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Sedentary behavior and prostate cancer risk in the NIH-AARP Diet and Health Study

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Abstract

Sedentary behavior (sitting time) has been proposed as an independent risk factor for some cancers; however, its role in the development of prostate cancer has not been determined. We examined the prospective associations of self-reported daily sitting time and daily television/video viewing time with risk of developing or dying from prostate cancer among 170,481 men in the NIH-AARP Diet and Health Study. We estimated hazard ratios and 95% confidence intervals using Cox Proportional Hazards regression. Between 1996 and 2006 there were 13,751 incident (including 1,365 advanced) prostate cancer cases identified; prostate cancer mortality (through 2008) was 669. No strong or significant association with prostate cancer risk was seen in fully adjusted models for either daily sitting or television/video time. There was some suggestion of effect modification by body mass index (interaction for television/video time and body mass index, p = 0.02). For total prostate cancer risk, television/video time was associated with a slightly elevated, but non-significant increased amongst obese men (HR=1.28, 95%CI: 0.98, 1.69); a null association was observed amongst overweight men (HR=1.04, 0.89, 1.22); and, for men with a normal body mass index, television/video time was associated with a non-significant risk decrease (HR=0.82, 95%CI: 0.66, 1.01). Similar patterns were observed for total daily sitting and television/video time in advanced prostate cancer and prostate cancer mortality. Sedentary

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behavior appears to play a limited role in the development of prostate cancer, however we cannot rule out potential effect modification by body mass index or the impact of measurement error on results.

Keywords

sitting time; television; prostate neoplasms; body mass index; cohort studies

INTRODUCTION

The etiology of prostate cancer remains poorly understood, and few modifiable risk factors have been identified.(1) Sedentary behavior (sitting time) is now considered an important chronic disease risk factor, independent of moderate- to vigorous-intensity physical activity.(2, 3) Sedentary behavior has been adversely associated with obesity, metabolic dysfunction and chronic inflammation, processes that may be operative in carcinogenesis.(4) Whether sedentary behavior is associated with prostate cancer risk has not yet been established. A small number of studies have examined prostate cancer risk across categories of occupations, comparing sedentary jobs with physically active jobs, but they produced conflicting results. Orsini *et al.* reported that men whose lifetime occupation has involved mostly sitting had a 27% increased risk of prostate cancer(5), while Thune and Lund reported a non-significant 30% increased risk among men reporting “mostly sedentary” occupations.(6) In contrast, Lacey Jr *et al.* found that men whose occupation entailed mainly sitting had a non-significant 40% lower risk of prostate cancer than men whose work involved light labor.(7) To date, time spent in sedentary behaviors outside of occupation has not been examined in the context of prostate cancer risk. We examined whether self-reported daily sitting or television/video viewing time were associated with prostate cancer, independent of moderate- to vigorous-intensity physical activity.

MATERIALS AND METHODS

The NIH-AARP Diet and Health Study was established in 1995–1996 with the mailing of a self-administered questionnaire that elicited information on diet, family history of cancer, anthropometry and other lifestyle factors to 3.5 million members of the AARP. Members selected for the cohort were aged 50 – 71 years and resided in one of six states (California, Florida, Louisiana, New Jersey, North Carolina, Pennsylvania) or two metropolitan areas (Atlanta, Georgia and Detroit, Michigan).(8) Individuals who responded initially (n=566,401) were sent a second questionnaire within six months of receipt of the baseline assessment. The second questionnaire collected more detailed information on cancer risk factors, including physical activity and sedentary behavior. The NIH-AARP Diet and Health Study received ethical approval from the Special Studies Institutional Review Board of the U.S. National Cancer Institute. All participants provided written, informed consent.

Study population

The second questionnaire was completed by 334,906 participants between 1996–1997. We excluded participants who had had their baseline (n=6,959) or second questionnaire

(n=3,424) completed by proxy respondents, females (n = 136,407) and participants with a previous diagnosis of cancer (n = 10,607). We further excluded 1,300 men due to missing data on sedentary behavior variables and 5,728 men with missing or extreme values of body mass index or caloric intake. Extreme values were defined as log-transformed values two or more interquartile ranges below the 25th percentile, or two or more interquartile ranges above the 75th percentile. The analytic cohort comprised 170,481 men.

