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Title: Supporting prostate cancer survivors in primary care: findings from a pilot trial of a nurse-led psycho-educational intervention (PROSPECTIV).

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Abstract

Purpose: This study sought to test the acceptability and feasibility of a nurse-led psycho-educational intervention (NLPI) delivered in primary care to prostate cancer survivors, and to provide preliminary estimates of the effectiveness of the intervention.

Methods: Men who reported an ongoing problem with urinary, bowel, sexual or hormone-related functioning/vitality on a self-completion questionnaire were invited to participate. Participants were randomly assigned to the NLPI plus usual care, or to usual care alone. Recruitment and retention rates were assessed. Prostate-related quality of life, self-efficacy, unmet needs, and psychological morbidity were measured at baseline and 9 months. Health-care resource use data was also collected. An integrated qualitative study assessed experiences of the intervention.

Results: 61% eligible men (83/136) participated in the trial, with an 87% (72/83) completion rate. Interviews indicated that the intervention filled an important gap in care following treatment completion, helping men to self-manage, and improving their sense of well-being. However, only a small reduction in unmet needs and small improvement in self-efficacy was observed, and no difference in prostate-related quality of life or psychological morbidity. Patients receiving the NLPI recorded more primary care visits, while the usual care group recorded more secondary care visits. Most men (70%; (21/30)) felt the optimal time for the intervention was around the time of diagnosis/before the end of treatment.

Conclusions: Findings suggest a nurse-led psycho-educational intervention in primary care is feasible, acceptable and potentially useful to prostate cancer survivors.

Keywords: prostate cancer; randomised controlled trial; pilot trial; primary care; nurse-led intervention; feasibility; self-efficacy

Introduction

Prostate cancer is the most common non-dermatological cancer in men in the Western world, with around 40,000 and 220,000 cases diagnosed annually in the United Kingdom and United States of America respectively (Cancer Research UK, 2015, National Cancer Institute, 2015). As it is largely a disease of older men, increased PSA screening and improved survival rates, coupled with an ageing population means the prevalence of prostate cancer survivors is increasing dramatically (Maddams et al., 2012).

Following treatment men frequently experience urinary, bowel and sexual functioning problems) which can significantly impact on quality of life and result in psychological problems (Hamdy et al., 2016, Smith et al., 2009, Watson et al., 2016). Previous studies have highlighted unmet supportive care needs and shortcomings with existing follow-up services for men with prostate cancer (Prostate Cancer UK, 2012, O'Brien et al., 2010, King et al., 2015, Cockle-Hearne et al., 2013). The increasing demand for follow-up care is placing hospital outpatient clinics under strain, and they are not always able to meet the range of needs found in prostate cancer survivors. Alternative models of follow-up are required, and UK and US guidance now recommends follow-up outside the hospital setting soon after treatment finishes (National Institute For Health and Clinical Excellence, 2014, Skolarus et al., 2014). There is increasing interest in the role of primary care (Watson et al., 2011, Rubin et al., 2015), and a recent Australian trial found that shared hospital/primary care follow-up for men with low- to moderate risk prostate cancer is feasible and appears to produce clinically similar outcomes to those of standard care (Emery et al., 2017). Guided by the Medical Research Council (UK) Framework for the development and evaluation of complex interventions (Craig et al., 2008), in the PROSPECTIV study we have developed a nurse-led psycho-educational intervention (NLPI) based in primary care, aiming to improve prostate cancer-related quality of life, self-efficacy, psychological well-being and to reduce unmet

needs. We report here the findings from a pilot randomised controlled trial (RCT), which aimed to test the feasibility and acceptability of the intervention and to provide preliminary estimates of effectiveness and cost-effectiveness to inform the design of a future Phase III RCT

Subjects and Methods

In reporting the pilot trial methods and findings we referred to the TIDieR checklist which provides a template for intervention description and replication (Hoffmann et al., 2014). Feasibility of the study design was assessed with reference to ADePT framework (Bugge C et al, 2013).

Design, setting and subjects

The study was conducted in two phases, as summarised in Figure 1. Men were recruited to Phase 1 from cancer centres in two areas in England – Oxford University Hospitals Trust and Cambridge University Hospital NHS Trust. Men were eligible if their disease was stable as judged by the most recently available PSA result, and they had been treated with surgery, radiotherapy (including brachytherapy), androgen deprivation therapy (ADT) or active surveillance. Recruitment details for Phase 1 have been published elsewhere (Watson et al., 2014, Watson et al., 2016). Participants completed a baseline questionnaire (RR-64%), and indicated on this questionnaire if they were interested in participating in a pilot trial of the NLPI.

