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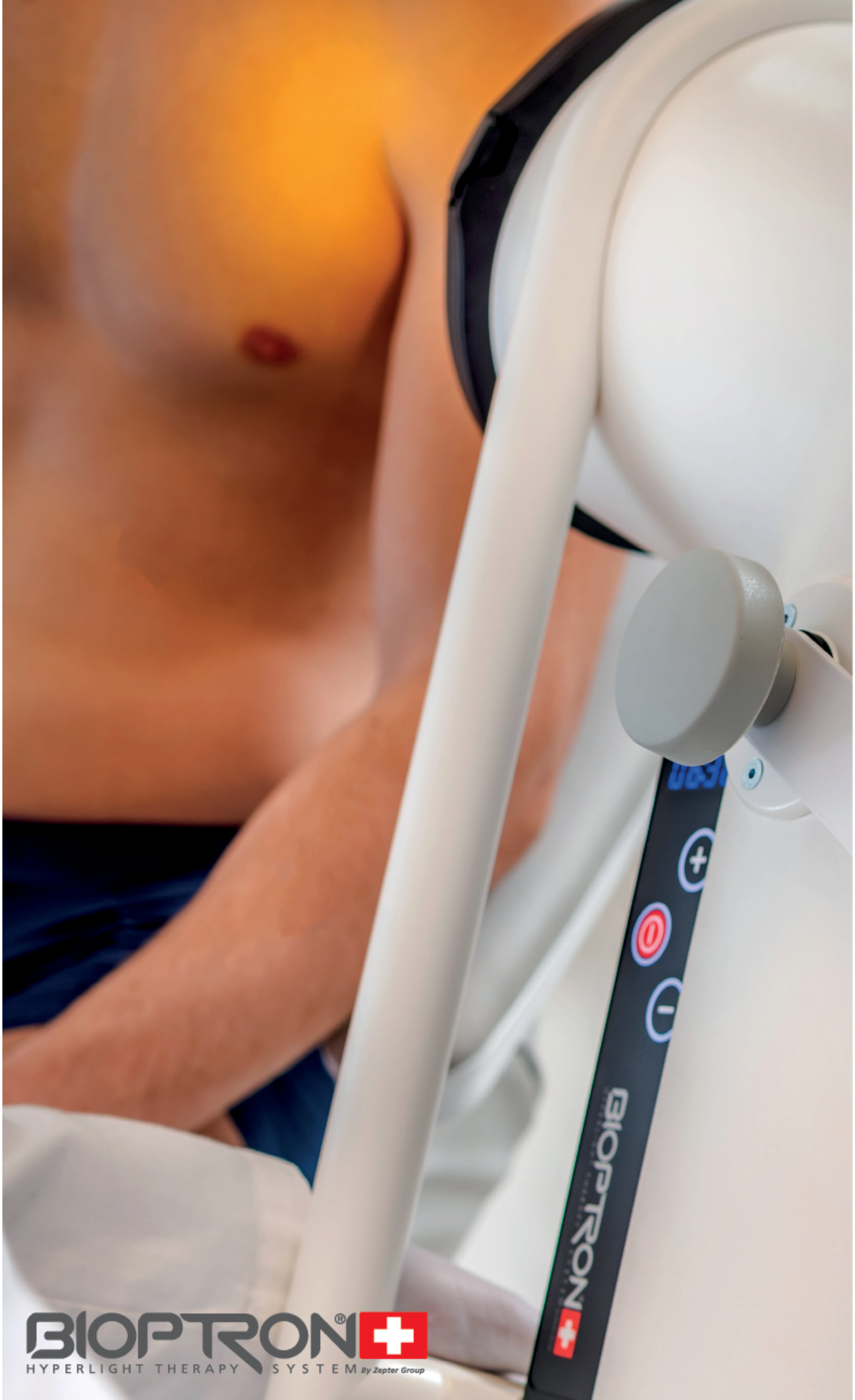

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nr 3/2021 (21)

Effect of ketogenic diet and aerobic exercise on glucose level in prediabetes female with normal weight: A randomized controlled trial

Wpływ diety ketogenicznej i ćwiczeń aerobowych na poziom glukozy u kobiet w stanie przedcukrzycowym o prawidłowej masie ciała: randomizowane badanie kontrolowane

