Original Research

MY DIABETES APPS: IMPROVING KNOWLEDGE, COMPLIANCE, AND CONTROL IN UNCONTROLLED TYPE 2 DIABETES PATIENTS IN KEDAH, MALAYSIA

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ABSTRACT

Introduction: Usage of mobile applications can be the game changer in managing diabetes patients and reducing the percentage of uncontrolled diabetes cases in Malaysia. This study aimed to measure the effectiveness of the locally developed diabetes mobile applications in improving knowledge, compliance and control of Type 2 Diabetes Mellitus patients. **Methods**: In the first phase, content of the mobile application was developed using Nominal Group Technique discussion by 11 experts. The produced prototype, My Diabetes Apps© undergone the second phase of pilot study for validation, SKAMA evaluation form. Final third phase interventional study was conducted in two districts in the state of Kedah (Kuala Muda as the control group, Kota Setar as the intervention group), involving eight health clinics. 82 respondents were selected using multi-stage random sampling technique among uncontrolled Diabetes Mellitus patients over four months. **Results:** Thirteen key contents recommended by the expert panels as mandatorily important for diabetic patients. The mean(±sd) usability score of My Diabetes Apps was 86 (±10.90), indicating the usability of the mobile application. The intervention study found there was significant difference in the mean knowledge score between the control group and the intervention group [F(1.79)=42.27; p<0.001] and mean HbA1C between groups pre and post intervention [F(1.79)= 6.03; p=0.016]. No difference in the mean value of the compliance score between the two groups [F(1.79)=1.58; p=0.212]. **Conclusion:** My Diabetes Apps© proved to be improve patient knowledge and helpful in diabetic control. Integrating the technology in patient's care improves patients' self-efficacy and monitoring of diabetes.

Keywords: Diabetes, intervention, mobile application, knowledge, compliance

Introduction:

Type 2 diabetes mellitus is a chronic disease that is steadily increasing in trend throughout the world, including Malaysia (Hieng 2017). Findings from the local National health morbidity survey 2019, 3.9 million people in Malaysia which is equivalent to one in five adult population have diabetes (Instittue of Public Health 2020) . This is very worrying because it can increase the rate of morbidity and mortality due to the complications of diabetes mellitus. (Critchley et al. 2018; Deshpande et al. 2008; Macioch et al. 2017)

It is well known that there are many factors that contribute to uncontrolled diabetes. The level of knowledge and compliance factors towards the treatment are among the contributing factors to this issue (Cannon et al. 2018). The patient's literacy level plays a detrimental role in improving the patient's knowledge level. Previous literature suggested that a high level of knowledge of the disease may inevitably change the perception and behaviour of the patient, hence subsequently increase the level of compliance to the treatment and ultimately led to a good control of the disease (American Diabetes Association 2018; Gibbons & Goebel-Fabbri 2017; Shahin et al. 2019). Apart from that, other factors that were shown to contribute to uncontrolled diabetes are age (Cowie et al. 2010), ethnicity (Lanting et al. 2008; Rothman et al. 2008), and socioeconomic factors. (Fisher et al. 2010; Wardian & Sun 2014; Warwick-Booth & Cross 2018)

Advancement in digital technology, especially mobile smart phone technology, has led to various innovative strategies aimed at improving the self-management skills of patients suffering from chronic diseases including diabetes. Nevertheless, the use of mHealth technology has paved the way to an increasing access to health-related information for both patients and healthcare providers as well as facilitating a remote patient monitoring. (Klonoff 2013; Whitehead & Seaton 2016). Some study showed that the usage of mobile app-based interventions becoming a promising tool to enhance compliance and glycaemic control in type 2 diabetes mellitus patients (Hakami et al. 2024).

On the other hand, some of the previous study also depicted limited depicted benefit of mobile apps usage. For instances, the results of one previous study that used diabetes mobile health applications, found that the available applications only provided general knowledge about Diabetes Mellitus and only cater the needs of western nation or restricted to some of Asian populations such as China, Japan and Sri Lanka (Baron et al. 2012). As such, limited evidence can be implied to the local setting as Malaysia is a unique country populated by multi-racial ethnicity.

Therefore, this study was aimed to develop a novel locally acceptable diabetes mobile application, called My Diabetes Apps©, and subsequently measure its effectiveness, to increase the level of knowledge, compliance and glycaemic control of diabetes mellitus patients in the state of Kedah. Malaysia.

