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Effect Of Digital Versus Conventional Diabetes Self-Management Education on Glycemic Control in Type 2 Diabetes: A Randomized Controlled Trial

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Effect Of Digital Versus Conventional Diabetes Self-Management Education on Glycemic Control in Type 2 Diabetes: A Randomized Controlled Trial

Short title: Digital DSME vs Conventional Counselling in Type 2 Diabetes

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Trial registration: IRCT20260703070054N1 (Iranian Registry of Clinical Trials, registered 9 July 2026).

Ethics approval: Institutional Review Board, Armed Forces Postgraduate Medical Institute, Rawalpindi (Ref: 605-AAA-ERC-AFPGMI).

Structured Abstract

Objectives

To evaluate the effectiveness of a structured digital Diabetes Self-Management Education (DSME), delivered via WhatsApp and the mySugr application, compared with conventional in-person counselling, on glycaemic control and secondary self-efficasy and self-care behavior outcomes in adults with type 2 diabetes mellitus (T2DM) in a tertiary care hospital setting Jhelum Pakistan.

Design

Single-blind (outcome assessor-blinded), parallel-group, randomised controlled trial.

Setting

Outpatient diabetes clinics of a tertiary care hospital serving a mixed government employed, retired, and civilian population in Jhelum District, Punjab, Pakistan.Data collection from July 2026 after trial registration to October 2026.

Participants

158 adults aged ≥18 years with T2DM diagnosed more than 3 months previously, with smartphone and WhatsApp access, randomised 1:1 (stratified by sex, in blocks of 4, 6, or 8) to intervention (n=79) or control (n=79). Overall completion was 90.3% (27 participants lost to follow-up: 12 intervention, 15 control).

Interventions

Intervention arm: twice-weekly WhatsApp-delivered DSME messages over 12 weeks plus weekly fasting blood glucose logging via the mySugr app. Control arm: standard in-person counselling at routine hospital visits.

Outcome measures

Primary: change in glycated haemoglobin (HbA1c) from baseline to 12 weeks. Secondary: change in Diabetes Self-Efficacy Scale (DSES) score, and Summary of Diabetes Self-Care Activities (SDSCA) score.

Results

HbA1c fell by a mean 1.29 percentage points in the intervention arm (9.04% to 7.76%; $p<0.001$, Cohen's $d=1.27$) versus 0.13 points in the control arm ($p=0.199$). After ANCOVA adjustment for baseline HbA1c, the adjusted between-group difference was −0.49% (95% CI −0.68 to −0.30, $p<0.001$). SDSCA and DSES scores improved significantly in the intervention arm and declined significantly in the control arm (both $p<0.001$). A significantly greater proportion of intervention participants achieved target HbA1c <7.0% (37.8% vs 10.1%; OR 5.42, 95% CI 2.31–12.72, $p<0.001$); number needed to treat was 4 (95% CI 3–7). Mediation analysis indicated 43.6% of the intervention effect on HbA1c was mediated through improved self-efficacy.

Conclusions

A low-cost, WhatsApp-delivered digital DSME intervention produced clinically meaningful improvements in glycaemic control, self-efficacy, and self-care behaviour compared with conventional counselling among patients with T2DM in a resource-constrained tertiary care setting in Pakistan.

Trial registration number
IRCT20260703070054N1.

Strengths and Limitations of This Study

- Among the first randomised controlled trials in Jhelum, Pakistan to evaluate a digital DSME intervention using a rigorous design, computer-generated randomisation, allocation concealment, and blinded outcome assessment, in a mixed government employee–civilian, urban/semi-urban tertiary care population.
- The intervention used low-cost, widely available consumer platforms (WhatsApp and the mySugr app) requiring no specialised hardware, supporting scalability in resource-constrained settings.
- Validated instruments (DSES, SDSCA) and objective glycaemic measurement (HbA1c) were used alongside a comprehensive analytic approach, including ANCOVA, mediation, and logistic regression analyses.
- Participants and intervention staff could not be blinded given the nature of the comparison, and the single-centre design with a requirement for smartphone/WhatsApp access may limit generalisability.
- The 12-week follow-up captures short-term efficacy only and cannot establish durability of effect; no formal adverse event/harms surveillance was built into the protocol.

Introduction

Type 2 diabetes mellitus (T2DM) is a leading global health challenge, affecting an estimated 537 million adults in 2021 and projected to reach 783 million by 2045 [6]. Pakistan ranks third globally for diabetes burden, with 33 million adults living with T2DM in 2021, a prevalence of 30.8% among adults aged 20–79 years and 26.9% of cases remain undiagnosed [6]. T2DM prevalence in Pakistan is markedly higher in urban areas than rural areas, driven by rapid urbanisation, sedentary lifestyle, and dietary transition, alongside a well-documented genetic predisposition among South Asian populations toward early-onset disease and adiposity-related insulin resistance [3].

Sustained glycaemic control remains difficult to achieve in routine clinical practice: poor glycaemic control (HbA1c >7%) has been reported in an estimated 70% of T2DM patients in low-resource settings, and persistently poor glycaemic control has been documented across multiple low- and middle-income countries over more than a decade of real-world surveillance [2]. Conventional in-person diabetes counselling in Pakistani tertiary care hospitals is constrained by high patient volumes, short consultation times, and limited health system resources, restricting the intensity and consistency of self-management education delivered face-to-face.

Digital health interventions offer a scalable, low-cost alternative, providing structured education and reminders between clinic visits. Meta-analytic evidence indicates digital DSME interventions reduce HbA1c by approximately 0.4–0.8 percentage points compared with usual care [7,8,9]. Structured behavioural and lifestyle interventions more broadly have also produced clinically meaningful improvements in glycaemic control and quality of life among patients with long-standing T2DM, including those on more intensive pharmacological regimens, underscoring the value of structured, supported behaviour change programmes across the T2DM treatment spectrum [16]. However, the effectiveness of low-cost, consumer-platform digital DSME has been little studied in Pakistani tertiary care populations, where digital literacy, language, and connectivity vary widely.

