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Effects of sesame, canola and sesame-canola oils on body weight and composition in adults with type 2 diabetes mellitus: a randomized, triple-blind, cross-over clinical trial

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Abstract

BACKGROUND: Recent investigations have proposed that sesame and canola oils might affect body fat distribution. The present study aimed to examine the effects of sesame, canola and sesame-canola (a blend of sesame and canola oils) oils on body weight and composition in adults with type 2 diabetes mellitus in the context of a randomized, triple-blind, three-way, cross-over clinical trial.

RESULTS: Eligible participants were randomized to replace their regular dietary oil with sesame oil (SO), canola oil (CO) and sesame-canola oil (SCO) (with 40% SO and 60% CO). Treatment periods lasted 9 weeks and were separated by 4-week washout periods. Body weight and composition were measured at the beginning, in the middle and at the end of each intervention phase. In total, 93 participants completed the study. After adjustment for confounders, within-period changes were observed following SO and CO intake for body weight (0.34 ± 0.16 kg and 0.33 ± 0.17 kg) and visceral fat ($0.13 \pm 0.06\%$ and $0.13 \pm 0.05\%$, P < 0.05), respectively. Body mass index was increased within SO intake (0.13 ± 0.05 kg m⁻², P = 0.031). All of the treatment oils resulted in reduced waist circumference and index of central obesity (P < 0.05). A significant difference in change values was observed for visceral fat between SCO ($-0.14 \pm 0.07\%$) and SO ($0.12 \pm 0.08\%$) treatment periods in females (P = 0.02).

CONCLUSION: Sesame and canola oils might lead to a modest favorable body fat redistribution by reducing central adiposity, particularly in females; however, the changes were of little clinical importance. © 2021 Society of Chemical Industry.

Supporting information may be found in the online version of this article.

Keywords: type 2 diabetes mellitus; dietary oils; sesame oil; canola oil; body weight; body composition

INTRODUCTION

Obesity has become a major health concern not only in highincome countries, but also in low- and middle-income populations.¹ Nowadays, the role of central obesity is more obvious as a result of its interference in a cluster of cardiovascular risk factors, including type 2 diabetes mellitus (T2DM).² Additionally, central obesity is considered as an important criterion for metabolic syndrome,³ which independently increases the risk of cardiovascular disease and T2DM.⁴ Therefore, a large body of research has been conducted all-around the world toward determining the appropriate approaches to reduce general and abdominal obesity.⁵

Obesity and T2DM are closely correlated⁶; therefore, weight management strategies should be considered to help prevent the progression of diabetes.^{7,8} Dietary modifications are regarded as the most practical strategies against obesity.⁹ Although energy intake restriction is the most important component, the

macronutrient composition of the diet (i.e. protein, carbohydrate and dietary fat) might also affect obesity.^{10–12} In recent decades, evidence supporting the favorable effects of vegetable oils on body weight and composition has been accumulating.^{13, 14} For example, the literature supports the beneficial effects of dietary

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monounsaturated fatty acids (MUFAs) and omega-3 polyunsaturated fatty acids (PUFAs) with respect to controlling body weight and composition.^{8, 15, 16}

Canola oil (CO) is recognized as one of the favorable vegetable oils as a result of its fatty acid profile.¹⁷ Indeed, the reasonable omega-6 to omega-3 fatty acid (2:1) and unsaturated to saturated fatty acid (15:1) ratios make CO a healthy vegetable oil.^{18, 19} Additionally, CO has considerable amounts of MUFAs (64.4%) and alpha-linolenic acid (8.3%),²⁰ with the latter being the precursor of eicosapentaenoic acid and docosahexaenoic acid in the human body.²¹ Recently, a multi-center cross-over clinical trial carried out by Liu *et al.*²² revealed that CO consumption results in a reduced android fat mass (approximately 3%) compared to a high PUFAs oil, a blend of flaxseed oil and safflower oil. However, other studies reported non-significant effects of CO intake on adiposity indices.^{23, 24}

Sesame oil (SO), an antioxidant-rich vegetable oil, is used in large quantities worldwide, particularly in Asian countries.²⁵ It is proposed that sesame and its oil might beneficially affect different aspects of health.²⁵ SO is characterized by approximately equal amounts of PUFAs (43%) and MUFAs (40%), considerable amounts of vitamin E (40 mg/100 g oil), and low amounts of alpha-linolenic acid (0.4%).²⁶ The omega-6 to omega-3 fatty acid and unsaturated to saturated fatty acid ratios for SO are 100:1 and 5:1, respectively.²⁷ A recent meta-analysis showed that body fat percentage and adiposity index (BAI) were decreased after sesame seeds consumption. In addition, SO decreased body weight and body mass index (BMI), whereas it had no effects on other anthropometric indices.²⁸ It is worth noting that the results of our previous study examining the effects of dietary CO, SO and SCO (SCO: a blend of the two oils) on adults without any chronic diseases revealed no different effects on body fat and composition.²⁹ The results of our parent project³⁰ on other health-related aspects have been reported elsewhere.^{29, 31–33} Because the metabolic responses to dietary interventions may differ between healthy individuals and those with chronic diseases, we examined the effects of dietary CO, SO and SCO on body weight and composition, which were assessed as secondary outcomes in a large controlled clinical trial conducted in patients with T2DM. In addition, although sex-specific effects are well acknowledged in some area of research,³⁴ they are not sufficiently elucidated in nutrition research studies. Thus, we aimed to provide sex-stratified analyses to gain more insight into the potential sex-specific effects.

