Effectiveness of Mediterranean Diet on Daytime Sleepiness among Individuals with Type 2 Diabetes Mellitus in Oman

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Abstract

Background Sleep disturbance is a major complaint among individuals with diabetes mellitus and may be augmented by dietary interventions. The objective of this randomized controlled trial was to determine the effectiveness of a Mediterranean diet intervention on daytime sleepiness among individuals with type 2 diabetes mellitus (T2DM) in Oman.

Methods In total, 134 eligible individuals with T2DM (61 and 73 participants in the intervention and control groups, respectively) were recruited. The intervention participants underwent a 6-month Mediterranean diet intervention consisting of individual dietary counseling, cooking classes, phone calls, and social media messages, while the control group continued with standard diabetes care. Daytime sleepiness was assessed using the Epworth Sleepiness Scale. All data was analyzed using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA).

Results Daytime sleepiness was evident, with ~30% of the participants experiencing it, with no significant difference between control and intervention participants at baseline. There was a significant reduction in daytime sleepiness in both the intervention and control groups after 6 months, with daytime sleepiness significantly lower in the intervention group, with a modest difference of 42.56% ($p < 0.001$).

Conclusion Adherence to the Mediterranean diet is effective in reducing daytime sleepiness among individuals with T2DM.

Clinical Trial UMIN000041152

Keywords
- daytime sleepiness
- Mediterranean diet
- type 2 diabetes mellitus

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Introduction

Excessive sleepiness is defined as the difficulty of staying awake and alert during the major waking episodes of the day, with sleep occurring unintentionally or at inappropriate times during the wake period.[1] Excessive sleepiness is one of the greatest challenges faced by modern society.[2] An increasing number of individuals sacrifice their sleep to accommodate contemporary lifestyles and economic demands. The prevalence of excessive sleepiness varies widely, from below 10% in some populations,[3] to 10 to 20% in others,[4] with the highest rates of $\sim$ 30% reported among American,[2] Japanese,[5] and Omani populations.[6] The wide variation can be attributed to differences in cultural and demographic factors, assessment tools to reflect excessive sleepiness, and inconsistencies in the study design.[7] Previous studies reported that patients with diabetes mellitus were more likely to be sleepy during the day than non-diabetics.[8,9]

Excessive sleepiness is associated with greater risk of vehicular accidents,[10] mortality,[11] and a diminished quality of life.[5] In patients with diabetes, serious risk of traffic accidents due to somnolence has been documented.[12] In addition to the above-mentioned complications, there is growing evidence that sleep disturbances can have detrimental effects on glucose metabolism and weight regulation.[13] However, most of the previously mentioned evidence was found in studies investigating sleep characteristics, whereas sleepiness itself has been less explored.[14,15] On the other hand, many studies have focused on how sleep may augment the risk of diabetes mellitus development[13] or its complications,[16] with relatively little about how sleepiness may influence glycemic control in T2DM patients.[17] Increasing evidence suggests a bidirectional relationship between sleep disorders and type T2DM, implying a vicious circle.

The traditional Mediterranean diet describes the traditional dietary habits of people living around the Mediterranean basin, specifically in olive tree growing regions, before globalization expanded to the food culture. The Mediterranean diet (MD) is characterized by abundant plant foods, mainly fruits, vegetables, nuts, seeds, bread, beans, cereals, and legumes, in addition to olive oil, which is the main source of healthy fat and highlights the use of spices and herbs. The diet also consists of a moderate intake of dairy products, such as yoghurt and cheese, low-to-moderate amounts of fish, and low amounts of red meat and poultry.[18–20] The Mediterranean diet is a healthy dietary pattern associated with lower mortality[21] and a reduced risk of cardiovascular diseases.[22] To our knowledge, no study has focused on the association between Mediterranean diet and daytime sleepiness in Oman. Therefore, this study aimed to address the gap between current knowledge and clinical care by exploring the effectiveness of managing excessive daytime sleepiness among individuals with T2DM via lifestyle interventions (Mediterranean diet), hoping to serve as a fundamental work to improve glycemic control among individuals with diabetes mellitus.

