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A Prospective, Open-label, Dietary Intervention to assess the Efficacy, Tolerability and Safety of Celnutra RDM in Remission of Type-2 Diabetes Mellitus in Indian Population

Research Article

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Abstract

Background: Traditional management of Type 2 diabetes emphasizes glycemic control through education and medication, assuming the condition is irreversible. However, it often fails to provide adequate control, highlighting the need for alternative approaches. Lifestyle therapies, including those targeting weight loss and Type 2 diabetes remission, are being explored, with oral nutritional supplements high in protein and low in carbohydrates showing particular promise. The aim was to evaluate the efficacy and safety of Celnutra RDM dietary supplementation in individuals with prediabetes and Type-2 diabetes.

Methods: This was a prospective, open-label, dietary intervention conducted in newly diagnosed participants with prediabetes or Type-2 diabetes. Participants were placed on Celnutra RDM dietary supplementation of 50 g once a day for 90 days. Anthropometric measurements, glycemic profiles, blood pressure and dietary intake were measured at baseline, day-45 and day-90 post intervention. Global overall patient rating responses on the efficacy and safety was obtained post-intervention.

Results: Celnutra RDM supplementation for 90 days resulted in a significant reduction in anthropometric, glycemic profiles and blood pressure. The nutritional supplementation significantly reduced median values of weight, BMI, waist circumference, and waist hip ratio from baseline to post-intervention timepoints (P<0.001). Similarly, the nutritional supplementation significantly reduced median fasting blood glucose, post-prandial blood glucose, and Hb1Ac levels from baseline to post-intervention (P<0.001). Majority participants rated the efficacy and safety profile of the supplementation as good to excellent.

Conclusion: Overall, Celnutra RDM appears to be a viable option for satisfying the unmet need for effective, safe, and well-tolerated nutritional therapy for weight reduction and diabetes remission in prediabetes and Type-2 diabetes.

Keywords: Nutrition; Dietary; Glycemic; Weight loss; Celnutra; Prediabetes; Type-2 diabetes

Introduction

The global prevalence of Type-2 diabetes is rising. The World Health Organization (WHO) and International Diabetes Federation (IDF) report that there are over 537 million diabetics globally. Given the high frequency of prediabetes, this statistic is anticipated to increase considerably in the next decades. In India, around 74 million individuals have diabetes, with one in every two adults going untreated [1]. According to the most recent ICMR-INDIAB-13 research, 63.7% of individuals with diabetes had poor blood glucose control, which is a major problem in India [2].

Classical type 2 diabetes management, based on the premise that Type-2 diabetes is an irreversible and progressing chronic condition, has concentrated on glycemic control through diabetes education and increasing glucose-lowering medication usage [3,4,5]. However, this strategy does not result in appropriate glycemic control in a substantial number of patients [3,4,5]. Obesity and excessive fat accumulation in the liver and pancreas are strongly associated with Type-2 diabetes [3,6,7]. Studies, including the Diabetes Remission Clinical Trial (DiRECT), Counterpoint, and Counterbalance, have challenged this initial result and documented that effective diet-induced weight loss has been shown to result in long-term Type-2 diabetes remission [8,9,10,11,12]. Thus, weight management is rapidly taking priority in Type-2 diabetes, with substantial evidence that remission may be accomplished with weight loss interventions.

The American Diabetes Association (ADA) defines remission as HbA1c <6.5% (48 mmol/mol) measured at least 3 months after cessation of glucose-lowering pharmacotherapy, which is the standard diagnostic criteria[13].

Recently, the emphasis has switched toward intensive lifestyle interventions to achieve weight reduction and diabetes remission. Oral nutritional supplement therapy are promising options, which involve high protein and low carbohydrate dietary interventions to accomplish weight loss and Type-2 diabetes remission [14,15,16].

Celnutra RDM is a nutritionally balanced supplement designed for sustained energy release. It features a high-protein, low-glycemic formulation with low carbohydrate content, which has the potential for weight reduction management and diabetes remission in Type-2 diabetes. Therefore, this study was conducted to evaluate the efficacy and safety of Celnutra RDM dietary supplementation in individuals with prediabetes and Type-2 diabetes.