Men who expressed interest in the pilot trial and who indicated an ongoing problem (small, moderate or large) with urinary, bowel, sexual or hormone-related functioning/vitality on the EPIC-26 measure were contacted by telephone and, if willing, consented to participate in the pilot trial (Phase 2)(Watson et al., 2014). We aimed to recruit 80 men to the pilot trial (sufficient for assessing feasibility and acceptability outcomes and to provide an indication of

likely effect sizes and associated variation to inform power calculations for a future trial). Anticipating an uptake rate of approximately 60%, we therefore invited 136 of the 177 eligible men to participate in the trial. Selection for invitation was sequential according to time of receipt of baseline questionnaire. Participants were then randomly assigned 1:1 to the intervention or control group. Randomisation was stratified by treatment into three groups: surgery; radiotherapy; ADT alone or active surveillance (combined because of small numbers). Participants were allocated to a randomisation group by the study co-ordinator on entry to the study using a random allocation spreadsheet provided by the statistician.

Intervention (NLPI)

The intervention was a nurse-delivered psycho-educational intervention, based on a self-management approach (de Silva, 2011, Cockle-Hearne and Faithfull, 2010) underpinned by Bandura's Social Cognitive Theory (1977) andencompassing the following four domains: *understanding the context of prostate cancer treatment; eliciting needs; self-management and behavioural activation; cognitive restructuring (identification of specific situations or thought patterns that cause distress and tailored support for managing these, or onward referral if required).* Further details are provided elsewhere (Watson et al., 2014).

Appointment of the study nurses varied by Region, according to local funding arrangements. The study nurses included practice nurses(n=2)(Oxfordshire), who had no prior research experience and who expressed interest in participating in the study to one of the investigators (PR), or primary care research nurses (n=3) recruited through the East of England Primary Care Research Network who had no prior experience of caring for men with prostate cancer. All study nurses received two days of intensive training which included: information on the best available evidence for the management of treatment side effects; guidance on dealing with psychological issues; communication skills training; information on

study procedures; and guidance on when and how to refer men to their general practitioner (GP), secondary care or other support services e.g. incontinence and counselling services. They were also provided with written materials from Prostate Cancer UK and Macmillan Cancer Support to give to participants as appropriate. The training was delivered by a range of relevant experts and included sessions on managing urinary, bowel and sexual dysfunction and hormone-related problems, communication skills, role playing sessions, and an introduction to resources available via Prostate Cancer UK. The training was accompanied by an intervention manual . (Further details of the training are available from the authors on request). A second training session took place six weeks later where nurses were able to discuss experiences of pilot intervention delivery sessions. Regular monitoring and feedback was provided throughout the study (via monthly teleconferences with the lead study clinicans (PR/SF), the study PI and trial administrator (EW/EF) to ensure intervention fidelity.

Intervention delivery involved an initial face-to face appointment in the patient's own general practice. These appointments were tailored to the specific problems of the patient, with nurses using the completed Phase 1 questionnaires as a prompt. Further nurse contact (either face-to-face or telephone) was individually tailored, according to need. All men received a final follow-up telephone call at 6 months. Wherever possible, a single nurse took responsibility for each patient throughout the delivery of the intervention.

Study nurses were not responsible for routine PSA monitoring.

Outcome measures

We measured prostate-related quality of life using the Expanded Prostate Cancer Index Composite-26 item version (EPIC-26) (Szymanski et al., 2010), unmet needs using the Supportive Care Needs Survey 34 item version (SCNS-SF34) (Boyes et al., 2009), and psychological wellbeing using the Hospital Anxiety and Depression Scale (HADS) (Zigmond

and Snaith, 1983). We used the Cancer Survivors Self-Efficacy Scale, a modified version of the Self Efficacy for Managing Chronic Disease Scale (Lorig, 2001) to measure respondents' confidence in performing 11 behaviours (Foster et al., 2013). Participants completed these measures at baseline and at nine months. No primary outcome measure was specified, as this was a pilot trial. Participants were also asked to complete a health service resource use questionnaire over three separate time periods; 0-3 months, >3-6 months, >6-7 months to record their prostate-related health service contacts, use of medication/devices, and sick days preventing usual activities. This information, plus self-reported health status as measured by the EQ-5D-5L and EQ-5D VAS (Brooks, 1996), was used to assess the cost-effectiveness of the intervention where quality adjusted survival (QAS) was the primary outcome measure. The follow-up questionnaire also included questions seeking views on the intervention. Further details of the measures used (Watson et al., 2014) and the cost-effectiveness analysis are reported elsewhere (Burns et al, 2017).

Qualitative evaluation

A maximum variation sample of men who received the intervention (by Region, treatment group, age and study nurse who delivered the intervention) were invited to participate in a semi-structured telephone interview (conducted by either EW or LM) to seek their experiences and views of the intervention. Interviews were conducted following the end of the intervention (mean time = 4 months, range 1-5 months post final nurse telephone follow-up call). Interviews with each of the study nurses were also conducted at the end of the trial. Nurses were asked about their experiences of delivering the intervention and any challenges they encountered, their views regarding the training they had received, and their views on the potential usefulness of this model of follow-up.

All interviews were digitally recorded and transcribed verbatim, and any identifiable information was anonymised. In addition, all free text data were extracted from relevant sections of the study follow-up questionnaire.

