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Title Page

Title

How does Active Surveillance for prostate cancer impact on quality of life? A systematic review

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Abstract

Context: The optimal management for screen-detected localised prostate cancer remains controversial, related to over-treatment issues of screening and the non-randomised evidence base. Active Surveillance (AS) aims to delay or avoid curative therapy but may potentially harm patients' well-being through living with untreated prostate cancer.

Objective: To systematically review the literature on quality of life (QoL) in AS patients.

Evidence acquisition: Embase, Medline, Psychinfo, Cochrane Central, Web of Science and PubMed databases were searched in May 2014 using *quality of life (QoL)*, *active surveillance*, *prostate cancer*, their synonyms and targeted manual searches. The psychological dimensions related to HRQoL outcomes were anxiety and depression, distress, decisional conflict and mental health.

Evidence synthesis: Ten clinical and research-based AS studies worldwide measured HRQoL and related psychological facets in 6 cross-sectional studies and 4 cohorts (follow-up: 9-36 months, published: 2006-2014). Six studies were linked to published AS cohorts. In total, 966 AS men (mean 102/study) were assessed (mean age 66 years). AS patients had good overall HRQoL scores which were comparable or better than those of patients undergoing or post-radical treatment (comparator group in four studies), men's partners (one) and population-based data (three). Anxiety and depression scores were favourable. Selection bias may be present as none were randomised comparisons. Decreased psychological well-being may be partly predicted by AS patients' baseline and clinical characteristics.

Conclusions: AS patients reported good QoL and did not appear to suffer major negative psychological impacts. Longer follow-up is required as well as investigation into which patients are predisposed to negative impacts and leaving AS prematurely.

Patient summary: We reviewed the published evidence for quality of life impacts for men with prostate cancer being monitored by Active Surveillance (AS). The men who were on AS usually reported good levels of well-being and did not appear to suffer major negative psychological impacts. The research findings suggest little presence of anxiety and depression and high overall quality of life related to their disease. However, there are few long-term studies so more high quality research is needed to make definitive recommendations.

1. Introduction

The incidence of prostate cancer (PCa) worldwide is increasing as opportunistic screening becomes more widespread and average life expectancy rises [1]. A large randomised controlled trial showed disease-specific mortality benefits to population-based prostate cancer screening in Europe (ERSPC) [2,3] with less clear results in a similar trial in the USA (PLCO), possibly due to the high rates of prostate specific antigen (PSA) testing in their control group [4]. However, both over-diagnosis and resulting over-treatment are problematic sequelae of prostate cancer screening due to the low diagnostic specificity of PSA and prostatic biopsies.

Active Surveillance (AS) is an option for patients with favourable risk, localised PCa, which aims to avoid or delay radical treatments without compromising long term disease-specific survival. AS involves regular monitoring by multimode imaging, PSA and prostatic biopsies [5-7]. AS has existed for around fifteen years worldwide although uptake has generally been modest outside established research cohorts such as the PRostate cancer International Active Surveillance (PRIAS) study [8]. However, recent prominence of AS in American and European prostate cancer management guidelines will potentially further increase utilisation of this approach [9].

Radical treatment can result in lifetime impacts for patients' quality of life (QoL), including erectile, rectal and urinary dysfunctions [10]. AS patients can potentially avoid these consequences of radical treatment but may suffer negative psychological effects due to living with an untreated cancer and the fear of disease progression [11-13]. If AS patients experience heightened distress and anxiety, they are potentially more likely to opt for radical treatment in advance of protocol-based recommendations [14].

The need to understand the potential psychological burden of AS was identified during and international AS conference, in February 2014 in Amsterdam. This systematic review aimed to evaluate the published evidence on the health-related quality of life (HRQoL) and its related psychological dimensions in men undergoing AS to help inform clinical practice and treatment decision-making. Previous literature reviews in this area were either non-systematic [13-15] or combined HRQoL studies of AS patients with those of passive observation without radical intervention (“watchful waiting”, WW) for patients unsuitable for radical treatment [12] or were focused on the clinical outcomes of AS [5].

2. Evidence Acquisition

This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines [16] with predefined search terms, inclusion/exclusion criteria, data collection and analysis processes.

2.1 Study eligibility criteria. All study designs with quantitative HRQoL data from men with localised PCa receiving AS were eligible (without age restriction). This review focused on overall HRQoL and on the psychological dimensions related to HRQoL, i.e. anxiety, depression, decisional conflict, coping, distress, satisfaction, and mental health as well as other psychological factors potentially related to AS as shown in previous qualitative studies (e.g. uncertainty) and measured with standardised or validated questionnaires. Studies purely reporting on the physical aspects of HRQoL (e.g. urinary or bowel symptoms or erectile function) were ineligible. Studies either with men receiving WW, or where it was unclear if they were AS patients were excluded as QoL data for men on WW are not comparable to that from men on AS given the palliative aim of WW versus the curative intent of AS [9, 17]. Full-text original articles in English were eligible without restriction on publication date. If multiple papers originated from one dataset, we included the one with the longest follow-up period.