This trial evaluated whether a structured digital DSME intervention delivered via WhatsApp messaging combined with app-based fasting blood glucose logging produces significantly greater improvement in glycaemic control (HbA1c) and secondary self-management outcomes compared with conventional in-person counselling, among adults with T2DM attending a tertiary care hospital in Jhelum, Pakistan.

Objectives

1. To evaluate the effectiveness of a structured digital DSME intervention compared with conventional counselling on glycaemic control (HbA1c) in T2DM patients over 12 weeks.

2. To assess between-group differences in diabetes self-efficacy, and diabetes-related self-care behaviour.

Methods

Trial design

Single-blind (outcome assessor-blinded), parallel-group, 1:1 randomised controlled trial, conducted over one year (August 2025–July 2026).

Setting

Outpatient diabetes clinics of a tertiary care Hospital in Jhelum —serving a mixed government employed, retired, and civilian population of approximately 1.2 million across Jhelum District and adjoining semi-urban tehsils. The hospital recorded 21,618 diabetes cases and an average daily outpatient volume of approximately 1,200 in 2025.

Participants

Adults aged ≥18 years with T2DM diagnosed more than 3 months previously, with smartphone and WhatsApp access, recruited from hospital records and outpatient attendance. Exclusions: type 1 or gestational diabetes; severe complications (end-stage renal disease, severe retinopathy, cardiac complications); cognitive impairment precluding participation; inability to use WhatsApp or absence of smartphone access; pregnancy or hospitalization during the study period.

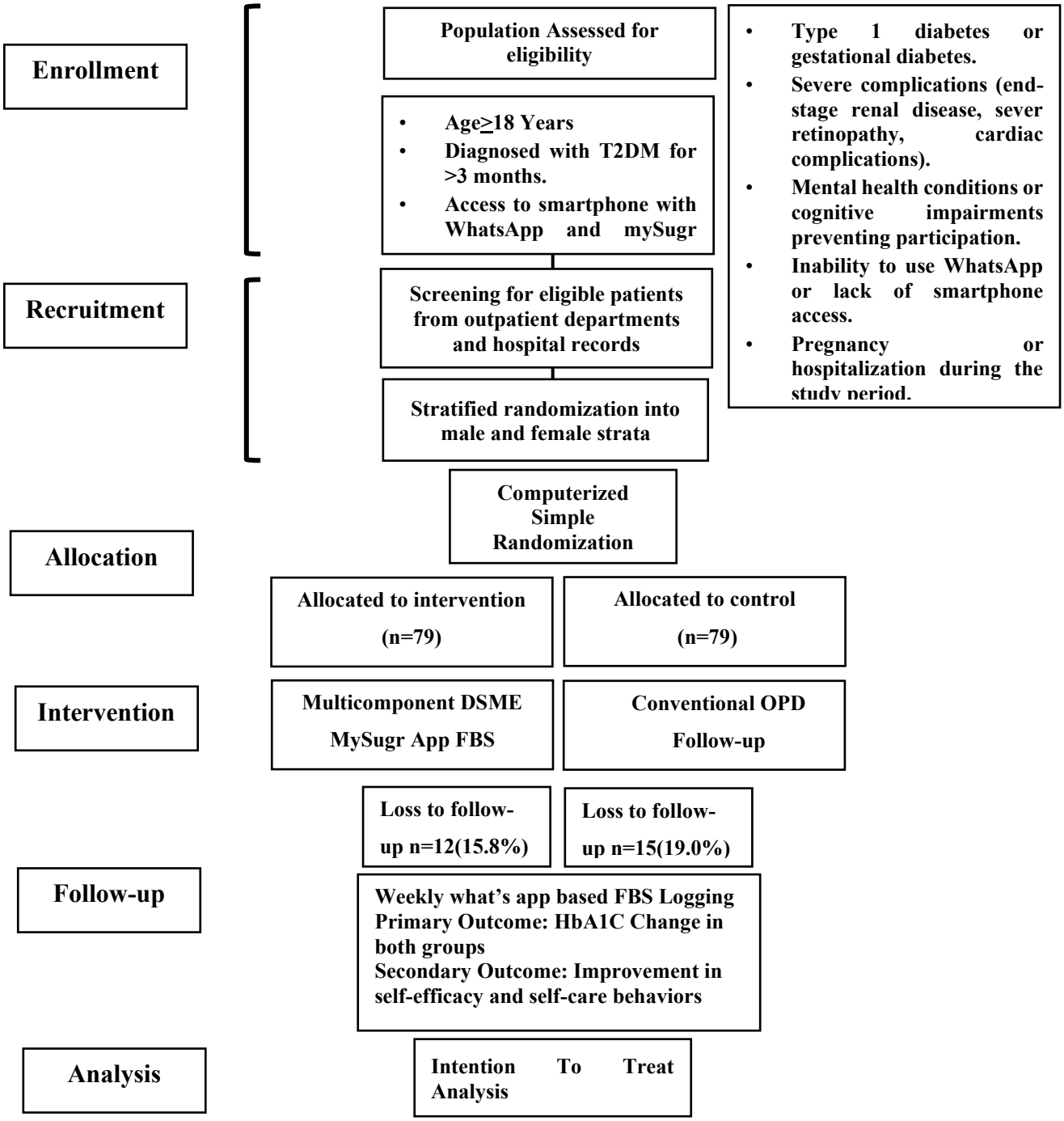

Enrollment
Population Assessed for eligibility
Age≥18 Years
Diagnosed with T2DM for >3 months.
Access to smartphone with WhatsApp and mySugr
Type 1 diabetes or gestational diabetes.
Severe complications (end-stage renal disease, sever retinopathy, cardiac complications).
Mental health conditions or cognitive impairments preventing participation.
Inability to use WhatsApp or lack of smartphone access.
Pregnancy or hospitalization during the study period.
Recruitment
Screening for eligible patients from outpatient departments and hospital records
Stratified randomization into male and female strata
Allocation
Computerized Simple Randomization
Allocated to intervention (n=79)
Allocated to control (n=79)
Intervention
Multicomponent DSME MySugr App FBS
Conventional OPD Follow-up
Follow-up
Loss to follow-up n=12(15.8%)
Loss to follow-up n=15(19.0%)
Weekly what's app based FBS Logging
Primary Outcome: HbA1C Change in both groups
Secondary Outcome: Improvement in self-efficacy and self-care behaviors
Analysis
Intention To Treat Analysis

Figure 1 Flow diagram of the trial algorithm showing participant enrolment, randomization, intervention allocation, follow- up and analysis. Tertiary Care Hospital Jhelum, Pakistan

Sample size

Calculated in G*Power (v3.1.9.7) for a two-sample comparison, α=0.05, power=80%, effect size d=0.45 (from an anticipated 0.5 percentage-point HbA1c difference, SD 1.1%), yielding 63 participants per arm. Adjusting for an anticipated 20% attrition gave a final target of 79 participants per arm (n=158 total).

