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EFFECT OF AYURVEDA BASED LIFESTYLE MODIFICATION IN PRE-DIABETES- A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

Pre-diabetes, a state of abnormal glucose homeostasis is the latent stage of development of Type 2 Diabetes mellitus. It manifests due to the faulty dietary habits and erratic lifestyle with lack of exercise. Ayurveda identifies this stage as the *Prameha purvarupa*. As it is the early stage of the development of a lifestyle disorder, arresting it with timely management through diet, yoga and a modification in the lifestyle can cause a reversal of the pre-diabetic stage. Therefore, the present trial was initiated. 30 cases meeting the diagnostic criteria of HbA1c of 5.7-6.4 % between the age group 18-50 years of either sex were enrolled from the OPD of KLE Ayurveda Hospital, Shahapur, Belagavi. The participants were randomly divided into two groups where Group A received *Nishamalaki Churna* and Group B received Ayurveda based Lifestyle modification for 90 days duration. Assessment was done through HbA1c, FBS, PPBS, IDRS score, MAT score and WHO QOL Bref.

The study showed significant results in Ayurveda based Lifestyle modification group in most of the variables as compared to the Nishamalaki group. Improvement was seen in objective parameters like HbA1c, FBS, PPBS as well as subjective parameters like IDRS score, MAT

score and WHO QOL in Group B than in Group A. Hence, Ayurveda based Lifestyle modification was found effective in the management of Pre-diabetes.

Keywords: Pre-diabetes, Lifestyle modification, Ayurveda, diet, Yoga

I. INTRODUCTION

The present era experiences various types of non-communicable diseases. The increase in westernization and modernization has changed the active lifestyle of the people and has created a sedentary environment to thrive. Amongst the many diseases, Diabetes mellitus has been on a rise since many decades. The early onset of the disease, identified as Pre-diabetes can be identified and managed to further prevent the full clinical manifestation of Diabetes. Pre-diabetes is defined as a state of abnormal glucose homeostasis where blood glucose levels are elevated above those considered normal, but not as high as those required for a diagnosis of Diabetes **[1]**. The concept of Pre-diabetes was first described in the late 1970's when The National Diabetes Data Group in 1979 used IGT of 140-199mg/dl to define Pre-diabetes. Later, ADA & WHO added IFG of 110-125 mg/dl in 1997-1998. In 2003, the above organisations widened the range for IFG to 100-125mg/dl. Later in 2010, ADA had introduced HbA1c for the diagnosis of Pre-diabetes **[2]**. The prevalence of Pre-diabetes in adults, globally and in India is about 7.3% i.e. 352 million people and 14.0% **[3, 4]**.

The management of Pre-diabetes can be done through strict adherence to lifestyle modification in terms of diet and physical activity. In Ayurveda, the prodromal symptoms of Diabetes are explained as *prameha purvarupa.* And the importance of *pathya* (wholesome diet) and yoga has been highlighted. This article hence identifies Ayurveda based lifestyle modification for the treatment of Pre-diabetes in comparison to *Nishamalaki* (Ayurveda herbal drug) as the control drug.

II. MATERIAL & METHODS

The study was approved by the Institutional Ethics Committee (Protocol Id-BMK/20/PG/SW/3) in KAHER's BMK Ayurveda Mahavidyalaya & Research Centre, Belagavi on 18/8/2021. The CTRI Number for this trial was CTRI/2021/12/038888. Patients that attended the Outpatient Department of the hospital were enrolled in the study after the blood investigations.

2.1 Patients

36 patients were screened, and 30 patients who were diagnosed as Pre-diabetics were enrolled in the study from KLE Ayurveda Hospital, Belagavi, Karnataka, India **(Figure 1)**.

