IJBMC International Journal of Body, Mind and Culture

Volume 13, Issue 6, Article e2026-1358
DOI: 10.61838/ijbmc.v13i6.1358

Article type:
Original Research

Arabic mHealth and Pharmacist Teleconsultation for Medication Adherence, Self-Care, and Quality of Life in Iraqi Adults with Type 2 Diabetes: A Randomized Controlled Trial

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Article history:

Received 17 Mar 2026
Revised 22 Apr 2026
Accepted 01 May 2026
Published online 01 June 2026

How to cite this article:
Alkhafaje, Z., & Al-Hamadani, F. (2026). Arabic mHealth and Pharmacist Teleconsultation for Medication Adherence, Self-Care, and Quality of Life in Iraqi Adults with Type 2 Diabetes: A Randomized Controlled Trial. International Journal of Body, Mind and Culture, 13(6), Article e2026-1358. https://doi.org/10.61838/ijbmc.v13i6.1358

ABSTRACT

Objective: This study evaluated the effectiveness of an Arabic mobile health application combined with pharmacist-led telephone and video consultations on medication adherence, self-care behaviors, and quality of life among adults with type 2 diabetes in Iraq.

Methods and Materials: This parallel-group randomized controlled trial was conducted at the Endocrinology and Diabetes Center in Baghdad, Iraq. A total of 146 adults with type 2 diabetes completed the 6-month study and were included in the analysis: intervention group (n = 76) and standard-care control group (n = 70). Participants were stratified by baseline HbA1c and randomized. The intervention group received standard care plus the Arabic Edarat Alsukari mHealth application and biweekly pharmacist-led telephone or video consultations. Outcomes were assessed using the Iraqi Anti-Diabetic Medication Adherence Scale, Diabetic Self-Care Knowledge and Practice Scale, and Quality of Life Scale for Iraqi Diabetics.

Findings: At 6 months, medication adherence was significantly higher in the intervention group than in the control group (16.32 ± 1.83 vs. 14.10 ± 1.90, $p < 0.001$, $d = 1.19$). Total self-care also improved significantly (17.23 ± 2.08 vs. 12.10 ± 3.90, $p < 0.001$, $d = 1.63$), especially foot care (3.20 ± 0.95 vs. 1.20 ± 1.30, $p < 0.001$, $d = 1.74$). Dietary self-care did not differ significantly ($p = 0.720$). Quality of life was higher in the intervention group (15.79 ± 2.75 vs. 14.10 ± 3.10, $p < 0.001$), with lower disease burden (3.08 ± 1.53 vs. 4.15 ± 1.80, $p = 0.003$).

Conclusion: The Arabic mHealth and pharmacist teleconsultation intervention significantly improved adherence, self-care, and quality of life, but not dietary behavior.

Keywords: Diabetes Mellitus, Mobile Applications, Medication Adherence, Self Care, Quality of Life, Telemedicine.

Introduction

Type 2 diabetes mellitus (T2DM) presents a critical public health challenge in the Middle East and North Africa (MENA) region, which has some of the highest reported rates of the disease globally (Diabetes, 2015). Iraq, specifically, faces a rising burden, with the International Diabetes Federation (IDF) estimating an age-adjusted comparative prevalence of approximately 13.4% in the adult population (Diabetes, 2015). Despite the availability of medication, diabetes management in Iraq is severely hampered by a fragmented healthcare system where patients often experience long gaps between visits and limited access to ongoing diabetes education (Mansour, 2009).

Effective T2DM management requires a daily regimen of medication adherence, glucose monitoring, and behavioral self-management (Yousefpour & Asgharvand, 2026). However, local studies indicate that adherence rates in Iraq are low. Research in Baghdad and other governorates suggests that about 60% to 66% of patients fail to meet glycemic targets, mainly due to insufficient disease awareness and lack of continuous professional guidance between clinic appointments (Mikhael et al., 2018). Often, patients leave appointments with prescriptions but receive few resources to support daily disease management, leading to poor outcomes.

