"EFFICACY OF INTEGRATED AYURVEDA MANAGEMENT PROTOCOL IN PREDIABETES – A RANDOMIZED CONTROLLED CLINICAL TRIAL"

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For the award of the degree of

Doctor of Philosophy

In ROGA NIDAN EVAM VIKRITI VIGYAN

Under the Faculty of Ayurveda

By

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LIST OF ABBREVIATIONS USED

T2DM	:	Type 2 Diabetes mellitus
HbA1C	:	Glycated hemoglobin
IFG	:	Impaired Fasting Glucose
IGT	:	Impaired Glucose Tolerance
WHO	:	World health organization
IDF	:	International Diabetes Federation
ADA	:	American diabetes association
RCT	:	Randomized controlled trial
CAN	:	Cardiac Autonomic Neuropathy
NCCIH	:	National Centre for alternative and Integrative Health
IDF	:	International Diabetes Federation
GH	:	Growth Hormone
IGF-1	:	Insulin Growth Factor 1
QoL	:	Quality of Life
HOMA-IR	:	Homeostatic Model Assessment of Insulin Resistance
BDNF	:	Brain Derived Neurotrophic Factors
SNPs	:	Single Nucleotide Polymorphisms
PCOS	:	Polycystic Ovary Syndrome
NAFLD	:	Non-Alcoholic Fatty Liver Disease
OGTT	:	Oral Glucose Tolerance Test
LDL	:	Low-density lipoprotein
FBS	:	Fasting blood sugar
PPBS	:	Post prandial blood sugar
FPG	:	Fasting plasma glucose

LFT	:	Liver Function Test
RFT	:	Renal Function Test
NIDDM	:	Non-insulin-dependent diabetes mellitus
BMI	:	Body mass index
GCP	:	Good Clinical Practice
SD	:	Standard Deviation
GI	:	Glycaemic index
RS	:	Resistant starch type 3
MUFA	:	Monounsaturated fatty acids
HDL	:	High density lipoprotein
VLC	:	Very low carbohydrate diet
DASH	:	Dietary approach to Stop Hypertension
HIIT	:	High intensity interval training
IR	:	Immediate Release
ER	:	Extended Release
OS	:	Oxidative stress
OGTT	:	Oral glucose tolerance test
SGLT2	:	Sodium-glucose co-transporter-2
HOMA IR	:	Homeostatic model for assessment for insulin resistance
CAD	:	Coronary artery disease
SD	:	Standard deviation
CRF	:	Case report form
DQOL	:	Diabetes Quality of Life
GCP	:	Good clinical practice
HB	:	Haemoglobin

KCAL	:	Kilocalorie
TC	:	Total cholesterol
VLDL	:	Very low-density lipoprotein
IF	:	Intermittent fasting
ADR	:	Adverse drug reaction.
SGOT	:	Serum Glutamic-Oxaloacetic Transaminase
SGPT	:	Serum Glutamic Pyruvic Transaminase
A/G Ratio	:	Albumin/Globulin Ratio
NS	:	Not Significant
LSMs	:	Lifestyle Modifications

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ABSTRACT

Introduction

Prediabetes is a metabolic disorder characterized by blood sugar levels that are elevated but not high enough to meet the diagnostic criteria for Type 2 Diabetes Mellitus (T2DM). It represents a critical phase where timely intervention can help prevent the onset of diabetes. The condition is identified through diagnostic markers such as impaired fasting glucose (IFG), impaired glucose tolerance (IGT), and increased HbA1c levels. Affecting 8–14% of the global population, its prevalence is increasing due to sedentary lifestyles, poor dietary habits, and obesity.

Prediabetes results from insulin resistance, where cells fail to respond to insulin, and beta-cell dysfunction, impairing insulin production. Contributing factors include chronic low-grade inflammation, oxidative stress, and genetic predisposition. Key risk factors include obesity, sedentary behavior, an unhealthy diet, and advancing age, with central fat accumulation playing a pivotal role in the development of insulin resistance. Beyond its transitional nature, prediabetes is linked to severe health risks, such as cardiovascular disease, kidney dysfunction, and neuropathy.

Management typically involves lifestyle changes, including diet, exercise, and weight control, supplemented by pharmacological options like metformin. However, adherence to these interventions is challenging, and pharmacotherapy may have side effects. Ayurveda, a holistic Indian medical system, offers promising management strategies for prediabetes, termed *Prameha*, emphasizing dosha balance, Panchakarma, and herbal remedies like *Guduchi*, *Haridra*, and *Amla*. These

interventions target root causes like Kapha dosha imbalance and provide comprehensive care through dietary modifications and lifestyle adjustments.

Yoga complements Ayurveda by improving insulin sensitivity, reducing stress, and enhancing metabolic health. Studies highlight the benefits of asanas, pranayama, and meditation for fasting glucose and HbA1c control. Despite encouraging findings, integrated Ayurveda and Yoga therapies remain underexplored, necessitating robust randomized controlled trials to validate their efficacy. These traditional interventions offer a holistic and sustainable alternative for addressing the growing public health challenge of prediabetes.

Objective:

- To evaluate the efficacy of Integrated Ayurveda Management protocol in patients of prediabetes in achieving the glycemic control.
- To compare the effect of Integrated Ayurveda Management protocol and Standard treatment regimen intervention on changes in biochemical parameters of Prediabetes (HbA1c, Lipid profile, Fasting Insulin, HOMA IR)
- To compare the effect of Integrated Ayurveda treatment protocol and Standard treatment regimen intervention on quality of life in Prediabetes (DQoL)

Materials and Methods

- The medical trial received approval from the KAHER ethical committee for human subjects.
    - **Ref ID: KAHER/EC/21-22/012**

- The institutional ethical committee approval was obtained to conduct clinical study.
    - **BMK/23/PhD/KMS**
- Study was registered in Clinical trial for Registry of India
    - Ref.no: **CTRI/2022/01/039395**

- This study comprises two key components: drug preparation and a clinical trial. The polyherbal formulation, *Madhumehahari Kashaya*, was prepared using standardized procedures with authenticated raw materials, including *Gymnema sylvestre*, *Pterocarpus marsupium*, *Syzygium cumini*, and others. The ingredients were processed into a concentrated liquid extract with added preservatives and stored for use.

- The clinical trial was a randomized controlled design conducted at KLE Ayurveda Hospital, involving 180 prediabetic participants with HbA1c levels of 5.7%–6.4%. Participants were randomly assigned to two groups: the control group received standard care with lifestyle and nutritional counseling, while the trial group followed an integrated Ayurveda protocol. This protocol included *Madhumehahari Kashaya* (35 ml twice daily), an Ayurvedic diet emphasizing low-glycemic foods, and a structured yoga regimen comprising asanas, pranayama, and meditation.

- Data collection occurred at baseline, 30, 60, and 90 days, assessing primary outcomes like HbA1c levels and secondary outcomes including fasting insulin, HOMA-IR, lipid profile, BMI, and quality of life (DQOL). Statistical analysis employed descriptive statistics, chi-square tests, and ANOVA, with significance set at $p<0.05$. Ethical approval and informed consent were

obtained, ensuring adherence to Good Clinical Practice and the Declaration of Helsinki.

- The study's Ayurvedic dietary plan incorporated traditional Indian principles, emphasizing balanced meals with soluble fiber, low-glycemic grains like millets, and herbal supplements. Yoga interventions targeted improved insulin sensitivity, stress reduction, and metabolic health. The trial aimed to validate the efficacy of this integrated approach in managing prediabetes.

Discussion

- The randomized controlled clinical trial evaluated the efficacy of an integrated Ayurveda management protocol in prediabetes. The study involved 180 participants divided into two groups: one receiving standard prediabetic care with lifestyle and nutritional counseling, and the other receiving an Ayurveda protocol comprising *Madhumehahari Kashaya*, dietary interventions, and yoga. Assessments over 90 days revealed improvements in BMI, waist circumference, fasting and postprandial blood sugar, HbA1c, insulin sensitivity (HOMA-IR), and lipid profiles, demonstrating the protocol's metabolic benefits.

- Key components of the intervention included *Tinospora cordifolia*, *Syzygium cumini*, and curcumin, which were shown to improve insulin sensitivity, reduce oxidative stress, and lower lipid levels. Additionally, *Madhumehahari Kashaya* exhibited antihyperglycemic effects, aiding in weight management without adverse effects. The Ayurveda diet focused on balanced glycemic outcomes through low-glycemic grains, whole foods, and mindful eating

practices, while yoga contributed to stress reduction, improved insulin sensitivity, and better sleep quality.

- The study highlighted significant quality-of-life improvements (DQOL) through the integration of these practices. Safety evaluations confirmed the interventions did not affect renal or liver function. Comparisons with other studies affirmed the potential of lifestyle modifications, yoga, and herbal formulations in managing prediabetes. However, the need for broader trials to validate these findings across diverse populations was emphasized.

Conclusion

- The study demonstrates the efficacy of the trial intervention in significantly improving prediabetes outcomes. The integrated Ayurveda management protocol, combining Ayurvedic medicine, dietary interventions, and yoga, showed superior results compared to standard care. Specifically, group comparisons revealed significantly greater reductions in HbA1c, fasting blood sugar (FBS), postprandial blood sugar (PPBS), fasting insulin levels, and HOMA-IR values in the Ayurveda protocol group. These findings highlight the potential of Ayurveda-based therapies to address key metabolic markers associated with prediabetes.

- Within-group assessments further emphasized the benefits of the Ayurveda protocol, with significant improvements observed across various parameters, including glycemic markers (HbA1c, FBS, PPBS), lipid profile components (HDL and LDL cholesterol), and anthropometric measures such as waist circumference and BMI. Quality of life, assessed through the Diabetes Quality

of Life (DQOL) scale, also improved substantially, suggesting the holistic benefits of the integrative approach in enhancing both physical and mental well-being.

- The safety profile of the intervention was noteworthy, as renal and liver function tests (RFT and LFT) remained within normal limits both before and after the treatment, and no adverse events were reported during the study. This underscores the safety and tolerability of the integrated approach, which is crucial for long-term management strategies.

- The findings of this study validate the effectiveness of combining traditional Ayurvedic formulations, such as *Madhumehahari Kashaya*, with modern lifestyle interventions, including diet and yoga, for managing prediabetes. This integrative treatment approach offers a holistic, sustainable, and culturally resonant alternative to standard care.

- **Keyword:** Prediabetes, *Prameha*, HbA1C, Yoga, Diet

1. INTRODUCTION

Prediabetes is a metabolic disorder where blood sugar levels exceed the normal range but remain below the threshold for Type 2 Diabetes Mellitus (T2DM). It acts as an important early warning stage, providing an opportunity to intervene and potentially prevent or delay the progression to full-fledged diabetes. According to the American Diabetes Association (ADA), the condition is diagnosed using criteria such as impaired fasting glucose (IFG), impaired glucose tolerance (IGT), and elevated HbA1c levels ranging from 5.7% to 6.4%.[1] Worldwide, prediabetes impacts around 8–14% of people, and its incidence is growing rapidly, driven by sedentary behaviors, unhealthy eating patterns, and increasing rates of obesity. [2]

Prediabetes mainly arises from insulin resistance and dysfunction of beta cells. Insulin resistance occurs when muscle, fat, and liver cells do not respond effectively to insulin, resulting in elevated blood sugar levels.[3] Beta-cell dysfunction refers to the pancreas's reduced ability to produce enough insulin to compensate for insulin resistance.[4] Persistent low-grade inflammation, oxidative stress, and genetic predisposition are key factors that contribute to the onset of prediabetes.[5]

Prediabetes is impacted by various factors such as age, obesity, lack of physical activity, genetic predisposition, and unhealthy eating habits. [6] Lifestyle factors, including a high-calorie diet, excessive intake of refined carbohydrates, and insufficient physical activity, greatly elevate the risk. Furthermore, obesity, particularly central fat accumulation, is closely associated with the development of insulin resistance and the progression of prediabetes.[7] Research suggests that people with a family history of diabetes face an increased likelihood of developing prediabetes.[8]

Prediabetes is more than just a transitional stage; it is linked to significant health risks. It notably raises the chances of developing cardiovascular conditions, kidney disorders, and neuropathy, even before advancing to diabetes.[9] Studies indicate that individuals with prediabetes face a 1.5 times higher risk of dying from cardiovascular conditions. [10] Additionally, high blood sugar levels in prediabetes can lead to damage in blood vessels and nerves, contributing to increased morbidity and greater healthcare challenges.

The main strategy for managing prediabetes focuses on lifestyle changes, such as adopting a healthier diet, engaging in regular physical activity, and maintaining a healthy weight. [11]. Pharmacological interventions, such as metformin, are also used in high-risk individuals to reduce glucose production in the liver and improve insulin sensitivity[12]. However, adherence to lifestyle interventions remains a significant challenge, and pharmacotherapy is often associated with side effects.

Ayurveda, the traditional Indian system of medicine, provides a comprehensive approach to managing prediabetes, referred to as '*Prameha*' in ancient texts.[13] Ayurvedic interventions focus on balancing the *doshas,Panchakarma*, dietary modifications, herbal formulations, and lifestyle changes (*Dinacharya and Ritucharya*). Herbs such as *Guduchi*, *Haridra*, and *Amla* have shown anti-diabetic and antioxidant properties[14].

Ayurvedic texts attribute the causes of *Prameha* to factors such as a sedentary lifestyle, early consumption of milk and dairy products, the use of animal feed grown in swampy regions, newly harvested grains, and refined sugars, closely aligning with the causes of Type 2 Diabetes Mellitus (T2DM).[15] In Ayurvedic literature, *Prameha* is described as a group of intricate clinical disorders marked by frequent abnormal urination. Its causes are linked to genetic factors, poor dietary habits, and an

unhealthy lifestyle. The symptoms and conditions associated with *Prameha* closely resemble those of diabetes mellitus.

Nidana sevana causes vitiation of the *kapha dosha* in dominance, as well as the other two *doshas*, which then vitiates *meda*, resulting in *prameha*. *Purvaroopas* include body flabbiness (*shitilangatha*), malaise (*sada*), sweating, body odor (*swedoangagandha*), a preference for lying, sitting, and sleeping comfortably (*shayaasana swapna sukhe*), limb numbness, and so on.[16,17].

Clinical features include *prabhutavilamutrata* (copious urination and turbid urine), *asyamadhurya* (sweet taste in the mouth), *galatalu shosha* (dryness of the palate and throat), excessive sleep, and continuous drowsiness, among others[18].

Ayurveda recommends various treatment modalities for *prameha*, including *nidana parivarjana*, *shodana*, *shamana*, and *Pathyapathya*. In *Prameha*, the imbalance of *Kapha dosha* leads to the disruption of adipose tissue (*medas*), muscle tissue (*mamsa*), and bodily fluids (*kleda*). When *medas* becomes excessively imbalanced, it results in the early symptoms (*Purvarupas*) of *Prameha*. The disturbance of *kleda*, on the other hand, is responsible for the manifestation of urinary symptoms.[19]

Extensive research has highlighted yoga's effectiveness in managing metabolic disorders, such as pre-diabetes. Consistent practice of yoga postures (asanas), breathing techniques (pranayama), and meditation has been found to boost insulin sensitivity, alleviate stress, and improve overall metabolic well-being.[20] A randomized controlled trial revealed notable enhancements in fasting blood glucose and HbA1c levels in pre-diabetic individuals who engaged in yoga practice. [21]

Despite promising findings, research on the efficacy of integrated Ayurveda and Yoga interventions in managing pre-diabetes remains limited. Most studies are small-scale, lack methodological rigor, and are geographically restricted to Indian populations. To develop evidence-based guidelines, future randomized controlled trials should involve larger sample sizes and employ rigorous methodologies.

Pre-diabetes is a critical public health concern with far-reaching consequences if left unmanaged. While conventional interventions remain the standard, Ayurveda and Yoga present a holistic and sustainable approach to addressing this condition. Rigorous clinical trials are essential to validate their efficacy, especially in diverse cultural settings.

1.1. BACKGROUND

The global prevalence of prediabetes is rapidly rising, with estimates suggesting that approximately 8–14% of the global population is affected[22]. In 2021, the International Diabetes Federation (IDF) estimated that more than 541 million adults had impaired glucose tolerance, a significant marker of prediabetes.[23] In India, the prevalence of prediabetes varies between 10.3% and 14.6%, influenced by the diagnostic criteria applied and regional differences[24]. It is concerning that approximately 70% of people with prediabetes are projected to develop Type 2 Diabetes within ten years if preventive actions are not implemented. [25] Studies also indicate significant regional and gender-based disparities in prediabetes prevalence, with urban populations exhibiting higher incidence rates due to sedentary lifestyles and poor dietary habits[26].

Age is another critical factor, with prediabetes being more prevalent among individuals above 40 years. Additionally, obesity, physical inactivity, and genetic predisposition further exacerbate the risk of developing prediabetes[27]. The increasing prevalence poses a substantial burden on healthcare systems worldwide, highlighting the need for effective preventive strategies.

Daniel Asmelash and colleagues conducted a systematic review and meta-analysis on the prevalence and associated factors of prediabetes in the adult East African population. They systematically searched databases for studies published between January 1, 2013, and December 30, 2022, including all observational community-based research that reported on prediabetes prevalence or its associated factors in adults from East Africa. Three authors independently extracted the necessary data using an Excel format, and the analysis was performed with Stata™

Version 11. The study concluded that prediabetes is highly prevalent and is significantly associated with advanced age, hypertension, and elevated BMI. It recommends that health policymakers focus on prevention and control strategies specifically aimed at individuals with obesity, hypertension, and older age.[28]

Matthias Li and colleagues explored the question, "Is Type 2 Diabetes Mellitus a Behavioral Disorder?" in their evidence review on the prevention and remission of Type 2 Diabetes Mellitus (T2DM) through lifestyle modification. The American Diabetes Association recommends several lifestyle changes for preventing T2DM: 1) significant lifestyle adjustments to achieve and maintain a 7% weight loss from initial weight and engage in at least 150 minutes per week of moderate-intensity physical activity; 2) adopting various eating patterns to assist individuals with prediabetes; and 3) incorporating a certified, technology-assisted diabetes prevention program tailored to patient preferences. Yoga is highlighted for its role in activating anti-stress mechanisms and the parasympathetic system, supporting lipid metabolism, enhancing glucose tolerance, and increasing insulin sensitivity, thereby improving the psychological and metabolic profiles of patients. Yoga practices, including asanas, mudras, meditation, pranayamas, and bandhas, are effective in lowering blood glucose levels and managing T2DM-related comorbidities, making it a beneficial approach to T2DM management.[29]

Type 2 diabetes mellitus was once regarded as an irreversible and progressive condition. However, over the past 12 years, clinical studies have shed light on the underlying mechanisms of the disease. It has been found that the processes causing type 2 diabetes can be restored to normal through dietary energy restriction leading to a weight loss of approximately 15 kg. About half of those diagnosed within 10 years and who successfully adhere to such dietary restrictions can discontinue all diabetes

medications and regain non-diabetic glucose levels. Remission is defined as achieving HbA1c levels of 48 mmol/mol or lower after weight loss, sustained for at least six months without the use of anti-diabetic drugs. Randomized clinical trials have shown that 15% of participants normalized fasting glucose levels following an initial dietary weight loss phase. The Look-Ahead trial, which compared intensive lifestyle advice (including physical activity and dietary restriction) to standard diabetes management, reported diabetes remission in 11.5% of participants in the intensive intervention group, despite remission not being a primary objective. Simply providing individuals with information on the weight loss necessary for remission can empower motivated individuals to achieve it using their preferred methods.[30]

Jenny Roosenn and colleagues conducted the Sophia Step Study, a randomized controlled trial (RCT), to explore the promotion of physical activity in primary care for individuals with prediabetes and type 2 diabetes. The study highlights that physical activity can prevent or delay the progression of impaired glucose tolerance in high-risk individuals and should be a cornerstone of diabetes management. The study's objective is to assess the effectiveness of a multi-component versus a single-component physical activity intervention in improving HbA1c (the primary outcome), along with other metabolic and cardiovascular risk factors, physical activity levels, and overall health in this patient population. The researchers aim to determine whether a comprehensive intervention involving pedometers, combined with group and individual consultations, is more effective than using pedometers alone in achieving these health improvements.[31]

Hostalek et al. conducted a study highlighting the significant variability in reported prevalence estimates of prediabetes, largely due to differences in diagnostic criteria, testing methods, and the populations examined. For example, in a cohort of

1,547 American adults without diabetes, lowering the impaired fasting glucose (IFG) threshold from 110 mg/dL to 100 mg/dL increased the prevalence of prediabetes from 19.8% to 34.6%. A meta-analysis of studies involving Caucasian and Asian cohorts found IFG prevalence rates of 36.0% based on WHO guidelines and 53.1% based on ADA guidelines. Interestingly, the prevalence rates for individuals with both IFG and impaired glucose tolerance (IGT) were more consistent: 15.8% (WHO) and 20.2% (ADA). In 2017, the global prevalence of IGT was estimated at 7.3% of the adult population, or 352.1 million individuals. This figure is projected to rise to 8.3%, or 587 million people, by 2045. The study concludes that the prevalence of prediabetes is growing rapidly worldwide, necessitating urgent action to curb this trend and prevent a diabetes epidemic that could overwhelm global healthcare systems.[32]

In 2013, Schellenberg et al. conducted a meta-analysis comparing lifestyle interventions to standard care in their effectiveness at slowing the progression of prediabetes to diabetes and reducing all-cause mortality in individuals with diabetes. The analysis included nine randomized controlled trials involving prediabetic individuals at risk for diabetes and eleven trials involving individuals already diagnosed with diabetes. Of the nine studies focused on at-risk patients, seven reported that lifestyle interventions significantly reduced the risk of developing diabetes, with these benefits lasting for up to 10 years post-intervention.[33]

Gujjar P et al. conducted a case-control study investigating cardiac autonomic neuropathy (CAN) in individuals with prediabetes. The participants were purposively selected from those attending a tertiary care hospital between January 2018 and June 2019. The study included 50 individuals with prediabetes, diagnosed using the American Diabetes Association's glycated hemoglobin criteria, and 50 healthy controls matched for age and gender. CAN was assessed using standard

cardiovascular reflex tests as outlined by Ewing and Clarke, which involved evaluating R-R interval changes during deep breathing, the Valsalva maneuver, and blood pressure responses to standing and sustained handgrip. The results indicated the presence of subclinical autonomic dysfunction in individuals with prediabetes. Identifying CAN at an early stage in prediabetes may have significant implications for reducing future cardiovascular risks.[34]

1.2. OBJECTIVES AND HYPOTHESIS

Objectives:

- To evaluate the efficacy of Integrated Ayurveda Management protocol in patients of prediabetes in achieving the glycemic control.
- To compare the effect of Integrated Ayurveda Management protocol and Standard treatment regimen intervention on changes in biochemical parameters of Prediabetes (HbA1c, Lipid profile, Fasting Insulin, HOMA IR)
- To compare the effect of Integrated Ayurveda treatment protocol and Standard treatment regimen intervention on quality of life in Prediabetes (DQoL)

Hypothesis

Null hypothesis: Integrated Ayurveda Management protocol which include Ayurveda formulation, Diet and Yogic intervention given for a duration of 90 days has no role in the management of Prediabetes**.**

Alternate Hypothesis: Integrated Ayurveda Management protocol which include Ayurveda formulation, Diet and Yogic intervention given for a duration of 90 days has role in the management of Prediabetes**.**

1.3. JUSTIFICATION

Prediabetes is an important transitional metabolic condition marked by impaired glucose regulation, including impaired fasting glucose (IFG), impaired glucose tolerance (IGT), or elevated HbA1c levels that fall below the diagnostic threshold for diabetes. This condition increases the risk of developing type 2 diabetes mellitus (T2DM) and cardiovascular diseases, highlighting the need for early detection and intervention. Lifestyle changes, such as dietary adjustments, regular exercise, and weight management, are fundamental to managing prediabetes, as outlined in international guidelines. Research indicates that structured lifestyle interventions can improve insulin sensitivity, lower blood sugar levels, and delay or prevent the progression from prediabetes to T2DM.[113]

Despite these preventive measures, many individuals progress to T2DM due to various factors such as lack of awareness, inadequate access to care, and limited adherence to lifestyle recommendations.[114] Pharmacological treatments, like metformin, have proven effective in managing prediabetes by decreasing liver glucose production and enhancing insulin sensitivity in peripheral tissues.[115]However, long-term use of pharmacological agents may pose risks such as gastrointestinal disturbances and vitamin B12 deficiency.[116]

An integrative approach incorporating conventional and complementary therapies holds promise in addressing the multifactorial aspects of prediabetes. Such an approach emphasizes holistic care by combining modern medical treatments with evidence-based complementary strategies, including dietary recommendations, herbal supplements, and lifestyle interventions like yoga and meditation.[117] Herbal medications such as *Madhunashini, Vijayasara,* and *Guduchi* have shown properties

of enhancing insulin sensitivity and providing antihyperglycemic effects in traditional Ayurvedic medicine.[118] Furthermore, yoga and other lifestyle interventions have been reported to reduce stress and improve metabolic markers in prediabetes, enhancing the efficacy of conventional treatments.[119]

While numerous clinical trials have investigated the benefits of Ayurveda-based treatments for diabetes management, only a few have specifically examined their impact on prediabetes using measurable indicators such as fasting insulin levels and the homeostatic model assessment of insulin resistance (HOMA-IR). Many of these studies are constrained by small sample sizes and a lack of interdisciplinary methodologies.[120] Thus, there is a pressing need for rigorous research to evaluate the efficacy of integrative approaches combining Ayurveda, diet, yoga, and conventional pharmacotherapy in prediabetes management. Such research can potentially offer a comprehensive and cost-effective strategy to delay or prevent the onset of T2DM, improve glycemic control, and enhance the quality of life in individuals with prediabetes.

1.4. REVIEW OF LITERATURE

1.4.1. Review on *Prameha Poorvarupa, Pathya* and Yoga

Prameha purvarupa: The significance of *purvarupa* is highlighted in *Sushruta Nidanasthana*, that a person who displays the *purvarupa* symptoms and whose quantity of urine excretion has slightly increased, such a person should be treated like a *pramehi*[16]. Hence the *Acharya* clearly states, that there is no need to wait for all the symptoms to manifest.

Charaka samhita[35]: *Acharya Charaka* explains the *purvarupa* of *prameha* in both *Nidanasthana* & *Chikitsasthana*. These consist of both physical and mental features that can be observed priorly. The physical symptoms are described as *jatilibhava kesha* (knotting of hair), *madhurya asyam* (sweetness of mouth), *kara-pada supta-daha* (occasional shifting of symptoms like numbness and burning sensation in hands and feet), *mukha-taalu-kanta-shosha* (drying of the mouth, palate & throat), *pippasa* (thirst), *mala kaaye* (feeling of a layer of dirt surrounding the body), *kaya-chidra-updeha* (all the orifices of the body appear to be layered), *paridaha* (burning sensation around the body), *supta anga* (numbness of the body parts), *shatpada-pippilika sharira-mutra abhisarana* (attraction of insects and ants towards the body and urine) and *visra sharira gandha* (foul body odour). The mental features can be seen as *aalasya* (lethargy) and *sarva kala nidra- tandra* (to feel sleepiness & tiredness throughout the day).

In *Chikitsa sthana*,[36] the physical features are elaborated like *sweda* (increased perspiration), *shithila angata* (laxity of body parts), *hrud-netra-jiwha-shravan-updeha* (feeling as if cardiac region is covered with extraneous material and exudation from

eyes, tongue and ears), *ghana anga* (rise in the body weight) and *kesha-nakha ativruddhi* (rapid growth of hair and nails).

The mental features that are added are *shayya-asana-swapna- sukhe rati* (the profound desire to lie down or to sit comfortably without involving in any work) and *sheeta priyata* (desire for cold items).

Sushruta samhita[37]: Added symptoms have been explained by *Acharya Sushruta*. These are *hasta-pada-tala daha* (burning sensation in the soles of the palm and feet), *snigdha-picchila- guru gatra* (smoothness, stickiness and heaviness of the body), *madhura-shukla mutra* (presence of sweetness and pale white colour in urine), *sada* (heaviness), *shwasa* (dyspnoea), *talu-gala-jiwha-danta malotpatti* (increased accumulation of dirt in palate, throat, tongue and teeth), *nakha vruddhi* (rapid growth of nails).

Ashtanga sangraha*: Acharya Vruddha Vagbhata* has added *bahi kaaye- kaaya chidreshu shitecha* (Desire of coldness specifically in the external body parts and in the external pores), *sneha- sweda* (without any oleation or fomentation, the body appears unctuous and sweaty), *ati madhurya pippilika sarpana* (the sweetness of the body causes the ants to roam over the body) and *mutra shuklata* (pale white urine) [38].

Ashtanga hrudaya, Yogaratnakara, Bhaishajya ratnavali, Madhava nidana: These texts quote the same *purvarupa lakshanas* as told by *Acharya Charaka* and *Sushruta*[39-42].

Harita samhita: This text does not mention the *purvarupa lakshanas*.

Table no.1: *Purvarupa* of *Prameha* in *Bruhatrayi's*

S.N	Symptoms	*Charak*	*Sushruta*	*Astanga Hridaya*	*Astanga Sangraha*
1.	Burning Sensation on feet	+	+	+	+
2.	Rapid growth of nails and hairs	+	+	+	+
3.	Foul Smelling of Body	+	+	-	+
4.	Matting and nasty appearance of hair	+	+	-	+
5.	Drowsiness, sleepiness	+	+	-	+
6.	Excreta over body	+	+	-	+
7.	Sweetness of Mouth	+	-	+	+
8.	Dryness of oral cavity	+	-	+	+
9.	Excessive Thirst	+	+	+	+
10.	Desire of Cold things	+	-	+	+
11.	Ants attracted to urine	+	-	+	-
12.	Numbness of body parts	+	-	-	+

Increased levels of glucose in the saliva can be co-related to *aasya madhuryam.* The rise in body weight or bulk mentioned as *ghanangata* is due to the nitrogen retention, which is caused by GH (growth hormone) and IGF-1 (Insulin like growth factor 1), during energy surplus. Also, excessive growth of hair and nails are due to the affinity of keratin to glucose. Reduced salivary secretions can cause *gala talu shosha.* Also due to the increase of protein and calcium levels in the saliva and a decrease in magnesium, zinc and potassium, dysfunction at the level of salivary glands is usually seen. Faulty thermoregulation can cause symptoms of *sheeta priyatvam,*

sweda and *kara pada daha*. The production of bacterial flora due to the excess glucose in the sweat on the skin can produce a specific odour as an outcome[43].

Nidana:

1. *Aharaja nidana*
2. *Viharaja nidana*

Aharaja nidana:

Charaka: *Acharya Charaka* in *Nidanasthana* highlights that higher intake of fragrant grains like *hayanaka*, *yavaka*, *pramodaka*, *sugandhaka* etc that are freshly harvested can cause *Prameha*. Also *nava harenu* (freshly harvested green peas), *masha* (black gram) and other *supya* (lentils) when eaten with a lot of ghee, meat of reared animals, *anupa* (meat of animals that are from the marshy lands), *audaka* (aquatic animals- fish etc), *palala* (sesame paste), *pishtanna* (food preparations made from flour), different *ahara kalpana's* like *paayasa* (kheer), *krishra* (khichdi), *vilepi* (thick gruel), *ikshu vikara* (products of processed sugarcane), *guda vikruti* (jaggery preparations), milk, newly prepared alcohol, *mandaka dadhi* (improperly set curd) are listed as causes of *prameha*. These causes are broadly grouped into *drava* (excessive liquids), *madhura* (sweet preparations) and *taruna* (fresh or newly harvested) foods[44].

Sushruta: Along with the above causes, *Acharya Sushruta* has added that intake of *sheeta* (cold), *snigdha* (unctuous) and *medya* (foods that will increase the fat in the body) will increase the chances of *prameha* manifestation[45].

Ashtanga hridaya: Along with the other properties, the food and drinks possessing *amla* (sour), *lavana* (salty) taste, and which are *guru* (heavy to digest), and *picchila* (slimy) can cause *prameha*. Intake of *sura* (alcohol made from rice flour), jaggery are also mentioned amongst the causes[46].

Table no. 2: Ayurvedic perspective of *aharaja nidana* for *prameha*

S.N	Causes	*Charak*	*Sushruta*	*Astanga Hridaya*	*Astanga Sangraha*
1.	Intake of freshly harvested fragrant grains	+	-	+	-
2.	Intake of marshy land and aquatic	+	+	+	+
3.	Excessive intake of sweet and liquid substances	+	+	+	+
4.	Intake of milk and s ugarcane preparations	+	+	+	+
5.	Intake of improperly formed curd	+	+	-	+
6.	Intake of unctuous, cold and heavy foods	-	+	+	-

Viharaja nidana:

Charaka: Non-indulgence in exercise or in any other physical activity that creates mild exertion, non-maintenance of hygiene i.e. laziness to bath or keep oneself presentable, the desire to remain sitting or lying down all through the day, and desire to sleep are the *viharaja* causes of *prameha*[44].

Sushruta: *Acharya Sushruta* has added *diwaswapna* (sleeping during the daytime) and *alasya* (laziness) in the causes of *prameha*[45].

Table no. 3: Ayurvedic perspective of *viharaja nidana* of *prameha*

S.N	Symtoms	*Charak*	*Sushruta*	*Astanga Hridaya*	*Astanga Sangraha*
1.	Non-indulgence in exercise	+	+	+	+
2.	Non-maintenance of hygiene	+	-	-	-
3.	Day-sleeping	+	+	+	-
4.	Laziness/ non-desire for activity	+	+	+	+

Samprapti of prameha:

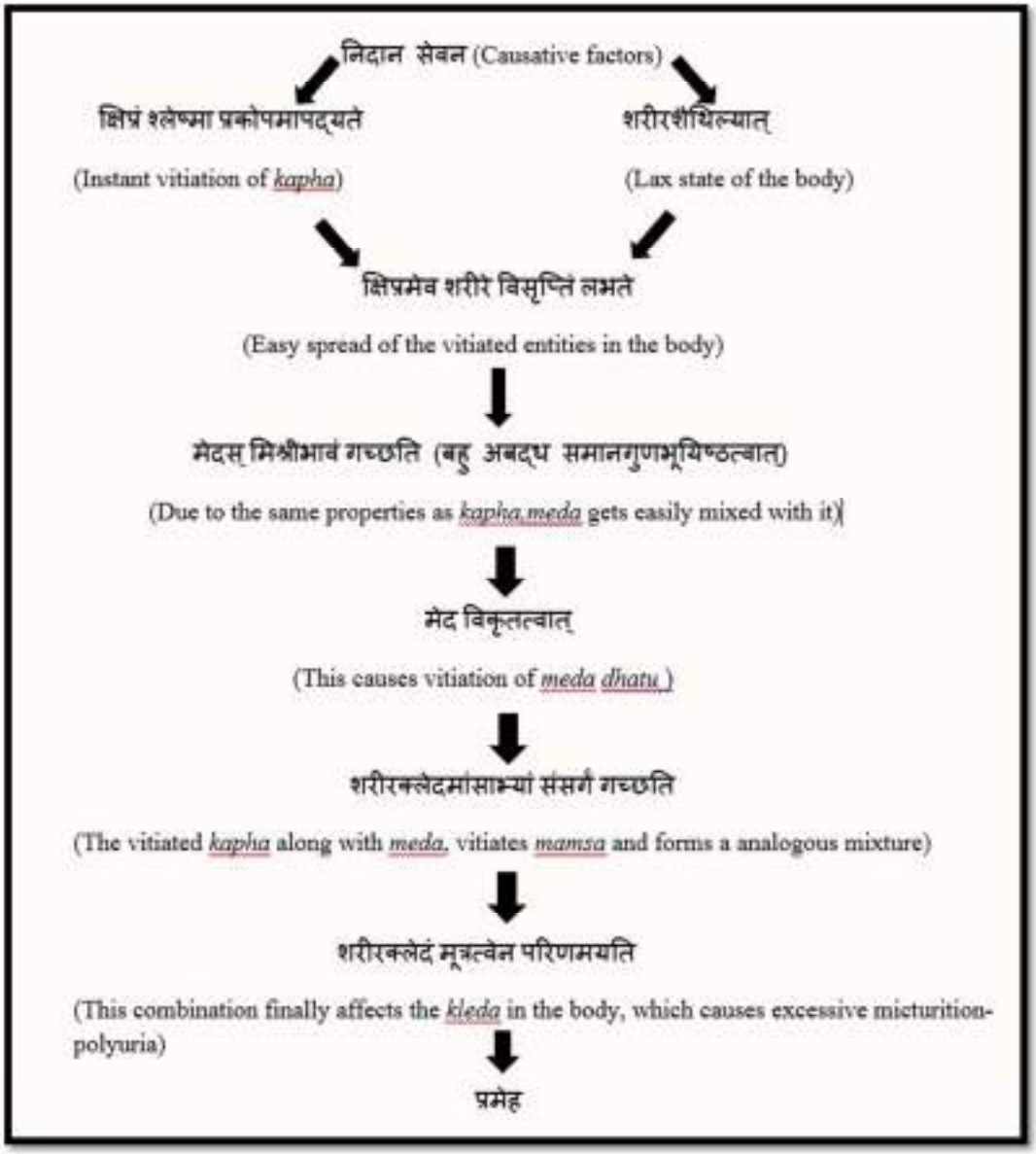
A separate *samprapti* is not mentioned in the context of *prameha purvarupa* in *Bruhatrayi's*. But *Acharya Charaka* in *Nidanasthana* elaborates about the association between *nidana- dosha-dushya*. It is seen that the disease will only manifest when this relationship between these 3 entities is built. But even if it is developed over an extended amount of time, the manifestation of the disease will take a longer time. And if the strength of the 3 factors is less, the disease produced will have a mild intensity or will manifest with less symptoms. This stage can be co-related with the *purvarupa avastha* where the *nidana-dosha-dushya* of *prameha* have established a relation that is not powerful enough to manifest a full-fledged disease like *prameha*, but has disrupted the metabolism at the earlier stage[47].

Also for *prameha* to occur, there are some pre-requisites that are noted. The body when becomes *shithila* (lax), due to non-indulgence in exercise, *kapha* can easily increase quantitatively. Also due to inactivity and consumption of fatty substances, *meda* loses its firmness and the moisture content in the body increases. This creates a suitable atmosphere for the disease to manifest[48].

Samprapti ghataka:

Dosha- Bahu-drava-shleshma (*Kapha* increased quantitatively in its liquid property) *Dushya- Meda* (fatty tissue), *mamsa* (muscles), *kleda* (moisture content), *shukra* (semen), *shonita* (blood), *vasa* (fascia), *majja* (bone marrow), *lasika* (lymph), *rasa* (the first *dhatu* after the transformation of the *ahara rasa*) and *oja* (essence of all tissues) [49].

Figure no.1: *Samprapthi* of *Prameha*



Pathya:

According to *Acharya Charaka*, it is quoted that *prameha* usually manifests in an individual who always has a strong desire towards food and drinks, who eats without thinking about its influence on the body, who hates bathing and movement i.e. any sort of physical exertion. It is said that *prameha* returns to such an individual in the same manner as a bird returns to a tree that holds a nest[50]. Also, the significance of *nidana parivarjana* is stated, where it is said that the *samanya chikitsa* (general treatment) of *prameha* is *hetu aseva* (leaving the cause) [51]. Two types of *pramehi* are described in the classics. One is *sahaja* (due to heredity) and *apathya- nimitta* (due to erratic lifestyle) [52]. The second type can only be prevented by modifying the lifestyle of the individual.

***Charaka*:** Purana *shaali* (1 year old harvested rice), *shashastika shaali* (rice that is harvested in 60 days), *trunadhanya* (millets) and *yava* (barley) are indicated in *shaali varga* (class of cereals). In legumes, *mudga yusha* (soups made out of green gram) is mentioned. All the *tikta shaka* (bitter vegetables) are indicated. Amongst *taila varga*, *danti*, *ingudi*, *atasi* (flaxseed) and *sarshapa* (mustard seeds) oil is recommended. Also *madhu* (honey) can be added in the preparations of barley[53].

***Sushruta*:** In the *shaalivarga*, *godhuma* (wheat) has been added. 4 main *shimbidhanya* has been mentioned- *chanaka* (chickpeas), *aadaki* (pigeon pea), *kulattha* (horse gram), *mudga* (green gram). Also it has been specially mentioned to use ghee of the milk of animals that are reared in the temperate areas. And also meat of skinny animals should be consumed[54].