Methods:

Study Design

This was randomized control trial study conducted in 2 districts (Kota Setar and Kuala Muda) in the state of Kedah, Malaysia from February 2020 until August 2022. The study was divided into 3 phases: (1) My Diabetes Apps development, (2) Apps usability test-, and (3) interventional studies. Overall, the study was completed within 2 years beginning from September 2020 until August 2022.

The first phase was aimed to determine the content of the mobile application to be developed. This phase uses the Nominal Group Technique (NGT) method (Mcmillan et al. 2016). This method is carried out through six levels of discussion, namely (1) Introduction, (2) Generation of silent ideas, (3) Sharing of ideas, (4) Discussion of ideas, (5) Voting and ranking and (6) Discussion and conclusion. A total of 11 expert panels have been appointed to participate in this discussion consisting of Public Health Physicians, Endocrine Specialists, Family Physicians, Medical Officers, Information Technology Specialists, and Diabetes Mellitus patients as target users.

The second phase was the pilot study phase of the newly developed diabetes mobile application prototype (Usability Analysis). In this phase, the My Diabetes Apps prototype will be pilot tested by selected respondents for a period of 4 weeks. This study involved 30 respondents who were selected among uncontrolled diabetes patients at a health clinic in Kedah (Bujang et al. 2018; Six & Macefield 2016). The Mobile Application Usability Scale (SKAMA) was used to evaluate the usability of the My Diabetes Apps application (Marzuki et al. 2018). This My Diabetes Apps prototype can be used if you get a SKAMA score ≥ 68.

The third phase was the interventional study. This study was conducted in the state of Kedah which has more than 140,000 registered diabetes patients. The districts of Kota Setar and Kuala Muda have been selected as study locations based on location considerations, population and patient distribution, distribution of health clinics and broadband access in both districts.

Data collection

The sample population were registered uncontrolled Type 2 Diabetes Mellitus patients who attend the follow-up treatment at public health clinics from selected districts during the study. The sampling frame of this study was based on the list of Uncontrolled Type 2 Diabetes Mellitus patients that were registered at health clinics from two selected districts taken from the National Diabetes Registry (NDR) provided by the Non-Communicable Disease Control Unit (NCD), Kedah State Health Department.

The participation inclusion criteria were; (1) Age 18-80 years (Beverly et al. 2013; Lygidakis et al. 2019), (2) Diagnosed with Type 2 Diabetes Mellitus by a registered Medical Officer, (3) Registered and actively follow-up treatment at health clinics in selected districts, (4) Have a smartphone with Android platform. And (5) HbA1C >7%. Meanwhile, the exclusion criteria were (1) Gestational Diabetes Mellitus (GDM), (2) Illiteracy, (3) Anemia / Thalassemia and (4) Not agreeing to be a study sample.

The researcher used the Epi Info Stat Calculator to calculate the sample size of the study by comparing two means. Error α is set at 5%. The value of B is set at 80. The required sample size for each group is 31 (taking into account a dropout rate of 20%). This study uses three instruments, namely (1) the newly developed and validated "My Diabetes Apps" mobile application, (2) a questionnaire on knowledge and compliance with treatment and medication, and (3) an HbA1C kit to measure participants' glycaemic control research.

The participants from all localities were selected based on patient appointment lists on the day of the study. Selected participants were asked to answer a questionnaire about knowledge and compliance to the treatment of Type 2 Diabetes Mellitus. Participants in the intervention group were then introduced to My Diabetes Apps© and asked to download the application onto their smartphones. They were given a period of four months to use this application.

After 4 months, all selected participants were called back to the health clinic to undergo a post-intervention assessment. All participants were again asked to answer the same questionnaire as at the beginning of the program 4 months ago. Afterwards, participants' blood samples were taken for the HbA1C test. Participants in the intervention group were also asked to answer the SKAMA questionnaire after using the application for the previous four months. As a reward, participants in the control group were also introduced to the My Diabetes Apps© application and allowed to download the mobile application onto their smartphones. Figure 1 shows the flow chart of the study data collection process.

