

Impact of a personalized mHealth program for type 2 diabetes mellitus during the COVID-19 pandemic: single-group pre-post retrospective analysis

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Abstract

Background: With increasing type 2 diabetes mellitus (T2DM) prevalence, mobile health (mHealth) interventions have shown promising results in supporting diabetes management and improving T2DM outcomes. With the COVID-19 pandemic, the world is increasingly embracing digital solutions to limit in-person interactions.

Objective: The study objective was to evaluate a personalized mHealth-anchored intervention in its effectiveness and feasibility for improving glycemic control and enhancing care experience in diabetes management. The program was coincidentally implemented during the national-level partial lockdown for COVID-19 in Singapore, allowing for a timely study of the use of mHealth for chronic disease management.

Methods: Thirty patients were enrolled from the Singapore Armed Forces and offered a 3-month intervention program in addition to the usual care they received for their T2DM or prediabetes. The program was standardized to include the following components: (1) in-person consultation with dietitian, (2) in-person review with diabetes specialist doctor, (3) one continuous glucose monitoring device in the first two weeks, (4) access to the mobile app that allows food and physical activity tracking, and communication via text messaging with the dietitian and doctor, and (5) context-sensitive digital health coaching provided by the dietitian over the mobile app. Medical advice was rendered to patients as needed when they experienced hypoglycemia requiring medication adjustments, or when they required adjustment of medications. Measurements of weight, height, and glycated hemoglobin A (HbA1c) were conducted at the two in-person visits at the start and end of the program. At the end of the program, patients were asked to complete a short survey to understand the motivation for joining the program, their feedback, and suggestions for improvement.

Results: of this study suggest that the mHealth-anchored intervention program was able to produce significant reductions in body weight and HbA1c in individuals with T2DM, when added to usual care. A program with a strong mHealth component can overcome challenges posed by COVID-19 to chronic disease management, including disruptions to in-person healthcare access.

Conclusions: Results of this study suggest that the mHealth-anchored intervention program was able to produce significant reductions in body weight and HbA1c in individuals with T2DM, when added to usual care. A program with a strong mHealth component can overcome challenges posed by COVID-19 to chronic disease management, including disruptions to in-person healthcare access.

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Original Manuscript

Original Paper

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Impact of a personalized mHealth program for type 2 diabetes mellitus during the COVID-19 pandemic: single-group pre-post retrospective analysis

Abstract

Background: With increasing type 2 diabetes mellitus (T2DM) prevalence, there is a need for effective programs that support diabetes management and improve T2DM outcomes. Mobile health (mHealth) interventions have shown promising results. With advances in wearable sensors and improved integration, mHealth programs could become more accessible and personalized.

Objective: The study aimed to evaluate the feasibility, acceptability, and effectiveness of a personalized mHealth-anchored intervention program in improving glycemic control and enhancing care experience in diabetes management. The program was coincidentally implemented during the national-level lockdown for COVID-19 in Singapore, allowing for a timely study of the use of mHealth for chronic disease management.

Methods: Patients with T2DM or prediabetes were enrolled from the Singapore Armed Forces and offered a 3-month intervention program in addition to the usual care they received. The program was standardized to include: (1) in-person initial consultation with a clinical dietitian, (2) in-person review with a diabetes specialist doctor, (3) one Continuous Glucose Monitoring device, (4) access to the mobile app for dietary intake and physical activity tracking, and communication via messaging with the dietitian and doctor, and (5) context-sensitive digital health coaching over the mobile app. Medical support was rendered to the patients on an as-needed basis when they required advice on adjustment of medications. Measurements of weight, height, and glycated hemoglobin A (HbA1c) were conducted at two in-person visits at the start and end of the program. At the end of the program,

patients were asked to complete a short acceptability feedback survey to understand the motivation for joining the program, their satisfaction, and suggestions for improvement.