Case ascertainment

Histologically confirmed incident prostate cancer cases, diagnosed through 31 December 2006, were identified through linkage to 11 state cancer registry databases. These state cancer registries all met the certification requirements defined by the North American Association of Central Cancer Registries, and were estimated to achieve close to 90% case ascertainment within 24 months.(9) Advanced prostate cancer cases had clinical or pathological tumor classifications of T3 or T4, N1 status, or M1 status, or were incident cases first identified by state cancer registry who subsequently died of prostate cancer between 1995 and 2006. Prostate cancer mortality cases were extracted from the National Death Index through 31 December 2008; mortality cases were not linked to incidence data derived from state cancer registries. Prostate cancer mortality was defined as cases where the underlying or contributing cause of death was prostate cancer.

Assessment of sedentary behavior and covariates

The main exposure variables – total daily sitting and television/video viewing time – were assessed by the second questionnaire. Participants were asked "During a typical 24-hour period over the past 12 months, how many hours did you spend": sitting (*less than 3 hours; 3–4 hours; 5–6 hours; 7–8 hours; 9 or more hours per day)* or watching television or videos *(none; less than 1 hour; 1–2 hours; 3–4 hours; 5–6 hours; 7–8 hours*; and, *9 or more hours per day)*. We combined the first two response options for television into *less than 1 hour per day*, due to the very small proportion (0.6%) of respondents who reported watching no television/videos. Similarly, we combined the final two response options for television into *7 or more hours per day* (only 1.9% of respondents had reported watching *9 or more hours per day*). To ensure an adequate number of cases across categories for analyses examining risk of advanced prostate cancer or prostate cancer mortality, we collapsed the exposure categories for sitting (*less than 3 hours; 3–4 hours; 5–6 hours; 7 or more hours per day*) and television/video viewing (*less than 3 hours; 3–4 hours; 5 or more hours per day*).

We examined the bivariate associations of potentially confounding variables with total prostate cancer risk and sedentary behavior variables to help guide the selection of covariates to be included in multivariate models. All covariates were assessed by self-administered questionnaire. Sociodemographic factors were reported at baseline: age (*years*), race (*white; black; other*); marital status (*married/de facto; widowed; divorced/ separated; never married*) and educational attainment (*less than 12 years; finished high school; some college; college graduate*). Also assessed at baseline were family history of prostate cancer (*yes; no*), personal history of diabetes (*yes, no*), body mass index (kg/m^2), smoking status (*never; former; current*), caloric intake (*kcal, quartiles*) and alcohol intake (*ethanol g/day, quartiles*). Moderate- to vigorous-intensity physical activity in the past ten

years was assessed by the second questionnaire (*less than weekly; weekly, but less than 1 hour per week; 1–3 hours per week; 4–7 hours per week; more than 7 hours per week)*. History of prostate specific antigen testing and digital rectal examination (*in past three years, yes; no*) were also recorded by the second questionnaire.

Statistical analysis

Cox proportional hazards regression was used to estimate multivariate hazard ratios and 95% confidence intervals of prostate cancer, using time of follow-up as the underlying time metric. Person-time was calculated starting with the date at second questionnaire return and ending at date at event (diagnosis of prostate cancer; death; move out of cancer registry catchment area; end of study follow-up). We considered potential interactions of sedentary behavior variables with family history of prostate cancer, race, body mass index, moderate- to vigorous-intensity physical activity, history of digital rectal examination and history of prostate specific antigen testing. We also examined risk separately for disease onset prior to age 65, and after age 65.

RESULTS

The cohort was followed for an average period of 8.5 years, during which 13,751 incident prostate cancer cases were ascertained. The median age at diagnosis was 69.5 years. We also examined associations of sedentary behavior with risk of advanced prostate cancer (n=1,365) and with prostate cancer mortality (n=669).

The characteristics of the study population at baseline are presented in Table 1. Greater amounts of sitting time were associated with receiving a college education, a higher BMI, personal history of diabetes, more television viewing and less recreational physical activity.

Neither self-reported daily sitting time nor television/video viewing time was associated with risk of total or advanced prostate cancer, nor with prostate cancer mortality (Tables 2 and 3). There were no meaningful differences in hazard ratios or 95% confidence intervals between age-adjusted and multivariate models; hence only multivariate results are presented.

