Research Square Preprint: Please note that this article has not completed peer review.

Consumption of melatonin supplement improves cardiovascular disease risk factors and new anthropometric indices (as predictors of obesity) in type 2 diabetes mellitus patients: A double–blind, randomized, placebo-controlled trial

CURRENT STATUS: UNDER REVIEW

Trials BMC

Hadi Bazyar
Ahvaz Jundishapour University of Medical Sciences

Ahmad Zare Javid
Ahvaz Jundishapour University of Medical Sciences

Hossein Bavi Behbahani
Ahvaz Jondishapour University of Medical Sciences

Fardin Moradi
Ahvaz Jondishapour University of Medical Sciences

Bahman Moradi Poode
Tabriz University of Medical Sciences

Parichehr Amiri
Ahvaz Jundishapour University of Medical Sciences

amiriparichehr70@gmail.com*Corresponding Author*
ORCiD: https://orcid.org/0000-0003-4230-9383

DOI:
10.21203/rs.3.rs-18733/v1

SUBJECT AREAS
Nutrition & Dietetics *Pulmonology*

KEYWORDS
Type 2 diabetes mellitus, Melatonin, Blood pressure, New anthropometric indices

Abstract

Background: Diabetes mellitus is a common chronic disease. Dyslipidemia and hypertension are two complications may develop in diabetic patients if hyperglycemia, insulin resistance, and weight gain are not controlled. The objective of this study was to investigate the effects of melatonin supplementation on some cardiovascular disease risk factors and new anthropometric indices in patients with type 2 diabetes mellitus (T2DM).

Materials and Methods: In this double-blind, randomized, placebo-controlled trial, 50 T2DM patients were randomly allocated to intervention and control groups. The intervention and control groups received either 2 tablets melatonin or placebo (250 mg) once a day for 8 weeks. Mean arterial pressure (MAP), pulse pressure (PP), atherogenic index of plasma (AIP), body shape index (ABSI), abdominal volume index (AVI), body adiposity index (BAI), lipid accumulation product (LAP), conicity index, and waist to height ratio (WHR) were evaluated in all patients pre and post-intervention.

Results: Melatonin supplementation for 8 weeks significantly decreased the mean levels of MAP, PP, BAI, AVI, conicity index, and WHR post intervention (p <0.05). Also, the mean changes of MAP, PP, BAI, AVI, and Conicity index were significantly lower in the intervention group compared with the control group (p <0.05). A significant increase (p <0.001) was observed in the mean levels of ABSI in the intervention group. The mean changes of ABSI was significantly greater in the intervention group compared with the control group (p <0.001).

Conclusions: Consumption of melatonin supplement may be effective in controlling arterial pressure and new anthropometric indices (as predictors of obesity) in T2DM patients.

Trial registration: This trial was registered in the Iranian Registry of Clinical Trials website at 2019/5/17. (IRCT20190303042905N1).

Full Text

Due to technical limitations, full-text HTML conversion of this manuscript could not be completed. However, the manuscript can be downloaded and accessed as a PDF.

Tables

Table 1: The characteristics of subjects at baseline

Variable	Control group (n=22)	Intervention group (n=22)
Age (years)	51.45 ± 5.03	53.72 ± 6.68
Female / Male (N)	16 / 6	14 / 8
Weight (kg)	72.54 ± 6.94	73.68 ± 8.38
Height (m)	162.95 ± 9.27	164.4 ± 6.7
BMI (kg/m2)	27.36 ± 2.1	27.21 ± 2.19
WC(cm)	102.04 ± 8.69	101.22 ± 9.99
HC (cm)	107.18 ± 8.08	106.59 ± 9.7
WHR	0.95 ± 0.08	0.95 ± 0.05
Physical Activity (met-min/ week)	320.86 ± 170.58	293.31 ± 172.15
MAP (mmHg)	90.60 ±11.06	90.30 ± 10.17
PP (mmHg)	46.81 ± 13.93	50.00 ± 11.95
AIP	0.52 ± 0.16	0.54 ± 0.12
LAP	67.78 ± 24.17	77.36 ± 41.01
ABSI ($m^{11/6}$ $Kg^{-2/3}$)	0.038 ±0.009	0.037 ± 0.005
AVI	20.97 ± 3.46	20.68 ± 4.07
BAI (Kg/m^2)	32.94 ± 4.30	32.70 ± 5.55
Conicity	1.40 ± 10	1.41 ± 0.08
Waist to height ratio	0.62 ± 0.05	0.61 ± 0.05

Values are expressed as means ± SD. *P <0.05* was considered as significant.

