ORIGINAL ARTICLE

Improving Diabetes Self management Using Digital Therapeutics: Insights into User Engagement from a Randomized Controlled Trial in Urban Aligarh

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Abstract

Introduction: Diabetes mellitus, one of the greatest contributors of global burden, and its aftermath necessitates a holistic perspective for its treatment and prevention. Self-Monitoring of Blood glucose encompasses all the fundamental principles and approaches of Diabetic management. Applying novel digital innovation in SMBG can improve clinical outcomes and quality of life. **Aims:** To assess user engagement and acceptability of DTI and SMBG and also identify potential association with outcome results. **Settings and Design**: Randomized Controlled Trial in urban Aligarh. **Methods and Material**: After enrollment of 132 participants, they were allocated into 3 groups by randomization- (1) No SMBG (2) SMBG thrice weekly (3) thrice weekly SMBG users with digital feedback by Simple Random Sampling followed by Randomization. Data was captured on socio-demographic correlates at the begging of study and user engagement and feedback using Mobile Application Rating Score was collected at the end of study. **Statistical analysis used**: Descriptive statistics. **Results:** Among those who received DTI along with SMBG, 72.5% of the users were highly engaged and 27.5% users were lowly engaged. More than half of the participants rated between 2 and 3 for most of the parameters. The difficulties faced by the participants while using the app, which were fear of security issues (59%), user issues (26%) and operational and technical issues (15%). Overall rating of the app was acceptable.**Conclusions**: The study highlights the potential of SMBG and DTI to be a valuable adjunct to conventional diabetes management. It reinforces the need to bridge the gap between available technology and real-world application in patient care.

Keywords

Digital Therapeutic Intervention (DTI), Digital Therapeutics, Self-Monitoring of Blood Glucose (SMBG), Type 2 Diabetes mellitus (T2DM), Randomized Controlled Trial (RCT), User Engagement, Mobile App, Aligarh/India

Introduction

Diabetes mellitus has emerged to be one of the most prevalent, consequential, chronic metabolic disease of the 21st century. It is estimated that by 2045, India will have 124.9 million adults with diabetes, which accounts to 16% of the global burden of the disease. Key contributors to this escalation include rise in ageing population, urbanization, decreased physical activity and increased prevalence of obesity.(1)

Long term, persistent hyperglycemia is associated with serious complications and rigorous measures have been taken in all aspects to tackle this issue. However, changing guidelines and numerous treatment options leave both patients and physicians at a critical and often confused junctures. This can affect the quality of patient care and therefore, warrants for procurement of more evidence based from real world data. Studies have established the impact of metabolic memory or legacy effect, i.e., early optimization of glycemic control can lower the risk of complications and also have a beneficial effect for at least 10 years.(2)

Amidst various treatment protocols and preventive measures, Self-Monitoring of Blood glucose encompasses all the fundamental principles and approaches of Diabetic management and care. Here, patients can check their own blood glucose levels in real time via a glucose meter and its implementation is based on safety, efficacy and flexibility for users. This enhances the user's education and awareness about healthy diabetic practices and thereby, make appropriate decisions in their anti-diabetic therapy on a daily basis.(3)

Although complications of T2DM can be mitigated by bringing about lifestyle modifications, limitation of resources can make it difficult for administering traditional interventions with respect to lifestyle. These issues can be addressed by adjunct use of technology in health-care, using mobile health apps. It has the advantage of easy access, communication, availability of

information as well as overcoming barriers of physical transportation, particularly in restricted conditions. Several studies have demonstrated the considerable role of technology in overall management of Type 2 Diabetes mellitus without requiring any escalation of existing medication. This can render better health outcomes and reduce economic burden on a wide scale community level and thereby, contribute to decrease of overall mortality and morbidity due to the disease and improve quality of life**.** (4) India has the second highest usage of smartphone following China. 32% of patients in urban settings surfed the internet and 75% of them accessed internet for seeking health related information.(5)