Ashtanga hridaya: *Apupa* (malpua), *saktu* (porridge) etc should be made out of barley. *Raga- shaadava* (sour savouries) of *kapittha*, *tinduka* & *jambu* (jamun) are mentioned. *Shulya mamsa* (pierced and cooked- tandoori) and *shushka mamsa* (dried meat) is mentioned in the processing of meat. Also, *sidhu* (alcohol made out of rice flour) is indicated. Another important beverage that is mentioned is *maakshikodakam* (honey water)[55].

Ashtanga sangraha: In *Chikitsa sthana*, the *pathya* for *prameha* has been explained. *Bhrashta chanaka* (dry roasted chickpeas) and different kind of *asava* (alcohol preparations) are mentioned in *pathya*[56].

Table no. 4: *Prameha pathya* as per classics

S.N	Symtoms	*Charak*	*Sushruta*	*Astanga Hridaya*	*Astanga Sangraha*
1.	1 year old rice, 60 days harvested rice	+	+	+	+
2.	Barley, millets	+	+	+	-
3.	Wheat	-	+	-	+
4.	Green gram	+	+	-	+
5.	Chickpea, pigeon pea, horse gram	+	+	-	+
6.	Bitter vegetables	+	+	+	+
7.	Danti, ingudi, sarshapa, atasi taila	+	+	+	+
8.	Jangala mamsa	-	+	+	+

Pathya as per Vargas:

Shaali varga [57]

Table no. 5: *Prameha pathya* amongst *Shaali varga*

Sr. No	Food article	*Rasa*	*Guna*	*Virya*	*Vipaaka*	*Karma*	*Doshagnata*	*Rogagnata*
1.	*Kangu*		*Guru*			*Bhagna sandhankara, brimhana*	*Vatakara, shleshmahara Athiv*	
2.	*Shyamaka*	*Madhura, kashaya* 58	*Ruksha, laghu*			*shoshana*	*Vatakara, kapha-pitta hara*	
3.	*Yaavnaal*	*Madhura, kashaya*	*ruksha, laghu*	*sheeta*			*kapha-pitta hara*	
4.	*Yava* [59]	*Madhura, kashaya*	*Mrudu, ruksha, laghu*	*sheeta*	*katu*	*Lekhana, medha vruddhi, agnikara, balya, sthairyakara* 60	*Vatakara, kapha-pitta hara (shleshma-vikaara-nut)* 60	*Vrana, medoroga, trushna*
5.	*Puraana shaali*		*Laghu*					
6.	*Raktashaali* 59					*Balya, Shukrala, agnipushti*	*Tridoshahara*	*Trushna, vrana*

Shimbi varga [61]

Table no. 6: *Prameha pathya* amongst *Shimbhi varga*

Sr. No	Food Article	*Rasa*	*Guna*	*Virya*	*Vipaaka*	*Karma*	*Doshagnata*	*Rogagnata*
1.	*Mudga*	*Kashaya, madhura* [62]	*Ruksha, laghu, Vishada* [62]	*Sheeta*	*Katu* [51]	*Grahi*	*kapha-pitta hara,alpa vatakara*	
2.	*Chanaka*	*Kashaya, madhura* [62]	*Sheeta, ruksha, Laghu*	*sheeta*			*Vatakara, kapha-pitta hara*	
3.	*Aadaki*	*Madhura kashaya*	*ruksha, laghu*	*sheeta*		*grahi*	*Vatakara, kapha-pitta hara*	
4.	*Kulattha*	*kashaya*	*laghu*	*ushna*	*amla*	*Grahi* [63]	*Vata-kapha hara, pittakara*	*Medoroga*
5.	*Masoora*	*Kashaya,*	*Laghu,*	*Sheeta*		*grahi*	*Vatakara,*	

Shaaka varga

Table no. 7: *Prameha pathya* amongst *Shaka varga*

Sr. No	Food article	*Rasa*	*Guna*	*Virya*	*Vipaaka*	*Karma*	*Doshagnata*	*Rogagnata*
1.	*Karavellaka*	*tikta*	*laghu*	*sheeta*		*Bhedana, dipana*	*Vatakara, kapha-pitta hara*	*Prameha, pandu, krimi*
2.	*Patola*	*Tikta* [60]	*laghu*	*ushna*		*Hrudya, dipana, pachana, vrushya*	*Tridoshahara*	*krimi*
3.	*Alaabu*		*guru*			*Hrudya, vrushya, dhaatu pushti vardhanam*	*kapha-pitta hara*	
4.	*Rajkoshataki*					*dipana*		*krimi*
5.	*Vruntaaka* [65]		*Tikshna, ushna, laghu*		*katu*	*Dipana, shukrala*	*Vata-kaphahara*	
6.	*Mulaka* [66]	*katu*	*Ushna laghu*			*pachana*	*Tridoshahara*	
7.	*Tanduliyaka* 67		*Sheeta, ruksha, laghu*			*dipana*	*kapha-pitta hara*	*Visha* [68]
8.	*Palankya* [67]		*guru*			*bhedana*	*Vatakara, kapha-pitta hara*	
9.	*Apakva*		*Sheeta*				*Vatahara*	*trushna*

	kadali phala [69]		*, guru*					
7.	*Tanduliyaka* [67]		*Sheeta , ruksha , laghu*			*dipana*	*kapha-pitta hara*	*Visha* [68]
8.	*Palankya* [67]		*guru*			*bhedana*	*Vatakara, kapha-pitta hara*	
9.	*Apakva kadali phala* [69]		*Sheeta , guru*				*Vatahara*	*trushna*
7.	*Tanduliyaka* [67]		*Sheeta , ruksha , laghu*			*dipana*	*kapha-pitta hara*	*Visha* [68]
8.	*Palankya* [67]		*guru*			*bhedana*	*Vatakara, kapha-pitta hara*	
9.	*Apakva kadali phala* [69]		*Sheeta , guru*				*Vatahara*	*trushna*

Phala varga

Table no. 8: *Prameha pathya* amongst *Phala varga*

Sr. No	Food article	*Rasa*	*Guna*	*Virya*	*Vipaaka*	*Karma*	*Doshagnata*	*Rogagnata*
1.	*Jambu* [70]	*madhura*	*Guru, ruksha*			*rochana*	*Kapha pittahara*	
2.	*Daadima* [71]	*Madhura, kashaya*	*laghu*			*Shukrala, tarpana,*	*Tridoshahara*	*Trushna*

		anurasa				*grahi, balya*		
3.	*Amalaki* [72]	*Amla, madhura, kashaya*	*ruksha*	*sheeta*		*Vrushya, rasayana,*	*Tridoshahara*	*Prameha,*
4	*Amrut phala*[73]		Laghu			Vrshya	Tridosha hara	

YOGA

Yoga for a pre-diabetic individual can begin with *sukshma vyayama* (loosening exercises) for all joints to decrease the overall *shaithilya* (laxity) of the body. The protocol can be followed by a few rounds of *Suryanamaskara*. It builds a strong mind-body connection and also generates extra energy in the body which uplifts the mood of the individual and creates enthusiasm and a positive outlook towards life. It also trains your mind to focus on the matter at hand, which reduces the emphasis on other problematic aspects of life. This helps in reducing stress and anxiety.[74]

Then a sequence of standing, sitting, prone and supine asanas can be brought into practice. Few asanas like Vakrasana, Ushtrasana, Dhanurasana, Naukasana have a special action of stimulating pancreas. The other asanas like Trikonasana and Bhujangasana reduces the waist circumference as it targets the abdominal fat. When comparing yoga to exercise, health-related outcome variables such as blood glucose, blood lipids, oxidative stress, and so on frequently improve along with QoL (Quality of Life) [75]. The stretching motions of muscles that are an intrinsic part of the yoga regimen promote glucose sensitivity and glucose tolerance. [76]. Also, activation of the

HPA pathway and sympatho-adrenal system increases insulin resistance, blocks insulin release, and increases hepatic glucose production[77].

Yoga therapy is a physical activity with mild to moderate intensity that possesses a unique energy retaining effect which provides goodness to the subjects after practice [78]. This may be the sole reason for the increased Quality of Life in the subjects post 3 month of practice. Yoga therapy improves the initial stage insulin release in pre-diabetes through autonomic balance, lowering the incidence of Type 2 diabetes. This has also been accepted by ADA as a part of lifestyle modification. Also, this therapy improves beta-cell function, by its effect on serotonin and brain derived neurotrophic factors (BDNF), through the neurophysiological mechanism.

Yoga also aids in the utilisation of glucose in the cells as energy rather than increasing blood glucose levels, particularly in cases with poor insulin-dependent glucose elimination in skeletal muscles. In a nutshell, yoga facilitates the nervous system's connection with pancreatic beta cells through vagal regulation. It also improves autonomic balance, promotes beta cell proliferation, and so improves neurophysiology and neuroendocrine mechanisms. The parasympathetic activity that regains the autonomic balance, which is required for glycaemic control, is regained by moderate and mild intensity *yogasanas* with slow breathing. Also when the *asanas* are practised followed by pranayama, it reduces the stress hormone which decreases the glucocorticoids secretion that achieves glycaemic control [79].

1.4.2. Review on Prediabetes stage

Prediabetes is a metabolic disorder in which blood glucose levels are above the normal range but not sufficiently high to meet the diagnostic criteria for Type 2 Diabetes Mellitus (T2DM). It is primarily marked by impaired glucose metabolism,

along with early signs of disrupted fat and protein metabolism. Prediabetes serves as an intermediate stage between normal glucose regulation and T2DM.

Insulin resistance is a key factor in prediabetes, where the body's cells exhibit reduced sensitivity to the effects of insulin.[80] At first, the pancreas compensates by increasing insulin production to keep blood glucose levels within the normal range. However, this compensatory response can eventually become inadequate, leading to a continuous rise in blood glucose levels and a higher risk of developing Type 2 Diabetes Mellitus (T2DM).[81] Although prediabetes is more frequently seen in individuals aged 45 and older, it is becoming increasingly prevalent among younger populations, including children, adolescents, and young adults. This shift is largely attributed to rising obesity rates, sedentary lifestyles, and increased consumption of high-calorie, processed diets.[82]

Major risk factors for Prediabetes:[83]

The development of prediabetes is influenced by various risk factors, with lifestyle choices and genetic predispositions being particularly significant contributors. Key risk factors include:

1. Obesity, particularly central obesity
2. Sedentary lifestyle and lack of physical activity
3. Poor dietary habits, including high intake of refined carbohydrates and sugary beverages
4. Family history of diabetes
5. Advanced age (45 years and older)
6. Ethnicity, with higher prevalence among South Asians, Hispanics, and African Americans

7. History of gestational diabetes or polycystic ovary syndrome (PCOS)
8. Hypertension and dyslipidemia
9. These risk factors often interact, amplifying the likelihood of developing prediabetes and subsequent progression to T2DM.

Etiopathogenesis:[84]

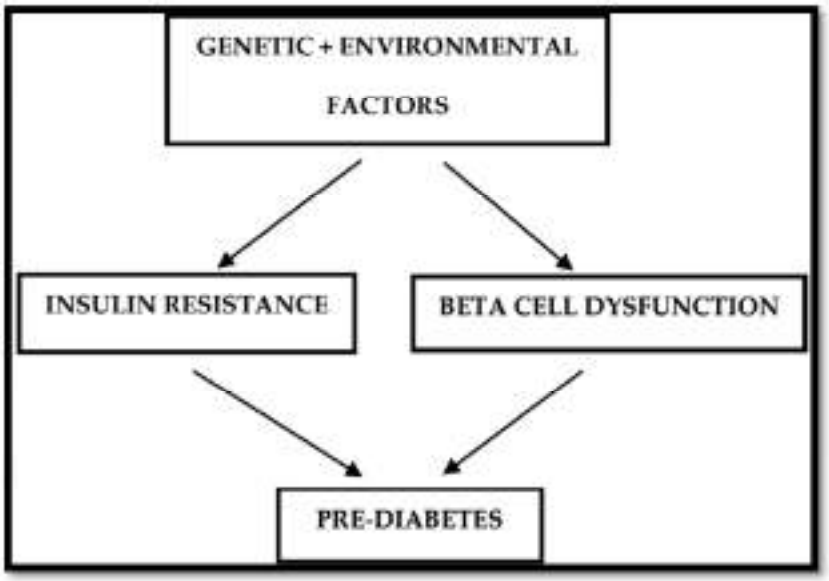
The etiopathogenesis of prediabetes is multifactorial and involves complex interactions between genetic, environmental, and behavioural factors. The primary mechanisms include insulin resistance, beta-cell dysfunction, and low-grade chronic inflammation.

- **Insulin Resistance:** Insulin resistance in peripheral tissues, especially muscles, liver, and adipose tissue, reduces glucose uptake and utilization, leading to hyperglycemia.
- **Beta-Cell Dysfunction:** Pancreatic beta-cells are unable to produce sufficient insulin to effectively regulate elevated glucose levels, which further exacerbates hyperglycemia.
- **Inflammation and Oxidative Stress:** Chronic low-grade inflammation and oxidative stress damage beta-cells and impair insulin signaling pathways.
- **Genetic Predisposition:** Individuals with a family history of diabetes are at higher risk due to inherited genetic factors affecting insulin sensitivity and secretion.

- **Gut Microbiota Dysbiosis:** Changes in the composition of gut microbiota have been associated with the development of insulin resistance and glucose intolerance.

These interconnected mechanisms emphasize the need for a multi-faceted approach to prediabetes management.

Fig. No.2: Pathogenesis of Prediabetes



1. **Genetic factors**

Genetic predisposition significantly influences the development of prediabetes, with several key genetic variants being identified as risk factors across diverse populations. In the study, six single nucleotide polymorphisms (SNPs) associated with type 2 diabetes were found to also increase prediabetes risk, with an additive effect observed as the number of risk alleles increased (Zyriax *et al.*, 2013)

(link). Moreover, genetic variants in genes such as *HNF4A*, *WFS1*, *DUSP9*, *FTO*, and *ZFAND6* have been implicated in prediabetes risk, highlighting their role in insulin secretion, inflammation, and metabolic regulation.[85] These findings emphasize that genetic predisposition to prediabetes results from the cumulative impact of multiple variants, each contributing to impaired glucose regulation through distinct biological pathways. Genetic screening, combined with traditional risk assessments, could improve early detection and intervention strategies for individuals at high risk of progressing from prediabetes to type 2 diabetes.

2. Constitutional factors

Specific environmental factors, including obesity, hypertension, and level of physical activity, have a contributory role and influence the expression of the disease phenotype.

3. Insulin resistance

Insulin resistance is a key feature of prediabetes, a condition where blood glucose levels are elevated but not yet within the range for a diabetes diagnosis. In this state, peripheral tissues such as skeletal muscle, liver, and adipose tissue become less responsive to insulin, leading to reduced glucose uptake and increased glucose production by the liver, even in the presence of high insulin levels. This dysfunction is often driven by factors like obesity, physical inactivity, and genetic predisposition, which promote chronic low-grade inflammation, ectopic fat accumulation, and oxidative stress. Dysfunctional adipose tissue, particularly visceral fat, contributes by releasing excessive free fatty acids and pro-inflammatory cytokines like TNF-α and IL-6, further worsening insulin resistance. Initially, pancreatic β-cells compensate by producing more insulin, but this compensatory capacity diminishes over time,

resulting in persistent hyperglycemia. Lifestyle changes, including healthier dietary choices, regular physical activity, and weight loss, are critical for improving insulin sensitivity and β-cell function, helping to prevent the progression from prediabetes to type 2 diabetes.[86]

4. β-cell Dysfunction

Beta-cell dysfunction plays a pivotal role in the progression from prediabetes to type 2 diabetes, marked by the pancreas's inability to adequately compensate for insulin resistance. During prediabetes, insulin-producing beta cells in the pancreatic islets initially respond to insulin resistance by increasing insulin output. However, persistent hyperglycemia, lipotoxicity due to elevated free fatty acids, and pro-inflammatory cytokines such as IL-1β and TNF-α induce beta-cell stress, suppress insulin gene expression, and trigger apoptosis. Over time, these factors lead to a reduction in beta-cell mass and impaired insulin secretion, particularly during postprandial glucose regulation.[87]

Clinical Features:[83]

1. Prediabetes is often asymptomatic, and individuals may not be aware of their condition until detected through routine screening or incidental blood glucose testing.
2. In some cases, individuals with prediabetes may present with symptoms related to insulin resistance, such as increased hunger, mild fatigue, or subtle changes in energy levels.
3. Obesity, particularly central obesity, is frequently observed in individuals with prediabetes, along with associated metabolic abnormalities such as hypertension and dyslipidemia.

4. Clinical indicators such as acanthosis nigricans, a skin condition marked by dark, velvety patches, and polycystic ovary syndrome (PCOS) in women are commonly linked to prediabetes.
5. Prediabetes is closely associated with a heightened risk of cardiovascular disease and non-alcoholic fatty liver disease (NAFLD).

Diagnosis:[88]

- An HbA1C of 5.7–6.4%
- Fasting blood glucose of 100–125 mg/dL.

Treatment:

The main aim of management is to improve symptom of hyperglycemia and to minimize the risk of long term microvascular and macrovascular complications.[89]

1. Treatment methods include[90]
    a. Dietary and lifestyle modifications

a) Dietary recommendation

- **Benefits of nutrition therapy**

It is advised that all adults with diabetes and prediabetes receive nutrition counseling aimed at enhancing or sustaining glycemic control, reaching weight management objectives, and addressing cardiovascular risk factors such as blood pressure and cholesterol, in alignment with personalized treatment plans.

- **Goals of nutrition therapy**
    - Achieve and maintain body weight goals.
    - Delay or prevent complications of diabetes.
- **Nutritional requirements**

- Macronutrient requirements
  - Approximately 45% of calories come from carbohydrates, 36-40% from fat, and 16-18% from protein. Chosen carbohydrates will be with a low glycaemic index and load.
  - Increase fibre intake through food (e.g., vegetables, legumes, fruits, whole grains) or nutritional supplements. A minimum of 14 g of fibre per 1,000 kcal and around 50 g of fibre per day lowers glycaemic consequences.
  - Limit saturated fat to less than 7% of total calories. Consumption of trans fat should be minimized. Very-long-chain n-3 polyunsaturated fatty acid supplements were recommended.
  - Omega-3 fatty acids should be consumed in the form of fish or supplements. Eat 2-3 servings of fish every week. Protein accounts for 10-35% of total energy consumption from high-quality sources such as meat, poultry, fish, eggs, milk, cheese, and soybeans[91].

- Eating patterns
  - Mediterranean-Style Eating Pattern
    - Focus on antioxidant-rich foods like vegetables, fruits, whole grains, legumes, seeds, nuts, and spices. The primary source of fat is olive oil, which contains MUFA, while fish, which contains polyunsaturated omega 3 fatty acids, is consumed in moderation, and dairy products are used on a low-to-moderate basis. On the other hand, red and processed

meat is consumed very infrequently, usually only during special occasions[74].

- Vegetarian or vegan eating patterns
  - A conventional vegan diet excludes any animal-derived items. The diet emphasizes on whole grains, legumes, fruits, and vegetables.
- United states USDA Dietary Guidelines for Americans
  - Emphasizes a diverse range of vegetables, fruits, grains (at least half of which are whole), lower-fat dairy, protein sources, and oils. This diet reduces saturated and trans fats, added sweets, and sodium.
- Low-fat diet
  - Emphasizes vegetables, fruits, carbohydrates (e.g., breads/crackers, pasta, whole grains, starchy vegetables), lean protein sources (including beans), and low-fat dairy.
- Very low-fat diet
  - Includes fibre-rich vegetables, legumes, fruits, whole grains, non-fat dairy, salmon, and egg whites. Contains 70-77% carbs (with 30--60 g fibre), 10% fat, and 13-20% protein.
- Low-carbohydrate diet
  - Low-carbohydrate vegetables (such as salad greens, broccoli, cauliflower, cucumber, cabbage, and others); fat from animal products, oils, butter, and avocado; and protein from meat, chicken, fish, shellfish, eggs, cheese, nuts, and seeds. Some plans contain fruit (such as berries) and a wider variety of non-starchy veggies. Avoids starchy and sugary

foods including pasta, rice, potatoes, bread, and desserts. There is no standard definition of "low" carbohydrate. In this review, a low-carbohydrate eating pattern is defined as limiting carbohydrates to 26–45% of total calories.

- Very low-carbohydrate diet [VLC]
  - It is like the low-carbohydrate diet, but it further restricts carbohydrate-containing items, and meals often contain more than half of their calories from fat. To induce nutritional ketosis, it is common to aim for 20-50 g of non-fibre carbs per day. In this review, a VLC eating pattern is described as limiting carbohydrate to 26% of total calories.
- Dietary Approaches to Stop Hypertension (DASH)
  - Emphasizes vegetables, fruits, low-fat dairy products, whole grains, chicken, fish, and nuts, while limiting saturated fat, red meat, sweets, and sugary beverages. The sodium level may also be lowered.
- Paleo diet
  - Emphasizes foods often consumed during early human evolution, including lean meat, fish, shellfish, vegetables, eggs, nuts, and berries. Avoids grains, dairy products, salt, refined fats, and sugar[92].

- **Type of exercise and Physical Activity in Prediabetes [as per ADA[93-94]]**

The American Diabetes Association (ADA) suggests that individuals with prediabetes engage in a mix of aerobic activities, resistance workouts, and flexibility exercises to enhance insulin sensitivity and improve glucose metabolism.

Aerobic activities like brisk walking, cycling, or swimming should be done for a minimum of 150 minutes each week, distributed over at least three days, ensuring that no more than two consecutive days pass without exercise.The intensity should be moderate to vigorous, aiming to raise the heart rate and induce mild sweating. Additionally, resistance training involving major muscle groups (e.g., weightlifting, bodyweight exercises) is recommended at least twice a week on non-consecutive days.

Flexibility and balance exercises, such as yoga or stretching, are also encouraged to improve overall fitness and reduce the risk of injury. The ADA emphasizes that even light physical activity, such as frequent standing or walking breaks, can provide metabolic benefits, especially for sedentary individuals. Structured exercise programs and lifestyle modifications have been shown to significantly reduce the risk of progression from prediabetes to type 2 diabetes.

Table no.9. Showing the Physical activity protocol for Prediabetes [as per ADA]

Exercise training recommendations: types of exercise, intensity, duration, frequency, and progression			
	Aerobic	Resistance	Flexibility and Balance
Type of exercise	Prolonged, rhythmic activities using large muscle groups (e.g., walking, cycling, and swimming) c May be done continuously or as HIIT	Resistance machines, free weights, resistance bands, and/or body weight as resistance exercises	Stretching: static, dynamic, and other stretching; yoga Balance (for older adults): practice standing on one leg, exercises using balance equipment, lower-body and core resistance exercises, tai chi

Intensity	Moderate to vigorous (subjectively experienced as “moderate” to “very hard”)	Moderate (e.g., 15 repetitions of an exercise that can be repeated no more than 15 times) to vigorous (e.g., 6–8 repetitions of an exercise that can be repeated no more than 6–8 times)	Stretch to the point of tightness or slight discomfort c Balance exercises of light to moderate intensity
Duration	At least 150 min/week at moderate to vigorous intensity for most adults with diabetes. For adults able to run steadily at 6 miles per h (9.7 km/h) for 25 min, 75 min/week of vigorous activity may provide similar cardio protective and metabolic benefits	At least 8–10 exercises with completion of 1–3 sets of 10–15 repetitions to near fatigue per set on every exercise early in training	Hold static or do dynamic stretch. repetitions of each exercise. Balance training can be any duration
Frequency	3–7 days/week, with no more than 2 consecutive days without exercise	A minimum of 2 nonconsecutive days/ week, but preferably 3	Flexibility, Balance
Progression	A greater emphasis should be placed on vigorous intensity aerobic exercise if fitness is a primary goal of exercise and not contraindicated by complications c Both high intensity interval training (HIIT) and continuous exercise training are appropriate activities for most individuals with diabetes	Beginning training intensity should be moderate, involving 10215 repetitions per set, with increases in weight or resistance undertaken with a lower number of repetitions (8210) only after the target number of repetitions per set can consistently be exceeded c Increase in resistance can be followed by a greater number of sets and finally by increased	Continue to work on flexibility and balance training, increasing duration and/or frequency to progress over time

		training frequency	

1.4.3. Drug review.

- Review on *Madhumehari Kashaya*
- It contains a total of 10 ingredients – *Madhunashini, Asana, Jambu, Haridra, Daruharidra, Bibhitaki, Haritaki, Amalaki, Guduci, Tamalapatra*

1. Madhunashini

- **Botanical Name**- Gymnema sylvestrae R. Br
- **Family**- Asclepiadaceae
- **Synomyms**- *Meshashringi, Madhunashini, Vishani, Meshavalli, Meshavishanama, Meshavishani.*
- **Useful Part**- Leaf
- **Pharmacodynamics**-
  - ***Rasa***- *Kashaya,Tikta*
  - ***Guna***- *Laghu,Ruksha*
  - ***Virya***- *Ushna*
  - ***Vipaka***- *Katu*
  - ***Doshakarma***- *Kaphavata shamaka*
- ***Rogaghnakarma***- *Yakrit shotha, Pleeha vriddhi, Agnimandya, Vibandha, Madhumeha, Ikshumeha*
- **Chemical Constituents**- Gymnemic acid, gurmarin,tartaric acid, calcium oxalate, stigmasterol, glucose, betaine and choline.
- **Related Research Updates**- Diet supplemented with Gymnema Silvestre reduced polyphagia, fatigue, blood glucose (fasting and post-prandial), and glycated hemoglobin and there was a favorable shift in lipid profiles and in other clinico-biochemical tests. These findings suggest a beneficial effect of gymnema sylvestre in the management of diabetes mellitus.[111]

2. Asana

- **Botanical Name**- Pterocarpus marsupium Roxb.
- **Family**- Fabaceae
- **Synomyms**- *Asana, Beejaka, Peetashalaka, Pitasara, Bandhookapushpa, Priyaka, Saradru, Sarjaka*
- **Useful Part**- Heart wood.

- **Pharmacodynamics**-
  - **Rasa**- Kashaya,Tikta
  - **Guna**- Laghu,Ruksha
  - **Virya**- Ushna
  - **Vipaka**- Katu
- **Doshakarma**- Kaphapitta shamaka
- ***Rogaghnakarma***- *Madhumeha, Prameha, Sthoylya, Kushtha, Udarda, Visarpa, Shwitra, Shotha, Palitya, Abhighataja vedana, Bhagna, Atisara, Pravahika, Krimi, Dantashoola, Raktapitta, Raktavikara.*
- **Chemical Constituents**- Pterostilbene
- **Related Research Updates**- Antidiabetic, Antibacterial, antifungal, anti-inflammatory, Antioxidant, anti-arthritic, immune modulator, hepato protective, anti-histaminic.[95]

3. Jambu[96,97]

- **Botanical Name**- Syzygium cumini (Linn)
- **Family**- Myrtaceae
- **Synomyms**- *Jambu, Mahaphala, Phalendra, Surabhipatra, Raja jambu, Mahajambu Nilaphala, Syamala.*

- **Useful Part**- Seed
- **Pharmacodynamics-**
    - **Rasa**- Kashaya, madhura, amla
    - **Guna**- Laghu,Ruksha
    - **Virya**- Sita
    - **Vipaka**- Katu
- **Doshakarma**- Pitta shamaka
- ***Rogaghnakarma***- *Madhumeha, Prameha, Sthoylya, Kushtha, Udarda, Visarpa, Shwitra, Shotha, Palitya, Abhighataja vedana, Bhagna, Atisara, Pravahika, Krimi, Dantashoola, Raktapitta, Raktavikara.*
- **Chemical Constituents**- Gallic acid, Glycosides
- **Related Research Updates**- Jamun fruit and seeds have potent prophylactic role against hyperglycemia.

4. Amlaki

- **Botanical Name**- Phyllanthus emblica Linn
- **Family**- Euphorbiaceae
- **Synomyms**- *Amalaki, Vayasya, Vrishya, Dhatriphala, Vayastha, Amritaphala, Amalaka, Tishyaphala.*
- **Useful Part**- Fruit
- **Pharmacodynamics-**
    - **Rasa**- Pancharasa (alavana) Amla (Pradhana)
    - **Guna**- Laghu, Ruksha, Sita
    - **Virya**- Sita
    - **Vipaka**- Madhura
- ***Doshakarma***- *Tridoshashamaka,* especially *Pittashamaka.*

- ***Rogaghnakarma***- *Paittika vikara, Daha, Palitya, Trishna, Udavarta, Kasa, Shwasa, Yakshma, Arsha, Hridroga, Raktvikara, Shukrameha, Pradara, Mootrakrichra, Visarpa, Jeernajwara, Daurbalya, Daha, Shotha*
- **Chemical Constituents**- Chebulin, corilagin
- **Related Research Updates**- Supplementation with Triphala (a blend of the three Myrobalans) demonstrated a notable reduction in blood glucose levels when taken at a dosage of 5 grams. Triphala contains active compounds such as menthol and sorbitol, which are thought to possess hypoglycemic properties. The significant decrease in both fasting and postprandial glucose levels may be attributed to the effects of these key active ingredients.[98]

5. Hareetaki

- **Botanical Name**- Terminalia chebula Retz
- **Family**- Combretaceae
- **Synomyms**- Haritaki, Pathya, Abhaya, Kaystha, Putana, Haimavati, Avyatha, Chetaki, Shiva, Vaystha, Rohini
- **Useful Part**- Fruit
- **Pharmacodynamics**-
    - **Rasa**- Kashaya pradhana Pancha rasa lavana varjita,
    - **Guna**- Laghu, Ruksha
    - **Virya**- Ushna
    - **Vipaka**- Madhura
- **Doshakarma**- Tridoshashamaka
- ***Rogaghnakarma***- Nadi daurbalya, Agnimandya, Shoola, Anaha, Gulma, Vibandha, Udara roga, Arsha, Kamala, Krimiroga, Vatarakta, Hriddaurbalya, Prameha, Shukrameha, Mootra krichra, Mootraghata, Ashmari, Kushta, Visarpa, Vishamajwara.

- **Chemical Constituents**- Chebulin, corilagin
- **Related Research Updates**- Supplementation with Triphala (a blend of the three Myrobalans) demonstrated a notable reduction in blood glucose levels when taken at a dosage of 5 grams. Triphala contains active compounds such as menthol and sorbitol, which are thought to possess hypoglycemic properties. The significant decrease in both fasting and postprandial glucose levels may be attributed to the effects of these key active ingredients.[98]

6. Bibheetaki

- **Botanical Name**- Terminalia bellerica Roxb
- **Family**- Combretaceae
- **Synomyms**- *Bibhitaka, Aksha, Karshaphala, Kaliphala, Bhutavasa, kalidruma, karnaphala, Kaliyugalaya.*
- **Useful Part**- Fruit
- **Pharmacodynamics-**
    - **Rasa**- Kashaya
    - **Guna**- Laghu, Ruksha
    - **Virya**- Ushna
    - **Vipaka**- Madhura
- **Doshakarma**- Tridoshashamaka
- ***Rogaghnakarma***- *Agnimandya, Palitya, Hridroga, Vrana, Netrabhishyanda, Vatavyadhi, Anidra, Chhardi, Arsha, Krimiroga, Vibandha, Rakta nishthivana, Ashmari, Klaibya, Jwara, Samanya daurbalya, Netraroga*
- **Chemical Constituents**- Chebulin, corilagin
- **Related Research Updates**- Supplementation with Triphala (a blend of the three Myrobalans) demonstrated a notable reduction in blood glucose levels when taken at a dosage of 5 grams. Triphala contains active compounds such

as menthol and sorbitol, which are thought to possess hypoglycemic properties. The significant decrease in both fasting and postprandial glucose levels may be attributed to the effects of these key active ingredients.[98]

7. Haridara

- **Botanical Name**- Curcuma longa Linn
- **Family**- Zingiberaceae
- **Synomyms**- *Rajani, Nisha, Gouri, Krimighna, Yoshitapriya, Varavarnini, Hattavilasini, Haridra.*
- **Useful Part**- Rhizome
- **Pharmacodynamics-**
    - **Rasa**- Katu, Tikta
    - **Guna**- Ruksa, Laghu
    - **Virya**- Ushna
    - **Vipaka**- Katu
    - **Doshakarma**- Kapha pitta shamaka
- **Rogaghnakarma**- Shotha, Netrabhishyanda, Aruchi, Agnimandya, *Yakridvikara, Kamala,Prameha*
- **Chemical Constituents**- Curcuminoides
- **Related Research Updates**- In animal studies, curcumin extract has been shown to delay the onset of diabetes, enhance β-cell function, prevent β-cell apoptosis, and reduce insulin resistance. This review highlights both pre-

clinical and clinical trials involving curcumin supplementation in type 2 diabetes mellitus (T2DM) and explores the unique mechanisms through which curcumin may improve diabetes management.[99]

8. Guduchi

- **Botanical Name**- Tinospora cordifolia (Willd) Miers.
- **Family**- Menispermaceae
- **Synomyms**- Guduchi, Madhuparni, Amrita, Amritavallari, Chhinna,Chinnaruha, Kundalini, Vatsadini, , Chakrangi, Tantrika, Kundalini, Somavalli, Dhira, Vayastha, Mandali.
- **Useful Part**- Stem
- **Pharmacodynamics-**
    - ***Rasa***- *Kashaya,Tikta*
    - ***Guna***- *Guru,snigda*
    - ***Virya***- *Ushna*
    - ***Vipaka***- *Madhura*
    - ***Doshakarma***- *Tridosha shamaka*
- ***Rogaghnakarma***- *Kushta, Vatarakta, Netraroga, Trishna, Daha, Aruchi, Agnimandya, Shoola, Yakridvikara, Kamala, Pandu, Prameha, Madhumeha, Mootra krichhra, Kushta, Jwara, Vishama jwara, Jeerna jwara*.
- **Chemical Constituents**- alkaloids, diterpenoid lactones, glycosides, steroids, sesquiterpenoid, phenolics, aliphatic compounds and polysaccharides

- **Related Research Updates**- *Guduchi* has potential immunomodulatory and cytotoxic effects. mediate its anti-diabetic potential through mitigating oxidative stress (OS), promoting insulin secretion and by inhibiting gluconeogenesis and glycogenolysis, thereby regulating blood glucose. Alkaloids, tannins, cardiac glycosides, flavonoids, saponins, and steroids as the major phytoconstituents of *Tinospora cordifolia* have been reported to play an anti-diabetic role.[100]

9. Tamala Patra

- **Botanical Name**- Cinnamomum tamala (Buch-Ham)
- **Family**- Lauraceae
- **Synomyms**- *Tamala patra, Patra, Patranamaka, Ptraka, Tamala, Gandha patraka.*
- **Useful Part**- Leaves
- **Pharmacodynamics**-
    - ***Rasa***- *Madhura, Katu*
    - ***Guna***- *laghu, picchila, tikshna*
    - ***Virya***- *Ushna*
    - ***Vipaka***- *Katu*
- ***Doshakarma***- *Kapha vata shamaka*
- ***Rogaghnakarma***- *Arsha, Hrillasa, Aruchi, Peenasa, Atisara, Udara shoola, Kasa, Shwasa, Medoroga, Kandu, Kushta, Garbhashaya shaithilya*
- **Chemical Constituents**- Monoterpenes and Sesquiterpenes.
- **Related Research Updates**- The leaf extract of Cinnamomum tamala significantly reduced blood glucose levels and helped maintain body weight and lipid profile parameters close to normal in diabetic animals.[101]

10. Dharuharidra

- **Botanical Name**- Berberis Aristata DC
- **Family**- Berberidaceae
- **Synomyms**- *Daruharidra, Darvi, Kateyaka, Pitadaru, Parjanya, Pachampacha, Peeta, Kaliyaka,Parjani, Haridru, Kantankateri*
- **Useful Part**- Rhizome
- **Pharmacodynamics-**
    - **Rasa**- Tikta, kashaya
    - **Guna**- Ruksa, Laghu
    - **Virya**- Ushna
    - **Vipaka**- Katu
    - **Doshakarma**- Tridosha shamaka.
- **Rogaghnakarma**- Shotha, Vedana, Vrana, Aruchi, Vibandha, Shukrameha, Prameha, Kandu, Shitapitta, Kushtha.
- **Chemical Constituents**- Berberine and berbamine
- **Related Research Updates**- Adding Berberis aristata to the diet led to reductions in polyphagia, fatigue, fasting and postprandial blood glucose, and glycated hemoglobin levels. Additionally, it resulted in favorable changes in

lipid profiles and other clinical biochemical tests, indicating its potential benefit in managing diabetes mellitus.[102]

Table no.10. Showing mode of action of herbs of *Madhumehari kashaya*.

Si. No.	Name of the herb (Part used)	Common name/ Sanskrit name	Part	Potential health effects [Type of study]
1.	Gymnema sylvestre R. Br. [leaves]	*Meshashringi/ Gurmar*	1	Hypoglycemic (Animal/human), Lipid lowering potential[112]
2.	Pterocarpus marsupium Roxb. [heart wood]	Indian kino tree/ Asana	2	Antihyperglycemic, Anti inflammatory[95] (Animal)
3.	Syzygium cumini Linn [seed]	Jamun /*Jambu*	2	Useful in insulin resistance[103] (Animal/in vitro)
4.	Terminalia chebula Retz [fruit]	*Triphala*	1	Antioxidant[104], Immunomodulator[105][In vitro]
	Terminalia belirica Roxb [fruit]			
	Emblica officinalis Gaertn [fruit]			
5.	Curcuma longa Linn [Rhizome]	Turmeric/*Haridra*	1	Antioxidant[106][Human, animal]
6.	Tinospora cordifolia willd [leaves]	Giloy/*Guduchi*	1	Antiinflammatory[107][Animal, in vitro]

7.	Gymnema sylvestre R. Br. [leaves]	*Meshashringi/ Gurmar*	1	Hypoglycemic (Animal/human), Lipid lowering potential[108]
8.	Cinnamomum tamala (Buch,Ham) [Leaves]	Bay leaf/*Tamala patra*	1/4	Significance in oral glucose Tolerance test [OGTT], Antihyperglycaemic[109][Animal]
9.	Berberis aristata DC [stem]	Indian barberry/ *Daruharidra*	1	Antidiabetic, Lipid lowering[110][Human]

2. MATERIALS AND METHODS

Study was conducted in two parts namely Drug preparation and clinical study**.**

2.1 Drug preparation:

a. Raw drugs procurement was done from reliable sources and ingredients of polyherbal formulation i.e *Madhumehahari Kashaya*.

b. Drug identification and authentication at KAHER's Shri B M K Ayurveda Mahavidyalaya's AYUSH approved Ayurveda Siddha Unani-Drug Testing Laboratory.

c. Processing of raw drug.

d. Preparation of *Madhumehahari kashaya* as per standard operating procedures[i]

Table no.11: Ingredients of *Madhumehahari kashaya*

Sl. No	Drug	Latin name	Part
1.	*Madhunashini*	*Gymnema sylvestre*	Leaves
2.	*Asana*	*Pterocarpus marsupium Roxb*	Heart wood
3.	*Jambu*	*Syzygium cumini Linn*	Seeds
4.	*Haridra*	*Curcuma longa Linn*	Rhizome
5.	*Daruharidra*	*Berberis aristata DC*	Stem
6.	*Bibhitaki*	*Terminalia belirica Roxb*	Fruit
7.	*Haritaki*	*Terminalia chebula Retz*	Fruit
8.	*Amalaki*	*Emblica officinalis Gaertn*	Fruit
9.	*Guduci*	*Tinospora cordifolia willd*	Stem
10.	*Tamalapatra*	*Cinnamomum tamala Buch,Ham*	Leaves

- **The procedure of Preparation of Trial Drug**

Table no.12. Showing Ingredients and Proportion (Coarse powder 40-60 mesh number) **of *Madhumehari Kashaya***

Si.No	Ingredients	Proportion
1	*Madhunashini leaves (Gymnema sylvestre)*	1 part
2	*Asana Heart wood (Pterocarpus marsupiumRoxb):*	2 Part
3	*Jambu Seeds (Syzygium cuminiLinn):*	2 Part
4	*Haridra Rhizome (Curcuma longa Linn):*	1 Part
5	*Daruharidra Stem (Berberis aristata DC)*	1 Part
6	*Bibhitaki Fruit (Terminalia belirica Roxb)* *Haritaki Fruit (Terminalia chebula Retz)* *Amalaki Fruit (Emblica officinalis Gaertn)*	1 Part
7	*Guduchi*	1 Part
8	*Tamala Patra*	1/4th Part
9	Water	8 parts

Fig.03. Drug preparation steps.

