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Anxiety associated with prostate cancer screening with special reference to men with a positive screening test (elevated PSA) – Results from a prospective, population-based, randomised study

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ABSTRACT

Levels of anxiety were assessed through questionnaires completed by 1781 screen-positive (PSA ≥ 3 ng/mL) men attending the European Randomised Study of Screening for Prostate Cancer in Gothenburg, Sweden. During the first visit (clinical examination, including biopsies), no anxiety whilst awaiting the PSA test results was reported by 66% and 2% reported high levels of anxiety. A multinomial logistics model for repeated measurements, adjusted for age, PSA level, heredity, biopsy finding and urinary symptoms, revealed that anxiety awaiting the PSA was only influenced (increased) by the existence of previously elevated PSA tests ($p < .0001$). No anxiety associated with biopsy was reported by 45%, while 6% experienced high levels of anxiety. Levels of anxiety decreased significantly with subsequent rounds of examinations ($p < 0.0001$) and with increasing age ($p = 0.0016$). Anxiety associated with prostate cancer screening in general is low to moderate, even in men with elevated PSA, and severe anxiety affects a smaller group of susceptible men.

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1. Introduction

Prostate cancer is a major health problem in Western countries. In Sweden, prostate cancer is the most common cancer and the leading cause of cancer death among Swedish men.¹ Screening with determination of prostate-specific antigen (PSA) has to date not been recommended by Swedish authorities, mainly due to the absence of randomised trials on the benefits of early detection. To evaluate the effectiveness of prostate cancer screening in terms of decreased prostate cancer mortality, two large-scale, randomised, population-based trials are currently in progress: the European randomised study of screening for prostate cancer (ERSPC) in Europe and the prostate, lung, colorectal, and ovarian (PLCO) cancer-

screening trial in the United States.² Analyses of the end-points of these trials are scheduled for 2008. However, if the outcome is to provide evidence that participants will benefit from screening programmes, such programmes must take into account the participants' tolerance of the methods used and the potential psychological morbidity associated with the screening procedures. One objection to population screening in general has been the assumption that invitation to and participation in a screening examination for cancer cause psychological distress.^{3,4} Previous studies on prostate cancer screening and anxiety diverge. It has been shown that attendance for screening for prostate cancer does not seem to cause any major psychological distress in the majority of men.^{3–6} However, as expected, higher levels of psychological

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distress have been observed in those who turn out to be screen-positive,⁷ especially while waiting for biopsy results.^{4,8,9} In prostate cancer screening, at least 10% of men will have an elevated PSA value ('screen-positive'). Due to the low specificity of PSA, only 25% of these men will turn out to have prostate cancer and 75% are thus 'false-positives'.¹⁰ Most of these men will continue with elevated PSA and will be screen-positive in subsequent screening rounds,¹¹ and more biopsies will be required. This group of men with persistently elevated PSA values is probably the group which is most susceptible to developing psychological distress due to screening. Previous studies have shown that men with a suspicious screening test but benign biopsy report increased cancer-related worry compared with men with normal PSA.^{12,13} Indeed, one could fear that psychological distress in these men would escalate over time. However, the anxiety over a long period of time in men examined repeatedly because of persistently elevated PSA has not been previously reported.

The present study is part of the Gothenburg branch of the ERSPC trial focusing on the aspects of men's reported anxiety related to the screening procedures. The aim of the study was to only evaluate the degree of anxiety among men who turned out to be screen-positive, i.e. those who had elevated PSA values (≥ 3 ng/mL). The study focuses on anxiety associated with waiting for the results of PSA measurement and anxiety concerning the invitation to attend clinical examination (including prostate biopsies). A secondary objective was to study possible influences of age, PSA level, heredity, lower urinary tract symptoms, biopsy finding and round of examination.

