



Orange juice in association to low-caloric diet contributes to weight-loss and glucose metabolism

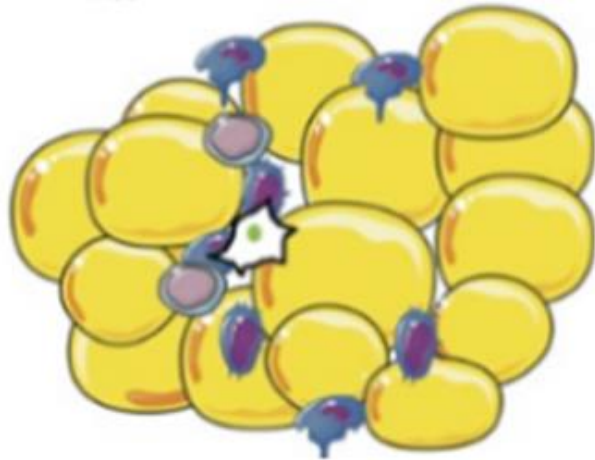


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*High adipose tissue stored
in Obesity:*



**Cluster of
complications**

- Glucose intolerance
- High Cholesterol and TG
- Hypertension
- Systemic inflammation

CVD, Diabetes
Premature death

Diets rich in fruits and vegetables, plenty of water and fibers

- reduce the diet energy density
- promote satiety
- decrease caloric intake

- Contribute to weight control
- Regulate metabolic parameters

Fruits and their juices
Nutrient-dense foods,
providing vitamins, minerals,
and bioactive compounds with
relatively few calories

Giugliano, et al, 2006; Tohill, 2004.

- Emerging speculations:
- Do the fruit juices play a role in the obesity epidemic, contributing to weight-gain in children and adults?

Shefferly 2016, Pan et al 2013, Hyson 2015,



- Beverages containing fruit juice X 100% fruit juices
- Nutritional composition: energy, sugars and bioactive compounds
- different effects on body composition

Rampersaud & Valim 2015; Dourado & Cesar 2015,
Silveira, Dourado & Cesar, 2015

Recent evidences: daily consumption of OJ does not contribute:

- 1) Adiposity or weight gain [*Dourado & Cesar, 2015*]
- 2) Insulin resistance and inflammation [*Simpson & Macdonald, 2016,*
Silveira et al, 2015]
- 3) Increasing cholesterol [*Aptekmann & Cesar, 2015*]



**Counteracting negative reports
about the consumption of OJ.**

Study proposal:

- **Obese Subjects:** men and women, apparently healthy
- Eligibility criteria: $30 \geq \text{BMI} \leq 40 \text{ kg/m}^2$



- **Subjects assigned to two groups:**

- “orange juice (OJ)” or “control” by a random-number generator program.



- **Treatment:**

- Low-caloric diet (LCD): Personal and balanced (DRI, 2006)
- Six meals/day (breakfast, morning snack, lunch, afternoon snack, dinner, supper)
- LCD + Orange juice: 250mL OJ morning snack + 250mL OJ afternoon snack

Interventions

- **Trial design:** A 12-week, parallel group, randomized (block size), controlled trial, conducted at the Pharmacy School, Sao Paulo State University, UNESP, Brazil.
- Body composition measurements were collected monthly.
- Blood samples and dietary questionnaires: collected every two weeks (Figure 1).
- **Primary endpoint:** Reduction of weight-loss by 5% between to initial and final body weight
- **Secondary endpoint:** modification of the levels of biomarkers related to obesity
- Ethics Board of Pharmacy School, UNESP, approved the study (#1.241.033).
- All participants provided written informed consent.

This clinical study has been declared to the website ClinicalTrials.com under the # NCT02914249.