Results: Over a four-week recruitment period, 130 individuals were screened and the enrolment target of 30 patients was met. Twenty-one patients completed the program and were included in the final analyses. Nine patients were lost to follow-up and did not have full data available for the final analyses. There were no significant differences in the baseline characteristics between patients that were included and excluded from the final analyses. The 21 completers rated a mean of 9.0 out of 10 on the Likert scale for both satisfaction questions. For the Yes-No question on benefit of the program, all of the patients selected "Yes". Mean HbA1c decreased from 7.6% to 7.0% (P=.004). There were no severe hypoglycemia events (glucose level <3.0 mmol/L) reported. Mean weight decreased from 76.8 kg to 73.9 kg (P<.001) – mean decrease of 3.5% from baseline weight. Mean body mass index decreased from 27.8 kg/m² to 26.7 kg/m² (P<.001).

Conclusions: The personalized mHealth program was feasible and acceptable, and produced significant reductions in HbA1c and body weight in individuals with T2DM. Such mHealth programs could overcome challenges posed to chronic disease management by COVID-19, including disruptions to in-person healthcare access.

Keywords: Diabetes Mellitus, Type 2; Prediabetic State; Text Messaging; Mobile Applications; Glycated Hemoglobin A; HbA1c; Blood Glucose; Body Mass Index

Introduction

Close to half a billion people in the world live with type 2 diabetes mellitus (T2DM) and this prevalence is expected to increase by 25% by 2030 [1]. An estimated 430,000 (14.4% prevalence) Singapore residents aged 21 years and older had T2DM in 2015, and the number was estimated to grow to 820,000 in the year 2035 (22.7% prevalence), assuming no change to the current landscape [2]. In addition, an estimated 560,000 (18.6% prevalence) Singapore residents in 2015 have prediabetes, of which an estimated 490,000 (16.2% prevalence) were undetected. T2DM has been identified as one of the chronic diseases that characterizes patients that persistently incur high healthcare costs [3]. Effective scalable prevention measures are thus urgently needed to prevent and better manage T2DM to reduce its burden.

Lifestyle and behavior modification interventions for the prevention and management of T2DM have been shown to be effective in reducing risk of disease progression [4, 5]. Executed well, lifestyle and behavior modification intervention programs can even have long-term sustained beneficial effects in decreased diabetes incidences and associated complications [6]. Such programs have traditionally been structured with high frequency of in-person group-based sessions over a long duration (at least six months) [4, 5]. Such programs could require a sizeable multidisciplinary professional team to run, which would be costly [7, 8], thereby limiting the scalability and sustainability of such interventions.

Simultaneously, many of these traditional lifestyle and behavior modification intervention programs have been found to experience low participation rates [4] and high attrition [9]. Reasons for dropping out from such intervention programs include conflict between work schedules and center's hours of operation, distance to center, forgetfulness, lack of familiarity with the center and services, and apathy towards diabetes education [10]. Potential solutions to these barriers include running the program in the community [11, 12], with reduced intensity [13], and leveraging mobile health (mHealth) interventions [14].

The use of mHealth for lifestyle and behavior modification interventions capitalize on easily rolled out technologies to make communication and self-management education components easily accessible and independent of location. Over the years, mHealth interventions have progressed from using phone calls, text messages, and internet websites, to more recently, smartphone applications (apps). The use of mHealth interventions for chronic disease care and management has been well-received with high acceptability and engagement [15-17]. In the care and management of T2DM, mHealth interventions have been successful in achieving improvements in clinical outcomes [18, 19]. The use of adaptable feedback on behaviors with tailored messaging in mHealth interventions further allows for personalization according to the needs and preferences of patients [20, 21]. Such patient-centered approach of mHealth interventions could improve motivation in patients to make lifestyle and behavioral modifications and to sustain the changes made [22, 23].

The use of wearable sensors in mHealth interventions provides real-time tracking and monitoring in patients with T2DM. Self-monitoring of blood glucose either by finger-stick, or newer Continuous Glucose Monitoring (CGM) technology, has been shown to be useful in helping patients improve their diabetes control [24-27]. Blood glucose data logged in mHealth apps can be consolidated with app-recorded diet and physical activity data and has been found to help facilitate self-care in patients at risk of, or with T2DM [28, 29]. Drawing on advancements in technology, integration of various successful features could bring about synergistic improvements in mHealth interventions for the management of T2DM.