1. All coarse powders were weighed in accordance with the specified quantities and processed using a 40-mesh pulverizer to create a uniform mixture.

⇩

2. The drug blend was then placed in a stainless steel container and immersed in eight parts of tap water for a duration of 8 hours.

⇩

3. After soaking overnight, the drug mixture was boiled over moderate heat until the volume reduced to one-fourth of its original amount, releasing a pleasant aroma characteristic of Kashaya during the process. To preserve the preparation, sodium benzoate, methyl paraben, and propyl paraben were added.

⇩

4. Filtered and transferred to one-liter bottles.

Image 1. Showing Raw materials used in the *Madhumehari kashaya*

Image 2. Showing *Madhumehari Kashaya* preparation.

2.2. Clinical Study:

- The medical trial received approval from the KAHER ethical committee for human subjects.
    - **Ref ID: KAHER/EC/21-22/012**
- The institutional ethical committee approval was obtained to conduct clinical study.
    - **BMK/23/PhD/KMS**
- Study was registered in Clinical trial for Registry of India
    - Ref.no: **CTRI/2022/01/039395**

2.2.1. Study type: Study is a Randomized Controlled Clinical Trial.

2.2.2. Site of study: Patients diagnosed with Prediabetes - HbA1c - 5.7 -6.4%were selected from OPD & IPD of KLE Ayurveda Hospital & research Centre, Belagavi.

2.2.3. Sample size: 180 patients were enrolled in the study and randomly divided into two groups.

2.2.4. Time points: Baseline, 30th, 60th and 90th day.

2.2.5. Statistical test: Descriptive statistics (%, mean, SD etc), Chi square test, Parametric tests like T test. Statistical significance was determined at a 5% level. ($p<0.05$).

2.3 Study population:

2.3.1. Diagnostic criteria: Subjects with Prediabetes - HbA1c - 5.7 -6.4% (ADA Criteria and Heianza Y et al Lancet 2011.)

2.3.2. Inclusion criteria:

1. Subjects of either sex, 18-70 years
2. Pre-diabetic subjects with HbA1c of 5.7-6.4%.
3. FBS <126mg/dl
4. Subject who submit a written informed consent

2.3.3. Exclusion criteria:

1. Known Cases of DM, both type I and II.
2. Past history of gestational diabetes
3. Uncontrolled Hypertensive subjects(with or without medication > 140/90 mmHg)
4. Pregnant / Lactating women.

5. Alcoholics and/or drug abusers
6. Patients suffering from major systemic illness necessitating long term drug treatment (Rheumatoid arthritis, Psycho-Neuroendocrinal disorders, etc.)
7. Any other medical illness like Coronary Artery disease, Stroke etc
8. Patients who have completed participation in any other clinical trial during the past six (06) months

2.3.4. Withdrawal criteria:

- The investigator shall withdraw the subjects from the study if

I. Fasting blood sugar rises to >126 mg% or Post prandial Blood sugar level increases to >200 mg%.

II. Any concomitant serious illness develops which requires urgent treatment with any other drug/ therapy (Not related to Diabetes Mellitus) compromising the total drug compliance < 80%

III. Any suspected AE/ADR

- The subject himself/herself wants to withdraw from the study/ non-compliance.

2.3.5. Rescue medication: To alleviate any emergency, the use of rescue medication was permitted as per the wisdom/discretion of the guide/co-guide. However, the same will be documented in the case report form (CRF).

2.3.6. Criteria for assessment:

Primary outcome measures: Changes in HbA1c level from baseline and in 90 days

Secondary outcome measures:

- Changes in fasting insulin level from baseline and in 90 days

- Changes in Homa IR level from baseline and in 90 days
- Changes in fasting and Post prandial blood sugar from baseline and at 30th, 60th and 90th days
- Changes in lipid profile from baseline and at 90 days
- Changes in Liver function tests and Serum creatinine profiles from baseline and at 90 days
- Changes in BMI and waist circumference at baseline and at 30th , 60th and 90th days
- Changes in Quality of Life (DQoL): at baseline and at 30th, 60th and 90th days

2.4. Study Design:

Randomised Controlled Clinical Trial

- **Control Group:** Has received the standard prediabetic care (nutritional and lifestyle management counselling)
- **Trial group:**
- Integrated Ayurvedic polyherbal formulation - Madhumehahari Kashaya 35ml Twice a day after food with luke warm water for a duration of 90 days.
- Ayurveda dietary intervention and yoga.

2.5. Study group (Annexures 07)

Control Group: Standard Prediabetic care

- ✓ Nutritional and
- ✓ lifestyle management counselling

Trial group: Integrated Ayurveda Protocol

- ✓ **Ayurveda formulation (Madhumehaari Kashaya)**
- ✓ **Ayurveda Dietary intervention**
- ✓ **Yoga intervention:** Yoga-based lifestyle changes with components of breathing practices, loosening practices, *surya namaskara*, *asanas*, *pranayama*, relaxation techniques and meditations.

***Ayurveda* diet**: The study sought to design and implement dietary interventions rooted in the principles of Ayurveda, the traditional Indian system of medicine. To achieve this, an extensive literature review was conducted, along with an analysis of local dietary habits, to develop a suitable diet plan. Caloric requirements were carefully calculated based on individual weight, physical activity levels, and portion control guidelines(Attached in Annexures 2A, 2B, 2C). The proposed plan was reviewed and validated by an experienced nutritionist with over a decade of expertise in diabetes management, incorporating feedback for necessary refinements.

The diet plan follows three primary meal patterns, with the main meal scheduled between 10 a.m. and 2 p.m., and the evening meal kept light and easy to digest. Nutrient distribution typically includes 20–25% protein, 50–55% carbohydrates, and 20–25% healthy fats. Breakfast emphasizes beans and lentils, while lunch and dinner feature millet-based grains paired with vegetables and healthy fats.

The approach aligns with the ‘plate method’ (Traditional Thali), where half the plate is filled with vegetables, one-fourth with millets or barley, and the final one-fourth with protein and healthy fats. To limit carbohydrate intake, two-thirds of

the meal consists of vegetables and low-glycemic fruits, while one-third includes grains and starchy vegetables. Refined grains are replaced with barley and millet varieties.

The Ayurvedic dietary framework emphasizes soluble fiber sources such as whole grains, beans, lentils, seeds, herbal drinks, vegetables, and fruits. Mornings typically start with herbal infusions or green vegetable smoothies. Healthy fats from sources like flaxseeds, sesame, safflower, fenugreek, and peanuts are incorporated through traditional Indian condiments, including chutneys, and many dishes are finished with clarified butter.

This carefully crafted dietary plan is not only nutritionally balanced and flavorful but also effectively meets the dietary needs of individuals managing diabetes.

***Yoga* protocol.**

Table no. 13: Therapeutic *Yoga* technique with appropriate duration and remarks

Name	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 mins
	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		
Sooryanam askara	with *Shashankasana*	4-5 rounds at the beginning	5 minutes
Standing *asana*	*Trikonasana, Veerabhadrasana, Hasta padottanasana*	2 rounds each	15 minutes
Sitting *asana*	*Vakrasana, Gomukhasana*	2 rounds each	
Prone *asana*	*Ardha shalabhasana, Bhujangasana, Dhanurasana*	2 rounds each	
Supine *asana*	*Vipareeta karani, Pavanamuktasana*	2 rounds each	
Pranayama	*Ujjaayi Pranayama, Bhramari Pranayama*	5 rounds each	5 minutes
	Nadishuddhi Pranayama, Suryabhedi Pranayama	10 rounds each	

Table no.14: Assessment Parameters

Sl. No	Parameters	Base line	30th day	60th day	90th day
1	BMI, Waist circumference	✓	✓	✓	✓

2	FBS	✓	✓	✓	✓
3	PPBS	✓	✓	✓	✓
4	DQoL	✓	✓	✓	✓
5	HbA1C	✓			✓
6	Fasting Insulin	✓			✓
7	HOMA IR	✓			✓
8	Lipid profile (Triglyceride, LDL,HDL, TC,)	✓			✓
9	LFT	✓			✓
10	Serum creatinine	✓			✓

2.6. Study Duration: Following the Ethics Committee approval the study was initiated, and recruitment and completion of trial was done over a period of maximum 30 months.

2.7. Informed Consent: Written informed consent was obtained from all participants using the designated format before initiating any study-related procedures, such as physical examinations, laboratory tests, or other investigational activities. Participants were provided with comprehensive details about the study, including potential risks and discomforts. They were also informed of their right to withdraw from the study at any point without the need to provide an explanation.

2.8. Good Clinical Practice (GCP): The study was conducted in accordance with the principles of Good Clinical Practice that has its principles as reported in the Declaration of Helsinki.

2.9. Sample size calculation: As this is a proof of concept, study aimed to evaluate Integrated Ayurveda Management Protocol in Prediabetes, a sample size 'n' of 88 participants in each group has been considered as adequate

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (SD_1 + SD_2)^2}{(X_1 - X_2)^2}$$

- Sample size at 95% confidence interval

  95% Power

  10% alterations

- Sample size per group = 88

  In two groups 88X2 = 176, which is rounded to 180

- Descriptive statistics (%, mean, SD etc)
  - Chi square test, one way analysis of variance and Z test
- Statistical significance was determined at 5% level ($p<0.05$)

3. OBSERVATIONS AND RESULTS

3.1. Drug Analysis of *Madhumehari Kashaya*

1. Macroscopic, phytochemical standards of 9 drugs of *Madhumehari Kashaya.*
2. Microscopic phytochemical analysis of *Madhumehari Kashaya.*

Table no.15: Analytical report of *Madhumehari Kashaya* (macroscopic)

Macroscopic	
Test	**Results**
Form	Kashaya
Colour	Brown
Odour	Characteristic
Taste	Slightly Bitter
Physiochemical standards	
Test	**Result**
Specific Gravity	1.024
pH	3.49
Total Solids	5.655%

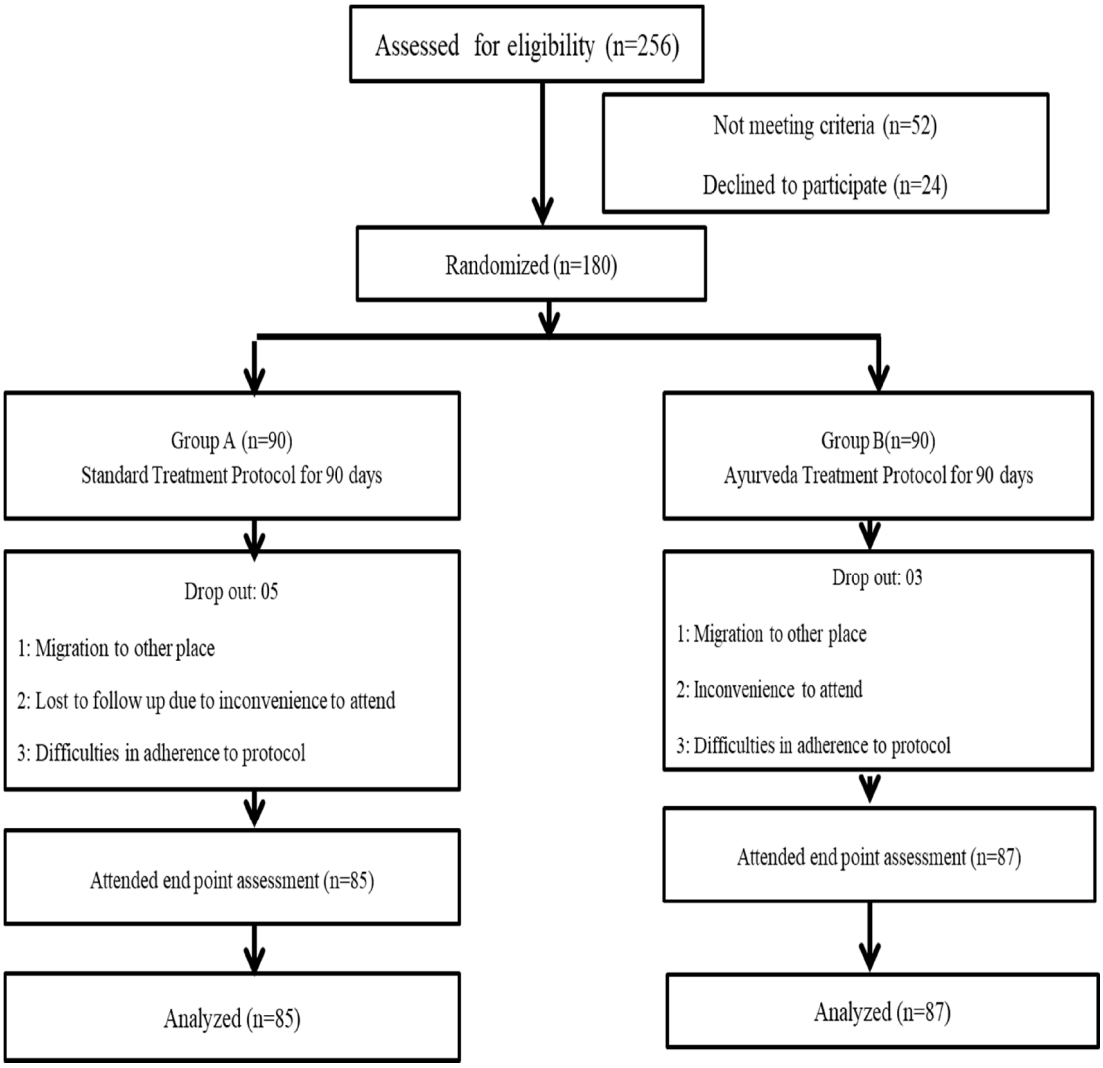
Table no. 16. Analytical report of *Madhumehari Kashaya* (microscopic)

Test for specified Micro-organisms (Qualitative)	Limits (as per IP)	Results
E coli	Absent/100 ml	Absent
S Aureus	Absent/100 ml	Absent
P aeruginosa	Absent/100 ml	Absent
Microbial limit test (Quantitative)	Limits (As per IP)	Results
Total Bacterial count	30-300cfu/ml	110cfu/ml
Total Fungal count	10-100cfu/ml	06cfu/ml

3.1. Clinical Study

CONSORT CHART

Fig.04. Consort chart.



No adverse events were reported in either of the study groups.

3.2.1. Observation

Table no.17: Gender wise distribution of the patient

Gender	Group A	Group B	χ^2	P value
Male	**47.8(43)%**	**56.6(51)%**	**1.425**	**0.296**
Female	**52.2(47)%**	**43.3(39)%**		
Grand Total	**100(90)**	**100.0(90)**		

The gender distribution reveals that Group A exhibits a slightly higher percentage of females (52.2%) compared to males (47.8%), whereas Group B exhibits a higher percentage of males (56.6%) than females (43.3%).

Table no.18: Age wise distribution of the patient

Age-group	Group A	Group B	χ^2	P Value
18-30	**10(9) %**	**7.7(7) %**	**4.799**	**0.187**
31-40	**46.6(42) %**	**33.3(30)%**		
41-50	**24.4(22) %**	**37.7(34) %**		
51-60	**15.5(14) %**	**15.5(14) %**		
61+	**3.3(3) %**	**5.6(5) %**		
Grand Total	**100(90)**	**100(90)**		

The age distribution of the participants reveals that the majority of individuals in Group A are between the ages of 31 and 40 (46.6%), while Group B has a higher percentage of participants aged 41 to 50 (37.7%). Conversely, Group A has the least number of participants from the 61+ age group (3), while Group B has the highest number (5).

Table no.19: Religion wise distribution of the patient

Religion	Group A%	Group B%	χ^2	P Value
Hindu	93.3(84)	96.6(87)	3.053	0.217
Muslim	6.7(6)	2.2(2)		
Christian	0	1.1(1)		
Grand Total	100(90)	100(90)		

Religious distribution indicates that most participants in both groups are Hindu (93.3% in Group A and 96.6% in Group B), with very few Muslims and Christians.

Table no.20: Education status wise distribution of the patient

Educational status	Group A%	Group B%	χ^2	P Value
Illiterate	**8.8(8)**	**15.5(14)**	**12.061**	**0.050**
Primary	**0**	**6.6(6)**		
Middle	**11.1(10)**	**5.5(5)**		
High	**2.2(33)**	**1.1(1)**		
Intermediate	**36.6(33)**	**33.3(30)**		
Graduate	**38.8(35)**	**34.4(31)**		
Profession	**2.2(2)**	**3.3(3)**		
Grand Total	**100(90)**	**100(90)**		

The educational attainment of the two groups is evident from the data. Group A exhibits a higher percentage of graduates (38.8%) and an intermediate education level (36.6%). Conversely, Group B has a slightly lower percentage of graduates (34.4%) and an intermediate education level (33.3%).

Table no.21: Occupation wise distribution of the patient

Occupation	Group A%(f)	Group B %(f)	χ^2	P Value
UNEMPLOYED	17.8 (16)	28.8(26)	8.813	0.266
ELEMENTARY OCCUPATION	10 (9)	6.6(6)		
PLANT & MACHINE OPERATORS & ASSEMBLERS	13.3(12)	20(18)		
CRAFT & RELATED TRADE WORKERS	14.4(13)	13.3(12)		
SKILLED AGRICULTURAL & WORKERS	8.9(8)	2.2(2)		
SKILLED WORKERS, SHOP & MARKET SALES WORKERS	20.0(18)	16.6(15)		
CLERKS	4.4(4)	2.2(2)		
PROFESSIONALS	11.1(10)	10(9)		
Grand Total	90	90		

Occupational distribution shows higher unemployment in Group B (28.8%) than Group A (17.8%). Clerks were 4.4% in Group A and 2.2% in Group B, the lowest.

Table no.22: Socioeconomic status wise distribution of the patient

Socio-economic status	Group A%	Group B%	χ^2	P Value
Upper	5.5(5)	5.5(5)	0.0001	1.000
Upper middle	42.2(38)	42.2(38)		
Lower middle	52.2(47)	52.2(47)		
Grand Total	100(90)	100(90)		

The socioeconomic status distribution indicates that both groups exhibit similar socioeconomic profiles, with the majority belonging to the lower middle class (52.2%) and the upper middle class (42.2%).

Table no.23: Marital status wise distribution of the patient

Marital status	Group A%	Group B%	χ^2	P Value
Married	**96.6(87)**	**97.7(88)**	**0.206**	**0.650**
Unmarried	**3.3(8)**	**2.2(2)**		
Grand Total	**100(90)**	**100(90)**		

The marital status distribution indicates that a substantial majority of participants in both groups are married. Notably, Group A has a marital status of 96.6%, while Group B has a marital status of 97.7%.

Table no.24*:* Desha wise distribution of the patient

Characteristics	Group A		Group B		Total		χ^2	p-value
	N	%	N	%	n	%	2.0200	0.3640
Desha								
Sadharana	97	97.00	99	99.00	196	98.00		
Anupa	2	2.00	0	0.00	2	1.00		
Jangala	1	1.00	1	1.00	2	1.00		

Maximum number of subjects belong to *sadharana desha* i.e 97% in group A and 99% in group B.

Table no.25: Prakruti wise distribution of the subjects

Characteristics	Group A		Group B		Total		χ^2	p-value
	N	%	N	%	n	%	0.8970	0.9250
Prakruti								
VP	47	47.00	43	43.00	90	45.00		
VK	19	19.00	18	18.00	37	18.50		
PK	26	26.00	31	31.00	57	28.50		
KP	3	3.00	4	4.00	7	3.50		
PV	5	5.00	4	4.00	9	4.50		

Prakruti wise distribution of subjects revealed that, majority were *vata pitta prakrati* (47% in A and 43% in B) followed by *pitta kapha prakrati* (43% in A and 31% in B).

Table no.26: *Saara* wise distribution of the patient

Characteristics	Group A		Group B		Total		χ^2	p-value
	N	%	N	%	n	%	8.7490	0.1200
Sara								
Medasara	47	47.00	64	64.00	111	55.50		
Asthisara	26	26.00	19	19.00	45	22.50		
Mamsa sara	10	10.00	10	10.00	20	10.00		
Raktasara	7	7.00	4	4.00	11	5.50		
Rasasara	4	4.00	2	2.00	6	3.00		

Mamsa medasara	6	6.00	1	1.00	7	3.50		

In both the groups, majority had *Medasara* (47% in A and 64% in B).

Table no.27: Comparison of Group A and Group B with Diet adherence, Yoga, and exercise adherence by independent t test

Time points	Group A		Group B		t-value	p-value
	Mean	Std.Dev.	Mean	Std.Dev.		
Calorie Given	1378.72	177.12	1338.64	167.08	1.5682	0.1186
Diet adherence %	80.39	9.60	85.15	9.49	3.3576	0.0010*
Yoga/Exercised adherence %	80.51	9.93	86.06	9.96	3.7600	0.0002*

*$p<0.05$

Diet adherence ($p=0.001$) and exercise/yoga practice adherence ($p=0.0002$) were higher in group B compared to group A.

Table no.28: Distribution of Mean BMI across Groups

BMI	DAY 0	DAY 30	DAY 60	DAY 90
Group A	25.3	25.1	24.7	24.8
Group B	25.1	24.9	24.3	24.7

The study found that most individuals in Group A had a BMI of 25.3 on Day 0, which decreased to 24.7 by Day 60, followed by a slight increase to 24.8 on Day 90. In Group B, the majority had a BMI of 25.1 on Day 0, which decreased to 24.3 by Day 60, followed by an increase to 24.7 on Day 90.

Graph No.1: Distribution of Mean BMI across Groups

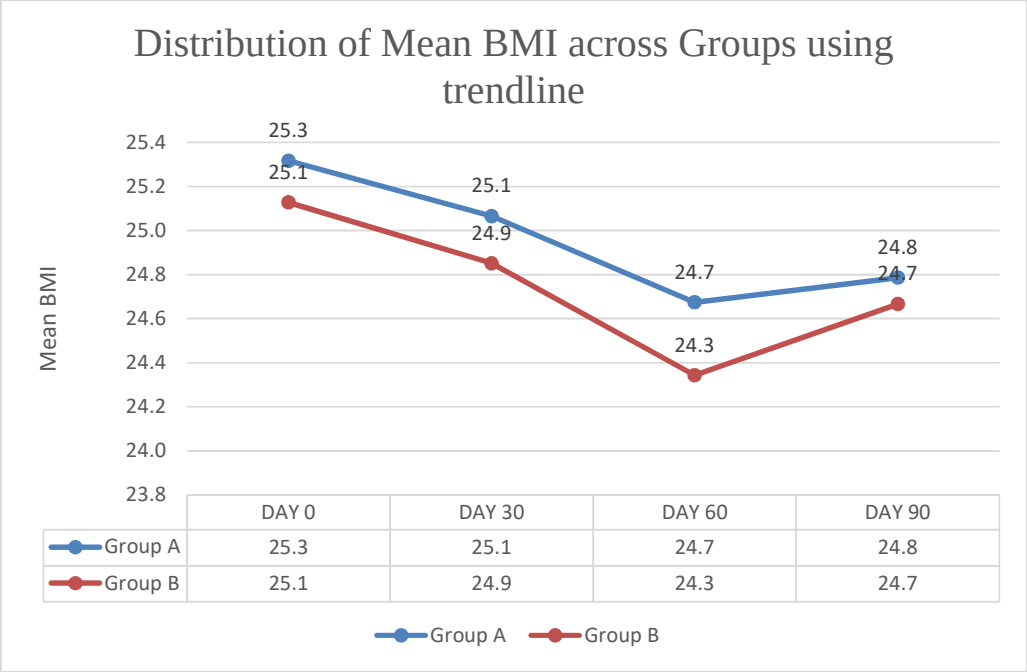


Table no.29: Comparison Between Group A and Group B with BMI at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0-BMI	25.32	1.24	25.12	1.38	0.07	0.33	0.614
DAY 30-BMI	25.07	1.09	24.85	1.20	0.08	0.44	0.703
DAY 60-BMI	24.67	1.01	24.34	1.30	0.20	1.12	0.065
DAY 90-BMI	24.79	0.89	24.66	1.23	0.02	0.10	0.816

Study data show significant BMI reductions in both groups across time points (A's ANOVA, $p < 0.001$). Group A showed significant reductions from Day 0 to Day 30 and Day 0 to Day 60, but not from Day 0 to Day 90. Group B showed significant reductions at all intervals, with greater overall improvements.

Table no.30: Comparison of different treatment time points with BMI in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value	ANOVA	p-value
Group A BMI	**Day 0 to Day 30**	0.25	0.45	5.33	<0.001	75.78	<0.001
	Day 0 to Day 60	0.39	0.44	8.51	<0.001		
	Day 0 to Day 90	0.11	0.75	1.42	0.160		
Group B BMI	**Day 0 to Day 30**	0.26	0.44	5.61	<0.001	60.65	<0.001
	Day 0 to Day 60	0.51	0.77	6.36	<0.001		
	Day 0 to Day 90	0.30	1.01	2.76	<0.007		

This study shows that at day 0 to day 90, Group B's increase remained significant (**0.30 ± 1.01, T = 2.76, p = 0.007**), while Group A's change was minor and statistically non-significant (**0.11 ± 0.75, T = 1.42, p = 0.160**).

Table no.31: Mean waist circumference(cms) across both the groups

WAIST CIRCUMFERENCE	DAY 0	DAY 30	DAY 60	DAY 90
Group A	86.0	85.2	84.5	83.3
Group B	85.7	85.1	85.0	83.4

The study found that most individuals in Group A had a waist circumference of 86.0 cm on Day 0, which decreased to 84.5 cm by Day 60, followed by a further reduction to 83.3 cm on Day 90. In Group B, the majority had a waist circumference of 85.7 cm on Day 0, which decreased to 85.0 cm by Day 60, followed by a further reduction to 83.4 cm on Day 90.

Graph No.2: Mean waist circumference across both the groups

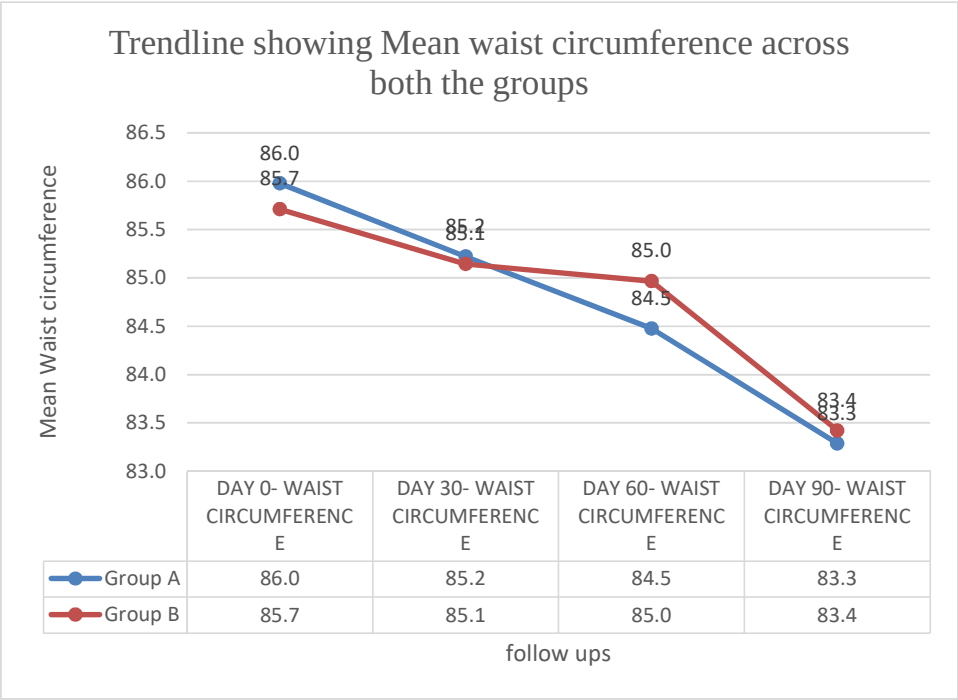


Table no.32: Comparison of Group A and Group B Between Waist circumference at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0- WAIST CIRCUMFERENCE	85.98	2.74	85.71	2.67	0.13	0.33	0.865
DAY 30- WAIST CIRCUMFERENCE	85.22	3.13	85.14	3.24	0.8	0.16	0.956
DAY 60- WAIST CIRCUMFERENCE	84.48	3.19	84.96	3.36	0.59	1.21	0.157

DAY 90- WAIST CIRCUMFERENCE	83.29	2.07	83.42	2.13	0.23	0.70	0.483

Study data indicate that reductions in waist circumference showed comparable results between the groups across all time points ($p > 0.05$). No significant changes were observed at any of the time points, with p-values of 0.865 at Day 0, 0.956 at Day 30, 0.157 at Day 60, and 0.483 at Day 90, indicating no statistically significant differences between Group A and Group B.

Table no.33: Comparison of different treatment time points with Waist Circumference in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value	A's ANOVA	p-value
A	**Day 0 to Day 30**	0.76	1.69	4.24	<0.001	151.89	<0.001
	Day 0 to Day 60	0.74	1.29	5.46	<0.001		
	Day 0 to Day 90	1.19	1.59	7.08	<0.001		
B	**Day 0 to Day 30**	0.54	1.58	3.27	<0.002	119.1	<0.001
	Day 0 to Day 60	0.23	1.37	1.62	0.109		
	Day 0 to Day 90	1.54	1.85	7.92	<0.001		

Study data indicate that improvements in the measured parameter showed significant changes within both groups across all time points (A's ANOVA, $p < 0.001$). In Group A, significant improvements were observed from Day 0 to Day 30 ($p < 0.001$), Day 0 to Day 60 ($p < 0.001$), and Day 0 to Day 90 ($p < 0.001$), with a mean difference of 1.19 by Day 90. Similarly, in Group B, significant improvements were noted from Day 0 to Day 30 ($p < 0.001$), Day 0 to

Day 60 ($p < 0.002$), and Day 0 to Day 90 ($p < 0.001$), with a mean difference of 1.54 by Day 90.

Table no.34: Mean DQOL-Bref across both groups

DQOL-Bref	DAY 0	DAY 30	DAY 60	DAY 90
Group A	83.7	84.2	84.8	86.5
Group B	83.6	83.8	85.0	87.2

The study found that in Group A, the DQOL-Bref score increased progressively from 83.7 on Day 0 to 84.2 on Day 30, 84.8 on Day 60, and 86.5 on Day 90. Similarly, in Group B, the DQOL-Bref score rose steadily from 83.6 on Day 0 to 83.8 on Day 30, 85.0 on Day 60, and 87.2 on Day 90.

Graph No.3: Mean DQOL-Bref across both groups

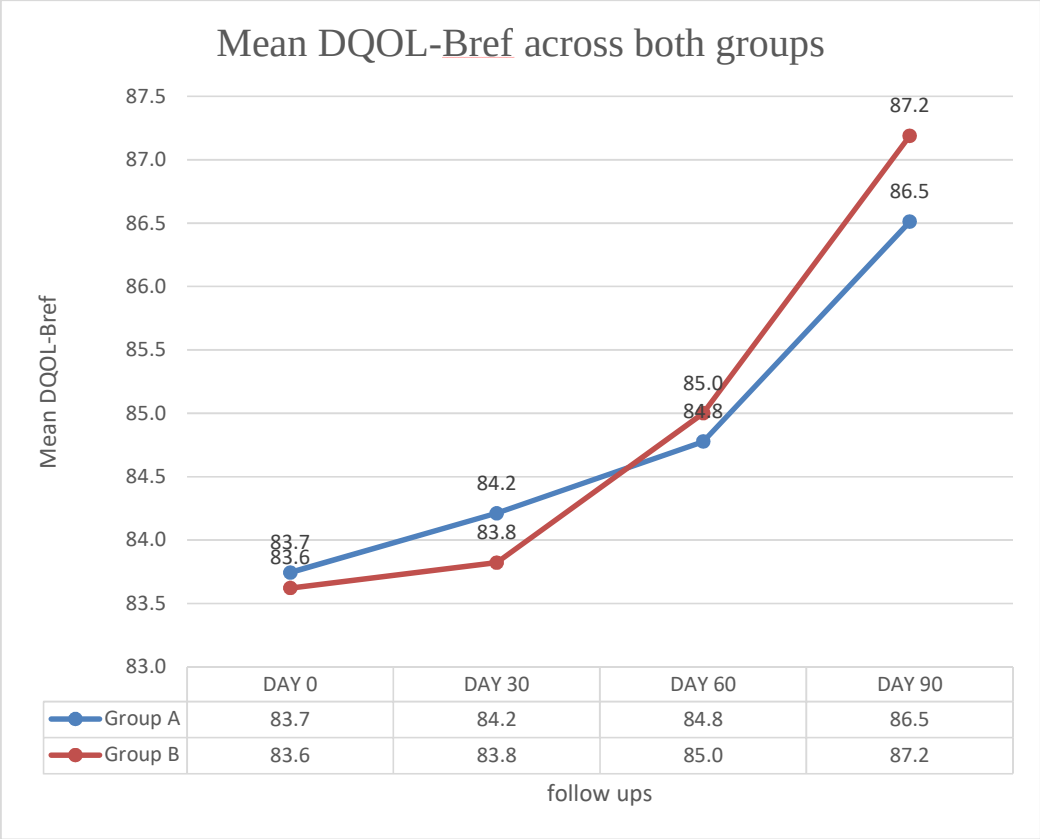


Table no.35: Comparison Between Group A and Group B with DQOL at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0-DQOL-Bref	83.74	3.03	83.6	2.90	0.28	0.62	0.39
DAY 30-DQOL-Bref	84.21	2.35	83.82	2.13	0.32	0.92	0.11

DAY 60-DQOL-Bref	84.78	2.76	85	2.65	0.46	-1.10	0.15
DAY 90-DQOL-Bref	86.51	3.31	87.1	3.32	0.86	-1.71	0.11
Day 0 – 90 DQOL	2.77	3.67	3.9	4.0	1.13	-1.97	0.05

Study data indicate that improvements in DQOL-Bref scores showed comparable results between the groups across all time points ($p > 0.05$). No significant differences were observed at Day 0 ($p = 0.39$), Day 30 ($p = 0.11$), Day 60 ($p = 0.15$), or Day 90 ($p = 0.11$), Group B(3.9) showed a slightly greater improvement in quality of life over the 90-day period compared to Group A(2.77), suggesting that both Group A and Group B experienced similar quality-of-life outcomes throughout the study period.

Table no.36: Comparison of different treatment time points with DQOL in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value	ANOVA	p-value
DQOL	**Day 0 to Day 30**	0.47	2.15	2.06	0.042	65.80	<0.001
	Day 0 to Day 60	0.57	1.78	3.02	0.003		
	Day 0 to Day 90	1.73	1.99	8.27	0.001		
DQOL	**Day 0 to Day 30**	0.42	2.14rr	1.87	0.065	109.55	<0.001
	Day 0 to Day 60	1.34	2.64	4.82	0.001		

	Day 0 to Day 90	2.13	2.05	9.89	0.001		

Study data indicate that changes in DQOL scores revealed significant improvements within both groups across time points (ANOVA, $p < 0.001$). In the first group, significant changes were observed from Day 0 to Day 60 ($p = 0.009$) and Day 0 to Day 90 ($p = 0.001$), while changes from Day 0 to Day 30 were not significant ($p = 0.118$). In the second group, significant improvements were seen from Day 0 to Day 60 ($p = 0.005$) and Day 0 to Day 90 ($p = 0.001$), with no significant change from Day 0 to Day 30 ($p = 0.881$).

Table no.37: HbA1C(%) across both groups

HbA1C (%)	DAY 0	DAY 90
Group A	6.3	5.8
Group B	6.1	5.1

The study found that in Group A, the HbA1C levels decreased from 6.3% on Day 0 to 5.8% on Day 90, and in Group B, the levels dropped from 6.1% on Day 0 to 5.1% on Day 90.

Graph No.4: Mean HbA1C across both groups

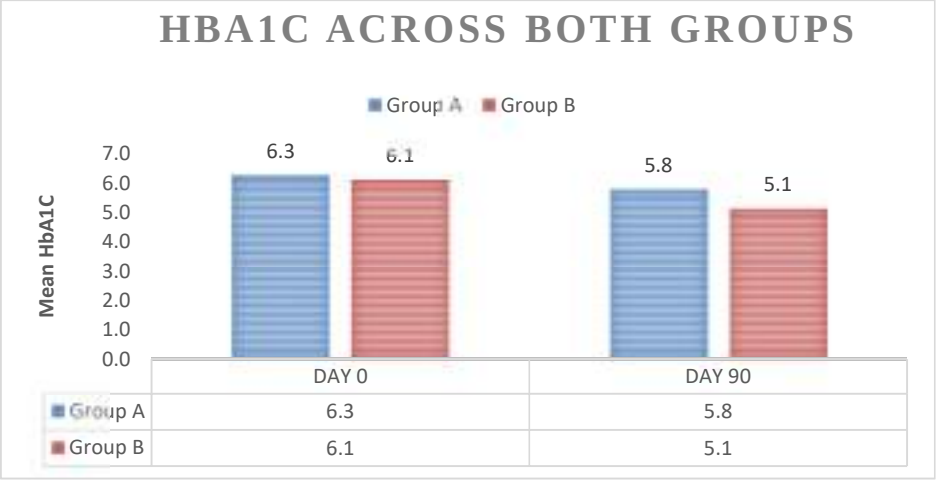


Table no.38: Comparison Between Group A and Group B with HbA1C at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	6.28	0.33	6.11	0.31	0.17	3.66	<0.001
DAY 90	5.8	0.26	5.13	0.33	0.67	13.72	<0.001
DAY 0-DAY 90	0.48	0.19	0.93	0.40	0.45	-9.64	<0.0001

The table compares the changes in a measured parameter between Group A and Group B over 90 days. At baseline, Group A had a slightly higher value (**p < 0.001**). Both groups showed a significant reduction by Day 90 (**p < 0.001**), with Group B experiencing a greater decrease (**0.93 vs. 0.48**). The overall reduction from Day 0 to Day 90 was significantly greater in Group B (**p < 0.0001**), indicating better improvement.

Table no.39: Comparison of different treatment time points with HbA1C in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	0.48	0.19	23.92	<0.001
B	Day 0 to Day 90	0.93	0.40	21.87	<0.001

This study found that on Day 0, there was a statistically significant difference between Group A and Group B. By Day 90, the difference in HbA1C levels became more pronounced, suggesting that Group B experienced a more substantial reduction in HbA1C levels compared to Group A.

Table no.40: Mean FBS mg/dl at different Group A and B

FBS(mg/dl)	DAY 0	DAY 30	DAY 60	DAY 90
Group A	98.9	96.1	95.6	94.1
Group B	98.9	92.9	93.1	89.9

The study found that in Group A, fasting blood sugar (FBS) levels decreased progressively from 98.9 mg/dl on Day 0 to 96.1 mg/dl on Day 30, 95.6 mg/dl on Day 60, and 94.1 mg/dl on Day 90. In Group B, FBS levels also showed a decline, starting at 98.9 mg/dl on Day 0 and reducing to 92.9 mg/dl on Day 30, 93.1 mg/dl on Day 60, and 89.9 mg/dl on Day 90.

