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# IMPACT OF SOVA HEALTH PRECISION NUTRITION PROGRAM ON METABOLIC PARAMETERS IN TYPE 2 DIABETES AND DYSLIPIDEMIA - A RETROSPECTIVE STUDY

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## ABSTRACT

**Purpose:** This retrospective study is aimed at evaluating the impact of the Sova Health Precision Nutrition Program (digital remote outpatient care program) on HbA1C, fasting blood sugar and lipid parameters over a period of 90 days. Additionally, the concurrent changes in anthropometric measurements, subjective improvements in quality of life were also assessed.
**Methods:** A cohort of 75 participants with type 2 diabetes and dyslipidemia was included in the Sova Health Precision Nutrition Program over a period of 90 days. 70 participants participated fully in the program with all the relevant criteria being fulfilled. This study assessed changes in primary outcomes for Blood Glucose Parameters- HbA1C (%) and Fasting glucose (mg/dL), as well as Lipid parameters- Triglycerides (mg/dL), Total cholesterol (mg/dL), High density lipoprotein (HDL) (mg/dL), Low density lipoprotein (LDL) (mg/dL). Secondary outcome measures included anthropometric measures weight (in kg) and waist circumference (in inches) and subjective parameters including energy levels (1-10 scale) and sleep quality (1-10 scale). Paired samples t-test was used to measure whether the change in all the above parameters was significant from baseline to 90 days.
**Results:** Significant improvements were observed in participants' HbA1C (6.9 ± 1.6% to 6.4 ± 1%) and Fasting glucose levels (118.9 ± 50 mg/dl to 107.7 ± 38.1 mg/dl), Total Cholesterol (237.7 ± 27.4 mg/dL to 209.5 ± 32.5 mg/dL), LDL cholesterol (142.94 ± 28.9 mg/dl to 129.9 ± 29.1 mg/dl) and Triglycerides (235.4 ± 143.1 mg/dL to 178.3 ± 81.3 mg/dL) on average. Anthropometric measures like Weight (78.9 ± 16.3 kg to 76.2 ± 16.1 kg) and Waist circumference (39.9 ± 4.6 inches to 37.9 ± 4.7 inches) saw a significant reduction. Energy Levels and sleep quality also improved significantly.
**Conclusion:** The Sova Health Precision Nutrition Program has demonstrated a significant role in the improvement and management of metabolic parameters in participants with Type 2 diabetes and dyslipidemia. Further, improvement in anthropometric measures and quality of life was also noted.

**KEYWORDS :** Diabetes mellitus, Dyslipidemia, Nutritional intervention, Behavioral therapy, Metabolic health, Remote monitoring, Digital Therapeutics

## INTRODUCTION:

India has seen an exponential increase in prevalence of lifestyle related chronic metabolic diseases over the last few years (Kwasnicka et al., 2020). This is a cause of concern for many individuals as it is associated with significant end organ damage including impact on the kidneys, eyes and cardiovascular morbidities (Guo et al., 2020). This burgeoning population which includes those with type 2 diabetes and dyslipidemia exerts high pressure on the country's healthcare infrastructure with significant medical and economic burden. Studies have indicated the need for strong preventive care measures, implementation of measures to manage modifiable risk factors in stalling disease progression with technology adaptation and robust policy interventions implementable on a large scale in the Indian settings (Kesavadev et al., 2021). Reviews of studies have indicated that appropriate nutrition interventions play a major role in the management of T2DM (Diabetes UK, n.d.). Furthermore, it points out to the importance of digitalisation and the pivotal role individualised precision nutrition will play in formulation of future therapeutic strategies. Among obese individuals, a digital application that provides personalized nutrition recommendations and change in one's food purchasing environment was found to be successful in systematically reducing weight (Pradeepa & Mohan, 2021). These studies are indicative of the promising role that precision nutrition holds for the future therapeutics in managing metabolic disorders.

In this study we aim to study the effectiveness of the Sova Health precision nutrition program in managing blood sugar and lipid parameters. Sova Health precision nutrition program is a fully digital remote outpatient care program aimed at improving treatment outcomes for chronic metabolic conditions (INCHC).

## AIMS

1. To study the impact of Sova Health precision nutrition program on HbA1C, Fasting blood sugar and lipid levels
2. To assess concurrent changes in anthropometric measures (weight, waist circumference) and quality of life (energy levels, sleep quality)

## METHODOLOGY

Sova Health is a remote health platform specializing in precision nutrition therapy for metabolic diseases. This was a retrospective study with 75 participants enrolled at the baseline. Amongst the 75 participants included initially, 70 completed the study as adjudged by the fulfilment of participation criteria and the availability of data at the start and end-point. Five participants were unable to complete the 90 day program owing to personal factors.

