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A pilot randomised controlled trial of personalised care after treatment for prostate cancer (TOPCAT-P): nurse-led holistic-needs assessment and individualised psychoeducational intervention: study protocol

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ABSTRACT

Introduction: Prostate cancer is common and the incidence is increasing, but more men are living longer after diagnosis, and die with their disease rather than of it. Nonetheless, specific and substantial physical, sexual, emotional and mental health problems often lead to a poor quality of life. Urology services increasingly struggle to cope with the demands of follow-up care, and primary care is likely to play the central role in long-term follow-up. The present phase II trial will evaluate the feasibility and acceptability of a nurse-led, person-centred psychoeducational intervention, delivered in community or primary care settings.

Methods and analysis: Prostate cancer survivors diagnosed in the past 9–48 months and currently biochemically stable will be identified from hospital records by their treating clinician. Eligible men would have either completed radical treatment, or would be followed up with prostate specific antigen monitoring and symptom reporting. We will recruit 120 patients who will be randomised to receive either an augmented form of usual care, or an additional nurse-led intervention for a period of 36 weeks. Following the health policy in Wales, the intervention is offered by a key worker, is promoting prudent healthcare and is using a holistic needs assessment. Outcome measures will assess physical symptoms, psychological well-being, confidence in managing own health and quality of life. Healthcare service use will be measured over 36 weeks. Feedback interviews with patients and clinicians will further inform the acceptability of the intervention. Recruitment, attrition, questionnaire completion rates and outcome measures variability will be assessed, and results will inform the design of a future phase III trial and accompanying economic evaluation.

Ethics and dissemination: Ethics approval was granted by Bangor University and North Wales REC (13/WA/0291). Results will be reported in peer-reviewed publications, at scientific conferences, and directly through national cancer and primary care networks.

Trial registration number: ISRCTN 34516019.

Strengths and limitations of this study

- The intervention is designed in line with new Welsh health policy by promoting prudent healthcare principles and offering a key worker for each cancer survivor.
- The holistic needs assessment uses novel and comprehensive instruments bridging research and hospital best practice, which will be shared with patients, primary and secondary care.
- The study adopts an augmented form of usual care, in line with ongoing developments of the care system in the recruitment area.
- The intervention is offered to stable survivors, irrespective of risk-stratification, or self-reported level of need, for an accurate assessment of its overall effectiveness.
- Recruitment area covers rural as well as urban regions, with a wide mix of socioeconomic strata.

INTRODUCTION

Prostate cancer is the most common cancer for men in the UK (second worldwide), and many survivors experience long-lasting physical and psychological needs. Over the past 20 years, in the UK, incidence rates have doubled, but mortality rates have dropped by a quarter.[1 2] Common physical symptoms are related to sexual function, urinary incontinence,[3] bowel symptoms,[4] hot flushes and the risk of bone fracture.[5] The management of chronic comorbid conditions (eg, cardiovascular disease and cerebrovascular disease,

hypertension, diabetes) often further increases the level of need, and about two-thirds of patients with prostate cancer are expected to have at least one major comorbidity.[6–8] Psychological distress is also significant, and most prostate cancer survivors require prompt information about treatment outcomes and its impact on daily living.[9] The diagnosis and treatment toxicities also affect the patients' immediate families,[10] particularly through psychological distress related to anxiety, depression[11 12] and psychosexual problems.[13] Thus, the assessment and management of the adverse treatment effects, related psychosocial needs (also affecting their partners) and the impact on the management of other comorbid conditions is, for many patients, complex and prolonged.

Current usual care and evidence base

Patients with prostate cancer are normally followed up in out-patient clinics in hospital for up to 5 years, to monitor and manage the risk of recurrence, and the physical symptoms following treatment.[14] However, current practice is not underpinned by robust evidence, and is notoriously variable between hospitals.[15] In the absence of reliable empirical evidence, the National Institute for Health and Care Excellence (NICE) guidelines recommend that unless significant treatment complications develop, after 2 years, their follow-up care should take place out of hospital.[16] However, recommendations on the type of follow-up to be undertaken are notably missing from the guidelines.

In the last decade and a half, attempts have been made to address the lack of empirical evidence regarding the efficacy and cost-effectiveness of prostate cancer follow-up. Early initiatives showed that by involving primary and community care, the utilisation of specialist care may be reduced, especially for the more elderly patients.[17] Also, patients perceive they receive more care from the general practitioner (GP),[18] while their quality of life remains similar between hospital and primary care follow-up. However, notable concerns were reported about the continuity of care, the miscommunication between hospitals and GPs and the integration of prostate specific antigen (PSA) testing. A number of hospital-based alternatives have been proposed, such as hospital group clinics,[19] nurse face-to-face and telephone clinics[20–22] and e-health technology based follow-up.[23–25] Such approaches fail to address the issues about the capacity and scope of specialist secondary care teams, which may struggle to offer, assess and manage a holistic range of physical, psychosocial and educational needs of patients. Recently, improvements in e-health platforms facilitating the communication between hospital and primary care, especially surrounding the safe monitoring of PSA levels and cancer recurrence, have revived efforts to consider a primary-care-led model of follow-up.[26]

Nurse-led interventions have been consistently shown to be effective in a range of diseases, from diabetes and depression,[27 28] to various cancers,[29] and, more specifically, when interventions were administered in primary care settings.[30] There is sufficient literature showing the gaps in care to argue for a more intensive approach initially,[31] and most emerging models include a nurse-led assessment of needs. There is evidence that increasing the participation of patients with cancer in their own care can reduce their psychosocial and information needs.[32] Self-management is now accepted as a potential solution for the complex needs of prostate cancer survivors,[33] but conclusive evidence is still needed regarding the design and delivery of such interventions.

