Combined effect of Yog-vyayama on different levels of HbA1c in patients with Type 2 Diabetes Mellitus

A Synopsis

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1. INTRODUCTION

1.1 Background of the study:

Clinical structures related to diabetes were identified 3000 years prior to the ancient World. In Ayurveda Diabetes Mellitus is significantly similar to Madhumeha, one of twenty forms of Prameha as described in all Ayurvedic texts.[43] The word "Diabetes" was first discovered by Araetus of Cappodocia (81-133 AD). Later, the term Mellitus (sweet honey) was merged by British physician Thomas Willis in 1675 after reliving the sweet taste of diabetic urine named 'Madhumeha' (honey urine) in Ayurveda.[6] Harold Percival Himsworth first differentiated between type 1 and type 2 diabetes in 1936.[150, 92] Type 2 diabetes mellitus (T2DM) is categorized by autoimmunity of carbohydrate, lipid and protein metabolism, and outcomes from diminished insulin secretion, insulin resistance or a blend of together. [61]

Type 2 diabetes mellitus (T2DM) is a most common metabolic disorder categorized by prolonged hyperglycemia,[90] is caused by combining two primary factors: imperfect insulin secretion through β-cells of pancreas and the failure of insulin-sensitive tissues to respond properly to insulin.[73] A key property of type 2 diabetes mellitus is insulin resistance (IR).[1]

Maximum guidelines follow International Diabetes Federation (IDF), World Health Organization (WHO) and American Diabetes Association (ADA) diagnostic criteria. According to the ADA, "prediabetes" should be identified when the fasting plasma glucose level is between 100–125 mg/dL and the HbA1c value is between 5.7–6.4%. The WHO recommends HbA1c above 6.5% for diabetes.[111, 112]

Urbanization leads to changes of lifestyle for example diet, inactivity, stress, causing increased insulin resistance through sedentary lifestyles. Both active and passive smoking,[111] combined with alcohol consumption and lifestyle risk behaviours, contribute to (Type 2 diabetes Mellitus) T2DM.[97] Over the past few decades, energy intake has gradually increased in developing countries such as India. Evidence from both epidemiologic and experimental studies suggests that Individuals with lower levels of physical activity have a greater chance of becoming diabetes.[87]

The global prevalence of T2DM and Prediabetes has significantly increased in recent decades, with the rate expected to rise due to rising obesity and reduced physical activity levels. Type 2 Diabetes Mellitus (T2DM) is a serious and deteriorating health

problem in humanity. As stated by the International Diabetes Federation's (Diabetes Atlas - 2021b) of, the global diabetes population is estimated to reach 536.6 million in 2021, rising to 642.7million in 2030 and 783.2million in 2045.

For individuals with Type 2 Diabetes, Complementary and Alternative Medicine (CAM) offers promising adjunctive therapies to conventional treatments. CAM approaches such as botanicals, Naturopathy, mind-body practices, Acupuncture, tai chi, Qigong and exercise therapy have shown potential in improving insulin sensitivity, glucose metabolism, and blood sugar control.

The practice of yoga is believed to have originated in the early stages of civilization. Yoga and Vyayama of Ayurveda is the term of Indian origin, while the concept of "Mind-Body Medicine" is essentially the western one. Yoga and Ayurveda are sister sciences that influence each other throughout history, rooted in the Vedic tradition of India. Ayurveda is the science of healing for both body and mind. Yoga is the science of self-realization that signifies the harmonious relationship between mind and body. Both disciplines developed together and have always been used together. [160]

Mind-body medicine focuses on the relationships between the brain, mind, body, and behaviour of an individual in order to promote positive health. Yoga plays a vital role in managing Type 2 Diabetes Mellitus (T2DM) by improving insulin sensitivity, glucose metabolism, and cardiovascular health. Regular yoga practice, including asanas, pranayama, and meditation, reduces stress, anxiety, and inflammation, while enhancing pancreatic beta-cell function and autonomic nervous system balance. Studies show yoga significantly improves glycemic control, reduces HbA1c levels, and promotes weight management. As an adjunct therapy, yoga complements conventional T2DM treatment, improving overall well-being and quality of life. [48, 77, 198]

1.2 Relevance of the study based on research gap:

Despite existing research on the individual benefits of Yoga and Vyayama for patients with type 2 diabetes mellitus, a significant research gap remains in understanding the combined effect of Yog-vyayama on different levels of HbA1c, particularly in relation to specifically structured training regimen having six-month duration of practice. This gap highlights the need for a comprehensive insightful study to investigate the synergistic impact of Yog-vyayama on glycemic control in patients with type 2 diabetes mellitus. Hence this study has been designed to achieve its unsolved queries.

1.3 Aim of the Study:

To investigate the combined effect of Yog-vyayama on glycemic control in patients with type 2 diabetes mellitus, and to determine its efficacy in improving glycemic control across different HbA1c categories.

1.4 Objectives of the study:

The present study was taken into consideration based on the following objectives:

i. To determine the effects of Yog-vyayama on selected anthropometric characteristics, muscular fitness and vitals in patients with T2DM at three different time points.
ii. To assess the impact of Yog-vyayama on glycemic control, insulin resistance and insulin sensitivity in patients with T2DM at three different time points.
iii. To compare the effects of Yog-vyayama in three different groups of HbA1c levels; i.e., 5.7% - 6.4%, 6.5% - 8%, and >8%.

1.5 Hypothesis:

It was hypothesized that –

i. To determine the effects of Yog-vyayama on selected anthropometric characteristics, muscular fitness and vitals in patients with T2DM at three different time points.
ii. To assess the impact of Yog-vyayama on glycemic control, insulin resistance and insulin sensitivity in patients with T2DM at three different time points.
iii. To compare the effects of Yog-vyayama in three different groups of HbA1c levels; i.e., 5.7% - 6.4%, 6.5% - 8%, and >8%.

2. REVIEW OF RELATED LITERATURE

After a thorough literature review with a detailed comprehensive reading of all relevant recorded data, an extensive analysis and in-depth study of the relevant research works were conducted. The present investigator has completed through available books, journals, articles, research papers, and literature by searching the online databases Scopus, PubMed, Web of Science, and the International Clinical Trials Registry Platform (ICTRP). The related research works acquired from the above databases were brought together and duplicates were removed; some inappropriate studies were further screened and excluded by reading the title, abstract, and full manuscripts. After the final calculation, eligible articles that are related to this current study exist in this chapter. The reviews of the literature have been classified under the following headings and meaningful sections arranged in chronological order for better understanding and to justify the study.