All participants were either previously or newly diagnosed with Type 2 diabetes, dyslipidemia or both and were medication naïve at the start of the study. They opted to participate in the Sova Health precision nutrition program as a primary management tool for the aforementioned metabolic diseases and were enrolled after taking appropriate informed consent. Metabolic laboratory parameters and anthropometric data were measured at baseline and at the end of 3 months of the nutrition intervention. Individualized software enabled dietary interventions and meal plans were formulated. Photo logs of all meals consumed by each participant were mandated on a daily basis. Back-end analysis of meal composition was done and the percentage of meals which were program compliant was calculated. A compliance of 90% and beyond was considered good adherence to the program.

Participants with end-organ damage including renal, hepatic, cardiac, ophthalmic or neurological complications were excluded from the study. Also, participants with acute complications of the disease or other coexisting morbidities were not included in the study.

**Sova Health Precision Nutrition Program**

The Sova Health Precision Nutrition Program is a fully digital remote outpatient care program aimed at improving treatment outcomes for chronic metabolic conditions (CMC). The program is based on the realization that CMCs stem from years of multiple small nutritional and lifestyle choices on a daily basis. Sova Health's proprietary algorithm draws data from over 60 unique data points daily and over 3000 unique health data points over a 3-month iteration. The data spans digital and biochemical biomarkers, food and exercise logs, to identify the root cause of metabolic impairment in the patient. The algorithm identifies the deleterious everyday habits unique to each patient and suggests high-impact interventions.

**There are 3 steps to this process:**

**Step 1: Ultra personalized profile created for every user**

Separate data blocks are used to categorize the user into an archetype. Data is collected iteratively and continually fed back to enrich the user profile. Every data block consists of multiple data points that are mapped to tags.

**Step 2: Initial set of high impact/high adoption recommendations generated.**

The algorithm shortlists the highest impact recommendations to reduce the burden of habit change. Recommendations are assessed for medical impact and an adherence score is generated based on user demographic data (user profile).

**Step 3: Self- learning system enabled by artificial intelligence**

Food consumption and habits are tracked continuously. Food items that have high adoption probability are offered to the user instead of harmful items. If the recommendation is validated by the user, it is scored higher for users with similar profiles.

The recommendations are then delivered to the patient over a digital program that includes video consultations, daily monitoring by a certified nutritionist and learning modules. The cycle repeats with a self-learning system based on a feedback loop taking into account multiple patient parameters.

**Outcome measures**

**Primary outcomes**

The primary outcomes measured were HbA1C (%), Fasting blood sugar (FBS) (mg/dL) and Lipid parameters, including Triglycerides (TG) (mg/dL), Total cholesterol (TC) (mg/dL), High density lipoprotein (HDL) (mg/dL) and Low density lipoprotein (LDL) (mg/dL).

**Secondary outcomes**

Anthropometric parameters including weight (in kg) and waist circumference (in) were measured at end points. Further, subjective changes in quality of life as reflected by energy levels (self-report on a 1-10 scale) and sleep quality (self-report on a 1-10 scale) were assessed at the end of 3 months.

**Statistical Analysis**

Data was entered in Microsoft Office Excel and statistical analysis was carried out using SPSS software version 24.0 (IBM SPSS. US). Description of categorical variables was done using frequency and percentage whereas those of continuous variables in mean and standard deviation. Statistically significant differences between the continuous variables before and after intervention were identified using a paired sample t-test. All tests were two tailed and results were considered significant for a p value of less than 0.05.

**RESULTS**

A total of 75 participants were enrolled in the Sova Health Precision Nutrition Program at the baseline. Of the 70 participants who completed the program and were subsequently included for statistical analysis, 47.1% were women and 52.9% were men. At enrollment, 32.9% of participants were below the age of 35 years and 67.1% of the participants were of age 35 years or above (Table 1). For statistical analysis, data of participants was systematically analysed and individuals with abnormal parameters at baseline were evaluated for changes in the said parameters at the end of 90 days. Compliance to the prescribed nutritional plan was assessed and overall adherence based on photo logging was considered good amongst 92% of the participants.