Mobile health (mHealth) offers a solution to bridge this gap by providing ongoing remote assistance. The infrastructure for such interventions is now well established; recent data indicate that internet penetration in Iraq has reached about 78.7%, with over 46 million active cellular connections, providing a robust platform for digital health delivery (Othman et al., 2025). While considerable evidence supports the use of mHealth in Western populations, there is a lack of rigorous randomized controlled trials in Iraq evaluating interventions that combine digital tools with human clinical oversight. Systematic reviews of mHealth in the Arab world indicate that while general health apps exist, few are tailored to the specific cultural context, such as addressing high-carbohydrate hospitality norms, or integrated with direct clinician oversight, a key factor in reducing user attrition and ensuring sustained use (Alsswey et al., 2021).

To address the identified barriers, this study uses a dual-component model that aligns intervention components with specific gaps. First, to mitigate fragmented healthcare and insufficient follow-up, the intervention includes biweekly pharmacist consultations via video and telephone to promote clinical accountability and continuity of care. Second, to overcome cultural and educational barriers, the 'Edarat Alsukari' App provides localized, visual content tailored to Iraqi norms. It was hypothesized that combining human accountability with digital accessibility would yield significantly better outcomes than standard care alone.

The intervention group was expected to demonstrate a statistically significant improvement in medication adherence compared to the control group at 6 months. It was further hypothesized that the intervention would result in significant improvements in self-care behaviors (specifically, foot care and diet) and quality of life, as well as a reduction in the perceived burden of disease management.

Methods and Materials

Study Design, Randomization, and Blinding

This study was a parallel-group, single-center, randomized controlled trial (RCT) conducted at the Endocrinology and Diabetes Center in the Al-Rasafa district of Baghdad, Iraq. The study protocol adhered to the CONSORT guidelines for reporting clinical trials.

Randomization and Allocation: To ensure that disease severity was balanced between the intervention and control groups, participants were assigned using a stratified randomization method based on baseline HbA1c levels. Three specific strata were defined: 1. HbA1c 7% – 9%, 2. HbA1c 9% – 11% and 3. HbA1c > 11%.

Each stratum contained between 42 and 50 participants. Within these strata, participants were randomized 1:1 to either the intervention or control arm. The principal investigator conducted participant enrollment. To minimize selection bias during allocation, the randomization sequence was concealed until assignment.

Blinding: Due to the nature of the intervention (which involved active participation in video calls and app use), it was not possible to blind participants or the principal investigator delivering the intervention. However, to

ensure internal validity, the study employed a single-blinded design for outcome assessment.

All follow-up questionnaires (at 3 and 6 months) were administered by an independent pharmacist at the endocrinology center, who was blinded to participants' group assignments. The statistical analysis was performed by an independent statistician who was also blinded to group identity (groups were coded as A and B).

Participants, Sample Size, and Recruitment

Study Setting and Eligibility

This parallel-group randomized controlled trial (RCT) was conducted at the Endocrinology and Diabetes Center in the Al-Rasafa district of Baghdad, Iraq. Eligible participants were adults (aged ≥18 years) diagnosed with Type 2 Diabetes Mellitus (T2DM) for at least one year. Inclusion criteria required participants to have a baseline HbA1c ≥7%, own a smartphone with internet access, and demonstrate basic ability to operate mobile applications.

Exclusion and Withdrawal Criteria

Potential participants were excluded if they had Type 1 Diabetes, severe cognitive impairment, or advanced complications (e.g., blindness, end-stage renal disease). To ensure the integrity of the intervention data, specific withdrawal criteria were established. Participants were withdrawn from the study if they: Missed three consecutive mobile pharmacist consultations (Intervention Group). Failed to attend the mandatory 6-month follow-up assessment (Control or Intervention Group).

Sample Size and Power Calculation

A priori power analysis was conducted using G*Power software. We anticipated a medium effect size (Cohen's d = 0.5) for the primary outcome of medication adherence. To detect this difference with 80% power at a 5% significance level (two-tailed $\alpha = 0.05$), a minimum of 64 participants per group was required. To account for potential attrition, we aimed for higher initial enrollment.

Recruitment Flow

A total of 230 patients were screened for eligibility during routine clinic visits. Of these, 41 were excluded before randomization because they did not meet the inclusion criteria or declined to participate. The remaining 189 eligible participants provided informed consent and were randomized to the control group (n = 70) or the intervention group (n = 76).

