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Advanced Lifestyle Modifications in Sugarfit's Diabetes Reversal and Management Program Drive Significant Glycemic Improvements: Evidence of a 2% HbA1c Reduction in Just 3 Months

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Abstract: <u>Background and Aim</u>: Type 2 diabetes (T2D) is increasingly recognized as a significant global health issue, characterized by insulin resistance and elevated blood glucose levels, which can lead to serious complications such as vascular diseases and neuropathy. Conventional management strategies for diabetes have often struggled to address the complexities of this condition. This study aimed to evaluate the effectiveness of the SugarFit Diabetes Reversal and Management Program (SDRMP) in achieving reductions in glycated hemoglobin (HbA1c) and fasting blood sugar (FBS), as well as promoting weight loss within a 3-month timeframe while focusing on implementing lifestyle modifications and holistic care, including essential mental health support. Methodology: This retrospective study assessed data from 2590 T2D patients (1918 males and 672 females) who completed the SDRMP over 3 months. The participants underwent continuous glucose monitoring and received personalized dietary and physical activity interventions. Clinical evaluations, including HbA1c, FBS, and weight measurements were conducted at baseline and after 90 days. Additionally, psychological consultations were integrated to address diabetes-related distress. Statistical analyses were executed to evaluate the program's impact on improvements in key health metrics. <u>Results</u>: The findings revealed noteworthy advancements in both glycemic control and weight management among the participants. Average HbA1c level saw a decrease from 9.9% to 7.9%, representing a mean reduction of 2%, accompanied by an average decline in FBS levels by 49.1 mg/dL. Remarkably, participants achieved an average weight loss of 2.3 kg. Furthermore, the psychological support provided throughout the program was instrumental in addressing diabetes-related distress, which subsequently improved adherence to the program and positively influenced overall health outcomes. <u>Conclusion</u>: The findings from the SDRMP highlight its substantial effectiveness in reducing HbA1c and FBS levels while promoting weight loss within a short time frame of just three months. The program's individualized approach, which places a strong emphasis on mental health support, establishes a comprehensive care model that effectively addresses the complex nature of managing type 2 diabetes. This study highlights the essential value of combining lifestyle interventions with emotional assistance to achieve lasting outcomes in diabetes management.

Keywords: Type 2 diabetes management, personalized lifestyle modifications, continuous glucose monitoring, HbA1c reduction, weight loss, diabetes distress, emotional well-being

1. Aim and Objective

This retrospective study evaluated the efficacy of the SugarFit's Diabetes Reversal and Management Program (SDRMP) in achieving substantial reduction in HbA1c level, while examining the lifestyle modifications undertaken by participants.

Primary Objective:

To evaluate the effectiveness of the SDRMP in achieving a significant reduction in HbA1c level.

Secondary Objectives

• To assess the impact of the SDRMP on participants' weight loss and its correlation with HbA1c reduction.

- To study the association between program adherence and improvements in health outcomes, including fasting blood sugar (FBS) and quality of life.
- To investigate how demographic factors, such as age, gender, and duration of diabetes, influence the effectiveness of SDRMP in reducing HbA1c level.

2. Introduction

Type 2 diabetes (T2D) is a chronic metabolic disorder characterized by persistent hyperglycemia due to a combination of insulin resistance and inadequate insulin secretion [1]. In the initial stages of type 2 diabetes (T2D), the condition is marked by insulin resistance, where insulin's ability to act on target tissues like muscle, liver, and fat is significantly reduced, leading to elevated fasting insulin levels. Over time, as hyperglycemia persists, the beta cells of

the pancreatic islets become progressively unable to produce enough insulin, worsening the condition [2]. These disruptions result in impaired glucose metabolism and persistent hyperglycemia, leading to a range of complications such as cardiovascular disease, kidney failure, and neuropathy [3].

The rapid pace of global urbanization and modernization has led to the widespread availability of unhealthy, processed foods, a decline in physical activity, and higher stress levels. These shifts have contributed to an alarming rise in lifestyle diseases like obesity and T2D worldwide [4]. In India, the prevalence of type 2 diabetes has escalated to concerning levels, with recent estimates indicating a troubling upward trend. Most recent estimates highlight that the prevalence of type 2 diabetes in India has escalated alarmingly, with the ICMR-INDIAB study (2023) reporting a prevalence of 11.4%, impacting over 101 million people. The study also revealed that 136 million individuals (15.3%) have prediabetes, a condition that increases their risk of developing type 2 diabetes in the future (Mohan et al., 2023) [5]. This situation underscores the urgent need for continued research and targeted interventions to manage and prevent diabetes effectively in India.