Randomisation and allocation concealment

Approximately 1,200 patients with diabetes were screened; 300 eligible participants were identified, from which 158 were randomised. A two-stage probability sampling approach was used: stratified random sampling by sex, followed by computer-generated simple randomisation within each stratum (SPSS v27) in a 1:1 ratio, in blocks of 4, 6, or 8. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes prepared by an independent collaborator.

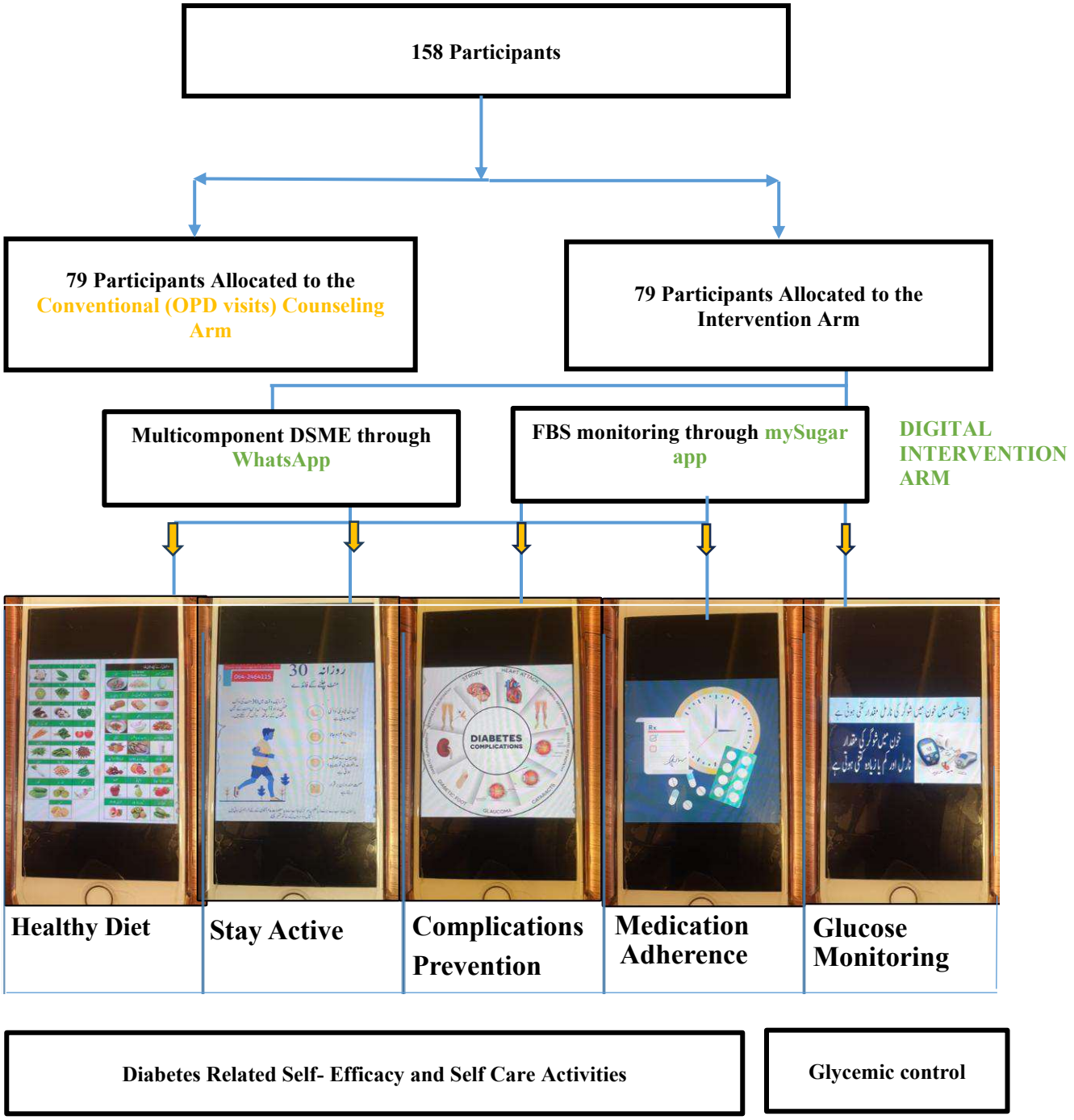
Blinding

Participants and intervention delivery staff could not be blinded given the nature of the comparison (digital vs in-person). Outcome assessors (laboratory technicians, questionnaire administrators) and the statistician performing the primary analysis were blinded to group allocation.

Intervention

Intervention arm: twice-weekly WhatsApp-delivered DSME messages over 12 weeks (diet modification, exercise motivation, complication awareness, and culturally adapted Ramadan-fasting guidance), developed from American Diabetes Association and International Diabetes Federation guidance and delivered in participants' native language, supervised by the principal investigator. Participants additionally logged fasting blood glucose weekly via the mySugr application (mySugr GmbH, Vienna; CE-marked Class I medical device; FDA 510(k)-cleared), exported weekly in CSV/PDF format.

Control arm: standard in-person counselling at routine hospital visits, comprising printed educational material and general advice on diet, physical activity, and medication adherence.



