Title: The psychological impact of being on a monitoring pathway for localised prostate cancer: a UK-wide mixed methods study

Lauren Matheson[1], Sarah Wilding[2], Richard Wagland[3], Johana Nayoan[3]*, Carol Rivas[3] *, Amy Downing[2], Penny Wright[2], Jo Brett[1], Therese Kearney[4], William Cross[5], Adam Glaser[2 3], Anna Gavin[5], Eila Watson[1]

[1]Oxford Brookes University

[2]University of Leeds

[3] University of Southampton

[4]Queen's University Belfast

[5]Leeds Teaching Hospitals NHS Trust

***different current address**

* University College London

Corresponding author: Eila Watson, Faculty of Health and Life Sciences, Oxford Brookes University, Oxford OX3 OFL, 01865 482665, ewatson@brookes.ac.uk

Running head: Well-being in Men with Prostate Cancer on a Monitoring pathway

Keywords: active surveillance; LAPCD; mixed methods; monitoring; Prostate cancer; psychological well-being; watchful waiting; cancer; oncology

Abstract

Objective: To address concerns over the psychological impact of being on a monitoring pathway following prostate cancer (PCa) diagnosis, this study compared the psychological status of men on active surveillance (AS) or watchful waiting (WW) with men on active treatment (AT), and explored psychological adjustment in men on AS/WW.

Methods: Cross-sectional survey of UK men diagnosed with PCa 18-42 months previously (n=16,726, localised disease at diagnosis) and telephone interviews with 24 men on AS/WW***.*** Psychological outcomes were measured using two validated scales (Short Warwick-Edinburgh Mental-Well-being Scale; Kessler Psychological Distress Scale). Univariable and multivariable analyses compared outcomes between men on AS/WW and AT. Thematic analysis of interviews was undertaken, informed by a previously developed theory of adjustment to cancer.

Results: 3,986 (23.8%) respondents were on AS/WW. Overall, psychological outcomes were similar or better in men on AS/WW compared to those receiving AT (SWEMWBS: Poor well-being; 12.3% AS/WW vs 13.9% AT, adjusted OR=0.86, 95% CI 0.76-0.97; K6: severe psychological distress; 4.6% vs 5.4%, adjusted OR=0.90, 95% CI 0.74-1.08). Interviews indicated most men on AS/WW had adjusted positively. Men with poorer well-being were less able to accept, reframe positively and normalise the diagnosis, described receiving insufficient information and support, and a lack of confidence in their health-care professionals.

Conclusions: Most men on AS/WW cope well psychologically. Men making treatment decisions should be given this information. Psychological health should be assessed to

determine suitability for AS/WW, and at monitoring appointments. A clear action plan and support from healthcare professionals is important.

Introduction

Prostate cancer (PCa) is the most common cancer in men in Europe [1]. Many men have localised disease with treatment options being one or a combination of prostatectomy, radiotherapy or active surveillance (AS). Following concerns regarding over-treatment, AS is now offered to all men diagnosed with localised, low-risk PCa [2], as a way to avoid treatment-related impairments in urinary, bowel and sexual functioning [3-5]. AS is also an option for men with intermediate risk disease [6]. Men on AS typically undergo periodic Prostate-Specific Antigen (PSA) testing, Digital Rectal Examinations (DRE), MRI scans and biopsies with a view to moving to radical intervention if the disease progresses [7]. Watchful Waiting (WW) is another alternative to active treatment (AT), although this is typically offered to older men and/or men with pre-existing health conditions or more advanced PCa [8].

Concerns have been raised over the psychological impact of being on an AS/WW regime. Systematic reviews of quantitative studies suggest quality of life and psychological well-being in men on AS/WW is generally good and comparable to [9-13], or better than, [10, 14] men who received AT. However, evidence from qualitative studies suggests men on AS/WW may struggle with anxiety [15-20]. Further exploration is needed to understand how men adjust to being on AS/WW.

The Life After Prostate Cancer Diagnosis (LAPCD) study is a UK-wide mixed methods study [21], which aimed to explore the impact of PCa on men's well-being through a large-scale survey of men with PCa and interviews with a sub-sample. In this paper we a) compared the psychological outcomes in men with localised disease on AS/WW and men who received AT, using survey responses, and b) explored the psychological adjustment of all interviewees on AS/WW, drawn from the total sample of interviewed men, to inform how future health services may best support this growing group of men.