Currently, for diabetes management and monitoring the effectiveness of interventions—whether lifestyle changes or medications—HbA1c is an essential metric. In this landscape, HbA1c emerges as a pivotal aspect of diabetes management. During the 69th Scientific Sessions of the American Diabetes Association (ADA), David Nathan from Boston, MA, emphasized the significance of HbA1c in diagnosing diabetes, especially for individuals with T2D. His insights were supported by an expert committee from the ADA and the European Association for the Study of Diabetes (EASD), which advocates that HbA1c levels can be a more reliable indicator of diabetes than traditional plasma glucose measurements **[6].**

Beyond its diagnostic utility, HbA1c serves as a vital metric for monitoring long-term blood sugar control in T2D patients, providing insights into overall glucose management while offering a broader perspective on blood sugar control, and allowing doctors to tailor treatment plans. HbA1c levels not only aid in the diagnosis of type 2 diabetes (with values above 6.5% indicating the condition) but also play a key role in predicting the risk of diabetes-related complications [7]. Stumvoll M et al., stated that elevated HbA1c is directly associated with an increased risk of complications associated with diabetes, making its reduction a primary target in T2D management [8].

Despite advancements in diabetes care that have enhanced our grasp of glycemic control, many traditional methods do not effectively address the intricate biomolecular pathways leading to increased HbA1c levels. A comprehensive understanding of the biological mechanisms driving hyperglycemia and insulin resistance in T2D is necessary to identify ongoing challenges and explore potential solutions for managing HbA1c effectively.

Investigating the biomolecular pathways that result in heightened HbA1c levels is critical for developing more

targeted intervention strategies. Elevated glucose levels in the blood cause the non-enzymatic glycation of hemoglobin, which leads to the production of glycated hemoglobin (HbA1c). Furthermore, chronic hyperglycemia can trigger glucose toxicity and the subsequent formation of advanced glycation end-products (AGEs), intensifying insulin resistance and impairing cellular functionality.

To tackle these issues, the SugarFit Diabetes Reversal and Management Program (SDRMP) offers an innovative and precision-driven personalized framework that combines lifestyle modifications, nutritional advice, physical activity, and ongoing monitoring to achieve substantial HbA1c reduction in just three months. By leveraging a combination of tailored diet plans, enhanced physical activity, and continuous glucose monitoring, the SDRMP not only strives to lower HbA1c levels but also facilitates improvements in fasting blood sugar (FBS), body mass index (BMI), and overall weight management. By prioritizing individualized care and addressing the underlying factors contributing to hyperglycemia and insulin resistance, SDRMP aims to enhance patient outcomes and mitigate the risk of long-term complications.

3. Background

Type 2 diabetes mellitus (T2DM) is defined by a series of metabolic dysfunctions that culminate in persistent hyperglycemia. This condition arises from a combination of insulin resistance, impaired insulin secretion, and dysregulated glucagon production, all of which contribute to the onset and advancement of T2D [9]. Over time, the body's inability to effectively utilize insulin results in sustained high blood glucose levels, which initiates a cascade of associated complications. Despite the progress made in therapeutic interventions, maintaining glycemic control continues to pose significant challenges, leading to the ongoing elevation of HbA1c levels, a critical indicator of long-term glucose management [8,9].

According to Brooks-Worrell et al., While traditional treatment strategies often emphasize pharmacological approaches to lower blood sugar levels, they frequently neglect the intricate biomolecular mechanisms involved, such as protein glycation and glucose toxicity. These factors exacerbate insulin resistance and accelerate the progression of hyperglycemia. Consequently, many individuals experience inadequate treatment outcomes, highlighting the urgent necessity for a more comprehensive understanding of the mechanisms that contribute to elevated HbA1c and the onset of T2D [10].

Mechanistic link leading to increase in HbA1c and T2D onset

Insulin Resistance

Existing research indicates that insulin resistance arises when muscle, fat, and liver cells show diminished responsiveness to insulin, a hormone crucial for facilitating glucose absorption. This decreased responsiveness results in ineffective glucose uptake, causing elevated blood glucose levels [11]. Several factors contribute to this condition, including genetic predispositions, environmental influences, and lifestyle

choices—particularly poor dietary habits and lack of physical activity. As a result, the persistent hyperglycemia from impaired glucose assimilation initiates a continuous process of hemoglobin glycation [12]. This glycation process occurs when glucose molecules attach to hemoglobin, the protein responsible for oxygen transport in red blood cells. Over time, this leads to the accumulation of HbA1c, which serves as a crucial marker for assessing long-term glucose control in patients with diabetes [13].