**P <0.05* was considered as significant using Independent t-test between the two groups at baseline.

***P <0.05* was considered as significant using Chi-square test

BMI = body mass index; WC = waist circumference; HC = hip circumference; MAP= mean arterial pressure; PP = pulse pressure; AIP= atherogenic index of plasma; ABSI = a body shape index; AVI = abdominal volume index; BAI = body adiposity index; LAP = lipid accumulation product

Table 2. Mean ± SD of energy, carbohydrate, protein, fat intake at baseline and post-intervention

Variable		Baseline	post-intervention	*P*
Energy (kcal/d)	Control group	1868.52±167.39	1880.4±167.1	
	Intervention group	1925.11±181.17	1896.45±179.73	
	*P-value**	0.28	0.22	
Carbohydrate (%)	Control group	52.08 ± 0.28	52.06 ± 0.22	
	Intervention group	52.09 ± 0.24	52.10 ± 0.28	
	*P-value**	0.89	0.60	
Protein (%)	Control group	15.97 ± 0.15	15.96 ± 0.20	
	Intervention group	15.95 ± 0.19	15.95 ± 0.25	
	*P-value**	0.61	0.85	
Fat (%)	Control group	31.99 ± 0.29	31.99 ± 0.28	
	Intervention group	31.87 ± 0.61	31.88 ± 0.57	
	*P-value**	0.42	0.44	

**$P < 0.05$* was considered as significant using Independent t-test between the two groups post-intervention.

***$P < 0.05$* was considered as significant using Paired t-test.

Table 3. Atherogenic index of plasma, mean arterial pressure, pulse pressure and new anthropometric index at baseline and post-intervention.

Variable	Control group (n=22)			Intervention group (n=22)		
	Baseline	After 8 weeks	P-value	Baseline	After 8 weeks	P-value
MAP (mmHg)	90.60 ±11.06	91.96 ± 9.23	0.38	90.30 ± 10.17	84.54 ± 8.88	0.006
Change		1.36 ± 7.17			-5.57 ± 8.91	
PP (mmHg)	46.81 ± 13.93	46.81 ± 12.86	1.00	50.00 ± 11.95	43.63 ± 11.76	0.01
Change		0.00 ± 8.16			- 6.36 ± 11.35	
AIP	0.52 ± 0.16	0.53 ± 0.19	0.86	0.54 ± 0.12	0.49 ± 0.16	0.12
Change		0.004 ± 0.10			-0.054 ± 0.16	
LAP (cm.mmol.l)	67.78 ± 24.17	68. 82 ± 28.14	0.72	77.36 ± 41.01	72.08 ± 34.39	0.35
Change		1.03 ± 13.44			-5.27 ± 25.88	
ABSI ($^{m11/6.Kg-2/3}$)	0.038 ± 0.009	0.037 ± 0.009	0.46	0.037 ± 0.005	0.04 ± 0.005	<0.001
Change		-0.000 ± 0.002			0.003 ± 0.002	
AVI	20.97 ± 3.46	20.89 ± 3.50	0.38	20.68 ± 4.07	20.07 ± 4.10	<0.001
Change		-0.07 ± 0.38			-0.61 ± 0.59	
BAI (Kg/m^2)	32.94 ± 4.30	31.69 ± 3.84	0.058	32.70 ± 5.55	29.68 ± 4.87	<0.001
Change		-1.25 ± 2.91			-3.02 ± 2.54	
Conicity	1.40 ± 0.10	1.39 ± 0.10	0.39	1.41 ± 0.08	1.39 ± 0.08	<0.001
Change		-0.002 ± 0.01			-0.02 ± 0.02	
Waist to height ratio	0.62 ± 0.051	0.62 ± 0.050	0.35	0.61 ± 0.05	0.60 ± 0.06	<0.001

Values are expressed as means ± SD.

P <0.05 was considered as significant using Paired t-test.

