VER
Vascular & Endovascular Review

Modified Ketogenic Diet and Exercise Program on Weight Reduction in Obese Patient with Multiple Sclerosis

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ABSTRACT

Background: Multiple sclerosis (MS) is the most common inflammatory disease of the central nervous system in young adults that may lead to progressive disability. Since pharmacological treatments may have substantial side effects, there is a need for complementary treatment options such as specific dietary approaches

Aim: To investigate the effect of adding modified ketogenic diet (KD) to exercise program on body weight and Body Mass Index (BMI) in obese patients with multiple sclerosis (MS).

Patients and methods: This study was a single-blind (assessor), Parallel-group, randomized controlled trial. Patients were randomly allocated into two equal groups, 20 patients in each group. The experimental group (20 patients) was treated with a modified ketogenic diet and aerobic exercise while the control group (20 patients) was treated with aerobic exercise. The frequency of the intervention was received as 3 sessions a week for 12 weeks for both groups.

Results: Both groups showed significant within-group reductions in weight and BMI ($p=0.001$). However, the study group demonstrated significantly greater improvements: mean weight loss of 9.8 kg (95% CI: 8.24–11.36) versus 3.25 kg in controls, and BMI reduction of 3.58 kg/m² versus 1.16 kg/m² ($p=0.001$ between groups). Large effect sizes (partial $\eta^2 = 0.39–0.50$) supported clinical significance.

Conclusion: Adding a modified ketogenic diet to aerobic exercise results in significantly greater reductions in body weight and BMI compared to exercise alone, offering a promising integrative approach for managing obesity in MS patients.

KEYWORDS: Multiple Sclerosis, Ketogenic Diet, Obese, Aerobic Exercise.

How to Cite: Mohamed Ekbal Abdelkader Bayomie*, Mohsen Mohamed Elsayyad, Nabil Mahmoud Ismail, Sameh Mahmoud Said, Hanaa Kenway Atta, (2025) Modified Ketogenic Diet and Exercise Program on Weight Reduction in Obese Patient with Multiple Sclerosis, Vascular and Endovascular Review, Vol.8, No.6s, 138-144.

INTRODUCTION

Multiple Sclerosis (MS) is a chronic immune-mediated disease of the central nervous system where inflammation causes demyelination and neurodegeneration. This disrupts nerve signals, leading to a wide variety of neurological symptoms and potential disability (1). The epidemiology of MS is changing worldwide, as is the understanding of its immune pathogenesis and natural history. There is an increase in prevalence and incidence of MS over the last few decades including the Middle East, where prevalence estimates have risen dramatically from a range of 5–30 per 100,000 in the 1980s and 1990s to between 65–85 per 100,000 during the period from 2010 to 2015, with countries such as Iran and Kuwait reporting the highest regional rates (2).

A community-based survey conducted in Al Quseir city found a prevalence of 13.74 per 100,000, which corresponds to an age-specific prevalence of 13.7 per 100,000 for individuals aged 17 years and older (3). The most frequent presenting symptoms included weakness (57%), sensory disturbances (19.9%), visual symptoms (15.9%), and ataxia (15.8%). A consistent demographic feature across the region is the marked female predominance of the disease; in Egypt, the age- and sex-specific prevalence among females 17 years and older was significantly higher, at 27.5 per 100,000.

The nutritional lifestyle leading to high BMI, abdominal obesity, or dysbiosis might induce a systemic pro-inflammatory state contributing to disease pathogenesis and severity (4). Ketogenic diets (KDs) are high-fat, low-carbohydrate diets that mimic a fasting state. KDs create a metabolic shift from glycolytic energy production toward oxidative phosphorylation energetics by using fatty acids as a primary source of energy. As these fatty acids undergo beta-oxidation, ketones are produced. This increase in oxidative phosphorylation coupled with ketone production modifies the tri carboxylic acid cycle to limit reactive oxygen species generation (5). In addition, ketone bodies transported across the blood-brain barrier up regulate antioxidant pathway genes and boost energy production in brain tissue (6).

Ketogenic diet is safe, feasible to study, and well tolerated in subjects with relapsing MS. Ketogenic diet improves fatigue and depression while also promoting weight loss and reducing serologic pro inflammatory adipokines (7). Ketogenic diets, the potential for safe and inexpensive complementary treatment, may enhance the pulmonary functions in MS patients.

