

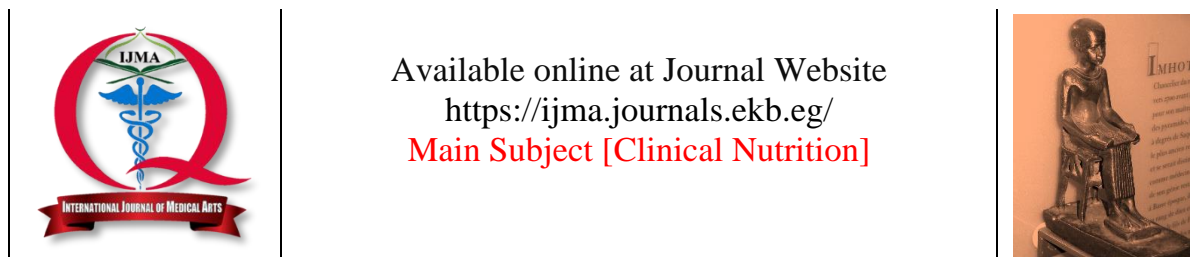
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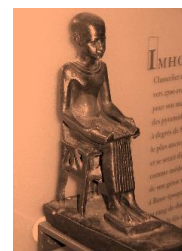
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Original Article

Response of Glycated Hemoglobin to Diabetes Remission Outcome Program in Type 2 Diabetes Mellitus

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ABSTRACT

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Background: The literature on diabetes mellitus [DM] remission by lifestyle changes has been sparse, although there is evidence of remission following bariatric surgery and a recent movement toward the objective of diabetes remission through lifestyle modification.

The aim of the work: To investigate the response of glycated hemoglobin [HbA1c] to diabetes remission outcome program [DROP] in type 2 diabetes mellitus [T2DM].

Patients and Methods: In this randomized controlled study, sixty patients suffering from T2DM with HbA1c of 6.5% to <8%, and taking one or two oral for-DM medications were included. Patients were randomly and equally assigned into 2 groups; [30 patients for each T2DM group]. Group A received their prescribed oral medications associated with DROP [the protocol of DROP contained intermittent fasting diet and aerobic exercise [3 session/weeks] for 12 weeks while Group B received their prescribed oral medications only. Besides the random blood glucose [RBG], HbA1c, total cholesterol [TC], low-density lipoprotein [LDL], triglycerides [TG], and high-density lipoprotein [HDL], timed up and go test [TUGT], mental component score of The Short Form 12 Life Quality Questionnaire [SF12MCS], and physical component score [SF12PCS] were assessed at day number 0 [baseline], day number 90, and day number 180.

Results: Group A showed a significant improvement in the SF12MCS, LDL, HbA1c, TG, TC, SF12PCS, RBG, HDL, and TUGT when comparing the baseline values of outcomes with their values at 90 days or 180 days. No significant improvement in all outcomes was reported within group B at 90 days or 180 days. At day 90 or day 180, the between-group comparison of post-values of outcomes showed a significant improvement in the assessed outcomes in the direction of group A.

Conclusion: The application of DROP in T2DM can produce a significant long-term improvement in RBG, TUGT, HbA1c, QoL, and lipid profile.

Keywords: Diabetes remission outcome program; Lifestyle interventions; Glycated hemoglobin; Lipid profile; Type 2 diabetes mellitus.



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INTRODUCTION

Diabetes mellitus [DM] is a highly prevalent [1-4] and the concept of DM remission is a relatively new phrase that is frequently used in scientific fields. For type 2 diabetes mellitus [T2DM] to be diagnosed, glycemia must be achieved below the current threshold and maintained for at least six months after the patient has stopped using all glucose-lowering medications [5].

Reversing the underlying mechanisms of T2DM can lead to its remission, as has long been known. The initial proof of this was found in research on bariatric surgery performed on T2DM patients [6].

It has been demonstrated that changing one's lifestyle can quickly restore hyperglycemia and the pathophysiological abnormalities it causes. There are enough studies to demonstrate that a substantial lifestyle change can greatly improve diabetes control, and a sizable number of patients may be able to reduce or stop taking their glucose-lowering medications [5].