The literature review reveals that yoga and vyayama (physical exercise) have a positive impact on Type 2 Diabetes Mellitus (T2DM) management, demonstrating significant reductions in blood glucose levels, HbA1c, and blood pressure, and improvements in insulin sensitivity, cardiovascular health, and stress reduction. Studies show that yoga-based interventions enhance pancreatic beta-cell function, improve glycemic control, and reduce inflammation, while vyayama increases muscle strength, flexibility, and glucose uptake. Combination therapy of yoga and vyayama yields better outcomes than either alone, highlighting the potential for these complementary therapies to augment conventional T2DM treatments. However, limitations include variability in study designs, small sample sizes, and inconsistent protocols, underscoring the need for standardized interventions and further investigation into molecular mechanisms and long-term adherence.

3. METHODOLOGY

3.1 Study Location with Laboratory setup:

The present study was Carried out in the exercise and sports physiology laboratory and Yoga Centre, Dept. of physical education, Jadavpur University, Kolkata, India. A "Yog-vyayama Camp" was organized jointly by the researcher, Jadavpur University Yoga Centre and Health Centre of Jadavpur University. Practice areas of Yog-vyayama Camp were Yoga Centre, Small Area Games Arena and Open-Air Theatre (OAT) in the premises of Jadavpur University.

3.2 Participants:

3.2.1 Targeted Population:

In the present study, an interested elderly population with pre-diabetes and type 2 diabetes mellitus patients were considered as subjects of the study for this research work.

3.2.2 Sample Size:

The sample size calculated using G*Power software was 54. Sample size was arrived at considering a power (1-β = 0.95), (α = 0.05) and effect size (d = 0.25), from a research study conducted at Jadavpur University.

3.2.3 Selection of subjects:

Initially 162 subjects from a total 230 registered participants of both gender, ages ranging from 40 to 70 years from both genders (Male:75, Female:87), having no prior regular practice of yogic exercise were selected for this study. All participants were near Jadavpur area and other areas around Kolkata, West Bengal, India.

3.3 Enrolment of subjects and follow up scheduled:

A total of 230 registered members were assessed and 47 members excluded from the study as they did not meet the inclusion criteria; 21 members were denied participation in the study. The remaining members recruited for the study are 162 members. These 162 members were purposively divided into three groups these are Group: A (Pre-diabetes - HbA1c Level 5.7% to 6.4%) n=51 (M-24, F-37) did not take any oral hypoglycaemic agent or insulin, Group: B (T2DM Stage 1 - HbA1c Level 6.5% to 8%) n=54 (M-24, F-30) with taking oral hypoglycaemic agent and Group: C (T2DM Stage 2 - HbA1c Level > 8%) n=57 (M-27, F-30) with taking oral hypoglycaemic. Baseline measurements were done before the start the Yog-vyayama intervention, after 3 months intervention total 22 members

dropped out; finally, after six months intervention total 31 members dropped out from the study. Therefore, data analysis was done for all the participants' n=109 that is illustrated in figure-1.

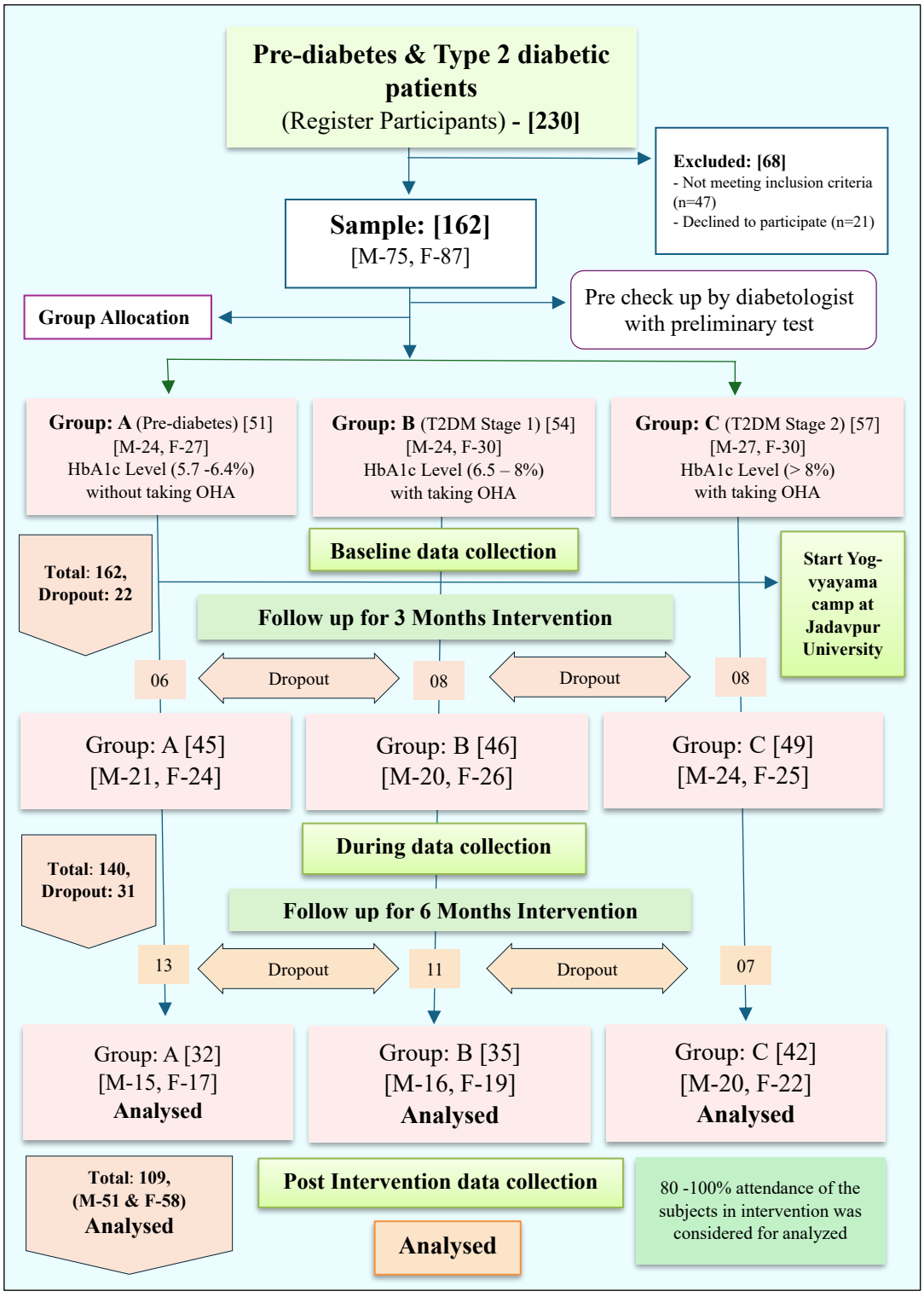

Figure 1: Enrolment of Subjects and Follow up scheduled

3.4 Ethical Consideration

- This present study followed the ICMR prescribe Ethical guidelines (Last accessed on 28th April 2020)[132]
- Individual consent was taken from each subject according to ICMR guideline of ICMR Common Forms for Ethics Review. (Last accessed on 28th April 2020)[91]
- This clinical trial was approved by the Institutional Ethics Committee (IEC) of Jadavpur University (Reference No: IEC/27/C/23 dated 06.07.2023). **(Annexure 2)**
- This clinical trial was further registered at the Clinical Trial Registry of India (Trial Registration No: CTRI/2024/08/072487). **(Annexure 2)**

3.5 Variables with Criterion measure:

Table 1 Criterion measure of selected variables with unit.

