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RESEARCH

Resting heart rate as a low tech predictor of coronary events in women: prospective cohort study

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ABSTRACT

Objective To evaluate resting heart rate as an independent predictor of cardiovascular risk in women.

Design Prospective cohort study.

Setting The Women's Health Initiative was undertaken at 40 research clinics in the United States.

Participants 129 135 postmenopausal women.

Main outcome measure Clinical cardiovascular events.

Results During a mean of 7.8 (SD 1.6) years of follow up, 2281 women were identified with myocardial infarction or coronary death and 1877 with stroke. We evaluated associations between resting heart rate and cardiovascular events in Cox regression models adjusted for multiple covariates. Higher resting heart rate was independently associated with coronary events (hazard ratio 1.26, 95% confidence interval 1.11 to 1.42 for highest [>76 beats per minute] *v* lowest quintile [≤62 beats per minute]; P=0.001), but not with stroke. The relation between heart rate and coronary events did not differ between white women and women from other ethnic groups (P for interaction=0.45) or between women with and without diabetes (P for interaction=0.31), but it was stronger in women aged 50-64 at baseline than in those aged 65-79 (P for interaction=0.009).

Conclusion Resting heart rate, a low tech and inexpensive measure of autonomic tone, independently predicts myocardial infarction or coronary death, but not stroke, in women.

Trial registration ClinicalTrials.gov NCT00000611.

INTRODUCTION

Resting heart rate, an indicator of autonomic nervous system tone, independently predicts coronary events in men.[1-4] Evidence suggests this relation is weaker or absent in women[2 3 5-8] except for one study that showed a strong association of heart rate with cardiovascular death in African-American women.[9] The relation between heart rate and stroke in women is also unclear.

We assessed resting heart rate as an independent predictor of myocardial infarction or coronary death and stroke in a large cohort of women with a broad range of cardiovascular risk, and compared the strength of these associations by age and ethnic group.

METHODS

Study population

The Women's Health Initiative includes 161 808 postmenopausal women enrolled at 40 clinical sites into four randomised trials and an observational study from 1993 to 1998.[10] The present analysis included participants from the observational study and women from the intervention and control groups in the randomised trials. We excluded women with previous myocardial infarction, stroke, or coronary revascularisation at baseline, and those reporting current use of drugs that might affect heart rate. Accordingly the analysis included 129 135 women.

Measurement of heart rate and covariates

At baseline, women sat quietly for 5 minutes before a trained observer measured heart rate by palpating the radial pulse for 30 seconds. Hypertension, smoking, consumption of caffeine and alcohol, diabetes mellitus requiring dietary or drug therapy, and high cholesterol requiring drug treatment were assessed by self-reported questionnaire at baseline. Total physical activity[11] depression[12] anxiety (assessed by asking "Have you been a very nervous person?" and discrete response categories) and hormone use (blinded treatment assignment in the randomised trials and open label use of oestrogen) were also assessed.

Ascertainment of outcomes

Participants reported emergency room visits, overnight stays in hospital, and outpatient coronary revascularisation procedures every 6 months, and medical records were scrutinised by centrally trained physician adjudicators for potential outcomes of interest.

Statistical analysis

We divided resting heart rate into quintiles or deciles. For continuous markers, we evaluated differences in baseline characteristics by modelling the covariate of interest by a continuous term of heart rate category in a linear model. Categorical models were evaluated using a χ^2 test comparing the marker of interest and the categories of heart rate. For multivariable analysis, we

calculated hazard ratios from Cox regression models adjusted for all covariates. We assessed interactions between heart rate or change in heart rate quintile and coronary heart disease or risk of stroke by age, ethnic origin, and presence of diabetes mellitus at baseline.

RESULTS

During a mean of 7.8 (SD 1.6) years of follow-up, 2281 coronary events (myocardial infarction or coronary death) and 1877 strokes were identified. Baseline characteristics showed that age, body mass index, and saturated fat consumption were higher and cardiovascular risk factors such as hypertension, diabetes, smoking, hypercholesterolaemia, and depressive symptoms were more prevalent in women with higher resting heart rate, as was self reported nervousness. See bmj.com. Physical activity and alcohol use were inversely related to heart rate (both P<0.001), and heart rate was lower in women who used postmenopausal hormone therapy than in those who did not (P<0.001).

In univariate analysis, resting heart rate predicted myocardial infarction or coronary death, with a hazard ratio of 1.68 (95% confidence interval 1.49 to 1.89) for the highest (>76 beats per minute) versus lowest (≤62 beats per minute) quintile (p<0.001). In multivariable analysis, higher resting heart rate was independently associated with increased coronary risk.

In univariate analysis, resting heart rate also predicted stroke, with hazard ratio 1.23 (95% confidence interval 1.07 to 1.41) for the highest versus lowest quintile (P=0.007). In multivariable analysis,

Resting heart rate as an independent predictor of coronary events and stroke in multivariable analysis

	Myocardial infarction or coronary death		Stroke	
	Hazard ratio (95% CI)	P value	Hazard ratio (95% CI)	P value
Resting heart rate, beats per minute	—	0.001	—	0.64
≤62 (referent)	1.00		1.00	—
63-66	1.02 (0.89 to 1.17)		1.04 (0.90 to 1.20)	—
67-70	1.08 (0.95 to 1.23)		0.96 (0.83 to 1.11)	—
71-76	1.02 (0.89 to 1.16)		1.07 (0.94 to 1.23)	—
>76	1.26 (1.11 to 1.42)		1.01 (0.87 to 1.16)	—
Age, per 5 year increase	1.53 (1.48 to 1.58)	<0.001	1.69 (1.63 to 1.76)	<0.001
Ethnic origin	—	<0.001	—	0.02
White (referent)	1.00	—	1.00	—
Black	0.68 (0.57 to 0.80)	—	1.18 (1.00 to 1.40)	—
Hispanic	0.54 (0.40 to 0.74)	—	0.71 (0.51 to 0.99)	—
American Indian/Alaskan native	1.11 (0.63 to 1.96)	—	0.56 (0.21 to 1.48)	—
Asian/Pacific Islander	0.60 (0.43 to 0.85)	—	0.94 (0.70 to 1.27)	—
Unknown	0.91 (0.64 to 1.31)	—	1.36 (0.98 to 1.91)	—
Hypertension	1.69 (1.55 to 1.84)	<0.001	1.87 (1.70 to 2.06)	<0.001
Diabetes mellitus ever	2.68 (2.36 to 3.03)	<0.001	1.94 (1.66 to 2.27)	<0.001
Current smoking	2.32 (2.03 to 2.65)	<0.001	1.95 (1.67 to 2.28)	<0.001
High cholesterol requiring drugs	1.14 (0.98 to 1.33)	0.057	1.18 (1.00 to 1.40)	0.15
Depression construct >5	1.08 (0.94 to 1.24)	0.29	1.14 (0.98 to 1.33)	0.09
Nervousness	—	0.09	—	0.67
None of the time (referent)	1.00	—	1.00	—
A little bit of the time	1.09 (0.99 to 1.20)	—	0.96 (0.86 to 1.06)	—
At least some of the time	1.12 (1.00 to 1.25)	—	1.00 (0.89 to 1.14)	—
Body mass index, per 5 kg/m^2 increase	1.08 (1.04 to 1.12)	<0.001	1.00 (0.96 to 1.05)	0.98
Physical activity, per 5 metabolic equivalent-h/week increase	0.97 (0.95 to 0.99)	<0.001	0.98 (0.97 to 1.00)	0.08
Alcohol use	—	0.007	—	0.21
Never (referent)	1.00	—	1.00	—
Past	1.07 (0.92 to 1.24)	—	1.02 (0.86 to 1.20)	—
Current	0.91 (0.79 to 1.04)	—	0.92 (0.80 to 1.07)	—
Dietary caffeine, per 50 mg increase	0.98 (0.97 to 1.00)	0.048	0.99 (0.97 to 1.01)	0.36
Dietary saturated fat, per 5% increase	1.13 (1.05 to 1.20)	<0.001	1.11 (1.03 to 1.19)	0.008
Hormone use at baseline	—	0.002	—	<0.001
None (referent)	1.00	—	1.00	—
Unopposed oestrogen	0.86 (0.77 to 0.97)	—	1.19 (1.06 to 1.34)	—
Oestrogen with progestogen	0.81 (0.71 to 0.94)	—	0.85 (0.72 to 0.99)	—
Statin use	1.06 (0.87 to 1.30)	0.57	0.81 (0.64 to 1.03)	0.08