The primary objectives of this study were to evaluate the changes in the anthropometric, glycemic profiles and blood pressure after Celnutra RDM dietary supplementation in individuals with prediabetes and Type-2 diabetes.

Methods

Study design

This was a prospective, open-label, clinical study conducted at Multiple hospitals across India.

Ethical Consideration

Ethical committee approval was obtained from the participating hospital. The study was carried out in accordance with the Declaration of Helsinki, ethical standards established by the Indian Council of Medical Research (ICMR), and good clinical practice (GCP). Informed written consent was taken from the participants.

Study participants

The study participants included newly diagnosed prediabetic and Type-2 diabetic patients.

Sample size

It was a convenient sample size. A total of 149 participants attending the hospital sites during the study period were enrolled.

Participant eligibility criteria

Newly diagnosed participants of either gender with more than 25 years with prediabetes or Type-2 diabetes according on American

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Diabetes Association guidelines, with fasting blood glucose ≥100 mg/dL for prediabetes or ≥126 mg/dL for Type-2 diabetes, and/or glycated haemoglobin (HbA1c) ≥5.7% for prediabetes or ≥6.5% for Type-2 diabetes, not consuming antidiabetic drugs were included.

Exclusion criteria for the study included newly diagnosed Type-2 diabetes with HbA1c levels ≥9%, Type-2 diabetes on hypoglycemic drugs, regular intake of nutraceuticals products or multivitamin supplement (last 3 months) that may affect lipid and/or glycemic metabolism, currently on weight loss medications or (last 3 months) or , and any other severe comorbid condition that could impact study outcomes, known hypersensitivity to the contents of the interventional nutraceutical product, participants not willing for dietary intervention compliance and not willing for written consent.

Interventional dietary supplementation/nutraceutical product

The proposed nutraceutical/ dietary intervention supplement was CELNUTRA RDM, a high-protein supplement with low glycemic and carbohydrate content. It is an exclusive product of NUCGNEX LIFESCIENCES, India[17]. The product contains whey proteins, milk solids, micronutrients such as vitamins and minerals, as well as various functional ingredients[17]. Participants were given proposed nutritional supplement product containing a net 400 g of the supplement. Participants were advised to take the intervention supplement in a quantity of 50 g (approximately 5 leveled scoops) in 170 ml water once a day for 90 days. One higher-calorie meal each day was substituted by the proposed nutraceutical supplement.

Study procedure

Written Informed consent was obtained from the participants during screening and enrolment. The participants were screened for brief medical history, general physical examination, vital parameters and nutritional assessment was conducted by a certified qualified dietician. Once enrolled, the participants were assessed for the efficacy parameters: anthropometric parameters, glycemic parameters and blood pressure. For 90 days, participants received 50 g of Celnutra RDM as a dietary supplement replacing one meal of the day. Anthropometric, glycemic, and blood pressure baselines were measured and evaluated on Day-45 and Day-90 after the dietary intervention. Post-intervention, global overall patient ratings of effectiveness and safety were obtained from the participants.

Primary outcome

Efficacy

Change in the anthropometric parameters, which included weight, waist circumference, hip circumference and waist to hip ratio.

Change in the glycemic parameters, which included fasting blood glucose, post prandial blood pressure and HbA1c levels

Change in the systolic and diastolic pressure parameters

Safety assessment

Assessment of the adverse events reported was considered as part of the safety evaluation

Secondary outcomes

Patient rated Global Assessment of Efficacy and Safety of the supplement

Patient-rated global evaluation scales were utilized to determine clinically relevant two elements of treatment outcome: a perceived efficacy and tolerability /safety of the proposed nutraceutical supplement.[18] It consisted of a four-category ordinal response scale for the participants ('Poor', 'Fair', 'Good' and 'Excellent') for assessment.

Statistical analysis

Statistical Package for the Social Sciences (IBM SPSS) Statistics for Windows, Version 21 was used for the statistical analysis. Descriptive statistics were used to express the data in terms of actual numbers, percentage, mean with standard deviation (SD) and median with interquartile range (IQR). Data normality was assessed. Nonparametric test Friedman Test and Wilcoxon Signed Ranks Test were used. A P-value of <0.05 was considered statistically significant.