Exercise and diet interventions have proven to be critical factors associated with a decrease in the risk of developing cardiovascular complications. Therefore, the implementation of these interventions has gradually increased in the management of MS patients. Non-pharmacological interventions, such as diet and exercise, have shown improvement in patient's health-related quality of life (8).

Obesity is a significant concern in Multiple Sclerosis (MS) as it can promote a pro-inflammatory state and worsen comorbidities. While aerobic exercise is a standard intervention, the ketogenic diet (KD) is an emerging nutritional strategy with potential benefits for both weight loss and neuroprotection. However, the combined effect of these two approaches is not well understood in the MS population. This study is significant for its comprehensive investigation of a Modified Ketogenic Diet (MKD) as non-pharmacological strategy to improve a wide spectrum of outcomes in individuals with MS. Its primary significance lies in its multi-domain approach, carefully evaluating the impact of an MKD on body weight and BMI.

MATERIALS AND METHODS

This was a single-blind (assessor), Parallel-group, randomized controlled trial conducted to determine if adding a modified ketogenic diet to an aerobic exercise program results in superior reductions in body weight and BMI compared to exercise alone in obese patients with MS. The clinical application of the exercise program and the physical assessment of the patients were conducted at the outpatient clinic, Faculty of Physical Therapy, Pharos University, Alexandria, Egypt, between November 2023 to October 2024.

Participants:

Forty patients with MS of both genders participated in the study. Patients were randomly allocated into two equal groups of 20 patients each. Group A (experimental group) received a modified ketogenic diet combined with aerobic exercise, delivered in 3 sessions per week for 12 weeks. Group B (control group) received aerobic exercise alone, delivered in 3 sessions per week for 12 weeks.

Inclusion Criteria

Participants were eligible if they met the following criteria: age between 18 and 50 years; a confirmed diagnosis of multiple sclerosis (MS) according to the revised McDonald Criteria; fully ambulatory without the need for assistive devices; body mass index (BMI) less than 30 kg/m²; and both male and female patients were included.

Exclusion Criteria

Participants were excluded if they had any of the following: evidence of active disease or MS relapses within the preceding 30 days; chronic heart failure; malignancy; chronic kidney disease; human immunodeficiency virus (HIV) infection; substance or alcohol abuse; pregnancy; or a diagnosis of diabetes mellitus.

The sample Size:

The sample size was determined using G*Power version 3.1.9.2, an a priori power analysis for a two-tailed independent t-test (effect size = 0.50, α = 0.05, power = 0.80) indicated a required sample size of 36. To enhance statistical reliability and accommodate potential variability or dropout, the sample size was increased to 40, with 20 participants allocated to each group.

Randomization:

Fourty subjects were assigned randomly to the experimental group (A) (modified ketogenic diet and aerobic exercise) and control group (B) (aerobic exercise). The randomization was carried out using computer-generated block randomization program at http://www.randomization.com/. The participants were randomized in block sizes of 4, 6 and 6 with a 2:1 allocation ratio female to male. Concealed allocation was done using sealed, sequentially numbered opaque envelopes. The randomization was carried out by a blinded researcher who was not involved in recruiting, data collection or treatment.

Evaluation Procedures:
Body weight and height were measured using a standard scale. Height was recorded in centimeters with the patient standing with their back to the graduated longitudinal arm, measuring from the vertex to the feet. Weight was recorded in kilograms with the patient wearing light clothing and standing facing the scale on the platform. BMI was calculated for each patient as weight (kg) divided by height squared (m²). These measurements were performed for all patients in both groups immediately before and after the 12-week intervention period.

Intervention: Group A (Study Group):

Participants received a supervised aerobic exercise program combined with a modified ketogenic diet.

Group B (Control Group):

Participants received the supervised aerobic exercise program only.

Modified ketogenic diet program:

Alternative diet therapy for the KD, Similar to the classic KD (CKD) in that it is high fat/low carbohydrate, less restrictive that does not require weighing of foods, beneficial for patients who have difficulty tolerating the restrictiveness of the KD, need quick dietary intervention and limited time/resources for the CKD may help with initiation of the CKD (9). The KD during nutritional counseling, patients are instructed to start by limiting carbohydrate intake to just 20 g/day for 12 weeks in order to establish ketosis. Then, patients increase their carbohydrate intake by 5 g each week until they reach their individual maximum (approximately 40 g) to maintain stable ketosis. All carbohydrates relevant for elevating blood glucose are limited to 40-50 g/ day. In addition, the glycemic index and glycemic load of carbohydrates have to be below 50 and 60, respectively. This KD is equivalent to a traditional KD, but with a liberalized macronutrient composition of 70-80% fats, 15-20% proteins and 5-10% carbohydrates (compared to a traditional KD with 90% fat, 6% proteins and 4% carbohydrates) (10). The KD ranges from 1400 to 1500 Calories and is changed every week by the nutritionist according to the patient' adaptation to diets.