MATERIALS AND METHODS

The present study was derived from a three-way, cross-over, randomized controlled clinical trial that aimed to compare the effects of CO, SO and SCO on cardiovascular risk factors in patients with T2DM and their spouses. The effects of dietary oils on body weight and composition (assessed as secondary outcomes in the parent trial) in patients with T2DM are investigated and reported in the present study. Detailed information on the parent study's protocol, participants' characteristics and ethical approval has been provided elsewhere.³⁰ The trial was registered in the Iranian Registry of Clinical Trials (IRCT) (registration ID: IRCT2016091312571N6) and written informed consent was obtained from all participants prior to the start of the study. The present study was also approved by the ethics committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran, with reference number IR.SSU.SPH.REC.1396.156.

Participants

Patients attending the Diabetes Research Center of Shahid Sadoughi University of Medical Sciences, Yazd, Iran, who were eligible to be entered into the current study were invited. The inclusion criteria were: age between 18-60 years; diagnosis of T2DM for at least 6 months or a history of diabetes of at most 10 years; treated with oral anti-glycemic agents and not taking insulin therapy; not changing the dose of lipid-lowering medications at least for 3 months prior to the beginning of the study; and HbA1c values \leq 8%. Furthermore, participants with a history of any chronic diseases (cardiovascular diseases such as coronary artery disease, stroke, congestive heart disease, and coronary artery bypass grafting, as well as kidney or liver diseases, and any types of cancer) were not included. Those who dramatically changed their dietary habits during the study period, went on a special diet, went on insulin therapy throughout the study period, experienced pregnancy, or chronic diseases such as cardiovascular diseases or cancer, or intentionally discontinued the study for any reason, were excluded from the study.³⁰

Study design

The study comprised a three-way randomized, triple-blind, crossover clinical trial. After stratification by sex, eligible participants (50 males and 52 females) were randomly assigned to one of six rolling methods to consecutively receive canola, sesame or sesame-canola [a blend of sesame (40%) and canola (60%)] oils using SPSS (IBM Corp., Armonk, NY, USA) by an independent researcher. The sequences were written on a paper and were kept in sealed opaque envelopes. The intervention oils were provided in exactly the same bottles labeled with three codes (B, G and S). The participants, personnel, biochemical technicians and statisticians were blinded to treatments up to the end of the statistical analysis.³⁰

The daily energy requirement of the participants was estimated using suggested formula.³⁵ Afterwards, a healthy dietary recommendation that provided 30-32% of total calorie needs from fats, 50-52% from carbohydrates and 16-18% from proteins was prescribed. The participants were referred to a trained nutritionist to receive nutrition counselling, as well. The participants entered a 4-week run-in period in which the usual dietary oil was replaced with sunflower oil for the study participants. Then, the usual dietary oil of adults with T2DM was replaced by CO, SO and SCO (with 40% SO and 60% CO). The treatment periods lasted 9 weeks and were separated by 4-week wash-out periods (sunflower oil was provided for the wash-out periods). Sunflower oil was selected to be used for washout and run-in periods because it is commonly consumed by Iranians and was also similar in its appearance to the intervention oils. The intervention oils were provided for the participants and their families by investigators.³⁰

Anthropometric measurements

There were three clinical visits (at the start, in the middle and at the end of each intervention period) in which body weight and body composition indices [waist circumference (WC), hip circumference (HC), visceral fat, total body fat and muscle mass] were measured. Using a wall-fixed measuring tape, height was measured to the nearest 0.1 cm. Standard methods were incorporated to measure WC and HC to the nearest 1 cm, using a nonstretchable measuring tape. Body weight, total body fat percentage, visceral fat and muscle mass were measured, when participants were with light clothes and without shoes using an digital scale and bioimpedance analyzer (model: BF51; Omron, Body weight (kg) was divided by height squared (m²) to calculate BMI. The waist to hip ratio (WHR) was calculated as WC divided by HC. The index of central obesity (ICO) was also calculated as WC divided by height.³⁶ The BAI was calculated using: $BAI = [(HC)/(height)^{1.5}) - 18]$.³⁷

Dietary intake measurement

Three-day weighed food records (2 weekdays and 1 weekend day) were obtained to measure the energy, macro- and micronutrient intake at the start, in the middle and at the end of the intervention periods. At the initial visit, the participants were trained about how to fill the food records by a nutritionist and written instructions were provided as well. Furthemore, the participants were asked not to go on a diet and to maintain their dietary habits and energy intake throughout the study.

The daily intake of all food items was computed and then converted to grams per day using household measures.³⁸ The daily energy and nutrients were calculated using Nutritionist IV, version 3.5.2 (Axxya Systems, Redmond, WA, USA), modified for Iranian foods.

