BALANCE PROGRAMME: A Digital Therapeutic Solution for Type 2 Diabetes Management

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Abstract

Background: Type 2 diabetes mellitus (T2DM) is a growing global health issue. In 2016, 9.7% of Bruneian adults aged 18-69 have diabetes, and it was the third leading cause of death. Effective self-management can mitigate complications requiring healthcare interventions and thereby reduce healthcare costs. Leveraging on digital technology, Brunei Darussalam has deployed a comprehensive, national mobile health (mHealth) platform, BruHealth; synced with the Brunei Health Information Management System (BruHIMS), enabling patients to access their health records in real time, schedule appointments and explore medical articles like nutrition and lifestyle. A Digital Therapeutics (DTx) module focused on the management of Type 2 Diabetes Mellitus (DM DTx) has been developed in Brunei Darussalam. DM DTx consists of a digital lifestyle intervention module which is integrated into the BruHealth application, and a separate Healthcare Professional (HCP) Portal for health coaches to manage their patients. The intervention, named BALANCE Programme, runs for 16 weeks and focuses on enabling self-management. This study explores the effectiveness of DM DTx in managing T2DM through digital lifestyle interventions. As there is a predominant Muslim population, this study additionally aims to gain insight into fasting practices for Muslim participants with T2DM.

Objective: The primary objective is to determine the proportion of participants who achieve a 0.6% reduction in HbA1c after 16 weeks. Secondary objectives include evaluating changes in HbA1c, fasting lipid profile, blood glucose, BMI, and waist circumference; analysing participant feedback; and examining the fasting experience of Muslim participants with T2DM during Ramadan.

Methods: This is a single-arm, non-randomized intervention study. Participants with T2DM will undergo an online 16-week lifestyle management module (the BALANCE programme) on BruHealth, which includes diabetes self-management education (DSME), personalised lifestyle recommendations, and health coach support. Anthropometric measurements (BMI and waist circumference) and blood tests (HbA1c, fasting blood glucose, lipid profile) will be taken at baseline and after the intervention for comparison.

Results: Recruitment is currently ongoing. As of 31st January 2025, 334 participants have been enrolled into the programme and 61 participants have completed the programme.

Conclusions: Self-management mHealth applications are a promising tool for chronic disease management, including T2DM. The BALANCE Programme will be the first national scale study to investigate the effectiveness and feasibility of a fully online T2DM intervention. The localisation to a region’s population can create a solution that is fit for purpose and contributes to improved health outcomes.

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BALANCE PROGRAMME: A Digital Therapeutic Solution for Type 2 Diabetes Management

Authors: Jane, Dr Joshua, Dr Kwang, Dr Mus, Dr Shaz, Dr Alice, Yvonne, Dr Lina

Introduction

Background

Type 2 diabetes mellitus (T2DM) has emerged as a significant global health concern, with a worldwide prevalence of 537 million in adults in 2021 and is projected to rise to 783 million in 2045 [1]. In 2016, 9.7% of the Bruneians aged between 18 and 69 years were diagnosed with diabetes [2]. Diabetes is the third leading cause of death in Brunei Darussalam accounting for 10.1% of total deaths in 2017 [3]. Therefore, there is a need for effective management strategies tailored for patients with T2DM to achieve target glycaemic control and reduce the risks of developing complications. This will lead to more efficient utilisation of health resources.

In Brunei Darussalam, diabetes-related healthcare costs strain the national budget and heighten demand for services necessary to manage complications related to diabetes. The global cost of diabetes was estimated at USD 966 billion in 2021, projected to rise to USD 1.03 trillion by 2045 [4]. This burden includes direct medical expenses and indirect costs from increased prescription use, costly hospital services and complications that can reduce overall productivity and lead to unemployment [5][6].

T2DM is a chronic disease that can lead to severe complications if it is not managed appropriately. This underscores the critical role of self-management. Effective lifestyle management which incorporates regular physical activity, healthy diets, and medication adherence can reduce both disease complication risks and healthcare costs [8]. By employing SMART (Specific, Measurable, Achievable, Relevant, and Time-bound) goals and behavioral techniques, individuals can improve their diabetes control and disease outcomes [9]. Additionally, mobile health (mHealth) has been shown to positively improve health self-management practices on chronic conditions [10][11][12].

The digitalisation of healthcare can further benefit management of chronic diseases, such as T2DM [13]. With mobile ownership reaching 78% globally [14], healthcare can access a broad audience, enhancing health equity by providing vital information and resources. This accessibility equips underserved populations with tools for effective self-management, such as tracking health metrices and connecting with healthcare providers for personalised guidance.

BruHealth is the national mHealth application and healthcare portal in Brunei Darussalam, initially developed to mitigate COVID-19 spread. It has since evolved into a comprehensive digital health solution, benefiting the general population. The application is synced with the Brunei Health Information Management System (BruHIMS), which covers over 95% of residents, allowing real-time access to healthcare data. Users can view their health records through BruHealth, enabling them to monitor their health status and, access their blood tests results. Beyond pandemic-related features, BruHealth now offers online appointment scheduling, health assessments and access to medical articles on topics like nutrition and lifestyle. By providing an accessible, user-friendly platform, BruHealth promotes the adoption of digital health technologies while allowing users to manage their health effectively [12].