Person-centred and prudent healthcare for prostate cancer survivors

Despite a tradition of predominantly disease-centred follow-up, the person-centred approach features highly in the UK health policy agenda. The 2004 NICE guidelines[34] recognised the complex needs of cancer survivors, and the Cancer Reform Strategy[35] set out to understand and address them. In Wales, the government's Together for Health—Cancer Delivery Plan[36] directed Health Boards to assign a Key Worker to assess and record the clinical and non-clinical needs of cancer survivors in a personalised care plan, and to ensure care is coordinated between hospital and community. The policy highlighted the need for new multidisciplinary models of follow-up to be developed and evaluated. Moreover, the Bevan Commission[37] recommended the application of prudent healthcare principles, such as: (1) offering early interventions, (2) promoting self-management and the coproduction of healthcare, (3) involving community assets in order to reduce the level of unmet need, (4) removing unnecessary processes (especially the duplication of support services), and (5) adopting services that achieve similar or better patient outcomes, while using less expensive human and technical resources. Thus, for prostate cancer follow-up, the government health policy directs towards holistic and person-centred care, delivered safely and at the earliest opportunity, outside of hospital, with the aim of empowering patients to take an active role in managing and improving their health.

The present trial (TOPCAT-P) is directly addressing the growing capacity challenges facing hospital based services in the UK, by engaging primary and community care soon after the end of prostate cancer treatment. The pilot trial, PROSPECTIV,[14 38] served as the basis for the development of the present work. TOPCAT-P is expanding the personalised nurse-led intervention being piloted in PROSPECTIV in three significant areas: (1) the intervention (including the holistic needs assessment) is being offered irrespective of the patient-reported level of need; (2) the care planning documentation and sharing are updated in response to on-going changes to policy and practice; (3) all participants in the intervention and control arms will receive Macmillan written materials as part of usual practice. The manualised nurse-led

psychoeducational intervention includes an exploratory and person-centred holistic needs assessment, promotes self-management of symptoms, is delivered out-of-hospital and includes patients' partners, carers, or close family members, where necessary. The aim of the current pilot trial is to evaluate the feasibility and acceptability of the intervention, addressing the wider group of cancer survivors, using the novel holistic needs assessment and care planning tools.

METHODS AND ANALYSIS

Trial design

TOPCAT-P is a randomised two-arm parallel-group phase II external feasibility trial, comparing the effectiveness and cost-effectiveness of a personalised, nurse-led, psychoeducational intervention versus the augmented version of usual care beginning to be delivered in North Wales. The present trial follows the new Medical Research Council (MRC) guidelines for the development of complex interventions[39] by investigating the feasibility and acceptability of the intervention, the novel holistic needs assessment instruments, and enhanced information documenting and sharing procedure. This will be used to inform the design of a phase III trial, which will assess the effectiveness and cost-effectiveness of the intervention.

Participant recruitment and consent

Inclusion criteria

The Urology Clinical Nurse Specialist will identify biochemically stable incident patients with prostate cancer, 9–48 months postdiagnosis, from the multidisciplinary team (MDT) records in the Wrexham Maelor Hospital. They would have either received radical curative treatment (surgery, radiotherapy, or hormone therapy), or be followed up with PSA monitoring and symptom reporting, but deemed unlikely to receive curative treatment (watchful waiting). Notably, patients currently followed up in the hospital or in the community will be invited to participate in the study.

Exclusion criteria

The study will exclude men suitable for curative treatment, but who choose to be monitored until proof of further progression (active surveillance). Also, palliative patients who are in the terminal stage of their disease or who lack the capacity to consent (as assessed by the referring clinician) will not be included.

Sample size

We intend to invite 300 patients to take part in the pilot trial and estimate a recruitment rate of approximately 40%. This will allow the recruitment of 120 participants (60 per trial arm—optimum for the randomisation procedure described below).[40] A maximum attrition rate of 50% will ensure at least 30 patients per arm will complete the trial. This will provide a satisfactory number of participants for estimating the variation within the sample (ie, the SD of the outcome measures), in order to inform the power calculation for a future phase III trial, which would be powered to detect clinically relevant changes in prostate-related health and cost-effectiveness.

Randomisation

Participants will be randomised individually to one of the two arms of the trial (usual care or nurse-led intervention), on a 1:1 basis and stratifying for age (65 or under, 66–72, 73–80, over 80), according to the Cancer Incidence Report 2007–2011.[41] The concealed allocation procedure will use a secure, off-site electronic system managed by the North Wales Organisation for Randomised Trials in Health (NWORTH)—a UKCRC fully registered trials unit. The system uses a sequential dynamic adaptive randomisation algorithm,[40] tuned to balance within stratification levels and overall, while maintaining an acceptable level of unpredictability.

Augmented usual care

Patients in both arms of the study will continue to receive the usual care delivered outside of the trial, including any follow-up appointments (at the hospital or general practice). To account for the variable patterns of follow-up care, all contacts with healthcare professionals will be recorded in bespoke health service-use diaries (client service receipt inventory (CSRI)). To reflect the changes to usual care being implemented in Wales, all patients will be offered, in person, after providing informed consent (see online supplementary appendices 1 and 2), a Macmillan Organiser[42] to help self-record and monitor any physical and psychological symptoms, as well as the results of relevant medical tests and medication taken. All patients will also be signposted to contact the local Macmillan information centre for information and advice regarding any cancer-related concerns, as well as to contact their GP or hospital team, if necessary, for appropriate medical support.

Intervention

Supplementary to augmented usual care, patients in the intervention arm will be offered an initial appointment with the research nurse for a holistic needs assessment, and tailored follow-up appointments, as appropriate. Before the start of the intervention, the research nurse will complete the 2-day course, 'The detection of psychological distress in patients with cancer', needed for National Health Service (NHS) staff to qualify at level 2 of the 4-tier model of Psychological Support.[34 43] Additionally, through the Macmillan network, the nurse will complete three training modules routinely recommended for clinical staff delivering holistic needs assessments: 'Maguire Advanced Communication Skills' training,[44] 'Motivational Interviewing' and '10-min CBT'.[45 46] The intervention will make use of dynamic personal care plans, and encourage self-management

