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Research Article

A Retrospective Evaluation of the Combined Effectiveness of using a Coach Led, Technology Enabled, Habit based Approach, with Precise Nutrition, Progressive Fitness and Behavioral Interventions on Improving Glycemic Levels and reducing hba1c Levels in Adults with Type-2 Diabetes

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ABSTRACT

Background: Type - 2 Diabetes is a chronic progressive lifestyle condition that has emerged as one of the most rapidly growing health challenges of the 21st-century. But until quite recently it was believed that Diabetes is irreversible and a lifelong affliction. There have been several trials and studies published on the effectiveness of bariatric surgery, intensive glucose-lowering pharmacotherapy and aggressive insulin therapy in improving glycemic control and achieving remission of type 2 diabetes. However, there aren't many studies about Type 2 diabetic individuals being able to sustain this remission in the long term without depending on medications.

This manuscript reviews the use of multifaceted and holistic interventions personalized for each participant and delivered one-on-one by diabetes coaches and educators over 90 days of the study, and its effectiveness in reducing glycemic levels, body weight and their overall quality of life.

Methods: A total of 32 participants matching the ADA specified criteria for type 2 diabetes diagnosis (HbA1c of 6.5% or over) were enrolled into the 3-month Sugar. Fit programed through a self-signup process. The study aimed to retrospectively evaluate the Sugar. Fit approach; a selection of lifestyle interventions, education and self-monitoring with or without involvement of pharmacological therapy. The manuscript focuses on evaluating the combined impact of the approach on HbA1c, fasting glucose, body weight and quality of life post 90 days from enrolment.

Results: The findings on completion of the study showed that the Sugar. Fit approach led to significant improvements in glycemic control with 67.8% of the users normalizing their Fasting Blood Sugar Levels, average reduction in HbA1c by 1.5 points and an average weight loss of 4.2 kgs in overweight participants over a 90 day period.

Conclusion: Personalized diet, fitness and mental wellness interventions, along with educating and motivating an individual to make small changes to their routines resulted in a significantly improving both clinical and emotional parameters. It also shows the direct relationship between intervention adherence and outcomes, thus highlighting the potential of non-pharmacologic interventions in influencing positive clinical outcomes.

Keywords: Diabetes; Diabetes reversal; Precision nutrition; Progressive fitness; Habit approach; Behavior modification; Lifestyle interventions

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INTRODUCTION

Type 2 Diabetes believed to be an incurable chronic disease has emerged as being one of the most rapidly growing healthcare challenges of the 21st-century. Based on traditional means of treatment, it was believed that Diabetes is irreversible and a lifelong affliction. Post-remission follow-up studies, also indicate that a majority of participants who achieved remission through intensive medical and surgical interventions had to resort back to taking medication and required continuous treatment in order to maintain their glycemic targets. Although there are research studies that show reversal is possible through other means, its inclusion into standard guidelines have only happened in recent times.

The 2021 Standards of Medical Care, by the American Diabetes Association (ADA) places strong emphasis on lifestyle management, calling it the cornerstone of treatment for people with diabetes, and individualized evidence based diet and exercise recommendations have better outcomes [1].

STUDY OBJECTIVES

General

- Identify distinctive components and aspects of an individual's life that influence outcomes of Type 2 diabetes management.
- Target the identified components and aspects using relevant approaches and personalized interventions to achieve improved glycaemic levels and reduction in HbA1c levels.

Specific

- To assess the extent of the impact of each component in achieving the defined primary and secondary outcomes of the study.
- To assess the extent of the impact of adherence levels on glycaemic control.
- To assess the impact of one-on-one interaction with a health coach on adherence percentage/glycaemic control.

STUDY DESIGN

Recruitment

The 3 month long observational study was done retrospectively to evaluate the Sugar.Fit approach which comprised a selection of lifestyle interventions, pharmacological therapy, education, self-monitoring and its combined impact on Hemoglobin A1c (HbA1c), fasting glucose normalization, body weight goals and improved quality of life post 90 days from enrolment. Based on a self-signup process, a curated group of 32 adult participants with a diagnosis of T2 Diabetes were enrolled into the 3-month Sugar. Fit pilot programme.

Respondents met the inclusion criteria if they matched ADA specified criteria for type 2 diabetes diagnoses (HbA1c of 6.5% or over) and were able to commit 3 months study duration. Respondents having an HbA1c level>14 with existing diabetic complications or comorbidities that may require extensive tertiary support, or preclude them from following the dietary plan given were not included in the study.

Out of the 32 participants enrolled in the diabetic cohort of the Sugar. Fit program, 28 participants finished the programme, three participants (M=2, F=1) did not complete the programme and one participant passed away before the 90 day follow-up could be done. The final study sample included 61% males and 39% females; with an average age of 49 years. (M=48, F=51)

Baseline measurements

Following recruitment, participants were enrolled into the programed and assigned their own personal health coaches. Post-enrolment, a comprehensive assessment was done and baseline metrics were collected for metabolic and anthropometric/health characteristics like Body weight, height and waist measurements. This was correlated with current clinical condition, dietary habits, and preferences, level of physical activity, emotional state, personal interest, motivation, support system and willingness to engage in successfully completing the programme.

