

Effectiveness of a hybrid technology enabled care model as measured by ICHOM standard set on established and managed type 2 diabetes already using medications: A RWE retrospective study

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ABSTRACT

Aims: Diabetes is a pressing global health issue, demanding innovative strategies for improved treatment. However, traditional care often falls short of patient goals. To address this, digital health solutions, including smartphone apps and remote monitoring, have emerged as crucial in diabetes management. This study aims to assess a comprehensive intervention, combining remote continuous data monitoring (RCDM) with in-clinic care, for enhancing diabetes-related outcomes. Additionally, it seeks to evaluate the effectiveness of the digital RCDM component by comparing adherent and non-adherent patients.

Methods: Conducted in the United Arab Emirates, a retrospective study involved 89 patients primarily on anti-diabetic medications. They were split into two groups based on adherence to RCDM. Over time, significant improvements were observed across various parameters.

Results: Notably, patients exhibited weight loss (-4.0 ± 5.3 , $p < 0.001$), reduced waist circumference (-4.74 ± 7.8 , $p < 0.001$), lowered HbA1c levels (-1.00 ± 1.3 , $p < 0.001$), decreased systolic BP (-3.1 ± 13.1 , $p = 0.035$), and diminished diastolic BP (-3.4 ± 9.9 , $p = 0.002$) annually. Furthermore, patients adhering to the GluCare model demonstrated substantial HbA1c reductions (-1.53 ± 1.5 , $p < 0.001$), improved lipid profiles, notably decreased total Cholesterol (-16.6 ± 50.3 , $p = 0.034$), and lowered LDL levels (-18.65 ± 42.6 , $p = 0.006$).

Conclusions: The intervention model effectively managed T2D patients through a comprehensive approach, yielding notable improvements in HbA1c levels and other outcomes within a year. The study underscores the limitations of traditional care and reliance simply on pharmacotherapy, and emphasizes the need for a hyper-personalized, and continuous approach for T2D management.

1. Introduction

Diabetes presents a significant global health challenge, impacting an estimated 463 million adults and an increasing proportion of the younger population worldwide [1]. Type 2 diabetes (T2D) accounts for approximately 90% of all diabetes cases and its prevalence is on the rise, placing a substantial burden on affected individuals and straining healthcare systems worldwide [1]. Despite the advancements made in antidiabetic medications and diabetes technologies, a significant proportion of individuals with diabetes do not reach their treatment goals, leading to suboptimal clinical results and a worsened disease prognosis

over time [2]. In the United Arab Emirates (UAE), a country with access to considerable healthcare resources, over 75% of diabetic patients are classified as poorly controlled, with the largest diabetes provider reporting an average HbA1c of 7.4% [3]. A complex landscape of individual, social, and systemic factors hinder the effective management of diabetes, namely the lack of patient knowledge, education, treatment compliance and behavioral change, lack of continuous patient management which is necessary for a time-intensive chronic disease like diabetes, and lack of adequate and equitable insurance coverage of valuable diagnostic and self-management tools such as novel diabetes technology, for which cost is a major access barrier [4].

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The integration of technology such as smartphone apps, telemedicine, and medical devices has emerged as a cost-effective and scalable option to enhancing patients' engagement in their care, enabling better self-management, facilitating lifestyle modification, supporting continuous patient-provider communication, and allowing the integration of more data-points into the care plan [5]. Many digital solutions have been shown to have significant impacts on diabetes related outcomes including HbA1c levels [6]. In a systematic review by Greenwood DA. et al. [7], the utilization of technology-driven self-management solutions for diabetes was shown to lead to a notable reduction in A1c levels in type 2 diabetes patients [7]. Moreover, the most effective interventions were found to be those that incorporated a feedback system between patients and their healthcare providers [7]. These systems also often involved patient health data analysis, personalized educational content, and individualized feedback [7]. In recent years, there has been an increase in the number of point-of-care companies offering connected diabetes care solutions [8]. Despite their promising applications, several barriers to adoption persist in clinical practice. These barriers include high costs, lack of insurance coverage, and patients' limited knowledge and comfort with usage of technology. Challenges faced by healthcare providers include limited appointment time, lack of integration within the electronic medical records, insufficient supportive staff (e.g., diabetes educators, nurses, dietitians), and lack of incentives to adopt such technologies, among other barriers [9]. Few studies have explored the effectiveness of technology-enabled diabetes management programs [7,10,11]. Recognizing the barriers, this study aims to test the effectiveness of a whole system intervention that combines remote continuous data monitoring (RCDM) with an in-clinic management model in improving diabetes-related outcomes. This study also aims to test the effectiveness of the digital RCDM component of the care model by comparing patients who were adherent to the RCDM versus those who were not.

