EFFECT OF MEDITERRANEAN DIET ON SEXUAL FUNCTION IN WOMEN WITH METABOLIC SYNDROME

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Article History: Received: 05.06.2023 **Revised:** 08.07.2023 **Accepted:** 11.07.2023

Abstract

Aim of the study: This study aimed to assess the impact of the Mediterranean diet (Med-Diet) on sexual function in women diagnosed with metabolic syndrome (MS). **Subjects and Methods:** The study was conducted as a randomized controlled trial. Herein, 200 female patients diagnosed with MS and between 35 and 40 years of age and experiencing sexual dysfunction were randomly assigned into two equal groups. The control group (A) was on Kegel exercise sessions three times/week for 12 weeks, while the study group (B) had a combination of Kegel exercise and a Med-Diet regimen for the same 12-week duration. Two questionnaires were used for all female participants in both groups before and post-treatment; the female sexual function index (FSFI) questionnaire was used to assess sexual function, while the women's sexual quality of life questionnaire (SQOL-F) was used to assess the quality of life (QoL). **Results:** Our post-treatment findings showed a significant elevation in the FSFI questionnaire score in group B (M = 18.57, SD = 6.73) compared to group A (M = 15.87, SD = 6.98), with Z- and p-values of -3.805 and 0.001, respectively. Furthermore, the results indicated a significant increase in the SQOL-F questionnaire score in group B (75.05 ± 4.21) compared to group A (58.40 ± 11.95), with a statistically significant Z- and p- values of -9.763 and 0.001, respectively. **Conclusions:** The combination of a Med-Diet regimen and Kegel exercise is more efficacious than Kegel exercise alone in enhancing sexual function and quality of life among women diagnosed with MS.

Keywords: Mediterranean diet; Kegel exercise; female sexual function; metabolic syndrome.

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INTRODUCTION

Metabolic syndrome (MS) is a set of metabolic irregularities that include hypertension (HT), central obesity, insulin resistance, type 2 diabetes mellitus (T2DM), as well as atherogenic dyslipidemia (1). The sexual health of women is associated with various psychological and interpersonal variables, which can be influenced by the natural aging process and metabolic alterations (2). Obesity, HT, dyslipidemia, and TBM2 in women diagnosed with MS are commonly considered risk factors for developing atherosclerosis and endothelial malfunction and can lead to altered tissue oxygenation, which can subsequently cause damage to the functional and structural integrity of the female genital tract. Atherosclerotic disease-induced reduction in pelvic blood flow leads to the development of fibrosis in the vaginal wall and clitoral smooth muscle, ultimately, the occurrence of vaginal dryness and dyspareunia (3).

Women diagnosed with MS exhibited a higher incidence of sexual inactivity, as well as reduced sexual desire, orgasm, satisfaction, and overall female sexual function index (FSFI) score compared to their counterparts without MS (4). The relationship between diet and sexual performance indicators such as lubrication, orgasm, and frequency of sexual activity has been established (5). Furthermore, it has been observed that food can have either a positive or negative effect on sexual activity for both genders of all ages (6).

The Mediterranean diet (Med-Diet) has been extensively documented and analyzed in the scientific literature, making it one of the most prevalent dietary patterns. The Med-Diet is founded on the consumption patterns of traditional cuisine in nations adjacent to the Mediterranean Sea, including Italy, Greece, Spain, and France. The dietary pattern is distinguished by an elevated intake of vegetables, legumes, fruits, nuts, grains, fish, seafood, and extra virgin olive oil, as well as a restrained consumption of red wine. (7). Previous studies have shown that Kegel exercise increases the level of sexual satisfaction because the pelvic floor muscle (PFM), specifically the pubococcygeus and iliococcygeus muscles, contributes to the involuntary rhythmic contractions that accompany orgasm (8).

To our knowledge, no previous research was conducted to investigate the Med-Diet impact on the sexual function of women diagnosed with MS. Consequently, our objective was to investigate the synergistic impact of Med-Diet and Kegel exercise on the sexual function of female patients with MS. It was hypothesized that the Med-Diet combined with Kegel exercise would have no significant effect on female sexual function (FSF).

