NATUREA

Clinical Study Conclusions

The results of the conducted study provided reliable proof that the "Sugar Crush" & "Sugar Crush Daily":

1. As part of a combined sugar-lowering therapy contributes to a durable sugar-lowering effect:
- lowers the glycemia level on an empty stomach,
- lowers the postprandial glycemia level,
- decreases the variability of the glycemia level during the day/24 hrs,
- decreases the risk of glycemic conditions,
- increases the duration of normal glycemia episodes,
- contributes to the improvement of the glycated hemoglobin indicators.

2. Provides positive impact to the indicators of the lipid spectrum, arterial pressure and body mass.

3. The "Sugar Crush" & "Sugar Crush Daily" may be utilized as a component of the combined therapy aimed for multi-factor maintenance of sugar diabetes for patients with a predisposition and risk factors for developing a metabolic syndrome (extra body mass and obesity, dyslipidemia, arterial hypertension, dysfunction of the glucose tolerance).

The Open Non-Randomized Research Study of the Biologically Active Food Supplement "Sugar Crush" and "Sugar Crush Daily"

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BACKGROUND

Type 2 diabetes - a chronic, progressive and currently non-curable disease – has escalated to the level of an epidemic during the last decades. It has been known for a long time that improper diet, sedentary life, unhealthy habits, chronic stress and poor ecology increase the risks of developing many chronic diseases, particularly sugar diabetes. However, the leading role in the pathogenesis of Type 2 diabetes belongs to such risk factors as increased weight and obesity. Epidemiological research conducted in economically developed countries, including Russia, in evaluating the population's diet and health conditions provided evidence of the substantial changes in the structure of diet and way of life of the contemporary human beings. On the one hand, it shows the decrease of energetic expenditures due to a sedentary lifestyle, on the other hand, a non-balanced diet, characterized by high calories and Glycemic Index, as well as decreased contents of essential food components and minimal presence of biologically active components and micronutrients was permanently present. As a result, there is an increased risk of developing alimentary-dependant and metabolic diseases (Type 2 diabetes among them), chronization of these diseases, decrease in the body's resistance towards unfavorable environmental factors, formation of immunodeficiency conditions and malfunctioning of the antioxidant defense system.

Type 2 diabetes is characterized by 2 pathogenic "deficiencies" – insulin resistance and the malfunctioning of insulin secretion by the pancreatic gland's β-cells. Insulin resistance is the lack of response in the peripheral tissue towards the impact of its own (endogenous) insulin – a genetically pre-determined factor, which develops and increases as obesity progresses. The malfunctioning of insulin secretion by the pancreatic gland's β-cells means the inability of the insular system to produce the adequate amount of insulin to overcome the insulin resistance. As a result, the increasing insulin resistance leads to the drainage of the reserve capacity of the β-cell pool, which, in turn, expresses itself in hyperglycemia – both the "fasting" and the postprandial one. However, hyperglycemia is not the only symptom of Type 2 diabetes. Increasing data is available proving the correlation between Type 2 diabetes with the malfunctioning of fat and protein breakdown in the body and purine metabolism, as well as coagulopathy, hyperglucagonemia, CHD, hypertonic disease, etc. Consequently, maintaining and treating Type 2 diabetes must have a multi-factored approach. Available medical treatment covers a wide spectrum of drugs – from tablets to insulin to medicines delivered intravenously. Unfortunately, many drugs have numerous contra-indications and undesired side effects, which may limit their application. As an alternative to medical methods of treatment, biologically active food supplements (BAFS) containing active herbal components mandatory to individualize a diet and to make up for a component deficiency and lower the risk of developing many chronic conditions, including Type 2 diabetes, have been developed and applied in practice. Thus, the "Sugar Crush" & "Sugar Crush Daily" consisting of the "Sugar Crush" syrup and "Sugar Crush Daily" drink based upon ecologically clean herbs were developed in Israel. The herbal components (senna fenugreek, common fennel, medical sage, olive tree, dappled milk thistle, medical dandelion, sabdariffa hibiscus, lemon verbena, lemon grass, Ceylon cinnamon, bare licorice, common bilberry) contained within the "Sugar Crush" & "Sugar Crush Daily", improve the lipid and carbohydrate balance indicators, provide hepato-protective, anti-inflammatory and anti-oxidative impact, all of which contribute to lowering the risk of developing the alimentary-dependant, metabolic, heart and vascular diseases, which, in turn, improves the quality of patients' lives.