Data analyses

Quantitative data were analysed in accordance with the manual for each measure included in the questionnaire. Scores were summarised using means and standard deviations, unless heavy skewness warranted the use of medians and interquartile ranges. Missing data is reported; no imputation was carried out. For the EPIC-26, we also assessed change in the proportion of those reporting moderate or large problems within each domain. Significance testing was not routinely carried out for all items as the study was not powered for such analysis and due to multiplicity issues. Resource use differences across trial arms were assessed using Pearson's chi-squared test and associated p values were reported. Mean differences between baseline and seven month follow-up were instead calculated, with 95% confidence intervals. Where confidence intervals suggested statistically significant differences within groups, ANCOVA analyses were carried out to compare the averages across groups, adjusting for baseline results.

The qualitative data from the patient and nurse interviews, together with the (generally short) free text data from the follow-up questionnaire, were analysed thematically. Data collection and analysis occurred simultaneously and iteratively, so initial themes which arose were explored further in subsequent interviews. Common themes were constructed, and similarities and differences between participants examined. Patient and nurse interviews were examined individually and then collectively to explore similarities and differences in their experiences of the intervention. Finally, overarching themes for the combined data were generated, and confirmed by consensus within the larger research group.

Results

Feasibility and acceptability

Feasibility of the study design was assessed with reference to the ADePT framework (A Process for Decision-making after Pilot and Feasibilty trials (Bugge C et al, 2013).

Recruitment and randomisation

Recruitment to the study was acceptable. Of those eligible and invited to participate in the trial following Phase 1 (n=136), 42 were randomised to the intervention group and 41 to the control group (n=83, 61% in total). No participants withdrew from the study subsequent to group allocation, indicating acceptability of the randomisation process. Demographic and treatment characteristics of the trial participants are presented in Table 1. No notable differences were observed between the two groups. Despite stratifying randomisation by treatment type, our participant group did consist of more surgical patients than any other treatment group. In a larger study, we would expect that stratified randomisation would be more effective.

Retention

Two patients in the intervention group discontinued the intervention: one man withdrew on account of disease progression, and one for other health reasons. All men in the intervention group attended the first nurse appointment. The follow-up questionnaire was completed by 38 (95%) and 34 (83%) men in the intervention and control groups, respectively. Completion rate of individual measures was high, in particular, the SCNS-SF34 and the Cancer Survivors Self-Efficacy Scale which was fully completed by all respondents. Thirty men provided free text comments relating to their experiences and views of the intervention.

Delivery of intervention

In all cases it was feasible for the study nurse to deliver the intervention in the participant's own GP practice as planned. The initial face-to-face appointments were typically around 60 minutes long (SD=14.4). Two thirds of men did not require or wish a follow-up appointment (28/42). Nine men (21.4%) received one follow-up appointment, three men (7.1%) received two follow-up appointments and two men (4.7%) received three follow-up appointments. 15/21(71.4%) follow-up appointments were conducted by telephone, which were, on average, 12 minutes long (SD=6.13). In addition all participants received a final follow-up telephone call.

Views on the intervention

Questionnaire findings

Thirty men responded to the section of the questionnaire evaluating the nurse intervention. All found the intervention schedule to be appropriate to their needs, and of about the right duration. Most (n=26/29, 90%) found the initial face-to-face appointment and the telephone follow-up calls (n=23/29, 79%) to be useful/very useful. Over half (n=18/30, 60%) thought all men should definitely be routinely offered this sort of nurse-led care in primary care, and a further 33% (n=10/30) thought they probably should. Opinions were divided regarding the optimal time for this sort of support, with 30% (n=9/30) favouring at diagnosis, 40% (n=12/30) during initial treatment, and 30% (n=9/30) after initial treatment has finished.

Interview findings

Thirteen of those in the intervention group were interviewed (65% response rate), in addition to all five study nurses. Three main themes emerged from the analysis:

Impact of the intervention: promoting active self-management and an improved sense of wellbeing

Men generally felt the intervention had been beneficial to their sense of wellbeing, and reported feeling reassured and more emotionally supported. They valued being able to talk about their emotions and fears in what they considered to be a safe and welcoming environment.

> *'I could speak openly to her - more so than my doctor, she understood everything I was worried about'* (ID: 493)

> '…..because otherwise it's just presented as a physical thing you've got and there's that awful feeling…..you've got when you have cancer and it's really good to have someone who says; well you can do this or that, you may feel this or you may feel that. So it's just absolutely brilliant. It takes all the fear away' (ID:10)

Some men described greater feelings of control over their body and increased confidence in their ability to manage their condition and adopt more active coping strategies. Some noted improvements in their urinary, sexual or bowel functioning.

> '*getting more control over your body…which again is good, not to feel that you've been landed with something that just controls you rather than vice versa…[Nurse] helped me get my self-confidence back and indirectly improve sexual relations with my wife - and left us happy*.' (ID: 503) *'she gave me quite a number of handouts, which had information, when you take the exercises [pelvic floor], what you should do, all the things which the GPs hadn't done...but this [study nurse] did seem very knowledgeable…and she did fill me with a certain degree of confidence' (ID: 401)*

Men valued the opportunity to talk about issues such as sexual functioning, where previously embarrassment had been a barrier to seeking help.