Application of novel digital innovation in SMBG can improve clinical outcomes and quality of care as well as save time and efforts from the patient's side by offering cost-effective and adaptable platforms for disseminating these interventions(.6) Studies that had SMBG on a daily basis have had inconclusive findings and proved to be cumbersome while weekly SMBG had been found ineffective. Moreover, the wide range of technical resources of SMBG are grossly underutilized and there is a need for continuous improvisation and research in this developing sector with multiple guidelines. By doing a thrice weekly study, the process is expected to be user-friendly as well as to mitigate the potential limitations found in the previous study.

Aim & Objective(s): The aim and objective is to assess user engagement and acceptability of DTI and SMBG and also identify potential association with outcome results and to evaluate the effect of combining digital therapeutic intervention with self-monitoring of blood glucose on type 2 diabetic patients in urban Aligarh.

Material & Methods

The research was a randomized controlled trial conducted from January 2024 to December 2024. It included a 132 diabetes patients, who were residents of registered practice areas of UHTC, JNMC, AMU and attended the out-patient department of Rajiv Gandhi Centre for Diabetes and Endocrinology, AMU. It included diabetic individuals aged 30-65 years, on treatment with diet and oral hypoglycemic agents (OHA), patients or their close family members who have compatible smartphones, literacy for application usage and commitment for sustained Internet connection and all those who gave consent. Pregnant women and those in immuno-compromised state and palliative care were excluded from the study. After obtaining the list of patients, recruitment and enrollment of those who fulfilled inclusion criteria were done. Then, Simple Random Sampling followed by Randomization was done after which participants were allocated into 3 groups- (1) Those who do not use SMBG (2) those who use SMBG three times a week and (3) thrice weekly SMBG users who received feedback in the form of digital application including tailored messages. The sample size calculation was based on the study of Chawla *et al.* 2022. According to formulae, $2SD^2(Z_{\alpha/2}+Z_\beta)\ /\ d^2$, where SD – Pooled standard deviation = 1.34, $Z\alpha/2 = Z0.05/2 = Z0.025 = 1.96$ at type 1 error of 5%, $Z\beta = Z0.20 = 0.842$ at 80% power, d = effect size = difference between mean values- 0.84, using a 5% level of significance, a sample size of 40 was needed in each arm, coming to a total of 120. Assuming a dropout rate of 10%, a sample size of 132 was chosen for this study with 44 participants in each arm.(7)

Data was captured on socio-demographic correlates at the begging of study and user engagement and feedback using Mobile Application Rating Score was collected at the end of study. Modifications were done to the original questionnaire in accordance with previous literature. (8,9)

The DTI model, used in intervention group, was developed by Mobrise Health. Patients fulfilling the inclusion criteria received a notification of unique invitation code (via email or SMS) by which they download the mobile app, which is available on Google Playstore/Appstore, through individual, network–connected (cellular/Wi-Fi) smartphones. Participants then set up their own profile and login using their email ID, phone number or digital fingerprint. Patients were then requested to provide the acceptance of Terms and Conditions for their participation. Patients could manually enter data related to diabetes management into the app, including baseline health (blood pressure, weight, hours of sleep), daily blood glucose readings, exercise activity, medication intake, and their meals. Moreover, it is possible to check the trends over time (up to 3 months) using the app's activity tracker mechanism, thereby enabling patients to have a big picture of their health status and better understanding of their pattern changes at a glance. This accumulated information generated from the patient portal is then transferred to a clinician portal through the app developer. Clinicians can get an overview of the patient's condition and accordingly track, monitor and provide customized feedback to individuals. Messages and reminders are personally sent to the patients, which further encourages and motivates them to actively participate in their diabetes management. The content validity of this tool was assessed and reviewed by experts from Computer Engineering and Diabetes and Endocrinology Centre, along with pilot testing on 10% population.