Reducing weight through lifestyle modifications enhances β -cell function and insulin sensitivity, and can lead to a diabetes remission. T2DM remission enhances health-related quality of life, eliminates the stigma associated with the disease, lowers health-care expenditures, and may lessen dyslipidemia and microvascular problems related to diabetes [7].

Diabetes Remission Outcome Program [DROP] which usually contain diet restriction [e.g. low-calorie diet, intermittent fasting diet] and different types of exercises aiming for increasing physical activity and energy expenditure [8] enhances glycemic control and might block inflammatory pathways connected to malfunctioning pancreatic β -cells. Therefore, it is possible to hypothesize that, in addition to nutritional interventions, concentrating on increasing activity levels may aid in T2DM remission [9].

The literature on DM remission by lifestyle changes has been sparse, although there is evidence of remission following bariatric surgery and a recent movement toward the objective of diabetes remission through lifestyle modification [10].

The aim of this DROP study was to investigate the response of HbA1c to Diabetics Remission Outcome Program in T2DM.

PATIENTS AND METHODS

Design: This was a randomized controlled DROP trial in T2DM patients.

Settings: Patients [males and females] with T2DM were recruited from Rashied General Hospital [outpatient clinic of Internal Diseases].

Ethics: The Faculty of Physical Therapy at Cairo University's Institutional Local Human and Clinical Research Committee accepted the DROP study [P.T./REC/012/004898]. A signed written agreement was obtained from sixty T2DM patients, both male and female. The Helsinki Declaration's tenets were adhered to. Data of patients were secured and all ethical rights of withdrawal at any time were allowed.

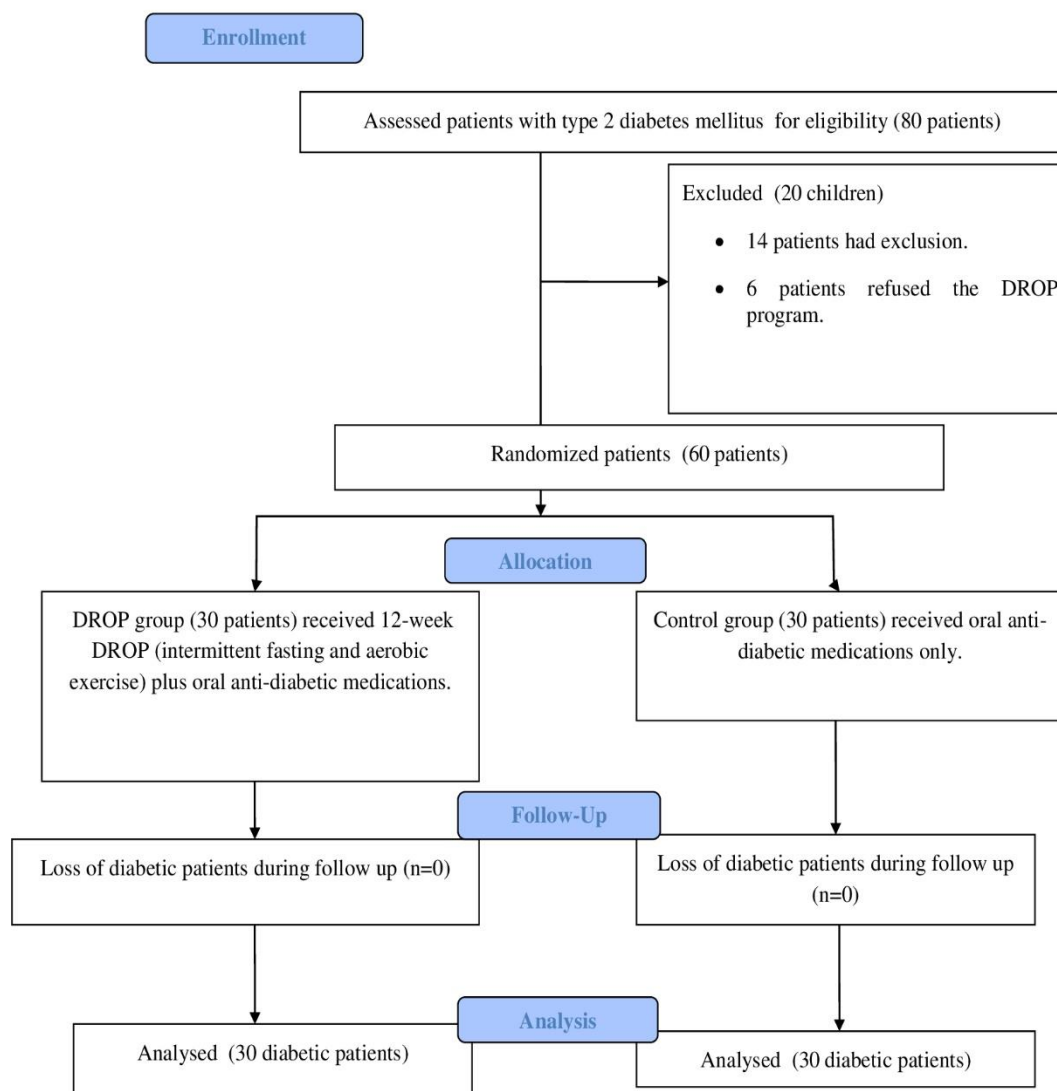
Inclusion criteria: The T2DM patients that were included in the study ranged in age from 40 to 55 years. Within the last six months, the patients did not engage in any alternative lifestyle programs to the recommended procedure. Individuals were Class I obese and overweight. They had a body mass index that varied from 25.0 to 34.9 kg/m². The patients' borderline lipid profile was as follows: total cholesterol [TC] was between 200 and 239 mg/dL, low-density lipoprotein [LDL] was between 130 and 159 mg/dL, and high-density lipoprotein [HDL] was at least 40-59 mg/dL [for females] and at least 50-59 mg/dL [for males]. Triglycerides [TG] 150 to 199 mg/dL [11]. Patients had a HbA1c of 6.5% to less than 8%. They were administered one or two oral medicines for type 2 diabetes.