WHAT IS ALREADY KNOWN ON THIS TOPIC

Resting heart rate predicts coronary events in men

For women, the relation between heart rate and coronary events or stroke has been uncertain

WHAT THIS STUDY ADDS

Resting heart rate predicts coronary events in women

This relation is independent of physical activity and conventional risk factors

This association appears stronger in women aged 50-64 than in those aged 65 or older

Resting heart rate does not predict stroke in women

however, heart rate was not independently associated with stroke. See table for all independent predictors (table).

In formal interaction testing, we found that the relation between resting heart rate and coronary events or stroke did not differ between white women and those from other ethnic groups (P for interaction=0.45 for coronary events and 0.85 for stroke), and between women with and without diabetes mellitus at baseline (P for interaction =0.31 for coronary events and 0.92 for stroke). The relation with resting heart rate differed by age for coronary events (P for interaction=0.009). The association of higher heart rate with coronary events was stronger in women aged 50-64 years than in those aged 65-79 years at baseline. We noted no such interaction between heart rate and age for stroke (P for interaction=0.14).

DISCUSSION

Principal findings

In a large, diverse cohort of postmenopausal women, resting heart rate was an independent predictor of coronary events, with higher heart rate associated with greater risk. The relation between resting heart rate and risk of coronary events was stronger in younger postmenopausal women than in older ones. Resting heart rate did not independently predict stroke.

Strengths and limitations

Strengths include the size and diversity of the cohort, the use of prospective ascertainment and adjudication of outcomes, the large number of clinical events, and the range of covariates available for analysis, including physical activity and depression. Limitations were that we had no electrocardiograms and that the cohort included no women younger than 50 and no men.

Relation to other studies

Other studies have found an association between depression and coronary heart disease. The fact that we found no association might be attributable to the fact that this cohort had quite low scores for depressive symptoms—that is, was not very depressed.

Heart rate was higher in women with self reported nervousness than in less nervous women, but nervousness was not independently associated with either coronary events or stroke in our analysis. This finding contrasts with reports identifying anxiety as a predictor of coronary events or of poor outcome after coronary artery bypass surgery.[13 14] Possible explanations are that our dataset did not include a true anxiety scale, or that adjustment for heart rate and several other variables weakened the association of coronary events with anxiety. The latter explanation might also account for the absence of an association between alcohol consumption and coronary events in the multivariable analysis.

Hormone use in the current analysis includes randomised treatment assignment in the hormone trials, as well as open label use by women not participating in those trials. Unsurprisingly, the associations with cardiovascular disease present a mixed picture.

We did not confirm the previously reported increased predictive value of resting heart rate for cardiovascular death in African-American women.[9] Our models included more coronary events among black women than in the previous survey, and disparities between ethnic groups in identification and management of risk factors have changed since the 1970s and early 1980s when that analysis was undertaken.

We found a stronger association between increased heart rate and coronary events in women aged 50-64 than in those aged 65-79. A possible explanation for this finding is that chronotropic insufficiency is more frequent in the older women, reducing the reliability of heart rate as a predictor of coronary events. Individuals with heart rates in the highest quintile or decile for age could be readily identified and targeted for aggressive management of risk factors.

Women's Health Initiative investigators are listed at www.whiscience.org/publications/WHI_investigators_shortlist.pdf.

Contributors: See bmj.com

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Competing interests: None declared.

Ethical approval: The protocol and consent forms were approved by institutional review boards of the participating institutions; all trial participants provided written informed consent.

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Use of fertility drugs and risk of ovarian cancer: Danish population based cohort study

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ABSTRACT

Objective To examine the effects of fertility drugs on overall risk of ovarian cancer using data from a large cohort of infertile women.

Design Population based cohort study.

Setting Danish hospitals and private fertility clinics.

Participants 54 362 women with infertility problems referred to all Danish fertility clinics during 1963-98. The median age at first evaluation of infertility was 30 years (range 16-55 years), and the median age at the end of follow-up was 47 (range 18-81) years. Included in the analysis were 156 women with invasive epithelial ovarian cancer (cases) and 1241 subcohort members identified in the cohort during follow-up in 2006.

Main outcome measure Effect of four groups of fertility drugs (gonadotrophins, clomifene citrate, human chorionic gonadotrophin, and gonadotrophin releasing hormone) on overall risk of ovarian cancer after adjustment for potential confounding factors.

Results Analyses within cohort showed no overall increased risk of ovarian cancer after any use of gonadotrophins (rate ratio 0.83, 95% confidence interval 0.50 to 1.37), clomifene (1.14, 0.79 to 1.64), human chorionic gonadotrophin (0.89, 0.62 to 1.29), or gonadotrophin releasing hormone (0.80, 0.42 to 1.51). Furthermore, no associations were found between all four groups of fertility drugs and number of cycles of use, length of follow-up, or parity.

Conclusion No convincing association was found between use of fertility drugs and risk of ovarian cancer.

INTRODUCTION

Whether fertility drugs increase the risk of ovarian cancer has received much attention. Three studies showed increased risks,[1-3] particularly in nulliparous women and those who had used fertility drugs long term. Several subsequent studies failed to confirm a link,[4-18] although many had methodological limitations.

We established a cohort of 54 362 Danish women who attended infertility clinics during 1963-98. These women were found to have a 46% higher risk of ovarian cancer than women in the general Danish population after adjustment for parity.[19] We evaluated the effects of different fertility drugs on the risk of ovarian cancer in this cohort.

METHODS

The cohort is described elsewhere.[20-22] Briefly, it comprised women referred for infertility during 1963-98. We also included women with infertility recorded in the national patient registry, a register of virtually all discharges for somatic conditions from Danish hospitals since 1977. Overall, 54 449 infertile women were enrolled. All but 87 had a valid civil registry number, leaving 54 362 women for analysis.