Aerobic exercise program:

The supervised treadmill training program was structured as a 12-week intervention delivered in three weekly sessions. Each session began with a 5-minute warm-up of light stretching and concluded with a 5-minute cool-down period of gradual speed reduction. Initial walking duration started at 10-15 minutes per session, progressively increasing by 2-5 minutes weekly based on individual tolerance, with a maximum allowance of three brief rest periods per session. Once participants achieved the target duration of 30 minutes of sustained walking, exercise intensity was systematically increased through incremental speed elevations of 0.1-0.3 km/h per week. Heart rate monitoring served as the primary intensity metric, with participants encouraged to maintain 55-85% of their age-predicted maximum heart rate (APMHR = 220 - age) throughout each session. To accommodate the unique physiological challenges of MS, real-time adjustments were made using the Borg Rating of Perceived Exertion (RPE 6-20 scale), with speed reduced if RPE exceeded 16 or if participants exhibited signs of overheating or fatigue exacerbation (11). This two-phase progression protocol (duration-first, then intensity) specifically addresses the energy conservation needs of MS patients by initially building aerobic capacity without overwhelming participants. The heart rate ceiling of 85% APMHR prevents triggering Uhthoff's phenomenon (symptom exacerbation due to overheating), while integrated rest periods accommodate fluctuating fatigue patterns. The RPE scale provides critical complementary data given the prevalence of autonomic dysfunction in MS, which can distort heart rate responsiveness. Recent evidence confirms that this graded approach optimizes neuroplasticity while minimizing relapse risks, particularly when sessions are capped at 30 minutes for those with moderate disability (EDSS 4.0-6.0). Cooling protocols, including pre-cooling vests and controlled room temperatures (20-22°C), were implemented to further mitigate thermal sensitivity (12,13).

Statistical analysis

Software Platform: All analyses were performed using SPSS Statistics for Windows (Version 23; SPSS Inc., Chicago, IL). Significance Threshold: The alpha level (α) was set at 0.05 for all statistical tests. Preliminary Data Screening: Assessed normality using the Shapiro-Wilk test ($p > 0.05$ confirmed normal distribution). Verified homogeneity of variance via Levene's test. Identified and addressed extreme scores (outliers). Data Presentation: Continuous variables: Reported as mean ± standard deviation (SD). Categorical variables (e.g., gender): Reported as counts (frequencies). Missing Data Handling: Implemented intention-to-treat (ITT) analysis with multiple imputations to account for data loss over the 3-month intervention period. Primary Analysis: Conducted a two-way mixed-design MANOVA (Group × Time) to evaluate: Combined effects on all dependent variables simultaneously and interaction effects between group assignment and time points (pre/post-intervention). Follow-up Testing (if MANOVA significant): Performed univariate ANOVAs for each individual outcome measure and applied Bonferroni correction to adjust for family-wise error rate (Type I error control).