Materials and Methods

Study Design and Participants

The present study was part of a randomized controlled trial designed to evaluate the effectiveness of a 6-month Mediterranean diet intervention on glycemic control and cardiovascular risk among individuals with T2DM. Ethical approval was granted by the Research Ethics Committee of Universiti Putra Malaysia, with study approval obtained from the Ministry of Health, Oman, and the National Diabetes and Endocrine Centre of the Royal Hospital (SRC#22|2019) before the study commencement. The study was registered in the UMIN Clinical Registry Trial (UMIN000041152).

The study participants were recruited from the Nutrition Clinic of the National Diabetes and Endocrine Centre (NDEC), Royal Hospital Oman. They were outpatients referred to NDEC to optimize dietary interventions for diabetes control. Participants were recruited over a period of 12 months, from April 2019 to March 2020. Only new patients (based on a new admission record) were recruited to ensure that there was no influence from the previous education and counselling sessions. Participants were first given a briefing on the study, its purpose, duration, methodology, and the level of commitment required from them. Face-to-face discussions were held to enable full understanding of the participants on the trial prior to receiving written consent from them. Eligibilities were limited to those aged between 18 and 75 years, men or women, with a medical diagnosis of type 2 diabetes, and with a stable HbA1c of $< 10\%$. Pregnant or lactating women, those who were diagnosed with cardiac failure and/or severe renal disease, with physical or mental disability, neurological or cognitive impairment, severely impaired vision, hearing or speech, and those who had known allergies to peanuts or any components of the Mediterranean diet were excluded from the study. Allocation, concealment, and randomization were performed accordingly.[23] Participants from the control and intervention groups were scheduled to visit the Nutrition Clinic on different days or at different times to reduce or eliminate the risk of contamination between the control and intervention groups. The dietary intake of participants was monitored continuously, and participants in the control group were assured that they would receive the same intervention package upon study completion and, hence, were encouraged not to modify their eating habits during the trial. ►**Fig. 1** depicts the workflow of the study based on the Consolidated Standards of Reporting Trails (CONSORT) design.

Study Instruments and Measurements

In this study, a set of pretested structured questionnaires was used to collect information. The questionnaire was first prepared in English and translated into Arabic, and back translation was performed before its final use.

A one-day 24-hour dietary recall was administered at each visit to provide comprehensive and quantitative information on participant's diets by querying participants about the type and quantity of all food and beverages consumed during the previous 24-hour period. Food portions recorded