Exclusion criteria: The DROP study's authors eliminated from consideration anyone with lower limb musculoskeletal discomfort or deformity, respiratory, cardiac, kidney, or liver problems, psychiatric, hypertensive, neurological, or autoimmune diseases. Patients with smoking history or alcohol drinking, HbA1c > 8%, peripheral neuropathy or peripheral vascular disease, or receiving statin or insulin-injected medications were excluded. Patients who were pregnant/breast-feeding or had a history of ≥ 2 episodes/attacks of severe hypoglycaemia within the last 6 months were excluded.

Randomization: In this DROP study, sixty adult T2DM patients were randomly [by sealed envelope technique] assigned to two equal groups [30 patients for each T2DM group] [Figure 1]. Group A received their prescribed oral medications associated with DROP [the protocol of DROP contained intermittent fasting diet and aerobic

exercise [3 session/weeks] for 12 weeks while Group B received their prescribed oral medications only. According to every patient, the anti-diabetic

medications prescribed by patients' physician in both groups were as follows: vildagliptin, metformin, or glimepiride.



Details of the applied DROP

DROP contained intermittent fasting diet [IFD] and aerobic exercise. Regarding IFD, the IFD meal timing schedule had to be followed by the participants. This involved setting aside 18 to 20 hours a day for fasting, during which time one may consume as much water, tea, and coffee as one desires without counting calories. Participants were free to eat anything they wanted during feeding time, although it was advised that they eat at least one-third of a plate of protein to help them feel full [12].

Regarding the aerobic exercise part of the DROP, it contained warming up and light exercises, 15-step marching in place [one step per second in the first two months followed by two steps per second in the last month], and two sets of 5-

repetition chair raising training [the speed of performing this exercise was increased gradually every month] [13].

To be noted, patients of both groups received the full medical continuous supervision by the treating physician to avoid hypoglycemia in the group of DROP program and to avoid the deterioration of HbA1c in the control group.

Outcomes

All outcomes were assessed at day number 0, day number 90, and day number 180.

Besides the random blood glucose [RBG, measured by blood glucose meter], HbA1c, TC,

LDL, TG, and HDL were assessed via automatic blood analyser.