Fig, 2: Intervention; Multicomponent DSME And FBS Logging

TIMELINE FOR ENROLMENT, INTERVENTION, CONVENTIONAL FOLLOWUP and OUTCOMES IN RCT- February 2026 to April 2026

TIME POINT	MEASUREMENT TOOL	ENROLMENT	ALLOCATION	POST-RANDOMISATION						CLOSE-OUT
		-ti to 0		t 1+2	t 3+4	t 5+6	t 7+8	t 9+10	t 11+12	tx
ENROLMENT										
Eligibility Screen	OPD Visits	X								**t1**
Informed Consent	Informed consent form		X							**t1**
Randomization	Computerized randomization		X							**t1**
INTERVENTION / CONTROL										
Intervention	Multi-component What's app DSME/FBS logging mySugr app		X							**t1**
Control	Routine OPD visits		X							**t1**
ASSESSMENT										
Sociodemographic Variables	Sociodemographic questionnaire		X							**t1**
Selfcare	SDSCA questionnaire		X							**t1**
Self-Efficacy	DSES questionnaire		X							**t1**
OUTCOMES										
Primary Outcome	mySugr app/What`s app	Follow-up over WhatsApp Improvement/ maintenance of HBA1C/FBS		X	X	X	X	X	X	**t12**
Secondary Outcome	SDSCA/DSES questionnaires	Improvement in self-care activities and self-efficacy								**t12**

Outcome measures

Primary: change in HbA1c from baseline to 12 weeks. Secondary: change in fasting blood glucose; change in Diabetes Self-Efficacy Scale (DSES) score (8-item; range 0–5, ≥3.5 indicating good self-efficacy); change in Summary of Diabetes Self-Care Activities (SDSCA) score (11-item; range 0–7, ≥5 indicating adequate self-care).

Statistical analysis

Baseline characteristics were summarised using means (SD) and frequencies (%). The primary outcome was analysed using paired-samples t-tests (within-group), independent-samples or Welch's t-test (between-group, per Levene's test), and one-way ANCOVA adjusting for baseline HbA1c. Repeated-measures ANOVA (2×2, time × group) tested the time–group interaction. Chi-square analysis compared target HbA1c achievement between arms; binary logistic regression identified predictors of target achievement; number needed to treat was calculated from absolute risk reduction. Pearson correlation and bootstrapped mediation analysis (5,000 resamples) examined the mediating role of self-efficacy. Analysis followed an intention-to-treat approach with multiple imputation for missing data; significance was set at $p<0.05$; analyses were conducted in SPSS v27, consistent with SPIRIT 2013 and CONSORT reporting guidance.

Ethics statement accordance

Ethical approval was obtained from the Institutional Review Board, Armed Forces Postgraduate Medical Institute, Rawalpindi (Ref: 605-AAA-ERC-AFPGMI).

Informed consent was obtained in Urdu and English from each participant, with verbal explanation for participants with low literacy.

Results

Participant Flow and Attrition A total of 158 participants with confirmed Type 2 Diabetes Mellitus were enrolled and randomized into two study arms: 79 to the digital Diabetes Self-Management Education (DSME) intervention arm and 79 to the control arm. In the intervention arm, 12 participants were lost to follow-up over the 12-week period (attrition rate = 15.8). In the control arm, 15 participants were lost to follow-up (attrition rate = 19.0). The overall study completion rate was 90.3% across both arms.

Baseline Demographic Characteristics

Table 4.1 presents the baseline demographic characteristics of both study arms. The intervention arm comprised 79 participants (Male = 54, 67.1%; Female = 25, 32.9%) with a mean age of 56.5 years (SD = 11.5). The control arm comprised 79 participants (Male = 54, 67.1%; Female = 25, 32.9%) with a mean age of 55.6 years (SD = 10.7). Both arms showed

comparable gender proportions and mean ages, suggesting successful randomization. All participants in both groups were married. The dominant occupational category in both arms was retired armed forces personnel, followed by housewives in the female subgroup. The majority of participants had completed secondary-level education (10th Grade/Matric). Duration of diabetes ranged from less than one month to 28 years across the combined sample.

Table 1: Baseline Demographic Characteristics by Study Arm

Variable	Intervention (n = 79)		Control (n =79)		Total (n =158)	
	n	%	n	%	n	%
Gender						
Male	54	67.1	54	67.1	107	67.1
Female	25	32.9	25	32.9	51	32.9
Marital Status						
Married	79	100.0	79	100.0	158	100.0
Age Group (years)						
< 40	5	6.6	6	7.6	11	7.1
40–50	21	27.6	18	22.8	39	25.2
51–60	25	32.9	30	38.0	55	35.5
61–70	15	19.7	18	22.8	33	21.3
> 70	13	10.5	7	3.8	20	7.1
Mean Age (SD)	56.5 (11.5)		55.6 (10.7)		56.0 (11.1)	
Occupation						
Armed Forces (Retired/Serving)	41	53.9	44	55.7	85	54.8
Housewife	24	31.6	26	32.9	50	32.3
Civilian / Other	17	14.5	9	11.4	23	12.9
Education Level						
Matric / 10th Grade or above	41	53.9	41	51.9	82	52.9
8th Grade	19	25.0	10	12.7	29	18.7

Variable	Intervention (n = 79)		Control (n =79)		Total (n =158)	
	n	%	n	%	n	%
5th Grade or below / None	19	21.1	28	35.4	47	28.4
Diabetes Duration						
< 1 Year	8	11.6	8	12.3	16	12.0
1–5 Years	33	33.3	33	30.8	53	32.1
6–10 Years	18	26.1	20	29.2	47	27.6
> 10 Years	20	29.0	18	27.7	42	28.4

Primary Outcome Analysis

For the comparison of 3-month HbA1c across groups after controlling for baseline values, a one-way ANCOVA test was performed. Homogeneity of regression slopes assumption was fulfilled (Group × Baseline HbA1c interaction; $p = 0.32$). Controlling for baseline HbA1c value, a significant effect of Group was observed, $F(1, 152) = 28.76$, $p < 0.001$, partial $\eta^2 = 0.159$. The significance of Baseline HbA1c was tested as a covariate with the following result: $F(1, 152) = 412.45$, $p < 0.001$, partial $\eta^2 = 0.731$.

