

## Original Research Article

# Meal plan prescription, biochemical parameters, and practicality in poorly controlled type-II diabetes mellitus patients

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## ABSTRACT

**Background:** Diabetes health complications seen in everyday life are strongly related to consumption of high carbohydrate and fat foods and the overweight or the obesity.

**Methods:** To shift this equilibrium and to decrease the probability of health problems the opposite was advised; a low carbohydrate and a low-fat daily food plan.

**Results:** The food plan encountered a few environmental and individual hindering factors but the patients who finished the 12-months plan duration achieved significant improvements.

**Conclusions:** The prescribed meal plan was very useful to the poorly controlled type-2 diabetes mellitus patient however it needs further investigation to make it more practical with a wider applicability.

**Keywords:** Blood glucose, Cholesterol, Diet control, Hemoglobin A1c, Triglycerides, Weight

## INTRODUCTION

The probability of micro-vascular complications (common: neuropathy, nephropathy, and retinopathy) and macro-vascular complications (common: peripheral artery disease, cerebrovascular disease, and coronary artery disease) increase in poorly controlled diabetes mellitus patients.<sup>1,2</sup> Two main parameters govern occurrence of type-1 and type-2 diabetes (T1DM and T2DM, respectively): the genetics and the environment. Aging, food availability, and urbanization are associated with a decline in the average daily physical activities and obesity, which is strongly related to the occurrence of T2DM. Nearly 80% of the diabetic patients are overweight.<sup>3</sup> Common among the overweight and the obese individuals, there are elevated concentrations of the plasma fatty acids, leptin, and tumor necrosis factors, which develop insulin resistance in the various body tissues and consequently T2DM.<sup>4</sup> Individuals who are overweight at younger age are more susceptible to become diabetic later as they become older.<sup>5</sup> Therefore, it

is always advisable to consider weight control at younger age. What about people who are above 40 years old and diabetic (T2DM)? Medications and nutrition management are the only available chances to deal with and to manage their diabetes at the present time. To avoid adding more chemicals (the medications) to the human body, the literature data suggest strongly that a better planning of food consumption could be a promising approach.

The objectives of this study were as the following: to describe a suggested low-carbohydrate and a low-fat meal plan to be applied to the daily diet of a poorly controlled T2DM patients, to examine its practicality and investigate the reasons that may embed its applicability, and to examine its effect on biochemical parameters of the selected patients.

## METHODS

A specific diet plan was suggested to type-II diabetes mellitus patients (DM-II) who were not achieving an

improvement in managing their diabetes and therefore at a higher risk and more susceptibility to develop diabetes complications. The study was based on a self-motivated adoption of a controlled diet and a self-reporting of the data progression with time (duration of 12-months), without any form of a reward to convert it to a habitual behavior (internal self-decision). The data were donated by the patients voluntarily between January 2019 and February 2020. The patients were residents of Irbid governorate in the north of Jordan.

### ***The patient selection criteria***

At the beginning, the intention was to accept data donation from males and females in the 40-70 years old age range, diagnosed previously by T2DM and currently taking an oral medication to manage the blood glucose level, had fluctuating and/or high glycosylated hemoglobin results >8.0%, didn't take other medications regularly (to eliminate any potential source of interference), had normal biochemical tests for liver and kidney functions, did not have a history of gastrointestinal problems or complains, and didn't drink alcohol or smoke. The patients were on metformin mono-therapy (1500 mg/day; 3 x 500 mg/day). All the patients confirmed keeping a portable working finger stick tester.

### ***The dietary plan***

A paid nutrition specialist specified 10-days meals contents (30 meals, 3-meals/day; average=1200 kcal/day). The diet description was explained briefly and given as a hardcopy. The average meal contained 85 g of protein (28%), 120 g of carbohydrates (40%), 42 g of fat (32%), and 28g of fiber, distributed nearly equally on the three daily meals.

The dietary plan was based on items from the local markets and included five main components: (1) vegetables, (2) low-fat meat (only white meat), (3) low-fat dairy products, (4) eggs, and (5) fruits.

Coffee, teas, or the commercial herbal drinks may be ingested without adding sugar and may be sweetened by a zero-calorie sweetener. Each patient was asked to add a multi-vitamin tablet daily and to drink at least 2.5-3.5 L of water; 0.5 L in the early morning.