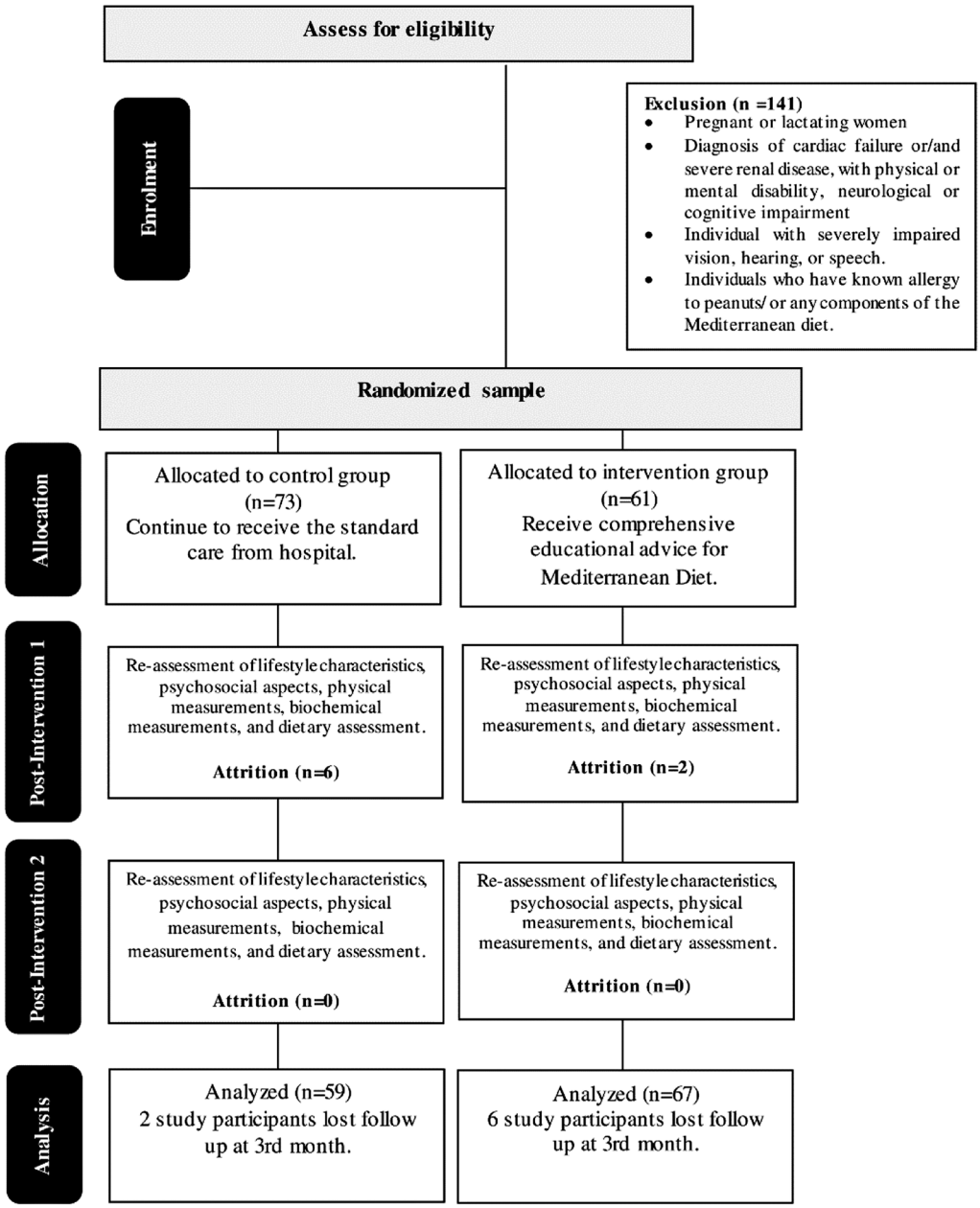

Fig. 1 Consort diagram: flow of study.

in household measurements were converted into absolute weight in grams before data entry. The dietary intake of participants was analyzed using the Cronometer application (Cronometer Software Inc., Revelstoke, BC, Canada) within the nutritional analysis software program ESHA Food Processor (version 11.1) (Esha Research, Salem, OR, USA). Adherence to the Mediterranean diet was assessed using a validated, self-administered questionnaire (23) at baseline and at the subsequent two visits. The questionnaire consisted of 14 items, with each item related to a specific dietary aspect such as the number of daily servings of fruits and vegetables, the use of olive oil as the main source of fat, the number of seafood-based dishes consumed per week, the consumption of red meat and the amount of carbonated and/or sweetened beverages consumed. Each item had a two-option answer, enabling a unitary score of 1 (adherence) or 0 (no adherence). Poor adherence was scored as ≤ 5, moderate adherence as 6 to 9 and high adherence as > 10.

The body weight and height of participants were measured using a digital weight scale (Tanita BC541) and recorded to the nearest 0.1 kg, and 0.1 cm, respectively. Height was recorded using a wall mounted Seca 206. Body mass index (BMI) as a proxy measure of the body weight status of the study participants was computed using the weight and height measurements using the universal equation (BMI = body weight (kg)/height $(m)^2$). A Backman machine that uses a spectrophotometer was used to measure the HbA1c levels.

Daytime sleepiness was assessed using the Epworth Sleepiness Scale (ESS), a widely used subjective measure of

sleepiness in the field of sleep medicine. This scale estimates whether the participant is experiencing excessive sleepiness that may require medical attention.[24] It is the most widely used tool for assessing daytime sleepiness[25] and has acceptable reliability among the Omani population.[26,27] There were eight items in the questionnaire, and participants were required to rate their chances of dozing during certain daily activities, such as reading, riding as a passenger in a car for an hour, sitting quietly, and talking to someone over the past month. Each item is rated from 0 (would never doze) to 3 (high chance of dozing). The total score ranged from 0 to 24, with higher scores representing a higher degree of sleepiness. An ESS score greater than 10 was defined as excessive daytime sleepiness.