Operational definitions: Self-Monitoring of Blood Glucose (SMBG) is defined as the testing and recording of blood glucose levels by a patient, oneself and/or caretaker, at home or in hospital, at any point of time.(10,11)

Digital Therapeutic Intervention (DTI)/Digital Therapeutics is a form of evidence-based therapeutic intervention which delivers patients to prevent, manage, or treat a broad spectrum of physical, mental & behavioural conditions and that are driven by high quality software programs(.12)

Data was managed and analyzed by using SPSS version 20.0. Descriptive statistics was done for studies with mean, frequency, distribution, and percentage. Approval was taken from the Institutional Ethics Committee, JNMC, AMU, Aligarh **(**Ref No.: IECJNMC/1071) as well as CTRI trial registration number (CTRI/2024/02/063351). Written informed consent was obtained from the participants in both English and Hindi, in collaboration with app developers, after providing full explanation of information regarding the study plan. Privacy and Confidentiality of personal data was ensured and maintained throughout the study as assured. Individuals had the freedom to withdraw from the study at any point

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of time. Health education and timely referral, if required, was given.

RESULTS

A total of 122 persons participated in the study (10 persons were lost to follow-up). In the depiction of tables and interpretation, the following labels will be assigned to the groups: Group 1 - No SMBG containing 41 participants , Group 2 - Thrice weekly SMBG containing 41 participants and Group 3 - Thrice weekly SMBG + DTI containing 40 participants.

Sociodemographic characteristics and Diabetic Status of study patients: The mean age of participants in this study was 49.6 (SD 9.7 years). 60% of participants were females. 79% were married and 85% followed Islam. 51% were employed of which most of them were skilled workers/clerical job/worked/owned shop. Among those who were unemployed, 78% were home-makers. 80% of participants had 10th up to graduates and 50.8% had a joint type of family. Mean number of family members in total was 6.32 (SD 3.24). Average per capita income of ₹3531.34 in total. According to the modified B.G. Prasad scale (2024), the Upper Middle Class (IV) constitutes the greatest percentage (44.3%) of participants. Both occupation (p=0.003) and education (p=0.001), on between group analysis, were found to be statistically significant. The mean duration of diabetes was 5.7 years (SD 4.7 years) at the time of enrollment. Although all the patients recruited in the study had their treatment regimen as OHA, 1% of study population had taken local medication as well. Overall, all the participants had one follow-up visit every 3 months and 99% of participants did not have any hospitalization over 1 year. Out of the 52.5% of the participants who had history of coomorbidites, 60% had hypertension followed by coronary artery disease in 20% of participants. Only 11% of the study population had complications related to diabetes. Only 29.5% of participants had family history of co-morbidities, especially out of which 46% was only diabetes and 67% were both diabetes and hypertension. This reflects the diabetic status as well as mixture of early and long-standing cases in the study population.

User Engagement: The third arm (n=40), of those who were augmented with intervention tool (Digital app) along with SMBG, were further categorized based on their logging activity. Details regarding login of users, which was based on the number of times the manual entry of data regarding blood sugar levels, was retrieved from the clinician portal. Users who were logging in at least thrice or more times a week during these 6 months were categorized as high engagement users and those who logged in less than 3 times were categorized as low engagement users.

Table 1 shows the distribution of user engagement of Group 3, ie, those who received DTI along with SMBG. 72.5% of the users were highly engaged and 27.5% users were lowly engaged. Table 2 depicts the distribution of HbA1c, FBS and PPBS among high and low users at the end of the study. It was observed that all the three parameters were decreased in high engagement users when compared to low engagement users.

Evaluation Of Digital Tool: The third arm (n=40), of those who were augmented with Intervention tool (Digital app) along with SMBG, were inquired about the app. The Mobile App Rating Scale (MARS), which comprises of 4 dimensions- Engagement, Functionality, Aesthetics and Information Quality was incorporated during collection of data at the end of the study.