### ***Precautions***

The patients were advised to prepare a sugar bottle (weighed 20 g table sugar) as an emergency precaution in case of a low blood glucose level (sudden change of the normal state; to low energy, severe hunger, blurred vision, shaky, tachycardia, feeling colder, and/or cold sweetening) that should be confirmed by a finger stick tester at home, at the nearest pharmacy, or at a clinic. They were instructed to ingest the sugar bottle if the level was equal or below 70 mg/dl and to slow down any physical activity and to repeat the measurement every

half an hour if the reading was in the 80-71 mg/dl range. None of the patients reported a hypoglycemic incidence. Also, the patients were advised to use 1-3 glycerin suppositories in case of experiencing constipation.

### ***Ethical consideration***

Taking into consideration the international and the local guidelines and part of the ministry of health general policy to increase the awareness and to motivate patients to adopt healthy nutritional daily meal plans, educative brochures were already available, handed and explained systematically. Written consent was obtained from each patient to publish the data based on the condition that the identity will not be released.

### ***Measurements and laboratory analyses***

Each patient was asked to record the daily food intake on a notebook which was reviewed once a week. They were advised to stay on the same therapeutic procedure; they were originally on metformin mono-therapy (500 mg three-times/day). All the enrolled patients were advised to merge the diet program into their family daily life over a period of one week. Before this week the zero-point data (the base line data); the laboratory tests and the other measurements, were recorded and this week was not considered part of the plan.

Before the beginning of the program, these poorly controlled T2DM patients were scheduled originally for a monthly routine blood analyses (after overnight 12-hours fasting) as part of the monitoring process until each case is resolved. The standard laboratory procedures in authors clinic were followed as usual without any modification. (1) weight, (2) the fasting blood glucose level, (3) the glycosylated (glycated) hemoglobin, (4) the plasma triglycerides, and (5) the plasma total cholesterol measurements were obtained.

### ***Statistical analysis***

At the end of the study, the values that were obtained before adopting the meal plan (base line data denoted as (0) in Table 3) and the data of each patient at the end of the 12-months monitoring period were compared. The calculated statistical analyses were: the change (the difference) between the initial and the final value for each patient, the "the average" of the change, and the percent (when applicable as illustrated in the result section). Due to the small number of the patients that could adhere to the rules strictly no further statistical analysis was sought. These calculations, the parameters' gradual change plotting, and the derived equations in Table 4 were performed using the Microsoft excel program version-10.

## **RESULTS**

Among hundreds of diabetics authors examine yearly, authors identified and talked to 27 patients with poorly

managed T2DM who fit into the general criteria. Only 19 patients (workers and non-workers, males and females; 7 men and 12 women) showed their willingness to adhere to the plan voluntarily. To obtain systematic data derived based on the 1200 kcal/day plan and among these 19 patients, 13 patients were excluded due to the violation of one or more of the diet rules and consumed forbidden calorie sources (consumed >1600 kcal/day) during the first six weeks, and unfortunately, only six women committed strictly and systematically provided their data over the 12-months period.

Among the 19 patients, these women were in the 51-61 years old range (6/19 of the patients) and were the most enthusiastic about the diet (Table 1). Table 2 presents the calorie violation among the patients and illustrates that only nearly one-third (32%) could adhere to the plan strictly, nearly the half (53%) would like to have up to

2000 kcal/day whereas nearly one-fifth (18%) of the patients' violation reached up to 2500 kcal/day.

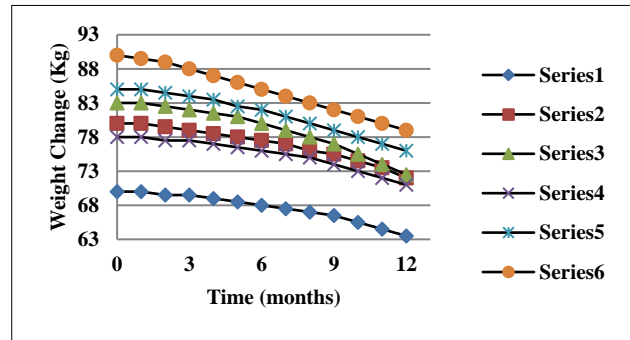


Figure 1: The change in the weight (kg) over the 12-months of the dietary plan period (patients 1-6; series 1-6, respectively).

Table 1: The initial distribution of the self-motivated volunteers and the satisfactory (S) or unsatisfactory (U) compliance with the dietary plan.