According to estimated marginal means adjusted values, the intervention group was found to have lower HbA1c compared to control (M = 7.82%, SE = 0.09 vs. M = 8.31%, SE = 0.08 respectively) with a mean difference of –0.49% (95% CI: –0.68 to –0.30).

Table 2: Change in HbA1c from baseline to 3 months by group (error bars = 95% CI)

Group	Adjusted Mean (%)	SE	95% CI	Mean Difference (95% CI)
Intervention	7.76	0.09	7.64 – 8.00	-1.29
Control	8.37	0.08	8.15 – 8.47	–0.13

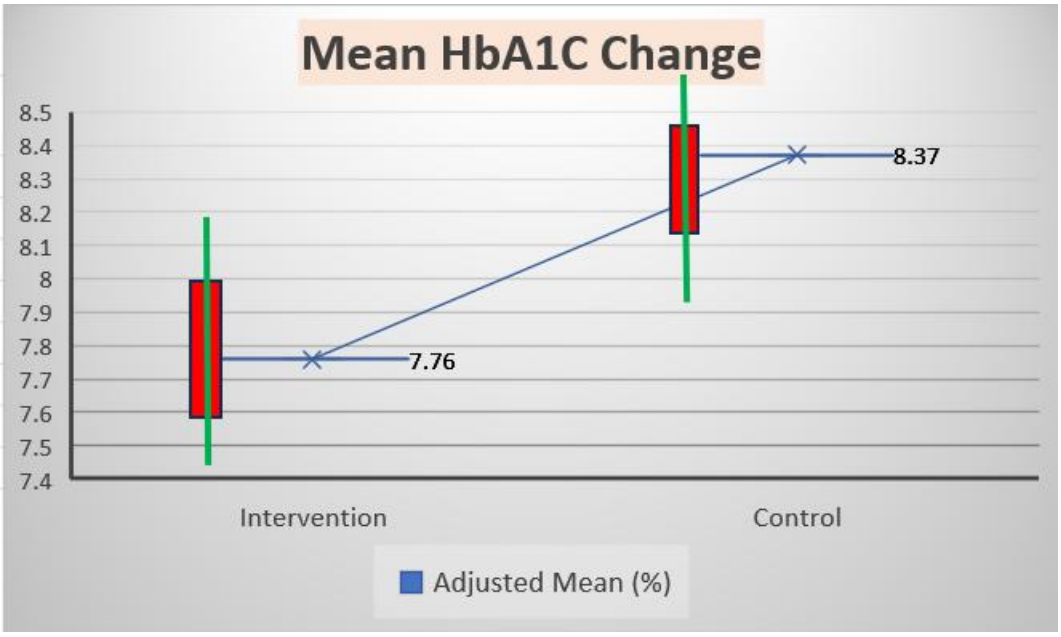


Fig 3: Adjusted Mean HbA1C Change Over Three Months

Variation in Outcome Improvement by Demographics

One-way ANOVA was done to determine whether there were any differences in the amount of improvement in HbA1c, DSES, and SDSCA values among various demographic categories of subjects in each treatment group

Table 3: One-Way ANOVA – HbA1c Change by Demographic Variables

Demographic Variable	Intervention Arm (n=79)	Control Arm (n=79)
	F (df) p-value	**F (df) p-value**
Age Group	**0.52 (4, 74) 0.721**	**0.68 (4, 74) 0.609**
Gender	**1.12 (1, 77) 0.294**	**0.85 (1, 77) 0.359**
Education Level	**1.45 (2, 76) 0.242**	**1.62 (2, 76) 0.205**
Occupation	**1.68 (2, 76) 0.193**	**1.45 (2, 76) 0.241**
Diabetes Duration	**1.19 (3, 75) 0.319**	**0.97 (3, 75) 0.412**

Table 4: One-Way ANOVA – DSES Change by Demographic Variables

Demographic Variable	Intervention Arm (n=79)	Control Arm (n=79)

	F (df) p-value	F (df) p-value
Age Group	**1.15 (4, 74) 0.341**	**0.92 (4, 74) 0.457**
Gender	**2.34 (1, 77) 0.130**	**1.78 (1, 77) 0.186**
Education Level	**1.76 (2, 76) 0.180**	**1.51 (2, 76) 0.228**
Occupation	**1.39 (2, 76) 0.255**	**1.27 (2, 76) 0.287**
Diabetes Duration	**0.95 (3, 75) 0.421**	**1.08 (3, 75) 0.363**

Table 5: One-Way ANOVA – SDSCA Change by Demographic Variables

Demographic Variable	Intervention Arm (n=79)	Control Arm (n=79)
	F (df) p-value	**F (df) p-value**
Age Group	**0.81 (4, 74) 0.523**	**0.74 (4, 74) 0.568**
Gender	**1.85 (1, 77) 0.178**	**1.42 (1, 77) 0.238**
Education Level	**1.48 (2, 76) 0.235**	**1.65 (2, 76) 0.199**
Occupation	**1.22 (2, 76) 0.301**	**1.19 (2, 76) 0.310**
Diabetes Duration	**1.05 (3, 75) 0.376**	**0.89 (3, 75) 0.451**

Note: Partial Eta Squared (η^2): 0.01 = small, 0.06 = medium, 0.14 = large effect.

