

# To Correlate our Proprietary Metabolic Score with Clinical Biomarkers of Metabolic Health: Metabolic Insights from Glucose Variability, Time in Range and Average Glucose Scores

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Running Title: Ateeb et al Decoding Metabolic Health with Metabolic Score Insights

**Abstract:** *The study delves into the correlation between Actofit's Metabolic Score and clinical biomarkers of metabolic health in individuals with diabetes. This Metabolic Score draws from metrics like glucose variability, average glucose, and time in target. Notably, a strong positive correlation emerges between the Metabolic Score and the Quality of Life Instrument for Indian Diabetes Patients (QOLID) score, both before and after treatment. These findings suggest that elevated Metabolic Scores align with improved quality of life. This research accentuates Actofit's potential in prognosticating metabolic health, steering behavioral shifts, and guiding individualized interventions. These discoveries foster more precise health evaluations and the formulation of efficacious health strategies. The pursuit and sustenance of metabolic health hold pivotal importance for holistic well - being. This article deeply delves into the significance of diverse metrics in appraising metabolic health. The spotlight is cast on parameters such as glucose variability, spikes, crashes, and average glucose values. These aspects wield a critical influence on diabetes management and broader health consequences. Glucose variability, which mirrors oscillations in daily glucose levels, is intertwined with oxidative stress and plausible health hazards. Excessive glucose spikes, surpassing recommended thresholds, can trigger metabolic irregularities and hasten aging processes. Conversely, glucose crashes signify episodes of hypoglycemia. The article accentuates the significance of upholding an optimal average glucose score and maximizing time spent within the targeted glucose range. Furthermore, the article introduces the electronic HbA1C (eHbA1C) as a valuable instrument for real - time evaluation of glucose control. Proficiency in understanding these metrics empowers individuals to judiciously navigate decisions that optimize their metabolic well - being.*

**Keywords:** Actofit, Metabolic Score, clinical biomarkers, metabolic health, diabetes, glucose variability, average glucose, time in target, Quality of Life Instrument for Indian Diabetes Patients (QOLID), behavior change, personalized interventions, health assessments, diabetes management, glucose response, physical activity, personalized health interventions, metabolic health, glucose variability, glucose spikes, glucose crashes, average glucose score.

## 1. Introduction

Metabolism is the process by which the body converts all that food and drinks you consume into energy. Metabolic health, on the other hand, is described as having ideal levels of blood sugar, triglycerides, high - density lipoprotein (HDL) cholesterol, blood pressure, and waist circumference, without using medication. Gaining a perspective on your well - being through the lens of metabolic health makes for a sustainable approach. One of the easiest methods of measuring your metabolic health is by calculating your metabolic score through the CGM device<sup>1-2</sup>.

Managing diabetes can be a complex and challenging task. In addition to monitoring blood glucose levels, healthcare providers also use various metrics to assess long - term glucose control and to make treatment decisions. One of the most commonly used metrics is hemoglobin A1C (HbA1C), which provides an average glucose level over a period of

several months. However, recent research has shown that glucose variability and time in range are also important factors in diabetes management. Glucose variability refers to the fluctuations in glucose levels throughout the day, while time in range reflects the amount of time spent within a target glucose range. These metrics provide additional insights into glucose control and can help patients and healthcare providers make more informed decisions about diabetes management. In this context, electronic HbA1C (eHbA1C) has emerged as a useful tool for tracking long - term glucose control, glucose variability and time in range, as it provides a continuous and real - time picture of glucose control that can be used to personalize treatment plans. In this article, we will explore the importance of eHbA1C, glucose variability and time in range in diabetes management and their potential impact on patient outcomes<sup>3-5</sup>.

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**Decoding the metabolic score<sup>5-7</sup>**

A metabolic score is an indicator of overall metabolic health. It is calculated on the basis of glucose variability, average glucose as well as time in target metrics and ranges from 0 - 100.

Your score gets activated within an hour of scanning and applying the sensor and it can slightly vary in the first 24 hours of usage as the sensor calibrates with your body.

The scores get reset to 100 at midnight and based on your activities such as exercise, eating, stress, sleep and your body's response to these activities - your score increases or decreases accordingly through the day.

The goal is to obtain a maximum score and the key is to maintain glucose levels within the recommended range of 70 - 100 mg/dl.