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Abstract

Objectives. It is well known that Individuals with prediabetes have a high risk of developing type 2 diabetes. This study aimed to compare the effect of combination of ketogenic diet and aerobic exercise interventions versus ketogenic diet alone on the glucose level in prediabetes female with normal weight. Methods. A total of sixty volunteer prediabetes females with normal body mass index (BMI) from 20-25 kg/m2 their age ranged from 40-60 years old, randomly divided into two equal groups and were recruited for a three-month trial. Group (I) (n = 30) treated by continuous aerobic exercise in form of treadmill 5 sessions per week and ketogenic diet. Group (II) (n = 30) treated by ketogenic diet alone. The primary outcome was the fasting plasma glucose and glycated hemoglobin while the secondary outcome was body mass index and waist circumference. The outcome measures were measured before and after intervention for both groups. Results. Comparing both groups post-treatment revealed that there was significant improvement in fasting plasma glucose and glycated hemoglobin in favor of Group (I). Conclusion. combined continuous aerobic exercise and ketogenic diet improve glucose level in prediabetes female through decrease fasting plasma glucose and glycated hemoglobin.

Key words:

prediabetes, ketogenic diet, aerobic exercise, fasting plasma glucose, glycated hemoglobin

Streszczenie

Cel. Powszechnie wiadomo, że osoby ze stanem przedcukrzycowym mają wysokie ryzyko zachorowania na cukrzycę typu 2. Badanie to miało na celu porównanie wpływu połączenia diety ketogenicznej i ćwiczeń aerobowych ze stosowaniem samej diety ketogenicznej na poziom glukozy u kobiet w stanie przedcukrzycowym o prawidłowej masie ciała. Metody. W sumie sześćdziesiąt ochotniczek ze stanem przedcukrzycowym z prawidłowym wskaźnikiem masy ciała (BMI) od 20-25 kg/m^2 w wieku od 40 do 60 lat, podzielonych losowo na dwie równe grupy, zrekrutowano do udziału w trzymiesięcznym badaniu. Leczenie grupy (I) (n = 30) obejmowało ćwiczenia aerobowe: ćwiczenia na bieżni 5 sesji w tygodniu oraz dietę ketogeniczną. Leczenie grupy (II) (n = 30) obejmowało samą dietą ketogeniczną. Poziom glukozy na czczo i hemoglobina glikowana stanowiły wyniki pierwszorzędne, natomiast wskaźnik masy ciała i obwód talii stanowiły wyniki drugorzędne. Miary wyniku zostały zmierzone przed i po zastosowanym leczeniu dla obu grup. Wyniki. Porównanie obu grup po leczeniu wykazało znaczną poprawę stężenia glukozy na czczo i hemoglobiny glikowanej na korzyść grupy (I). Wniosek. Połączenie ćwiczeń aerobowych i diety ketogenicznej poprawia poziom glukozy u kobiet w stanie przedcukrzycowym poprzez zmniejszenie poziomu glukozy w osoczu na czczo i hemoglobiny glikowanej.

Słowa kluczowe

dieta ketogeniczna, ćwiczenia aerobowe, glukoza w osoczu na czczo, hemoglobina glikowana

Introduction

Pre-diabetes is the preceding condition of diabetes, where the blood sugar level is higher than normal but lower than the diagnostic criteria of type II diabetes and in most of the cases, this ultimately leads to the development type II diabetes. It has been estimated that the number of pre-diabetic cases will increase to more than 470 million people worldwide, and this is understandably a worrying trend [1, 2]. Many studies have been done on diabetes patients. However, little is known about the pre-diabetic conditions [3].

It is vital to stop pre-diabetes from developing into type 2 diabetes mellitus as diabetes has general complication which can be categorized into two classes: microvascular and macrovascular. Retinopathy, nephropathy, and neuropathy are classified in microvascular complications, while stroke, cardiovascular disorder, and peripheral artery disease be a member of macrovascular complications [4]. Furthermore, prediabetes was associated with an increased possibility of coronary heart disease, stroke, and all-cause mortality [5,6].

Impaired β-cell function and increased insulin resistance are two pathological pathways that cause pre-diabetes, and successively, diabetes. The beginning of increased insulin resistance starts years before diabetes and even pre-diabetes [7,8]. More precisely, insulin resistance in skeletal muscle tissues are often considered the initiating factor that is present decades before impaired β-cell function. Merging the continuous increase in insulin resistance with a decrease in β-cell function, glucose levels within the blood become unregulated and pre-diabetes then develops into complete diabetes [9].