There were no interaction effects between sitting time or television/video viewing time and family history of disease, race, moderate- to vigorous-intensity physical activity, history of digital rectal examination or history of prostate specific antigen testing (results not shown). However, a statistically significant interaction effect was found for television/video viewing time and body mass index ($p = 0.02$). We therefore stratified our analyses by body mass index, and saw some suggestion that sedentary behavior may be associated with an increased risk of prostate cancer amongst obese men, and with a reduced risk of prostate cancer amongst men in the healthy weight range (Tables 2 and 3).

For men aged less than 65 years, no significant association was seen for daily sitting time (HR ≥7 versus <3 h/day = 0.92, 95% CI: 0.74, 1.15) or for television/video viewing time (HR ≥5 versus <3 h/day = 1.01, 95% CI: 0.81, 1.26). Similarly, amongst men aged 65 years or older, there was no association for either daily sitting time (HR = 0.92, 95% CI: 0.75, 1.12) or for television/video viewing time (HR = 0.90, 95% CI: 0.75, 1.09).

DISCUSSION

In this large, prospective investigation we found scant evidence for associations between self-reported measures of sedentary behavior and risk of prostate cancer. The data were suggestive of some effect modification by body mass index category for television/video viewing time and total prostate cancer risk, and for both daily sitting and television/video viewing time and advanced prostate cancer risk/prostate cancer mortality.

Previous studies that examined prostate cancer risk across occupational activity categories found conflicting results.(5–7) These studies used an estimate of usual occupational activity to examine the association with sitting in the workplace, whereas we were able to examine prostate cancer risk in relation to estimated daily sitting and television/video viewing time (a highly prevalent leisure-time sedentary behavior). It is unlikely, however, that the different behavior setting in which sitting occurs would significantly affect the biological response to the exposure. Hence, our mostly null results provide further conflicting evidence pertaining to sedentary behavior and prostate cancer risk.

The etiology of prostate cancer remains poorly understood, and few modifiable risk factors have been identified, although there is evidence to suggest that the interrelations of energy intake, body composition and physical activity play some role in prostate cancer etiology.(10) Studies that have examined the associations between physical activity and prostate cancer risk stratified by BMI have demonstrated no associations amongst healthy weight and overweight men, but an inverse association amongst obese men.(1)

The reasons for the observed risk variation across body mass index categories in this study are not clear. The apparent elevation in risk amongst obese men could reflect the compounded biological exposures resulting from obesity and sedentary behavior. For example, both obesity and sedentary behavior have been independently associated with metabolic dysfunction(4), a factor that may facilitate prostate cancer development and progression.(1, 11) The favorable muscle:fat ratio of lean men may help to counteract some of the deleterious biological consequences of sedentary behavior that may be operative in prostate cancer risk.(12) Obesity has been hypothesized to mediate many of the pathways by which sedentary behavior affects cancer risk.(4) The associations between sedentary behavior, body composition and prostate cancer are clearly complex, and further research is necessary to elucidate these pathways.

A previous report from the NIH-AARP Diet and Health Study did not find a significant association between vigorous-intensity physical activity and total, advanced or fatal prostate cancer.(13) However, another report from the same cohort examined the associations of physical activity with prostate cancer risk separately for white and black men, and found that four or more hours of moderate/vigorous intensity physical activity, compared to infrequent activity, during early adulthood provided a 35% lower risk of prostate cancer.(14) No significant interaction effect was noted in our study; hence, we did not stratify our analyses by race.

In this study, advanced prostate cancer was defined primarily by TNM criteria. The Gleason scoring system offers a prostate cancer-specific method for defining advanced disease, and

this method would likely have enlarged the number of cases defined as “advanced”. For the purpose of our analyses, however, it is unlikely that use of the Gleason scoring system would have altered study results, given the consistently null associations demonstrated across the different prostate cancer outcomes.

Our findings imply that sedentary behavior does not make a significant, independent contribution towards prostate cancer risk. However, some pertinent methodological issues should be considered when interpreting the results. It is possible that use of self-report measures led to measurement error, biasing results towards the null. Although the psychometric properties of the sedentary behavior items used in this study have not been established, they have previously been associated with an increased risk of all-cause and cancer mortality(15), colon cancer(16) and endometrial cancer(17), and are similar to items that have demonstrated reasonable reliability and validity.(18–21) However, the validation of these similar items was limited by the lack of adequate gold-standard for sedentary behavior. Studies have estimated convergent validity by comparing sedentary behavior items against activity logs(19, 20) or accelerometer data,(19, 21) which can be imprecise.