**Table-1: Age and gender distribution of study participants (N=70).**

| Characteristics | Frequency | Percentage |
|---|---|---|
| **Age category in years** | | |
| ≤ 35 | 23 | 32.9 |
| > 35 | 47 | 67.1 |
| **Gender** | | |
| Male | 37 | 52.9 |
| Female | 33 | 47.1 |

**Table-2: Comparison of metabolic laboratory parameters and quality of life measurements at baseline and at the end of 3 months of nutritional intervention.**

| Characteristics | Frequency (n) | Baseline Mean (± SD) | At 3 months Mean (± SD) | p value |
|---|---|---|---|---|
| FBS (mg/dL) | 43 | 118.9 (± 50) | 107.7 (± 38.1) | 0.02* |
| HbA1c (%) | 45 | 6.9 (± 1.6) | 6.4 (± 1) | < 0.001* |
| HDL cholesterol (mg/dL) | 29 | 42.9 (± 16.9) | 43.1 (± 12.8) | 0.84 |
| LDL cholesterol (mg/dL) | 50 | 142.94 (± 28.9) | 129.9 (± 29.1) | 0.003* |
| Total cholesterol (mg/dL) | 30 | 237.7 (± 27.4) | 209.5 (± 32.5) | < 0.001* |
| Triglyceride (mg/dL) | 23 | 235.4 (± 143.1) | 178.3 (± 81.3) | 0.01* |
| Weight (kg) | 49 | 78.9 (± 16.3) | 76.2 (± 16.1) | < 0.001* |
| Waist circumference (inches) | 35 | 39.9 (± 4.6) | 37.9 (± 4.7) | < 0.001* |
| Energy levels (1-10) | 46 | 5.9 (± 1.9) | 8.3 (± 1) | < 0.001* |
| Sleep quality (1-10) | 26 | 6.7 (± 1.8) | 7.8 (± 1) | 0.002* |

***Note: SD-standard Deviation, p value based on paired sample t-test, * statistically significant (p < 0.05).***

**Type 2 Diabetes:**

For participants who had abnormal HbA1c at baseline (N = 45), HbA1C decreased significantly over the study period, from 6.9% (± 1.6%) at baseline to 6.4% (± 1%) at 90 days (p < 0.001). Corresponding FBS (N = 43) fell from 118.9 (± 50) mg/dl at baseline to 107.7 (± 38.1) mg/dl at 90 days (p = 0.02) (Table 2).

**Dyslipidemia parameters:**

For participants who had abnormal LDL cholesterol at baseline (N = 50), LDL cholesterol reduced from 142.9 (± 28.9) mg/dL at baseline to 129.9 (± 29.1) mg/dL at 90 days (p = 0.003). Similarly, a significant reduction was observed in the participants who had initial elevated serum triglyceride levels (N = 23), from 235.4 (± 143.1) mg/dL at baseline to 178.3 (± 81.3) mg/dL at 90 days (p = 0.01). Also, those with elevated total cholesterol levels initially (N = 30), a significant improvement from 237.7 (± 27.4) mg/dL at baseline to 209.5 (± 32.5) mg/dL at 90 days (p < 0.001) (Table 2).

**Anthropometric Measures:**

For the participants with weight loss goals (N = 45), the mean body weight decreased from 78.9 (± 16.3) kg at baseline to 76.2 (± 16.1) kg at 90 days (p <0.001) (Table 2). Mean waist circumference (in inches) showed significant reduction from 39.9 (4.6) inches at baseline to 37.9 (± 4.7) inches at 90 Days (p < 0.001). (Table 2)

**Energy Levels and Sleep Quality:**

For the participants with improving energy as their goal (N = 46), their average energy level rating improved from 5.9 (± 1.9) at baseline to 8.3 (± 1) at 90 Days (p < 0.001). Similarly, a significant improvement was observed in the participants who had sleep quality as their goal (26), sleep quality ratings of the participants improved from 6.7 (± 1.8) at baseline to 7.8 (± 1) at 90 Days (p = 0.002) (Table 2).

**DISCUSSION**

Chronic metabolic lifestyle related disorders including diabetes, hypertension, dyslipidemia and obesity are increasing at epidemic proportions. The fallacy of having conquered disease with curative treatment for infectious and tropical diseases, with a strong impetus on pharmaceutical approach to managing chronic lifestyle illness has been detrimental to primary and secondary interventions in managing cardio-metabolic risk factors and the manifold consequences.