Presently, the American Diabetes Association (ADA) recommends the use of any of the following four criteria for diagnosing diabetes: 1) glycated hemoglobin (A_{1C}), 2) fasting plasma glucose 3) 2-h plasma glucose and/or 4) classic symptoms of hyperglycemia (e.g., polyuria and polydipsia), Within the absence of clear symptoms of hyperglycemia, the primary three criteria should be confirmed by repeat testing [10, 11]. Diagnosed prediabetes was stated as any participants who did not have diabetes but who had fasting plasma glucose level of 100–125 mg/dL, an HbA_{1c} level of 5.7%– 6.4%, or 2-hour plasma glucose level of 140199 mg/Dl [12].

Treatment of pre-diabetes and prevention of the development of pre-diabetes to T2DM,through lifestyle intervention mainly includes nutritious dietary advice, exercises and weight loss and these are often achieved by aerobics exercise which improves insulin sensitivity by increasing free fatty acid oxidation and improving skeletal muscle mitochondrial function, as well as reducing lipotoxicity in skeletal muscles and the liver [13] additionally in recent years there has been a tendency towards individual, patient-centered medical nutrition therapy in which ketogenic diet (KD) regimens have been modified to the specific needs of individuals[14]. ketogenic diet which assumes a really very high-fat and low-carbohydrate diet, reducing carbohydrate to ≤ 10% of consumed energy. This reduction of carbohydrate causes change of metabolism from glucose metabolism toward the metabolism of fatty acids (FAs) yielding ketone bodies (KBs), like acetoacetate (AcAc) and β-hydroxybutyrate (β-OHB) as substrates for energy [15, 16].

Combining a ketogenic diet with exercise is a powerful way to reducing insulin resistance, control blood glucose levels and achieve weight loss. As ketogenic diets are nowadays predictable as being useful, there is presently a shortage of research studies examining just how useful the combination of exercise and a ketogenic diet [17, 18]. Thus, the aim of this study to investigate the effect of combination of aerobic exercises with ketogenic diet versus the ketogenic diet alone in prediabetes women.

Materials and methods

Study Design

The study was designed as a prospective, randomized trial. The study followed the Guidelines of Declaration of Helsinki on the conduct of human research. It was conducted between July 2020 and January 2021.

Participants

A sample of 60 females was recruited from Outpatient Clinic, Badr University in Cairo, Egypt. Inclusion criteria were women with their age ranged from 40–60 years; body mass index (BMI) from 20-25 kg/m2; and fasting serum glucose range 5.6 to 6.9 mmol/L and hemoglobin A_{1C} value fell within the prediabetes range (5.7%–6.4%) as defined by the American Diabetes Association (ADA) and without medications, or treatment with oral hypoglycemic agents (OHA) and/or insulin. Exclusion criteria were evidence of renal insufficiency, liver disease, or abnormal cardiovascular function, diabetes, untreated hypertension, dyslipidemia, abnormal thyroid function, anyone who has undergone gallbladder removal and musculoskeletal constraint preventing them from fully participating in the exercise intervention [19]. All participants provided written informed consent.

Randomization

Each female was informed about the study description, aim and benefits, the right to leave at any time, and the privacy of any obtained data. The females were randomly assigned into 2 equal groups (group I and group II) with the use of a computer based randomization program. Distribution was hidden in sequentially numbered opaque envelopes [20]. All participants continued in the study after randomization, Figure (1).

Interventions

Participants were randomly divided into two groups: Group I (n = 30) on moderate intensity continuous aerobic exercises with ketogenic diet and Group II (n = 30) on only ketogenic diet, this study continued for three months.

Moderate intensity continuous aerobic training (CON)

All females in Group (I) underwent supervised moderate-intensity exercised on a treadmill at 50%–70% of heart rate reserve, which was calculated using the Karvonen equation and the resting heart rate was measured before exercise [21]. Recent joint American Heart Association guidelines recommended 150 min/week of aerobic exercise undertaken at moderate intensity, supervised sessions were completed five times per week until 12 weeks were completed [22]. After a 5-min warm-up on the tre-

