24.0	0.0	84.6	26.4				
6 Months	Shared Care	40	26.2	21.1	0.0	84.6	25.5	-0.9	-8.7	6.9	0.8292
12 Months	Standard Care	40	29.8	23.8	0.0	82.7	30.4				
12 Months	Shared Care	39	26.1	19.1	0.0	82.7	25.1	-5.3	-13.1	2.6	0.1869

EPIC Urinary scale

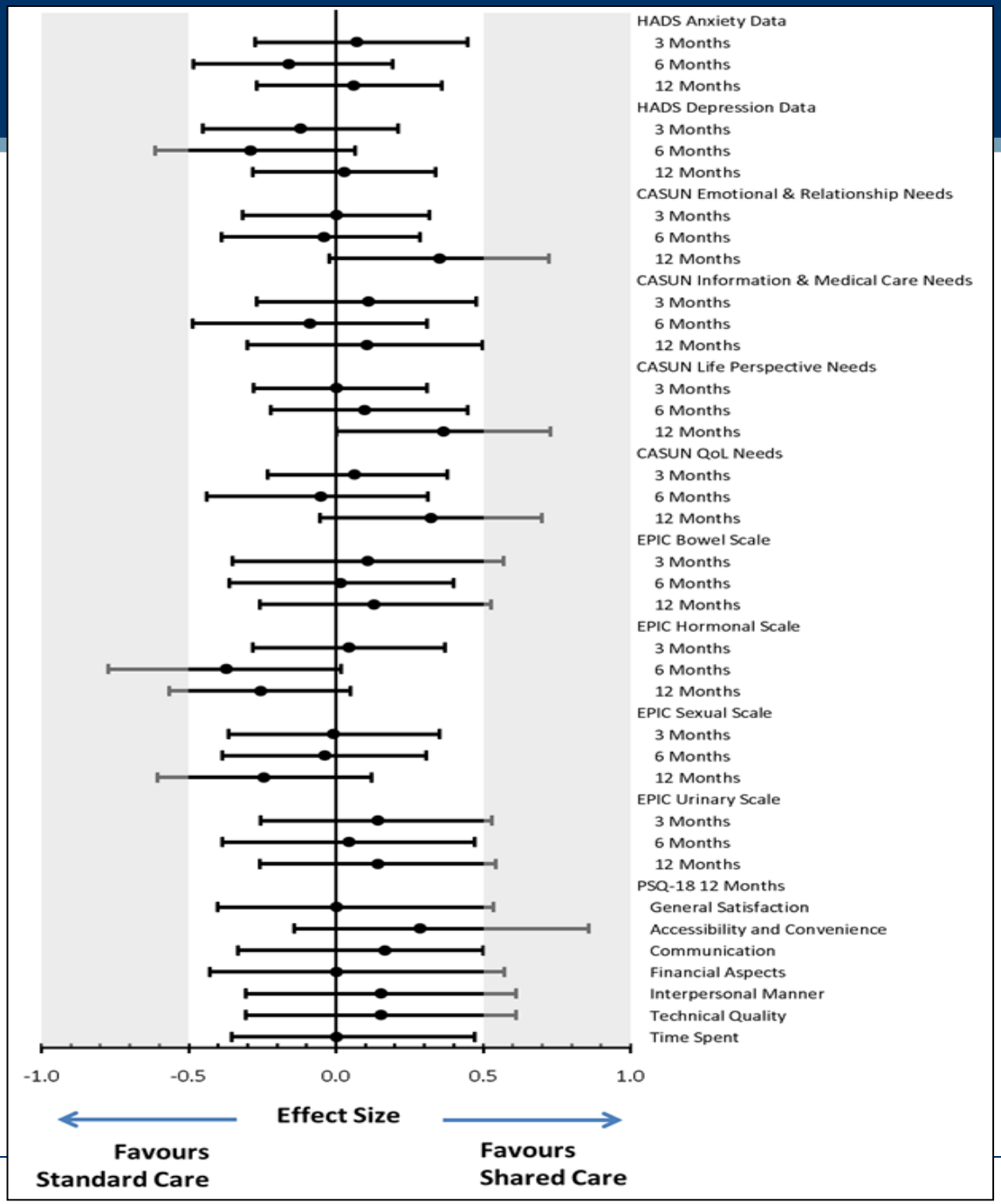
							Mixed Model Repeated Measures Analysis			
Assessment Number	Randomisation	N	Mean	SD	Min	Max	LS Mean	LS Mean Difference	Lower 95%CL	Upper 95%CL	P-value for Difference
Baseline	Standard Care	42	66.2	18.7	31.3	97.9					
Baseline	Shared Care	44	68.6	15.4	28.4	95.8					
3 Months	Standard Care	42	80.2	17.0	38.3	100.0	79.5				
3 Months	Shared Care	40	80.7	12.3	55.6	100.0	81.6	2.1	-3.8	7.9	0.4820
6 Months	Standard Care	43	83.1	16.5	35.4	100.0	83.5				
6 Months	Shared Care	38	84.7	9.8	64.6	100.0	84.1	0.6	-5.3	6.5	0.8466
12 Months	Standard Care	42	81.6	16.0	47.9	100.0	82.4				
12 Months	Shared Care	39	85.2	13.3	49.3	100.0	84.5	2.1	-3.8	8.0	0.4755

PSQ general satisfaction

	N	Mean	SD	Min	Max	LS Mean	LS Mean Diff	LCL	UCL	p-value
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

Similar findings on sub-scales

Exclude clinically significant harm on 33/37 confidence intervals
12 suggest possible benefit



PSA monitoring

PSA Result Available	Standard Care	Shared Care
Month 3	42 (98%)	43 (96%)
Month 6	40 (93%)	42 (93%)
Month 9	32 (74%)	39 (87%)
Month 12	39 (91%)	42 (93%)

- 2 men with biochemical recurrence in shared care arm
- Both seen within <1 week by specialist after detection in primary care

THE UNIVERSITY OF MELBOURNE

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

	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

THE UNIVERSITY OF MELBOURNE

Incremental costs between models of care

Item	Standard Care	Shared Care	Difference
Develop Care Plan	0	$128	$128
Scheduling and Reminder System	-	-	-
Outpatient Clinic Visit	$1,180	$590	-$590
Medications	$39 (SD: $75)	$62 (SD: $134)	$18 (95% CI: -$31 to $67)
Medical Services	$509 (SD: $467)	$631 (SD: $369)	$121 (95% CI: -$61 to $304
Total			-$323 [plausible range: -$554 to -$91]

Summary

- Findings consistent with PC4 evidence review from other cancers
- Shared care for prostate cancer is acceptable, feasible and cheaper
- Small phase II trial
- Feasibility of phase III and increase in active surveillance?
- No evidence of large harmful effects
- Consumer preferences altered by experience

Is this enough to start implementation into routine practice?