

Effects of 3-month regular consumption of vitamin D-fortified low fat yogurt on quality of life indices in diabetic postmenopausal women: A randomized controlled clinical trial

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ABSTRACT

Background and aims: Diabetes affects all physical, emotional, and psychological aspects of patient's health. Postmenopausal diabetic women are more susceptible due to their crucial conditions. The emotional regulatory role of vitamin D may be because of the existence of its receptors distributed in brain areas involved in emotional processing and affective disorders. The aim of this study is to assess the effect of 3-month regular consumption of vitamin D-fortified low fat yogurt on QOL indices in diabetic postmenopausal women.

Methods: Fifty nine postmenopausal diabetic women randomly allocated to the 'FY' (received vitamin D-fortified low fat yogurt, containing 2000 IU vitamin D in 100 g) or 'PY' (received plain low fat yogurt without additive) treatment groups. The quality of life questionnaire SF-36 which is the most widely used method to assess the QOL was used before and after the intervention.

Results: After the 3-month intervention, physical performance, vitality, and mental health scores significantly increased and the score of physical pain decreased in the FY group. In the PY group, physical performance, vitality, and emotional role scores significantly decreased. Final scores of physical performance and vitality significantly increased in the FY group compare to the PY group while physical?

Conclusion: Three months daily consumption of 2000 IU vitamin D fortified low-fat yogurt improved physical performance, physical pain, and vitality while the other domains of QOL assessments did not show significant changes.

Keywords: Vitamin D-fortified food; Quality of life; Diabetes; Postmenopausal women.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) has become a worldwide health problem with a great deal of therapeutic expenses due to its complications. It has been estimated that the number of diabetic patients reaches to

592 millions cases in 2035. In Iran, more than 4 millions of adults (8.34% of total population) suffered from type 2 diabetes mellitus.¹ Diabetes affects all physical, emotional, and psychological aspects of

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patients health. Postmenopausal diabetic women are more susceptible due to their crucial conditions like aging, probable co-morbidities such as osteoporosis, and socio-economic problems.²

Patients with T2DM are in challenge with their disease because diabetes is a disabling chronic problem. Diabetes related distress, depression, and anxiety are emotional distresses that affect about 40% of the patients; therefore, the quality of life (QOL) will be affected.³⁻⁵ Patient satisfaction that is in interconnection with QOL, plays an important role in management of diabetes as well as self-care behaviors.⁶

Vitamin D is recognized as a factor not just involved in calcium homeostasis. The existence of vitamin D receptor in almost all cells and tissues justifies its extra-skeletal effects like anti-depressive, anti-anxiety, anti-inflammatory, immune-modulatory, insulin secretion, gene expression, and cardio-protection.⁷ The emotional regulatory role of vitamin D maybe because of the existence of its receptors distributed in brain areas involved in emotional processing and affective disorders.⁸ Epidemiological studies showed that low levels of serum 25-hydroxyvitamin D (25(OH)D) may contribute to emotional, spiritual, and physical disorders.⁹ Few studies assessed the effect of vitamin D on QOL of postmenopausal diabetic women. Motesinger et al. Conducted a cross-sectional study in old women of Iowa Women's Health Study and showed that subjects who consumed <400 IU vitamin D per day had significantly lower mental health related QOL compare to those received \geq 400 IU/day.¹⁰ Witham et al. Reported that 10 weeks vitamin D supplementation with 100,000 IU, did not improve the QOL in patients with heart failure.

METHODS

This study is a part of a randomized, placebo-controlled, double blinded, parallel

group clinical trial on diabetic postmenopausal women registered at Isfahan Endocrine and Metabolism Research Center. The primary objective of this project was to evaluate the effects of 2000 IU/day vitamin D-fortified yogurt on glycemic control, anthropometric indices, and bone markers in type 2 diabetic postmenopausal women. The results were mentioned in our previous article.² As the secondary objective, we assessed the effect of 12 weeks intervention on QOL of the participants. To compute the sample size, we used the suitable formula for parallel-design randomized controlled trials considering $\alpha=0.05$, 90% power, and a standardized effect size of $\Delta=1$ in N-terminal type-1 collagen (one of the bone markers) as a key variable of primary goals.² Therefore, we needed 22 participants in each group but 30 subjects were considered for each groups to avoid missing the participants. postmenopausal women who had not menses for at least 12 months were selected and enrolled in the study if they met the inclusion criteria: (i) not taking any forms of vitamin D, calcium, or omega-3 supplements within the past 3-month before the intervention, (ii) not taking drugs which have obvious interaction with vitamin D or influence its metabolism i.e. corticosteroids or estrogens, (iii) baseline serum 25(OH)D <125 nmol/l, and (iv) not having history of malignancy, renal failure, liver, endocrinologic, or inflammatory disorders.² Briefly, postmenopausal women who had not menses for at least 12 months were selected and enrolled in the study if they met the inclusion criteria: (i) not taking any forms of vitamin D, calcium, or omega-3 supplements within the past 3-month before the intervention, (ii) not taking drugs which have obvious interaction with vitamin D or influence its metabolism i.e. corticosteroids or estrogens, (iii) baseline serum 25(OH)D <125 nmol/l, and (iv) not having history of malignancy, renal failure, liver,