The different components that were inquired were about logging into app, logging of medication, blood sugar logging and tracking, meal logging, physical activity, receive of notification, goal setting and attainment, ease of use and following advice.

The distribution of participants for each components according to rating has been depicted in Fig 2. More than half of the participants rated 3-point for the process of logging into app, logging of medication, blood sugar logging and tracking, receive of notification and visual appeal. More than half of the participants rated 2-2.5 point for meal logging, physical activity, goal setting and attainment, ease of use and following advice.

Fig 3. illustrates the difficulties faced by the participants while using the app, which were fear of security issues (59%) like breach of privacy as well as malware, user issues (26%) like decreased motivation due to complex and confusing navigation and operational and technical issues (15%) like delayed loading and crashes.

The mean participant rating of components of digital tool has been illustrated in Fig 4. Average rating of app logging, medication logging, blood sugar logging, food logging, exercise logging, notification, goal setting and attainment, navigation and following advice was 3, 3.5, 3.5, 2.53, 2.38, 3.5, 3, 2.4 and 2.5, respectively. Visual appeal was rated 2.8. Overall rating of the app was 3, which is interpreted as acceptable, ie, although the app has met the basic requirements, there are still some areas for improvement. Participants have reported mean rating of 3 point for recommendation to others.

Figure 1: Consort flow chart of Study

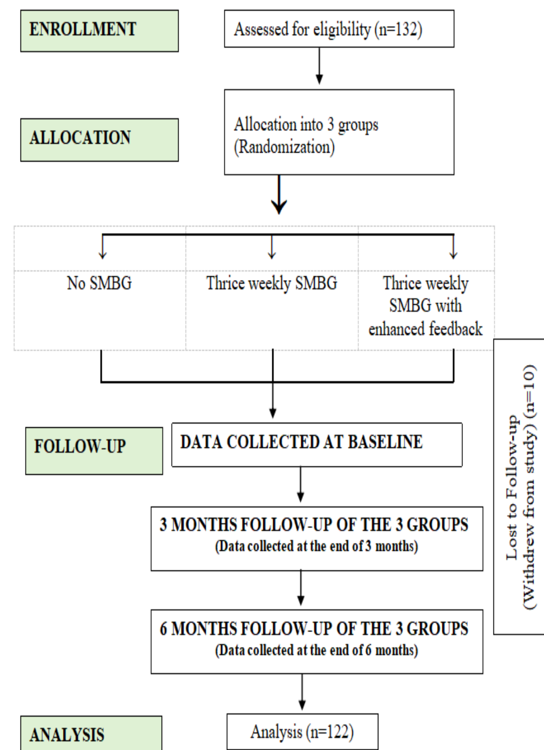


Table 1. Distribution of User engagement (n=40)

Engagement Level	Frequency	Percentage
High	29	72.5
Low	11	27.5

Table 2. Distribution of HbA1c, FBS and PPBS with Engagement Levels

Engagement Level	HbA1c	FBS	PPBS
High	6.66 (0.33)	133.8 (31.32)	156.6 (31.5)
Low	6.83(0.55)	138.8 (27.77)	156.73 (36.89)