2.2 Search strategy and study selection. Studies were identified by searching electronic databases and scanning reference lists of selected articles. In May 2014, Embase, Medline, Psycinfo, Cochrane Central, Web of Science, and PubMed (strategy in Appendix 1) were searched using 'quality of life', 'active surveillance' and 'prostate cancer' and their relevant synonyms. Reference lists were also searched of potentially eligible publications and previous literature reviews of QoL and AS [13-15]. Two authors (I.K., L.B.) independently screened all the titles/abstracts and the resulting reference list was compiled by a third author (J.A.L.) for full text screening and data extraction. Disagreements were resolved by consensus.

2.3 Data collection. Three authors (J.A.L., I.K., L.B.) extracted data onto a form that was designed and piloted on six AS studies for one third of the selected references. Two other authors (L.V., R.vdB.) each checked half of the data extraction forms (randomly assigned) against the full-text papers. Data extracted included: study design, setting, timing of HRQoL assessments, country, AS protocol, outcomes, follow-up duration, study population (clinical, research or population registry), HRQoL data collection methods, inclusion/exclusion criteria, risk of bias, standardised/validated questionnaires, number of participants, response rates, responder and non-responder characteristics, effect estimates for outcomes and rates of leaving AS due to anxiety.

3. Evidence synthesis

The literature search identified 1,157 unique citations (Fig. 1 – flowchart); 1087 citations were excluded as they were reviews, commentaries, abstracts, validation of questionnaires or participants were on WW. Three citations were identified by searches of bibliographies, thus leaving 73 citations for a full-text screening. Of these, 63 citations were excluded. Major reasons for exclusion were that patients did not meet eligibility criteria for AS (n=27), no mental quality of life data was reported (n=9); papers reported on reviews (n=8) or that combined data was reported of men treated by various therapies (n=4).. Data extraction from these papers was concordant between the first and second reviewers. Table 1 presents the design, sample and key methodological features of the 10 included studies.

3.1 Study and AS patients characteristics. Seven of the 10 included AS studies were conducted in Europe, two in Northern America and one in Australia (Table 1). Three AS studies reported using the PRIAS protocol for monitoring patients, two the UCSF protocol and one the Royal Marsden Hospital protocol. The HRQoL assessments were reported between 2006-2014 and all the study designs were observational: six cross-sectional and four cohorts with follow-up up to three years in one cohort and up to a year in the others. Eight studies reported on QoL assessment at different time points after opting for AS; one of the selected studies reported specifically on predictors of QoL and one assessed the impact of a life-style change intervention in men on AS. The total number of AS patients was 996 ranging from 61-150 men per study (mean 102) with 557 patients who had undergone radical prostatectomy as the largest comparator group [21]. Mean age across the different studies was 66 years. Four studies used (combinations of) comparison groups of prostate cancer patients. These were men undergoing or having undergone active treatment; post radical prostatectomy (n=2), radiotherapy (n=4) and hormonal therapy (n=2). One study assessed men's partners and three used population-based data.

3.2 Outcomes. Fifteen different measures were used to assess the various facets of HRQoL and psychological dimensions (Table 2). Global HRQoL indexes were obtained by using the SF-36 [28] or SF-12 [29], the EORTC QLQ-C30 [30] and the Quality of Life – Cancer Survivors scale [31]. The Functional Assessment for Cancer Therapy scale was also used in one study to assess both general and prostate-related HRQoL (FACT-G and FACT-P) [32]. Mental health was measured with the SF-36 or SF-12 (four studies) mental health subscale. Two studies measured anxiety and depression with the Hospital Anxiety and Depression Scale (HADS) [33] and one with the Patient Health Questionnaire [34]; depression was also measured by the CES-D in one study [35]. The tools to assess anxiety were also the General Anxiety Disorder Scale [36] and the State Trait Anxiety Inventory [37]. Specific PCa-related anxiety was measured with the Memorial Anxiety for Prostate Cancer (MAX-PC) scale [38] in three studies. One study assessed stress levels by using the Perceived Stress Scale [39, another decisional conflict [40] and another coping (Mini-Mental Adjustment to Cancer Scale, (Mini-MAC) [41]. One study used the Distress Thermometer (DT) [42] which specifically measures psychological burden in oncology patients.

Overall HRQoL. High overall HRQoL scores were reported in seven AS studies, thus indicating good quality of life. No major differences were observed between the HRQoL scores of AS patients

and their comparison groups [19, 21, 23, 25, 26]. There were also no major changes in HRQoL after 9 or 12 months on AS in two PRIAS cohorts [24, 26]. Finnish PRIAS men also reported higher scores than a population sample at baseline and follow-up assessments, which the authors suggested may result from men with favourable psychological characteristics choosing AS. Vanagas et al. [25] highlighted that men on AS reported significantly better HRQoL than men who underwent radical treatment in both functional and symptom scales although these results by treatment group were not sub-divided by tumour stage.

