

DRAFT

Enhanced nurse led telephone review in prostate cancer (EnTeR): a randomised exploratory trial of patient on-line bio-psychosocial self-assessment.

Background

Prostate cancer is the most common cancer in men in the United Kingdom accounting for 25% of all male cancer. Its incidence has risen by around 36% since the early 1980s, largely due to improved detection, with 37000 men diagnosed in 2008. African Caribbean men are at particular risk and the previously lower incidence in Asian men is increasing. While incidence rises with age, 25% of patients are under 65 years at onset.

The increasing numbers of men diagnosed and treated for prostate cancer and five year survival now at a level of 77%, have led to growing pressure on hospital based follow up clinics. The potential of alternative models of on-going patient monitoring and review have thus become an increasing focus of interest and innovation.

Clinical nurse specialists are playing an increasingly major role in cancer follow up care and nurse led telephone follow up is becoming established in relation to a number of cancers where it has been shown to be safe and well accepted. .

In prostate cancer, a number of NHS Trusts have developed a variety of systems of nurse led telephone follow up with men attending face to face appointments only when PSA levels rise or other causes of concern are identified. Patients are reported as finding telephone follow up more convenient and time saving than attending outpatient clinics. While satisfaction is generally high however, there is some evidence that patients perceive a decrease in 'Depth of Relationship' and 'Time Spent with Clinician' when contact is limited to the telephone. There is as yet little evidence of impact upon symptom recognition and management, patient quality of life or health economic benefit.

The last ten years have also seen a rapid expansion in the use of e-health interventions within the field of oncology. Web based and standalone applications now offer a wide variety of approaches to facilitate monitoring, patient decision making, self-management and experience of the clinical consultation. Computerised clinical decision support (CCDS) tools for health care professionals have become widely used in a variety of contexts.

A recent innovation in prostate cancer management has been the development of a nurse led telephone follow up clinic with guided clinical decision making through the use of CCDS. This system is attracting interest from several Trusts, and experience suggests that it is cost effective, safe and acceptable to patients although to date there has been little formal evaluation of the impact of the system

Alongside the increasing use of IT to support clinical decision making, there has also been a huge growth in the extent to which patients use online information to support their care needs. Cancer Research UK now estimate 47% of patients access cancer-related web resources. The NHS information strategy stresses the importance of enabling patients to take control of their own healthcare experience, and of using information technology to help drive their experience.

Self management has been recognised as an important aspect of cancer survivorship . The concept describes an active involvement by the patient in looking after his own health and well being through diet, exercise and engaging in new ways of coping. Men who have prostate cancer live with a range of direct consequences of their illness or its treatment, such as urinary and sexual problems and fatigue. In addition they experience a range of indirect consequences that may include social, financial and psychological aspects. These consequences, as well as uncertainty regarding their condition that may persist over many years, represent a huge challenge to men's capacity for self management. Research shows that many have a range of support and information needs which have gone unrecognised and unaddressed within traditional models of follow up care and give rise to considerable psychological and physical morbidity.

To date there has been limited attention in the UK to the potential role of information technology in contributing to the effective long term management of the care of this patient group or to its potential as an aid to self management.

We have been involved in a series of studies of the information needs of men with prostate cancer that led to the development of a self-assessment tool designed to address such needs and so facilitate communication in the clinical consultation. The Patient Information Aid (prostate cancer) was originally paper based, but more recently was adapted for use on a touch-screen computer. It is now being developed for use online, so making it accessible to men from their own homes. Men who evaluated the aid in a focus group setting felt that it was useful in helping to articulate particular information needs and in potentially focusing the consultation on such concerns. All found it easy to use and expressed willingness to use it, regardless of age or previous experience of information technology. The evaluation also identified scope for further development and adaptation of the aid in order to reflect the range of concerns expressed by men over the long term.