Rationale

Digital therapeutics (DTx) are software-based treatments that deliver interventions with best available evidence to manage or prevent diseases. They supplement or replace traditional

therapies and are prescribed for chronic conditions like diabetes and mental health disorders. In Brunei Darussalam, a DTx module focused on the management of Type 2 Diabetes Mellitus (DM DTx) has been developed.

The DM DTx module consists of a digital lifestyle intervention (named the BALANCE programme which is integrated into the BruHealth application), and a Healthcare Professional (HCP) Portal where Health Coaches can interact with their patients and help them manage their condition. The benefits of the DM DTx include patient education on diabetes management through lifestyle adjustments for better glycaemic control, and real-time advice that have been designed to seamlessly integrate into daily activities thus enabling patients to self-manage their diabetes with greater confidence.

DM DTx may improve self-management and the quality of life of individuals with T2DM while paving the way for a more efficient and effective healthcare model. This is the first study in Brunei Darussalam designed to evaluate the potential effectiveness and feasibility of a T2DM digital intervention which employs a fully online management approach.

Separately, as Brunei Darussalam has a Muslim-majority community, there is an optional component within the DM DTx offered to Muslim participants as an opportunistic way of gaining more insights into their fasting practices during the last Ramadan. Studies have shown that a significant number of Muslim patients in Brunei Darussalam with diabetes fast during Ramadan. For instance, a study found that 93.4% of participants fasted during Ramadan, with an average of 24.1 days. This optional component in the DM DTx could provide valuable insights into how fasting impacts diabetes management and help tailor more effective treatment plans for Muslim patients [15].

Aims and Objectives

Our study aims to evaluate the effectiveness of the DM DTx in managing patients with T2DM by delivering digital lifestyle interventions through an easily accessible platform (BruHealth), and to evaluate participants' feedback to improve the application's content and structure for better user experience.

The primary objective is to determine the proportion of participants who achieve at least 0.6% reduction in HbA1c from baseline following a 16-week lifestyle intervention provided by the DM DTx module [16]. Secondary objectives are: (1) to evaluate overall changes in HbA1c, fasting lipid profile, fasting blood glucose, BMI and waist circumference over a 16-week period, (2) to analyse participants' feedback on the BALANCE programme; and (3) to evaluate and fasting experience amongst Muslims with T2DM during Ramadan and to calculate their fasting risk using IDF-DAR score [17].

Methods

Study Design

This is a single-arm, non-randomised intervention study which involves the utilisation of BALANCE, a 16-week diabetes lifestyle management programme (described in more detail under 'Intervention'). Patients with T2DM are enrolled and taught diabetes self-management with structured educational courses, and their progress is monitored through the DM DTx as with dedicated health coaches.

Anthropometric measurements are taken at baseline and at the end of the study. These include BMI (height and weight) and waist circumference. A fasting blood sample is also taken at baseline and at the end of the study. The blood tests include:

- Fasting blood glucose
- HbA1c
- Fasting lipid profile (total cholesterol, triglycerides, LDL cholesterol and HDL cholesterol)

A serum creatinine is also taken at baseline if there is no result available within 1 year of enrolment.

Participants

Sample Size

Through sample size calculation, it was found that a sample of 439 participants provides 90% power to detect a 0.14 effect size using a paired t-test at a 0.05 significance level. Considering potential attrition rates, the target sample size is set at 500 participants.

Inclusion Criteria

Individuals with T2DM between the ages of 18 to 70 years old either through diet control, or on treatment with oral hypoglycaemic agents, once or twice daily insulin injections, or established on at least 6 months of glucagon like peptide-1 receptor agonists (GLP1-RA) are included into the study.

Exclusion Criteria

The following individuals are excluded from the study: (1) those with T2DM requiring more than twice daily insulin injections; (2) those with type 1 diabetes; (3) those who are pregnant or breastfeeding; (4) individuals with a recent history of recent myocardial infarction or cerebrovascular accident in the past 6 months; (5) those with a history of heart failure, liver failure, or active cancer diagnosis; (6) those undergoing treatment for active foot disease or active diabetes-related eye disease; 7) those with chronic kidney disease (CKD) stage 4 or 5 according to estimated glomerular filtration rate (GFR) (based on CKD-EPI); (8) those with a history of hospitalisation in the past 6 months; (9) those with doctor's advice not to participate in intense physical activity; (10) those with physical disability and/or unable to perform activities of daily living; and (11) those unable to use the BruHealth application or watch YouTube videos independently on their mobile devices.

Recruitment

The study utilises volunteer sampling strategy. Recruitment is undertaken through the BruHealth application, which can be accessed by residents with a mobile device in Brunei Darussalam. Upon completion of the screening questionnaire on BruHealth, potential participants who are eligible will be enrolled into the study.