RESULTS

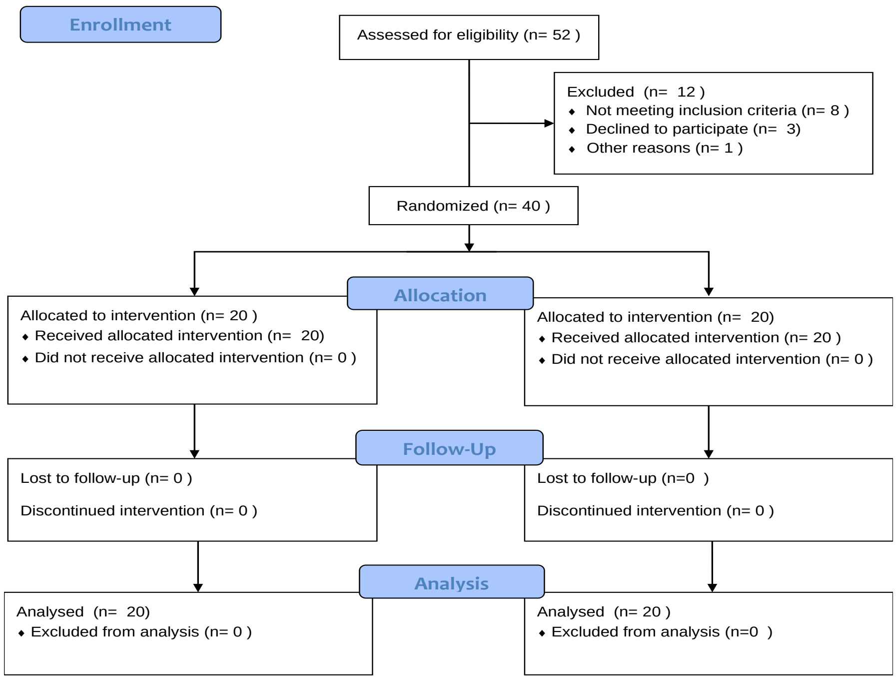

Figure 1: CONSORT diagram showing the flow of participants through each stage of a randomized trial of the study

The baseline demographic and anthropometric characteristics of the 40 participants with multiple sclerosis (MS) who were equally divided into a study group (group A) who received ketogenic diet and aerobic exercises and a control group (group B) who received aerobic exercises. The results show no statistically significant differences between the two groups in terms of age (p = 0.77), height (p = 0.80), or gender distribution (p = 0.31), as indicated by the high p-values (>0.05). The mean age of participants was approximately 34 years in both groups, and the majority were female (Table 1).

The impact of the 12-week intervention on body weight and BMI in both the study group and the control group is shown in table 2. Both groups showed statistically significant reductions in body weight (Figure 2) and BMI (Figure 3) after the intervention (p = 0.001 for all), indicating that aerobic exercise alone (control group) had a beneficial effect on weight and adiposity. The study group exhibited significantly greater improvements compared to the control group. The mean difference (MD) in body weight reduction was 9.8 kg (95% CI: 8.24–11.36) in the study group versus 3.25 kg (95% CI: 1.69–4.81) in the control group, with a significant between-group difference (p = 0.001). Similarly, for BMI, the study group showed a mean reduction of 3.58 kg/m² compared to 1.16 kg/m² in the control group, with a significant between-group effect (p = 0.001).

Table 1: Demographic characteristics of subjects (N =40)

	Study group	**Control group**	**t- value**	**p-value**
	$\bar{X}$ ±SD	**$\bar{X}$ ±SD**		
Age (years)	34.45±4.58	33.7±3.59	0.3	0.77 [a]
Height (cm)	164.9±6.38	165.35±6.23	-0.25	0.8 [a]
Gender, n (%)				
Female	8 (40%)	5 (25%)	$\chi 2$=1.03	0.31
Male	12 (60%)	15 (75%)		

a: Not significant, SD: Standard deviation, P: probability, BMI: body mass index; X2= Chi square

Table 2: Within and between group analysis for body weight and BMI

Variables	**Study group**	**Control group**	**MD(95% CI)**	**p-value (between groups)**	**η^2**
Body weight (kg)					
Pre-treatment	78.85±5.54	79.7±5.01	-0.85(-4.23, 2.53)	0.85 [a]	
Post-treatment	69.05±4.22	76.45±5.16	-7.4(-10.42 ,-4.38)	0.001 [b]	0.39
p-value (within-group)	0.001 [b]	0.001 [b]			
MD(95% CI)	9.8(8.24 , 11.36)	3.25 (1.69 , 4.81)			
BMI (kg/cm2)					
Pre-treatment	29±0.75	29.15±0.74	-0.15 (-0.62 ,0.33)	0.54 [a]	
Post-treatment	25.52±0.94	27.99±1.61	-2.57(-3.42 ,-1.72)	0.001 [b]	0.5
p-value (within-group)	0.001 [b]	0.001[b]			
MD(95% CI)	3.58 (3.05,4.12)	1.16 (0.63 ,1.69)			

BMI: body mass index; p-value: probability; a: non-significance difference; b: significance difference; CI: confidence interval; MD: mean difference; $\eta 2$: partial eta square.