endocrinologic, or inflammatory disorders. The study protocol was approved by the Ethical Committee of Research, Isfahan University of Medical Sciences (registration number: 192015). The study protocol and its progress were recorded at www.irct.ir (registration ID: IRCT2013110515294N1). At first, the study protocol and objectives were fully explained to each subject and then written informed consent was obtained from all participants.

After 3 weeks running-in period, subjects were randomly divided to 2 groups. The equivalent amounts of dairy products were replaced by 100 g of low-fat yogurt per day in their diet. During the intervention, subjects who had any changes in type or dosage of oral anti-diabetic drugs or used insulin, received vitamin D, calcium or omega-3 supplements were excluded.

We used random permuted block method. Each block had permuted, even-numbered, randomly varying block sizes with 1: 1 allocation ratio. The block sizes were hidden until the end of the study. Postmenopausal diabetic women were randomly allocated to the 'FY' (received vitamin D-fortified low fat yogurt, containing 2000 IU vitamin D in 100 g) or 'PY' (received plain low fat yogurt without additive) treatment groups. An investigator uninvolved in recruiting the subjects performed the random sequence generation. Both participants and investigators were blinded to the content of interventions.

In this study the quality of life questionnaire SF-36 which is the most widely used method to assess the QOL was used. The mentioned questionnaire includes 36 questions that evaluates the quality of life in 8 domains; (i) physical performance, (ii) physical health, (iii) physical pain, (iv) general health, (v) vitality, (vi) social performance, (vii) emotional role, and (viii) mental health. Each question has a minimum

of 2 and a maximum of 6 options to answer. The options for each questions is graded based on a scale of 0 to 100. The zero and one hundred scores show the lowest and the highest levels of performance, respectively. The total score for each domain is calculated from the sum of the scores in that domain divided by the number of questions. Therefore, the total QOL score of each domain ranges from 0 (the lowest score) to 100 (the highest score). In another category, scores from 0 to 49 was classified as poor, 50 to 74 as relatively favorable, and 75 and more was ranked as favorable. The SF-36 questionnaire is a standard method designed by Ware et al. to measure the QOL of patients and healthy subjects.¹² Its validity is approved and its reliability has been reported from a minimum of 0.73 in social performance to a maximum of 0.96 in emotional role.^{13,14}

Demographic data, duration of daily sun exposure, durations of diabetes and menopause, concomitant diseases, drugs, smoking habits, and QOL were collected using questionnaires. The questionnaires were completed by 2 expert nurses not involved in the study.

Quantitative data were expressed as mean \pm SE and qualitative data were represented as number and percentage. Normality of studied variables was evaluated using Kolmogorove-Smirnov test and Q-Q plot. Positively skewed data were subjected to logarithmic transformation. Within-group Changes from baseline were assessed using paired-Student t-test for continuous variables or Mann-Whitney U test for non-normally distributed continuous variables. Pearson Chi-squared test was used to compare categorical variables. Between-group analyses were conducted using analysis of covariance (ANCOVA) in order to compare final values after adjusting the baselines. Data were entered and analyzed using the SPSS version 20.

RESULTS

Among 93 subjects, 29 patients did not meet the inclusion criteria. The remaining 64 patients were randomly divided into FY or PY groups as previously explained. Five women

were excluded during the intervention (week 3) due to change in treatment. Table 1 shows the general characteristics of 59 patients who completed the 3-month intervention.