'I can sit and talk to [study nurse] about these sexual matters, and don't feel embarrassed, I don't know why, but… I don't feel happy about going up to the hospital and seeing someone in the clinic' (ID: 455)

A few men reported no particular changes following the intervention in terms of their symptoms. These men either perceived few problems to begin with, or were reluctant to implement pelvic floor exercises or to see the GP regarding medications for sexual dysfunction.

The intervention appeared to be particularly valued by men who perceived that their contact with health professionals was limited, or that there was a lack of holistic support after treatment completion and/or a lack of verbal or written information provided on dealing with symptoms.

'*It was particularly good to be able to discuss one's personal problems frankly and at length with someone with plenty of relevant experience but not involved with one's treatment. Distance lends objectivity and time for reflection: not many GPs or hospital consultants can afford to give patients so much attention*' (ID: 459)

Both men and nurses felt that this type of intervention was useful for men who had passively accepted their symptoms and for those who displayed gendered coping styles, such as avoiding help-seeking or talking to health professionals about their problems, prior to the intervention.

'*the impotence that follows on, I had just accepted as being par for the course, and really a small price to pay, but she said well no, you shouldn't have to just shrug and get on with it, if you want to do something about it here's what you can do, and lots of advice on that, …that was all very encouraging and not making light of something that could be considered to be peripheral*' (ID: 503)

2: Nurses' experiences of delivering the intervention

In general, nurses felt the intervention worked very well, and found the training, resources and manual very helpful. Nurses mentioned the usefulness of asking men to complete a urine diary and urine chart prior in enabling them to assess urinary continence and advise men on bladder retraining.

> *'So the fluid balance and the urine, for me I felt was the thing I made the biggest impact on, really, of doing the bladder retraining'* (ID:2)

As issues with forgetfulness and/or lack of motivation were reported in some men, the nurses felt the tailored follow-up design was particularly useful for addressing this.

Nurses observed that many men lacked preparedness for life after prostate cancer treatment, so felt that these men particularly valued being given information during the intervention.

> *'I would say three or four of the six that I saw hadn't had any [written] literature given to them at all…they found that particularly useful*' (ID 3)

Nurses also felt that men had previously been reluctant to address their issues, sometimes due to lack of knowledge or embarrassment, so they felt able to motivate them to become more active.

> *'A lot of them were of the opinion, well, you know, I'm 70, can I really go to the GP and discuss it [sexual dysfunction]'* (ID: 1)

Regarding the timing of the intervention, the study nurses felt that men who were several years post treatment already knew some of the advice they had to offer and/or had often learned to live with their symptoms and were less receptive to implementing behavioural changes, such as pelvic floor exercises., and that intervening earlier may be more beneficial.

'some of the advice they already knew… so earlier might be better…' (ID:5)*A lot of them by two years [post-treatment] are slightly, well, I've been living like this for two years, I'm fine, I don't really want to rock the boat, I don't really want to change what I'm doing, so….' (ID:1)*

Challenges in delivering the intervention

Nurses reported some frustration at times over dealing with sexual dysfunction, in that while they felt they could be helpful at advising men on medication for sexual dysfunction and recommending men speak further to their GP, they were disappointed to find some men failing to act on this advice. While they acknowledged this area was not a priority for all men, and that some had accepted celibacy in their relationships or were no longer sexually active, they felt others could have benefited.

Nurses also reported they that they found it quite challenging dealing with men who had already been told their sexual functioning may not return.

'… sometimes the professionals at the clinic had pretty much said to the man that there was nothing more really they can do, they had tried lots of different options already…. also specific questions that the men had asked me whether their sexual function would return, I found that quite hard to answer' (ID: 3)

Despite initial willingness from men, nurses also felt that their attempts to motivate men to exercise in order to improve fatigue were largely unsuccessful, and some attributed this to older age.

In terms of future improvements to the training programme, nurses felt further training on how to deal with psychological issues, particularly fear of recurrence could be helpful.

'*I found it quite hard to deal with anxiety, depression, and the psychological side of things'* (ID: 3)

Looking to the future, nurses felt that a trained practice (or other) nurse could deliver the intervention in primary care. However, because of the low numbers of men with prostate cancer in any one practice, to be effective and cost-effective they felt that one potential model would be for a nurse who is trained in cancer follow-up to work across practices. A couple of the study nurses experienced fairly long gaps between appointments which led to them feeling '*de-skilled'.*

Patient reported outcomes

Prostate-related quality of life

No between-group differences were observed in the domain scores for urinary, bowel, sexual or hormone-related symptoms, although general deterioration from baseline over time was evident (apart from sexual function which improved). The proportion reporting moderate/big problems within each domain of the EPIC-26 can be found in Supplementary Material, Appendix A. Mean scores for each domain by study group, and the change from baselines are presented in Appendix B.