Physical activity assessment

Physical activity was assessed during the study (at the start, middle and end of each phase) through 3-day records (2 weekdays and 1 weekend day). The participants were asked to keep their physical activity constant during the study. The physical activity data were converted to metabolic equivalent-min day⁻¹, using the updated version of the compendium of physical activities.³⁹

Intervention compliance

Because the present study aimed to replace the participants' regular oil consumption with the intervention oils and the intervention oils were provided for the subjects and their family, it was difficult to assess the exact amount of intervention oils consumed by each participant. However, two methods were incorporated to check the compliance: (i) the given and returned intervention oil bottles were weighed and the amounts of oils consumed was calculated and (ii) the 3-day food records were used to assess the amounts of oil consumed by the participants.

Assessment of the adiposity-related metabolic markers

Systolic and diastolic blood pressure (SBP and DBP) were measured when participants seated relaxed for 5 min in a comfortable chair using a sphygmomanometer (model: Diplomat-presameter; Riester, Jungingen, Germany). Triglyceride (TG) levels were analyzed by an auto-analyzer (model: AT⁺⁺; Alpha-classic; Sanjesh Company, Tehran, Iran) using Pars Azmoon standard kits (Pars Azmoon Inc., Tehran, Iran). Visceral adiposity index (VAI), which is a novel recent sex-specific index, based on WC, BMI, TG and high-density lipoprotein-cholesterol, indirectly expressing visceral adiposity, was also calculated based on suggested formulas.⁴⁰

Sample size calculation

The present study represents the effects of dietary CO, SO, and SCO on body weight and composition which were the secondary outcomes of a larger clinical study in which fasting blood sugar and serum lipid profile were the primary outcomes.³⁰

calculated based on the formula for cross-over studies $[n = [(z1 - \alpha/2 + z1 - \beta)^2 \times s^2]/2\Delta^2]$.⁴¹ The type one error was 5% and the type 2 error was 10% (power of 90%). Although a minimum of 34 participants was calculated as the required sample size, we decided to recruit 50 men and 50 women with the eligibility criteria to perform sex-stratified analysis.

Statistical analysis

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The quantitative variables were checked for normal distribution using the Kolmogorov-Smirnov test. Baseline and endpoint measurements were compared using the repeated measures analysis of variance model for the determination of within treatment changes. The effects of intervention oils were compared using a linear mixed-method procedure with the rolling method as a between-subjects factor with the crude model and a multivariable adjusted model considering potential confounders such as age, sex, baseline BMI, the calculated intervention oils consumed per subject, physical activity level and energy intake in each intervention period as covariates. The intervention oils were compared with the use of Bonferroni adjustment for multiple comparisons. Sex-stratified analyses were also conducted to show the possible specific effects in men and women. The results are expressed as means with their corresponding SEMs. All analyses were conducted using SPSS, version 20 (IBM Corp., Armonk, NY, USA). $P \le 0.05$ was considered statistically significant.

RESULTS

One hundred and two participants with T2DM were entered into the study and randomly assigned to treatment periods. Seven participants were dropped out from the analysis for the following reasons: did not intend to continue the study (n = 3), moved to another city (n = 1), went on insulin therapy (n = 1), experienced cardiovascular disease (n = 1) and had low compliance (n = 1). Additionally, two individuals did not participate in at least one visit in the SO intervention period and were excluded from the analysis. The study flow diagram is shown in Fig. 1.

Finally, 93 patients with T2DM (91% of total included subjects), aged 49.1 \pm 0.7 years (46 males and 47 females) completed the trial. The participants' characteristics are provided in Table 1.

Table 2 demonstrates dietary nutrients intake and physical activity level in each treatment period. No significant difference was observed between intervention periods in terms of total energy or energy percent from protein, carbohydrate and total fat intake. The analyses revealed that MUFAs intake was greatest in the CO, followed by SCO and SO treatment periods (P < 0.001). The differences between treatment oils was also significant for PUFAs intake (P = 0.001).

The effects of intervention oils on obesity markers

No carry-over effect was observed between the intervention periods for outcome variables (P > 0.05). In total, 93, 95 and 95 participants completed the treatment periods for SO, SCO and CO, respectively. The crude, as well as multivariable-adjusted models for after intervention and change values for body weight and body composition indices by intervention period, are provided in Table 3. Body weight ($+0.34 \pm 0.16$ kg), BMI ($+0.13 \pm 0.05$ kg m⁻²) and visceral fat ($+0.13 \pm 0.06\%$) were increased; However, WC (-0.67 ± 0.19 cm), WHR (-0.005 ± 0.002) and ICO (-0.004 ± 0.002) were decreased from baseline in the SO treatment period (P < 0.05). The results remained significant after



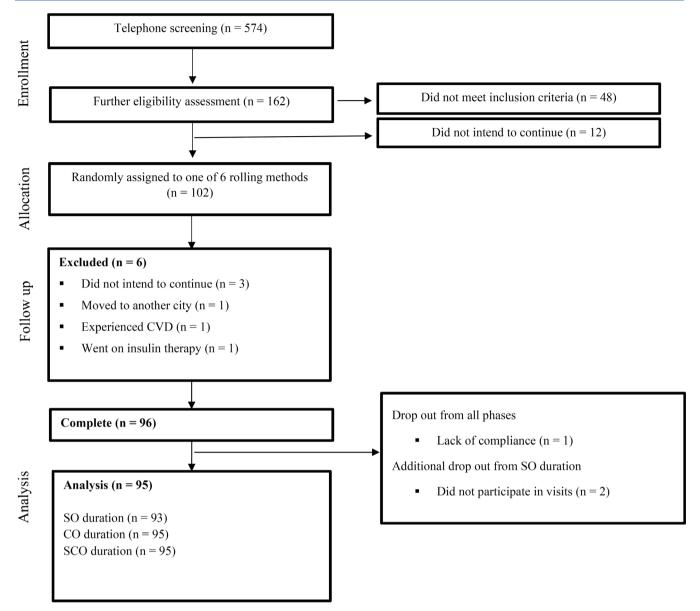


Figure 1. Flow-chart of participants attendance in the present study. CVD, cardiovascular disease.

