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Role of Omega-3 Supplementation on Blood Pressure in Patients with Type 2 Diabetes Mellitus at Thi-Qar 2020

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Abstract:

Background: a role for dietary omega-3 fatty acids in reducing systolic and diastolic blood pressure, which might be more or less among diabetes type 2.

Aim: To determine the effect of omega-3 supplementation on blood pressure in patients with type 2diabetes**.**

Method: A single-blind, controlled clinical trial on patients admitted to Nasiriya Diabetes Center was involved randomly to 2 groups receiving either 2 g/day omega-3 and the comparator group received the same consultations exactly as the intervention group but provided anon-specific intervention. Our study period was 6 weeks. Participants were asked to follow the same lifestyle programs (physical activity, diet, and routine medicine) during an intervention, at the beginning and last of the study blood pressure were measured out and compared.

Results: Out of 60 participants 56 completed the study and 4 patients were excluded. Age, body mass index, SBP, DBP, and duration of diabetes at the beginning of the study in both groups. No significant difference was observed in baseline variables. 43% of the intervention group and 36% among the comparator group were diagnosed with hypertension. systolic and diastolic blood pressure in both groups was not statistically significant before and after the intervention.

Recommendation:
Consumption of 2 g/day omega-3supplement for 6 weeks has no significant effect on systolic and diastolic blood pressure in diabetes mellitus type2.
Key: omega 3, BP, DM, Thiqar, 2020
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Introduction:

Type 2 diabetes mellitus (DM) is one of the most progressive metabolic disorder in which prevalence has been interestingly rising all over the world. As a result of this trend, the number of people affected is expected to double in the next decade due to an increase in the aging population, thereby adding to the already existing burden for healthcare facilities, especially in poorly developed countries(1).

Hypertension is present in more than 50% of patients with diabetes mellitus (DM) and contributes significantly to both micro and macrovascular disease in DM (2, 3, 4). Indeed, the risk for cardiovascular disease (CVD) is four-time higher in patients with both DM and hypertension as compared to the normotensive non-diabetic controls (4, 5).

Previous study reveals that diet and lifestyle modifications, including physical activity, sodium reduction, and fish oil supplementation, can decrease blood pressure (BP), promote antihypertensive drug efficacy, and decrease cardiovascular disease (CVD) risk(6). Studies also suggest that omega-3 fatty acids enhance the production of nitric oxide from the endothelial cells (7, 8) .and improve endothelial function (9). Previous investigations have revealed that patients with essential hypertension have impaired nitric oxide-mediated vasodilation in the coronary arteries (10).

Long-chain omega-3 polyunsaturated fatty acids obtained in the diet from fatty fish and fish oils are cardioprotective nutrients with many beneficial features including anti-inflammatory, anti-thrombotic, anti-arrhythmic, anti-hypertensive, and antihyperlipidemic (11). Potent evidence suggests the beneficial effect of dietary omega-3 fatty acids in lowering systolic and diastolic blood pressure (12, 13).

The dose range of 2-4 grams/day of omega 3 has reduced both systolic and diastolic blood pressure by 4 and 2 mmHg, respectively as clinical trials for blood pressure reducing, with omega-3 fatty acid (14). Some other studies measured the effect of dietary omega-3 intake on blood pressure (15, 16, 17).

The study aimed to investigate the role of omega-3 polyunsaturated fatty acid supplements on blood pressure in patients with DM-2.

Materials and Methods:
A total number of 60 DM-2 patients admitted to Nasiriya Diabetes Center were involve randomly in 2 groups as a single-blind, controlled clinical trial, receiving 2 g/day omega-3soft gels (240 mg of DHA, 360 mg EPA, 6mg vitamin E) and the comparator group received the same consultations exactly as the intervention group but provided anon-specific intervention. Exclusion criteria included age > 60 years old, diagnosed DM-2 more than four years and less than one year, those with insulin therapy, or with kidney, liver, thyroid, or bleeding tendency disorders, and malignancies, in addition to not on omega-3 supplementation recently and those

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with hypertension more or equal to 4 years.