The goal of this study was to evaluate the effectiveness of the "Sugar Crush" & "Sugar Crush Daily" in regulating the carbohydrate and lipid metabolism, as well as arterial pressure and body mass of patients suffering from Type 2 diabetes.

Materials and Methodology

In order to evaluate the effectiveness of the "Sugar Crush" & "Sugar Crush Daily", a clinical study was developed, with the participation of 20 patients officially diagnosed with "Type 2 diabetes," 11 of whom were male and 9 of whom were female patients. The median age of patients was 56.3. All patients included in the study were under therapy consisting of oral sugar-lowering medicinal tablets. 7 patients were receiving

mono-therapy consisting of Sulfonylurea medications; 3 patients were receiving mono-therapy consisting of Metformin medication; 6 patients were receiving combined therapy consisting of Sulfonylurea and Metformin medications; 3 patients were receiving a combined therapy of Metformin and Incretin medication; and 1 patient was receiving therapy consisting of Sulfonylurea and Alphaglucosidase medications. The initial indicators of each patient were identified: their body mass, level of arterial pressure, glycated hemoglobin, total cholesterol, triglycerides, HDL, LDL, glycemia on an empty stomach and 2 hours after consumption of food. In addition, 7 patients were under non-stop 24-hour glucose monitoring (CGMS) for 72 hours. The "Sugar Crush" & "Sugar Crush Daily" was added to the patients' routine therapy for 30 days: one table spoon of syrup in the morning and at night, as well as 200 ml of the drink at lunch time. Then the consumption of the "Sugar Crush" & "Sugar Crush Daily" was interrupted for 15 days. Hence, the total duration of the study was 45 days. The monitoring of the arterial pressure and glycemia on an empty stomach and 2 hours after food consumption was maintained on a daily basis; monitoring of the glycated hemoglobin, total cholesterol, triglycerides, HDL, LDL, and body mass – 45 days from the beginning of the study. 7 patients were in the control group with non-stop 24-hour glucose monitoring (CGMS) for 72 hours (Table 1).

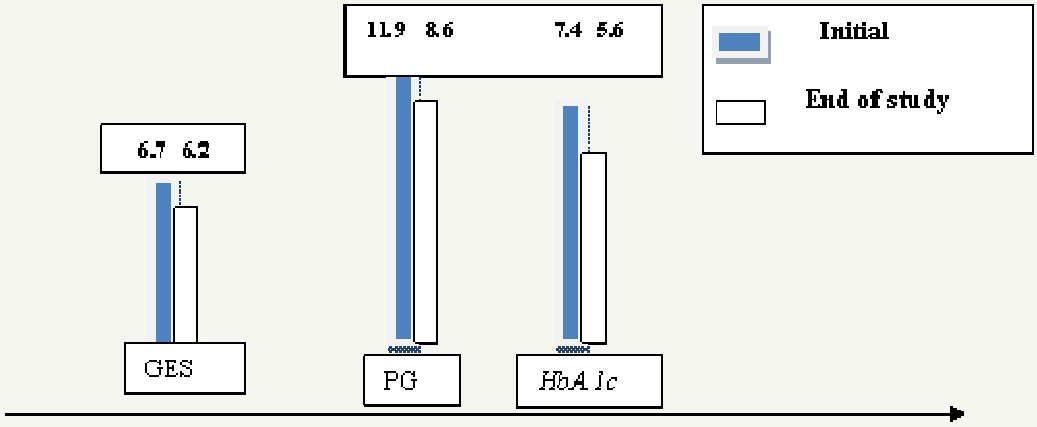
Table One: General characteristics of patients

