Trial of personalised care after treatment – Prostate cancer: A randomised feasibility trial of a nurse-led psycho-educational intervention

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Abstract

Objective: The present parallel randomised control trial evaluated the feasibility of a nurse-led psycho-educational intervention aimed at improving the self-management of prostate cancer survivors.

Methods: We identified 305 eligible patients from a district general hospital, diagnosed 9-48 months previously, who completed radical treatment, or were monitored clinically (ineligible for treatment). Ninety-five patients were recruited by blinded selection and randomised to Intervention (N=48) and Control (*N*=47) groups. Participant allocation was revealed to patients and researchers after recruitment was completed. For 36 weeks, participants received augmented usual care (Control) or augmented usual care and additional nurse support (Intervention) provided in two community hospitals and a university clinic, or by telephone.

Results: Data from 91 participants (Intervention, *N*=45; Control, *N*=46) was analysed. All feasibility metrics met predefined targets: recruitment rate (31.15%; 95%CI:25.95%-36.35%), attrition rate (9.47%; 95%CI:3.58%-15.36%), and outcome measures completion rates (77%-92%). Forty-five patients received the intervention, with no adverse events. The Extended Prostate Cancer Index Composite can inform the minimum sample size for a future effectiveness trial. The net intervention cost was £317 per patient.

Conclusions: The results supported the feasibility and acceptability of the intervention, suggesting that it should be evaluated in a fully-powered trial to assess its effectiveness and cost-effectiveness.

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Keywords: Prostate Cancer; General Practice; Urology; Needs Assessment; Patient Care; Nurse Practitioners

Introduction

In the UK, prostate cancer is more common among men than breast cancer is for women (2014 age standardised data), both being the most common cancers for each gender (Smittenaar, Petersen, Stewart, & Moitt, 2016). This difference is likely to increase further by 2035, when it is predicted that in absolute terms, there will be more new diagnoses of prostate than breast cancer, and 66% more prostate cancer patients will be diagnosed each year (c. 77,000) compared to 2014 (c. 47,000). Survival rates of prostate cancer are also improving and are predicted to continue to do so, as a result of earlier diagnosis and treatment, making follow-up care one of the greatest prostate cancer-related challenges facing the National Health Service (NHS) in the decades to come (Smittenaar et al., 2016).

The care needs of prostate cancer survivors are often complex and, if unmanaged, can have a substantial impact on quality of life. Firstly, in common with other cancers, the diagnosis of prostate cancer is linked with a range of psychological symptoms and conditions, such as anxiety, depression (Armes et al., 2009; Ream et al., 2008). Secondly, the most common categories of treatment (surgery, radiotherapy, hormone therapy, or a combination thereof) can produce physical symptoms, such as sexual dysfunction, urinary or bowel incontinence, hot flushes and bone fracture (Shahinian et al., 2005). In turn, these physical symptoms then lead to a range of secondary psychosocial problems, such as, increased anxiety, loss of identity, shame, social isolation, reduced physical activity, depression (Stein, Syrjala, Andrykowski, 2008). Thirdly, a majority of prostate cancer patients live with multiple morbidities (e.g., diabetes, cardiovascular disease), which further compound their care needs and complicate the management (Crawford et al., 2011; Daskivitch, et al., 2013). Moreover, psychosexual symptoms, anxiety and distress affect not only patients, but also their families (Harden et al., 2013; Northouse et al., 2007; Segrin et al., 2012), resulting in a high level of complex, unmet needs. The range and complexity of subsequent symptoms of prostate cancer survivors, together with the large volume of patients being diagnosed and treated are major challenges to improving the quality and consistency of post-treatment care.

The capacity of the traditional medical-led model of long-term follow-up care for cancer has been increasingly regarded as inadequate and unsustainable (Watson et al., 2016; Bulger et al., 2014). As with other chronic conditions, the long-term management of cancer treatment side-effects is increasingly regarded as being best delivered by nurses, with specialist input provided when needed (Jefford et al, 2013; Richardson et al., 2008; Skolarus et al., 2009). Nurse-led care has already shown to be effective in managing chronic conditions such as diabetes (Renders et al., 2000), depression (Gilbody, 2004), and some cancers (Lewis et al., 2009). This is unsurprising, considering that the management of multiple chronic conditions is part of the core skills of general practice nurses (NMC, 2015), and leading cancer charities have recognised the opportunity to develop the nursing role in primary care and have set up educational programmes to prepare Practice Nurses for taking an enhanced role in managing cancer as a long-term condition (Macmillan Cancer Support, 2013).