Online promotions comprise of several methods such as digital banners on the BruHealth application, targeted nudges to BruHealth users diagnosed with T2DM and digital marketing strategies on social media platforms. Offline strategies include health promotional events,

radio promotions and printed promotional materials distribution in hospitals and health centres.

Intervention

Participants who have been enrolled onto the study will undergo a briefing session on the BALANCE programme. During the briefing session, Muslim participants who had fasted during Ramadan in 2024 and who intend to fast this year will be assessed using the IDF-DAR risk stratification tool to determine their risk score to determine the safety of fasting. Risk stratification is an important step in the process of providing guidance to individuals with diabetes who fast during Ramadan. Each participant is assigned a health coach for personalised care and provided with tailored lifestyle modification recommendations on the BALANCE programme.

Participants are provided with the following equipment: a glucometer, a lancing device, blood test strips, and lancets to measure blood glucose, a resistance band for exercise, a measuring tape to measure waist circumference, a Bluetooth-enabled weighing scale to measure weight, and a smart watch to track step count and aerobic exercise. The glucometer, weighing scale and smart watch are synced to the application to enable automatic data logging.

Diabetes Self-Management Education (DSME)

The structured DSME course focuses on sharing healthcare knowledge and tips specifically for individuals with diabetes. The aim is to increase health literacy to enable participants to be more aware of how their lifestyle choices may affect their glycaemic control.

The materials are presented in the form of videos and educational articles, split across 4 phases (Table 1) to build upon knowledge acquired in earlier phases. There is also practice and review components to test the participants' understanding of materials.

Table 1: 4 Phases of DSME Across 16-week Intensive Education Programme

Phase I (Week 1 to 2)	• Pathophysiology • Diabetes self-management • Goal setting and motivation and coping skills • Hypo- and hyper-glycaemia management, healthy eating pattern, exercising with diabetes and precautions
Phase II (Week 3 to 6)	• Advance nutrition education on grocery shopping, tips for special occasions, etc. • Monitoring skills and importance, medications • Best exercise practices and planning tips
Phase III (Week 7 to 10)	• Diabetes-related complications and prevention • Incorporating nutrition into daily life and eating habits • Problem solving skills and tips to encourage diabetes self-management
Phase IV (Week 11 to 16)	• No new courses, focus on converting learning to behaviour • Recommend articles or animations targeting barriers

Lifestyle Modification Plans, Logging and Reports

The BALANCE programme administers lifestyle modification intervention in blood glucose monitoring, exercise and diet through personalised recommendations and goals based on participants' current state of health and lifestyle habits. SMART goals which are Specific, Measurable, Achievable, Relevant, and Time-bound, are incorporated into the programme through the design of logging functions,and further re-enforced through educational courses and active monitoring by the health coaches. Health coaches encourage participants to achieve lifestyle changes by ensuring that the goals set are clear, measurable, and time-sensitive, which enhances motivation and accountability. This approach helps participants to clearly define and track their progress towards managing their condition more effectively through goal setting and behavioral activation.
At the start of the programme, personalised plans are generated for each participant as below:

Blood Glucose Monitoring

Participants are taught to undergo structured capillary blood glucose monitoring with logging of their blood glucose readings (Figure 1). Management of hypoglycaemia and significant hyperglycaemia (defined by our study protocol), will be discussed in the "Escalation Model" section. For non-severe hypoglycaemia or hyperglycaemia, participants will receive self-management guidance through the DM DTx.

