

# Outcomes of a digital intervention focusing on wearable technology and lifestyle modifications on persons with diabetes

A pilot study

**Dr Usha Sriram**

Voluntary Health Services (VHS)  
Chennai, India  
drushasriram@gmail.com

**Dr Dianna Henry Selvaraj**

Securra Health  
Chennai, India  
dianna@securrahealth.com

**Dr Jagdish Devarajan**

Securra Health  
Chennai, India  
Jagdish.devarajan@securrahealth.com

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**Abstract-** This study aims to evaluate the effectiveness of adopting a digital approach to manage diabetes. Especially during these COVID times, when physical visits are challenging, digital interventions have gained popularity. However, there are not many studies which establish the advantages of this intervention. The aim of this pilot is to evaluate the quantitative and qualitative outcomes of using digital therapeutic interventions that use wearables and focus on lifestyle modifications on persons with diabetes. The pilot program was conducted by Securra Health Global Technologies, based in Siruseri, India and was designed by Dr Usha Sriram, a leading endocrinologist and diabetologist in India. Twenty-six participants received 'Diabetes Kits' that comprised of FDA approved, pre-calibrated, remote patient monitoring devices. These devices were connected to the Securra Health program smart phone app via Bluetooth. Interventions included 12 weeks of remote patient monitoring, periodic tele-consultations, personalised diet charts, push-notifications, quick check questions, digitalised health report, synced lab reports, etc. These interventions were aimed to increase adherence to the program and improve outcomes. 69% of the participants who were actively engaged with the program touchpoints had reduced HbA1c levels at the end of the program. There was a 0.4% increase in the reduction of HbA1c levels for those who completed the 12 weeks duration of the program. Overall adherence and acceptance of the program was high- at 62% and the ratio of men: women who participated was 1:3. 82% of the participants recorded blood glucose levels at least 3 times a day and the remote monitoring devices were widely accepted in general. This pilot therefore laid the foundation for further research on digital interventions by proving to have successful outcomes.

**Index Terms—** REMOTE PATIENT MONITORING, DIGITAL THERAPEUTICS, DIABETES MELLITUS, TELE-CONSULTATION, WEARABLES, HEALTH TECHNOLOGY

## Introduction

Diabetes Mellitus [DM] refers to an endocrine disorder, caused due to an abnormality in glucose metabolism. Owing to an impairment in insulin secretion by the pancreas or the action of insulin, a state of chronic hyperglycemia exists. [1] Long term effects of increase in the blood sugar levels include disturbances in the metabolism of fat, protein, and carbohydrates. [2] An amalgamation of all these above-mentioned disturbances in the body functions may lead to impairment, loss, or failure of organs such as the heart, blood vessels, nerves, eyes, and kidneys. [3]

## Classification of diabetes mellitus:

Predominantly, diabetes mellitus can be classified into two based on the need for insulin supplementation.

*Type 1 diabetes mellitus [T1DM] or juvenile onset diabetes mellitus or insulin dependent diabetes mellitus:*

This is caused mainly due to auto-immune dysfunction or destruction of the beta cells in the pancreas, leading to insulin deficiency. [1]

*Type 2 diabetes mellitus [T2DM] or adult-onset diabetes or non-insulin dependent diabetes mellitus:*

This is a more common variant in which there is defective insulin secretion, insulin resistance or a relative deficiency of insulin. [1]

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Apart from the types mentioned above, there are other diabetes classifications based on the etiologic origin. This includes gestational diabetes, genetic defects in insulin action, drug or chemical induced diabetes, infections, etc.

### **Epidemiology:**

Diabetes is the most prevalent endocrine disorder globally. In 2015, incidence of diabetes mellitus in those above 18 years of age was nearly 10%. 5-10% of these had type 1 diabetes while 90-95% of the cases had type 2 diabetes mellitus.

As of 2017, more than 6% of the world population was diagnosed with type 2 diabetes mellitus. Over 100 billion dollars is spent globally in treating diabetes and diabetes related complications.