Key Factors that drive the Metabolic Score

**1) Glucose Variability**

Glucose Variability can be defined as the fluctuations in your glucose levels throughout the day. It is important to maintain a low glucose variability, ideally below 12% to ensure there is less oxidative stress on your body.

Oxidative stress paves the way for cellular damage in the body and causes neurodegenerative diseases, cancer, hypertension and more.

Maintaining stable glucose levels can help one maintain improved energy levels and cognitive performance throughout the day. Research has identified glucose variability as a predictor of hypoglycemia and has been found to be related to intensive care unit mortality in non-diabetic individuals.

Blood glucose levels change throughout the day. It is the degree of fluctuation in glucose that determines a good score.

**2) Glucose Spikes**

When blood glucose levels rise beyond the upper limit range, glucose spikes can occur.

Glucose spikes beyond 120 mg/dl can cause hyperglycemic events in the body. Frequent hyperglycemia can eventually lead to metabolic dysfunction. Studies have shown that high blood glucose variability can accelerate the process of aging.

Glucose spikes can also occur during exercise however these are considered healthy. During intense exercise bouts gluconeogenesis can occur due to the breakdown of muscle protein – especially during the absence of carbohydrates.

Hyperglycemia can prevent healing, elevate the risk of infections, heart attacks and strokes and cause irreversible damage to the nerves, blood vessels and organs such as eyes and kidneys and increase the risk of heart attacks and strokes.

Postprandial or post - meal blood sugar levels exceeding the ideal range can lead to prediabetes or diabetes.

**3) Glucose Crashes**

A drop in blood glucose levels in the body is referred to as hypoglycemia. During such an episode, there is excess production of insulin in the body, causing the cells to absorb more blood glucose than is required to maintain the optimal level. It is marked by a blood glucose level below 70 milligrams per deciliter (mg/dL). Some symptoms include tiredness, shakiness, anxiety, sweating, hunger, irritability, fast heartbeat, pale skin, hunger etc.

**4) Average Glucose Score**

Another parameter which is measured by Ultrahuman M1 and which we need to optimize is our HbA1c levels also known as glycated haemoglobin.

It is a measure of your average blood glucose level over the last 2 - 3 months, since red blood cells live for an average of 3 months, glycated haemoglobin reflects sugar exposure to the cells over a similar time range.

HbA1c is made when the glucose in your body sticks to your red blood cells. It accumulates over time and melds with your blood when your cells can't absorb the sugar well.

According to the American Diabetes Association, the normal range of HbA1c is between 4% to 5.6%. A range of 5.7% to 6.4% could indicate that you are pre-diabetic and susceptible to diabetes, in which case you should consult a doctor. 6.5% or higher indicates that you may have diabetes and should visit a doctor for consultation.

BIOS uses average glucose data points to calculate your estimated HbA1c. The average glucose is calculated from the point of scanning the sensor till midnight at 12: 00 am.

So if you scan your sensor at 1: 00 pm, your average glucose levels will be the average of all glucose levels from 12: 00 AM to 1: 00 PM on the same day. The ideal recommended range is 70 - 140 mg/dl.

**5) Time in Target Range**

The ideal range of glucose levels is 70 - 110 mg/dl. The goal is to stay within the target score for as long as possible to maximize your score which will improve your cognitive ability through the day. The time in the target range is the metric that measures the amount of time your blood glucose is within the recommended range.

This metric is measured as a percentage. The lower the percentage is the lower the fluctuation out of the target range, the better your score. You should aim to keep this below 12% to reduce the amount of oxidative stress on the body. Oxidative stress disrupts the necessary oxidation process that takes place in the body. It occurs when there is an imbalance between free radical activity and antioxidant activity. These free radicals are required to fight off pathogens, which can cause infections in the body.

The HbA1c test does not account for hypoglycemia (low blood sugar levels) and therefore time in target remains an important metric in measuring your metabolic score.