Building on recent work of the National Cancer Research Institute (NCRI) in the UK, novel and comprehensive holistic needs assessment instruments are available for cancer patients, but they have not been tested for prostate cancer. Prostate cancer is a strong litmus test for whether the use of such instruments and models of care – promising as they may be - are effective and cost effective when scaled-up at healthcare service level. Similar efforts have already shown some promising results (Watson et al., 2016), and together with colleagues from Oxford we adapted and integrated local third sector models for use in the NHS. In line with Medical Research Council (MRC) guidelines for developing complex interventions (Craig et al., 2013), before a fully-powered evaluation of the nurse-led holistic care model can be recommended, questions need to be answered about its feasibility and acceptability. The present study aimed to: (1) assess the feasibility metrics of the intervention (patient recruitment, attrition and response rates), and its acceptability to patients; (2)

pilot the intervention delivery, and collect process data, including the number of appointments needed to deliver the intervention, the duration of intervention delivery (planning, travel, patient-contact and administrative time), the range and severity of the symptoms addressed, and the support techniques used; (3) investigate the suitability of key clinical and cost effectiveness measures for a future fully-powered trial. Progression to a fully-powered trial is predicated on the present study meeting the following pre-determined targets: (a) a recruitment rate of at least 25% of the clinically eligible patients (invited to the trial); (b) an attrition rate of less than 20%; and (c) outcome measures completion rates above 66%.

Methods

TOPCAT-P is an individually randomised feasibility trial, comparing a personalised, nurse-led, psycho-educational intervention with the augmented usual care in North Wales.

Participants

Eligible participants (*N*=305) were identified from hospital records by a team led by the Urology Advanced Nurse Practitioner, and were biochemically stable incident prostate cancer patients, 9-48 months post-diagnosis, at the end of radical curative treatment (surgery, radiotherapy), hormone therapy, or deemed unlikely to receive further treatment (watchful waiting). The study excluded men awaiting curative treatment or monitored until proof of progression (active surveillance), in the terminal stage of their disease, who lacked capacity, or with cognitive, visual or neurological impairments that would impede completing the trial (as assessed by the referring clinician). Ninety-five participants were recruited by blinded selection and individually randomised to Intervention (*N*=48) or Control (*N*=47) groups, on a 1:1 basis and balanced for age quartiles (see Stanciu et al., 2015; Appendix A). Participant allocation was revealed to patients and researchers after recruitment.

Intervention

Participants in the Control group continued to receive their usual care delivered outside of the trial, and a Macmillan Organiser to self-record and monitor physical and psychological symptoms. Patients in the Intervention group received the above, followed by an initial appointment with the Research Nurse for a holistic needs assessment, and as many tailored follow-up appointments as appropriate (by agreement with the Research Nurse). Further details about the training undertaken by the nurse, the rationale and the description of the intervention have already been published (Stanciu et al., 2015).

Outcome measures

Patient self-reported outcome measures assessed changes in physical symptoms (EPIC-26, Expanded Prostate Cancer Index Composite; Szymanski et al., 2010), psychological wellbeing (Hospital Anxiety and Depression Scale; Zigmond & Snaith, 1983), confidence in managing own health (Lorig at el., 2001), medical and support needs (Supportive Care Needs Survey – simplified response format; Boyes, Girgis, & Lecathelinas, 2009; Schofield et al., 2012), and general health and quality of life (EuroQoL EQ-5D-5L; Brooks, 1996). The patients' satisfaction with the healthcare services was a secondary outcome measure, and consisted in ratings on a five point Likert scale

anchored at “Not at all satisfied” and “Totally satisfied”. This measure was developed and first used in the PROSPECTIV trial, and included with the authors’ permission (Watson et al., 2016). The Recruiting Officer administered the baseline measures to all patients after consent, and prior to randomisation. Subsequent questionnaires were sent by post to be completed by patients in both arms and similarly returned to the research team by post (see Table 1).

{Insert Table 1}

The use of health and social care services during the intervention was measured at 12, 24 and 36 weeks using a purpose-built Client Service Receipt Inventory (CSRI), documenting the frequency and types of contacts with health, social and Third Sector providers. Relevant medical history data (e.g., cancer diagnosis, comorbid conditions) were collected from GP records with patients’ consent.

Feedback interviews

A purposive sample of patients in the Intervention arm (*N*=25) and GPs whose patients received the intervention (*N*=3) took part in feedback interviews 5-9 months after the end of the study. The patient sub-sample was proportionate with the Intervention group for age, cancer stage at diagnosis, treatment type, and level of need. GPs were selected among those who had the largest number of patients in trial. Interviews were semi-structured (see Table 2) and conducted by a researcher not involved in the intervention delivery.

{Insert Table 2}

The risk assessment identified a low impact risks for patient safety, with a low probability. An independent data monitoring group was not required for this pilot and feasibility study, and interim analyses were not conducted. Provisions were made to record all adverse events and serious adverse events and to follow them up for the duration of the study or until resolution. Data management strategy is reported elsewhere (Stanciu et al., 2015).