(empowering men to help themselves). Distinctly, the research nurse will use a comprehensive holistic needs assessment tool and care plan[47]—specifically exploring physical, emotional, spiritual, lifestyle and family aspects of cancer survivorship, together with an additional bespoke instrument developed in secondary care to monitor physical symptoms (H Nikkhouy-Toussi. Consultant urological surgeon. Personal communication, 16 September 2013). Following the assessment, the nurse will provide individualised information, advice and support tailored to each patient, in order to help men improve their symptoms or cope better with symptoms they cannot improve. Patient referral to GP or secondary care and signposting to community or third sector support services will be made as appropriate. The holistic needs assessment will be documented and shared with patients and, following consent, with their GP. If acute physical symptoms are identified or if disease recurrence is suspected, these will be communicated directly to the secondary care team and GPs. All referrals to tertiary services will be documented in the secondary care cancer network information system (CaNISC) to be available to Oncology teams and facilitate seamless care between healthcare providers.[48]

The initial holistic needs assessment

The first appointment will be in person and will take place out of hospital, in the patient's own primary care setting (by agreement with the general practice), at the local community hospital, or, alternatively, in a dedicated space at the research unit. Housebound patients will be offered home visits. The needs assessment will explore a comprehensive range of symptoms and concerns (see table 1). The nurse will encourage patients to consider all the aspects of survivorship, and will specifically explore symptoms and concerns beyond the formalised checklist.

The delivery of the intervention is based on the novel needs assessment instruments and care plan.[47 49] Following the assessment, a range of person-tailored and symptom-specific management strategies will be taught. Physical and psychological needs will not be treated separately, but in relation to each other.[50] Thus, physical management techniques (eg, pelvic floor exercises, double-void technique) will be taught in the context of established cognitive-behaviour therapy techniques such as self-monitoring, guided-discovery, life-style adjustment and cognitive re-appraisal.[51] The nurse will invite patients to examine their lifestyle prior to their prostate cancer diagnosis, identify how their thoughts, ideas,

Table 1 Summary of holistic needs assessment

Categories of need	Symptom	Summary of key assessment points
1. Physical symptoms	1. Pain	Type of pain, duration and level of pain
	2. Breathing problems	Relevant comorbidities
	3. Appetite	Appetite levels, weight loss, soreness to the mouth, difficulties with digestion, symptoms of nausea or vomiting
	4. Urinary function	Lower urinary tract symptoms, bleeding, incontinence concerns, impact on everyday life (including psychological impact)
	5. Bowel function	Loose stools, bleeding or incontinence, impact on everyday life (including emotional aspects)
	6. Mobility	Limitations to mobility, relations to fatigue, impact on mood, general well-being and energy levels
	7. Fatigue	Dietary intake, impact on mood, enjoyment of daily activities, quality of sleep, background stressors, fears or anxieties, relaxation therapies, organisation of daily activities
	8. Sexual function	Erectile dysfunction, loss of libido, impact on relationship with partner, patients' and partner's feelings, and anxieties
	9. Hot flushes	Emotional impact, participation in social activities, relations with others
2. Emotional concerns, anxieties	1. Depression	Low mood, loss of interest in everyday activities, depressive thoughts, behaviour changes, isolation, social relations, utility of mood record
	2. Anger	Anger towards diagnosis, guilt at causing stress to partner or family, strain on relationships
	3. Fear of disease recurrence	Lifestyle before diagnosis, hobbies, regular PSA monitoring
	4. Altered body image/sexuality	Weight gain/loss, breast swelling, impact on mood and sexuality, behavioural changes, healthy nutrition, regular exercise
	5. Spirituality	Loss of faith, meaning of life after diagnosis
	6. Financial concerns	Loss of finance, insecurities about future earnings/costs, inability to afford past hobbies, financial support
	7. Lifestyle changes	Travel insurance, planning of daily journeys, self-monitoring of symptoms
	8. Memory and attention	Increased overall stress, general self-confidence, change in sleep patterns

PSA, prostate specific antigen.

feelings, attitudes and behaviours affect their day-to-day life, and to reflect on the impact this is having on their life. For patients who have fully adjusted to survivorship, the process is expected to be relatively quick and seamless. However, patients who experience any level of unmet need will first benefit from the guided self-reflection.[52] Second, where action is necessary to address individual symptoms, patients will be offered specific and personalised advice. Supported by the nurse, patients will consider which aims and strategies are attainable and relevant for their circumstances. A plan will be devised together with the nurse to accomplish these goals, and will be documented in the personalised care plan. A copy of the initial holistic needs assessment summary and the complete personalised plan of care will be given to patients, and, with their consent, will be sent to their GP for information and long-term management. A covering letter will explain to GPs the context of the care plan, the scope and duration of the intervention, and will provide a point of contact for any related queries. Where the level of support and complexity of need will exceed the capability of the current intervention, the nurse will specifically refer patients to their GP or for specialist support, as appropriate.

The follow-up sessions

By agreement with patients, the nurse will arrange follow-up appointments to monitor the progress of the self-management strategies advised during the initial assessment. The progress made and any related patient concerns will be documented in the patient's plan of care, and again shared with patients and their GP, as before. The accompanying covering letter will inform GPs of the remaining support available from the intervention, and the outstanding patient needs and concerns. Patients will also be given the opportunity to request follow-up sessions at any point during the intervention by contacting the nurse by telephone. As above, follow-up appointments will take place in general practice, community hospital, the research unit, or at the patient's home, for housebound patients. These appointments will be in addition to any referrals to support outside the intervention. We anticipate men will need on average 1–2 follow-up sessions, but their number will not be limited. The frequency, setting and content of these sessions will be recorded by the nurse for the process evaluation.