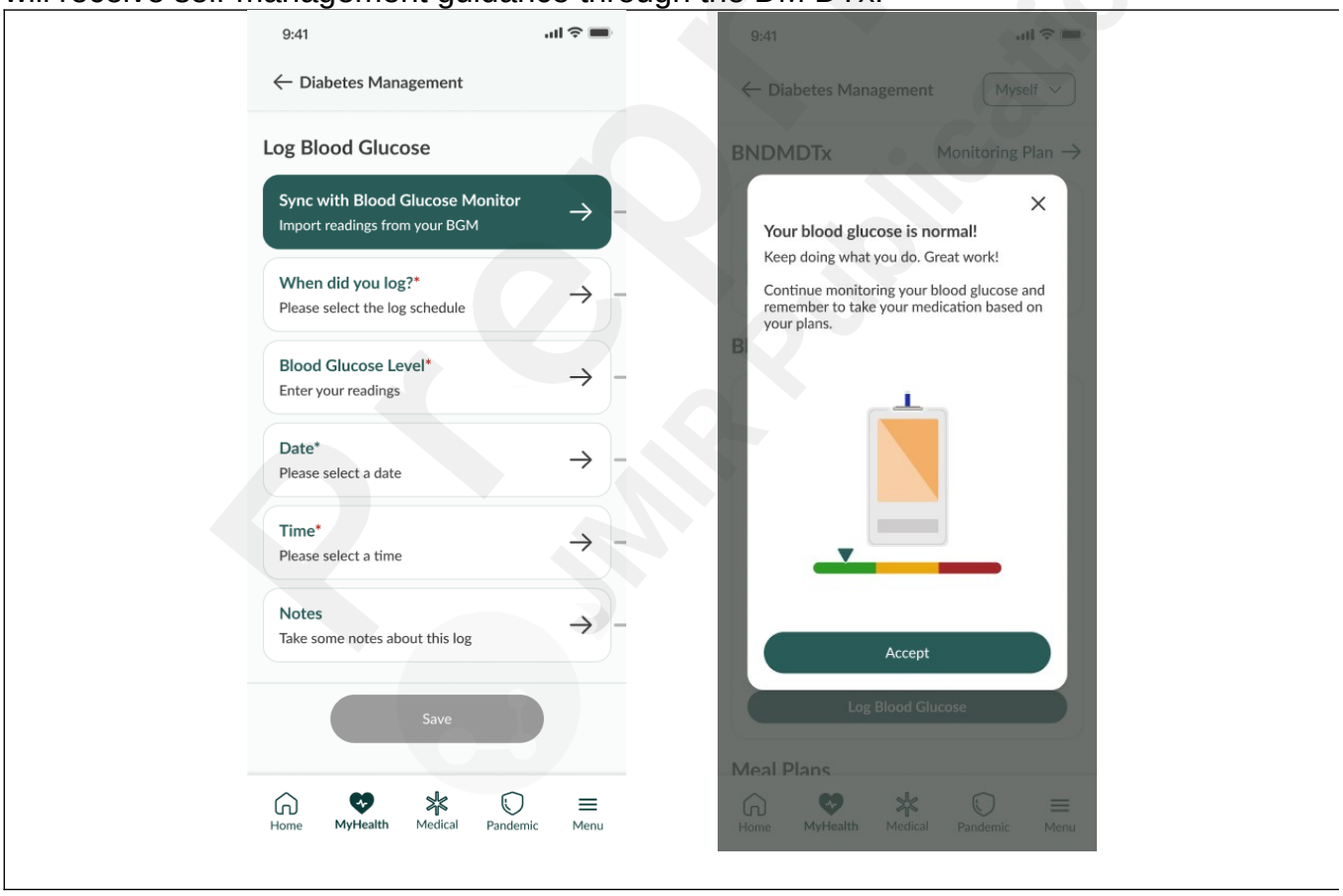


Figure 1: Blood Glucose Logging Feature and Instant Feedback

Exercise

A weekly exercise plan is created based on each participant's current level of physical activity and mobility to recommend the duration and intensity of exercise most suited for them. Participants can record the type, duration and intensity of their exercise for the day by syncing data from their smart watch or through manual entry (Figure 2).