All measurements were recorded after training the participant to follow a standardized process of taking them; like for e.g. "Body weight to be measured by the participant wearing light indoor clothing and without shoes using a digital scale. Both height and weight were measured to the nearest 0.1 cm and Body Mass Index (BMI) and waist: height ratio was calculated.

Current dietary intake was assessed using three 24-h dietary recalls (2 weekdays and 1 weekend day) participants were asked to report all the medications being used (name of drug, frequency of use and dose). Current physical state was assessed, categorizing users based on activity levels of their lifestyles.

Comprehensive at home diagnostic testing was done comprising 70+ parameters including HbA1c, FBS, Renal and Liver Function Tests, Lipids, TSH and Vitamin Profiles, CBC, Urine Routine and more. Glucose monitoring devices (both flash and self-monitoring) were home delivered to all the participants to facilitate blood glucose monitoring and glycemic control.

They were given a Continuous Glucose Monitoring (CGM) sensor for the first 2 weeks from enrolment (Days 1-14) and a strips and lancets for Self-Monitoring of Blood Glucose, starting post CGM and for the remainder of the pilot programme. (Days 15-90).

The CGM sensor was installed in Week 1 by a trained health technician, who also visited the participants thereafter to collect the flash readings tri-weekly for that 2 week period. All participants were assigned a personal Diabetes expert educator comprising Specialist Doctors and, registered Nutritionists and Health Coaches. A one-hour long consultation with the health coach was scheduled for every week, apart from which the users were also given unlimited and unencumbered access to their coaches for the entire program duration of 90 days.

This was followed by a collaborative exercise, where participants were educated on the long term target of glycemic control and the individual-specific core components unique to them that impact it. This exercise enabled the entrants to get involved,

make important health decisions, by including and taking their preferences and choices into consideration, while setting the primary and secondary goals and its corresponding interventions.

All of the above measurements were tabulated as baseline values for each participant and categorized based on gender and age (Table 1).

Table 1: Study baseline characteristics.

Variable	Total cohort	Men	Women	<50 years	>=50 years
Demographic and anthropometric variables					
Participants	32	62.5% (n=20)	37.5% (n=12)	18	14
Age (avg in years)	48.5	48.2	49	36.7	60.3
Weight (avg in kgs)	76.09	75	77.8	78.1	73.3
Body mass index (avg in kg/m^2)	27.5	25.5	30.7	27	27.9
Waist circumference (avg in cms)	95.1	90	102.3	98.7	93.1
Metabolic health variables					
Hba1c (avg in %)	8.30%	8.40%	8%	8.30%	8.30%
Fbs (avg in mg/dl)	153.6	162.3	134	148	161
Pharmacotherapy variables					
Percent (%) on insulin	21.9% (n=7)	20% (n=4)	25% (n=3)	20% (n=4)	25% (n=3)
Percent (%) on ohas	56.3% (n=18)	66.7% (n=12)	33.3% (n=6)	50% (n=9)	50% (n=9)
Percent (%) on other medicines	43.8% (n=14)	78.6% (n=11)	21.4% (n=3)	64.3% (n=9)	35.7% (n=5)

METHODOLOGY

The Sugar fit Approach is a habit-based, science-backed set of interventions, incorporating elements of nutrition, fitness, mindfulness, behavioral science, emotional wellness and habit building, to create a personalized care plan with or without adjuvant pharmacotherapy, delivered by compassionate, motivating Health Coaches for the holistic management of Type 2 diabetes.

- Focused nutrition
- Progressive fitness
- Blood glucose monitoring (cgm & smbg)
- Medications (glycaemic control & comorbid risk prevention)
- Behavioural change
- Habit formation
- Mindfulness
- Quality sleep
- One-on-one guidance & holistic care
- Focused nutrition

The 2021 ADA Standards of Medical Care in Diabetes says that "A weight loss of 3% to 5% is the minimum amount of loss necessary for clinical benefit, A weight loss of 15% is the optimum amount to realize maximum reduction in HbA1c for people with type 2 diabetes and a 7% to 10% weight loss has been shown to prevent the conversion of pre-diabetes to type 2 diabetes". Each participant was assigned a personal health coach who worked with them to assess their nutritional needs and create a personalized balanced meal plan consistent with the individual's situation, lifestyle, resources and food preferences. In accordance with recommended best practices for diabetic nutrition, users were given interventions that subscribed to the tenets of Sugar fit philosophy as detailed in (Table 2).

Table 2: Tenets of nutritional interventions.

Choose	Minimize and restrict
Complex carbohydrates & non-starchy vegetables	Simple carbs
Nutrient-dense foods rich in vitamins, minerals and fibre.	Refined grains
Whole foods	Salt intake <5g/day
Keeping portion control	Processed foods
Timely eating	Added sugars

Table 3: Sample weekly weal plan.

Meal	Item 1	Item 2
8:30 am Breakfast	3 Idlis	2 Dosas
	1 bowl vegetable upma	1 bowl vegetable poha
	1-½ parathas	2 sandwiches
11:30 am Mid-Morning	120 g fruits	25 g nuts & seeds
1:30 pm Pre-Lunch	150 g raw salad	1 bowl vegetable soup
2:00 pm Lunch	120 g rice	2 rotis
	1 cup dal/sambhar	120 g sabzi/veggies
5:30 pm Evening Snack	250 g roasted makhana	250 g boiled groundnuts
7:30 pm Dinner	250 g dalia khichdi	2 moong dal cheela

Table 4: Focused nutritional interventions.