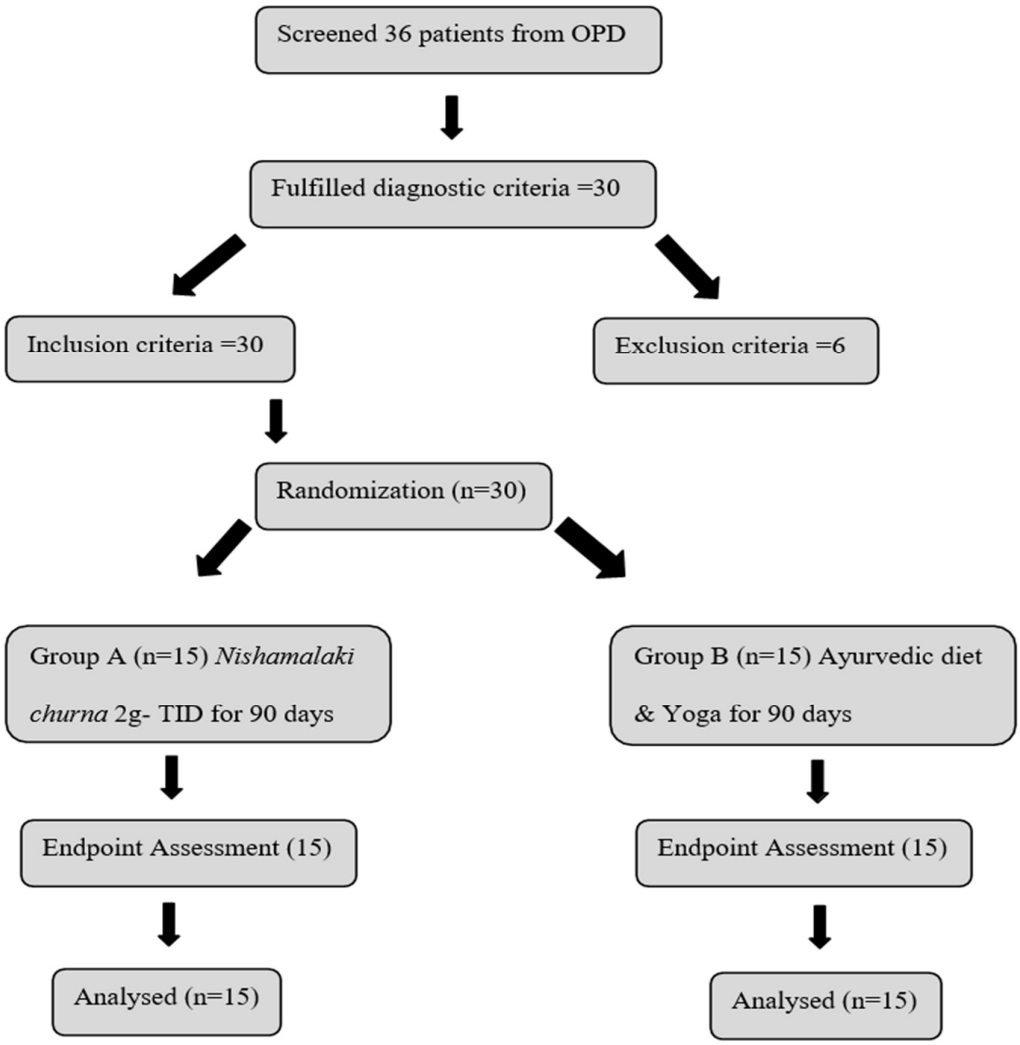

Figure 1: Consort Chart of Clinical Trial

2.1.1 Inclusion criteria

Patients between the age group of 18- 50 years of either sex were included who reported HbA1c levels between 5.7- 6.4%

2.1.2 Exclusion criteria

Patients who were diagnosed with Diabetes mellitus (type I and type II), uncontrolled Hypertensive subjects (with or without medication > 140/90 mm Hg), who had a past history of Gestational diabetes were excluded. Also, Alcoholics and/or drug abusers, Pregnant, lactating mothers were excluded. Patients suffering from major systemic illness necessitating long term drug treatment (Rheumatoid arthritis, Psycho-neuroendocrinal disorders etc), and patients who had completed participation in any other clinical trial during a period of 6 months were not included in the study.

2.1.3 Screening methods

All the patients were subjected to a detailed clinical evaluation and the data was recorded. Subjective & objective parameters were recorded. The laboratory

investigations like HbA1c, Fasting blood sugar and Post prandial blood sugar were carried out at the Pathology Laboratory of KLE Ayurveda Hospital, Belagavi at Baseline, 30th, 60th and 90th day of intervention.

2.2 Research Design

The study was a randomized controlled clinical study. Computer generated random numbers were utilised to make 2 groups for intervention. Allocation of patients into control and trial groups were done through randomization. The sample size was 15 in each group. And the assessment was done by HbA1c values at baseline and 90th day and FBS, PPBS, IDRS (Indian Diabetes Risk Score) **[5]**, MAT (Madhumeha Assessment Tool) **[6]** score and WHO QOL BREF **[7]** were assessed on baseline, 30th, 60th and 90th day **(Table 1)**.

2.2.1 Intervention

The patients were randomly divided into 2 groups. Group A was given Nishamalaki Churna 2g thrice a day, before food with lukewarm water for 90 days. The Churna was procured from GMP certified KLE Ayurveda Pharmacy, Khasbag, Belagavi as per the standard procedures.

In Group B, the patients were subjected to Lifestyle modification that included Ayurveda diet protocol and yoga protocol which was implemented for 90 days. There were no internal medications advised in the second group. This was done to solely appreciate the role of lifestyle modification in the management of Pre-diabetes. The diagnosis of Pre-diabetes in Ayurveda is through the identification of the *purvarupa* (prodromal features) of *prameha.* The detailed demographic information regarding the educational status, occupational status, habitat etc were noted. Also, the chief complaints, associated complaints, history of past illness, treatment history, family history were noted. Disease specific personal history related to diet pattern, sleep pattern, appetite, bowel habits, micturition frequency, water intake, nature of stress and emotional status were documented. The clinical manifestations of Pre-diabetes were assessed.