Graph No.5: Mean FBS mg/dl at different Group A & B

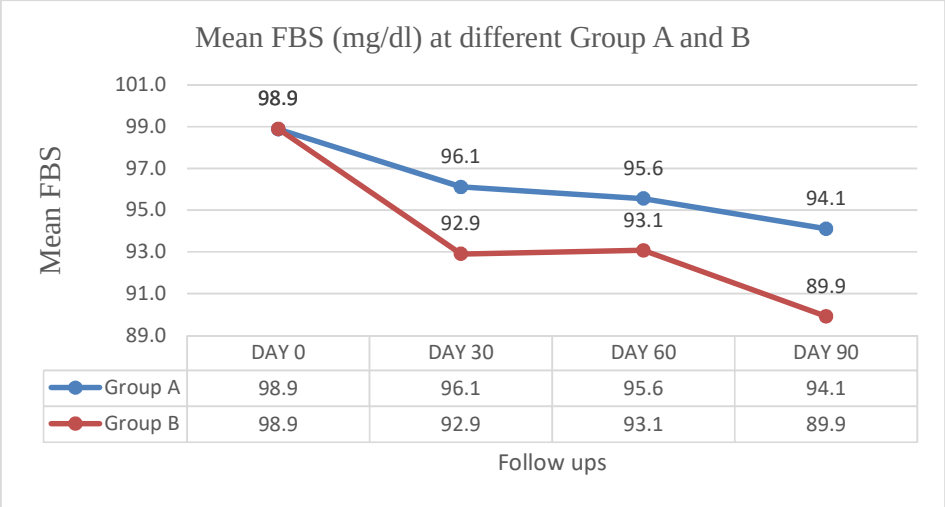


Table no.41: Comparison Between Group A and Group B with FBS(mg/dl) at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0-FBS	98.88	9.08	98.88	10.02	0.64	-0.48	0.428
DAY 30-FBS	96.11	5.63	92.91	8.07	3.32	3.30	0.001
DAY 60-FBS	95.56	6.61	93.07	8.40	2.53	2.35	0.005
DAY 90-FBS	94.11	7.16	89.92	7.79	4.09	3.71	<0.001
Day 0 - 90	4.76	8.93	9.5	9.38	4.74	3.46	<0.0008

The table compares fasting blood sugar (FBS) levels between Group A and Group B over 90 days. Both groups showed a significant reduction, with Group B experiencing a greater decrease. While there was no difference at baseline ($p = 0.428$), Group B had significantly lower FBS from Day 30 onward ($p \leq 0.005$). The overall reduction from Day 0 to Day 90 was significantly greater in Group B ($p < 0.0008$),

Table no.42: Comparison of different treatment time points with FBS(mg/dl) in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value	ANOVA	p-value
A	Day 0 to Day 30	2.77	8.08	3.25	0.002	46.50	<0.001
	Day 0 to Day 60	0.56	6.14	0.86	0.393		
	Day 0 to Day 90	1.44	7.79	1.76	0.082		
B	Day 0 to Day 30	6.74	10.84	5.90	0.001	84.41	<0.001
	Day 0 to Day 60	0.14	9.45	0.15	0.885		
	Day 0 to Day 90	2.90	9.50	2.90	0.005		

Study data show significant improvements in the measured parameter across all time points for both groups (A's ANOVA, $p < 0.001$). Group A showed improvements from Day 0 to Day 30, Day 0 to Day 60, and Day 0 to Day 90, with a mean difference of 4.77 by Day 90. Group B also showed significant changes at all time points with mean difference of 9.50.

Table no.43: Mean PPBS(mg/dl) at different time points across both groups

PPBS(mg/dl)	DAY 0	DAY 30	DAY 60	DAY 90
Group A	135.3	130.4	124.9	116.1
Group B	144.9	135.1	128.2	113.9

The study found that in Group A, most individuals had postprandial blood sugar (PPBS) levels of 135.3 mg/dl on Day 0, which decreased to 130.4 mg/dl on Day 30, 124.9 mg/dl on Day 60, and 116.1 mg/dl on Day 90. In Group B, the majority had PPBS levels of 144.9 mg/dl on Day 0, which dropped to 135.1 mg/dl on Day 30, 128.2 mg/dl on Day 60, and 113.9 mg/dl on Day 90.

Graph No.6: Mean PPBS(mg/dl) at different time points across both groups

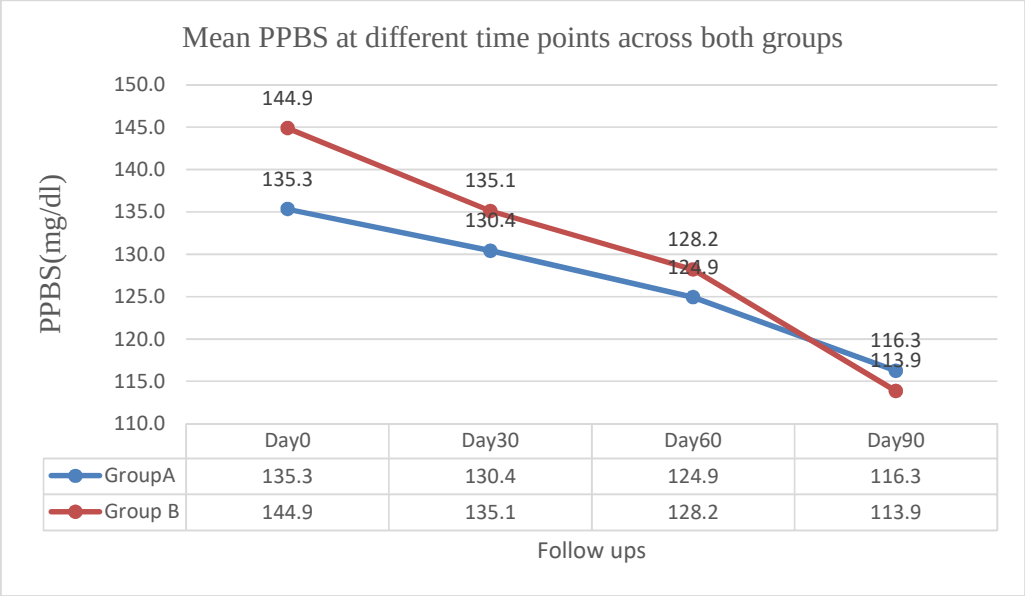


Table no.44: Comparison Between Group A and Group B with PPBS(mg/dl) at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0-PPBS	135.33	2.91	140.87	3.35	7.43	8.58	0.001
DAY 30-PPBS	130.41	5.32	135.1	2.99	2.91	3.30	0.001
DAY 60-PPBS	124.92	5.53	128.18	4.58	1.42	1.48	0.012
DAY 90-PPBS	116.26	6.57	113.85	4.80	3.34	3.72	0.001
Day 0 - 90	19.08	7.27	29.86	7.62	10.78	-9.71	<0.0001

The table compares postprandial blood sugar (PPBS) levels between Group A and Group B over 90 days. At baseline, Group B had a significantly higher PPBS (**$p = 0.001$**), but both groups showed a steady decline over time. From Day 30 onward, Group B consistently had lower PPBS levels, with statistically significant differences (**$p \leq 0.012$**). The overall reduction from Day 0 to Day 90 was significantly greater in Group B ($p < 0.0001$).

Table no.45: Comparison of different treatment time points with PPBS(mg/dl) in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T -value	p-value	A's ANOVA	p-value

Group A PPBS(mg/dl)	**Day 0 to Day 30**	4.92	5.77	8.10	0.001	199.11	<0.001
	Day 0 to Day 60	5.49	7.50	6.95	0.001		
	Day 0 to Day 90	8.67	8.67	9.48	0.001		
Group B PPBS(mg/dl)	**Day 0 to Day 30**	9.44	3.69	24.30	0.001	94.17	<0.001
	Day 0 to Day 60	6.98	6.07	10.91	0.001		
	Day 0 to Day 90	13.43	6.90	18.48	0.001		

Both Groups show significant reduction in PPBS overtime($p<0.001$), statisticaly test confirms a highly significant overtime in both groups.

Table no.46: Pre-Post Fasting Insulin(µU/ml) in Both Group A & B

FASTING INSULIN(µU/ml)	DAY 0	DAY 90
Group A	13.5	14.6
Group B	13.7	15.5

The study found that in Group A, most individuals had fasting insulin levels of 13.5 µU/ml on Day 0, which increased to 14.6 µU/ml on Day 90. In Group B, the majority had fasting insulin levels of 13.7 µU/ml on Day 0, which rose to 15.5 µU/ml on Day 90.

Graph No.7: Pre-Post Fasting Insulin in Both Group A & B

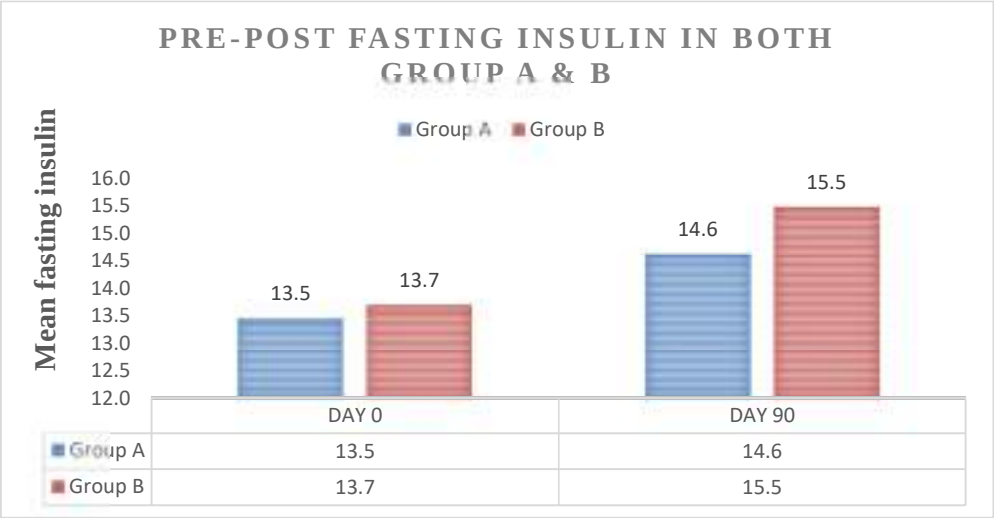


Table no.47: Comparison Between Group A and Group B with FASTING INSULIN at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			

DAY 0	13.46	1.67	13.70	2.10	0.22	0.79	0.039
DAY 90	14.63	1.71	15.48	2.66	0.77	2.36	0.002
Day 0 - 90	1.16	1.12	1.72	1.77		2.51	0.013

The table compares changes in a measured parameter (likely hemoglobin or a biochemical marker) between Group A and Group B over 90 days. At baseline, both groups had similar values (**p = 0.039**). By Day 90, both groups showed a significant increase, with Group B having a greater improvement (**p = 0.002**). The overall increase from Day 0 to Day 90 was significantly higher in Group B (**p = 0.013**), indicating better progress.

Table no.48: Comparison of different treatment time points with FASTING INSULIN(µU/ml) in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T -value	p-value
A	Day 0 to Day 90	1.16	1.12	9.83	<0.001
B	Day 0 to Day 90	1.72	1.77	9.21	<0.001

This study showed significant differences in Fasting Insulin levels between the two groups. Group A experienced a mean difference of 1.16 µU/ml and a standard deviation of 1.12 µU/ml, while Group B showed a mean difference of 1.72 µU/ml and a standard deviation of 1.77 µU/ml. The p-value for the difference between the two groups was less than 0.001, indicating a statistically significant difference.

Table no.49: Pre-post HOMA IR in Group A & B

HOMA IR	DAY 0	DAY 90
Group A	1332.2	1666.6
Group B	1354.3	1852.0

The study found that in Group A, most individuals had HOMA-IR levels of 1332.2 on Day 0, which increased to 1666.6 on Day 90. In Group B, the majority had HOMA-IR levels of 1354.3 on Day 0, which rose to 1852.0 on Day 90.

Graph No.8: Pre-post HOMA IR in Group A & B

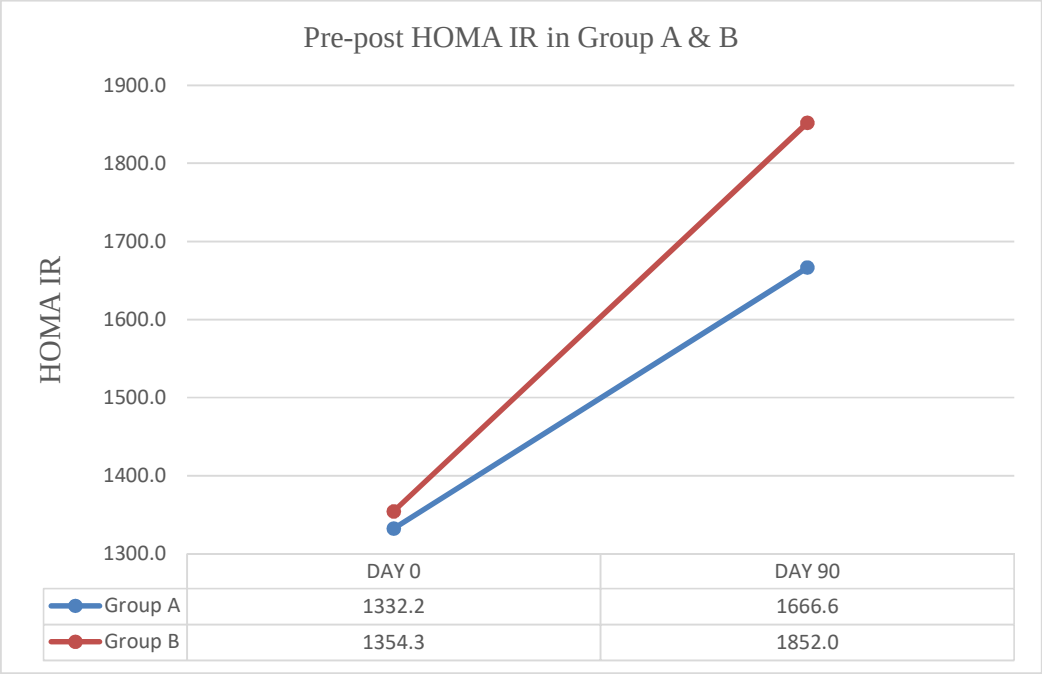


Table no.50: Comparison Between Group A and Group B with HOMAIR at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	1332.23	195.45	1354.31	255.35	29.09	0.88	0.099
DAY 90	1666.63	384.52	1852.01	585.32	3010.5	3.01	0.003

Study data indicate that reductions in measurements showed comparable results between the groups at Day 0 (p=0.099). However, outcome differences at different time points revealed significant changes favoring Group B at Day 90 (p=0.003).

Table no.51: Comparison of different treatment time points with HOMAIR in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T -value	p-value
A	Day 0 to Day 90	334.40	315.89	10.04	<0.001
B	Day 0 to Day 90	521.88	473.98	10.45	<0.001

Study data indicate that changes in measurements showed comparable results between the groups (p=0.94). However, outcome differences at different time points revealed significant changes favoring Group B (p<0.001).

Table no.52: Pre-Post total Cholesterol(mg/dl) in group A and Group B

TOTAL CHOLESTEROL(mg/dl)	Day 0	Day 90
Group A	143.7	137.7
Group B	150.5	141.8

The study found that in Group A, most individuals had total cholesterol levels of 143.7 mg/dl on Day 0, which decreased to 137.7 mg/dl on Day 90. In Group B, the majority had total cholesterol levels of 150.5 mg/dl on Day 0, which dropped to 141.8 mg/dl on Day 90.

Graph No.9: Pre-Post total Cholesterol in group A and Group B

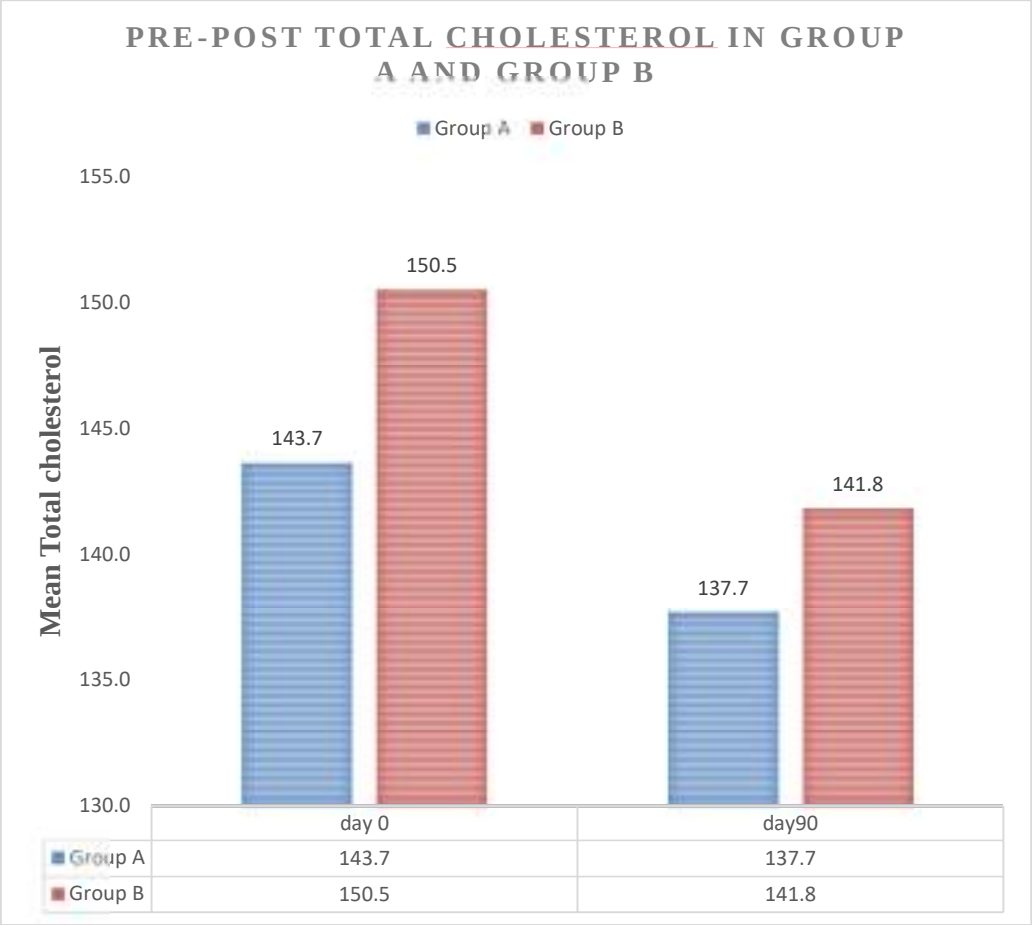


Table no.53: Comparison Between Group A and Group B with TOTAL CHOLESTEROL at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	143.66	15.47	150.52	32.38	4.44	1.60	0.19
DAY 90	137.69	16.83	141.82	22.80	3.13	1.07	0.37

Study data indicate that reductions in measurements showed comparable results between the groups at both Day 0 (p=0.19) and Day 90 (p=0.37). There were no significant outcome differences at different time points, suggesting similar trends between Group A and Group B.

Table no.54: Comparison of different treatment time points with TOTAL CHOLESTEROL in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	5.97	17.67	3.20	<0.001
B	Day 0 to Day 90	7.28	20.36	3.39	<0.001

Study data suggest that changes in measurements yielded comparable results across the groups (p=0.94). However, outcome differences observed at various time points revealed significant changes that favored Group B (p<0.001). Group A exhibited a mean difference of 5.97, while Group B showed a mean difference of 7.28, both with p-values less than 0.001.

Table no.55: Pre-post HDL-Cholesterol(mg/dl) in Both the Groups

HDL-CHOLESTEROL(mg/dl)	Day 0	Day 90
Group A	43.8	43.6
Group B	44.0	43.6

The study found that in Group A, most individuals had HDL-cholesterol levels of 43.8 mg/dl on Day 0, which slightly decreased to 43.6 mg/dl on Day 90. In Group B, the majority had HDL-cholesterol levels of 44.0 mg/dl on Day 0, which also reduced marginally to 43.6 mg/dl on Day 90.

Graph No.10: Pre-post HDL-Cholesterol(mg/dl)

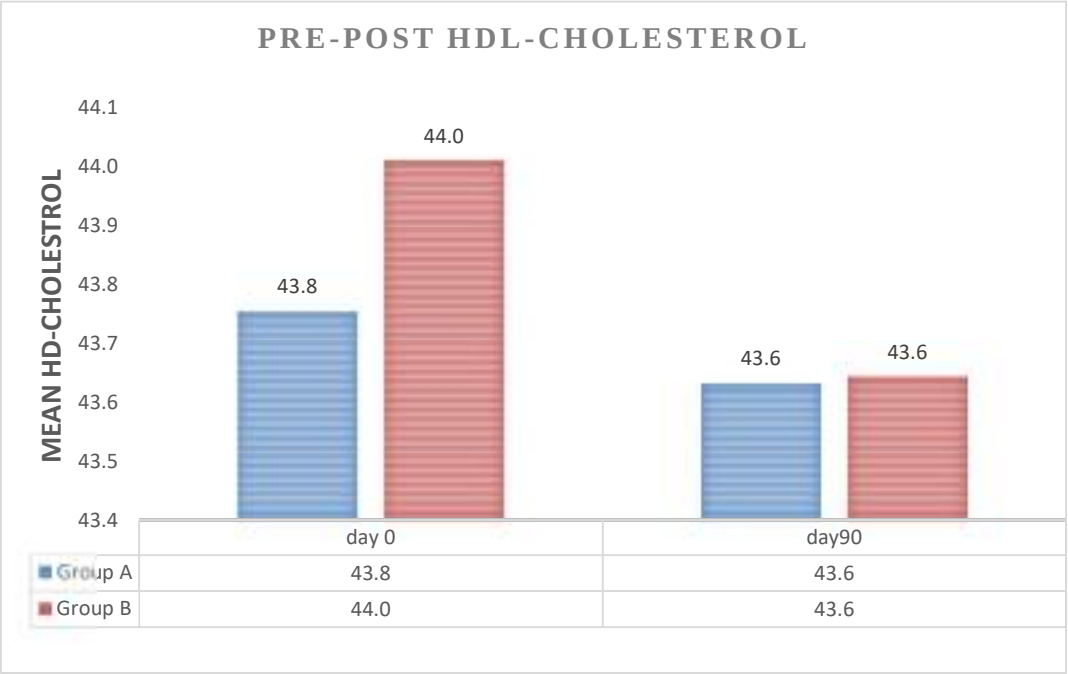


Table no.56: Comparison Between Group A and Group B with HDL-CHOLESTEROL at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	43.76	2.88	44.01	3.39	-0.60	-1.27	0.321
DAY 90	43.63	2.93	43.64	4.01	-0.44	-0.85	0.608

Study data indicate that reductions in measurements showed comparable results between the groups at both Day 0 (p=0.321) and Day 90 (p=0.608). There were no significant outcome differences at different time points, suggesting similar trends between Group A and Group B.

Table no.57: Comparison of different treatment time points with HDL-CHOLESTEROL in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	0.12	1.59	0.73	0.468
B	Day 0 to Day 90	0.28	2.39	1.10	0.273

Study data indicate that reductions in measurements showed comparable results between the groups (p=0.468). However, outcome differences at different time points revealed significant changes favoring Group B (p=0.273). Group A had a mean difference of 0.12, while Group B had a mean difference of 0.28.

Table no.58: Total Cholesterol/HDL ratio across both groups before and after intervention

TOTAL CHOLESTEROL/ HDL RATIO	Day 0	Day 90
Group A	3.3	3.0
Group B	3.5	3.3

The study found that in Group A, most individuals had a total cholesterol/HDL ratio of 3.3 on Day 0, which decreased to 3.0 on Day 90. In Group B, the majority had a ratio of 3.5 on Day 0, which reduced to 3.3 on Day 90.

Graph No.11: Total Cholesterol/HDL ratio across both groups before and after intervention

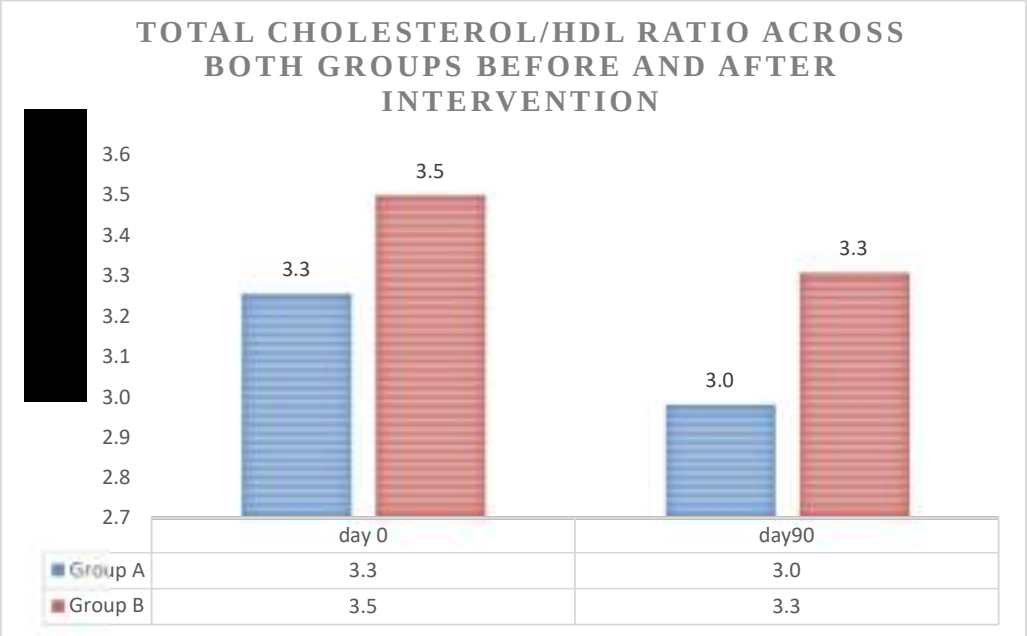


Table no.59: Comparison of different treatment time points with Total CHOLESTEROL/HDL Ratio in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value

A	Day 0 to Day 90	0.27	0.55	4.77	<0.001
B	Day 0 to Day 90	0.13	0.16	8.12	<0.001

Study data indicate that reductions from Day 0 to Day 90 showed significant changes in both groups. Group A had a mean difference of 0.27 (SD = 0.55) and Group B had a mean differnec of 0.13, with a significant outcome (p = 0.001).

Table no.60: LDL Cholesterol(mg/dl) across both groups at different time points

LDL-CHOLESTEROL	DAY 0	DAY 90
Group A	72.1	69.6
Group B	79.0	75.7

The study found that in Group A, the LDL-cholesterol levels decreased from 72.1 mg/dL on Day 0 to 69.6 mg/dL on Day 90. Similarly, in Group B, LDL-cholesterol levels decreased from 79.0 mg/dL on Day 0 to 75.7 mg/dL on Day 90.

Graph No.12: LDL Cholesterol(mg/dl) across both groups at different time points

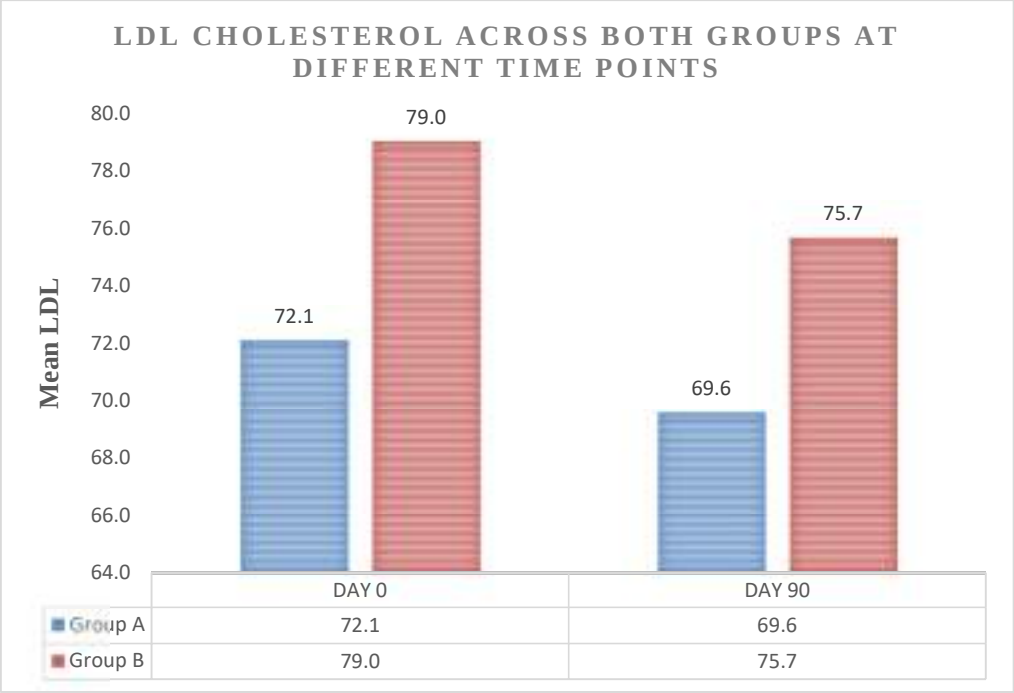


Table no.61: Comparison Between Group A and Group B with LDL-CHOLESTEROL at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	72.11	15.36	79.04	28.29	4.24	1.70	0.243
DAY 90	69.58	13.95	75.68	15.96	5.04	2.38	0.112

Study data indicate that at Day 0, the mean values between Group A (72.11, SD = 15.36) and Group B (79.04, SD = 28.29) showed comparable results (p = 0.243). However, by Day 90, although the mean values for Group A (69.58, SD = 13.95) and Group B (75.68, SD = 15.96) indicated a trend towards improvement in Group B, the outcome difference was not statistically significant (p = 0.112).

Table no.62: Comparison of different treatment time points with LDL-CHOLESTEROL in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	2.53	9.28	2.59	0.011
B	Day 0 to Day 90	1.73	8.85	1.86	0.066

Study data indicate that reductions from Day 0 to Day 90 showed significant changes in both groups. Group A had a mean difference of 2.53 (SD = 9.28) and Group B had a mean difference of 1.73, with a significant outcome (p = 0.011).

Table no.63: Triglycerides(mg/dl) across both groups at different time points

TRIGLYCERIDES(mg/dl)	DAY 0	DAY 90
Group A	135.9	127.9
Group B	139.4	133.0

The study found that in Group A, triglyceride levels decreased from 135.9 mg/dL on Day 0 to 127.9 mg/dL on Day 90. In Group B, triglyceride levels also decreased from 139.4 mg/dL on Day 0 to 133.0 mg/dL on Day 90.

Graph No.13: Triglycerides(mg/dl) across both groups at different time points

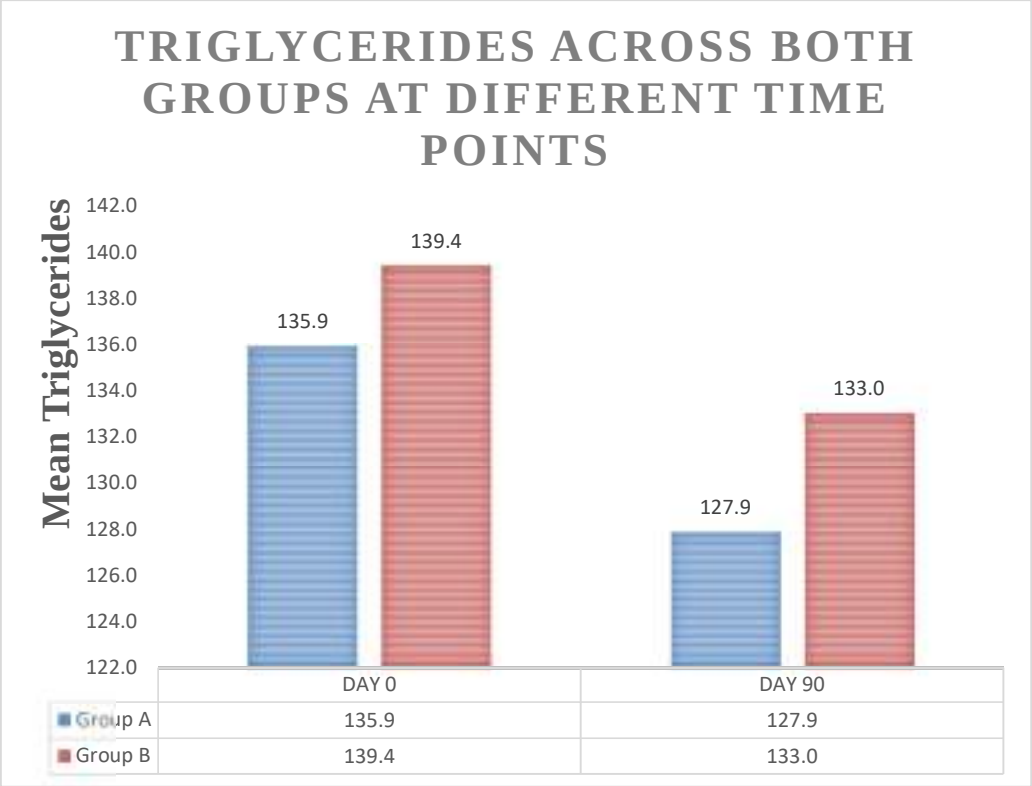


Table no.64: Comparison Between Group A and Group B with TRIGLYCERIDES at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	135.93	28.09	139.43	45.28	-3.72	-0.68	0.63
DAY 90	127.9	21.83	133.04	42.01	-6.17	-1.25	0.47

Study data indicate that reductions in triglyceride levels showed comparable results between the groups at both Day 0 (p = 0.63) and Day 90 (p = 0.47). No significant

outcome differences were observed at different time points between Group A and Group B.

Table no.65: Comparison of different treatment time points with TRIGLYCERIDES in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	8.03	11.81	6.45	<0.001
B	Day 0 to Day 90	5.59	5.43	9.77	<0.001

Study data indicate that reductions from Day 0 to Day 90 showed significant changes in both groups. Group A had a mean difference of 8.03 (SD = 11.81)and Group B had a mean difference of 5.59 , with a highly significant outcome ($p < 0.001$).

Table no.36: Pre-post Total Protein(g/dl)

TOTAL PROTEIN	Day 0	Day 90
Group A	7.2	7.1
Group B	7.1	7.7

The study found that in Group A, total protein levels slightly decreased from 7.2 g/dL on Day 0 to 7.1 g/dL on Day 90. In Group B, total protein levels increased from 7.1 g/dL on Day 0 to 7.7 g/dL on Day 90.

Graph No.14: Pre-post total protein

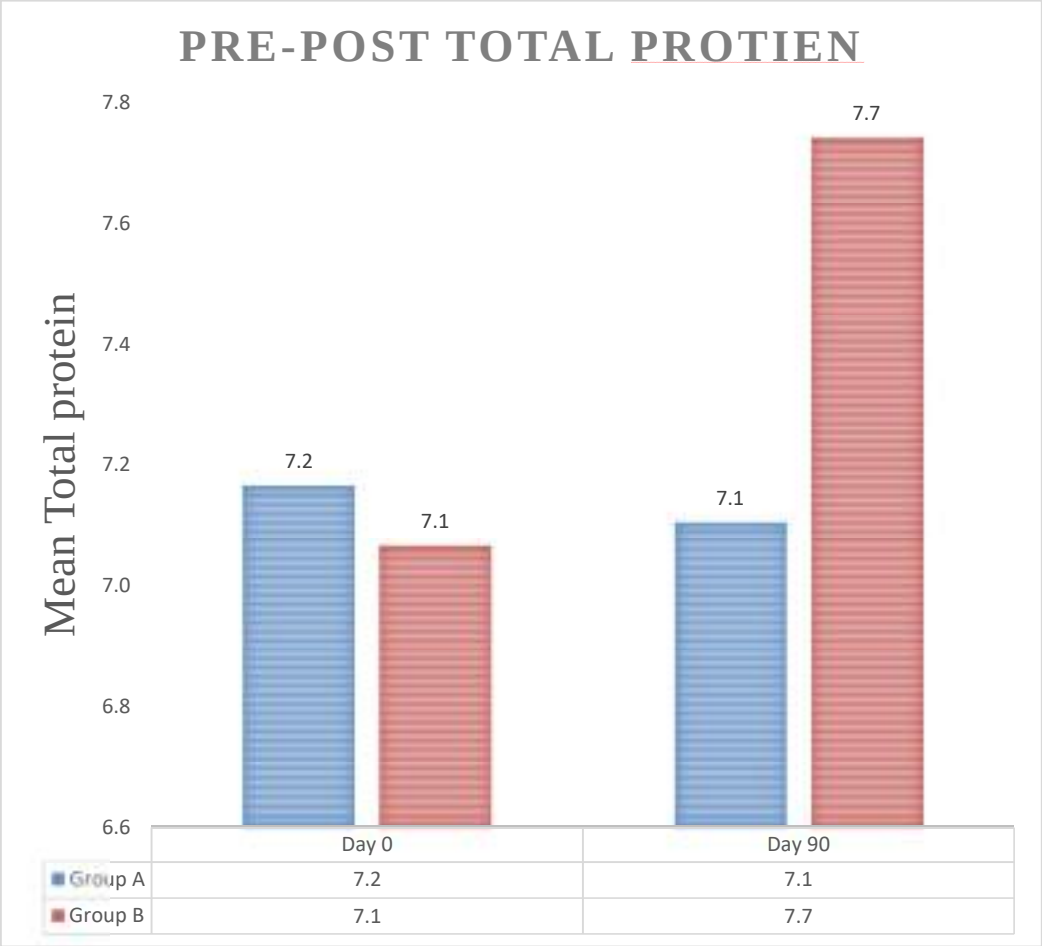


Table no.67: Comparison Between Group A and Group B with Total Protein at different treatment time points by Unpaired T test

Time points	Group A			Group B			Mean Diff	T-value	p-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
DAY 0	7.17	0.2	98.87	7.06	0.37	82.13	0.10	2.26	0.025
DAY 90	7.11	0.37	98.66	7.01	6.75	82.34	0.10	2.26	0.025

Study data reveal substantial differences in the measured variable between the groups at both Day 0 (p = 0.025) and Day 90 (p = 0.025). Moreover, significant differences in outcomes were observed at various time points between Group A and Group B.

Table no.68: Comparison of different treatment time points with Total Protein in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	0.06	0.32	1.79	0.076
B	Day 0 to Day 90	1.39	9.49	1.39	0.169

Study data indicate that reductions in the measured variable showed non significant changes within Group A from Day 0 to Day 90 (p = 0.076). However, no significant changes were observed within Group B (p = 0.169).

Table no.69: Pre post Albumin(g/dl) in both the groups

ALBUMIN	DAY 0	DAY 90
Group A	4.1	4.0
Group B	4.0	4.0

The study found that in Group A, albumin levels slightly decreased from 4.1 g/dL on Day 0 to 4.0 g/dL on Day 90. In Group B, albumin levels remained stable at 4.0 g/dL from Day 0 to Day 90.

Graph No.15: Pre post Albumin(g/dl) in both the groups

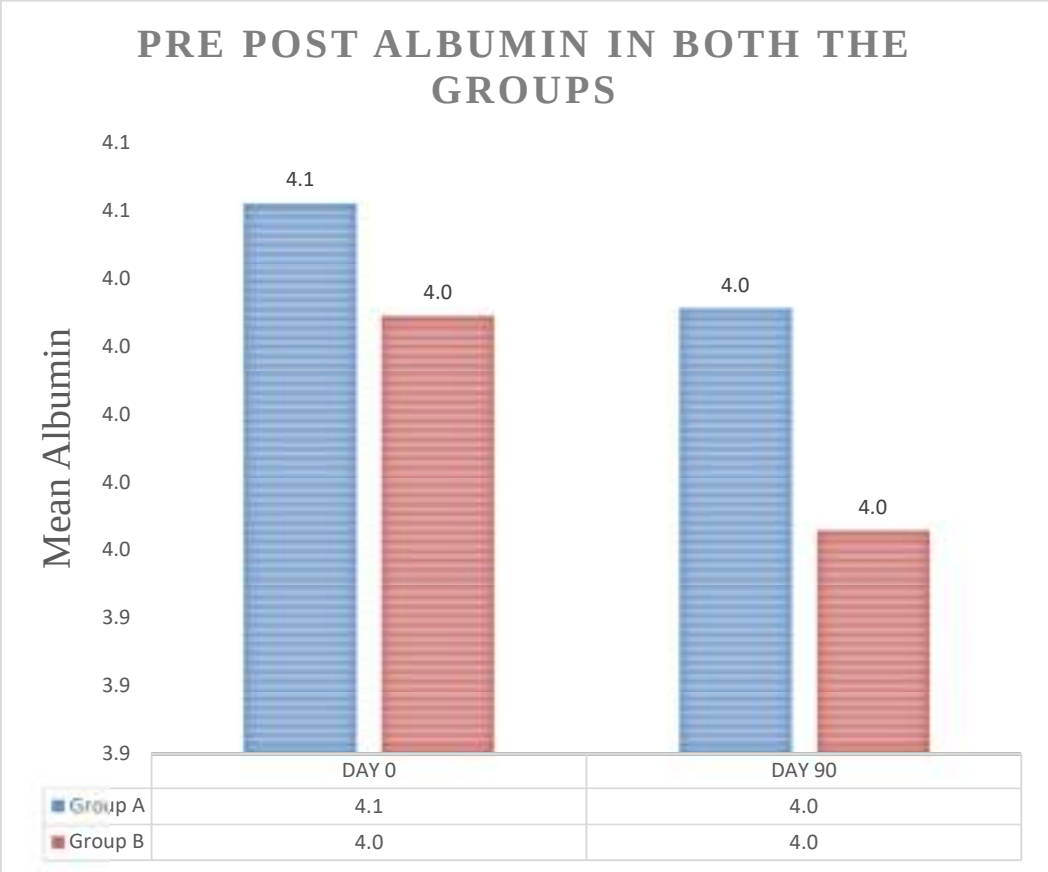


Table no.70: Comparison Between Group A and Group B with ALBUMIN at different treatment time points by Unpaired T test

Time points0	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	4.06	0.12	4.02	0.12	0.03	1.78	0.051

DAY 90	4.03	0.11	3.96	0.12	0.06	3.47	0.001

Study data indicate that reductions in the measured variable showed comparable results between the groups at Day 0 (p = 0.051). However, significant differences were observed between the groups at Day 90 (p = 0.001), showing significant reduction in Group B.