Results

Baseline characteristics

A total of 149 diabetics participated in this study. The mean age of the patients was 45.58 ± 12.39 years with 49% males and 51% females. The male to female ratio was 0.96. The baseline characteristics of the patients are summarized in (Table 1).

Pre/post intervention Outcomes

Changes in Antropometric parameters

The intervention led to significant reduction in the median weight from baseline of 82 kg to 80 kg at Day-45, further decreasing to 75.2kg at Day-90 (P<0.001). At follow-up visit, the median weight was 76 kg, indicating significant sustained loss (P<0.001). (Graph 1) The post hoc analysis of baseline median weight compared to weight at different time points (Day-45, Day-90 and Follow-up visit) showed significant reductions in median weight post -intervention (P<0.001). Similarly, it was observed that, the intervention led to significant reduction in median values of anthropometric parameters like the BMI, waist circumference and waist hip ratio from baseline to post intervention time points (P<0.001). (Table 2)

Changes in Glycemic profile

The intervention significantly reduced median fasting glucose from a baseline of 151.76 mg/dL to 130.17 mg/dL at Day-45 and further to 114.54 mg/dL at Day-90 (P<0.001). Similarly, the intervention also significantly reduced median postprandial blood glucose from baseline of 205.5 mg/dL to 167.8 mg/dL at Day-45 and 148.9 mg/dL at Day-90 (P<0.001). (Table 3) The HbA1c level showed a significant decrease from baseline of 7.66% to 6.54% post-intervention Day-90. (Graph 2) These findings suggests that the intervention had a positive impact on glycemic profile

Changes in Blood pressure

The intervention significantly reduced the median systolic blood pressure from a baseline of 130 mm of Hg to 128 mm of Hg at Day-

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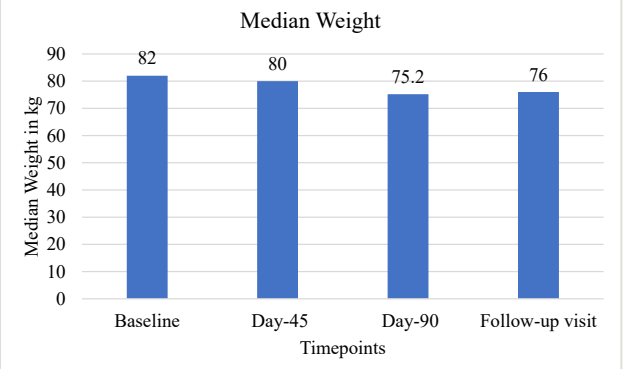
Table 1: Baseline characteristics of the participants

Parameter	Mean	SD	25th Percentile	Median	75th Percentile
Age	45.60	12.35	36.0	45.0	55.0
Baseline Weight (kg)	81.23	19.78	67.5	82.0	90.55
Baseline Height (cm)	163.42	8.94	156.75	162.0	170.0
Baseline BMI (kg/m2)	30.10	5.93	25.30	29.76	34.22
Baseline Waist circumference (cm)	88.83	28.30	85.0	97.0	106.3
Baseline Hip circumference (cm)	93.74	30.16	89.5	100.0	111.0
Baseline Waist /Hip ratio	0.94	0.09	0.89	0.94	1.0
Baseline Systolic Blood pressure (mm of hg)	130.17	11.11	120.0	130.0	139.0
Baseline Diastolic Blood pressure (mm of hg)	84.18	8.16	80.0	82.0	90.0
Baseline Fasting blood glucose (mg/dl)	151.76	52.18	120.0	140.0	168.0
Baseline Postprandial blood glucose (mg/dl)	205.51	69.76	160.0	185.0	230.0
Baseline HbA1c	7.66	1.71	6.5	7.10	8.45

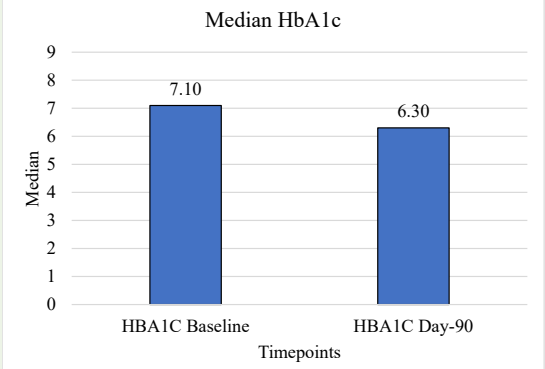
Table 2: Changes in the Anthropometric parameters - Pre/Post intervention