Timed up and go test [TUGT] was also assessed. The task of TUGT required the participants to get out of their 46 cm-tall padded armchairs, walk to a mark at a distance of three meters, turn around, and return to the chair before taking a seat. The duration in seconds between getting out of the chair and touching the back of the seat was recorded [14].

The short form 12 life quality questionnaire [SF12] was used to assess T2DM patients' quality of life [QoL] [15]. The mental component score [SF12MCS] and physical component score [SF12PCS] of the SF12 were examined [16].

Blinding: The assessors of SF12PCS, lipid profile, TUGT, SF12MCS, RBG, and HbA1c in groups of T2DM did not know the nature of applied interventions [details of mediations or DROP].

Statistical analysis: With an alpha level set at 0.05, the measured variables were statistically analyzed and compared using SPSS for Windows version 23 [SPSS, Inc., Chicago, IL]. Data were examined for normality assumption, homogeneity of variance, and presence of extreme scores. The measured variables had a normal distribution, according to the Shapiro-Wilks test [$p > 0.5$]. With the exception of gender [counts], all outcomes' data are expressed as mean and standard deviation. The cumulative effect of all outcomes was compared between the groups using a two-way mixed design MANOVA. When MANOVA shows statistically significant, follow-up univariate ANOVAs with Bonferroni correction were performed for every outcome measure to protect against type I error.

RESULTS

The demographic characteristics of T2DM participants with overweight and class-I obesity

did not differ statistically significantly between the two groups, according to the data in **Tables 1** [$p > 0.5$].

To determine how participants in the two groups differed in terms of how much their scores on the outcome measures changed, mixed design multivariate analysis was used. Statistically Significant multivariate effects were found for the main effects of groups, Wilk's A = 0.14, $F_{[9, 50]} = 35.64$, P-value < 0.001, Partial Eta Squared [η^2] = 0.87. Also, there was statistical significant effect on time [pre-post treatment] as Wilk's A = 0.06, $F_{[18, 41]} = 38.28$, p-value < 0.001, $\eta^2 = 0.94$, as well as for the interaction between groups and time as Wilk's A = 0.04, $F_{[18, 41]} = 49.65$, p-value < 0.001, $\eta^2 = 0.96$.

Between-groups comparison: Baseline, after three months [90 days] of intervention and at follow-up [180 days]: Table 2 indicates that at baseline, there were no statistically significant differences [P-value ≥ 0.05] between the study and control groups in any of the evaluated variables. Table 2 and Table 3 demonstrate that there were statistically significant differences between the study and control groups at three months [90 days] of intervention and at follow-up [180 days] for all evaluated variables, with the study group benefiting more [P-value < 0.05].

Comparative analysis within groups: When comparing the pre and post intervention results in the study groups, there were statistically significant differences in all outcome measures [p-value < 0.001], but there was also a statistically significant difference between the pre and follow-up at all variables in the study group. Table 2 and Table 3 indicate that there was no statistically significant difference in the control group between pre and post-treatment or between pre and follow-up at any of the variables [p-value > 0.001].

Table [1]: Demographic Characteristics of participants [n=60]

Characteristics	Study Group [n=30]	Control Group [n=30]	t- value	P Value
Age[years]	47.5±4.42	48.03±4.64	-0.46	0.65
BMI [kg/m ²]	28.82±2.66	29.79±2.3	-1.51	0.14
Gender, n [%]				
Male	14 [46.67%]	13 [43.33%]	X ² =0.1	0.8
Female	16 [53.33%]	17 [56.67%]		

BMI, body mass index; X², Chi Square; MD, Mean Difference; * Data are mean± SD for all demographics except gender [%], P-Value < 0.05 indicate statistical significance.