Evidence of the success of e-health interventions in prostate cancer in Northern Europe, and the rapidly expanding use of technology amongst older people, underline the potential of online developments. The recent Department of Health report, The Power of Information, emphasised the importance of the creative use of information technology at a time of change and restructuring within healthcare and we intend to take up this opportunity and to address the challenge that these changes represent in terms of prostate cancer care.

In this study we aim to further develop and test the feasibility within an exploratory trial of a web based system designed to enhance the delivery of safe, efficient prostate cancer follow up care that is effective in addressing the broad spectrum of needs that have been identified among this patient group. We plan to extend the online version of the aid to enable men to undertake a more comprehensive self-assessment prior to their consultation and to adapt it to fit seamlessly into the operation of the nurse led telephone follow-up clinic.

The new iteration takes the form of a menu driven web based application, the Prostate Self-Assessment System (PROSAS) and together with the Information Needs in Prostate Cancer Tool it will include the International Prostate Symptom Scale and a psychosocial concerns tool, an extended version of the Distress thermometer (a rapid screening tool currently in use in a number of Cancer Networks). 1057

Aim:

The aim of the proposed study is to test the feasibility and utility of an enhanced model of prostate cancer follow-up that comprises of a web-based self-assessment tool to identify patients' concerns prior to a nurse telephone consultation. This study will determine the value of a future RCT and inform refinement of the methodology, including the choice of valid and reliable outcome measures for assessing the impact of this model of care on the efficiency of the consultation in terms of use of time, patients' experience of prostate cancer follow up and confidence in self-management,

The objectives of the study are to address the following:

- 1 What proportion of eligible men use the online self-assessment system and to explore any early indications of associations with socio-demographic and clinical variables?
- 2 To identify recruitment and attrition rates, and to estimate the distribution and properties of the primary outcome measure to inform the design of a full trial
- 3 To test the feasibility of data collection methods
- 4 To explore the impact of the online self-assessment on use of time in the telephone consultation and on content covered and advice given / referrals made by the nurse
- 5 To explore how men's expectations and experiences of the enhanced consultation compare with their experience of the standard telephone follow up consultation and whether these change as they become more fluent in using the online self-assessment for subsequent encounters?
- 6 To identify training needs, commissioning and service delivery issues that should be addressed in planning the implementation of this model of care
- 7 What might be the cost implications and economic consequences of wider implementation of this model of care?

Setting and study population: One cancer centre in the West Midlands South that plans to introduce nurse led telephone review of prostate cancer patients. Most men are considered suitable to enter such follow up at one year post definitive intervention such as radiotherapy or surgery or immediately if treated with hormones or on 'watchful waiting'

The follow-up consultations will be supported by a CCDS (IQUDOS system) which has been designed for this purpose. The software both guides and documents the follow-up assessment and produces a letter written for the GP outlining patient progress and any action needed. It advises on common problems after prostate cancer treatment. The system is database driven thus ensuring that clinical outcome measures are closely monitored and a clear audit trail is maintained. It is intended that the output from the on-line self-assessment system (PROSAS) will be integrated with the IQUDOS system, thus allowing the nurse immediate access to both clinical data and men's self-assessment.

Design

A randomised exploratory trial is planned. The control group will be invited to take part in the intervention after 6 months (ie at their subsequent telephone clinic appointment). This will allow within subject comparison in baseline and intervention conditions and will encourage recruitment.

Data collection will involve two overlapping phases.

Phase 1 Qualitative investigation: interviews and focus groups with patients, nurses, managers and commissioners.

Phase 2 Main study: Randomised exploratory trial with 1:1 allocation. The intervention group will be invited to use the PROSAS prior to their prostate cancer follow-up consultation on two occasions over a 6 month period. The control group will undergo one standard telephone follow-up consultation at baseline, and be invited to use the PROSAS at the subsequent consultation. Qualitative investigation will also be undertaken to understand the experience of using the PROSAS and how this affects the consultation from patient and clinician perspectives

Sample size

The sample size has been determined to test the feasibility of the intervention and of the recruitment and data collection methods.