Every year, diabetes claims at least one million lives either directly or indirectly. Over 40% of hospitalizations worldwide is directly or indirectly related to diabetes. It is one of the top ten reasons for mortality in the world. Both male and female genders are equally affected by diabetes and diabetes prevalence is rising rapidly in developed countries. [5, 6, 15]

By 2030, diabetes is estimated to affect more than 7000 individuals out of every 100,000 population, worldwide. Widespread increase in the diabetes cases in low-income countries, early onset of type 2 diabetes due to obesity and lack of physical activity and global increase in the diabetes related DALYs burden have led to desperate measures by public health organizations. [15, 16]

A vast number of undiagnosed persons with diabetes exist in developing countries due to the rapid change in diet and lifestyle habits and urbanization. The health systems in these countries have become incapable of keeping in pace with the increase in the need for screening and treatment.

According to the Indian national statistics by the International Diabetes Foundation Diabetes Atlas in India, there are over 77 million people with diabetes currently and over 1 lakh deaths attributed to diabetes annually. [16]

Keeping in mind the high healthcare costs, resource allocation needs, and availability of sub-specialty healthcare workers, the current system that primarily involves physical visits and conventional screening and treatment methods are not sustainable options. [5, 7]

### **Risk factors, symptoms, and complications:**

Common risk factors for diabetes include genetic predisposition, unhealthy dietary habits, lack of physical activity, social habits such as smoking of tobacco and consuming alcohol, improved glucagon activity, reduced sensitivity of  $\beta$  cells and hyperinsulinemia to name a few. [8]

Obesity is the major etiologic factor for around 90% of the those who develop type 2 diabetes mellitus. Dysregulation in the secretion of adipokines and resistins also contribute to the development of type 2 diabetes. Sleep apnea and sleep disorders that are commonly seen in obese individuals also lead to glucose sensitivity and insulin resistance.

A carbohydrate rich diet with high glycemic index and low fiber content also increases the risk of developing type 2 diabetes.

Apart from the above, certain medications like beta blockers, diuretics or immune suppressants, reactive nitrogen species [RNS], certain infections such as cytomegalovirus can also trigger diabetes. [8, 4]

The key clinical features of type 1 diabetes mellitus include loss of weight, increased urination [polyurea], increased thirst [polydipsia] and increased hunger [polyphagia].

Other symptoms of type 1 include general tiredness, cramping, digestive issues such as constipation, susceptibility to infections such as candidiasis and vision disturbances.

Chronic diabetes patients may be prone to microvascular and macrovascular complications such as retinopathy and coronary artery disease respectively. [4, 6]

Early stage of type 2 diabetes mellitus is commonly asymptomatic and hence the diagnosis is usually incidental during this stage. Warning signs however may include unexplained fatigue or loss of weight, dryness of mouth, repeated oral or genital infections, delayed wound healing, reactive hypoglycemia, vision disturbances, erectile dysfunction, etc. [8, 9]

Long standing diabetes leads to complications such as: Nephropathy, neuropathy, retinopathy, cataracts, impaired vision etc. Overall, complications can be classified broadly into micro-vascular and macro-vascular.

Production of ketone bodies in persons with diabetes increases the risk of keto-acidosis. Fournier's gangrene or gangrene in general are also more commonly seen in these individuals.

Furthermore, obstructive pancreatitis, atherosclerosis, hypertension and cardiovascular disorders, cognitive disorders and cancers are also shown to be of higher incidence in persons with diabetes. [4, 6, 8, 9]

### **Diagnosis and Treatment plans:**

The biochemical tests that are most commonly carried out globally are:

- **OGTT:** Oral glucose tolerance test – It is a measure of how capable the body cells are, in absorbing glucose, after orally consuming 75g of sugar, diluted with water.

Plasma glucose levels are then estimated after two hours. According to the American Diabetes Association [ADA], levels that are more than or equal to 200 mg/dL are considered as an indication of 'Diabetes'.

- **Fasting plasma glucose test:** A value of 126mg/dL is an indicator of diabetes according to the ADA.

- **HbA1c:** Glycosylated hemoglobin – This test is an estimate of the average blood glucose levels over two to three months prior to the test. The ADA suggests that a value between 5.7%-6.4% is indicative of pre-diabetes while a value higher than 6.5% is indicative of diabetes. [9, 10]

Apart from the above, tests such as random plasma glucose test and fructosamine tests are also done to diagnose diabetes.

Management of plasma glucose levels involves regular and continued follow-up visits with the healthcare provider. This is of utmost importance especially in avoiding long term complications of diabetes, improving disease adjusted life years [DALYs] and improving overall health status.

