

Tehtäväänanto:

Sites=3,4

For background variables, we are interested to know:

-is there association between BMD and BMI?

-is there association between alcohol use and spring D vitamin values?

-is there association between eye disease and back disease?

The main objectives of the study are:

- to compare occurrence of eye diseases between the treatment groups
- to compare d-vitamin level in spring between the treatment groups
- whether there is association between BMD values d-vitamin spring values
- to compare d-vitamin levels between spring and autumn (whether there is mean decrease or mean increase)
- to compare d-vitamin level changes (between spring and autumn) between the treatment groups

Drinking whole eggs does not have an effect on Vitamin D levels of older Finnish women

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Abstract

Objective: Vitamin D is a steroid hormone responsible for many roles in human physiology, for example calcium homeostasis as well as cellular differentiation and proliferation. The role of vitamin D in bone mineral density (BMD) and ocular surface conditions are well recognized. In this study we aim to further evaluate the vitamin D status of older Finnish women, its changes when intaking uncooked whole eggs, and relationship to BMD as well as eye disease.

Design: The study was conducted as a randomized control trial (RCT) involving older Finnish women, who were randomized and divided into two groups.

Methods: A total of 670 ambulatory women aged 48-65 were studied. They were split into two groups: group 0 being the control group while group 1 was the intervention group. Group 1 were told to drink three (3) whole uncooked eggs daily every morning all throughout the study, which was conducted from April 1st to October 1st 2023. Every subjects baseline vitamin D on April 1st as well their final vitamin D on October 1st were measured as serum 25(OH)D3 levels using the HPLC method. Heel BMD (g/cm²) was measured by DXA-scan using a densitometer from GE Medical Systems.

The subjects were also examined for the presence of eye disease and back pain. Their BMIs were measured and they were also asked if they consumed alcohol regularly, which was represented in the data as a yes (1) or a no (0).

Results: There was no significant difference observed in the change of levels of vitamin D between the two different groups ($p=0.48$).

Conclusion: Drinking three whole eggs every morning had no significant effect in the levels of vitamin D in older Finnish women. Thus, uncooked whole eggs cannot be recommended for increasing vitamin D levels.

Statistical Analysis

Continuous variables, which followed normal distribution, were summarized with mean and standard deviation (SD), with median and lower quartile (Q1) and upper quartile (Q3) otherwise. Age was summarized with mean together with range. Categorical variables were summarized with counts (n) and percentages.

To assess the association between continuous variables such as heel BMD and BMI, and heel BMD and spring vitamin D levels, Pearson correlation coefficients were calculated (all were normally distributed).

To evaluate the association between alcohol use and spring vitamin D levels, two sample t-test was performed.

To evaluate the association between categorical variables like the presence of eye disease and back pain, chi-square tests were conducted. The minimum expected frequency was met and enabled usage of this method.

To assess the mean change in vitamin D levels from spring to autumn within each treatment group, paired t-test was performed for group 1 and a Wilcoxon signed rank test for group 0.

To compare the means of vitamin D levels in spring and autumn, and changes between these seasons between treatment groups, Wilcoxon Rank sum test was used as the data for change between seasons was not normally distributed in treatment group 0. Even though the data nearly followed a normal distribution, it was decided that it was to be handled as non-normally distributed as the kurtosis was over 1.

Normality assumption was checked visually e.g. using normal quantile plot, box-plot, kurtosis and skewness evaluation. Leneve's test was used to evaluate assumption of equality of variances.

Significance level of 0.05 was used (two-tailed). Also, 95% confidence intervals (CI) were calculated.

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Results

The study included 670 Finnish women. The mean age was 58.2 years (SD 4.0; range 48-65). The mean age between treatment groups did differ significantly ($p=0.0006$; two sample t-test), but the difference is likely clinically insignificant, as the mean ages for groups 0 and 1 were 58.7 and 57.7, respectively.

Wilcoxon Rank sum test was used to analyze the difference in spring vitamin D levels between treatment groups as the distribution for group 0 was not normal. The test indicated no significant differences in spring vitamin D levels between the treatment groups ($p=0.055$).

The overall mean change for Vit D levels between spring and autumn was an increase of 7.7 (95% CI 6.3 to 9.1; $p<0.0001$; Wilcoxon signed rank test) and the change was statistically significant.

When we compared the change between the treatment groups, it was noticed that the two groups show an insignificant difference ($p=0.48$; Wilcoxon Rank sum test) between spring and autumn

indicating that the treatment groups did not experience different magnitudes of change in vitamin D levels across the seasons. In more detail, the mean difference between seasons was an increase of 8.3 (95% CI 6.1 to 10.4; p<0.0001; Wilcoxon signed rank) for group 0 and an increase of 7.1 (95% CI 5.4 to 8.9; p<0.0001; paired t-test) for group 1.