Group A was the control group which consisted of a proven drug. Nishamalaki Churna has been the drug of choice for Diabetes in Ayurveda classics **[8]**. Group B consisted of Ayurveda diet that consisted of food articles that were *lekhaniya* (scraping of excessive fat)*, karshaniya* (weight reducing) and *kleda shoshaka* (drying up the excessive fluids or moisture in the body) in properties. Also, the yoga protocol designed mainly focused on improving the insulin sensitivity along with reduction of abdominal fat.

The patients enrolled in Group B were explained the formulated diet chart in detail along with the special emphasis on the do's and don'ts **(Table 2)**. After this, the yoga

protocol was demonstrated to the patient with his/her simultaneous involvement in performing the *asanas* **(Table 3)**. The video demonstrating the same protocol was personally shared to the patient for better understanding. The patient visited the hospital for the next 7 days to learn the yoga protocol to be followed for 90 days.

The nature and study design were explained and informed consent was taken from the subjects. Data collection was from April 2021 to March 2023.

Table 2: Ayurveda based diet

Time of Food serving	Timing	Food Item	Serving size (Gms)	Calories
Early morning	6 am	Madhoodaka (Honey water)	2 tsp+500 ml of water	31.9 K.Cal
Breakfast	8.30 am	Navane Upma (Fox tail millet) (less oily)	1 medium bowl (100 gm)	331 K.Cal
		Ginger black tea (sugarless)	100 ml	1 K.Cal
	Options	-Ragi dumplings -Barley/ Ragi ambali -Barley porridge (saktu) -Puffed rice upma -Fox tail/ Barnyard millet dosa/ idli/ appam/ uttappa -Green gram/ lentil usal -Jowar/ bajra thalipeeth		
At 11am		Daadima 65 kcal/ 100g	Dadima- 1 fruit	65 K.Cal
Options		-Parched paddy/ popped rice- laaja -Figs -Guava Papaya Pears Jambu fruit Apple Amla Cashew fruit Buttermilk- 100ml	Jambu fruit- 5 Laaja- small bowl	
At Lunch	1.30 pm	Jowar roti	2 medium size jawar roti (125g)	436.25 K.Cal
		Options- Bajra roti/ Barley roti/Makai roti/ Ragi roti		
		Kaaravellaka sabji With methika beeja chatni	1 medium bowl (100 gm) 2 tsp (10g)	25 K.Cal 33.3 K.Cal
		Options- Snake gourd/ Raw banana/ Amaranth/ Green sorrel/ Cabbage/ Radish with leaves/ Spinach/ Bottle gourd/ brinjal/ French beans/ knol-knol/ green papaya/ ridged gourd/ Green tomato		
		Mudga curry	1 small bowl (50 gm)	174 K.Cal
		Options- Chickpea curry/Tur dal/ Kulattha sambhaar /drumstick curry/ Radish curry/ Lentil curry/ Red gram curry/ Green peas curry		
		Puraana shaali odana	1 medium bowl (100 gm)	345 K.Cal
		Options- red rice/ brown rice/ navane/ saame khichadi		
At Evening	5 pm	Black Tea (sugarless)	1 tea cup (50 ml)	1K.Cal
Dinner (Options same as mentioned for lunch)	7.30 pm	Raagi roti	1 medium size roti	196.8 K.Cal
		Sheegru patra curry	1 small bowl (50) gm	46 K.Cal
		Saame kichadi (Barnyard millet)	1 medium bowl (50 gm)	154 K.Cal
		Masoora (lentil) Sambhara	1 medium bowl (50 ml)	58 K.Cal
Total K.Cal				1,898.25 K.Cal

Non- veg eaters- Boiled egg/ dry roasted chicken/ dry roasted mutton/ Boiled chicken soup- once/week- 100g

Note: 1 small bowl = 50 ml
1 medium bowl = 100 ml
1 big bowl = 200 ml

Table 3: Yoga Intervention
(Beginning of Yoga practice- Prayer)
(yogen chittasya padena vacham malam sharirasya cha vaidyaken. Yoapakarottam pravaram muninaam patanjalim pranjaliranathosmi)