Methods

Design

Full methodological details can be found in the protocol [21]. Ethical and regulatory approvals were obtained (Newcastle and North Tyneside Research Ethics Committee (15/NE/0036), Health Research Authority Confidentiality Advisory Group (15/CAG/0110), NHS Scotland Public Benefit and Privacy Panel (0516-0364)). In brief, all men who were 18-42 months post diagnosis of PCa were identified through cancer registries in England, Wales and Northern Ireland and through hospital activity data in Scotland, and invited by their treating centre to complete a postal questionnaire. Respondents indicated on the questionnaire willingness to be interviewed. COREQ reporting guidelines were followed [22].

Data collection

Measures

The questionnaire included socio-demographic items including: age, ethnicity, long term conditions (LTCs), marital status, sexuality, employment status, caring responsibilities, and previous professional help-seeking for mental health or alcohol-related problems. Treatment was self-reported. An area-based measure of socioeconomic deprivation (Index of Multiple Deprivation) was obtained using postcode at diagnosis.

Validated outcome measures included the Short Warwick-Edinburgh Mental-Well-being Scale (SWEMWBS) [23] and the six item version of the Kessler Psychological Distress Scale (K6) [24] (see supplementary file 1). The SWEMWBS aims to measure psychological well-being through items relating to participants' thoughts and feelings 'over the past two weeks'. Scores range from 7-35 and it is suggested scores ≤19.25 indicate poor well-being [25]. The K6 measure assesses nonspecific psychological distress. Scores range from 6-30, with a cut-off of ≥19 indicating severe psychological distress [26].

Interviews

Interview participants were recruited following survey completion. For the main LAPCD study of all interviewed men, a purposive sampling frame was developed, stratified by treatment type. We included unpartnered, Black Asian and Minority Ethnic (BAME) and gay/bisexual men and men from different geographical locations. We also included a range of men with regards to level of physical and psychological functioning as shown in their survey responses.

A semi-structured interview topic guide (see supplementary file 2) was developed in collaboration with the study clinical and patient advisory groups, and informed by previous research [19]. This included questions regarding the physical, emotional, sexual and psychosocial impact of PCa and experiences of health services. Interviewers were guided by participants' responses. Telephone interviews lasted 50 minutes on average. Interviews were transcribed verbatim.

Data Analysis

Survey

Analyses were restricted to individuals with a diagnosis of localised PCa (stage I/II), according to cancer registration data. Descriptive statistics compared men on AS/WW and those who received AT in terms of sociodemographic variables, other patient factors, and psychological outcomes (well-being and psychological distress). As there is non-standard usage of the terms AS and WW and they are sometime used interchangeably, similar to previous work [27, 11], men on AS and WW were combined .

Chi-square tests compared categorical variables and T-tests were used for continuous variables. Multivariable logistic regression analyses compared psychological outcomes in the AS/WW and AT groups, after adjustment for relevant sociodemographic and other patient factors. Analyses were repeated with poor psychological well-being (SWEMWBS score ≤19.25) and severe psychological distress (K6 score ≥19) as the outcome. Missing data were excluded on a question-by-question basis, thus all results refer to the men who responded to that question. Stata v15.0 was used for all analyses. A p value of <.05 was used to indicate significance.

Interviews

A thematic analysis was undertaken of all interviewed men for the main LAPCD study using a Framework approach, involving seven stages [28, 29]. Familiarisation was followed by independent inductive coding and group discussion of the first five transcripts (LM,EW,CR,JN,RW). A coding framework was developed (see supplementary file 3), which was primarily informed by these discussions but also using themes deduced from the topic guide. The framework was then iteratively refined following further interviews and initial coding, and was discussed with the LAPCD user advisory group. All interview transcripts were uploaded onto NVivo [30] and indexed, which involved identification of sections of data corresponding to each coding frame. Researchers summarised each section of transcript into coding summaries in the coding framework.

Subgroup analysis

We extracted all men on AS/WW from the whole interview dataset for separate analysis. This involved collation of all coding frames of all men on AS/WW, with a focus on those relevant to the psychological and social impact of PCa. Descriptive themes were then developed and it became apparent the themes corresponded to those in a theory of adjustment to testicular cancer [31]. The data were therefore able to test the theory with reference to the process of positive adjustment in men on AS/WW. Most authors were not involved in the original theory development [31], and so were able to maintain a critical distance from the data. Most of the main themes in this theory, presented as processes, were used (see Figure 1), with some requiring minor modification, such as process 3 which has been altered to reflect that men on AS/WW did not receive treatment.

Findings

Survey data

Descriptive statistics

In the LAPCD sample, 35,823 men returned a completed questionnaire (60.8% response; 19,599 with stage I/II disease (61.3% response). Of those with stage I/II disease, 16,726 men provided valid treatment data. A quarter of these (3,986; 23.8%) reported they were on AS (*N* = 2,320) or WW (*N* = 1,666). No significant differences were found between men on

AS/WW and men undergoing AT with respect to sociodemographic and patient factors, apart from socioeconomic deprivation (Table 1).