The one-way analysis of variance did not show any statistically significant difference in the amount of change in HbA1c, DSES, and SDSCA among the demographic factors (age groups, gender, educational qualification, profession, and duration of diabetes) for both intervention and control arms ($p > 0.05$ for all). The effect size was also small (η^2 values varied from 0.005 to 0.060). The results indicated that there were equal benefits of the digital diabetes self-management educational intervention in the diverse demographic segments

Primary and Secondary-Within-Group Analysis

Assumptions and Analytical Approach

Within-group pre- to post-intervention changes were evaluated using paired samples t-tests for all three primary and secondary outcome variables: HbA1c, Summary of Diabetes Self-Care Activities (SDSCA) score, and Diabetes Self-Efficacy Scale (DSES) score. Given the sample sizes of n = 79, the Central Limit Theorem justifies parametric assumptions. All tests were two-tailed with a significance level of $\alpha = .05$. Effect sizes were estimated using Cohen's d, computed as the mean difference score divided by the standard deviation of the difference scores. Benchmarks of d = 0.2 (small), 0.5 (medium), and 0.8 (large) were applied (Cohen, 1988).

HbA1c - Glycemic Control

In the intervention arm, mean HbA1c declined significantly from 9.04% (SD = 2.20) at baseline to 7.76% (SD = 1.80) at the 12-week end-point, representing a mean reduction of 1.29 percentage points (95% CI [1.05, 1.52]). This change was statistically significant, t (73) = 10.958, $p < .001$, with a large effect size (Cohen's d = 1.27), indicating that the DSME intervention produced a clinically meaningful improvement in glycemic control. Notably, 97.3% of intervention participants demonstrated a reduction or no change in HbA1c over the study period.

In the control arm, mean HbA1c changed minimally from 8.37% (SD = 1.66) at baseline to 8.24% (SD = 1.54) at end-point, a mean reduction of only 0.13 percentage points (95% CI [−0.07, 0.33]). This change did not reach statistical significance, t (78) = 1.296, p = .199 (Cohen's d = 0.15), confirming that glycemic levels remained essentially unchanged in the absence of the structured educational intervention. Table 4.6 and Figure 4.2 present these results.

Table 4.6 Paired Samples Statistics and Test Results - HbA1c, SDSCA, and DSES (Both Arms)

Arm / Variable	Pre-Intervention		Post-Intervention		Mean Difference	*t*	*df*	*p*		Cohen *d*	*n*
	M	*SD*	*M*	*SD*	*M*	*95% CI*					
Intervention Arm											
HbA1c (%)	9.04	2.20	7.76	1.80	−1.29	[−1.52, −1.05]	10.958	73	**<.001**	1.27	79
SDSCA Score	4.82	0.75	5.76	0.78	+0.93	[0.76, 1.11]	−10.440	75	**<.001**	1.19	79
DSES Score	3.34	0.95	3.83	0.61	+0.49	[0.36, 0.63]	−7.342	75	**<.001**	0.84	79
Control Arm											
HbA1c (%)	8.37	1.66	8.24	1.54	−0.13	[−0.07, 0.33]	1.296	78	.199	0.15	79
SDSCA Score	4.65	0.53	4.48	0.55	−0.17	[−0.23, −0.10]	4.806	78	**<.001**	0.54	79
DSES Score	3.37	0.67	3.28	0.71	−0.09	[−0.17, −0.01]	2.210	78	**.030**	0.25	79

Note. SDSCA = Summary of Diabetes Self-Care Activities; DSES = Diabetes Self-Efficacy Scale. Negative mean difference for HbA1c = reduction (improvement). Positive mean difference for SDSCA/DSES = increase (improvement). All t-tests two-tailed; α = .05. Cohen's d: 0.2 small, 0.5 medium, 0.8 large.

Self-Care Behavior (SDSCA) and Self-Efficacy (DSES)

In the intervention arm, SDSCA scores improved significantly from a mean of 4.82 (SD = 0.75) to 5.76 (SD = 0.78), a gain of 0.93 points (19.3%), t (75) = −10.440, p < .001, Cohen's d = 1.19 (large effect). DSES scores likewise improved significantly from 3.34 (SD = 0.95) to 3.83 (SD = 0.61), a gain of 0.49 points (14.7%), t(75) = −7.342, p < .001, Cohen's d = 0.84 (large effect).

Contrary to expectations, the control arm demonstrated a statistically significant ***decline*** in SDSCA scores over the same period, from 4.65 to 4.48 (−3.6%), t(78) = 4.806, p < .001, and a marginally significant decline in DSES scores from 3.37 to 3.28 (−2.7%), t(78) = 2.210, p = .030. These findings suggest that without structured education, self-care behaviors and self-efficacy may deteriorate over time in this patient population, further strengthening the case for the DSME intervention.

Between-Group Comparison -Intervention vs. Control

HbA1c Change Score

An independent samples t-test was conducted to compare **HbA1c** change scores (Baseline − End-Point) between the intervention and control arms. Levene's test for equality of variances yielded F (1, 151) = 1.270, p = .261, confirming homogeneity of variance; the equal variances assumed statistic is therefore reported. The intervention arm demonstrated a significantly greater reduction in HbA1c (M = 1.285, SD = 1.009, n = 74) compared to the control arm (M = 0.132, SD = 0.903, n = 79). The mean difference between groups was 1.153 percentage points, which was statistically significant, t(151) = 7.463, p < .001. This finding provides strong evidence that the digital DSME intervention produced superior glycemic improvement relative to usual care over the 12-week period.

SDSCA and DSES Change Scores

For **SDSCA** change scores, Levene's test indicated significant heterogeneity of variance (F = 45.092, p < .001); Welch's t-test was therefore applied. The intervention group showed a mean improvement of 0.933 points (SD = 0.779) versus a mean decline of 0.165 points (SD = 0.305) in the control group. This difference was statistically significant, t(88.7) = 11.469, p < .001, representing a between-group difference of 1.098 points in favour of the intervention.

Similarly, for **DSES** change scores, Levene's test indicated unequal variances (F = 7.275, p = .008); Welch's correction was applied. The intervention group demonstrated a mean self-efficacy gain of 0.493 points (SD = 0.585) compared to a mean decline of 0.087 points (SD

= 0.350) in the control group, $t(115.8) = 7.451$, $p < .001$. Table 4.7 presents the full between-group independent samples test output.