Table no.71: Comparison of different treatment time points with ALBUMIN in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	0.03	0.09	3.39	<0.001
B	Day 0 to Day 90	0.06	0.08	6.84	<0.001

Study data indicate that reductions in the measured variable showed significant changes within both groups from Day 0 to Day 90 (p < 0.001 for both Group A and Group B). Significant outcome differences were observed at different time points between Group A and Group B.

Table no.72: Pre-post A/G RATIO across both groups

A/G RATIO	Day 0	Day 90
Group A	1.3	1.2
Group B	1.2	1.2

The study found that in Group A, the A/G ratio decreased from 1.3 on Day 0 to 1.2 on Day 90. In Group B, the A/G ratio remained stable at 1.2 from Day 0 to Day 90.

Graph No.16: Pre-post A/G RATIO across both groups

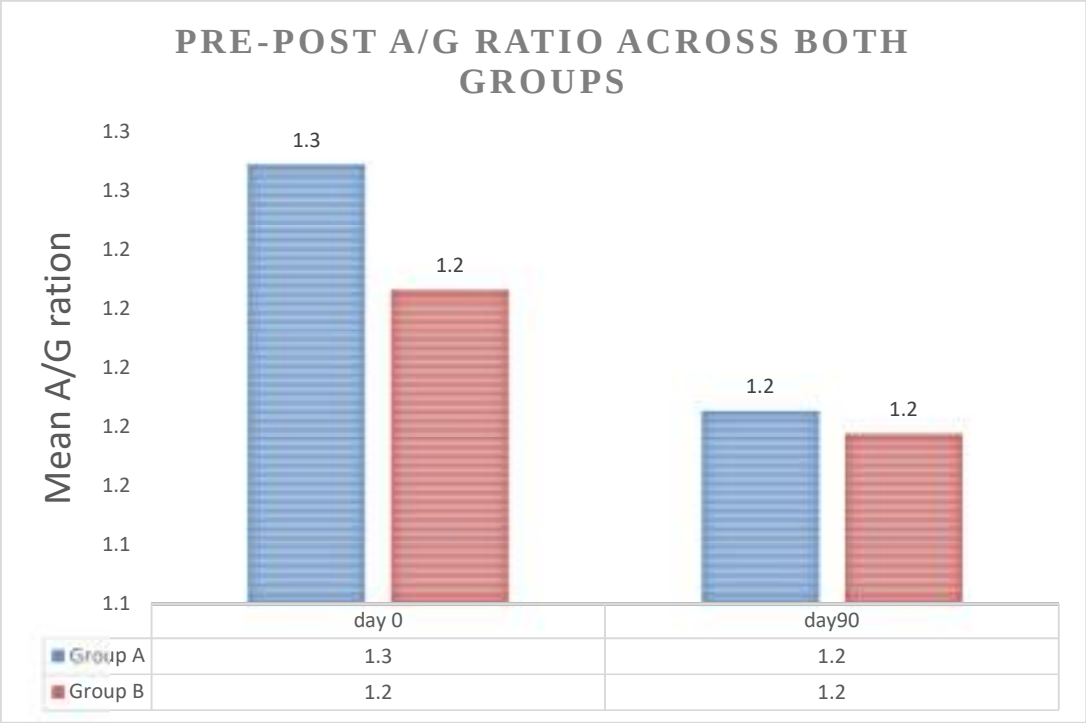


Table no.73: Comparison Between Group A and Group B with A/G ratio at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			

DAY 0	1.27	0.66	1.22	0.11	0.04	0.52	0.026
DAY 90	1.19	0.11	1.17	0.13	0.01	0.48	0.808

Study data indicate that reductions in the measured variable showed significant differences between the groups at Day 0 (p = 0.026). However, comparable results were observed between the groups at Day 90 (p = 0.808). No significant outcome differences were observed at different time points between Group A and Group B.

Table no.74: Comparison of different treatment time points with A/G ratio in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	0.08	0.66	1.20	0.232
B	Day 0 to Day 90	0.06	0.11	4.97	<0.001

Study data indicate that reductions in the measured variable showed no significant changes within Group A from Day 0 to Day 90 (p = 0.232). However, significant changes were observed within Group B during the same period (p < 0.001).

Table no.75: Alkaline phosphatase(U/L) across both groups

ALKALINE PHOSPHATASE	Day 0	Day 90

Group A	125.0	120.6
Group B	127.1	124.0

The study found that in Group A, alkaline phosphatase levels decreased from 125.0 U/L on Day 0 to 120.6 U/L on Day 90. In Group B, alkaline phosphatase levels decreased from 127.1 U/L on Day 0 to 124.0 U/L on Day 90.

Graph No.17: Alkaline phosphatase across both groups

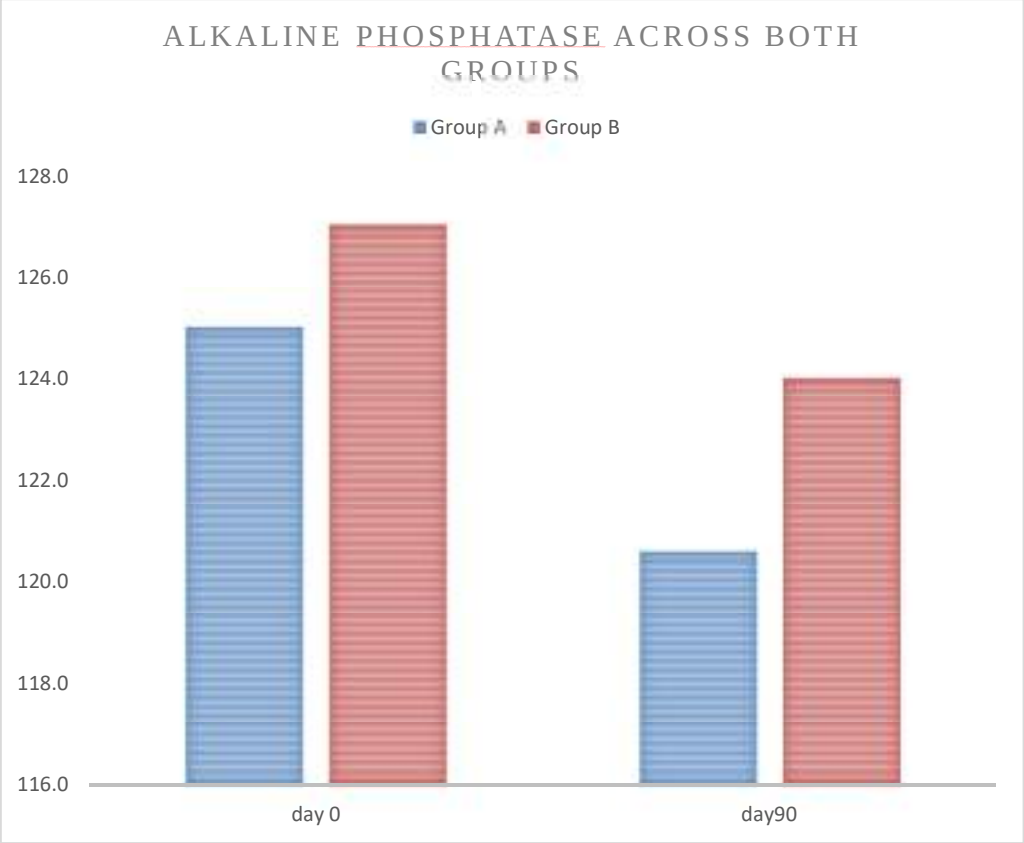


Table no.76: Comparison Between Group A and Group B with ALKALINE PHOSPHATASE at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	125.03	16.56	127.05	23.175	-4.54	-1.70	0.041
DAY 90	120.6	14.71	124.03	18.363	-5.67	-2.35	0.040

Study data indicate that reductions in the measured variable showed significant differences between the groups at both Day 0 (p = 0.041) and Day 90 (p = 0.040). Significant outcome differences were observed at different time points between Group A and Group B.

Table no.77: Comparison of different treatment time points with ALKALINE PHOSPHATASE in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	4.43	12.76	3.29	<0.001
B	Day 0 to Day 90	3.31	3.66	8.59	<0.001

Study data indicate that reductions in the measured variable showed significant changes within both Group A (p < 0.001) and Group B (p < 0.001) from Day 0 to Day 90.

Table no.78: Total Bilirubin(mg/dl) in Group A and Group B at different time point

TOTAL BILIRUBIN(mg/dl)	Day 0	Day 90
Group A	0.4	0.4
Group B	0.4	0.4

The study found that in both Group A and Group B, total bilirubin levels remained stable at 0.4 mg/dL from Day 0 to Day 90.

Graph No.18: Total Bilirubin in Group A and Group B at different time point

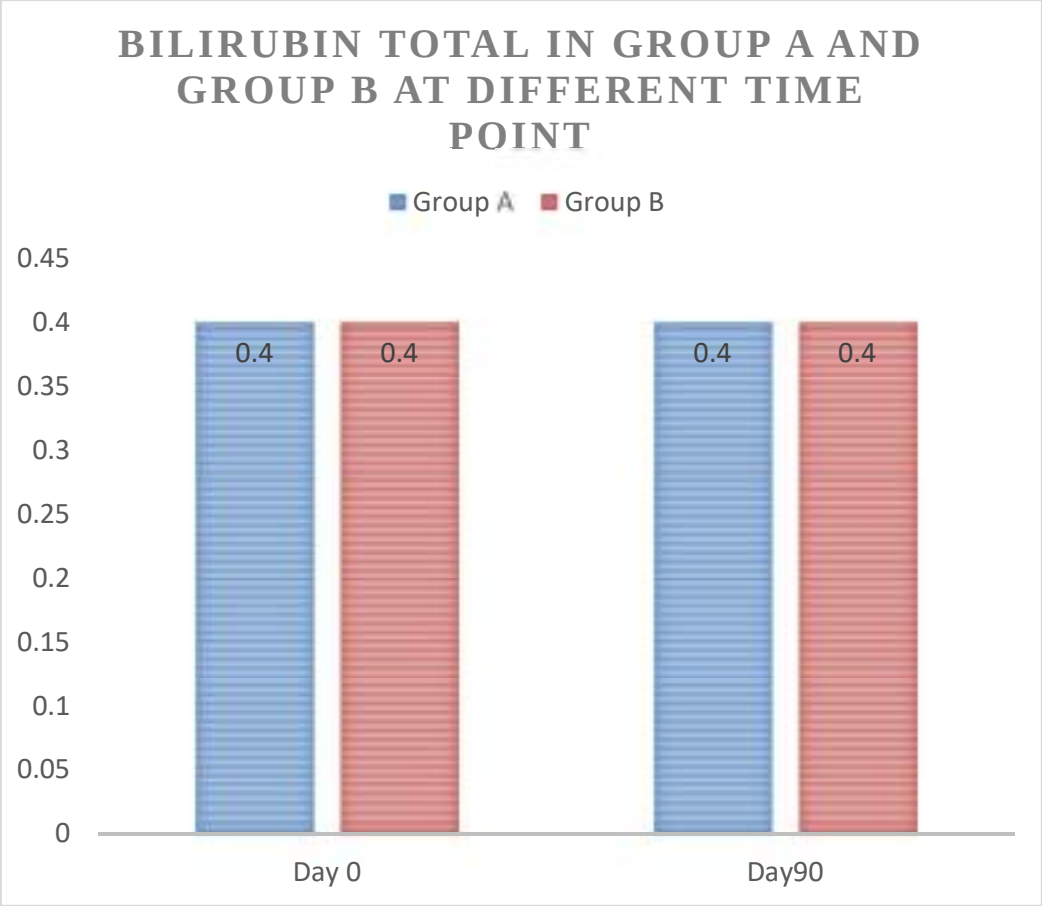


Table no.79: Comparison Between Group A and Group B with TOTAL BILIRUBIN at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	0.43	0.05	0.44	0.09	0.01	0.80	0.52
DAY 90	0.43	0.06	0.43	0.05	0.01	0.94	0.30

This study compares total bilirubin levels in Group A and B at different time points. No significant differences were found between the groups.

Table no.80: Comparison of different treatment time points with TOTAL BILIRUBIN in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	**Day 0 to Day 90**	0.00	0.04	0.53	0.596
B	**Day 0 to Day 90**	0.00	0.04	0.24	0.810

This study compares total bilirubin changes from Day 0 to Day 90 in Groups A and B. Group A showed a mean reduction of 0.04 (SD = 0.04), but the change was not significant (p = 0.596). Group B had almost no change (mean = 0.00, SD = 0.04) with p = 0.810. Both groups showed no statistically significant bilirubin reduction over 90 days.

Table no.81: Pre-post Creatinine(mg/dl) Group A & B

S. Creatinine(mg/dl)	Day 0	Day 90
Group A	0.9	0.9
Group B	1.0	0.9

The study found that in Group A, serum creatinine levels remained stable at 0.9 mg/dL from Day 0 to Day 90. In Group B, serum creatinine levels decreased from 1.0 mg/dL on Day 0 to 0.9 mg/dL on Day 90.

Graph No.19: Pre-post Creatinine Group A & B

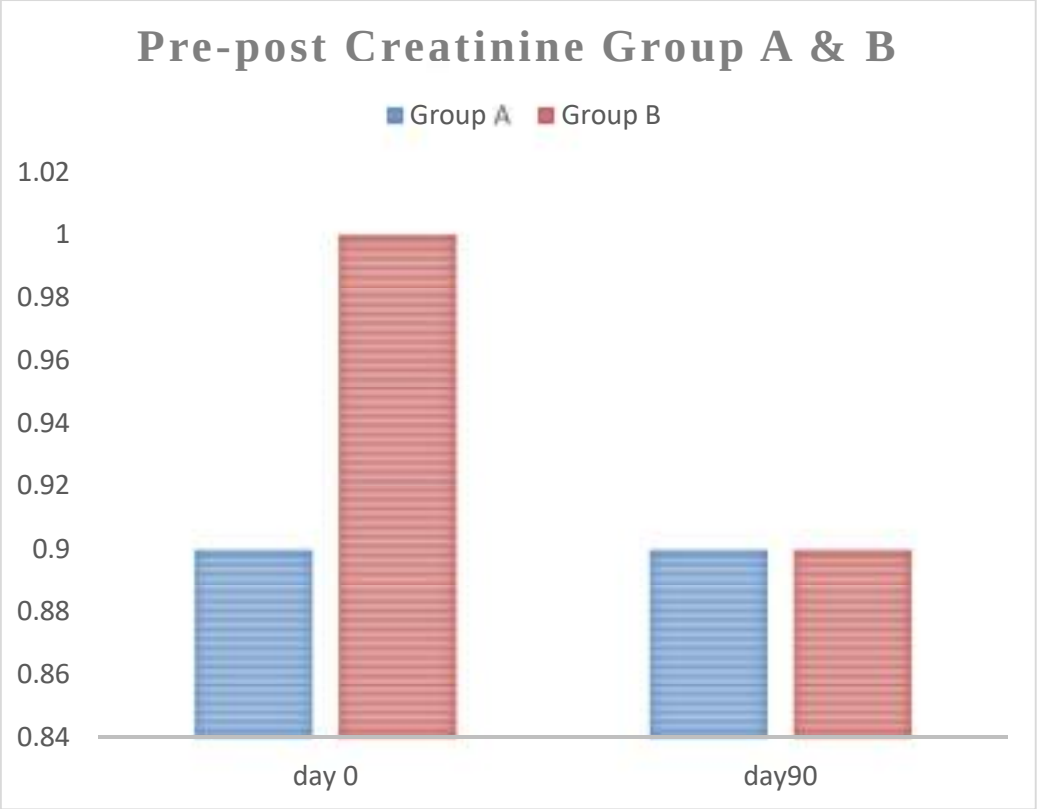


Table no.82: Comparison Between Group A and Group B with Creatinine at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	0.94	0.09	0.99	0.52	0.00	0.18	0.644
DAY 90	0.91	0.07	0.93	0.06	0.02	2.29	0.008

Study data indicate that reductions in the measured variable showed comparable results between the groups at Day 0 (p = 0.644). However, significant differences were observed between the groups at Day 90 (p = 0.008).

Table no.83: Comparison of different treatment time points with Creatinine in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	0.03	0.08	3.26	0.002
B	Day 0 to Day 90	0.00	0.08	0.12	0.902

Study data indicate that reductions in the measured variable showed significant changes within Group A from Day 0 to Day 90 (p = 0.002). However, no significant changes were observed within Group B during the same period (p = 0.902).

Table no.84: Pre-Post SGOT(U/L) across both the groups

SGOT(U/L)	Day 0	DAY 90
Group A	25.8	24.7
Group B	25.8	24.3

The study found that in Group A, SGOT levels decreased from 25.8 U/L on Day 0 to 24.7 U/L on Day 90. In Group B, SGOT levels also decreased from 25.8 U/L on Day 0 to 24.3 U/L on Day 90.

Graph No.20: Pre-Post SGOT(U/L) across both the groups

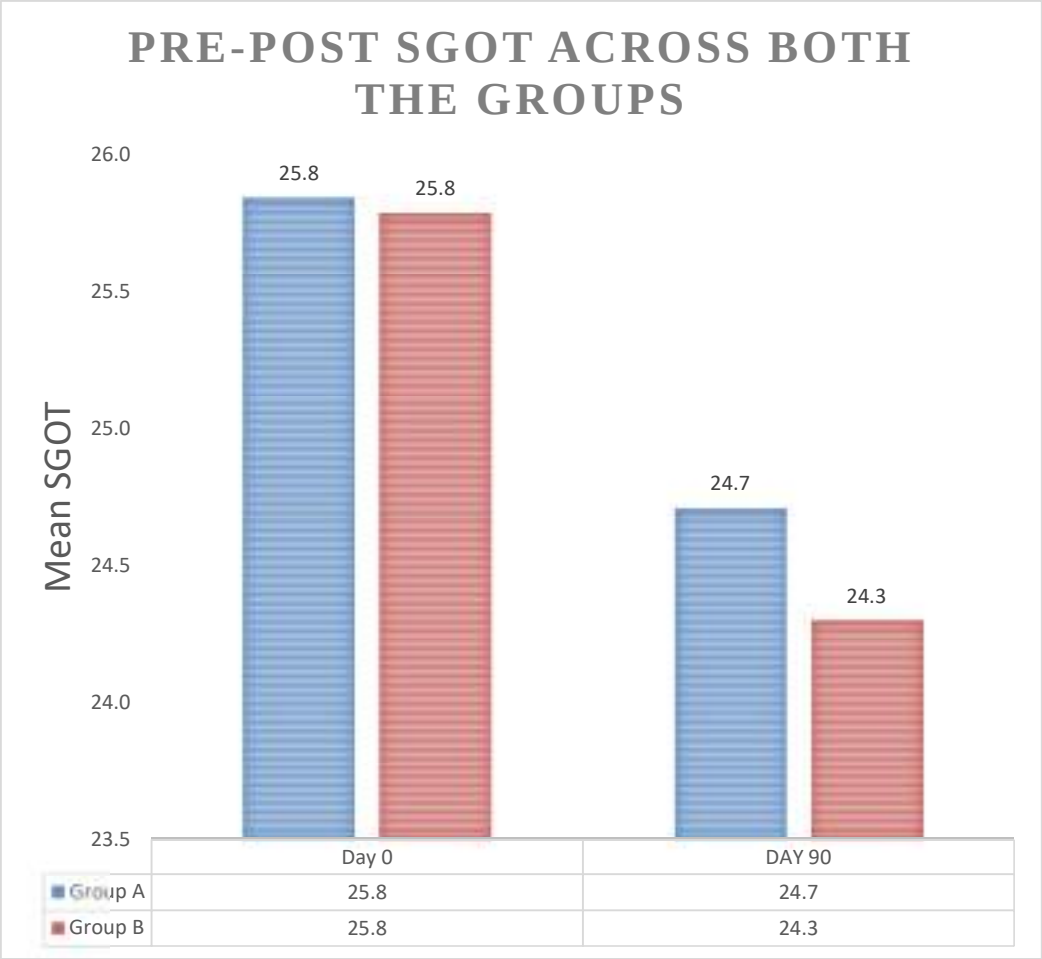


Table no.85 Comparison Between Group A and Group B with SGOT at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	25.84	5.57	25.78	5.82	-0.24	-0.29	0.732
DAY 90	24.71	5.11	24.3	5.29	0.09	0.12	0.823

Study data indicate that reductions in the measured variable showed comparable results between the groups at both Day 0 ($p = 0.732$) and Day 90 ($p = 0.823$). No significant outcome differences were observed at different time points between Group A and Group B.

Table no.86: Comparison of different treatment time points with SGOT in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	1.13	3.77	2.85	0.005
B	Day 0 to Day 90	1.47	1.77	7.87	0.001

Study data indicate that reductions in the measured variable showed significant changes within both groups from Day 0 to Day 90 ($p < 0.001$ for both Group A and Group B).

Table no.87: SGPT(U/L) At Different Time Points Across Group A And Group B

SGPT(U/L)	Day 0	Day 90
Group A	26.0	25.6
Group B	26.0	24.0

The study found that in Group A, SGPT levels slightly decreased from 26.0 U/L on Day 0 to 25.6 U/L on Day 90. In Group B, SGPT levels decreased from 26.0 U/L on Day 0 to 24.0 U/L on Day 90.

Graph No.21: SGPT(U/L) At Different Time Points Across Group A And Group B

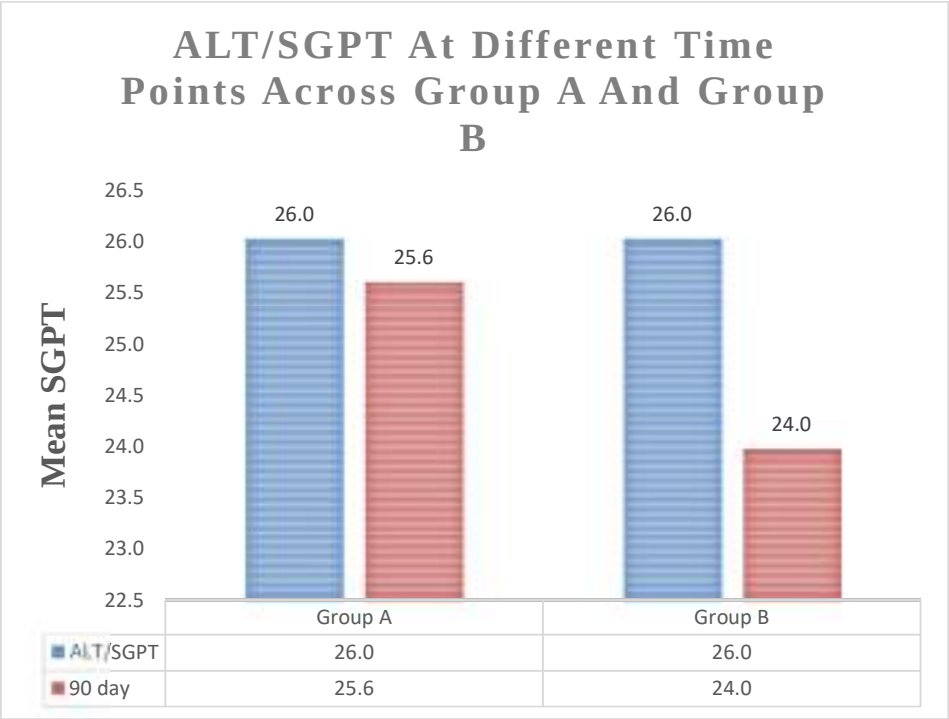


Table no.88: Comparison Between Group A and Group B with SGPT at different treatment time points by by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	26.03	6.5	26.03	7.07	-0.53	-0.53	0.696
DAY 90	25.61	18.19	23.97	6.02	1.10	0.54	0.344

Study data indicate that reductions in the measured variable showed comparable results between the groups at both Day 0 ($p = 0.696$) and Day 90 ($p = 0.344$). No significant outcome differences were observed at different time points between Group A and Group B.

Table no 89.: Comparison of different treatment time points with SGPT in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	0.42	18.62	0.22	0.830
B	Day 0 to Day 90	2.06	4.31	4.52	<0.001

Study data indicate that reductions in the measured variable showed significant changes within both groups from Day 0 to Day 90 ($p < 0.001$) for both Group A and Group B.

Table no.90: VLDL(mg/dl) at different time points across both the groups

VLDL(mg/dl)	DAY 0	DAY 90
Group A	27.0	25.0
Group B	27.3	25.7

The study found that in Group A, most individuals had VLDL levels of 27.0 mg/dl on Day 0, which decreased to 25.0 mg/dl on Day 90. In Group B, the majority had VLDL levels of 27.3 mg/dl on Day 0, which dropped to 25.7 mg/dl on Day 90.

Graph No.22: VLDL at different time points across both the groups

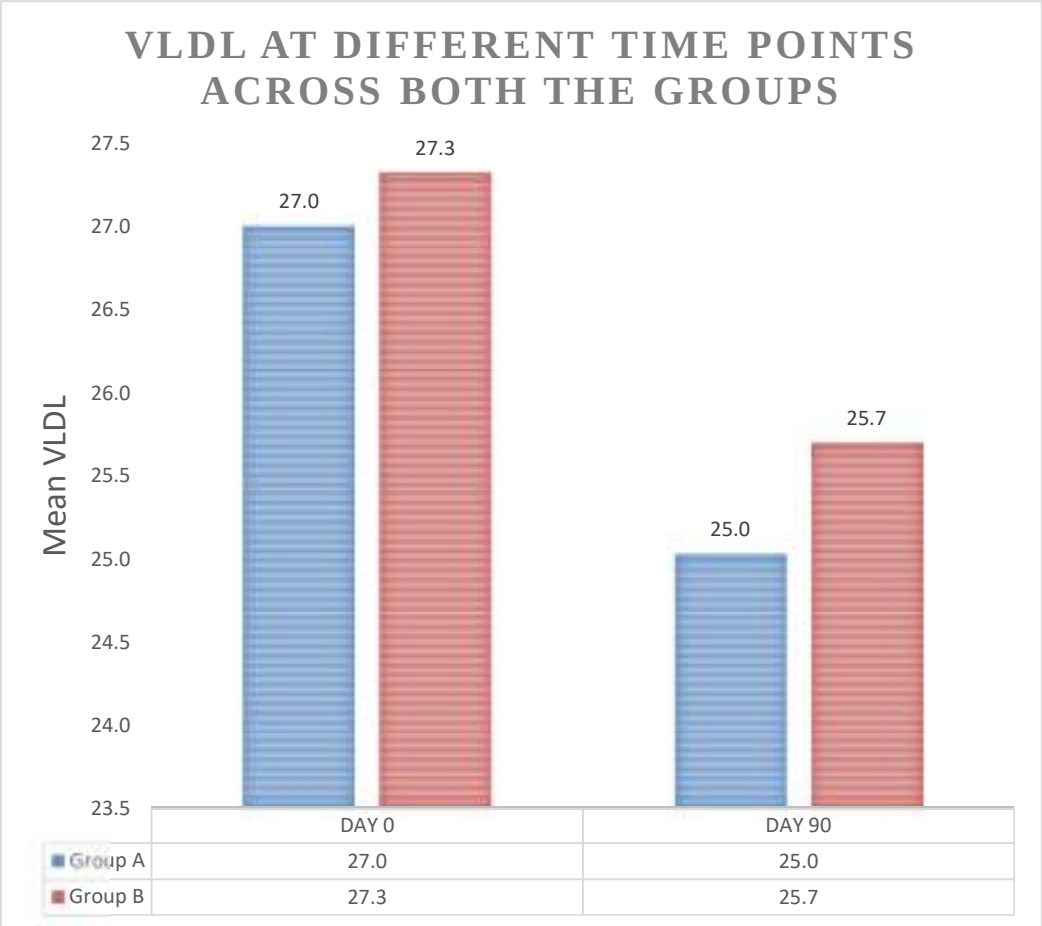


Table no.91: Comparison Between Group A and Group B with VLDL at different treatment time points by Unpaired T test

Time points	Group A		Group B		Mean difference	T-value	p-value
	Mean	SD	Mean	SD			
DAY 0	27.01	6.14	27.32	9.73	0.36	0.30	0.891
DAY 90	25.03	5.65	25.70	8.87	0.86	0.78	0.767

Study data indicate that reductions in the measured variable showed comparable results between the groups at both Day 0 (p = 0.891) and Day 90 (p = 0.767). No significant outcome differences were observed at different time points between Group A and Group B.

Table no.92: Comparison of different treatment time points with VLDL in Group A and Group B by Paired T test

Groups	Changes from	Mean Diff	SD Dv	T-value	p-value
A	Day 0 to Day 90	1.97	2.66	7.05	<0.001
B	Day 0 to Day 90	1.47	1.20	11.66	<0.001

Study data indicate that reductions from Day 0 to Day 90 showed significant changes in both groups. Group A had a mean difference of 1.97 (SD = 2.66) and Group B ahd a mena difference of 1.20, with a highly significant outcome (p < 0.001).

Table no.93: Effect on *Prameha purvaroopa* variables using Mann-Whitney U test (between the groups) and Wilcoxon matched pairs (within the group).

Si.no	Parameter	Intervention group	Base line	30th day	60th day	90th day	P value	Baseline (BL)-30th day	BL-60th day	BL-90th day
1.	*Madhuryamasya*	A	0.5±0.9	0.5±0.8	0.5±8	0.5±8	0.55	<0.038*	<0.040*	<0.036*
		B	0.7±0.9	0.50±8	0.40±7	0.40±7		<0.001*	<0.001*	<0.001*
2.	*Angashaitilya*	A	1.5±1.0	1.4±10	1.4±10	1.41±0	<0.025*	0.1614	0.1097	0.35
		B	1.3±1.0	1.2±1.0	1.1±1.0	1.0±0.9		0.0010*	0.0001*	0.0001*
3.	*Alasya*	A	1.7±0.8	1.4±0.8	1.3±0.8	1.3±0.8	0.0012*	0.0001*	0.0001*	0.0001*
		B	1.9±0.8	1.4±0.8	1.0±0.8	0.9±0.8		0.0001*	0.0001*	0.0001*
4.	*Shitapriyatwa*	A	1.1±0.9	1.0±0.9	0.9±0.9	0.9±0.9	0.0011*	0.0117*	0.0003*	0.0002*
		B	0.9±1.0	0.7±0.8	0.5±0.6	0.4±0.6		0.0010*	0.0001*	0.0001*

5.	*Angaganda*	A	1.1±0.9	0.9±0.8	0.8±0.8	0.7±0.8	0.0059*	0.0001*	0.0001*	0.0001*
		B	1.10±0.9	0.8±0.8	0.5±0.7	0.4±0.6		0.0001*	0.0001*	0.0001*
6.	*Shramashwasa*	A	1.4±0.9	1.2±0.8	1.1±0.9	1.1±0.9	0.0001*	0.0022*	0.0001*	0.0001*
		B	1.3±0.9	1.0±0.8	0.5±0.6	0.5±0.6		0.0001*	0.0001*	0.0001*
7.	*Swedadikyata*	A	1.5±0.8	1.3±0.8	1.1±0.8	1.1±0.8	0.0001*	0.0001*	0.0001*	0.0001*
		B	1.6±0.8	1.3±0.9	0.7±0.8	0.6±0.8		0.0001*	0.0001*	0.0001*
8.	*Angasaada*	A	1.7±0.8	1.5±0.8	1.3±0.9	1.3±0.8	0.0001*	0.0004*	0.0001*	0.0001*
		B	1.8±0.7	1.4±0.8	0.9±0.8	0.8±0.8		0.0001*	0.0001*	0.0001*

This study evaluated the clinical aspects of prameha poorvaroopa (premonitory symptoms) using classical references. Poorvaroopa assessment parameters include madhuryamasyata (feeling sweetness in the mouth), angashaitilya (muscle laccidity), alasya (indolence), shitapriyatva (desire for cold things), angaganda (body odor),

shramashwasa (dysnoea on exertion), swedadikyata (perspiration), and angasada (physical fatigability).

The impact of intervention on the outcome of prameha poorva roopa (PPR) was evaluated, revealing significant differences favoring group B in the angashaitilya, alasya, shitapriyatva, angaganda, swedadikya, and angasada features. Notably, in Angashaitilya decreased significantly in Group B (p = 0.0001), while Group A showed moderate improvement (p = 0.025). Alasya reduced notably in both groups, with Group B experiencing a more significant decrease (p = 0.0001). Similarly, Shitapriyatwa improved in both groups, but Group B had a more pronounced reduction (p = 0.0001). Angagandha also showed a stronger decrease in Group B (p = 0.0001) compared to Group A (p = 0.0059). In Shramashwasa, Group B showed significant improvement (p = 0.0001), while Group A also had a notable reduction (p = 0.0022). Swedadikyata improved significantly in both groups, with a greater reduction in Group B (p = 0.0001). Lastly, Angasaada showed significant improvement in both groups (p = 0.0001), with Group B demonstrating a larger reduction. Overall, both groups experienced symptom relief, but Group B consistently showed greater improvement across all parameters.No differences were observed between the groups in madhuryamasya, but significant changes were observed within both groups A (p=0.0007) and group B (p=0.0001).

Tabe no 94: Showing summary results.

Parameters	Within Group – A (Control Group)			Within Group – B (Integrated Treatment Group)			B/W Groups
	0-30	0-60	0-90	0-30	0-60	0-90	
BMI	***	***	***	***	***	***	NS
Waist cir	***	***	***	***	***	***	NS
HbA1C	-	-	***	-	-	***	*** (B>A)
FBS	NS	NS	***	***	***	***	*** (B>A)
PPBS	NS	NS	NS	***	***	***	***(B>A)
Fasting Insulin	-	-	**	-	-	***	*(B>A)
HOMA-IR	-	-	**	-	-	***	**(B>A)
Total CHOL	-	-	*	-	-	**	NS
HDL	-	-	**	-	-	***	NS
LDL	-	-	**	-	-	***	NS
VLDL	-	-	**	-	-	***	NS
Triglycerides	-	-	***	-	-	***	NS
Creatinine	-	-	NS	-	-	NS	*** (B>A)
DQOL	***	***	***	***	***	***	NS

T Bilirubin	-	-	NS	-	-	NS	NS
D Bilirubin	-	-	NS	-	-	NS	NS
SGOPT	-	-	**	-	-	***	NS
SGPT	-	-	**	-	-	***	NS
T PROTEIN	-	-	NS	-	-	NS	NS
ALBUMIN	-	-	**	-	-	**	*** (B>A)
ALP	***	***	***	***	***	***	*** (B>A)

Note: * P<0.05, **P<0.01, ***P<0.001, NS: Non-significant

The study data reveal the following significant findings:

- BMI, and Waist Circumference: Both the control group (Group A) and the integrated treatment group (Group B) demonstrated highly significant changes ($p < 0.001$) across all time points (0-30, 0-60, and 0-90 days). No significant differences were observed between the groups (NS).
- HbA1C: Significant reductions ($p < 0.001$) were observed within both groups at the 0-90 day mark. However, between-group analysis revealed significantly greater reductions in Group B compared to Group A.
- Fasting Blood Sugar (FBS): While no significant changes were observed within Group A for the first two intervals (0-30 and 0-60 days), significant improvements ($p < 0.001$) were seen by 0-90 days. Group B, however, showed consistent and significant reductions ($p < 0.001$) across all time points. Group B performed significantly better than Group A.

- Postprandial Blood Sugar (PPBS): Significant reductions ($p < 0.001$) were observed within Group B across all time points. No significant changes were observed within Group A. Group B outperformed Group A significantly.
- Fasting Insulin: Group A showed significant reductions ($p < 0.001$) only at the 0-90 day mark, while Group B exhibited significant changes ($p < 0.001$) at the same time point. Group B demonstrated significantly greater reductions compared to Group A ($p < 0.043$).
- HOMA-IR: Group A showed significant reductions ($p < 0.001$) at the 0-90 day mark, whereas Group B demonstrated significant improvements ($p < 0.001$) over the same period. Group B showed significantly better outcomes compared to Group A ($p < 0.001$).
- Total Cholesterol (CHO): Within-group analysis showed significant reductions in Group A by 0-90 days ($p < 0.038$) and in Group B by 0-90 days ($p < 0.001$). However, no significant differences were observed between the groups (NS).
- High-Density Lipoprotein (HDL): No significant changes were observed within either group across any time points (NS). Between-group comparisons also showed no significant differences (NS).
- Low-Density Lipoprotein (LDL): No significant changes were observed within either group (NS) or between the groups (NS).
- Very Low-Density Lipoprotein (VLDL): Group A showed significant reductions ($p < 0.001$) by 0-90 days, while Group B demonstrated even greater reductions (*$p < 0.001$). However, between-group differences were not significant (NS).

- Triglycerides: Both groups demonstrated highly significant reductions ($p < 0.001$) by 0-90 days. No significant differences were observed between the groups (NS).
- Creatinine: No significant changes were observed within either group. However, between-group comparisons revealed significantly better results in Group B compared to Group A ($p < 0.001$).
- Diabetes Quality of Life (DQOL): Both groups showed highly significant improvements ($p < 0.001$) at all time points (0-30, 0-60, and 0-90 days). Between-group comparisons also indicated significant improvements favoring Group B ($p < 0.001$).
- Both treatment protocols resulted in significant within-group improvements in several metabolic parameters, particularly in total cholesterol, VLDL, triglycerides, and DQOL. However, Group B (Integrated Treatment Protocol) demonstrated significantly better outcomes for creatinine and DQOL in between-group comparisons, highlighting the effectiveness of the integrated approach.

4. DISCUSSION

The clinical trial aimed to assess the effectiveness of an Integrated Ayurveda treatment protocol for managing Prediabetes. The study was conducted as a Randomized Controlled Clinical Trial, enrolling a total of 180 participants, with 90 individuals assigned to each group. Patients in Group A received Standard Prediabetic care with Nutritional and lifestyle management counselling for 90 days. Patients in Group B received Ayurveda intervention which include ayurveda polyherbal formulation (*Madhumehahari kashaya*) 35 ml twice daily after food with water along with Ayurveda dietary and Yoga intervention. The parameters BMI, Waist circumference, FBS, PPBS, DQol were assessed on Baseline, 30th, 60th and 90th day of intervention. The parameters HbA1C, Fasting insulin, HomaIR, Lipid profile (Triglyceride, LDL, HDL, TC), LFT and Serum creatinine were assessed on baseline and 90th day.

4.1. Discussion on Observation

- The study population had a nearly equal gender distribution, with a slightly higher proportion of males (52.2%) compared to females (47.8%). In terms of religion, the majority of participants were Hindus (93.95%), followed by Muslims (6.95%), while other religious groups accounted for only 0.1%. Age-wise, the study predominantly included individuals between 31–40 years (39.9%), followed by those aged 41–50 years (31%), with the remaining age groups comprising 29.1% of the study population.
- Regarding educational status, a significant portion of participants were graduates (36.6%), followed by those with an intermediate level of education (34.95%). Illiterate individuals made up 12.15% of the study group, while 16% belonged to other educational categories. Socioeconomic classification revealed that a majority belonged to the lower middle class (52.2%), followed by the upper middle class (42.2%), while the remaining 5.6% fell into other socioeconomic status.
- Occupational distribution showed that 23.3% of participants were unemployed, while 18.3% were engaged as skilled workers or sales executives. Craft-related workers made up 14.4%, while the remaining 44% were engaged in various other occupations.

Geographically, the majority of participants (98%) were from Sadharana Desha, while Jangala and Anupa Desha had an equal representation of 1% each.