adjusting for age, sex, baseline BMI, the calculated intervention oils consumed per subject, changes in physical activity level, and energy intake in each intervention period. The sex-stratified analysis revealed that SO had no effect on body weight, BMI and visceral fat in males or in females in crude and multivariable-adjusted models (see Supporting information, Tables S1 and S2, respectively). WC and ICO were decreased within SO treatment exclusively in females both in crude and adjusted models (P < 0.05).

WC (-0.73 ± 0.24 cm), HC (-0.54 ± 0.20 cm), BAI (-0.26 ± 0.09) and ICO (-0.004 ± 0.002) were reduced within the SCO intervention period either in crude or in adjusted models (P < 0.05). In women, SCO significantly reduced visceral fat, WC, HC, BAI and ICO compared to baseline values and the results remained significant in the multivariable-adjusted model (see Supporting information, Table S2) (P < 0.05). By contrast, there was no significant anthropometric change in males in the SCO consumption period (see Supporting information, Table S1) (P > 0.05). Participants experienced a slight increase in body weight (+0.33 ± 0.17 kg), visceral fat (+0.13 ± 0.05%) and body fat (+0.26 ± 0.12%), along with a decrease in WC (-0.56 ± 0.25 cm), HC (-0.32 ± 0.01 cm) muscle mass (-0.15 ± 0.07 kg) and ICO (-0.004 ± 0.002) within the CO intake period (P < 0.05). The results remained unchanged in the multivariable-adjusted model (Table 4). Body weight and BMI were increased in response to the CO intervention in men in the adjusted model (see Supporting information, Table S1) (P < 0.05). On the other hand, women experienced a reduction in WC and ICO in the CO intake period in both crude and adjusted models (see Supporting information, Table S2) (P < 0.05).

No differences were seen between the treatment oils in terms of end values or change values for body weight and other body composition indices (Table 3). However, the stratified analysis based on sex revealed a significant difference between after-intervention values for body weight between SCO (83.05 \pm 2.16 kg) and CO (83.77 \pm 2.23 kg) treatments in males after adjustment

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Variables	Males ($n = 46$)	Females ($n = 47$)	Total (n = 95)
Age (years)	49.73 ± 1.02	48.65 ± 0.96	49.17 ± 0.70
Body weight (kg)	82.85 ± 2.09	71.02 ± 1.54	76.75 ± 1.42
BMI (kg m ⁻²)	28.52 ± 0.54	29.32 ± 0.56	28.93 ± 0.39
Visceral fat (%)	12.76 ± 0.55	8.73 ± 0.26	10.68 ± 0.36
Body fat (%)	25.58 ± 0.91	41.32 ± 0.73	33.70 ± 0.99
WC (cm)	101.96 ± 1.40	100.13 ± 1.24	101.02 ± 0.93
HC (cm)	102.75 ± 0.96	106.07 ± 1.15	104.46 ± 0.77
WHR	0.99 ± 0.006	0.94 ± 0.007	0.96 ± 0.005
Muscle mass (%)	34.44 ± 0.43	25.32 ± 0.27	29.73 ± 0.53
BAI	28.38 ± 0.40	36.73 ± 0.60	32.69 ± 0.56
ICO	0.59 ± 0.007	0.64 ± 0.007	0.62 ± 0.005
TG (mg dL^{-1})	155.17 ± 10.89	156.28 ± 11.86	155.74 <u>+</u> 8.03
VAI	3.42 ± 0.54	3.93 ± 0.54	3.68 ± 0.38
SBP (cm Hg)	11.25 ± 1.75	10.71 ± 0.22	10.95 ± 0.17
DBP (cm Hg)	7.50 ± 1.25	7.15 ± 0.13	7.37 ± 0.11
Education			
Elementary or lower	10.5%	22.1%	32.6%
High school	26.3%	21.1%	47.4%
College and university	11.6%	8.4%	20%

Abbreviations: BAI, body adiposity index; BMI, body mass index; DBP, diastolic blood pressure; HC, hip circumference; ICO, index of central obesity; SBP, systolic blood pressure; TG, triglyceride; VAI, visceral adiposity index: a novel recent sex-specific index, based on waist circumference, BMI, triglyceride and high-density lipoprotein-cholesterol, indirectly expressing visceral adiposity⁴¹; WC, waist circumference; WHR, waist to hip ratio. Values are expressed as the mean ± SEM, unless otherwise indicated.