Parameters	Initial Median Figures	Control Median Figures
Age (η= 20)	56.3	- - -
Gender (male/female) η= 20	11/9	- - -
Glycemia on an empty stomach mmol/l η= 20	6.7 ± 1.49	6.2 ± 1.38
Glycemia postprandial mmol/l η= 20	11.9 ± 2.66	8.6 ± 1.92
HbA 1c % η= 20	7.4 ± 1.65	5.6 ± 1.25
Median glycemia based upon CGMC mmol/l η= 20	7.6 ± 1.67	6.7 ± 1.49
Minimal glycemia based upon CGMC mmol/l η= 7	5.4 ± 1.2	4.6 ± 1.0
Maximal glycemia based upon CGMC mmol/l η= 7	11.6 ± 2.59	9.7 ± 2.16
Duration of normal glycemia episodes based upon CGMC % η= 7	61.4 ± [3.7	82.0 ± 18.3
Duration of hyper-glycemia episodes based upon CGMC % η= 7	35.7 ± 7.98	17.0 ± 3. 8
Duration of hypo-glycemia episodes based upon CGMC % η= 7	2.7 ± 0.6	0.0 ± 0.0
Total cholesterol mmol/l η= 20	5.6 ± 1.25	4.4 ± 0.98
Triglycerides mmol/l η= 20	1.7 ± 0.38	1.0 ± 0.22
HDL mmol/l η= 20	1.2 ± 0.26	1.4 ± 0.31
LDL mmol/l η= 20	3.4 ± 0.76	2.2 ± 0.49
Body mass kg η= 20	85.5 ± 19.1	81.2 ± 18.1
Systolic arterial pressure mm/mercury column η= 20	137.5 ± 30	131.7 ± 29.4
Diastolic arterial pressure mm/mercury column η= 20	83.9 ± 18.7	75.7 ± 16.9

Study Results

During the study data was obtained about the positive impact of the "Sugar Crush Daily" on carbohydrate metabolism. The initial median level of glycemia on an empty stomach was 6.7 ± 1.49 m/mol/l, postprandial - 11.9 ± 2.66 m/mol/l; at the end of the study the median level of glycemia on an empty stomach was 6.2 ± 1.38 m/mol/l, postprandial - 8.6 ± 1.92 m/mol/l (Illustration 1). In addition, the positive dynamics of glycated hemoglobin was observed (Table 1). As seen in the illustration, the initial level of glycated hemoglobin was 7.4 ± 1.65%, but the control figures were 5.6 ± 1.25%.

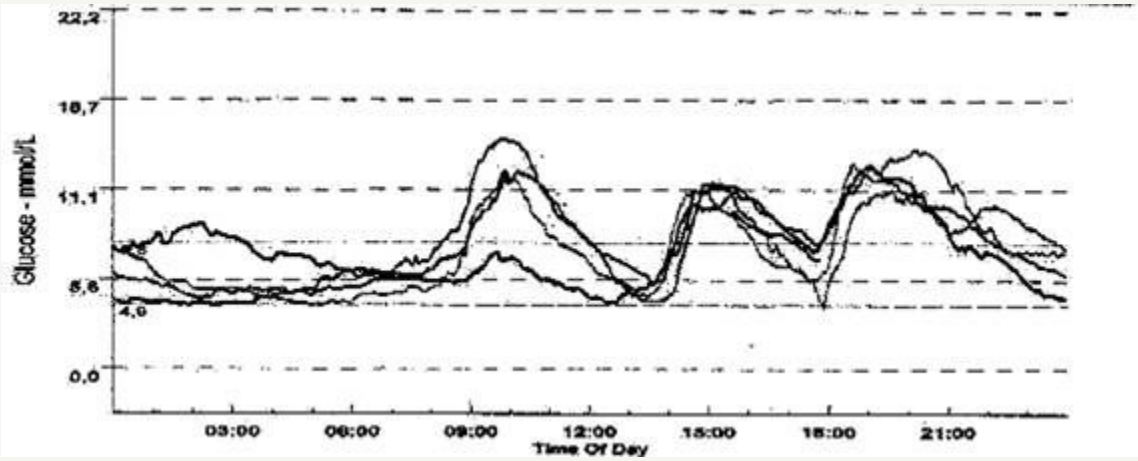
Illustration 1. The dynamics of basic indicators of the carbohydrate metabolism: glycemia on an empty stomach (GES), postprandial glycemia (PG), and glycated hemoglobin (HbA 1c), initially and at the end of the study.