For those with type 1 diabetes, insulin therapy is the most commonly prescribed management plan. However, for type 2

diabetes, diet therapy to correct dietary habits, improvement of physical activity, reducing stress, improving sleep habits are also recommended management modalities in addition to oral hypoglycemic drugs and insulin in some cases. [11, 12]

### **Barriers in chronic care:**

The various barriers that are prevalent in the existing delivery of care pose challenges to optimal management of diabetes. These issues can be either based on the patient, the provider, or the health care system in itself.

#### ***Barriers based on patients include:***

**-Socio-economic factors:** Persons with diabetes who have a lower socio-economic status have been found to be less likely to visit a specialist, have medical insurance or focus on preventive care. Therefore, poorer glycemic control and diabetes related complications are more prevalent among this population. [29]

**-Health care costs:** The increasing costs of treatment or management modalities for diabetes in addition to the lack of universal medical insurance coverage in a country like India contributes to the exacerbation of problems related to diabetes management. Paying out of the pocket negatively influenced people's actions. For example, people with diabetes opted for blood tests less frequently when the costs of lab investigations are high, and they are paying from their pockets. [11, 29]

**-Education status:** Persons who had a poorer educational background had lesser chances of understanding the impact of poor glycemic control and its complications. Thereby, these people had lesser chances of seeking preventive care or adhering to their care plans. [6, 11, 29]

#### ***Barriers based on providers or health-care systems include:***

**-Accessibility of healthcare facilities:** Follow-up of diabetes requires regular physical visits to the healthcare facility. Accessibility of the facility thus plays a vital role in the completion of such visits. Low income, increased age, presence of mobility issues and absence of sufficient facilities in rural areas act as catalysts to the current challenges in chronic care. [11, 29]

**-Unavailability of health care personnel:** There is an apparent urban-rural divide in the availability of health care specialists. Only one third of the physicians practicing in rural areas are specialists. Therefore, more motivation and education tools are required to enable persons with diabetes to access the available healthcare. [29]

**-Preventive care:** Preventive care for those with diabetes is essential to ensure that the course and progression of the disease takes place in a controlled manner. The availability, awareness, and accessibility of preventive care especially in the rural population is limited and thus, primary, and secondary prevention of diabetes complications are a challenge. [5, 11, 29]

**-Physician attitude towards treating of diabetes:** A study of physician attitudes to treating diabetes concluded that primary care physicians considered diabetes to be more difficult to treat as compared to other chronic conditions. There was also a consensus that the guidelines available to treat diabetes was not very clear. Lack of support from the health care facility administration and also a hesitance of patients to adhere to

treatment plans are added hassles to existing challenges. All of these factors thereby impacted physicians treating persons with diabetes. [29]

### **Use of digital interventions in diabetes:**

As discussed previously, the high cost of healthcare, resource allocation needs, and availability of sub-specialty healthcare workers, coupled with a large population who require proper diabetes screening, and lack of education, awareness and motivation to come for physical visits or follow-ups contribute substantially to the diabetes surge and mismanagement globally. [5, 6, 11]

The need for alternatives to physical visits was even more pronounced during the COVID19 pandemic. Therefore, as an adjunct to physical visits and conventional diabetes management protocols, digital therapeutics in the form of smart phone applications and wearable devices or remote monitoring devices are booming in popularity. [11]

Diabetes self-management education [DSME] has shown to improve control of glucose levels and delay onset of complications. Online and digital tools aid with the delivery of DSME in addition to helping with remote monitoring of glucose levels, vitals and reducing costs associated with diabetes management. [13]

In 2002, Field et al showed that remote patient monitoring for diabetes not only reduces the chances of infection during pandemics, and reduces the health care costs, but will also play a major role in improving patient education, promoting awareness and increasing access to healthcare professionals. [14]

### **Aim:**

The aim of this pilot is to evaluate the quantitative and qualitative outcomes of using digital therapeutic interventions that use wearables and focus on lifestyle modifications on persons with diabetes.

### **KEY POINTS**

- *Diabetes is one of the most prevalent non-communicable diseases [NCDs] in the world.*
- *Type 2 diabetes mellitus can be controlled by lifestyle modifications in the form of healthier diet and increased physical activity as adjuncts to medication.*
- *Increasing healthcare costs associated with diabetes combined with the lack of effective screening and in compliance of patients to come for periodic physical visits have led to an increased need for alternative healthcare delivery modes.*
- *Digital therapeutics in the form of remote patient monitoring of vitals and app-based diabetes management protocols have shown a promising future.*
- *Digital diabetes management has shown to improve treatment adherence, increase patient to healthcare worker/doctor engagement and enhanced clinical outcomes.*

## **METHODS- DESIGN, PARTICIPANTS, INTERVENTION, OUTCOME ASSESSMENTS, STATISTICAL METHODS**

### **DESIGN**

#### **Initiation:**

The pilot program was conducted by Securra Health Global Technologies, based in Siruseri, India and headquartered by Amtex Systems, US. The pilot program was designed by Dr Usha Sriram, a leading endocrinologist and diabetologist in India and Securra Health helped in digitalizing the program wherever feasible.