A SWEMWBS score was available for 3,747 (94.0%) of the AS/WW group and 12,000 (94.2%) of the AT group (surgery, radiotherapy, ADT). A lower proportion of men in the AS/WW group reported poor emotional well-being according to the cut-off (12.3%, N=462) compared to the AT group (13.9%, *N*=1665; *p*=0.02) (see Table 2). A K6 score was available for 3,799 (95.3%) of the AS/WW group and 12,190 (95.7%) of the AT group. There was a smaller, non-significant, difference in the proportion of men reporting severe psychological distress based on the cut-off (AS/WW: 4.6%, *N* = 174 vs AT: 5.4%, *N* = 656; *p* =0.05).

When comparing the characteristics of men on AS or WW, men on AS were significantly younger than men on WW (Mean = 68.4 years vs. 73.8 years, p <0.001) and reported fewer LTCs (p<0.001). However, no differences in well-being or distress were found between the AS and WW groups.

Multivariable analyses

After adjustment for sociodemographic and other patient factors, the odds of reporting poor well-being were lower in men on AS/WW than those receiving AT (OR=0.86, 95% CI 0.76-0.97)(Table 2). There was no difference in the odds of reporting severe psychological distress between the men on AS/WW and AT (OR=0.90, 95% CI 0.74-1.08).

Interview data

Participant characteristics of the interview sub-set of men on AS/WW are reported (see supplementary file 4). The majority of men on AS/WW had made a positive adjustment to their diagnosis and AS/WW pathway with a minority struggling to do so. Positive adjustment centred around a process of dismantling the threats of cancer and the impact of being on a monitoring pathway. This involved six key processes (Figure 1[31]).

Herein, we describe the processes through which men were able to adjust positively to PCa and being on a monitoring pathway and, for some, the barriers to doing so (i.e. negative adjustment).

Process 1: Appraisal of PCa as a minimal threat (vs. significant threat)

While the diagnosis of PCa was sometimes described as an emotionally difficult period involving '*shock*' and *'worry'*, most men appeared to have adjusted positively to both their diagnosis and being on AS/WW. Many appraised the current impact of PCa as minimal in terms of their overall health and well-being with some feeling it had never really had any impact (*'it's not a big deal'*). Men also held positive appraisals of being on a monitoring pathway.

> *"It's made no difference to my life whatsoever apart from having to go and have pretty regular check-ups*" (P24, WW, 70 years)

Only four men expressed a greater or more enduring impact on their lives, attributing this to the greater psychological threat of cancer rather than any physical impact.

> *"It hasn't had any significant clinical impact yet. But psychologically of course it was devastating for me"* (P3, AS, 58 years)

Process 2: Positive Reframing of the threats of PCa (vs. holding a generalised view of cancer)

Perceiving PCa specifically as a cancer with a good prognosis facilitated positive adjustment. Participants often reframed PCa positively as a cancer they would '*die with and not of*' and generally held positive expectations towards the future *('the future to me is fine'*).

> *"If you're going to have cancer, prostate cancer is probably one of the better ones to have*" (P9, AS, 64 years)

Conversely, perceiving the disease negatively in more generalised terms meant a few participants struggled to get away from the negative connotations of cancer, and its association with death. These perceptions could be exacerbated by the media, knowing friends or family members who had died of cancer, or men reporting having personality traits such as neuroticism, which translated into greater fears over their PCa.

> "*It's there in the back of your mind… cancer's an awful word, no matter which way you look at it*" (P6, AS, 70 years)

Positive reframing was also facilitated by making comparisons to others perceived as worse off, including other PCa patients on AT or those with different cancers or other illnesses, enabling them to put their own diagnosis into perspective. Comparisons to other life events that had been worse also helped them reframe their diagnosis in a positive light.

> *"……sometimes you just feel 'life is tough'. But …it's not the worst case scenario and people have far worse conditions and far worse diagnoses than I have, so therefore it's not something to worry too much about"* (P7, AS, 53 years)

Process 3: Taking an independent approach and getting on with life (vs. struggling to get on with life)

Most participants preferred to take an independent approach and described getting on with life, not feeling the need to utilise support services, whether NHS, charities or PCa support groups. Some felt further support would only be needed should they require treatment. The diagnosis was not commonly disclosed outside their immediate families, as men often felt there was no need to gain support and/or did not perceive the diagnosis as particularly threatening.