Identification of cases and the subcohort

We linked the cohort to the Danish Cancer Registry and the Danish Registry of Pathology. As the cancer registry was updated only until 31 December 2003 at the time of analysis, we used the pathology register to determine ovarian cancer status in the cohort from 1 January 2004. We followed the cohort for ovarian cancer from the date infertility was evaluated until the date of emigration or death, or 30 June 2006, whichever occurred first. Ovarian cancer was diagnosed in 193 women during follow-up. After exclusions, 176 women with epithelial cancer remained.

In the case-cohort design the experience of all cases is compared with those of a subcohort.[23] We randomly selected 1360 women from the cohort in strata according to both age at entry to the cohort (18-26, 27-30, 31-36, and ≥37 years) and year at entry (1965-77, 1978-84, 1985-9, 1990-6, and 1997-8).

Ascertainment of drug use and potential confounders

We collected medical records on all infertility related visits for the women with ovarian cancer and members

of the subcohort. After exclusions, 156 women with ovarian cancer (89%) were available for analysis in the cohort. After exclusions, 1241 women remained in the subcohort. Ovarian cancer was diagnosed in eight women in the subcohort during follow-up. We included these women as cases and as members of the subcohort in the analyses.

Information was abstracted on fertility drugs prescribed and number of treatment cycles. For each cycle we recorded the dates of starting and stopping. To obtain information on reproductive history for all women, we linked the cohort to the civil registration system and the Danish National Birth Registry. We obtained information on reproductive history from 1973 from the birth registry and reproductive history before 1973 from the civil registration system.

Statistical analysis

We used the unweighted case-cohort approach[24 25] to estimate rate ratios for ovarian cancer in a Cox proportional hazard regression model, stratified according to age and year of enrolment. We estimated rate ratios[23] such that the women in the subcohort contributed to all the relevant risk sets until the end of follow-up due to cancer, death, migration, or censoring, whereas women who were cases entered only their own risk set. The 95% confidence intervals were based on robust estimates of the variance-covariance matrix of the Cox regression variables.

We evaluated the effects on overall risk of ovarian cancer and risks for different histological subtypes according to use of follicle stimulating hormone, human menopausal gonadotrophins, clomifene citrate, human chorionic gonadotrophins, and gonadotrophin releasing hormone, measured as any use, number of cycles of use, and years since first use. In the analyses, we pooled follicle stimulating hormone and human menopausal gonadotrophins into one group called gonadotrophins, as they have identical modes of action.

The 156 epithelial tumours were classified into five histological types: serous (n=90), mucinous (n=12), endometrioid (n=23), clear cell (n=8), and other (n=23). Potential confounders investigated included parity (nulliparous, parous), number of additional births, and maternal age at birth of first and last child. We entered variables as time dependent covariables, which changed values at the ages at which new events occurred. Statistical analyses were carried out with SAS/STAT version 8.2.

RESULTS

The median age at first evaluation of infertility was 30 and at end of follow-up was 47. The women were followed for a median of 16.0 years (range 0.0-42.6 years). The median time from entry to the cohort and diagnosis of cancer was 14.5 years (range 0.02-34.2 years), and the age at diagnosis ranged from 25 to 68 years (median 46 years). Fertility drugs were used by 77 of the 156 (49%) women with ovarian cancer and 615 of the 1241 (50%) subcohort members. Clomifene was most commonly used, by 58 cases (37%) and 415 subcohort members (33%), followed by human chorionic gonadotrophins (31% and 33%), gonadotrophins (17% and 15%), and gonadotrophin releasing hormone (10% and 9%).

Maternal age at birth of first and last child did not significantly affect the overall risk of ovarian cancer. In contrast, parous women had a notably lower risk than nulliparous women (rate ratio 0.45, 95% confidence interval 0.32 to 0.63), which decreased with number of births (rate ratio 0.68, 0.47 to 0.99; see bmj.com).

After adjustment for parity and additional births, the overall risk of ovarian cancer was not significantly affected by use of any fertility drug (rate ratio 1.03, 0.73 to 1.47; data not shown), gonadotrophins (0.83, 0.50 to 1.37), clomifene (1.14, 0.79 to 1.64), human chorionic gonadotrophins (0.89, 0.62 to 1.29), or gonadotrophin releasing hormone (0.80, 0.42 to 1.51; table). For all groups of fertility drugs the risk of ovarian cancer was

Rate ratios for ovarian cancer according to use of fertility drugs

Variables	No with ovarian cancer/No in subcohort				Adjusted rate ratio (95% CI)			
	Gonadotrophins*	Clomifene citrate	hCG	GnRH	Gonadotrophins*	Clomifene citrate	hCG	GnRH
Use:								
Never	130/1057	98/824	107/828	141/1131	1.00	1.00	1.00	1.00
Ever	26/184	58/417	49/413	15/110	0.83 (0.50 to 1.37)	1.14 (0.79 to 1.64)	0.89 (0.62 to 1.29)	0.80 (0.42 to 1.51)
No of cycles:								
1-4	18/130	35/226	31/232	14/100	0.74 (0.41 to 1.33)	1.27 (0.83 to 1.94)	0.96 (0.62 to 1.48)	0.81 (0.42 to 1.56)
5-9	7/46	15/117	13/121	1/10	1.09 (0.49 to 2.44)	1.03 (0.57 to 1.86)	0.86 (0.47 to 1.57)	0.68 (0.09 to 5.38)
≥10	1/8	8/74	5/60	0/0	0.96 (0.09 to 10.30)	0.92 (0.42 to 2.02)	0.70 (0.28 to 1.80)	—
Time since first use (years):								
<5	8/3	8/3	9/3	5/1	0.67 (0.29 to 1.54)	0.80 (0.32 to 1.99)	0.78 (0.35 to 1.75)	0.72 (0.28 to 1.89)
5-9	12/33	17/14	16/26	8/32	1.12 (0.58 to 2.21)	1.48 (0.80 to 2.73)	1.22 (0.67 to 2.23)	0.99 (0.43 to 2.33)
10-14	5/77	13/77	10/81	2/57	0.80 (0.29 to 2.18)	0.99 (0.53 to 1.87)	0.83 (0.43 to 1.62)	0.60 (0.13 to 2.70)
≥15	1/71	20/323	14/303	0/20	0.44 (0.06 to 3.14)	1.18 (0.70 to 1.99)	0.78 (0.43 to 1.42)	—

All analyses stratified according to calendar year (in categories) and age at start of follow-up (in categories). Rate ratios adjusted for parity (nulliparous or parous) and number of additional births (linear). hCG=human chorionic gonadotrophin; GnRH=gonadotrophin releasing hormone.
*Follicle stimulating hormone and human menopausal gonadotrophins.

not substantially different according to number of cycles of use or years since first use (table). For all four types of fertility drug, the overall risk of ovarian cancer was not noticeably affected by parity, and none of the interaction terms were statistically significant (see bmj.com).

The risk of serous cancers was significantly increased after use of clomifene (1.67, 1.07 to 2.61), mainly among women followed for 15 years or more after first use compared with never use (<5 years 1.22, 0.45 to 3.34 to ≥15 years 2.17, 1.15 to 4.08). The risk was not related to the number of cycles, however, and did not differ according to parity (data not shown).