Parameters		Mean ± SD	Median [IQR]	P value *
Weight (kg)	Baseline	81.23 ± 19.78	82 [67.5, 90.55]	<0.001
	Day-45	78.02 ± 17.19	80 [65, 87.25] [a]	
	Day-90	75.69 ±16.28	75.2 [63.75, 83.65] [a]	
	Follow-up	76.31 ±16.29	76 [64.35, 84] [a]	
BMI (kg/m2)	Baseline	30.10 ± 5.93	29.76 [25.3, 34.22]	<0.001
	Day-45	29.17 ±5.60	28.71 [24.6, 32.90] [a]	
	Day-90	28.27 ± 5.22	27.66 [23.8, 31.58] [a]	
	Follow-up visit	28.53 ± 5.31	28.15 [23.94, 31.62] [a]	
Waist Circumference (cm)	Baseline	88.83 ± 28.30	97 [85, 106.3]	<0.001
	Day-45	86.32 ±27.66	95 [83, 103.75] [a]	
	Day-90	84.59 ± 27.45	92 [81.28, 101] [a]	
Hip Circumference (cm)	Baseline	93.74 ±30.16	100 [89.5, 111]	<0.001
	Day-45	91.84 ±30.04	99 [87.65, 110] [a]	
	Day-90	84.91 ±34.48	97 [58 ,107] [a]	
Waist-Hip ratio	Baseline	0.94 ± 0.09	0.94 [0.89, 1.0]	<0.001
	Day-45	0.93 ± 0.09	0.94 [0.88, 0.97]	
	Day-90	0.91 ± 0.08	0.91 [0.86, 0.95] [a]	

*-Friedman Test, [a]- *P* value <0.05 versus baseline using Wilcoxon Signed Ranks Test



Graph 1: Change in the median weight pre and post intervention



Graph 2: Change in the median HbA1c pre and post intervention

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Table 3: Changes in the Glycemic parameters- Pre/Post intervention

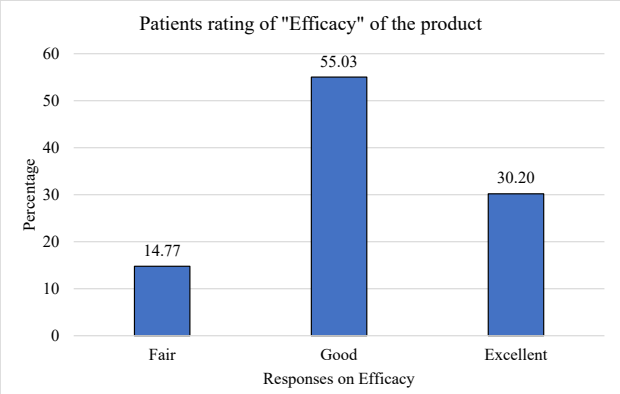
Parameters		Mean ± SD	Median [IQR]	P value
Fasting Blood Glucose (mg/dl)	Baseline	151.76 ± 52.18	140 [120, 168]	<0.001 *
	Day-45	130.17 ± 30.91	125 [110, 142.5][a]	
	Day-90	114.54 ± 20.05	110 [100, 122.5][a]	
	Follow-up	115.44 ± 20.48	110 [102, 124.5][a]	
Post-prandialBlood Glucose (mg/dl)	Baseline	205.5 ± 69.8	185 [160, 230]	<0.001 *
	Day-45	167.8 ± 45.3	160 [135.5, 189.1][a]	
	Day-90	148.9 ± 32.8	142 [130, 160][a]	
	Follow-up	151.2 ± 32.6	145 [130.5, 161.5][a]	
HbA1c	Baseline	7.66 ± 1.71	7.1 [6.5, 8.45]	<0.001 #
	Day-90	6.54 ± 1.02	6.3 [5.8, 7.05]	