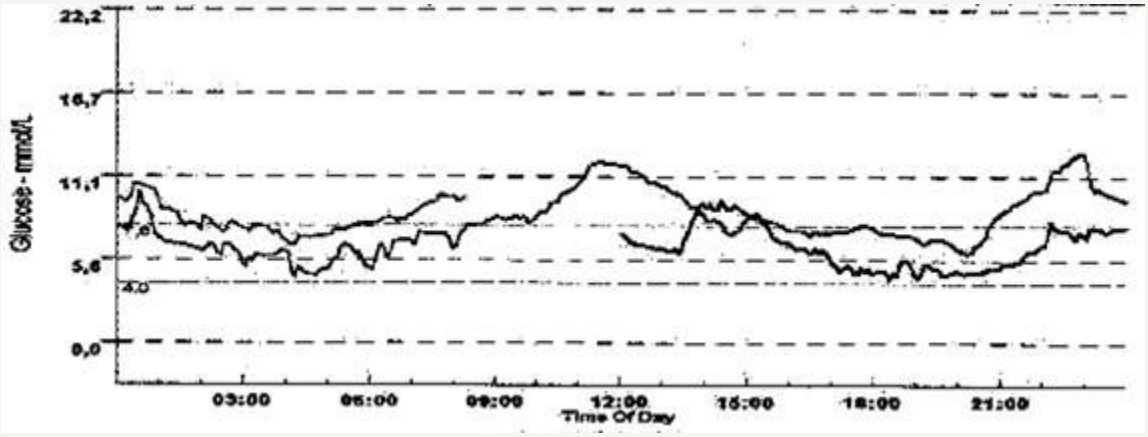
7 patients were initially under non-stop 24-hour glucose monitoring (CGMS) for 72 hours, upon which the following data was obtained: the median glycemia level – 7.6. ± 1.67 m/mol/l, minimal - 5.4 ± 1.2 m/mol/l, maximal – 11.6 ± 2.59 m/mol/l; the duration of normal glycemia episodes - (4-7.8 mmol/l) - 61.4 ± 13.7%, from the beginning of the study the duration of hyperglycemia episodes (over 7.8 mmol/l) - 35.7 ± 7.98%, the duration of hypoglycemia episodes (less than 4.0 mmol/l) - 2.7 ± 0.6%. After the control CGMS for the same 7 patients the following data was obtained: the median glycemia level – 6.7. ± 1.49 m/mol/l, minimal - 4.6 ± 1 m/mol/l, maximal – 9.7 ± 2.16 m/mol/l; the duration of normal glycemia episodes - (4-7.8 mmol/l) – 82 ± 18.3%, from the beginning of the study the duration of hyperglycemia episodes (over 7.8 mmol/l) -17 ± 3.8%, the duration of hypoglycemia episodes (less than 4.0 mmol/l) - 0.0 ± 0.0% (Table 1, Illustration 2).

Illustration 2. The protocol of Patient B. the 24-hour non-stop glucose monitoring (CGMS) before and at the end of the study.