#### **Start date and duration:**

The pilot program began on the last week of December 2020 and was designed to be a 12-week program.

#### **Securra Health Sugar Care Application:**

The Securra Health Sugar Care app aimed to assist, enable and partner with users to manage their diabetes, improve access to their healthcare delivery professionals and reduce the complications and adverse effects due to long standing diabetes. The app helped deliver the Securra Health Sugar Care Program formulated by Dr Usha Sriram to the participants.

The program focused on lifestyle and diet modification in addition to medication adherence and personalized coaching as ways to improve the blood glucose levels in participants.

#### **The key features of the Sugar Care app included:**

- Teleconsultation with provision for adding e-prescriptions.
- Remote patient monitoring [RPM] by FDA approved, BLE enabled devices.
- Personalized notifications and nudges to increase engagement and improve adherence.
- SOS triggers that can be automatically initiated by abnormal device readings or manually initiated by the user for any emergency. SOS triggers were directed to a control room helpdesk person who gave the user information on the nearest hospital.
- Digi-locker to store user data in a HIPAA compliant manner.
- Complete user health report generated periodically to get a snap-shot view of the users' health status.
- Quick check questions and daily logs to track user experience, engagement and keep a log on progress.
- Home visits for collection of lab samples to check the lab parameters and automatically syncing data to the participant profile on the app.
- Assessment questionnaires integrated into the app.
- In-app chat with the healthcare team.

### **PARTICIPANTS**

#### **Participant selection:**

Out of a 1000+ cohort of people with known type II diabetes and on oral medications, 60 participants were randomly selected to participate in the program. 50% of those selected were unable to participate due to personal reasons such as unavailability of time.

#### **Final participant count:**

Out of the final 30 participants who were onboarded into the program, 26 participants completed all the steps needed during onboarding and registration.

### **INTERVENTIONS**

#### **Diabetes Kits:**

These 26 participants received 'Diabetes Kits' that comprised of the following:

- Weighing scale
- Glucometer with glucose testing strips
- BP monitor

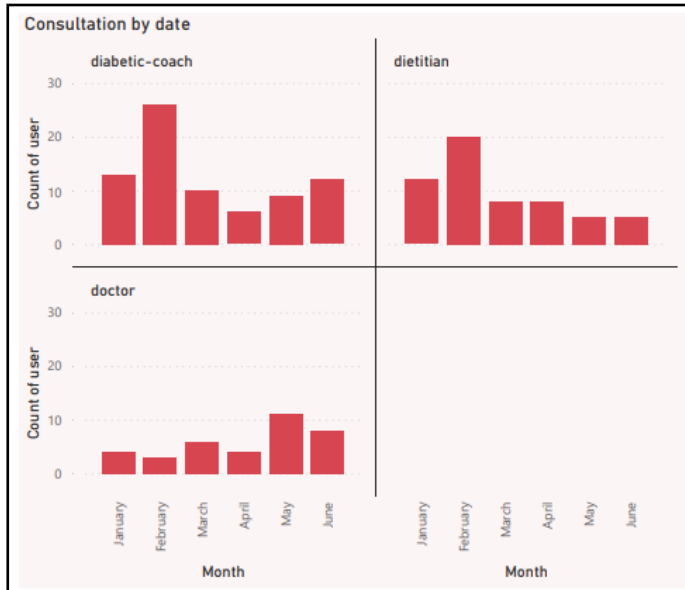
All the above devices were FDA approved, pre-calibrated devices procured by Securra Health and connected to the Securra Health program smart phone app via Bluetooth. These devices enabled the healthcare delivery team to remotely monitor the vital parameters of the users.