Outcome measures

As a phase II trial, the primary measures of interest are patient recruitment, attrition and response rate for questionnaires. To capture the intervention outcome, a battery of established patient reported measures will be used to assess changes in the physical symptoms (Expanded Prostate Cancer Index Composite, EPIC-26),[53] psychological well-being (Hospital Anxiety and Depression Scale; HADS),[54] confidence in managing own health,[55] medical and support needs (Supportive Care Needs Survey—simplified response format),[56 57] and general health and quality of life (EuroQoL EQ-5D-5L),[58] along with a bespoke questionnaire assessing patients' satisfaction with the healthcare services. To reduce participant burden, the questionnaires have been collated in a single booklet. All questionnaires will be self-completed by patients. The researcher recruiting the patients will offer the baseline measures to all patients after consent, and prior to randomisation. The researcher will remain blind to the randomisation results until the end of recruitment. Subsequent questionnaires will be sent by post to be completed by patients in both arms and similarly returned to the research team by post (see table 2). The ongoing use of health and social care services during the intervention will be collected at 12, 24 and 36 weeks, using a purpose-built diary. The questionnaire documents the frequency and types of contacts with primary and secondary healthcare services, social services and voluntary sector services. The diary will include information about: the number of times the patient had to see a doctor, nurse, or other healthcare professional in relation to his prostate cancer-related symptoms; the special medication, aids and adaptations prescribed to patients to help with their prostate cancer-related symptoms; and the number of days patients felt too unwell to participate in their normal activities due to prostate cancer-related symptoms. Moreover, relevant medical history data (eg, cancer diagnosis, stage, treatment type, chronic and acute comorbid conditions, etc) will be collected from GP-and hospital-held records with patients' consent.

A subsample of patients in the intervention group (N=32), the research nurse and secondary and primary care clinicians (N=10), will be invited to take part in individual feedback interviews at the end of the trial. Patients will be selected through purposive sampling to include all types of treatment (surgery, radiotherapy, hormone therapy, watchful waiting), cancer stage (localised, locally advanced/advanced), and represent a balanced median split for age and level of need. Clinicians will be selected from those who had the largest number of patients in trial. A researcher not involved in the intervention delivery will conduct the interviews face-to-face, or alternatively by telephone. The interviews will be semistructured and investigate the patients' experience of the intervention, the perceived benefits and missed opportunities of the trial, and possible effects beyond those captured in the proposed outcome measures (both for patients and healthcare services/clinicians).

Data safety and monitoring

The study procedure and intervention were assessed to present only low impact risks for patient safety, with a low probability. Thus, an independent data monitoring group will not be needed, and interim analyses will not be conducted. However, the intervention will be continuously monitored for safety by the research team,

Table 2 Timeline of intervention delivery and outcome measures

	Augmented usual care				Nurse-led intervention			
	T0 Consent	T1 12 weeks	T2 24 weeks	T3 36 weeks	T0 Consent	T1 12 weeks	T2 24 weeks	T3 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 healthcare services	✓			✓	✓			✓
Health service-use diary		✓	✓	✓		✓	✓	✓
Feedback interview								✓

EPIC-26, Expanded Prostate Cancer Index Composite; GP, general practitioner; HADS, Hospital Anxiety and Depression Scale; SCNS, Supportive Care Needs Survey.

with direct input from the patients' general practice and referring secondary care clinicians. All process and safety monitoring records will be maintained in accordance with national and local research governance regulations. All adverse events and serious adverse events will be recorded, and followed up for the duration of the study or until resolution. Assessment of adverse events will be performed by the clinical lead of the research team. All serious adverse events will be graded and reported to the sponsor, funder, and the ethics and research governance committees.

Data management

All data will be collected on paper questionnaires, which will be stored, linked and entered electronically in an anonymised format. Routine data checks will be performed at two time points: (1) when the questionnaires are received from patients, and (2) when the data are entered into a secure electronic data capture system (MACRO, V.4.2.4, InferMed Limited), hosted and managed by the clinical trials unit (NWORTH). Electronic data will be audited on an ongoing basis by two independent auditors, and outcomes will inform the remaining data collection and entry. All data queries will be managed directly by a single Data Manager, and the complete audit trail will be recorded electronically in MACRO. At the end of the trial, all paper questionnaires and electronic data will be archived securely and stored for 5 years, after which they will be confidentially destroyed.

Data analysis

Feasibility metrics (eg, recruitment and retention rates, clinical characteristics, randomisation, duration of the intervention, etc) will be analysed first, together with adherence outcomes (patient acceptance and adherence to the intervention). Medical history data will be assessed for completeness in conjunction with the outcome measures. The semistructured interviews will be analysed using the matrix based thematic Framework approach, which facilitates analysis both by case and theme.[59 60]

A preliminary analysis of the intervention outcomes will be carried out, following an intention-to-treat approach. Point and 95% CI estimates will be calculated for the changes in prostate-specific symptoms, quality of life, psychological well-being, self-confidence in managing own health, and ongoing medical and support needs between the two groups. Results will be used to estimate SDs and effect sizes to help inform a sample size calculation for a future phase III randomised control trial (RCT)—if feasibility and acceptability are confirmed.

The analysis will also address the health economics of the intervention. The benefit measurement will use both generic health-related quality of life (EQ-5D-5L) and prostate cancer specific quality of life measures. The analysis will take a societal perspective, given the broad impact on the NHS (both primary and secondary care), the patients, their families and the third sector. In line with established guidelines for economic evaluation of complex interventions,[61] the costing analysis will use the national unit costs.[62] The outcome of the preliminary economic analysis estimates will serve to develop the protocol for a full primary cost utility analysis, with a secondary cost–consequence analysis, in a future phase III RCT.

DISCUSSION

The TOPCAT-P trial proposes a novel model of care for prostate cancer survivors, in line with recent NICE

guidelines, local government health policy and charity sector initiatives in Wales, to offer a holistic and personalised care delivered in primary and community care settings. These changes to presently hospital-based models of care come in response to increased levels of patient unmet need, raising numbers of prostate cancer survivors with continuing upward estimates, and unavoidable logistical and financial pressures on secondary care teams.