Bellardita et al. [18] found that high levels of HRQoL were predicted by a patient having consulted several physicians about the choice of AS, by the presence of a partner, and a diagnostic biopsy with more than 18 core specimens. Daubennier et al. [20], comparing two groups of patients undergoing or not a lifestyle intervention, pointed out that participants of both groups reported high HRQoL at baseline; interestingly, those who improved their lifestyle, also enhanced their HRQoL further.

Mental health. Four studies reported on mental health by using the SF-36 mental health index and found that patients were doing well [20, 23, 24, 26]. Thong et al. found that mean mental health score of men on AS was about 80 and was similar to the mean score for a normative population, matched for age and sex, and up to ten years after diagnosis. In the same study it was highlighted that 17 AS patients with subjective perception of disease progression showed worse mental health scores than AS patients without such a perception of disease progression. In the Dutch PRIAS cohort the baseline mental health score was associated with 9-month follow-up scores [24] and there were no changes over 9 or 12 months follow-up in either of the two PRIAS cohorts [24, 26]. In summary, these findings do not seem to justify the concern that “living with untreated cancer” negatively impacts on the mental health of patients on AS. Longer term follow-up will be essential, however, to elucidate whether there may be later subtle erosion of patients’ mental health and wellbeing over time on AS.

Anxiety. There was a low frequency of general and disease-specific anxiety in all five AS studies that assessed anxiety (usually in the range of 4-15%) [19, 21, 22, 24, 27]. Two studies also highlighted that anxiety scores of AS patients were comparable to those of radical prostatectomy patients [19, 21]. Punnen et al. [21] compared a group of patients managed with AS with another group of men who underwent RP, finding that in both samples moderate to severe levels of anxiety were reported by less than 5%, and levels of mild anxiety ranged from 4% to 16%. Burnet et al. [19] highlighted that anxiety scores in patients who chose AS did not differ from those of patients who were being treated for PCa or were followed-up after radical treatment. In particular, authors noticed that younger men were more anxious than older men, and the longer the time since diagnosis the more anxious the men became. The general and PCa-specific anxiety declined slightly (<0.5 of a standard deviation) over 9 months in Dutch PRIAS patients but this was not clinically significant [24]. The fear of disease progression declined significantly over nine months (mean score 4.2 to 3.5, $p=0.005$) in the Dutch PRIAS cohort, which warrants further exploration in other AS cohorts. Furthermore, baseline scores were predictive of scores at nine months in this PRIAS cohort.

Seiler et al. [22] investigated the level of anxiety not only in patients with PCa, but in their wives as well, arguing that the partners could suffer more from the diagnosis than the men themselves. As predicted, the partners' anxiety scores indicated higher levels of concern than their husbands: overall, among men, the domain for PSA anxiety was rated very low (it should be noticed that in this cohort men do not dread PSA testing, despite having to undergo it regularly). More generally, since the values scored by both men and their partners were within the normal range of the general population, the authors concluded that anxiety for these individuals was not clinically relevant. Similarly, Wilcox et al. [27] underlined that the level of anxiety relating specifically to prostate cancer, in a cohort of Australian patients on AS, was below the defined threshold of clinical relevance.

Depression. Depression is an established response to a diagnosis of cancer which is unrelated to disease stage or severity [43]. Four studies showed that few AS patients reported depressive symptoms [19, 21, 22, 24]. No major changes in depressive symptoms were observed over the first nine months of AS in the Dutch cohort [24]. There were no major differences in depressive symptoms between AS and radical prostatectomy patients in the American study [21] nor in the Swiss cohort [22] with men's partners or population data. For instance, less than 5% of men in the UCSF cohort reported moderate-to-severe depression [21]. Burnet et al. [19], comparing three groups of patients (on AS; currently undergoing radical treatment; on follow-up after radical treatment), found that the extent of reported depression was associated with a longer interval since diagnosis, but not with being on AS.

Decisional conflict. The decisional conflict scale aims to elicit patients' uncertainty in making a health-related decision; the factors contributing to the uncertainty; and patients' perceived effective decision making. Van den Bergh et al. [24] found that the extent of reported decisional conflict was associated with shared decision making (large perceived physician role) and emotional insecurity. Considering the score of decisional conflict over time, authors highlighted that it appeared quite stable between the time of diagnosis (t1) and 9 months (t2) after diagnosis (only few men who scored within the normal range at t1 then exceeded the clinical threshold at t2). In a previous study on the same cohort, the same authors reported that men who elected AS in their cohort reported less decisional conflict than a cohort of American patients with localized PCa who had decided on their treatment (mostly radical prostatectomy) [44].

3.3 Predictors of QoL. HRQoL was predicted by baseline socio-demographic, clinical or other characteristics in two AS studies [18, 24]. In one study, [24] greater decisional conflict (linked to a higher perceived physician role in treatment decision-making) or a higher score in emotional instability predicted increased anxiety and distress at nine months whilst better physical health was associated with lower scores. In patients within their first 10 months of AS, having a partner, multiple physicians during AS selection and an extended diagnostic biopsy (> 18 cores) decreased the risk of experiencing poor QoL [18]. Additionally, AS patients with good coping or adjustment to cancer scores (i.e. fighting spirit, anxious preoccupation and helplessness/hopelessness) had higher QoL scores, whereas low coping scores were associated with the time taken between diagnosis and commencing AS.