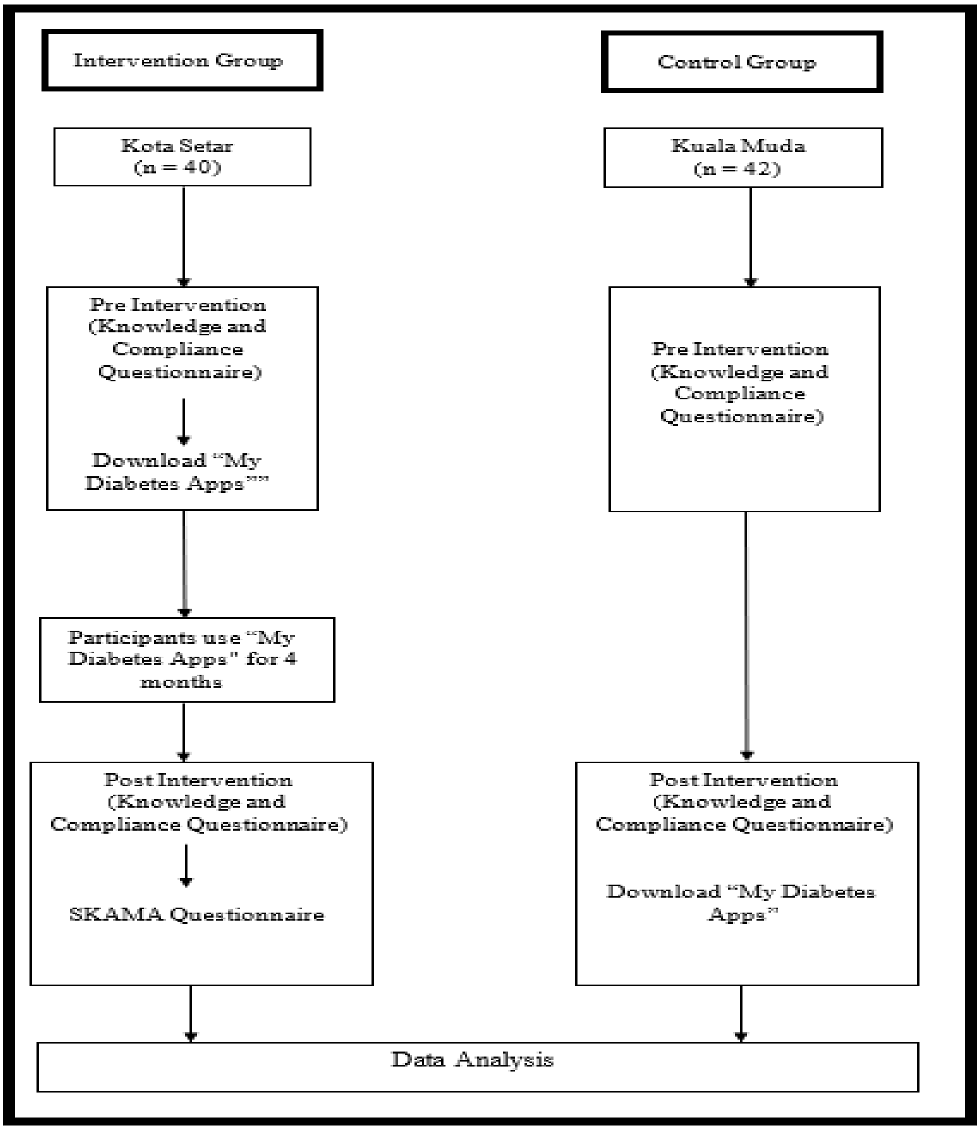

Figure 1: Data Collection Process

Outcome

The intervention was expected to increase the level of knowledge and the level of patient compliance with the treatment of diabetes mellitus type 2 (primary outcome) and in turn help improve glycaemic control (HbA1C) of patients (secondary outcome).

Statistical Analysis

All data that has been checked and cleaned were analysed using IBM Statistical Package for Social Sciences (SPSS) Version 21. Descriptive statistics was used to summarize the sociodemographic characteristics of the participants of both groups. Nominal data was presented as mean (±SD). Categorical data was presented as frequencies (percentages). Independent t-tests were used to compare means between 2 groups. Meanwhile, comparisons between groups for categorical data were made using the Pearson Chi-square Test.