A. Patient B: CGMS before the beginning of the study.

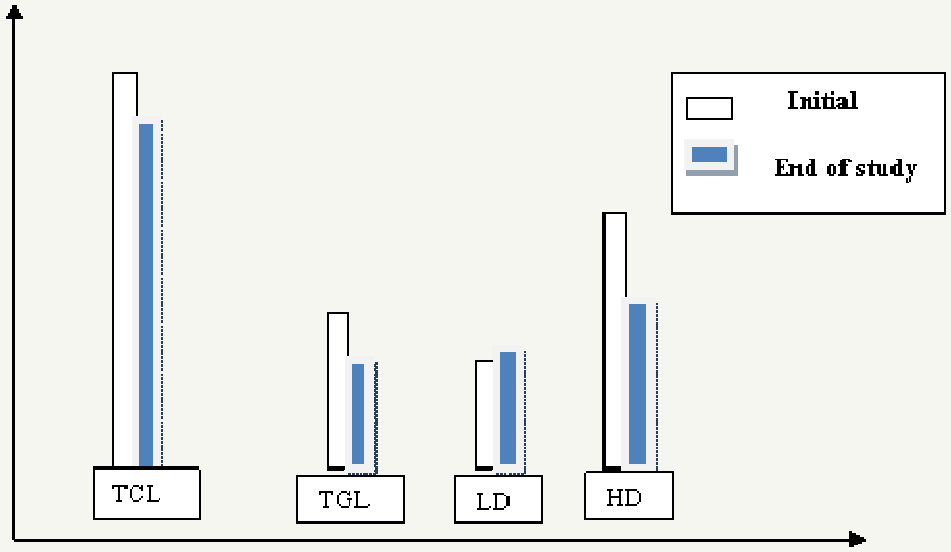


B. Patient B: CGMS at the end of the study.



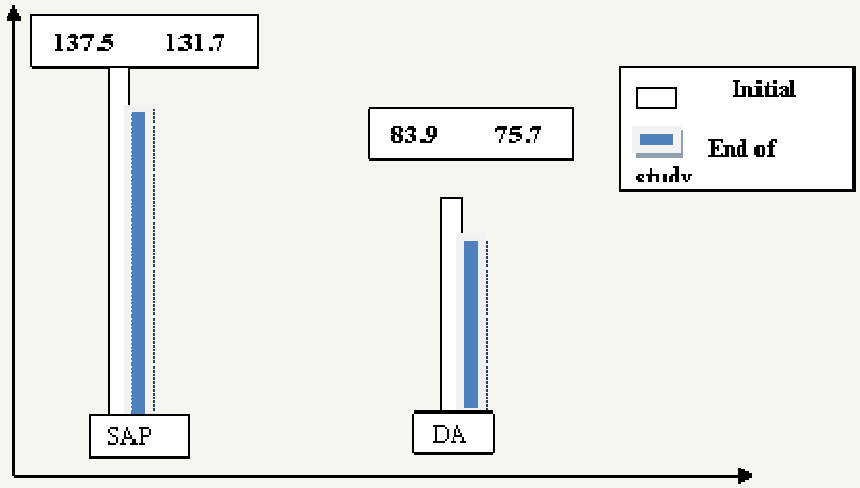
In order to evaluate lipid metabolism, the levels of cholesterol, triglycerides, HDL and LDL were checked. Upon the dynamic comparison of the initial and control data of the study parameters, positive data was obtained as to the impact of the “Sugar Crush” & “Sugar Crush Daily” on the lipid metabolism. The average levels of the total cholesterol lowered from the initial data of 5.6 ± 1.25 m/mol/l to 4.4 ± 0.98 mmol/l during the controlled study (Illustration 3); triglycerides – from 1.7 ± 0.38 mmol/l to 1.0 ± 0.22 mmol/l (Illustration 3); LDL – from 3.4 ± 0.76 m/mol/l to 2.2 ± 0.49 mmol/l (Illustration 3); the median level of HDL increased from 1.2 ± 0.26 mmol/l to 1.40 ± 0.31 mmol/l (Illustration 3).