Unmet needs, psychological well-being and self-efficacy

There was a reduction in the proportion of patients reporting unmet need in both the intervention and control groups from baseline to post-intervention. The reduction was greater in the intervention group for four of the five domains of the SCNS-24, although this did not reach statistical significance (see Table 2).

No between-group differences in psychological well-being as measured by the HADS were observed (see Table 2).

The intervention group reported improved self-efficacy across the majority of items. The most notable improvements related to being: 'confident in keeping symptoms or other health problems from interfering with things you want to do'; 'confident in contacting your doctor about any problems caused by cancer and/or cancer treatment'; and 'confident that you can get support with problems caused by your cancer and/or cancer treatment from health and/or social care professionals'. However, these differences did not reach statistical significance (see Table 2).

Resource Use

Self-reported contacts with healthcare providers varied across contact type and by trial arm. Table 3 highlights the types of discussion that took place at healthcare visits and the extent to which this varied across trial arms. A higher proportion of men reported discussing PSA test results (35/62) and implications of tumour growth/spread (14/17) in an outpatient setting with the consultant and/or clinic nurse in the control group compared to the intervention group; this was statistically significant for those discussing tumour growth or spread concerns ($P = 0.021$). A higher proportion of men in the intervention group discussed sexual (12/15) and urinary problems (12/14) with their GP in a primary care setting compared to the control group while higher proportions in the control group discussed these problems in an outpatient setting, neither,however, was statistically significant. A statistically significant difference was evident for the proportions of men who discussed bowel problems (25/36) across all settings in the intervention group ($P < 0.01$) relative to the control group; this discussion was predominantly in the primary care setting (see Table 3).

Discussion

To our knowledge this is the first study to trial a primary-care based supportive care intervention for prostate cancer survivors in the UK. We have shown that our relatively brief intervention can be successfully delivered by nurses in primary care, and that it is acceptable to, and valued by, men. Whilst the qualitative evaluation clearly suggested that men gained a range of positive outcomes from the intervention, the benefits were less clear from analysis of the patient reported outcome measures used in the study, and although not powered to detect differences, it is possible that the intervention was not effective.

Although men reported reduced levels of unmet needs and improved self-efficacy, we did not observe any between-group differences in prostate-related quality of life or psychological well-being. As already highlighted, this pilot study was not powered to detect statistically significant differences and therefore it is unclear whether the observed differences would be significant if a larger study was conducted. It is, however, encouraging that the intervention appeared to improve men's confidence in their ability to keep any symptoms or other health problems from interfering with the things they wanted to do, and also appeared to improve men's confidence in contacting their doctor about any cancer-related problems.Resource use varied between the trial groups, as did the type of resources utilised. Patients receiving the intervention reported a higher number of primary care visits while the control group reported a higher number of secondary care visits. We also found indications of a possible redistribution of resource use with men in the intervention group more likely to consult their GP regarding side-effects of treatment, whereas men in the control group were more likely to discuss PSA results and the implications of tumour growth with their hospital consultant. Given that secondary care services have a higher cost implication than services delivered in the community, the economic impact of the redistribution of care to a primary setting may be substantial. Cost-effectiveness has been reported elsewhere (Burns et al., 2017), and

concluded that the intervention could potentially be cost-effective based on the evidence assessed at the pilot stage. An Australian trial which evaluated a shared care model of post-treatment follow-up found that the shared care model cost less to deliver and outcomes were similar (Emery et al., 2017).

A number of issues warrant consideration when interpreting the study findings. Men were, on average, two years post-diagnosis when they entered the trial and intervening earlier may have been more effective (Giesler et al., 2005, Dieperink et al., 2013), as suggested by both the patients and nurses. Secondly, men were included in the study regardless of their disease status or treatment received. Whilst in some ways this was a strength of the study as it reflected routine primary care practice, it also meant the sample was very heterogeneous with only small numbers per treatment type, thus limiting the analysis and conclusions that could be drawn. Thirdly, levels of functioning, self-efficacy, and well-being were relatively high and rates of unmet need relatively low at baseline, making it harder to show any effect of the intervention – this has implications for further targeting of similar interventions in future. Finding ways to stratify those with the greatest needs or risks remains an important challenge for the provision of good quality cancer care (Watson et al., 2012). It is also possible that the quantitative outcome measures we used were not well-suited for the evaluation of our intervention. We were keen to implement more generic, well-validated questionnaires in our study to ensure robustness, however this may have meant that the benefits of our intervention were not fully captured.

. We observed a level of disparity between the accounts of men who were interviewed, who were largely positive about the intervention, and the relatively small effects of the intervention on the quantitative patient reported outcome measures used. The HADS, for example, is designed to screen for potential clinical levels of anxiety and depression, and a measure of prostate-specific anxiety may have been more sensitive. *We did not find any*

evidence of improvement in the proportions of men reporting moderate or big problems for any of the EPIC domains. This may be due to the timing of our intervention, where earlier intervention would have been required to improve functioning. Measures of self-efficacy, coping and unmet need are more likely to be useful outcome measures at the time we intervened in this study. Our follow-up period was also short (three months following the end of the intervention) and it is possible that longer follow-up may have yielded further benefits.