Gender	40-50	51-60	61-70
	3	11	5
Women	2U	7 (5S, 2U)	3 (1S, 2U)
Men	1U	4U	2U

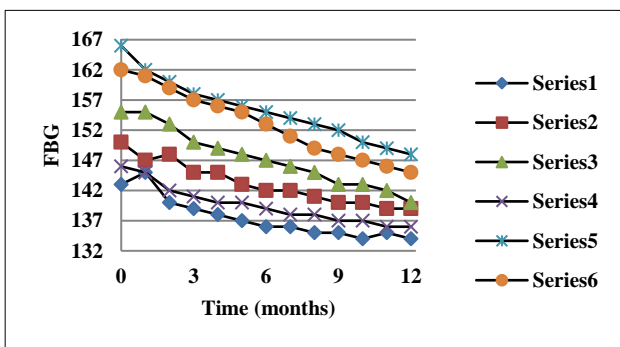


Figure 2: The change in the fasting blood glucose (mg/dl) over the 12-months of the dietary plan period (patients 1-6; series 1-6, respectively).

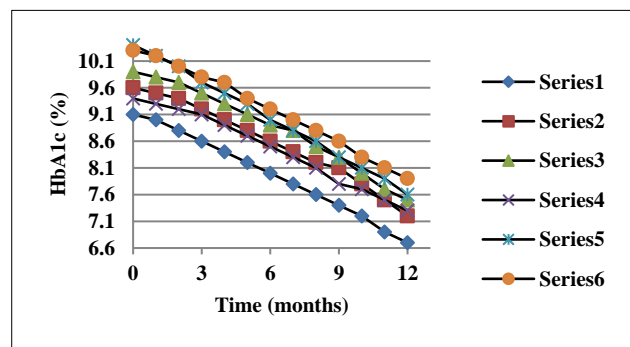


Figure 3: The change in the glycosylated (glycated) hemoglobin (HbA1c; %) over the 12-months of the dietary plan period (patients 1-6; series 1-6, respectively).

Table 2: The violation (KCA/mol) distribution and the education of all the patients.

	CV	Carbohydrates	Fats	Proteins
6-W	-	-	-	-
Notes	4W had bachelor degrees 1W completed the high school 1W had less than high school education			
4-W, 6-M	400-700	55%	31%	14%
Notes	2W and 4M had a bachelor degree 2W and 1M had a 2-years diploma 1M completed the high school			
2-W, 1-M	700-1300	58%	36%	6%
Notes	2W and 1M had less than high school education			

M: Men, W: Women, CV; Patients' estimated calorie violation kcal of the dietary plan in the first six weeks

**Table 3: The changes in the investigated parameters over the 12 months study duration.**

	1	2	3	4	5	6
<b>Age</b>	54	55	55	57	60	61
<b>DD</b>	3	8	5	10	12	9
<b>ACI</b>	1599	1537	1391	1549	1488	1282
<b>Height</b>	159	162	160	163	157	165
<b>Weight (0)</b>	70	80	83	78	85	90
<b>BMI (0)</b>	27.7	30.5	32.4	29.4	34.5	33.1
<b>Weight (12)</b>	63.5	72	72.5	71	76	79
<b>BMI (12)</b>	25.1	27.4	28.3	26.7	30.8	29.0
<b>ΔWeight</b>	-6.5	-8	-10.5	-7	-9	-11
<b>Av. Δweight</b>	-8.7					
<b>ΔBMI</b>	-2.6	-3.1	-4.1	-2.7	-3.7	-4.1
<b>Av. ΔBMI</b>	-3.4					
<b>FBG (0)</b>	143	150	155	146	166	162
<b>FBG (12)</b>	134	139	140	136	148	145
<b>ΔFBG</b>	-9	-11	-15	-10	-18	-17
<b>Av. ΔFBG</b>	-13.3					
<b>HbA1c (0)</b>	9.1	9.6	9.9	9.4	10.4	10.3
<b>HbA1c (12)</b>	6.7	7.1	7.3	6.9	7.8	7.6
<b>ΔHbA1c</b>	-2.4	-2.5	-2.6	-2.5	-2.6	-2.7
<b>Av. ΔHbA1c</b>	-2.6					
<b>TG (0)</b>	153	161	164	157	171	167
<b>TG (12)</b>	138	145	143	143	155	147
<b>ΔTG</b>	-15	-16	-21	-14	-16	-20
<b>Ave. ΔTG</b>	-17					
<b>TC (0)</b>	177	183	186	181	195	190
<b>TC (12)</b>	167	171	172	170	182	175
<b>ΔTC</b>	-10	-12	-14	-11	-13	-15
<b>Ave. ΔTC</b>	-12.5					

DD: Diabetes duration (years), 0: Baseline, 12:12-months, ACI: Dietary plan results of the average calorie intake (kcal), Kg: Weight, BMI: Body mass index (kg/m<sup>2</sup>), FBG: Fasting blood glucose, TG: Plasma triglycerides, TC: Plasma total cholesterol, Δ: Difference, Av: Average of the difference.