Given the increasing burden and cost of uncontrolled T2DM and related complications, there is a great urgency for scalable and effective solutions that reduce such a burden and cost [30, 31]. In response to this need, a personalized mHealth-anchored intervention program was designed and implemented in patients with T2DM or prediabetes. This study aimed to evaluate the effectiveness and feasibility of this personalized mHealth program in improving glycemic control and enhancing care experience in diabetes management.

Methods

Site and Population

The program was conducted in Singapore, a city-state in tropical Southeast Asia with a population of 5.64 million people [32]. The patients were recruited from the Singapore Armed Forces in collaboration with their Headquarters Medical Corps. The Singapore Armed Forces provided primary healthcare services within military camps for its full-time service personnel and conscripts, and a range of risk-based health screening programs for personnel in the older age bands. These older personnel with chronic health conditions were also free to obtain care from the national healthcare system outside of the Singapore Armed Forces.

The patients were recruited from active full-time service personnel and conscripts. Invitation to participate in the program was conducted by the Singapore Armed Forces' Headquarters Medical Corps through a series of intranet publicity advertisements posted over four weeks in February 2020. Interested patients were screened by the Headquarters Medical Corps and were enrolled into the program if they were interested and met the eligibility criteria of having T2DM or prediabetes. The patients were deemed to have: (1) T2DM, if they had a glycated hemoglobin A (HbA1c) test result of ≥6.5% in the past one year, or if they were on medication for T2DM, or (2) prediabetes, if they had a HbA1c test result of between 5.7-6.4% in the past year, and they were not on any medications for T2DM. The enrolment target was set at 30 individuals, which was deemed as sufficient to assess the feasibility and acceptability of an intervention in such pilot programs [33, 34].

Intervention Program

The Singapore Armed Forces' Headquarters Medical Corps worked with NOVI Health, a healthcare-technology start-up based in Singapore, to provide their proprietary mHealth program in the enrolled population.

All eligible patients were offered the 3-month intervention program in addition to the usual care that they received for their T2DM or prediabetes (Figure 1). The program was standardized to include the following components: (1) in-person initial consultation with a clinical dietitian that served as a health coach, (2) in-person review with a diabetes specialist doctor, (3) one Abbott Freestyle Libre CGM device that provided monitoring in the first two weeks, (4) access to the mobile app that allowed food and physical activity tracking, and communication via text messaging with the dietitian and doctor, and (5) context-sensitive digital health coaching provided by the dietitian over the mobile app (Figure 2).

In the first in-person visit to the clinic (Visit 1), the patients have a consultation with the dietitian to set their health goals and discuss behavioral lifestyle changes that could be made. The patients also have a consultation with the diabetes specialist doctor, which allowed for the review of comorbidities and medication regime. The patients were also provided with one CGM device and were guided on how to use it for glucose monitoring and how to provide the care team with access to their real-time CGM data.

In the subsequent three months after Visit 1, the patients were free-living and used the mobile app to log their dietary intake and physical activity. The dietitian and doctor were able to correlate the CGM, dietary intake, and physical activity data, together with available information on the patients' health status (information on HbA1c, comorbidities, and medication regime). This allowed them to deliver timely personalized recommendations through the messaging function of the mobile app. The health coaching via the mobile app was led by the clinical dietitian, with input from the fitness coaches provided when needed, and with medical oversight from the reviewing diabetes specialist doctor. Medical support via the mobile app was also rendered to the patients on an as-needed basis. This could be if they experienced hypoglycemia requiring medication adjustments, or if they required advice on the adjustment of medications. After three months, the patients returned to the clinic for their second in-person visit (Visit 2), to meet with the diabetes specialist doctor and dietitian for final review.

Patient recruitment for the program started in February 2020 and the interventions in the program ran from March 2020 to June 2020. The recruitment period and the first month of the intervention program corresponded with a worsening COVID-19 situation in Singapore through the months of February and March 2020. This culminated in a national-level lockdown, which started on 7 April 2020 and ended on 1 June 2020, coinciding with the second and third months of the intervention program. The two in-person visits to the clinic (Visits 1 and 2) happened to have been scheduled in the periods before and after the lockdown in Singapore and so were not impacted.