Table [2]: Within and between group analysis for HbA1c, total cholesterol, LDL, HDL and triglyceride [n=60]

Variables	Study Group	Control Group	MD[95% CI]	p-value [between groups]	η^2
HbA1c [%]					
Pre-treatment	7.48±0.23	7.4±0.29	0.08 [-0.06 to 0.21]	0.26 ^a	
Post-treatment	7.09±0.28	7.41±0.3	-0.32 [-0.47 to -0.17]	0.001 ^b	0.24
Follow-up	6.84±0.29	7.42±0.34	-0.58[-0.74 to -0.42]	0.001 ^b	0.47
p-value [within-pre-post]	0.001 ^b	0.99 ^a			
p-value [within pre-follow-up]	0.001 ^b	0.99 ^a			
Total cholesterol [mg/dl]					
Pre-treatment	225.53±9.25	223±7.45	2.53[-1.81 to 6.87]	0.25 ^a	
Post-treatment	215.67±6.9	225.33±8.5	-9.67 [-13.67 to -5.67]	0.001 ^b	0.29
Follow-up	205.7±3.72	226.07±9.51	-20.37[-24.1 to -16.64]	0.001 ^b	0.67
p-value [within-pre-post]	0.001 ^b	0.36 ^a			
p-value [within pre-follow-up]	0.001 ^b	0.38 ^a			
LDL [mg/dl]					
Pre-treatment	149.13±7.54	147.31±6.89	1.83 [-1.91 to 5.56]	0.33 ^a	
Post-treatment	141.57±5.43	149.16±7.52	-7.59 [-10.99 to -4.2]	0.001 ^b	0.26
Follow-up	134.17±2.61	149.68±7.68	-15.51[-18.47 to -12.55]	0.001 ^b	0.65
p-value [within-pre-post]	0.001 ^b	0.31 ^a			
p-value [within pre-follow-up]	0.001 ^b	0.22 ^a			
HDL [mg/dl]					
Pre-treatment	41.53±1.7	41.47±2.27	0.07[-0.97 to 1.1]	0.9 ^a	
Post-treatment	43.23±2.39	40.93±1.48	2.3[1.27 to 3.33]	0.001 ^b	0.26
Follow-up	44.57±2.16	40.87±2.3	3.7[2.55 to 4.85]	0.001 ^b	0.42
p-value [within-pre-post]	0.001 ^b	0.65 ^a			
p-value [within pre-follow-up]	0.001 ^b	0.74 ^a			
Triglyceride [mg/dl]					
Pre-treatment	173.97±10.54	172.53±6.25	1.43 [-3.04 to 5.91]	0.52 ^a	
Post-treatment	161.3±7.53	173.17±6.85	-11.87 [-15.59 to -8.15]	0.001 ^b	0.41
Follow-up	152.9±2.6	174.57±6.37	-21.67[-24.18 to -19.15]	0.001 ^b	0.84
p-value [within-pre-post]	0.001 ^b	0.99 ^b			
p-value [within pre-follow-up]	0.001 ^b	0.61 ^b			

p-value: probability; ^a: non-significance difference; ^b: significance difference; CI: confidence interval.MD: mean difference; mg/dl: milligram per deciliter; HDL: High density lipoprotein; LDL: low density lipoprotein; HbA1c: Hemoglobin A1c; η^2 : partial eta squared.

Table [3]: Within and between group analysis for TUGT, random blood glucose level, and physical and mental summary components of short form 12 [n=60]