Data analysis

Feasibility metrics were assessed against the predetermined progression criteria. Intervention delivery and process evaluation data were analysed descriptively. The preliminary analysis of proposed outcome measures followed an intention-to-treat approach and is reported descriptively. Limited exploratory inferential analyses are reported in text for secondary outcome measures.

The exploratory health economics analysis adopted a societal perspective due to the expected broad impact of the intervention on the NHS (both primary and secondary care), the patients, their families, and the third sector. The costing analysis used the national unit costs (Curtis, 2014).

The feedback interviews were analysed using a thematic framework approach (Richie & Spencer, 1994; Richie, Spencer, & O’Connor, 2003). Two researchers coded the data and identified

recurrent themes manually using printed transcripts, in two stages, firstly determining overall themes, and secondly, more specific trends and patterns in the data. Difference between coders were discussed and settled by agreement. The patients' and GPs' interviews were analysed separately.

Results

Feasibility metrics, randomisation, baseline demographic and clinical characteristics

Between November 2013 and April 2014, 1,469 cases were screened for eligibility, and all 305 eligible patients were invited to take part in the trial, in two letters sent to them by their treating clinician. The reasons for ineligibility are included in Appendix B. Ninety-five patients were recruited from January, 2014 to July, 2014, (recruitment rate 31.15%; 95% *CI*: 25.95% to 36.35%), thus, meeting the target of recruiting at least 25% of eligible patients (see Table 3, for baseline demographics and clinical characteristics). Five patients declined to participate (1.64%; 95% *CI*: 0.21% to 3.07%) and 205 patients did not respond (67.21%; 95% *CI*: 61.94% to 72.48%).

The flow of participants through the trial is presented in Figure 1. Three patients withdrew from the Intervention group (before their first contact with the Research Nurse) and one patient withdrew from the Control group. Five patients were lost to follow-up (Intervention group, *N*=1; Control group *N*=4). Eighty-six patients completed the trial (retention rate 90.53%; 95% *CI*: 84.64% to 96.42%), 44 patients from the Intervention group (retention rate, 91.67%; 95% *CI*: 83.85% to 99.49%) and 42 from the Control group (retention rate, 89.36%; 95% *CI*: 80.54% to 98.18%). Overall attrition rate was 9.47% (95% *CI*: 3.58% to 15.36%), meeting the target of no more than 20% of the recruited patients not completing the trial.

{Insert Table 3}

{Insert Figure 1}

Completion rates of outcome measures were high for all questionnaires: 100% for the baseline assessment prior to randomisation for both groups, 92% and 87% (Intervention and Control groups respectively) for the follow-up assessment (main outcome measures), 88% and 89% for the CSRI (see for details Appendix B). All completed questionnaires were included for analysis. Overall, the target completion rate of at least 66% of the recruited participants was achieved for all individual measures in each group, both at baseline and follow-up.

Intervention delivery

The intervention was delivered successfully to all participants (*N*=45) without significant adverse events, over a total of 123 hours of patient contact. Overall, the intervention delivery required approximately 10 hours of nurse time per patient (587 minutes), with a larger share of the time taken by administrative duties (see Table 4). Half of the patients (*N*=22) required two

appointments to identify and assess all symptoms, and the remaining (N=23) up to four appointments (face-to-face or telephone).

The intervention identified all categories of emotional and physical symptoms predicted in the protocol (except for financial concerns), and also new symptoms and concerns, both physical and emotional. The most common symptoms were related to physical functioning (*urinary incontinence*, *sleep problems*, and *sexual dysfunction*), but the symptoms that took longest to address had a significant psychological component (*social functioning*, *living with cancer*, and *sexual dysfunction*). Notably, ten patients reported further concerns beyond those identified in the initial assessment, later on during the course of the intervention. Most often these were common physical symptoms (urinary incontinence, bowel problems, sexual dysfunction) and on few occasions social and emotional (social functioning, living with cancer).

Almost half of the symptoms identified in the intervention had never been reported to a healthcare professional before (with reasons included in Appendix C), and the majority of the symptoms reported previously to clinicians were physical rather than emotional. Symptoms had previously been first reported in secondary care (54%) or to the GP (44%), with attempts to address symptoms having had a varied outcome: a third improved or resolved, another third failed to improve, but patients reported improved coping, and for the final third both symptoms and patient coping remained unchanged.

The most frequently used component of the intervention was teaching self-management strategies (72%). On fewer occasions, participants received information materials (14%), and were signposted (13%) or referred (1%) to other services. The most commonly taught self-management strategies were aimed at improving the *recognition of symptoms*, and the *development of coping strategies* (e.g., symptom self-monitoring, life-style adjustment, cognitive reappraisal). Information materials were most often offered in relation to physical symptoms, such as urinary incontinence, sexual dysfunction and sleep/fatigue problems. Signposting was most often to the GP (38%), Third Sector organisations (29%), or local patient support groups (28%).