Meal times	Include	Replace or remove	Other
Before breakfast	2 egg whites	-	Have green leafy vegetables at least thrice a week Enjoy food by eating slowly and relishing every bite.
With breakfast	1 bowl sprouts	-	
Mid-morning	1 bowl fresh fruits topped with nuts and seeds in a 1:1 ratio	-	
Before lunch	1 bowl/250 g of raw vegetables like carrots or cucumber.	-	
For lunch	1 bowl or 250 g of raw vegetables like carrots or cucumber with lemon.	Replace 2 portions of grain with 1 grain portion and 1 bowl of raw salad with lemon.	Include superfoods like amla on a daily basis in late evening or early morning
Evening	Vegetable soup or smoothie in the evening at least thrice a week	-	
Dinner	1 bowl or 250 g of raw vegetables like carrots or cucumber with lemon.	Replace 25% of grains, cereals, starches with keep lentils 30% and vegetables 70%	Finish dinner before 8.30 or 9 pm

Progressive fitness

Type 2 diabetes mellitus (T2D) is characterized by insulin resistance, impaired glycogen synthesis, lipid accumulation, and impaired mitochondrial function. Emerging research suggests that resistance training (RT) has the power to combat metabolic dysfunction in patients with T2D and seems to be an effective measure to improve overall metabolic health and reduce

metabolic risk factors in diabetic patients [2]. The American Diabetes Association (ADA) recommends that individuals with Type 2 diabetes should perform moderate-intensity exercises for at least 150 mins or 2-½ hours in a week [3].

Although a lifestyle modification of this nature could have substantial impact on the metabolic and cardiovascular health of the individual, it is not the easiest thing to accomplish and depends on multiple variables that can act as barriers impeding an individual from being able to reach their goals. For individuals who are elderly or have morbid obesity, arthritis, physical disabilities, diabetes complications, even a 20–30 min walk may be challenging, uncomfortable, and painful to do.

This is quite likely to happen even in a young or middle-aged person, who has been habitually sedentary for a long time or undergoing any sort of emotional distress with dismal motivation levels (Table 3).

The Sugar fit philosophy believes that preparing an individual with diabetes for a safe and enjoyable exercise program is as important if not more as the exercise itself. Several studies have shown preliminary evidence for the beneficial effects of Progressive Resistance Exercise and hailed it as the most preferred fitness recommendation for people with diabetes. Gamified workouts improved adherence to fitness interventions It has not only been demonstrated to be safe and efficacious for the elderly and obese individuals, but also helps in improving insulin sensitivity, daily energy expenditure and quality of life by diminishing elevated blood glucose levels into the normal range [4]. Progressive resistance exercise (PRE) is a method of increasing the ability of one's muscles to generate force by gradually increasing the weight, frequency, or number of repetitions in the strength training routine, thus making your musculoskeletal system stronger (Table 4).

Muscle weakness, decreased muscle mass, and changes in skeletal muscle fibers are related to compromised glycaemic control in diabetes, possibly because of peripheral neuropathy and reduced vascular supply. Since the skeletal muscle is a large reservoir for glucose disposal in the body, exercise acts as a powerful stimulant of glucose uptake partly through the action of the skeletal muscle glucose transporter protein. Therefore, resistance exercise has a direct effect on skeletal muscle and is the most feasible option in the management of glycaemia in type 2 diabetes [5]. All participants were evaluated thoroughly with a focus on the signs and symptoms of micro and macro vascular complications or comorbidities affecting the heart and blood vessels, eyes, kidneys, and nervous system. By identifying areas of concern, a comprehensive fitness plan was designed to minimize risks specific to the user and ensure safe participation in all forms of physical activity consistent with the participant's desires and goals.

Young, middle-aged and able-bodied senior participants with impaired glucose tolerance, mild uncomplicated diabetes, showing acceptable adherence rates were given interventions of all levels of exercise, and personalized to include leisure activities, recreational sports, cycling, swimming or any other physical activities they prefer and more importantly enjoy doing.

Participants with a starting BMI of 23 kg/m^2 or higher were categorized as being overweight (23.0–24.9 kg/m^2) or obese (≥ 25.0 kg/m^2) and one of the goals being weight loss and reducing abdominal or belly fat in order to improve glycaemic values.

Abdominal obesity (belly fat) is a major driver in the development of diabetes and cardiovascular disease. Weight reduction, therefore, was a key therapeutic goal for participants falling under the categories of obesity and being overweight.

Studies show that even a loss of 5–10% of body weight can improve fitness, reduce HbA1c levels and improve cardiovascular disease (CVD) risk factors.

Additionally it can reduce your medications not just for diabetes, but also those used to lower hypertension and high cholesterol.

Participants in this group were given fitness plans that included a proper 5-6 mins of warm-up (arm/hip rotations or forward bends) and 3-4 mins of a cool-down period (basic back, quad, neck stretches). The main workout is between 30 to 60 minutes and aims at burning belly fat by combining strength training with any moderate-intensity level of physical activity like brisk, moderate-intensity walking, climbing stairs and Yoga Asanas.

Participants with limited or difficult mobility were given very low-intensity actions like free hand exercises, chair surya namaskars and encouraged to generally be physically active rather than sedentary. Obesity or being overweight leads to impaired glycogen synthesis and lipid accumulation that contributes to a decline in glucose uptake and the development of insulin resistance, arising from increases in intracellular lipid stores (Table 5).