	Yoga	Rounds	Duration
Loosening exercises	**Head and neck exercise - Up and down movement of head and neck - Right and left movement of head and neck - Rotation (clockwise & anti clock-wise) of head and neck**	**1 round each on both sides**	**5 minutes**
	Shoulder exercise -Forward rotation of shoulder. -Backward rotation of shoulder		
	Elbow joint exercise -Flexion of elbow joint -Extension of elbow joint		
	Wrist joint exercise -Flexion of wrist joint -Extension of wrist joint -Rotation of wrist joint		
	Waist exercise -Forward bending -Backward bending -Rotation		
	Knee joint exercise- -Rotation (clock wise and anti- clock wise)		
	Ankle joint - Plantar flexion of ankle joint - Dorsiflexion of ankle joint		
Sooryanamaskara	**with Shashankasana**	**4-5 rounds at the beginning**	**5 minutes**
Standing asana	**Trikonasana**	**2 rounds**	**15 minutes**
	Veerabhadrasana	**2 rounds**	
	Hasta padottanasana	**2 rounds**	
Sitting asana	**Vakrasana**	**2 rounds**	
	Gomukhasana	**2 rounds**	
	Ushtrasana	**2 rounds**	
Prone asana	**Ardha shalabhasana**	**2 rounds**	
	Bhujangasana	**2 rounds**	
	Dhanurasana	**2 rounds**	
Supine asana	**Vipareeta karani**	**2 rounds**	
	Naukasana	**2 rounds**	
Pranayama	**Ujjaayi Pranayama**	**5 rounds**	**5 minutes**
	Suryabhedi Pranayama	**10 rounds**	
	Bhramari Pranayama	**5 rounds**	
	Nadishuddhi Pranayama	**10 rounds**	
	TOTAL		**30 minutes**

(Concludes with- Prayer)
(om sarve bhavanthu sukinah sarve santhu niramayaa Sarve bhadrani pashyanthu maa kashchidda duhkh bhagbavet. Om shanti shanti shanti)

2.3 Criteria of assessment

2.3.1 Objective Assessment

1. HbA1c
2. FBS
3. PPBS

2.3.2 Subjective criteria

1. IDRS score (Indian Diabetes Risk Score)- 4 main parameters were used- two modifiable factors (waist circumference & physical inability) & two non-modifiable risk factors (age & family history of Diabetes mellitus) **[5]**.

2. MAT score- Madhumeha Assessment Tool **[6]**
3. WHO QOL BREF **[7]**- 26 item questionnaire was used for evaluation.

2.3.3 Statistical methods

Statistical method was carried out by SPSS.

III. RESULTS

3.1 Patient profiles

The prevalent age group was between 40-50 years (63.33%). Females were predominant in the study (73.33 %). Most of the patients belonged to the Hindu religion (96.67%). The patients belonged to the Graduate group in educational status (43.33%). In Group A, majority of the patients were involved in elementary occupation (26.67%), whereas in Group B, most of them were unemployed (40%). In both the groups, the patients were distributed in the middle-class category, with Group A in lower middle class (60%) & Group B in upper middle class (60%). Most of the patients were married (93.33%) and belonged to the urban habitat (96.67%) **(Table 4)**.

Table 4: Demographic data

Characteristics	Group A group	%	Group B group	%	Total %
Age	40-50	66.66%	**40-50**	60%	63.33%
Gender	Females	60.00%	**Females**	86.67%	73.33%
Religion	Hindu	100.00%	**Hindu**	93.33%	96.67%
Education	Graduates Middle school	46.67% 46.67%	**Graduates**	40.00%	43.33%
Occupation	Elementary	26.67%	**Unemployed**	40.00%	26.67%
Socioeconomic status	Lower middle class	60.00%	**Upper middle class**	60.00%	46.67%
Marital status	Married	93.33%	**Married**	93.33%	93.33%
Habitat	Urban	93.33%	**Urban**	100.00%	96.67%

3.2 Objective assessment outcomes

3.2.1 HbA1c outcome

Effect of the intervention on HbA1c showed significant difference (p=0.0035) in both the groups **(Figure 2)**. The mean score in between the groups was significant in both the groups but was more in Group B (p=0.0007). The percentage change was greater from baseline to 90th day in Group B (7.25%) than in Group A (5.52%). Within group analysis showed that there were comparable results in both the groups from baseline to 90th day (p=0.0001) **(Table 5)**.

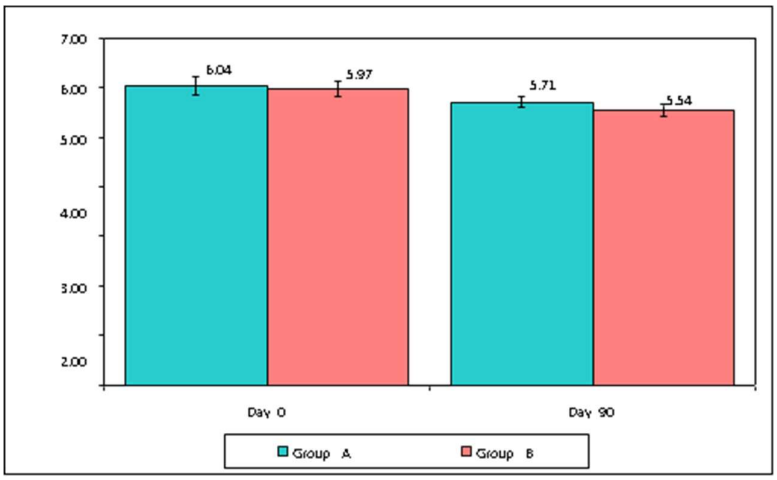

Figure 2: Comparison of Group A and B with HbA1c scores at different treatment time points

3.2.2 FBS outcome

FBS was comparable between the groups **(Figure 3)**. Within the group analysis, showed that the reduction in FBS was significant with mean value decreasing from 98.53 mg/dl to 85.73 mg/dl in group A and 91.80 mg/dl decreasing to 78.07 in group B. The FBS mean value was on the normal range from the beginning owing to the early stage of the disease in both the groups **(Table 5)**.