Research by Kahn SE, et al., showed that several key biomolecular components are critical in glucose metabolism and development of insulin resistance, which are deeply intertwined with lifestyle factors. Insulin receptors on target cells bind to insulin, initiating a cascade of biological effects essential for proper glucose regulation. One such effect involves the activation of glucose transporter type 4 (GLUT4) transporters, which allows glucose to enter cells-dependent on proper insulin signaling [14]. Further exploring this complexity, Quon, M. J. et al., highlighted the intricacies of intracellular signaling pathways, particularly the phosphatidylinositol 3-kinase (PI3K)/protein kinase B (AKT) PI3K/AKT pathway, underscoring the interdependent roles these molecular elements-play in the emergence and progression of insulin resistance. These signaling disruptions exacerbated by poor lifestyle choices, further impede glucose metabolism and contribute to the progression of type 2 diabetes [15].

β-Cell Dysfunction

In addition to insulin resistance, β -cell dysfunction plays a crucial role in the pathogenesis of diabetes. As highlighted by Qiu Z et al. and Marchetti P et al, pancreatic β -cells, which are integral to insulin secretion, may degenerate over time due to several factors such as oxidative stress, endoplasmic reticulum (ER) stress, and accumulation of amyloid deposits. These damaging influences reduce the capacity of β -cells to produce insulin, thus exacerbating hyperglycemia [16,17]. As insulin secretion declines due to β-cell dysfunction, blood glucose levels rise, leading to an increase in HbA1c levels, a key marker of long-term glucose control [18]. The primary contributors to β -cell impairment include oxidative stress, caused by reactive oxygen species, ER stress from misfolded protein accumulation, and amyloid fibril formation. Each of these factors disrupts normal β-cell function, further driving the progression of diabetes [19,20].

Inflammation and Adipocytokines

Following the dysfunction of β -cells, inflammation, and adipocytokines emerge as significant contributors to the progression of diabetes. Chronic low-grade inflammation in adipose tissue triggers the release of pro-inflammatory cytokines, including tumor necrosis factor (TNF)-a and interleukin (IL)-6, as well as adipokines such as leptin and resistin, as noted by Haataja L et al. and Kaser S et al. [21,22]. These substances collectively worsen insulin resistance, further hindering glucose uptake by cells. The ongoing inflammatory environment results in persistent hyperglycemia, which over time contributes to elevated HbA1c levels. As insulin resistance intensifies, the capacity to effectively regulate blood glucose declines, increasing the risk of long-term complications related to diabetes.

Central to this inflammatory response is the nuclear factor- κ B (NF- κ B) signaling pathway, which drives the production of inflammatory cytokines and maintains the inflammatory state. On the other hand, adiponectin, an adipokine with protective properties, enhances insulin sensitivity and assists in lowering HbA1c levels. Achieving a balance between these pro-inflammatory and anti-inflammatory signals is essential for sustaining metabolic health [22, 23].

Mitochondrial Dysfunction and Oxidative Stress

Furthermore, mitochondrial dysfunction contributes to an increased generation of reactive oxygen species (ROS), leading to oxidative damage on cellular components [24]. This oxidative stress contributes to insulin resistance by disrupting crucial signaling pathways involved in glucose metabolism [25]. Persistently high ROS levels further induce hyperglycemia, which in turn fosters an increase in hemoglobin glycation. This process results in elevated HbA1c levels, reflecting inadequate long-term glucose control. Mitochondrial enzymes play vital roles in maintaining cellular function and energy production. When mitochondrial dysfunction occurs, a mismatch between ROS production and antioxidant defenses worsens insulin resistance, culminating in heightened HbA1c levels [26].

Gaps in Traditional Care Approaches for HbA1c Management

While traditional strategies for managing T2D have made significant strides and provided substantial benefits, persistent challenges remain that can limit the effectiveness of glycemic control and increase the risk of complications. A comprehensive analysis of the biomolecular mechanisms underlying elevated HbA1c levels underscores the need for a more refined and adaptive treatment approach.

Conventional management, often based on intermittent HbA1c monitoring every three to six months, provides valuable insights into long-term glycemic trends. However, this method may not fully capture the daily fluctuations in blood glucose, potentially delaying critical interventions for hyperglycemia. To complement the existing approach, continuous glucose monitoring (CGM) offers a more dynamic and precise understanding of glycemic variability, helping to address these limitations and improve patient outcomes.

Furthermore, standard approaches often prioritize pharmacological interventions while neglecting the essential role of lifestyle modifications. Although medications can assist in regulating blood glucose levels, they cannot replace the critical benefits of a balanced diet and regular physical activity. Without thorough guidance on nutrition and exercise, patients may struggle to manage insulin resistance and glucose toxicity effectively, complicating their overall care journey.

Additionally, traditional diabetes care often lacks personalization, overlooking the unique variations in metabolism, genetics, and lifestyle among patients. This onesize-fits-all approach can lead to ineffective treatment plans that fail to meet the specific needs of individuals, particularly those confronting issues like obesity, stress, or inactivity. Consequently, the fundamental factors contributing to insulin resistance and elevated HbA1c levels remain unaddressed.