Table 5: Progressive Fitness Interventions.

Start simple	Increase frequency	Increase intensity	Increase intensity& frequency	Reach target
Starta small walk for 15 minutes in the evening	Include 10 minutes of walk post all 3 major meals	Post meal brisk walks for 45 mins after all 3 major meals	Increase step count to 8000 per day	Push everyday step count to 10K+(at least twice/week)
	Add strength based exercise for 15 to 20 mins in a day thrice a week.	30-45 mins strength based trainings	Add abdominal leg raise exercises for aiming fat loss in the lower abdomen	
Include a strength routine in the evening		(2-3 times a week)		Add a small core workout (belly burn)

BLOOD GLUCOSE MONITORING

Using both flash monitoring and Self-monitoring methods to get crucial near real-time information on blood sugar highs and lows to make instantaneous and precise changes in nutrition, fitness and medications.

In order to map ambulatory continuous glucose profiling, all participants were provided with Glucose monitoring devices; a Freestyle Libre Pro Continuous Glucose Monitoring device for the first 2 weeks from enrolment (Days 1-14) and a Glucometer with strips and lancets for Self-Monitoring of Blood Glucose, starting post CGM and for the remainder of the pilot programme. (Days 15-90).

All participants were asked to log in their daily activities including details of food intake, physical exercise, sleep and medications into a Habit Tracker for further analysis by their personal diabetes experts; physician and coach. For the next 14 days, these daily readings were closely monitored for variations in blood glucose levels and its corresponding responses to the activities logged in by the user.

The daily engagement coupled with near real-time CGM insights made it possible for the experts to be more hands-on in crafting precision interventions, titrating medications and monitoring their progress.

Based on the trends and insights derived from the CGM, a comprehensive personalized treatment plan was created with well-defined goals and clear outcomes. After the 14 day CGM period, all 32 participants were advised to start blood sugar point profiling using the glucometer given (Table 6).

1-point, 2-point and 6-point profiling was advised for all participants based on various factors including baseline HbA1c levels, presence of comorbidities/complications and extent of progression (Table 7).

Table 6: Blood glucose monitoring intervention and interpretation.

SMBG check points		Conditional check
Point 1	Fasting or pre-breakfast	Before taking medications
Point 2	2 hours post-breakfast	After taking medications
Point 3	Pre-lunch	
Point 4	2 hours post-lunch	
Point 5	Pre-dinner	
Point 6	2 hours post-dinner	
Point 7	At dawn	

Table 7: Sample of SMBG profile recommended for 2-point check.

2-Point Check		
One week distribution	**Point 1**	**Point 2**
Day 1	Fasting	Post breakfast
Day 2	Pre-dinner	Post breakfast
Day 3	Pre-dinner	Post breakfast
Day 4	Pre-dinner	Post breakfast
Day 5	Pre-dinner	Post breakfast
Day 6	Pre-dinner	Post breakfast
Day 7	Pre-dinner	Post breakfast

MEDICATION ITERATION

Adherence to a prescribed treatment is an investment that provides significant positive returns through primary prevention of risk and secondary prevention of adverse health outcomes [6]. Pharmacological therapies were prescribed wherever needed to sustain glycemic control and reduce complications. The participants were counseled about the need for short-term compliance to medication in order to curb dependency in the long term.

BEHAVIOR CHANGE

Diabetes management is complex, demanding and very dynamic with changing medications, technologies and approaches. The only thing that can be considered a constant is behavior. For an individual with diabetes, there are several behaviors involved from getting a test, getting diagnosed with diabetes, starting treatment, changing to a new treatment, and dealing with aspects of their regular day-to-day life. A 2007 study highlighted that behavioral patterns were more robust contributors than type of healthcare, genetic influences and social factors [7]. Execution of the behavior or the lack thereof is the driving force behind health outcomes for people with diabetes [6]. While diabetes education is critical and necessary to build foundational knowledge, imparting knowledge alone is not sufficient to change or sustain behavioral changes. Many traditional methods used to teach or invoke behavior change tend to be ineffective as they are focused on a 'you should' approach rather than a collaborative one (Table 8 (a)).

There is still debate over how habits should be conceptualized and operationalized, but there is consensus that habits are acquired through incremental strengthening of the association between a situation (cue) and an action, i.e. repetition of behavior in a consistent context progressively increases the automaticity with which the behavior is performed [8].

Encouraging behavior change is highly dependent on the provider being able to convey information about the desired 'behavior change' and ensuring that the recommendations are at least heard and understood. Sugar fit providers were trained on tenets of clear communication with associated strategies to employ when interacting with the participant as outlined in (Table 8 (b)).

Table 8 (a): Communication tenets to facilitate behavior change: Conveying information.