Table 1: General characteristics of participants at baseline

Variables	FY ^a (n=30)	PY ^b (n=29)	P ^c
Age(year)	57.8±5.5	56.8±5.7	0.47
Diabetes duration(year)	9.3±5.3	8.8±4.8	0.70
Menopausal duration(year)	8.1±6.2	8±4.5	0.94
Physical activity(MET h ⁻¹ d ⁻¹)	23.4±1.8	23.3±2.0	0.94
Sun exposure(minute/day)	24.7±11.0	23±11.2	0.84
25-hydroxy vitamin D(nmol/l)	62.23±4.52	62.72±4.27	0.94
Physical performance	46.96±3.16	58.48±3.26	0.02
Physical health	54.39±3.30	53.46±3.24	0.84
Physical pain	57.12±3.18	63.49±3.22	0.02
General health	52.12±3.13	43.92±3.28	0.07
Vitality	58.84±3.27	61.88±4.04	0.03
Social performance	46.03±4.25	41.01±3.94	0.39
Emotional role	50.31±3.77	46.08±3.29	0.40
Mental health	40.26±3.26	43.78±4.13	0.52
Total QOL score	48.00±1.32	51.51±1.17	0.53

All presented values are means ± Ses; ^aFortified yogurt group; ^bPlain yogurt group; ^cDenote significance of within-group changes.

The distribution of age, diabetes and menopausal duration, physical activity, sun exposure, and total QOL score did not differ significantly between 2 groups. Physical performance, physical pain, and vitality were significantly different between the 2 groups which considered in final analyses by adjusting for the baseline values. The percentages of patients taking oral antidiabetic drugs were as follows: metformin, 66.6% in FY group and 65.5% in PY group; glitazone, 10% in FY group and 10.4% in PY group; oral agent

combination, 23.3% in FY group and 24.1% in PY group.

At start, 79.7% of subjects were vitamin D deficient or insufficient while at the end of the study period, the vitamin D status of the FY group was substantially improved: serum 25(OH)D significantly increased, and none of the subjects were deficient. Otherwise, in PY group, serum 25(OH)D, even if not significantly decreased and the percentage of sufficient subjects lowered from 20.7% to 3.4% (Table 2).

Table 2: Comparison of baseline and final values of serum 25(OH)D and QOL domains

Domain	FY ^a group			PY ^b group		
	Before	After	P ^c	Before	After	P ^c
25(OH)D (nmol/l)	62.23±4.5	86.83±4.87	<0.001	62.72±4.27	56.13±2.89	0.27
Physical performance	46.95±3.16	55.48±3.17	0.04	58.47±3.62	44.72±3.19	0.01
Physical health	54.39±3.30	53.99±3.48	0.92	53.46±3.23	45.53±2.83	0.09
Physical pain	53.12±3.18	42.91±2.24	<0.01	63.48±3.22	55.11±4.02	0.09
General health	52.14±3.13	52.07±2.73	0.98	43.91±3.28	54.07±4.37	0.06
Vitality	40.84±3.27	56.57±3.95	<0.01	61.88±4.04	40.62±3.68	<0.01
Social performance	46.03±4.25	36.02±3.29	0.08	41.01±3.93	46.42±4.40	0.38
Emotional role	50.30±3.77	53.72±3.24	0.50	46.08±3.29	54.66±3.60	0.02
Mental health	40.25±3.66	59.09±3.60	<0.01	43.78±4.13	47.32±3.90	0.59
Total QOL score	48.00±1.32	51.23±1.07	0.09	51.52±1.17	48.55±1.24	0.14

All presented values are means ± Ses; ^aFortified yogurt; ^bPlain yogurt; ^cP-values denote significance of within-group changes (paired t-test).

At baseline, 55.9% of participants had poor QOL scores. The remaining 44.1% had relatively favorable QOL scores. At the end of the intervention, the number of subjects with poor QOL score decreased in the FY

group; however, in the PY group most of the subjects had poor QOL scores. There were no significant differences between the 2 groups in QOL categories before and after the intervention (Table 3).

Table 3: Distribution of participants based on QOL categories before and after the intervention

Group	Before intervention				After intervention			
	Poor ^a	Relatively favorable ^b	Favorable ^c	P ^f	Poor ^a	Relatively favorable ^b	Favorable ^c	P ^f
FY ^d [n(%)]	21(70)	9(30)	0(0)	0.07	12(40)	18(60)	0(0)	0.12
PY ^e [n(%)]	12(41.4)	17(50.6)	0(0)		17(58.6)	12(41.4)	0(0)	
Total [n(%)]	33(55.9)	26(44.1)	0(0)		29(49.9)	30(50.8)	0(0)	

^aPoor QOL (QOL score<49); ^bRelatively favorable QOL (50<QOL score<74); ^cFavorable QOL (QOL score>75); ^dFortified yogurt; ^ePlain yogurt; ^fDenotes the significance of differences in QOL categories between the groups before and after the intervention (chi-square test).

Compare to baseline, total QOL score in both groups did not significantly changed but trends of increase and decrease were seen in the FY group and the PY group, respectively (Table 2).