Outcome Measurements

Measurements of weight, height, and HbA1c were conducted at Visits 1 and 2. Weight and height were measured by a trained nurse, using a Surgico Healthweigh® machine. At the end of the program at Visit 2, the patients were asked to complete a short acceptability feedback survey to

understand the motivation for joining the program, their satisfaction, and suggestions for improvement. The question on motivation, "What was your primary motivation for signing up for this program?", was multiple choice with four options: 1. Wanted to get my diabetes under control 2. Wanted to get dietary advice for my diabetes, 3. Wanted to lose weight, 4. Was asked to participate by HQMC There were two satisfaction questions on a 10-point Likert scale, "How satisfied were you with the program?" and "How likely are you to recommend this program to your colleague?". A fourth question, "Do you think that other servicemen would benefit from this program?", was a Yes-No question asking the patients on whether the program would be beneficial to others.

Data Analysis

Patients were considered completers and included in the final outcomes analyses if they had completed the full 14 weeks of the intervention program, with weight, height, and HbA1c measurements at baseline (Visit 1), and at completion of the program (Visit 2). Means were calculated for baseline characteristics that were continuous variables. Due to non-normality of data, Wilcoxon's signed rank test was used to compare means between completers and those that were lost to follow-up and excluded. Proportions were calculated for baseline characteristics that were categorical variables. With counts less than five, Fisher's exact test was used to compare distributions of completers and those that were lost to follow-up and excluded.

The final analyses of main outcomes of interest for acceptability and effectiveness were limited to only the completers. For the outcomes of HbA1c, weight and BMI, the patients were further split for subgroup analyses: (1) by baseline HbA1c \leq 7% or >7%, and (2) by baseline body mass index (BMI) <27.5 kg/m² (Normal and Overweight) or \geq 27.5 kg/m² (Obese). The HbA1c cut-off was selected based on the HbA1c threshold set by major clinical guidelines for what is considered good diabetes control [35-37], and the BMI threshold was selected based on what is considered obese in the Asian population [38]. Due to non-normality of data, Wilcoxon's signed rank test was used for the paired comparisons of the main outcomes at Visit 1 and Visit 2, with significance level set at α =0.05. Analyses were all conducted in R version 3.6.1. Means and standard deviations (SD) of the main outcomes are presented, along with statistical p-values (P) when applicable. Calculation of Type II beta errors were also conducted for the main outcomes of interest using G*Power version 3.1.9.4, for a two-tailed test according to a Laplace parent distribution and α = 0.05. Beta errors of more than 0.2 are indicated.

Study Approval

This study was conducted as part of a program evaluation. The data collected was presented at the Singapore Armed Forces' Joint Medical Committee for Research, and approved for exemption from full review at the Institutional Review Board.

Results

Baseline Characteristics

Over the recruitment period of four weeks in February 2020, there were 130 individuals that were screened, of which 30 met criteria and were interested in participating in the program after more information was shared. The baseline characteristics of the patients in this study are shown in Table 1. Of the 30 enrolled patients, seven were lost to follow-up, and two had completed the program but did not have complete measurements from Visit 2. As such, 21 patients were completers and were

included in the final outcomes analyses. There were no significant differences in any of the baseline characteristics between the patients that were excluded and those that were included in the final outcomes analyses.

The majority of the patients were male. The majority of the patients have diabetes; the patients who had diabetes were all on glucose lowering medication at enrollment into the program. While there were patients who were on insulin therapy on entry into the program, no patient was newly started on insulin during the program. There were five patients with medication adjustments made. One patient on insulin had his insulin dosage reduced, two patients had their sulfonylurea switched to another oral anti-hyperglycemic medication to reduce hypoglycemic risk, and two patients had one oral anti-hyperglycemic medication added to their existing regime. About two-thirds of the patients had baseline HbA1c >7%, and about half were in the Obese BMI category.

Table 1. Baseline characteristics of all enrolled patients, patients lost to follow-up, and patients who

completed the program and were included in the final analyses.