Addressing Selection Bias

The requirement for smartphone ownership may introduce socioeconomic bias. However, given the high smartphone penetration rate in Iraq (about 78%) and the specific objective of evaluating an *app-based* intervention, this criterion was necessary. To address digital literacy barriers, the research team provided a 15-minute onboarding session to ensure all enrolled participants could use the 'Edarat Alsukari' interface. To further reassure readers that vulnerable groups were not sidelined, a future strategy could include caregiver-assisted onboarding or subsidized devices to increase accessibility.

2.3 Intervention

Control Group: Participants received standard institutional care, including routine 3-month follow-up visits. To ensure a clear comparison with the intervention, the parameters of standard care were defined as follows: Routine consultations were brief, typically lasting 5 to 8 minutes. The primary focus of these visits was medication renewal and review of laboratory results. Advice provided during these sessions was limited to standard verbal instructions regarding medication adherence. No written educational materials, structured dietary plans, or specific physical activity regimens were provided. Participants in the control group did not receive access to the 'Edarat Alsukari' application. Although participants were not formally prohibited from using other digital tools, baseline assessments confirmed that none of the enrolled participants was currently using any diabetes management applications. The study center served as the primary source of diabetes care for these patients. No additional external co-interventions (e.g., private workshops or structured education programs) were involved in their management during the study period.

Intervention Group: Participants received standard care plus a dual-component digital intervention to address both behavioral and clinical barriers to diabetes management.

1. The 'Edarat Alsukari' Application Participants were provided with the 'Edarat Alsukari' app, a custom-developed Arabic-language tool available on the Android platform.

The app features culturally tailored educational modules covering diet (specifically addressing local carbohydrate-rich foods), medication management, physical activity, and foot care. It also serves as a digital logbook for recording self-monitored blood glucose (SMBG) readings. Participants were instructed to log their blood glucose readings at least 3 times per week. Unlike automated systems, the app relies on active user engagement and does not send push notifications, aiming to foster intrinsic motivation rather than dependence on alerts. The app interface is designed to be easy to use for patients with varying levels of digital literacy (see Figure 1).

2. Pharmacist-Led Remote Consultations To ensure clinical fidelity and overcome the limitations of standalone apps, participants received biweekly remote consultations via video or telephone calls.

All consultations were conducted by a single clinical pharmacist (the principal investigator) to ensure consistency in communication style and adherence to protocol. Each consultation lasted 5 to 15 minutes.

Consultations followed a standardized clinical checklist covering four key domains: (1) Review of glucose logs; (2) Medication adherence barriers; (3) Dietary and physical activity behaviors; and (4) Foot care practices. The pharmacist utilized motivational interviewing techniques to support patient autonomy. Importantly, while the pharmacist identified necessary treatment modifications (e.g., insulin titration) based on patient data, all clinical decisions were reviewed and approved by the treating endocrinologist before implementation. This collaborative model ensured patient safety while maximizing care efficiency.

This study evaluates the combined effectiveness of the digital tool and human clinical support. While this design does not isolate the app's independent contribution from that of the pharmacist, it was chosen to reflect a holistic model of care in which technology enables professional guidance rather than replaces it.

Figure 1

Edarat Al-Sukari mobile app interface

Instruments

Data collection was performed by an independent pharmacist blinded to study group allocation. Outcome measures were assessed at specific intervals as detailed below.

Medication Adherence

Adherence to anti-diabetic treatment was assessed at baseline, three months, and six months using the Iraqi Anti-Diabetic Medication Adherence Scale (IADMAS), a tool specifically developed and validated for the Iraqi population (Mikhael et al., 2019). The scale consists of 8 items that assess medication-taking behaviors and barriers. Responses are scored on a summative scale ranging from 0 to 20. A cutoff score >12 indicates "good adherence," while a score ≤12 indicates "poor adherence." The scale has demonstrated high internal consistency and concurrent validity with HbA1c levels in Iraqi patients (Mikhael et al., 2019).

Self-Care Behaviors

Self-management practices were evaluated at baseline and at six months using the Diabetic Self-Care Knowledge and Practice Scale, which was validated for use in Iraq by Mikhael et al. (2018). The questionnaire comprises 25 items covering six key domains: Physical Activity, Diet, Medication Intake, Glucose Testing, Foot Care, and Follow-up. Items utilized a mix of frequency-based Likert scales (e.g., "0–7 days per week") and binary response options (Yes/No). Example Item (Physical Activity): "During the past month, how often did you engage in physical exercise?" (scored 0 to 7 days). Example Item (Follow-up): "During the past year, did you visit an ophthalmologist?" (scored Yes/No). Higher aggregate scores indicate higher engagement in diabetes self-management activities.