DISCUSSION

We found no convincing association between use of fertility drugs and risk of ovarian cancer. Risk did not differ according to any use of fertility drugs, number of cycles of use, length of follow-up since first use, or parity. When we analysed differences in risk according to histological subtype, we found a 67% increased risk of serous ovarian cancer after use of clomifene, primarily among women followed for 15 or more years.

Strengths and limitations

An important strength of the present study compared with earlier cohort studies is the large number (n=156) of women with ovarian cancer studied, compared with one to 12 in most previous cohort studies.[1 4 5 9 10 13-15] Forty five cases were included in another study,[16] although it consisted of a mixture of non-epithelial, epithelial, and borderline ovarian tumours. Thus all the earlier cohort studies were limited by imprecise risk estimates, especially in subgroups of fertility drug users. Furthermore, only two cohort studies[1 16] used a control group of infertile women who had not taken fertility drugs. The others used standardised incidence ratios to compare risk in cohorts of infertile women with that of the general population. This comparison controls for the potential confounders of age and calendar time only.

We showed previously that the infertile women in this cohort are at a higher risk of ovarian cancer than women in the general Danish population.[19] The case-cohort technique used in the present study, however, showed no strong association between use of fertility drugs and risk of ovarian cancer in the cohort. Our data therefore suggest that factors related to the diagnosis of infertility and not the use of fertility drugs increase the overall risk of ovarian cancer. One strength of our study is the minimal losses to follow-up. Furthermore, we had detailed information on the types of fertility drugs used, which allowed examination of their potentially different effects. Few of the previous cohort studies[1 5 9 10 16] and case-control studies[3 7 17] were able to assess such effects.

Although follow-up was relatively long, the median age at the end of follow-up (47 years) was below the usual age (early 60s) for ovarian cancer, which might have weakened our estimates.

Comparisons with the literature

The incessant ovulation theory suggests that repeated, uninterrupted ovulation causes microtrauma to the ovarian epithelium, leading to malignant transformations.[26] The gonadotrophin theory suggests that exposure of the ovaries to endogenous or exogenous gonadotrophins is directly carcinogenic.[27] Even though these theories are biologically plausible, only two epidemiological studies[1 2] found a notable association between use of fertility drugs and the risk of invasive ovarian cancer. Our results contrast with those of the these studies but are in line with most subsequent epidemiological studies[4-18] as we found no difference in overall risk of ovarian cancer according to any use of the four groups of fertility drug studied, number of cycles of use, length of follow-up since first use, and parity. The absence of a dose-response relation between the number of cycles and risk of ovarian cancer we found is in line with most previous findings,[5 8 14-17] but not all.[1]

The collaborative analysis of 12 case-control studies in the United States[2] and two other studies[12 16] suggested that infertile women who received fertility drugs but remained nulliparous may be at particularly high risk. We found no association between overall risk of ovarian cancer and use of fertility drugs after stratifying for parity, similar to some other studies.[7 11 17]

In contrast to the analyses of overall risk of ovarian cancer, we found a significant 67% increase in risk of serous tumours after use of clomifene, primarily when follow-up was for more than 15 years since first use. In a pooled analysis of case-control studies, researchers[12] found no association between use of fertility drugs and risks of different histological subtypes of epithelial ovarian tumours. Although the association between use of clomifene and risk of serous tumours may be real, we are not able to draw firm conclusions on the other histological types of ovarian cancer. Also, we cannot rule out that the association between use of clomifene and risk of serous tumours arose from multiple comparisons.

Conclusions

The results of our large, nationwide study, which represents the largest number of cases of ovarian cancer in any cohort of women with infertility problems to date, generally concur with those of most previous epidemiological studies and provide reassuring evidence for the absence of a strong association between use of fertility drugs and risk of ovarian cancer. However, as many of the women in our cohort have not yet reached the usual peak age for ovarian cancer, we will continue to monitor the risk to try to establish a more definite link between use of fertility drugs and risk of ovarian cancer.

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Contributors: See bmj.com.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Most epidemiological studies have found no strong link between use of fertility drugs and risk of ovarian cancer, but controversy persists

Most earlier cohort studies have had methodological problems

WHAT THIS STUDY ADDS

No convincing association was found between overall risk of ovarian cancer and use of fertility drugs

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Abuse of people with dementia by family carers: representative cross sectional survey

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ABSTRACT

Objective To determine the prevalence of abusive behaviours by family carers of people with dementia.
Design Representative cross sectional survey.
Setting Community mental health teams in Essex and London.
Participants 220 family carers of people newly referred to secondary psychiatric services with dementia who were living at home.
Main outcome measure Psychological and physical abuse (revised modified conflict tactics scale).
Results 115 (52%, 95% confidence interval 46% to 59%) carers reported some abusive behaviour and 74 (34%, 27% to 40%) reported important levels of abuse. Verbal abuse was most commonly reported. Only three (1.4%) carers reported occasional physical abuse.
Conclusions Abusive behaviour by family carers towards people with dementia is common, with a third reporting important levels of abuse and half some abusive behaviour. We found few cases of physical or frequent abuse, although those with the most abusive behaviour may have been reluctant to report it.

INTRODUCTION

Elder abuse is a priority of both the UK government[1] and the US federal government.[2] In the UK it is defined

as a single or repeated act or lack of appropriate action occurring within any relationship where there is an expectation of trust, which causes harm or distress to an older person.[1]

In the UK the government is consulting about a revision of the current policy for safeguarding vulnerable adults.[3] This review is entirely focused on preventing abuse by paid carers, suggesting that abuse is confined to the formal care system. This is in line with the 2004 statement by the House of Commons select committee that "few incidents of abuse are committed by loving, supportive people who have lashed out."[1] Abuse can be psychological, financial, sexual, physical, or by neglect. Despite the select committee's contention, many family carers for people with dementia report acting abusively when asked and might see no alternative way to manage the situation and be unaware that their behaviour would be defined as abusive.[4 5] No studies of abusive behaviours in representative populations of family carers currently exist, but our systematic review found that the prevalence of elder abuse reported by family carers ranged from 12-55%.[6] Few of these studies used instruments with known psychometric properties.[6] We determined the prevalence of abuse by family carers of people with dementia in a representative population of care recipients referred to secondary care.

METHODS

We recruited family carers of people with a clinical diagnosis of dementia who were living at home and referred to community mental health teams covering London and Essex (which included inner city, suburban, and rural areas).

A researcher attended team meetings and reviewed the notes of all people consecutively referred to the team after being assessed. The clinical team initially contacted potentially eligible family carers (defined as providing care for four or more hours a week), and gave them an information sheet on the study. One week later a researcher telephoned the carers, unless they had asked not to be contacted. Interviews took place at a time and place convenient to the carer, usually their home.

Participants gave written informed consent. The information sheet specified that "we respect confidentiality but cannot keep it a secret if anyone is being seriously harmed." The care recipients were asked for consent to access their medical notes but not interviewed. When they lacked capacity to consent (judged from psychiatrist and carer reports), we asked the carers whether they thought that the care recipient would have agreed when they had capacity. Three experienced psychiatrists carried out interviews between January 2007 and April 2008.