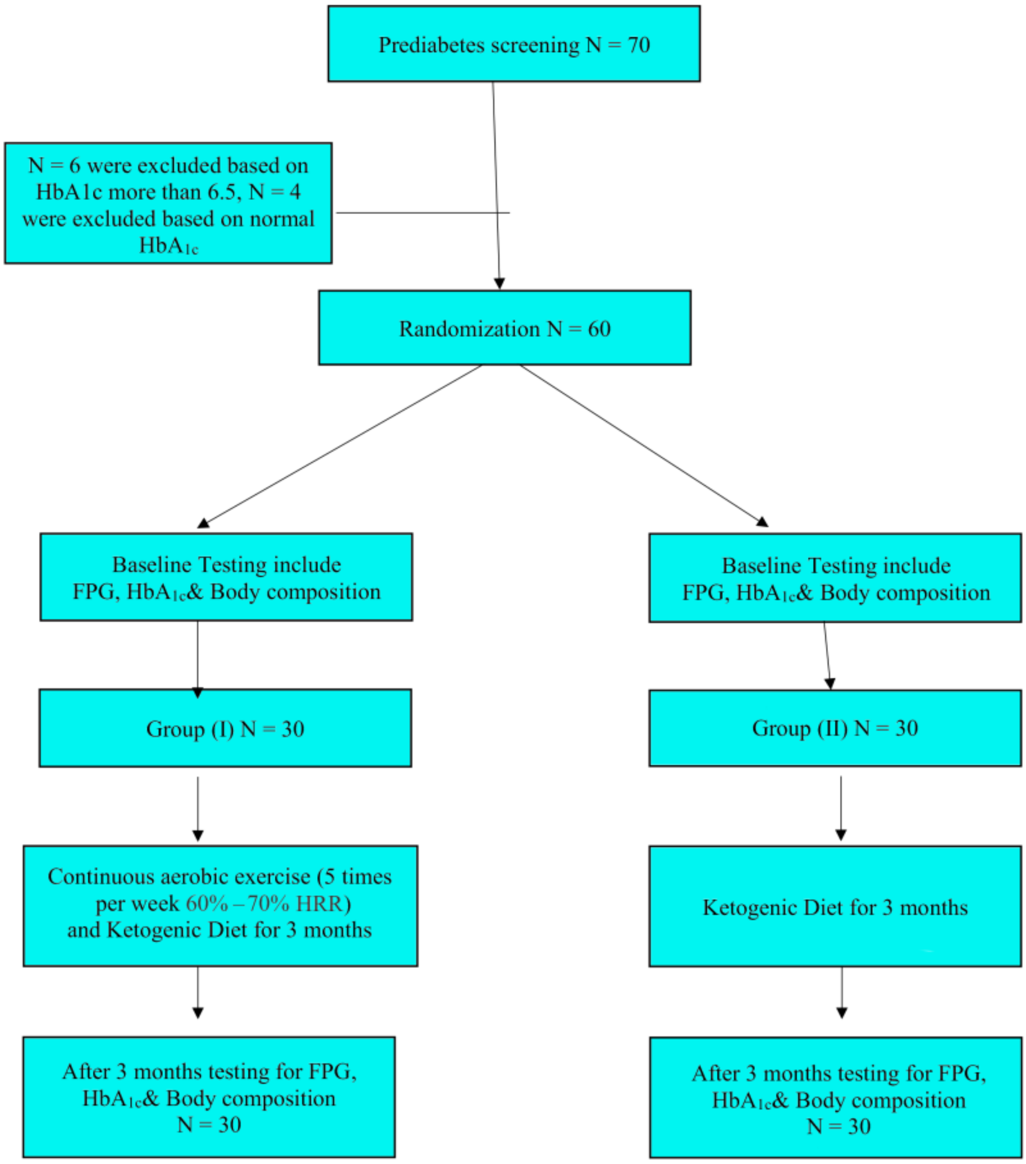

Figure 1. Randomization description of the two intervention and participants run from

admill, participants exercised at their designated moderate intensity (60%–70% HRR) for a period of 28 min. This was followed by an active cooldown on the treadmill lasting 5 min [23].

Ketogenic diet

All females in both groups (I) and (II) underwent ketogenic diet which is a low carbohydrate high-fat diet consisted of the following nutrient conformation: 80% fat, 15% protein and 5% carbohydrates, entire daily intake was estimated to be 20–30 g of carbohydrates [24]. Patients were taught the way to follow the KD at the primary visit and were informed about foods to avoid and also the exact kinds and quantities of foods they might eat. Protein was mainly and unlimited amount of fish, grass-fed beef, poultry, eggs and shellfish. Most of the carbohydrates in the diet formed of 2 cups of leafy greens salad vegetables per day; 1 cup of low-carbohydrate raw or fermented vegetables per day; 4 ounces of hard cheese; and restricted amounts of avocado, olives, and cream. Fats and oils were not restricted as eating natural, unrefined fats except that intake of trans fats was to be minimized. Grains, starches, legumes and the majority of fruits were excluded. Participants were provided a 3-page handout and a handbook describing these advices. Participants were furthermore instructed to drink 6–8 glasses of water daily Participants prepared or bought all of their own meals and snacks after these instructions. Participants returned every other week for 12 weeks for more diet advising [25].