> *"I've never really said to anybody, 'I've got prostate cancer'. Not because it's the word cancer but, with the few cells with one sample it's very serious yet…"* (P21, WW, 69 years)

In contrast, some men who were struggling more discussed the importance of additional psychological support being available for men on AS/WW.

> *"The area that needs to be improved is the psychological support. Not everybody will want it or need it, but I do think it needs to be more proactive."* (P3, AS, 58 years)

Process 4: Acceptance and normalisation of cancer diagnosis (vs. struggling to accept and normalise PCa diagnosis)

Acceptance and normalisation of the diagnosis of PCa as relatively common in older men helped men dismantle the threat of cancer, facilitating positive adjustment. Some reflected that at their age they would eventually die of something.

> *"At 75, it's just one of those things. It's life"* (P5, AS, 75 years).

Others reported they were pleased to know their diagnosis and to be monitored while other men their age might have PCa and not be aware of it. Whilst some men initially struggled to accept and normalise their diagnosis this was felt to improve with the passing of time in some.

> *"I've grown to accept it. As time's gone on, you just sort of accept it more.. put it to the back of your mind as much as you can."* (P14, AS, 56 years)

Process 5: Preserving the normal self (vs. holding greater illness centrality)

For most men, the impact on their self-identities appeared to be minimal, and some did not identify as a cancer patient. Most men also reported little impact on their social or working lives, and felt normality had been restored.

> *"I never think: 'oh my goodness, I've got prostate cancer' other than talking with you [or] when I fill in medical questionnaires"* (P20, WW, 66 years)

Conversely, for men whose struggles were predominantly psychological, PCa appeared to be more central and impactful on their lives and self-identities.

> *"I've had to face up to the issues of mortality and potential for this to actually change my life very quickly.. So in that way it's made me, I self-identify in a different way"* (P3, AS, 58 years)

Process 6: Re-establishing a sense of security and letting go of fears (vs. struggling with uncertainty)

Re-establishing a sense of security following diagnosis helped facilitate positive adjustment. This was influenced by a strong sense of trust and confidence in the health care team, including good communication, a plan of action and continuity of care. Gaining reassurance their disease was low grade and contained was also important, as was receipt of stable PSA tests. Some participants discussed the value of receiving signposts to information resources which increased their confidence over future treatment and empowered men to ask health professionals more detailed questions about AS/WW.

> *"Emotionally I don't have a problem….Because I feel that the NHS are paying attention to me and are doing their job….They have stuck to what they have said and they have listened to me, talked to me and advised me"* (P18, WW, 73 years)

The few participants who were less well-adjusted appeared more dissatisfied with their past and/or current care, including support and information received. A lack of information or discussions on potential future treatments seemed to exacerbate uncertainties and made men feel '*left in the dark'* and worried about the future. A few expressed concerns over future treatment side effects. A lack of rapport with their health professional or feeling they had limited information contributed to feelings of disempowerment.

> *"A little bit upset, disappointed, worried what the future holds… I'm worried more about what the treatment options will be"* (P1, AS, 53 years)

Most participants referred to the uncertainty associated with not knowing if and when PCa may progress, and anxiety leading up to PSA testing was common. However, many reported increasing tolerance of this uncertainty and greater ability to get on with life and to let go of fears.

> *"As time goes by and nothing is getting worse I'm generally more reassured and I just carry on with life as per normal"* (P22, AS or WW*, 68 years)

A few men struggled more in dealing with uncertainty. Men were helped in tolerating uncertainty by the knowledge they were avoiding the side effects of AT and, should they need them, they might benefit from improved treatments in the future.

Discussion

This is the largest study of well-being in men on AS/WW to date. Survey findings suggest, overall, psychological well-being is good in men who have been on AS/WW for >18 months, and equivalent to or better than those on AT. These findings have been confirmed by interviews, which provide an insight into how most men adjusted positively to being on a monitoring pathway, whilst a minority adjusted less well. Positive adjustment has been conceptualised using a modified theory of adjustment to cancer [31].

Our findings are broadly consistent with previous quantitative studies [9-13], but appear to differ from some previous qualitative research, that reports persistent worry, altered social activities and greater psychological needs in men on AS/WW [15-18]. These studies were, however, based on much smaller samples of men on WW (<10 participants) [15, 16], those who switched from AS to AT [18] or focused on men closer to diagnosis. Men in our sample were 18-42 months post-diagnosis and it is possible those initially on AS experiencing greater anxiety had opted for AT within the study time-frame. While previous work [32] suggests a quarter of men on AS received AT within three years, the reasons behind this change are unclear.