Variables	SO (<i>n</i> = 93)	SCO (<i>n</i> = 95)	CO (<i>n</i> = 95)	P value ^a	
Total energy (kcal day ⁻¹)	1764.42 ± 37.61	1805.77 ± 37.65	1768.20 ± 37.70	0.298	
Physical activity (MET-min day ⁻¹)	2182.69 ± 26.56	2144.98 ± 26.58	2182.88 ± 26.70	0.190	
Carbohydrate (En%)	58.95 ± 0.60	59.55 ± 0.60	59.04 ± 0.60	0.635	
Protein (En%)	15.48 ± 0.20	15.38 ± 0.20	15.49 ± 0.20	0.856	
Fat (En%)	27.21 ± 0.50	26.63 ± 0.50	27.18 ± 0.49	0.488	
SFAs (En%)	7.93 ± 0.17	7.73 ± 0.17	7.80 ± 0.17	0.638	
MUFAs (En%)	8.46 ± 0.20^{a}	9.06 ± 0.20^{b}	$9.75 \pm 0.20^{\circ}$	< 0.001	
PUFAs (En%)	6.25 ± 0.21^{a}	5.34 ± 0.20^{bc}	5.60 ± 0.20^{bc}	0.001	

Values with different lowercase letters are significantly different, P < 0.05.

Abbreviations: CO, canola oil period; En %, percentage of total energy intake; MUFAs, mono unsaturated fatty acids; PUFAs, poly unsaturated fatty acids; SCO, sesame-canola oil period; SFAs, saturated fats; SO, sesame oil period.

^a P value for the comparison between treatment periods. The analysis was done using linear mixed method.

Values are reported as the mean \pm SEM.

for covariates (see Supporting information, Table S1) (P < 0.05). A significant difference was also reported for change values in visceral fat between SO ($0.12 \pm 0.08\%$) and SCO ($-0.14 \pm 0.06\%$) treatments in females (P < 0.05). The difference remained significant even after adjustment for confounding variables (see Supporting information, Table S2).

The multivariable-adjusted model for baseline, midintervention and after intervention values for body weight and all other anthropometric parameters are reported in the Supporting information (Figs S1–S3). None of the values were significantly different between SO, SCO and CO periods at baseline, midintervention and after-intervention (P > 0.05).

The correlation between anthropometric measurements and cardiometabolic risk factors

The correlation between anthropometric measurements and cardiovascular risk factors at baseline and their change values in different intervention periods are presented in Table 4. Serum TG concentrations and VAI were positively correlated with body weight, BMI, WC and HC at baseline (P < 0.05). Significant positive correlations were also seen between baseline body weight, BMI, visceral fat, WC and baseline blood pressure values (SBP and DBP) (P < 0.05). HC was positively correlated with DBP at baseline (P < 0.05).

Changes in WC were positively correlated with decreases in plasma TG concentrations, as well as VAI, in the SCO period

Table 3. End- and change values for body weight and body composition indices based on the treatment periods in the total participants											
	Ses	ame oil (<i>n</i> = 93)		Sesame	-Canola oil (n = 95)		Can				
	After	change	P ^a	After	change	P ^a	After	change	P ^a	P ^b	P ^c
Body weight (kg)											
Crude	77.14 ± 1.40^{d}	0.33 ± 0.15	0.035	77.09 ± 1.37	0.00 ± 0.14	0.998	77.20 ± 1.41	0.27 ± 0.16	0.100	0.811	0.289
Adjusted ^e	77.09 ± 1.45	0.34 ± 0.16	0.037	77.06 ± 1.42	-0.01 ± 0.14	0.887	77.19 ± 1.46	0.33 ± 0.17	0.040	0.754	0.212
BMI (kg m ⁻²)											
Crude	29.10 ± 0.38	0.12 ± 0.05	0.029	29.09 ± 0.38	-0.002 ± 0.05	0.978	29.11 ± 0.38	0.09 ± 0.06	0.128	0.940	0.292
Adjusted	29.11 ± 0.39	0.13 ± 0.05	0.031	29.12 ± 0.39	-0.009 ± 0.05	0.848	29.14 ± 0.40	0.11 ± 0.06	0.057	0.892	0.222
Visceral fat (%)											
Crude	10.84 ± 0.35	0.13 ± 0.06	0.031	10.78 ± 0.35	-0.07 ± 0.12	0.562	10.83 ± 0.35	0.09 ± 0.05	0.103	0.694	0.356
Adjusted	10.70 ± 0.35	0.13 ± 0.06	0.034	10.64 ± 0.34	-0.08 ± 0.13	0.547	10.69 ± 0.35	0.13 ± 0.05	0.024	0.718	0.317
Body fat (%)											
Crude	34.49 ± 0.95	0.23 ± 0.20	0.260	34.66 ± 0.95	0.16 ± 0.17	0.350	34.57 ± 0.94	0.25 ± 0.12	0.044	0.547	0.919
Adjusted	34.80 ± 0.99	0.27 ± 0.21	0.208	34.96 ± 0.99	0.12 ± 0.18	0.503	34.84 ± 0.98	0.26 ± 0.12	0.047	0.536	0.789
WC (cm)											
Crude	98.73 ± 0.89	-0.68 ± 0.18	<0.001	98.66 ± 0.86	-0.71 ± 0.22	0.002	98.75 ± 0.89	-0.58 ± 0.23	0.016	0.925	0.930
Adjusted	98.54 ± 0.92	-0.67 ± 0.19	0.001	98.53 ± 0.88	-0.73 ± 0.24	0.001	98.62 ± 0.91	-0.56 ± 0.25	0.028	0.920	0.905
HC (cm)											
Crude	103.67 ± 0.74	-0.15 ± 0.17	0.318	103.22 ± 0.76	-0.57 ± 0.19	0.005	103.24 ± 0.76	-0.35 ± 0.16	0.028	0.384	0.113
Adjusted	103.83 ± 0.77	-0.17 ± 0.17	0.305	103.47 ± 0.79	-0.54 ± 0.20	0.011	103.44 ± 0.80	-0.32 ± 0.16	0.050	0.234	0.482
WHR											
Crude	0.95 ± 0.005	-0.005 ± 0.002	0.012	0.95 ± 0.005	-0.002 ± 0.002	0.464	0.95 ± 0.006	-0.002 ± 0.002	0.321	0.102	0.477
Adjusted	0.94 ± 0.005	-0.005 ± 0.002	0.015	0.95 ± 0.005	-0.002 ± 0.002	0.311	0.95 ± 0.006	-0.002 ± 0.002	0.354	0.104	0.507
Muscle mass (%)										
Crude	29.29 ± 0.52	-0.04 ± 0.07	0.610	29.21 ± 0.52	-0.06 ± 0.08	0.460	29.26 ± 0.52	-0.13 ± 0.07	0.057	0.615	0.656
Adjusted	29.14 ± 0.54	-0.06 ± 0.07	0.362	29.07 ± 0.54	-0.03 ± 0.08	0.667	29.15 ± 0.54	-0.15 ± 0.07	0.048	0.601	0.585
BAI											
Crude	32.34 ± 0.55	-0.08 ± 0.08	0.268	32.12 ± 0.57	-0.27 ± 0.09	0.004	32.12 ± 0.57	-0.17 ± 0.07	0.031	0.118	0.413
Adjusted	32.47 ± 0.58	-0.09 ± 0.08	0.250	32.30 ± 0.60	-0.26 ± 0.09	0.009	32.27 ± 0.60	-0.15 ± 0.08	0.054	0.235	0.506
ICO											
Crude	0.60 ± 0.005	-0.004 ± 0.002	0.001	0.60 ± 0.005	-0.003 ± 0.002	0.003	0.60 ± 0.005	-0.002 ± 0.002	0.015	0.709	0.764
Adjusted	0.60 ± 0.006	-0.004 ± 0.002	0.001	0.60 ± 0.006	-0.004 ± 0.002	0.003	0.60 ± 0.006	-0.004 ± 0.002	0.015	0.677	0.821