#### **The key features of the Securra Health Sugar Care Program included:**

- 12-week program with personalized coaching by a diabetes coach and a dietician.
- One initial tele-consultation with the diabetologist with more appointments scheduled either on suggestion by coach or dietician or request from participant.
- Diabetes kits [as specified above] for all participants.
- Remote monitoring of blood pressure, blood sugar and body weight with syncing of data to the participant profile on the app.
- Personalized meals plan, activity charts and goals for every participant.
- Periodic tele-consultations with the diabetologist, dietician and the diabetes coach [Healthcare delivery team] to provide training, support, and handholding.
- One assessment tele consultation and four follow-up tele-consultations with the diabetes coach and dieticians.
- 30-day health report card to track progress of the participant.
- Two sets of lab test data synced to the participant profile on the app. Lab data included the following parameters:
  1. Glucose
  2. HBA1c
  3. Lipid profile
  4. CBC
  5. Blood Urea Nitrogen [BUN]
  6. Creatinine
  7. SGOT/PT
  8. TSH

9. Vit D

- 24/7 availability of healthcare team and support team in case of emergencies.



- Quick check questions popped up in the app on periodic intervals to keep a tab on whether participants followed their meal plans, were being benefitted by the program and were closer to their goals.
- Notifications from the app reminded participants to adhere to their meal plans, take their medications and keep up with their goals.

Figure 2: Summary of teleconsultations through the app

RESULTS

The results of the pilot study involving 26 active participants who downloaded the Sugar Care App and received the ‘Diabetes Kit’ are as follows:

- Participation:

- Total: 30
- Participants who downloaded app: 28
- Participants who completed lab tests: 27
- Participants who received diabetes kits: 26
- Participants who actively engaged with the healthcare delivery team: 16
- Participants who stayed for the entire 12-week program and completed it: 14

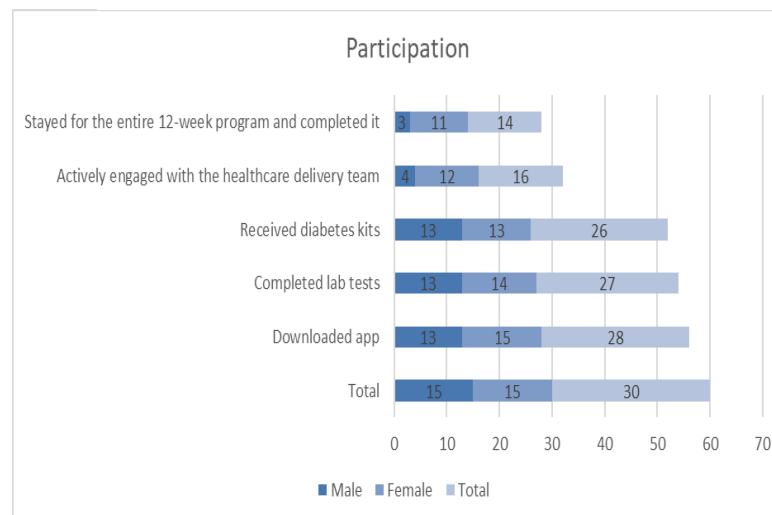


Figure 1: Participant numbers at different touch points

Total adherence: 16/26 participants = 61.54%  
Male: Female ratio = 4:12 = 1:3

- Initial consultation with the Diabetologist:

All 26 participants completed initial consultation with the diabetologist.

- Assessments and follow-up Tele-consultations:

- 16 participants completed at least 3 out of 4 tele-consultation calls with the diabetes coach and the dietician. Remaining 10 participants completed less than 3 tele-consultation calls with their respective coaches and dieticians.

**- Personalized meal plans:**

16 participants received personalized meal plans from the dietician, post assessment.

**- Quick check questions:**

14 participants regularly answered the quick check questions on the app.

**- Vitals tracking:**

Out of the 26 participants who received diabetes care kits,

- 7 participants had their vitals data captured every day using the BLE synced devices.
- 11 participants had data captured weekly once using the BLE synced devices.
- participants had synced the data less than three times during the entire program duration.
- 21 participants used the glucose monitor at least once during the program.