Fig. 2 Distribution of Participants for each Components According to Rating

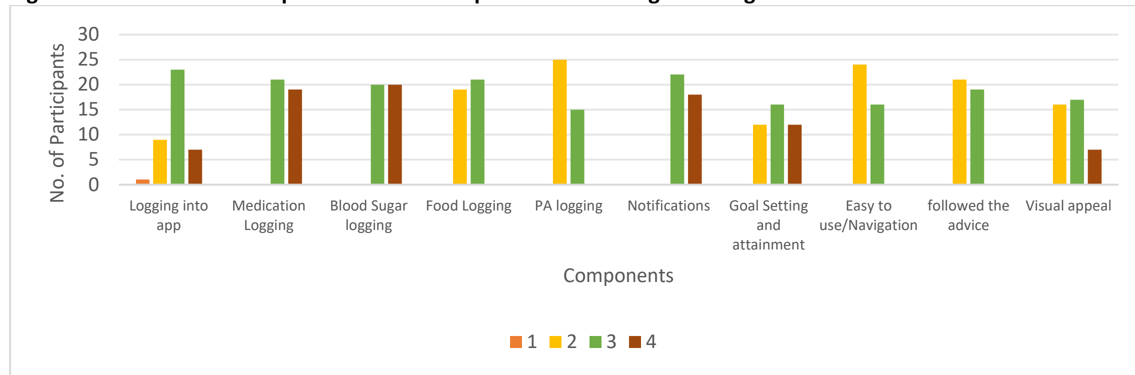


Fig 3. Difficulties related to digital tool

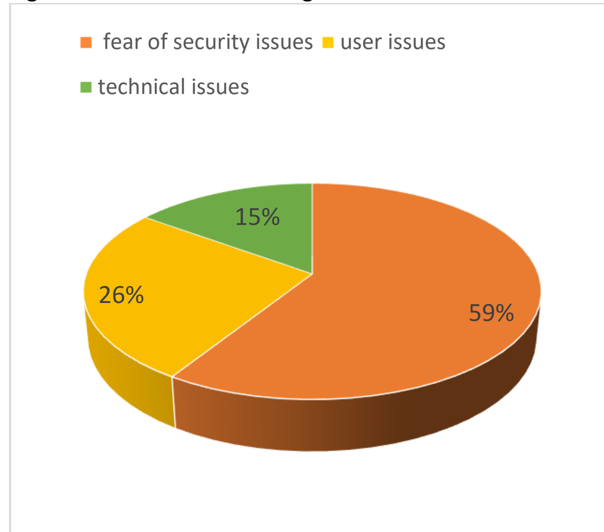
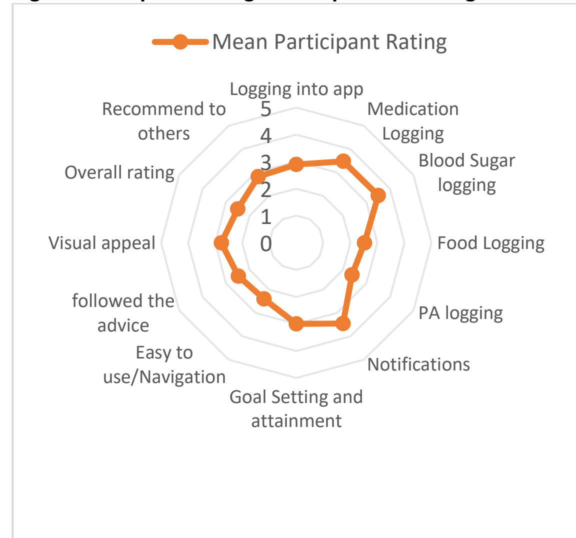


Fig. 4. Participant Rating of Components of Digital Tool



Discussion

The present study highlights the distribution of user engagement with glycemic outcomes along with the evaluation of a digital therapeutic tool. The findings are consistent with existing evidence that emphasizes the growing role of digital therapeutics (DTIs) and self-monitoring of blood glucose (SMBG) in diabetes management, particularly in resource-constrained settings where innovative solutions are needed to improve care delivery[4,11,12]. The observed association between higher user engagement and improved glycemic outcomes in this study aligns with the findings of Alodhialah et al., who reported significant improvements in HbA1c levels and mental health parameters among highly engaged participants compared to those with lower engagement[13]. Similarly, Lim et al. demonstrated high engagement rates (approximately 90%) with mobile health applications, with selective utilization of app features such as step tracking and meal logging, highlighting variability in user interaction with different components of digital platforms[14].