2. Methodology

2.1. Overview of GluCare intervention model

The program was provided by a medical health facility (GluCare Integrated Diabetes Center, Dubai, UAE). The intervention program under study comprises two synergistic components: an in-clinic, human-delivered aspect and a continuous digital monitoring aspect termed Remote Continuous Data Monitoring (RCDM) [12]. This integrated approach is specifically tailored to foster the behavioral changes required for effective diabetes management between in-clinic visits.

2.1.1. In-clinic component

Following the American Diabetes Association's standards of care, the in-clinic component provides personalized consultations with an assigned healthcare team, including physicians, dietitians, diabetes nurse educators, and health coaches. Key to this aspect are remote pharmacotherapy titrations, particularly concerning multidose medications like GLPs. Consent was obtained from all participants prior to the study, ensuring the collection and evaluation of all protected health information in a Health Insurance Portability and Accountability Act (HIPAA)-compliant manner.

2.1.2. Remote continuous data monitoring

The RCDM complements in-clinic care with real-time, continuous tracking and analysis of various diabetes-related parameters, such as glucose levels via Continuous Glucose Monitoring (CGM), sleep quality, food and physical activity logs, and body weight measures. This digital component involves a combination of mobile app technology, live and remote personalized coaching from health coaches, consultations with nurse educators, dietitians, and board-certified endocrinologists for medication management. Participants log meals through the app, receiving dietitian feedback to enhance their understanding of

macronutrients and carbohydrate counting. Physicians provide feedback and adjust prescriptions as necessary, often within days of initiating the program, and the healthcare team reviews the data daily.

2.1.3. Educational outreach

A vital aspect of the program is educational content, delivered through an accredited curriculum (QISMET, United Kingdom). Visual and text cards tailored to individual health conditions are sent periodically over the 12-months period.

2.2. Study design and participants

This is a retrospective observational study which involved the extraction and analysis of medical records for GluCare patients who fit the following inclusion criteria:

- Patients Diagnosed with T2D Mellitus
- Patients who were previously managed by a UAE based healthcare provider and were already on antidiabetic medication (oral antidiabetic drugs, insulin, and/or GLP-1)
- Patients who have been under the GluCare model of care for a minimum period of 12 months

2.3. Metrics for participants' adherence to the GluCare model

The following metrics were used to assess patients' adherence, patients were considered adherent if 2 out of the 3 criteria below were met:

1. Communication with a coach/physician/dietician/educator at least once every 2 weeks via the chat function on the app, phone call or online consultation.
2. A minimum of 1 body weight reading received on the app for every 30-day period.
3. CGM/Blood Glucose Monitoring (BGM) readings continuously over a single 30-day period collected.

2.4. Data collection

The data was extracted from the physicians' patient records (at baseline and annually) using the Electronic Medical Record (EMR) (Diamond, Hicom, UK), and categorized based on the International Consortium for Health Outcomes Measurement (ICHOM) set scales of measures [13]. Variables collected included: patients' gender, age, ethnicity, weight, height, waist circumference, diabetes duration, current diabetes-related drug intake, anti-hypertensive drug intake, statin drug intake, physical activity and physical function. Laboratory variables were also extracted including lipid profile (total cholesterol, LDL, HDL, and triglycerides), TSH, and HbA1c. Mental health scores were assessed using 3 standards: the World Health Organization-5 score (WHO-5), Problem Areas in Diabetes Questionnaire (PAID) and Patient Health Questionnaire-9 (PHQ9). The WHO-5 is a self-reporting measure of mental being with scores ranging from 0 to 25, with 0 representing the worst possible quality of life and 25 representing the best possible quality of life [14,15]. PAID is a 20-item screening instrument for clinical and research use designed to measure emotional responsiveness specific to DM as opposed to general emotional distress. The items are rated on a 5-point Likert scale and cover treatment-related issues (three items), food-related problems (three items), social support-related problems (two items), and DM-related emotional distress (12 items). Total scores are multiplied by 1.25 to give a score with the range of possible scores being 0–100 (with higher scores indicating greater emotional distress) [16]. The PHQ9 is a self-administered questionnaire of the Primary Care Evaluation of Mental Disorders diagnostic tool for common mental illnesses, Total scores of 27 is given (higher scores indicates greater risk) [17]. Adherence to diet, exercise, blood glucose (BG) monitoring, and medications were assessed using the ICHOM set of

measures. A score 1–10 was given for each patient individually from the healthcare team. A score 1 indicates “not adherent” and a score of 10 indicates “fully adherent”, the higher the score indicates how well the patient adhered to different parameter [13]. Adherent to diet score was assessed by the Dietitian on how well the patient stick to the dietary advice. Adherence to exercise was assessed by the lifestyle coach to wither the patient sticked to exercise advice. As for adherence to blood glucose monitoring, the score was assessed either by the physician or diabetic educator on how well the patient sticked to blood glucose monitoring. Lastly, adherence to medication was assessed by the physician on how well the patient sticked to the prescribed medication and/or insulin regimen. Lastly, Blood pressure and statin therapy were recorded. Blood pressure treatments encompass patients who were on medications to treat their hypertension condition. Treatments include whether the patient was on either ACE inhibitor or beta-blockers.