The present trial aims to evaluate the feasibility and acceptability of the intervention, addressing the wider group of cancer survivors, using the novel holistic needs assessment and care planning tools, in the context of care in Wales. The results will inform the design of a definitive stage III trial, for this model of prostate cancer follow-up. A phase III; RCT would be deemed feasible if: (1) a minimum of 25% of the clinically eligible patients, who will be invited to take part in the trial are recruited, (2) the attrition rate during the trial is no greater than 20%, and (3) the outcome measures completion rate for the active participants (ie, those who have not withdrawn, died or been lost to follow-up) is above 66%. All the feasibility metrics will be calculated using 95% CIs. Moreover, the patients' and clinicians' feedback will be used to assess the acceptability of the intervention and shape its future administration as well as the overall communication with participants and healthcare professionals. The recruitment, attrition and questionnaire completion rates, together with the SD of the main intervention outcomes will inform the estimation of the sample size for a future phase III trial. The time needed to collect and analyse the data will be used to determine the optimum timings of each activity, and the overall duration of the trial.

The nurse-led intervention piloted in TOPCAT-P is based on a similar trial conducted in England (PROSPECTIV),[38] but is significantly different in three methodological areas, which will extend the knowledge gained from PROSPECTIV, and assess the feasibility and acceptability of the intervention in a different area, and in different settings. First, the intervention is offered to stable prostate cancer survivors irrespective of their self-reported level of need. Second, the holistic needs assessment, care planning and information sharing documentation is based on novel instruments currently being considered for routine clinical use in the TOPCAT-P recruitment area. Third, the definition of usual care is updated in response to on-going changes to practice in Wales, including new routine third sector improvements, which will provide a contextualised assessment of the intervention's effects. However, similarly to PROSPECTIV, the intervention is nurse-led, based on a psychoeducational framework, promotes self-management of symptoms, is delivered in the community and includes patients' close social group (eg, partner, family, carers), where this is relevant and helpful for the patient.

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Contributors CW, MM, EW, RE, JB and RDN coordinated the design and funding award. MAS finalised the design of the recruitment, and data collection processes and instruments, managed the ethical and governance approval process, led the implementation of the study and the writing of the manuscript. CM contributed to the development of the intervention and the symptom screening and assessment instruments, the screening of patients, delivered the intervention and collected the medical data from general practice. CW, RDN and MM provided clinical expertise. ZH provided expertise regarding the design, sampling, randomisation and statistical analysis plan for the quantitative measures. JH provided expertise regarding the design, sampling and analysis plan of the feedback interviews. RTE provided expertise on the economic evaluation and health economic instruments, data collection and analysis. All authors had a significant contribution to the manuscript and approved the final version.

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Patient consent Obtained.

Ethics approval Ethics approval has been granted by Bangor University (HMSAEC, School of Healthcare Sciences), and by the North Wales Research Ethics Committee (Central and East) and the Betsi Cadwaladr University Health Board Research and Development Internal Review Panel (13/WA/0291). All protocol amendments will be communicated to the Ethics Committee (substantial amendments) and to the R and D review panel (minor and substantial amendments) for approval, according to the research governance regulations in Wales, UK. With the funder's consent, results will be reported in peer-reviewed journals, presented at scientific conferences, and disseminated directly to policymakers, and more widely through national cancer and primary care networks. All participants in the trial will be offered a summary of the study's outcomes.

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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Appendix 1. Bilingual Participant Information Sheet

Dalen Wybodaeth i Gyfranogwyr

Teitl yr astudiaeth: Treial Gofal Personol ar ôl Triniaeth – Canser y Prostad (TOPCAT-PC)

Hoffem eich gwahodd i gymryd rhan yn ein hastudiaeth ymchwil (gelwir hefyd yn 'dreial'). Cyn i chi benderfynu, hoffem i chi ddeall pam mae'r ymchwil yn cael ei wneud a beth y byddai'n ei olygu i chi. Bydd ein tîm ymchwil yn hapus i fynd drwy'r ddalen wybodaeth gyda chi ac ateb unrhyw gwestiynau sydd gennych. Hefyd, mae croeso i chi siarad â phobl eraill am yr astudiaeth.

Beth yw diben yr astudiaeth?

Rydym yn chwilio drwy'r amser am ffyrdd gwell o wella eich gofal. Un ffordd o wneud hyn yw edrych ar sut mae cleifion yn teimlo am eu gofal iechyd ar ôl triniaeth. Hoffem weld a fydd cynnig mwy o gymorth i ddynion, a'u galluogi i'w reoli eu hunain, yn helpu i wella eu gwellhad, eu profiad o ofal dilynol, a'u hansawdd bywyd cyffredinol. Gwneir hyn naill ai gyda, neu heb, apwyntiadau dilynol yn eu meddygfa deulu gyda nyrs wedi'i hyfforddi'n arbennig (gan ddibynnu pa un o'r ddau ymyriad a roddir yn yr astudiaeth hon y byddant yn ei gael).

Pam yr wyf wedi cael fy ngwahodd?

Cawsoch eich gwahodd i gymryd rhan yn y treial hwn gan fod y Clinigwr sy'n eich trin o'r farn bod eich canser y prostad yn sefydlog ar hyn o bryd, hyd yn oed os ydych yn dal i fynychu apwyntiadau rheolaidd i fonitro ei gyflwr, ac unrhyw ddatblygiadau yn y dyfodol. Hoffem i chi fod yn un o'r 120 o gleifion a fydd yn cymryd rhan yn y treial hwn.

Oes rhaid i mi gymryd rhan?

Nac oes. Eich penderfyniad chi yw ymuno â'r astudiaeth. Os penderfynwch gymryd rhan yn y treial, cysylltwch â Rheolwr y Treial. Byddwn yn disgrifio'r astudiaeth ac yn eich arwain drwy'r ddalen wybodaeth hon. Os cytunwch i gymryd rhan, byddwn yna'n gofyn i chi lofnodi ffurflen caniatâd. Fodd bynnag, ar ôl hynny, cewch dynnu'n ôl o'r astudiaeth unrhyw bryd, heb roi rheswm. Ni fyddai hyn yn effeithio ar y gofal rheolaidd a gewch.

Beth fydd yn digwydd i mi os wyf yn cymryd rhan? Beth fydd gofyn i mi ei wneud?

