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CAN VITAMIN D SUPPLEMENTATION PREVENT WINTER-TIME BLUES? A RANDOMISED TRIAL AMONG OLDER WOMEN

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Abstract: Background: Seasonal Affective Disorder (SAD) is a sub-type of depression that only occurs during the winter months. A reduction in vitamin D may be linked to SAD. Since vitamin D deficiency has been reported to be common in older people, vitamin D supplementation may be expected to reduce seasonal mood disturbance in this group. Objective: To assess the effect of vitamin D supplementation on the mental health of older women. Setting: Primary care in three areas of the UK (Herts, Newcastle, York). Subjects: Women aged 70 years or more recruited to the trial in the months May–October. Intervention: Eligible women were randomised to receive calcium and vitamin D supplementation or no supplementation. Outcome measure: At baseline and the six monthly assessment the mental component score (MCS), calculated from the SF-12 questionnaire was used to assess participants' subjective psychological well-being. Results: A total of 2117 women recruited to the trial had their baseline measures taken between the months of May–October (1205 woman in the control group and 912 women in the intervention group). Of these women, 1621 had a MCS score at baseline and six months. Comparison of the six month mean MCS scores, adjusting for baseline MCS score and age, showed there was no significant difference between the two scores ($p = 0.262$). Conclusions: Supplementing elderly women with 800IU of vitamin D daily did not lead to an improvement in mental health scores.

Key words: Older women, vitamin D, mental health.

Introduction

Sufferers of seasonal affective disorder (SAD) typically report depression-like symptoms in the winter months, when the photoperiod and levels of light are reduced (1). The prevalence of SAD in the UK has been estimated at 2.4–3.5% (2,3). Whilst the cause of SAD has not been fully elucidated, a number of mechanisms, linked to reduced daylight and length light, have been suggested as possible causes — leading to SAD via an eye-brain-endocrine system pathway or via a possible skin-vitamin D causal pathway (4).

In mammals, sunlight is required for the first stage of *in vivo* vitamin D synthesis and levels in humans are generally lower in the winter months than the summer months (5). It has been postulated that, at a cellular level, vitamin D can influence the body's endocrine system directly via a number of vitamin D receptors in the brain and spinal cord (4,6), although current evidence for these cellular influences is limited.

Randomised controlled trials using light therapy provide evidence that this treatment can be effective in relieving SAD symptoms. Additionally, two small–scale randomised controlled trials have suggested that a short course of vitamin D supplementation may improve positive psychological well-being in SAD-sufferers (7) and non-SAD sufferers (8). Yet these studies are by no means conclusive — not only were they small and under-powered but they monitored the impact of vitamin D over short periods of time (seven days and five days, respectively).

We have conducted a multi-centred randomised controlled trial of elderly women with one or more risk factors for hip fracture, where the treatment group received calcium and vitamin D. Since vitamin D deficiency has been reported to be common in older people (9), vitamin D supplementation may be expected to reduce seasonal mood disturbance in this group. Thus, as a secondary outcome we investigated whether there was any influence of vitamin D on psychological well-being related to seasonality over a six month period.

Methods

Participants

Women aged 70 years and over were recruited from general practices in three areas of the UK. Initial mailings were sent out from practices to women ≥70 years of age. Woman were excluded from this mailing if they had a life expectancy of <six months. All women were mailed trial details, a consent form, a dietary questionnaire and a health-related quality of life questionnaire (SF-12) (10). Women were also asked to: list their current supplements and medications, complete a brief medical history and then to return all documentation if they wished to participate further in the trial. Based on the results of the questionnaires women were considered eligible for randomisation if they: were ≥70 years of age, took < 500 mg of supplemental calcium daily, did not have bladder or kidney stones and had one or more of the following risk factors: weighed ≤58 kg; had at least one self-reported previous

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fracture; had a family history of hip fracture; was a smoker; had fair or poor reported health. Women with cognitive impairments were unable to return informed consent and thus also excluded from the study.

Concealed randomisation of eligible participants was carried out by independent researchers, not involved in the study. Patients were stratified by GP practice and multiple block sizes were used.

Treatments

Participants randomised to the intervention group received the study intervention, which consisted of an information sheet on increasing calcium in their diet and a visit to a practice or study nurse to receive a six month supply of Calcichew D3 forte tablets where this was not contraindicated. Two tablets per day were taken providing a daily total of 1000mg calcium and 800IU vitamin D. After six months, those in the intervention group were then invited back to be reviewed by the nurse and discuss any problems with the supplement. If there were no problems a further 18 months supply of supplements was given. Participants in the control group only received the information sheet and did not visit a nurse in relation to this study and were not supplied with any study-related supplement or placebo. This study used baseline data from those patients recruited in the months where vitamin D production is highest (May–October) and six month follow-up data from months where vitamin D production is lowest (November–April).