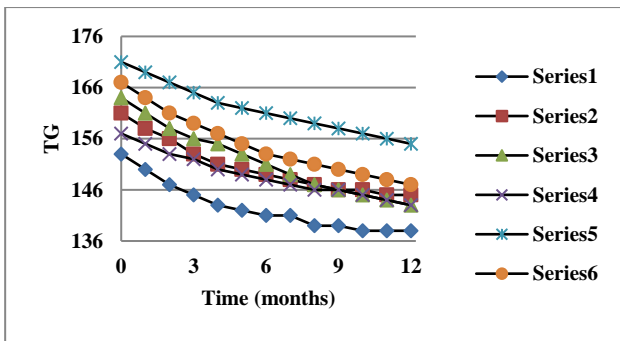
**Table 4: The weight change description as second order polynomial equation and its extrapolation for the six patients.**

Patient	TW	WCP	Equation	RDD
<b>P-1</b>	61	P	-0.0367X <sup>2</sup> -0.0897X + 69.989	14
<b>P-2</b>	63	P	-0.0385X <sup>2</sup> -0.1813X + 80.011	19
<b>P-3</b>	61	P	-0.0629X <sup>2</sup> -0.1239X + 83.044	17
<b>P-4</b>	64	P	-0.0442X <sup>2</sup> -0.0492X + 77.967	18
<b>P-5</b>	59	P	-0.0372X <sup>2</sup> -0.3419X + 85.258	20
<b>P-6</b>	65	P	-0.0137X <sup>2</sup> -0.7885X + 90.302	23

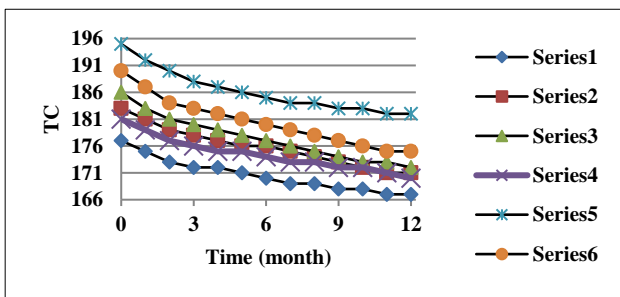
P: Patients, TW: Target weigh (kg; based on BMI=24), WCP: Type of weight change plot, P: Second order polynomial, RDD: Required diet duration (in months).

The data in Table 3 and Figures 1-5 revealed that living as usual along with the proposed diet without including any intervention of a physical exercise program (just the regular in-house and daily life physical activities that they had before adopting the dietary plan) caused a significant decrease (improvements) in all the monitored elementary parameters; weight= -8.7 kg, BMI= -3.4 kg/m<sup>2</sup>, FBG= -13.3 mg/dl, HbA1c= -2.6%, TG= -17 mg/dl, and TC= -12.5 mg/dl.

The change with time in these parameters was not linear in most cases but best described as second order polynomial model. The weight change in Figure 1 for each of the six patients was found to fit a second order polynomial equation (Table 4) and its extrapolation produced the expected necessary time (in months) to achieve a BMI= 24 kg/m<sup>2</sup> (a proposed target).



**Figure 4: The change in the plasma triglycerides (mg/dl) over the 12-months of the dietary plan period (patients 1-6; series 1-6, respectively).**



**Figure 5: The change in the plasma total cholesterol (mg/dl) over the 12-months of the dietary plan period (patients 1-6; series 1-6, respectively).**

## DISCUSSION

Next, three axes of the study are presented; (1) the strategic details of the diet planning, (2) the reasons of the violation from the patients' points of view, and (3) the effect of the dietary plan on the biochemical parameters of the patient who managed to adhere strictly to the diet rules.