Patients with T2D commonly present with comorbid conditions such as obesity, hypertension, and dyslipidemia. Conventional management tends to focus predominantly on blood glucose control, while the complex interactions among these conditions can further complicate treatment and elevate the risk of cardiovascular disease and other severe complications. This reality underscores the necessity for an integrated care approach.

Lastly, numerous patients often need more education regarding blood glucose monitoring and the underlying mechanisms of their condition, including glycation and glucose toxicity. This gap in understanding can impede their ability to implement necessary lifestyle changes effectively. Therefore, comprehensive education and support are essential for empowering patients to take control of their health and fostering adherence to management plans.

In light of these challenges, traditional diabetes management methods do not effectively address the multifaceted issues associated with T2D. The ongoing presence of hyperglycemia, elevated HbA1c levels, and related health complications indicates an urgent need for a transition to a more holistic approach. To navigate these challenges successfully, the integration of lifestyle interventions, personalized care, and continuous education is vital. By adopting this tailored strategy, healthcare providers can better address the complexities of T2D and significantly enhance the quality of life for affected individuals.

4. Methodology

Study Design

This retrospective study evaluated the effectiveness of the SDRMP for a 3-month period. The study analyzed the clinical data of participants who completed the program, focusing on changes in key health markers such as HbA1c, FBS, and weight. Participants underwent evaluations at baseline, and at the end of 90 days, allowing for comprehensive insights into the program's impact on their health outcomes.

Study Subjects

A total of 2590 participants enrolled in this study were individuals with T2D who had joined SDRMP and completed scheduled follow-ups. Of these, 1918 were males and 672 were females. The study included participants across different demographics, ensuring diversity in age, gender, and baseline clinical parameters.

Inclusion Criteria

- **Confirmed Diagnosis**: Participants must have a confirmed diagnosis of T2D with an HbA1c of more than 6.5%.
- **Enrollment Period:** Individuals who enrolled in the SDRMP during the timeframe from January 2024 to July 2024 were selected for the study.
- Active Engagement: Participants who completed the entire program, including clinical evaluations at the start and who underwent retesting within 90-180 days, were included for the study.

Exclusion Criteria

- **Significant Health Issues**: Participants with serious health conditions that could affect diabetes management, such as severe heart disease, cancer, and chronic kidney disease.
- **Pregnancy or Recent Surgery**: Those who were pregnant or lactating mothers were also excluded.
- **Incomplete Program**: Individuals who did not complete the follow-up diagnostic tests after the baseline measurement were excluded.

Comprehensive SDRMP Approach

SDRMP utilizes a holistic, patient-centered approach that combines personalized dietary guidance, customized physical activity plans, and medication management to achieve optimal diabetes control. Participants received continuous remote consultations with healthcare professionals, including nutritionists, fitness experts, physicians, and psychologists to potentially improve overall diabetes management and quality of life. The dietary plan emphasized balanced nutrition through whole foods and low glycemic index options, while the exercise plan was customized based on individual fitness levels and preferences. Regular assessments and feedback ensured that interventions were adjusted based on participants' progress and evolving needs.

Dietary counseling:

Dietary counseling serves as a fundamental component of the SDRMP. During these sessions, participants were provided with individualized guidance on food selections and meal planning, specifically crafted to align with their nutritional requirements and health aspirations. This strategy is designed not only to facilitate effective blood sugar regulation but also to encourage sustainable dietary practices that yield long-term health advantages. Each meal plan specifies an optimal nutrient distribution, comprising approximately 50% carbohydrates, 30% fats, and 20% proteins, ensuring that individuals with T2D receive balanced nutrition. Furthermore, the program included concepts such as grainless meals and intermittent fasting, adhering to a 12- or 14-hours of fasting window. By establishing precise, attainable interventions and goals customized for each participant, the initiative aims to enhance compliance and achieve the most favourable results.

Fitness plans:

The SDRMP features carefully constructed physical activity plans based on personal preferences. These plans are tailored to accommodate each participant's fitness level and any preexisting health issues, promoting the integration of consistent exercise into their diabetes management strategy. The program offers a diverse range of activities, including cardiovascular workouts, strength training, resistance exercises, yoga, daily live classes, and one-on-one coaching sessions via the app. Participants can also benefit from meditation and mindfulness practices, including yoga nidra, to support both physical and mental well-being. By merging these customized exercise regimens with nutritional counseling and emotional support, the SDRMP promotes a comprehensive approach to diabetes care, enabling individuals to realize their long-term wellness objectives.