- In terms of Prakriti (body constitution), Vata-Pitta (VP) was the most prevalent, observed in 45% of participants, followed by Pitta-Kapha (PK) in 28.5%, and Vata-Kapha (VK) in 14.5%, with the remaining 11.2% exhibiting other constitutions. The Sara (tissue quality) assessment showed that Medasara (dominance of adipose tissue) was the most common (55%), followed by Asthisara (bone tissue dominance) at 22.5%, Mamsasara (muscle tissue dominance) at 10%, and the remaining 12.5% falling into other categories.
- **Diet adherence (in %)**
  - Diet adherence was found more in the group B compared to the group A (p=0.001).
- **Exercise /*yoga* adherence.**
  - Exercise/yoga practice adherence were more in group B compared to the group A (p=0.001).

4.2 Discussion on Results:

4.2.1 Discussion on glycemic parameters:

- Group B experiencing a greater decrease (**0.93)** than Group B **(0.48**). The baseline difference (**p < 0.001**) became more pronounced by Day 90, indicating Group B had a significantly better improvement (**p < 0.0001**).
- Group B had significantly lower mean FBS levels than Group A at day 30, day 60, and day 90. Both groups improved in the measured parameter over time. Group B had a mean difference of 8.96 in FBS levels by Day 90, while Group A had a mean difference of 4.77.
- The table compares PPBS levels between Group A and Group B over 90 days. At baseline, Group B had a significantly higher PPBS (**p = 0.001**), but both groups showed a significant reduction over time (**p < 0.001**). From Day 30 onward, Group B had consistently lower PPBS with significant differences (**p ≤ 0.012**). The overall reduction was greater in Group B (**p < 0.0001**).

- **4.2.2 Discussion on Insulin resistance parameters**
  - This study shows significant changes in fasting insulin levels over 90 days in both groups. At baseline, values were similar (**p = 0.039**), but by Day 90, Group B showed a greater increase (**p = 0.002**). The overall rise was higher in Group B (**1.72 ± 1.77 µU/ml**) than in Group A (**1.16 ± 1.12 µU/ml**), with a statistically significant difference (**p = 0.013**).
  - Outcome of intervention on HomaIR showed significant difference (**p=0.001**) revealed that group B had greater improvement (**p=0.0001**).
  - Result of glycemic outcome and insulin resistance parameter in group B is due to integrated ayurveda protocol consists of Madhumehari kashaya (an ayurveda polyherbal formulation), Ayurveda diet and Yoga.

  - **Madhumehari Kashaya**
    - Meshashringi, Asana, Jambu, Dharuharidra, Tamala patra ,Gududchi are having best pramehagna property.[112,103,106]
    - Gymnema sylvestre R. Br., Pterocarpus marsupium Roxb, Syzygium cumini Linn, Berberis aristata DC, Cinnamomum tamala (Buch,Ham) , Curcuma longa Linn, Triphala are having antihyperglycemic and insulin sensitizing action.[104,105,106,102,103]

  - **Ayurveda diet**
    - Ayurveda food works at insulin resistance characteristics, as it contains time restricted eating pattern. Time restricted eating is a pattern of Intermittent Fasting (IF). A recent meta-analysis reviewed of IF diets found that they reduce insulin resistance[123].
    - In response to the high prevalence of glucose intolerance in the morning, we introduced low-carbohydrate (LC) breakfast options, which are prepared using lentils and beans. After a 12-week period of consuming LC breakfasts, a randomized clinical

trial compared the effects of LC breakfasts with low-fat breakfasts on blood glucose control in individuals with type 2 diabetes. The study revealed a significant decrease in HbA1c levels after consuming LC breakfasts.[124]

- Millet, a staple food in India, holds immense significance in various aspects of daily life and is widely consumed locally. Millet possesses the ability to reduce the frequency of meals, promote satiety, and provide a substantial amount of fiber. Furthermore, a study conducted on diabetic mice demonstrated that millet could enhance insulin sensitivity and lower blood glucose and lipid levels.[125]
- The Ayurveda diet emphasizes more on eating fresh herbal preparations and nuts & seeds. We get the same dietary pattern in Mediterranean-style diet. A higher rate of mediterranean diet observance is linked to a 20–23% lower incidence of T2DM[126] due to its antioxidant and anti-inflammatory properties[127].

- **Yoga**
  - Yoga, according to various studies, may reduce insulin resistance[128]. Improved Insulin Sensitivity: *Asanas, pranayamas* and yoga postures, Enhance insulin sensitivity and manage blood sugar levels.[133]
  - Surya Namaskar, the basic dynamic yoga position that decreases hip circumference and improves glycemic outcomes, is the foundation of physical activity-related yoga [129].
  - A review of prior studies on T2DM analysis included nine eligible studies, of which four showed that yoga with the intervention led to a substantial drop in HbA1c compared to the control group[130].
  - Yoga significantly affects how well T2DM patients use their glucose [131].
  - In a study of 35 T2DM patients, yoga intervention significantly improved insulin and HOMA-IR compared to controls[132].

- **4.2.3 Anthropometric outcome**
  - BMI, and Waist Circumference: Both the control group (Group A) and the integrated treatment group (Group B) demonstrated highly significant changes ($p < 0.001$) across all time points (0-30, 0-60, and 0-90 days). No significant differences were observed between the groups.
  - The result of intervention might be due to Ayurveda polyherbal formulation, Ayurveda diet and Yoga.
  - ***Madhumehari kashaya***
    - *Vijayasara, Jambu, Triphala,Tamala patra* have *sthoulya and medohara* property.[112,103]
    - Based on in vitro and human studies, *Gymnema sylvestre R. Br*[133]*., Pterocarpus marsupium Roxb*[134]*., Cinnamom Tamala (Buch,Ham)*[135] *and Triphala*[136] *showed* reduction in waiste circumference and BMI.
  - **Ayurveda diet**
    - Low Glycemic index food helped in weight loss.
    - *Yava* (barley), *Trina dhanya's* (millets) have *lekhana* action might assisted in weight loss.
    - *Mudga* (green gram) has *medohara* property.
    - *Shushka phala varga's* (dry fruits) light and digestive, had *kaphahara* action might facilitated in weight loss.
  - **Yoga**
    - Surya Namaskar, the basic dynamic yoga position that decreases hip and waist circumference and improves glycemic outcomes, is the foundation of physical activity-related yoga [137].
    - Yoga can aid in weight management, which is crucial for those with prediabetes.[134]

➢ 4.2.4 Mode of action on Lipid Profile

In this study, there was a reduction in the lipid profile(HDL, LDL, Total Cholesterol) in both the groups. The integrated Ayurveda protocol helped to reduce the lipid levels through the various ingredients. Few of the ingredients and their established mode of action is listed below.

- Tinospora cordifolia is recognized for its ability to enhance insulin sensitivity, regulate blood glucose levels, and minimize fat accumulation. It also aids in detoxification and reduces oxidative stress, which can help in weight management. Tinospora cordifolia has anti-diabetic, anti-inflammatory, and lipid-lowering properties, contributing to reductions in body fat and waist circumference.[121]
- Syzygium cumini: The use of Syzygium cumini seed powder in diabetic patients demonstrated a notable decrease in blood sugar, cholesterol, and triglyceride levels. Enhanced lipid metabolism contributed to reductions in body weight and waist circumference.[122]
- Curcumin, the primary active compound in turmeric, helps decrease inflammation and the formation of fat cells (adipogenesis), resulting in lower body weight and a reduced waist circumference. Additionally, it supports improved glucose metabolism and promotes lipid breakdown.[123]
- Curcumin was found to significantly reduce glycosylated hemoglobin (HbA1c) levels in individuals with prediabetes (MD: -0.9%, 95% CI: -1.7 to -0.1%, p = 0.03). Additionally, participants with type 2 diabetes mellitus (T2DM) experienced favorable decreases in HbA1c (MD: -0.5%, 95% CI: -1.0 to -0.0%, p = 0.04) and fasting plasma glucose levels (MD: -11.7 mg/dL, 95% CI: -22.1 to -1.3 mg/dL, p = 0.03). There was also an observed trend toward improvement in lipid profiles.[124]
- Safety Profile: Significant differences were observed between the groups in renal function (serum creatinine) and liver function (serum albumin, A/G

ratio) tests; however, all values, both before and after testing, remained within the normal range.

- The meta-analysis included sixteen randomized controlled trials, which revealed that cinnamon significantly lowered fasting blood glucose (FBG) and homeostatic model assessment for insulin resistance (HOMA-IR) levels compared to the placebo, as indicated by the weighted mean difference.[125]

4.3. IMPACT ON DQOL

Stabilizing blood glucose reduces fatigue, neuropathy, and the risk of complications, leading to better physical well-being.[126]

Madhumehaari Kashaya

The drugs exhibit significant antihyperglycemic and insulin-sensitizing effects without causing any adverse events, making them a safe and effective option for managing blood sugar levels. They also contribute to healthy weight loss, which further supports overall metabolic health. As a result, these benefits collectively lead to an improved quality of life, enhancing overall well-being and reducing the risk of complications associated with metabolic disorders.

Yoga Intervention

1. Yoga promotes overall well-being by harmonizing the body, mind, and emotions, fostering a balanced state of physical, emotional, and spiritual health. Its positive impact on enhancing sleep quality further contributes to relaxation and rejuvenation. As a result, regular yoga practice has been shown to improve the overall quality of life by reducing stress, enhancing mental clarity, and supporting holistic health. Chronic stress can lead to insulin resistance. Yoga helps reduce stress through relaxation techniques and mindfulness.[132]Enhanced Physical Activity: Yoga encourages physical activity, which is important for managing prediabetes.[135]

Ayurveda Dietary Intervention

A well-balanced diet plays a crucial role in managing glycemic outcomes, supporting digestive health, and promoting healthy weight management while fulfilling essential nutritional requirements for optimal performance. Meal timing is a key factor in metabolic regulation, with Ayurveda emphasizing that the main meal should be consumed between 9 AM and 2 PM when digestion is at its peak, while dinner should be light and easy to digest. Breakfast should focus on beans and lentils due to their low glycemic load, while lunch and dinner should emphasize grains like millets and barley to aid in blood sugar management. A structured plate method is recommended, consisting of 50% steamed or sautéed vegetables, 25% grains such as millets and barley, and 25% protein sources with healthy fats, ensuring balanced meals that regulate blood sugar levels and provide essential nutrients.

Prioritizing whole, unprocessed foods—including whole grains like quinoa and barley, legumes, fresh vegetables, and low-glycemic fruits—can significantly improve blood sugar control. Additionally, incorporating medicinal spices such as turmeric (curcumin), cinnamon, and fenugreek has been shown to enhance insulin sensitivity and support glucose metabolism. Ayurveda also emphasizes mindful eating practices, such as consuming meals in a calm environment, chewing food thoroughly, and being aware of hunger cues, which help prevent overeating and improve digestion. Avoiding processed foods, particularly refined sugars, white flour, and highly processed products, is essential, as their consumption can cause blood sugar spikes and contribute to insulin resistance. Moreover, maintaining regular meal timings is a fundamental Ayurvedic principle for metabolic balance, with an emphasis on consuming lighter meals in the evening to support optimal digestion and overall well-being.

- **4.4: *Prameha* parameters**
  - Effect of intervention on *prameha poorva roopa* outcome showed significant difference favoring group B in *angashaitilya*, *alasya*,

shitapriyatva, *angaganda*, *swedadikya* and *angasada* features. Impact of intervention on *Prameharoopa* parameter showed significant difference towards group B in *mutramadhurya*, *prabhutamutrata*, *pipasa*, *Khsudadikyata*, *klama* and *Purishabaddata.*

- Drugs like Jambu, Asana, and Haridra possess potent anti-diabetic properties and have pitta-mitigating effects, which may help alleviate symptoms of Pitasadikyata, Kshudadikyata, and other conditions. An open-label clinical trial conducted in four centers of India investigated the efficacy of Vijayasara (Pterocarpus marsupium Roxb) in non-insulin-dependent diabetes mellitus. The trial demonstrated a reduction in glycemic parameters and lipid changes.[149]

- Research on the extract of Syzygium cumini has revealed the presence of phenolic compounds with antioxidant and anti-glycation properties, which contribute to their anti-diabetic benefits[150]. A meta-analysis of various studies has shown the positive effects of curcumin and its preparation in Asian pre-diabetes and Type 2 Diabetes Mellitus (T2DM) patients, as it reduces HbA1c levels.[151]

- Meshashringi, Tamala patra, and Daruharidra have Kapha medohara and lekhana (scrapping) actions, which may help reverse the pathogenesis of diabetes.[152,153] A clinical trial conducted on T2DM patients administered 500 mg of Meshashringi (Gymnema sylvestre R. Br.) along with a diet for a period of 90 days demonstrated beneficial effects on polyphagia and other symptoms.

- Patients with T2DM who received 1 mg of daruharidra fruit extract showed positive results in blood glucose regulation. Guduchi and Triphala have additional rasayana benefits, including those that may impact Angashitilya, Sada, and Klama.[156,157]
- The *Ayurvedic* concept of dietary recommendations for lifestyle diseases is *guru cha aatarpana,* i.e., food that is heavy and rich in nutrients without causing over nourishment [158] and avoids excess fat storage, like foods made of millet. This theory helps to balance metabolism and prevent

overeating, which is why this study found effective outcomes. This diet contained most of the plant-based food. A meta-analysis of six randomized controlled trials (N = 255) found that plant diets were associated with a 0.4% larger drop in glycated hemoglobin (HbA1c) than other suggested dietary patterns for diabetic people[159]. Review on benefits of yogasana's reveal that, ten minutes of yoga intervention combined with standard medical care for 10 minutes helped to improve metabolic health significantly.

- **Safety profile**
  - Both the group showed favorable safety outcomes
  - Both the group exhibited no major adverse events throughout the study

This integrated protocol demonstrated a synergistic effect, highlighting the possibility of combining these modalities into effective prediabetes management strategies.

- **Discussion on other comparable studies**

  - Two randomized controlled trials (RCTs) have identified three phases of yoga: Asanas, Pranayama, and meditation. However, specific details regarding yoga postures, styles (e.g., Vinyasa, Ashtanga, Iyengar, Kripalu, Kundalini), the intensity and duration of individual asanas or postures, and the type and duration of meditation were not comprehensively reported.[136]
  - Out of the 54 studies reviewed in the systematic analysis, 47 were included in the meta-analysis (n=26,460, average age=53 years, 46% male, 31% White). The research encompassed 27 lifestyle modification interventions, 25 medication-based treatments, 5 dietary supplement interventions, and 10 Chinese medicine approaches. The evidence was particularly robust for lifestyle modification interventions.[137]
  - Nineteen studies focused on evaluating one or more medications, another nineteen examined lifestyle modifications (LSMs), and five explored both medications and LSMs together.[138]

- Sixteen studies involved populations with an average age of 45 years or younger. Twenty-eight studies included participants with pre-diabetes or metabolic syndrome, while 46 studies involved individuals with type 2 diabetes (T2DM) who were not on oral glycemic medications.[139]

6. CONCLUSION

- This study shows that Trial intervention had significant effect on Prediabetes.
- The comparison between groups revealed that the Integrated Ayurveda Management protocol led to significantly greater improvements in HbA1c, FBS, PPBS, fasting insulin, and HOMA-IR compared to standard care.
- The within-group assessment indicated that the Ayurveda management protocol group demonstrated significant improvements in HbA1c, FBS, PPBS, fasting insulin, HOMA-IR, lipid profile (HDL, LDL), anthropometric parameters (waist circumference), BMI and Diabetes Quality of Life (DQOL).
- The safety parameters (RFT and LFT) remained within normal limits both pre- and post-treatment, and no adverse events were reported throughout the study.
- Study showed that integrative treatments combining Ayurvedic medicine, diet, and Yoga had significant improvement in prediabetes compared to standard care.

5. SUMMARY

The dissertation entitled "Efficacy of Integrated Ayurveda Management Protocol in Prediabetes - A Randomized Controlled Clinical Trial" comprises of following:

Introduction: Pre-diabetes is a metabolic disorder marked by higher-than-normal blood glucose levels, though not high enough to be classified as Type 2 Diabetes Mellitus (T2DM). Early intervention is essential, as factors like insulin resistance, unhealthy eating patterns, and genetic susceptibility play significant roles in its advancement. Management typically involves lifestyle modifications and pharmacological treatments like metformin. Ayurveda and Yoga present holistic alternatives for managing pre-diabetes, though further research is required to substantiate their efficacy. Addressing pre-diabetes is essential to mitigate the risk of severe health complications.

Objective: The thesis examines the effectiveness of an Integrated Ayurveda Management Protocol for prediabetes, incorporating Ayurveda formulations, dietary guidelines, and yogic practices over 90 days. It aims to evaluate the protocol's impact on glycemic control, biochemical parameters (HbA1c, lipid profile, fasting insulin, HOMA-IR), and quality of life using the Diabetes Quality of Life (DQoL) scale. A comparison is made between this protocol and the standard treatment regimen. The study hypothesizes that the Ayurveda-based approach has a significant role in managing prediabetes, contrasting with the null hypothesis asserting no effect. The findings aim to provide evidence for Ayurveda's role in prediabetes care.

Review of Literature: The review of literature explains prediabetes as a metabolic disorder with elevated blood glucose levels, often linked to insulin resistance and

beta-cell dysfunction. It highlights the role of Ayurveda's *purvarupa* symptoms for early detection and identifies lifestyle, dietary, and genetic factors as primary contributors. Management emphasizes integrative therapies, including dietary regulation, yoga, and Ayurvedic formulations, targeting biochemical parameters, insulin sensitivity, and quality of life. The comprehensive approach also incorporates yoga for improving glucose utilization and reducing stress, further validating its preventive role against progression to Type 2 diabetes. This holistic strategy underscores the thesis' aim of demonstrating the efficacy of Integrated Ayurveda Management in addressing prediabetes effectively.

Materials and Methods: The work investigates the efficacy of an Integrated Ayurveda Management Protocol for prediabetes through a randomized controlled clinical trial. It involves the preparation of a polyherbal formulation, *Madhumehahari Kashaya*, composed of traditional Ayurvedic ingredients and assessed for safety and efficacy. The clinical study, conducted with 180 participants, evaluates glycemic control, lipid profiles, insulin resistance (HOMA-IR), and quality of life over 90 days. The intervention group received Ayurvedic formulations, yoga, and a tailored Ayurvedic diet, while the control group received standard lifestyle management. The study follows Good Clinical Practice guidelines and aims to establish Ayurveda's potential in mitigating the progression of prediabetes.

Observation: Demographic variables such as Age, gender, religion, education, occupation, socioeconomic status, marital status, weight, BMI, waist circumference, glycemic parameters, including fasting blood sugar (FBS), postprandial blood sugar (PPBS), and HbA1c; HOMA-IR; DQoL; Lipid profile variables were compared between the two groups.

Results: The study observed that the Integrated Ayurveda Management Protocol significantly reduced weight, BMI, and waist circumference across all time points. Notable improvements were seen in glycemic parameters, including fasting blood sugar (FBS), postprandial blood sugar (PPBS), and HbA1c, particularly in the treatment group compared to the control group. Insulin sensitivity, as measured by fasting insulin levels and HOMA-IR, also improved more significantly in the treatment group. Additionally, lipid profiles, including total cholesterol, LDL, and triglycerides, showed favorable changes, with reductions being more pronounced in the treatment group.

Discussion: The randomized controlled clinical trial aimed to evaluate the efficacy of an integrated Ayurveda management protocol for prediabetes. Participants were divided into two groups: one received standard care involving nutrition and lifestyle counseling, while the other followed an Ayurveda-based regimen, including a polyherbal formulation, dietary guidelines, and yoga. Results showed significant improvements in key metrics like BMI, blood glucose levels (FBS, PPBS, HbA1c), insulin sensitivity, and lipid profiles in the Ayurveda group. The study highlighted the therapeutic roles of Ayurveda interventions like *Madhumehahari Kashaya*, dietary modifications, and yoga in enhancing quality of life, glycemic outcomes, and metabolic health. Safety evaluations confirmed the interventions were well-tolerated without adverse effects.

Conclusion: Integrated *Ayurveda* treatment protocol proved effective in the management of Prediabetes.

6.1. STRENGTH OF STUDY

- The study follows a rigorous randomized controlled trial (RCT) design, ensuring reliability and minimizing bias in the results.
- The combination of yoga, diet, and Ayurveda provides synergistic effects, addressing multiple facets of prediabetes, including glycemic control, stress reduction, and overall quality of life.
- Evaluates a wide range of parameters, including HbA1c, FBS, PPBS, HOMA-IR, lipid profiles, BMI, waist circumference, and quality of life, offering a detailed assessment of the intervention's efficacy.

6.2. LIMITATION OF STUDY

- The study primarily examined clinical outcomes (e.g., HbA1c, FBS, HOMA-IR) but lacked molecular-level insights into the mechanisms by which interventions influence insulin signaling pathways at the genetic and epigenetic levels.
- The study's focus on Indian traditional practices (Ayurveda and yoga) may restrict its generalizability to other settings.

6.3. RECOMMENDATIONS FOR FURTHER STUDY

- Extend the study duration to evaluate the sustainability of glycemic control, progression to diabetes, and long-term metabolic benefits of the integrative protocol.
- The integrative management protocol, which combines conventional medications, Ayurvedic drugs, Ayurveda diet, and yoga, necessitates further research to elucidate drug-to-drug and drug-to-food interactions associated with multimodal treatments.

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8. ANNEXURES

ANNEXURE I: ETHICAL CLEARANCE AND CTRI REGISTRATION

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Formerly known as KLE University)
(Deemed-to-be-University established u/s 3 of the UGC Act, 1956)
Accredited '**A**' **Grade** by NAAC (2nd Cycle) Placed in **Category** 'A' by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India
☎: 0831-2444444 FAX: 0831-2493777 Web: http://www.kledeemeduniversity.edu.in E-mail: info@kledeemeduniversity.edu.in

Ref.No.KAHER/EC/21-22/ 01 2 29th July 2021

To,
Dr Keertan M S
Part-Time Ph.D. Research Scholar,
2020-21Batch, Faculty of Ayurveda,
KAHER, Belagavi.

Dear Research Scholar,

The KAHER Ethics Committee on Human Subjects for Ph.D. Research Project met on **the 7th and 8th June, 2021** to consider your application for approval of the research project **"Efficacy of Integrated Ayurveda management protocol in prediabetes-A randomized controlled clinical trial"**

As there are no ethical issues involved in your proposed research project, the committee has provided approval for this research project.

You are requested to report to Ethical Committee of the following:

1. Any deviation from or change of the protocol.
2. Any changes in study documents.

(Dr. Sheetal U. Harakuni)
Member-Secretary
Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.

(Dr. B.C. Kotintot)
Chairman
Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.

CC to:

- Special Officer to Hon. Vice Chancellor, KAHER, Belagavi
- The Registrar, KAHER, Belagavi.
- The Director Research Foundation, KAHER, Belagavi.
- The Director Academic Affairs, KAHER, Belagavi.

CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics

PDF of Trial
CTRI Website URL - http://ctri.nic.in

Clinical Trial Details (PDF Generation Date :- Wed, 15 Jun 2022 05:30:23 GMT)

CTRI Number	CTRI/2022/01/039395 [Registered on: 13/01/2022] - **Trial Registered Prospectively**
Last Modified On	11/01/2022
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Ayurveda Yoga & Naturopathy
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Ayurvedic approach to Prediabetes
Scientific Title of Study	"Efficacy of Integrated Ayurveda Management Protocol in Prediabetes - A Randomized Controlled Clinical Trial"

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Keertan M S
Designation	Associate Professor
Affiliation	KAHER Belagavi
Address	KAHER Shri BMKankanwadi Ayurveda Mahavidyalaya Shahapur, Belagavi JNMC Campus Nehru Nagar Belagavi Karnataka 590010 Belgaum KARNATAKA 590003 India
Phone	9886238888
Fax	
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Basavaraj Tubaki
Designation	Professor
Affiliation	KAHER Belagavi
Address	KAHER Shri B M Kankanwadi Ayurveda Mahavidyalaya Shahapur, Belagavi JNMC Campus Nehru Nagar Belagavi Karnataka 590010 Belgaum KARNATAKA 590003 India
Phone	9448634660
Fax	
Email	ayurbasavaraj@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Keertan M S
Designation	Associate Professor
Affiliation	KAHER Belagavi
Address	KAHER Shri BMKankanwadi Ayurveda Mahavidyalaya Shahapur, Belagavi JNMC Campus Nehru Nagar Belagavi Karnataka 590010 Belgaum KARNATAKA 590003 India

ANNEXURE II: STUDY DRUG AUTHENTICATION

SHRI B.M.K. AYURVEDA MAHAVIDYALAYA

A constituent unit of KLE Academy of Higher Education & Research

Deemed-to-be-University

Central Research Facility

DRUG AUTHENTICATION REPORT

Submitted by: D. Keertan M.S.

Submitted date: 16/12/2021

Date of Issue: 20/12/2021

S.N.	Sample Name	Scientific Name	Family	Part submitted	CRF Code	Authenticated as			
						Ayurvedic Name	Scientific Name	Family	Part Authenticated
1.	Guduchi	*Tinospora cordifolia* Linn.	Menispermaceae	Stem	CRF/Auth 98/2021	Guduchi	*Tinospora cordifolia* Linn.	Menispermaceae	Stem
2.	Haridra	*Curcuma longa* Linn.	Zingiberaceae	Rhizome	CRF/Auth 99/2021	Haridra	*Curcuma longa* Linn.	Zingiberaceae	Rhizome
3.	Vibheetaki	*Terminalia belerica* Roxb.	Combretaceae	Fruit	CRF/Auth 100/2021	Vibheetaki	*Terminalia belerica* Roxb.	Combretaceae	Fruit
4.	Amalaki	*Phyllanthus emblica* Linn.	Euphorbiaceae	Fruit	CRF/Auth 101/2021	Amalaki	*Phyllanthus emblica* Linn.	Euphorbiaceae	Fruit
5.	Vijayasara	*Pterocarpus marsupium* Roxb.	Fabaceae	Stem	CRF/Auth 102/2021	Vijayasara	*Pterocarpus marsupium* Roxb.	Fabaceae	Stem
6.	Jambu	*Eugenia jambolana* Lam	Myrtaceae	Seeds	CRF/Auth 103/2021	Jambu	*Eugenia jambolana* Lam	Myrtaceae	Seeds
7.	Hareetaki	*Terminalia chebula* Retz.	Combretaceae	Fruit	CRF/Auth 104/2021	Hareetaki	*Terminalia chebula* Retz.	Combretaceae	Fruit
8.	Tamalpatra	*Cinnamomum tamala* Nees.	Lauraceae	Leave	CRF/Auth 105/2021	Tamalpatra	*Cinnamomum tamala* Nees.	Lauraceae	Leave
9.	Daruharidra	*Berberis aristata* DC	Berberidaceae	Stem	CRF/Auth 106/2021	Daruharidra	*Berberis aristata* DC	Berberidaceae	Stem

Signature:
Authentication Expert Name: Dr. Ajit Lingayat
Date:20 /12/2021

CRF SHAHAPUR, BELGAUM

Signature of Coordinator
ASU Drug Testing Laboratory

ANNEXURE III: CASE REPORT FORM

STUDY TITLE

"Efficacy of Integrated Ayurveda Management Protocol in Prediabetes - A Randomized Controlled Clinical Trial"

PATIENT INFORMATION SHEET

1. Invitation

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve; please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. You should not sign this form until you understand all of the information presented in the following pages and until all of your questions about the research have been answered to your satisfaction.

2. What is the purpose of the study?

This is a research study being conducted by KLE University's Ayurveda hospital, involving administration of integrated Ayurveda management which includes Ayurvedic polyherbal medication, Ayurveda Diet and Yogic intervention in management of Prediabetes.

3. Why have I been chosen?

Being a patient of Prediabetes with HbA1c (5.7 to 6.4%) you are considered as an ideal candidate for the study.

4. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form later. If you agree to take part you are still free to withdraw at any time and without giving any reason. This will not affect the standard of care you receive.

5. What will happen to me if I take part?

If you agree to take part in this study, you will receive the Standard Prediabetic care (include Nutritional and lifestyle management counseling) in one group and Integrated Ayurveda Protocol (include Ayurveda formulation, Ayurveda Dietary and Yoga intervention) in another group. The formulation you will receive will be based on a computer based randomization and will be just by chance. All the participants of the trial therefore will belong to either of the group. If you give your consent to continue in the study, you have to undergo general physical examination and laboratory investigations from time to time for the assessment of the effect of the treatment protocol you would be taking at that time. In the first visit, i.e. on baseline (day 0) you may have to devote approximately 2 hours to facilitate your investigating physician in recording your medical history in detail. Thereafter, in the subsequent visits it may take nearly 15 – 20 minutes to make the assessment.

6. What do I have to do?

You have to adhere to the instructions given to you by your investigating physician regarding taking the medicines as advised and reporting for follow up on the prescribed day. During the course of the trial you can safely continue with your regular medication (for which you need to intimate your investigating physician) and the only word of caution is that you should follow and obey the instructions of your investigator very religiously while continuing with the trial drugs.

7. What is the drug or procedure that is being tested?

The patient selected in the clinical trial will receive on random the following:

Group 1: Madhumehahari kashaya 35ml twice a day after food, Ayurveda Dietary and Yoga Intervention

Group 2: Standard Prediabetic care (include Nutritional and lifestyle management counseling)

8. What are the alternatives for diagnosis or treatment?

There are other treatment options available in all recognized systems of medicines.

9. What are the expected side effects / risks of the treatment?

The ingredients of the Ayurvedic formulation are in use for a long time, yet individual specific side effects may appear such as gastrointestinal disturbances at any time during the course of the clinical trial, which you are to report immediately to your investigating physician.

10. What are the possible benefits of taking part?

Your participation will help us in generating sufficient data to validate the efficacy and safety of these therapies in managing/treating Prediabetes.

11. What if new information becomes available?

If during the course of the clinical trial some new information becomes available about the Ayurvedic management being studied, you will be informed about that by your investigating physician after which you are free to decide whether you want to continue in the study or not. If you decide to withdraw, this will not at all affect your routine care in the hospital. If you decide to continue in the study, you will be asked to sign a fresh consent form. On the other hand upon receiving new information your

investigating physician might consider it to be in your best interests to withdraw you from the study. Your investigating physician will explain the reasons for dropping you from the study and arrange for your routine care to continue.

12. What happens when the research study stops?

You will be given appropriate advice for future line of treatment.

13. What if something goes wrong?

Compensation for any adverse effect caused by taking part in this study and related to study would be taken care by appropriate treatment or referrals. Contact address of the Researcher: Dr. Keertan M S, KAHER's Shri BMK Ayurveda Mahavidyalaya,Shahapur, Belagavi, Karnataka-590003; Mob: +91- 9886238888, Fax: +91 831 2424157; Email: keertanms@gmail.com; ayurbasavaraj@gmail.com

14. Will my taking part in this study be kept confidential?

Yes, all your information will be kept confidential .Your name will not be made public and any sensitive matter regarding your state of health will be kept confidential.

15. What will happen to the results of the research study?

The results of the clinical trial will be published in leading medical journals so that other doctors and researchers can benefit from the results. You can ask your investigating physician for a copy of the publication. If published, your identity and personal details will be kept strictly confidential. No named information about you will be published in any of the trial reports.

16. Who is organizing and funding the research?

No organising or funding agency for this study.

17. Contact for further information

If desirous of any relevant information at any stage of the clinical trial, you may feel free to ask your investigating physician for that information. You would be given a copy of the information sheet and a signed consent form.

Researcher

Dr. Keertan M S, MD (Roga Nidana), Reader, Dept of Roga Nidana, KAHER's Shri BMK Ayurveda Mahavidyalaya, Shahapur, Belgavi, Karnataka-590003; Mob - +919886238888 Email: keertanms@gmail.com

Research Guide

Dr. Basavaraj R Tubaki MD (Kayachikitsa) PhD (NIMHANS), Vaidya Scientist Fellow, Professor & Head, Dept of Kayachikitsa, KAHER's Shri BMK Ayurveda Mahavidyalaya Shahapur, Belgavi, Karnataka-590003; Tel: +91 831 2486286; Mob- +919448634660; 9035486286; Email: ayurbasavaraj@gmail.com;

Consent Form - to be signed on the day of Screening

Center Name:-KAHER's Shri B M K Ayurveda Mahavidyalaya & Hospital. Shahapur, Belagavi, Karnataka-590003

I certify that I have disclosed all details about the study in the terms easily understood by the subject.

Date: _____

Signature of the researcher: _____

Name: _____

CONSENT BY PARTICIPANT

1. I confirm that I have read / the study has been explained to me adequately and I have understood the information sheet for the above study and had the opportunity to ask questions.

2. I hope to complete the study, but I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, and without my medical care or legal rights being affected.

3. I understand that my doctor will provide information about my progress, in confidence, to the related guide of this research. I understand that the information held by the researchers, guide and records maintained for this research might be used to follow up my health status.

4. I understand that the information will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. I understand that sections of any of my medical notes may be looked at by the Sponsors or responsible individuals from the members of the Institutional Ethics Committee (IEC), Regulatory authorities or Court, if necessary. I give permission for these individuals to have access to my records.

5. I understand what is involved in this trial and agree to take part in the clinical trial for a period of 12 weeks.

Date……

Address: **Name of the Participant ……..…**

Signature or thumb impression…… **Contact details: ……..…**

Date ……

Name of the witness ……... **Signature or thumb impression……**

DRUG COMPLIANCE REPORT FORM- 2

(To be filled by the trial participant)

[To be issued on Enrollment Day **and taken back in the next visit]**

Participant Enrollment No: _____

Please come for next visit on_____ (Date & time to be filled by the Investigator)

Day	**Date**	**Trial drug**			**Any other information**
		Morning dose	**Afternoon dose**	**Evening dose**	
		Please put √	**Please put √ mark**	**Please put √ mark**	
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Signature/ Thumb impression of Participant with date: _____

Signature of the Investigator with date:_____

DRUG COMPLIANCE REPORT FORM- 2

(To be filled by the trial participant)

[To be issued on Enrollment Day **and taken back in the next visit]**

Participant Enrollment No: _____

Please come for next visit on_____ (Date & time to be filled by the Investigator)

Day	**Date**	**Trial drug**			**Any other information**
		Morning dose	**Afternoon dose**	**Evening dose**	
		Please put √	**Please put √ mark**	**Please put √ mark**	
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Signature/ Thumb impression of Participant with date: _____

Signature of the Investigator with date:_____

DRUG COMPLIANCE REPORT FORM- 3

(To be filled by the trial participant)

[To be issued on Enrollment Day **and taken back in the next visit]**

Participant Enrollment No: _____

Please come for next visit on_____ (Date & time to be filled by the Investigator)

Day	**Date**	**Trial drug**			**Any other information**
		Morning dose	**Afternoon dose**	**Evening dose**	
		Please put √	**Please put √ mark**	**Please put √ mark**	
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Signature/ Thumb impression of Participant with date: _____

Signature of the Investigator with date:_____

ANNEXURE IV: PHD PROGRESS REPORT

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Formerly known as KLE University)
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Ref. No. KAHER/AA/24-25/D-452 23/9/2024

Ph.D. PROGRAM

Evaluation of Six Monthly Reports submitted by the Candidate

Name of the Ph. D Scholar:	Dr. Keertan M S
Name of the Guide:	Dr. Basavaraj R Tubaki
Batch / Faculty/Category	2020-21 / Ayurveda/Part-time
Registration No.:	DO1220025

Topic: Efficacy of Integrated Ayurveda management protocol in prediabetes-A randomized controlled clinical trial.

Report	Excellent	Good	Satisfactory	Poor
I			✓	
II			✓	
III			✓	
IV			✓	
V			✓	
VI			✓	
VII			✓	
VIII			✓	

DIRECTOR ACADEMIC AFFAIRS

(Dr. Jyoti M Nagamoti)
Director, Academic Affairs

Ce to :
Dr. Basavaraj R Tubaki, Prof. of Kayachikitsa , KLE Shri. BMK Ayurveda Mahavidyalaya, Belagavi-Guide

NB: Research scholars are hereby informed in future to strictly enclose the source of documents to review half yearly reports

ANNEXURE V: PUBLICATION

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

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GALLERY

INTEGRATED AYURVEDIC MANAGEMENT PROTOCOL IN GLYCEMIC CONTROL PARAMETERS IN PREDIABETES - A RANDOMIZED CONTROLLED CLINICAL STUDY

Authors: Kiertar MS, TUBAKI BR* AND SHETE H

ABSTRACT

Background: Prediabetes, characterized by elevated blood glucose levels and a risk of progressing to diabetes, is linked to various health problems and worsened by sedentary lifestyles and poor diet. This study assesses the effectiveness of an integrated Ayurvedic approach, including herbal remedies, diet, and Yoga, in managing glycemic control and enhancing quality of life compared to standard treatments over a 90-day period. Objective: To evaluate the efficacy of the Integrated Ayurvedic Management Protocol in participants with prediabetes. Materials and Methods: The study involved 180 prediabetic patients (HbA1c levels between 5.7% and 6.4%). The control group (Group A) received standard prediabetes care, while the treatment group (Group B) followed an integrated Ayurvedic protocol that included Madhumehahari Kashaya, a personalized diet, and a 30-minute daily Yoga regimen. Fasting blood sugar (FBS), post-prandial blood sugar (PPBS), and quality of life (QOL) were

African Journal of Biomedical Research

CURRENT ARCHIVES INDEXING & ARCHIVING ANNOUNCEMENTS ABOUT *

Vol. 27 No. 3S (2024)

Efficacy Of Madhumehari Kashaya In The Management Of Prediabetes – A Pilot Study

RESEARCH ARTICLE

Published 2024-10-18

Dr Keertan N S*, Dr B R Tabaki*, Dr Hemlata Shete*

Abstract

Background:

The condition known as prediabetes exists before diabetes mellitus is identified. The alarmingly high incidence of type 2 diabetes mellitus (DM) is putting a strain on global health care systems. Adults with prediabetes frequently have blood sugar levels that are higher than usual but do not exhibit any of the symptoms or indicators of diabetes. Globally, prediabetes is becoming more common, and by 2030, over 470 million individuals are expected to have prediabetes. As a result, there is a growing interest worldwide in finding safe and efficient treatments to stop the development of prediabetes into diabetes.

African Journal of Biomedical Research

CURRENT ARCHIVES INDEXING & ARCHIVING ANNOUNCEMENTS ABOUT

Vol. 27 No. 1S (2024)

"A Hidden Encounter: Development of malignancy in benign Fistula in Ano - A Cautionary Tale for Colorectal Surgeons"

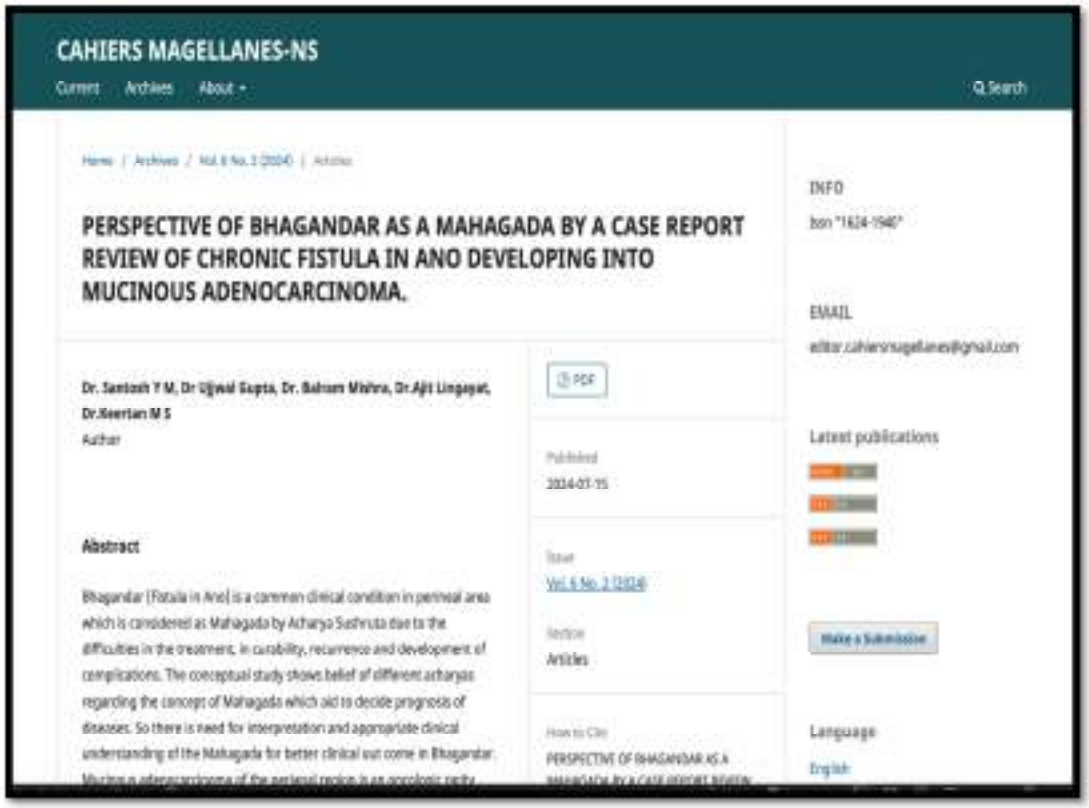
RESEARCH ARTICLE

Published 2024-09-16

Dr. Santosh Y.M*, Dr. UjjwalGupta*, Dr. Bahram Mishra*, Dr. Ajit Lingayat*, Dr. Keerlan M S*

Abstract

Perianal fistula is a common clinical condition encountered in day today surgical practice usually present as benign pathology.However, this case report highlights an oncologic rarity but significant complication: the development of mucinous adenocarcinoma within a fistulous tract, which accounts for 2% to 3% of all gastrointestinal malignancies posing a diagnostic and therapeutic challenge. This case report details 53 year old male patient with a history of anal fistula for 10 years with multiple surgical interventions in the past and earlier diagnosis was questioned due to the recurrence and typical presentation. Later on



CAHIERS MAGELLANES-NS

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PERSPECTIVE OF BHAGANDAR AS A MAHAGADA BY A CASE REPORT REVIEW OF CHRONIC FISTULA IN ANO DEVELOPING INTO MUCINOUS ADENOCARCINOMA.