2.5. Statistical analysis

Data were analyzed using SPSS software, version 29.0 (SPSS, Chicago, IL, USA). Continuous data like age, weight and laboratory values were expressed as means and standard deviations (SD) and categorical data like ethnicity, diabetes type and diabetes treatment were expressed as counts and percentages. The Paired T-test was used to compare between variables at baseline and annually, and to compare pre and post intervention outcomes. The P values at <0.05 were considered statistically significant.

3. Results

3.1. Overall patients demographics and characteristics

Table 1 provides an overview of the main characteristics of patients with T2D. The mean age of participants was 49.6 years, most of the participants were males (68.5 %) and Asians (43.8 %). Diabetes duration ranged between 0 and 10 (77.5 %), 11–20 (13.5 %) and 21–30 (9.7 %) years. Every patient was managed by an existing UAE-based traditional care provider before intake with the majority already using anti-diabetic medications.

3.2. Overall patients characteristics baseline vs. annually

Over the course of the study, significant changes were observed in several parameters (Table 2). Patients experienced a considerable reduction in weight (−4.0 kg), BMI (−1.32 kg/m²), and waist circumference (−4.74 cm), indicating improvements in their body composition. Additionally, there was a significant decrease in HbA1c levels (−0.82 %). Moreover, systolic blood pressure (−3.1 mmHg), diastolic blood pressure (−3.4 mmHg) and HDL cholesterol levels (+3.58 mg/dl) also showed significant improvements. However, changes in total cholesterol, LDL cholesterol, triglycerides, TSH, eGFR, and albumin/creatinine ratio were not statistically significant.

3.3. Mental health and adherence scores among participants (n = 89)

The table below presents the results of mental health scores and adherence to various aspects of diabetes management among the study participants (Table 3). The WHO-5 scores, representing quality of life, showed a significant improvement from 23.56 ± 1.1 at baseline to 24.60 ± 0.7 annually (p < 0.0001). Similarly, emotional distress measured by the PAID and PHQ9 scores decreased over time, indicating improved mental well-being. Additionally, the participants demonstrated substantial enhancements in adherence to diet, exercise, blood glucose monitoring, and medication, as reflected by significant increases in adherence scores.

Table 1

Overall patients demographics and characteristics (n = 89).

Variable	n (%)
Age, (mean ± SD)	49.66 ± 11.2
Gender, n (%)	
Female	28 (31.5)
Male	61 (68.5)
Ethnicity	
Asian	39 (43.8)
Arab	37 (41.6)
Caucasian	6 (6.7)
European	6 (6.7)
African	1 (1.1)
Tertiary Education	89 (100)
Social Support - partner/spouse/family/friend	89 (100)
Smoking Status	
Not Smoking	74 (83.1)
Smoking (Cigarettes/shisha)	8 (9.0)
Passive	2 (2.2)
Stopped	5 (5.6)
Diabetes Duration, (years)	
0-10	69 (77.5)
11-20	12 (13.5)
21-30	7 (7.9)
Blood Pressure Treatment	
No	56 (62.9)
Yes	33 (37.1)
Statin Treatment	
No	30 (33.7)
Yes	59 (66.3)

Table 2

Overall patients characteristics at baseline and annually (n = 89).

Variable	Baseline (n = 89)	Annually (n = 89)	Mean difference	p-value
Weight (kg)	84.89 ± 19.53	80.54 ± 16.6	−4.0 ± 5.3	<0.001*
BMI (kg/m²)	29.04 ± 5.3	27.71 ± 4.5	−1.32 ± 6.6	0.071
Waist circumference (cm)	100.8 ± 13.3	95.66 ± 11.7	−4.74 ± 7.8	<0.001*
HbA1c (%)	7.76 ± 1.8	6.96 ± 1.43	−0.82 ± 1.4	<0.001*
Systolic BP (mmHg)	123.68 ± 14.7	120.46 ± 15.5	−3.1 ± 13.1	0.035*
Diastolic BP (mmHg)	80.3 ± 10.3	76.9 ± 9.1	−3.4 ± 9.9	0.002 c*
Cholesterol (mg/dl)	175.19 ± 36.2	166.48 ± 50.3	−8.84 ± 55.2	0.095
LDL (mg/dl)	114.87 ± 32.6	105.96 ± 43.5	−8.77 ± 47.6	0.053
HDL (mg/dl)	44.26 ± 11.1	47.84 ± 12.8	+3.58 ± 7.2	0.010*
Triglycerides (mg/dl)	195.12 ± 129.9	165.92 ± 162.9	−29.2 ± 176.5	0.129
TSH (mIU/L)	1.58 ± 1.0	1.51 ± 1.04	−0.07 ± 1.27	0.598
eGFR (ml/min/1.7m²)	110.9 ± 29.9	107.9 ± 34.9	−2.95 ± 23.3	0.243
Albumin/Crt Ratio	73.6 ± 244.5	25.4 ± 47.8	−48.25 ± 208.1	0.039*

*The P-values <0.05 indicate the statistical significance of paired sample t-test.