{Insert Table 4}

Intervention outcome measures

Follow-up primary outcome measures data were analysed using ANCOVAs controlling for baseline levels (see Appendix D for details). Summary results are reported in Table 5, and informed the sample size estimation for a future fully-powered trial. Using EPIC-26 as the primary outcome for a future trial would require further consideration of the impact of the intervention on the five dimensions of the measure. One approach is to pick the subscale with the largest noted effect (i.e., urinary incontinence, d=0.38) as the primary outcome measure. A simple t-test approach to sample size, with 90% power and 5% significance would require a total sample of 280 participants. Alternatively, all five EPIC-26 subscales could be used, with an adjustment to the significance level (α=.01). However, some of the dimensions showed very little change and this will likely inflate the sample to an unachievable size. For example, the effect size for hormonal symptoms was 0.1, and with a reduced significance level of 1% to accommodate the five dimensions, this approach would require a sample of 5954 at 90% power. As it is likely that the analysis in a future trial will incorporate the baseline measurements, an ANCOVA would be appropriate, with an estimated minimum sample of 88 or 3418 participants, respectively.

{Insert Table 5}

The participants' satisfaction with key elements of follow-on cancer care (the intervention's secondary outcome measure) was similar at baseline between the two groups, and seemed to improve marginally for the Intervention group at follow-up (Mann-Whitney U tests for emotional and psychological symptoms $U(57)=252.50$, $Z=-2.986$, $p=.03$; and relationship problems $U(46)=172.00$, $Z=-2.554$, $p=.011$).

Health economics analysis

Two sources of data for economic evaluation were used and compared for agreement: a bespoke CSRI questionnaires and selected extracts of GP records. Overall, there was a strong agreement between respondents' self-reported data and GP records data, with values ranging from 66.25% to 90.00% (see Appendix E for details).

The EQ-5D-5L response rate was 100% at baseline and 88.4% at follow-up. Both participant groups reported similar EQ-5D-5L score distributions (median and interquartile range) at baseline and follow-up, for each domain (see Appendix E), with a non-significant mean QALY gain of 0.0191 (bootstrapped *95%CI*: -0.0371 to 0.0774) in favour of the Intervention group (see Table 6).

In the absence of a significant difference in the primary outcome measures, we performed an exploratory cost-consequence analysis (Drummond, Sculpher, Claxton, Stoddart, & Torrance, 2015). This included the complete data (at baseline and follow-up) of 80 participants (84.2% of the clinical sample), and used published national average unit costs for the UK for the year 2013/14 (Department of Health, 2015). Any costs from previous years were inflated to 2013/14 using the Hospital & Community Health Service inflation indices from the national average unit costs.

{Insert Table 6}

The mean total cost per participant in the Intervention group was £847 (including the cost of delivering the intervention: £354) and £529 for the Control group over the 9 month period between baseline and follow-up. Thus the net cost of the intervention was £317 (bootstrapped 95% CI: £46 to £558). Further details of the health economic analysis are included in Appendix E.

Feedback interviews with patients and GPs

The patient interviews revealed four major themes: (1) low research burden; (2) three key elements of the intervention; (3) two important aspects of intervention delivery; and (4) a high potential for improving the role of the GP and the community care team in prostate cancer follow-up. Most patients reported no problems completing the questionnaires at home and returning them at set intervals, but some found the CSRI form particularly long. Three most salient aspects of the intervention were identified: the psychological support, the practical information about cancer survivorship, and the opportunity to speak to the same clinician throughout the intervention. Two aspects of the intervention delivery were discussed: timing and location. Firstly, several patients would have preferred to receive the intervention sooner in the cancer pathway, when their need was greater, but opinions varied on what would be the ideal timeframe. Secondly, many patients preferred to have the intervention appointments in a non-clinical environment, pointing to the relaxed atmosphere and absence of time pressure as being conducive to exploring their concerns and receiving the information and psychological support needed. Finally, patients perceived the GP's role in their follow-up care to be presently very limited. This contrasted the patients' high confidence in the Research Nurse, and preference to receive this support generally out of the hospital, in the community.

The interviewed GPs recognised the importance of the extra nurse support delivered in the intervention. One GP mentioned the positive effect it had on the patients seen in clinic, without any noticeable impact on own workload, and another GP estimated that the intervention may have reduced the number of times patients came to seek an appointment. However, all GPs identified substantial capacity challenges to integrating a similar type of support in the services provided by their practice (e.g., staff recruitment, funding the posts, and available clinical space; see Appendix F for details).