The screenshot shows a web browser window with the ClinicalTrials.gov search results page. The browser tabs include 'Nutrition - Journal - Elsevier', 'clinical trial gov - Yahoo', and 'CT Search of: Low-calorie Di...'. The address bar shows the URL: <https://clinicaltrials.gov/ct2/results?term=Low-calorie+Diet+Combined+With+Orange+Juice+Results+in+Weight+Loss%3A+Randomized+Controlled+Trial&Search>. The page header features the 'ClinicalTrials.gov' logo and the text 'A service of the U.S. National Institutes of Health'. A search bar contains the text 'Search for studies:' and a 'Search' button. Below the search bar are links for 'Advanced Search', 'Help', 'Studies by Topic', and 'Glossary'. A yellow banner highlights the text: 'Now Available: Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting'. A navigation menu includes 'Find Studies', 'About Clinical Studies', 'Submit Studies', 'Resources', and 'About This Site'. The breadcrumb trail reads 'Home > Find Studies > Search Results'. The search results section displays '1 study found for: Low-calorie Diet Combined With Orange Juice Results in Weight Loss: Randomized Controlled Trial' with a link to 'Modify this search | How to Use Search Results'. Below this are tabs for 'List', 'By Topic', 'On Map', and 'Search Details'. There are also links for '+ Show Display Options', 'Download', and 'Subscribe to RSS'. Filter options include 'Include only open studies' and 'Exclude studies with Unknown status'. The results table has columns for Rank, Status, and Study. The first result is ranked 1, with a status of 'Completed' and the title 'Effect of Low-calorie Diet and Orange Juice on Body Weight and Metabolic Parameters of Obese Subjects'. The study details include 'Condition: Obesity' and 'Intervention: Other: Orange juice (500 mL/d)'. A 'TO TOP' link is visible at the bottom right of the results area. The Windows taskbar at the bottom shows the time as 7:55 AM on 10/11/2016.

ClinicalTrials.gov
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1 study found for: Low-calorie Diet Combined With Orange Juice Results in Weight Loss: Randomized Controlled Trial

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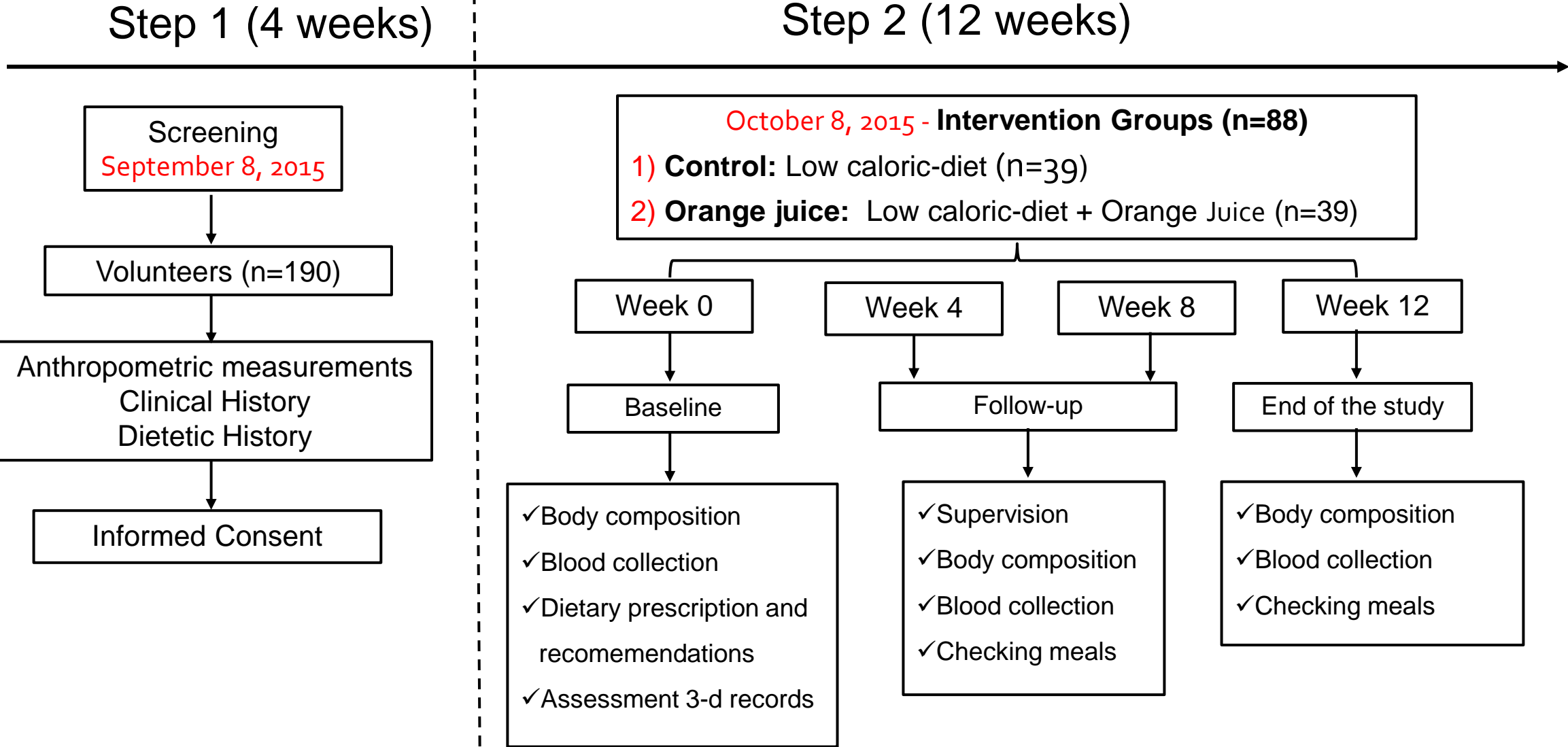
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Rank	Status	Study
1	Completed	Effect of Low-calorie Diet and Orange Juice on Body Weight and Metabolic Parameters of Obese Subjects Condition: Obesity Intervention: Other: Orange juice (500 mL/d)