2. Materials and methods

2.1. Population

The Gothenburg, Sweden, branch of the ERSPC was established in 1995. As of December 31, 1994, there were 32,298 men living in the city of Gothenburg who were born between 1st January 1930 and 31st December 1944. The study cohort of 20,000 of these men was selected by a blinded computer randomisation. The cohort was divided into an intervention group and a control group of 10,000 men in each. Using the regional cancer registry, males with prevalent prostate cancer were excluded. This yielded an intervention group of 9972 men and a control group of 9973. Men in the intervention group were invited for the measurements of serum PSA every second year until they reached the age of 70 years, with the first screening round performed between January 1995 and December 1996. To date, five screening rounds have been completed, analysed and referred to in this study. The screening trial was approved by the Ethics Committee at Göteborg University in 1994.

2.2. Design

If the PSA value was below 3 ng/mL, no further investigations were made. These men were offered re-screening with PSA every second year. Men with elevated PSA (≥ 3 ng/mL) were informed of their PSA result through a standardised letter.

In the same letter these men were invited to a clinical examination and they were informed that they had about a 15% risk of prostate cancer. The clinical examination comprised digital rectal examination and transrectal ultrasound (TRUS) with concomitant laterally directed sextant biopsy of the prostate. Men with elevated PSA and benign biopsy findings were re-invited for biennial measurement of PSA. Every time the PSA was elevated, the participants were invited for a new TRUS and biopsy. Hitherto, one participant could have attended a maximum of five clinical examinations. Non-responders in every screening round were re-invited for another PSA measurement in the following round. The consort diagram in Fig. 1 shows the study design.

2.3. Measures

In the waiting room, immediately before biopsy, men with elevated PSA values invited to undergo clinical examination were requested to fill in a questionnaire concerning their experienced anxiety. Two questions yielded information on levels of anxiety: 'Do you experience anxiety whilst awaiting the results of the PSA measurement?' and 'Do you experience anxiety on receiving an invitation to the clinical examination (due to an elevated PSA)?' The questions permitted three levels of anxiety: 0 = 'No', 1 = 'Intermediate' or 2 = 'High'. Information on family history of prostate cancer and lower urinary tract symptoms was obtained from the same questionnaire. Heredity was graded into two different categories: 'Heredity' or 'No heredity'. The intensity of lower urinary tract symptoms was graded as 'No', 'Minor' or 'Major'. Biopsy findings were classified as 'Cancer' or 'Benign biopsy finding'.

2.4. Statistical analysis

Descriptive statistics in terms of frequencies and percentages were calculated using conventional methods. Tables were calculated using SPSS® 12.0.1 statistical software. A multinomial logistics model for repeated measurements of individuals was performed to analyse the impact of the covariates age, PSA level, heredity, symptoms of urinary outflow obstruction, irritative urinary symptoms, biopsy finding and round of examination on anxiety. To avoid selection problems, only men with repeated measures (longitudinal data) were incorporated into the multinomial logistics model. We assumed that data followed a proportional odds model when analysing the impact of these covariates. The intensity of lower urinary tract symptoms was analysed statistically as 'No symptoms' or 'Symptoms' (including minor or major symptoms). Odds ratios (ORs) and confidence intervals (CIs, 95%) for all covariates were calculated. The relative risk (RR) was calculated using conventional methods when analysing the probability of reporting high levels of anxiety at repeated screening as shown in Table 5. The χ^2 -test was used for testing the level of significance. The possible relationship between non-participation rate and degree of self-reported anxiety (Table 2) was also analysed by means of the χ^2 -test. P values ≤ 0.05 were considered significant. Statistical analyses were performed using SAS® 9.1.3. statistical software.