Discussion

All feasibility and acceptability targets were achieved during the study. Feedback questionnaires with patients and GPs revealed a high level of support for the intervention, and identified opportunities for a future effectiveness evaluation. The intervention was delivered successfully without significant adverse events. Potential intervention outcome measures have been successfully tested and minimum sample size of 230 participants was estimated to be needed for a fully-power trial with EPIC-26 as the primary outcome measure. For the economic evaluation of the intervention, alternatives to the EQ-5D-5L should be considered, for example, the Short Form 36 Health Survey Questionnaire (SF-36; Brazier et al., 1992), Health Utility Index (HUI; Horsman, Furlong, Feeny, & Torrance, 2003), or the ICEpop CAPability measure for adults (ICECAP-A; Al-Janabi, Flynn, & Coast, 2012).

Implication for a future delivery of the intervention

Three major elements of care provided by the intervention should inform future practice. Importantly, the intervention nearly doubled the number of cancer survivorship symptoms ever

reported by participants, and the underreporting of symptoms by cancer survivors is well-known (Breetvelt & Van Dam, 1991; Ristvedt & Trinkaus, 2005). The range of reasons why patients failed to report the symptoms previously was varied, but two critical elements seemed to be a structured consultation (i.e., "clinician had not asked"), and sufficient time. Moreover, a quarter of patients continued to reveal symptoms, beyond those initially reported in the comprehensive self-screening instrument used in the trial. Notably, these were common, high burden symptoms, which were arguably top-of-mind for patients, such as urinary incontinence, sexual dysfunction, and bowel problems. Thus, the reasons for the initial under-reporting may be psychological. The rapport and continuity of care provided by the research nurse may have facilitated their subsequent reporting. It was beyond the aim of the present study to establish why patient underreport obvious and significant prostate cancer sequelae. However, alongside a structured consultation and sufficient time (mentioned by patients during the intervention), continuity of care seems to be a third essential component of follow-up care (as identified by patients in the feedback interviews).

Risk stratification is often employed to identify patients with "highest need" and selectively target interventions to improve their effectiveness (Watson et al., 2012). However, this was not supported by the present data. Firstly, as discussed earlier, almost half of the symptoms assessed and managed in the intervention had not been reported before, thus, restricting the patients' access to the intervention would result in many patients and their unmet needs being missed. Secondly, the sensitivity of screening instruments is inherently limited. This was highlighted presently when patients failed to identify common and high-burden symptoms initially, but did so eventually throughout the trial. Therefore, a stratification of needs prior to the exploration of symptoms and concerns is likely to miss a significant number of patients and unmet needs, many of which might have never been reported before.

The effectiveness of the intervention could potentially be increased by improving the timing of its delivery. There was no single time point preferred by all the patients, but the data suggested that possibly many would benefit from having the extra psychological support and information available earlier in the cancer pathway, soon after diagnosis and before the treatment decision. This would allow patients to access the support, as needed, at any point (1) after diagnosis, and before deciding on the treatment option, (2) after the end the of the treatment, and (3) for some patients even some time after the end of the treatment. The difference from current usual practice is that the holistic needs assessment would need to be made available at an earlier stage (after diagnosis), and followed-up with psychological support and information if-and-when needed. As the patient progresses through the cancer pathway, the holistic needs assessment could be updated (e.g., at the end of the treatment, or later in the recovery period, by agreement between patient and clinician). As shown in the present feasibility trial, giving patients the opportunity to complete a holistic needs assessment raises their awareness of possible psychological and physical concerns. This, in turn, makes it more likely for patients to report symptoms earlier and seek adequate management or coping strategies. Beginning this assessment and management process early is likely to produce a greater improvement in the patients' quality of life than an intervention delivered once patients are ready for discharge from secondary care.

Methodological implications for future research

The administrative burden in this trial was high, but can be improved in a future fully-powered trial, by using simpler, electronic case report forms, which can be completed immediately after the appointment (e.g., on a tablet or portable computer). The nurse planning time was approximately one quarter of the patient contact time, and was used by the nurse to review the patient documentation, plan the upcoming appointment, and prepare the information materials related to the symptoms and relevant self-management techniques. This process too could be optimised further, as the range and

frequency of the information materials needed can be estimated from the extensive results of the current trial.

Conclusions

TOPCAT-P confirmed that the level of need of prostate cancer survivors is varied, and in many cases, substantial, having a considerable impact on quality of life. The successful feasibility trial suggested incremental improvements to the intervention and usual care. However, the fundamental questions regarding the effectiveness and cost-effectiveness of these changes remain to be answered by a future fully-powered trial.

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TOPCAT-P; RCT of nurse-led intervention

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		Augmented Usual Care				Nurse-led Intervention			
		T0	T1	T2	T3	T0	T1	T2	T3
		Consent	12 weeks	24 weeks	36 weeks	Consent	12 weeks	24 weeks	36 weeks
Follow-up care	Macmillan organiser	✓				✓			
	Routine signposting to Macmillan information centre, GP, hospital services	✓				✓			
	Ongoing follow-up appointments			✓				✓	
	Holistic need assessment							✓	
	Follow-up appointments							✓	
Outcome measures	EPIC-26, HADS, SCNS-34, EQ-5D-5L, confidence in managing own health, satisfaction with health care services	✓			✓	✓			✓
	Client Service Receipt Inventory		✓	✓	✓		✓	✓	✓
	Feedback interview								✓

Note: GP: General Practitioner; EPIC-26: The Expanded Prostate Cancer Index Composite – Short Form (26 items); HADS: Hospital Anxiety and Depression Scale; SCNS-34: Supportive Care Needs Survey - Short Form (34 items); EQ-5D-5L: The 5-level EQ-5D version.