Quality of Life (QoL)

Quality of life was measured at baseline and 6 months using the Quality of Life Scale for Iraqi Diabetics (QOLSID), a culturally validated instrument (Mikhael et al., 2020). The scale consists of 10 items, divided into two subscales: Satisfaction (6 items), which measures patients' satisfaction with their health and treatment; and Disease Burden (4 items), which measures the perceived negative impact of diabetes on daily life. The tool has been validated for reliability and content validity in the Iraqi context [8].

Data Analysis

Data analysis was performed using SPSS version 26 and Python (Pandas/SciPy). Continuous variables were expressed as mean ± standard deviation (SD) for normally distributed data or median for non-normally distributed data. The normality of distribution was assessed using the [Shapiro-Wilk / Kolmogorov-Smirnov] test. Differences between the Intervention and Control groups at baseline and follow-up were analyzed using the Independent t-test (for normally distributed data) or the Mann-Whitney U test (for non-normally distributed data).

Changes over time (Baseline vs 3m vs 6m) were analyzed using Friedman's test, followed by Wilcoxon Signed-Rank tests for pairwise comparisons. To quantify the magnitude of change, effect sizes were calculated. For parametric tests, Cohen's d was used (Small: 0.2, Medium: 0.5, Large: 0.8). For non-parametric tests, the effect size **r** was calculated as Z. Participants who did not complete follow-up were excluded from the analysis. A p-value of < 0.05 was considered statistically significant.

Ethical Considerations and Data Protection

The study protocol was reviewed and approved by the University of Baghdad-College of Pharmacy Research Ethics Committee (Ref/Approval Number: [2023/104]. The committee confirmed that the study complies with the *International Ethical Guidelines for Health-related Research Involving Humans* prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), as well as the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Belmont Report).

Written informed consent was obtained from all participants before screening. Participants were provided with a detailed explanation of the study purpose, the nature of the mobile intervention, and their right to withdraw at any time without affecting their routine medical care.

This clinical trial was not registered in a public database before recruitment, as prospective registration was not a mandatory institutional requirement at the time of study initiation. However, the study adhered strictly to the original protocol approved by the Ethics Committee, and no changes were made to the primary outcomes after the trial commenced.

To ensure participant confidentiality, all personal identifiers were removed from the analytical dataset; participants were assigned unique coded identification numbers. Data transmitted via the mobile application (including glucose logs and medication queries) were stored on password-protected servers accessible only to the principal investigator. No sensitive health data were stored locally on participant devices, and all teleconsultation messages were encrypted to protect patient privacy.

Findings and Results

Participant Flow and Recruitment

The flow of participants through the study is detailed in the CONSORT diagram (Figure 2). A total of 230 patients were screened for eligibility at the endocrinology facility. Of these, 41 were excluded before randomization because they did not meet the inclusion criteria (e.g., medical ineligibility or lack of smartphone).

The remaining 189 eligible participants were randomized into two groups: Control Group: n = 93; Intervention Group: n = 96

During the first three months of the study, 43 participants (22.7%) discontinued the study and were lost to follow-up. The attrition was distributed as follows:

Control Group: 23 participants dropped out (Reasons: withdrew consent or lost contact).

Intervention Group: 20 participants dropped out (Reasons: missed consultations or technical difficulties).

Consequently, the final analysis at 6 months included 146 participants (n=70 in the Control group and n=76 in the Intervention group). This final sample size exceeded the required target of 128 participants for the power calculation.