Abbreviations: BAI, body adiposity index; BMI, body mass index; HC, hip circumference; ICO, index of central obesity; WC, waist circumference; WHR, waist to hip ratio.

^a P values for within treatment period comparisons using general linear model, repeated measures analysis.

^b *P* values for comparison of after treatment values between the treatment oils using linear mixed effects model.

^c *P* values for comparison of change values between the treatment oils using linear mixed effects model.

^d Values are reported as the mean \pm SEM.

^e Adjusted for age, sex, baseline BMI, the calculated intervention oils consumed per subject, changes in physical activity level and energy intake in each intervention period. No significant changes were observed for comparison of after treatment values and change values between the treatment oils.

Table 4.	Pearson correlation coefficients between anthropometric measurements and cardiovascular risk factors at baseline and their change values
in differe	ant intervention periods

	Triglyceride				Visceral adiposity index				Systolic blood pressure				Diastolic blood pressure			
	Baseline		Chang	es	Baseline	Changes		Baseline	Changes		Baseline	Changes				
Variables	buschine	SO	SCO	CO	busenne	SO	SCO	CO	busenne	SO	SCO	CO	buschine	SO	SCO	CO
Body weight	0.29*	0.03	0.15	0.37**	0.27*	0.07	0.11	0.30*	0.20*	0.22*	-0.06	0.18	0.37**	0.14	-0.07	0.20
BMI	0.31*	0.03	0.13	0.35**	0.31*	0.07	0.09	0.27*	0.20*	0.23*	-0.06	0.17	0.33*	0.14	-0.06	0.20
Body fat	0.17	0.13	0.16	0.10	0.20*	0.10	0.08	0.16	-0.07	0.04	0.0	0.20	0.0	0.12	-0.04	0.31*
Visceral fat	0.12	0.03	0.12	0.31*	0.10	-0.02	0.07	0.26*	0.35**	0.17	-0.06	0.12	0.38**	0.05	-0.08	0.16
WC	0.33*	0.03	0.30	0.22*	0.33*	0.11	0.39**	0.23*	0.20*	0.0	-0.11	-0.04	0.34*	0.05	-0.13	0.01
HC	0.28*	0.03	0.11	0.28*	0.26*	0.18	0.10	0.30*	0.10	0.17	0.17	0.01	0.22*	0.12	-0.04	0.05

P* < 0.05; *P* < 0.001.

Abbreviations: BMI, body mass index; CO, canola oil, HC, hip circumference; SCO, sesame-canola oil; SO, sesame oil; WC, waist circumference.



(P < 0.05). Changes in body weight, BMI, visceral fat, HC and WC within CO intake were positively correlated with TG and VAI (P < 0.05). Positive correlations were seen between changes in body weight and BMI with SBP in the SO period. Body fat change was also positively correlated with changes in DBP in the CO intervention period (P < 0.05).