Our interview findings highlight several factors influencing adjustment. As previously shown for PCa [33] and other cancer types [31, 34-36], illness perceptions were important in adjustment, influencing positive reframing and were often shaped by health professionals discussing the generally positive prognosis [31]. A nurse-led intervention to help men on WW cognitively reframe their diagnosis indicated uncertainty can be reduced and quality of life improved [37], but further larger scale work is warranted. Most men on AS did not feel they needed additional support services, so resources or future interventions should be targeted to patients with psychological problems, rather than all men on AS/WW. Similar to the theory used [31], acceptance and normalisation of their diagnosis, low illness centrality and positive reframing influenced positive adjustment, confirming previous findings in PCa patients [19, 20] and other cancer types [31, 34, 38].

These findings extend the theory employed [31] to illustrate the importance of having trust and confidence in health professionals to promote men's feelings of security from the threat of PCa monitoring. Previous studies have reported similar findings [15, 16, 39, 20]. A lack of confidence, information and reassurance were indicators of poorer adjustment, and some wanted greater information, particularly regarding future treatments. Elsewhere, predictors of poorer adjustment have included younger age, fear of recurrence, and misunderstandings towards active monitoring [11, 40, 20].

Clinical Implications

Clinicians should ensure men diagnosed with localised PCa fully understand the potentially indolent trajectory of PCa and that most men have positive psychological outcomes whilst on AS/WW. Patients on AS should have a clear plan of action regarding their surveillance protocol and should know when to expect investigations and subsequent results. Health professionals should routinely ask men about their psychological health at monitoring appointments, and use distress screening tools at diagnosis to assess suitability for AS/WW. Men who are struggling with managing distress should be offered an opportunity to discuss their concerns and offered information and support. Future research needs to develop tools that might facilitate such discussions, and indicate ways men might be encouraged to seek psychological support. Health professionals have a key role in helping to shape positive perceptions towards AS/WW pathways, helping men positively reframe and accept their diagnoses. For men who struggle with being on a monitoring strategy, alternative treatments should be offered where clinically appropriate.

Limitations

Despite a good survey response rate (61%), the potential for non-response bias must be acknowledged. It may be those who were more, or less, anxious chose not to participate. It is also possible anxiety levels may be higher in men closer to diagnosis, as suggested previously [40]. No measure of risk of progression was included, therefore it was not possible to control for this. Equally, disease stage could not be broken down further, so men with low and intermediate risk disease were included but we were unable to examine differences in outcomes between these groups. We considered men on either AS or WW, given the difficulties of determining which regime men were on. No difference in well-being was found between the AS or WW groups when analyses were repeated separately, which supported combining these groups.

Conclusions

Most men on a monitoring pathway for PCa appear to adjust well. An important minority adjust less well and need greater support. Results have identified ways in which health services can optimise the information and support provided to these men.

Words: 4496

Data availability statement

The datasets generated and/or analysed in the current study are not available publicly as eligible patients were informed at the time of the survey their data would be stored securely and confidentially.

Funding statement

The Life After Prostate Cancer Diagnosis study was funded by the Movember Foundation, in partnership with Prostate Cancer UK, as part of the Prostate Cancer Outcomes programme, grant number B026/MO.

Acknowledgements

The authors thank all the men who responded to the survey. We acknowledge the following people for their contribution to the development, setting up and running of the study: Rebecca Mottram, Majorie Allen, Heather Kinnear, Conan Donnelly, Oonagh McSorley, Victoria Cairnduff, Linda Roberts, Adrian Slater, Picker Institute Europe, the LAPCD User Advisory Group and Clinical and Scientific Advisory Group. We would particularly like to thank John Keenan and George Crawford for their comments on the manuscript. This study is based in part on information collected and quality assured by the cancer registries in each nation. Their work uses data provided by patients and collected by health services as part of their care and support.

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

References

1. Bray F, Lortet-Tieulent J, Ferlay J, Forman D, Auvinen A. Prostate cancer incidence and mortality trends in 37 European countries: an overview. *Eur J Cancer*. 2010;46(17):3040-52. doi:10.1016/j.ejca.2010.09.013.