Emotional wellness sessions:

Upon enrolling in the SDRMP, participants underwent a Diabetes Distress Scale (DDS) assessment to evaluate their diabetes-related distress levels. Based on the assessment outcomes, those identified with high levels of distress were offered tailored psychological consultations. Meanwhile, participants with moderate and lower distress levels received support from health coaches, who were trained by psychologists to provide guidance on stress management, along with personalized nutrition and fitness plans.

The virtual psychological consultations, designed to address the emotional challenges linked to managing T2D, involved a 60-minute one-on-one session, focusing on delivering tailored assistance and coping strategies to improve key clinical indicators such as HbA1c, fasting blood sugar (FBS), and weight, while promoting overall well-being. The psychological consultations also aimed to complement the physical aspects of diabetes management by reducing stress, fostering program adherence, and encouraging healthy lifestyle changes. To further support participants, health coaches received specialized training from psychologists to enhance their ability to provide integrated care. This ensured that participants remained motivated, engaged, and on track toward achieving sustainable health improvements and optimal glycemic control throughout their journey in the program.

By focusing on individual needs and providing continuous support, the program aimed to facilitate sustainable health improvements and optimal glycemic control in participants with type 2 diabetes.

Integration of Technological Solutions in the SDRMP

During the initial phase of SDRMP, each participant is provided with a Continuous Glucose Monitoring (CGM) sensor, which is subcutaneously placed on the back of the arm for 14 days. This sophisticated sensor, equipped with an ultrathin filament, connects to a transmitter that wirelessly relays glucose data to the SugarFit app, developed by **Ragus Healthcare Private Limited** in India. Participants are guided to scan the sensor periodically, enabling effortless, real-time monitoring of their glucose levels throughout the day.

The CGM system effectively measures glucose in the interstitial fluid, yielding valuable insights into glycemic trends, which can be visualized directly within the SugarFit app. These visual representations help individuals grasp their glucose fluctuations. Moreover, specialized coaches associated with SugarFit interpret this data and collaborate with users in shared decision-making to enhance their health outcomes. The app also generates personalized scores based on various categories, including metabolic health, food intake, sleep, and fitness, providing a comprehensive overview of glycemic variability and nocturnal glucose patterns.

Once the CGM monitoring period concludes, the SugarFit app continues to support users by encouraging them to track their progress and set personalized goals tailored to their profiles. Participants have the ability to log their food intake, and sleep patterns while monitoring their total calorie consumption against daily requirements. Additional features of the app include video calls with health coaches and physicians, unlimited chat support, live fitness classes, recorded DIY sessions, and personalized recipe recommendations from health coaches.

To further bolster adherence to the program, community engagement is fostered through weekly challenges and activities, aimed at keeping participants motivated. The app also provides access to over 800 blogs that cover a wide range of topics related to diabetes management, ensuring comprehensive support for individuals throughout their journey.

5. Results

The study's results provide a comprehensive overview of the impact of the SDRMP on various clinical parameters over 3 months. These findings highlight the program's effectiveness in reducing HbA1c, FBS, and weight in participants with T2D.

Cohort Demographics

The demographic characteristics of the study participants are summarised in **Table 1** as depicted below. The demographic data indicate that participants had an average age of 49 ± 11 years and an average height of 167.8 ± 8.7 cm. The improvements in glycemic parameters alongside reduction in weight, suggest that the SDRMP not only aids in diabetes management but also promotes healthier body composition among individuals with type 2 diabetes.

Participants			
Demographic variable	Cohorts		
Number of Participants	2590		
Gender (Male/Female)	1918/672		
Age (Years)	49±11		
Height (cm)	167.8±8.7		

Assessment of Improvements in Clinical Parameters

The clinical parameters observed in this study provide insight into the health status and progress of participants across different distress levels.

Reduction in HbA1c Level

The clinical parameter assessment revealed notable improvements in glycemic control among SDRMP participants over the 3-month period. The average HbA1c levels declined from $9.8\pm1.4\%$ at baseline (Q₀) to $7.8\pm1.3\%$ at the 3-month follow-up (Q₁), marking a mean reduction of 2.0% which indicates consistent outcomes across participants as depicted in **Table 2 and Figure 1**.

 Table 2: Overview of Glycemic Control Based on HbA1c

 Paduation

Reduction			
Parameter	Q ₀ (Baseline)	Q1 (3-Month Follow-Up)	Change (Q0-Q1)
HbA1c (%)	9.8±1.4	7.8±1.3	2

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This significant decrease demonstrates the program's effectiveness in enhancing long-term glucose management within the cohort.

Reduction in FBS Level

FBS levels also exhibited a significant drop, decreasing from an average of $183.7\pm59.9 \text{ mg/dL}$ at Q_0 to $134.6\pm45.9 \text{ mg/dL}$ at Q_1 , which represents a mean reduction of 49.1 mg/dL as depicted in **Table 3 and Figure 2**.