Screening bias has also been suggested as a possible problem in studies such as ours. Health-conscious men may spend less time sitting and also may be more likely to be screened for, and therefore diagnosed with, prostate cancer. (22) We adjusted our multivariate models for participants’ prostate specific antigen and digital rectal examination screening prior to baseline, but were unable to adjust for subsequent screening, and therefore our adjustment may be incomplete. Study strengths include the prospective design, large sample and ability to control for many important confounding factors. We were also able to isolate advanced cases of prostate cancer to examine these separately.

This is the first study to consider whether self-reported daily sitting or television/video viewing time were associated with prostate cancer risk. We did not demonstrate an association, but there is sufficient biological plausibility to warrant further investigation that may confirm or refute our findings. Future studies would benefit from use of more accurate and comprehensive assessment of sedentary behavior, such as previous-day recalls or objective measures of sedentary time.(23, 24)

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Table 1

Baseline Characteristics of the NIH-AARP Study Population (n = 170,481), by Daily Sitting Time Categories, 1995 – 1996

	Daily sitting time				
Participant characteristics	**< 3h/day**	**3 – 4 h/day**	**5 – 6 h/day**	**7 – 8 h/day**	**≥ 9 h/day**
Age (yrs)	62.9 (5.1)	63.0 (5.1)	62.6 (5.2)	61.6 (5.3)	60.5 (5.4)
Non-Hispanic white (%)	91.3	94.0	94.4	94.7	95.1
College graduate (%)	38.6	43.6	50.2	56.7	59.8
Currently married or de facto (%)	84.4	85.7	85.7	85.0	83.3
Body mass index (kg/m^2)	26.8 (3.6)	26.9 (3.7)	27.1 (3.8)	27.2 (4.0)	27.5 (4.2)
Family history of prostate cancer (%)	8.2	8.3	8.4	8.3	8.9
Personal history of diabetes (%)	9.0	9.3	9.7	9.8	10.3
Previous prostate specific antigen screening[a] (%)	70.7	72.5	72.6	71.8	68.8
Previous digital rectal examination screening[a] (%)	81.9	83.8	84.8	84.5	83.1
Caloric intake (kcal/day)	2006 (863)	1979 (806)	1994 (791)	2018 (789)	2066 (807)
Alcohol intake (g/day)	15.9 (37.3)	16.5 (36.9)	17.3 (37.2)	17.5 (37.8)	17.9 (39.7)
Never smoker (%)	31.5	29.2	29.3	30.4	30.0
Recreational physical activity[a]					
< 1 h/wk	21.5	21.9	23.7	28.2	36.1
1 – 3 h/day	23.1	24.9	25.8	26.8	26.7
4 – 7 h/day	25.9	27.0	26.6	25.6	22.4
> 7 h/day	29.5	26.3	23.9	19.4	14.8
Television or video viewing[a]					
< 1 h/day	9.3	5.2	5.1	6.8	7.4
1 – 2 h/day	46.5	30.4	23.5	24.1	23.6
3 – 4 h/day	35.8	55.1	47.1	37.0	36.8
5 – 6 h/day	6.1	7.1	21.4	23.8	19.1
≥ 7 h/day	2.3	2.2	3.0	8.3	13.1

Data are mean (SD) or %

[a] Assessed by second questionnaire (1996 – 1997)

Table 2

Risk of Prostate Cancer According to Categories of Daily Sitting Among 170,481 Men in the NIH-AARP Diet and Health Study, 1996 – 2006