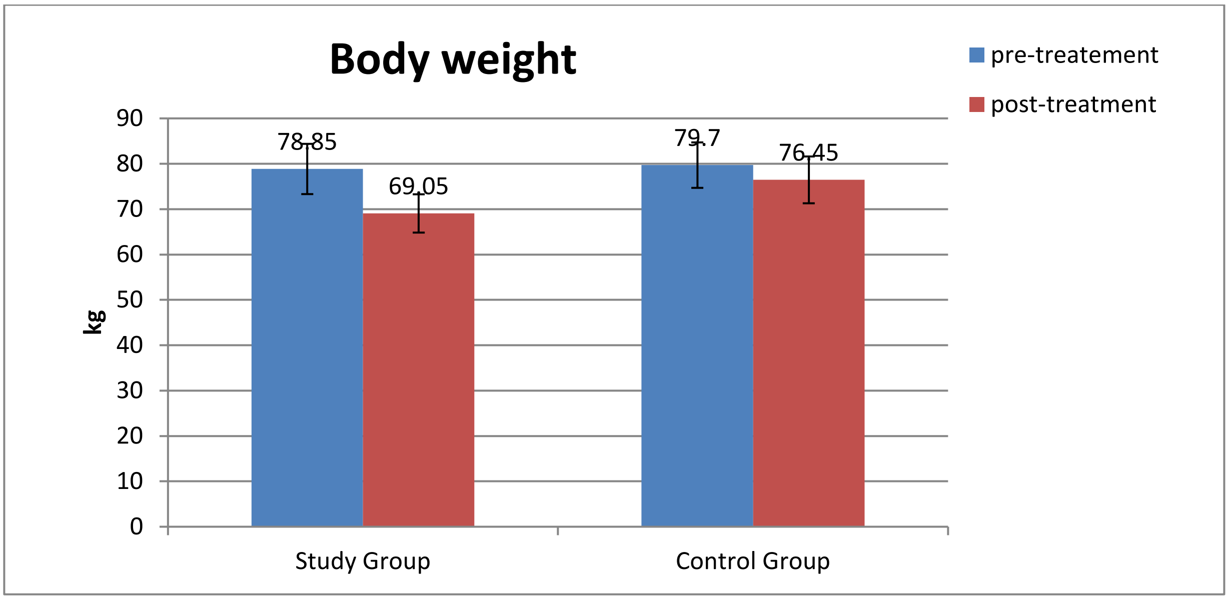

Fig. (2). Estimated Marginal Means of body weight for both groups

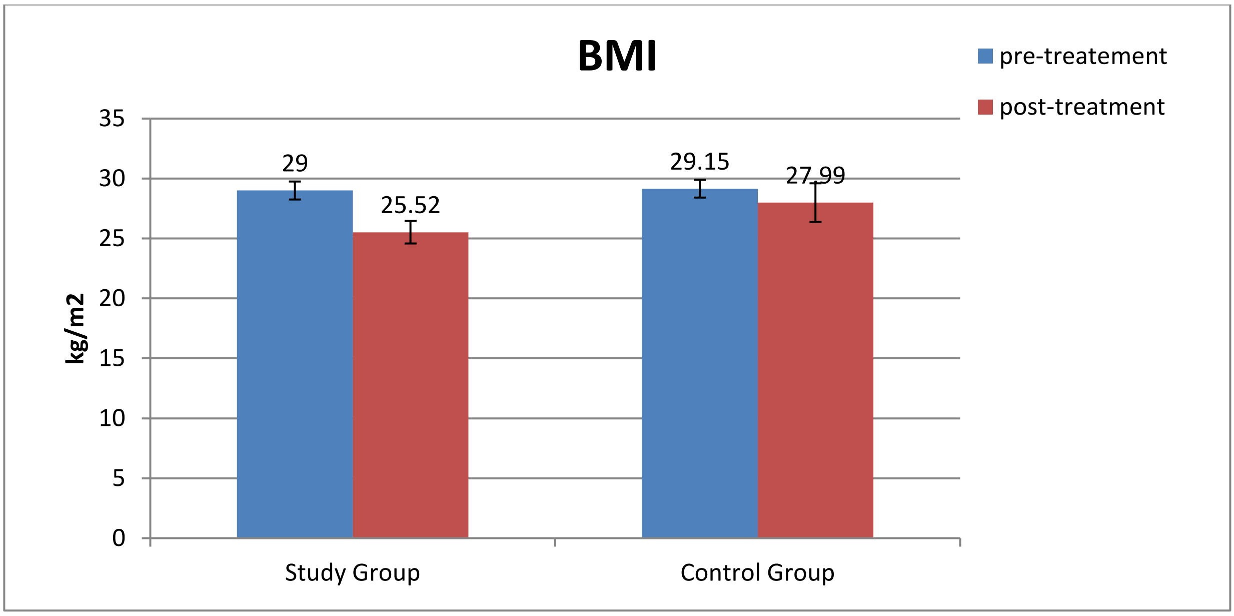

Fig. (3). Estimated Marginal Means of BMI for both groups

DISCUSSION

The relationship between weight status and MS is complex and multifaceted. Some studies have reported a close relationship between obesity and MS susceptibility, especially in women (14). The purpose of this study was to investigate the impact of adding modified ketogenic diet to exercise programs in obese patients with multiple sclerosis. Forty patients with multiple sclerosis aged from 18 to 50 years participated in the study. Patients were randomly assigned into two equal groups. Data obtained from the two groups regarding body weight, BMI, were measured before starting the treatment and after three months of intervention for both groups.

After 3 months of intervention, there was statistically significant difference between the two groups ($P<0.001$).While investigating The Effect of Adding Modified Ketogenic Diet to exercise Program in Obese Patient with Multiple sclerosis on BMI our result agreed with study of Brenton & Goldman (15), Fitzgerald et al. (16) who confirmed that dietary interventions in form of KD are rapidly gaining popularity within the MS patients, and recently, patterns of dietary intake have been directly linked with disability in MS. In particular, KD have potential for multimodal benefits in an MS population, given the documented properties of these diets in reducing serologic inflammation, providing a more efficient central energy source, and by upregulation of antioxidant pathways.

Also, the study applied by Brenton et al. (17) in human MS patients found that KD provided significant benefits to subjects throughout the study with a significant reduction in several anthropometric measures including BMI, fat mass, waist circumference, and resting metabolic rate. Importantly, there was a strong correlation between BMI and leptin levels, suggesting that KD's influence on leptin regulation is likely multimodal and not just secondary to its ability to induce a reduction in adiposity.

Given leptin's role as a proinflammatory adipokine, this suggests one immunologic pathway in which these diets may benefit MS disease.

Comparison between the results of the present study between the two groups before and after treatment by using BMI, the significant results were revealed that are accepted with the results of Hansen et al. (18) aerobic exercises such as treadmill can improve the gait style of the people with MS as well as their endurance and strength and reduce BMI.