The design and development of an intervention educational material

A booklet with extensive elaboration on the Mediterranean diet was developed after reviewing published articles and educational materials from other researchers.[28,29] Despite the health benefits of the Mediterranean diet being evident from clinical trials, which mostly came from Mediterranean basins, adhering to its principles in non-Mediterranean populations, such as Omani populations, remains a great challenge and requires careful planning to ensure reproducibility and translation of the favorable effects of the Mediterranean diet for Omanis. Potential barriers that were likely to occur were acknowledged,[30–32] with appropriate strategies being adopted to address them.

After detailed planning and review, a booklet containing pertinent information on the Mediterranean diet was developed. The booklet underwent content validity testing by 2 dietitians and 2 clinicians, with face validity testing performed on 20 individuals with T2DM to ensure its practicality. Within the booklet, there is information on the definition, common principles, and health benefits of the Mediterranean diet as well as a schematic diagram of the Mediterranean diet pyramid. Handy and practical tips were given to assist participants to comply with the recommendation of diet. To ensure consistency and avoid overeating, the Hand Jive Method was incorporated as a guide to portion control. With these handy tips, participants can easily and consistently judge the amount of food they can have for each meal. The participants were also instructed on practical tips to scale up healthy oil (olive oil) in their diet and make healthier choices for snacks. The booklet provides clear illustrations on easy-to-prepare menus or recipes, which empowered participants with adequate skills in meal preparation. Besides the booklet on Mediterranean diet, a series of leaflets were developed, including food labels reading and practical guides for grocery shopping, which aimed to complement the knowledge and skills of the participants.

Implementation of Intervention

Intervention Group

The Mediterranean diet program was oriented by a nutritionist, with the guidance of dietitians. The Health Belief Model (HBM) was used as a theoretical framework for health education intervention according to the Mediterranean diet approach and lifestyle changes and was the underpinning theory used to facilitate behavioral change. The researchers intended that the adoption of the HBM could assist participants in adopting a healthier diet pattern by recognizing that they have issues with lifestyle (physical inactivity, poor diet quality), accepting the reality, feeling threatened, being sensitive to its impact on health, and being convinced that adopting the Mediterranean diet is critical. Additionally, a counseling method adapted from cognitive behavioral therapy was employed, whereby strategies including self-monitoring and goal-setting were employed. The researchers set goals together with the participants by giving each of them a goal chart during the baseline. Participants were encouraged to bring their partners or family members, as support from the family members was considered one of the most important factors in promoting behavioral change.[33]

The intervention participants underwent a 6-month Mediterranean diet program that included 3 sessions of personal dietary counselling and 2 sessions of cooking classes, with a duration of 30 to 45 minutes for each session. The participants were advised to consume seafood such as salmon and tuna twice a week, moderate the consumption of poultry at 2 servings per week, cut down the consumption of red meat to once every 3 weeks, consume 1 to 2 servings of dairy products per day, and emphasize raw unsalted nut intake (1–2 servings per day) and legumes (at least 2 servings per week). They were also asked to choose whole grain products and use olive oil as the main source of fat in cooking and salad dressings.

At the cooking classes, practical ways to prepare Mediterranean diet meals were demonstrated. The researcher and participants interacted actively with frequently exchanged ideas on optimizing the application of the Mediterranean diet in their cooking and food selection when eating out, the challenges they faced, and possible solutions. In addition to personal counselling and cooking classes, 2 telephone calls were made throughout the 6-month period. During the calls, there was reinforcement of individual goals, follow-up on their adherence to nutrition advice, and discussions on possible barriers encountered. All intervention participants were advised on the potential symptoms of allergies, and clear instructions were provided on when participants with allergy symptoms should seek medical treatment immediately.

Statistical Analyses

The IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, NY, USA) was used to perform statistical analyses. Descriptive analysis was used to determine the standard deviation, mean, median, mode, percentage, and frequency of data. Percentages and frequencies were used to describe categorical variables, whereas standard deviations and means were used to describe continuous variables. The changes in study variables over time were assessed using a repeated-measure analysis of variance (ANOVA) over the three time points and a paired *t*-test at each time point (T0 versus T1). The differences in the study variables between

the intervention and control groups were assessed using an independent *t*-test for each time point. To assess the effectiveness of the intervention, a mixed-model ANOVA and the within-group, between-group, and group-time interaction effects were assessed and reported. A p-value < 0.05 at 95% confidence interval was considered statistically significant.