Analysis of Covariates (ANCOVA) was used to compare the mean knowledge score about Diabetes Mellitus between the intervention group and the control group by considering the mean pre-intervention knowledge score as a covariate. A similar analysis was also performed to compare the mean score of compliances to medication and diabetes treatment between the intervention group and the control group by considering the mean score of pre-intervention compliance as a covariate. The purpose of making the pre-intervention mean score as a covariate was to balance the effect of high participant scores since the beginning of the study.

Results:

The results of discussions with 11 Expert Panels using the Nominal Group Technique (NGT) (Mcmillan et al. 2016) resulted in 21 proposals for the content of the application. Then, each panel member was given 24 hours to vote. Votes were submitted to researchers to be counted and ranked. The results of the voting resulted in 13 application content priorities according to the ranking, which are:

- Diabetes info (definition, symptoms, complications)
- Purpose of diabetes control, how to control DM, main factors of optimal DM control, target of DM control.
- Nutrition info (type of food, amount of food intake, nutrition table, My Nutri Diary link, Malaysian healthy plate)
- Diabetic emergency
- Drug info (oral & injection)
- Injection technique
- Daily sugar reading schedule (SMBG) - along with evaluation of sugar readings and instructions to patients in the event of a diabetes emergency)
- Graphic report of sugar readings (daily, weekly, monthly)
- Myths related to diabetes
- Diabetes in Ramadan
- Appointment reminders and medication times

After reaching a consensus, the list of mobile app content proposals was then submitted to the app development team for the mobile app prototype development process. Development takes 2 months. This application uses the Ionic framework, Net core and a Structured Query Language or SQL database. Patient information will be encrypted using MD5 Mesh to strengthen data security and privacy. This prototype was named My Diabetes Apps©. The prototype was then tested by all expert panels to obtain a consensus of agreement from all group members.

The second phase was the usability study phase of My Diabetes Apps©. This study used the Mobile Application Usability Scale (SKAMA) (Marzuki et al. 2018). A total of 30 respondents were selected to help carry out the verification process of this mobile application. Selected respondents have used the My Diabetes Apps© application for 4 weeks before answering the SKAMA questionnaire. All participants answered each item contained in the SKAMA questionnaire. The majority of users agreed that they will use My Diabetes Apps© regularly, the mobile application is easy to use, does not require the help of others to use it, all functions are well integrated, and the content of the mobile application is consistent. The usability score for the My Diabetes Apps© prototype showed a total mean score (±SD) of 86 (10.90) higher than the SKAMA minimum score of 68, with a score difference of 18 (95% CI: 81.93, 90.07 $p < 0.001$). This shows the good usability of My Diabetes Apps© as a mobile application. The descriptive analysis of SKAMA items is as shown in the following.

Table 1: Analysis of The Mobile Application Usability Scale (SKAMA) (n=30)

Item	The Mobile Application Usability Scale (SKAMA)	(1) Totally Agree n (%)	(2) Agree n (%)	(3) Neutral n (%)	(4) Disagree n (%)	(5) Totally Disagree n (%)
1.	I think I would like to use this mobile app regularly.	18 (60)	9 (30)	2 (7)	0 (0)	1 (3)
2.*	I think this mobile application is something complicated.	0 (0)	0 (0)	0 (0)	8 (27)	22 (73)
3.	I think this mobile app is easy to use.	21 (70)	8 (27)	1 (3)	0 (0)	0 (0)
4.*	I need help from others to use this mobile application.	5 (17)	4 (13)	6 (20)	5 (17)	10 (33)
5.	I found the functions in this mobile application to be mutually exclusive well integrated.	22 (73)	7 (24)	1 (3)	0	0
6.*	I think there is a lot of content in this mobile app which are inconsistent with each other	0	1 (3)	3 (10)	5 (17)	21 (70)
7.	I imagine that most people will quickly learn using this mobile application	23 (77)	7 (23)	0	0	0
8.*	I found this mobile app cumbersome to use.	0	1 (3)	3 (10)	2 (7)	24 (80)
9.	I feel confident using this mobile app	25 (84)	4 (13)	1 (3)	0	0
10.*	I have to learn too many things before I can use this mobile application.	6 (20)	1 (3)	1 (3)	8 (27)	14 (47)

**Negative statement*

The third phase involved 82 participants (40 intervention group participants and 42 control group participants). Statistical analysis using independent t-test, and chi square test, found no significant differences in terms of age, gender, race, education level and marital status. However, there is a significant difference in employment status (x2=3.935(1), p=0.047).