2. Kinsella N, Helleman J, Bruinsma S, Carlsson S, Cahill D, Brown C *et al.* Active surveillance for prostate cancer: a systematic review of contemporary worldwide practices. *Transl Androl Urol*. 2018;7(1):83-97. doi:10.21037/tau.2017.12.24.
3. Gavin AT, Drummond FJ, Donnelly C, O'Leary E, Sharp L, Kinnear HR. Patient-reported 'ever had' and 'current' long-term physical symptoms after prostate cancer treatments. *BJU Int*. 2015;116(3):397-406. doi:10.1111/bju.13036.
4. Watson E, Shinkins B, Frith E, Neal D, Hamdy F, Walter F *et al.* Symptoms, unmet needs, psychological well-being and health status in survivors of prostate cancer: implications for redesigning follow-up. *BJU Int*. 2016;117(6B):E10-9. doi:10.1111/bju.13122.
5. Downing A, Wright P, Hounsome L, Kind P, Selby P, Wilding S *et al.* Quality of life in men living with advanced and localised prostate cancer: A United Kingdom population-wide patient-reported outcome study of 30,000 men. *The Lancet Oncology*. 2019.
6. Merriel SWD, Hetherington L, Seggie A, Castle JT, Cross W, Roobol MJ *et al.* Best practice in Active Surveillance for men with prostate cancer: A Prostate Cancer UK consensus statement. *BJU International*. 2019;0(ja). doi:10.1111/bju.14707.
7. National Institute For Health and Clinical Excellence. Prostate cancer: protocol for active surveillance. Implementing the NICE guideline on prostate cancer (CG175)2014.
8. Adolfsson J. Watchful waiting and active surveillance: the current position. *BJU International*. 2008;102(1):10-4. doi:10.1111/j.1464-410X.2008.07585.x.
9. Carter G, Clover K, Britton B, Mitchell AJ, White M, McLeod N *et al.* Wellbeing during Active Surveillance for localised prostate cancer: a systematic review of psychological morbidity and quality of life. *Cancer Treat Rev*. 2015;41(1):46-60. doi:10.1016/j.ctrv.2014.11.001.
10. Bellardita L, Valdagni R, van den Bergh R, Randsdorp H, Repetto C, Venderbos LD *et al.* How does active surveillance for prostate cancer affect quality of life? A systematic review. *Eur Urol*. 2015;67(4):637-45. doi:10.1016/j.eururo.2014.10.028.
11. Ruane-McAteer E, Porter S, O'sullivan JM, Santin O, Prue G. Active Surveillance for Favourable-Risk Prostate Cancer: Is there a Greater Psychological Impact than Previously Thought? A Systematic, Mixed Studies Literature Review. *Psycho-Oncology*. 2016.
12. Donovan JL, Hamdy FC, Lane JA, Mason M, Metcalfe C, Walsh E *et al.* Patient-Reported Outcomes after Monitoring, Surgery, or Radiotherapy for Prostate Cancer. *N Engl J Med*. 2016;375(15):1425-37. doi:10.1056/NEJMoa1606221.
13. Venderbos LDF, Aluwini S, Roobol MJ, Bokhorst LP, Oomens E, Bangma CH *et al.* Long-term follow-up after active surveillance or curative treatment: quality-of-life outcomes of men with low-risk prostate cancer. *Qual Life Res*. 2017;26(6):1635-45. doi:10.1007/s11136-017-1507-7.
14. Seiler D, Randazzo M, Leupold U, Zeh N, Isbarn H, Chun FK *et al.* Protocol-based active surveillance for low-risk prostate cancer: anxiety levels in both men and their partners. *Urology*. 2012;80(3):564-9. doi:10.1016/j.urology.2012.04.053.
15. Bailey DE, Jr., Wallace M, Mishel MH. Watching, waiting and uncertainty in prostate cancer. *J Clin Nurs*. 2007;16(4):734-41. doi:10.1111/j.1365-2702.2005.01545.x.
16. Hedestig O, Sandman PO, Widmark A. Living with untreated localized prostate cancer: a qualitative analysis of patient narratives. *Cancer Nurs*. 2003;26(1):55-60. doi:10.1097/00002820-200302000-00008.
17. Oliffe JL, Davison BJ, Pickles T, Mroz L. The self-management of uncertainty among men undertaking active surveillance for low-risk prostate cancer. *Qual Health Res*. 2009;19(4):432-43. doi:10.1177/1049732309332692.
18. Kazer MW. Conversion from active surveillance to active treatment for prostate cancer: A qualitative analysis. *Journal of Nursing Education and Practice*. 2012;2(2):80.
19. Rivas C, Matheson, L., Nayoan, J., Glaser, A., Wright, P., Gavin, A, Watson, E. and Wagland, R Men’s transformations following a prostate cancer diagnosis and opportunities for intervention: a metaethnographic study. Submitted.