	Cases	Person years	Multivariable adjusted	
			HR	95% CI
Total prostate cancer				
< 3 h/day	2745	270172	1.00	
3 – 4 h/day	4142	424819	0.95	0.90, 1.00
5 – 6 h/day	3859	410382	0.94	0.89, 0.98
7 – 8 h/day	1928	216519	0.93	0.88, 0.99
≥ 9 h/day	1077	124578	0.98	0.91, 1.05
P trend			0.09	
By body mass index category (interaction term: p=0.62)				
18.5 – 24.9 kg/m^2				
< 3 h/day	933	86809	1.00	
3 – 4 h/day	1363	132031	0.94	0.87, 1.02
5 – 6 h/day	1230	123079	0.94	0.86, 1.02
7 – 8 h/day	583	64628	0.89	0.80, 0.99
≥ 9 h/day	326	35700	0.97	0.85, 1.10
P trend			0.13	
25.0 – 29.9 kg/m^2				
< 3 h/day	1404	137367	1.00	
3 – 4 h/day	2081	213025	0.94	0.88, 1.01
5 – 6 h/day	1938	204247	0.94	0.87, 1.00
7 – 8 h/day	957	104720	0.94	0.86, 1.02
≥ 9 h/day	515	57472	0.99	0.89, 1.10
P trend			0.30	
≥ 30.0 kg/m^2				
< 3 h/day	397	45118	1.00	
3 – 4 h/day	681	78259	0.98	0.88, 1.01
5 – 6 h/day	681	81684	0.96	0.87, 1.00
7 – 8 h/day	375	46408	1.00	0.86, 1.02
≥ 9 h/day	232	30955	0.99	0.89, 1.10
P trend			0.79	
Advanced prostate cancer				
< 3 h/day	284	270172	1.00	
3 – 4 h/day	408	424819	0.90	0.77, 1.05
5 – 6 h/day	358	410382	0.83	0.71, 0.97
≥ 7 h/day	315	341097	0.91	0.77, 1.08
P trend			0.16	
By body mass index category (interaction term: p=0.10)				
18.5 – 24.9 kg/m^2				

	Cases	Person years	Multivariable adjusted	
			HR	95% CI
< 3 h/day	97	86809	1.00	
3 – 4 h/day	134	132031	0.89	0.68, 1.15
5 – 6 h/day	92	123079	0.65	0.49, 0.87
≥ 7 h/day	97	100327	0.86	0.64, 1.14
P trend			0.08	
25.0 – 29.9 kg/m^2				
< 3 h/day	147	137367	1.00	
3 – 4 h/day	205	213025	0.89	0.72, 1.10
5 – 6 h/day	177	204247	0.81	0.65, 1.01
≥ 7 h/day	144	162192	0.87	0.69, 1.10
P trend			0.14	
≥ 30.0 kg/m^2				
< 3 h/day	37	45118	1.00	
3 – 4 h/day	67	78259	1.03	0.69, 1.55
5 – 6 h/day	86	81684	1.30	0.88, 1.91
≥ 7 h/day	72	77363	1.24	0.82, 1.85
P trend			0.18	
Prostate cancer mortality				
< 3 h/day	133	270172	1.00	
3 – 4 h/day	215	424819	1.01	0.81, 1.25
5 – 6 h/day	168	410382	0.86	0.68, 1.08
≥ 7 h/day	153	341097	1.07	0.84, 1.35
P trend			0.98	
By body mass index category (interaction term: p=0.07)				
18.5 – 24.9 kg/m^2				
< 3 h/day	41	86809	1.00	
3 – 4 h/day	65	132031	1.01	0.69, 1.50
5 – 6 h/day	39	123079	0.69	0.44, 1.07
≥ 7 h/day	36	100327	0.90	0.57, 1.42
P trend			0.23	
25.0 – 29.9 kg/m^2				
< 3 h/day	70	137367	1.00	
3 – 4 h/day	109	213025	0.99	0.74, 1.34
5 – 6 h/day	82	204247	0.83	0.60, 1.15
≥ 7 h/day	74	162192	1.07	0.77, 1.49
P trend			0.91	
≥ 30.0 kg/m^2				
< 3 h/day	22	45118	1.00	
3 – 4 h/day	41	78259	1.06	0.63, 1.78
5 – 6 h/day	45	81684	1.16	0.69, 1.93
≥ 7 h/day	43	77363	1.34	0.79, 2.26

	Cases	Person years	Multivariable adjusted	
			HR	95% CI
P trend			0.18	

[a]Models are adjusted for age at baseline, age squared, race, marital status, highest level of education, family history of prostate cancer, digital rectal examination in past three years, prostate specific antigen test in past three years, history of diabetes, smoking status, caloric intake, alcohol intake, recreational moderate- to vigorous-intensity physical activity, body mass index at baseline (not models stratified by body mass index).