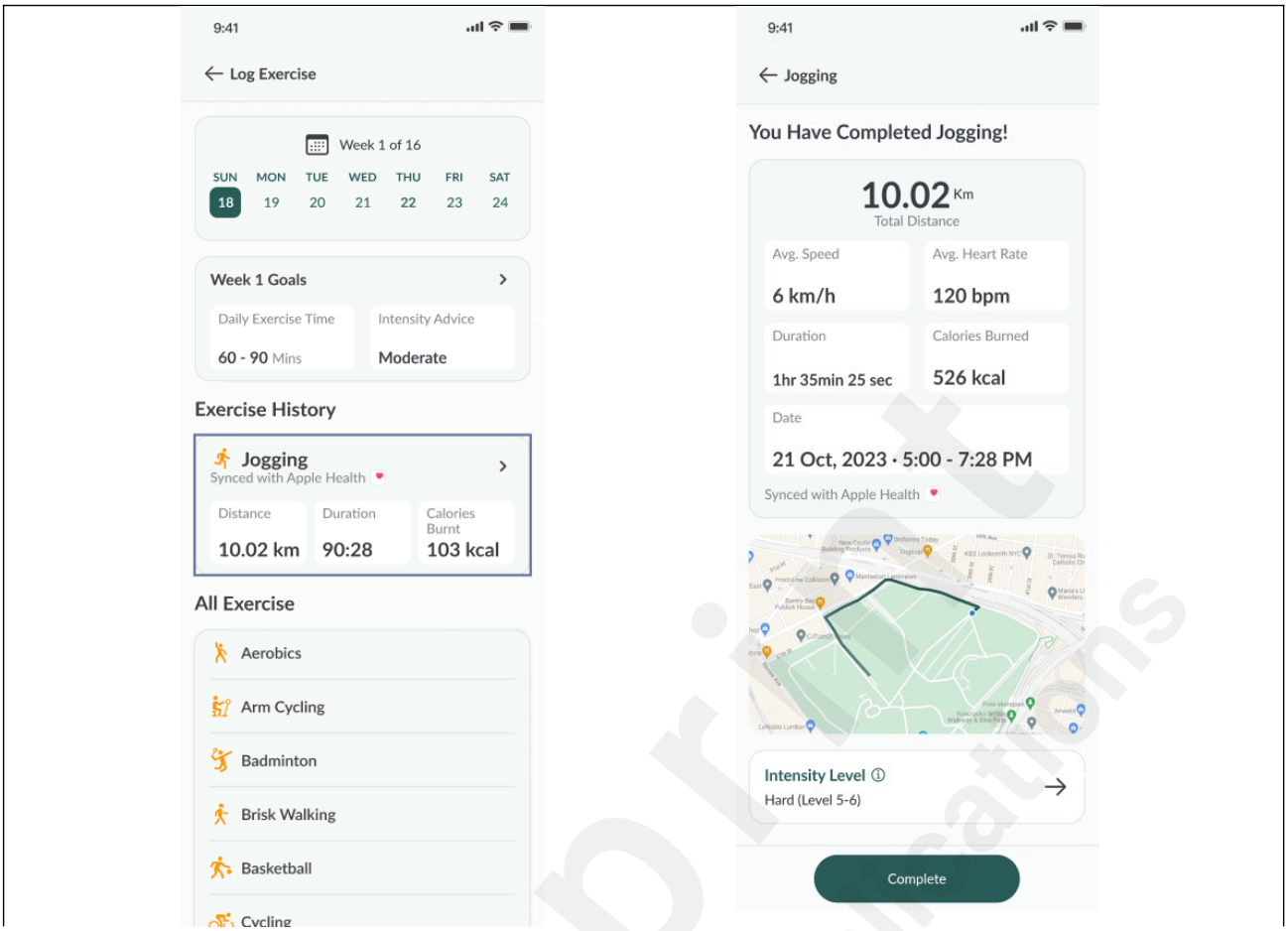


Figure 2: Exercise Plan and Exercise Log Feature

Diet

A daily nutritional plan, detailing recommended total calorie intake, carbohydrate, fat, and protein intake across three meals (breakfast, lunch, dinner), is created based on the participant's demographic data and physical activity level. Participants have access to a localised food database to help log their meals (Figure 3).

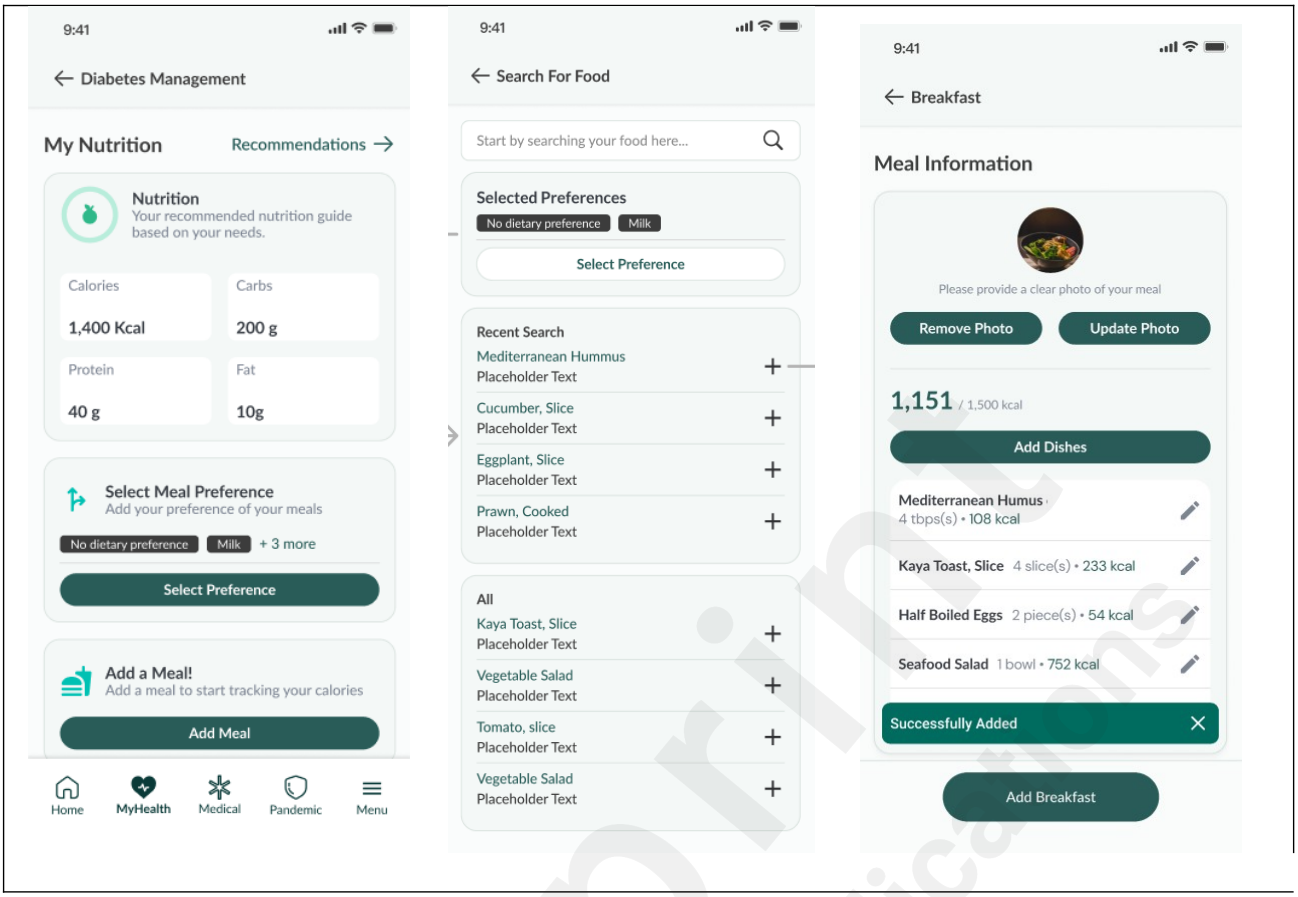
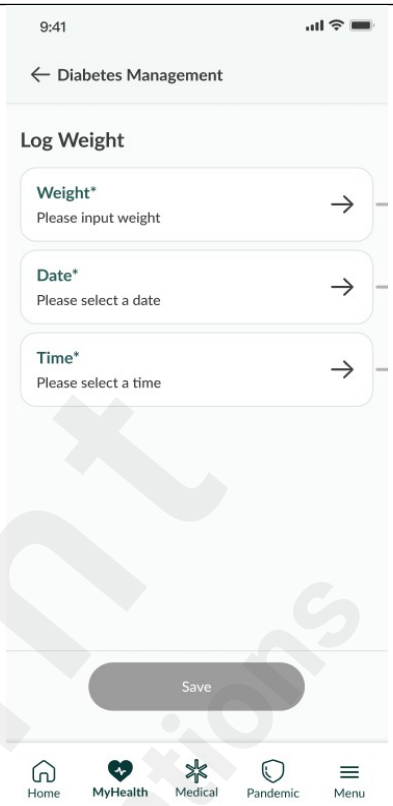