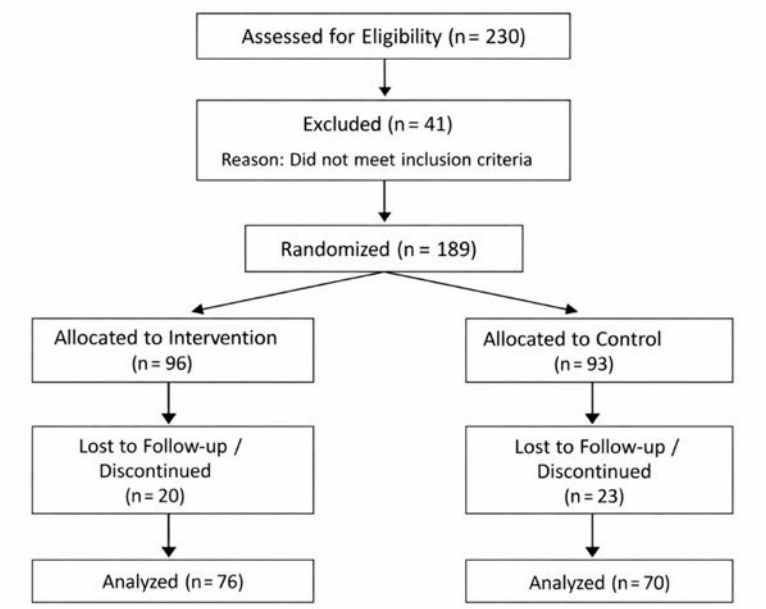

Figure 2

Participant Flow and Recruitment

Demographic Characteristics

The two groups were comparable in age, diabetes duration, and family history. The control group included a higher proportion of women than the intervention group; however, other baseline characteristics were similar.

Impact on Medication Adherence

Table 1 presents the comparative efficacy of the pharmacist-led intervention on medication adherence scores (IADMAS) over the six-month study period.

Baseline Equivalence

At baseline, there were no statistically significant differences in adherence scores between the Intervention group (14.14 ± 1.87) and the Control group (14.05 ± 1.95) (p = 0.775), confirming successful

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randomization and comparability between the two groups at the outset of the study.

Impact at 3 Months

At the 3-month follow-up, the Intervention group demonstrated a substantial, statistically significant improvement in medication adherence compared with the Control group. The mean IADMAS score in the Intervention group rose to 17.72 (SD 1.36), whereas the Control group showed a negligible change with a mean of 14.20 (SD 1.80). The mean difference between groups was 3.52 points (95% CI: 3.00 to 4.04). This difference was highly significant ($p < 0.001$). The magnitude of this effect was very large (Cohen's d = 2.21), indicating that the intervention had a profound impact on adherence behaviors during the active phase.

Sustained Impact at 6 Months

At the 6-month endpoint, the intervention's beneficial effect was sustained, although adherence scores in the Intervention group decreased slightly to 16.32 (SD 1.83). Despite this decline, the Intervention group remained significantly superior to the Control group, which maintained a mean score of 14.10 (SD 1.90). The mean difference at 6 months remained clinically meaningful at 2.22 points (95% CI: 1.61 to 2.83). The difference remained highly significant ($p < 0.001$). The effect size remained large (Cohen's d = 1.19), suggesting that the intervention provided durable benefits beyond the initial intensive phase.

Clinical Relevance

Critically, the Intervention group's mean scores at both follow-up points (17.72 and 16.32) were well above the validated cut-off of 12, indicating "Good Adherence." In contrast, the Control group's average scores remained closer to the threshold, indicating that standard care alone was insufficient to drive substantial behavioral change.

Table 1

Longitudinal Trajectory of Medication Adherence (IADMAS)
Intervention Group (n=76) control group n=70

Time Point	Intervention Group (n=76)	Control Group (n=70)	Mean Difference (95% CI)	P-value*	Effect Size (Cohen's d)
Baseline					
Mean (SD)	14.14 (1.87)	14.05 (1.95)	0.09 (-0.53 to 0.71)	0.775	0.05
Median (IQR)	14.0 (13.0–15.3)	14.0 (13.0–15.0)	—	—	—
3 Months					
Mean (SD)	17.72 (1.36)	14.20 (1.80)	3.52 (3.00 to 4.04)	< 0.001	2.21
Median (IQR)	18.0 (17.0–19.0)	14.0 (13.0–15.5)	—	—	—
6 Months					
Mean (SD)	16.32 (1.83)	14.10 (1.90)	2.22 (1.61 to 2.83)	< 0.001	1.19
Median (IQR)	16.0 (15.0–18.0)	14.0 (13.0–15.0)	—	—	—

Notes: *Values are Mean (Standard Deviation). IADMAS scores range from 0 to 20; scores >12 indicate good adherence. *P-values derived from an independent samples t-test. Effect size (Cohen's d) interpreted as: 0.2=Small, 0.5=Medium, 0.8=Large.*

Impact on Self-Care Domains

Overall Self-Care Improvements

At baseline, there were no significant differences in total self-care scores between the Intervention group (11.59 ± 4.30) and the Control group (11.50 ± 4.10) ($p = 0.91$), confirming comparability. By the 6-month endpoint, the Intervention group achieved a mean Total Self-Care score of 17.23 (SD 2.08), representing a statistically significant improvement compared to the Control group, which remained largely unchanged at 12.10 (SD 3.90) ($p < 0.001$). The effect size for this difference was large (Cohen's d = 1.63), indicating a substantial shift in overall self-management competence.