Conveying information	Strategy employed by diabetes expert
Simplify messages	Avoiding the use of clinical/technical terms when educating the participant
Focus on one recommendation at a time	Starting small - giving tiny routines with small chunks of information, and then building on it over time to multiply outcomes.
Provide information in multiple formats	Conveying information in formats (e.g. Spoken, written, pictorial etc.) Based on the participant's preference, comprehension levels, in a language they can understand and through modes that are most accessible. (e.g., phone call, text message or whatsapp).
Understand if the planned interventions are meaningful and relevant to the individual's personal beliefs. (personal beliefs and meaningfulness)	Using motivational interviewing techniques to ask non- judgmental, open-ended questions about their experiences, views, expectations and beliefs. Link the interventions or advice being given to the health consequences the participant deems as relevant and beneficial.
Use relevant examples and comparators	Recommending behaviours tailored to suit the individual's age, gender, ethnicity and resources.
Assess the participant's comprehension and interpretation of information conveyed.	Using the 'teach me back' method Once the key information was conveyed, the participants were asked to repeat it back to see how much of it was absorbed.
Be compassionate and supportive.	Encouraging participants for behaviour change using an empathetic and supportive tone. Employing a collaborative approach to identify health and behaviour goals to increase the relevance and likelihood of implementation.
	Avoid shaming, guilt trips and scare tactics

Table 8 (b): Communication tenets to facilitate behavior change: Maintain c ommunication & sustain change.

Maintaining communication & sustaining behavior change	Strategy employed by diabetes expert
Pair the recommended behavior with a specific existing routine.	E.g. Blood glucose monitoring with morning and evening tooth brushing.
Identify supports	E.g. Family, friends, who can provide regular reinforcement when diabetes management behaviors are completed.
Identify upcoming events that can make or break the desired health behavior.	Upcoming Event /Wedding in the Family **Make:** E.g. Participant wanting to lose weight to fit into the dress to be color coordinated with her cousins. **Break:** E.g. Participant traveling for an out of town wedding with limited dietary options with 5 days of rich heavy catered food.

HABIT FORMATION

The Sugar fit patient-centric habit approach integrated diabetes education with counseling and behavior change strategies for a long lasting impact. The main objective of the approach was to provide an end-to- end program that will help people with type 2 diabetes live healthier, happier lives through the power of habit.

Each participant was assigned their own diabetes expert and health coach who utilized techniques and frameworks from cognitive and behavior al sciences to identify the multilevel influences that could be a barrier in carrying out the target 'behavior change'.

These barriers were personal and/or contextual including the participant's environment or immediate surroundings, extent of health literacy, past experiences, personal health beliefs, family structure and involvement, expectations, intentions, access to resources, psychosocial variables and more.

There are multiple variables that can influence an individual's behavior, but to be able to change or better it requires time, patience and holistic team-effort focused on problem solving.

The most important factors to optimize communication and embed behavior change were to start small and build on it over time. The Habit Loop (Figure 1) is a neurological loop that governs any habit. The habit loop consists of four laws of Behavior Change - Cue, Craving, Response and Reward. (Figure 2) Understanding these elements can help in understanding how to change badly habits or forms better ones [9].

Figure 1: The habit loop, adapted from "Atomic Habits" by James Clear.

The participant was made to feel included and engaged by involving them in every aspect of their management. First, the desired habit was identified and broken down bit by bit until it reached its simplest form.

This was then taken as an incremental goal on which the participant would have to build going forward. The four elements or laws of the habit loop were identified for each of the set goals to create specific step-by-step interventions to achieve it.

Some examples of the four components of the Habit Loop are as elaborated in (Table 9).

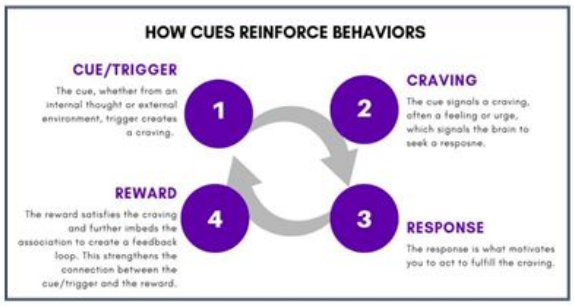

Figure 2: How cues reinforce behavior, adapted from "Atomic Habits" by James Clear.

Table 9: Interventions for behavior change and habit formation.

Interventions for behavior change and habit formation
Increase water intake by 500 ml
Take medications on time without skipping a dose
Check sugars at least thrice a week
Remember to have your glucometer handy at all times including at work and when travelling.
Reduce cigarettes to 1 a day - and then completely
Restrict Alcohol consumption to once a week - and then completely

MINDFULNESS

In recent times, there has been a surge in studies exploring and promoting mindfulness and its applied psychological interventions as an effective way to reduce stress and emotional distress associated with chronic conditions including Diabetes Mellitus.

Mindfulness can be defined as a heightened sense of present or centered self-awareness that fosters non-judgmental observations of emotions, bodily states and other sensations leading to holistic wellbeing [10].

This state of awareness can be enhanced through the use of mindfulness-based interventions (MBIs), which are preventive and complementary interventions in T2DM, particularly for the relief of symptoms related to depression, anxiety, diabetes-related distress and insomnia [11].

According the Bishop's Theory [12]. Two Components in the Mindfulness Model are:

- Self-regulation of attention to focus on immediate experience, allowing mental events to be recognized in the present moment.
- Orientation of experience towards the present moment, leading to openness, curiosity, and acceptance.

Addressing emotional eating is another important component of mindfulness and effective weight- management strategies. Some people turn to food as a response to emotions. Collaborating to identify coping strategies like meditation, yoga and mindful eating techniques supports their efforts to respond to emotions while eating a nutritious diet. Building a behavior change plan around past strategies and what is important to the individual is a way to set up each person for success [13].