Figure 3: Meal Plan and Food Log Feature

Others

Other logging features such as weight logging (Figure 4), sleep logging, mood logging and more are available for users to keep track of other parameters. Participants are also able to sync their medication list from the national electronic medical records (EMR), BruHIMs, into a medication logging function to remind them to take their medication in a timely manner (Figure 5).

Participants receive daily nudges to remind them to log their daily progress. They also receive reports that outlined their blood glucose monitoring, dietary and exercise habits to



monitor their changes throughout the programme

Figure 4: Weight Logging Feature

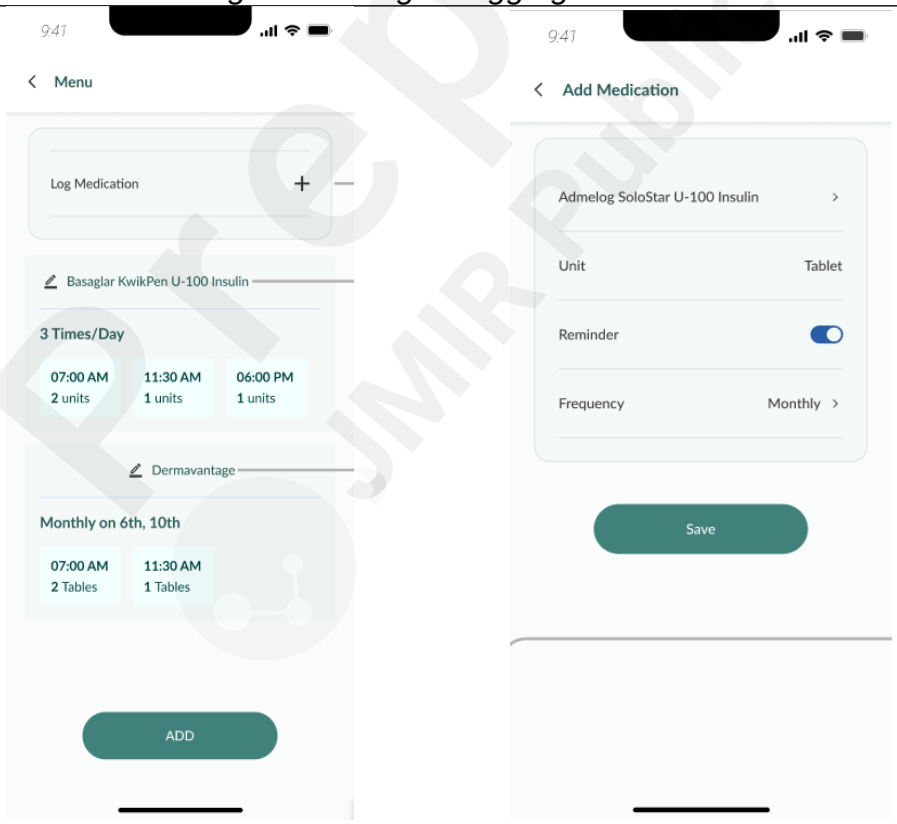


Figure 5: Medication Log and Reminders

Health Coach Support

Health coaches manage and communicate with their participants through the Healthcare Professional (HCP) Portal. The Portal, designed for Health Coaches and relevant healthcare professionals, enables access to the treatment plan for close monitoring and further action.