*Friedman Test, # Wilcoxon Signed Ranks Test, [a]- *P* value <0.05 versus baseline values using Wilcoxon Signed Ranks Test

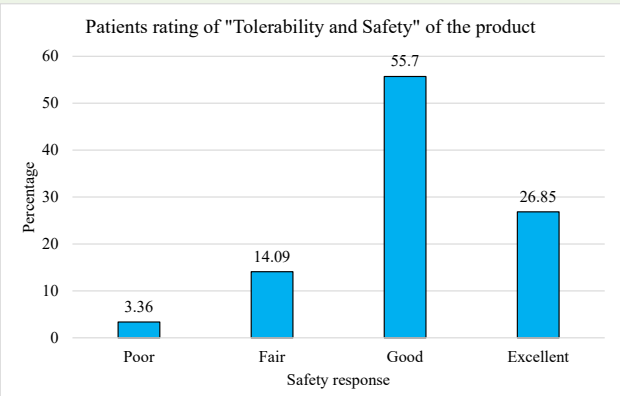
Table 4: Changes in the Blood Pressure - Pre/Post intervention

Parameters		Mean ± SD	Median [IQR]	P value
Systolic Blood Pressure (mm of hg)	Baseline	130.17 ± 11.11	130 [120, 139]	<0.001 *
	Day-45	126.32 ± 11.46	128 [120, 130][a]	
	Day-90	124.88 ± 7.63	125 [120, 130][a]	
Diastolic Blood Pressure (mm of hg)	Baseline	84.18 ± 8.16	82 [80, 90]	<0.001 *
	Day-45	82.35 ± 6.42	80 [80, 87][a]	
	Day-90	80.74 ± 5.76	80 [80, 84.5][a]	

*Friedman Test, [a]- *P* value <0.05 versus baseline values using Wilcoxon Signed Ranks Test



Graph 3: Patients rated overall efficacy of the product



Graph 4: Patients rated overall safety and tolerability of the product

45 and further to 125 mm of Hg at Day-90 (P<0.001). Similarly, the intervention significantly reduced median diastolic blood pressure from a baseline of 82 mm of Hg to 80 mm of Hg at Day-45 and further to 80 mm of Hg at Day-90 (P<0.001). (Table 4) This continuous decline indicates effective management of blood pressure over timepoints.

Patient rated – outcomes

Patient rated- Efficacy

A majority of patients rated the efficacy of product as "Good" (55.03%) and "Excellent" (30.2%). (Graph 3) Similarly, majority rated safety and tolerability of the product as "Good" (55.7%) and "Excellent" (26.85%), (Graph 4) indicating a generally positive view of the treatment's efficacy and safety profile.

Adverse events

In a total of 149 patients, 11 experienced adverse events (AEs) of Gastro-intestinal tract (abdominal bloating and loose stool), representing 7.38% of the cohort. Notably, there were no serious adverse events (SAEs) observed in the cohort.

Discussion

This study found that supplementation of Celnutra RDM, a high protein, low glycemic and carbohydrate dietary supplement, daily for 90 days resulted in a substantial decrease ($p < 0.001$) in anthropometric parameters, including weight, as well as improvement in glycemic profiles and blood pressure in newly diagnosed prediabetics and Type-2 diabetics.

Type-2 diabetes is still a devastating medical condition with a high global prevalence. Obesity and increased fat accumulation in the liver and pancreas are strongly linked to Type-2 diabetes [3,4,5,6]. Weight management, in contrast to intensified medication therapy and

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glycemic control, are rapidly taking center stage in Type-2 diabetes [9,10,12]. The focus has recently switched to intensive lifestyle interventions which involve high protein and low carbohydrate dietary interventions to accomplish weight loss and Type-2 diabetes remission.

High-protein diets offers myriad health benefits and offers to manage blood glucose levels in Type-2 diabetes. It aids in decreasing glucose absorption, enhancing insulin sensitivity, increasing satiety, improvement in lipid profile and immunity, and retaining muscle mass, and reducing the glycemic impact of meals helping in weight management[19]. Low glycemic index contents give continuous energy throughout the day and prevent rapid glucose spikes, resulting in more stable blood glucose levels[20,21]. These combined effects contribute to better blood glucose control and help in managing or preventing complications associated with diabetes.