Measures

We collected data on the age of the carer and care recipient, sex, ethnicity, qualifications, the carer's relationship to the care recipient (spouse, child, other), if the carer lived with the care recipient, and whether the carer worked. Our main outcome measure was abuse using the validated modified conflict tactics scale, completed by the carer.[5 7] This scale asks how often in the past three months the carers had acted in each of five psychologically and five physically abusive ways towards the care recipient, on a Likert scale from 0 (never) to 4 (all the time). A score of 2 or more (sometimes) on any question denotes important abuse. The scale has subscales for psychological and physical abuse. From the care recipient's medical notes we also obtained the most recent mini-mental state examination score and drugs. Carers were asked about the care recipient's neuropsychiatric symptoms using the neuropsychiatric inventory.[8]

Data analysis

Using appropriate summary statistics we reported the sociodemographic characteristics of the sample and the illness characteristics of the care recipient. We also reported the proportion of carers meeting criteria for abuse (caseness), and the proportion who indicated that each of the 10 behaviours occurred "at least sometimes." We used online software to calculate 95% confidence intervals.[9]

RESULTS

Overall, 220 of 319 (69%) eligible carers participated; 98 refused or were not contactable. Participants and non-participants did not differ for sex of the carer and care recipient (χ^2=1.3, P=0.26; χ^2=0.0, P=1.00), whether they lived together (χ^2=2.2, P=0.14), or the relationship (partner, child, other) between them (χ^2=2.7, P=0.26).

One hundred and forty four (66%) family carers were women, 182 (83%) were of white UK ethnicity, 157 (71%) were living with a partner, and 118 (54%) were living with the care recipient. Their mean age was 61.7 (SD 13.1) years (range 24-92 years). One hundred and twenty (56%) were caring for a parent, 72 (33%) for a spouse, and 28 (13%) for another relative or friend. Ninety (41%) had remained in education until age 18, and 86 (39%) were in full time or part time employment. One hundred and fifty nine (72%) of the care recipients were women (mean age of 81.6 (SD 7.8) years, range 58-99 years). Mini-mental state examination scores were available for 211 care recipients (mean score 18.4 (SD 7.0), range 0-29). The mean neuropsychiatric inventory score was 18.3 (SD 1.1, range 0-75). According to the family carers, the care recipients had experienced problems with their memory for a mean of 33.7 (SD 38.9) months (range 0-300).

Prevalence of abusive behaviour

In total, 115 (52%, 95% confidence interval 46% to 59%) carers reported some abusive behaviour. Total scores on the abuse instrument ranged from 0 to 11, with a median score of 1 (interquartile range 0-2). Seventy four (34%, 27% to 40%) family carers reported abusive behaviours occurring "at least sometimes" in the past three months (see bmj.com), the threshold used in this study to denote important abuse. The verbal

abuse items were most commonly reported. Only one carer stated that any of the abusive behaviours were taking place "most of the time," and none that any abuse was happening "all of the time."

Seventy two (33%, 27% to 39%) carers reported that psychological abuse occurred sometimes and eight (4%, 1% to 6%) that physical abuse occurred sometimes. Seven (3%) of the cases of physical abuse was because the carer reported that they were sometimes afraid that they might hit or hurt the care recipient. Only three (1%) carers reported that actual physical abuse sometimes occurred. Four people said "almost never" (subthreshold for case level) to physical abuse items of whom three were "afraid that they might hit or hurt" and one reported "almost never" handling the care recipient roughly.

DISCUSSION

Family carers commonly reported acting abusively towards people with dementia, with a third scoring equivalent to cases of abuse. This suggests that any policy for safeguarding vulnerable adults must consider strategies directed towards families who provide most care for older people, rather than exclusively concentrating on formal carers.

The prevalence of elder abuse reported by family carers in previous studies has ranged from 12-55%,[6] with some of the variation due to differences in definitions of what constitutes a case of abuse. Different definitions of abuse would have changed our figures for prevalence as half of family carers interviewed in our study reported abusive behaviour, mostly verbal, whereas few reported frequent or physical abuse. It is unsurprising that disagreement exists about what form of behaviour constitutes elder abuse and what is part of normal family relationships. In one US study, for example, 5% of older couples, and a higher percentage of younger couples, reported physical violence within their relationship over the previous year.[10] Abusive behaviour may be a continuation of an earlier, possibly mutually aggressive relationship,[10] which could become abusive if the care recipient no longer has the capacity to decide whether to stay in that relationship or to leave it and live independently.

Professionals are often reluctant to ask about abuse,[11] perhaps because of a fear that discussing and acknowledging it would necessitate referral of an adult for protection and trigger a punitive response such as removal of the person with dementia. This may result in an "all or nothing" approach to abuse, where it is ignored until the problem becomes serious. Similarly, clinicians may not consider abuse when seeing most carers, if abuse is perceived as a rare action purposefully perpetrated by amoral abusers, in contrast to most carers who would never act abusively. This paradigm has been used to describe societal reactions to child abuse, where abusers are construed as evil and other, who can be removed from society,[12] thus eliminating abuse.

We suggest that considering abusive behaviour on a continuous spectrum rather than dichotomising it would be more helpful in clinical practice. While professionals have a duty to make a referral for the protection of an adult if they believe that someone is being harmed or is at significant risk of being harmed, it is also important to detect and manage abusive behaviour below this threshold. This may help to prevent more serious abuse.

Limitations

Although many carers were willing to report abusive actions, some may not have been or may have underreported the severity, so our numbers could be an underestimate. Compared with an earlier study,[10] the rate of actual physical abuse was low and people may have been particularly reluctant to report serious physical abuse. Our study could not detect these and any other behaviours that the carer wanted to hide. Similarly, despite our high response rate and the comparability in sociodemographic characteristics between non-participants and participants, non-participants may have been more likely to abuse. The study comprised an hour long interview on a range of topics and was not presented specifically as being about elder abuse, but carers who were abusing may well have been more reluctant to meet with a researcher than those who did not consider themselves to be abusive. Although this was a representative (rather than convenience) sample of people with dementia, as new referrals to secondary care they comprise disproportionately those with a new diagnosis or with acute problems. Thus our population was less cognitively impaired than the population with dementia.[13] Care recipients may have had untreated neuropsychiatric symptoms (although the mean score was almost identical to that of a previous representative sample).[14]

Conclusions

Most family carers reported some abusive behaviour, and a third reported important levels of abuse. We found few cases of physical or frequent abuse. We suggest that any policy for safeguarding vulnerable adults must consider strategies directed towards families who provide the majority of care for older people, rather than exclusively formal carers. Considering elder abuse as a spectrum of behaviour rather than an "all or nothing" phenomenon could help professionals to feel more able to ask about it and therefore offer appropriate help.

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WHAT IS ALREADY KNOWN ON THIS TOPIC

People with dementia are particularly vulnerable to abuse

Many family carers of people with dementia report acting abusively

Professionals are reluctant to ask about elder abuse

WHAT THIS STUDY ADDS

A third of family carers reported significant abusive behaviour towards people with dementia in a secondary care setting

Most carers reported some abusive behaviour but few reported more serious and physical abuse

Elder abuse may be more realistically considered on a spectrum rather than as an "all or nothing" phenomenon

Ethical approval: This study was approved by the London multicentre research ethics committee.

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Women's compliance with nutrition and lifestyle recommendations before pregnancy: general population cohort study

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ABSTRACT

Objective To examine the extent to which women planning a pregnancy comply with recommendations for nutrition and lifestyle.