DISCUSSION

The present study revealed that, after 9 weeks, body weight (0.34 \pm 0.16 kg and 0.33 \pm 0.17 kg) and visceral fat (0.13 \pm 0.06% and 0.13 \pm 0.05%) were significantly increased within SO and CO consumption, respectively. Body fat percentage was also increased after CO consumption compared to the baseline values (0.26 \pm 0.12%). By contrast, all of the treatment oils resulted in a significant decrease in WC and ICO in all participants. Sex-stratified analyses revealed significant reductions in WC and ICO following the treatment oils in females as well. Within-period changes were seen following SCO treatment for HC (-0.54 \pm 0.20 cm) and BAI (-0.26 \pm 0.09). No significant differences were observed for body weight and body composition measurements between SO, SCO and CO treatments at baseline, mid-intervention and after intervention periods.

Sex-stratified analysis revealed that body weight was significantly decreased after SCO intake compared to CO intake in men. Visceral fat was significantly reduced in SCO compared to SO in women. No other significant difference in body weight and body composition was seen in end values or change values between SO, SCO and CO treatment periods.

These findings add to the emerging evidence that, although CO and SO slightly increase body weight and visceral fat, their reducing effects on central obesity indices (WC, HC and ICO) are noteworthy. It should be considered that, although statistically significant changes were observed for body weight and composition following the treatment oils, these changes are of little clinical importance. In support of our findings, Liu *et al.*²² reported a reduced android fat mass, as an index of central obesity (approximately 3%), after MUFA-rich diets (canola oil and canola-oleic oil). This finding supports the reducing effects of high-MUFAs diets on central obesity rather than the redistribution of adipose tissue to the lower parts of the body. It is worth noting that Liu *et al.*²² only reported the results of after intervention data in their study for body composition indices and the change from baseline values were not reported.²²

In a study performed by Gillingham et al.,⁴² 34 patients with hypercholesterolemia were treated with three diets (high-oleic canola oil, high-oleic canola oil with flaxseed oil and saturated fat) in a cross-over clinical trial. After 28 days of intervention, no changes were observed in body composition measures between the three diets. However, android to gynoid ratio was increased within high-oleic canola oil with flaxseed oil period compared to high-oleic canola oil. By contrast to our findings, a recent metaanalysis,⁴³ revealed that CO consumption results in a slight decrease in body weight (approximately 0.3 kg); however, CO consumption did not change other body composition indices. The majority of studies included in that meta-analysis prescribed specific amounts of CO in the context of high-CO diets or CO was supplemented in the context of foods. However, in the present study, we replaced the ordinary edible oils of the family with the treatment oils.

In a study reported by Sankar *et al.*,⁴⁴ the regular edible oil of 50 patients with hypertension was replaced by SO for 45 days.

Afterward, the subjects were asked to switch to whatever they had been taking before enrollment in the study. They revealed that SO decreased body weight and BMI, which is in contrast to our observations. A study by Namayandeh et al.45 on 48 patients with hypercholesterolemia, in which patients were given olive oil or SO in a parallel design for 4 weeks, concluded that there were no significant changes in body weight and WC within SO consumption. The results of a meta-analysis concerning sesame and intake of its products on body weight and composition indicated that SO consumption results in a decrease in body weight and BMI at the same time as not affecting other body composition values. The lack of a rigorous methodological design in the included studies in the meta-analysis, such as having no randomization or blinding, ignoring the assessment of dietary intakes and physical activity, and an absence of an appropriate control group, may justify the inconsistencies.²⁸

Although the increasing effects of dietary oils on general adiposity markers (body weight and BMI) were seen in all participants, the reducing effects on central obesity indices remained significant in all participants and exclusively in women. In accordance with our observations, Paniagua et al.⁴⁶ presented an interesting claim that the macronutrient composition of diets may change body fat distribution regardless of affecting total body weight. Their results indicated the distribution of body fat from peripheral adipose tissue to central obesity deposits in insulinresistant patients fed a low-fat, carbohydrate-enriched diet; however, a MUFA-rich diet prevented central obesity. High-MUFAs diets may increase thermogenesis by stimulating the sympathetic nervous system.^{47, 48} Furthermore, faster gastric emptying,⁴⁹ increases intestinal absorption^{48, 50} and upregulation of peroxisome proliferator-activated receptor α expression which contribute to the transcription of genes involved in fat oxidation and suppression of the genes regulating fatty acid synthesis simultaneously.⁵¹ It has been proposed that the metabolic response to dietary fat intake may be tangibly seen by prescribing more than 50% of energy intake from fat.^{52–55} However, in the present study, we tried to replace the ordinary edible oils based on a healthy dietary recommendation (30-32% fat intake from total calorie). Therefore, it is assumed that the modest fat intake may not have changed endogenous lipid trafficking efficiently to alter energy expenditure or fat oxidation to a degree resulting in weight loss⁴²; Nevertheless, the intervention oils might have facilitated the oxidation of subcutaneous fat, with respect to WC or HC. In addition, the thermogenic effects of dietary fats have been reported in studies following consumption of unsaturated fats from vegetable origins versus animal-derived fats.47, 53