	All Recruited (n=30)	Lost to Follow- Up (n=9)	Completers (n=21)
Age, years (range)	49.1 (21-64)	43.7 (21-61)	51.4 (32-64)
<50 years	17 (57%)	7 (78%)	10 (48%)
≥50 years	13 (43%)	2 (22%)	11 (52%)
Gender (%)		30	
Female	9 (30%)	1 (11%)	8 (38%)
Male	21 (70%)	8 (89%)	13 (62%)
Ethnicity (%)			
Chinese	24 (80.0%)	8 (89%)	16 (76%)
Malay	1 (3%)	0 (0%)	1 (5%)
Indian/Pakistani	5 (17%)	1 (11%)	4 (19.0%)
Diabetes Status (%)	1		
Prediabetes	2 (7%)	1 (11%)	1 (5%)
T2DM	28 (93%)	8 (89%)	20 (95%)
Medication Adjustments (%)			
Adjusted	8 (27%)	3 (33%)	5 (24%)
Not Adjusted	22 (73%)	6 (67%)	16 (76%)
Baseline HbA1c Category			

(%	5)			
	Baseline HbA1c ≤7%	11 (37%)	4 (44%)	7 (33%)
	Baseline HbA1c >7%	19 (63%)	5 (56%)	14 (67%)
Ba (%	seline BMI Category			
	Normal and Overweight Baseline BMI <27.5 kg/ m ²	15 (50%)	4 (44%)	11 (52%)
	Obese Baseline BMI ≥27.5 kg/ m²	15 (50%)	5 (56%)	10 (48%)
Ba	seline Mean HbA1c, %	7.7	7.9	7.6
Ba kg	seline Mean Weight,	77.7	79.7	76.8
Ba m²	seline Mean BMI, kg/	27.9	28.2	27.8

Acceptability Feedback

For the multiple-choice question on motivation, 10 (47.6%) patients selected "Wanted to get my diabetes under control", four (19.0%) patients selected "Wanted to get dietary advice for my diabetes", three (14.3%) patients selected "Wanted to lose weight", and four (19.0%) patients selected "Was asked to participate by HQMC". The patients rated a mean of 9.0 out of 10 on the Likert scale for both satisfaction questions. For the Yes-No question on the benefit of the program, all of the patients selected "Yes".

Effectiveness Outcomes

For all 21 completers, mean HbA1c decreased from 7.6% to 7.0% (P=.004) (Table 2). Mean weight had decreased from 76.8 kg to 73.9 kg (P<.001), which was a mean decrease of 3.5% (SD = 3.2) from the baseline weight. Mean BMI had decreased from 27.8 kg/m² to 26.7 kg/m² (P<.001).

Table 2. Mean values and standard deviations (SD) of HbA1c, weight, and body mass index (BMI) at Visit 1 and Visit 2 for all completers, along with statistical p-values (*P*) of Wilcoxon's signed rank test.

	Visit 1	Visit 2	P
Mean HbA1c (SD),	7.6 (1.1)	7.0 (0.8)	.004
Mean Weight (SD), kg	76.8 (15.6)	73.9 (13.8)	<.001

Mean BMI (SD),	27.8 (5.4)	26.7 (4.8)	<.001
kg/m²			

Subgroup Analyses by Baseline HbA1c Category

For the patients that had baseline HbA1c \leq 7%, there was no statistically significant change in HbA1c upon completion of the 3-month intervention program, recorded in Visit 2 (Table 3). However, mean weight decreased from 75.0 kg to 73.0 kg (P=.02), which was a mean decrease of 3.9% (SD=3.7) from the baseline weight. Mean BMI decreased from 26.8 kg/m² to 26.1 kg/m² (P=.02). For the patients that had baseline HbA1c >7%, mean HbA1c decreased from 8.1% to 7.2% (P=.005). Mean weight also decreased from 77.8 kg to 74.3 kg (P=.006), which was a mean decrease of 2.5% (SD=1.8) from the baseline weight. Mean BMI decreased from 28.3 kg/m² to 27.1 kg/m² (P=.006).

Table 3. Mean values and standard deviations (SD) of HbA1c, weight, and body mass index (BMI) at Visit 1 and Visit 2 for the patients that had baseline HbA1c \leq 7% or \geq 7%, along with statistical p-

values (*P*) of Wilcoxon's signed rank test.