3.4 Intervention studies. One intervention trial aimed to improve eating habits and physical exercise levels of AS patients [20]. There were no differences in HRQoL between the randomised groups from baseline to 12-months follow-up. It was also noted that some control group AS patients pursued lifestyle changes. Men participating in the ProtecT randomised trial of active monitoring (a surveillance strategy), radical prostatectomy and radiotherapy generally made healthy dietary changes following diagnosis (e.g. less red meat) with greater changes made by those on active monitoring [45].

3.5 Limitations of QoL AS studies. Summarising the 10 studies gave novel insights into the QoL of AS patients. However, none of the AS studies had a randomised comparison group, some were rather small or had limited follow-up. Most studies lacked an appropriate control group making it difficult to disaggregate the psychological impacts for AS patients of “living with untreated disease” and the general burden for cancer survivors [46, 47]. Measurement of the HRQoL across a wider demographic range of AS patients could enhance the generalisability of these results given that most studies did not report the ethnicity or socio-demographics of their patients. All 10 studies lacked assessment of men’s HRQoL before commencing on AS which may have introduced a self-selection bias and few studies made analytic adjustments for age or other demographic variables or missing data. Only two studies included men who left AS. Questionnaire performance metrics were poorly reported, e.g. the reliability, responsiveness and sensitivity of measures, thus making it difficult to assess the quality of findings. Moreover, the statistical significance of some HRQoL scores needs to be translated into quality of life differences that are meaningful to both patients and clinicians.

3.6 Limitations of the systematic review. Some relevant studies may have been omitted from this review as there are at least seven published AS cohorts worldwide and yet we only identified HRQoL results from three institutions participating in PRIAS, the Royal Marsden Hospital and UCSF cohorts. This may reflect the absence of HRQoL results from the other AS cohorts as HRQoL research into AS is relatively recent but it is unlikely to be a language bias as clinical data from these cohorts have been published in English. We excluded interview-based studies [48] which can give useful insights into men’s perspectives as they could not be combined with quantitative data and also studies where it was not possible to determine if patients were receiving passive observation (WW) or AS. Finally, the QoL outcomes could not be combined in a meta-analysis as there were no universal measures across the 10 studies so we were also unable to assess the overall impact of different AS protocols on HRQoL, including triggers for radical treatment.

3.7 Future directions. Understanding the complexity of the HRQoL of AS patients requires multidimensional assessment, including interpretation of QoL scores for clinical practice and patients. Longitudinal assessment of HRQoL with a core set of QoL measures in all AS cohorts to inform future meta-analyses would be advantageous with the PRIAS studies currently increasing the evidence base most strongly. Further investigation of the characteristics of men commencing AS that may predict subsequent psychological harms and their potential for leaving AS prematurely would be highly beneficial, including how patients interpret AS tools (e.g. PSA, imaging and biopsy results) which may also impact negatively their QoL and their decision to remain on AS. The partners of AS patients [22] were shown to experience slightly higher depressive symptoms

(but not anxiety) and lower general health status, role and emotional functioning than the men. Partners and other family members may be influential regarding initiation and maintenance on AS so further empirical data on the potentially mutual emotional influences and supportive role of partners/family could be instructive. Finally, the ProtecT randomised trial of prostate cancer treatments with HRQoL, anxiety and depression measured pre-diagnosis and annually for at least 10 years in active monitoring patients will report in 2016 [49] which should provide detailed insights both clinically and for AS patients on the immediate and long term psychological impacts of active surveillance.

4. Conclusions

Controversy exists around the nature and extent of the burden of living with untreated PCa for AS patients. This systematic review based on around 1,000 AS patients in 10 studies indicated no major perturbations to their HRQoL and psychological wellbeing in the first few years. These findings are, to our knowledge, the first systematic review to focus entirely on the HRQoL of AS patients. Limitations of the review included a potential self-selection bias as no studies were randomised, comparator groups were used infrequently and follow-up was limited. Nevertheless, men on AS generally reported high levels of overall HRQoL in the short term, which was comparable to men who underwent radical treatments. Anxiety, depression and distress also seemed not to represent a major burden for most AS patients in their first few years. However, assessment of anxiety, depression and distress should nevertheless be considered for AS patients and support offered where psychological distress is severe and unremitting over time [50] or arises during AS. Further research should aim to provide robust high quality long term data that can inform clinical practice, patients and the patient-physician decision making process.