Subjects and Methods

- **Design**

This is a single-blind, randomized, and prospective controlled trial that was conducted from June 2022 to January 2023, and its protocol was thoroughly elucidated to participants who provided informed consent at the start of the study.

The protocol for the study conducted by the Faculty of Physical Therapy at Cairo University (***P.T.REC/012/004338***) was approved by the Ethics Committee. Furthermore, it possesses a ClinicalTrials.gov Identifier: ***NCT05859789.***

- **Sample size calculation**

Sample size calculation was performed prior to the study using G*POWER statistical software (*version 3.1.9.2; Franz Faul, Universitat Kiel, Germany*) expecting large difference between kegel exercise and Mediterranean diet compared with kegel exercise alone and revealed that the required sample size for this study would be 100 women per group. Calculations were made using α=0.05, power=80% and effect size = 0.8 and allocation ratio N2/N1 =1.

- **Participants**

A total of 200 women with MS suffering from sexual dissatisfaction were recruited from the outpatient clinic of the gynecology department of Kasr El-Ainy University Hospital, Cairo, Egypt. The inclusion criteria incorporate sexually active women diagnosed with MS and complaining of sexual dysfunction. They had abdominal adiposity (waist circumference > 88cm), hypertriglyceridemia (elevated triglyceride >150 mg/dl), low serum high density lipoprotein cholesterol, elevated blood pressure > 130/85 mmHg and abnormal glucose homeostasis (fasting plasma glucose concentration >110 mg/dl). Their age was 35 to 40 years, and their body mass index (BMI) was $\geq$ 30 kg/m^2. Exclusion criteria involved a medical history of cardiovascular disease, psychiatric disorders, alcohol abuse, smoking, female gender with a smoking habit, and current use of medication.

- **Randomization**

The participants were randomly assigned into two equal groups (control and study groups) using a sealed envelope technique that consisted of a letter determining the group assignment of female participants, given by an independent researcher. The patients were subjected to a double-blind study design, whereby they were unaware of their assigned group.

- **Interventions**

- **Kegel exercise**

For an entire period of 12 weeks, each participant in both groups underwent three sessions of the Kegel exercise along with thorough teaching on the PFM exercises, using XFT-0010 Pelvic Muscle Trainer device. Each participant was given instructions to evacuate her bladder before the session. The perineal region was cleaned, and the vaginal pressure electrode was lubricated with KY gel before being carefully inserted into the vagina to measure the activity of deeper internal PFMs. The use of an internal probe enhances proprioceptive feedback and promotes the growth of muscle awareness.

Each female participant was asked to "try to squeeze her PFMs as much as possible" and was instructed that the numbers seen at the top of the screen indicated the muscle activity (electrical activity) measured in microvolts (mv). Female participants were instructed to carry out a series of PFM contractions as part of the study protocol. They were given specific instructions to contract their PFMs, keep them contracted for three to five seconds, release all muscles, and then repeat the cycle ten times.

As a home program, this workout routine was to be done three times a day, with at least three sets of 10 to 15 repetitions in each session (9). The participants were instructed not to use the abdomen, thighs, or buttock muscles during contraction to avoid holding their breath. It is recommended to maintain a steady and relaxed breathing pattern while performing the exercises.

- **Med-Diet regimen**

The intervention was administered to every participant within the study group (B) for a duration of 12 weeks. The prescribed dietary protocol comprised a range of constituents, encompassing a cumulative quantity of 275 g/day of carbohydrates, which accounts for 50% to 60% of the overall daily caloric intake, and 50 g/day of protein, which represents 15% to 20% of the total caloric intake. The proportion of total calories derived from fats is 30%, with saturated fats comprising 10% of total fat calories or 20 g/day. Additionally, the recommended daily intake of cholesterol is less than 300 mg. In addition, it has been advised that females incorporate into their dietary regimen a minimum daily consumption of 250-300 g of fruits, 125-150 g of vegetables, and 25-50 g of nuts (5).