Although according to the prior studies, omega-3 supplement dosage was between 200 mg/day to 6 g/day (18). Considering the effective dosage, we intended 2 g/day in this study. The time requires for the chemical effects of omega-3 supplementation is about 4 to 12 weeks (19). So our intervention period was 6 weeks. Participants were asked to follow the same lifestyle programs (physical activity, diet, and routine medicine) during an intervention.

Measurements:

General Information about demographic characteristics, geographic location, duration of disease, type, and the dose of drugs was completed. The weight was measured, by using a digital scale with an accuracy of 200 g and the less clothes possible and height by the stadiometer with an accuracy of 0.5 cm was measured barefoot. Calories and supplement intake and participants' dietary habits changes were estimated at the first and end of a study by 24-hours dietary recall questionnaire. All patients consumed less than 2 servings of fish per day. At baseline and the last of 6 weeks, the blood pressure was measure out by a mercury sphygmomanometer in the right arm sitting position and after 5 minutes of rest. High blood pressure is defined as SBP>140mmHg or DBP>90 mmHg or taking antihypertensive medication (20). Those who consumed less than 80% of the capsules or changed their medications were excluded. Assessment of the rate of patients' compliance with the intake of capsules was performed by determining the number of capsules left at the end of the study.

Ethical Considerations:

Entering and leaving the study was completely voluntary and oral consent was obtained. All experiments were performed free of charge.

Statistical Analysis:
The variables of the two groups were analyzed by using SPSS software v.26. The Student t-test was used to compare the variables between the groups. P-value <0.05 was considered to be statistically significant.

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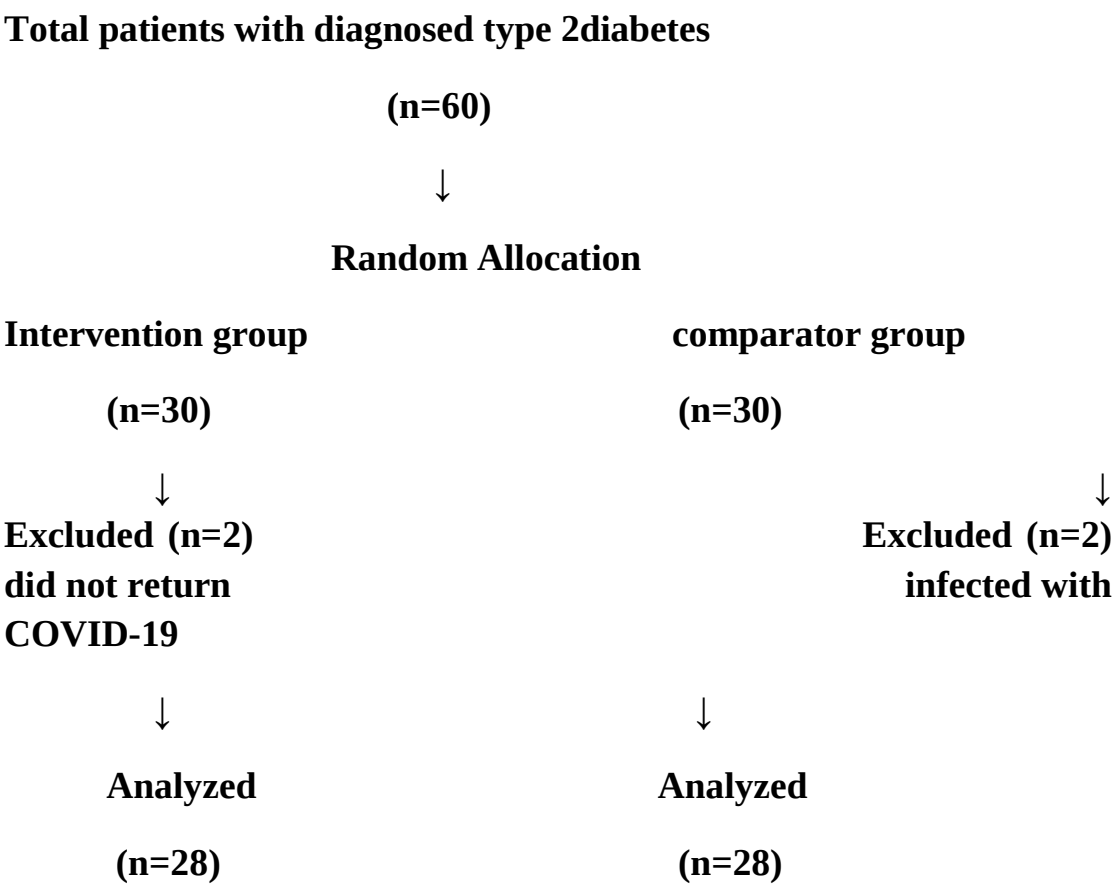