Illustration 3. The median levels of total cholesterol (TCL), triglycerides (TGL), LDL, and HDL initially and at the end of the study.



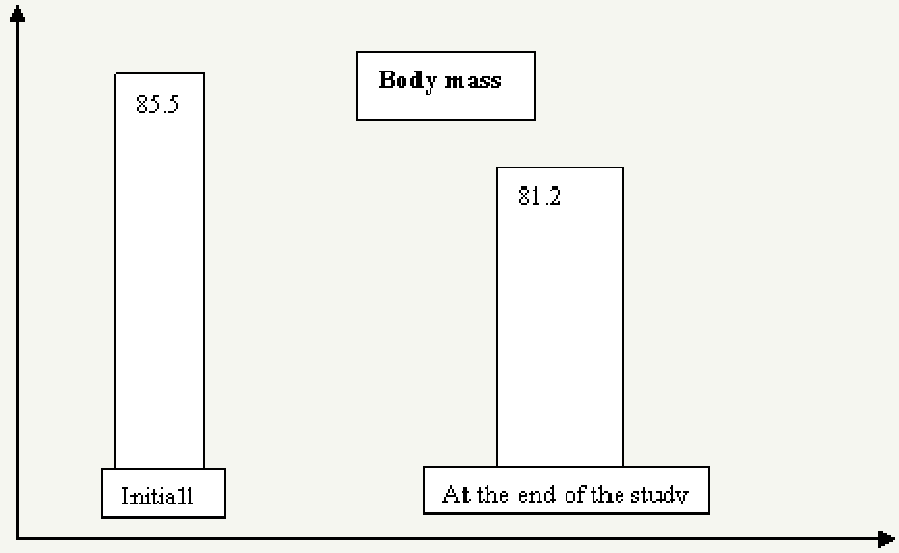
In addition, data was obtained about the positive impact of the “Sugar Crush” & “Sugar Crush Daily” to balance the arterial pressure and weight dynamics. It was observed that the median level of systolic arterial pressure has lowered from the initial 137.5 ± 30.0 mm of the mercury column to 131.7 ± 29.4 mm of the mercury column (Illustration 4), as well as the diastolic one - from 83.9 ± 18.7 mm of the mercury column to 75.7 ± 16.9 mm of the mercury column (Illustration 4). As may be seen from Illustration 5, the “Sugar Crush” & “Sugar Crush Daily” contributed to the lowering of the patients’ body mass from the initial 85.5 ± 19.1 kg to 81.2 ± 18.1 kg when the study was completed.

Illustration 4. The median levels of systolic arterial pressure (SAP) and diastolic arterial pressure (DAP) initially and at the end of the study.



As it may be seen from Illustration 5, the “Sugar Crush” & “Sugar Crush Daily” contributed to lowering of patients’ body mass from the initial 85.5 ± 19.1 kg to 81.2 ± 18.1 kg at the end of the study.

Illustration 5. The median body mass level initially and at the end of the study.



Conclusions

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- lowers the glycemia level on an empty stomach,
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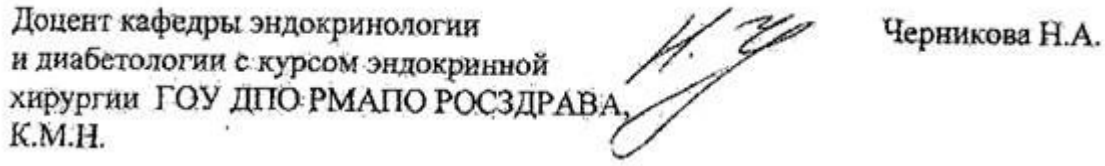

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