## 2. Methodology

Methodology to correlate our proprietary Metabolic Score with clinical biomarkers of metabolic health

- **Study Design:** A randomized observational comparative study was conducted
- **Participants:** 132 Participants were recruited for the study, 76 for BIOS with at least 3 months of continuous glucose monitoring, 56 in Monotherapy with standard diabetic management
- **Data Collection:** In the interventional group, 76 BIOS Participants completed a QOLID questionnaire, a baseline assessment, which includes a CGM with Deep Glucose Insights, and then be monitored for 3 months. During this time, participants will provide blood glucose levels, and track their food intake using the data - driven behavioral tool Metabolic Score.
- **Masking:** To maintain the blinding of participants, their CGM records were de - identified.
- **Selection Criteria:**

Type - 2 Diabetes

The study followed (ADA) criteria  $HbA1c \geq 6.5\%$

Age Group 20 - 45

Individuals looking for Lifestyle Changes

Exclusion Criteria:

Type - 1 Diabetes

Chronic Metabolic Disorders

Age Group >18 and <45

### BIOS

The BIOS program is a personalized intervention program aimed at managing Type 2 diabetes in a holistic manner. The program combines technology - enabled medical management with dedicated coach - led support and expert advice from diabetes specialists and nutritionists and performance coaches. The program begins with recruitment, where 132 participants undergo, a baseline assessment with HbA1C Levels, 76 diabetics were enrolled in BIOS intervention and 56 were in the Monotherapy control group.

Each participant is then assigned a personal team of diabetes specialists, nutritionists, and fitness coaches who provide customized nutrition plans, progressive fitness programs, and behavioral modification support. Participants have unlimited access to their coaches through an app and via telephone and can receive on - demand doctor consultations for the duration of the program. The program will be monitored and evaluated regularly to assess its effectiveness in improving eHbA1c levels, and promoting weight loss and improved overall health. Data collected during the program will be analyzed to assess the impact of the intervention on participants. Overall, the BIOS program offers a unique and comprehensive approach to managing Type 2 diabetes, combining technology, expert guidance, and coach - led support for a personalized and effective intervention.

### Quality of Life Instrument for Indian Diabetes Patients (QOLID) <sup>8</sup>

(Questionnaire in Annexure)

The Quality of Life Instrument for Indian Diabetes Patients (QOLID) is a self - reported questionnaire that measures the quality of life of individuals with diabetes in India. The QOLID consists of 33 items that assess four domains of quality of life, including physical, psychological, social, and disease - related factors. The physical domain includes items related to physical symptoms, functional status, and energy levels. The psychological domain includes items related to anxiety, depression, and emotional well - being. The social domain includes items related to social support, social functioning, and interpersonal relationships. The disease - related domain includes items related to diabetes - specific concerns, such as blood glucose monitoring, medication adherence, and diabetes - related complications.

### CGM <sup>9-13</sup>

A continuous glucose monitor (CGM) is a wearable biosensor that can give you real - time information about your blood sugar (glucose) level. This information is vital to people with Type 1 or Type 2 diabetes, for whom high or low blood sugar can be life - threatening. But CGMs are also valuable for people without metabolic impairment, serving as a window onto how diet and lifestyle decisions affect their health. Consistently high glucose levels or frequent glucose spikes and crashes can lead to short - term health effects like fatigue, brain fog, and depression and are associated with several chronic diseases, including cancer, cognitive decline, stroke, and cardiovascular disease. CGM can help you maintain stable glucose levels before metabolic dysfunction like insulin resistance (prediabetes) sets in and sets the stage for more severe disease.

A continuous glucose monitor is a plastic disc (about the size of two quarters stacked together) that sticks to the skin, typically on the stomach or upper arm. It sends glucose data continuously (at least every 5 minutes) to a smartphone or handheld device, where the user can see it on a graph or chart. People who have Type 1 diabetes sometimes have their CGM connected to an insulin pump that can automatically deliver insulin if their blood sugar gets too high. Most CGMs last anywhere from 7 - 14 days before they need to be removed and replaced.

There are three primary manufacturers of CGMs in the US: Abbott, which makes the FreeStyle Libre monitor; which makes the Guardian system.

**Metabolic score** is the overall rating given to your daily blood sugar pattern. It is an indicator of your overall metabolic health and depends on three factors – glucose variability, average glucose and time in target score. The metabolic score ranges from 0 to 100 and it resets itself every midnight to 100. Based on your lifestyle – food and beverages consumed, daily activities, stress levels, quality of sleep and your body's unique response, the score increases or decreases daily. The goal is to maximize this score every day.