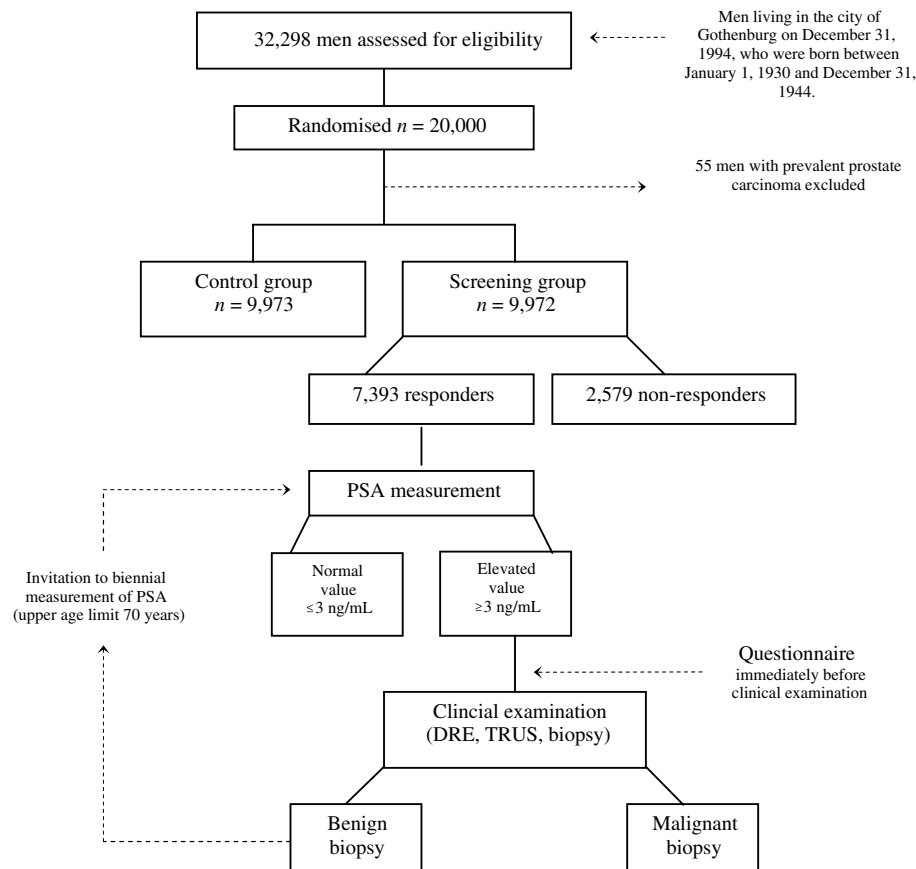


Fig. 1 – Consort diagram. DRE = digital rectal examination, TRUS = trans-rectal ultra sound examination.

3. Results

Of 9972 men allocated to the screening group, 7393 were responders, i.e. they attended the screening programme at least once. Of the responders, 1926 men had elevated PSA values at least once within these five first screening rounds. The number of men who participated in repeated investigations decreased for a number of reasons, such as normalisation of PSA, prostate cancer diagnosis, death, reaching the upper age limit of 70 years and hence not being invited any more, or true non-responders. The attendance rate for clinical examination in those with elevated PSA was high, as was the percentage of men who completed the questionnaire (Table 1). The true non-participation rate in those with one previous positive screening round (i.e. a repeated invitation in previous screen-positive individuals but with no cancer in the first round) was low, around 10%, and was not related to the level of reported anxiety (Table 2).

The majority of men in the screened population with elevated PSA values reported that the time awaiting the results of PSA measurement was associated with no anxiety. This was true for every examination round (Fig. 2). Prior to the first clinical examination, no anxiety awaiting the results of PSA measurement was reported by 66%, intermediate levels of anxiety were reported by 32% and 2% reported high levels of anxiety. Among men with repeatedly elevated PSA values,

multinomial logistics regression analyses controlling for age, PSA level, heredity, biopsy finding and obstructive and irritative urinary symptoms revealed that levels of anxiety awaiting the results of PSA measurement was only influenced by the existence of previous elevated PSA tests ($p < 0.0001$), although the majority of men reported no anxiety, regardless of the number of previous positive screen tests. Men reported a lower degree of anxiety at first-time elevation compared to subsequent screening with recurrent PSA elevation (Table 3). The degree of anxiety measured at first-time elevation did not differ between men who had PSA measured for the first time and men who had normal PSA test(-s) at the previous screening.