Cewch eich gwahodd i gyfarfod â'r Swyddog Ymchwil, drwy gydgytundeb, yn eich meddygfa deulu leol, eich ysbyty cymunedol lleol, neu ganolfan ymchwil, i lofnodi'r ffurflen caniatâd a llenwi holiadur yn ymwneud ag iechyd. Cewch yr holl gymorth sydd ei angen i lenwi'r holiadur, ac, ar ôl gorffen, cewch ei roi'n ôl ar unwaith. Cewch hefyd lenwi'r holiadur yn nes ymlaen, os byddai hynny'n well gennych.

Profir dau wahanol ymyriad yn y treial hwn. Dim ond mewn un o'r ddau y byddwch yn cymryd rhan; bydd cyfrifiadur yn dewis pa un ar hap. Ni fydd neb yn gallu dylanwadu ar eich dyraniad. Bydd cyfranogwyr mewn un grŵp yn cael amrywiaeth o ddeunydd gwybodaeth a chymorth i'w ddefnyddio eu hunain. Bydd y grŵp arall yn cael cynnig yr un deunyddiau, a gofynnir iddynt hefyd fod yn bresennol mewn apwyntiad cychwynnol gyda Nyrs Glinigol Arbenigol, ac mewn apwyntiadau dilynol posibl (os yw'r cleifion yn gofyn amdanynt yn yr ymyriad hwnnw). Ar y ffurflen caniatâd, byddwn yn gofyn am eich caniatâd i wneud recordiadau sain o'r apwyntiadau hyn (rhag ofn y caiff yr ymyriad hwn ei ddyrannu i chi), i sicrhau nad ydym yn methu unrhyw beth o'r sesiynau hyn. Cynhelir yr apwyntiadau yn y feddygfa deulu leol, neu yn yr uned ymchwil ger Ysbyty Maelor yn Wrecsam.

Bydd yr astudiaeth yn para 9 mis. Yn ystod y cyfnod hwn, gofynnir i chi lenwi tri holiadur dyddiadur (un bob tri mis) i gofnodi pa mor aml yr ydych yn gweld eich meddyg teulu a/neu weithwyr proffesiynol gofal iechyd a gwasanaethau cymdeithasol eraill. Ar ddiwedd y 9 mis, cewch yr un holiadur i'w lenwi ag y gwnaethoch ei lenwi ar y dechrau. Bydd y ffurflen caniatâd hefyd yn gofyn i chi a hoffech gymryd rhan mewn cyfweliad ar ddiwedd yr astudiaeth, i ddweud wrthym pa mor ddefnyddiol oedd yr astudiaeth i chi. Bydd cyfrifiadur yn dewis grŵp bach o gyfranogwyr o'r rheini a gytunodd i gymryd rhan, a gwahoddir y rhain i gyfweliad 45 munud.

Wedi i ni ddadansoddi'r holl ddata a gesglir gan y 120 o gyfranogwyr, cynigir canlyniadau'r astudiaeth gyfan i chi. Bydd y canlyniadau'n gwbl gyfrinachol ac yn cyfeirio at y 120 o gyfranogwyr i gyd. Ni fydd yn bosibl adnabod eich data unigol (atebion, sgorau ac ati) mewn unrhyw ffordd.

Ar ôl i mi gymryd rhan, a gaf i newid fy meddwl?

Cewch. Os hoffech dynnu'n ôl unrhyw bryd yn ystod y treial, cysylltwch â Rheolwr y Treial neu'r Swyddog Ymchwil i roi gwybod iddynt. Ni wnânt ofyn pam yr ydych yn tynnu'n ôl, ac ni fydd cymryd rhan yn y treial hwn, na thynnu'n ôl oddi wrtho, yn effeithio mewn unrhyw ffordd ar eich gofal meddygol parhaus.

A gaf i unrhyw dâl am gymryd rhan?

Na chewch. Ni chewch ddim arian am gymryd rhan, ac ni allwn dalu am dreuliau megis costau teithio ac ati.

Beth yw anfanteision a risgiau posibl cymryd rhan?

Ni ddylai cymryd rhan yn yr astudiaeth hon beri unrhyw risgiau nac anfanteision i chi. Os yw'n anghyfforddus i chi ateb unrhyw rannau o'r holiadur hwn, cewch adael y rhannau hynny'n wag. Os cewch eich dyrannu i'r ymyriad sy'n cynnwys apwyntiad gyda Nyrs Glinigol Arbenigol yn eich meddygfa deulu leol, neu yn yr uned ymchwil, chi fydd yn gyfrifol am y teithio.

A gaiff fy rhan yn yr astudiaeth ei chadw'n gyfrinachol?

Caiff; cedwir eich holl atebion yn gyfrinachol. Ni chaiff eich enw ei gysylltu â'r atebion a rowch yn yr holiaduron. Caiff y data a gesglir gennym yn ystod yr astudiaeth (holiadur a recordiadau sain) eu cadw'n ddiogel, mewn cwpwrdd ffeilio wedi'i gloi, a chânt eu dinistrio'n gyfrinachol 5 mlynedd ar ôl diwedd yr astudiaeth, yn unol â'r gyfraith a'r canllawiau moesegol perthnasol.

Yn y ffurflen caniatâd, byddwn yn gofyn i chi a ydych yn fodlon i ni ddweud wrth eich meddyg teulu presennol eich bod yn cymryd rhan yn yr astudiaeth hon. Chi fydd yn penderfynu a hoffech i hyn ddigwydd a byddwn yn gwneud beth bynnag y penderfynwch chi. Ni wnawn ddweud wrth neb arall eich bod yn cymryd rhan yn yr astudiaeth hon, a byddwn yn trin popeth a ddywedwch wrthym yn gwbl gyfrinachol. Fodd bynnag, os gwnawn ddarganfod rhywbeth yn ystod yr astudiaeth a allai beryglu eich bywyd, neu fywydau unrhyw bobl eraill, mae'n ddyletswydd arnom i hysbysu'r arbenigwyr hynny a all eich achub chi a phawb arall a all fod mewn perygl.

Pwy sydd wedi adolygu'r astudiaeth?