### *The diet planning*

Commonly, frequent consumption of high carbohydrate and fat meals leads to weight gain (higher concentrations of plasma fatty acids, leptin, and tumor necrosis factors), less control of T2DM, and eventually higher probability of health complications. Seeing this as an equilibrium (input  $\leftrightarrow$  output), less likelihood of obstacles and a better control of T2DM would be achieved by a low carbohydrate and a low-fat regimen. The medical advices and the educative brochures are usually very general and very broad, illustrate only the food families and consequently a patient may lose the correct guidance through all this. Therefore, it was necessary to narrow and limit to less and specific boarder lines; the low-carbohydrate and low-fat daily food meal plans, as a "rescue plan".

The plan was based on including items available in the local markets around the year to make it reachable as

possible. Several instructions were given to guide the nutrition specialist who specified the contents. Lipids (oils and fats; naturally saturated, naturally unsaturated, or hydrogenated), sugar syrups, bread (white or whole grain), potatoes, and rice compose main part of the daily diet intake in the local societies. Also, lamb meat, honey, dates, nuts, and olive oil are common table food items. Despite the potential health benefits, all these components and other similar items that might be a source of simple sugars, starch, or lipids were excluded from the proposed diet plan.

The nutrition specialist was asked to take into consideration the following rules. The vegetables, one or more, must be part of the three meals. The beans and the peas may be eaten only boiled, in one or the three meals. The white or yellow fat must be removed before cooking the boneless skinless chicken, white fish fillets (low fat), or the canned fish (in brine not oil). A Beef meat without apparent white or yellow fat may be part of only one meal/week; cooked in water. The low-fat meat types (including the single beef meal) must be alternating through time (days) and must be eaten at least two times per week. Only the low-fat dairy products are allowed; low fat milk and low-fat white cheese (not yellow, spongy, not creamy, not greasy, and not salty) are not very popular but conveniently available at the local markets. The chicken egg white must be eaten boiled without the yolk. The daily fruit or a mix (not specified; as a whole not juice) must be distributed over 12 hours of the day (not in a single meal).

### *The reasons of the violation*

The previous studies in the literature imposed specific dietary interventions to the lives of the individuals while in this study the patients had the complete freedom to merge this food planning into their lives. To best of our knowledge, this privileged complete freedom-to-choose allowed to the first time in the literature to quantify and to measure the "practicality" of the suggested modification, which is a unique feature of the study design.

Individuals who fight food temptation experience an emotional disturbance, that's why it is a rescue plan, that's why the patients, all the way, were provided with a psychological support to achieve a life-long determination and behavioral change. Emotional weakness may pull back to eat more than needed as a way to release part of a stress, this issue was given and should be handled with full attention.<sup>6-9</sup>

The reasons behind the plan violations were discussed with the patients. Qualitative notes were recorded. The reasons form the patients' points of view were: (1) the pure desire versus the lack of a serious determination, (2) the work conditions, (3) the cultural habits, (4) the financial challenge, (5) the education; the overestimation



of the personal health and the underestimation of the disease strength.

The pure desire to carbohydrate- and fat-rich food is an important factor (reason 1; the pure desire versus the lack of a serious determination). A note common among all the thirteen patients who violated the plan was that all of them agreed that fat, bread, rice, and potato are better fillers and more effective in suppressing significant portion of the appetite and the desire to eat. This note was also common among the other six successful women but the six women could adhere to the dietary plan and had stronger self-determination.

Unexpectedly and unfortunately all the thirteen patients who violated the dietary plan were workers. Seven of them mentioned that they did not have a lunch break at work (work starts at 08:00 am and ends at 03:00 pm) and they had to eat a snack while working, like the others. Nine of the patients mentioned that they did not have a private place at work to eat the second meal so they could not bring a meal to work (reason 2; the work conditions). Three of them took their meals to work but, while seeing the others eating snacks they liked, they struggled with their selves and the desires to eat the snacks or the fast food that they liked and used to eat regularly (reasons 1 and 2).

It is very common that while visiting others (socialization) food is served, it is traditional that a host insists strongly and repeatedly to drink and eat more. In these gatherings, most meals include rice, bread, meat, sweetened drinks, and deserts; are high carbohydrate and fat meals. Five of the thirteen patients confessed that they could not resist or did not have the chance to explain their restricted diet (reason 3; the cultural habits).

Especially bread, it is relatively cheaper than the average price of the other food items in the designed diet which makes bread a basic meal component in this un-wealthy society. Twelve of the patients illustrated that the designed meals were tempting to the family members and these patients couldn't isolate themselves from the rest of the family members which became a financial burden that could not be resolved. Similarly, previous studies found that a higher probability to develop T2DM is associated with a lower income.<sup>10,11</sup> There was a barrier with most of the patients in discussing the actual income of the family or the specific portion of the income that belongs to each of the patients therefore the "financial challenge" could not be discussed further with the patients (reason 4; the financial aspect of eating healthy diet).