As regards anxiety associated with further clinical examinations, 45% of the participants reported no anxiety prior to the first clinical examination, while 49% reported intermediate levels of anxiety and 6% experienced high levels of anxiety (Fig. 3). Levels of anxiety prior to clinical examination decreased significantly with repeated examinations ($p < 0.0001$). The degree of anxiety was also influenced by and inversely related to age. Though modest effects, levels of anxiety decreased with increasing age ($p = 0.0016$). None of the covariates, PSA level, biopsy finding, lower urinary tract symptoms or heredity, had an effect on the degree of anxiety. (Table 4) For both anxiety awaiting PSA measurement and anxiety associated with further clinical examination, it was

Table 1 – Attendance rates and questionnaire frequencies at first to fifth time of PSA elevation

	Total number of men with elevated PSA	Total number of men who accepted clinical examination		Total number of men who answered questionnaire	
	No.	No.	(%)	No.	(%)
First-time elevation	1926	1819	(94.4)	1781	(92.5)
Second-time elevation	861	790	(91.8)	770	(89.4)
Third-time elevation	407	379	(93.1)	374	(91.9)
Fourth-time elevation	174	167	(96.0)	163	(93.7)
Fifth-time elevation	64	60	(93.8)	60	(93.8)

This table shows the total number of men with elevated PSA values, the number of men who accepted clinical examination and the number of men who answered the questionnaire at the first, second, third, fourth and fifth time, if a persistently elevated PSA value was found. The number of men who accepted clinical examination is expressed as a percentage of the number of men with elevated PSA. The number of men who answered the questionnaire is given as a percentage of the number of men who accepted clinical examination.

the first round compared to subsequent rounds that showed a significant difference in anxiety levels, but no difference was observed between subsequent rounds (second to third, third to fourth and so on).

The level of anxiety reported at first examination had a significant influence on the level of anxiety reported at subsequent examinations. A man who reported a high level of anxiety at his first examination had more than a 30-fold increased risk of reporting a high level of anxiety at subsequent examination compared to men who reported no anxiety (Table 5).

4. Discussion

Experiences of adverse psychological effects from attending screening for prostate cancer have not been studied extensively. The present study focused on aspects of men's reported anxiety related to the screening procedures within the Swedish branch of the ERSPC. Among a total of 1781 screen-positive men included in this study, few men reported high levels of anxiety awaiting the results of PSA measurement. Furthermore, very few men experienced high levels of anxiety regarding the invitation to attend clinical examination,

despite elevated PSA levels. These findings concur entirely with Brindle and colleagues who found that the receipt of an abnormal PSA test and attendance for further clinical investigation did not appear to have an impact on psychological health among men screened for prostate cancer within ProtecT (prostate testing for cancer and treatment) in the UK.¹⁴

Participation rates were high in the present study. The number of men with PSA elevation who also accepted clinical examination was high. The majority of these men completed the questionnaire. There was no relationship between the non-participation rate at the subsequent screening round and the degree of self-reported anxiety at the first round. However, it ought to be mentioned that we do not have information on non-participants who did not attend the first screening round. Did men who refused the first PSA testing, or who did not accept clinical examination, do so because of psychological distress? Essink-Bot challenged the hypothesis of psychological self-selection.⁴ They hypothesised that men with a predisposition to anxiety would be more likely not to respond to a screening invitation. However, they found no difference between attendants and non-attendants, i.e. non-attendants did not have higher levels of anxiety. This suggests that in the majority of cases non-attendance is not explained by psychological distress. The high participation rates among men with persistently elevated PSA at repeated screening rounds in the present study might support this and indicate that screening for prostate cancer seems to have a reassurance value, as was reported by Cantor et al.¹⁵

Furthermore, the present study indicates that experiences of high levels of anxiety for the screening procedures seems to affect only a small sub-group of men, who also repeatedly reported high levels of anxiety at subsequent screening rounds. This could reflect the hypothesis that there is a small sub-group of men with a predisposition for high anxiety levels when attending the screening programme. The findings are in accordance with those reported from the Rotterdam arm of the ERSPC⁴ and are also supported by Brindle and colleagues, who found that men who had higher levels of anxiety before PSA testing also had higher scores at biopsy.¹⁴ Hence, similar to the present study, anxiety seems to be related to the individual. The results obtained by Brindle and colleagues showed little change in scores when men returned for biopsy as a result of an abnormal PSA test result. Receiving