Knowledge

Paired t-analysis was used to compare the mean score of compliances in the pre- and post-intervention groups. The analysis found that there was a very significant increase in knowledge scores among participants in the intervention group after using the application (t=8.066, P<0.001), compared to the control group which was not statistically significant (t=1.574, p=0.123).

Table 2: Comparison of Mean Knowledge Scores of Intervention Group Participants (n=40)

Time	Mean (±SD)	Mean Different (±SD)	t (dk)	p value
Pre Intervention	7.55 (±1.947)			
		3.35 (±2.63)	8.066 (39)	<0.001
Post Intervention	10.90 (±1.795)			

±SD= Standard Deviation, df= Degree of freedom

Table 3: Comparison of Mean Knowledge Score of Control Group Participants (n=42)

Time	Mean (±SD)	Mean Different (±SD)	t (dk)	p value
Pre Intervention	7.62 (±1.780)			
		0.59 (±2.45)	1.574 (41)	0.123
Post Intervention	8.21 (±1.93)			

±SD= Standard Deviation, df= Degree of freedom

Comparison of mean knowledge scores between groups using ANCOVA, where the pre-intervention knowledge score was set as a covariate. The results of the analysis found that there was a significant difference in the mean score of knowledge between the intervention group and the control group [F (1,79) = 42.27; p < 0.001]. The mean score plot profile adjusted between the control and intervention groups as shown on the screen clearly shows that the intervention group has a significant increase in knowledge scores after using “My Diabetes Apps”, Figure 2.

Table 4: Comparison of Mean Knowledge Scores Between Control Group Participants and Intervention Group Participants (n=82)

Group	Adjusted Mean 95% CI	Diff Adjusted Mean 95% CI	F (df)	P value
Intervention	10.90(10.31, 11.50)	2.69(1.87, 3.52)	42.27 (1,79)	<0.001
Control	8.21(7.64, 8.79)			

CI= Confident Interval, df= Degree of freedom

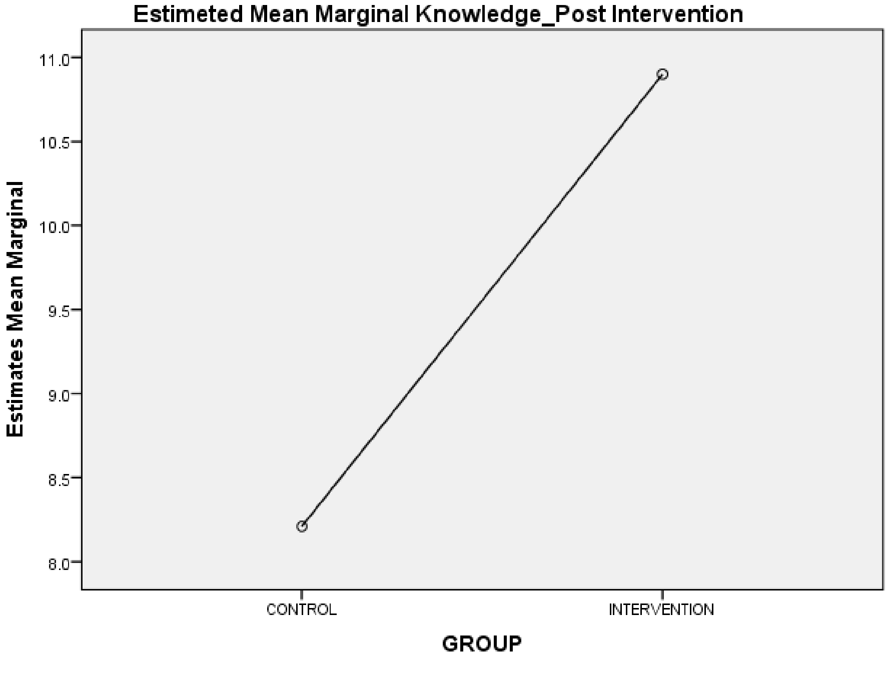

Figure 2: Pre- and post- result for knowledge

Compliance

Comparative analysis of the Median Score of compliances to treatment in the Group was conducted using the Wilcoxon Signed Rank Test. The analysis found that the compliance score of the participants in the intervention group increased significantly and was statistically significant (Z = -2.271, p = 0.023). compared to the compliance scores of participants in the control group. For the comparative analysis of the mean score of Compliance Related to the Treatment of Type 2 Diabetes Mellitus between groups, Analysis of Covariate (ANCOVA) was used by setting the pre-intervention compliance score as a covariate. The analysis found no significant difference in the overall mean score of knowledge between the intervention group and the control group [F (1,79) = 1.58; p =0.212]. The adjusted mean score plot profile between the control and intervention groups as shown on the screen did not show a significant increase in compliance scores after the intervention, Figure 3.