Metabolic score is calculated based on three metrics - glucose variability, average glucose, and time in target score. Glucose variability is calculated using the coefficient of variability, obtained by dividing the standard glucose deviation value over the mean glucose value multiplied by 100. The ideal glucose variability is less than 12% and indicates good metabolic health. Average glucose is calculated from all glucose points in a given day, and an average glucose range of 70 - 100 mg/dL is considered ideal. Time in target score measures the percentage of time in which blood glucose is within the target range of 70 - 110 mg/dL, with a higher percentage indicating better metabolic health.

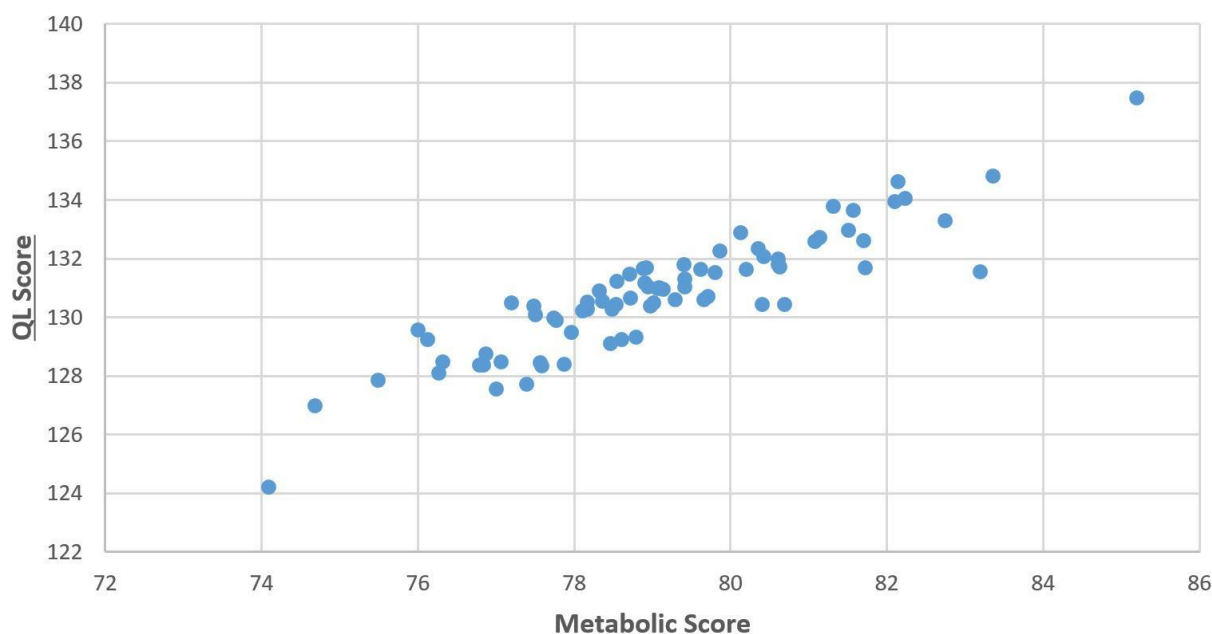
regularly. Eating food with a lower glycemic response can also help stabilize average glucose levels. In case glucose levels fall below the target range, having a light snack can help bring them back up. Conversely, if glucose levels exceed the target range, taking a walk can help lower them.

The metabolic score ranges from 0 to 100 and resets every midnight to 100. The goal is to maximize this score every day by adopting healthy habits that stabilize glucose levels. The HbA1c test is used to determine average glucose levels over a period of 2 - 3 months and can indicate pre - diabetes or diabetes. However, it does not account for hypoglycemia, which is accounted for by time in target score.