Table 2 – Non-participation rates (NPR) in the second screening round among those who attended in the first round, stratified for anxiety levels

Level of anxiety in first screening round	Non-participation rate in the second screening round	
	NPR ^a	(%)
<i>(a) Anxiety awaiting results of PSA measurement</i>		
0	97/1,171	(8.2 %)
1	69/574	(12.0%) N.S. ^b
2	3/36	(8.3%) N.S. ^b
<i>(b) Anxiety concerning invitation to attend clinical examination</i>		
0	67/793	(8.4%)
1	90/876	(10.2%) N.S. ^b
2	15/111	(13.5%) N.S. ^b

Anxiety level 0 = 'No', 1 = 'Intermediate', 2 = 'High'.
^a NPR – non-participation rate.
^b Compared to No anxiety.

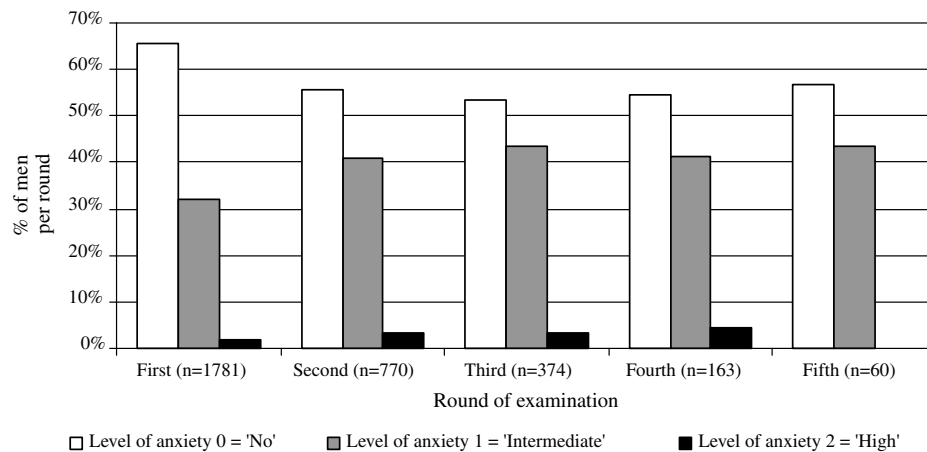


Fig. 2 is based on the following table:

Round of examination	First (n = 1,781)	Second (n = 770)	Third (n = 374)	Fourth (n = 163)	Fifth (n = 60)
Level of anxiety 0 = 'No'	1,171	429	200	89	34
Level of anxiety 1 = 'Intermediate'	574	315	162	67	26
Level of anxiety 2 = 'High'	36	26	12	7	0
Total	1,781	770	374	163	60

Fig. 2 – Anxiety awaiting the results of PSA measurement related to the number of examinations. Results are given as a percentage for every round of examination. * $p < .0001$.**

Table 3 – Impact of PSA level, age, round of examination, biopsy finding, heredity and lower urinary tract symptoms on anxiety awaiting results of PSA measurement

Covariate	OR ^a	95% CI ^b	P value
PSA level	1.00	(0.99–1.01)	0.64
Age	1.00	(0.97–1.03)	0.99
Round			
First	1.00	–	
Repeated	1.49	(1.22–1.81)	<.0001
Biopsy finding			
Benign	1.00	–	
Cancer	1.09	(0.88–1.36)	0.42
Heredity			
Yes	1.02	(0.73–1.31)	0.90
No	1.00	–	
Obstructive symptoms			
Yes	0.99	(0.79–1.24)	0.96
No	1.00	–	
Irritative symptoms			
Yes	1.20	(0.97–1.50)	0.09
No	1.00	–	

a OR – odds ratio.
b CI – confidence interval.

information about an elevated PSA does not seem to increase levels of anxiety. Similar findings, that anxiety seems to affect a sub-group of susceptible individuals, have been reported for breast cancer screening.^{16–18} Screening in general thus causes moderate or low levels of psychological distress, except in a smaller group of susceptible individuals.