Table 3: Overview of Glycemic Control Based on FBS

Reduction			
Parameter	Q ₀ (Baseline)	Q1 (3-Month	Change
		Follow-Up)	(Q_0-Q_1)
FBS (mg/dL)	183.7±59.9	134.6±45.9	49.1

Figure 1: Graphical representation of reduction in HbA1c



Figure 2: Graphical Representation of Reduction in FBS

This remarkable improvement highlights the program's efficacy in reducing acute hyperglycemia, a critical component of effective diabetes management. The observed reduction in FBS levels can be attributed to the personalized dietary and lifestyle interventions implemented in the program.

Reduction in Weight

Alongside improvements in glycemic control, participants experienced a decrease in body weight, with average weight dropping from 75.7 kg at Q_0 to 73.4 kg at Q_1 , signifying a

mean weight loss of 2.3 kg as provided in **Table 4**. This weight reduction is crucial, as it correlates with the observed improvements in glycemic parameters, emphasizing the relationship between weight management and diabetes outcomes.

Table 4: Overview of Reduction in weight

			U
Parameter	Q ₀ (Baseline)	Q1 (3-Month Follow-Up)	Change (Q ₀ -Q ₁)
Weight (Kg)	75.7±13.4	73.4±13.1	2.3



Figure 3: Graphical Representation of Reduction in Weight

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The results from this clinical parameter assessment emphasize the substantial impact of the SDRMP in enhancing glycemic control and supporting weight reduction for 3month duration. The significant decreases in HbA1c and FBS levels, along with effective weight loss, reinforce the program's potential to aid in diabetes reversal and improve overall metabolic health. These findings highlight the importance of comprehensive lifestyle interventions in diabetes management and the promotion of long-term health benefits for participants.

Statistical Analysis

The data analysis utilized robust statistical techniques to assess the impact of the SDRMP on various clinical outcomes in participants diagnosed with T2D. Key parameters of interest included HbA1c, FBS, and weight. Descriptive statistics, specifically means and standard deviations, were calculated for both the baseline values and the outcomes measured after a 90-day intervention period, offering a comprehensive overview of the observed changes in clinical parameters.

To determine the statistical significance of the changes observed in health outcomes (including HbA1c, FBS, and weight), Paired t-test (or Wilcoxon signed-rank test for nonnormal distributions) was conducted. This analysis aimed to ascertain whether the differences noted in clinical outcomes post-intervention were statistically meaningful. The significant results are summarized in **Table 5**.

 Table 5: Representation of Statistical Significance of clinical Parameters (HbA1c, FBS, and weight) in participants with T2D

participants with 12D			
Parameters	p-value		
HbA1c	p < 0.001		
FBS	p < 0.001		
Weight	p < 0.001		

The findings from the statistical analysis indicated highly significant p-values for all examined parameters: HbA1c (p <0.001), FBS (p <0.001), and weight (p <0.001). These results provide compelling statistical evidence that the changes witnessed in these clinical indicators were not random, but rather indicative of substantive adjustments in participants' health following the SDRMP intervention. The threshold of p <0.001 reinforces the reliability of these results, suggesting that the interventions effectively enhanced glycemic control and contributed to better weight management outcomes.

Specifically for HbA1c, the p-value of < 0.001 reflects a significant reduction over the study duration, underlining its critical role as a marker of long-term blood glucose control. This data strongly supports the efficacy of the program in aiding participants with their diabetes management. The statistical significance underscores the reliability of the improvements in HbA1c as meaningful rather than incidental.

Moreover, the observed p-value of <0.001 for FBS highlights a significant decrease in fasting blood sugar levels among the participants. Given that FBS serves as a vital indicator for short-term blood sugar regulation, this improvement is crucial for mitigating the risks associated with acute hyperglycemia. The strong statistical evidence suggests the intervention played a critical role in stabilizing these blood sugar levels, which is fundamental in diabetes management.

Furthermore, the weight reduction observed within the study also revealed a significant p-value of < 0.001. As weight management is intricately linked to insulin sensitivity and overall diabetes control, such a marked decrease signifies that the SDRMP not only promotes better blood sugar regulation but could also diminish the likelihood of associated complications like cardiovascular disease and obesity-related issues.

Finally, the remarkably significant p-values identified for HbA1c, FBS, and weight showcase the tangible impact of the SDRMP intervention. These results strongly affirm the program's effectiveness in fostering improved glycemic control and facilitating weight management among participants, thus contributing positively to their overall health trajectory.