Framework: Study Flowchart, the process of screening of selected patients

Results:

An identical number of intervention and comparator (28 for each group) had been chosen by convenience sampling procedure, they were well crossly matched regarding age and gender distribution, with no significant difference between different gender and residence and employment history among intervention and comparator group, as shown in table 1.

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Table 1: Distribution according to the demography of the studied population

					Total	Pearson Chi-Square
			Intervention	Comparator		P vale
Gender	Male	No.	10	12	22	.299[a] .584
		%	45.5%	54.5%	100.0 %	
	Female	No.	18	16	34	
		%	52.9%	47.1%	100.0 %	
Residence						
Urban		No.	20	19	39	.084[a] 0.991
		%	51.3%	48.7%	100.0%	
Rural		No.	8	9	17	
		%	47.1%	52.9%	100.0%	
Employment history:						
Employed		No.	18	17	35	0.076 0.783
		%	51.4%	48.6%	100.0%	
Non		No.	10	11	21	
		%	47.6%	52.4%	100.0%	
Total		No.	28	28	56	
		%	50.0%	50.0%	100.0%	

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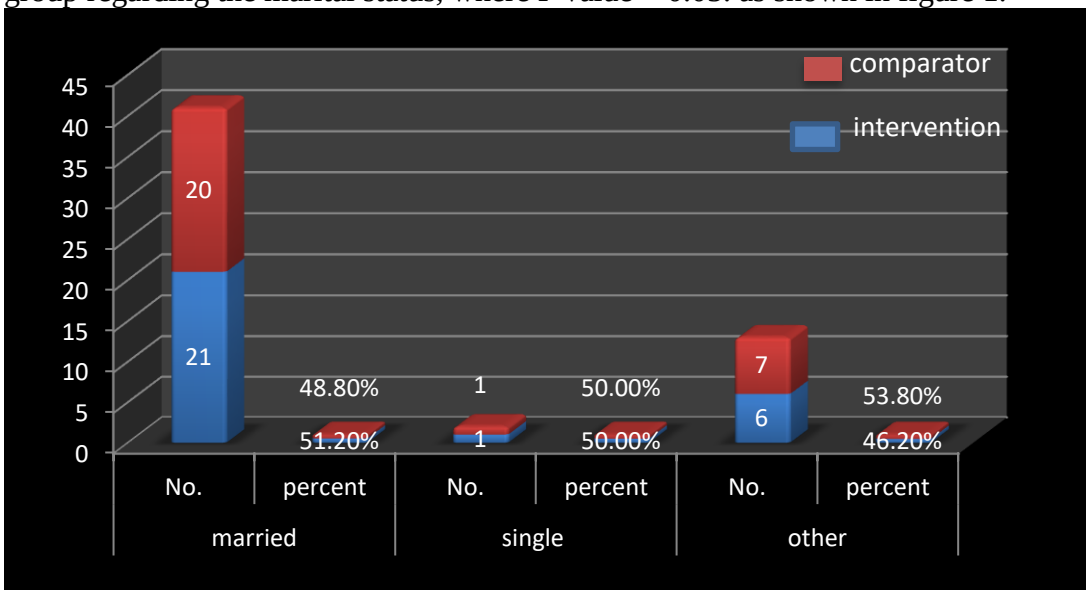
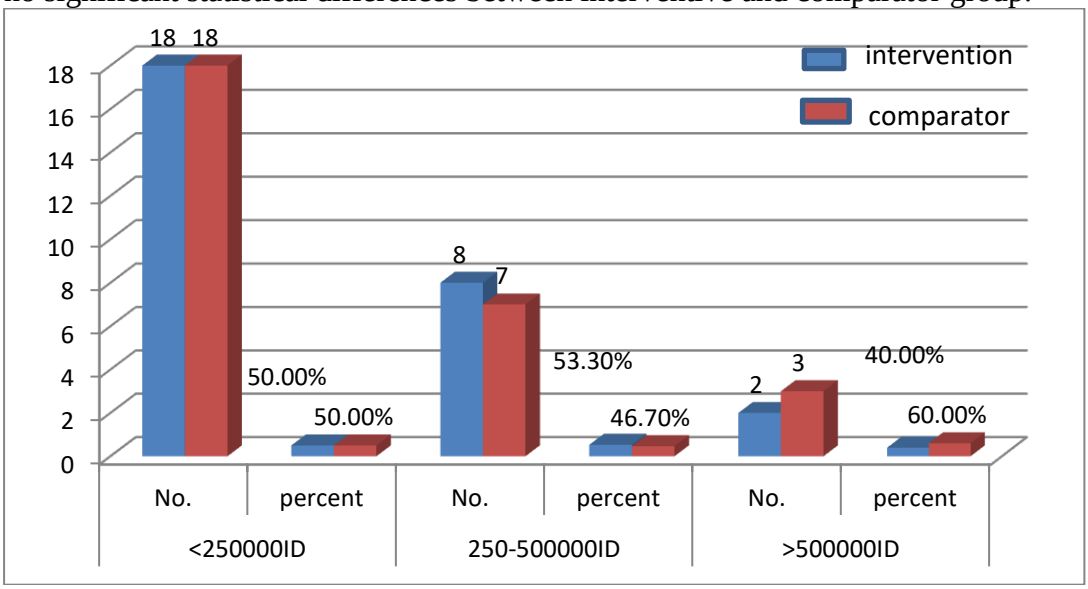
There was no significant statistical difference between intervention and comparator group regarding the marital status, where P value < 0.05. as shown in figure 1.