The three patients who consumed up to 2500 kcal (educated less than the high school level) expressed their suspicions about the reality of their illness and the actual need for a strict diet. They were living a contradiction; they kept taking their medications but at the same time they thought that they were not feeling good because of a black magic or envy (the bad omen of an eye). Here, the

level and the type of the education plays important role (reason 5; the personal education).

### ***The effect of the dietary plan on the biochemical parameters***

The drug dose of the poorly-controlled T2DM patients in this study (500 mg of metformin; 3-times daily, a total of 1500 mg/day) could be increased and/or combined with other medications to manage their diabetes. Common among the patients, the investigation and the discussion revealed that all of them used to eat randomly (without being actually hungry) and excessively high carbohydrate and fat food items and had in mind the food as an amusement especially in the in-house family gatherings or in the social occasions. This encouraged, instead of changing the medication, to prescribe a strict food plan.

Compared to the popular local dishes, the proposed diet in this study, besides being a low-carbohydrate and a low-fat diet, it includes plenty of vegetables, reasonable amounts of proteins from plant and animal sources, and fruits, which guaranteed continuous supply of important minerals, vitamins, antioxidants, and fibers.<sup>12-16</sup>

Table 3 and Figures 1-5 show that the suggested food plan is effective in decreasing the weight and in lowering the FBG, HbA1c, TG, and TC in the six patients. Despite the limited patients' sample, the change in these data supports that poor control of diabetes can be stopped and the equilibrium can be shifted to decrease the elevated concentrations of the plasma fatty acids, leptin, and tumor necrosis factors (unfortunately, there wasn't an access to their measurements). The extrapolations of the graph in Figure 1 (Table 4) indicate that the six patients can reach a relatively safer weight, FBG, and HbA1c values in a reasonable time based on the variation in the initial values. The TG and the TC values were closer to the upper limits. The diet plan prevented any potential elevation and their values started to decline gradually and already reached to the desired values of healthy individuals.

The dietary intervention studies presented in the literature may be one of the following. It might be based on a normal diet but includes an interfering parameter (like adding a fiber or a bioactive compound), or based on a low-calorie diet, or based on a low-fat diet, or based on a low-carbohydrate diet, and these types may include a specific physical activity program. The study that is presented here has the following characteristics: it targeted only the T2DM patients who were in direct danger of the poorly controlled blood glucose complications, it was based on a specific low-carbohydrate and low-fat diet details, it was a suggested addition to the life of the individuals to be adopted voluntarily (a self-motivated adoption) and the resulted data to be donated voluntarily, it was designed initially as a 12-months plan to be planted to become part of the normal daily behavior and attitude, and it didn't include

any specific physical activity program. To best of our knowledge, this is the first study in the literature with the specifications of these five characteristics in one study, which makes it unique. Thus, it wasn't possible to compare the final results with those from previous studies due to the differences in one or more of the study characteristics or details. However, and in general, the results of the suggested lifestyle interventions (diet and physical activities) of DM patients are consistent and strongly support the present study findings.<sup>17,18</sup>

The diet on one side, a recent review elaborated that metformin itself has many potential medical benefits and has been successfully used to lower the body weight along with a low-calorie diet.<sup>19</sup> A study was carried out on T2DM women, who were treated with metformin and a controlled diet plan, revealed that metformin helps to decrease the amount of the consumed food and to lose weight which consequently led to a lower fasting blood glucose levels and HbA1c values.<sup>20</sup>

## CONCLUSION

The data of the present study is strong evidence on the effectiveness of the suggested meal plan prescription in improving the health status of the T2DM patients especially those who continuously experienced challenges in managing their disease. It is believed that in un-wealthy societies the financial factor (the personal income) is the most important factor that would retard a strict compliance to the suggested plan rules. However, at the present time, the results allow hypothesizing qualitatively two consequences regarding its practicality: (1) may be adopted solely by nearly one-third of the DM-patient's population, or (2) may be one of three daily meals of all the DM-patient's population. Despite the limited success of the dietary plan, the successful results encourage further investigations on the factors that would make it more practical to facilitate worldwide espousal by the T2DM patients and the overweight or obese individuals.

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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