Results

A total of 134 eligible participants with T2DM were recruited and signed informed consents. Of the 134 participants, 61 were allocated to the intervention group and 73 to the control group. In the intervention group, a total of 59 participants completed the study, but 2 intervention participants were lost follow-up in the 3rd month and were withdrawn from the study. A total of 67 control participants completed the study, and 6 withdrew from the study during the 3rd month follow-up. Hence, the overall dropout rate was 6.0%, comprised of 3.3% and 8.2% from the intervention and control groups, respectively. ►**Table 1** shows the comparison of sociodemographic characteristics between the intervention and control participants at baseline. The mean age of the

Table 1 Baseline comparison of sociodemographic, anthropometric, and biochemical characteristics between intervention ($n = 59$) and control ($n = 67$) participants.

Sociodemographic characteristics	All ($n = 126$) N (%)	Control ($n = 67$) N (%)	Intervention ($n = 59$) N (%)	χ^2	p
Age (years)					
Mean ± SD	44.0 ± 11.0	44.2 ± 10.9	43.9 ± 10.4	0.141[a]	0.888
Min–max	22.0–75.0	22.0–75.0	24.0–75.0		
Gender					
Male	55 (43.7)	27 (40.3)	28 (47.5)	0.654	0.419
Female	71 (56.3)	40 (59.7)	31 (52.5)		
Marital status					
Single	23 (18.3)	11 (16.4)	12 (20.3)	1.064	0.786
Married	84 (66.7)	44 (65.7)	44 (74.6)		
Widowed/Divorced	19 (17.4)	12 (17.9)	7 (5.1)		
Educational level				5.911	0.315
Illiterate	10 (7.9)	5 (7.5)	5 (8.47)		
No format education	23 (18.3)	14 (20.9)	9 (13.6)		
Primary	5 (4.0)	3 (4.5)	2 (3.39)		
Secondary	27 (21.4)	17 (25.4)	10 (16.9)		
Preparatory	32 (25.4)	18 (26.9)	14 (23.7)		
University	29 (23.0)	10 (14.8)	19 (32.2)		
Working				1.280	0.258
Working	68 (54.0)	33 (49.3)	35 (59.3)		
Not working	58 (46.0)	34 (50.7)	24 (40.7)		
Monthly household income (Rial)				9.424	**0.024**[*]
< 400	10 (7.9)	9 (13.4)	1 (1.7)		
400–800	54 (42.9)	32 (47.8)	22 (37.3)		
800–1,200	47 (37.3)	20 (29.9)	27 (45.8)		
> 1,200	15 (11.9)	6 (8.9)	9 (15.3)		
Smoking					
Has smoked/Smokes	19 (15.1)	7 (10.4)	12 (20.3)	2.397	0.122
Never smoked	107 (84.9)	60 (89.6)	47 (79.7)		
Alcohol consumption					
Ever consumed	8 (6.3)	4 (6.0)	4 (6.8)	0.035[g]	0.852
Never consume	118 (93.7)	63 (94.0)	55 (93.2)		

Note: [a]independent *t*-test.
[*]*p*-value.

participants was 44.0 ± 11.0 years old. A higher proportion of the study participants were female (56.3%) and married (66.7%). In this study, ~ 8% of the participants were illiterate, 18.3% had no formal education, and 4% had only attended primary school education. A higher proportion of study participants had preparatory educational level (25.4%), while 21.4% had secondary school, and another 23.0% had tertiary education. More than half of the participants were working (54.0%). A majority of the participants had household income of 400 to 800 Rial. There was a significantly higher proportion of participants from the intervention group with high household income (> 1,200 Rial) compared with the control group ($\chi^2 = 9.424$, 0.024), while other sociodemographic characteristics were comparable between the two groups.