Table 3

Risk of Prostate Cancer According to Categories of Television or Video Viewing Among 170,481 Men in the NIH-AARP Diet and Health Study, 1996 – 2006

	Cases	Person years	Multivariable adjusted	
			HR	95% CI
Total prostate cancer				
< 1 h/day	864	94,369	1.00	
1 – 2 h/day	4193	438771	1.01	0.94, 1.09
3 – 4 h/day	6224	649360	1.01	0.94, 1.08
5 – 6 h/day	1930	205797	0.98	0.91, 1.07
≥ 7 h/day	540	58172	1.03	0.92, 1.15
P trend			0.53	
By body mass index category (interaction term: p=0.02)				
18.5 – 24.9 kg/m^2				
< 1 h/day	397	41537	1.00	
1 – 2 h/day	1541	151049	1.01	0.90, 1.13
3 – 4 h/day	1907	184951	1.01	0.90, 1.13
5 – 6 h/day	482	51043	0.92	0.80, 1.05
≥ 7 h/day	108	13667	0.82	0.66, 1.01
P trend			0.04	
25.0 – 29.9 kg/m^2				
< 1 h/day	386	41823	1.00	
1 – 2 h/day	2057	216731	1.00	0.89, 1.11
3 – 4 h/day	3215	330940	1.00	0.90, 1.11
5 – 6 h/day	978	101110	0.98	0.87, 1.11
≥ 7 h/day	259	26226	1.04	0.89, 1.22
P trend			0.98	
≥ 30.0 kg/m^2				
< 1 h/day	76	10581	1.00	
1 – 2 h/day	576	69501	1.13	0.89, 1.44
3 – 4 h/day	1078	131350	1.10	0.87, 1.39
5 – 6 h/day	466	52932	1.16	0.91, 1.48
≥ 7 h/day	170	18058	1.28	0.98, 1.69
P trend			0.11	
Advanced prostate cancer				
< 3 h/day	512	533141	1.00	
3 – 4 h/day	613	649360	0.97	0.86, 1.10
≥ 5 h/day	240	263969	0.93	0.79, 1.09
P trend			0.49	
By body mass index category (interaction term: p=0.84)				
18.5 – 24.9 kg/m^2				
< 3 h/day	191	192586	1.00	

	Cases	Person years	Multivariable adjusted	
			HR	95% CI
3 – 4 h/day	174	184951	0.95	0.77, 1.18
≥ 5 h/day	55	64710	0.86	0.63, 1.17
P trend			0.44	
25.0 – 29.9 kg/m^2				
< 3 h/day	252	258555	1.00	
3 – 4 h/day	309	330940	0.94	0.79, 1.11
≥ 5 h/day	112	127336	0.88	0.70, 1.11
P trend			0.27	
≥ 30.0 kg/m^2				
< 3 h/day	64	80083	1.00	
3 – 4 h/day	126	131350	1.18	0.87, 1.59
≥ 5 h/day	72	70991	1.22	0.86, 1.73
P trend			0.22	
Prostate cancer mortality				
< 3 h/day	205	533141	1.00	
3 – 4 h/day	320	649360	1.10	0.92, 1.32
≥ 5 h/day	144	263969	1.07	0.85, 1.33
P trend			0.15	
By body mass index category (interaction term: p=0.67)				
18.5 – 24.9 kg/m^2				
< 3 h/day	71	192586	1.00	
3 – 4 h/day	82	184951	1.01	0.73, 1.39
≥ 5 h/day	28	64710	0.83	0.53, 1.30
P trend			0.96	
25.0 – 29.9 kg/m^2				
< 3 h/day	102	258555	1.00	
3 – 4 h/day	171	330940	1.17	0.91, 1.50
≥ 5 h/day	62	127336	0.99	0.72, 1.38
P trend			0.59	
≥ 30.0 kg/m^2				
< 3 h/day	31	80083	1.00	
3 – 4 h/day	66	131350	1.13	0.74, 1.74
≥ 5 h/day	54	70991	1.52	0.97, 2.40
P trend			0.03	

[a]Models are adjusted for age at baseline, age squared, race, marital status, highest level of education, family history of prostate cancer, digital rectal examination in past three years, prostate specific antigen test in past three years, history of diabetes, smoking status, caloric intake, alcohol intake, recreational moderate- to vigorous-intensity physical activity, body mass index at baseline (not models stratified by body mass index).