Outcome measures

All variables included as HbA1c, fasting glucose, BMI and Waist circumference were measured before and after trial.

Blood testing protocols

Fasting blood specimen was obtained and measured participants' HbA1c and fasting glucose.

Diagnosed Prediabetes was stated as any participants who did not have diabetes but who had fasting plasma glucose level of 5.6 to 7.0 mmol/L and HbA1c level of 5.7% - 6.4% [26].

Body composition assessment
Body Weight and Height were obtained and body mass index (BMI) was calculated using standard techniques. Waist circumference measurements have been made to the nearest 0.1 centimeter using a tape measure at the uppermost lateral border of the hip crest (ilium) [27].

Statistical Analysis
The data were collected and analyzed through two types of statistics by using SPSS version 17 as follows:
Descriptive statistics: the mean and standard deviation of each group were calculated for each parameter; mean (X) = summation of x / number of x and standard deviation (SD) = root square of variance.
Inferential statistics: comparing mean values between pre and post of each parameter within each group was done by paired t-test while comparing mean values of each parameter between the two groups before and after treatment program was done by unpaired t- test. The probability in this study was > 0.05%.

Results
A sample of 60 females with their age ranged from 40–60 years; body mass index (BMI) from 20-25 kg/m^2; and divided equally into two groups, Group (I) and Group (II) as shown in table (1). Both groups were similar at baseline (P > 0.05) regarding age (Table 1). All components of the BMI, fasting glucose, glycated hemoglobin and waist circumference showed a statistically significant decrease within group (I) (P < 0.05), while they showed a statistically significant difference within group (II) (P < 0.05). Also, the post-treatment comparison of both groups revealed a statistically significant decrease in all components (P < 0.05) in favor of group (I) (Table 2).

Table 1. Baseline characteristics of participants in both groups

	Group I	Group II	P-value
Age [yrs.]	50.77 ± 4.81	48.7 ± 4.93	0.106NS

^{NS} = P > 0.05 = non-significant, P = Probability

Table 2. Descriptive and Inferential Statistics of the Dependent Variables in the Experimental and Control Groups Pre and Post the Eight-Week Study Period

		Group I [n = 30]	Group II [n = 30	P value*
BMI	Pre training	24.22 ± 0.62	24.07 ± 0.65	0.372^{NS}
	Post training	22.28 ± 0.8	23.53 ± 0.77	0.005^{S}
	P value**	0.001^{S}	0.002^{S}	
Fasting glucose	Pre training	6.27 ± 0.38	6.12 ± 0.38	0.15^{NS}
	Post training	5.72 ± 0.35	5.92 ± 0.34	0.027^{S}
	P value**	0.002^{S}	0.003^{S}	
Glycated hemoglobin	Pre training	5.97 ± 0.35	6.05 ± 0.34	0.394^{NS}
	Post training	5.52 ± 0.34	5.81 ± 0.36	0.002^{S}
	P value**	0.003^{S}	0.004^{S}	
Waist circumference	Pre training	89.7 ± 4.14	90.87 ± 3.67	0.252^{NS}
	Post training	85.83 ± 3.9	88.4 ± 3.09	0.00^{7S}
	P value**	0.001^{S}	0.003^{S}	

** Inter-group comparison; ** intra-group comparison of the results pre- and post-treatment, NS P>0.05 = non-significant, S P < 0.05 = significant, P = Probability*

Discussion

Nowadays ketogenic diets are approved as valuable methods but presently there is shortage of research studies investigate the effect of adding ketogenic diets and exercise together. In prediabetes merging ketogenic diet with exercise is a great method to decrease insulin resistance and regulate blood glucose levels.

Therefore, the current study aimed to compare the outcomes of combination of continuous moderate intensity aerobic exercises with ketogenic diet versus ketogenic diet intervention alone on glucose level in prediabetes female. The existing study was conducted on prediabetes female divided randomly into two groups, Group (I) 30 participant's females on continuous moderate intensity aerobic exercises with ketogenic diet and Group (II) 30 participant's females on Ketogenic Diet. The important finding in this study is the improvement in fasting glucose level (FPG), glycated hemoglobin (HbA_{1c}) and waist circumference in both groups after 12 weeks of intervention with more notable improvement in group (I).