6. Discussion

The results of this study provide compelling evidence for the efficacy of the SDRMP in achieving significant reductions in HbA1c levels among participants diagnosed with T2D. The holistic methodology program's integrates dietary modifications, increased physical activity, and continuous health monitoring while placing significant emphasis on participant's mental well-being. This comprehensive approach has led to remarkable 2% reductions in HbA1c along with reductions in FBS and body weight. Notably, the SDRMP achieved an impressive 2% reduction in HbA1c within 3 months, highlighting its superiority over conventional diabetes management techniques while ensuring that participants receive the emotional support necessary for successful long-term diabetes management.

Conventionally, achieving meaningful reductions in HbA1c within a three-month timeframe has proven to be a formidable challenge. Existing literature highlights the difficulties associated with this goal, especially when treatments rely solely on traditional protocols as depicted in Table 6. For instance, research by Monnier et al. (2003) highlighted the significant role of postprandial glucose (PPG) in overall HbA1c levels, noting that typical short-term interventions often inadequately address PPG, thereby hindering substantial HbA1c reductions. Similar standpoints were echoed by the UKPDS Study Group (1998), which documented a modest 0.5-0.9% reduction in HbA1c over six months, even with intensive medication management. Likewise, Gaede et al. (2008) reported an average reduction in HbA1c by only 1%, necessitating over a year of sustained intervention to achieve that outcome.

Furthermore, studies by Noah Wayne et al. (2023) revealed that health coaching, with or without mobile phone monitoring support, led to an average HbA1c reduction of 0.8% after six months. Similarly, research by Tanu-udom Maneesing et al. (2023) indicated that dietary interventions, such as general nutrition counseling (GCN) and portioned meal boxes (PMB), resulted in HbA1c reductions in a range of 0.76% to 0.87% after 12 weeks. However, these short-term

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deemed insufficient for achieving approaches were substantial decreases in HbA1c levels. This cumulative evidence underscores the ongoing challenges in effectively

managing HbA1c levels, particularly when standard interventions are employed.

	Table	b: Daily Management and Challenges	in Reducing HDATC in	various Studies
Study type	Author (s)	Challenges in HbA1c Reduction	HbA1c Reduction (%)	Daily Management during the Study Period
Clinical Study	Monnier et al.	Postprandial glucose plays a significant role in HbA1c. Short-term interventions do not sufficiently lower PPG, making rapid HbA1c reduction difficult.	2-3% reduction in PPG leads to 0.4-0.5% HbA1c reduction over 3 months	Daily monitoring of PPG through continuous glucose monitoring (CGM), adjustment in carbohydrate intake after meals
Longitudinal Trial	UKPDS Study [28]	Intensive blood glucose control using medications (e.g., insulin or sulfonylureas) takes longer than 3 months to show significant reductions in HbA1c	0.5-0.9% reduction in HbA1c over 6 months	Daily medication adjustments (sulfonylureas/insulin), frequent monitoring of blood glucose, adherence to dietary recommendations
Randomized Control Trial	Gaede et al. ^[29]	Lifestyle interventions (diet and exercise) take time to show significant HbA1c reduction, usually more than 3 months	1.0% reduction after 12 months.	Daily physical activity and adherence to a structured low-glycemic diet, regular consultations with health coaches
Observational Study	Barnard et al.	Dietary changes can improve postprandial glucose, but these changes are not enough to significantly reduce HbA1c in 3 months	0.4-0.6% HbA1c reduction after 3 months.	Daily tracking of dietary intake, focused on plant-based meals, and monitoring of postprandial glucose with periodic fasting glucose checks
Randomized Control Trial	Noah Wayne et al. ^[31]	Health coaching with or without mobile phone monitoring support along with usual care control group	0.8% HbA1c reduction after 6 months.	Intervention groups accessed with a mobile phone-based self-management system that enabled users to track blood glucose, diet, physical activity, and personal goals.
Randomized, parallel intervention Trial	Tanu-udom Maneesing et al. ^[32]	Dietary interventions like general nutrition counseling (GCN) and portioned meal boxes (PMB) reduce HbA1c levels, but short-term approaches are insufficient for substantial decreases.	0.76% to 0.87% of reduction in HbA1c after 12 weeks	Participants tracked their food intake and exercise routines; regular check-ins by health coaches ensured accountability. Additionally, users reported decreased energy, carbohydrate, and fat intake compared to baseline.

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In contrast, the SDRMP has demonstrated a unique capability to overcome these challenges through its comprehensive and personalized approach. By integrating lifestyle modifications with continuous monitoring and behavioral support, the program effectively enhances insulin sensitivity and promotes better glucose uptake by muscle, fat, and liver cells. This effect can be attributed to restoring normal insulin signaling, which is often impaired in individuals with T2D due to insulin resistance. The ability to rapidly lower HbA1c not only reflects improved short-term glycemic control but also significantly reduces the risk of microvascular complications associated with T2D, such as retinopathy, nephropathy, and neuropathy.