Each participant's assigned health coach conducts 5 scheduled video consultations with participants in the 16-week programme. Health coaches review information logged by participants, track the changes in their anthropometric measures and habits, and provide additional guidance and advice to enable positive change in measured parameters. Sessions are aimed to reinforce materials learnt and emphasise on sustaining healthy habits for long-term management.

On top of the regular video consultations, participants can engage with their health coaches through instant messaging. Health coaches also actively engage with participants to discuss their well-being, recent blood glucose readings, any symptoms, and adherence to prescribed medications. Health coaches also encourage participants to share details about their diet, exercise, and other factors influencing their blood glucose levels.

Additionally, health coaches respond to hypoglycaemic events. During these times, if a hypoglycaemic event alert is received, a health coach will initiate a video call to assess the situation based on symptoms and signs presented by the participant.

Event Safety Monitoring

Health coaches are trained to identify and escalate cases of suspected diabetic emergencies such as diabetic ketoacidosis, hyperosmolar hyperglycaemic syndrome and symptomatic hypoglycaemia. They will contact participants or their emergency contacts to direct them to emergency services or provide advice on blood glucose management based on study protocol.

Escalation Model

The escalation pathway for managing participants in this study begins with a health coach designated to the participant. Participants who have hyperglycaemia (defined per study protocol) will be escalated to a dietitian or clinician in the research team for video consultation. Participants who experience (1) two or more episodes of hypoglycaemia or (2) three or more episodes of hyperglycaemia in a week despite dietetic interventions, will be escalated to a clinical investigator for further evaluation.

Outcome

Primary Outcome

The primary outcome is to measure the proportion of participants with a reduction in HbA1c of at least 0.6% at the end of the study.

Secondary Outcomes

(1) Absolute change in HbA1c

(2) Changes in body mass index (BMI), waist circumference, fasting blood glucose and fasting lipid panel [total cholesterol, low-density lipoprotein cholesterol (LDL-c), high-density lipoprotein (HDL-c) and triglycerides] at the end of the study compared to baseline readings

(3) To describe the rate of fasting, rate of hypoglycaemia and frequency of blood glucose monitoring and fasting experience of Muslim participants in 2024

(4) Calculate fasting risk using the IDF-DAR Risk Score

Data Collection, Management and Analysis

Data Collection

Data for the study is collected from different channels as follows:
(1) BruHIMS: Blood test results (baseline and final), eligibility data, medication data
(2) BruHealth Application: Lifestyle data through logging, wearable data synced with the application
(3) Health Coach Portal: Eligibility data, monitoring data

Data Security

Participant data will be captured within the HCP Portal software application developed in conjunction with the DM DTX application and data access is in compliance with Ministry of Health (MOH) regulatory requirements. Analysis will be undertaken in password protected computers.

Statistical Analysis

Descriptive statistics will be calculated to summarise the demographic profile of the research population and the primary and secondary outcomes outlined above. The mean, median, standard deviation, and interquartile range will be reported for continuous variables, while frequencies and percentages will be used for categorical variables. Depending on the distribution of independent variables, appropriate paired statistical tests, such as the paired t-test or the Wilcoxon signed-rank test, will be employed to assess statistically significant differences between pre- and post-treatment outcomes for both primary and secondary measures. Additionally, subgroup analyses will be conducted to assess for any significant differences in primary and secondary outcomes based on patient classifications, such as BMI categories, diabetic medication usage profiles, or levels of engagement with the Educational Modules and Health Coaches in the BALANCE Programme.

Withdrawal

Participants are withdrawn from the study if it is deemed that continued participation in the study poses significant health risks to them. These considerations include: (1) participants who require hospitalisation during the study period (which may or may not be related to the study), (2) those deemed by clinical investigators to require immediate adjustments to their diabetes medications as delay may cause harm, and (3) those who fail to provide two local emergency contacts.

Results

Recruitment for the study began on 20th August 2024 and will aim to be completed by 20th August 2025. As of 31st January 2025, 334 participants have been enrolled into the programme and 61 participants have completed the programme.

Discussion

With the rising prevalence of diabetes in South-East Asia, organisations such as the International Diabetes Federation are increasing efforts in diabetes advocacy and exploring new ways to improve access to quality healthcare and affordable treatments. Patient empowerment by incorporating self-management represents an important component of diabetes care which will improve health outcomes and reduce diabetes-related complications. Therefore, new interventions should be designed with a focus on incorporating latest clinical guideline with an all-encompassing programme that includes monitoring, diabetes education, maintaining a healthy lifestyle through diet and physical

activity, medication tracking and motivational coaching [18]. A reduction of 1% in HbA1c levels over 3 months is associated with decreased mortality and a reduction in microvascular disease, while a reduction in weight has been shown to improve glycemic control and insulin sensitivity and potentially reduce medication dosage [19][20]. As such, an effective programme would focus on methods to improve key cardiovascular risk factors such as a reduction in HbA1c and weight.