Design Prospective cohort study.

Setting Southampton, United Kingdom.

Participants 12 445 non-pregnant women aged 20-34 recruited to the Southampton Women's Survey through general practices, 238 of whom became pregnant within three months of being interviewed.

Main outcome measures Folic acid supplement intake, alcohol consumption, smoking, diet, and physical activity before pregnancy.

Results The 238 women who became pregnant within three months of the interview were only marginally more likely to comply with recommendations for those planning a pregnancy than those who did not become pregnant in this period. Among those who became pregnant, 2.9% (95% confidence interval 1.2% to 6.0%) were taking 400 µg or more of folic acid supplements a day and drinking four or fewer units of alcohol a week, compared with 0.66% (0.52% to 0.82%) of those who did not become pregnant. 74% of those who became pregnant were non-smokers compared with 69% of those who did not become pregnant (P=0.08). Women in both groups were equally likely to consume five or more portions of fruit and vegetables a day (53% in each group, P=1.0), but only 57% of those who became pregnant had taken any strenuous exercise in the past three months compared with 64% in those who did not become pregnant (P=0.03).

Conclusion Only a small proportion of women planning a pregnancy follow the recommendations for nutrition and lifestyle. Greater publicity for the recommendations is needed, but as many pregnancies are unplanned, improved nutrition and lifestyles of women of childbearing age is also required.

INTRODUCTION

In recent years there has been increasing focus on optimising women's nutrition and lifestyle in the

periconceptional period, a key time for fetal development.[1] However, as women are often unaware they are pregnant for the first few weeks, any changes will miss this period. Therefore promoting good health before pregnancy may be at least as important as during pregnancy. The National Institute for Health and Clinical Excellence has reinforced this focus on the periconceptional period. Its guidance on nutrition for mothers[2] also includes recommendations for those who may become pregnant.

Using data from the Southampton Women's Survey,[3] we examined the nutrition and lifestyle of women during the three months before they became pregnant and compared them with non-pregnant participants during that period.

METHODS

Between 1998 and 2002, 12 583 non-pregnant women aged 20-34 were recruited to the Southampton Women's Survey,[3] to examine factors operating before and during pregnancy on early growth and development. Information was recorded during a home interview on diet, physical activity, smoking, alcohol consumption, and use of nutritional supplements over the preceding three months. Diet was assessed using a 100 item food frequency questionnaire,[4] from which principal components analysis was used to derive a "prudent" diet score.[5] High scores reflect diets in line with healthy eating. From the questionnaire we also derived the number of portions of fruit and vegetables consumed daily. The women were asked about the brands of dietary supplements used, the amount taken daily, and how many days each supplement had been taken over the past three months. From these reported intakes we identified those women who reported taking 400 μg or more of folic acid a day over the three months before the interview. To capture those who had started taking folic acid only recently or on some days we also classified women according to whether or not they averaged an intake of 200 μg or more folic acid a day over the three months.

We collected data on menstruation and ultrasonography from the women early in pregnancy[3] and estimated the date the pregnancy started. For the main analyses we compared those who became pregnant within three months with those who did not. We did a similar analysis for women who became pregnant within one month of the interview, to see if those close to pregnancy were more likely to conform to the recommendations.

Statistical analysis

We compared proportions using χ^2 tests and, when appropriate, Fisher's exact tests, and we derived exact binomial confidence intervals. To compare continuous variables we used *t* tests, with skewed data being transformed using a logarithmic transformation before analysis.

RESULTS

After exclusions, data on 12 445 women were available for analysis. Of these women, 238 became pregnant within three months of the interview (see bmj.com for characteristics of all the women). The only significant difference between the groups of women who did and did not become pregnant within three months was the percentage in receipt of social security benefits (12% *v* 18%, respectively; P=0.03).

The table summarises the ways the women conformed to the general lifestyle guidelines and the specific recommendations for those planning a pregnancy. Those who became pregnant within three months of the interview were slightly less likely to be smoking than those who did not become pregnant (69% *v* 74% were non-smokers), but the difference did not reach significance (P=0.08). They were, however, less likely to have taken any strenuous exercise in the three months (P=0.03). Their diets were marginally more healthy but the effect was small, and in both groups 53% of women reported consuming five or more portions of fruit and vegetables a day.

Those women who became pregnant consumed a median 4.0 units of alcohol a week, corresponding to the upper limit recommended for women planning a pregnancy; for those who did not become pregnant the median was 4.8 units a week. The data were, however, strongly positively skewed, and some women reported high levels of consumption. Proportionally, more

Compliance with general healthy lifestyle recommendations and specific prepregnancy recommendations in women who did or did not become pregnant within three months of being interviewed. Values are percentages (95% confidence intervals) unless stated otherwise

Variables	Not pregnant within 3 months (n=12 207)	Pregnant within 3 months (n=238)
General healthy lifestyle recommendations		
Not smoking	69 (68 to 70)	74 (68 to 80)
Healthy eating:		
Mean (95% CI) prudent diet score (SD)	0.00 (−0.02 to 0.02)	0.07 (−0.06 to 0.19)
Consumes ≥5 portions of fruit and vegetables daily	53 (52 to 54)	53 (46 to 59)
Any strenuous activity in past 3 months*	64 (63 to 65)	57 (50 to 63)
Specific prepregnancy recommendations		
Alcohol intake:		
Median (interquartile range) units consumed per week†	4.8 (1.3-12.0)	4.0 (1.0-9.5)
Mean (range) units consumed per week†	9.0 (0-251)	7.6 (0-92)
Never	10 (9.5 to 11)	7.6 (4.5 to 12)
≤4 units/week	46 (45 to 46)	51 (44 to 57)
≤14 units/week‡	80 (79 to 80)	85 (80 to 89)
Folic acid supplements in past 3 months:		
Any§	26 (25 to 26)	44 (37 to 50)
≥200 μg/day§	4.4 (4.0 to 4.7)	19 (14 to 24)
≥400 μg/day§	1.1 (0.91 to 1.3)	5.5 (2.9 to 9.2)
≤4 units alcohol per week and folic acid ≥400 μg/day§	0.66 (0.52 to 0.82)	2.9 (1.2 to 6.0)

Comparisons are not statistically significant at 5% level unless stated otherwise.
*P=0.03.
†P=0.007 for differences among those drinking any alcohol.
‡P=0.049.
§P<0.001.

women who became pregnant consumed 14 units or less of alcohol a week compared with those who did not become pregnant (85% *v* 80%), and this difference was of borderline significance. Among those consuming alcohol at higher levels, reported units consumed weekly differed little between the two groups (median 22 units).

Only 44% of the pregnant women had taken any folic acid supplements in the three months before the interview and only 5.5% had taken 400 μg or more a day. At 11 weeks' gestation, 203 of the 238 women interviewed (93%) were taking some folic acid and 12% were taking 400 μg or more a day over the preceding three months.

Only seven of the 238 women (2.9%) who became pregnant complied fully with the recommendations on alcohol and folic acid intake before pregnancy at the time of being interviewed, compared with 0.66% of those who did not become pregnant. Thus women who became pregnant were 4.5 times more likely to follow the recommendations than those who did not (relative risk 4.5, 95% confidence interval 2.1 to 9.6), with an absolute difference in risk of 2.3% (95% confidence interval 1.2% to 3.4%).