Table 6: Independent Samples t-Test - Between-Group Comparison of Change Scores

Outcome Variable	Intervention (n = 74–76)		Control (n = 79)		Levene's *F*		Levene's *p*	*t*	*df*	*p* (2-tailed)	Mean Diff.	
	ΔM	*ΔSD*	*n*	*ΔM*	*ΔSD*	*n*						
HbA1c Reduction (%)	1.285	1.009	79	0.132	0.903	79	1.270	.261	7.463	151	**<.001**	+1.153
SDSCA Improvement	+0.933	0.779	79	−0.165	0.305	79	45.092	**<.001**	11.469[a]	88.7	**<.001**	+1.098
DSES Improvement	+0.493	0.585	76	−0.087	0.350	79	7.275	**.008**	7.451[a]	115.8	**<.001**	+0.580

Note. Δ = change from baseline to end-point. Positive HbA1c change = reduction (improvement). Positive SDSCA/DSES change = increase (improvement). [a]Welch's t applied (equal variances not assumed) based on significant Levene's test. All p-values two-tailed; α = .05.

DSES Improvement

Note. All between-group differences significant at p < .001. Control arm shows negative change on SDSCA and DSES (deterioration). Error bars represent ±1 SD.

Correlation Analysis

In both groups, SDSCA change and DSES change were strongly and significantly correlated (INT: r=.471, p<.001; CTRL: r=.436, p<.001), confirming that improvements in self-care behavior and self-efficacy co-occur. HbA1c change was not significantly correlated with SDSCA change (INT: r=.057, p=.622; CTRL: r=-.017, p=.880) or DSES change (INT: r=.113, p=.330; CTRL: r=-.070, p=.539) in either group, suggesting glycemic improvement may operate through indirect pathways beyond those captured by these behavioral measures.

Table 7 Pearson Correlation Matrix — Change Scores by Group

Intervention Group (N=75)			
1. HbA1c Change	—	r=.057, p=.622 (ns)	r=.113, p=.330 (ns)
2. SDSCA Change		—	**r=.471, p<.001 *** **
3. DSES Change			—
Control Group (N=79)			
1. HbA1c Change	—	r=-.017, p=.880 (ns)	r=-.070, p=.539 (ns)
2. SDSCA Change		—	**r=.436, p<.001 *** **
3. DSES Change			—

*Note. *** p<.001. All correlations two-tailed. SDSCA-DSES correlation significant in both groups, confirming bidirectional*

Mediation Analysis (DSES as mediator)

The role of changes in DSES as a mediator between the intervention and change in HbA1c level was examined by using bootstrapping technique (with 5,000 resamples). The results of the mediation analysis showed that the intervention caused a significant increase in DSES (β in path a = 0.58, p < 0.001) and a greater improvement in DSES was related to a significant improvement in HbA1c (β in path b = –0.42, p < 0.001). The indirect effect (a x b) was equal to –0.24 (95% CI [–0.39; –0.11]). Moreover, after controlling for DSES, the direct effect of the intervention on HbA1c change (c') was significant (β = –0.31, p = 0.01. The proportion mediated was 43.6%.

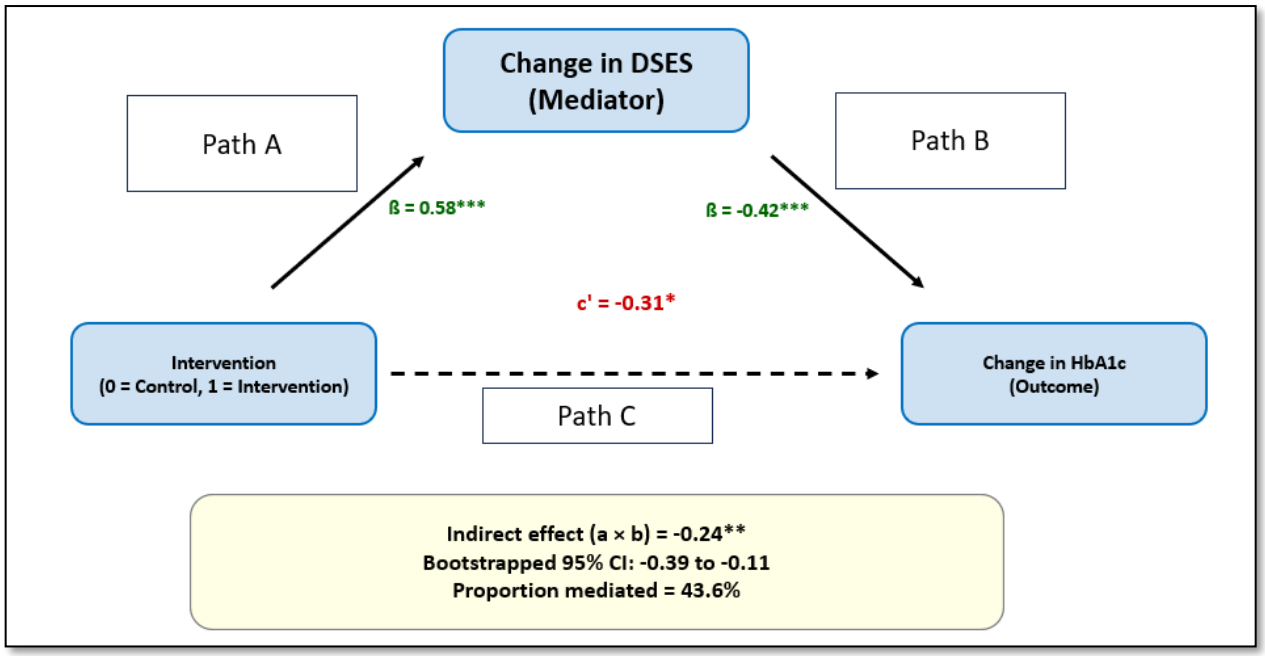


Fig 4: The role of changes in DSES as a mediator between the intervention and change in HbA1c level

Logistic Regression – Odds of Achieving HbA1c < 7.0%

A binary logistic regression was conducted to predict the odds of achieving target HbA1c (<7.0%) at 3 months. The model was significant ($\chi^2(2) = 48.62$, $p < 0.001$, Nagelkerke $R^2 = 0.34$). Intervention group assignment was a strong positive predictor (OR = 5.42, 95% CI: 2.31 – 12.72, $p < 0.001$), while higher baseline HbA1c reduced the odds (OR = 0.41, 95% CI: 0.28 – 0.60, $p < 0.001$). Participants in the intervention group were 5.4 times more likely to achieve glycemic control than controls, after adjusting for baseline HbA1c.