3.4. Adherent vs. non-adherent outcomes

Adherence was measured upon the adherence metrics as mentioned in section 2.3. The distribution of patients who are adherent are presented below (Fig. 1). Adherent patients were 50.6 % of the total population. However, 49.4 % of participants were not adherent, primarily due to insurance companies' unwillingness to pay for the service or did not meet the adherence criteria. These patients followed more of what traditional episodic care resembles although they did receive detailed in-clinic education from the care team composed of physicians,

Table 3
Mental Health and Adherence Scores among T2D Patients (Baseline vs. Annually) (n = 89).

Variable	Baseline	Annually	Mean difference	p-value
WHO-5 Score	23.56 ± 1.1	24.60 ± 0.7	+1.03 ± 1.2	<0.001*
PAID Score	17.46 ± 13.6	12.65 ± 9.2	-4.81 ± 12.1	<0.001*
PHQ9 Score	1.67 ± 1.4	1.18 ± 1.2	-0.48 ± 1.5	0.005*
Adherence to Diet	2.09 ± 1.4	3.36 ± 2.0	+1.26 ± 1.3	<0.001*
Adherence to Exercise	1.80 ± 1.1	4.72 ± 1.8	+2.91 ± 1.7	<0.001*
Adherence to BG Monitoring	1.59 ± 2.1	4.09 ± 2.3	+2.50 ± 1.48	<0.001*
Adherence to Medication	3.85 ± 2.12	6.31 ± 2.1	+2.45 ± 1.76	<0.001*

*The P-values <0.05 indicate the statistical significance of paired sample t-test.

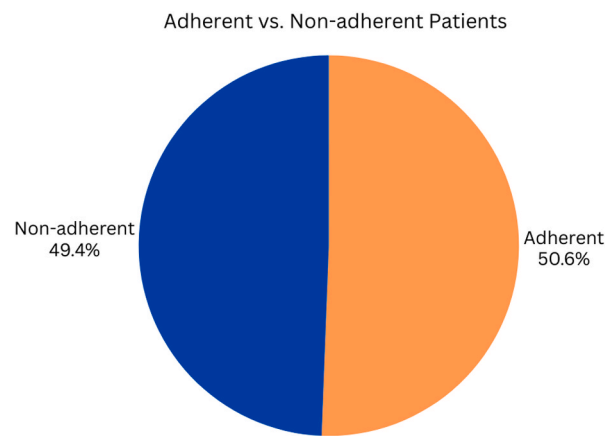


Fig. 1. Patients distribution among adherent and non-adherent.

dietitians, and diabetes educators.

3.4.1. Differences between adherent vs. non-adherent patients' outcomes

Table 4 presents a comparison between adherent vs. non-adherent patients at baseline and annually for various health parameters. Among the adherent patients, there were significant improvements in weight (-3.72 kg), waist circumference (-3.62 cm), HbA1c levels (-1.54 %), systolic blood pressure (-3.02 mmHg), diastolic blood pressure (-2.46 mmHg), total cholesterol (-16.6 mg/dl), and LDL cholesterol (-18.7 mg/dl) at the annual assessment compared to

Table 4
Differences among adherents vs. non-adherent at baseline and annually (n = 89).