Sl. No.	Variables	Measured by	Unit
1	Age	Age proof ID card	Year
2	Weight	Digital Weighing Machine	kg
3	Height	Stadiometer	cm
4	BMI	Weight in kg/Height in m2	kg/m2
5	Waist circumference	Anthropometric tape	cm
6	Hip circumference	Anthropometric tape	cm
7	Grip strength	Digital Grip dynamometer	kg
8	Trunk Flexibility	Sit and reach test box	cm
9	Heart rate	Patient Monitoring Device (Nasan PARA 1005, 12.1" Multipara Monitor)	b/m
10	Systolic blood pressure		mm/Hg
11	Diastolic blood pressure		mm/Hg
12	Pulse oximeter (SpO_2)		%
13	Fasting plasma glucose (FPG)	Semi Auto Biochemistry Analyzer [2, 3] (AGD 2020 Clinical Chemistry Analyzer)	mg/dL
14	HbA1c		%
15	Fasting Insulin	Elisa machine (BeneSphera™ E-21, ELISA microplate reader)	µIU/mL
16	Insulin Resistance	HOMA IR formula[121] [Fasting insulin (µU/ml) × Fasting glucose (mmol/l) / 22.5]	µU/mL x mmol/L
17	Insulin Sensitivity	QUICKI Formula[104] 1 / [log (Fasting Insulin in µU/mL) + log (Fasting Glucose in mg/dL)]	-

3.7 Details of Intervention: (Yog-vyayama Training Protocol)

The Yog-vayayama intervention regimen was designed specifically for the individuals' health and physical circumstances. All included participants took part in a specific Yog-vyayama intervention. This intervention included prayer, Yogic Suksma Vyayama, Surya namaskara, brisk walking, dynamic stretching and deep breathing, asana, kriya, pranayama, and meditation. Certified yoga trainers took the classes of Yog-vayayama and they recorded regular attendance. Detailed yogic practices are set in

accordance with the demands of science of yoga to fulfil the purposes of the study. The principles of "Holistic approach of Yogic science", were considered in the present study. 50-75 minutes (200-280 minutes per week) per day and four (4) days per week for six (6) months of structured Yog-vyayama intervention modules were considered in this current study. The method of progressive training load was applied in the arrangement of duration, intensity, repetitions, volume from 1st month to 6th months of schedule that is illustrated in table 8 to 14. [44, 45]

Table 2: Outlook of Structured Yog-vyayama Module	
1	**Initial Prayer:** oṃ saha nāvavatu । saha nau bhunaktu । saha vīryaṃ karavāvahai । tejasvi nāvadhītamastu mā vidviṣāvahai ।oṃ śāntiḥ śāntiḥ śāntiḥ ॥
2	**Yogic Suksma Vyayama:** Tatha Dhrti-Sakti-Vikasaka, Medha Sakti-Vikasaka-1, Griva-Sakthi-Vikasaka-1, Griva-Sakthi-Vikasaka-2, Griva-Sakthi-Vikasaka-3, Mani-Bandha-Sakthi-Vikasaka, Kara-Tala-Sakti-Vikasaka, Anguli-Sakti-Vikasaka, Vaksha-Sthala-Sakti-Vikasaka-1, Kati-Sakti-Vikasaka-1, Kati-Sakti-Vikasaka-3, Kati-Sakti-Vikasaka-4, Kati-Sakti-Vikasaka-5, Jangha-Sakti-Vikasaka-2, Janu-Sakthi-Vikasaka, Pada-Mula-Sakti, Gulpha-Pada-Prstha-Pada-Tala-Sakti-Vikasaka.
3	**Surya Namaskara:** 1.Pranamasana; 2.Hasta utthanasana; 3.Pada hastasana; 4.Ashwasanchalanasana; 5.Parvatasana; 6.Ashtanga namaskara; 7.Bhujangasana; 8.Parvatasana; 9.Ashwasanchalanasana; 10.Pada hastasana; 11.Hasta utthanasana; 12.Pranamasana.
4	**Brisk Walking:** 80-100 steps/min.
5	**Recovery** (Slow Walking with dynamic stretching and deep breathing).
6	**Asanas:** Vakrasana, Uttanapadasana, Ardha Halasana, Pavanmuktasana, Setubandhasana, Makarasana, Parivrtta Trikonasana, Bhujangasana, Salvasana and Savasana.
7	**Kriya:** Kapalbhati. **Pranayamas**: Nadisodhan, Bhastrika and Bhramari.
8	**A – U – M** Meditation / chanting or complete Aum
9.	**Closing Prayer:** Oṃ sarve bhavantu sukhinaḥ sarve santu nirāmayāḥ| sarve bhadrāṇi paśyantu mā kaścidduḥkhabhāg bhavet||

3.10 Statistical Analysis

In the present study, G*Power statistical software was used to determine the sample size. To ensure the authenticity and accuracy of the result of parametric tests, a normality test was conducted to examine the normal distribution of the data. Here Shapiro–Wilk normality test was applied to know the normal form of the sample population. [9, 123] The subjects' basic characteristics were summarised using descriptive statistics such as mean and standard deviation. The statistical analysis was conducted using the Statistical Package for Social Sciences (SPSS) for Windows version 20.0 computer program. In the present study the Repeated measures analysis of variance (RM ANOVA) was used for significant differences between the assessments, that is, at baseline (pre-test), after three months (mid-test), and after six months (post-test), and this was a within subjects' factor represented by time, followed by Post hoc analysis with Bonferroni adjustment to determine which of the paired means difference was significant at 0.05 level of significance. Percentage changes were calculated to establish the effect or outcomes of treatment on both male and female of every group of the study.

4. RESULTS AND DISCUSSION:

4.1 Results:

Table 3: Baseline Characteristics of Study Participants.