There was no significant correlation between BMD and BMI (p=0.063; Pearson correlation r=0.072), alcohol use and spring vitamin D values (p=0.19; two-sample t-test) or back pain and eye disease (p=0.072; chi-square test).

There was an insignificant association between eye disease and treatment group (p=0.15; chi-square test). In more detail, treatment group 0 had 16.0% of patients with eye disease and the corresponding value for group 1 was 20.4%.

The correlation between spring vitamin D and BMD was insignificant (p=0.071; Pearson correlation r=-0.070).

Table 1 Baseline characteristics for the two treatment groups. Age was described with median and range and the other characteristics were described with mean and standard deviation, since they were normally distributed.

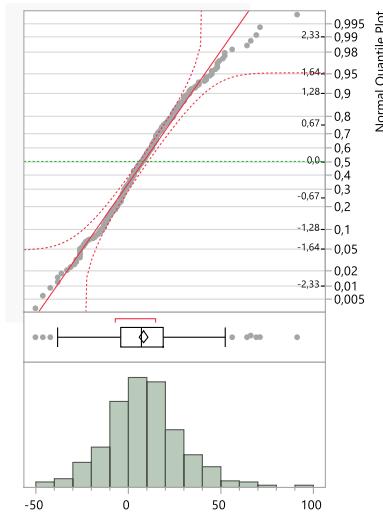
	All (n=670)	Group 0 (n=331)	Group 1 (n=339)	P-value
Age Mean (Range)	58 (48-65)	58.7 (49-65)	57.7 (48-65)	0.00060*
BMI Mean (SD)	25.99 (2.94)	25.92 (2.92)	26.07 (2.97)	0.52*
Spring Vitamin D, Mean (SD) (nmol/l)	48.1 (18.9)	46.7 (18.3)	49.5 (19.4)	0.054*
Autumn Vitamin D, Mean (SD) (nmol/l)	55.8 (19.7)	55.0 (19.9)	56.7 (19.6)	0.28*
Back disease	n=669			0.0014**
yes (percentage)	217 (32.4)	88 (26.6)	129 (38.2)	
no (percentage)	452 (67.6)	243 (73.4)	209 (61.8)	
Eye disease	n=670			0.15**
yes (percentage)	122 (18.2)	53 (16.0)	69 (20.4)	
no (percentage)	548 (81.8)	278 (84.0)	270 (79.6)	
Alcohol use	n=670			0.0010**
yes (percentage)	366 (54.6)	202 (61.0)	164 (48.4)	
no (percentage)	304 (45.4)	129 (39.0)	175 (51.6)	

*two sample t-test

**chi-square test

Here we show that the difference between seasons does not follow normal distribution in group 0.

FIGURE 1: The changes in vitamin D levels in group 0 (no intervention), with skewness and kurtosis



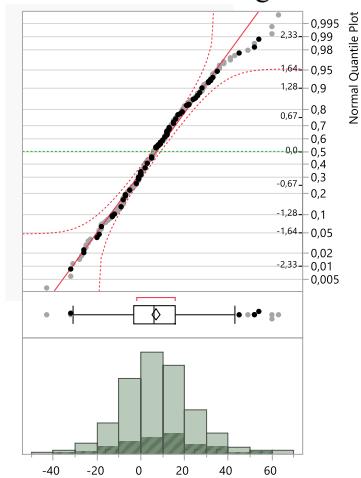
Quantiles

100.0%	maximum	91
99.5%		77,8
97.5%		51,7
90.0%		33
75.0%	quartile	19
50.0%	median	7
25.0%	quartile	-4
10.0%		-14,8
2.5%		-30,4
0.5%		-47,36
0.0%	minimum	-50

Summary Statistics

Mean	8,3081571
Std Dev	20,112303
Std Err Mean	1,1054722
Upper 95% Mean	10,482818
Lower 95% Mean	6,1334958
N	331
Skewness	0,3686069
Kurtosis	1,1760798
N Missing	0

FIGURE 2 The changes in vitamin D levels in group 1 (intervention), with skewness and kurtosis



Quantiles

100.0%	maximum	63
99.5%		60,9
97.5%		44
90.0%		28
75.0%	quartile	16
50.0%	median	6
25.0%	quartile	-3
10.0%		-13
2.5%		-25,5
0.5%		-35,3
0.0%	minimum	-43

Summary Statistics

Mean	7,1445428
Std Dev	16,566159
Std Err Mean	0,8997503
Upper 95% Mean	8,9143581
Lower 95% Mean	5,3747274
N	339
Skewness	0,3317658
Kurtosis	0,7602355
N Missing	0