Variable	Baseline adherent (n = 45)	Annual adherent Patients (n = 45)	Adherent p-value	Baseline Non-adherent Patients (n = 44)	Annual Non-adherent Patients (n = 44)	Non-adherent p-value
Weight (kg)	83.7 ± 18.5	79.98 ± 16.4	<0.001*	81.99 ± 18.5	78.4 ± 16.2	<0.001*
BMI (kg/m²)	29.68 ± 5.6	28.47 ± 5.2	<0.001*	28.28 ± 5.0	27.03 ± 3.9	<0.001*
Waist Circumference (cm)	98.92 ± 13.1	95.3 ± 13.5	<0.001*	102.13 ± 12.7	99.13 ± 11.4	0.001*
HbA1c (%)	8.48 ± 2.0	6.94 ± 1.6	<0.001*	7.08 ± 1.5	6.98 ± 1.4	0.490
TSH (mIU/L)	1.46 ± 1.0	1.42 ± 1.1	0.812	1.70 ± 1.0	1.60 ± 1.2	0.631
eGFR (ml/min/1.7m²)	116.7 ± 25.9	116.5 ± 37.3	0.579	117.0 ± 26.9	100.7 ± 31.0	0.004*
Creatinine/Albumin Ratio	63.18 ± 199.4	22.06 ± 44.6	0.103	84.7 ± 286.6	28.9 ± 51.2	0.168
Systolic BP (mmHg)	124.89 ± 14.6	121.87 ± 15.0	<0.001*	122.5 ± 14.7	118.95 ± 16.1	0.148
Diastolic BP (mmHg)	80.5 ± 9.7	78.04 ± 8.4	0.030*	79.71 ± 10.2	75.24 ± 9.4	0.011*
Cholesterol (mg/dl)	186.7 ± 39.0	170.1 ± 53.1	0.034*	164.7 ± 38.4	162.0 ± 49.4	0.823
LDL (mg/dl)	125.8 ± 35.3	107.1 ± 43.9	0.006*	103.8 ± 31.6	102.9 ± 44.3	0.917
HDL (mg/dl)	43.9 ± 9.3	45.9 ± 10.3	0.610	46.2 ± 13.7	49.8 ± 14.5	0.030*
Triglycerides (mg/dl)	205.9 ± 131.9	194.4 ± 216.9	0.666	183.8 ± 128.4	139.2 ± 65.3	0.014*

*The P-values <0.05 indicate the statistical significance of Paired Sample T-test.

baseline. Additionally, the reduction in HbA1c levels in the adherent group was found to be statistically significant (p < 0.001) compared to the non-adherent patients. However, both adherent and non-adherent patients showed some positive changes in weight, waist circumference, diastolic blood pressure, and triglyceride levels. Still, the overall improvements were more pronounced and statistically significant in the adherent group.

3.4.2. Medication use among adherent vs. non-adherent

Both cohorts, as managed by their previous healthcare provider, were on various combinations of diabetes medications, at annual assessment, the percentage of adherent patients on these specific combinations dropped to 0 %, indicating a complete shift away from non-GLP multi-medication approaches (Table 5). Furthermore, there were significant changes in blood pressure treatment and statin therapy among adherent patients.

4. Discussion

The research focuses on the management of Type 2 Diabetes Mellitus (T2DM) in an integrated approach utilizing continuous engagement and monitoring, behavioral change and pharmacotherapy titrations. However, existing diabetes management services for T2DM patients in the UAE, and most developed systems, are not correctly structured or incentivized in providing the additional components of RCDM using integrated teams that are given the necessary time and tools (example: wearables, apps, etc) to continuously engage with patients. To address this, efforts are being made to leverage digital healthcare technology [18], however, digital only offerings that act as an independent point-solutions or a separate monitoring layer may have limited benefits when it comes to physician decisions on treatment (including medication therapy) [8]. An end-to-end hybrid model, the GluCare Health model, where both the physical and digital components are managed by the same care team, has shown promising outcomes [12,19]. The findings of the present study will additionally highlight the effectiveness of using RCDM when measured through the ICHOM set [13].

Annual improvement of the outcomes was observed to be significant in patients who followed the GluCare model. Overall, patients started with an average baseline HbA1c of 7.76 % which is above the recommended target by the ADA (20), a typical observation seen and reported in the UAE despite these patients being actively managed and having access to up-to-date medication therapies. For example, the largest traditional care providers in the UAE have reported average HbA1c of patients to be 7.4 % [3], despite most of these patients being under management for a decade and costing on average \$ 4205 per annum [21] for their diabetes care. Studies have shown that patients that

Table 5
Diabetes Treatment Regimen among Adherent and Non-adherent patients.

Variable	Baseline Adherent (n = 45)	Annual Adherent Patients (n = 45)	% of change	Baseline Non-adherent Patients (n = 44)	Annual Non-adherent Patients (n = 44)	% of change
Diabetes Treatment						
NA	5.3 %	2.6 %	-50.9 %	7.3 %	2.4 %	-67.1 %
Oral antidiabetic drugs	15.8 %	18.4 %	+16.4 %	41.5 %	36.6 %	-11.8 %
Insulin	5.3 %	5.3 %	0	0	0	0
Insulin + Oral antidiabetic drugs	5.3 %	0	-100 %	4.9 %	2.4 %	-51.0 %
Insulin + GLP1	5.3 %	0	-100 %	2.4 %	2.4 %	0
Insulin + GLP1+ Oral antidiabetic drugs	2.6 %	0	-100 %	2.4 %	4.9 %	+104.1 %
GLP1+ Oral antidiabetic drugs	57.9 %	60.5 %	+4.4 %	34.1 %	41.5 %	+21.7 %
GLP	7.9 %	13.2 %	+67.0 %	7.3 %	9.8 %	+34.2 %
Blood Pressure Treatment						
Yes	43.20 %	34.10 %	-21.10 %	31.1 %	26.7 %	-14.1 %
No	56.80 %	65.90 %	16.00 %	68.9 %	73.3 %	6.4 %
Statin Therapy						
Yes	60.0 %	73.3 %	22.2 %	72.5 %	79.5 %	9.7 %
No	40.0 %	26.7 %	-33.3 %	27.3 %	20.5 %	-24.9 %

remain poorly controlled had 23 % higher healthcare costs annually compared to well-controlled diabetics [22].