Characteristics (Mean ± SD)	**Group A** (Pre-Diabetes) **n=32**		**Group B** (T2DM stage 1) **n=35**		**Group C** (T2DM stage 2) **n=42**	
Gander (%)	Male (46.88%)	Female (53.12%)	Male (45.71%)	Female (54.29%)	Male (47.62%)	Female (52.38%)
Age (y)	61.53±6.20	56.82±7.367	64.13±7.22	55.89±7.07	58.00±9.36	53.86±8.89
40 – 50	2	4	2	7	6	8
>50 – 60	4	7	3	6	4	9
>60 – 70	9	6	11	6	10	5
Total	15	17	16	19	20	22
Weight (kg)	69.13±7.32	59.76±8.057	64.13±7.22	65.74±8.20	70.00±11.18	64.57±9.59
Height (cm)	168.00±2.98	150.41±5.112	169.88±4.62	153.11±4.58	166.10±5.31	154.59±5.44
BMI (kg/m2)	24.48±2.47	26.44±3.64	25.46±2.53	28.07±3.53	25.28±3.21	27.03±3.85
Waist circumference (cm)	94.33±7.07	97.00±7.84	97.75±6.70	103.26±9.72	99.60±10.15	102.00±9.28
Hip circumference (cm)	96.67±3.48	101.41±9.33	97.50±3.58	104.84±7.65	97.05±6.04	101.23±8.64
Left Grip Strength (kg)	29.40±6.10	16.55±3.17	25.27±7.10	16.32±3.38	25.09±6.10	16.27±3.99
Right Grip Strength (kg)	31.77±7.59	17.04±4.23	25.91±7.17	18.46±2.85	27.64±7.51	18.58±4.64
Flexibility (cm)	15.60±5.29	25.50±6.65	19.83±6.15	22.00±4.89	19.65±10.97	19.32±4.24
Heart Rate (b/m)	69.33±5.73	85.18±8.37	77.88±6.66	84.74±9.72	82.05±13.16	84.18±10.96
Systolic Blood Pressure (mm/Hg)	136.60±14.36	144.53±21.66	144.13±13.86	143.58±16.54	141.35±18.33	136.45±13.84
Diastolic Blood Pressure (mm/Hg)	76.47±8.32	83.47±9.52	84.81±6.48	79.58±7.32	81.80±8.97	79.82±6.46
SpO_2 (%)	97.93±0.96	97.65±1.17	97.44±0.96	97.16±1.12	97.90±1.07	97.77±1.02
Fasting Plasma Glucose (mg/dL)	120.35±12.54	114.69±8.05	146.52±19.40	140.18±18.69	185.56±45.07	199.10±53.75
HbA1c (%)	6.28±0.30	6.15±0.24	7.40±0.45	7.35±0.41	11.03±2.33	10.55±1.78
Fasting Insulin (µIU/mL)	19.08±5.81	23.49±8.61	29.18±8.71	28.97±6.90	33.93±9.72	34.60±8.19
Insulin Resistance (µU/mL x mmol/L)	5.76±2.18	6.60±2.35	10.50±3.47	10.04±2.97	16.06±7.62	17.29±7.19
Insulin Sensitivity	0.30±0.01	0.29±0.01	0.28±0.01	0.28±0.01	0.27±0.01	0.26±0.01

4.1.1 Results of Normality Tests:

Normality tests were used before parametric tests to examine the normal distribution of the data by ensuring that the data meets the assumptions of the statistical test. Shapiro-Wilk test is the most popular normality test, especially for smaller (<50) sample sizes. It revealed a significant deviation from normality ($p < 0.05$), indicating that the data is not normally distributed. Here the present researcher used the Shapiro-Wilk test to assess data of all variables of the entire group where baseline scores of male and female indicate that all variables had no significant difference ($p>0.05$) which assesses whether the data follows a normal distribution.

4.1.2 Results of Anthropometric and Physical Variables:

Table 4: Repeated Measure ANOVA with mean and SD of Anthropometric and physical variables of each group.

Variables	Groups	Male							Female						
		Pre (Mean± SD)	(Mid (Mean± SD)	Post (Mean± SD)	df	F	Sig	η_p^2	Pre (Mean± SD)	Mid (Mean± SD)	Post (Mean± SD)	df	F	Sig	η_p^2
BMI (kg/m2)	Pre-Diabetes [n=15(m), 17(f)]	24.48± 2.47	23.73± 2.35	23.11± 2.37	2, 28	56.680*	.000	.802	26.44± 3.64	25.71± 3.72	24.74± 3.53	2, 28	39.813*	.000	.713
	T2DM stage 1 [n=16(m), 19(f)]	25.46± 2.53	24.85± 2.69	24.33± 2.93	2, 30	47.675*	.000	.761	28.07± 3.53	27.48± 3.55	26.77± 3.51	2, 30	152.422*	.000	.894
	T2DM stage 2 [n=20(m), 22(f)]	25.28± 3.21	24.84± 2.98	24.72± 2.83	2, 38	2.862	.070	.131	27.03± 3.85	26.51± 3.82	25.59± 3.80	2, 38	42.500*	.000	.669
Waist circumference (cm)	Pre-Diabetes [n=15(m), 17(f)]	94.33± 7.07	91.47± 5.50	88.87± 5.85	2, 32	51.462*	.000	.786	97.00± 7.84	93.53± 7.09	89.12± 6.59	2, 32	27.986*	.000	.636
	T2DM stage 1 [n=16(m), 19(f)]	97.75± 6.70	95.00± 6.48	91.69± 5.97	2, 36	46.826*	.000	.757	103.26± 9.72	99.58± 9.17	96.32± 9.35	2, 36	117.638*	.000	.867
	T2DM stage 2 [n=20(m), 22(f)]	99.60± 10.15	96.15± 9.33	90.70± 11.12	2, 42	37.764*	.000	.665	102.00± 9.28	98.36± 9.38	95.27± 9.07	2, 42	69.038*	.000	.767
Hip circumference (cm)	Pre-Diabetes [n=15(m), 17(f)]	96.67± 3.48	92.93± 4.43	90.67± 4.56	2, 28	49.455*	.000	.779	101.41± 9.33	98.53± 9.11	95.29± 7.48	2, 28	48.592*	.000	.752
	T2DM stage 1 [n=16(m), 19(f)]	97.50± 3.58	95.25± 3.15	92.13± 2.80	2, 30	66.199*	.000	.815	104.84± 7.65	102.37± 7.31	98.47± 7.39	2, 30	72.201*	.000	.800
	T2DM stage 2 [n=20(m), 22(f)]	97.05± 6.04	96.10± 6.45	92.20± 5.67	2, 38	60.903*	.000	.762	101.23± 8.64	98.68± 7.95	96.23± 7.87	2, 38	67.973*	.000	.764
Left Grip Strength (kg)	Pre-Diabetes [n=15(m), 17(f)]	29.40± 6.10	30.86± 5.60	37.29± 5.71	2, 32	51.179*	.000	.785	16.55± 3.17	20.36± 2.44	24.66± 5.74	2, 32	17.671*	.000	.525
	T2DM stage 1 [n=16(m), 19(f)]	25.27± 7.10	29.32± 6.41	34.43± 7.15	2, 36	18.748*	.000	.556	16.32± 3.38	19.97± 3.31	23.15± 4.10	2, 36	35.970*	.000	.666
	T2DM stage 2 [n=20(m), 22(f)]	25.09± 6.10	29.06± 7.11	32.49± 5.49	2, 42	36.492*	.000	.658	16.27± 3.99	20.64± 4.75	24.04± 3.82	2, 42	111.302*	.000	.841
Right Grip Strength (kg)	Pre-Diabetes [n=15(m), 17(f)]	31.77± 7.59	34.52± 8.54	38.85± 6.87	2, 28	20.078*	.000	.589	17.04± 4.23	20.25± 2.97	23.41± 5.36	2, 28	16.586*	.000	.509
	T2DM stage 1 [n=16(m), 19(f)]	25.91± 7.17	30.56± 6.43	34.58± 8.37	2, 30	36.176*	.000	.707	18.46± 2.85	20.34± 3.00	22.51± 3.10	2, 30	31.960*	.000	.640
	T2DM stage 2 [n=20(m), 22(f)]	27.64± 7.51	30.76± 6.15	34.88± 5.94	2, 38	60.063*	.000	.760	18.58± 4.64	21.98± 5.03	23.76± 4.42	2, 38	89.086*	.000	.809
Flexibility (cm)	Pre-Diabetes [n=15(m), 17(f)]	15.60± 5.29	21.30± 7.65	26.17± 7.65	2, 32	60.239*	.000	.811	25.50± 6.65	32.62± 5.87	34.12± 5.03	2, 32	27.119*	.000	.629
	T2DM stage 1 [n=16(m), 19(f)]	19.83± 6.15	24.50± 6.82	29.09± 5.77	2, 36	86.181*	.000	.852	22.00± 4.89	31.92± 6.81	33.84± 6.86	2, 36	80.331*	.000	.817
	T2DM stage 2 [n=20(m), 22(f)]	19.65± 10.97	24.10± 10.60	24.48± 8.88	2, 42	15.502*	.000	.449	19.32± 4.24	28.05± 7.19	30.55± 6.99	2, 42	127.274*	.000	.858