Table 5: Comparison of Mean Compliance Scores Between Control Group Participants and Intervention Group Participants (n=82)

Group	Adjusted Mean	Diff Adjusted Mean	F (df)	P value
	95% CI	95% CI		
Control	53.24 (51.20, 55.29)			
		1.85 (-1.08, 4.78)	1.58 (1,79)	0.212
Intervention	55.09 (53.00, 57.19)			

CI= Confident Interval, df= Degree of freedom

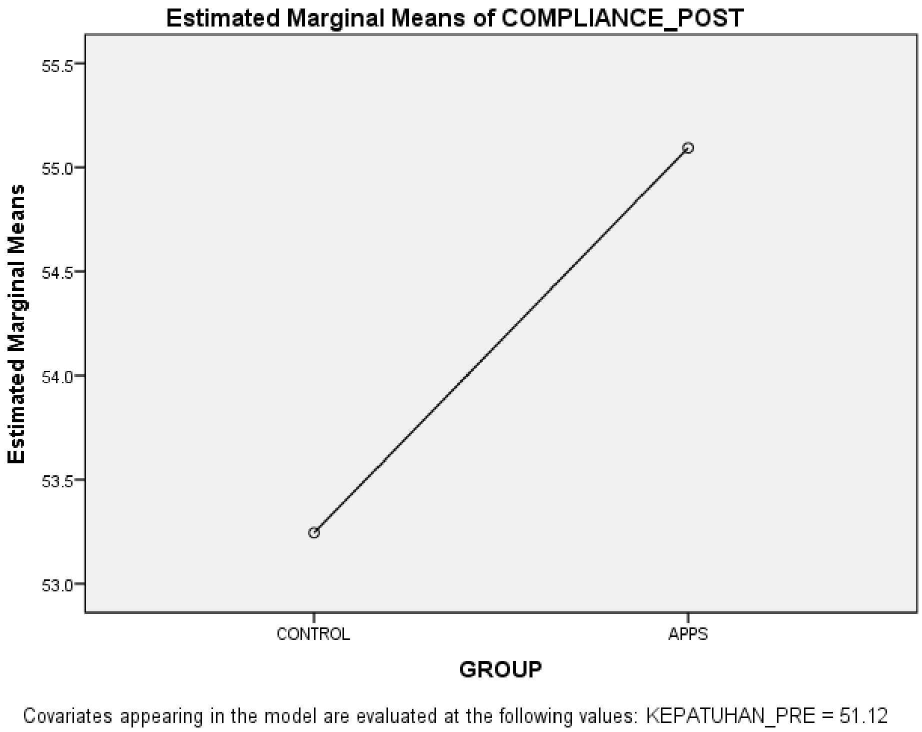

Figure 3: Pre- and post- result for compliance

Diabetes Control

The achievement of diabetes control was seen from the comparative analysis of the median HbA1C of the participants in the group using the Wilcoxon Signed Rank Test. The median Hba1C of participants in the intervention group recorded a statistically significant decrease ($Z = -5.413$, $p < 0.001$). The median HbA1c of participants in the control group also showed a statistically significant decrease ($Z = -2.80$, $p = 0.005$). However, if seen from the gradient of HbA1c reduction, the intervention group showed a more significant reduction than the control group. Indirectly, these findings also show that existing diabetes treatment interventions used in health facilities are good, Figure 4. However, the additional use of the My Diabetes Apps application was found to help strengthen the effectiveness of diabetes management.