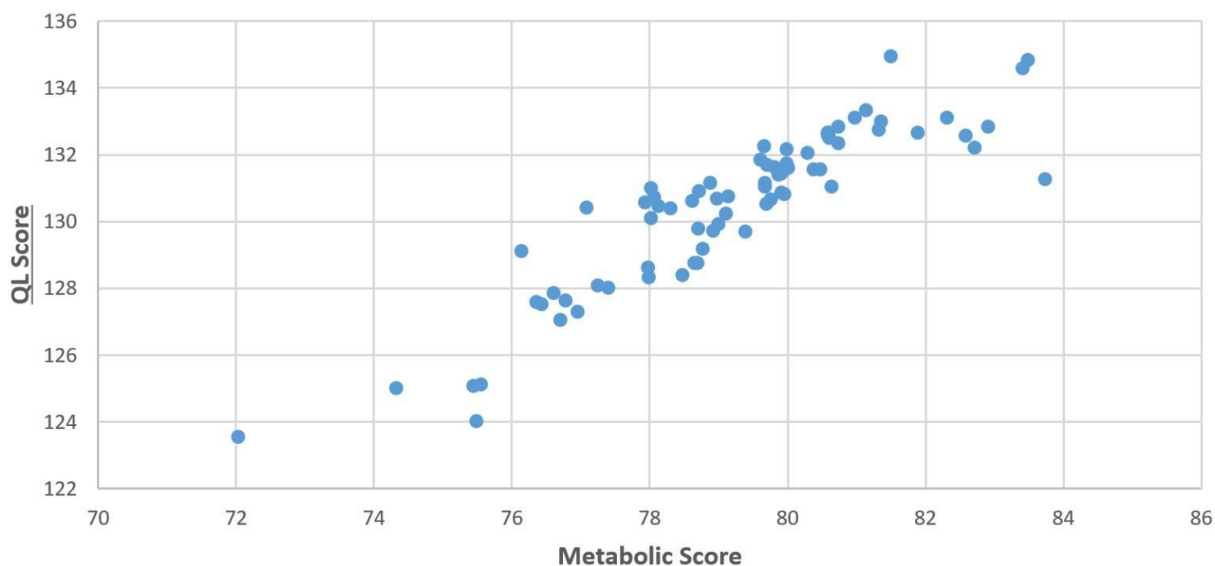
To improve metabolic score, it is recommended to consume a balanced diet, get quality sleep, reduce stress, and exercise

### 3. Results

#### Pre Treatment (Study Group of 76 Subject on Bios Plan )



#### Post Treatment (Study Group of 76 Subject on Bios Plan )





**Interpretation: Metabolic score** is positively correlated with **QOLID** score with Pearson product - moment correlation coefficient  $r = 0.900$  in case of pre - treatment and post - treatment is 0.9038 in the study group

#### 4. Discussion

The study findings indicate a strong positive correlation between BIOS score and QOLID score, with Pearson product - moment correlation coefficient  $r = 0.900$  in the pre - treatment stage and  $r = 0.9038$  in the post - treatment stage in the study group.

In this case, BIOS score and QOLID score are the two variables under consideration. The correlation coefficient ranges from - 1 to 1, where - 1 indicates a perfect negative correlation, 0 indicates no correlation, and 1 indicates a perfect positive correlation.

The results of this study suggest a strong positive relationship between BIOS score and QOLID score, indicating that as the BIOS score increases, the QOLID score also increases. This finding suggests that patients with higher BIOS scores are likely to have better quality of life after treatment.

Moreover, the study shows that the correlation coefficient remains high even after treatment, indicating that the positive relationship between BIOS score and QOLID score is consistent both before and after treatment. This finding suggests that the treatment provided to patients did not significantly alter the relationship between BIOS score and QOLID score.

Overall, these findings provide important insights into the relationship between BIOS score and QOLID score, and suggest that clinicians should pay close attention to BIOS scores when evaluating patient outcomes. The strong positive correlation between these two measures indicates that improvements in BIOS scores are likely to lead to improvements in QOLID scores, and thus a better quality of life for patients.

The results of this study provided valuable insights into the relationship between clinical biomarkers of metabolic health and Actofit's Metabolic Score. The study established the validity of Actofit's Health Score algorithm in predicting metabolic health and its effectiveness in driving behavior change. Additionally, the study shed light on the impact of physical activity and food on glucose levels and provided insights into the relationship between glucose response and other factors such as sleep and stress.

The findings of this study were likely to have significant implications for the development of personalized health interventions. By establishing the relationship between various clinical biomarkers of metabolic health and Actofit's Metabolic Score, the study contributed to the development of more accurate and comprehensive health assessments. The findings also informed the design of personalized health interventions that leverage the Actofit platform to promote behavior change and improve metabolic health.

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**Annexure**

**Final Qolid Questionnaire**

**Instruction**

The following assessment asks how you feel about the impact of diabetes on your quality of life. Your response will help us find ways for improving diabetes care. If you are unsure about which response to give to a question, please choose the one that appears to be the most appropriate. We would request you to attempt to answer all questions. However the choice or decision to not to answer a particular question is entirely yours. You can always seek the help of the interviewer in case there is any confusion regarding the meaning of some questions or choice.