One problem with PSA screening is the high false-positive rate.¹⁹ As a result, the majority of screen-positive men will continue to be invited in subsequent screening rounds.¹¹ Having persistently abnormal PSA values, these men are the ones expected to be most likely to experience anxiety from the screening procedures, as suggested by both Katz and colleagues and Fowler and colleagues.^{12,13} This has also been shown in breast cancer screening, where high levels of psychological distress have been observed in those who prove to be screen-positive,^{20,21} especially women who have repeated false-positive mammograms.²² In this study more men reported anxiety while waiting for PSA at repeated screening (Fig. 2). This could probably be explained: men attend screening for reassurance i.e. a man prior to his first invitation assumes his PSA to be normal. When the PSA instead turns out to be abnormal, the awareness of a cancer disease becomes evident and affects the level of anxiety in subsequent screening. However, the majority of men still reported no anxiety while waiting for PSA even in those with several abnormal PSAs previously. On the other hand, anxiety associated with biopsy was lower at subsequent screening (Fig. 3). The explanation for this is not obvious but one possible explanation could be that these men had confidence in the care process. On a biennial basis they met a limited number of nurses and urologists. Whether these results would be the same in men with another cultural background or with a different screening organisation remains unanswered.

In this study, there was no significant correlation between the level of anxiety and family history of prostate cancer, a finding consistent with the following previous studies. Taylor and colleagues reported an increased level of psychological distress prior to prostate cancer screening only among men

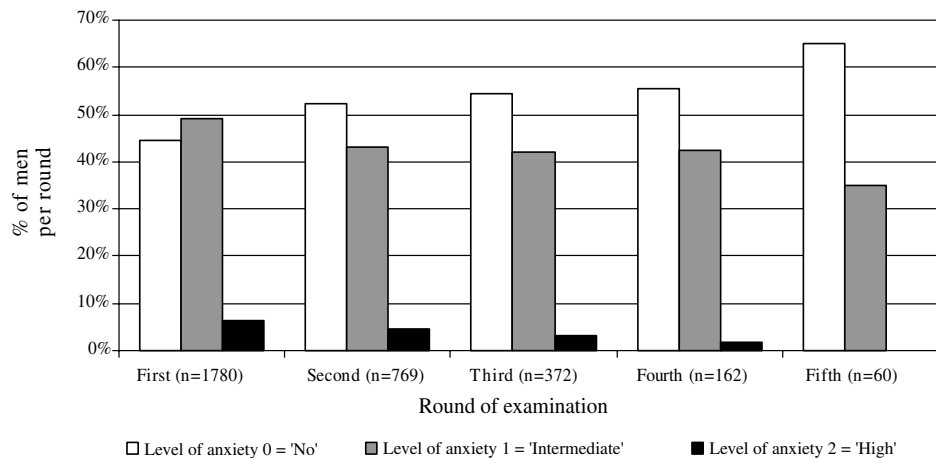


Fig 3. is based on the following table:

	First (n = 1,780)	Second (n = 769)	Third (n = 372)	Fourth (n = 162)	Fifth (n = 60)
Level of anxiety 0 = 'No'	793	403	203	90	39
Level of anxiety 1 = 'Intermediate'	876	331	157	69	21
Level of anxiety 2 = 'High'	111	35	12	3	0
Total	1,780	769	372	162	60

Fig. 3 – Anxiety associated with further clinical examination related to the number of examinations. Results are given as a percentage for every round of examination. * $p < .0001$.**

Table 4 – Impact of PSA level, age, round of examination, biopsy finding, heredity and lower urinary tract symptoms on anxiety concerning invitation to attend clinical examination