Domain-Specific Outcomes

Analysis of the specific self-care domains revealed varied effectiveness: The most pronounced between-group differences were observed in Foot Care ($p < 0.001$; d = 1.74) and Glucose Monitoring ($p < 0.001$; d = 0.52), with the intervention group demonstrating markedly better practices than controls.

Consistent with the primary IADMAS results, the medication intake self-care subscale was significantly higher in the Intervention group ($p < 0.001$). Note: While this domain overlaps with the primary adherence measure (IADMAS), it was retained here to preserve the structural integrity of the validated self-care instrument.

In contrast to other domains, Dietary Control showed no significant difference between the Intervention (2.38 ± 0.49) and Control groups (2.35 ± 0.45) at 6 months (p

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= 0.72). Both groups scored low in this domain, suggesting that the mobile intervention was less effective at modifying complex dietary habits than at modifying specific tasks such as foot inspections.

Clinical Interpretation

The increase in the Total Self-Care score from ~11.6 to 17.23 in the Intervention group represents a shift from "poor/inconsistent" self-care to "moderate/active" engagement, as validated by the significant parallel reduction in HbA1c.

Table 2

Changes in Diabetes Self-Care Behaviors (Baseline vs 6 Months)

Domain	Intervention (n=76) Mean (SD)	Control (n=70) Mean (SD)*	Between-Group P-value	Effect Size (Cohen's d)
Total Self-Care Score	17.23 (2.08)	12.10 (3.90)	< 0.001	1.63 (Large)
Physical Activity	2.24 (1.03)	1.50 (0.95)	< 0.001	0.75 (Medium)
Diet Control	2.38 (0.49)	2.35 (0.45)	0.720	0.06 (Negligible)
Medication Intake†	4.76 (0.49)	4.25 (0.80)	< 0.001	0.76 (Medium)
Glucose Monitoring	2.07 (0.97)	1.60 (0.85)	< 0.001	0.52 (Medium)
Foot Care	3.20 (0.95)	1.20 (1.30)	< 0.001	1.74 (Large)
Follow-up (Disease Control)	2.58 (0.90)	1.20 (0.80)	< 0.001	1.62 (Large)

Impact on Quality of Life

The intervention resulted in a statistically significant improvement in overall quality of life (QoL) compared with standard care. At baseline, the Total QoL scores were similar between groups (p = 0.65). However, by month 6, the Intervention group's Total QoL score increased to 15.79 (SD 2.75), whereas the Control group showed no significant change (14.10, SD 3.10).

The Intervention group scored significantly higher than the Control group at the endpoint (p < 0.001). The magnitude of this difference was moderate-to-large (Cohen's d = 0.58).

Subscale Analysis

The Satisfaction subscale largely drove the improvement. The Intervention group reported significantly higher satisfaction with their health and treatment than controls (12.71 vs 10.15; p < 0.001), suggesting that the mobile tool helped patients feel more satisfied with their diabetes management.

Contrary to concerns that additional self-care tasks might increase patient stress, the Intervention group reported a significantly lower perceived disease burden (Score: 3.08) than the Control group (Score: 4.15) at 6 months (p = 0.003). This reduction in perceived burden indicates that the pharmacist's support likely mitigated the stress of daily management.