From UHCW data, it is assumed that there will be at least 400 prostate cancer patients who will meet the criteria for telephone follow up. According to when men's follow-up appointments are due, men will be invited at an average rate of 33 per month to participate in the study. Assuming that around 40% (ie 13 patients per month) will have access to the internet either directly or through a close relative or friend, and about 66% of those eligible to participate will agree to do so, we will aim to recruitment about 9 patients per month to the study.

Over a 10 month period, we anticipate 90 participants will be recruited who will be randomised to intervention and control groups at T1. Follow-up will be undertaken over a 6 month period. For this size sample group, an attrition rate of .10 is estimated with a confidence interval of 5.351% - 17.924% at the 95% level resulting in 40 patients in the control and 40 patients in the intervention group providing baseline and 6-month data.

Randomisation process: Randomisation will be carried out by an independent central telephone service with allocation performed using random permuted blocks

Method

A mixed methods approach will be utilised to maximise the value of the investigation. Qualitative methods will be used to inform the assessment of all relevant outcomes and to ensure capture of in depth aspects of individual experience. Quantifiable data will be gathered for measurement of the, time spent on patient concerns, particular concerns identified by patients and the outcomes of the consultation.

Developmental phase

Semi structured individual interviews will be undertaken with the range of stakeholders , doctors, nurses, managers and commissioners to elicit their views on desired characteristics and outcomes of the telephone consultation to ensure these are captured in phase two(n=8-10). Interviews with nurses will also address issues regarding training needs in the use of the enhanced system (n=2-3). Data from these interviews will be used to inform the development of a brief training package for use by nurses delivering the intervention consultation.

Patient interviews and focus groups will elicit patient views on important aspects of the consultation.(n=10-12)The utility of the patient reported outcome measures identified for use in phase two, the Patient Activation Measure, the Consultational and Relational Empathy Scale, the Patient Enablement Instrument will be assessed in relation to findings from interview and focus group data.

Development of the web based self-assessment system will take place during this phase. Focus groups will be recruited at two time points during this development to review content and design of the system. Men will be recruited from local prostate support associations to take part in these groups.

Exploratory trial

Phase 1

Participants will be randomised to take part in:

(Arm 1) the intervention group, receiving access to PROSAS prior to the nurse led telephone follow-up consultation at T1 and T2

or

(Arm 2) the control group, receiving usual care in the form of the standard nurse led telephone consultation at (T1), and access to PROSAS at 6 months (T2)

Quantifiable aspects of the consultation and its outcomes will be measured. Audio recording of all telephone consultations will allow capture of data relating to content of the consultation and time spent. Output from the IQUDOS clinical decision support system will allow the identification of actions initiated and recommendations made by the nurse.

Control and Intervention group participants will be asked to complete the patient reported outcome measures on line following the consultation. Relevant clinical data will be gathered from the patient records held on the clinical decision support system. Hospital records will be used to identify basic socio-demographic characteristics including age, marital status and deprivation score of participants' area of residence.

Semi structured interviews will be undertaken with a subsample of 15-18 patients to explore their experiences of the telephone and enhanced telephone consultation and the impact of the

consultations upon their confidence and knowledge regarding self-management. Purposive sampling will ensure the inclusion of patients who have undergone surgery, radiotherapy, those on hormone treatment and those on watchful waiting. We will also aim to include men under and over 70 years of age.

Interviews will also be undertaken to elucidate the views of nurse's experience of running the telephone follow up clinic at baseline and in intervention conditions.

The intervention

The intervention comprises an intuitive on-line prostate patient self-assessment system (PROSAS) with simple menu prompts that are intended to help men determine and prioritise needs and symptoms which are important to them.