Multiple dietary approaches have been designed with varying degrees of impact on the management of type 2 diabetes and dyslipidemia. In a recent meta-analysis evaluating various diets including low-fat, Vegetarian, Mediterranean, high-protein, carbohydrate restricted, low-glycemic index, Palaeolithic diets revealed a reduction in HbA1c (− 0.82% to − 0.47%) and fasting glucose (− 1.61 to − 1.00 mmol/l). But the meta-analysis was limited by heterogeneity in the population studied and varying definitions of the prescribed diet. This lack of standardisation makes it difficult to extrapolate the evidence and hence translation into implementation (Schwingshackl et al., 2018). The Indian population by virtue of ethnicity is at a higher susceptibility to Type 2 diabetes. Further, given the vast socio-cultural variations in the Indian subcontinent, the composition of diet varies significantly. It is important to understand dietary and cultural practices to design appropriate nutrition plans. Furthermore, drastic alterations in the diet are subject to long term loss of adherence, lack of sustainability which defeats the purpose of medical nutrition therapy as a primary management tool (Kirk et al., 2008). Our study demonstrated a high degree of adherence (92%) and corresponding low dropout rate in comparison to the aforementioned dietary interventions.

### Impact on HbA1c, FBS, lipids

Primary cardiovascular indicators include Type 2 Diabetes control and lipid parameters. Our study demonstrated a significant reduction in FBS (118.9 ± 50 mg/dl to 107.7 ± 38.1mg/dl) and HbA1c (6.9% ± 1.6% to 6.4% ± 1%). Similar studies showed comparable reductions in FBS and HbA1C (7.6% to 6.3%). Our study showed an added benefit of reduction in Triglyceride levels (235.4 ± 143.1 mg/dL to 178.3 ± 81.3 mg/dL), Total Cholesterol (237.7 ± 27.4 mg/dL to 209.5 ± 32.5 mg/dL) and LDL cholesterol (142.94 ± 28.9 mg/dl to 129.9 ± 29.1 mg/dl), while a similar study showed an elevation in LDL cholesterol (+ 10%) (Hallberg et al., 2018; Mottalib et al., 2018). A meta-analysis of low carbohydrate diets showed a significant reduction in HbA1C and triglycerides concentration but did not significantly reduce total and LDL cholesterol. Low calorie diets have demonstrated a quick impact on improvement in diabetes, but maintenance of the diet was difficult and hence long-term metabolic goals could not be sustained (Meng et al., 2017).

### Impact on weight, waist circumference, energy levels and sleep quality

Meal replacement diets and meal plans requiring significant alteration of dietary composition have shown significant reduction in body weight (13.5 ± 5.9 kg) over 16 weeks, but the overall drop-out rate was extremely high at 42.3%. Similar attrition (between 35-50%) has been noted in various popular meal plans including Atkins, Ornish, Weight Watchers and Zone. Further, during the maintenance phase, there was a higher resultant rebound weight gain. Though in the short-term, the impact on weight loss and anthropometric measurements was pertinent, it failed to demonstrate an impact on long term weight management (Davis et al., 2010; Meng et al., 2017). Our study demonstrated a significant reduction in body weight (78.9 ± 16.3 kg to 76.2 ± 16.1 kg) as well as waist circumference (39.9 ± 4.6 inches to 37.9 ± 4.7 inches) with adherence and participant satisfaction with the prescribed nutrition plan. This goes on to suggest that on long-term follow up and during maintenance, compliance to the diet plan and stabilisation of body composition is likely to be higher 78.9 (16.3) kg at baseline to 76.2 (16.1) kg at 90 days (p <<0.001 vs. baseline) (Table 2). The participants mean waist circumference (in inches) reduced from 39.9 (4.6) inches at baseline to 37.9 (4.7).

Traditionally, the goals of various nutrition intervention plans have focussed on absolute measures of improvement in obesity, diabetes, cholesterol and hypertension. Energy levels and sleep quality are reflective of the larger holistic goals that indicate an overall improvement in quality of life. There is mounting evidence that a healthy diet promotes good sleep and improves energy levels, with foods which promote tryptophan production and aid serotonin and melatonin metabolism (Chaput, 2014). Most dietary plans focus on a single dietary factor like low energy density, while additive effects of multiple-component modification including fibre, micronutrients are thought to be more beneficial (Roberts et al., 2014). The Sova Health Precision Nutrition program was built to address not only conventional objective outcomes, but also included and demonstrated a significant improvement in sleep quality and energy levels by following a multi-pronged dietary approach. Our study demonstrated a significant improvement in the energy levels 5.9 (± 1.9) to 8.3 (± 1) on a scale of 1-10 as well as sleep quality of the participants 6.7 (± 1.8) to 7.8 (± 1) on a scale of 1-10.

Though our retrospective study over 90 days is of a short-term duration to assess sustainability, easy adaptation to dietary recommendations, good adherence to the prescribed diet are strong indicators of sustainability and the probable success in achieving long-term goals.