In contrast, the SDRMP effectively surmounts these traditional hurdles through its multifaceted and individualized approach. By seamlessly combining lifestyle alterations with ongoing monitoring, regular sessions with health coaches, and periodic consultations with doctors, the program ensures continuous, personalized support. This frequent engagement allows for real-time adjustments and expert guidance, significantly enhancing insulin sensitivity. As a result, the participants experience notable reductions in body weight and HbA1c levels, leading to improved metabolic health. These improvements are driven by the restoration of normal insulin signaling, often impaired in individuals with T2D due to insulin resistance, which further promotes effective glucose absorption and utilization, helping to maintain lower blood sugar levels. This swift improvement in glycemic control not only aids in short-term management but also reduces the T2D

risks, including microvascular complications (e.g. retinopathy, nephropathy, and neuropathy).

Furthermore, the program places a dual emphasis on both weight management and mental health support, recognizing the importance of addressing diabetes-related distress through psychological consultations to enhance overall well-being and diabetes management. Excess body fat is intricately associated with metabolic dysfunctions that worsen T2D. Consequently, weight loss facilitated by the SDRMP plays a critical role in improving insulin sensitivity and decreasing the accumulation of HbA1c levels. Research indicates that even modest reductions in body weight can yield notable improvements in glycemic control, thereby affirming the biological relevance of the results observed in the program.

Another pivotal aspect of the SDRMP is its focus on participant's education concerning diabetes management and glycemic control, which empowers the individuals with vital self-management skills about their conditions. This education encompasses the significance of a self-monitoring of blood glucose (SMBG) protocol for tracking blood sugar levels, along with education on meal sequencing and selection of low glycemic index (GI) foods, which can greatly improve glycemic control. Additionally, the program underscores the importance of post-meal exercises to aid in lowering blood glucose levels, while understanding hyperglycemia and the glycation process further reinforces the need to maintain stable blood sugar levels to prevent long-term complications.

An innovative feature of the SDRMP is its personalized approach that acknowledges individual variations in metabolism, lifestyle, and genetic factors. Traditional diabetes care often employs a uniform approach; however, the personalized interventions offered by SDRMP specifically target individual needs associated with insulin resistance and symptom manifestation. This tailored methodology is vital as it addresses the various underlying factors, such as obesity and inactivity, that contribute to the exacerbation of T2D.

In summary, the striking reductions in HbA1c, FBS and weight are attributable to not only dietary and activity changes but also pivotal shifts within metabolic mechanisms. Moving forward, it is essential for diabetes management programs to prioritize continuous education, personalized strategies, and ongoing support, thus reducing the likelihood of reverting to previous unhealthy habits.

7. Conclusion

The SDRMP provides a robust framework for achieving significant improvements in HbA1c levels among individuals with T2D within a concise 3-month period. This study underscores not only the program's effectiveness in lowering HbA1c but also its associated health benefits, including weight reduction and advancements in dietary and physical activity practices. By emphasizing personalized lifestyle modifications, continuous health monitoring, and a comprehensive understanding of the metabolic underpinnings of diabetes, the SDRMP presents an innovative and practical approach to managing the complexities of T2D. In addition, the program's dedicated support for mental health, including targeted interventions to reduce diabetes distress, ensures participants receive holistic care that addresses both the physical and emotional challenges of managing their condition.

The findings from this research highlight the potential of holistic intervention strategies in reversing the detrimental impacts of type 2 diabetes, ultimately paving the way for enhanced long-term health outcomes and improved quality of life for affected individuals. Future research efforts should aim to assess the sustainability of the benefits observed through the SDRMP and explore its applicability across diverse populations, ensuring broad access to effective diabetes management solutions.

8. Limitations

- Limited Duration of Intervention: The three-month period may be insufficient for participants to fully adapt to new dietary and exercise habits, making it difficult to sustain initial reductions in HbA1c levels long-term.
- Individual Variability in Response: Variations in baseline health, genetics, and psychological factors can lead to differing responses among participants, resulting in substantial differences in HbA1c reduction and weight reduction and impacting the program's overall effectiveness.
- **Program Duration and Challenges in Sustaining Lifestyle Modifications:** A three-month program may be brief to effectively assess the integration of new healthy routines and habits. Extending the program duration to 6-

9 months can enhance adherence to lifestyle changes, resulting in sustainable reductions in key health parameters. Continuous support during this period is crucial for ingraining positive behaviors, which ultimately leads to better long-term outcomes in glycemic control and overall health.

Conflict of Interest

The authors declare that there are no conflicts of interest regarding the content of this article.

Approval from Ethics Committee

Due to the retrospective nature of this study, formal approval from an ethics committee was not required. Nevertheless, electronic consent was secured from all participants involved in the research.

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