In the present study, we explored the efficacy, tolerability and safety of Celnutra RDM, a high-protein, low-glycemic formulation in newly diagnosed individuals of prediabetes and Type-2 diabetes.

In the present study, daily consumption of Celnutra RDM for 90 days resulted in a significant reduction in anthropometric parameters. The nutritional intervention significantly reduced median values of weight, BMI, waist circumference, and waist hip ratio from baseline to post-intervention timepoints ($P<0.001$), making it a promising option for weight control, an important parameter for metabolic health. Similarly, the nutritional intervention significantly reduced median fasting blood glucose, post-prandial blood glucose, and Hb1Ac levels from baseline to post-intervention ($P<0.001$). The decrease in HbA1c levels is critical, since it is one of important indicator of diabetes remission.

Celnutra RDM is a nutritionally balanced supplement designed for sustained energy release. It features a high-protein, low-glycemic formulation with low carbohydrate content, enriched with essential vitamins and minerals. Key components include[17]:

•Low Carbohydrate Blend: A combination of maltodextrin and glycerin with a low glycemic index, free from sucrose.

•High in Fiber: Coated with a blend of cellular carbs such as Nutriose FB 06, hydrolyzed guar gum, and inulin, promoting early satiety, reducing cravings, and enhancing gut health.

•Protein Blend: A slow-release protein formula comprising whey protein and calcium caseinate, with a Protein Digestibility Corrected Amino Acid Score (PDCASS) of 1.0, ensuring high protein quality.

•Probiotics: Includes Lactobacillus Rhamnosus, Bifidobacterium Bifidum, Lactobacillus Acidophilus, And Bacillus Coagulans to support gut dysbiosis and also exerts glycemic-moderating effects.

•Special nutrients: Enriched with Myoinositol, Arginine, Taurine, Carnitine, And Coenzyme Q10, which contribute to the management of diabetic complications by moderating glycemic levels and reducing inflammation and oxidative stress.

•Functional ingredients: Contains Fenugreek extract, Gymnema Sylvestre extract, and Glycyrrhiza Glabra extract, which aid in regulating insulin sensitivity[17].

A balance combination of the components commensurate provides weight loss, glycemic-moderating effect and promotes remission.

In this study, it was also observed that nutritional intervention was well tolerated, only 7.38% experienced mild AEs of gastro-intestinal tract (abdominal bloating and loose stool). No severe or serious adverse events were encountered during the study period.

Overall, Celnutra RDM appears to be a viable option for satisfying the unmet need for effective, safe, and well-tolerated nutritional therapy for weight reduction and diabetes remission in individuals with prediabetes and Type 2 diabetes.

Strength of the study

The strength of this study lies in its provision of real-time evidence across multiple hospitals regarding a nutritional formulation that is high in protein, low in glycemic index, and low in carbohydrates, while being enriched with essential vitamins, minerals, probiotics, and functional ingredients. This formulation has been shown to reduce key anthropometric parameters, including body weight, as well as improve glycemic parameters and blood pressure in newly diagnosed prediabetes and Type-2 diabetes individuals. The findings of this study are particularly valuable for the broader application of dietary management strategies in the treatment of diabetes.

We are presently working on long-term monitoring of these individuals in order to determine the dietary intervention's long-term effectiveness. We want to publish this extended data in the future, adding new insights to the field of diabetes management.

Limitation of the study

The study was conducted with a modest sample size. Larger population studies with a broader cross-section of individuals and multiple locations may yield more conclusive results. Second, the study looked at the mid-term effects of the dietary supplement on anthropometric and glycemic profiles. Confirming the findings in longer-term research might assist to better formulate dietary recommendations for prediabetes and type 2 diabetes prevention and management. Third, there was no comparator or control arm since the research design was a quasi-experiment in a real-world setting.

Conclusion

Celnutra RDM appears to be a viable option for satisfying the unmet need for effective, safe, and well-tolerated nutritional therapy for weight reduction and diabetes remission in individuals with prediabetes and type 2 diabetes. The findings of this study are particularly valuable for the broader application of dietary management strategies for prediabetes and Type-2 diabetes.

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