Daytime Sleepiness

►**Table 2** shows the distribution of participants according to the level of daytime sleepiness. A total of 43.7%, 34.1%, and 11.1% of the participants had a high chance of dozing when sitting and reading, watching television, and lying down, respectively. On the other hand, 40 to 50% of the participants had moderate daytime sleepiness when sitting and reading, watching television, lying down, and sitting quietly after lunch. More than 10% of the participants experienced daytime sleepiness when they were in a car that stopped for a few minutes.

►**Table 3** shows the baseline comparison of daytime sleepiness among participants between the intervention and control groups according to gender. Approximately 30% of the participants experienced daytime sleepiness, with no significant difference between the control and intervention groups. However, it is noteworthy that when comparisons were made according to gender, male intervention participants (t = -2.507, $p = 0.015$) and female control participants (t = 2.22, $p = 0.030$) had significant higher risk of daytime sleepiness. A significantly higher proportion of female control participants experienced daytime sleepiness ($\chi 2 = 4.673$, $p < 0.05$).

Table 2 Distribution of participants according to daytime sleepiness.

	No chance of dozing	Slight chance of dozing	Moderate chance of dozing	High chance of dozing
Sitting and reading	2 (1.6)	19 (15.1)	50 (39.7)	55 (43.7)
Watching TV	5 (4.0)	17 (13.5)	61 (48.4)	43 (34.1)
Sitting inactive in a public place	79 (62.7)	47 (37.3)	0	0
As a passenger in a car for an hour without a break	71 (56.3)	41 (32.5)	12 (9.5)	2 (1.6)
Lying down to rest in the afternoon when circumstances permit	13 (10.3)	46 (36.5)	53 (42.1)	14 (11.1)
Sitting and talking to someone	111 (88.1)	13 (10.3)	2 (1.6)	–
Sitting quietly after a lunch without alcohol	30 (23.8)	41 (32.5)	48 (38.1)	7 (5.6)
In a car, while stopped for a few minutes in traffic	110 (87.3)	12 (9.5)	3 (2.4)	1 (0.8)

Table 3 Baseline comparison in daytime sleepiness among intervention ($n = 59$) and control ($n = 67$) participants according to gender.

Daytime sleepiness	All ($n = 126$)	Control ($n = 67$)	Intervention ($n = 59$)	t or χ^2	p
ESS, total score					
Mean ± SD	8.41 ± 2.56	8.40 ± 2.49	8.42 ± 2.67	-0.045[a]	0.964
No risk	89 (70.6)	44 (65.7)	45 (76.3)	1.699	0.192
Risk of dozing off	37 (29.4)	23 (34.3)	14 (23.7)		
Gender					
Male					
Mean ± SD	8.11 ± 2.70	7.22 ± 2.22	8.96 ± 2.87	-2.507[a]	0.015*
No risk	44 (80.0)	23 (85.2)	21 (75.0)	0.891	0.345
Risk of dozing off	11 (20.0)	4 (14.8)	7 (25.0)		
Female					
Mean ± SD	8.65 ± 2.44	9.20 ± 2.37	7.94 ± 2.39	2.222[a]	0.030*
No risk	45 (63.4)	21 (52.5)	24 (77.4)	4.673	0.031*
Risk of dozing off	26 (36.6)	19 (47.5)	7 (22.6)		

Note: [a]independent *t*-test.

Table 4 Comparison of mean changes of daytime sleepiness within and between the intervention ($n = 59$) and control groups ($n = 67$) across three different time points.

				Within-group comparison				Between-group comparison			
	Time (I)	Mean ± SD	Time (J)	Mean difference[a]	Percent difference	t-test	95% CI for difference[b]	*p*-value[b]	Intervention effect[c]	Percent difference	95% CI for difference	*p*-value	*d*
Intervention	T0	8.42 ± 2.67	T1	-2.54	-30.17	-10.7	-3.02, - 2.06	< 0.001	-1.24	-30.72	-1.92, -0.56	< 0.001	0.096
	T1	5.88 ± 2.69	T2	-3.61	-42.87	-10.1	-4.33, -2.89	< 0.001	-2.16	-42.56	-3.13, -1.19	< 0.001	0.136
	T2	4.81 ± 2.77	T2	-1.07	-18.20	-5.86	-1.43, -0.70	< 0.001	-0.92	-20.20	-1.42, -0.42	< 0.001	0.097
Control	T0	8.40 ± 2.49	T1	-1.30	-15.48	-5.31	-1.79, -0.81	< 0.001					
	T1	7.10 ± 2.75	T2	-1.45	-17.26	-4.33	-2.11, -0.78	< 0.001					
	T2	6.96 ± 3.17	T2	-0.15	-2.11	-0.86	-0.49, 0.20	0.392					