Finally, participants in our study were almost exclusively white and further work is needed to establish the acceptability and usefulness of this and similar interventions in men from other ethnic groups, particularly men of African or Caribbean origin who have a higher incidence of prostate cancer.

Several previous studies have trialled psychosocial interventions for men with prostate cancer in other settings and are the subject of a recent review (Chambers, 2017). Our study differs from previous studies in that it has tested a primary-care based intervention for prostate cancer survivors. In the UK the National Cancer Survivorship Initiative (NCSI) recommends a move away from traditional models of consultant-led hospital follow-up to a model of supported self-management in the community for stable, low risk patients (Department of Health et al., 2013). Previous studies have elicited patient concerns about GP-led follow-up (Lewis et al., 2009). However, men in our study were amenable to survivorship care being provided in primary care, provided it was delivered by someone who was knowledgeable. Similarly, the PROCARE study found men were equally satisfied with shared versus hospital-led follow-up care (Emery et al., 2017).

We have shown that it is feasible to train nurses in primary care to deliver a relatively low – intensity, low-cost intervention which supports and promotes self-management, is valued by men, and is potentially cost-effective. Costs could be reduced further by offering group sessions or using online support, although without some face-to-face contact we think it is

likely that at least some of the potential benefit of our intervention would be lost. Given the relatively low number of prostate cancer patients per individual UK general practice, a model whereby one nurse with expertise in this area works across a group or federation of practices may make sense, or a nurse within a given practice develops expertise in survivorship issues across the range of cancers commonly seen in primary care.

In summary, this pilot trial adds to the evidence base regarding the provision of prostate cancer survivorship care. The findings indicate the potential value of a nurse-led intervention in primary care to promote self-management and reduce unmet needs. We believe a larger trial is warranted delivering the intervention earlier in the patient pathway.

Compliance with Ethical Standards

Funding: This study was funded by Prostate Cancer UK (grant number PG10-09-SV).

Conflicts of Interest: The authors declare that they have no conflict of interest.

Informed consent: Informed consent was obtained from all individual participants included in the study.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors. The study received ethics approval from favour from Oxfordshire Research Ethics Committee A (12/SC/0500).

Trial registration: The trial was registered with ISRCTN (97242511).

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Table 1: Patient characteristics by trial group allocation

Participants Characteristics	Intervention Group (N=42) Mean (SD)	Control Group (N=41) Mean (SD)	Total (n=83) Mean (SD)
Patient age (years)*	68.43 (7.43) Range 52-84	68.68 (7.23) Range 51-83	68.56 (7.29) Range 51-84
Time since diagnosis* (months)	23.24 (5.31) Range 13-34	24.01 (5.05 Range 13-34	23.62 (5.16) Range 13-34
Age Group (years)*	**N (%)**	**N (%)**	**N (%)**
50-59	6 (14.3)	6 (14.6)	12 (14.5)
60-69	20 (47.6)	19 (46.3)	39 (47.0)
70-79	14 (33.3)	12 (29.3)	26 (31.3)
80-89	2 (4.8)	4 (9.8)	6 (7.2)
Highest Educational Qualification			
GCSE's or equivalent	7 (16.7)	7 (17.1)	14 (16.9)
A-levels or equivalent	3 (7.1)	0 (0)	3 (3.6)
Clerical or commercial	2 (4.8)	8 (19.5)	10 (12.0)
College or University degree	10 (23.8)	11 (26.8)	21 (25.3)
Postgraduate qualification	7 (16.7)	5 (12.2)	12 (14.5)
None of these	13 (31.0)	10 (24.4)	23 (27.7)
Employment			
Employed in paid work	17 (40.5)	15 (36.6)	32 (38.6)
Temporarily off sick	0 (0)	1 (2.4)	1 (1.2)
Retired	25 (59.5)	25 (61.0)	50 (60.2)
Unemployed	0 (0)	0 (0)	0 (0)
Long-term disability or ill health	0 (0)	0 (0)	0 (0)
Full time education or training	0 (0)	0 (0)	0 (0)
Marital status			
Married/cohabiting	36 (85.7)	37 (90.2)	73 (88.0)
In partnership/not cohabiting	3 (7.1)	0 (0)	3 (3.6)
Widowed	2 (4.8)	1 (2.4)	3 (3.6)
Divorced/separated	1 (2.4)	2 (4.9)	3 (3.6)
Single	0 (0)	0 (0)	0 (0)
Other	0 (0)	1 (2.4)	1 (1.2)
Ethnicity			
White British	41 (97.6)	39 (95.1)	80 (96.4)
White – Other	1 (2.4)	1 (2.4)	2 (2.4)
Black- Other	0 (0)	0 (0)	0 (0)
Chinese	0 (0)	0 (0)	0 (0)
Other	0 (0)	1 (2.4)	1 (1.2)
Previous Treatment (Primary) **			
Surgery	15 (35.7)	10 (24.3)	25 (30.1)
Radiotherapy – external beam	4 (9.5)	5 (12.1)	9 (10.8)
Radiotherapy- plus hormone	12 (28.6)	10 (24.3)	22 (26.5)
Hormone only	3 (7.1)	3 (7.3)	6 (7.2)
Active surveillance	3 (7.1)	6 (14.6)	9 (10.8)
Other	1 (2.4)	0 (0)	1 (1.2)
Co-morbidities			