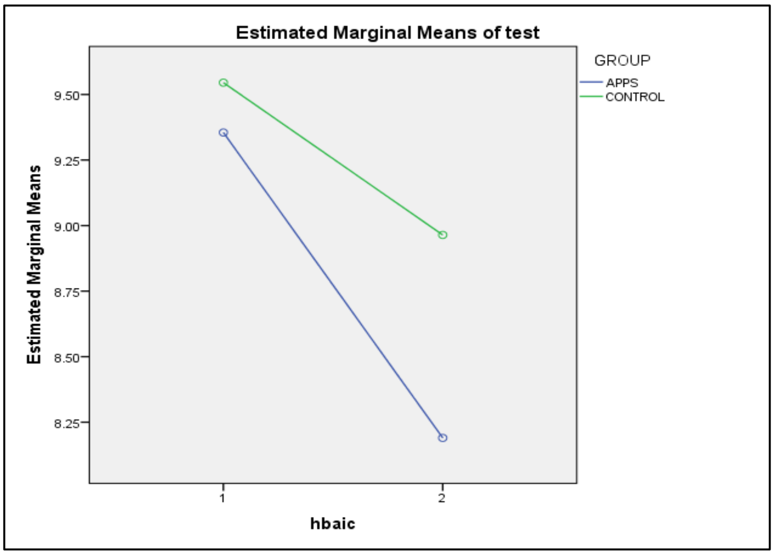

Figure 4: Pre- and post- result for diabetic control

Meanwhile, the analysis of Mean Comparison of HbA1C Between Groups was made using the Analysis of Covariate (ANCOVA) test. The results of the analysis proved that there was a significant difference in mean HbA1c between the two control groups after the intervention [F (1,79) = 6.03; p =0.016]. The HbA1c mean plot profile was adjusted between the control group and the post-intervention group as shown on the screen clearly showing the difference in the mean hbA1c reading after using the "My Diabetes Apps" mobile application, Figure 5.

Table 6: Comparison of Mean HbA1C Between Participants in the Control Group and Participants in the Intervention Group (n=82)

Group	Adjusted Mean	Diff Adjusted Mean	F (df)	P value
	95% CI	95% CI		
Control	8.902 (8.536, 9.267)			
		0.646 (0.123, 1.170)	6.034 (1,79)	0.016
Intervention	8.256 (7.881, 8.630)			

CI= Confident Interval, df= Degree of freedom

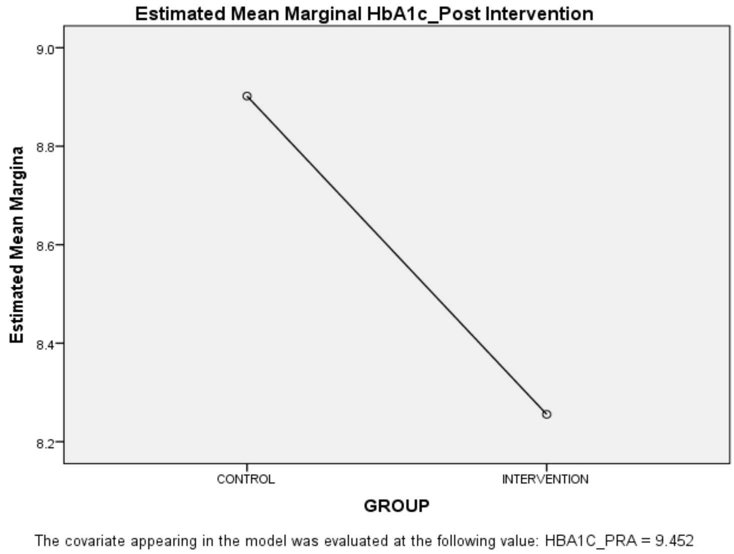

Figure 5: Pre- and post- result for HbA1c

Discussion:

This intervention study was conducted to see the impact of using the My Diabetes Apps application on patient knowledge. The time factor during the intervention was found to have a great influence in increasing the patient's level of knowledge about diabetes (Baron et al. 2012). This means, the longer the intervention is done, the better the patient's level of knowledge will increase.

The increase in smartphone ownership was also found to help disseminate health information and education to the target group and further help them live a healthier lifestyle (Kayyali et al. 2017). Mobile applications such as My Diabetes Apps can be an authentic reference for patients to obtain disease-related information, which can help patients manage the disease independently. However, the existence of these mobile applications does not negate the use of existing health education materials. The educational material is still relevant and can still be used mainly to convey health information to rural areas.