Note: SD – standard deviation; CI – confidence intervals; T0–baseline; T1–postintervention 1; T2–postintervention 2; *d* – Cohen *d* effect size: small effect = 0.2, medium effect = 0.5, large effect = 0.8, very large effect = 1.3. [a]Time (J) – Time (I); [b]Adjusted for Bonferroni multiple comparisons; [c]Intervention effect measured as change in intervention group minus change in control group: Time (J) – Time (I).

Changes in Daytime Sleepiness

►**Table 4** shows the comparison of the mean changes in daytime sleepiness within and between the intervention and control groups across the three different time points. There was a significant reduction in daytime sleepiness in both the intervention and control groups over the three time points. This indicates that the tendency to doze off or fall asleep was reduced in both groups. The mean changes in daytime sleepiness were significantly higher in the intervention participants postintervention 2, with a modest difference of 42.56% ($p < 0.001$).

To examine whether the changes in daytime sleepiness differed between the two treatment groups across the 3 time periods, a 2 × 3 mixed-design ANOVA was performed, and the results are shown in ►**Table 5**. There were significant interaction effects on participants' daytime sleepiness ($F = 8.89$, $p < 0.001$), indicating that the changes in daytime sleepiness over time were significantly different between the intervention and control groups, independent of the other covariates.

Changes in Anthropometry Parameters and HbA1c

►**Table 6** shows the comparison of mean changes in anthropometric measurements and HbA1c levels within and between the intervention and control groups over time. There were significant decreases in body weight ($t = -12.41$, $p \leq 0.001$), body mass index (BMI) ($t = -11.95$, $p \leq 0.001$), waist circumference (WC) ($t = -7.84$, $p \leq 0.001$), and HbA1c ($t = -13.57$, $p \leq 0.001$) among the intervention groups. Similar findings were documented among the control participants for HbA1c ($t = -4.75$, $p \leq 0.001$) after 6 months. On the other hand, despite participants recording a lower body weight ($t = 0.18$, $p = 0.858$), body mass index (BMI) ($t = 0.09$, $p = 0.933$), and waist circumference (WC) ($t = -1.01$, $p = 0.318$) 6 months later compared with baseline, such changes were not significant. As shown in ►**Table 6**, there were significant differences on the weight ($F = 44.19$, $p < 0.001$), BMI ($F = 41.23$, $p < 0.001$), WC ($F = 13.60$, $p < 0.001$), and HbA1c ($F = 24.61$, $p < 0.001$) between the control and intervention groups, attributed to a smaller magnitude of changes occurred among the control participants.

Discussion

Daytime sleepiness was prevalent in this study cohort, which is in accordance with the results of other studies.[34,35] On the other hand, there was a high proportion of participants who dozed when they were sitting, reading, watching TV, or lying down to rest in the afternoon when circumstances permitted. Previous studies have consistently reported that sleep disorders are not only a risk factor for the onset of diabetes but also have a great impact on individuals with T2DM.[36,37] Possible pathophysiological mechanisms may be attributed to peripheral neuropathy due to small-fiber neuropathy, which increases the risk of restless legs syndrome, which is commonly reported among individuals with diabetes mellitus.[38,39] Pain from common complications, such as peripheral neuropathy or nocturia from poor glycemic control,[40] and a periodic breathing pattern during sleep, which

Table 5 Mixed model multivariate analysis of variance on effectiveness of intervention on daytime sleepiness.