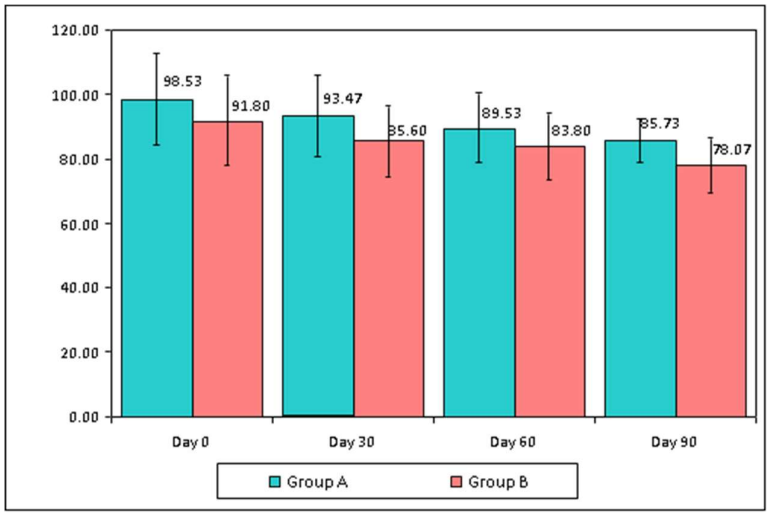

Figure 3: Comparison of Group A and B with FBS scores at different treatment time points

3.2.3 PPBS outcome

PPBS was comparable between the groups **(Figure 4)**. Within the group, there is significant difference in mean value with 133.27mg/dl at baseline reducing to 119.33 mg/dl in group A and 136 mg/dl at baseline reducing to 116.60 mg/dl in group B. Within the group analysis showed that, there was significant change at 30th day (p=0.0008), 60th day (p=0.0007) and 90th day (p=0.0007) in group B than in group A (p=0.0018) **(Table 5)**.

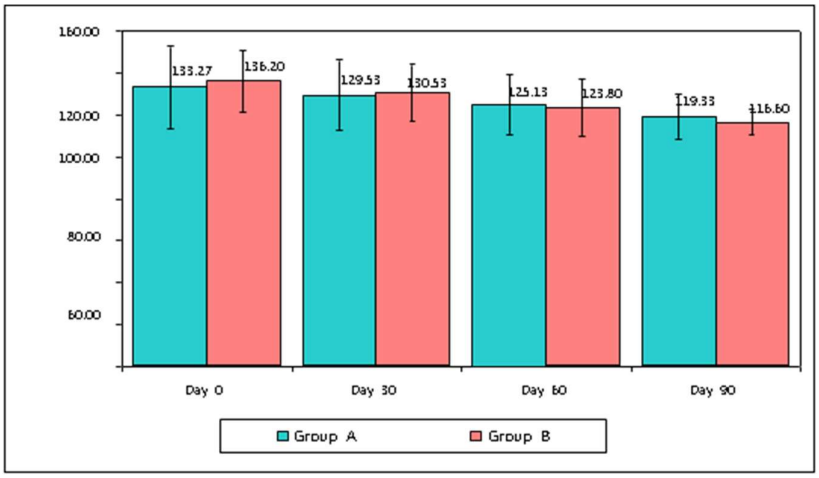

Figure 4: Comparison of Group A and B with PPBS scores at different treatment time points

3.2.4 IDRS scores

IDRS (Indian Diabetic Risk Score) consists of four main factors. Out of which, two are modifiable factors (Waist circumference, physical activity levels), and two are non-modifiable factors (Age, family history). There is significant reduction (p=0.0015) in the modifiable factors that have decreased the IDRS scores. IDRS score has reduced in group A with baseline mean value 50.67 to 43.33 at end point and in group B with 54 to 36 **(Figure 5)**. The decrease in the score is more prevalent from the 60th day (p=0.0277) and 90th day (p=0.0077) in group A, but in group B, it is prevalent from 30th day (p=0.0033), 60th day (p=0.0015) and 90th day (p=0.007), hence group B is more significant than group A **(Table 5)**.