*.P <0.05 was considered as significant using Independent t-test between the two groups post-intervention

**.P <0.05 was considered as significant changes using Independent t-test between the two groups post-intervention

Figures

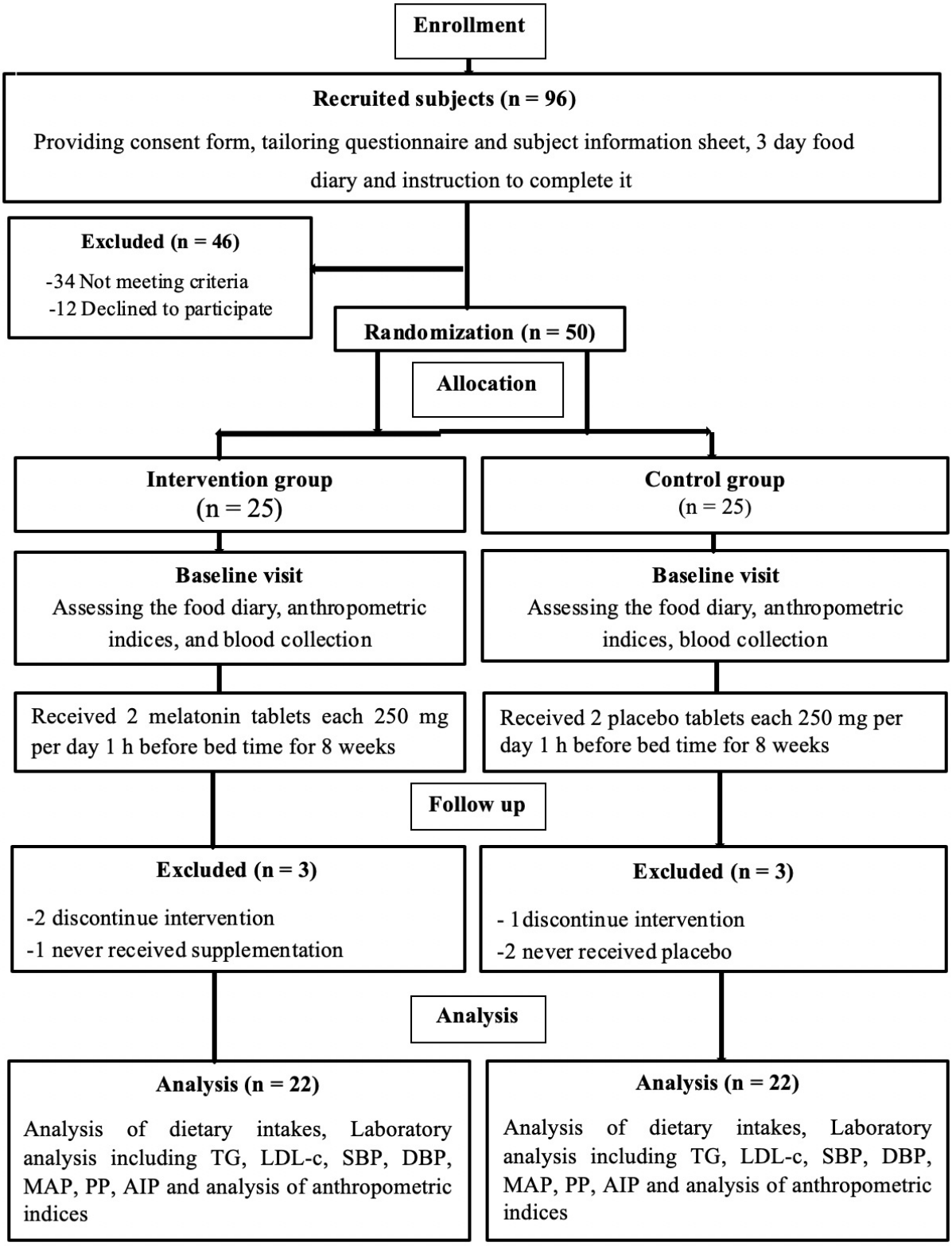

Figure 1

Stages of clinical trial progress Abbreviations: Triglycerid (TG), low-density lipoprotein

cholesterol (LDL-c), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), pulse pressure (PP) and atherogenic index of plasma (AIP)