Mae'r astudiaeth wedi cael ei hadolygu gan Bwyllgor Moeseg Academaidd yr Ysgolion Gofal Iechyd a Gwyddorau Meddygol ym Mhrifysgol Bangor, gan Bwyllgor Moeseg Ymchwil Gogledd Cymru (Canol a Dwyrain), a gan Banel Adolygu Mewnol Ymchwil a Datblygu Bwrdd Iechyd Prifysgol Betsi Cadwaladr.

Mae gennyf fwy o gwestiynau, pwy ddylwn i gysylltu â hwy?

Os oes gennych unrhyw gwestiynau, cysylltwch ag Andrei Stanciu (Rheolwr y Treial) ar: 01978726078, neu drwy e-bost yn: a.stanciu@bangor.ac.uk, neu Marie Burrows (Swyddog Ymchwil), ar: 01248388835, neu drwy e-bost yn: m.burrows@bangor.ac.uk.

Beth os nad wyf yn hapus â'r ffordd y cafodd yr ymchwil ei gyflawni?

Os ydych yn anhapus ag unrhyw rannau o'r astudiaeth, rhowch wybod i'r tîm ymchwil, a byddant yn gwneud popeth a allant i ddatrys unrhyw broblemau. Fodd bynnag, os oes gennych bryderon neu gwynion, cysylltwch â'r Athro Joanne Rycroft-Malone, Pennaeth yr Ysgol Gwyddorau Gofal Iechyd, Prifysgol Bangor, 01248383117, e-bost: j.rycroft-malone@bangor.ac.uk, neu dîm Pryderon Bwrdd Iechyd Prifysgol Betsi Cadwaladr yn y cyfeiriad e-bost canlynol: (ConcernsTeam.bcu@wales.nhs.uk).

Participant Information Sheet

Study title: Trial of Personalised Care After Treatment – Prostate Cancer (TOPCAT-PC)

We would like to invite you to take part in our research study (also known as a 'trial'). Before you decide, we would like you to understand why the research is being done and what it would involve for you. Our research team will be happy to go through the information sheet with you and answer any questions you have. Also, please talk to others about the study, if you wish.

What is the purpose of the study?

We are continually looking for better ways to improve your care. One way of doing this is to look at how patients feel about their health care after treatment. We want to see if offering men extra support, that they can manage themselves, will help to improve their recovery, experience of follow-up care, and overall quality of life. This will be done either with, or without follow-up appointments at their GP surgery with a specially trained nurse (according to which intervention they will receive from the two administered in this study).

Why have I been invited?

You have been invited to take part in this trial, because your treating Clinician considered that your prostate cancer is presently stable, even if you might still continue to attend regular appointments to monitor its state, and any future developments. We would like you to be one of the 120 patients who will take part in this trial.

Do I have to take part?

No. It is up to you to decide to join the study. If you decide to take part in the trial, please contact the Trial Manager. We will describe the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. However, afterwards you can withdraw at any time from the study, without giving a reason. This would not affect the regular care you receive.

What will happen to me if I take part? What will I be asked to do?

You will be invited to meet the Research Officer, by mutual agreement, in your local GP surgery, local community hospital, or research centre, to sign the consent form and fill in a health-related questionnaire. You will be given all the required assistance in filling in the questionnaire, and, once completed, you can hand it back straight away. You can also fill in the questionnaire at a later time, if you wish so.

There are two different interventions tested in this trial. You will be taking part in only one of them, as determined randomly by a computer. Nobody will be able to influence your allocation. Participants in one group will receive a range of information and support materials that they will use by themselves. The other group will be offered the same materials and will also be asked to attend an initial appointment with a Clinical Nurse Specialist, and possible follow-up appointments (if requested by the patients in that intervention). In the consent form, we will ask for your permission to take audio recordings of these appointments (in case you will be allocated to this intervention), to make sure we don't miss anything from these sessions. The appointments will take place at the local GP practice, or at the research unit, located near the Maelor Hospital in Wrexham.

The study will last for 9 months. During this time, you will also be asked to fill in three diary questionnaires (one every three months) to record how often you see your GP and/or other healthcare and social services professionals. At the end of the 9 months, you will receive for completion the same questionnaire as the one you filled in at the start. In the consent form we will also ask you if you would like to take part in an interview at the end of the study, to tell us how useful the study was for you. A small

group of participants will be selected by a computer from those who agreed to take part, and will be invited to attend a 45 minute interview.

Once we analyse all the data collected from the 120 participants, you will be offered the overall results of the study. The results will be completely confidential and will refer to the whole 120 participants. Your individual data (answers, scores, etc.) will not be possible to be identified in any way.

Once I take part, can I change my mind?

Yes. If at any time during the trial, you wish to withdraw, please, kindly contact the Trial Manager or the Research Officer to let them know. You will not be asked for a reason for withdrawing and your on-going medical care will never be affected by taking part, or withdrawing from this trial.

Will I receive any payment for taking part?

No. You will not receive any money for taking part, and we will not be able to cover any expenses, such as travel expenses, etc.

What are the possible disadvantages and risks of taking part?

Taking part in this study should not present any risks or disadvantages for you. If answering any parts of the questionnaire is uncomfortable, you can leave those blank. If you will be allocated to the intervention involving an appointment with a Clinical Nurse Specialist at your local GP surgery, or at the research unit, you will be responsible for the travel.

Will my taking part in the study be kept confidential?

Yes, all your answers are kept confidential. Your identity will not be linked with the answers you provide in the questionnaires. The data we collected during the study (questionnaire and audio recordings) will be kept securely, in a locked filling cabinet, and will be confidentially destroyed after 5 years from the end of the study, according with the law and governing ethical guidelines.

In the consent form, we will ask you if you are happy for us to tell your current GP that you are taking part in this study. It is up to you to decide if you would like this to happen and we will do exactly as you decide. We won't tell anybody else that you are taking part in this study, and we will treat everything you tell us, as strictly confidential. However, if during the study we discover something that could put your life in danger, or the lives of any other people, we have a duty to inform those specialists who can save you and everybody else who might be at risk.

Who has reviewed the study?

The study has been reviewed by the Schools of Healthcare and Medical Sciences Academic Ethics Committee of Bangor University, the North Wales Research Ethics Committee (Central and East), and the Research & Development Internal Review Panel of Betsi Cadwaladr University Health Board.