Mindfulness-based interventions can successfully target negative perseverative cognitions such as worry and thought suppression and have positive effects on stress reduction, on the quality of sleep, anxiety, depression, and stress in people with type 2 diabetes. Meditation and mindfulness skills led to improved sleep, greater relaxation, and more-accepting approaches to illness and illness experience (Table 10).

QUALITY SLEEP

Sleep disturbance is a common health complaint affecting a lot of the general population.

Accumulated sleep deficiency can increase the risk for mood and anxiety disorders, cognitive impairment, and a variety of medical conditions, including cardiovascular disease and obesity [14] (Table 11).

The practice of Mindfulness, designed with a focus on sleep, provides an opportunity to create the mental space needed to allow sleep to come back where meditation is effectively combined with other strategies to change behaviors that might be causing poor sleep [15, 16].

Table 10: Interventions for mindfulness.

Interventions for mindfulness
Take up Journaling or Keep a Gratitude Journal and write down the good things that have happened in your day.
Practice Deep Breathing or meditation for at least 10 minutes a day
Take time and find pleasure in your food by eating slowly and savoring or relishing every bite.
Maintain discipline in your eating habits by having your meals consistently at the same time every day.
Make mealtimes a single task by itself, without any distractions. Do not multitask or do something else simultaneously when you're eating.
Make it a practice to eat at least one meal with your family every day.
Enjoy your meal sitting down at the family table or dining area instead of your study room or workplace while also using a laptop or taking phone calls.
Go outdoors to get some fresh air and bask in the sunlight for at least 15 minutes in a day. This will improve your mood, lift your spirits and have a positive effect on your overall wellbeing.
Keep a set time to log off from work, after which do not schedule any meetings or go back to checking emails.

Table 11: Interventions for quality sleep.

Interventions for quality sleep
Get at least 7 - 9 hours of uninterrupted sleep every night
Aim to sleep an hour earlier than usual time or before 11 pm; whichever is earlier.
Maintain sleep hygiene by being in bed before 11 pm at least 4 times in a week.
Keep yourself away from any and all screens (laptop, phone, TV) for at least 30 minutes before sleeping.
If you have difficulty in falling asleep, use these 30 minutes before bedtime to read a book or listen to sleep stories or guided yoga nidra recordings.
Have a cup of warm chamomile tea or soak your feet in warm water with salt for 5 mins before bedtime to ensure a good night's sleep.

Person-centric one-on-one guidance for holistic wellbeing

This approach acknowledges the person with diabetes as the center of the patient-centered team, involved in setting goals and developing interventions. Progress toward individual goals is measured at each visit, and goals are adjusted over time.

Addressing and sustaining positive behavior changes requires commitment, encouragement and ongoing support.

This can become a make or break factor since the amount of time a person with diabetes spends with his or her clinician may be limited and sometimes inadequate to discuss complex health issues at length and in depth.

The Sugar. Fit one-on-one guidance addressed this limitation by focusing on team-based care and a person- centered approach, through the Sugar. Fit health coach who is a diabetes care expert, qualified diabetes educator, registered clinical nutritionist and life counselor all rolled into one.

A high-engagement routine was established, assisted by technology to deliver one-on-one guidance and personalized interventions. Every participant was assigned a coach, to whom they had unlimited access on multiple modes like chat, whatsapp, audio and video calls through which they could easily reach out to the coach and vice-versa.

In return, the coach was also able to understand each participant at an individual level in order to target user-specific needs and behaviors.

Participants were given customized goals that reflected their individual situations, and counseled about the importance of committing to the programme and the inputs, approaches and timelines required to achieve these goals.

This daily high frequency interaction made sure those users' concerns or queries don't go unaddressed and helped the coach guide them through the 90 day program.

The team-care approach was further fortified by the clinician reinforcing the already set goals and encouraging them to keep at it.

This ongoing and collaborative relationship was a key factor in minimizing the chances of early non- adherence, poor insights and unreliable outcomes (Table 12).

Table 12: Coach participant communication rate.

Time period	Average chat exchange
0–4 weeks	50 per week
>4 weeks	28 per week

STUDY RESULTS

Primary outcomes

Reduction of hba1c: Primary outcomes include a reduction in HbA1c levels derived by calculating the difference in HbA1c values measured between start and 3 months. The overall reduction in HbA1c in 90 days for the 28 participants showed a difference of 1.46 points. (From 8.36 to 6.9 pts.)

Weight loss: Lifestyle modification has long been hailed as being the foundation of Weight Loss; greater the loss, greater the clinical improvement seen. Studies have shown that a weight loss of can reduce the incidence of diabetes by 58%. (Rubin RR, 2000). To determine the need for weight loss, all participants were categorized based on their BMI as per the WHO and Asian-Indian specific guidelines. Out of 28 participants, 20 were identified as falling under the category of obese or overweight and thus making weight loss one of the primary goals. From the other 8 participants, 3 participants were underweight and the BMI for the remaining 5 was seen to be normal. Among the 20 participants, 18 were identified as falling under the Obese category (BMI ≥ 25.0 kg/m^2) and the other 2 were Overweight (BMI 23.0–24.9 kg/m^2). The average weight loss for the group overall (n=20) was 2.4 kgs, with a drop of 1.04 points in HbA1c. For the obese category (n=18) the average weight loss was 2.2 kgs and showed an HbA1c dip of 1.12 points. The average weight loss in the overweight category (n=2) was 4.2 kgs, with a decrease of 0.25 points in Hba1c levels.