After a year of following the GluCare Health model, HbA1c has reduced to 6.96 %. It has been previously shown that an average of <7 % significantly reduces the risk of microvascular complications in patients with T2D and overall cost [23]. On the other hand, results of a meta-analysis showed a reduction of 0.49 % in HbA1c after the use of digital health alone without continuous care on the treatment of diabetes [10]. Moreover, a significant improvement in HbA1c (-1.48 %) was observed in patients who were adherent to the GluCare Health intervention model compared to non-adherent patients (-0.18 %). Considering that all these patients were already on medications and being managed by an existing provider, this demonstrates the limitations of traditional care systems that have primarily focused on medication therapy. Adherent patients who were poorly controlled at baseline had successfully reduced their HbA1c to 6.94 %; below the recommended ADA guidelines [20]. Interventions could have played a crucial role in encouraging healthier habits, medication adherence, and overall diabetes management. Moreover, adherent patients, despite having a higher baseline HbA1c and already being on medications, experienced more proactive medication titrations and management from the clinical team. Optimizing medication management, especially as most patients were using multi-dose pharmacotherapies that require proactive titrations such as GLPs, might have led to better glycemic control and contributed to the observed HbA1c reduction in adherent patients. Additionally, the high starting HbA1c levels in adherent patients may drive their improved adherence to the intervention due to increased motivation, perceived benefits, sense of urgency, personal experiences, and the availability of a supportive and comprehensive care environment.

Patients overall had a reduction in weight (-4 kg) and waist circumference (-4.74 cm). These findings are consistent with outcomes of a pilot study, where they measured the impact of digital lifestyle interventions using an app [24]. Moreover, improvements on lipid profile were promising with significant reductions in LDL and an increase in HDL observed in patients following the GluCare health care model. Approximately 25 % of individuals with T2D experience clinically significant depression [25]. This co-occurrence of depression and T2D poses a complex and bidirectional relationship [25]. On one hand, depression increases the risk of developing T2D and can exacerbate the associated risks of insulin resistance [25]. On the other hand, a diagnosis of T2D raises the likelihood of experiencing depression and can contribute to the severity of the depressive condition [25]. This interplay between T2D and depression underscores the importance of addressing mental health concerns in diabetes management and vice versa, recognizing that effective management of one condition can

positively impact the other [25].

Furthermore, behavioral change interventions play a crucial role in enhancing treatment adherence. Unfortunately, many traditional diabetes providers neither measure nor provide mental health support for their diabetic patients. The GluCare Health model focuses on these interventions and implements consistent monitoring, and self-care practices. In the present study, patients showed a doubling of adherence scores at annual settings. Moreover, patients showed an overall higher WHO-5 scores and lower PAID and PHQ9 scores. In line with our findings, it was previously reported that patients with good glycemic control had significantly higher WHO-5 scores [26]. The integration of behavioral interventions in diabetes care can lead to better glycemic control, decreased risk of complications, and improved overall quality of life for individuals living with T2DM as seen in the outcomes of this study.

In terms of diabetes treatment, adherent patients showed a significant reduction in medication use, with a 5.3 % decrease in the use of any diabetes treatment and a 50.9 % reduction in oral antidiabetic drugs. This indicates an improvement in glycemic control and suggests that these patients required fewer medications to manage their diabetes effectively. Similarly, adherent patients showed reductions in the use of insulin in combination with other medications. This is consistent with previous research that has demonstrated the effectiveness of continuous models in medication reduction for T2D [27]. Non-adherent patients did not experience significant changes, with some showing an increase in the use of certain medications. Regarding blood pressure treatment, both adherent and non-adherent patients showed reductions in medication use, indicating improved blood pressure control across the board.

5. Virtual disease management programs vs hybrid models

The success of virtual disease management programs is well documented [28–30] with HbA1c reductions ranging from -0.4 %, -0.6 % and -0.8 % in 12, 10 and 4 months respectively. Many of these studies have not reported other clinical parameter or medication changes due to the fact that such programs have not been part of the primary care providers' management plans, but act as an additional management/engagement tool used to assist patients and are usually employer-led. The GluCare approach is distinct due its hybrid approach: Both the physical locations and remote digital solution are entirely vertically integrated by the on-ground care team. These additional features added into a diabetes management solution may result in better HbA1c control perhaps due to a more holistic end-to-end approach and engagement as shown in this study. Allowing the same care team to access both remote and EMR data allows for more data-driven behavioral nudges or precision engagement and can lead to the relevant interventions in diabetes management. Many digital health solutions face

restrictions in reimbursement and limits healthcare providers from implementing such hybrid models at scale.