Outcome measures

1- FSFI questionnaire:

The FSFI questionnaire was used to evaluate the sexual function of each participant in both groups before and after the treatment program. The FSFI

is a self-reported instrument with multiple dimensions, comprising 19 elements, and evaluates six key dimensions (domains) of FSF, including orgasm (Q11,12,13), pain (Q17,18,19), arousal (Q3,4,5,6), desire (Q1,2), lubrication (Q7,8,9,10), and satisfaction (Q14,15,16). The evaluation process involves assigning scores to each answer (1–5 for questions 1–2; and 0–5 for questions 3–19). The domain score calculation involves the multiplication of each domain score summation by their corresponding domain factor. Furthermore, the overall score is determined by adding the six domain scores, ranging from 2.0 to 36.0 points. The risk of sexual dysfunction was considered present if the score was less than 26.55 (10). Comprehensive instructions regarding the questionnaire were provided to each participant, and sufficient time was given to ensure that her responses were not overly influenced.

2- Female Sexual Quality of Life Questionnaire (SQOL-F):

The SQOL-F questionnaire was used to assess the female sexual quality of life (QoL) of each participant in both groups prior to and after the treatment program. This self-report instrument has been specifically developed to assess sexual self-esteem, emotional and relational concerns.The questionnaire comprises 18 items, each item being assessed on a six-point scale that ranges from complete agreement to complete disagreement. The scoring of response categories can be performed using a scale of 1 to 6 or a scale of 0 to 5, resulting in a possible overall score range of 18 to 108 or 0 to 90. A higher score denotes an improved Qol related to female sexual experiences (11). Comprehensive instructions on the questionnaire were provided to each participant, and ample time was given to ensure that her responses were not overly influenced.

Statistical analysis

The collected data were presented as mean ± standard deviation. The distribution of pre-treatment measured data was evaluated through the Kolmogorov-Smirnov test, which is a standard normality test. The study employed both unpaired t-tests to compare normally distributed variables and the Mann-Whitney test to compare nonnormally distributed variables between the two groups. The Wilcoxon Sign Ranks test was utilized for comparing pre- and post-treatment data within the same group. Statistical analysis was performed using SPSS software (version 19 Windows). A P-value ≤ 0.05 indicated a significant difference.

RESULTS

General Characteristics

The present investigation was conducted on a sample of 200 individuals who were randomly allocated to two groups of equal size. Furthermore, the independent t-test did not indicate significant differences, **(Table 1).**

Table 1. Demographic characteristics (general features) of both groups.

	Group A (n= 100)	Group B (n= 100)	t-value	*P*-value
Age (years)	40.78 ± 2.81	40.06 ± 4.56	1.344	0.181 (NS)
Weight (kg.)	93.14 ± 5.36	94.71 ± 10.81	-1.302	0.195 (NS)
Height (cm)	159.72 ± 3.18	160.32 ± 3.38	-1.292	0.198 (NS)
BMI (kg/m^2)	36.58 ± 2.94	36.82 ± 3.72	-0.506	0.613 (NS)

NS= P > 0.05= non-significant

FSFI Questionnaire

intra-group comparison

The results indicated a significant increase in the FSFI questionnaire score in group A after treatment (15.87 ± 6.98) compared to pre-treatment (12.14 ± 6.83) (Z value= -9.952 and *P value* = 0.001) **(Table 2)**. Moreover, our findings showed a significant increase in the FSFI questionnaire score in group B after treatment (18.57 ± 6.73) compared to its pre-treatment score (11.32 ± 4.08) (Z value= -7.582 and *P value* = 0.001) **(Table2)**. Eventually, the percentage increase in the FSFI questionnaire score was observed to be 30.72% and 64.05% in groups A and B, respectively **(Table 2)**.

Between groups comparison

During the pre-treatment phase, the mean values (± SD) of the FSFI questionnaire were 12.14 ± 6.83 and 11.32 ± 4.08 in groups A and B, respectively. There were no significant differences observed between the two groups, as evidenced by a Z-value of -0.710 and a P-value of 0.478 **(Table 2) .** On the other hand, Upon completion of the treatment, it was observed that the FSFI questionnaire score of group B (18.57 ± 6.73) demonstrated a statistically significant increase in comparison to group A (15.87 ± 6.98) (Z-value= -3.805 & P-value= 0.001) **(Table 2)**.

Table 2. Comparison of FSFI Questionnaire Scores between Inter- and Intra-Groups Pre- and Post-Treatment.