Covariate	OR ^a	95% CI ^b	P value
PSA level	0.99	(0.98–1.00)	0.15
Age	0.96	(0.94–0.99)	0.0016
Round			
First	1.00	–	
Repeated	0.67	(0.56–0.81)	<.0001
Biopsy finding			
Benign	1.00	–	
Cancer	0.97	(0.78–1.20)	0.78
Heredity			
Yes	0.87	(0.66–1.16)	0.34
No	1.00	–	
Obstructive symptoms			
Yes	0.96	(0.78–1.19)	0.71
No	1.00	–	
Irritative symptoms			
Yes	1.15	(0.94–1.42)	0.18
No	1.00	–	

a OR – odds ratio.
b CI – confidence interval.

Table 5 – Relative risk of reporting high levels of anxiety at subsequent screening related to the level of anxiety at the first clinical examination due to a screen-positive PSA test

Anxiety level at the first examination	RR ^a	P value ^b
(a) Anxiety awaiting the results of PSA measurement		
0	1.0	
1	3.0	<.001
2	37.3	<.001
(b) Anxiety concerning invitation to attend a clinical examination		
0	1.0	
1	5.6	<.001
2	56.8	<.001

Anxiety level 0 = 'No', 1 = 'Intermediate', 2 = 'High'.
a RR – relative risk.
b Compared to men with no anxiety at the first examination.

who were also considered to have an elevated perceived risk of the disease, compared to those without a family history.²³ Sweetman and colleagues reported that first-degree relatives attending familial PSA screening do not experience high levels of psychological morbidity.²⁴ Similar results were reported by Bratt and colleagues, who concluded that men with a high

hereditary risk of prostate cancer do not experience severe negative psychological effects from attendance for screening.⁵ It could thus be concluded that most men with a family history of prostate cancer do not experience more anxiety associated with prostate cancer screening compared to other men.

The results of the present study revealed that levels of anxiety associated with clinical examination were inversely related to age, a finding consistent with screening not only for prostate cancer. The adverse psychological impact of screening in relation to younger age has been reported by Brett and colleagues for mammography screening²⁵ and by Hughson and colleagues among women awaiting breast biopsy.²⁶ The same inverse association between age and anxiety has also been observed in women with abnormal cervical

smear test results.²⁷ Suggesting that screening provides reassurance, Taylor and colleagues showed that prostate cancer-related distress, particularly among young men, decreased following receipt of a negative result.²³ Among screened men with elevated PSA recalled for biopsy, Brindle and colleagues found, contrary to the present study, no association between anxiety and age, but did find that before counselling linked to having a PSA test older men were less anxious than younger men.¹⁴

In the present study, there was no correlation between urinary tract symptoms and anxiety in a multinomial analysis, contrary to the findings of Steginga and colleagues, who reported that men with urologic symptoms at the time of PSA testing were more worried about prostate cancer.²⁸ The presence of lower urinary tract symptoms is common in this age group of men and it seems plausible that symptoms from the urinary tract would be associated with an elevated level of anxiety for prostate cancer. As this study comprises as many as 1781 participating men one could at least conclude that if such a relationship exists it is weak and is probably not clinically significant.

5. Conclusions

In conclusion, the randomised sample of men in this study is most likely to resemble those who would participate if prostate cancer screening was to be introduced into routine practice. Considering a general, population-based screening process for prostate cancer, this study indicates that the majority of men would be likely to accept an invitation. In a review of 11 articles on the psychosocial implications of prostate cancer screening, Hewitson and colleagues concluded that screening is associated with some anxiety-raising reactions, although not sufficient to cause deleterious effects in men.²⁹ According to the results of this study, this further confirms that attending a screening programme for prostate cancer is seldom associated with severe negative psychological distress, even for men with persistently elevated PSA levels resulting in repeated examinations with prostate biopsies. There is an ethical responsibility to ensure that screening must not do more harm than good. Pending convincing evidence on the benefits of early detection, our findings remove one barrier to screening for prostate cancer.

Conflict of interest statement

None declared.

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