Comparable findings have been reported across multiple studies. Laird et al. and Kerr et al. emphasized the role of user perception and engagement in influencing outcomes of digital interventions[15,16], while Chawla et al. demonstrated the clinical utility of DTIs in improving glycemic control among Indian patients[7]. Oh et al. reported differential engagement patterns, with higher

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adherence to medication logging compared to lifestyle inputs such as diet and exercise[17]. Fundoiano-Hershcovitz et al. further reinforced the importance of sustained engagement, demonstrating significant improvements associated with digital interaction[18]. Additionally, studies by Kleinman et al. and Walle et al. highlighted improved medication adherence, frequent self-monitoring, and positive attitudes toward mHealth applications, influenced by perceived ease of use and usefulness[19,20]. The acceptability of physician-integrated feedback systems and mobile health interventions has also been supported by Potter et al. and Huda et al.[21,22].

A systematic review by Shabir et al. identified key facilitators of engagement, including motivational features, user-centered design, accessibility, and effective communication, while also highlighting barriers such as poor usability, lack of engagement, and perceived intrusiveness, which may explain variations in user engagement observed across studies[23].

However, not all studies report consistent benefits. Agarwal et al. and Koot et al. found no statistically significant improvement in glycemic outcomes despite digital intervention usage[6,24]. Similarly, the randomized trial by Young et al. reported no significant differences in HbA1c levels among different SMBG strategies, including enhanced feedback mechanisms[25]. Supporting this, a systematic review and meta-analysis by Spaulding et al. found no consistent association between user engagement and improved glycemic outcomes[26].

Overall, the findings of the present study contribute to the growing body of evidence suggesting that while DTIs and SMBG hold promise as adjuncts to conventional diabetes management, their effectiveness is closely linked to the level of user engagement, app usability, and contextual factors influencing adoption. These findings underscore the need for user-centered design, sustained engagement strategies, and integration into routine clinical care to maximize the potential benefits of digital health interventions.

Conclusion

User engagement data from the app revealed that the majority of participants were highly engaged, and this engagement correlated with better outcomes. App users rated it as acceptable overall, though challenges such as data privacy concerns, usability issues, and technical glitches were noted. Despite these limitations, participants found the digital tool beneficial, and a majority expressed willingness to recommend it to others. This demonstrates the feasibility and acceptability of such tools even in semi-urban settings, provided appropriate training and support are ensured.

Recommendation

The study highlights the potential of SMBG and DTI to be a valuable adjunct to conventional diabetes management. It reinforces the need to bridge the gap between available technology and real-world application in patient care. Health systems must consider adopting such innovations, especially in outpatient settings with resource limitations. In conclusion, the integration of DTI with SMBG has a promising future. Further long-term studies are needed to evaluate sustainability, cost-effectiveness, and scalability of these interventions on a larger population scale.

Limitation of the Study

The study has several limitations that should be considered while interpreting the findings. Although the digital tool was generally well accepted, user-reported challenges such as data privacy concerns, usability issues, and technical glitches may have influenced engagement and overall experience. The observed association between higher engagement and better outcomes may reflect engagement bias, as less-engaged participants—more representative of real-world settings—were relatively underrepresented. The study was to focus on short-term outcomes, thereby limiting insights into long-term sustainability, adherence, and clinical effectiveness. Additionally, being conducted in a semi-urban population, the findings may not be fully generalizable to rural or highly urban settings with differing levels of digital access and literacy. The intervention's effectiveness was also dependent on adequate training and support, which may not always be feasible in routine healthcare settings. Variations in access to smartphones, internet connectivity, and digital literacy could further impact the applicability of the intervention. Moreover, the study did not assess cost-effectiveness or scalability, which are critical for wider implementation. Reliance on self-reported measures of engagement and satisfaction may introduce reporting bias, and the absence of long-term clinical outcomes limits conclusions regarding sustained benefits.

Authors Contribution

All authors have contributed equally.

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Nil

Conflict of Interest

There are no conflicts of interest.

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Declaration of Generative AI and AI Assisted Technologies in the Writing Process

The authors haven't used any generative AI/AI assisted technologies in the writing process.

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