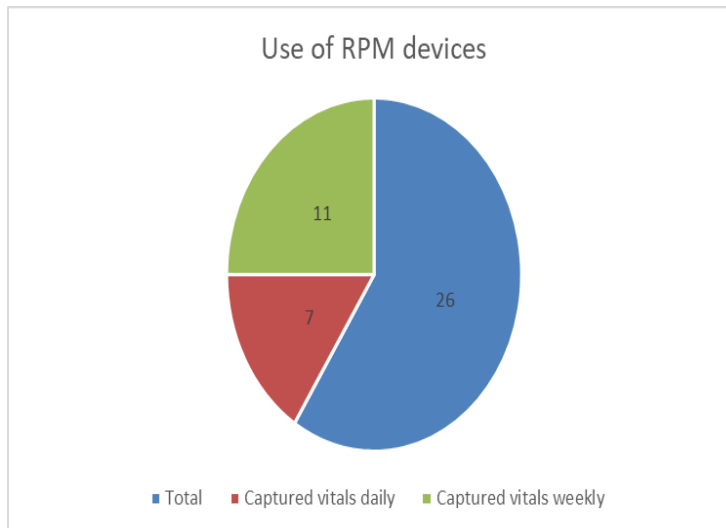


Figure 3: Summary of RPM use among participants

**- Number of automatic and manual logging of vitals across the 26 participants:**

There was a total of 468 manual and automatic [through BLE devices] recordings of vital data parameters using the Sugar Care app.

Table 1: Number of automated and manual vital entries

Row Labels	Sum of Count
Automated	67
Manual	401
<b>Grand Total</b>	<b>468</b>

**- Medication adherence and HbA1c variation:**

Of the 14 participants who regularly used the app, all 14 were found to have lesser chances of forgetting their daily

medications and therefore, showed better adherence to their regular medication compared to those who did not use the app regularly. There were no missed medication reports among the 14 participants who used the app regularly in contrast to 4 missed medication reports among the 12 participants who were neither adherent to the program in general, nor used the app regularly. This information was collected by the coaches during their review calls.

HbA1c of participants was periodically recorded throughout the program [Baseline, week 6 and week 12] and the variations were recorded as compared to the baseline. 11 out of 16 participants who actively engaged with the health care delivery team showed a positive trend in their HbA1c values. [Appendix -1]

The values remained consistently lower than baseline by 0.3%-0.4% in 11 participants.

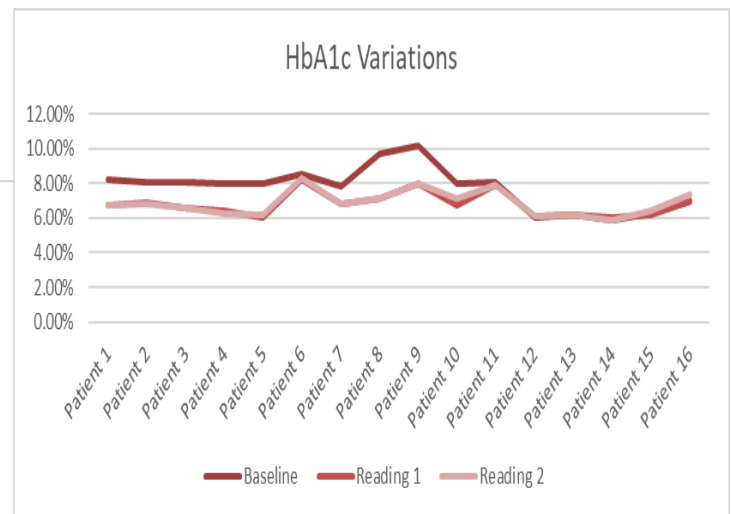


Figure 4: HbA1c reading of participants during the course of the program

**DISCUSSION**

Primarily, this program showed that most participants [68.75%] who were active, had an improvement in the HbA1c values towards the end of the program [0.3%-0.4% increased decrease in HbA1c compared to baseline]. This was similar to the study by Green et al., which showed that those with a higher mean baseline HbA1c value [>7%] reported better outcomes with digital interventions compared to those with HbA1c levels that were lower. [17]

The participants who completed the 12-week intervention program showed better control of HbA1c levels and glucose levels as compared to those who dropped off before the end of the program [0.4% more reduction in HbA1c at 12 weeks as compared to less than 10 weeks]. In a

previous study by Kirkland et al, HbA1c levels were reduced by 1.8% as compared to baseline after 6 weeks of intervention as compared to 1.3% reduction after 12 weeks. This could infer at a steady decline of glucose levels over a 6-month

period [remission phase], compared by a slowing down of the decline [maintenance phase] after this period. [23, 24]