Dr. Santosh Y M, Dr Ujjwal Gupta, Dr. Bahram Mishra, Dr.Ajit Lingayat, Dr.Keerlan M S
Author

PDF

Published
2024-07-15

Issue
Vol. 6 No. 2 (2024)

Section
Articles

How to Cite
PERSPECTIVE OF BHAGANDAR AS A MAHAGADA BY A CASE REPORT REVIEW

Abstract

Bhagandar (Fistula in Ano) is a common clinical condition in perineal area which is considered as Mahagada by Acharya Sushruta due to the difficulties in the treatment, in curability, recurrence and development of complications. The conceptual study shows belief of different acharyas regarding the concept of Mahagada which aid to decide prognosis of diseases. So there is need for interpretation and appropriate clinical understanding of the Mahagada for better clinical out come in Bhagandar. Mucinous adenocarcinoma of the perianal region is an oncologic rarity

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Afr. J. Biomed. Res. Vol. 27(3s) (October 2024); 3344 - 3349
Research Article

Efficacy Of Madhumehari Kashaya In The Management Of Prediabetes – A Pilot Study

Dr Keertan M S[1], Dr B R Tubaki[2*], Dr Hemlata Shete[3]

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Department(s) and institution(s): Department of Shalya Tantra

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Abstract
Background:
The condition known as prediabetes exists before diabetes mellitus is identified. The alarmingly high incidence of type 2 diabetes mellitus (DM) is putting a strain on global health care systems. Adults with prediabetes frequently have blood sugar levels that are higher than usual but do not exhibit any of the symptoms or indicators of diabetes. Globally, prediabetes is becoming more common, and by 2030, over 470 million individuals are expected to have prediabetes. As a result, there is a growing interest worldwide in finding safe and efficient treatments to stop the development of prediabetes into diabetes.
Objective: To evaluate the efficacy of *Madhumehahari Kashaya (MK)* in the management of Prediabetes.
Materials and method: Forty individuals with a HbA1c of 5.7% to 6.4% who were diagnosed with prediabetes and met all inclusion and exclusion criteria were enlisted. For ninety days, the patients were given the *Ayurvedic* polyherbal formulation *Madhumehahari Kashaya* 35ml twice a day after meals with lukewarm water as treatment. Assessments of the lipid profile (TC, LDL, HDL, and Triglycerides) and FBS, PPBS, HbA1C, and 90 days after enrollment were conducted. The student's 't' test was used to evaluate the results of the statistical study.
Results: Significant results ($p<0.05$) were observed in all the assessed parameters at various time points.
Conclusion: *Madhumehahari Kashaya* showed good results in the current study. Several randomised clinical studies in this area are required to produce evidence-based findings.

Keywords - *Madhumehahari Kashaya,* Prediabetes*, Ayurveda,* Polyherbal formulation.

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provided that the following statement is provided. "This article has been published in the African Journal of Biomedical Research"

1. Introduction

Prediabetes is a multifaceted metabolic condition that is complex and involves factors other than glucose regulation. By 2030, 470 million people are expected to have prediabetes. The National Urban Diabetes Survey estimates that 14% of Indians have prediabetes, with a greater prevalence in rural areas (7.9%)[1]. A toxic killer and risk factor for metabolic and cardiovascular disorders, pre-diabetes is asymptomatic[2]. No medication has received FDA approval in the United States to be used exclusively to treat prediabetes[2]. The current approach to treating prediabetes is lifestyle modification (exercise, weight loss)[3]. Research has indicated that there is an increased probability of prediabetes developing into type 2 diabetes mellitus[3].

Prompt intervention at the prediabetic stage can aid in delaying or halting the development of diabetes. Metformin, lifestyle modification, and other medications including orlistat, acarbose, and pioglitazone have all been studied on prediabetic persons to prevent the development of diabetes [4,5,6]. The main obstacles to the long-term sustainability of these therapies, however, have reportedly been identified include medication side effects and continuing LSM [4,5,6]. The hunt for safe and effective treatments to stop the progression of prediabetes to diabetes is therefore becoming more and more popular worldwide, and we think Ayurveda can offer such treatments[7]. Herbal Ayurvedic medications such as *Jambu, Madhunashini, Triphala, Vijayasara, Tamala Patra, Daruharidra, Haridra*, and *Guduchi* have been shown to improve insulin sensitivity, have antihyperglycemic and antihyperlipidemic effects, and have antioxidant qualities, among other benefits, in people with type 2 diabetes [8,9]. MK is polyherbal preparation containing above ingredients useful in the control of sugar levels. In order to determine whether *MK* for prediabetes can lessen the transition from prediabetes to type 2 diabetes mellitus, this study was conducted.

2. Objective of the trial:

To evaluate the efficacy of *MK* in the management of Prediabetes

3. Material and methods

The patients who met all inclusion and exclusion criteria and had prediabetes (HbA1c - 5.7–6.4%) were enrolled. The planned study included patients who saw our hospital's OPD and IPD, and prior to patient recruitment, written informed consent was acquired. The Institutional Ethics Committee KAHER BMK Ayurveda Mahavidyalaya, Belagavi accepted the research. The period of data collecting was June 2022–December 2022. Throughout the trial time, the participants were systemically recorded and monitored for any adverse events.

3.1 Sample size

Thirty participants with prediabetes (HbA1c 5.7–6.4%) were enrolled in the study. 40 patients were considered sufficient for drawing conclusions because it was a pilot study; the sample size was determined without the use of any particular statistical methods.

3.2 **Inclusion criteria**

Subjects with Pre-diabetic with HbA1c of 5.7-6.4%, FBS <126mg/dl, either sex and age between 18 and 70 years were included in the study.

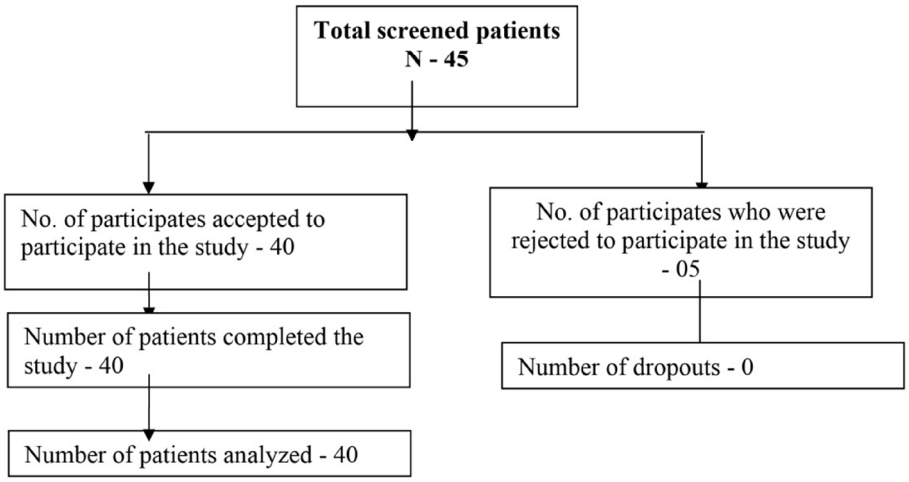
3.3. Exclusion criteria

Individuals having a history of gestational diabetes, known cases of type I and type II diabetes, Uncontrolled hypertensive individuals (140/90 mmHg or above, with or without treatment), Women who are expecting or nursing, those who abuse drugs or alcohol, The study excluded participants with serious systemic illnesses such as rheumatoid arthritis, psycho-neuroendocrine disorders, stroke, and coronary artery disease who required long-term medication treatment.

3.4. Screening method

According to the inclusion and exclusion criteria, patients with prediabetes (HbA1c - 5.7 -6.4%) were screened. Patients who met the study's requirements were enrolled and depicted as a consort chart (Fig. 1).

CONSORT CHART



3.5. Study design: A single-group, open-label clinical trial with a pre- and post-test design.

3.6. **Intervention**: Patients who met inclusion, diagnostic, or non-exclusion criteria and gave their assent to the trial were recruited following clinical screening. Prior to obtaining their informed consent, patients were made aware of the study's objectives and design. The Ayurvedic polyherbal formulation *Madhumehahari Kashaya* 35ml was used to treat each of the patients who were included. For ninety days, take a double daily dose of lukewarm water after meals. The MK ingredients were procured from KLE Ayurveda Pharmacy, Belagavi, which holds GMP certification. Belagavi's Central Research Facility, KAHER's Shri B M K Ayurveda Mahavidyalaya, handled the identification and authentication of drugs. The Kashaya preparation (Table no.1) and packing was done at KLE Ayurveda Pharmacy. A systematic recording and appropriate statistical techniques were used to analyse the data.

Table 1: Ingredients of *Madhumehahari Kashaya*

Sl. No	Drug	Latin name	Part
1.	*Vijaya sara*	*Pterocarpus marsupium*	Heart wood
2.	*Jambu*	*Syzygium cumini*	Seeds
3.	*Amalaki*	*Emblica Officiale*	Fruit
4.	*Hareetaki*	*Terminalia Chebula*	Fruit
5.	*Vibheetaki*	*Terminalia Bellirica*	Fruit
6.	*Haridra*	*Curcuma longa*	Rhizome
7.	*Guduchi*	*Tinospora cardifolia*	Stem
8.	*Tamala Patra*	*Cinnamom tamala*	Leave
9.	*Daruharidra*	*Berberis aristata*	Rhizome
10.	*Madhunashini*	*Gymnema Sylvestre*	Leaves

3.7 Criteria for Assessment of parameters

The parameters like FBS, PPBS, HbA1C, Lipid profile (Triglyceride, LDL, HDL, and TC) were assessed on baseline and 90th day.

3.8 Statistical methods

The student's test was used to compare the changes in the various parameters, such as FBS, PPBS, HbA1c, etc., from the baseline to the ninetieth day. At $p<0.05$, all tests were deemed statistically significant, and values were presented as mean + standard deviation.

Results: There were no dropouts in the 40 individuals who finished the research. Throughout the study, no adverse events occurred.

Subject characteristics

Table No.2 Demographic data of the recruited patients.

Sl No.	Parameters				
1)	Gender	Male	Female		Total
		26	14		40
2)	Religion	Hindu	Muslim	Others	
		34	03	03	40
3)	Educational Status	Illiterate	Graduate		
		11	29		40
4)	Occupation	Unemployed	Employed		
		09	31		40
5)	Socioeconomic Status	Upper	Middle	Lower	
		12	17	11	40
6)	Habitat	Rural	Urban		
		13	27		40
7)	Marital Status	Married	Unmarried		
		36	04		40

Table no. 3 Assessment of the various parameters from Baseline to 90th day.

Sl no.	Parameters	Mean		Variance		T value	P value
		Day 0	Day 90	Day 0	Day 90	2.110	0.014
1)	HbA1c	8.01	5.60	159.62	71.779		
2)	FBS	94.000	89.200	159.538	53.241	2.874	0.003
3)	PPBS	117.65	109.62	140.285	61.779	6.110	0.000
4)	Total Cholesterol	154.02	140.72	1560.58	241.43	2.860	0.003
5)	HDL-Cholesterol	43.475	42.975	11.179	11.769	1.314	0.098
6)	LDL-Cholesterol	81.425	76.075	1327.43	305.66	1.206	0.117
7)	Triglycerides	132.80	123.82	927.190	486.91	3.241	0.001
8)	VLDL	24.990	23.143	75.196	52.211	3.344	0.001
9)	Total Cholesterol/ HDL Ratio	3.665	3.400	2.970	2.625	2.836	0.004
10)	Serum Creatinine	1.078	0.893	0.622	0.007	1.517	0.069

DISCUSSION

India has a significant number of prediabetic individuals, and these high-risk subjects are increasingly turning into diabetics at a rapid rate[9]. Due to improper eating habits, a decrease in physical exercise, and elevated stress levels brought on by urbanization (Table no.2) and modernization, people are overweight and have greater levels of insulin resistance[10]. Due to comparable etiological elements, prediabetes can be linked to *Kaphaja prameha*, which is described in the context of *Prameha* in Ayurvedic classics[11]. *Acharya Charaka* has underlined that because vitiated *Kleda, Meda*, and *Kapha* are involved, the individual suffering from *Kaphaja Prameha* should have *Apatarpana Chikitsa* (depletion therapy). Patients with *Prameha* typically have decreased digestive activity and an excess buildup of *Kleda*, *Meda*, and *Mutra*[11]. Therefore, it is recommended to use *Ameda*, *Amutrala*, and *Vahni Dipana Aushadha* in order to increase *Tejo dhathu* and decrease *Kleda* and *Meda*[11].

MK is a combination of nine medications that has been shown to regulate blood sugar levels (Table no.3). Apart from glucose regulation, *Pterocarpus marsupium* (Asana) can regulate metabolic changes associated with diabetes[12]. Its decreased absorption of glucose from the gastrointestinal system may be the cause of its hypoglycemic impact[13]. According to a clinical trial, using P. marsupium extract orally can have strong hypoglycemic effects (during and after meals) that are similar to those of tolbutamide[14]. The favourable pharmacological effect of *Syzygium cumini* (Jambu) is established by the seeds' favoured hypoglycemic activity[15]. *Tinospora cordifolia* (*Guduchi*) exhibits hypoglycemic action, maybe through modifying the permeability of cell membranes to stimulate endogenous insulin release[16,17].

Triphala exhibits hypoglycemic action in the same proportions of *Terminalia chebula*, *Terminalia belerica*, and *Emblica officinalis*[18]. Additionally, *curcuma longa* root includes rutin, which is known for its antipruritic properties and may help people with hyperglycemia feel less itchy[19]. Its extra neuroprotective properties might be useful in treating other brain issues linked to diabetes. Similar to thiazolidinedione derivatives, curcuma longa

improves insulin resistance and mitigates type 2 diabetes by activating PPAR-γ[20]. For a very long time, the indigenous medical system has treated diabetes with *daruharidra*[21]. Barberin and isoquinoline, two chemical compounds with anti-fungal, antibacterial, anti-oxidant, anti-viral, anti-diabetic, and anti-inflammatory properties, are abundant in the root bark of this herb[21]. In male Wister albino rats, the plant extract (water) of *Cinnamomum Tamala* leaves shown anti-diabetic action[22]. The leaves of *G. sylvestre* have been shown in experimental animals to induce hypoglycemia, and they are used in herbal therapy to treat adult-onset diabetes mellitus[23]. According to this study, utilising a *MK* can help prevent type 2 diabetes mellitus from developing from pre-diabetes. It has been shown that using this MK to treat prediabetes is beneficial. Long term clinical study using this formulation would provide us with more evidence regarding the efficacy of this combination.

Conclusion –

Madhumehahari Kashaya, a polyherbal compound, has been shown to be a safe and effective way to control pre-diabetes by improving lipid profiles and blood glucose levels, which in turn reduces the risk of type 2 diabetes mellitus. Randomised clinical trials can be planned to compare the efficacy of the outcomes, and the current formulation can be used to carry out the study with a bigger sample size.

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Acknowledgement - NIL

Author statement

All the authors provided their contributions in treating the patients. Dr Keertan M S, involved in the collection of data. Dr Hemlata Shete has done the statistical analysis and interpretation of the data was done by all the authors. Manuscript drafting was done by Dr Keertan M S, and review, correction of manuscript was done by Dr B. R. Tubaki. Approval from all the authors was provided for the submitted manuscript.

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INTEGRATED AYURVEDIC MANAGEMENT PROTOCOL IN GLYCEMIC CONTROL PARAMETERS IN PREDIABETES - A RANDOMIZED CONTROLLED CLINICAL STUDY

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ABSTRACT

Background: Prediabetes, characterized by elevated blood glucose levels and a risk of progressing to diabetes, is linked to various health problems and worsened by sedentary lifestyles and poor diet. This study assesses the effectiveness of an integrated Ayurvedic approach, including herbal remedies, diet, and Yoga, in managing glycemic control and enhancing quality of life compared to standard treatments over a 90-day period. **Objective:** To evaluate the efficacy of the Integrated Ayurvedic Management Protocol in participants with prediabetes. **Materials and Methods:** The study involved 180 prediabetic patients (HbA1c levels between 5.7% and 6.4%). The control group (Group A) received standard prediabetes care, while the treatment group (Group B) followed an Integrated Ayurvedic protocol that included Madhumehahari Kashaya, a personalized diet, and a 30-minute daily Yoga regimen. Fasting blood sugar (FBS), post-prandial blood sugar (PPBS), and quality of life (DQol) were measured at baseline, and on days 30, 60, and 90, with HbA1c and fasting insulin assessed at baseline and day 90. **Results:** Both the Integrated Ayurvedic Management (IAM) protocol (HbA1c pre 6.11±0.31 and post 5.13±0.33) and the standard

prediabetes care (HbA1c pre 6.28±0.33 and post 5.8±0.26) effectively managed prediabetes. However, IAM showed significantly superior results in improving glycemic control compared to standard nutrition and lifestyle management alone. **Conclusion:** Although standard nutrition and lifestyle management was effective, the study's small sample size and short duration limit the applicability of the findings, highlighting the need for larger, long-term studies.

Keywords: Blood glucose level, HbA1c, Integrative management, Diet, Yoga

INTRODUCTION:

The American diabetes association defined "prediabetes" as a condition wherein the blood glucose level is above the normal level but below the threshold value of diabetes **[1]**. However, prediabetes is a complex multi factorial metabolic disorder that extends beyond glucose dysregulation. Once thought of as an innocuous condition, current studies have found that it is associated with various micro & macro vascular disorders, cognitive dysfunction, blood pressure changes, fatty liver disease, cancer and many more **[2]**.

Increase in sedentary lifestyle, consumption of calorie dense diet and less or no physical activity are the main reasons for this alarming rise in the prediabetic individuals **[3]**.

The ICMR-INDIAB survey estimated that the prevalence of prediabetes in India is 136 million which is much higher than the figures predicted in the earlier studies. Moreover, the progression of prediabetes to diabetes is also faster in Asian Indians because they tend to develop diabetes at lower levels of Obesity **[4]**.

Several studies conducted so far on Prediabetic individuals for prevention of progression to diabetes are use of metformin, lifestyle modification (LSM) and various other medicines. The reported major adverse reactions of the drugs and failure to maintain continuity in the lifestyle modifications posed a major challenge in the long-term sustainability of these treatment modalities **[5]**. Therefore there is an increasing interest towards safe and effective remedies for prevention of the progression of prediabetes to diabetes, which we believe an Integrative approach with Ayurvedic medication, diet and Yoga can provide.

Ayurveda herbal drugs like *Jambu* **[6]**, *Madhunashini, Triphala* **[7]**, *Vijayasara, Tamala* **[8]** *patra daruharidra, haridra* **[9]**, *guduchi* **[10]** have properties of increasing insulin sensitivity, anti hyperglycemic, anti hyper lipidemic, antioxidant properties etc. have beneficial effect in Type 2 DM. The above dugs have been combined in the ayurvedic formulation *Madhumehahari Kashaya* for effective glycemic control in

Diabetes mellitus. Ayurveda dietetics has shown to have a positive outcome in T2DM management **[11]**. Yoga, being lifestyle intervention, has been reported to be a successful complementary treatment for Type 2 DM **[12]**.

We have therefore designed an Integrated Ayurveda Management protocol for assessing its efficacy in glycemic control by evaluating biochemical parameters of Prediabetes (HbA1c, FBS, PPBS and Fasting Insulin) and compare it with Standard treatment regimen intervention on quality of life in Prediabetes (DQoL) over a period of 90 days.

MATERIALS & METHODS:

This study was a randomized control clinical study conducted at the KLE Ayurveda Hospital, Belagavi, between the time periods of July 2022– March 2023. The study was conducted in accordance with provisions of the Declaration of Helsinki and the Guidelines of Good Clinical Practice. The data was analyzed and interpreted by the investigators in collaboration with all authors. All the authors contributed to the drafting and review of the manuscript.

Ethics approval:

The trial protocol was approved by the Institutional Ethics Committee ((KAHER/EC/21-21/012) and was registered in the Clinical Trial Registry of India (REF/2021/12/049921).

Screening methods:

Each participant was included in the study after obtaining their informed written consent in the prescribed format. The participants were given full information about the study as well as description of any foreseeable risks and discomforts. Participants were also informed of their right to opt out of the study at any time without giving any reasons.

After receiving the written consent, the patient registered; was screened for study related examinations i.e. physical examination and laboratory screening procedures. Those participants who fulfilled the eligibility criteria were recruited in the study.

Study participants:

The participants were screened based on the eligibility criteria and those who fulfilled the same were recruited in the study.

The inclusion criteria were: Participants of either sex, in between 18 and 70 years of age who were pre-diabetics with HbA1c ranging between 5.7-6.4%, FBS <126mg/dl and those willing to give a written informed consent were included in the study.

The exclusion criteria were : Patients with Known Cases of DM, both type I and II, Past history of gestational diabetes, uncontrolled

Hypertensives (with or without medication > 140/90 mmHg), Pregnant and lactating women, alcoholics and/or drug abusers , patients suffering from major systemic illness necessitating long term drug treatment rheumatoid arthritis, psycho-neuroendocrinal disorders, etc.) and any other medical illness like Coronary Artery disease, Stroke etc were excluded from the study.

Also, patients who have completed participation in any other clinical trial during the past six (06) months were excluded from the study.

Sample size and randomization:

As this is a proof of concept, study aimed to evaluate Integrated Ayurveda Management Protocol in Prediabetes, a sample size 'n' of 90 participants (with 10% Attrition) in each group has been considered as adequate. Descriptive statistics (%, mean, SD etc), Chi square test, one way analysis of variance and Z test. Statistical significance will be taken at 5% level ($p<0.05$).

Enrollment and intervention

Selected participants were enrolled into two groups with control and treatment group. The participants in the control group (Group A) received the standard prediabetic care (nutritional and lifestyle management counseling) and the treatment group (Group B) received Integrated Ayurvedic protocol with oral medication Madhumehahari Kashaya 35ml twice daily orally after food with luke warm water along with diet (meal plans as per calorie requirement of the individuals were suggested) and a Yoga protocol including Suryanamaskar along with Trikonasana, Virabhadrasana, Padahastasana, Vakrasana and Gomukhasana were advised for a span of 30 minutes per day.

The fasting blood sugar (FBS), post-prandial blood sugar (PPBS) and DQol were measured at baseline and Day 30, 60 and 90 days. HbA1C and Fasting Insulin were measured at baseline and at the end of the study on 90th day.

Table 1: Ingredients for *Madhumehahari Kashaya*

Sl. No	Drug	Latin name	Part
1	*Vijaya sara*	*Pterocarpus marsupium*	Heart wood
2	*Jambu*	*Syzygium cumini*	Seeds
3	*Amalaki*	*Emblica Officiale*	Fruit
4	*Hareetaki*	*Terminalia Chebula*	Fruit
5	*Vibheetaki*	*Terminalia Bellirica*	Fruit
6	*Haridra*	*Curcuma longa*	Rhizome
7	*Guduchi*	*Tinospora cardifolia*	Stem
8	*Tamala Patra*	*Cinnamom tamala*	Leaves
9	*Daruharidra*	*Berberis aristata*	Rhizome
10	*Madhunashini*	*Gymnema sylvestre*	Leaves

Criteria of assessments:

Primary outcome measure:

The primary end points of the study were changes in HbA1c level from baseline (day 0) and end of the study period (Day 90) for evaluating glycemic control.

Secondary outcome measure:

The secondary outcome such as changes in fasting insulin level was evaluated from baseline and at 90 days. Changes in fasting and post prandial blood sugar were measured from baseline and at 30, 60 and 90 days. Changes in Quality of Life (DQoL) were evaluated at baseline and at 30, 60 and 90 days.

RESULTS:

The demographic data is presented in Table II. The patient's demographic and baseline data were evaluated, and the results indicated that there was no significant difference in the patients age, gender, socioeconomic status, educational status, religion; marital status and occupation in both the groups and they were comparable.

The comparison of different treatment time points of various parameters in Group A and Group B were tested by Wilcoxon matched pairs and Friedman's ANOVA test, while comparison of Group A and Group B for different parameters at different time points were tested by using Mann-Whitney U test. The results have been tabulated below.

Subject characteristics (Table 2)

1. Age Group: There were 180 patients, among them 88 were from the age group of 20-40 years old, 84 were from 40 – 60 years old, 08 were from above 60 years old.
2. Gender: There were 180 patients, among them 94 were male, 86 were female.
3. Socio economic status: There were 180 patients, among them 76 were Middle class, 10 were Upper class and 94 were Lower class.
4. Marital status: There were 180 patients, among them 175 were married and 05 were unmarried.

Quality of Life scale and Basic blood glucose levels at different intervals

The effect of interventions on various parameters of glycemic control assessed at baseline and on Day 30, 60 and 90 expressed as mean and standard deviations (SD) **(Table 3)**.

Glycemic Index Parameters Before and After Trail.

Effect of intervention on parameters to assess glycemic regulation at baseline and Day 90 expressed as Mean and standard deviations (SD) **(Table 4)**.

The effect of interventions on various parameters of glycemic control

The effect of interventions on various parameters of glycemic control assessed at baseline and on Day 30, 60 and 90 expressed as mean and standard deviations (SD) in between group A and Group B **(Table 5)**.

Table 2: Demographic data of Prediabetic Subjects

S. No	Category		Group A	Group B
1	Age-group	20-30	9	7
		30-40	42	30
		40-50	22	34
		50-60	14	14
		60+	3	5
2	Gender	Male	43	51
		Female	47	39
3	Socio-economic status	Upper	5	5
		Middle	38	38
		Lower	47	47
4	Marital status	Married	87	88
		Unmarried	3	2

Table 3: Quality of Life scale and Basic blood glucose levels at different intervals

Variable	Baseline	Day 30	Day 60	Day 90	P value
FBS					
Group A	98.88 ± 9.08	96.11±5.63	95.56±6.61	94.11±7.16	<0.001
Group B	98.88±10.02	92.91±8.07	93.07±8.40	89.92± 7.79	<0.001
PPBS					
Group A	135.33±2.91	130.41±5.32	124.92±5.53	116.26±6.57	<0.001
Group B	144.87±3.35	135.1± 2.99	128.1±4.58	113.85±4.80	<0.001
WHO-QOL-Bref					
Group A	83.74±3.03	84.21±2.35	84.78±2.76	86.51± 3.31	<0.001
Group B	83.62±2.90	83.82±2.13	85.0±2.65	87.18±3.32	<0.001

The parameter of glycemic control, FBS and PPBS were found to be statistically significant (p<0.001) in Group A and Group B individually. *WHO-QOL-Bref* was also found to be statistically significant in both groups. (p<0.001)

Table 4: Glycemic Index Parameters Before and After Trail

Variable	Day 0	Day 90	P value
HbA1c			
Group A	6.28±0.33	5.80± 0.26	<0.001
Group B	6.11±0.31	5.13±0.33	<0.001
Fasting Insulin			
Group A	13.46±1.67	14.63±1.71	<0.001
Group B	13.70±2.10	15.48±2.66	<0.001

The parameter of glycemic control, HbA1c and fasting insulin were found to be statistically significant (p<0.001) within Group A and Group B individually

Table 5: The effect of interventions on various parameters of glycemic control

Study Variable	Groups	DAY 0	DAY 90	P value
Fasting insulin	*A*	13.46±1.67	14.63±1.71	<0.01
	B	13.70±2.10	15.48±2.66	
HbA1C	*A*	6.28±0.33	5.8±0.26	<0.001
	B	6.11±0.31	5.13±0.33	

The parameter of glycemic control, fasting insulin was found to be statistically significant (p<0.01) in between both Group A and Group B, while HbA1c was also found to be statistically significant in between both Groups (p<0.001)

DISCUSSION:

In this study, the efficacy of Integrated Ayurvedic Management protocol was assessed in prediabetes against a controlled group with standard prediabetes protocol (nutrition and lifestyle management counseling). It was found that, both the standard prediabetes protocol and the Integrated Ayurveda Management (IAM) protocol were found to be efficient therapies in prediabetes individually. There was also a significant difference between Group A (the standard prediabetes protocol) and Group B (IAM protocol).

The standard prediabetes protocol included nutrition and lifestyle practices to combat prediabetic conditions; while the Integrated Ayurvedic management protocol included a combination of oral medication *Madhumehahari Kashaya* 35ml twice daily orally after food with luke warm water along with diet (meal plans as per calorie requirement of the individuals were suggested) and a Yoga protocol including *Suryanamaskar* along with *Trikonasana, Virabhadrasana, Padahastasana, Vakrasana* and *Gomukhasana* were advised for a span of 30 minutes per day. The individuals were given a training session in the hospital yoga hall before the commencement of the study and were then advised to follow the same daily.

The ingredients of the *Madhumehahari Kashaya* **[6-10]** have individually shown to possess properties of increasing insulin sensitivity and are reported to be anti-hyperglycemic in patients of Type 2 Diabetes Mellitus **[13, 14]**. Therefore, it was studied to evaluate its effect in gaining glycemic control in prediabetic individuals and accordingly was found to be effective in reducing the glycemic parameters.

The yoga intervention included *Suryanamaskar* along with asanas such as *Trikonasana, Virabhadrasana, Padahastasana, Vakrasana* and *Gomukhasana.*

Various studies conducted on the effect of *Suryanamaskar* in Diabetes mellitus report that it improves sensitivity of β-cells to the glucose signal thereby improving insulin sensitivity and glucose uptake. *Suryanamaskar* being a combination of *Yogasana* and breathing combined together; imparts a massaging effect on the pancreas and promotes proper secretion of Insulin **[15]**.

The similar principle of systematic muscle contraction and relaxation while performing asanas stimulates the pancreas and the pancreatic cells, thus increasing insulin secretion and regulation which is evident

significantly in the fasting insulin levels of the patients **[16]**.

It is reported that lifestyle changes along with improved nutrition and physical activity are the first line of treatment for prevention of transition from prediabetes to diabetes **[17]**. Accordingly the integrated Ayurvedic management protocol comprising of medication, diet and physical activity is found to be effective in all parameters of glycemic control.

The control group comprising of nutrition and lifestyle management counseling was found to be effective as well for effective management of glycemic indices.

However, there is significant difference between the two groups when compared to each other.

Limitations of the study

The present study was conducted in a smaller sample size over a period of 90 days. However, the study may require a larger sample size to be monitored over a greater period to arrive at a definitive strategy for prevention of transition from prediabetes to diabetes.

ABBREVIATIONS

IAM - Integrated Ayurveda Management, FBS - Fasting blood sugar, PPBS - post-prandial blood sugar, DQol – Diabetes Quality of life, LSM - Lifestyle modification, SD – Standard deviation.

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Conflict of Interest

The authors declare that there is no conflict of interest

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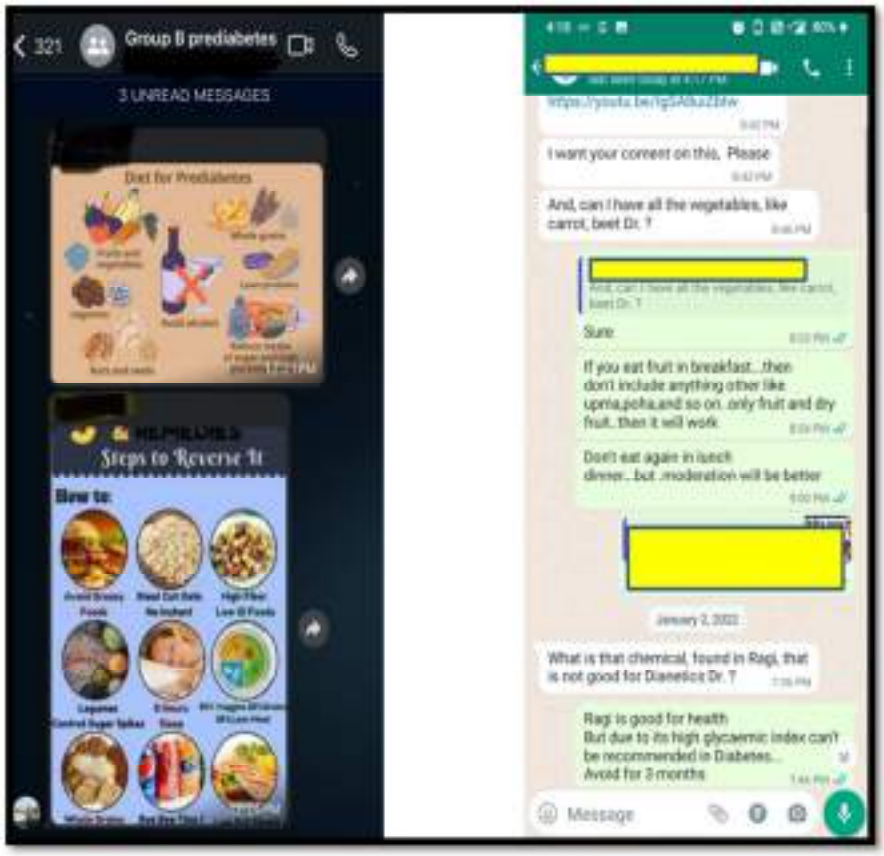
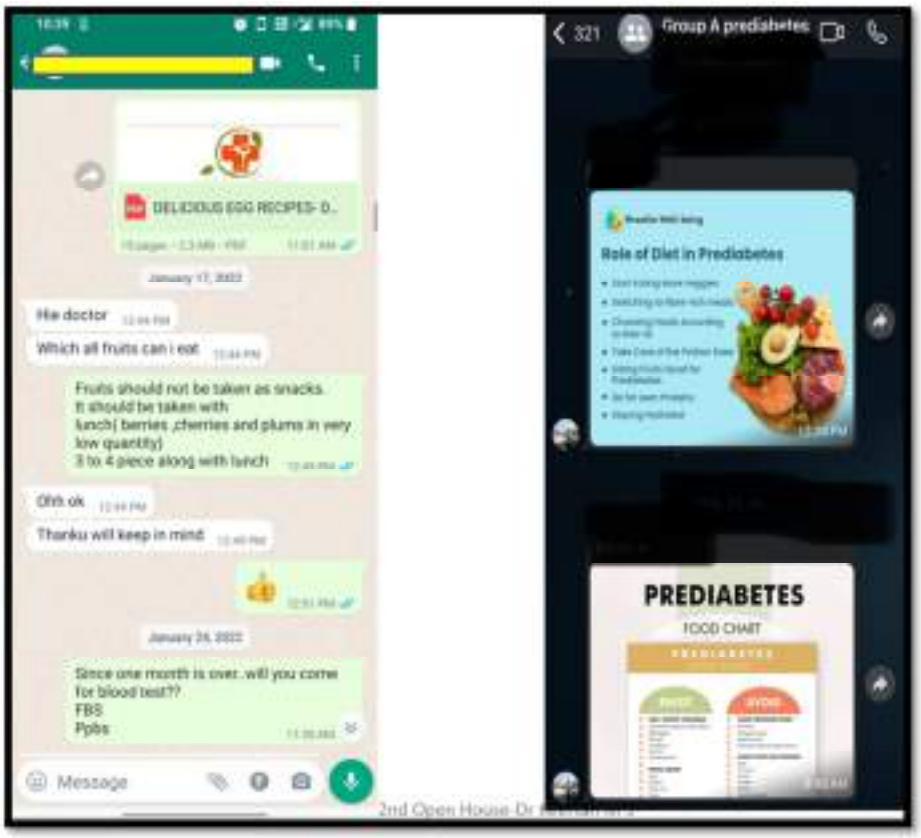
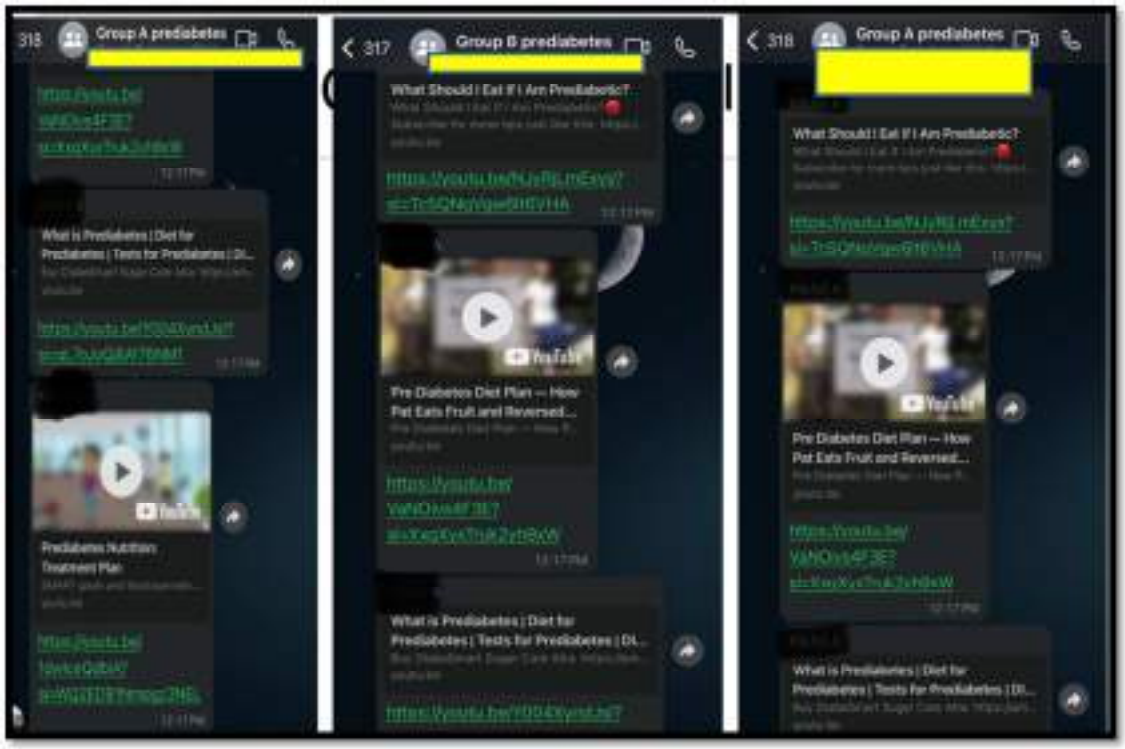
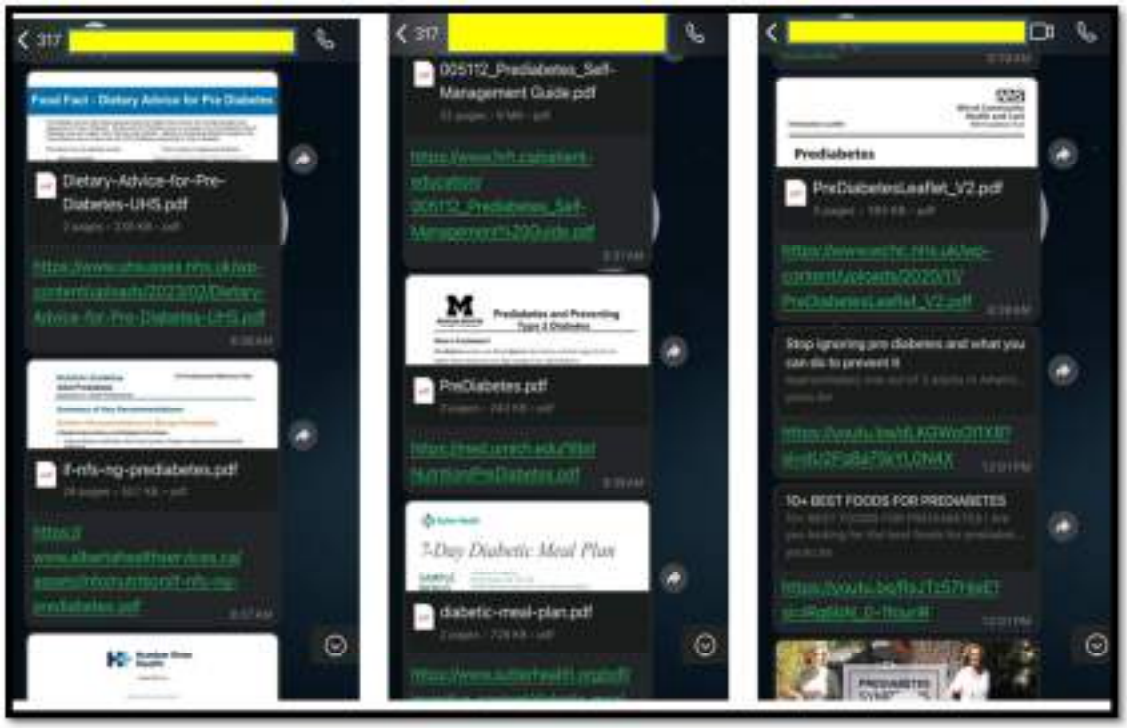
ANNEXURE VI: DIETARY AND LIFESTYLE ADHERENCE MONITORING AND SOCIAL SUPPORT