Table 2. *Feedback interview schedule for patients and GPs*

The main topics of the interview schedule for patients:	
	1) experience of the intervention (perceived benefits, missed opportunities, and possible broader impact)
	2) information received about prostate cancer survivorship
	3) views on the routine usual care received from the National Health Service
	4) feedback on improving the intervention (timing, location, and delivery)
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The main topics of the interview schedule for GPs:	
	1) the impact of the intervention on patients seen in general practice
	2) the impact of the intervention on GPs' own work
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Table 3. *Baseline demographic and clinical characteristics for the Intervention and Control groups.*

	Intervention group (*N*)	Control group (*N*)	Total (*N*)
Age group (balancing variable)	**48**	**47**	**95**
48-65	9	7	16
66-72	17	19	36
73-80	18	18	36
81-94	4	3	7
Ethnicity	**48**	**47**	**95**
White British	48	47	95
Marital status	**48**	**47**	**95**
Married or living as married	34	42	76
Widowed	7	3	10
In partnership, but not cohabiting	2	1	3
Divorced or separated	2	1	3
Single	3	-	3
Employment	**48**	**47**	**95**
Retired from paid work	41	37	78
In paid work (including self-employment) - full or part time	6	8	14
Unable to work because of long-term disability or ill health	-	2	2
Temporarily off sick from my job	1	-	1
Highest qualification	**48**	**47**	**95**
College or university degree, HND or HNC	12	13	25
O' Level, GCSE or equivalent	9	11	20
A' level or equivalent	3	6	9
Postgraduate qualification	4	3	7
Clerical or commercial qualification	3	2	5
Other	17	12	29
Treatment type	**48**	**47**	**95**
Radiotherapy	19	24	43
Surgery	18	16	34
Hormone therapy	8	5	13
Watchful waiting	3	2	5
Chronic comorbid conditions	**48**	**47**	**95**
High blood pressure (hypertension)	20	20	40
Rheumatoid or osteoarthritis	12	10	22
Heart problems	8	8	16
Asthma	6	3	9
Diabetes	4	3	7
Chronic Obstructive Pulmonary Disease (COPD)	3	2	5
Osteoporosis	2	2	4
Ischaemic heart disease (IHD)	2	1	3
Inflammatory Bowel Disease (e.g., Crohn's disease, colitis)	1	1	2
Upper Gastrointestinal Tract disease (Upper GIT)	2	-	2
Chronic kidney disease (CKD)	1	1	2
Stroke	-	1	1

Note: HND = Higher National Diploma; HNC = Higher National Certificate

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Table 4. *The duration of the intervention (in minutes), and the distance travelled (in miles) per patients and per appointment.*

	Total	Intervention duration/distance travelled per patient			Intervention duration/distance travelled per appointment		
		N	**Mean**	**SD**	**N**	**Mean**	**SD**
Intervention duration	(minutes)	(patients)	(minutes)	(minutes)	(appointments)	(minutes)	(minutes)
Nurse Planning Time	1,743	45	39	19	121	14	5
Nurse Travel Time	959	17	56	39	33	29	13
Nurse Contact Time	7,385	45	164	121	121	61	34
Nurse Admin Time	14,752	45	328	259	121	122	76
Patient Travel Time	1,125	45	25	24	95	25	11
Travel Distance	(miles)	(patients)	(miles)	(miles)	(appointments)	(miles)	(miles)
Nurse Travel Distance	676	17	40	34	33	20	17
Patient Travel Distance	377	45	8	8	95	4	3

Table 5. *Comparison between the Intervention and Control groups at follow-up, for all five intervention outcome measures (N=follow-up sample size; EMM=estimated marginal means (adjusted for baseline levels) with 95% confidence intervals; SE=standard error).*