As for the effect of using the application on patient compliance, the post-intervention results showed no significant improvement. This is because the pre-intervention score was already high. This shows that the level of patient compliance in both groups is already at a good level. However, if observed, there was a slight increase in post-intervention compliance scores (intervention group: 51 to 55. control group: 51 to 53). A study from Brath et al., (2013) found that the use of mobile health applications can increase the level of patient compliance with treatment even in patients with a high level of compliance.

The effect of using My Diabetes Apps on the patient's diabetes control (HbA1C) also showed a decrease in the participants' HbA1C readings post-intervention. This result is very encouraging because controlled diabetes control can reduce the risk of patients getting diabetes complications that can cause morbidity and mortality. According to studies, changes in HbA1c levels in diabetic patients typically occur within a timeframe of 8 to 12 weeks following adjustments to their treatment regimen (Hirst et al. 2014). A study indicated that approximately 79% of the change in HbA1c was observed within the first 8 weeks after a medication change or intervention. The HbA1c level measured at 8 weeks was strongly predictive of the level at 12 weeks, highlighting the importance of early monitoring to inform potential adjustments (Tu et al. 2021).

Mobile applications that are equipped with self-monitoring technology for blood glucose readings, reminder systems and the latest information related to the disease can help increase awareness, knowledge and control of the patient's diabetes disease (Martos-Cabrera et al. 2020).

The reminder or notification function can modify participants' beliefs about the disease they have and their self-management behaviours. The frequency of reminders related to care and self-care shows the importance of diabetes care and self-management, emphasizes the seriousness of the condition and reduces patient denial related to the disease. Studies show that health beliefs are closely related to self-management behaviour in individuals with diabetes (Bloom Cerkoney & Hart 1980; Harvey & Lawson 2009; Schafer et al. 1983).

However, the My Diabetes Apps intervention still did not succeed in lowering participants' HbA1C readings to optimal levels. Only 13 participants (out of 82 total participants) managed to lower the reading ≤7%. Researchers feel that this situation is influenced by several factors, namely the time interval of the intervention study, the small number of participants as well as external factors such as the patient's diet and lifestyle that can affect the patient's glucose control (Bajaj et al. 2019).

In this study, ANCOVA was used as the statistical tool for RCT analysis. This is because, ANCOVA (Analysis of Covariance) is often considered superior to ANOVA (Analysis of Variance) due to its ability to control baseline differences and enhance statistical power. ANCOVA also demonstrates greater power by incorporating baseline measurements as covariates, which helps to adjust for variability and isolate the treatment effect more effectively. ANCOVA may also reveal discrepancies in treatment effects compared to ANOVA or other statistical methods (Egbewale et al. 2014; O'connell et al. 2017; Van Breukelen 2006).

The strengths of this study are:

1. To the best of the researcher's knowledge, this study is the first intervention study in Malaysia that evaluates the usability of a diabetes mobile application developed and evaluates the effectiveness of this mobile application on increasing the level of knowledge, compliance and diabetes control of DM patients in Malaysia.

2. This study also integrates the use of mobile applications as health promotion and Diabetes Mellitus education materials that can guide patients to control the disease independently from home apart from this application can be replicated for the prevention of other chronic diseases.

This study also has some limitations.

1. The production of this application costs a lot of money, so the application cannot be published in the iOS platform due to the financial constraints faced by researchers.

2. The capacity of the database is limited because we take into account the capabilities of the patient's smartphone in general. This situation limits the amount of information that can be entered into the application.

3. There is no room for patient and doctor interaction. This has limited the patient to get a direct consultation from the attending physician at the required time.

Conclusion:

The use of the diabetes mobile application My Diabetes apps was found to increase the level of patient compliance and subsequently lower the patient's HbA1C reading post-intervention. This My Diabetes Apps intervention study was also found to be effective in strengthening the management of Type 2 Diabetes Mellitus. This study can open up more space for health service providers to improve treatment methods for chronic diseases, especially diabetes mellitus and further help reducing the burden of chronic disease management in Malaysia.

Acknowledgments

The authors would like to thank the Director General of Health, Malaysia, and Kedah State Health Department for the permission to publish this paper. We would also like to thank all research team members for their contributions and commitment in this study. Special thanks to all expert panels for the unconditional help and support to complete the study. We are also grateful for the kind cooperation of all participants.

Conflicts of Interest

The authors declare no conflicts of interest.

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