The strength of this study lies in the demonstration of significant improvement in metabolic parameters with the Sova Health Precision Nutrition program with engagement of AI powered algorithms with expert nutritionist guidance, meal-wise continual on-going and application-based logging and assessment. Further individualisation based on culturally accepted food, easy to cook and sustain with local produce, tailored to lifestyle habits and encouragement of behavioural modification with constant remote assistance were important measures instituted. The success of the program was demonstrated by the high level of adherence with 70% of participants reaching the second blood test.

The main limitation of the study is the retrospective design and a relatively small number of participants. The duration of the study was limited to 3 months which was not enough to demonstrate long term improvement in metabolic parameters. We look to overcome this in a subsequent prospective trial to study the long-term impact of the Sova Health precision nutrition program on extended metabolic parameters on a large scale.

## CONCLUSION

The Sova Health precision nutrition program has demonstrated a significant role in the improvement and management of metabolic parameters in participants with Type 2 diabetes and dyslipidemia, Furthermore, improvement in anthropometric measures and quality of life was also noted.

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## REFERENCES

1. Chaput, J. P. (2014). Sleep patterns, diet quality and energy balance. Physiology & Behavior, 134(C), 86–91. https://doi.org/10.1016/J.PHYSBEH.2013.09.006
2. Complications of diabetes | Guide to diabetes | Diabetes UK. (n.d.). Retrieved February 22, 2022, from https://www.diabetes.org.uk/guide-to-diabetes/complications
3. Guo, Y., Huang, Z., Sang, D., Gao, Q., & Li, Q. (2020). The Role of Nutrition in the Prevention and Intervention of Type 2 Diabetes. Frontiers in Bioengineering and Biotechnology, 8, 1054. https://doi.org/10.3389/FBIOE.2020.575442/BIBTEX
4. Hallberg, S. J., McKenzie, A. L., Williams, P. T., Bhanpuri, N. H., Peters, A. L., Campbell, W. W., Hazbun, T. L., Volk, B. M., McCarter, J. P., Phinney, S. D., & Volek, J. S. (2018). Effectiveness and Safety of a Novel Care Model for the Management of Type 2 Diabetes at 1 Year: An Open-Label, Non-Randomized, Controlled Study. Diabetes Therapy : Research, Treatment and Education of Diabetes and Related Disorders, 9(2), 583–612. https://doi.org/10.1007/S13300-018-0373-9
5. Kesavadev, J., Krishnan, G., & Mohan, V. (2021). Digital health and diabetes: experience from India: Https://Doi.Org/10.1177/20420188211054676, 12. https:// doi. org/10.1177/20420188211054676
6. Kirk, J. K., Graves, D. E., Craven, T. E., Lipkin, E. W., Austin, M., & Margolis, K. L. (2008). Restricted-carbohydrate diets in participants with type 2 diabetes: a meta-analysis. Journal of the American Dietetic Association, 108(1), 91–100. https:// doi.org/ 10.1016/J.JADA.2007.10.003
7. Kwasnicka, D., Luszczynska, A., Hagger, M. S., Quested, E., Pagoto, S. L., Verboon, P., Robinson, S., Januszewicz, A., Idziak, P., Palacz, I., & Naughton, F. (2020). Theory-based digital intervention to promote weight loss and weight loss maintenance (Choosing Health): protocol for a randomised controlled trial. BMJ Open, 10(11), e040183. https://doi.org/10.1136/BMJOPEN-2020-040183
8. Meng, Y., Bai, H., Wang, S., Li, Z., Wang, Q., & Chen, L. (2017). Efficacy of low carbohydrate diet for type 2 diabetes mellitus management: A systematic review and meta-analysis of randomized controlled trials. Diabetes Research and Clinical Practice, 131, 124–131. https://doi.org/10.1016/J.DIABRES.2017.07.006
9. Pradeepa, R., & Mohan, V. (2021). Epidemiology of type 2 diabetes in India. Indian Journal of Ophthalmology, 69(11), 2932–2938. https://doi.org/ 10.4103/ IJO.IJO 1627 21
10. Roberts, S. B., Urban, L. E., & Das, S. K. (2014). Effects of dietary factors on energy regulation: consideration of multiple- versus single-dietary-factor models. Physiology & Behavior, 134(C), 15–19. https://doi.org/10.1016/J.PHYSBEH.2014.04.024
11. Schwingshackl, L., Chaimani, A., Hoffmann, G., Schwedhelm, C., & Boeing, H. (2018). A network meta-analysis on the comparative efficacy of different dietary approaches on glycaemic control in participants with type 2 diabetes mellitus. European Journal of Epidemiology, 33(2), 157–170. https://doi.org/10.1007/S10654-017-0352-X