In addition, Sangelaji et al. (19) added that aerobic exercise can improve balance skills in patients with MS and lead to better walking abilities and enhance muscle strength and decrease BMI. Furthermore, all modalities used in this model are simple, convenient and feasible. Hence, the proper combination of aerobic exercises with smaller portions of resistance exercises may be much more suitable for patients with MS.

LIMITATIONS

Due to the inherent differences between interventions (KD & exercise vs. exercise alone), neither participants nor treating therapists were blinded to group allocation. However, outcome assessors and data analysts remained blinded to treatment assignments to minimize detection bias.

The relatively small sample size limits this study, so the study results need to be examined in a larger population with follow-up.

This study limited the relatively short period of the intervention, which may affect conclusions regarding the long-term safety and efficacy of the protocol.

This study was limited by the follow-up assessment or long-term effect assessment after several months.

This study was limited by the uncontrolled confounding variables, such as the associated medications or lifestyle factors.

RECOMMENDATIONS

Future research should include longer follow-up to assess long-term safety and sustainability, multi-center trials with diverse populations to improve generalizability, and comparisons with other dietary patterns to determine whether ketogenic interventions offer unique benefits. Integrating dietary strategies with structured exercise in controlled studies may further optimize management approaches for multiple sclerosis. Future research should focus on long-term randomized controlled trials that employ active dietary comparators, include comprehensive metabolic and neurological outcome measures, and further explore the mechanisms linking nutritional ketosis to improved body composition and overall health in multiple sclerosis.

CONCLUSION

Adding a modified ketogenic diet to aerobic exercise provided greater improvements than exercise alone in obese patients with multiple sclerosis. The combination showed superior results in body weight and BMI reduction. These synergistic effects likely result from reduced inflammation and enhanced neuroprotection. While limited by its 12-week duration, this evidence supports combined therapy as an effective adjunct for MS management.

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