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Appendix 1 Complete Search strategy

Question: How does *active surveillance* affect *quality of life* of men with *prostate cancer*?
Date: 22 May 2014
Databases: Embase, Medline (Ovid-SP), Cochrane Central (trials), PsycInfo, Web of Science, PubMed publisher (recent)

Results (after deduplication):

Total: 1812 (1157)

Embase(Embase plus Medline): 867 (864)

('Prostate Cancer'/exp OR (prostat* NEAR/6 (cancer* OR carcinom* OR tumor* OR tumour* OR neoplas* OR adenocarcino*)):ab,ti) AND ('Quality of life'/de OR 'Quality adjusted life year'/de OR 'Emotion'/exp OR 'Depression'/de OR 'Anxiety Disorder'/de OR 'Distress syndrome'/de OR 'Mixed anxiety and depression'/de OR 'Reactive depression'/de OR 'Stress'/exp OR 'Conflict'/de OR 'Psychological well being'/de OR 'Psychological aspect'/de OR 'Coping behavior'/de OR 'Satisfaction'/de OR 'Patient satisfaction'/de OR ((Quality NEAR/4 (life OR living)) OR QAL OR QALY OR HRQOL OR QOL OR emotion*OR depress* OR anxiet* OR anxious OR fear*OR stress* OR distress* OR resilien* OR nervous* OR nervos* OR worry* OR mood OR happiness OR happy OR unhapp* OR wellbeing OR well being* OR coping OR satisfaction* OR conflict OR conflicts OR uncertain* OR psycholog* OR psychosoci* OR (psycho NEXT/1 soci*)):ab,ti) AND ('Disease surveillance'/de OR 'Patient monitoring'/exp OR 'Watchful waiting'/de OR (((active OR patient OR observation*) NEAR/3 (surveillance OR monitoring)) OR watchful OR (expectant NEXT/1 manag*)):ab,ti) NOT ([animals]/lim NOT [humans]/lim)

Medline OVID-SP: 373 (82)

(exp "Prostatic Neoplasms"/ OR (prostat* ADJ6 (cancer* OR carcinom* OR tumor* OR tumour* OR neoplas* OR adenocarcino*)):ab,ti.) AND ("Quality of life"/ OR "Quality adjusted life years"/ OR exp "Emotions"/ OR "Depression"/ OR "Anxiety Disorders"/ OR "Depressive Disorder"/ OR "Behavioral symptoms"/de OR "Mental Fatigue"/de OR "Stress, Psychological"/ OR "Conflict (Psychology)"/ OR "Personal Satisfaction"/ OR exp "Patient Satisfaction"/ OR exp "Adaptation, Psychological"/ OR "psychology".xs. OR ((quality ADJ4 (life OR living)) OR QAL OR QALY OR HRQOL OR QOL OR emotion* OR feeling* OR depress* OR anxiet* OR anxious OR fear*OR stress* OR distress* OR resilien* OR nervous* OR nervos* OR worry* OR mood OR happiness OR happy OR unhapp* OR wellbeing OR well being* OR coping OR satisfaction* OR conflict OR conflicts OR uncertain* OR psycholog* OR psychosoci* OR (psycho ADJ soci*)):ab,ti.) AND ("Disease surveillance"/ OR "Patient monitoring"/ OR "Watchful waiting"/ OR (((active OR patient OR observation*) ADJ3 (surveillance OR monitoring)) OR watchful OR (expectant ADJ manag*)):ab,ti.) NOT (animals NOT humans).sh.

PsycInfo: 49 (22)

((exp "Neoplasms"/ AND ("Prostate"/ OR prostat*.ab,ti.)) OR (prostat* ADJ6 (cancer* OR carcinom* OR tumor* OR tumour* OR neoplas* OR adenocarcino*)):ab,ti.) AND (exp "Quality of life"/ OR exp "Emotions"/ OR "Emotional Stability"/ OR "Emotional Instability"/ OR "Depression (Emotion)"/ OR exp "Anxiety"/ OR exp "Behavior"/ OR "Psychological Stress"/ OR "Resilience (Psychological)"/ OR "Psychological Endurance"/ OR "Uncertainty"/ OR "Life Satisfaction"/ OR "Well being"/ OR "Mental Health"/ OR "Adjustment"/ OR "Adjustment Disorders"/ OR ((quality ADJ4 (life OR living)) OR QAL OR QALY OR HRQOL OR QOL OR emotion* OR feeling* OR depress* OR anxiet* OR anxious OR fear*OR stress* OR distress* OR resilien* OR nervous* OR nervos* OR worry* OR mood OR happiness OR happy OR unhapp* OR wellbeing OR well being* OR coping OR satisfaction* OR conflict OR conflicts OR

uncertain* OR psycholog* OR psychosoci* OR (psycho ADJ soci*).ab,ti.) AND (exp "Attention"/ OR "Disease management"/ OR (((active OR patient OR observation*) ADJ3 (surveillance OR monitoring)) OR watchful OR (expectant ADJ manag*).ab,ti.)