[TO TOP](#)

Clinical Trial Design # NCT02914249.



Body composition:

- standardized procedures (weight, height, BMI, waist, etc)
- Bioelectrical impedance: InBody 720, Biospace, Tokyo, Japan
- fat mass (kg), lean mass (kg), and % body fat

Biomarkers:

TG, total cholesterol, HDL-C, glucose, AST, ALT, AKP, γ GT: commercial kits, Labtest, Brazil
ultrasensitive C-reactive protein (hsCRP): Dade Behring, USA

HOMA-IR: cutoff was set at ≥ 2.71 [Matthews et al 1985].

Lipid peroxidation: TBARS assay [Yagi, K 1998]

Total antioxidant capacity by radical ABTS^{•+} assay [Re et al 1999].

Diet: 3-day dietary records: Avanutri[®] e TACO (UNICAMP)

100% Orange Juice: provided by a local producer (Citrosuco, Matao, SP)

Chemical analysis: 0.7% total titratable acidity, 15 °Brix, 204 mg ascorbic acid, 34 mg phenolic compounds, 950 TEAC μ mol antioxidant capacity, 240 kcal/500mL, 44 g total sugar, 162 mg hesperitin, and 7.7 mg naringenin [22] in two doses of OJ (500 mL).

• RESULTS

Low-caloric diet	Orange juice	Control	Subjects
	(n = 39)	(n = 39)	(n = 78)
Age, years	37 ± 1	35 ± 1	36 ± 1
BMI, kg/m ²	33 ± 3	34 ± 4	33 ± 3
Glucose, mg/dL	87 ± 7	85 ± 8	86 ± 7
Insulin, µU/mL	15 ± 6	15 ± 6	15 ± 6
HOMA-IR	3.2 ± 1.5	3.1 ± 1.3	3.1 ± 1.4
Total cholesterol, mg/dL	185 ± 21	181 ± 31	183 ± 27
LDL-C, mg/dL	119 ± 27	115 ± 27	118 ± 27
HDL-C, mg/dL	44 ± 8	47 ± 11	45 ± 10
Non-HDLC, mg/dL	145 ± 27	133 ± 29	139 ± 28
Triglycerides, mg/dL	140 ± 40	141 ± 43	140 ± 41
hsCRP, mg/dL	0.5 ± 0.1	0.5 ± 0.1	0.5 ± 0.1
Alcaline phosphatase, U/L	73 ± 18	72 ± 16	73 ± 17
AST, U/L	21 ± 9	21 ± 7	21 ± 8
ALT, U/L	23 ± 8	20 ± 9	21 ± 14
γ-GT, U/L	25 ± 7	24 ± 6	25 ± 7