Normalization of fasting blood sugar: 67.8% of the programed users were able to normalize their Fasting Blood Sugar Levels.

SECONDARY OUTCOMES

Adherence to interventions

One participant passed away before the end of the programme and 3 participants were non-compliant with the profiling advice. Hence 4 out of 32 did not have any or significant adherence to check their sugar levels at any point during the programme. The other 28 participants were given 6-point (35.7%;n=10), 5-point (14.3%;n=4), 3-point (25%;n=7) and 1 point (25%;n=7) checks; for which adherence levels were as below (Table 13).

Table 13: SMBG count adherence.

Points	Count	Adherence %	Men	Women	<50	>50
6-point	10	46.20%	6	4	8	2
5-point	4	33.75%	4	0	4	0
3-point	7	75%	2	5	3	3
1-point	7	53.50%	3	4	7	1

It was observed that Women participants had higher adherence levels of 66.4% across all point profiles when compared to Men participants who had an overall adherence of 39.2%.

Participants aged 50 years and over had a higher adherence percentage at 73.1% when compared to participants aged less than 50 years and over who showed 44.7%

A total of 530 interventions were given across all 28 participants in the 90 days duration of the study. These interventions were bucketed under 6 categories - Nutrition, Fitness, Habits, Sleep Hygiene, Mindfulness and Medications.

Adherence to interventions were bucketed under 4 levels based on compliance into Very Low (<25%), Low (<=25 to 49%), Intermediate (50 to 74%) and High (>=75%); with each of them assigned an appropriate weightage (Table 14).

Table 14: Adherence categories.

Levels	Adherence break-up	Weight age
High	>=75%	4
Intermediate	50 to 74%	3
Low	<=25 to 49%	2
Very Low	<25%	1

Out of the total interventions across 6 categories, the two categories with the highest number of interventions given were Diet and Nutrition at (n=269), followed by Fitness and Exercise interventions at (n=114). A small part namely (n=77) of Interventions were given for building good habits and breaking unwanted ones. The distribution of the remaining three categories were Sleep Hygiene (n=37), Mindfulness (n=23) and Medications (n=8).

Table 15: Intervention categories.

Category	Interventions count	Adherence score
Nutrition	51%	64.2%
Fitness	21.6%	55.9%
Habits	14.6%	59.1%
Sleep hygiene	7%	60.8%
Mindfulness	4.4%	49%
Medications	1.5%	59.4%

The average adherence score across all interventions was 58.1%, which shows an Intermediate level of adherence for interventions given during the study (Table 15).

Overall adherence levels across the 28 participants showed 43% of the participants having Intermediate levels of adherence, while 28.6% had Low and 18% of participants showed High levels of compliance to the interventions given. A small percentage of 10.4% participants fell under the category of Very Low where they showed minimal to no compliance for most interventions.

While 5 out of 28 participants showed high levels of adherence in at least one of the six intervention categories. The participant with the maximum reduction in HbA1c, showed a pattern of high to intermediate adherence to nutritional interventions, and intermediate adherence to the given fitness interventions.

Quality of life survey

Quality of life has been defined by WHO as an individual's perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. 'Quality of life' evaluation has emerged as an important outcome measure for chronic disease management. Even in Type 2 Diabetes, studies have shown that psychosocial factors not only have an important impact on self-care, acceptance of therapeutic regimens and treatment success.

But are also stronger predictors of critical outcomes like hospitalization & death when compared to standard clinical determinants like body mass index or hemoglobin A1C levels. [17]. Hence, the management model for diabetes includes strategies to identify and enhance patient's health- related quality of life issues that have the potential to improve compliance and hence their metabolic status. There are several standardized quality of life questionnaires that are validated and available for use including WHO- BREF, 1 SF-36 (Short Form- 36 questionnaire), 15 DQLCTQ (Diabetes Quality of Life Clinical Trial Questionnaire), 16 ADD QoL (Audit of Diabetes Dependent Quality of Life), 17 and DQOL (Diabetes Quality of Life) 18 to measure the impact of different components affecting an individual with diabetes based on their ethnicity, culture, education, income, etc.

However, most of these questionnaires have been developed in western population, 2-5 which are socially, culturally and economically different from Indian participants. For this study, we chose an instrument that was developed and validated in India using standard methodology that functioned as a reliable, valid and sensitive tool for the assessment of diabetes specific quality of life in Indian subjects [18]. Quality of Life Instrument for Indian Diabetes Patients (QOLID). The QOLID consolidates both qualitative and quantitative aspects to offer a holistic insight on potential factors influencing clinical outcomes and patient's perception of their diabetes-dependent quality of life. The questionnaire has 33 questions and 8 dimensions measuring General Health, Emotional & Mental Health, Treatment Satisfaction, Diet Satisfaction, Financial Worries, Bothersome Symptoms, Physical Health Limitation, and Physical Endurance [19].

A total of 20 participants took the QOLID questionnaire at the start of the Sugar. Fit programme, of which 19 participants retook the assessment upon finishing the programme 90 days later. One participant passed away before the 90 day follow-up could be done.