I have some more questions who should I contact?

For any questions, please contact Andrei Stanciu (Trial Manager) at: 01978726078, or by email at: a.stanciu@bangor.ac.uk, or Marie Burrows (Research Officer), at: 01248388835, or by email at: m.burrows@bangor.ac.uk.

What if I am not happy with how the research was conducted?

If you are unhappy with any parts of the study, please let the research team know, and they will do all they can to solve any problems. However, for any concerns or complaints, you can contact: Prof Joanne Rycroft-Malone, Head of the School of Healthcare Sciences, Bangor University, 01248383117, email: j.rycroft-malone@bangor.ac.uk, or the BCUHB Concerns team at the following email: (ConcernsTeam.bcu@wales.nhs.uk).

North Wales Centre for Primary Care Research
Canolfan Gogledd Cymru ar gyfer Ymchwil Gofal Cychwynnol

Appendix 2. Bilingual Participant Consent Form

FFURFLEN CANIATÂD

Teitl y Prosiect: Treial Gofal Personol ar ôl Triniaeth – Canser y Prostad (TOPCAT-P)

Prif Ymchwiliwr: Yr Athro Clare Wilkinson

Rhowch eich blaenlythrennau ym mhob blwch yr ydych yn rhoi caniatâd ar ei gyfer

1. Rwyf yn cadarnhau fy mod wedi darllen a deall y Ddalen Wybodaeth i Gyfranogwyr dyddiedig 09-09-2013 (fersiwn 1.1) ar gyfer yr astudiaeth uchod. Rwyf wedi cael cyfle i ystyried yr holl wybodaeth a roddwyd ac i ofyn cwestiynau, ac rwyf wedi cael atebion boddhaol. ☐
2. Rwyf yn deall bod fy nghyfranogiad yn wirfoddol a'm bod yn rhydd i dynnu'n ôl unrhyw bryd, heb roi rheswm, ac na fydd hynny'n effeithio ar fy ngofal meddygol na fy hawliau cyfreithiol. ☐
3. Rwyf yn rhoi fy nghaniatâd i gael cynnig un o'r ddwy ffordd o gyflenwi'r cymorth a ddarperir yn yr astudiaeth hon ar hap. Rwyf yn deall mai cyfrifiadur sy'n gwneud y penderfyniad rhwng y ddau ddewis, ac na fyddaf i, na thîm yr astudiaeth, yn gallu newid y penderfyniad. I sicrhau bod yr astudiaeth yn wyddonol, dim ond am y cymorth yr wyf yn ei gael y gallaf gael gwybod. ☐
4. Rwyf yn deall y gall rhan benodol o'r tîm ymchwil edrych ar adrannau perthnasol yn fy nodiadau meddygol, lle bo hyn yn gwbl hanfodol i fy nghyfranogiad yn yr ymchwil. Hefyd, bydd unrhyw ddata o'r fath a gesglir at ddibenion dadansoddi'n gwbl ddienw (felly bydd yn amhosibl canfod pwy ydw i). Rwyf yn rhoi caniatâd i ymchwilwyr weld fy nghofnodion. ☐
5. Rwyf yn rhoi caniatâd i ymchwilwyr wneud recordiadau sain o'n cyfarfodydd neu alwadau ffôn, i helpu'r broses o gasglu data. Caiff y recordiadau hyn i gyd eu codio'n ddienw (fel y bydd yn amhosibl canfod pwy ydw i), cânt eu storio'n ddiogel, a chânt eu dinistrio'n gyfrinachol 5 mlynedd ar ôl diwedd yr astudiaeth. ☐
6. Rwyf yn caniatáu i chi hysbysu fy meddyg teulu fy mod yn cymryd rhan yn yr astudiaeth. ☐
7. Hoffwn gymryd rhan mewn cyfweliad adborth byr ar ddiwedd y treial. ☐
8. Hoffwn i fy manylion cyswllt gael eu defnyddio i dderbyn canlyniadau'r astudiaeth. ☐
9. Rwyf yn cytuno i gymryd rhan yn yr astudiaeth uchod. ☐

Rhowch eich manylion cyswllt, os gwelwch yn dda:

Rhif ffôn: _____ E-bost: _____

Cyfeiriad: _____

_____	_____	_____
Enw'r Cyfranogwr	Dyddiad	Llofnod
_____	_____	_____
Enw'r ymchwilydd sy'n cymryd y caniatâd	Dyddiad	Llofnod

CONSENT FORM

Title of Project: Trial of Personalised Care After Treatment – Prostate cancer (TOPCAT-P)

Principal Investigator: Prof. Clare Wilkinson

Please initial each box you consent with

1. I confirm that I have read and understood the Participant Information Sheet dated 09-09-2013 (version 1.1) for the above study. I have had the opportunity to consider all the information presented, to ask questions and I have received satisfactory answers. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my medical care or legal rights being affected. ☐
3. I give my consent to be randomly offered one of the two ways of delivering the support provided in this study. I understand that the decision between the two options is made by a computer, and that neither I, nor the study team will be able to change it. To insure the study is scientific, I can only be told about the support that I am receiving. ☐
4. I understand that relevant sections of my medical notes may be confidentially looked at by a limited part of the research team, where this is absolutely essential for my participation in the study. Also, any such data collected for analysis purposes will be entirely anonymised (so my identity will be impossible to trace). I give my permission for researchers to have access to my records. ☐
5. I give my permission for researchers to take audio recordings of our meetings or telephone calls, to help the data collection process. All these recordings will be coded anonymously (so my identity will be impossible to trace), they will be stored securely, and will be confidentially destroyed after 5 years from the end of the study. ☐
6. I agree to my GP being informed of my participation in the study. ☐
7. I would like to take part in a brief feedback interview, at the end of the trial. ☐
8. I would like my contact details to be used to receive the study results. ☐
9. I agree to take part in the above study. ☐

Please, provide your preferred contact details:

Telephone: _____ Email: _____

Address: _____

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of researcher taking consent	Date	Signature