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## Effect of vitamin D supplementation on 25-hydroxyvitamin D status and parathyroid hormone concentrations in Brazilian women living in Southern England: a double-blind, randomised, controlled trial

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Vitamin D status is well recognised as an essential pro-hormone for optimum bone health and adequate status during wintertime can be particularly challenging for ethnic groups living in high latitudes(1). Low concentrations of 25-hydroxyvitamin (25(OH)D) are associated with a significant increase in parathyroid hormone (PTH). Therefore, the aim of the present study was to investigates the effect of vitamin D<sub>3</sub> supplementation on 25(OH)D status and PTH concentrations in Brazilian women living in Southern England.

In a double-blind randomized control trial (RCT), 56 women (age 35·75 ± 9·027 years) were supplemented with daily 15 μg vitamin D<sub>3</sub> or placebo, for 12 weeks during the wintertime.

At baseline, mean 25(OH)D concentrations were 36.06 ± 14.97 nmol/l, and 25% and 57.1% of women had 25(OH)D concentrations <25 nmol/l and <50 nmol/l, respectively. As shown in the Table below, mean 25(OH)D concentrations increased significantly in the supplemented group (+17.06 ± 17 nmol/l; p = 0.002), achieving a mean value above the inadequacy cut-off of  $\geq 50$  nmol/l<sup>(2)</sup>. As expected the increase in the placebo group was not statistically significant (p = 0.087). Post-intervention no participants had concentrations <25 nmol/l whereas 20.8% of the placebo group had concentrations below this threshold. Vitamin D intake from food was extremely low in both groups, but interestingly the placebo group had significantly higher intakes than the supplemented group postintervention (3.46  $\pm$  2.37 and 2.12  $\pm$  1.18 respectively, p = 0.017). An Analysis of Covariance (ANCOVA) was carried out with postintervention 25(OH)D as the dependent variable, the dichotomy of treatment group as the independent variable and baseline 25(OH) D as a covariate. There was a significant difference in post-intervention 25(OH)D concentrations between placebo and supplement, after having controlled for the baseline 25(OH)D [F(1.46), p = 0.002, partial eta squared = 0.2]. Both Intention-To-Treat (ITT), here presented, and Per-Protocol populations showed similar results for effectiveness of supplementation compared to placebo. Plasma PTH increased significantly in the placebo group (1.01  $\pm$  2.2 pmol/l; p = 0.04) whilst vitamin D supplementation prevented this seasonal increase (baseline and post-intervention:  $5.48 \pm 2.53$  and  $5.98 \pm 2.21$  pmol/l; p = 0.253), although only in the ITT analysis.

	25(OH)D nmol/l <sup>1</sup>						Plasma PTH, pmol/l 1					
	Baseline	SD	Post	SD	Change	SD	Baseline	SD	Post	SD	Change	SD
Placebo 15 μg/d	34·79 37·42	14·42 15·69	41.07 55.18	17·70 12·24	5.53 <sup>f</sup> 17.06 <sup>d</sup>	15·18 17·09	5·26 5·48	1·35 2·53	6·44 5·98	2·15 2·21	1.01 <sup>e</sup> 0.51 <sup>f</sup>	2·29 2·15
$p^3$	0.56 <sup>b</sup>		0.002 <sup>a</sup>		$0.002^{2}$		0.749 <sup>b</sup>		0.475 <sup>a</sup>		$0.403^{2}$	

<sup>1</sup>Values are means and SDs; <sup>2</sup> ANCOVA. <sup>3</sup> Statistical analysis: <sup>a</sup> Independent t-test; <sup>b</sup> Mann-Whitney; <sup>c</sup> Paired t-test; <sup>d</sup> p = 0.000; <sup>e</sup> p = 0.04; <sup>f</sup> p > 0.05.

The results suggest that vitamin D supplementation of 15 µg/d maintained mean 25OHD concentrations above the inadequacy threshold (<50 nmol/l)<sup>(2)</sup> and prevented vitamin D deficiency<sup>(3)</sup> (<25 nmol/l) during winter months for Brazilian women living in England. Considering the limited food sources rich in vitamin D and the very low intake observed, supplementation during wintertime was shown to be an effective strategy to help this ethnic group achieve adequate vitamin D status when sunlight exposure is limited. The findings for PTH and the potential impact on bone health warrants further investigation.

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