When assessing the potential Return on Investment (RoI) of additional digital health solutions to an existing model of care, it would be important to calculate the total cost of care for diabetic patients, including medications, and demonstrate the value that such hybrid models bring with improvement outcomes. The reporting of comprehensive clinical outcomes, including medication use and mental health scores, is an important initial step to encourage payers to reimburse for such solutions whether it be as a service, or more preferably, through value-based contracting.

6. Conclusion

In conclusion, this research emphasizes the effectiveness of an integrated and continuous hybrid approach, exemplified by the GluCare health model, in managing T2DM. Utilizing a ‘closed loop’ approach which incorporates continuous lifestyle adjustments, behavioral change interventions, personalized engagement and real-time monitoring alongside pharmacotherapy titrations, significant improvements in patient outcomes were observed, with adherent patients being well-controlled within 12 months as measured by HbA1c.

Additionally, the study highlighted the importance of addressing mental health concerns, and reported significant mental health score improvements when such models are adopted. Considering that all patients at intake were classified as poorly controlled despite being managed by traditional care providers with most already on antidiabetic medications, further research and implementation of such integrated and hybrid models are recommended to effectively manage diabetes on scale.

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CRedit authorship contribution statement

Ihsan Almarzooqi: Conceptualization, Writing – original draft, Writing – review & editing. **Hala Zakaria:** Data curation, Writing – original draft, Validation, Visualization, Supervision. **Sofia Aleabova:** Investigation. **Milena Caccelli:** Writing – review & editing. **Cigdem Ozkan:** Writing – review & editing. **Judith Skaf:** Writing – review & editing. **Jestoni Bangayan:** Investigation. **Dianne Catapang:** Investigation. **Zeinab Jaafar:** Writing – review & editing. **Ali Hashemi:** Writing – review & editing. **Yousef Said:** Writing – review & editing.

Declaration of competing interest

The following authors declared the following potential conflicts of interest: The following authors are full-time employees/interns at GluCare: Hala Zakaria, Sofia Aleabova, Milena Caccelli, Cigdem Ozkan, Judith Skaf, Jestoni Bangayan, Dianne Catapang, Ali Hasehmi, and Yousef Said The following authors have affiliations with organizations with direct or indirect financial interest in the subject matter discussed in the manuscript: Ali Hashemi, Ihsan AlMarzooqi.