The aid incorporates:

- An extension of the Distress Thermometer (a widely used rapid-screening tool that identifies level of distress; patients rate their distress and identify causes from a list of 36 items divided into subcategories related to physical, family, emotional, spiritual/religious, informational and practical needs
- The 21 items of the Information Needs in Prostate Cancer tool, a checklist developed and refined by members of the project team through interviews and focus groups with men with prostate cancer;
- A 'physical problems' menu within which the identification of urinary symptoms which leads to a further sub-menu offering a prostate specific symptom checklist (the IPSS) as well as a 'sexual difficulties' item.

The system collates and prioritises the patient's responses in order to produce a personalised on-line summary of concerns and symptoms. This highlights areas for discussion, and thus alerts the clinician to symptoms that may need further investigation or to issues that may require referral to other members of the healthcare team. Together with the on-line summary and according to the issues identified the system may suggest sources of help available to the patient. e.g. for financial advice or spiritual support. The intervention will be designed to work in a form that is complementary to and compatible with the IQUDOS CCDS that nurses will be using to support their telephone consultations.

Recruitment

Phase 1

Ten patients identified from clinic lists by clinical staff will be sent an information sheet regarding the study and invited to take part in one to one interviews or to a focus group according to preference.

Relevant hospital staff and commissioners will be contacted and invited to take part in face to face or telephone interview. It is anticipated that between 8 and 10 such interviews will take place.

Phase 2

All patients receiving telephone follow up or who have been identified by clinicians as suitable for telephone follow up will receive written information regarding the study. Study information will explain that participation requires that the patient have access to the internet either at home or elsewhere. Each information sheet will contain login information and an ID number for the patient. Any patient interested in joining the study will be asked to login to a study website where they will receive further information and where a consent form will be available. A contact telephone number will also be made available for patient who may have questions regarding the study.

Eligibility

Inclusion criteria:

- ☐ All men who are receiving telephone follow-up of prostate cancer or who have been identified as suitable for telephone follow up by their clinicians.
- ☐ Have means of accessing the internet either directly or via a friend/relative/neighbour
- ☐ Have sufficient literacy and visual capacity to read instructions and respond to the online self-assessment module

Exclusion Criteria:

- ☐ Men who are not eligible for telephone follow-up of prostate cancer
- ☐ Men who are unable to understand written English or give informed consent

Measures

1. Patient Activation Measure (Hibbard et al 2004, 2005)

The Patient Activation Measure assessment is a tool for measuring the level of patient engagement in their healthcare. It is designed to assess patient's knowledge, skill and confidence in their ability for self-management. PAM was developed by Hibbard and colleagues in 2004 as a 22 item scale (the PAM 22, and subsequently as a 13 item short form). The PAM's 13-item scale asks people about their beliefs, knowledge and confidence for engaging in a range of health behaviours and then assigns an activation score based on their responses to the 13-item scale.

2. Consultational and Relational Skills Questionnaire (CARE) (Mercer et al 2004). Within the CARE measure, 10 questions ask patients to rate aspects of empathy based on the question "*How was your nurse/doctor at ...?*" Examples of the questions are "*Being interested in you as a whole person*" and "*Really listening*", with each question scoring a maximum of five points

3. Patient Enablement Instrument (PEI) (Howie 1997, Howie 1998 Pawlikowska 2002), is a patient – driven self report questionnaire which elicits the patient's view of their needs (including psychological morbidity), the process of their consultation and the outcome measure of "patient enablement". The post-consultation PEI consists of six questions dealing with the change in patients' ability to cope and understanding of their problem as a result of the consultation. Though originally developed within a primary care context the derivation of this is holistic and patient-centred, making it appropriate for this study.