	Intervention group			Control group		
	N	***EMM (95%CI)***	***SE***	***N***	***EMM (95%CI)***	***SE***
Expanded Prostate Cancer Index Composite (EPIC-26)						
Urinary Incontinence	34	75.8 (71.5-80.1)	2.2	37	81.7 (77.5-85.8)	2.1
Urinary irritative / obstructive	34	86.8 (83.2-90.5)	1.8	37	88.9 (85.4-92.4	1.8
Bowel symptoms	40	91.2 (87.5-94.9)	1.9	38	91.6 (87.8-95.5)	1.9
Sexual symptoms	41	21.4 (17.1-25.7)	2.2	40	21.7 (17.4-26.1)	2.2
Hormonal symptoms	39	81.2 (75.9-86.5)	2.7	39	84.7 (75.9-86.5)	2.7
Self-confidence in managing own health						
Overall Score (average)	42	8.5 (8.2-8.9)	0.2	39	8.3 (7.9-8.7)	0.2
Supportive Care Needs Survey (SCNS-SF34) summed scores						
Psychological	43	17.2 (15.5-18.9)	0.9	40	17.1 (15.4-18.9)	0.9
Health Systems and Information	42	17.6 (14.9-20.3)	1.4	40	17.0 (14.2-19.7)	1.4
Physical and daily living	42	7.8 (6.8-8.7)	0.5	40	7.8 (6.8-8.8)	0.5
Patient care and support	43	7.3 (6.2-8.4)	0.6	40	7.0 (5.8-8.1)	0.6
Sexuality	42	5.5 (4.7-6.3)	0.4	39	5.6 (4.8-6.4)	0.4
Hospital Anxiety and Depression Scale (HADS)						
Anxiety	42	3.9 (3.2-4.6)	0.4	41	3.5 (2.8-4.2)	0.3
Depression	42	3.6 (2.9-4.2)	0.3	41	3.8 (3.2-4.4)	0.3
EuroQol 5D-5L quality of life index						
Index score (%)	42	76.1 (71.7-80.5)	2.2	40	78.7 (74.3-83.2)	2.2

TOPCAT-P; RCT of nurse-led intervention

Table 6. *Self-reported EQ-5D-5L index scores, mean QALYs and incremental mean QALYs at 9 months follow-up by group (N= 80).*

	Intervention (*N*= 40) Mean (*SD*)			**Control (*N*= 40) Mean (*SD*)**			**Incremental mean QALYs between groups[1] (bootstrapped *95% CI*)**
Measure	**Baseline**	**9 months**	**QALY over 9 months**	**Baseline**	**9 months**	**QALY over 9 months**	
EQ-5D-5L index	0.8257 (0.1436)	0.8184 (0.1895)	0.6165 (0.1194)	0.7942 (0.1935)	0.7989 (0.1937)	0.5974 (0.1397)	0.0191 (-0.0371 to 0.0774)

[1] Incremental mean QALYs between groups=mean QALYs for Intervention group minus mean QALYs for control group