**Role Limitation Due to Physical Health**

1) How often do you miss your work because of your diabetes?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

2) A person with diabetes has the requirement of adhering to a schedule for eating and taking regular medication. How often does this affect your work?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

3) How often does diabetes affect your efficiency at work?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

4) How often do you find diabetes limiting your social life?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

5) To what extent do you avoid traveling (business tour, holiday, general outings) because of your diabetes?

A lot	Highly	Little	Very little	Not at all
1	2	3	4	5

6) Compared to others of your age are your social activities (visiting friends/partying) limited because of your diabetes?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

**Physical Endurance**

An important part of understanding your general health and well being has to do with your ability to perform various activities.

Thus for the following questions please indicate if your health has limited your activities in following areas in the past three months. Please tick any one option.

1) How often in last three months has your overall health problems limited the kind of vigorous activities you can do like lifting heavy bags/objects, running, skipping, jumping.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

2) How often in last three months has your overall health problems limited the kind of moderate activities you can do like moving a table, carrying groceries or utensils.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

3) How often in last three months has your overall health problems limited you from walking uphill or climbing 1 - 2 floors.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

4) How often in last three months has your overall health problems limited you from walking 1 - 2 km at a stretch.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

5) How often in last three months has your overall health problems limited you from bending, squatting, or turning.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

6) How often in last three months has your overall health problems limited you from eating, dressing, bathing, or using the toilet.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

**General Health**

1) In general would you say your health

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

2) How well are you able to concentrate in everything like working, driving, reading etc?

Not at all	A little	Moderate	Very much	An extreme amount
1	2	3	4	5

3) How many times in the past three months have you had fatigue/felt very tired?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

**Treatment Satisfaction**

The following set of questions would enable us to know how satisfied are you with your treatment for diabetes. Please tick any one option.

1) How satisfied are you with your current diabetes treatment?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

2) How satisfied are you with amount of time it takes to manage your diabetes?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

3) How satisfied are you with the amount of time you spend getting regular checkups (once in 3 months)?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

4) A person with diabetes needs to exercise for 35 - 45 min, 4 times a week. Keeping this in mind how satisfied are you with the time you spend exercising?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

**Symptom Botherness**

1) How many times in the past three months have you had thirst/dry mouth?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

2) How many times in the past three months have you felt excessive hunger?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

3) How many times in the past three months have you had frequent urination related to diabetes management?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

**Financial Worries**

The following set of questions will help us know how your diabetes has affected your or your family's finances. Please tick any one option!

1) What do you think about the cost involved in your management of diabetes?

Very expensive	little expensive	reasonable	not at all expensive
1	2	3	4

2) To what extent has your priority of expenditure shifted towards diabetes management?

A lot	Highly	Little	Very little	Not at all
1	2	3	4	5

3) To what extent has your family budget got affected by the expenses related to the management of diabetes?

A lot	Highly	Little	Very little	Not at all
1	2	3	4	5

4) To what extent has your diabetes limited your expenditure on other aspects of life (Movies, outings, parties etc)?

A lot	Highly	Little	Very little	Not at all
1	2	3	4	5

**Emotional/Mental Health**

1) How satisfied are you with yourself?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

2) How satisfied are you with your personal relationships (family, friends, relatives and known tos)

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

3) How satisfied are you with the emotional support you get from your friends and family?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

- 4) How often are you discouraged by your health problems?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

- 5) All people want to fulfill certain roles and lead their lives in a purposeful manner. To what extent do you feel that you have been able to lead your life in the same way?

Not at all	A little	Moderate	Very much	An extreme amount
1	2	3	4	5

**Diet Satisfaction**

Diabetes demands a little modification in diet, thus the following set of questions would help us know how much satisfied you are with modifications in your diet. (For participants who have been advised some dietary modification/counseling).

- 1) How often do you feel because of your diabetes a restriction in choosing your food when eating out?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

- 2) As you have diabetes, how much choice do you feel you have in eating your meals or snacks away from home e. g. if you go in a party and there is a buffet where there are also a lot of fried snacks and desserts would you be able to make enough choice?

No choice	Very little	little	enough	A lot
1	2	3	4	5

- 3) How often do you eat the food items that you shouldn't, in order to hide the fact that you are having diabetes.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5