Cochrane Central (trials): 35 (5)

((prostat* NEAR/6 (cancer* OR carcinom* OR tumor* OR tumour* OR neoplas* OR adenocarcino*)):ab,ti) AND (((quality NEAR/4 (life OR living)) OR QAL OR QALY OR HRQOL OR QOL OR emotion*OR depress* OR anxiet* OR anxious OR fear*OR stress* OR distress* OR resilien* OR nervous* OR nervos* OR worry* OR mood OR happiness OR happy OR unhapp* OR wellbeing OR well being* OR coping OR satisfaction* OR conflict OR conflicts OR uncertain* OR psycholog* OR psychosoci* OR (psycho NEXT/1 soci*)):ab,ti) AND (((active OR patient OR observation*) NEAR/3 (surveillance OR monitoring)) OR watchful OR (expectant NEXT/1 manag*)):ab,ti)

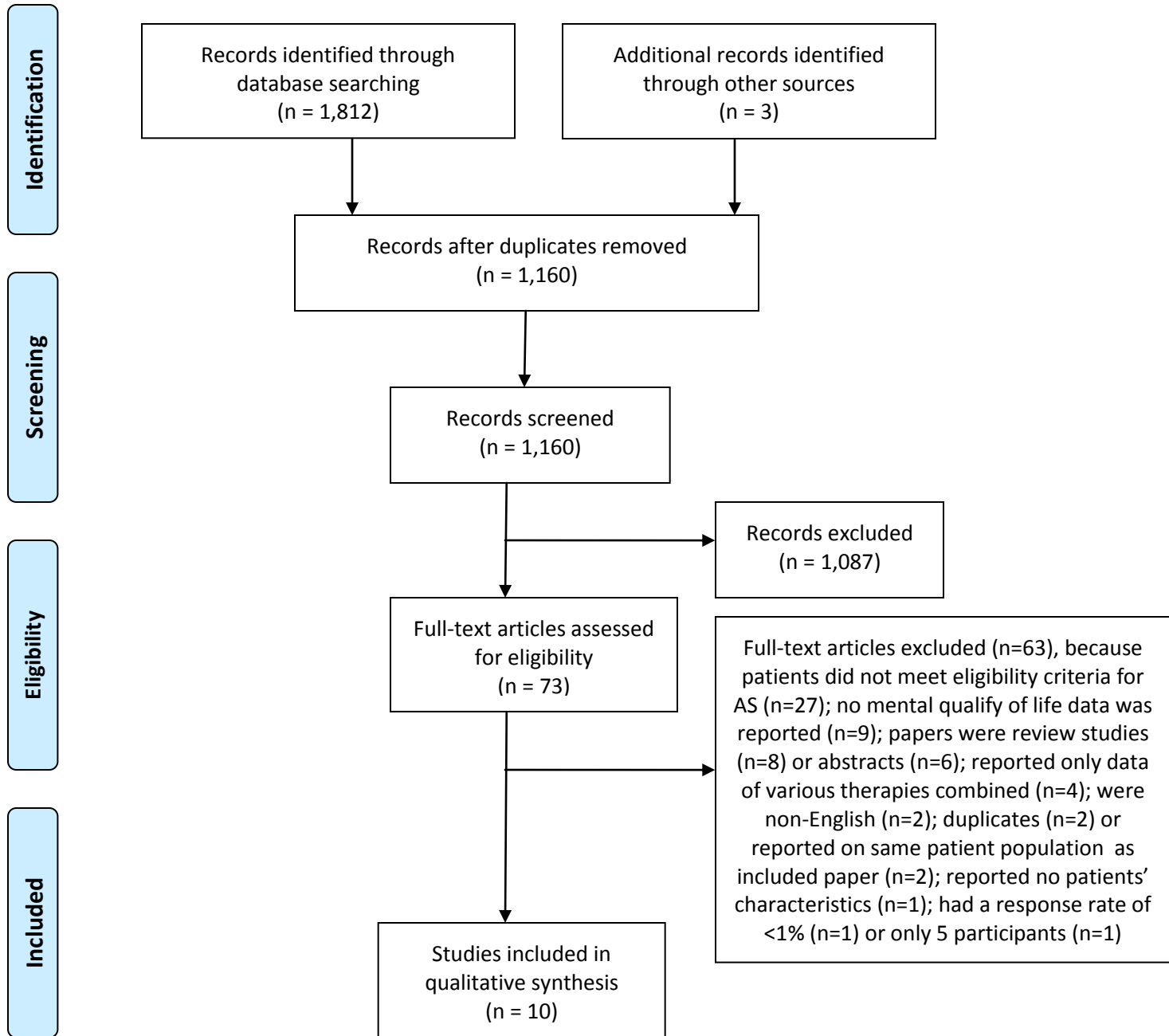
Web of Science: 472 (172)

TS=(((prostat* NEAR/6 (cancer* OR carcinom* OR tumor* OR tumour* OR neoplas* OR adenocarcino*))) AND (((quality NEAR/4 (life OR living)) OR QAL OR QALY OR HRQOL OR QOL OR emotion*OR depress* OR anxiet* OR anxious OR fear*OR stress* OR distress* OR resilien* OR nervous* OR nervos* OR worry* OR mood OR happiness OR happy OR unhapp* OR wellbeing OR well being* OR coping OR satisfaction* OR conflict OR conflicts OR uncertain* OR psycholog* OR psychosoci* OR (psycho NEXT/1 soci*))) AND (((active OR patient OR observation*) NEAR/3 (surveillance OR monitoring)) OR watchful OR (expectant NEXT/1 manag*))) NOT ((animal* OR mice OR mouse OR pig OR pigs OR rats) NOT human*))