	Group A (n= 100)	Group B (n= 100)	Z$^{\#}$ value	P-value
Pre-treatment	12.14 ± 6.83	11.32 ± 4.08	-0.710	0.478 (NS)

Post-treatment	15.87 ± 6.98	18.57 ± 6.73	-3.805	0.001 (S)
Mean difference	3.73	7.25		
% change	30.72 ↑↑	64.05 ↑↑		
$Z^{\#\#}$ value	-9.952	-7.582		
P-value	0.001 (S)	0.001 (S)		

Z# value= Mann-Whitney test; Z## value= Wilcoxon signed rank test. NS= p> 0.05= not significant; S= p≤ 0.05= significant.

The SQOL-F Questionnaire

intra-group comparison

The present study revealed a significant elevation in the SQOL-F questionnaire score among participants in group A subsequent to the completion of the treatment period (58.40 ± 11.95) in contrast to the pre-treatment score (42.86 ± 10.62) (Z-value= -8.692 and *P*-value = 0.001) **(Table 3)**. Furthermore, it should be noted that within group B, a significant increase in the SQOL-F questionnaire score was observed at post-treatment (75.05 ± 4.21) in comparison to the score recorded at pre-treatment (44.62 ± 10.58) (Z value= -8.684 and *P* value = 0.001) **(Table 3)**. Ultimately, the percentage increase in the SQOL-F questionnaire score was observed to be 36.26% and 68.20% in groups A and B, respectively **(Table 3)**.

Comparison between groups

At pre-treatment, the mean values (± SD) of the SQOL-F questionnaire were 42.86 ± 10.62 and 44.62 ± 10.58 in groups A and B, respectively, with no statistically significant differences observed between the groups (Z-value= -1.484 & P-value= 0.138) **(Table 3)**. In contrast, the outcomes indicated a significant elevation in the SQOL-F questionnaire score for group B (75.05 ± 4.21) in comparison to group A (58.40 ± 11.95) during the post-treatment phase (Z value= -9.763 & p= 0.001) **(Table 3)**.

Table 3. Comparison of SQOL-F Questionnaire Scores between the Two Groups Pre- and Post-Treatment.

	Group A (n= 100)	**Group B (n= 100)**	**$Z^{\#}$ value**	**P-value**
Pre-treatment	42.86 ± 10.62	44.62 ± 10.58	-1.484	0.138 (NS)
Post-treatment	58.40 ± 11.95	75.05 ± 4.21	-9.763	0.001 (S)
Mean difference	15.54	30.43		
% change	36.26 ↑↑	68.20 ↑↑		
$Z^{\#\#}$ value	-8.692	-8.684		
p-value	0.001 (S)	0.001 (S)		

Z# value= Mann-Whitney test; Z## value= Wilcoxon signed rank test; NS= *P* > 0.05= non significant; S= *P* ≤ 0.05= significant.

DISCUSSION

The relationship between sexual health and overall human well-being is highly correlated, given that any medical condition that affects general health has the potential to affect sexual functioning as well (12). The primary noncommunicable diseases (NCDs) exhibit a significant overlap in their risk factors, which contribute to the development of a pro-inflammatory state and sexual dysfunction. These risk factors include HT, hyperlipidemia, MS, overweight, and obesity (13). Therefore, our objective was to assess the effect of Med-Diet on sexual function in women diagnosed with MS. Herein, we revealed that the scores of the FSFI and SQOL-F questionnaires showed a significant increase in the two groups. Furthermore, the group that received Kegel exercise combined with the Med-Diet regimen exhibited more improvement than the Kegel exercise alone.

The precise mechanism underlying the potential enhancement of FSF in women diagnosed with MS by committing to a Med-Diet remains unclear. The diet was shown to reduce blood lipids, inflammatory environment, endothelial dysfunction, and oxidative stress, with beneficial repercussions on cardiometabolic health and sexual well-being. As dietary fiber may play anti-inflammatory roles, the fiber content of Med-Diet, eventually enhanced by other antioxidant-capable components, may have an effect on the transient oxidative stress that occurs after macronutrient ingestion (14). Making lifestyle changes, including the adoption of a healthy diet (such as the Med-Diet), regular physical activity, smoking cessation, and the reduction of alcohol consumption, was found to serve as a crucial step towards preventing and mitigating the impact of sexual dysfunctions (12). **Esposito et al.** (15) supported these findings by demonstrating that the adoption of a Med-Diet among women with MS and female sexual dysfunction (FSD) at baseline resulted in a significant improvement in sexual functions, along with a significant decrease in systemic vascular inflammation, according to lowered levels of C-reactive protein (CRP).