After the 3-month intervention, physical performance, vitality, and mental health scores significantly increased and the score of physical pain decreased in the FY group. In the PY group, physical performance, vitality, and emotional role scores

significantly decreased (Table 2). Physical health, general health, social performance, and emotional role scores did not significantly changed in the FY group but a trend of reduction was observed in these scores after the intervention. In the PY group, the scores of physical health, general health, social performance, and mental role

decreased but the results were not statistically significant (Table 2).

Final scores of physical performance and vitality significantly increased in the FY group compare to the PY group while physical pain score was significantly decreased. The other domains of QOL assessment did not show significant differences between the groups (Table 4).

Table 4: Effects of vitamin D fortified yogurt on QOL scores in type 2 postmenopausal women

Domain	FYgroup ^a	PY group ^b	P ^c
Physical performance	55.27±3.35	44.95±3.41	0.04
Physical health	53.91±3.28	45.62±3.34	0.08
Physical pain	43.86±3.34	54.13±3.40	0.04
General health	51.70±3.70	54.45±3.78	0.61
Vitality	55.12±4.06	42.12±4.14	0.04
Social performance	45.22±3.90	37.19±3.82	0.15
Emotional role	52.96±3.35	55.45±3.441	0.60
Mental health	57.79±3.43	48.66±3.49	0.07
Total QOL score	50.88±1.18	48.92±1.98	0.26

Variables are after intervention measurements and represented “estimated marginal means” ± SEs (Adjusted for baselines, age, diabetes duration, and menopausal duration); ^aFortified yogurt; ^bPlain yogurt; ^cP-values are resulted from ANCOVA for between group comparisons based on after intervention values.

DISCUSSION

Vitamin D is thought to affect cerebral functions and brain health through its receptors which are scattered throughout the brain especially in areas involved in behavioral regulation.¹⁵ Seasonal affective disorders as well as depression are associated with sunlight deprivation and winter months. It suggests an association between vitamin D deficiency and mood disorders.¹⁶⁻¹⁸ The inverse relationship between vitamin D intake and mood disorders are represented in some studies.¹⁹⁻²¹ Few studies assessed the effect of vitamin D on mood disorders in old people.²²

Elevated inflammatory condition and oxidative stress are hallmarks of diabetes which can damage neurons. Diabetes also affect the production, secretion, and regulation of neurotransmitters in the brain.²³ Amongst diabetic patients, elderly subjects especially women are more susceptible to develop mood disorders. Assessment of QOL in diabetic patients has been considered by researchers.^{24,25} Kashfi et al. compared the QOL of 124 diabetic patients with 124 healthy similar subjects. They suggested that diabetes decreased the QOL of

patients.²⁶ Saadatjoo et al.¹⁰ and Vazirinejad et al.²⁷ also reported similar findings in their studies. Motsinger et al. evaluated the association between vitamin D intake and mental health-related QOL in older women.²² They found that women who consumed <400 IU/day of vitamin D had significantly lower mental health-related QOL compared to those who consumed \geq 400 IU/day. Witham et al. used 100000 IU oral vitamin D₂ supplements in vitamin D deficient-older patients with heart failure and repeated it after 10 weeks. They concluded that vitamin D supplementation did not improve functional capacity or QOL.¹¹ All of the mentioned studies used SF-36 questionnaire to evaluate the QOL.

To our knowledge, this is the first study which assessed the effect of vitamin D on QOL and its domains, in diabetic postmenopausal women via consumption of a fortified food. We also reported the adjusted final scores for QOL and its sub domain instead of weak raw data that must be considered as strengths of the study. Our study had some limitations that are indicated in the following; we suggest that 3-month intervention may not be enough to improve all the aspects of QOL in type 2 diabetic postmenopausal women. In addition, older women, especially those with diabetes usually have very poor QOL, therefore, vitamin D alone or in the dose of 2000 IU which was used in this study may not be able to improve the QOL appropriately. Further precise studies are needed to achieve more clear and accurate consensus in this field.

CONCLUSION

Three months daily consumption of 2000 IU vitamin D fortified low-fat yogurt improved serum 25(OH)D status of postmenopausal diabetic women. A trend of improvement was observed in the average

total QOL score of patients in the FY group while in the PY group, a trend of deterioration was found. After adjustment for baseline scores, age, menopausal duration, and diabetes duration which thought to affect the QOL of patients, final scores of physical performance, physical pain, and vitality significantly improved in subjects who received vitamin D fortified yogurt while the other domains of QOL assessments did not show significant changes.

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest.

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