	Baseline HbA1c ≤7%				e HbA1c >7	7 %
		(n=7)			(n=14)	
	Visit 1	Visit 2	P	Visit 1	Visit 2	P
Mean HbA1c (SD),	6.7 (0.3)	6.6 (0.6)	.67ª	8.1 (1.0)	7.2 (0.8)	.00 5
Mean Weight (SD), kg	75.0 (13.5)	73.0 (12.2)	.02	77.8 (16.9)	74.3 (14.9)	.00
Mean BMI (SD), kg/m²	26.8 (5.1)	26.1 (4.8)	.02	28.3 (5.7)	27.1 (4.9)	.00 6

^a Type II beta error is >0.2

Subgroup Analyses by Baseline BMI Category

There were no statistically significant changes in HbA1c, weight, or BMI for patients that were in the Normal and Overweight BMI category, after the intervention in Visit 2 (Table 4). For the patients that were in the Obese BMI category, mean HbA1c decreased from 7.6% to 6.8% (P = .006). Mean weight also decreased from 89.3 kg to 84.1 kg (P = .002), which was a mean decrease of 5.9% (SD = 2.2) from the baseline weight. Mean BMI decreased from 32.5 kg/m² to 30.6 kg/m² (P = .002).

Table 4. Mean values and standard deviations (SD) of HbA1c, weight, and body mass index (BMI) at Visit 1 and Visit 2 for the patients that had baseline body mass index < 27.5 kg/m^2 (Normal and Overweight) or $\geq 27.5 \text{ kg/m}^2$ (Obese), along with statistical p-values (*P*) of Wilcoxon's signed rank test.

Normal and Overweight				Obese	
(n = 11)			(n = 10)	
Visit 1	Visit 2	P	Visit 1	Visit 2	P

Mean HbA1c (SD),	7.7 (1.3)	7.3 (0.9)	.14ª	7.6 (0.9)	6.8 (0.6)	.00
Mean Weight (SD), kg	65.5 (8.7)	64.6 (8.1)	.07ª	89.3 (11.1)	84.1 (11.2)	.00
Mean BMI (SD), kg/m²	23.5 (2.1)	23.2 (2.03)	.07ª	32.5 (3.6)	30.6 (3.7)	.00

^a Type II beta error is >0.2

Complications

Throughout the study, the patients had no hospitalization episodes for any diabetes-related complications. There were no severe hypoglycemia (glucose level < 3 mmol/L) events observed or reported.

Discussion

This study evaluated a real-world personalized mHealth-anchored intervention program in its feasibility, acceptability, and effectiveness for diabetes management. The program garnered a lot of interest and the enrolment target was met fairly quickly in less than a month. The program was also implemented as planned in spite of the disruptions from COVID-19. The program also received high patient ratings of satisfaction and perceived benefit from participation in the program. The patients achieved a significant reduction in HbA1c in 3 months, ending the program with an average HbA1c of 7%. Reduction of HbA1c levels to \leq 7% is consistent with the glycemic target set by most clinical guidelines [35, 36], and has been shown to reduce microvascular [39-43] and macrovascular [44] complications in individuals with T2DM. Patients in the study also achieved weight loss over three months that met the clinically significant threshold of 3% [45, 46]. Such reductions have been observed to lead to improvements in cardiovascular risk factor such as glycemic control, systolic and diastolic blood pressure, as well as LDL and HDL cholesterol levels [47].

The improvements observed were achieved in patients who had known T2DM and prediabetes, and who were already receiving their usual care and on existing medications. This suggests that there could be a role for a personalized mHealth program for patients with diabetes, even if they were already under usual medical care for their diabetes. Such a program could improve control of diabetes, and further reduce the risk of microvascular and macrovascular complications. In the subgroups of patients with glycemic and BMI measures above the ideal range, the impact of the personalized mHealth program was even greater. These results were not unexpected as the patients with starting HbA1c and weight that were further from target were likely to have more room for improvement. The mHealth program could benefit most individuals with diabetes, and targeting the program at individuals with higher HbA1c or higher BMI would yield greater improvements in both HbA1c and BMI.