Table 3

Changes in Quality of Life Outcomes

Domain	Intervention (n=76) Mean (SD)	Control (n=70) Mean (SD)*	Mean Difference (95% CI)	P-value†	Effect Size (Cohen's d)
Total Quality of Life	15.79 (2.75)	14.10 (3.10)	1.69 (0.75 to 2.63)	< 0.001	0.58 (Medium)
Satisfaction Subscale	12.71 (2.31)	10.15 (2.60)	2.56 (1.75 to 3.37)	< 0.001	1.04 (Large)
Disease Burden Subscale‡	3.08 (1.53)	4.15 (1.80)	-1.07 (-1.62 to -0.52)	0.003	0.64 (Medium)
Total Quality of Life	14.24 (3.52)	15.79 (2.75)	+1.55	< .001*	d=0.45
Satisfaction Subscale	10.00 (2.86)	12.71 (2.31)	+2.71	< .001*	r=0.74
Burden Subscale†	4.24 (1.99)	3.08 (1.53)	-1.16	< .001*	r=0.50

Discussion and Conclusion

This study provides the first randomized controlled trial (RCT) evidence in this setting, demonstrating that a pharmacist-led mobile health intervention significantly outperforms standard care in improving medication adherence and self-care behaviors among patients with type 2 diabetes. Unlike previous observational studies, our use of a control group allows us to attribute these improvements directly to the intervention rather than

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secular trends or the "Hawthorne effect." The results of this research was in line with Alkhafaje et al. (2026).

At the 6-month endpoint, the intervention group achieved “Good” adherence (IADMAS scores >16), while the control group remained at baseline. The large effect size (Cohen’s d > 1.0) observed for medication adherence suggests that continuous digital engagement effectively bridges the gap between clinical prescription and patient behavior (Cutler et al., 2018; Sabaté, 2003).

Mechanisms of Improvement

The divergence in outcomes between the two groups supports the efficacy of the intervention’s core components, though specific mechanisms warrant careful interpretation. While we did not directly measure app usage logs or specific read-receipt rates, the significant improvement in the "Medication Intake" and "Foot Care" subscales of the self-care assessment suggests that the intervention was most effective for *task-based* behaviors. This aligns with the mHealth literature, which suggests that digital prompts serve as "external cues to action," reducing the cognitive load of remembering daily regimens (Free et al., 2013). Conversely, the control group’s lack of improvement underscores that standard clinic visits alone are insufficient to sustain daily adherence behaviors in this population.

The Challenge of Dietary Modification

A notable finding was the discrepancy between medication adherence success ($p < 0.001$) and the lack of a statistically significant improvement in dietary control ($p = 0.72$). Both groups showed poor dietary scores at baseline and the 6-month endpoint.

This resistance to dietary change likely reflects the complex sociocultural environment of the study population. The traditional Iraqi diet is characterized by high consumption of refined carbohydrates (rice, bread) and saturated fats. It is often served in large, communal portions that are central to social hospitality (Musaiger, 2012). Altering such deeply ingrained cultural habits within a short six-month timeframe is notoriously difficult compared to adding a discrete new behavior, such as taking a pill or checking feet.

Although the *overall* diet score did not change significantly, a granular analysis of the data suggests a trend toward reduced high-sugar intake in the intervention group (from daily to 3-4 times/week). However, this did not reach statistical significance. This suggests that while mobile prompts can initiate small changes, they may be insufficient to counteract the "obesogenic" environment without more intensive, family-based nutritional counseling that respects cultural food norms (Al-Rubeaan et al., 2015).

Quality of Life and Treatment Burden

Contrary to our initial hypothesis that adding digital tasks might increase "treatment burden," the intervention group actually reported a statistically significant reduction in perceived disease burden (Score 3.08 vs 4.15 in controls). This finding contradicts the notion that self-monitoring is inherently burdensome. Instead, it supports the "buffering hypothesis," which posits that the perceived availability of professional support (via the pharmacist) reduces psychological distress associated with diabetes management (Polonsky et al., 2005). Patients in the intervention group demonstrated higher satisfaction, likely because the tool provided them with a sense of agency and safety, rather than just additional work.

Barriers to Implementation and Scaling

While the efficacy of the intervention is clear, several barriers must be addressed before scaling this approach into national policy. One of the most compelling reasons to adopt this intervention at the national level is the potential cost savings from improved medication adherence. Studies have shown that non-adherence to diabetes medication can result in significant healthcare costs due to increased hospitalizations and complications. By enhancing adherence through our intervention, we could significantly reduce these costs. For example, using regional data on the economic impact of non-adherence, it is possible to estimate that a modest improvement in adherence could lead to savings of up to 20% in diabetes-related healthcare expenditures. Quantifying these economic benefits could strengthen the case for policy adoption and align with the broader literature that underscores the financial advantages of mHealth interventions (Iribarren et al., 2017).