Pearson Chi-Square=0.101, p value= 0.951

Figure 1: Distribution according to marital status

The majority of intervention and comparator groups were with low income followed by intermediate and high per capita monthly income, and also there were no significant statistical differences between interventive and comparator group.



. Pearson Chi-Square=0. 267[a] , p value=0.875

Figure 2: Distribution according to per capita monthly income.

The majority of intervention and comparator were with primary and secondary learning fallowed by basic college and above, also there were no significant statistical differences between intervention and comparator group regarding their education.

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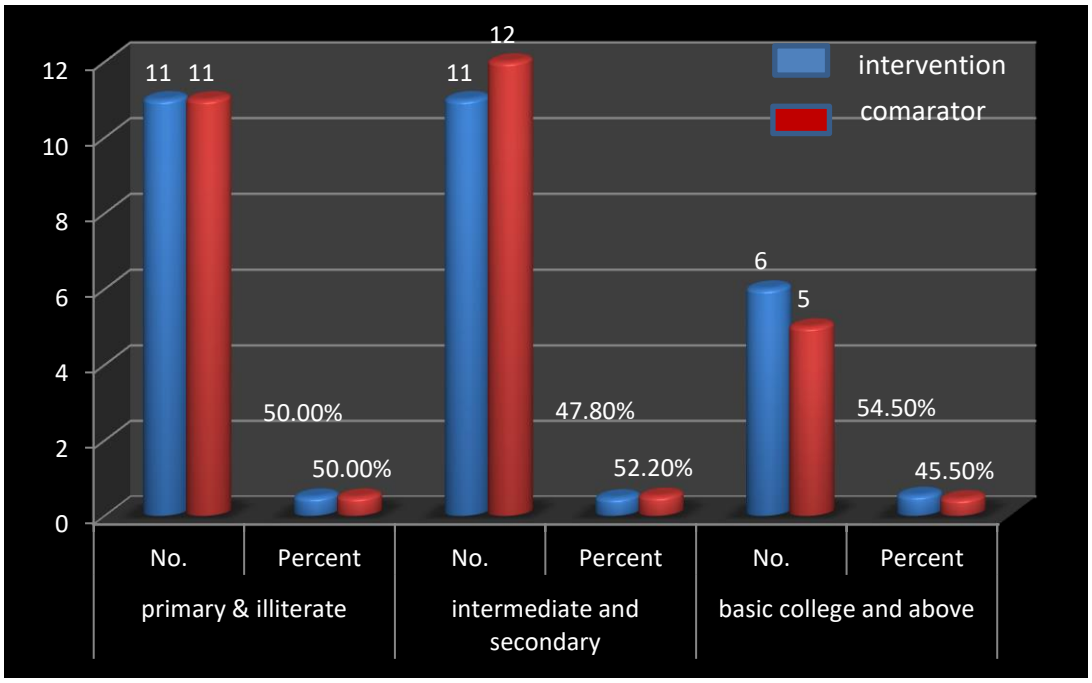
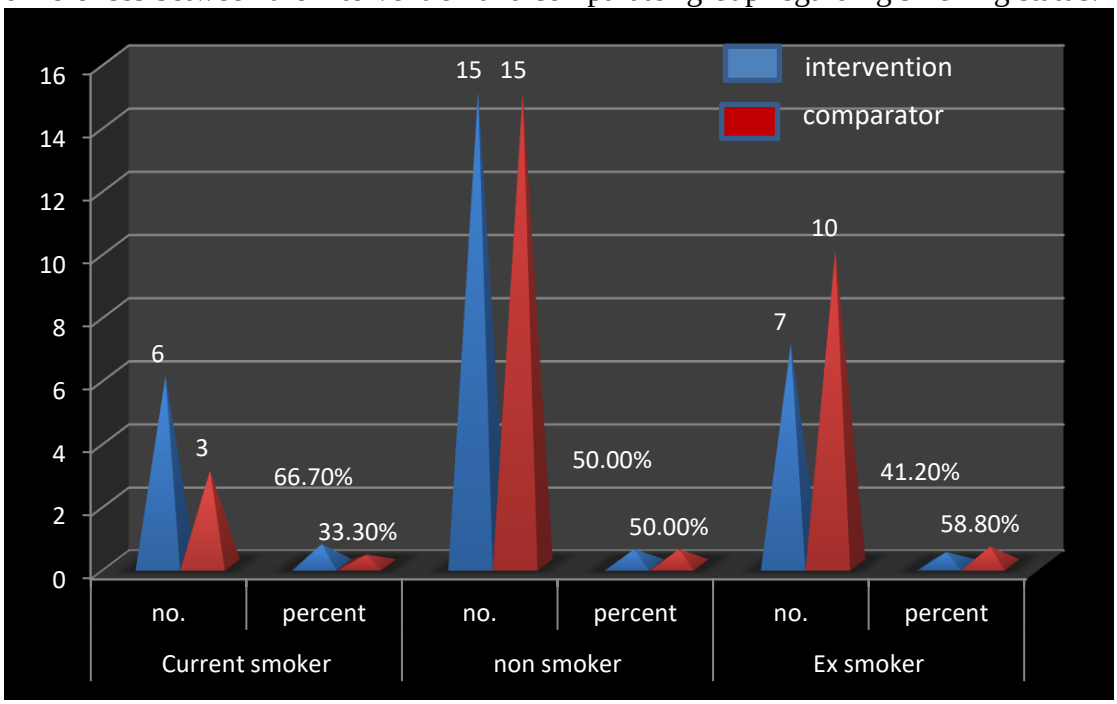


. Pearson Chi-Square=0. .134[a] , p value=0. .935

Figure 3: Distribution according to educational status

The majority of the intervention and comparator were non-smoker fallowed by current smoking and Ex smoker, and also there were no significant statistical differences between the intervention and comparator group regarding smoking status.