Heart problems	7 (16.7)	7 (17.1)	14 (16.9)
High blood pressure	11 (26.2)	14 (34.1)	25 (30.1)
COPD***	2 (4.8)	1 (2.4)	3 (3.6)
Asthma	3 (7.1)	3 (7.3)	6 (7.2)
Diabetes	6 (14.3)	5 (12.2)	11 (13.3)
Arthritis	6 (14.3)	8 (19.5)	14 (16.9)
Osteoporosis	2 (4.8)	0 (0)	2 (2.4)
Inflammatory bowel disease	0 (0)	1 (2.4)	1 (1.2)
Multiple Sclerosis	0 (0)	0 (0)	0 (0)
Parkinson's disease	0 (0)	0 (0)	0 (0)
Other	10 (23.8)	5 (12.2)	15 (18.1)
At least one co-morbidity	25 (59.5)	25 (61.0)	50 (60.2)
No co-morbidities	17 (40.5)	16 (39.0)	33 (39.8)

*At point of randomisation into the study; ** Some men had received more than one type of treatment

***Chronic Obstructive Pulmonary Disease

Table 2: Mean outcomes at baseline and follow up and differences between intervention and control groups

	Intervention (N=38)			Control (N=34)		
	Baseline	**7mth f/u**	**Difference (95% CI)**	**Baseline**	**7mth f/u**	**Difference (95% CI)**
Self-efficacy scores (possible range 1-10)						
Fatigue	7.84	8.11	0.26 (-0.39, 0.92)	8.18	8.29	0.12 (-0.44, 0.67)
Discomfort	8.45	8.76	0.32 (-0.50, 1.14)	8.82	8.41	-0.41 (-0.96, 0.14)
Emotional Distress	8.32	8.47	0.16 (-0.73,1.04)	8.21	8.18	-0.03 (-0.53, 0.47)
Symptoms	7.55	8.58	1.03 (0.21, 1.85)	7.97	7.79	-0.18 (-0.90, 0.54)
Manage Tasks	8.74	8.71	-0.03 (-0.73, 0.68)	9.00	8.41	-0.59 (-1.21, 0.04)
Do Other Things	8.47	8.45	-0.03 (-0.80, 0.74)	7.88	7.79	-0.09 (-1.13, 0.95)
Access Information	8.53	8.58	0.05 (-0.54, 0.65)	8.50	7.79	-0.71 (-1.59, 0.18)
Access People	8.26	8.24	-0.03 (-0.69, 0.63)	8.21	7.76	-0.44 (-1.15, 0.26)
Deal By Yourself	7.97	6.87	-1.11 (-2.08, -0.13)	7.71	7.32	-0.38 (-1.31, 0.54)
Contact Doctor	8.63	8.82	0.18 (-0.61, 0.98)	8.68	7.94	-0.74 (-1.37,-0.10)
Get Support	7.76	8.18	0.42 (-0.27, 1.11)	8.12	7.15	-0.94 (-1.78, -0.10)
Unmet needs domain scores (possible range)						
Psychological (10-50)	18.32	15.70	-2.62 (-4.51, -0.74)	17.18	16.00	-1.18 (-3.70, 1.34)
Health System & Information (11-55)	19.66	17.39	-2.26 (-4.46, -0.06)	19.88	17.94	-1.94 (-4.99, 1.11)
Physical & Daily Living (5-25)	7.70	7.00	-0.70 (-1.67, 0.26)	6.91	6.82	-0.15 (-0.92, 0.62)
Patient Care & Support (5-25)	7.39	6.79	-0.61 (-1.48, 0.27)	7.56	6.88	-0.68 (-1.77, 0.42)
Sexuality (3-15)	7.03	5.19	-1.84 (-3.03, -0.64)	6.56	5.32	-1.26 (-2.24, -0.29)

	Hospital Anxiety and Depression Scare (HADS)					
	Intervention (N=38)			Control (N=34)		
	Baseline	7mth f/u	Difference (95% CI)	Baseline	7mth f/u	Difference (95% CI)
Mean Depression Score	2.80	2.74	0.06 (-0.62, 0.74)	2.88	3.19	-0.31 (-1.00, 0.38)
Mean Anxiety Score	3.79	4.26	-0.47 (-1.33, 0.39)	4.19	3.94	0.25 (-0.52, 1.02)