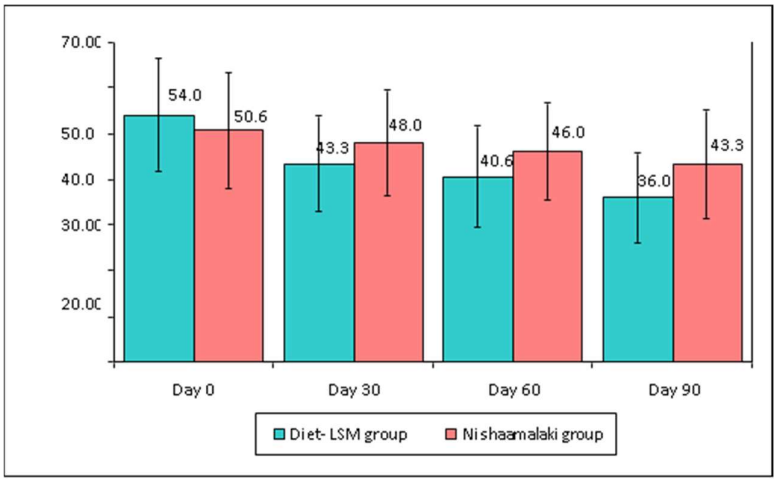

Figure 5: Comparison of Group A and B with IDRS scores at different treatment time points

3.2.5 MAT scores

The MAT score (Madhumeha Assessment Tool) is a tool containing 10 questions on the symptoms produced in Madhumeha. Within the group there is a significant reduction in *pippasa adhikya* (polydipsia) in group B (p=0.0277) from baseline to endpoint than in group A (p=0.0431). Also, there is no

significant reduction of *kshudha adhikya* (polyphagia) in group A (p=0.2249), while group B showed significant reduction (p=0.0277). There was significant reduction seen in *prabhuta mutrata* (polyuria) in group A (p=0.0277) than in group B (p=0.1797). *Swedadhikya* (increased sweating) scores were comparable till 60th day in both the groups. Significant decrease in group B was seen till 90th day (p=0.0077) as compared to group A (p=0.0180). Significant reduction in *gala talu shosha* (dryness of palate and throat) was seen in group A (p=0.0431) than in group B (p=0.1088). Within the group there was a significant reduction in *shrama shwasa* (exertional dyspnea) in group B (p=0.0431). Result showed that there was no significant reduction of *alasya* (laziness) in group A (p=0.1797). While group B showed significant reduction at 60th day (p=0.0180) and at 90th day (p=0.0033). *Angasada* (fatigability) score had significant reduction in group B both at 60th day (p=0.0180) and at 90th day (p=0.0051) than in group A (p=0.1797) **(Figure 6)**.

Significant reduction was seen in both the groups with MAT scores, with mean value of group B reducing from 8.87 to 5.07. The mean value of group A has reduced from 7.87 to 5.47. Within the group, group A showed reduction of MAT score from 60th day (p=0.0022) and 90th day (p=0.0007) while group A has shown significant reduction from 30th day (p=0.0077), 60th day (0.0007) and 90th day (0.0007) **(Table 5)**.

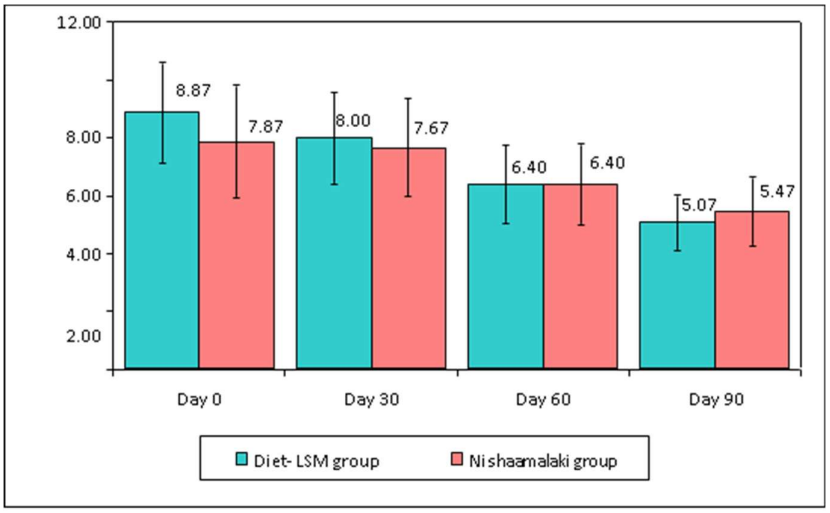

Figure 6: Comparison of Group A and B with MAT scores at different treatment time points

3.2.6 QOL scores

The WHO QOL BREF questionnaire consisting of 26 questions was used to estimate the Quality of Life. The results were categorized based on the 4 domains- physical, psychological, environmental and social domains. There was significant increase of QOL between the groups at day

60 (p=0.0465) and 90 (p=0.0310). The mean value in group B has increased from 83.93 at baseline to 91.67 at endpoint **(Figure 7)**. Within the group, there is significant increase of QOL seen in both the groups, with group B showing steady increase from baseline to 30th day (p=0.0249), 60th day (p=0.0010) and 90th day (p=0.0010). There were significant results in physical domain (p=0.001), psychological domain (p=0.0037) and in social domain (p= 0.0431) seen in group B than in group A **(Table 5)**.