Plan of Investigation

Phase 1: 1–9 months

Submission for Research Ethics committee and R&D approval

Refinement and set up of web based patient self-assessment system

Focus groups with men with prostate cancer to review content and design

Identification recruitment and conduct of patient interviews/ focus groups

Staff interviews

Transcription and analysis of interview data

Development of nurse training package

Delivery of training

Letters to patients potentially eligible for the study with telephone appointments due in month 10 and 11

Identification of eligible patients

Phase 2: 9- 26 months

Patient recruitment will occur on an on-going basis until month 18. This will allow 90 patients to be randomised to take part in intervention and control consultations while allowing some flexibility in case of delay (e.g. holidays).

Letters to GPs explaining study and requesting participation .

1:1 randomisation

Enhanced telephone consultation (T1)

One week prior to their telephone appointment, patients randomised to the intervention condition (arm 1) will receive a reminder via email to complete the self-assessment process. This can be done from one week before and until the day of the appointment.

Full instructions will be given as to how to use the system at the point of login.

When the patient has completed the assessment he will be provided with a summary and depending on his responses, information on useful points of contact.

At the time, or prior to the patient telephone appointment, the nurse will log in to the patients enhanced record. Scores in each area completed will be visible together with any alerts produced by the system regarding issues for referral or particular attention e.g. evidence of depression.

This consultation led by a clinical nurse specialist will follow the format of a standard nurse led telephone consultation guided by the IQDOS stable prostate system. All telephone consultations will be audio-recorded.

Data on actions taken, referrals made and need identified will be captured from the IQUDOS system and entered on to a database

Patients will complete the patient reported outcome measures online. Audio-recordings will be stored and coded for analysis. PRO data will be entered on to a database for analysis.

Outcome data regarding consultations, actions initiated and referrals made by GPs in a four-week period following each patient's telephone review will be collected by a research nurse. Patients randomised to the delayed intervention control group (Arm 2) will be advised and reminded to complete the on-line PROMS following their telephone consultation.

Patients will undergo a standard care telephone consultation. This will be audio-recorded.

Patients will complete the on-line assessments following their consultation. Data capture and storage will take place as in the intervention condition.

Interviews will be undertaken with 12-15 intervention and control group patients regarding their experience of the consultation.

Interviews will also be undertaken with the CNS running the clinics.

(Months 15 – 24) T2 follow-up consultation:

- Delayed intervention enhanced consultation: Control group patients will be invited to complete the on line on-line self-assessment. Procedures will be identical to those at T1.
- Intervention group: Patients will be invited to use the PROSAS for a second time

Quantitative data will be collected as at T1

Months 26-30

Completion of data collection from GPs coding and analysis of qualitative data.

Cleaning and analysis of quantitative data .

Report writing, dissemination of findings

Analysis

Quantitative

Quantitative analysis of study data will follow NETSCC guidelines. Analysis will identify

- Numbers of eligible patients
- Recruitment rate

- Response rate and follow up rate
- Time needed to collect and analyse data.

In addition, given the achievement of a minimum effect size of 8% difference between the two sample group in scores on the primary outcome measure, an estimation of the distribution and standard deviation will be used to calculate the sample size required for a fully powered RCT.

Descriptive statistics and Mann Whitney's u test will be used to explore the impact of the enhanced system on consultation, numbers of actions taken, referrals made, needs identified between intervention and control groups.

Summary statistics will be used to compare use of time in the consultations between patients having undergone different radical treatments or on long term hormone therapy or on watchful waiting

Qualitative

Thematic analysis will be used to examine patients' response to the enhanced system and their experiences of consultations involving its use. Analysis will identify patients' expectations of the system, its benefits, barriers to effectiveness and any negative consequences. Responses will be categorized and compared according to patient variables to identify emerging commonalities and differences in experience between patient sub-groups.

Ethical approval

Ethical approval for the study will be sought from Coventry local research ethics committee.

Data storage

Audio-taped recordings will be stored in locked filing cabinets at the University of Warwick with access restricted to members of the study team

All data will be anonymised. Names and other identifiable data will be removed so it will be impossible for anyone other than members of the study team to identify individual participants. Data will be destroyed at five years.

Study team

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