Despite well-known sex differences in body composition,^{56, 57} it is still not understood why, in the present study, the favorable effects of dietary oils on central obesity indices were seen in females but not males. Although the mechanisms are not fully understood, certain assumptions may shed light on this matter. A sex-specific genetic study has indicated that genetic variances are greatly higher in women for WC, HC and WHR, as central obesity indices, whereas no sex-specific genetic effects were reported for body weight and BMI. These findings indicate that more variance of fat distribution in women rather than men may be derived from genetic effects.⁵⁸ Moreover, the controversial findings for metabolic markers in different sexes following the same interventions may have been attributed to gene polymorphisms.⁵⁹

Previous studies have shown that almost all body composition measurements are positively correlated with TG, BP and VAI.^{40, 60, 61} In line with previous investigations, the present study showed that

the reduction in WC was correlated with decreases in cardiometabolic risk factors including TG and VAI following the SCO and CO treatments, but not the SO intake. HC reduction was associated with decreased TG and VAI only within the CO treatment period. On the other hand, the increase in body weight and BMI was directly correlated with an increase in SBP in the SO intake period.

The present study benefits from a large number of participants with low attrition rate (less than 10%) and relatively long intervention periods to enable observation of the possible effects on body weight and composition. Furthermore, because this was a clinical trial with a cross-over design, the study participants served as their own control. This resulted in the minimum influence of genetic polymorphisms and differences in lifestyle that contribute to varied diet responses and consequently inter-individual differences in results between participants.⁶² Moreover, using a crossover design limits the effect of confounding variables such as the choice of measurement instrument (operational confound) because the participants were acted as their own controls. The results of the present study might also be more practical than studies supplemented specific amounts of dietary oils because the intervention oils were replaced with the ordinary consumed oils. It should be noted that we aimed to replace the household's usual dietary oil with the intervention oils; therefore, we were not able to determine the exact amounts of consumed oil by each participant. Nevertheless, we calculated the consumed oil by measuring the dietary oil provided and returned in each intervention phase and also by using weighted dietary records. However, we could not use superior methods for checking the participants' adherence, such as assessing the fatty acid composition of serum or plasma samples, because of financial limitations. Additionally, we could not justify the controversial effects of SCO rather than CO and SO on some of the study outcomes. It is possible that SO and CO interact with each other. The literature lacks clinical studies comparing the effects of CO and SO on body weight and composition. In addition, the effects of their novel blend oil (SCO) have not been investigated until now. Thus, the underlying mechanisms for the observed results are unknown and further studies should be performed in this regard. Assessment of body composition using the Omron body composition analyzer was another limitation of the present study because body impedance analyzers do not have the accuracy of superior methods such as dual-energy X-ray absorptiometry.⁶³ Thus, our findings on body composition measurements (body fat, visceral fat and muscle mass) should be interpreted with caution. It should also be noticed that body weight and composition were secondary outcomes of the parent study and the sample size was not calculated based on these variables. To the best of our knowledge, none of the previous studies investigating the effects of SO on anthropometric measurements had a greater sample size compared to our study,44, 45, 64-71 and only one study investigating the effect of dietary CO on body weight and composition included a greater number of participants compared to our study.²² Previous investigations, as well as the present study, were not designed to explore the effects of dietary oils on anthropometric markers and such effects were reported as secondary outcomes. Therefore, future studies specially designed to examine the effect of sesame and canola oils on body weight and composition might help to confirm the current findings. Although some significant differences in change values were seen between intervention periods, no significant difference was observed between intervention oils when midintervention period values were compared. As acknowledged, 4 weeks comprises a short period of time in which to investigate changes in anthropometric values, and anthropometric changes should be investigated over longer time periods; therefore, we tried to focus on post-intervention and change values.

In conclusion, the present study provides novel findings concerning the impact of replacing vegetable oils with a different composition of fatty acids on body weight and composition in patients with T2DM. After a 9-week intervention period, although SO and CO intake resulted in an increase in general obesity markers, they reduced central obesity indices in all participants and in women exclusively. This suggests that vegetable oils might affect body fat distribution rather than total body weight. In future studies, the assessment of total whole-body fat oxidation and the thermic effects of food and energy expenditure (using indirect calorimetry), as well as the use of more accurate tools for body composition measurement, may provide more insight into the difference in metabolic effects of these vegetable oils.

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CONFLICT OF INTERESTS

The study was jointly funded by Shahid Sadoughi University of Medical sciences and Datis Corporation. The investigators declared that they did not have a direct financial relationship with Datis Corporation and Shahid Sadoughi University of Medical Sciences received the funds and delivered them to the investigators. Datis Corporation did not take any part in the conception, design, the execution of the study protocol, and the reporting of the study results. The corporation did not have any other relationship with the investigators. The authors declare that they have no other potential personal or financial conflicts of interest. The principal investigator (ASA) declares that he has full access to the data and samples provided by this project.

AUTHOR CONTRIBUTIONS

AS-A and MA conceived and designed the study. MA and FM recruited the participants and followed them. MA and FM conducted the data collection. MA, HR-D, FM and AZ performed the data entry. HR-D performed the biochemical analysis. AS-A conducted the statistical analysis. HM-K and MR provided counseling for conducting the analyses for the current study. HR-D wrote the first draft of the manuscript. AS-A critically reviewed the manuscript. All authors approved the final draft of the manuscript



submitted for publication and agree to be accountable for all aspects of the work, ensuring its integrity and accuracy.

SUPPORTING INFORMATION

Supporting information may be found in the online version of this article.

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