Table 1. Baseline characteristics of the subjects

Low-caloric diet	Orange juice (n = 39)				Control (n = 39)			
	0-wk	4-wk	8-wk	12-we	0-wk	4-wk	8-wk	12-wk
Body comp.								
Body wt, kg	97 ± 12 ^a	94 ± 12 ^b	92 ± 12 ^c	90 ± 11 ^d	98 ± 12 ^a	95 ± 12 ^b	93 ± 12 ^c	92 ± 11 ^d
BMI, kg/m²	33 ± 3 ^a	32 ± 3 ^b	31 ± 3 ^c	31 ± 3 ^c	34 ± 4 ^a	33 ± 3 ^b	32 ± 3 ^c	31 ± 3 ^d
Lean mass, kg	31 ± 6 ^a	30 ± 6 ^b	30 ± 6 ^b	30 ± 6 ^b	30 ± 5 ^a	29 ± 5 ^b	29 ± 5 ^b	29 ± 5 ^b
Fat mass, kg	36 ± 10 ^a	34 ± 10 ^b	32 ± 10 ^c	31 ± 10 ^d	38 ± 10 ^a	36 ± 10 ^b	34 ± 10 ^c	33 ± 9 ^d
Body fat, %	37 ± 9 ^a	36 ± 9 ^b	34 ± 9 ^c	34 ± 9 ^c	40 ± 8 ^a	39 ± 9 ^b	38 ± 9 ^c	37 ± 8 ^d
Waist, cm	104 ± 10 ^a	100 ± 10 ^b	97 ± 10 ^c	96 ± 9 ^c	102 ± 10 ^a	98 ± 10 ^b	95 ± 10 ^c	93 ± 9 ^d
Hip, cm	113 ± 9 ^a	110 ± 9 ^b	109 ± 10 ^c	108 ± 8 ^d	114 ± 9 ^a	113 ± 9 ^b	110 ± 8 ^c	109 ± 8 ^d
waist/hip	1.0 ± 0.1 ^a	1.0 ± 0.1 ^a	0.9 ± 0.1 ^b	0.9 ± 0.1 ^b	1.0 ± 0.1 ^a	1.0 ± 0.1 ^a	0.9 ± 0.1 ^b	0.9 ± 0.1 ^b

Table 2. Body composition over the 12 weeks experiment

Low-caloric diet	Orange juice (n = 39)				Control (n = 39)			
	0-week	4-week	8-week	12-week	0-week	4-week	8-week	12-week
Biomarkers								
Glucose, mg/dL	87 ± 10 ^a	83 ± 8 ^b	82 ± 7 ^{bc}	80 ± 7 ^c	85 ± 6 ^a	81 ± 6 ^b	81 ± 7 ^b	81 ± 6 ^b
Insulin, µU/mL	15 ± 6 ^{A,a}	13 ± 5 ^{A,b}	11 ± 4^{A,c}	11 ± 4^{A,c}	15 ± 6 ^{A,a}	15 ± 7 ^{A,a}	14 ± 5 ^{B,b}	13 ± 6 ^{B,c}
HOMA-IR	3.2 ± 1.5 ^{A,a}	2.8 ± 1.2 ^{A,b}	2.2 ± 0.8^{A,c}	2.1 ± 0.8^{A,c}	3.1 ± 1.3 ^{A,a}	3.1 ± 1.4 ^{A,a}	2.9 ± 1.4 ^{B,b}	2.7 ± 1.1 ^{B,c}
TC, mg/dL	185 ± 21 ^{A,a}	173 ± 21 ^{A,b}	170 ± 28 ^{A,c}	155 ± 20^{A,d}	181 ± 30 ^{A,a}	172 ± 30 ^{A,b}	171 ± 28 ^{A,b}	165 ± 28 ^{B,c}
LDL-C, mg/dL	119 ± 27 ^{A,a}	111 ± 24 ^{A,b}	107 ± 26 ^{A,b}	85 ± 18^{A,c}	115 ± 27 ^{A,a}	109 ± 23 ^{A,b}	108 ± 26 ^{A,b}	105 ± 27 ^{B,b}
HDL-C, mg/dL	44 ± 8 ^a	42 ± 8 ^b	43 ± 9 ^{a,b}	44 ± 10 ^a	47 ± 11 ^a	44 ± 10 ^b	44 ± 10 ^b	44 ± 10 ^b
Non-HDL	144 ± 27 ^a	135 ± 24 ^b	130 ± 25 ^c	115 ± 24 ^d	133 ± 30 ^a	130 ± 30 ^b	127 ± 29 ^c	121 ± 27 ^d
TG, mg/dL	140 ± 40 ^a	127 ± 41 ^b	117 ± 40 ^c	109 ± 34 ^d	141 ± 43 ^a	133 ± 40 ^b	119 ± 40 ^c	112 ± 38 ^c
hsCRP, mg/dL	0.5 ± 0.1 ^{A,a}	0.4 ± 0.1 ^{A,b}	0.4 ± 0.1 ^{A,b}	0.3 ± 0.1^{A,c}	0.5 ± 0.1 ^{A,a}	0.5 ± 0.1 ^{A,a}	0.4 ± 0.1 ^{A,b}	0.4 ± 0.1 ^{B,b}
Alcaline Phosp.	73 ± 18 ^a	71 ± 15 ^b	70 ± 16 ^b	68 ± 18 ^c	72 ± 18 ^a	69 ± 16 ^b	68 ± 15 ^b	67 ± 15 ^b
AST, U/L	21 ± 9 ^a	21 ± 6 ^a	19 ± 5 ^b	18 ± 5 ^b	21 ± 7 ^a	20 ± 6 ^{a,b}	19 ± 6 ^b	19 ± 6 ^b
ALT, U/L	22 ± 8 ^a	22 ± 8 ^a	19 ± 8 ^b	19 ± 9 ^b	20 ± 9 ^a	23 ± 10 ^b	21 ± 9 ^{a,c}	20 ± 7 ^{a,c}
γGT, U/L	25 ± 7 ^a	22 ± 9 ^b	22 ± 9 ^b	21 ± 8 ^c	24 ± 6 ^a	23 ± 7 ^b	23 ± 8 ^b	23 ± 8 ^b
TAC, mM	1.8 ± 0.03 ^a	1.8 ± 0.04 ^a	1.9 ± 0.04^b	1.9 ± 0.04^b	1.8 ± 0.08 ^a	1.8 ± 0.08 ^a	1.8 ± 0.05 ^a	1.8 ± 0.04 ^a
[MDA] mM	1.5 ± 0.9 ^a	1.2 ± 0.6 ^b	1.2 ± 0.6 ^b	0.8 ± 0.4 ^c	1.7 ± 0.8 ^a	1.5 ± 0.7 ^b	1.5 ± 0.7 ^b	0.9 ± 0.5 ^c