Pearson Chi-Square=1.529[a], p value=0.465

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Figure 4: Distribution according to the smoking status

Table 2: Distribution according to the medical history of studied population

					Total	Pearson Chi-Square
			intervention	Comparator		P vale
HTN	Yes	No.	12	10	22	0.299[a], 0.392
		%	54.5%	45.5%	100.0 %	
	No	No.	16	18	34	
		%	47.1%	52.9%	100.0 %	
Long term illnesses						
None		No.	14	11	25	3.429[a] 0.634
		%	56.0%	44.0%	100.0%	
1.00		No.	6	5	11	
		%	54.5%	45.5%	100.0%	
3.00		No.	2	7	9	
		%	22.2%	77.8%	100.0%	
12.00		No.	1	1	2	
		%	50.0%	50.0%	100.0%	
13.00		No.	3	2	5	
		%	60.0%	40.0%	100.0%	
123.00			2	2	4	
			50.0%	50.0%	100.0%	
Chronic medication						
None		No.	15	4	19	13.902[a] 0.01
		%	78.9%	21.1%	100.0%	
One		No.	13	17	30	
		%	43.3%	56.7%	100.0%	
More than one		No.	0	7	7	
		%	0.0%	100.0%	100.0%	
Total		No.	28	28	56	
		%	50.0%	50.0%	100.0%	

There was a significant statistical difference in chronic medication usage among the intervention and comparator groups, while the history of hypertension and coexisting diseases didn't show any difference.

Distribution according to physical activity of the intervention and comparator group also shows no significant differences.

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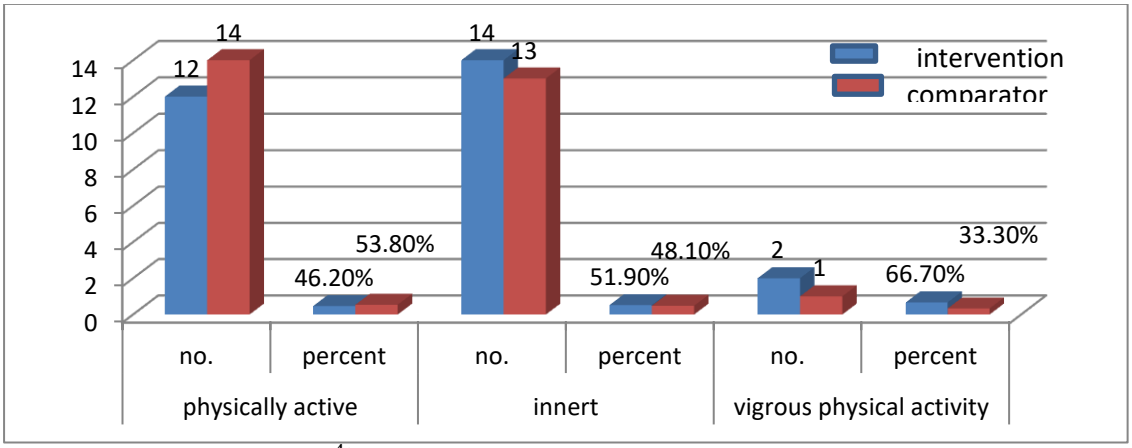

. Pearson Chi-Square=.52[4a], p value=0.**769**

Figure 5: Distribution according to the physical activity

Table 3:Group Statistics of the studied population

	Population	Mean	S. D	Mean Difference	t	P value
Age	Intervention	53.0357	5.07340	-1.67857-	-1.329-	.190
	Comparator	54.7143	4.35343	-1.67857-	-1.329-	.190
Duration of DM	Intervention	2.4286	1.28894	-.46429-	-1.397-	.168
	Comparator	2.8929	1.19689	-.46429-	-1.397-	.168
Duration of HT	Intervention	1.0000	1.27657	.17857	.535	.595
	Comparator	.8214	1.21879	.17857	.535	.595
BMI1	Intervention	31.5214	5.44231	.80357	.634	.529
	Comparator	30.7179	3.92514	.80357	.634	.529
SBP1	Intervention	126.6071	6.53390	-3.92857-	-1.982-	.053
	Comparator	130.5357	8.20335	-3.92857-	-1.982-	.053
DBP1	Intervention	83.7500	4.43576	-.17857-	-.127-	.900
	Comparator	83.9286	5.98720	-.17857-	-.127-	.900

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There was no significant statistical difference between the intervention and comparator group regarding age, duration of DM, duration of HTN, BMI (for the two occasions), systolic blood pressure and finally diastolic blood pressure.