* p-value ≤ 0.05 indicates the significant changes
Note: η_p^2 = partial eta square (effect size)

Table 5: percentage interchanges within time points (Pre, Mid & Post) of anthropometric and physical variables

Variables	Groups	Male			Female		
		Pre to Mid (% of First three months)	Mid to Post (% of Last three months)	Pre to Post (% of Six Months)	Pre to Mid (% of First three months)	Mid to Post (% of Last three months)	Pre to Post (% of Six Months)
BMI (kg/m2)	Pre-Diabetes [n=15(m), 17(f)]	3.07	2.64	5.62	2.82	3.72	6.45
	T2DM stage 1 [n=16(m), 19(f)]	2.46	2.21	4.60	2.12	2.61	4.67
	T2DM stage 2 [n=20(m), 22(f)]	1.64	0.35	1.91	1.95	3.51	5.38
Waist circumference (cm)	Pre-Diabetes [n=15(m), 17(f)]	2.93	2.86	5.73	3.50	4.61	7.92
	T2DM stage 1 [n=16(m), 19(f)]	2.79	3.45	6.14	3.54	3.30	6.73
	T2DM stage 2 [n=20(m), 22(f)]	3.37	5.83	8.94	3.56	3.13	6.58
Hip circumference (cm)	Pre-Diabetes [n=15(m), 17(f)]	3.87	2.45	6.21	2.83	3.16	5.90
	T2DM stage 1 [n=16(m), 19(f)]	2.28	3.26	5.47	2.34	3.79	6.06
	T2DM stage 2 [n=20(m), 22(f)]	0.98	4.01	4.97	2.46	2.49	4.89
Left Grip Strength (kg)	Pre-Diabetes [n=15(m), 17(f)]	6.31	21.77	29.36	26.59	21.60	56.41
	T2DM stage 1 [n=16(m), 19(f)]	21.89	18.46	46.39	25.03	16.73	47.57
	T2DM stage 2 [n=20(m), 22(f)]	16.45	15.27	33.61	28.48	18.78	51.83
Right Grip Strength (kg)	Pre-Diabetes [n=15(m), 17(f)]	9.28	14.89	25.31	23.60	16.47	42.69
	T2DM stage 1 [n=16(m), 19(f)]	22.84	12.67	37.77	10.55	11.39	23.24
	T2DM stage 2 [n=20(m), 22(f)]	14.78	14.26	31.55	19.93	9.33	31.01
Flexibility (cm)	Pre-Diabetes [n=15(m), 17(f)]	37.70	25.58	72.66	33.46	5.90	42.24
	T2DM stage 1 [n=16(m), 19(f)]	25.75	21.04	53.45	46.34	7.08	57.06
	T2DM stage 2 [n=20(m), 22(f)]	39.36	9.83	56.82	44.84	9.92	59.18

4.1.3 Results of Physiological Variables:

Table 6: Repeated Measure ANOVA of Physiological variables of individual group.

Variables	Groups	Male							Female						
		Pre (Mean± SD)	(Mid (Mean± SD)	Post (Mean± SD)	df	F	Sig (P value)	η_p^2	Pre (Mean± SD)	(Mid (Mean± SD)	Post (Mean± SD)	df	F	Sig (P value)	η_p^2
Heart Rate (b/m)	Pre-Diabetes [n=15(m), 17(f)]	69.33± 5.73	64.87± 7.59	63.27± 6.30	2, 28	9.639*	.006	.408	85.18± 8.37	79.88± 12.82	75.41± 10.74	2, 28	14.535*	.000	.476
	T2DM stage 1 [n=16(m), 19(f)]	77.88± 6.66	75.13± 4.38	70.94± 8.52	2, 30	13.473*	.000	.473	84.74± 9.72	78.05± 9.17	72.47± 7.70	2, 30	36.864*	.000	.672
	T2DM stage 2 [n=20(m), 22(f)]	82.05± 13.16	81.00± 12.99	75.70± 14.21	2, 38	3.636*	.036	.161	84.18± 10.96	79.41± 10.95	73.77± 7.35	2, 38	18.221*	.000	.465
Systolic Blood Pressure (mm/Hg)	Pre-Diabetes [n=15(m), 17(f)]	136.60± 14.36	124.67± 5.72	125.47± 9.55	2, 32	9.579*	.003	.406	144.53 21.66	132.94± 14.74	128.29± 16.09	2, 32	12.333*	.002	.435
	T2DM stage 1 [n=16(m), 19(f)]	144.13± 13.86	136.38± 11.95	130.13± 11.77	2, 36	7.714*	.002	.340	143.58± 16.54	135.11± 15.91	129.26± 12.24	2, 36	19.015*	.000	.514
	T2DM stage 2 [n=20(m), 22(f)]	141.35± 18.33	128.80± 13.80	130.7± 11.06	2, 42	12.111*	.001	.389	136.45± 13.84	131.91± 16.70	130.6± 12.97	2, 42	2.358	.122	.101
Diastolic Blood Pressure (mm/Hg)	Pre-Diabetes [n=15(m), 17(f)]	76.47± 8.32	71.80± 6.60	74.93± 6.42	2, 28	2.842	.075	.169	83.47± 9.52	78.24± 6.39	77.18± 6.01	2, 28	3.694*	.036	.188
	T2DM stage 1 [n=16(m), 19(f)]	84.81± 6.48	78.88± 6.94	75.88± 5.83	2, 30	12.383*	.000	.452	79.58± 7.32	76.16± 5.20	75.11± 6.69	2, 30	3.879*	.039	.177
	T2DM stage 2 [n=20(m), 22(f)]	81.80± 8.97	77.30± 8.96	74.85± 9.43	2, 38	7.442*	.005	.281	79.82± 6.46	74.50± 7.96	74.05± 7.05	2, 38	9.971*	.000	.322
SpO_2 (%)	Pre-Diabetes [n=15(m), 17(f)]	97.93± 0.96	98.13± 0.74	98.47± 0.64	2, 32	4.261*	.024	.233	97.65± 1.17	97.71± 0.77	98.41± 0.62	2, 32	13.727*	.000	.462
	T2DM stage 1 [n=16(m), 19(f)]	97.44± 0.96	97.56± 0.81	98.13± 0.62	2, 36	8.351*	.001	.358	97.16± 1.12	97.63± 0.68	98.42± 0.61	2, 36	22.235*	.000	.553
	T2DM stage 2 [n=20(m), 22(f)]	97.90± 1.07	97.95± 0.76	98.30± 0.66	2, 42	4.857	.020	.204	97.77± 1.02	97.86± 0.89	98.23± 0.61	2, 42	3.615	.036	.147