Outcome

At baseline and at the six month assessments the SF-12 questionnaire was used to assess all participants' subjective psychological well-being. The SF-12 is a widely-used generic health-related quality of life questionnaire that has been validated for use by older people as part of community studies (11). The questionnaire contains 12 questions covering eight domains related to well-being [physical functioning, role limitation (physical), role limitation (emotional), social functioning, mental health, energy/vitality, pain, general health perception]. Participants' scores from the eight domains can also be used to calculate two summary scores, the physical component score and mental component score (MCS), by using factor scores calculated previously from large population studies. Weighted algorithms were used to calculate the individual domain scores and the summary MCS as recommended by the authors of the score (10). Those participants who had completed < 5 items at either baseline or six months did not have an SF-12 score calculated.

Statistics

Results were analysed using SPSS 11. All analysis was on an intention-to-treat basis. Domain scores were analysed as non-parametric data using the Mann-Whitney test.

The age variable was transformed by squaring to produce normal data. The relationship between vitamin D supplementation and six month MCS score was assessed using ANCOVA adjusting for score at baseline and age.

Results

A total of 2117 women recruited to the trial had their baseline measures taken between the months of May–October (1205 woman in the control group and 912 women in the intervention group). Of these 1621 (77%) had a valid SF-12 score at both baseline and six months. Table 1 shows the

Table 1
Baseline characteristics

	Control Group n = 1205	**Control group with valid SF-12 score at baseline and six months n=941**	**Treatment Group n = 912**	**Control group with valid SF-12 score at baseline and six months n = 680**
Mean age (years; SD)	76.75; 5.0	76.71; 4.9	77.2; 5.2	76.97; 5.1
Current smoker (%)	8.7	8.2	9.4	8.8
SF12 mental component score (mean; SD)	50.53, 9.8	51.33; 9.4	51.37, 9.7	51.91; 9.2

Table 2
Mean mental component scores for the control and the treatment group

Difference between trial arm's mean MCS score at baseline and six months (95% CIs) n=1621		Difference (B) between control and treatment six month scores after controlling for baseline score and age (95% CI; p-value)
Baseline	6 months	
-0.59	1.76	-0.49
(-1.51– 0.33)	(-0.81–1.16)	(-1.34–0.81; p = 0.262)

baseline characteristics of all participants and of participants with a valid SF-12 score at baseline and six months, who were included in further analysis.

The average age of the participants was 77 years and 9% of participants were smokers. Less than 1% of participants had missing MCS data at baseline, however, this rose to 23% of participants in the six month assessment (22% in the control group and 25% in the treatment group). Comparison of the six month mean MCS scores, adjusting for baseline MCS score and age showed there was no significant difference between the two scores (p = 0. 262). The score of each individual six month SF-12 domain relating to psychological well-being [energy and vitality, social functioning, role functioning (emotional) and mental health] for the treatment and control group were compared. The treatment and control group had identical domain medians [energy and vitality = 50, social functioning = 100, role functioning (emotional) = 100 and mental health = 75] as well as interquartile ranges: there was no statistical difference between the scores.

Discussion

It is suggested that a reduction in the levels of vitamin D during the winter months is associated with SAD and that supplementation with vitamin D may improve positive psychological well-being. It has been reported that the *in vivo* production of vitamin D reduces with age (12,13), thus elderly people are at risk of vitamin D deficiency (9,14,15). Were a lack of vitamin D a risk factor for SAD, an elderly population would be expected to be particularly affected by SAD and thus to benefit from normal vitamin D supplementation. However, the addition of 800IU/day of vitamin D, slightly above the recommended daily amount, to elderly women's diets did not reverse any potential negative effect of vitamin D deficiency on mental health.

Indeed, we did not note any expected seasonal decline in mental health scores that we might expect if a significant proportion of our population had SAD. Therefore, our negative findings may be a consequence of either using an inappropriate measure of the psychological consequences of SAD and/or the prevalence of the problem in the population we studied was so small that any beneficial effects of supplementation would not be apparent. It has been reported that elderly women show only small, and not clinically important, changes in their psychological well-being during the winter (16).

This study offered the opportunity to assess the changes in psychological well-being over a six month period from summer to winter in a large sample of women. Because of the size of our study, had vitamin D supplementation had even a modest effect on mental health levels (as measured by the SF-12) then this would have been noticeable.

In conclusion, supplementing elderly women with 800IU of vitamin D daily did not lead to an improvement in mental health scores.

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