Diabetes Management Programs

Traditionally, diabetes management programs that supplement usual care for individuals with diabetes have focused on enhancing support and education, improving nutrition, and increasing physical activity with a structured, curriculum-based approach [4]. Such intervention programs were usually conducted in-person and have been shown to be effective in improving glycemic control. In the Look AHEAD trial, intensive lifestyle intervention components involved group and individual

meetings to achieve and maintain weight loss through decreased caloric intake and increased physical activity. The trial achieved a HbA1c reduction of 0.7% and weight loss of 8.6% over one year [48]. In recent years, mHealth lifestyle intervention programs have emerged, bringing convenience and accessibility to individuals with diabetes, achieving HbA1c reductions of about 0.3 to 0.5% [18, 19, 49-51], and insignificant changes in weight loss [19, 49, 51].

The personalized mHealth program in this study combined health coach-led personalized lifestyle intervention with medical support by a specialist doctor, the use of CGM, and the integrated delivery through a mobile app. The medical support allowed for adjustments in medication(s) where beneficial, for example, optimizing the timing of administration of the medication to more effectively suit the lifestyle patterns of the patient. However, it is important to note that in this study, there were no major adjustments of medications, such as initiating patients on insulin, that could have confounded the improvements observed. This is in contrast to another feasibility study with the same mHealth components, in which it was not possible to determine if improvements were due to intensification of medical therapy or from the other components of the intervention program [52].

The mobile app and CGM allowed the real-time tracking of diet, physical activity, and glucose, allowing interventions to be highly personalized, context sensitive, and delivered in a timely manner. Visualization of their own data, coupled with remote monitoring and actionable insights from trusted experts through the mobile app to make sense of that data, could enable the patients to appreciate the impact of their behaviors on their own health parameters. This could have further empowered and reinforced the user to implement behaviors that improve their health on a continuous, real-time basis in between clinic visits, with a low risk of adverse events like hypoglycemia. The integrated solution incorporating medical support, CGM, and lifestyle care delivery through a mobile app likely accounted for the intervention in this study to achieve results comparable to those reported in other diabetes lifestyle intervention programs, in a far shorter period of three months.

Based on the responses from the survey at the end of the program, patients found this personalized mHealth program to be beneficial in improving their diabetes control. Patients also reported that they were satisfied with the personalized mHealth program. These results suggested that patients found value in the mHealth program and were also receptive to the program. As there was no glycemic threshold effect, participation in a personalized mHealth program could be recommended to most individuals with diabetes or prediabetes, with the understanding that greater clinical improvement is seen with poorer starting glycemic control.

COVID-19 and Implications on Chronic Disease Management

This program was conducted against the backdrop of a worsening COVID-19 pandemic, which saw Singapore undergoing a national-level lockdown, termed "circuit breaker", from 7 April 2020 to 1 June 2020. This coincided with the mHealth-anchored digital coaching phase of the program. During this period, there was closure of premises, such as non-essential workplaces, schools, exercise and recreational facilities, and places of worship, along with prohibition of all social gatherings [53]. Essential services in healthcare, transport, cleaning, food services, and supply chains remained open, but on a reduced capacity basis. This had several implications on the health and diabetes control of the patients.

With the closure of sports facilities, many of the patients who performed their physical activity in these locations were unable to continue doing so. Closure of workplaces and recreational facilities, as well as banning of social gatherings, meant that patients were stepping out of their homes less and commuting less, resulting in lower physical activity levels [54]. The stress of being under lockdown

could increase the consumption of ultra-processed food, which could be detrimental to diabetes control. While it is too early to assess the impact of the lockdown on diabetes control, experts anticipate a negative impact on weight as well as glycemic control [55, 56].

During the "circuit breaker" period, the patients also had greater difficulty accessing healthcare. Many of the patients had their regular review with their primary care physicians postponed. Some of the patients in critical operational roles were confined to the military camps, with some reporting difficulties getting refills of certain medications from their external healthcare providers, and in some instances, difficulties in communication via the mobile app due to certain camp security restrictions. These healthcare access issues would have negatively impacted the patients' diabetes care and control during this period.

The patients in this study had experienced clinically significant improvements in their weight, BMI and glycemic control. This was in spite of the anticipated worsening of weight and glycemic control due to decreased physical activity, poorer diet, and lack of access to healthcare due to such national-level lockdowns [54-56]. This highlights the role that a diabetes solution with a mHealth component can play in improving the management of chronic diseases, such as T2DM, especially during periods where there are barriers to accessing healthcare in-person.