Note: η_p^2 = partial eta square (effect size)

* p-value ≤ 0.05 indicates the significant changes

Table 42: percentage interchanges within time points (Pre, Mid & Post) of Physiological variables							
Variables	Groups	Male			Female		
		Pre to Mid (% of First three months)	Mid to Post (% of Last three months)	Pre to Post (% of Six Months)	Pre to Mid (% of First three months)	Mid to Post (% of Last three months)	Pre to Post (% of Six Months)
Heart Rate (b/m)	Pre-Diabetes [n=15(m), 17(f)]	6.22	2.23	8.55	6.40	5.09	11.42
	T2DM stage 1 [n=16(m), 19(f)]	3.17	5.68	9.05	7.58	6.94	14.11
	T2DM stage 2 [n=20(m), 22(f)]	0.46	5.69	7.46	5.24	6.38	11.71
Systolic Blood Pressure (mm/Hg)	Pre-Diabetes [n=15(m), 17(f)]	7.89	0.62	7.53	7.17	3.51	10.15
	T2DM stage 1 [n=16(m), 19(f)]	4.89	4.09	9.15	5.84	3.78	9.49
	T2DM stage 2 [n=20(m), 22(f)]	8.27	1.82	6.61	2.90	0.40	3.91
Diastolic Blood Pressure (mm/Hg)	Pre-Diabetes [n=15(m), 17(f)]	5.47	4.93	1.42	5.25	0.76	6.54
	T2DM stage 1 [n=16(m), 19(f)]	6.80	3.34	10.09	3.78	1.26	5.06
	T2DM stage 2 [n=20(m), 22(f)]	4.95	3.08	8.11	6.50	0.08	7.02
SpO_2 (%)	Pre-Diabetes [n=15(m), 17(f)]	0.21	0.34	0.55	0.07	0.72	0.79
	T2DM stage 1 [n=16(m), 19(f)]	0.13	0.58	0.71	0.49	0.81	1.31
	T2DM stage 2 [n=20(m), 22(f)]	0.06	0.36	0.41	0.10	0.38	0.47

4.1.4 Results of Glycemic control:

	Table 43: Repeated Measure ANOVA of Fasting Plasma Glucose level (mg/dL) of individual group.								
	Groups		Pre (Mean± SD)	Mid (Mean± SD)	Post (Mean± SD)	df	F	Sig. (P–value)	η_p^2
FBG	Male	Pre-Diabetes (n=15)	120.35±12.54	112.47±13.71	104.06±10.37	2, 28	69.076	.000	.831
		T2DM stage 1 (n=16)	146.52±19.40	126.31±10.42	118.59±7.99	2, 30	28.446	.000	.655
		T2DM stage 2 (n=20)	185.56±45.07	158.85±39.05	134.3±32.26	2, 38	42.026	.000	.689
	Female	Pre-Diabetes (n=17)	114.69±8.05	101.20±13.52	96.08±9.87	2, 32	27.739	.000	.634
		T2DM stage 1 (n=19)	140.18±18.69	123.68±18.14	110.15±15.44	2, 36	73.746	.000	.804
		T2DM stage 2 (n=22)	199.10±53.75	159.83±47.45	131.10±29.84	2, 42	46.693	.000	.690
HbA1c	Male	Pre-Diabetes (n=15)	**6.28±0.30**	**5.41±1.54**	**5.38±0.33**	2, 28	5.189	.036	.270
		T2DM stage 1 (n=16)	**7.40±0.45**	**6.81±0.52**	**6.00±0.70**	2, 30	72.109	.000	.828
		T2DM stage 2 (n=20)	**11.03±2.33**	**9.33±2.23**	**7.73±1.72**	2, 38	56.770	.000	.749
	Female	Pre-Diabetes (n=17)	**6.15±0.24**	**5.83±0.39**	**5.37±0.41**	2, 32	66.855	.000	.807
		T2DM stage 1 (n=19)	**7.35±0.41**	**6.67±0.47**	**6.25±0.63**	2, 36	45.284	.000	.716
		T2DM stage 2 (n=22)	**10.55±1.78**	**9.37±1.82**	**7.96±1.35**	2, 42	42.004	.000	.667
Fasting Insulin	**Male**	Pre-Diabetes (n=15)	**19.08± 5.81**	**14.31±3.68**	**10.01± 4.99**	2, 28	66.327	.000	.826
		T2DM stage 1 (n=16)	**29.18± 8.71**	**19.43±8.21**	**13.87± 6.31**	2, 30	58.578	.000	.796
		T2DM stage 2 (n=20)	**33.93± 9.72**	**19.5±7.51**	**13.08± 6.28**	2, 38	106.499	.000	.849
	Female	Pre-Diabetes (n=17)	**23.49± 8.61**	**14.46±4.09**	**10.02± 2.65**	2, 32	41.090	.000	.720
		T2DM stage 1 (n=19)	**28.97± 6.90**	**18.48±6.77**	**13.53± 6.94**	2, 36	110.594	.000	.860
		T2DM stage 2 (n=22)	**34.60± 8.19**	**20.0±7.11**	**13.23± 5.19**	2, 42	112.586	.000	.843
Insulin Resistance	**Male**	Pre-Diabetes (n=15)	5.76± 2.18	4.00±1.23	2.58± 1.38	2, 28	65.299	.000	.823
		T2DM stage 1 (n=16)	10.50± 3.47	6.03±2.54	4.08± 1.92	2, 30	60.056	.000	.800
		T2DM stage 2 (n=20)	16.06± 7.62	8.19±5.62	4.70± 3.91	2, 38	74.594	.000	.797
	Female	Pre-Diabetes (n=17)	6.60± 2.35	3.60±1.06	2.36± 0.60	2, 32	49.128	.000	.754
		T2DM stage 1 (n=19)	10.04± 2.97	5.68±2.44	3.70± 2.07	2, 36	153.807	.000	.895
		T2DM stage 2 (n=22)	17.29± 7.19	8.03±4.36	7.69± 16.43	2, 42	7.864	.008	.272
Insulin Sensitivity	Male	Pre-Diabetes (n=15)	0.30±0.01	0.31±0.01	0.34±0.03	2, 28	45.052	.000	.763
		T2DM stage 1 (n=16)	0.28±0.01	0.30±0.02	0.32±0.03	2, 30	53.943	.000	.782
		T2DM stage 2 (n=20)	0.27±0.01	0.29±0.02	0.31±0.02	2, 38	113.700	.000	.857
	Female	Pre-Diabetes (n=17)	0.29±0.01	0.32±0.01	0.34±0.01	2, 32	97.478	.000	.859
		T2DM stage 1 (n=19)	0.28±0.01	0.30±0.02	0.32±0.02	2, 36	83.550	.000	.823
		T2DM stage 2 (n=22)	0.26±0.01	0.29±0.02	0.31±0.03	2, 42	62.453	.000	.748
	Note: η_p^2 = partial eta square (effect size)								