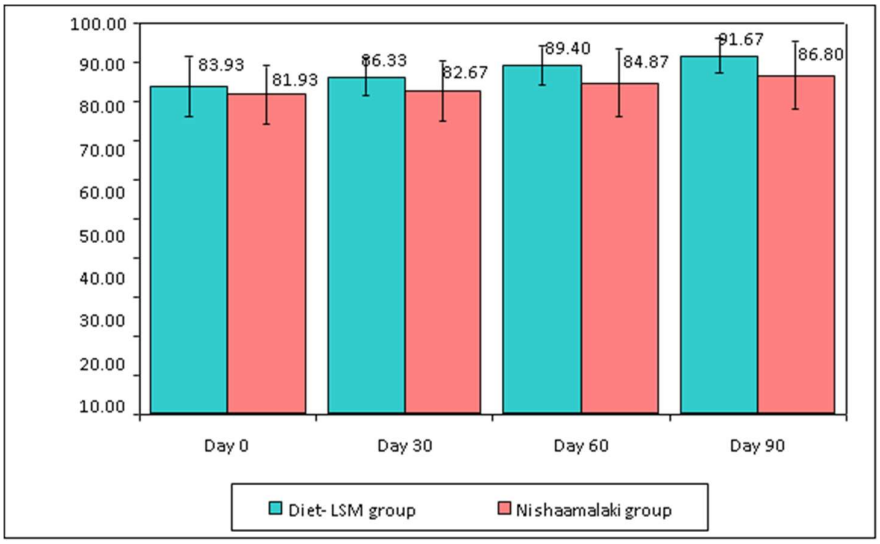

Figure 7: Comparison of Group A and B with QOL scores at different treatment time points

Table 5: Effect of intervention on assessment scales expressed in mean and standard deviation (S.D) *p<0.05, **p<0.01, ***p<0.001

Clinical Variables	Groups	Baseline	30th day	60th day	90th day	BL- 30th day	BL- 60th day	BL- 90th day	P value
HBA1c	A	6.04±0.19	-	-	5.70±0.12	-	-	0.0001***	0.0035**
	B	5.97±0.16	-	-	5.54±0.12	-	-	0.0001***	
FBS	A	98.53±14.37	93.47±12.79	89.53±10.88	85.73±6.98	0.0012**	0.0011**	0.0012**	0.9010
	B	91.58±13.99	85.60±11.02	83.80±10.51	78.07±8.47	0.0012**	0.0026**	0.0010**	
PPBS	A	133.27±19.52	129.53±16.59	125.13±14.23	119.33±10.88	0.0098**	0.0059**	0.0018**	0.4068
	B	136.20±15.09	130.53±13.69	123.80±13.66	116.60±6.28	0.0008**	0.0007**	0.0007**	
IDRS Scores	A	50.67±12.80	48±11.46	46±10.56	43.33±11.75	0.1088	0.0277*	0.0077**	0.0015**
	B	54±12.42	43.33±10.47	40.67±11.00	36.00±9.86	0.0033**	0.0015**	0.0007**	
MAT Scores	A	7.87±1.96	7.67±1.72	6.40±1.40	5.47±1.19	0.2733	0.0022**	0.0007**	0.0161*
	B	8.87±1.73	8.00±1.60	6.40±1.35	5.07±0.96	0.0077**	0.0007**	0.0007**	
QOL Scores	A	81.93±7.47	82.67±7.69	84.87±8.52	86.80±8.57	0.0679	0.0022**	0.0015**	0.1103
	B	83.93±7.55	86.33±4.78	89.40±4.95	91.67±4.39	0.0249**	0.0010**	0.0010**	

IV. DISCUSSION

4.1 Ayurveda based Lifestyle modification

The decrease in the blood sugar levels is attributed to the astringent, bitter and pungent taste of the food articles selected for the diet. Also, the dry and light to digest properties have further aided in the process. The diet predominantly consisted of Millets that work in decreasing the urine output and the excess water content in the body as per the Ayurveda texts. Also, it helps in scraping the excess fat in the body **[9]**. They contain dietary fibre that slows the gastric emptying