Only two of the 71 women (2.8%) who became pregnant within one month of the interview reported complying with the recommendations on alcohol and folic acid intake. Forty eight per cent were taking some folic acid, but this figure is only marginally higher than the 44% among the larger group of those who became pregnant within three months of the interview.

DISCUSSION

Few women comply with the nutrition and lifestyle recommendations for planning a pregnancy; only 2.9% complied fully with the recommendations on alcohol and folic acid intake in the three months before becoming pregnant. Less than half the women who became pregnant within the three months of being interviewed were taking any folic acid supplements. Although those who became pregnant within three months were slightly less likely to smoke and tended to eat a marginally more healthy diet than those who did not become pregnant, they were less likely to undertake strenuous exercise.

Comparison with other studies

Several studies asked women retrospectively about folic acid intake in the periconceptional period.[6-22] Generally, fewer than half the women took any folic acid, comparable with our findings. Studies from Denmark and the United States have shown lower levels of alcohol consumption than in our study. No alcohol consumption was reported by 28% of Danish couples currently planning a pregnancy,[15] and retrospectively reported by 12% of Danish women who had planned their pregnancy.[23] In women in the US who were asked in pregnancy or after the birth around 50% reported drinking no alcohol in the months leading up to the pregnancy.[8 9 12] These abstinence rates are higher than in our study, although alcohol consumption in the general population varies widely by country.

Strengths and weaknesses

The major strength of this study is that the women were asked about lifestyle and diet as part of a general survey on health and were not influenced by whether they would become pregnant. Only at the end of the interview were they asked whether they anticipated planning a pregnancy in the next year.

The Southampton Women's Survey is broadly representative of the general population of England and Wales except for a lower than average percentage of women from non-white ethnic groups.[3] Some 75% of those women contacted agreed to take part, a high participation rate for studies on general populations.

A limitation is that we asked about lifestyles and alcohol and folic acid intakes over the three months before the interview. Some women may have started planning their pregnancy during that time, or after they had been interviewed but before they became pregnant. It is thus possible that some women were better equipped for their pregnancy than our data reveal. However, among women who became pregnant within one month of the interview the increase in those conforming to the recommendations was marginal.

Interpretation and implications

No amount of advice for planning a pregnancy will affect those who become pregnant unintentionally. Nonetheless, even for women who want to plan for pregnancy, advice on nutrition and lifestyle is not promoted widely.

In the period leading up to pregnancy the recommendations for smoking, exercise, and diet are similar to those for women in the general population. However, our data show that there are no significant improvements in compliance with the recommendations for smoking and diet leading up to pregnancy. Those who became pregnant within three months of the interview were less likely to be taking strenuous exercise. This is hard to explain unless women are influenced by perceptions about the risks of exercise in pregnancy.

Folic acid was taken in sufficient quantities by only a small percentage of women. However, intakes were higher among those who became pregnant within three months than among those who did not. The percentages also increased in early pregnancy, showing that considerably more women comply with the recommendations once they become pregnant. Nonetheless, women's intakes of folic acid supplements leading up to pregnancy generally fall far short of the recommendations.

Median alcohol intakes before conception were slightly lower in women who planned pregnancy than in those not planning a pregnancy. However, almost half of those who became pregnant within three months reported drinking at levels above the

WHAT IS ALREADY KNOWN ON THIS TOPIC

Nutrition and lifestyle guidelines are provided for women planning pregnancies, but whether these are followed is unclear

Data on the general population have been obtained after women have become pregnant or given birth, and are prone recall bias

WHAT THIS STUDY ADDS

Few women adhere to the nutrition and lifestyle recommendations for planning a pregnancy

Greater efforts are needed to improve compliance with the recommendations

recommended limit for those planning a pregnancy that was in operation at the time of the study. Only 7.6% of those who became pregnant within three months were not consuming alcohol at the time of the interview. Once pregnant, many women do report lower levels of alcohol consumption than before pregnancy[24] and so are aware of the recommendations for pregnant women.

In conclusion, our data show limited evidence of changes in health behaviours before pregnancy. Higher percentages of women conform to recommendations during pregnancy,[24] therefore change in behaviour is possible. Although this might be improved by greater publicity, substantial rates of unplanned pregnancies[13 25 26] mean that greater efforts are needed to improve the nutrition and lifestyles in women of childbearing age.

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Adolescents' use of purpose built shade in secondary schools: cluster randomised controlled trial

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ABSTRACT

Objective To examine whether students use or avoid newly shaded areas created by shade sails installed at schools.

Design Cluster randomised controlled trial with secondary schools as the unit of randomisation.

Setting 51 secondary schools with limited available shade, in Australia, assessed over two spring and summer terms.

Participants Students outside at lunch times.

Intervention Purpose built shade sails were installed in winter 2005 at full sun study sites to increase available shade for students in the school grounds.

Main outcome measure Mean number of students using the primary study sites during weekly observations at lunch time.

Results Over the study period the mean change in students using the primary study site from pre-test to post-test was 2.63 (95% confidence interval 0.87 to 4.39) students in intervention schools and −0.03 (−1.16 to 1.09) students in control schools. The difference in mean change between groups was 2.67 (0.65 to 4.68) students (P=0.011).

Conclusions Students used rather than avoided newly shaded areas provided by purpose built shade sails at secondary schools in this trial, suggesting a practical means of reducing adolescents' exposure to ultraviolet radiation.

Trial registration Exempt.

INTRODUCTION

Exposure to ultraviolet radiation from sunlight during childhood and adolescence is associated with an increased risk of skin cancer in later life.[1-3] In Australia, the vast majority of adolescents have high levels of knowledge on the dangers of skin cancer.[4] However, adolescents are resistant to using adequate sun protective measures in their activities outdoors.[5 6] Moreover, adolescents' exposure to ultraviolet radiation during school hours is estimated to contribute significantly to total cumulated exposure up to age 20.[7] Given the substantial costs to schools in developing purpose built shade and adolescents' tendency for sun seeking,[5] we did a cluster trial to examine whether students would use or avoid newly shaded areas provided by a purpose built shade sail intervention in secondary schools.

METHODS

We approached 127 schools randomly selected from outer metropolitan areas of Melbourne. Of these, 31 schools did not meet the study requirements (see bmj.com), five schools declined owing to concern about potential vandalism of shade structures or the video observations, and 40 declined with limited reasons given (such as too busy).

Fifty one secondary schools that met the eligibility criteria participated in the study. After shade audits and consultations with school principals, we identified two full sun areas in each school to be observed over the study period. We considered the schools' preferred site for the shade development as the "primary" study site and the adjacent or nearby area as the "alternative" study site. In January 2005 the study statistician (JAS) randomly assigned schools to intervention (n=25) and control (n=26) groups. Allocation was concealed from the other researchers and the schools until randomisation occurred.

Intervention

The intervention entailed building shade sail structures for students to use during passive activities such as eating lunch. We used shade sail structures, as this type of built shade seemed to be popular with early childhood centres and swimming pools, offered good visual appeal, and provided visible light and warmth appropriate for a changeable climate but adequately reduced ultraviolet radiation levels by at least 94% under the sails according to shade manufacturers' advice.