20. O'Callaghan C, Dryden T, Hyatt A, Brooker J, Burney S, Wootten AC *et al.* 'What is this active surveillance thing?' Men's and partners' reactions to treatment decision making for prostate cancer when active surveillance is the recommended treatment option. *Psychooncology*. 2014. doi:10.1002/pon.3576 [doi]

10.1002/pon.3576.
21. Downing A, Wright P, Wagland R, Watson E, Kearney T, Mottram R *et al.* Life after prostate cancer diagnosis: protocol for a UK-wide patient-reported outcomes study. *BMJ Open*. 2016;6(12):e013555. doi:10.1136/bmjopen-2016-013555.
22. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care*. 2007;19(6):349-57. doi:10.1093/intqhc/mzm042.
23. Stewart-Brown S, Tennant A, Tennant R, Platt S, Parkinson J, Weich S. Internal construct validity of the Warwick-Edinburgh Mental Well-being Scale (WEMWBS): a Rasch analysis using data from the Scottish Health Education Population Survey. *Health Qual Life Outcomes*. 2009;7(1):15. doi:10.1186/1477-7525-7-15.
24. Kessler RC, Andrews G, Colpe LJ, Hiripi E, Mroczek DK, Normand SL *et al.* Short screening scales to monitor population prevalences and trends in non-specific psychological distress. *Psychol Med*. 2002;32(6):959-76. doi:10.1017/S0033291702006074.
25. Ng C, Kristjanson LJ, Medigovich K. Hormone ablation for the treatment of prostate cancer: the lived experience. *Urol Nurs*. 2006;26(3):204-12; discussion 15-8.
26. Prochaska JJ, Sung HY, Max W, Shi Y, Ong M. Validity study of the K6 scale as a measure of moderate mental distress based on mental health treatment need and utilization. *Int J Methods Psychiatr Res*. 2012;21(2):88-97. doi:10.1002/mpr.1349.
27. Ip S, Dahabreh IJ, Chung M, Yu WW, Balk EM, Iovin RC *et al.* An evidence review of active surveillance in men with localized prostate cancer. *Evidence report/technology assessment*. 2011(204):1.
28. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol*. 2013;13:117. doi:10.1186/1471-2288-13-117.
29. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG, editors. Analysing qualitative data. London: Routledge; 1994. p. 173-94.
30. QSR International Pty Ltd. NVivo qualitative data analysis Software: version 11. 2016.
31. Matheson L, Boulton M, Lavender V, Protheroe A, Brand S, Wanat M *et al.* Dismantling the present and future threats of testicular cancer: a grounded theory of positive and negative adjustment trajectories. *J Cancer Surviv*. 2016;10(1):194-205. doi:10.1007/s11764-015-0466-7.
32. Hamdy FC, Donovan JL, Lane JA, Mason M, Metcalfe C, Holding P *et al.* 10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer. *N Engl J Med*. 2016;375(15):1415-24. doi:10.1056/NEJMoa1606220.
33. Traeger L, Penedo FJ, Gonzalez JS, Dahn JR, Lechner SC, Schneiderman N *et al.* Illness perceptions and emotional well-being in men treated for localized prostate cancer. *J Psychosom Res*. 2009;67(5):389-97.
34. Matheson L, Boulton M, Lavender V, Collins G, Mitchell-Floyd T, Watson E. The Experiences of Young Adults With Hodgkin Lymphoma Transitioning to Survivorship: A Grounded Theory Study. *Oncol Nurs Forum*. 2016;43(5):E195-E2014. doi:10.1188/16.ONF.E195-E2014.
35. McCorry NK, Dempster M, Quinn J, Hogg A, Newell J, Moore M *et al.* Illness perception clusters at diagnosis predict psychological distress among women with breast cancer at 6 months post diagnosis. *Psycho-Oncology*. 2013;22(3):692-8. doi:10.1002/pon.3054.
36. Richardson EM, Schüz N, Sanderson K, Scott JL, Schüz B. Illness representations, coping, and illness outcomes in people with cancer: a systematic review and meta-analysis. *Psycho-Oncology*. 2017;26(6):724-37. doi:10.1002/pon.4213.

37. Bailey DE, Mishel MH, Belyea M, Stewart JL, Mohler J. Uncertainty intervention for watchful waiting in prostate cancer. *Cancer Nurs*. 2004;27(5):339-46.
38. Park CL, Bharadwaj AK, Blank TO. Illness centrality, disclosure, and well-being in younger and middle-aged adult cancer survivors. *Br J Health Psychol*. 2011;16(4):880-9. doi:10.1111/j.2044-8287.2011.02024.x.
39. Davison BJ, Oliffe JL, Pickles T, Mroz L. Factors influencing men undertaking active surveillance for the management of low-risk prostate cancer. *Oncol Nurs Forum*. 2009;36(1):89-96. doi:10.1188/09.ONF.89-96.
40. Bellardita L, Rancati T, Alvisi MF, Villani D, Magnani T, Marenghi C *et al.* Predictors of health-related quality of life and adjustment to prostate cancer during active surveillance. *Eur Urol*. 2013;64(1):30-6. doi:10.1016/j.eururo.2013.01.009.