PubMed recent (as supplied by publisher): 16 (12)

(prostat*[tiab] AND (cancer*[tiab] OR carcinom*[tiab] OR tumor*[tiab] OR tumour*[tiab] OR neoplas*[tiab] OR adenocarcino*[tiab])) AND ((Quality[tiab] AND (life[tiab] OR living[tiab])) OR QAL[tiab] OR QALY[tiab] OR HRQOL[tiab] OR QOL[tiab] OR emotion*[tiab]OR depress*[tiab] OR anxiet*[tiab] OR anxious[tiab] OR fear*[tiab]OR stress*[tiab] OR distress*[tiab] OR resilien*[tiab] OR nervous*[tiab] OR nervos*[tiab] OR worry*[tiab] OR mood[tiab] OR happiness[tiab] OR happy[tiab] OR unhapp*[tiab] OR wellbeing[tiab] OR well being*[tiab] OR coping[tiab] OR satisfaction*[tiab] OR conflict[tiab] OR conflicts[tiab] OR uncertain*[tiab] OR psycholog*[tiab] OR psychosoci*[tiab] OR psycho soci*[tiab]) AND (((active[tiab] OR patient[tiab] OR observation*[tiab]) AND (surveillance[tiab] OR monitoring[tiab])) OR watchful[tiab] OR expectant manag*[tiab]) AND publisher[sb])

Figure 1. PRISMA Flow Diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

Table 1

Active Surveillance study (AS), publication date	QoL study design	Assessment period	AS protocol Setting Country Total sample/response rate	N of AS men (mean age in years)	N of control men (mean age in years); Population data (PD)
Bellardita, 2013 [18]	Cohort	2007-2012	PRIAS Research Italy 154/67%	154 (67)	None
Burnet, 2007 [19]	Cross-sectional	NR	Royal Marsden Hospital Research United Kingdom 493/72% (24 excluded)	100 (67)	Radical treatment (=HT or RT; 81); or post-radical treatment (148)
Daubenmeier, 2006 [20]	Cross-sectional	NR	UCSF Research USA 93/NR	44 men on AS assigned to a lifestyle intervention (65)	49 men on AS assigned to usual-care control group (66)
Punnen, 2013 [21]	Cohort	2007-2010	UCSF Clinical USA 864/77%	122 newly diagnosed, no active treatment >6m post-diagnosis (61)	557 post-RP (60)
Seiler, 2012 [22]	Cross-sectional	2010	NR Clinical Switzerland 282/47%	133 with Epstein eligibility criteria (69)	133 partners of AS men PD
Thong, 2009 [23]	Cross-sectional	2004	Not protocol-based Clinical The Netherlands 128 from registry data eligible for AS /55%	71 (76)	71 men post-RT (76) patients of similar age and comparable disease characteristics PD

van den Bergh, 2010 [24]	Cohort	2007-2008	PRIAS Research The Netherlands 150/86%	129 (65)	None
Vanagas, 2013 [25]	Cross-sectional	2010-2011	NR Clinical Lithuania 650/79%	61 (NR)	92 post-RP, 73 post-RT and 187 on HT + 88 including CH and combined therapy (NR)
Vasarainen, 2012 [26]	Cohort	2006	PRIAS Research Finland 124/85%	105 (64)	None PD
Wilcox, 2014 [27]	Cross-sectional	2013	NR Clinical Australia 61/77%	47 (NR)	None

Table 1. Overview of Active Surveillance for prostate cancer QoL studies

AS = Active Surveillance; HT = hormone therapy, PRIAS= PRostate cancer International Active Surveillance; PCa = prostate cancer;; RM=Royal Marsden Hospital; RP = radical prostatectomy, RT = radiotherapy; CH = chemotherapy; UCSF = University of California San Francisco; NR = not reported; PD = population data.