The shade sails were designed to accommodate the varying size of study sites; the final size was on average 74 m^2. The costs per shade sail were on average approximately $A11 500 (£5205; €5840; $7708), and the construction costs varied depending on the site conditions, with a maximum cost of $A22 000 at one school.

Outcome measures

The primary outcome was the change in the mean number of students using the primary site during lunch times in spring and summer terms before and after installation of the shade sail intervention. The secondary outcome was the change from pre-test to post-test in the mean number of students using the alternative site.

Observation protocol—We observed the two defined sites weekly by using digital video cameras. Each site was filmed for three periods of two minutes at approximately equal intervals during the main part of

Table 1 | Intention to treat analysis, comparing mean change in numbers of students observed to use primary site from pre-test to post-test by group

	Control schools (n=26)	Intervention schools (n=25)	Group difference (95% CI)	P value
Pre-test				
Mean (SD) use*	3.49 (2.82)	3.24 (2.83)	−0.25	
Range of use	0-59	0-30		
Intra-school correlation coefficient	0.30	0.40		
Post-test				
Mean (SD) use†	3.46 (2.69)	5.87 (4.70)	2.41	
Range of use	0-34	0-47		
Intra-school correlation coefficient	0.34	0.52		
Change from pre-test to post-test				
Mean change‡	−0.03 (2.78)	2.63 (4.26)	2.67 (0.65 to 4.68)	0.011

*Aggregate mean of observations on 16 days.
†Aggregate mean of observations on 14 days.
‡Difference calculated as post-test mean use minus pre-test mean use.

the lunch time for each observation date. We randomly assigned schools to the day of the week for observations after exclusion of unsuitable days (planned events or other scheduled disruptions).

Content analysis of observations—Research assistants following written protocols reviewed the observation film and recorded tallies of the numbers of students "using" the sites within each two minute observation. Students were defined as "using the site" and added to the tally if they were not yet counted and were within the site boundaries either playing, standing, sitting, or chatting to others in the area for more than two frames (or approximately 20 seconds).

Statistical methods

We aggregated observations of students' use by calculating the mean value, separately for the pre-test and post-test periods. We then calculated the difference to describe the mean change in students' use from pre-test to post-test for each school study site. The primary analysis compared these school specific differences in students' use at the primary site between the intervention and control schools by using an unpaired *t* test and on an intention to treat basis. The secondary analysis included the school specific differences in students' use for both the primary and alternative study sites, resulting in two outcome measures per school.

RESULTS

The shade sails were not built at two intervention schools where unforeseen demands required different use of the areas. Two control schools built shade sails near or on the study sites before the end of the study. One intervention school used portable shade umbrellas at pre-test, and one control school built a wheelchair ramp on the alternative study site, which probably disturbed observations.

Group differences in potential confounders—Temperature, cloud cover, school enrolments, and the numbers of missed observations were similar for the two groups at both pre-test and post-test.

Students' use of primary study sites at pre-test—Use of the primary study site varied widely across schools and observation days. However, table 1 shows that the aggregated mean students' use of the primary site over the 16 weeks of pre-test was similar for control and intervention schools.

Effect of building shade sails at intervention study sites—The mean change in use of the primary site from pre-test to post-test was −0.03 (95% confidence interval −1.16 to 1.09) students for control schools and 2.63 (0.87 to 4.39) students for intervention schools. An unpaired *t* test comparing these mean changes showed evidence of an intervention effect (mean change 2.67, 0.65 to 4.68; P=0.011) (table 1).

Analysis of shade avoidance—Table 2 shows that the mean change from pre-test to post-test in use of the alternative sites was relatively stable for each group. Furthermore, we found evidence that at intervention schools the mean change was greater for the primary sites than for the alternative sites (difference in mean change between sites 2.70, 0.75 to 4.64; P=0.007 from the generalised estimating equation), so the shaded area was not being avoided.

DISCUSSION

We found this shade sail intervention to be effective, with greater use of the newly shaded areas by students at intervention schools compared with full sun areas at control schools. Furthermore, we found no evidence of shade avoidance. The study was implemented with no dropout of schools.

The mean change in use of the primary study sites between control and intervention schools was relatively small; an average of approximately three more students used the shaded sites at intervention schools compared with unshaded primary sites at control schools. Nevertheless, we believe the findings are important because no other rigorous studies of the

Table 2 | Mean change in numbers of students observed to use alternative sites from pre-test to post-test by group

Change from pre-test to post-test	Control schools (n=26)	Intervention schools (n=24)*	Group difference
Mean change (95% CI)	0.87 (−0.22 to 1.95)	−0.03 (−1.09 to 1.02)	0.90

*Excludes one intervention school where observations of the alternative site were not possible.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Reducing exposure to harmful ultraviolet radiation during childhood and adolescence is important for skin cancer prevention

Despite good knowledge and awareness of skin cancer, Australian adolescents are resistant to use of hats and clothing for sun protection

No quality studies on the effects of increasing available shade alone for adolescent skin cancer prevention have been done

WHAT THIS STUDY ADDS

A purpose built shade sail intervention increased students' use of newly shaded areas at schools

Building shade is an effective practical option for protecting students against ultraviolet radiation during lunch times

effects of environmental approaches alone for skin cancer prevention have been done.[8]

The results of this study suggest that environmental change alone can produce behavioural change. The findings are not unexpected given that health promotion frameworks and theoretical models of behaviour underline the role that supportive environments and organisational change can have in influencing behaviours.[9 10] Moreover, sun protective behaviours are considered to be strongly environmentally cued. Further research is needed to examine whether increasing shade can be beneficial for prevention of skin cancer in adolescents in settings other than schools.

Limitations

One limitation was that many study sites were underused for at least part of the lunch time, which may reflect several factors. A major criterion for selecting study sites was that they were well used areas in the main activity centres of the schools. However, we selected the sites in winter and patterns of use may have been different in the warmer months. Further research is needed to establish what type of areas in schools are well used and attractive to students for passive recreation where shade sails might be built. The intervention sites included a range of features that might be more or less attractive to students and, for example, included seating or tables; grass, bitumen, or paving ground surfaces; and nearby garden beds and sports fields. That the effects were found despite this variation in features of sites was encouraging. The findings that students' use of the shaded sites at intervention schools increased whereas use of the alternative full sun sites was steady implies that at least some attraction of students from other areas in the schools to at least one study site occurred. We recruited schools with limited shade, so we expect that migration of students to these sites would mainly be from other unshaded areas in the schools. If migration occurred from pre-existing shaded areas it would highlight that the type of shade provided by shade sails was more attractive than other shade provided by trees and buildings.

Moreover, although the shade sails were relatively large (46-120 m^2), on average only six students used them. Further research might examine whether factors such as seating arrangements, as well as size of sails, might maximise use. If friendship groups were limiting, building multiple shade sails within a school would be valuable.

Conclusions

This study provides clear evidence that secondary school students will use rather than avoid shade sails in schools when location and shade design have been carefully selected. Although more research is needed to identify factors that will maximise students' use of shade sails, these findings suggest that investing in shade in schools has potential for reducing students' exposure to ultraviolet radiation during school hours.

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