Variables	Study Group	Control Group	MD[95% CI]	p-value [between groups]	η^2
TUGT [seconds]					
Pre-treatment	14.32±0.89	14.75±0.55	-0.43 [-0.81 to 0.04]	0.3 ^a	
Post-treatment	11.33±1.9	15.1±0.63	-3.77 [-4.5 to -3.03]	0.001 ^b	0.65
Follow-up	10.06±0.98	15.12±0.61	-5.06[-5.97 to -4.16]	0.001 ^b	0.69
p-value [within-pre-post]	0.001 ^b	0.45 ^a			
p-value [within pre-follow-up]	0.001 ^b	0.73 ^a			
Random blood glucose level [mg/dl]					
Pre-treatment	188.87±8.34	189.4±7.26	-0.53[-4.57 to 3.51]	0.79 ^a	
Post-treatment	178.33±7.24	191.2±7.82	-12.87 [-16.76 to -8.97]	0.001 ^b	0.43
Follow-up	168.57±8.05	192.77±9.2	-24.2[-28.66 to -19.73]	0.001 ^b	0.67
p-value [within-pre-post]	0.001 ^b	0.67 ^a			
p-value [within pre-follow-up]	0.001 ^b	0.15 ^a			
Physical summary component of short form 12 [scores]					
Pre-treatment	34.72±4.63	35.07±4.96	-0.35 [-2.83 to 2.13]	0.77 ^a	
Post-treatment	47.36±5.78	34.95±4.91	12.41 [9.1 to 15.72]	0.001 ^b	0.5
Follow-up	53.61±4.54	34.7±5.12	18.92[16.41 to 21.42]	0.001 ^b	0.8
p-value [within-pre-post]	0.001 ^b	0.99 ^a			
p-value [within pre-follow-up]	0.001 ^b	0.99 ^a			
Mental summary component of short form 12 [scores]					
Pre-treatment	40.41±4.53	40.31±4.74	0.09[-3.54 to 3.72]	0.96 ^a	
Post-treatment	49.06±5.6	39.9±5.29	9.16[5.93 to 12.39]	0.001 ^b	0.36
Follow-up	53.54±4.24	39.61±5.23	13.93[10.46 to 17.4]	0.001 ^b	0.53
p-value [within-pre-post]	0.001 ^b	0.99 ^a			
p-value [within pre-follow-up]	0.001 ^b	0.99 ^a			

P-value: probability; ^a: non-significance difference; ^b: significance difference; CI: confidence interval.MD: mean difference; mg/dl: milligram per deciliter; TUGT: time and go test; η^2 : partial eta squared.

DISCUSSION

T2DM patients with a shorter duration of DM, a lower baseline HbA1c, and fewer prescriptions for anti-diabetic drugs at baseline were more likely to report a diabetes remission [17]. This may explain the reported improvement in HbA1c or RBG after the applied DROP in this study's T2DM patients.

Regarding lipids' improvement after lifestyle modifications, exercise-induced increases in growth hormone and sympathetic nervous system activity can spur lipolysis and accelerate the reduction of visceral and total body fat. Exercise can catabolize TG and TG-rich lipoproteins, accelerate TG uptake from the plasma, and increase TG transfer and usage by muscle. It can also boost lipoprotein-A and lipoprotein lipase enzyme activity. By quickening

the pace of lipolysis from adipose tissue, insulin reductions during and after exercise along with a corresponding rise in glucagon secretion are the primary mechanisms that lower cholesterol levels [18].

Regarding the improved RBG and HbA1c after lifestyle modifications, engaging in sports like marching that use major body muscles, particularly lower limb muscles, can have a hypoglycaemic effect on improved RBG and HbA1c following lifestyle adjustments. Due to the abundance of oxidative fibres containing hexokinase II and glucose transporter type 4 proteins in addition to electron transport chain complex-II, massive and repeated recruitment of oxidative muscle fibres - rather than glycolytic muscle fibres - can increase glucose transportation, phosphorylation, and ultimately oxidation [19]. Lifestyle modification is an important factor in preventing/correcting cardiovascular risk

factors, enhancing physical performance, and improving QoL in middle-aged population [20,21].

In a recently published study, participants with a duration of T2DM ranging from 1 to 11 years and ages 38 to 72 years took part in a 3-month IFD as a DROP program. After completing the three-month intervention and three-month follow-up, 47.2% [17/36] of participants in the IFD group and 2.8% [1/36] of participants in the control group respectively achieved diabetic remission. Participants in the IFD group experienced a 5.93 kg reduction in mean body weight, while those in the control group experienced a 0.27 kg [1.43] reduction. With a HbA1c level of 6.33% at the 12-month follow-up, 44.4% [16/36] of the individuals experienced remission. Compared to the control group, the IFD group's prescription costs were 77.22% less [60.4/month vs. 265.1/month]. Also, despite non-significant changes, QoL improved in IFD group immediately after ending IFD or at the follow-up assessment [22].

A recent study with patients' mean age of 59 years, 58% female participants, a duration of diabetes of 6 years, and a BMI of 35.8 kg/m² investigated the relationship between achieving diabetes remission in the context of a 12-year intensive lifestyle intervention and the incidence of chronic kidney disease [CKD] and cardiovascular diseases [CVD] later on. Results indicated that individuals with evidence of any remission during follow-up had a 40% lower rate of the composite CVD measure and a 33% lower rate of CKD compared with those who did not achieve remission. Improvements in weight, fitness, HbA1c, HDL, and LDL following baseline may have an impact on this connection [10].