Table 3. Metabolic biomarkers in both groups (Orange Juice and Control) during 12-weeks.

Time schedule	0-week	4-week	8-week	12-week
	Control (n = 39)			
Adiponectin (ug/mL)	18 ± 6. ^{B,a}	20 ^b ± 7 ^{B,b}	20 ± 7 ^{B,b}	21 ± 7 ^{B,b}
Leptin (ng/mL)	31 ± 9 ^a	29 ± 8 ^a	27 ± 9 ^b	27 ± 9 ^b
IL-6 (pg/mL)	6.1 ± 1.8 ^a	4.9 ± 1.7 ^b	4.1 ± 1.7 ^c	3.1 ± 1.6 ^d
TNF-α (pg/mL)	7.5 ± 2.4 ^a	6.7 ± 1.7 ^b	6.5 ± 1.7 ^b	5.7 ± 1.7 ^c
	Orange juice (n = 39)			
Adiponectin (ug/mL)	19 ± 5 ^{A,a}	18 ± 5 ^{A,b}	15 ± 5.3 ^{A,c}	15 ± 5 ^{A,c}
Leptin (ng/mL)	31 ± 14 ^a	29 ± 13 ^b	27 ± 12 ^c	27 ± 12 ^c
IL-6 (pg/mL)	6.0 ± 2.6 ^a	5.5 ± 2.6 ^b	4.6 ± 1.6 ^c	3.3 ± 2.0 ^d
TNF-α (pg/mL)	7.6 ± 2.7 ^a	7.4 ± 2.1 ^a	6.7 ± 2.0 ^b	5.9 ± 1.8 ^c

Table 4. Inflammatory biomarkers in both groups (Orange Juice and Control) during 12-weeks.

Conclusion:

OJ combined with low caloric-diet:



- ✓ Improved the nutritional quality of the diet (↑ Vit C and ↑ Folate);
- ✓ Improved biochemical (↓ LDL-C) and metabolic biomarkers (↓ IR and CRP), without increasing blood glucose;
- ✓ OJ worked together with low-calorie diet for a sustained weight loss

Moderate consumption of OJ provides nutritional and dietary benefits with no adverse impact on body weight, while improves metabolic parameters in obese people



Thank you