Strengths & Limitations

This study evaluated a real-world context-sensitive mHealth-anchored intervention program with free-living patients. The program also coincidentally began during the start of the COVID-19 pandemic, with the bulk of the encounters occurring during the national-level lockdown in Singapore. This allowed for a timely study of the use of mHealth for chronic disease management, just as the world needed to move towards embracing more digital solutions to limit in-person interactions.

A limitation of this study was that the program was conducted only with military personnel, which could be expanded to include other professions so that the results could be more generalizable. However, the focus on military personnel could inform specific occupational policy changes to improve chronic disease prevention and management for active military personnel [57], and could reduce productivity lost amongst active personnel [58].

Another limitation was that the study consisted of a single intervention arm with no control group. Without a control group, there was a possibility that patients who were not undergoing the same program might had still experienced the same improvements with usual care during the same time period. However, this study demonstrated the feasibility of the program and also provided pilot data that could pave the way for future studies. Further explorations could be done on the improvements of the personalized mHealth program intervention and its various components.

Close to a third of the patients had dropped out of the program. However, this was not higher than expected for a 3-month program and we did not observe any systemic differences between the patients that had completed the program compared to those that had dropped out. This was supported by the lack of statistical difference when the baseline characteristics of the two groups were compared. In spite of the small sample size, there was sufficient power for differences to be detected in the main analyses. However, there was insufficient power for a few of the subgroup analyses.

The patients were also only followed-up for three months until the end of the program, and so long-term effects of the program after it has ended were not known. This was a limitation commonly

found in the review of other mHealth interventions [18, 49, 51], but there had been some promising indications of positive long-term outcomes [59]. This warrants additional follow-up investigations in future studies to explore whether the effects were sustained after the program has ended, and whether some components could be implemented periodically in a cost-effective way to maintain the improvements achieved.

Conclusion

The personalized mHealth-anchored intervention program demonstrated feasibility and acceptability, and was able to produce significant reductions in body weight and HbA1c in individuals with T2DM, in addition to usual care. The results also suggested that a program with a strong mHealth component could overcome challenges posed by COVID-19 to chronic disease management, including disruptions to in-person healthcare access. Further investigation is warranted to test the durability of the results, and the use of such digital therapeutics as a scalable solution to address the burden of diabetes.

Author's Contributions

KTXQ, SAT, TCH, and CT were responsible for the design of the intervention program. TCH and JT assisted with recruitment of patients for the program and operational aspects to the implementation of the program. IYHA was responsible for data analysis. IYHA, and KTXQ wrote the first draft of the manuscript. All authors provided inputs, edited, and approved the final draft of this paper.

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Conflicts of Interest

KTXQ, JT, and SAT are co-founders and shareholders of NOVI Health. IYHA, CT, TCH, and JK declare no conflicts of interest.

Abbreviations

T2DM: Type 2 Diabetes Mellitus

mHealth: mobile health

CGM: continuous glucose monitoring

BMI: body mass index

HbA1c: glycated hemoglobin A

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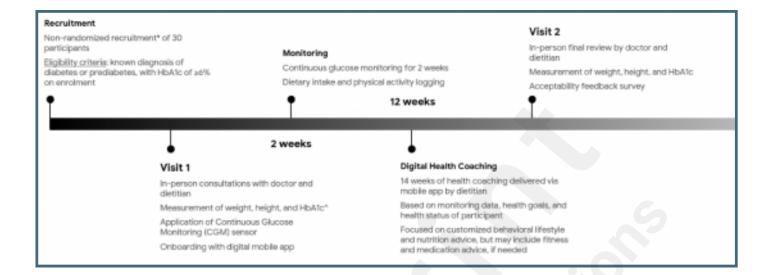
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Supplementary Files

Figures

Intervention program timeline and protocol. * Recruitment was done with a series of publicity advertisements on the Singapore Armed Forces' intranet ^ HbA1c was measured if there was no valid reading within the prior 3 months.



Screenshots of mobile app dashboard with diet and physical activity goals, real-time continuous glucose monitoring data, food and physical activity logs, and personalized recommendations delivered through the messaging function in the mobile app.