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References

- [1] Atlas ID. IDF diabetes atlas. ninth ed. International Diabetes Federation; 2019. Retrieved from.
- [2] Khunti K, Wolden ML, Thorsted BL, Andersen M, Davies MJ. Clinical inertia in people with type 2 diabetes: a retrospective cohort study of more than 80,000 people. *Diabetes Care* 2013;36(11):3411–7.
- [3] Center ICLD. Outcomes report. 2019.
- [4] Adu MD, Malabu UH, Malau-Aduli AEO, Malau-Aduli BS. Enablers and barriers to effective diabetes self-management: a multi-national investigation. *PLoS One* 2019; 14(6):e0217771.
- [5] Ashrafzadeh S, Hamdy O. Patient-driven diabetes care of the future in the technology era. *Cell Metabol* 2019;29(3):564–75.
- [6] Whaley CM, Bollyky JB, Lu W, Painter S, Schneider J, Zhao Z, et al. Reduced medical spending associated with increased use of a remote diabetes management program and lower mean blood glucose values. *J Med Econ* 2019;22(9):869–77.
- [7] Greenwood DA, Gee PM, Fatkin KJ, Peeples M. A systematic review of reviews evaluating technology-enabled diabetes self-management education and support. *J Diabetes Sci Technol* 2017;11(5):1015–27.
- [8] Levine BJ, Close KL, Gabbay RA. Reviewing U.S. Connected diabetes care: the newest member of the team. *Diabetes Technol Therapeut* 2020;22(1):1–9.
- [9] Smith S, Ayuk V, Scalzo P. Barriers to technology adoption by patients and providers in diabetes and hypertension care management. *Digital Med Healthcare Tech* 2023.
- [10] Kim J-e, Park T-s, Kim KJ, editors. The clinical effects of type 2 diabetes patient management using digital healthcare technology: a systematic review and meta-analysis. *Healthcare*; 2022 [MDPI].
- [11] Stevens S, Gallagher S, Andrews T, Ashall-Payne L, Humphreys L, Leigh S. The effectiveness of digital health technologies for patients with diabetes mellitus: a systematic review. *Front Clin Diabetes Healthcare* 2022;3.
- [12] Remote continuous data monitoring and personalized data-driven approach for managing diabetes in a virtual and physical setting. In: Caccelli M, Said Y, Mojado J, Palsky C, Hashemi A, Almarzooqi I, editors. *Diabetes technology & therapeutics*. INC 140 HUGUENOT STREET, 3RD FL, NEW ROCHELLE, NY 10801 USA: MARY ANN LIEBERT; 2022.
- [13] Measurement TICfHO. [2023]. Available from: <https://connect.ichom.org/patient-centered-outcome-measures/diabetes/>.
- [14] Omani-Samani R, Maroufizadeh S, Almasi-Hashiani A, Sepidarkish M, Amini P. The WHO-5 well-being index: a validation study in people with infertility. *Iran J Public Health* 2019;48(11):2058.
- [15] WHO-5 well-being index [cited 2023 24 July]. Available from: <https://www.psykiatri-regionh.dk/who-5/Pages/default.aspx>.
- [16] Polonsky WH, Anderson BJ, Lohrer PA, Welch G, Jacobson AM, Aponte JE, et al. Assessment of diabetes-related distress. *Diabetes Care* 1995;18(6):754–60.
- [17] Williams N. PHQ-9. *Occup Med* 2014;64(2):139–40.
- [18] Quinn CC, Butler EC, Swasey KK, Shardell MD, Terrin MD, Barr EA, et al. Mobile diabetes intervention study of patient engagement and impact on blood glucose: mixed methods analysis. *JMIR mHealth and uHealth* 2018;6(2):e31.
- [19] Caccelli M, Said Y, Mojado JFD, Palsky C, Colodetti R, Almarzooqi I, et al. 974-P: implementation of remote continuous data monitoring within a clinical setting for the management of type 2 diabetes mellitus. *Diabetes* 2022;71 (Supplement 1).
- [20] ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, et al. 6. Glycemic targets: standards of care in diabetes—2023. *Diabetes Care* 2022;46 (Supplement 1):S97–110.
- [21] Lee S-M, Song I, Suh D, Chang C, Suh D-C. Treatment costs and factors associated with glycemic control among patients with diabetes in the United Arab Emirates. *J Obes Metabolic Syndrome* 2018;27(4):238–47.
- [22] Mata-Cases M, Rodríguez-Sánchez B, Mauricio D, Real J, Vlachou B, Franch-Nadal J, et al. The association between poor glycemic control and health care costs in people with diabetes: a population-based study. *Diabetes Care* 2020;43(4):751–8.
- [23] Laiteerapong N, Ham SA, Gao Y, Moffet HH, Liu JY, Huang ES, et al. The legacy effect in type 2 diabetes: impact of early glycemic control on future complications (the Diabetes & Aging Study). *Diabetes Care* 2019;42(3):416–26.
- [24] Bretschneider MP, Klásek J, Karbanová M, Timpel P, Herrmann S, Schwarz PEH. Impact of a digital lifestyle intervention on diabetes self-management: a pilot study. *Nutrients* 2022;14(9):1810.
- [25] Semenkovich K, Brown ME, Svrakic DM, Lustman PJ. Depression in type 2 diabetes mellitus: prevalence, impact, and treatment. *Drugs* 2015;75(6):577–87.
- [26] Papanas N, Tsapas A, Papatheodorou K, Papazoglou D, Bekiari E, Sariganni M, et al. Glycaemic control is correlated with well-being index (WHO-5) in subjects with type 2 diabetes. *Exp Clin Endocrinol Diabetes* 2010;364–7.
- [27] Batalha A, Ponciano IC, Chaves G, Felício DC, Britto RR, da Silva LP. Behavior change interventions in patients with type 2 diabetes: a systematic review of the effects on self-management and A1c. *J Diabetes Metab Disord* 2021;20(2): 1815–36.
- [28] Amante DJ, Harlan DM, Lemon SC, McManus DD, Olaitan OO, Pagoto SL, et al. Evaluation of a diabetes remote monitoring program facilitated by connected glucose meters for patients with poorly controlled type 2 diabetes: randomized crossover trial. *JMIR Diabetes* 2021;6(1):e25574.
- [29] Remote application and use of real-time continuous glucose monitoring by adults with type 2 diabetes in a virtual diabetes clinic. *Diabetes Technol Therapeut* 2021; 23(2):128–32.
- [30] Wilson-Anumudu F, Quan R, Castro Sweet C, Cerrada C, Juusola J, Turken M, et al. Early insights from a digitally enhanced diabetes self-management education and support program: single-arm nonrandomized trial. *JMIR Diabetes* 2021;6(1): e25295.