9:37
Back
Group Info
Edit
Group A prediabetes
Add Group Description
Media, Links, and Docs
None
Starred Messages
None
Mute
No
Wallpaper & Sound
Save to Camera Roll
Default
Disappearing Messages
Off
Encryption
9:37
Back
Group Info
Edit
Group B prediabetes
Add Group Description
Media, Links, and Docs
Starred Messages
Mute
No
Wallpaper & Sound
Save to Camera Roll
Default
Disappearing Messages
Off
Encryption


321
Group B prediabetes
3 UNREAD MESSAGES
Diet for Prediabetes
Steps to Reverse It
How to:
I want your comment on this. Please
And, can I have all the vegetables, like carrot, beet Dr. ?
Sure
If you eat fruit in breakfast...then don't include anything other like upma,poha,and so on. only fruit and dry fruit..then it will work
Don't eat again in lunch dinner.. but ..moderation will be better
What is that chemical, found in Ragi, that is not good for Diaetics Dr. ?
Ragi is good for health
But due to its high glycaemic index can't be recommended in Diabetes...
Avoid for 3 months
Message


DELICIOUS EGG RECIPES- D...
Hie doctor
Which all fruits can i eat
Fruits should not be taken as snacks.
It should be taken with
lunch(berries ,cherries and plums in very low quantity)
3 to 4 piece along with lunch
Ohh ok
Thanku will keep in mind
Since one month is over..will you come for blood test??
FBS
Ppbs
Message
321
Group A prediabetes
Role of Diet in Prediabetes
PREDIABETES
FOOD CHART
2nd Open House Dr


318
Group A prediabetes
317
Group B prediabetes
What Should I Eat If I Am Prediabetic?
Pre Diabetes Diet Plan — How Pat Eats Fruit and Reversed...
What is Prediabetes | Diet for Prediabetes | Tests for Prediabetes | Di...
Prediabetes Nutrition Treatment Plan


317
Dietary-Advice-for-Pre-Diabetes-UHS.pdf
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PreDiabetes.pdf
7-Day Diabetic Meal Plan
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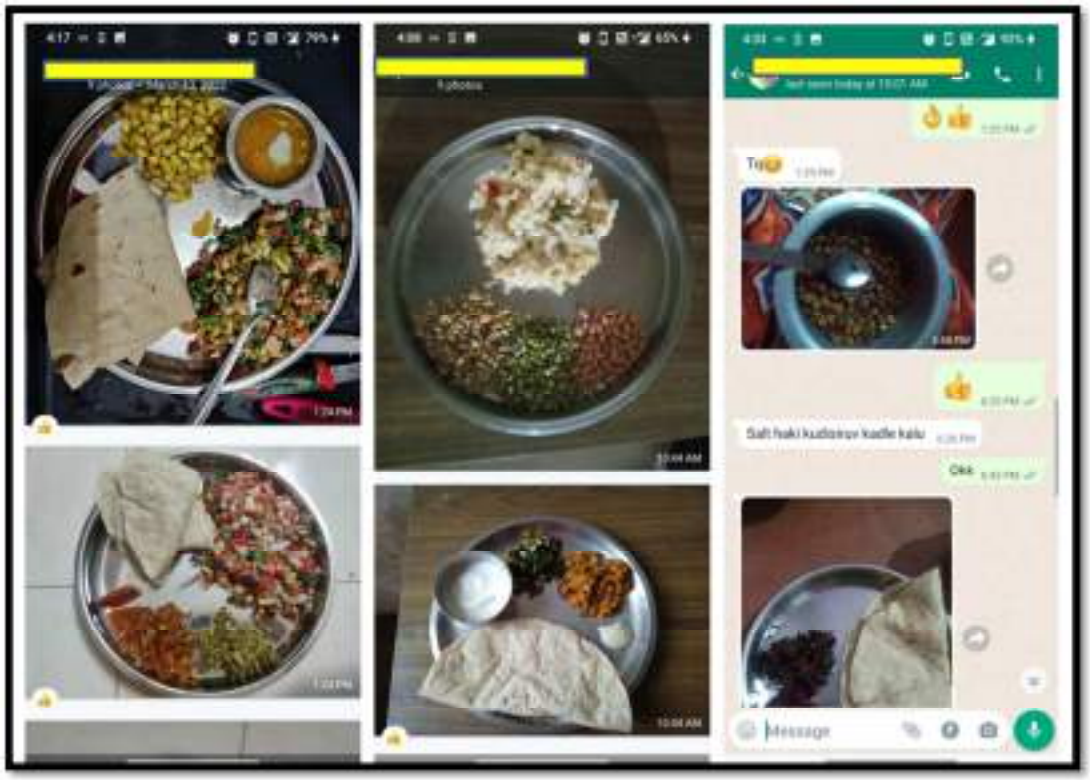
Prediabetes
PreDiabetesLeaflet_V2.pdf
Stop ignoring pre diabetes and what you can do to prevent it
10+ BEST FOODS FOR PREDIABETES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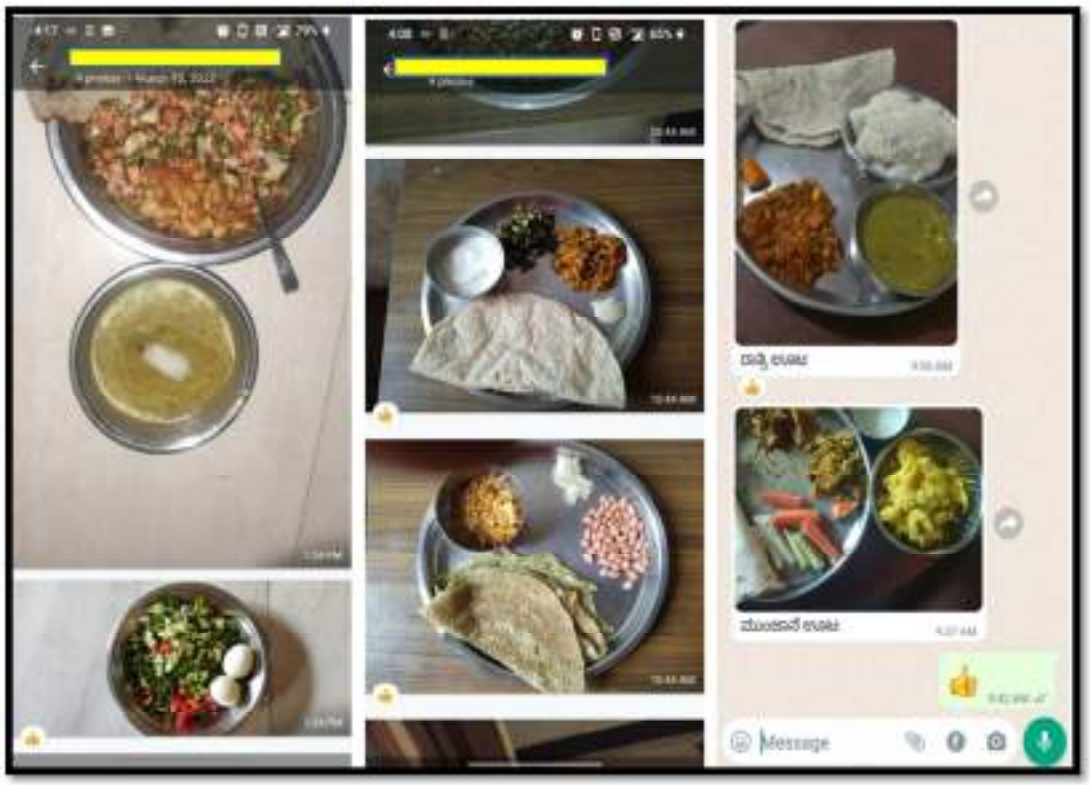
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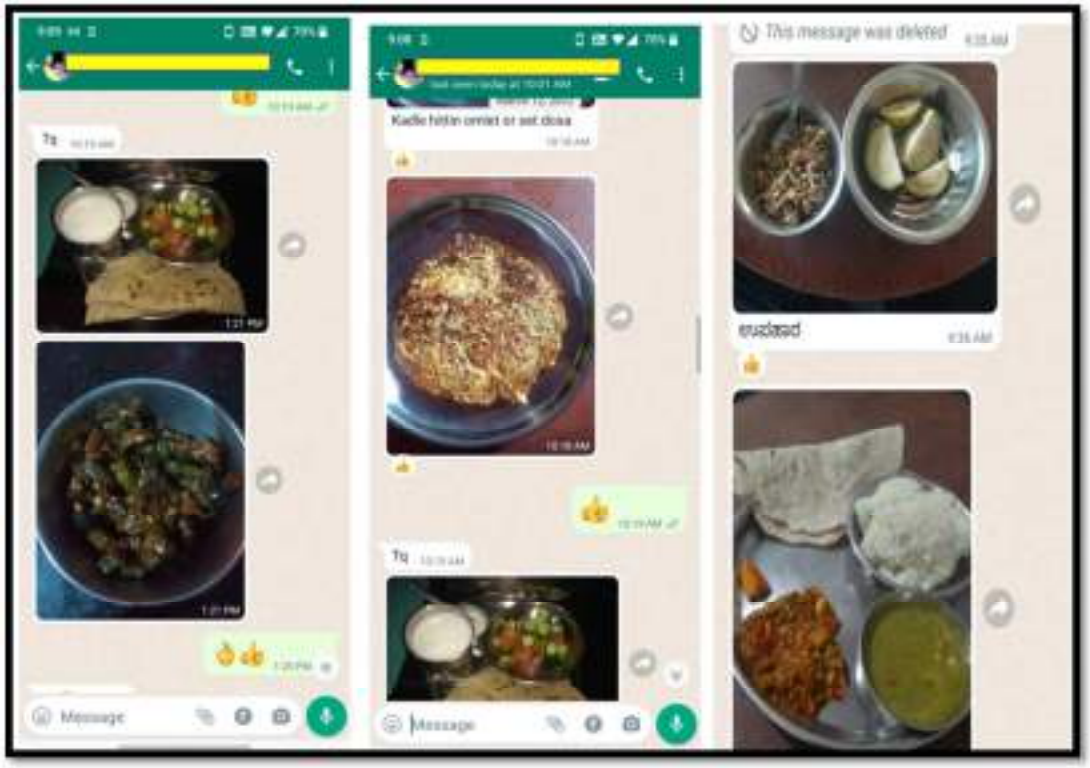
Tq
Message
Kadle hittin omlet or set dosa
Tq
Message
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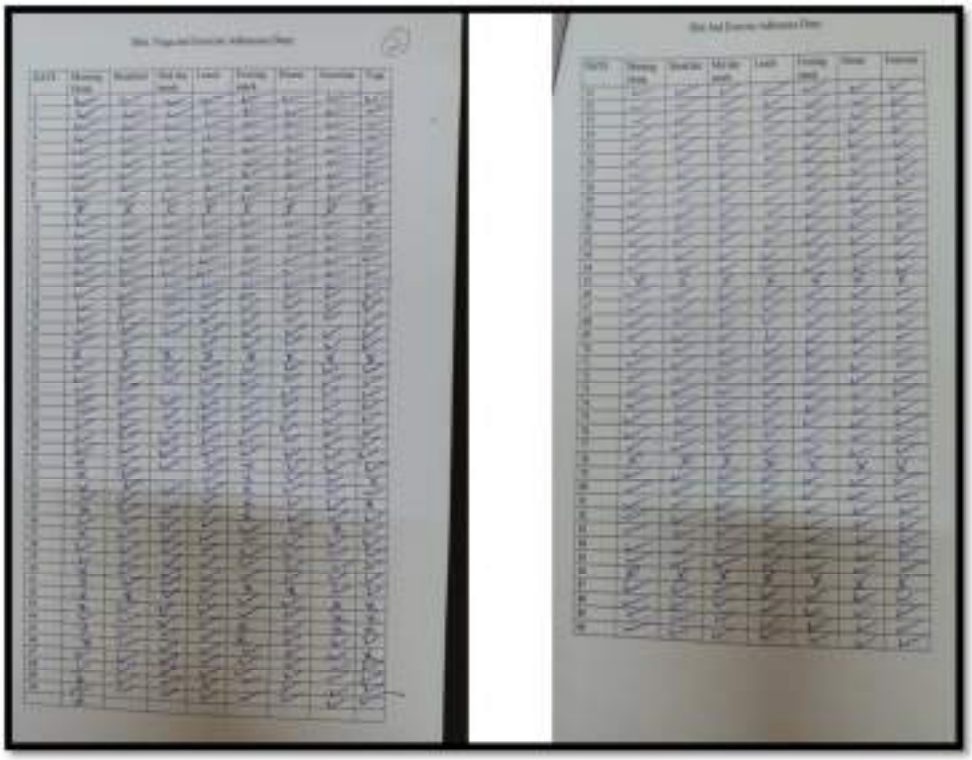

"Efficacy Of Integrated Ayurveda Management Protocol In Prediabetes – A Randomized Controlled Clinical Trial"

Diet chart for Prediabetes [**1200 Kcal** (+ or – 50 Kcal) Per day [Protein: 45.5 gm/day (+ or – 5 g), CHO: 177 gm, Fat: 31.7gm/day]

Ayurveda diet for Prediabetes- Sample Menu Plan

Table No : 2.A.1

Timing Food Diary	**Menu(with serving quantity)**
Morning Drink B/w 6.30 am to 7 am (Any One)	1. Herbal Infused Drink (Lemon Added)- 150 ml (1 glass)
	2. Ginger Lemon water -100 ml
	3. Cinnamon water (lemon added)- 100ml
	4. Chia Water (Lemon added)- 100 ml
	5. Soaked Methi water(added with lemon)- 100 ml
	6. Herbal Juice-100 ml
8 am to 9 am Breakfast options (Any one)	1. Besan Dosa(Tomato Omlette) -1 dosa + Herbal Chatni-2 tsf +Sambar-1 wati
	2. Millet Dosa/Millet Idli- 1 dosa/2 -3 idli + Herbal/ coconut Chatni- 2 tsf +Sambar -1 wati
	3. Millet Vegetable Upma-1 bowl/1 plate
	4. Moong dosa-1 dosa + Herbal / coconut Chatni-2 tsf +Sambar -1 wati
	Breakfast with Herbal /Cardamom/Green Tea without sugar-1 cup
Mid-Morning Snack 11.30 to 12 pm	1. Medicated Buttermilk (Spiced with Ginger, Pepper, Rock salt and Jeera)- 1 glass(150 ml)
Lunch 1pm to 2 Pm	Mix Veg Salad (Raw-spiced with pepper powder and Rock Salt)-1 bowl **+Unripe Guava/any citrous fruit-1/berries(3-4)** +Jowar/Bajra Roti- 1 roti +Vegetable Sabji-1 wati +Boiled Pulses Sabzi/ moong Dal-3/4th katori +Peanut/Methi/Flax Chatni-2 tsf
Mid-Evening Snack 4.30 pm to 5 pm (Option-Any one)	1. Almond -4 + Roasted or soaked Peanuts-1 handful +Walnut-2 + Green tea without sugar-1 cup

	2. Ghee Roasted makhanas added with Rock salt+ Turmeric -1 cup +Almond -4 +Walnut-2 + Green Tea/Lemon tea without Sugar-1 cup
	3. Unsalted Roasted Pea nut-1 handful + Green Tea/Lemon tea without Sugar-1 cup
	4. Roasted chana-1 cup +Almond-4 +Walnut-2 + Green Tea/Lemon tea without Sugar-1 cup
	5. Green moong dal Tikki/Bindi fry/Brinjal tawa fry/ Methi Muthia -1 plate (Any one)
	6. Lemon barley water-1 glass(150ml)
Dinner **(7 pm to 8 Pm)** **(Option-Any one)**	**1.** Salad (spiced with lemon, pepper, rock salt)-1 bowl + Herbal Soup -1 bowl +Millet Rice-1 katori + Moong dal -1 wati + Herbal Raita -1/2 wati
	2. Salad (spiced with lemon, pepper, rock salt)- 1 bowl + Moong Soup (spiced with Pepper and Rock Salt)-1 bowl(150ml) + Millet vegetable pulao-½ bowl +Herbal Raita-½ Wati
	3. Moong millet Khichdi (added with vegetables)- 1bowl + Salad (spiced with lemon, pepper, rock salt)-1 bowl + Herbal Raita-1/2 wati

Exchange List/Day

[Protein: 45 gm/day (+ or – 5 g), CHO: 195 gm, Fat: 26.5gm/day]

Table No : 2.A.2

Menu	Exchange	Gram	Calorie	Protein	CHO	Fat
Cereals	3	90	300	9	54	2.1
Rice	2	60	200	5	46	0.4
Pulses	2	60	180	13	30	1
Buttermilk	1	100 ml	26	2	2	1
Curd	1	100	62	4	4	3
Vegetable	4	400	160	8	26	1.7
Fruits	1	50-75	50	1	10	-
Oils and Fats	3	15	135	-	-	15
Nuts and oilseeds	1	20	100	3.5	5	7.5
Total	**-**	**-**	**1213 kcal**	**45.5 gm**	**177 gm**	**31.7 gm**

For Non vegetarian Table No : 2.A.3

Breakfast	Lunch	Dinner
2 egg omlette can be taken as one option (Kindly use organic egg)	In lunch, Dal can be replaced with Lean meat or chicken or fish (maximum 3 times a week) Note*: Do not use organ meat or red meat or poultry chicken	In Soup option, Chicken soup can be used (three times a week)

More recipe options (From recipe PDF) Table No : 2.A.4

Breakfast	Lunch	Dinner	Snacks
1. Red rice poha 2. Oats Upma	1. Roti with bindi fry 2. Bitter guard curry 3. Cabbage curry 4. Gobi sabzi 5. Curry leaves Chatni 6. Capsicm sabzi 7. Horse gram chatni 8. Methi chatni 9. Raw banana sabzi 10. Flax chatni 11. Onion chatni 12. Garlicchatni 13. Ginger chatni 14. Karela Tepla	1. Millet kichdi 2. Bajra Kichdi 3. Samai rice kichdi 4. Moong Kichdi 5. Chicken soup	1. Brinjal tawa fry 2. Cucumber coconut salad 3. Karela Tikki 4. Karela fry 5. Bindi fry 6. Moong and Peanut salad 7. Moong usali

General Instructions:

- Consume the food items in moderation and include variety of food
- Use millet/roasted Chana / soya flour / barley flours
- Consume pulses,whole grains adequately
- Avoid maida,rava,biscuits,preservatives,transfat
- Avoid Alcohol, Red meat (mutton) strictly.
- Adopt method of cooking require less oil, like marination (for chicken) followed by steaming/ grilling/ boiling.
- Maintain regularity in the timing & amount of food consumed each day.
- Avoid overeating and fasting
- Do not take Juice/ cold drink/aerated juices
- After having food, 5-10 min walk for at least 100 steps
- Maintain hygiene while cooking and taking food.
- Avoid fast food, ice creams
- Restrict sour and salty food items

Herbal Juice Recipe (Morning Drink) Table No : 2.A.5

Herbal Smoothie	Red Juice	Sweet Green Juice	Spicy Juice	Tangy Juice
Palak -5 to 6 leaves + Betel leaf-1 + Tuls-4 leaves + Pudina-4 leaves + Curry leaves-5-6 leaves + 1 glass water + Cinnamon -1/2 stick + Black pepper-2 + Turmeric-1/2 tsf + Rock salt Mix well in blender, consume fresh 1 to 2 glasses per day	2 carrots +1 Tomato +Small piece of capsicum +1/2 cup grated coconut Mix well in blender Consume 1 glass per day	1 cucumber +1 green apple +1/4 cup mint +2 cup palak +1/2-inch ginger +1/2 lemon juice Mix well in blender Consume 1 glass per day	1 carrot +1 Tomatoes +1 raddish +Small piece of ginger +1 green chillies Mix well in blender Consume 1 glass per day	1 Medium size Bottle gourd +1 green capsicum +1 Tomato Mix well in blender Consume 1 glass per day

"Efficacy Of Integrated Ayurveda Management Protocol In Prediabetes – A Randomized Controlled Clinical Trial"

Diet chart for Prediabetes [**1400 Kcal** (+ or – 50 Kcal) Per day [Protein: 45.5 gm/day (+ or – 5 g), CHO: 177 gm, Fat: 31.7gm/day]

Ayurveda diet for Prediabetes- Sample Menu Plan

Table No : 2.B.1

Timing Food Diary	**Menu**
Morning Drink B/w 6.30 am to 7 am (Any One)	1. Herbal Infused Drink (Lemon Added)-150 ml (1 Glass)
	2. Ginger Lemon water -100 ml
	3. Cinnamom water (lemon added)-100 ml
	4. Chia Water (Lemon added)-100 ml
	5. Methi water-100ml
	6. Herbal Juice-100 ml
8 am to 9 am Breakfast options (Any one)	1. Besan Dosa(Tomato Omlette)-1 in no + Herbal Chatni-2 tsf +Sambar-1 wati
	2. Millet Dosa 1 to 2 in no/Millet Idli-2-3 in no + Herbal/ coconut Chatni-2 tsf +Sambar -1 wati
	3. Millet Vegetable Upma-1 bowl/1 palte
	4. Moong dosa-1 to 2 in no. + Herbal / coconut Chatni-2 tsf +Sambar-1 wati
	5. Dhokla-2 pieces
	+ Herbal chatni-2 tbsp
	Breakfast with Herbal /Cardomom/Green Tea without sugar-1 cup
Mid-Morning Snack 11.30 am to 12 pm	1. Medicated Buttermilk (Spiced with Ginger, Pepper, Rock salt and Jeera)- 1 Glass(150ml)
Lunch 1pm to 2 Pm	Mix Veg Salad (Raw-spiced with pepper powder and Rock Salt)-1 bowl + Unripe guava (1),Any citrous fruit(1),Berries(3 to 4) +Jowar/Bajra Roti-1 to 2 in number +Vegetable Sabji-1 wati +Boiled Pulses Sabzi/Junka /moong Dal-/4th katori

	+Peanut/Methi/Flax Chatni-2 tsf + Dahi (Added with Rock salt or pink salt)
Mid-Evening Snack **4.30 pm to 5 pm** **(Option-Any one)**	1. Almond-6 to 8 +Walnut-4 + Roasted /Soaked Peanuts-1 handful + Green Tea/Lemon tea without Sugar-1 handful
	1. Boiled black Chana chat-1 cup +Almond -6 +Walnut-3 + Green Tea/Lemon tea without Sugar-1 cup
	2. Boiled Peanut Chat or unsalted peanuts- 1 plate/1 handful + Green Tea/Lemon tea without Sugar-1 cup
	3. Mix sprout bhel (lemon and rock salt added)- 1 bowl + Green Tea/Lemon tea without Sugar-1 cup
	4. Moong usali/chana dal tikki/green gram vada/veg cutlet/karela fry/Moong dal tikki (any one)- 1 plate + Green Tea/Lemon tea without Sugar-1 cup
Dinner **(7 pm to 8 Pm)** **(Option-Any one)**	1. Salad (spiced with lemon, pepper, rock salt)-1 bowl + Jowar /Bajra Roti-1 +Veg Sabzi-1 bowl +Millet Rice -1/2 wati + moong dal -1/2 katori + Herbal Raita-1 wati
	2. Salad (spiced with lemon, pepper, rock salt)- 1bowl + Moong Soup (spiced with Pepper and Rock Salt)-1 bowl(150ml) + Jowar roti/Bajra roti -1 in number + veg Sabzi -1 katori +vegetable pulao -1/2 bowl + Herbal Raita-1/2 wati
	3. Jowar roti/Bajra roti-1 in number + Vegetable Sabzi-1 katori + Moong millet Khichdi added with vegetables+ herbal raita-½ bowl + Salad (spiced with lemon, pepper, rock salt)-1 bowl

Exchange List/Day

[Protein: 55gm/day (+ or – 5 g), CHO: 212 gm, Fat: 32.9 gm/day]

Table No : 2.B.2

Menu	Exchange	Gram	Calorie	Protein	CHO	Fat
Cereals	4	120	400	12	74	2.8
Rice	2	60	200	5	46	0.4
Pulses	3	90	270	19.5	45	1.5
Buttermilk	1	100 ml	26	2	2	1
Curd	1	100	62	4	4	3
Vegetable	4	400	160	8	26	1.7
Fruits	1	50-75	50	1	10	-
Oils and Fats	3	15	135	-	-	15
Nuts and oilseeds	1	20	100	3.5	5	7.5
Total	**-**	**-**	**1413 kcal**	**55 gm**	**212 gm**	**32.9 gm**

For Non vegetarian **Table No : 2.B.3**

Breakfast	Lunch	Dinner
2 egg omlette can be taken as one option (Kindly use organic egg)	In lunch, Dal can be replaced with Lean meat or chicken or fish (maximum 3 times a week) Note*: Do not use organ meat or red meat or poultry chicken	In Soup option, Chicken soup can be used (three times a week)

More recipe options (From recipe PDF) **Table No : 2.B.4**

Breakfast	Lunch	Dinner	Snacks
1. Red rice poha 2. Oats Upma 3. Dhokla	1. Doodi ka parata 2. Capsicum parata 3. Veg parata	**1.** Millet kichdi 2. Bajra Kichdi 3. Samai rice kichdi	1. Almond peanut salad 2. Kothimbir vadi

	4. Jowar methi parata 5. Gobi parata 6. Cabbage curry 7. Gobi sabzi 8. chatni -Curry leaves,methi,flax seed,onion,garlic,ginger chatni 9. Capsicm sabzi 10. Raw banana sabzi	4. Moong Kichdi 5. Chicken soup	3. Lemon Barley water 4. Methi Pakora 5. Peanut salad 6. Sprout salad 7. Moong usali

General Instructions:

- Consume the food items in moderation and include variety of food
- Use millet/roasted Chana / soya flour / barley flours
- Consume pulses,whole grains and seasonal vegetables and fruits
- Avoid maida,rava,biscuits,preservatives,transfat
- Avoid Alcohol, Red meat (mutton) strictly.
- Adopt method of cooking require less oil, like marination (for chicken) followed by steaming/ grilling/ boiling.
- Maintain regularity in the timing & amount of food consumed each day.
- Avoid overeating and fasting
- Do not take Juice/ cold drink/aerated juices
- After having food, 5-10 min walk for at least 100 steps
- Maintain hygiene while cooking and taking food.
- Avoid fast food, ice creams
- Restrict sour and salty food items

Herbal Juice Recipe (Morning Drink) Table No : 2.B.5

Herbal Smoothie	Red Juice	Sweet Green Juice	Spicy Juice	Tangy Juice
Palak -5 to 6 leaves + Betel leaf-1 + Tuls-4 leaves + Pudina-4 leaves + Curry leaves-5-6 leaves + 1 glass water + Cinnamon -1/2 stick + Black pepper-2 + Turmeric-1/2 tsf + Rock salt Mix well in blender, consume fresh 1 to 2 glasses per day	2 carrots +1 Tomato +Small piece of capsicum +1/2 cup grated coconut Mix well in blender Consume 1 glass per day	1 cucumber +1 green apple +1/4 cup mint +2 cup palak +1/2-inch ginger +1/2 lemon juice Mix well in blender Consume 1 glass per day	1 carrot +1 Tomatoes +1 raddish +Small piece of ginger +1 green chillies Mix well in blender Consume 1 glass per day	1 Medium size Bottle gourd +1 green capsicum +1 Tomato Mix well in blender Consume 1 glass per day

"Efficacy Of Integrated Ayurveda Management Protocol In Prediabetes – A Randomized Controlled Clinical Trial"

Diet chart for Prediabetes [**1800 Kcal** (+ or – 50 Kcal) Per day [Protein: 45.5 gm/day (+ or – 5 g), CHO: 177 gm, Fat: 31.7gm/day]

Ayurveda diet for Prediabetes- Sample Menu Plan

Table No : 2.C.1

Timing Food Diary	**Menu**
Morning Drink B/w 6.30 am to 7 am (Any One)	1. Herbal Infused Drink (Lemon Added)-150 ml(1 glass)
	2. Ginger Lemon water-100ml
	3. Cinnamom water (lemon added)-100 ml
	4. Chia Water (Lemon added)-100 ml
	5. Methi water-100ml
	6. Herbal Juice-100 ml
8 am to 9 am Breakfast options (Any one)	1. Besan Dosa(Tomato Omlette)-1-2 in no + Herbal Chatni-2 tsf +Sambar-1 wati +Dahi-1 wati
	2. Millet Dosa 1-2 in no/Millet idli-2-3 in no + Herbal/ coconut Chatni-2 tsf +Sambar - 1wati + Dahi(added with pepper and Rock salt)-1 wati
	3. Millet Vegetable Upma-1 bowl/1 plate +Dahi(added with pepper and Rock salt)-1 wati
	4. Moong dosa-1-2 in no + Herbal / coconut Chatni-2 tsf +Sambar-1 wati +Dahi(added with pepper and Rock salt)-1 wati
	5. Dhokla-2 pieces +Herbal Chatni-2 tsf +Dahi(added with pepper and Rocksalt)-1 wati
	Breakfast with Herbal /Cardomom/Green Tea without sugar-1 cup
Mid-Morning Snack	• Sprouted Moong-½ bowl + Medicated Buttermilk (Spiced with Ginger, Pepper, Rock salt and Jeera)- 1 glass (150 ml)

Lunch **1pm to 2 Pm**	Mix Veg Salad (Raw-spiced with pepper powder and Rock Salt)-1 bowl + Unripe Guava(1)/any citrous fruit-1/berries(3-4)[any one fruit] +Jowar/Bajra Roti-2 in no +Vegetable Sabji-1 wati +Boiled Pulses Sabzi/Junka -3/4th Katori + Millet Rice-1 bowl + moong Dal-3/4th Katori +Peanut/Methi/Flax Chatni-1 tsf +Paneer -40 grams + Dahi (Added with Rock salt)-1 wati
Mid Evening Snack **4.30 pm to 5 pm** **(Option-Any one)**	1. Almond-6-8 +Soaked or roasted- unsalted peanuts-8 +Walnut -4 + Green Tea/Lemon tea without Sugar-1 cup
	2. Boiled Chana chat-1 cup +Almond -8 +Walnut-4 + Green Tea/Lemon tea without Sugar-1 cup
	3. Boiled Peanut Chat/unsalted peanuts-1 plate/1 handful + Green Tea/Lemon tea without Sugar-1 cup
	4. Methi pakoda/chana dal tikki/Mix sprout bhel/veg cutlet/Kothimbir vadi/cabbage Roll (**any one**)-1 plate
	5. Paneer grill -50 grams
Dinner **(7 pm to 8 Pm)** **(Option-Any one)**	1. Salad (spiced with lemon, pepper, rock salt)-1 bowl + Jowar /Bajra Roti-1 roti + Veg Sabzi-1/2 katori +Millet Rice -1/2 katori + moong dal -1/2 Katori + Herbal Raita-1/2 Wati
	2. Salad (spiced with lemon, pepper, rock salt)-1 bowl + Moong Soup (spiced with Pepper and Rock Salt)-150ml + Jowar roti/Bajra roti -1 in number +Veg sabzi-1/2 Katori + vegetable pulao with herbal raita
	3. Jowar roti/Bajra roti-1 roti + Moong millet Khichdi (added vegetables) with herbal raita-1/2 bowl + Salad (spiced with lemon, pepper, rock salt)-1 bowl

Exchange List/Day

[Protein: 62 gm/day (+ or – 5 g), CHO: 234 gm, Fat: 41.6 gm/day]

Table No : 2.C.2

Menu	Exchange	Gram	Calorie	Protein	CHO	Fat
Cereals	5	150	500	15	90	3.5
Rice	2	60	200	5	56	0.4
Pulses	4	120	360	26	60	2
Buttermilk	1	100 ml	26	2	2	1
Curd	2	200	124	8	8	8
Paneer	1	40	100	7.5	5	6
Vegetable	4	400	160	8	26	1.7
Fruits	1	50-75	50	1	10	-
Oils and Fats	4	20	180	-	-	20
Nuts and oilseeds	1	20	100	3.5	5	10
Total	**-**	**-**	**1800 kcal**	**76 gm**	**262 gm**	**52.6 gm**

For Non vegetarian Table No : 2.C.3

Breakfast	Lunch	Dinner
2 egg omlette can be taken as one option (Kindly use organic egg)	In lunch, Dal or paneer can be replaced with Lean meat or chicken or fish (maximum 3 times a week) Note*: Do not use organ meat or red meat or poultry chicken	In Soup option, Chicken soup can be used (three times a week)

More recipe options (From recipe PDF) Table No : 2.C.4

Breakfast	Lunch	Dinner	Snacks
1. Red rice poha 2. Oats Upma 3. Dhokla 4. Egg omlette	1. Doodi ka parata 2. Capsicum parata 3. Veg parata 4. Jowar methi parata 5. Gobi parata 6. Paneer Parata 7. Chana Palak 8. Peas parata 9. Soya Curry 10. Cabbage curry 11. Gobi sabzi 12. chatni -Curry leaves,methi,flax seed,onion,garlic,ginger chatni 13. Capsicm sabzi 14. Raw banana sabzi	**1.** Millet kichdi 2. Bajra Kichdi 3. Samai rice kichdi 4. Moong Kichdi 5. Chicken soup	1. Black chana Usali 2. Almond peanut salad 3. Kothimbir vadi 4. Lemon Barley water 5. Methi Pakora 6. Peanut salad 7. Sprout salad 8. Moong usali 9. Chana dal tikki 10. Green gram vada 11. Paneer Ghee roast 12. Paneer grill

General Instructions:

- Consume the food items in moderation and include variety of food
- Use millet/roasted Chana / soya flour / barley flours
- Consume pulses,whole grains and seasonal vegetables and fruits
- Avoid maida,rava,biscuits,preservatives,transfat
- Avoid Alcohol, Red meat (mutton) strictly.
- Adopt method of cooking require less oil, like marination (for chicken) followed by steaming/ grilling/ boiling.
- Maintain regularity in the timing & amount of food consumed each day.
- Avoid overeating and fasting
- Do not take Juice/ cold drink/aerated juices
- After having food, 5-10 min walk for at least 100 steps
- Maintain hygiene while cooking and taking food.
- Avoid fast food, ice creams
- Restrict sour and salty food items

Herbal Juice Recipe (Morning Drink) Table No : 2.C.5

Herbal Smoothie	Red Juice	Sweet Green Juice	Spicy Juice	Tangy Juice
Palak -5 to 6 leaves + Betel leaf-1 + Tuls-4 leaves + Pudina-4 leaves + Curry leaves-5-6 leaves + Apple-1 + 1 glass water + Cinnamon -1/2 stick + Black pepper-2 + Turmeric-1/2 tsf + Rock salt Mix well in blender, consume fresh 1 to 2 glasses per day	2 carrots +2 Tomato +Small piece of capsicum +1/2 cup grated coconut Mix well in blender Consume 1 glass per day	1 cucumber +1 green apple +1/4 cup mint +2 cup palak +1/2-inch ginger +1/2 lemon juice Mix well in blender Consume 1 glass per day	1carrots +2 Tomatoes +1 raddish +Small piece of ginger +2 green chillies Mix well in blender Consume 1 glass per day	1 Medium size Bottle gourd +1 green capsicum +1 Tomato Mix well in blender Consume 1 glass per day

EFFICACY OF INTEGRATED AYURVEDA MANAGEMENT PROTOCOL IN PREDIABETES
A RANDOMIZED CONTROLLED CLINICAL TRIAL

CALORIE :-1985KCAL / DAY - Group A Standard Diet

PROTEIN:- 58GM/D CHO – 271GM /D

S.NO	MENU	QUANTITY
6AM	LIME WATER + ALMONDS	1 GLASS + 5
7 am	TEA / COFFE WITHOUT SUGAR	1 CUP
8AM	VEGETABLES + UPMA POHA Or IDLI / DOSA ANY ONE Or ROTI / CHAPATI + BOILED PULSES / DAL / ZUNUKA + MILK / CURD	1 EXCHANGE 1 EXCHANGE 1/2 EXCHANGE 1 EXCHANGE
11am	FRUITS AMBIL / BUTTERMILK / COCONUT WATER	1 EXCHANGE 1 GLASS
2PM	ROTI / CHAPATI RICE / FOXTAIL MILLET / SMALL MILLETS VEGETABLE THICKDAL / ZUNUKA/ CHICKEN / FISH CURD / BUTTERMILK	2 EXCHANGE 1 EXCHANGE 2 EXCHANGE ½ EXCHANGE ½ EXCHANGE
5PM	TEA / COFEE WITHOUT SUGAR CHURMURA + CHANNA OR EGGWHITE /PANEER + BREAD / BISCUITS	1 CUP 1 EXCHANE 1 EXCHANGE
8PM	SAME AS LUNCH	
10pm	MILK	1 EXCHANGE

1985 KCAL PER DAY BECAUSE PATIENT WILL BE BOTH MALE AND FEMALE WITH MODERATE ACTIVITY AND THEY ARE ON 1000MG METFORMIN IF WILLGIVE LOWER THEN THIS CALORIE THEN THEY WILL GO INTO HYPOGLYCEMIA

FOODS TO BE AVOIDED

- BUTTER,GHEE,CREAM,FRIED ECT
- WHOLE MILK AND ITS PRODUCTS
- OUT SIDE FOOD
- RED MEAT AND YOLK
- ALL BAKERY PRODUCTS
- DRIED FRUITS
- COCONUT (DRIED / FRESH)
- ALCOHOLIC & AERATED DRINKS
- SUGAR/ JAGGARY/ HONEY/ JUICE/ RAGI
- POTATO / SWEETPOTATO

FOODS TO BE ALLOWED

- CEREALS GIVEN QUANTITY
- PULSES AND DALS AND ITS FLOUR GIVEN QUANTITY
- MILK & ITS PRODUCTS GIVEN QUANTITY
- EGG WHITE / WHITE MEAT /
- MONTHLY CHANGE THE OIL – 4 TEASPOON PER DAY PER PERSON
- ALL FRUITS
- ALL VEGETABLES

INSTRUCTIONS

- TAKE SMALL & FREQUENT MEALS AT REGULAR TIME
- DO NOT SKIP MEALS
- USE FLAX SEEDS
- USE METHI POWDER

EXCHANGE LIST /DAY

S.NO	MENU	EXCHANGE	GRAM	CALORIE	PROTEIN	CHO
1	CEREALS	8	240GM	800	24	160
2	PULSES	3	90GM	300	18	45
3	MILK AND MILK PRODUCTS	5	500ML	350	15	25
4	VEGETABLES	5	500GM	250	...	30
5	FRUITS	1	100GM	40	...	10
6	OILS AND FAT	4	20ML	180	...	...
7	NUTS	10GM	10GM	65	1	1
				1985KCAL	**58GM**	**271GM**