	Multivariate analysis[a]								
Sleep Quality	Within-subjects effects (time)			Between-subjects effects (group)			Interaction effects (time*group)		
	F	*p*-value	η^2	F	*p*-value	η^2	F	*p*-value	η^2
Epworth sleepiness scale (ESS)	0.01	0.991	0.000	6.59	0.012*	0.059	8.89	< 0.001*	0.078

Notes: [a]mixed model ANOVA adjusted for baseline covariates: weight (kg), body mass index (kg/m^2), waist circumference (cm), household income, type of treatment, presence of side effects, fiber (g), protein (g), trans-fats (g), vitamin B_2 (mg), vitamin B_3 (mg), vitamin B_5 (mg), vitamin A (IU), copper (mg), magnesium (mg), manganese (mg), phosphorus (mg), sodium (mg) and MedDiet; (*)-statistically significant.

Table 6 Comparison of changes of anthropometric and biochemical parameters among participants from baseline to month-6.[1]

	Control group			Intervention group			*p*-value*
	Baseline	Month-3	Month-6	Baseline	Month-3	Month-6	
Weight (kg)	108.9 ± 23.6	105.6 ± 23.4	105.7 ± 22.5	118.1 ± 23.2	109.9 ± 22.5	104.1 ± 22.3	< 0.001
BMI (kg/m^2)	41.6 ± 7.9	40.3 ± 7.9	40.3 ± 7.5	44.6 ± 7.7	41.5 ± 7.7	39.2 ± 7.0	< 0.001
WC (cm)	100.5 ± 12.5	99.2 ± 12.5	99.1 ± 12.3	90.3 ± 7.6	87.6 ± 7.4	85.9 ± 7.4	< 0.001
HbA1c (%)	7.99 ± 1.13	7.74 ± 1.0	7.57 ± 1.05	7.88 ± 1.05	7.31 ± 1.03	6.83 ± 0.98	< 0.001

Abbreviations: BMI, body mass index; WC, waist circumference.
*Between-group comparison, with $p < 0.05$ was considered significant.

is more common among those with diabetes, may further impact the sleep quality of individuals.[40]

The effectiveness of the Mediterranean diet in reducing excessive daytime sleepiness requires further elaboration. An earlier study showed that adherence to the Mediterranean diet eating pattern had a similar effect on specific sleep characteristics.[41] More recently, a study in Italy also indicated that a high level of adherence to the Mediterranean eating pattern is linked to higher sleep quality.[42] Assessment of sleep, education for healthy sleep, and referral for treatment of sleep disturbance were found to maximize the potential for achieving good glycemic control[17]; therefore, intervening in daytime sleepiness or improving sleep quality may benefit patients with diabetes. Previous studies have suggested a link between adherence to the Mediterranean diet and sleep duration and quality among adults,[43,44] and the current findings may provide a better understanding of this link, particularly among patients with diabetes.

This study had several advantages and limitations. The prospective design that allowed for the establishment of temporality is one of the strengths. The study included patients with newly diagnosed T2DM at all stages, increasing the generalizability of the findings. However, two limitations of this study are worth mentioning. The measure of daytime sleepiness is subjective and self-reported, which contributes to study limitations, whereby objective measures for sleep quality (e.g., polysomnography) would offer more valid results, but its implementation is not feasible in the current sample. In addition, there was a significant difference between groups in terms of monthly household income, gender, and weight. Despite the beneficial role observed in the Mediterranean diet, a relatively short intervention of 6 months should be reproduced with a longer intervention. It is beyond the scope of the paper to further analyze whether the effect of Mediterranean diet on the improvement of daytime sleepiness was attributed to the direct effect of Mediterranean diet or mediated by the improvement on anthropometric parameters and HbA1c. More work is warranted.

In conclusion, the effectiveness of the Mediterranean diet on daytime sleepiness indicated that the Mediterranean diet worked well among Omanis and superseded conventional dietary counselling. Hence, this study provides compelling evidence for dietitians to promote diets that incorporate aspects of the Mediterranean eating pattern with local diets for Omanis, to improve the sleep quality of individuals with T2DM. In light of the high prevalence of sleepiness among diabetes mellitus patients, future studies should explore interventions for sleep disturbance using the Mediterranean diet, hoping to improve glycemic control, thus providing an important aid in preventing T2DM progression, and ultimately leading to better quality of life and other health measures among individuals with diabetes mellitus.

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Conflict of Interests
The authors have no conflict of interests to declare.

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