Digital Literacy: A portion of our screened population was excluded due to a lack of smartphones or an inability to use them. This creates a risk of "digital exclusion," leaving the most vulnerable older adults behind (Schlomann et al., 2020).

Cost and Sustainability: The study accounted for data costs and pharmacists' time. In a real-world setting, the long-term cost of mobile data plans for low-income

patients and the remuneration models for pharmacists managing digital caseloads remain unresolved challenges (Iribarren et al., 2017).

Workload: The intervention required a dedicated pharmacist's time. Integrating this into a busy public clinic without increasing staffing could lead to provider burnout.

Limitations

Several limitations of this study must be acknowledged to contextualize the findings. First, this was a single-center randomized controlled trial conducted in an urban district of Baghdad. As a result, the findings may not be generalizable to rural populations or those receiving care in primary health centers with fewer resources. The open-label design, inherent in behavioral interventions where participants cannot be blinded to their group assignment, introduces the potential for performance bias, as participants may change their behavior simply because they are aware of being observed. Additionally, a key limitation on external validity is the requirement for smartphones. As detailed in the participant flow, approximately 18% of screened individuals were excluded due to a lack of compatible devices or digital literacy. This introduces selection bias, favoring younger, more affluent, or more educated participants, thereby creating a 'digital divide.' Therefore, the efficacy observed here may not be generalizable to the general Iraqi diabetic population without device subsidies or caregiver support for older adults.

Third, outcomes were assessed using self-reported measures (IADMAS, QOLSID, and Self-Care Inventory). While these are validated tools, they are susceptible to social desirability bias, in which participants in the intervention group may overestimate their adherence to please healthcare providers. We did not employ objective verification methods, such as pill counts, pharmacy refill records, or electronic monitoring caps, which would have provided more robust confirmation of adherence behaviors.

The study also experienced a notable attrition rate of 22.7% (43 dropouts). While we compared baseline characteristics to rule out major selective attrition, the analysis was restricted to a per-protocol basis (completers only). This reduction in sample size may limit the statistical power to detect smaller effect sizes, particularly for secondary outcomes such as dietary changes.

Finally, the six-month follow-up period, while sufficient to demonstrate initial efficacy, is relatively short for a chronic lifelong condition like type 2 diabetes. This study cannot determine whether the observed improvements in adherence and self-care would be sustained after the intervention ceases ("maintenance phase") or if "app fatigue" would lead to a decline in engagement over a longer period. Future longitudinal studies are needed to assess the cost-effectiveness and durability of this intervention over 12 to 24 months.

This randomized controlled trial demonstrates that a pharmacist-led mobile intervention yields statistically significant improvements in medication adherence, foot care behaviors, and quality of life compared with standard care alone. The superiority of the intervention group at the six-month endpoint—evidenced by large effect sizes in adherence scores—supports integrating continuous digital follow-up into diabetes management. Importantly, these clinical gains were achieved while simultaneously reducing the perceived burden of disease management, countering concerns that additional self-monitoring might overwhelm patients.

However, the efficacy of this intervention appears to be domain-specific. While the program successfully reinforced routine, task-based behaviors (such as medication intake and foot inspection), it failed to elicit significant changes in dietary habits, which remained suboptimal in both groups. This likely reflects the profound difficulty of modifying the traditional, carbohydrate-dense local diet within a short timeframe using only digital prompts.

Therefore, while mobile health tools are effective for regimen compliance, they appear insufficient to address the complex, multi-factorial challenges of nutritional modification in this cultural context. Future iterations must pair digital tools with culturally tailored, intensive nutritional counseling. Additionally, future research should incorporate qualitative evaluations to understand specific patient engagement patterns and the reasons for discontinuation, thereby better guiding implementation in the broader healthcare system.

Acknowledgments

The authors express their gratitude and appreciation to all participants.

Declaration of Interest

The authors of this article declared no conflict of interest.

Ethical Considerations

The study protocol adhered to the principles outlined in the Declaration of Helsinki, which provides guidelines for ethical research involving human participants. Ethical considerations in this study were that participation was entirely optional.

Transparency of Data

In accordance with the principles of transparency and open research, we declare that all data and materials used in this study are available upon request.

Funding

This research was carried out independently, with personal funding, and without financial support from any governmental or private institution or organization.

Authors' Contributions

All authors equally contribute to this study.

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