Table 3: Self-reported healthcare visits by discussion type

Visit Type[a]	**Discussed PSA rResult at visit type**			**No Did not dDiscussion of PSA rResult**	**Total Visits Reported**
	Total	*Intervention*	*Control*		
1- GP Visit	19	10	9	53	72
2- Practice Nurse	9	2	7	97	106
3- District Nurse	0	0	0	1	1
4- Macmillan Nurse	0	0	0	1	1
5- Physiotherapist	1	0	1	1	2
6- Occupational therapist	0	0	0	1	1
9- Hospital Consultant	42	18	24	25	67
10- Hospital Nurse	20	9	11	19	39
11- Other*	4	3	1	22	26
Not Classified	0	0	0	2	2
Missing	**1**		**1**	**1**	2
Visit Type	**Discussed tumour growth/ spread at visit type**			**Did notNo dDiscussion of tumour growth/ spread**	**Total Visits Reported**
	Total	*Intervention*	*Control*		
1- GP Visit	2	1	1	70	72
2- Practice Nurse	0	0	0	106	106
3- District Nurse	0	0	0	1	1
4- Macmillan Nurse	0	0	0	1	1
5- Physiotherapist	0	0	0	2	2
6- Occupational therapist	0	0	0	1	1
9- Hospital Consultant	13	2	11	54	67
10- Hospital Nurse	4	1	3	35	39
11- Other*	1	1	0	25	26
Not Classified	0	0	0	2	2
Missing				**2**	2
Visit Type	**Discussed sexual problems at visit type**			**No Did not dDiscussion of sexual problems**	**Total Visits Reported**
	Total	*Intervention*	*Control*		
1- GP Visit	15	12	3	57	72
2- Practice Nurse	3	0	3	103	106
3- District Nurse	0	0	0	1	1
4- Macmillan Nurse	0	0	0	1	1
5- Physiotherapist	1	0	1	1	2
6- Occupational therapist	1	0	1	0	1
9- Hospital Consultant	9	4	5	58	67
10- Hospital Nurse	17	7	10	22	39

11- Other*	7	6	1	19	26
Not Classified	0	0	0	2	2
Missing				**2**	2
Visit Type	**Discussed urinary problems at visit type**			**Did not No dDiscussion of urinary problems**	**Total Visits Reported**
	Total	*Intervention*	*Control*		
1- GP Visit	14	12	2	58	72
2- Practice Nurse	1	0	1	105	106
3- District Nurse	0	0	0	1	1
4- Macmillan Nurse	0	0	0	1	1
5- Physiotherapist	1	0	1	1	2
6- Occupational therapist	1	0	1	0	1
9- Hospital Consultant	12	5	7	55	67
10- Hospital Nurse	14	6	8	25	39
11- Other*	2	2	0	24	26
Not Classified	0	0	0	2	2
Missing			**1**	**1**	2
Visit Type	**Discussed bowel problems at visit type**			**No Did not dDiscussion of bowel problems**	**Total Visits Reported**
1- GP Visit	13	10	3	59	72
2- Practice Nurse	1	0	1	105	106
3- District Nurse	0	0	0	1	1
4- Macmillan Nurse	0	0	0	1	1
5- Physiotherapist	1	0	1	1	2
6- Occupational therapist	0	0	0	1	1
9- Hospital Consultant	10	6	4	57	67
10- Hospital Nurse	5	3	2	34	39
11- Other*	6	6	0	20	26
Not Classified	0	0	0	2	2
Missing				**2**	2

a. Participants reported type of healthcare visit in trial dairies and also highlighted the topic of discussion, based on the five sub-groups presented, at each visit.

Appendix A. Proportion in each group reporting moderate or large overall problems at baseline and after the intervention.

Overall Problems	Intervention			Control		
	Mod/Big Problem (%)			Mod/Big Problem (%)		
	N	Baseline	7mth f/u	N	Baseline	7mth f/u
Urinary function	37	22%	16%	33	27%	18%
Bowel habits	37	14%	19%	34	9%	6%
Sexual function	35	46%	46%	33	55%	33%
Hot Flushes	35	23%	14%	33	21%	18%
Breast Tenderness	33	6%	3%	32	3%	13%
Feeling Depressed	32	3%	9%	32	6%	10%
Lack of Energy	35	23%	37%	34	24%	18%
Change in Body Weight	32	19%	9%	33	18%	12%

Appendix B: Mean domain scores at baseline and post-intervention in each arm

	Intervention				Control			
	N	**Baseline**	**7mth f/u**	**Difference (95% CI)**	**N**	**Baseline**	**7mth f/u**	**Difference (95% CI)**
Urinary Incontinence	32	81.88	79.27	-2.61 (-7.68, 2.46)	30	82.46	80.04	-2.42 (-6.47,1.64)
Urinary Irritate/ Obstructive	31	84.88	64.31	-20.56 (-25.77, -15.36)	26	84.13	62.26	-21.88 (-29.17, -14.58)
Bowel	28	91.49	73.07	-18.42 (-22.77, -14.08)	31	88.84	68.20	-20.65 (-26.08, -15.22)
Sexual	33	20.81	29.33	8.53 (0.93, 16.12)	31	25.80	30.96	5.16 (0.70, 9.62)
Hormonal	33	79.85	59.70	-20.15 (-25.14, -15.17)	30	80.33	57.92	-22.52 (-27.47, -17.36)