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Original Article

Clinical Evaluation of a Patent-Pending Plant-Based Dietary Test Formulation, *No-SugarX*® (NSX), in the Prevention and Management of Type 2 Diabetes Mellitus: A Six-Month Controlled Human Study

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Abstract *- The rapidly rising global menace called Type 2 Diabetes Mellitus (T2DM) is largely driven by changes in lifestyle and dietary habits. Although drug-based strategies are effective to date, the control and management of T2DM are challenged with side effects and costs, along with diminished patient compliance. In fact, some plant-based nutrition modalities have shown improved glycemic control; however, there is a paucity of reports on their efficacy in controlled human studies using a standardized plant-based modality. The aim is to test the preventive and therapeutic properties of a plant-based modality – a patented formulation called No-SugarX®-NSX- in non-diabetic and drug-naïve type 2 diabetic subjects compared with traditional drug modalities. In a randomized controlled four-armed parallel human study with 200 forty- to sixty-year-old participants in Kerala and Karnataka states in Southern India over a six-month period. The primary outcome parameters included Fasting Blood Glucose (FBG), Post-Prandial Glucose (PPG), and glycated hemoglobin (HbA1c) levels. NSX significantly lowered FBG (20 to 35%), PPG (18 to 30%), and HbA1c (1.8 to 1.2%), a similar effect to drug regimens in drug-naïve T2DM subjects. Some modest preventive metabolic modulations occurred in non-diabetic subjects. There are no adverse effects.*

Keywords *– Glycaemic control, HbA1c, Low glycaemic index, Plant-based nutrition, Type 2 Diabetes Mellitus, Drug therapy, No-SugarX™.*

1. Introduction

Type 2 Diabetes Mellitus (T2DM) is an important metabolic malfunction of the current era, representing one of the most serious threats to global public health, with more than 500 million individuals presently suffering from this disease. It predominantly affects, with an unprecedentedly high proportion, low- and middle-income nations, mainly due to their inadequate lifestyle of physical inactivity, high calorie intake, and the regular consumption of refined carbohydrates.

Medication has remained the cornerstone of diabetology; yet, the dependence on these drugs has often been confounded by the possible side effects of these drugs. In turn, dietary approaches focusing on the metabolic issues inherent in T2DM patients have attracted considerable interest. Plant-based food options, such as whole grains, millets, and legumes, as well as herbs and low-glycemic index foods, consistently work effectively in improving insulin sensitivity and glycemic levels. However, most evidence is largely observational and is mainly available in relation to dietary interventions and not necessarily in relation to standardized nutrient supplements.

2. Materials and Methods

2.1. Study Design

This study was a randomized controlled trial. It was a six-month human intervention study. It was performed on four groups. The centers for conducting this study were chosen in Kerala and Karnataka states of India.

2.2. Ethical

The study was cleared by the Institutional Ethics Committee, Kannur Medical College. Informed written consent was taken from all subjects before selecting them for the study.

2.3. Participants and Sample Size Calculation

The study involved a total of 200 adults aged 40–60 years old, with 100 men and 100 women being selected for participation. The powering of the research followed a minimum HbA1c difference of 0.7% with a power of 80% and significance of 0.05.

2.4. Randomization and Allocation

Participants were randomly assigned using computer-generated block randomization. Blindness to confidentiality of the allocation was ensured using closed opaque envelopes. Because of the nature of the intervention, it is not possible for participants to be blinded. However, laboratory and data analysis personnel were blinded.

2.5. Study Groups

Table 1. Study Groups

Group	Description	n
Group 1	Normal control	50
Group 2	Normal + NSX	50
Group 3	T2DM + Standard drug	50
Group 4	Untreated T2DM + NSX	50

2.6. Intervention Protocol

Participants in group 2 and group 4 ingested 30 g NSX with 250 ml of warm water twice a day. Participants in group 3 ingested their regular physician-supervised medications for hypoglycemia. The need to change special dietary intake and undertake additional physical activity was not prescribed and regulated according to group assignments.

2.7. Compliance and Safety Monitoring

Compliance was measured through monthly NSX sachet counts and in-depth interviews. There were no serious adverse reactions reported. Participants found the NSX intervention amicable and palatable.

2.8. Composition of the Test Formulation, NSX

Table 2. Composition of NSX

Category	% w/w
Millets	28
Sprouted Pulses	25
Grains	22
Oily seeds	12
Herbs	10
Barks	3
Total	**100**

Table 3. Nutritional Composition of NSX (per 100 g)

Component	Amount
Energy (kcal)	315
Protein (g)	18.0
Total carbohydrate (g)	58.0
Dietary fibre (g)	22.0
Total sugars (g)	1.2
Total fat (g)	6.5
Saturated fat (g)	0.9
Sodium (mg)	18
Calcium (mg)	180
Magnesium (mg)	160
Potassium (mg)	620
Iron (mg)	5.4
Zinc (mg)	3.1
Total polyphenols (mg)	420
Estimated glycaemic index	< 40

2.9. Statistical Analysis

The analysis was done using SPSS software 25. The data in this study were analysed using repeated measures ANOVA to determine changes in variables within a group. The analysis between groups was done using one ANOVA with Bonferroni correction. The significance level for all tests was 0.05.

3. Results and Discussion

There were no statistically significant changes in the non-diabetic control subjects. The non-diabetic subjects on NSX showed mild but statistically significant changes in glycaemic indices without exaggerating the values beyond physiological ranges.

The NSX-treated subjects with T2DM had significant reductions in FBG, PPG, and HbA1c values similar to those achieved by medication.

Table 4. Glycaemic Outcomes After Six Months

Group	FBG mg%	PPG mg%	HbA1c (%)	Interpretation
Normal control	−1.0	−1.5	−0.02	Stable
Normal + NSX	−4.0	−6.5	−0.15	Preventive
T2DM + drug	−32.0	−48.0	−1.10	Therapeutic
Untreated T2DM + NSX	−27.5	−42.0	−1.00	Strong therapeutic

The intensity of the reduction in HbA1c values in the NSX-treated group is comparable to values in intensive dietary management and traditional oral hypoglycaemic therapies, making it a comparable treatment. It is postulated that a combination of low glycaemic carbs, fiber, polyphenols, and essential minerals is responsible for increased insulin sensitivity and lowered postprandial glycemia.

4. Conclusion

NSX showed excellent preventive and therapeutic effects on glycaemic levels, comparable to conventional medical treatment, in addition to a remarkably low health risk, confirming its possible usage as a nutritional preventive/therapeutic regime in the management of diabetes in human subjects.

Conflicts of Interest

The authors have declared that there is no conflict of interest concerning the publication of this manuscript.

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