Table 4:Paired Samples Statistics for the intervention group								
		Mean	N	Std. Deviation	t	p	Correlation	Sig.
Pair	BMI1	31.5214	28	5.44231	1.724	.096	.968	.000
	BMI2	31.0714	28	5.38811				
Pair	SBP1	126.607	28	6.53390	3.000	.006	.741	.000
	SBP2	124.107	28	5.27987				
Pair	DBP1	83.7500	28	4.43576	3.576	.001	.460	.014
	DBP2	81.0714	28	2.49338				

There was a significant statistical difference between the SBP & DBP at the 2 occasions of measurement

Table 5:Paired Samples Statistics for the comparator group								
		Mean	N	Std. Deviation	t	p	Correlation	Sig.
Pair	BMI1	30.7179	28	3.92514	2.738	.011	.992	.0001
	BMI2	30.4607	28	3.91222				
Pair	SBP1	130.5357	28	8.20335	1.000	0.326	.723	.0001
	SBP2	129.4643	28	5.82766				
Pair	DBP1	83.9286	28	5.98720	3.300	0.003	.783	.0001
	DBP2	81.6071	28	4.72456				

There was a significant statistical difference of the BMI and DBP at the 2 occasions of measurement

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Table6:Paired Samples Statistics for both intervention and comparator group collectively

		Mean	N	Std. Deviation	t	p	Correlation	Sig.
Pair 1	BMI1	31.1196	56	4.71888	2.562	.013	.976	.000
	BMI2	30.7661	56	4.67552				
Pair 2	SBP1	128.5714	56	7.61066	2.629	.011	.747	.000
	SBP2	126.7857	56	6.13696				
Pair 3	DBP1	83.8393	56	5.22155	4.905	.0001	.684	.000
	DBP2	81.3393	56	3.75270				

There was a significant statistical difference of the BMI, SBP & DBP at the 2 occasions of measurement

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Table7: Paired Samples Statistics for both intervention and comparator group (each item compared with correspondence)

		Mean	Std. Deviation	t	P value	correlation	Sign.
Pair 1	BMI1	31.5214	5.44231	.678	.503	.134	.495
	CoBMI1	30.7179	3.92514				
Pair 2	BMI2	31.0714	5.38811	.539	.594	.199	.311
	coBMI2	30.4607	3.91222				
Pair 3	SBP1	126.6071	6.53390	-1.834-	.078	-.172-	.381
	coSBP1	130.5357	8.20335				
Pair 4	DBP1	83.7500	4.43576	-.109-	.914	-.366-	.055
	CoDBP1	83.9286	5.98720				
Pair 5	SBP2	124.1071	5.27987	-3.382-	.002	-.136-	.489
	CoSBP2	129.4643	5.82766				
Pair 6	DBP2	81.0714	2.49338	-.451-	.656	-.466-	.012
	CODBP2	81.6071	4.72456				

There was no significant statistical difference between the SBP & DBP on the 2nd occasion of measurement

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Discussion

To confirm our knowledge, this study assesses the efficacy of omega-3 supplementation on blood pressure in patients with type 2diabetes the main findings are that 6 weeks of omega-3 had no significant effects on systolic and diastolic blood pressure. Our results corroborate with some studies (21, 22). ; while a number of studies have reported beneficial roles of omega-3 supplementation on endothelial function in patients with conditions associated with accelerated atherosclerosis, such as T2D, dyslipidemia, and obesity (23,24). A double-blind, controlled clinical trial, involved 60 DM-2 patients admitted to Diabetes (IRANIAN) Center. Inclusion criteria included age <60 years, diagnosed DM-2 at least four years, without any kidney, liver, heart, thyroid, or bleeding disorders, and malignancies, not taking omega-3 supplementation during the recent months and without insulin therapy, Subjects were randomly assigned into 2 groups: receiving either 2 g/day omega-3soft gels and 2g/day placebo (polyethylene glycol, PG), follow up for 6 weeks (Intervention period). Participants were asked not to change their lifestyle habits (physical activity, diet, routine medicine) during intervention After 6 weeks, no significant changes in both systolic and diastolic blood pressure between the intervention, and comparator groups were observed (22).