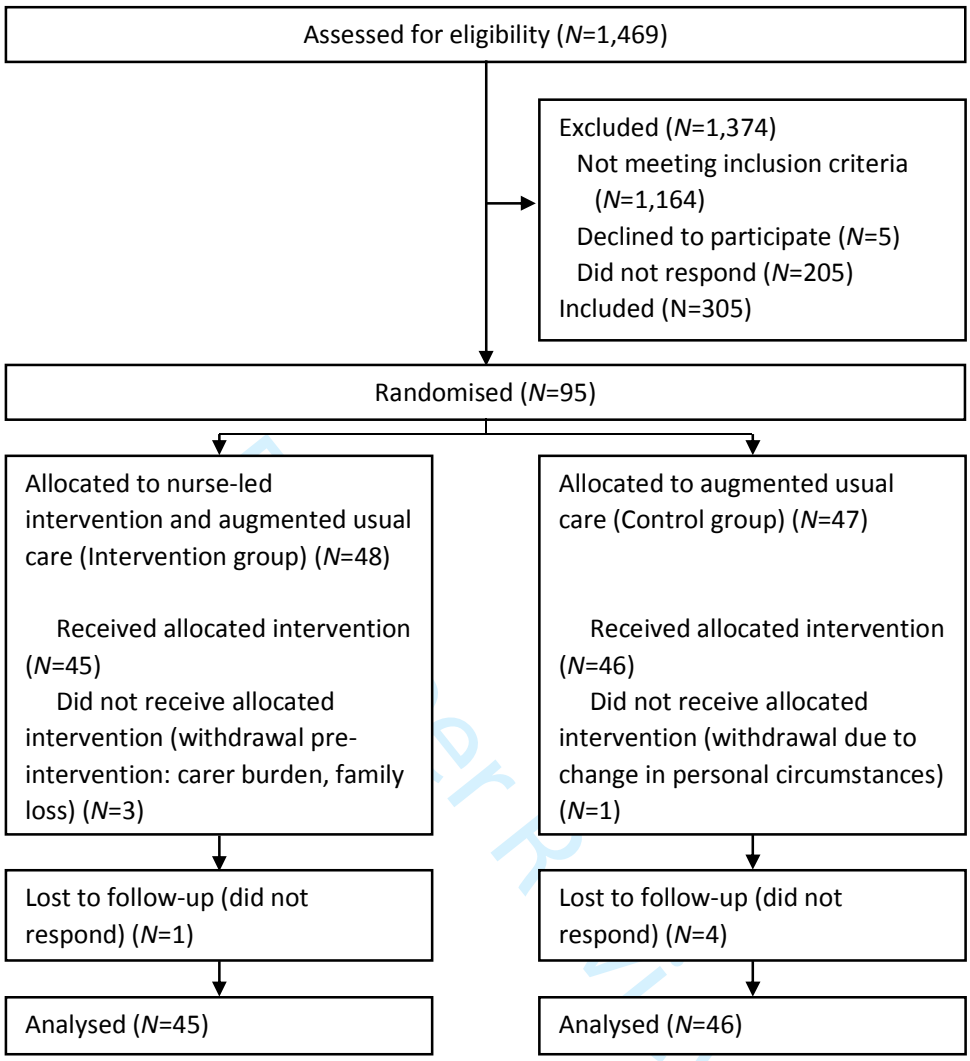

Figure 1. CONSORT diagram showing the flow of participants through each phase of the TOPCAT-P trial.

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	Holistic need assessment							✓	
	Follow-up appointments							✓	
Outcome measures	EPIC-26, HADS, SCNS-34, EQ-5D-5L, confidence in managing own health, satisfaction with health care services	✓			✓	✓			✓
	Client Service Receipt Inventory		✓	✓	✓		✓	✓	✓
	Feedback interview								✓

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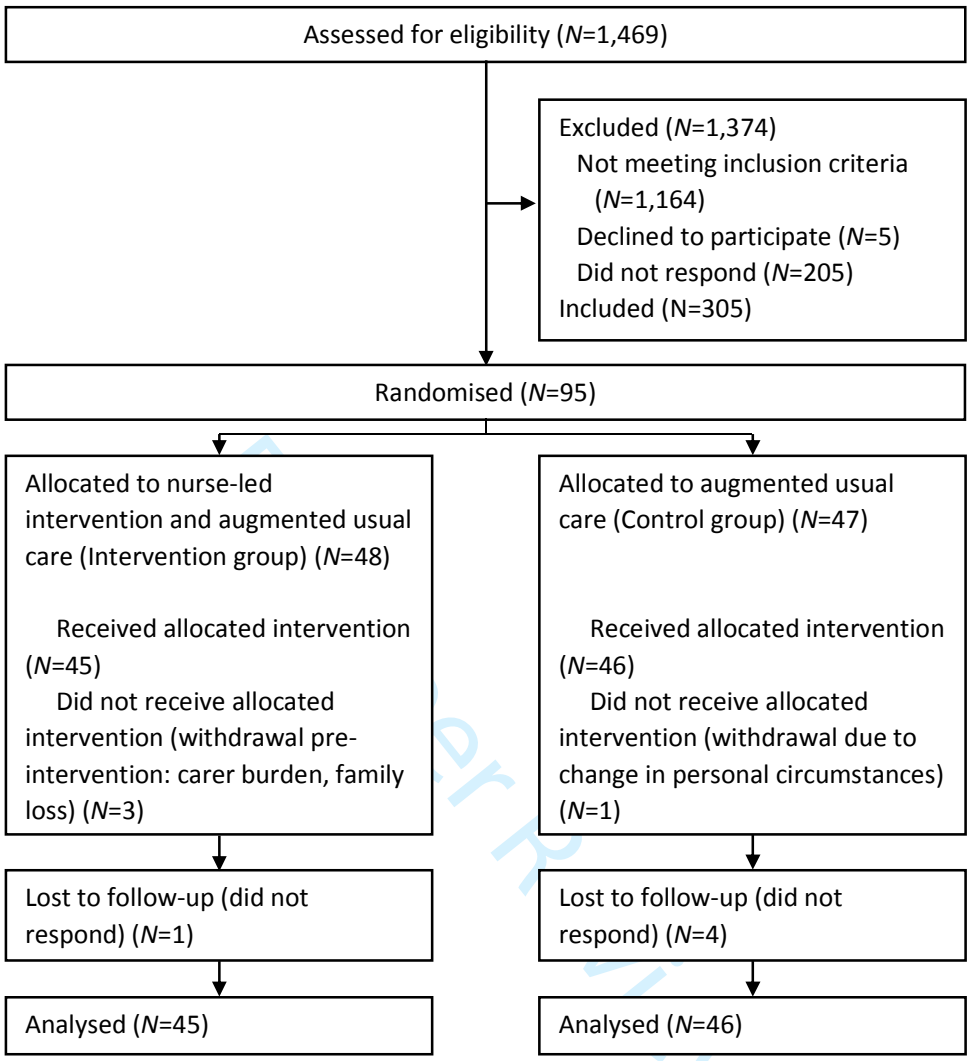

Figure 1. CONSORT diagram showing the flow of participants through each phase of the TOPCAT-P trial.