The final no. of participants for the QOLID questionnaire comprised 73.6% males and 26.3% females. (M=14, F=5). The mean age of participants taking the survey was 49, and 52.6% were over the age of 50 years (M=5, F=5).

At baseline: Overall, participants who were aged > 50 years, female subjects, taking insulin, obesity and presence of complications correlated with a lower baseline QOL than their counterparts.

In participants with comorbidities, QOL was poorer when compared to those without comorbidities, and those who used insulin had a lower QOL than those who did not use insulin. 26% (n=5) of the participants who took the survey were on insulin at the start of the programme

Participants who were obese and overweight (n=12) had a poorer baseline QOL of 78.3% in comparison with those having normal body mass index (n=6) which was 81.8%.

At 90+ days: The most significant improvement was seen across three domains - Treatment Satisfaction, Physical Health Limitation and Emotional & Mental Health, all equally improved by 9% from baseline.

Participants had a noteworthy shift when it came to 'satisfaction' about management At baseline, the scores portrayed uncertainty, low confidence, poor prioritization, high levels of dissatisfaction due to limitations, restrictions and more.

The Sugar fit approach targeted these weak spots using dietary interventions effective to normalize glycaemic levels and also provide satiety and culinary delight to the individual. Fitness interventions that started small, easy, progressive and built slowly into a sizable plan with achievable timeframes (Table 16).

The participants now had a routine they followed which was disciplined, achievable and most importantly showing glycemic changes, reducing medication dependency and boosting their self-confidence and improving their emotional states. Limitation caused by the requirement to adhere to an eating & medication schedule, DM limiting your social life, Satisfied with the time you spend exercising (24%) Moderate improvement of 3-7% from baseline was seen in the domains - General Health (7%), Physical Endurance (6%) and Diet Satisfaction (3%). There was minimal to no change from baseline for the domains - Bothersome Symptoms (0.3%), Financial Worries (0%).

Table 16: Quality of life scores.

QOL domain	QOL scores	
	Baseline	**Final**
Physical health limitation	82%	91%
Physical endurance	86%	92%
General health	73%	80%
Treatment satisfaction	74%	83%
Bothersome symptoms	78%	78.3%
Financial worries	76%	76%
Emotional & mental health	75%	84%
Diet satisfaction	71%	70%
Overall qol	77%	82%

CONCLUSION

In summary, we propose that the Sugar fit programmer's use of multifaceted and holistic interventions, focusing on team care and a person-centric approach led to significant improvements in glycemic control, lipid profile, and anthropometric measurements sustained over three months.

The study results demonstrated that one component alone did not account for the effect, but rather, several components worked together to produce the effect, lending strong support for the multicomponent approach and for the underlying mechanism of multiple risk factor reduction. Although we see that more interventions received by the patients, the better the response, these results cannot be called obvious or predictable. It is still likely that one component might have driven most of the effect, or that effectiveness might have been demonstrated only with complete adherence, rather than a graded response across adherence levels. Users who were engaged in active communication with their coaches were more efficacious in achieving reduction in HbA1c, than those who connected sparingly. Although both groups showed reductions, only the former was associated with significant reductions in HbA1c levels. Therefore, T2DM patients should be stimulated to

participate and engage in specifically designed intervention programs.

Adherence played an important independent role in the effectiveness of a non-pharmacologic, lifestyle oriented multicomponent intervention strategy. Some strengths of the study include the personalization of the diet plan to be culturally acceptable, clear, easy to follow, portion appropriated but having adequate nutrient intake and most importantly achieving satiation levels that helped improve diet adherence leading to better outcomes.

The detailed daily tracking of adherence by the coach for each intervention protocol, the daily assessment and comprehensive patient-related data on severity of illness, comorbidity, and other potential confounding variables are some of the other aspects of the study that influenced and led to positive outcomes. The study also had some limitations like participants not completing measures for outcomes including A1C and other anthropometric measurements, at the end of the intervention programed and three months post enrolment. There are various reasons for participants not completing the end of programed appointments such as taking holidays, lack of time, conflict with travel and lack of motivation or interest. Another factor is that the study did not include a control group and participants were self-selected volunteers, which may have affected overall motivation.

This missing data from 14% of participants limited our ability to analyze changes in weight, waist measurements, self-monitoring adherence etc. as a potential confounder. It was observed that participants with the highest weight loss (3 kgs) showed the least reduction in Hba1c levels (0.25 points). The relationship of HbA1c and weight persisted even after controlling for other baseline factors like severity of illness, comorbidities and complications.

However, increased levels of adherence to interventions were associated with higher dips in HbA1c levels. Hence, the degree of adherence correlated with the effectiveness of the protocol. Higher levels of adherence to medications and diet plans resulted in reduced rates of glycaemic incidents and improved glycemic levels. Our study demonstrates this direct relationship between adherence and outcome, lending strong support for the potential of multiple non-pharmacologic interventions in influencing important medical outcomes, and the effectiveness of which is critically dependent on the level of adherence.

Our results hold substantial implications and show that adherence to non-pharmacologic intervention strategies are equally necessary as they are to those involving only medications. Studies on non- pharmacological and non-invasive methods to treat and manage Type 2 Diabetes are few and far apart, but have a huge scope for new innovations and breakthroughs in in the near future. More work is needed to examine this further and this study may inspire more research on the factors influencing adherence, and strategies to improve the same with non-pharmacologic intervention protocols.

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