Table 1. Respondent characteristics for men on active surveillance/watchful waiting (AS/WW) and men who received active treatment (AT)[a]

	AS/WW ***(n=3,986)***		**AT *(n=12,740)***		
	N	**%**	**N**	**%**	**p**[b]
Age group					
<55	97	2.4	310	2.4	0.20
55-64	703	17.6	2,271	17.8	
65-74	1,908	47.9	6,225	48.9	
74-85	1,124	28.2	3,537	27.8	
85+	154	3.9	397	3.1	
Ethnicity					
White	3,785	95.0	12,015	94.3	0.06
Non-white	95	2.4	376	3.0	
Unknown	106	2.7	349	2.7	
Socioeconomic deprivation quintile					
1 (least deprived)	1,139	28.6	3,339	26.2	0.02
2	1,028	25.8	3,467	27.2	
3	834	20.9	2,639	20.7	
4	559	14.0	1,835	14.4	
5 (most deprived)	344	8.6	1,209	9.5	
Unknown	82	2.1	251	2.0	
Marital status					
Married/civil partnership	3,154	79.1	10,226	80.3	0.09
Separated/divorced	280	7.0	946	7.4	
Widowed	297	7.5	805	6.3	
Single	157	3.9	456	3.6	
Other	54	1.4	173	1.4	
Unknown	44	1.1	134	1.1	
Sexuality					
Heterosexual	11976	97.4	3749	97.2	0.36
Homosexual	92	0.7	38	1.0	
Bisexual	42	0.3	17	0.4	
Don't know/prefer not to answer	183	1.5	52	1.3	
Unknown	447	3.6	130	3.4	
Other long term conditions					
None	1,216	30.5	3,714	29.2	0.34
1	1,408	35.3	4,565	35.8	
2	767	19.2	2,453	19.3	
3	317	8.0	1,119	8.8	
4 or more	278	7.0	889	7.0	
Employment status					
Employed	840	21.1	2,789	21.9	0.27
Unemployed	82	2.1	312	2.4	

Retired	2,945	73.9	9,211	72.3	
Other	15	0.4	62	0.5	
Unknown	104	2.6	366	2.9	
Carer status [c]					
Yes	929	23.3	3,026	23.8	0.57
No	2,897	72.7	9,209	72.3	
Unknown	160	4.0	505	4.0	
Previous consultation with health professionals for mental health or alcohol/drug problem [d]					
Yes	675	16.9	2,223	17.4	0.46
No	3,201	80.3	10,171	79.8	
Unknown	110	2.8	346	2.7	

[a] Men who received one of the 8 most common treatments: Surgery; Androgen Deprivation therapy (ADT); External Beam radiotherapy (EBRT); Brachytherapy; EBRT + ADT; Surgery + EBRT/ADT; Systemic therapy + ADT; Systemic therapy + EBRT (+/- ADT).

[b] Chi-square tests excluding the Unknown groups.

[c] Carer status refers to the question “do you look after, or give any help or support (not part of your paid employment) to family members, friends, neighbours or others because of either: long term physical or mental health disability, or problems relating to old age.”

[d] Previous consultation with Health Professionals refers to the question “have you ever in your lifetime seen a healthcare professional for problems with your emotions or nerves or your use of alcohol or drugs?”

Table 2. Psychological outcomes in men on active surveillance/ watchful waiting (AS/WW) and men who received active treatment (AT)

SWEMWBS	Poor well-being			Unadjusted model		Adjusted model[a]	
	No (>19.25)	Yes (≤19.25)	p	OR	95% CI	OR	95% CI
AT	10,335 (86.1%)	1,665 (13.9%)	0.02	1.00		1.00	
AS/WW	3,285 (87.7%)	462 (12.3%)		0.87	0.78-0.97	0.86	0.76-0.97
K6	**Severe mental distress**			**Unadjusted model**		**Adjusted model[a]**	
	No (<19)	**Yes (≥19)**	**p**	**OR**	**95% CI**	**OR**	**95% CI**
AT	11,534 (94.9%)	656 (5.4%)	0.05	1.00		1.00	
AS/WW	3,625 (95.6%)	174 (4.6%)		0.84	0.71-1.00	0.90	0.74-1.08

[a] Adjusted for age, ethnicity, socioeconomic deprivation, other long term conditions, marital status, employment status, carer status

OR: odds ratios; CI: confidence interval

Figure 1: Adjustment in men on a monitoring pathway for PCa