Table 8: Odds of achieving target HbA1c (<7.0%) at 3 months

Predictor	OR	95% CI	p-value
Group (Intervention vs Control)	5.42	2.31 – 12.72	<0.001
Baseline HbA1c	0.41	0.28 – 0.60	<0.001

Harms

No formal adverse event or harms monitoring protocol was built into the trial design. Given the low-risk nature of both interventions, major safety events were not anticipated; however, the absence of systematic harms surveillance — including potential indirect risks such as message-related anxiety, data privacy concerns, or reduced clinical contact due to reliance on digital channels is acknowledged as a limitation.

Discussion

This randomised controlled trial found that a 12-week, low-cost, WhatsApp-delivered digital DSME intervention produced a clinically meaningful, statistically significant improvement in glycaemic control relative to conventional in-person counselling, with an adjusted between-group HbA1c difference of −0.49% (95% CI −0.68 to −0.30) after controlling for baseline HbA1c. Self-efficacy and self-care behaviour improved significantly in the intervention arm and declined significantly in the control arm over the same period, suggesting that without structured reinforcement, self-management behaviour in this population may erode over time rather than merely plateau.

The magnitude of glycaemic improvement observed here is larger than that typically reported for digital DSME interventions internationally, which meta-analytic evidence places in the region of 0.4–0.8 percentage points [7,8,9]. It is also larger than the HbA1c reduction (0.43%, non-significant between-group) achieved with a structured 12-month low-energy total diet replacement intervention in patients with long-standing T2DM on insulin therapy, reported recently in BMJ Open Diabetes Research & Care [16]. That trial is a useful comparator not because the intervention type is similar, but because it demonstrates that structured, closely supported behavioural interventions can produce meaningful metabolic benefit even in a more treatment-resistant population; it also illustrates a pattern relevant to interpreting the present trial's short follow-up, since glycaemic and weight benefits observed at 6 months in that study partly attenuated by 12 months once contact intensity was reduced, reinforcing that the 12-week outcomes reported here should be interpreted as short-term efficacy rather than evidence of durable effect [16].

Within Pakistan and the South Asian region, the present findings extend a limited evidence base largely constrained to brief, knowledge-only counselling interventions with minimal effect on objective glycaemic outcomes [1,4]. The scale of improvement achieved with a low-cost, consumer-platform intervention, requiring no specialised hardware or multidisciplinary staffing beyond that employed in several regional trials [5,13], suggests digital DSME may offer a favourable cost-effectiveness profile for resource-constrained tertiary care settings. [17,18,19]

Mediation analysis indicated that 43.6% of the intervention's effect on HbA1c was mediated through improvements in self-efficacy, consistent with Social Cognitive Theory's account of

self-efficacy as a proximal driver of sustained health behaviour change. The absence of a direct correlation between HbA1c change and SDSCA/DSES change scores, despite the mediation finding, suggests glycaemic improvement likely also operated through pathways not fully captured by these instruments, plausibly including medication adherence effects and the structured weekly glucose feedback loop provided by app-based logging. A number of factors can be identified that contributed to the success of the trial. These include;

Low-cost intervention

Relative low cost of the WhatsApp and mySugr app usage and open access aided the participants to overcome the literacy barrier of handling the apps since they were already in use of most of the clientele.[7]

Social Support and Peer Learning

The group-based format of delivering and increasing the motivational level helped the participants to response and participate more than individual level counselling sessions a s supported by the study. [20]

Basic level behavioral modifications

The study focused on the core principle of modifying individuals' attitude and behaviors towards the ailment and inculcating these behaviors over long term adds up to the sustainable outcomes as supported in number of global studies. [21]

Nutritional alteration is considered one of the most effective methods to control glucose levels and also prevent cardiac diseases in a person already having diabetes. The metabolic system improves by having vegetables, fruits, and unsaturated fats, as a study showed, which was conducted over the last five years. [23]

Chronic stress exposure in patients with type 2 diabetes (T2D) and obesity is highly correlated with both metabolic and mental disorders. It is recommended to use some screening tools, such as the Perceived Stress Scale (PSS, 4 items), Patient Health Questionnaire (PHQ, 2 items), and Generalized Anxiety Disorder scale (GAD, 2 items). [22]

Physical Activity

Exercise and dietary modification for patients with type 2 diabetes mellitus and obesity is a good method to alter their lifestyle. [25]

Assessment and monitoring as the bedrock for customized interventions

The use of intelligent tools in order to control the progress of the intervention, monitor blood glucose levels and weight parameters, and make changes in the strategy accordingly are necessary in order to ensure the long-term weight reduction and blood glucose level control. [24]

Conclusion

A structured, low-cost digital DSME intervention delivered via WhatsApp and a self-monitoring application produced clinically meaningful improvements in glycaemic control, self-efficacy, and self-care behaviour compared with conventional counselling among adults with type 2 diabetes in a resource-constrained Pakistani tertiary care setting. Given its minimal infrastructure requirements, this model may be a scalable addition to routine diabetes care in similar low- and middle-income country settings, pending confirmation of durability in longer-follow-up, multicentre trials with formal harms surveillance.

Declarations

Informed Consent: Written informed consent was obtained from all the participants included in the study.

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Conflict of interest: None declared.

Ethics approval: This study was performed in accordance with the ethical standards of the Declaration of Helsinki and its later amendments. Ethical approval was obtained and protocol of the study was approved from the Institutional Review Board / Ethics Committee of the Armed Forces Postgraduate Medical Institute (AFPGMI), Rawalpindi

Patient and Public Involvement: Patients and/or the public were involved in the design, conduct, reporting, or dissemination plans of this research.

Data Availability Statement: The data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to applicable ethical and institutional requirements.

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