The results of this study could be explained as follows; The ketogenic diet assumes a very high-fat and low-carbohydrate diet, reducing carbohydrate to ≤10% of consumed energy. So, after 3-4 days of carbohydrate restriction, glucose reserves become inadequate, this restriction of carbohydrate causes turn from glucose metabolism toward the fatty acids metabolism but The CNS not able to use fatty acids as a source of energy so the CNS is required to find another source of energy. This alternative source of energy is Ketone bodies which are two kinds: acetoacetate and β-hydroxybutyrate and produced in the liver. As ketone bodies are created by the breakdown of fats, ketosis is the most dependable sign of fat loss. Ketosis is a totally physiological mechanism [15, 16, 28].

The results of this study came in agreement of McDonald and Cervenka [29] the KD delivers inadequate quantities of carbohydrates for the metabolic needs but adequate protein for growing and development. Therefore, energy is mostly resulting from fat provided in the food and by the use of body fat, which stimulates tissues to use ketone body as the main energy source in spite of glucose for the central nervous system.

Also, the results of this study came in agreement with Tony et al. [30] normally, when blood glucose drops for more than couples of hours, ketonemia develops due to reduced insulin and the brain will use ketones as an alternate endogenous fuel. Another study by Vandenberghe et al. [31] reported that the combination of aerobic exercise and medium-chain triglycerides has more plasma ketone than using each intervention alone which develop ketone supply to the brain in older women.

In our study, the reduction of glucose level due to continuous aerobic exercise could be explained as follows; Physical activity acts as a physiological stimulus which increases glucose uptake by the muscle cells.in addition to that Physical activity increases insulin sensitivity by increasing free fatty acid oxidation, improving skeletal muscle mitochondrial function and decreasing lipotoxicity in skeletal muscles and the liver [32]. Also, Waryasz and McDermott [33] reported that regular exercise increase insulin sensitivity by increasing the GLUT-4 receptor concentration on the plasma membrane or sarcolemma, also exercise stimulus results in muscle fiber type conversion thus enhancing the glucose shuttle mechanism. In addition to the muscle fiber hypertrophy and general increase in skeletal muscle mass associated with exercise have also been associated with decreased hemoglobin A_{1c}, possibly related to increased glycogen and glucose within muscle.

The results of this study came in agreement with Berg and Scherer [34] that Physical exercise also increases the serum level of adiponectin, which helps to improve insulin sensitivity as well as moderate to intense exercise improves the β-cell function and glucose regulation, Additionally the concept of this study came in agreement with Glechner et al. [32] that lifestyle intervention play important role in the treatment of pre-diabetes.

On the other hand, the adverse effects frequently reported by McDonald and Cervenka [29] that patients with epilepsy on KD are suffered from hyperlipidemia, gastrointestinal effects and weight loss. Gastrointestinal side effects as nausea, constipation, lesser appetite and vomiting [35,36]. Also, prolonged KD may cause enhanced atherosclerosis, cardiomyopathy, neuropathy of the optic nerve, nephrolithiasis, impaired hepatic functions, anemia, reduction of mineral bone density, and deficiencies of vitamins and mineral components [37, 38].

In this study, the patient tolerated KD with reported constipation in group (II) but Group (I) not suffered from constipation. The results of the current study present new data about the reversal of prediabetes to normal glucose metabolism plus decrease transform from prediabetes to diabetes and therefore decrease complication of diabetes and from a financial part as money saved in health care costs. In addition to decrease adverse effect of ketogenic diet alone as constipation by adding continuous aerobic exercise with ketogenic diet.

The limitation of the current study is that this trial was designed with primary outcomes at 3 months, although we aim to continue follow-up to 12 months to detect possible adverse effects. Also, we excluded patients taking hypoglycemic medication, so our results may not extend to patients taking hypoglycemic medication. However, this study is strengthened by selection of patients with normal body mass index to make sure that reduction in glucose level after intervention is due to continuous aerobic exercise and ketogenic diet not due to decrease in obesity as well as, similar pre-intervention inclusion and exclusion criteria for both groups.

Conclusions

Results provide proof that combined continuous aerobic exercise and ketogenic diet can decrease fasting plasma glucose and glycated hemoglobin therefore, this new approach which can be translated as a better method for controlling glucose level in prediabetes female.

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