Table 2

Active Surveillance (AS) study, year of publication	QoL outcomes	QoL standardised measures	Baseline assessment (T1); months of follow-up (T2, T3)	Key findings	Quality of life on AS
Bellardita, 2013 [18]	HRQoL, coping	FACT-P, FACT-G, Mini-MAC	T1 = AS enrolment; T2 = 10	QoL predicted by lack of a partner; recent diagnosis, influence of physicians on decision, number of biopsy cores; impaired mental health at enrolment	Only a minority of patients reported low levels of QoL which could be predicted by patients' characteristics at baseline
Burnet, 2007 [19]	Anxiety, depression	HADS	T1 = AS enrolment; during or post-treatment for control subjects	33% of participants had high anxiety (mean 6.14 SD 3.76) and 11% met criteria for depression (mean 3.68 SD 3.07); threshold ≥ 8 based on normative sample	No major treatment effects on anxiety or depression
Daubenmeier, 2006 [20]	HRQoL (MH index), stress	SF-36, Perceived Stress Scale	T1 = post-randomisation before intervention; T2 = 12	Mental health scores did not change between T1 and T2 in both lifestyle change and control group (mean 51 and 56, respectively); Perceived stress scores remained about 1 in both groups at T1 and T2.	Men in the intervention group improved their life-style but no significant differences between groups were found from baseline to 12 m follow-up as far as QoL; lifestyle index scores were significantly related to scores on SF-36 subscales
Punnen, 2013 [21]	Anxiety, depression, distress	Patient Health Questionnaire; General Anxiety Disorder Scale; Distress Thermometer	T1= before RP or <6m from diagnosis for AS; T2= <1 yr after T1; T3= between 1 and 3yrs post-T1	Rates of moderate-to-severe depression were <5% in both groups; mild depression was reported by 3% to 12% of participants; anxiety was moderate to severe in <5% of men, mild in 4% to 16% in both groups; $\geq 4\%$ of men reported high distress scores.	No significant differences between AS and RP in severity of anxiety and/or depression nor in the proportion of men with high distress scores.
Seiler, 2012 [22]	HRQoL, general and PCa- anxiety, depression	HADS, MAX-PC, EORTC QLQ-C30	T1 = median of 45 m from diagnosis, 17, 32, 59 or 136 months	Patients' HRQoL scores were similar or higher to normative population scores; MAX-PC scores were lower than the reference value for 91.7%; 85.7% scored below the reference value of the HADS domains.	No major overall or disease-specific anxiety or distress at 4 times post-diagnosis for men; possibly more impact for partners

Thong, 2010 [23]	HRQoL (mental health)	SF-36, Quality of Life - Cancer Survivors	T1 = mean of 8 yrs on AS	No significant differences between AS, RT groups and PD AS men with disease progression had worse mental and emotional health	No major impacts on QoL for men up to 10 y on AS compared with RT. Negative impacts for those with disease progression on AS.
van den Bergh, 2010 [24]	HRQoL (MH index), anxiety, depression, decisional conflict	DCS, CES-D, STAI-6, MAX-PC, SF-12	T1 = <6 m from diagnosis; T2 = 9	Anxiety scores decreased as STAI (p = 0.016) and MAX-PC fear of progression (p= 0.005) with decreases > 0.5 SD (not clinically relevant); the incidence of men scoring above clinical thresholds at t1 and t2 was 20% and 25% for DCS; 6% and 8% for CES-D; 17% and 12% for STAI-6; and 7% and 9% for MAX-PC, respectively.	Anxiety and distress were clinically stable over 9 months. Baseline characteristics partly predicted distress and anxiety during follow-up
Vanagas, 2013 [25]	HRQoL ₇	EORTC QLQ-C30	NR	Mean scores for EORTC QLQ-C30 functional scales range was 73-90 for men on AS; AS men had highest emotional, role and social functioning scores of PCa treatments	Favourable QoL profile for AS patients compared with radical treatment or HT
Vasarainen, 2012 [26]	HRQoL (MH index)	SF-36	T1 = start of AS; T2 = 12	SF36 scores ranged from 65 (general health index) to 91 (social functioning) at T1 and from remained stable at T2; MH index mean score was 81 at both times.	No differences were found between baseline and follow-up assessment; men on AS who had better quality of life than the reference group (normative population).
Wilcox, 2014 [27]	PCa-related anxiety	MAX-PC	NR	The mean overall MAX-PC was 15.5 (95% CI 13.4–17.6) with subscale results of 7.4/33 for general anxiety (95% CI 5.5–9.3), 0.8/9 for PSA specific anxiety (95% CI 0.3–1.3) and 7.3/12 for fear of recurrence (95% CI 6.5–8.2).	No disease specific anxiety reported in Australian men

Table 2. QoL measurement, outcomes and key findings from AS for prostate cancer studies.

QoL = quality of life; HRQoL = health-related quality of life; MH = mental health; FACT-P = Functional Assessment of Cancer Therapy – Prostate version; FACT-G = Functional Assessment of Cancer Therapy – General; Mini-MAC = Mini-Mental Adjustment to Cancer;; HADS = Hospital Anxiety and Depression Scale; SF-36 = Short form 36; MAX-PC = Memorial Anxiety scale for Prostate Cancer; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire 30; DCS = Decisional Conflict Scale; CES-D = Center for Epidemiologic Studies Depression Scale; STAI-6 = State-Trait Anxiety Inventory; SF-12 = Short Form 12; PD = Population Data; PCa = prostate cancer; HT = hormone therapy; RP = radical prostatectomy; RT = radiotherapy; m = months; NR = not reported.

Take home message

Active surveillance for prostate cancer appears to have no major impacts on health-related quality of life and psychological wellbeing in the first few years. However, there is no randomised evidence and results are limited over the longer term.