On other hand, the evidence from randomized controlled trials reveals the provision of ≥2g/d EPA+DHA may reduce both SBP and DBP, with more benefits observed among hypertensive individuals who are not received antihypertensive medication. In addition, a lower dose (between 1 and 2g/d) may reduce SBP but not DBP. From a clinical and public health perspective, the provision of EPA+DHA may lower blood pressure and eventually decrease the incidence of other chronic diseases associated (23).

Most studies were used olive, corn, or sunflower oil as a placebo which may be a source of bias in results due to mono-unsaturated or polyunsaturated fatty acids and their beneficial effects, In our study we take a comparator group without any placebo, in order to eliminate the chance of confounding factors.

The main limitations of our study were general health status due to the pandemic (COVID-19), which also forced us to limit the sample size in addition to the short duration of intervention, future studies with longer periods are needed, more sample size, in addition to, determining the appropriate dosage of omega 3 supplementation for optimal blood pressure control in diabetic patients.

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دور مكملات ألاوميغا الثلاثي على ضغط الدم في المرضى الذين يعانون من مرض السكري النوع الثاني في ذي قار\ لسنة الفان وعشرون

د. نهله صالح حسن العبيدي/ اختصاص طب اسره
د. نوال الخالدي/ اختصاص جهاز هضمي وكبد
د. علي كاظم شويل/ اختصاص باطنية

الخلاصة:

الخلفية: دور للأحماض الدهنية -ألاوميغا الثلاثي الغذائية في الحد من ضغط الدم الانقباضي والانبساطي، والتي قد تكون أكثر أو أقل بين مرض السكري من النوع الثاني.

الهدف: لتحديد تأثير مكملات ألاوميغا الثلاثي على ضغط الدم في المرضى الذين يعانون من مرض السكري النوع الثاني.

طريقة: تجربة سريرية واحدة مكفوفين، تسيطر على المرضى الذين تم قبولهم في مركز الناصرية للسكري كانت تنطوي بشكل عشوائي على مجموعتين تلقي إما اثنان كبسول/يوم من ألاوميغا الثلاثي وتلقت مجموعة المقارنة نفس الاستشارات بالضبط كما مجموعة التدخل ولكن قدمت تدخل خاص. كانت فترة دراستنا سته أسابيع. وقد طلب من المشاركين اتباع نفس برامج نمط حياتهم (النشاط البدني، والنظام الغذائي، والطب الروتيني) خلال التدخل، في بداية وآخر من ضغط الدم الدراسة تم قياسها ومقارنتها.

النتائج: من بين ستون مشاركاً أكمل سته وخمسون الدراسة واستُبعد اربعه مرضى. العمر، مؤشر كتلة الجسم، ضغط الدم الانبساطي و الانقباضي، ومدة مرض السكري في بداية الدراسة في كلتا المجموعتين. ولم يلاحظ أي اختلاف هام في متغيرات خط الأساس. تم تشخيص ثلاثة واربعون بألميه من مجموعة التدخل 36 % بين مجموعة المقارنة بارتفاع ضغط الدم. ضغط الدم الانقباضي والانبساطي في كلتا المجموعتين لم تكن ذات دلالة إحصائية قبل وبعد التدخل.

التوصية:

استهلاك اثنين غرام / يوم من ألاوميغا الثلاثي كبسول لمدة سته أسابيع ليس له تأثير كبير على ضغط الدم الانقباضي والانبساطي على مرضى السكري من النوع الثاني.

المفتاح: ألاوميغا الثلاثي، ضغط الدم، داء السكروز ي قار، لسنة الفان وعشرون .