Table 46: percentage interchanges within time points (Pre, Mid & Post) of Fasting Plasma Glucose levels (mg/dL)					
	Groups		Pre to Mid [First three months] (%)	Mid to Post [Last three month] (%)	Pre to Post [Six Months] (%)
FBG	Male	Pre-Diabetes (A) (n=15)	6.65	7.18	13.40
		T2DM stage 1 (B) (n=16)	12.87	5.85	18.11
		T2DM stage 2 (C) (n=20)	13.76	14.05	25.86
	Female	Pre-Diabetes (A) (n=17)	11.94	3.86	16.06
		T2DM stage 1 (B) (n=19)	11.71	10.62	21.14
		T2DM stage 2 (C) (n=22)	18.97	15.71	32.64
HbA1c	**Male**	Pre-Diabetes (A) (n=15)	7.78	6.90	14.17
		T2DM stage 1 (B) (n=16)	7.90	11.98	19.14
		T2DM stage 2 (C) (n=20)	15.00	16.49	29.08
	Female	Pre-Diabetes (A) (n=17)	5.12	7.99	12.68
		T2DM stage 1 (B) (n=19)	9.09	6.30	14.74
		T2DM stage 2 (C) (n=22)	10.61	14.41	23.61
Fasting Insulin	**Male**	Pre-Diabetes (A) (n=15)	23.51	32.31	49.10
		T2DM stage 1 (B) (n=16)	34.27	28.90	53.34
		T2DM stage 2 (C) (n=20)	42.44	32.38	61.20
	Female	Pre-Diabetes (A) (n=17)	33.78	29.27	54.65
		T2DM stage 1 (B) (n=19)	36.66	28.35	58.60
		T2DM stage 2 (C) (n=22)	41.80	31.52	61.19
Insulin Resistance	Male	Pre-Diabetes (A) (n=15)	28.57	37.02	56.15
		T2DM stage 1 (B) (n=16)	42.49	33.14	61.47
		T2DM stage 2 (C) (n=20)	50.19	41.44	70.97
	Female	Pre-Diabetes (A) (n=17)	41.20	31.98	61.99
		T2DM stage 1 (B) (n=19)	43.91	36.29	63.79
		T2DM stage 2 (C) (n=22)	52.48	41.58	73.75
Insulin Sensitivity	Male	Pre-Diabetes (A) (n=15)	4.72	8.10	13.13
		T2DM stage 1 (B) (n=16)	8.30	5.84	14.65
		T2DM stage 2 (C) (n=20)	9.33	8.20	18.28
	Female	Pre-Diabetes (A) (n=17)	8.25	6.10	14.73
		T2DM stage 1 (B) (n=19)	8.11	6.96	15.67
		T2DM stage 2 (C) (n=22)	10.16	8.71	19.64

4.2 Discussion

Positive benefits of Yoga may be transmitted via neurohormonal pathways, lowering stress and anxiety while increasing autonomic balance towards parasympathetic activity. Furthermore, insulin receptor-expressing regions of the hypothalamus and striatum, as well as the amygdala, hippocampus, and prefrontal cortex, have a role in the pathophysiology of illness disorders affecting mood and behaviour.[109] Yoga may improve quality of life and well-being by establishing correct insulin signalling in these regions, which regulates dopaminergic and serotonin neural pathways that increase mood and behaviour. [108]

The most significant factor in lowering the likelihood of chronic Diabetes Mellitus complications is improved glycemic control. Home-based resistance tube training may help lower FBS and HbA1c levels in aged T2DM patients.[139] Elastic-band resistance exercise may lower FBS, HbA1c, and fasting insulin levels in Type 2 Diabetes Mellitus patients.[145] Yogic exercise increases blood flow to muscles, which improves insulin receptor expression and lowers blood sugar. Yoga decreases insulin resistance while increasing insulin receptors, resulting in changes in peak insulin levels.[182]