Also, the ease of access to this intervention via the use of smartphones, tele-consultations, e-prescriptions, and meal plans to name a few, further enhanced by the reduced resources [financial, time and healthcare personnel] needed for physical visits, the overall acceptance and adherence [61.54%] towards this intervention was improved. This is in accordance with previous studies which concluded the same. Furthermore, tele-medicine and remote patient monitoring during the post COVID era has shown to massively reduce spread of infection, but also helps in improving education and awareness. [18, 22]

The ratio of men is to women who had shown interest in the program and actively participated was 1:3. This was similar to the study by Michaud et al, in which, men had lower odds of completing the three-month program compared to women. Surprisingly, both the studies showcased the fact that the men who were enrolled to the program had a lower post-program HbA1c level as compared to women. [19]

Comparing the 16 participants who stayed active on the program with the 14 participants who were inactive, lack of motivation to stay active predominantly included fast-paced lifestyle, and unavailability of younger individuals at home, to help with connecting the RPM devices, troubleshooting the app, etc. Especially, a combination of the above along with an absence of short-term incentives, dropout rate was high [46.7%] among those who enrolled to the digital program. This finding was similar to previous studies that showed that incentives and gamification improved retention of participants to digital applications. [20]

20 of the 30 participants who were initially enrolled on the program were non-compliant and irregular with physical visits to their diabetologist and were not regularly taking their medication and lab tests. Social inequality and irregular access to health-promoting resources had been determined as the core reasons for lower interest on treatment plans and engagement with healthcare delivery personnel, thereby negatively affecting diabetes outcomes. [21]

Additionally, this pilot study showed that the most widely accepted intervention tool was the remote monitoring of glucose levels from the comfort of the user's own homes. 82% Of the 26 participants who received the diabetes kits monitored their blood glucose levels at least three times throughout the duration of the program. This finding is concomitant with the findings of Sigdel et al, who reported that the Self- monitoring of blood glucose [SMBG] with glucometers is the most widely used tool for the management of diabetes. [25]

Among all the features of the Securra Health Sugar Care app, the most valued feature for the healthcare delivery personnel as well as the participants was the ability to monitor their vital parameters remotely from home and sync these with the mobile app, in addition to receiving regular reminders via notifications, review calls and personalized coaching. The

doctor, diabetes coach and the dietician [HCPs] also found these vital values useful to monitor the health condition of the participants and to predict any major adversaries in the health of the participants and proactively treat or manage the condition by specific alterations to medication, food or lifestyle goals. [25]

The use of remote monitoring, tele-consultations, and digital intervention tools for persons with diabetes also showed to positively impact clinical outcomes such as a reduction of glucose levels [0.3%-0.4% increased decrease in HbA1c as compared to conventional methods], increased awareness among participants [80% knew more about diabetes management and benefits of controlling diabetes] and improved participant engagement [61% participants engaged actively with digital intervention]. [26, 27]

Participant's feedback on the program was also good. Appendix 2 elaborates these feedbacks. Overall, most feedbacks validated digital intervention tools as a better way to increase adherence to management methods and improve engagement with the health team.

The biggest advantage of digital health interventions was the enablement of a 360-degree intervention loop. This refers to cyclic data assimilation, pre-emptive interpretations, and proactive interventions to improve the clinical outcomes of persons with diabetes, thereby enhancing overall health. [28]

## CONCLUSION

This pilot study is valid proof that digital interventions for diabetes can potentially have multiple favorable outcomes. Previous studies on the same also have similar outcomes and results.

Keeping in mind the ever-increasing population of persons with diabetes, reduced access to healthcare, high costs of healthcare delivery, limited availability of specialists, lack of awareness and motivation among persons with diabetes and irregularity in going for physical visits to the doctor, digital interventions are a boon to healthcare.

However, this study involves a small cohort sample as compared to large population studies and is also conducted only for a short duration of time. Longitudinal studies involving larger populations will avoid any irregularities in study results and thus need to be conducted to validate the findings of this pilot study.

## DECLARATIONS

- Funding: None
- Conflicts of interest/Competing interests: None
- Availability of data and material: The datasets generated during and/or analysed during the current study are not publicly available due to [REASON(S) WHY DATA ARE NOT PUBLIC] but are available from the corresponding author on reasonable request.
- Code availability: HIPAA compliant Securra Health app available in play store and app store
- Ethics approval: Not applicable

- Consent to participate: Not applicable
- Consent for publication: Not applicable
- Author contributions: Program planned by Dr Usha; paper written by Dr Dianna with inputs from Dr Jagdish

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