Twelve studies including 3997 patients with T2DM mellitus were considered in a systematic review published and discussed the topic of T2DM remission as a response to lifestyle interventions. The two primary categories of lifestyle treatments included in the research were diet-only and diet-plus physical activity. There were three different kinds of diets among them: the low-energy diet, the low-carb diet, and the Mediterranean diet. Walking, maintaining a regular physical activity schedule, and moderate-intensity aerobic and resistance exercise were the three forms of physical activity interventions used in the included research. The findings showed that patients with T2DM could achieve diabetic remission, lose weight, and enhance their quality of life with lifestyle modifications [23].

Also, the results of a recently published systematic review agreed with the presented results. In this systematic review, there were 28 randomized studies totalling 6281 individuals. When compared to normal diet or usual treatment, calorie-restricted diets enhanced remission by 38 more patients per 100 at 6 months and by 13 more patients per 100 at 12 months, using a remission criterion of a HbA1c level of <6.5% without the use of anti-diabetic medication. By applying a cut-off point of HbA1c of < 6.5% following a minimum 2-month break from antidiabetic treatment, remission rose by 34 patients per 100 at 6 months and 16 patients per 100 at 12 months. Body weight and HbA1c decreased at a clinically significant rate at 6 months with every 500 kcal/d reduction in caloric consumption; these effects significantly diminished at 12 months [24].

In another trial published in 2023, a total of 160 individuals diagnosed with type 2 diabetes who were using insulin and no other diabetic drugs were randomized to receive either normal care or an intervention consisting of metformin, insulin glargine/lixisenatide and lifestyle modifications. Those whose 12-week HbA1c was less than 7.3% [56 mmol/mol] were instructed to discontinue taking their diabetes medications, and they were monitored for an additional 52 weeks. The main result of this study was diabetes relapse, which was measured as time-to-event and included HbA1c \geq 6.5% [48 mmol/mol] at 24 weeks or later, capillary glucose \geq 10 mmol/L on \geq 50% of measurements, or using diabetic medication. Complete or partial diabetes remission at 24, 36, 48, and 64 weeks was determined by measuring HbA1c < 6.5% [48 mmol/mol] after 12 weeks of randomization without the use of diabetes medication [these were the primary secondary outcomes]. The results showed that the intervention considerably decreased the risk of diabetes recurrence by 43%. Thirty [38.0%] members of the intervention group achieved complete or partial remission of their diabetes at 24 weeks, compared to sixteen [19.8%] controls; after 36 weeks, there were twenty-five [31.6%] against fourteen [17.3%] controls, and 1.83, respectively. At 48 weeks and 64 weeks, respectively, the intervention group's relative risk of diabetes remission was 1.88 and 2.05 [25].

The results agreed with another trial in which T2DM patients were divided into two groups: The Usual-care group received only standard treatment, whereas the Lifestyle Intervention Counselling [LIC] group received lifestyle-based counselling. At baseline, the third, sixth, and twelve months, study outcomes [fasting blood

glucose, HbA1c, health-related QoL, and post-prandial blood glucose] were measured. According to study findings, LIC participants had lower HbA1c - 2.82%, postprandial blood glucose -70.16 mg dL, and fasting blood glucose of 0.26 mg dL. In the LIC group, there was also a notable improvement in health-related QoL [26].

The 4-year follow-up to intensive lifestyle intervention in overweight or obese T2DM patients [59.5% female; mean age, 58.7 years] showed a sustained weight loss, improved fitness, enhanced glycemic control [HbA1c], and CVD risk factors [TC, LDL, TC, and TG] [27]. Another study utilized long-term community-based exercise training reported a significant improvement in TUGT in middle-aged/ older patients with T2DM [28].

Conclusion: The application of DROP in T2DM can produce a significant long-term improvement in RBG, TUGT, HbA1c, QoL, and lipid profile.

Conflict of Interest: None

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