The increasing digitalisation in the healthcare landscape has led to the deployment of mHealth and digital interventions to guide self-management of chronic conditions, particularly in diabetes management. Diabetes management applications can supplement traditional face-to-face care. This will help reduce the time and resources required from the healthcare system. Patients who have better self-management practices tend to manage their condition better [21]. By allowing users to actively participate in their own health management, users can increase their health literacy and become more confident in navigating their condition. However, an issue faced by the majority of diabetes management applications is low engagement with many lost to follow up [22]. A study showed that users are less likely to engage due to high effort and difficulty of use of the applications [23]. Therefore, collecting feedback on participant experience is crucial to identify functions and protocols that need to be re-designed to create an application that enhances the patient experience and level of engagement.

Due to the burden of diabetes globally, various applications on diabetes management are commercially available on the market [24]. The main functionalities offered include self-management tasks (medication, blood glucose monitoring, exercise and food intake), weight and blood pressure tracking, and education [25]. Most applications cover at least one self-management tasks, with blood glucose monitoring being the most common function [25]. Of the research that has been done to assess the effectiveness of these applications, diabetes self-management applications have demonstrated a significant reduction in HbA1c and body weight after a 6-month follow up [26][27]. A majority of these applications are free to download, with premium functions that require an additional fee. The average cost of diabetes management applications on the market is between USD$4.57 to USD$5.03 with higher annual cost for applications with multiple functions, making mHealth a cost-effective solution focused on preventing disease progression [25].

DM DTx is the first digital intervention solution of its kind in Southeast Asia. Many diabetes mHealth solutions are targeted to the North American market as part of an annual subscription plan usually provided by employers. This is largely attributed to the increasing penetration of smart consumer devices and higher acceptance of mHealth solutions in the region [28]. Additional research on the effectiveness of diabetes self-management applications in South-East Asia should be done as recommendations from solutions on the market may not be suitable in Southeast Asia due to different cutoff ranges for clinical parameters and cultural differences. Lifestyle habits and user behavior may also differ vastly between different populations, solidifying the need for region specific intervention designs. The majority of commercially available diabetes applications showed only low to moderate success in user adherence, proving that diabetes self-management solutions do not follow a one-size-fits-all approach.

This study possesses some limitations. For one, the study is designed based on volunteer sampling. Ideally, the study should be designed to be a randomised controlled trial to reduce selection bias and ensure that the results are generalisable to a broader population. Any observable effects cannot be conclusively attributed to the intervention due to the lack of a control group. Sampling is done within the Bruneian population so the results may not be applicable for populations outside of the current demographic. As the participants are not

followed long-term, there is a lack of understanding on the sustained effects and durability of the intervention over time. Participant's readiness to change their lifestyle habits was also not measured, as it was assumed that their participation translated to readiness. Finally, participants' digital literacy is not measured during recruitment, which may affect their participation in the digital intervention and lead to less optimal results due to external barriers.

Conclusion

Self-management mHealth applications remain a promising adjunct to chronic disease care, especially in T2DM. However, the impact of these applications in improving health is greatly dependent on localisation to a region's clinical and cultural context. Through data-driven research, gaps in intervention and application design can be identified to bridge the gap between theorised and realised improvements in health outcomes.

Ultimately, the research aims to understand the effectiveness of DM DTx to develop a solution that is fit for purpose, clinically sound, patient centered, and sufficiently personalised.

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Ethics Declaration

An online participant information sheet and consent form are available on the DM DTx module in the BruHealth application. Interested individuals are required to complete the online consent form before they proceed to complete the screening questionnaire.

Ethical approval was granted by Ministry of Health Brunei Darussalam's Medical and Health Research Ethics Committee (MHREC) (Reference Number: MHREC/MOH/2024/11(1)).

Conflict of Interest

Dr Joshua Lam, Jane Tey and Yvonne Lee are employed under EVYD Technology. EVYD Technology is the technology partner of this study and the developer of the BruHealth application and HCP Portal. The authors declare that there is no other conflict of interest.

Abbreviations

Bru-HIMS: Brunei Darussalam Healthcare Information and Management System
CKD: Chronic Kidney Disease
DM DTx: Diabetes Mellitus Digital Therapeutics
DSME: Diabetes Self-Management Education
EMR: Electronic Medical Records
GFR: Glomerular Filtration Rate
HbA1c: Glycated haemoglobin

HCP Portal: Healthcare Professional Portal
HDL: High-density lipoprotein
ICD-10: *International classification of diseases*
LDL: Low-density lipoprotein
mHealth: Mobile Health
MHREC: Medical and Health Research Ethics Committee
MOH: Ministry of Health
SMART Goals: Specific, Measurable, Achievable, Relevant, and Time-bound Goals
T1DM: Type 1 Diabetes Mellitus
T2DM: Type 2 Diabetes Mellitus
TG: Triglyceride
WHO: World Health Organization

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