Guasch-Ferré and Willett (16) presented compelling evidence supporting the advantageous effects of Med-Diet on cardiovascular health. Their findings indicate a decrease in cardiovascular outcomes and risk factors, including obesity, HT,

MS, and dyslipidemia. Med-Diet has a correlation with a reduced incidence of diabetes and enhanced glycemic control in people with diabetes, compared to control diets.

Prospective research has shown that adherence to the Med-Diet is correlated with a decrease in mortality, particularly cardiovascular mortality, thus promoting increased longevity. Furthermore, it has been associated with a decreased occurrence of age-associated cognitive impairment and a lower prevalence of neurodegenerative diseases, specifically Alzheimer's disease (16)**.** Furthermore, **Giugliano et al. (17)** reported a significant correlation between adherence to a Med-Diet and the FSFI score. Specifically, the study revealed that women who adhered to the Med-Diet to the greatest extent exhibited the lowest prevalence of sexual dysfunction. The correlation showed a significant difference regardless of the various anthropometric, lifestyle, as well as clinical features. Additionally, **Younis et al. (6)** revealed a correlation between dietary patterns and indicators of sexual performance, such as lubrication, orgasm, and frequency of sexual activity. According to the report, seafood, chocolate, and nuts were found to be the most frequently reported foods that have the potential to improve libido, increase the frequency and duration of coital, and facilitate orgasm in male partners. Fruits have been reported to frequently aid in lubrication.

Therefore, Previous research has demonstrated the clear Med-Diet efficacy in enhancing sexual function among women diagnosed with MS. The alignment of our results with those of previous research studies clearly suggests the potent impact of diet on improving sexual function. Therefore, we look forward to the development of future research directions and the potential implications of study findings for advancing the field of diet and sexual function, such as the need for longitudinal studies, randomized controlled trials, and multidisciplinary approaches. In contrast, **Kim et al. (18)** conducted a study on middle-aged women and reported a lack of correlation between MS and the majority of sexual function components.

The current investigation exhibits a number of advantages and drawbacks. Our study employed a methodological rigor design approach that incorporated various techniques such as randomization, blinding of the evaluator and participants, concealment allocation, validated instruments, and a standardized protocol.

LIMITATIONS

Despite the fact that our study revealed statistically significant differences between the two investigated groups, there are certain limitations. The main limitation refers to the short duration of the investigation. Therefore, it is essential to carry out extended research to assess the enduring impact of the Med-Diet on fatigue severity in females who have been diagnosed with MS. Furthermore, the validity of our results is limited to female patients from a singular medical facility. There exists a wide range of objective techniques that can be employed to evaluate the FSF. Consequently, the precision of the measurement may be compromised.

Ultimately, additional investigation is necessary to determine the efficacy of the multimodal technique, which combines a Med-Diet regimen, Kegel exercises, and diverse electrical stimulation modalities, in improving sexual function in females diagnosed with MS.

CONCLUSIONS

The findings of the present investigation indicate that the integration of kegel exercise with a Med-Diet regimen over a period of 12 weeks results in a significant enhancement of FSF and overall sexual quality of life among women diagnosed with MS.

Acknowledgments

The authors express their gratitude to all individuals who aided in the successful completion of this project, with a special acknowledgment to the study participants.

Disclosure statement

There were no financial interests or benefits received by any author in relation to this research.

Conflict of interest

The authors have declared the absence of any conflict of interest.

Funding

This research received no specific grant from the public, commercial, or not-for-profit funding agencies.

Ethical approval:

This was approved by the Ethics Committee of the Faculty of Physical Therapy at Cairo University (P.T.REC/012/004338) Clinical Trial Registration: ClinicalTrials.gov. Identifier: (NCT0585978).

Consent

Prior to the commencement of the study, all participants were provided with a detailed explanation of the study's procedures and subsequently signed a consent form.

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