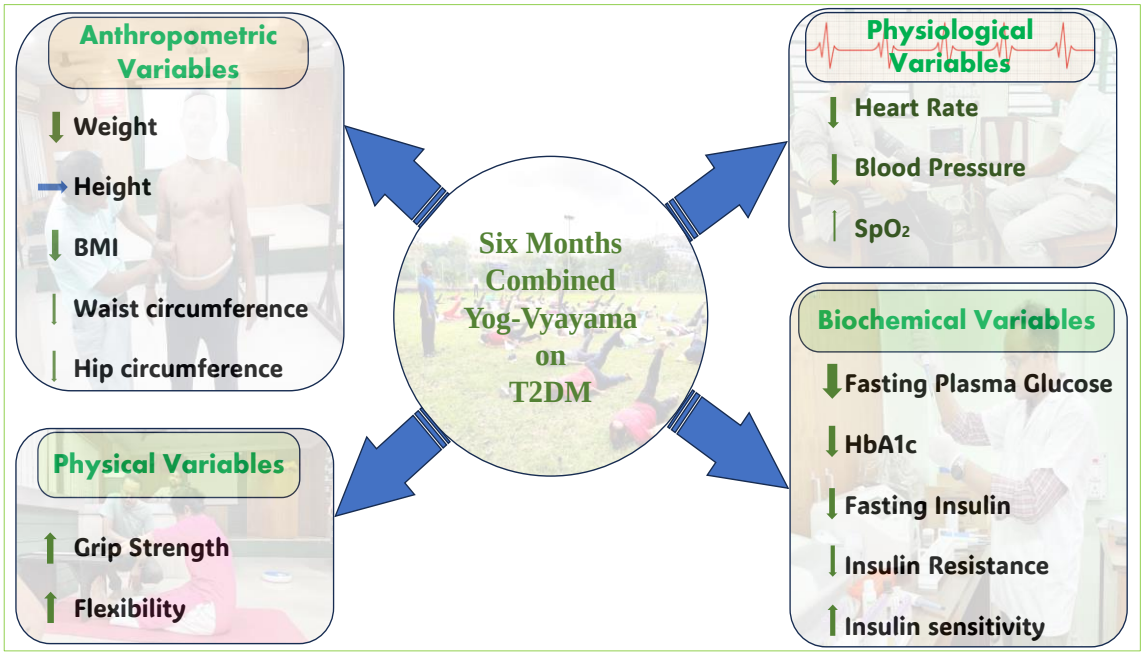

Figure 2: Effect of six months Yog-vyayama on T2DM

Within the limitations of the study, the researcher would like to present the prospective mechanisms of yoga for improving glycemic control and insulin resistance of type 2 diabetes patients after regular graded combined Yog-vyayama practices for 24 weeks. Mind and body are not separate entity in yoga. The practice of Kriya, Suryanamaskara and Asana (physical level), Pranayama (psychophysiological level), and Meditation (psychoneurological level) integrate and harmonise mind and body to provide an ideal neuroglandular adjustment within the individual and may positively stimulate the insulin secretion pattern in the aged type 2 diabetes patients.

Kriya (Kapalbhati) and Pranayama (Bhastrika) bring in control over the autonomic nervous system' function.[128] Kapalbhati kriya and Bhastrika pranayama give vigorous abdominal movements and an automatic abdominal massage may preserve the effective functioning of pancreas and thus improve insulin concentration in the blood. Autonomic

and proprioceptive neuromuscular reactions seem to have an important bearing in bringing about these results.[76]

Suryanamaskara or salutation to the sun is an important yogic practice which is a series of dynamic movements (12 counts) of forward and backward spinal bends and stretches with body and breathing awareness improve major muscle group in the body, strengthen joint structure and range of motion, digestion, circulation, aerobic capacity, body's circadian rhythms, nourishment, and stimulation of the nerves.[46, 49, 50, 51, 79] With this it is also equally activate and stimulates all the glands in the body including pancreas to get positive neuroendocrine feedback for maintaining a healthy secretion of insulin.

Cultural asanas (static physical posture with internal body awareness) provide a constant supply of proper nutrition to the tissues and the internal secretion of the endocrine glands.[116] Twisting asana and some asanas extensively compresses and squeezes the abdomen such as Vakrasana, Uttanapadasana, Ardha Halasana, Pavanmuktasana, Parivrtta Trikonasana poses not only massage the pancreas but also stimulate the surrounding organs, promoting overall digestive health and metabolic balance, promoting pancreatic secretions.

Regular practice of different forms of Pranayama (Nadisodhan & Bhramari) increases psychophysiological relaxation by quieting and calming the mind, decreases sympathetic tone, and enhances parasympathetic activation.[190, 191, 203]

Meditation is believed to gradually diminish sympathetic dominance, resulting in a better balance between the sympathetic and the parasympathetic activity.[14] It also brings about a hypometabolic state.[12] By modifying the state of tension and anxiety, mediation reduces stress induced sympathetic over reactivity.[13, 14, 63] Thus, a decrease in sympathetic response and ability to overcome stress can be a possible reason for the improvement in glucose level in the plasma blood.

Sukshma Vyayama, a subtle yoga practice, offers numerous benefits, including improved flexibility, relaxation, balance, and coordination.[95] Regular practice reduces stress and anxiety, [114] enhances concentration and emotional balance,[181] and promotes energy balance and spiritual growth. [168] Additionally, Sukshma Vyayama alleviates chronic pain,[130] improves sleep quality,[114] and boosts the immune system.[59] Overall, this practice cultivates physical, mental, and spiritual well-being.

5. SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion:

From the above discussion and based on the objectives of the study it may be concluded that Yog-Vyayama has a positive impact on:

- **Reducing Anthropometric characteristics:** Significant reductions in BMI, waist-hip circumference was observed.
- **Enhancing Muscular fitness**: Improvements in hand grip strength and trunk flexibility were noted.
- **Improving Vitals:** Decreases in heart rate and blood pressure; and increases SpO_2 were observed.
- **Improving glycemic control:** Reduced HbA1c levels and fasting blood glucose level.
- **Decreasing insulin level and insulin resistance:** Lowered fasting insulin level and Homeostatic Model Assessment insulin resistance (HOMA-IR) scores.
- **Enhancing insulin sensitivity**: Increased the value of Quantitative Insulin Sensitivity Check Index (QUICKI).
- **Improvement on Pre-diabetes Group (A) (HbA1c-5.7%-6.4%):** Yog-Vyayama improved BMI of both male and female, Waist circumference of female, Hip circumference of male, Grip Strength of female, Flexibility of male, Systolic Blood Pressure of male participants.
- **Improvement on T2DM Stage 1 Group (B) (HbA1c-6.5%-8%):** Yog-Vyayama improved Hip circumference of female, Grip Strength of male, Heart Rate of both male and female, Blood Pressure of male, Diastolic Blood Pressure of female,
- **Improvement on T2DM Stage 2 Group (C) (HbA1c->8%):** Yog-Vyayama demonstrated moderate improvements of Waist circumference of male, Flexibility of female, Diastolic Blood Pressure of female, SpO2 of both male and female, Fasting plasma glucose levels, HbA1c, Fasting Insulin, insulin resistance and Insulin Sensitivity of both male and female participants.
- Greatest improvements in Glycemic control, insulin resistance and Insulin Sensitivity were observed in the severe HbA1c group (HbA1c->8%).

5.2 Recommendations:

- Patients with T2DM should incorporate Yog-Vyayama into their lifestyle management plan.
- Future research should explore the molecular mechanisms underlying Yog-Vyayama's effects.
- Future research should explore personalized Yog-Vyayama protocols for different HbA1c levels.

5.3 Clinical Implications:

- Healthcare professionals may consider recommending Combined Yog-Vyayama as a valuable adjunctive therapy for the management of T2DM.
- Large-scale, randomized controlled trials are necessary to confirm these findings.
- Yog-vyayama may be use as complementary and alternative Medicine for the management of type 2 diabetes.
- Patients with poor glycemic control (HbA1c ≥ 8%) may benefit most considering combined Yog-vyayama treatment.
- Combination into existing treatment plans of Yog-vyayama may improve overall outcomes.

5.4 Constraints:

- Unrestricted Diet patterns
- Overall Biological clock of the subjects
- Non-residential training camp
- More Drop out participants from the intervention
- Adverse weather condition

5.5 Future Directions:

- Long-term follow-up studies.
- Investigation of Yog-Vyayama's effects on other T2DM-related outcomes.
- Development of standardized Yog-Vyayama protocols for different HbA1c levels.