and intestinal nutrient absorption which further controls postprandial glycemia, insulin responses & satiety **[10, 11]**. The complex carbohydrates, high dietary fibre and calorie restriction improved the beta-cell function, and increased the glucose uptake in the cells due to which the insulin resistance was decreased. The high fibre diet (*kudhanya*) helps in secreting hormones through incretins (GLP-1, GIP, CCK) which are endocrine cells in the GIT tract. By delaying stomach emptying and limiting food intake, they normalize post-prandial glycemia and suppress glucagon secretion. The legumes or *shimbhi dhanya* possess the above properties along with *baddha mutra* property that controls polyuria like symptoms. Vitamin C-rich foods such as amla, papaya, and tomato etc. aid in the synthesis of prostaglandin E1 (PGE1), a metabolite of dihomogamma-linoleic acid (DGLA, 20:3 n-6) that mimics and increases the action of insulin **[12]**. Insulin resistance and T2DM are caused by endothelial dysfunction caused by eNO (endothelial nitric oxide) insufficiency. Vitamin C helps in the formation of PGI2 (prostacyclin) along with PGE1 that helps in the production of eNO by the endothelial cells thus counteracting insulin resistance **[13]**. The presence of antioxidants in fruits and vegetables such as polyphenols contributes to its protective impact. Bioactive compounds like anthocyanins and anthocyanidins have been proven to exhibit hypoglycemic activity of fruits and vegetables **[14]**. Vitamin E rich foods (green leafy vegetables, fruits) decreases the protein glycosylation due to its antioxidant property, that gradually decreases the HbA1c levels **[15]**. Vitamin B3 (Niacin, nicotinamide) rich foods like Legumes, whole cereals etc. produces NAD (Nicotinamide Adenine Dinucleotide) which is important to facilitate entry of glucose in the cells through the sodium ions and potassium ATPase. If there is impaired membrane transport of glucose, then normal insulin levels also cannot prevent onset of Diabetes **[16]**. These dietary articles concentrate on boosting insulin sensitivity, boosting insulin secretion, prolonging carbohydrate absorption, enhancing peripheral glucose uptake, blocking hepatic glycogenolysis, exerting antioxidant effects, and enhancing endogenous incretins.

Yoga protocol helped in nourishing the *manovaha srotasa*, that further calmed the mind and reduced the stressful state of the individuals. It had inculcated a mild to moderate intensity of physical activity that worked on the adipose tissue accumulation and decreased the waist circumference. This improved the modifiable factors of the IDRS score, further decreasing the risk of developing type 2 diabetes.

Yogasana benefits the individual by providing *sthairya* (stability) which acts on

both *deha* & *mana.* It reduces the *chanchalta* (instability) of the physical as well as the mental body and overall reduces the *rajo guna* **[17]**. The stretching actions of the muscle groups and tissues in the asanas promote glucose sensitivity and tolerance. Also, activation of the HPA axis and sympatho-adrenal system decreases insulin resistance and decreases hepatic glucose production **[18, 19]**. It improves beta-cell function, by its effect on serotonin and brain derived neurotrophic factors (BDNF), through the neurophysiological mechanism **[20]**. Pranayama & meditation reduces the stress hormone which reduces the glucocorticoids secretion that achieves glycemic control. Also, it possesses a unique energy retaining effect which provides goodness to the subjects after practice, which may be the reason for the increased Quality of Life in the subjects post 3 months of practice **[21]**. Yoga toned the physical appearance of the individual due to the involvement of muscles during asana practice. Also, it acted on the parasympathetic nervous system and calmed the body. Hence, the physical domain and psychological domain of QOL had significantly improved. Most of the patients practiced the protocol in small focus groups, which helped in building a healthy social relationship within the community. This improved the social domain of QOL.

4.2 Nishamalaki intervention

Nisha (Curcuma longa) being *katu* (pungent) & *tikta rasa* (bitter taste) along with *ruksha guna* (dry property) decreases the *kleda* (excess moisture) accumulation, hence decreases symptoms of *prabhuta mutrata* (polyuria) **[22]**. It causes increased peripheral glucose utilization, decreases hepatic glucose synthesis & prevents protein glycosylation which imparts hypoglycaemic effect **[23]**. *Amalaki* (Emblica officinalis) possessing *rasayana* (rejuvenation therapy) properties **[22]**, improves digestive functions & metabolism that further boosts the glucose uptake in the cells. It exerts antioxidant activity due to the presence of ascorbic acid & tannins (Emblicanin A & B). *Nishamalaki* has anti-hyperglycemic, insulinomimetic, α-Amylase inhibitory and α- glucosidase inhibitory activities, as well as antioxidant characteristics. It enhances insulin sensitivity and increases glucose absorption by skeletal muscles, making it useful in the treatment of *Prameha* **[24]**.

V. CONCLUSION

The above study showed that there was a significant decrease seen in HbA1c levels in Group B (Diet-LSM group) than in Group A (Nishamalaki group). The FBS and PPBS levels were comparable in both the groups. IDRS scores has decreased in Group B. The WHO Quality of Life scores have significantly increased in group B than in group A. Overall, the Diet and Lifestyle modification group has showed better

results than Nishamalaki group. No adverse events or disease progress was reported in any of the groups. Hence, it can be concluded from the above study that Diet and yoga in the form of lifestyle modification can work effectively in Pre-diabetes as it is easily to administer and is an effective non-pharmacological treatment.

VI. FUNDING

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VII. CONFLICT OF INTEREST

None

VIII. REFERENCES

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